Biologicals Management

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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 Pediacel

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)

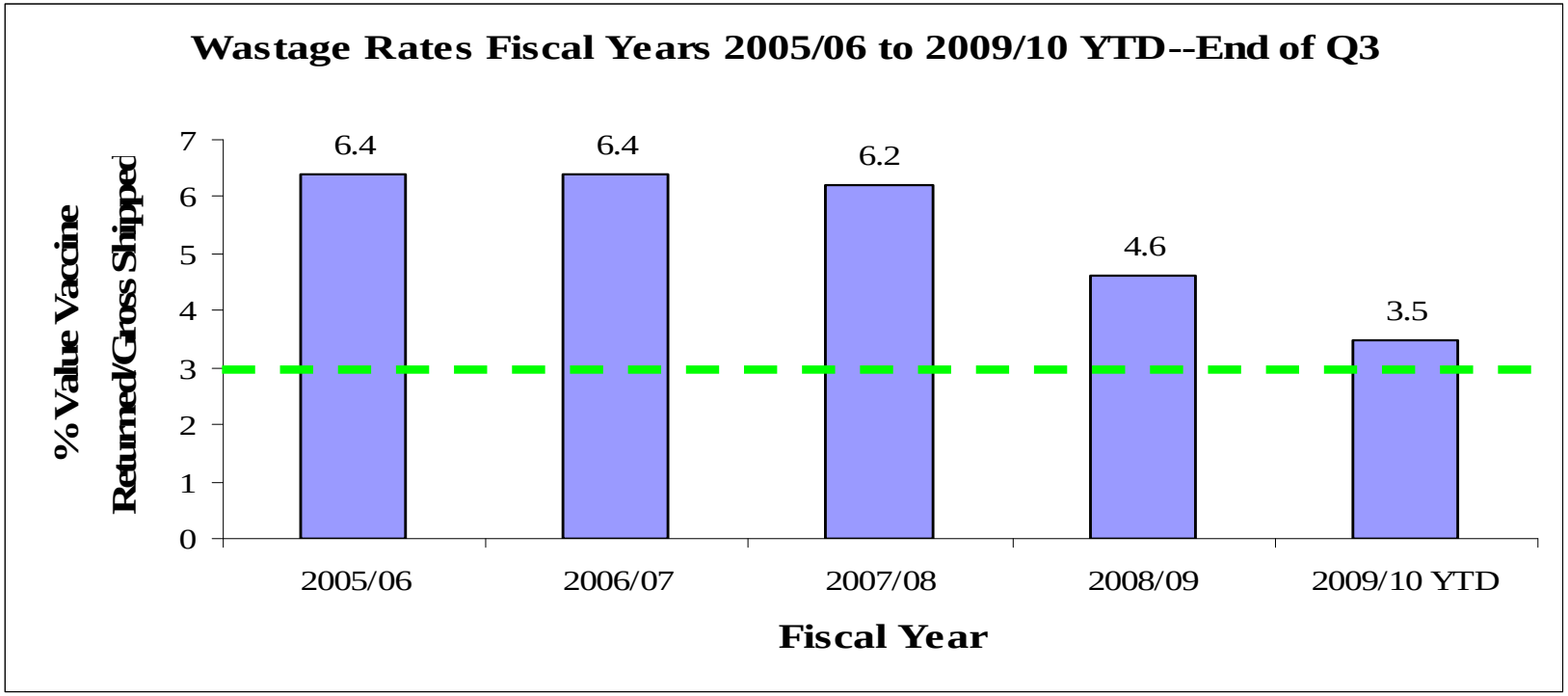
Biological Product Monitors

- 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

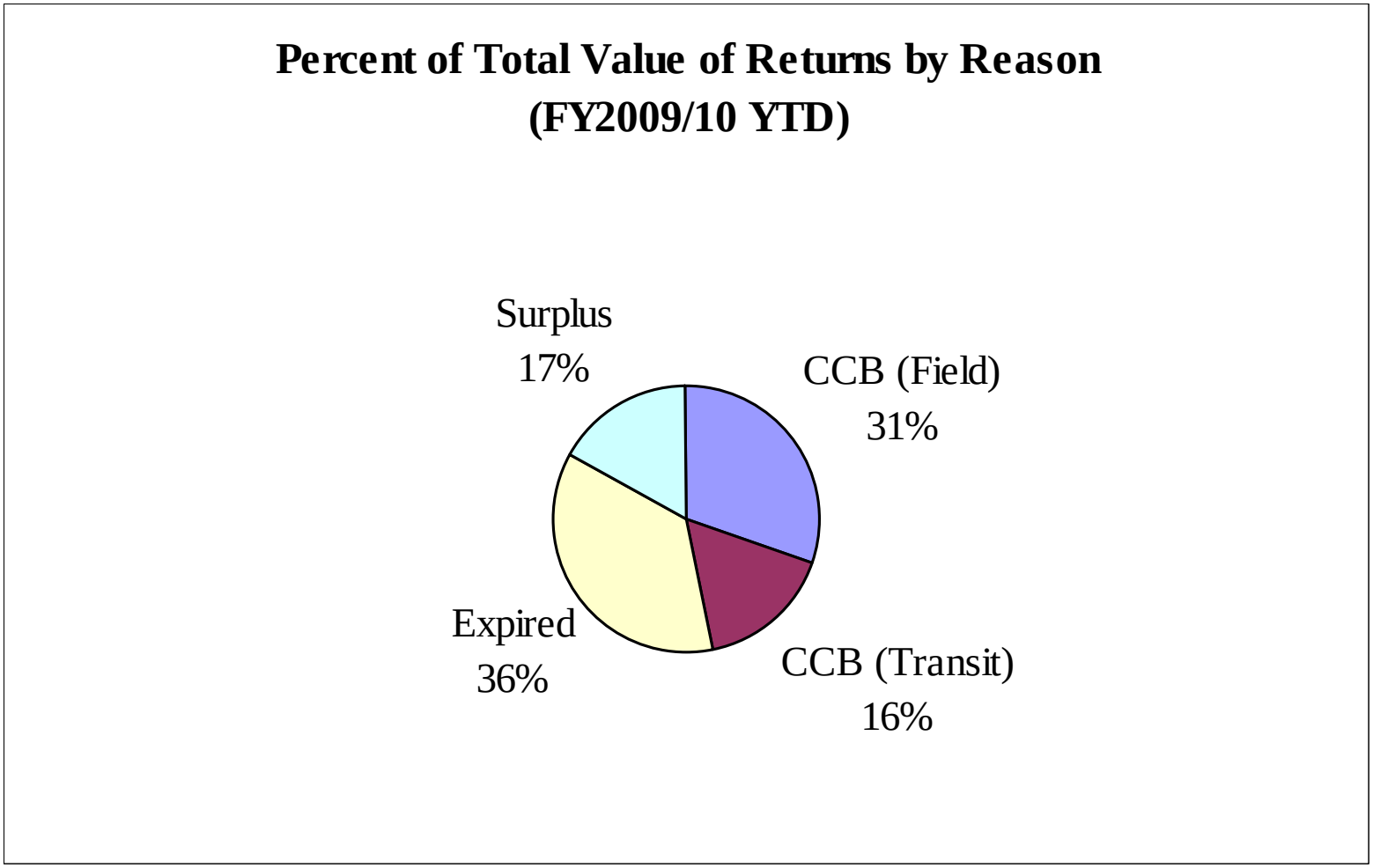
- Wastage goal: 3%



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



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).


3M Freeze Watch
9800 Indicator
Red stained paper = Activated
3M Freeze Watch
9805 Indicator
Dark stained paper = Activated

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: _____
Record Time

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 _____ ☐ [redacted]

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 ➡ [Store and segregate as per 5(a) – see reverse instructions] ☐ 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
(circle time unit of measurement)

Lowest Temp _____ Duration of Lowest Temp _____ minutes / hours
(circle time unit of measurement)

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.

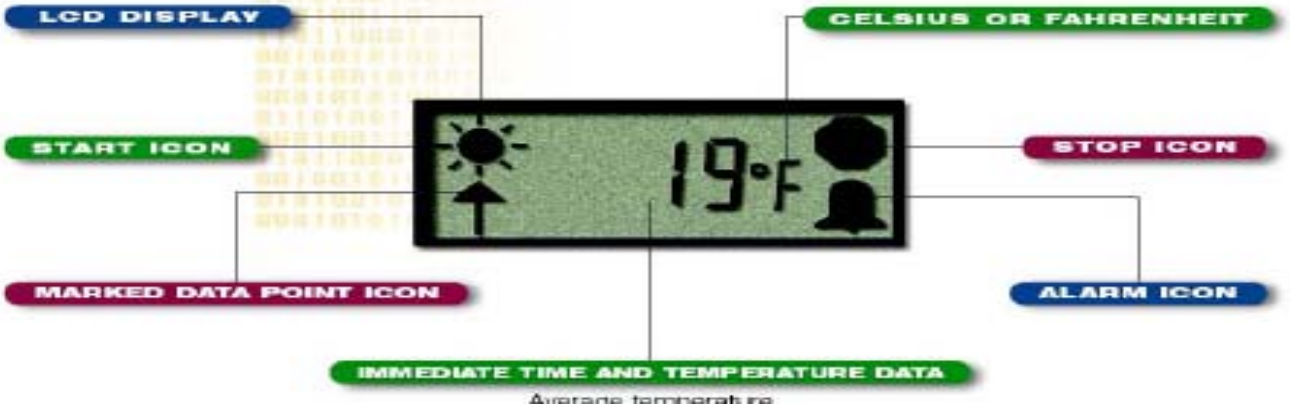
Monitoring temperature: Reading and returning Temp tales

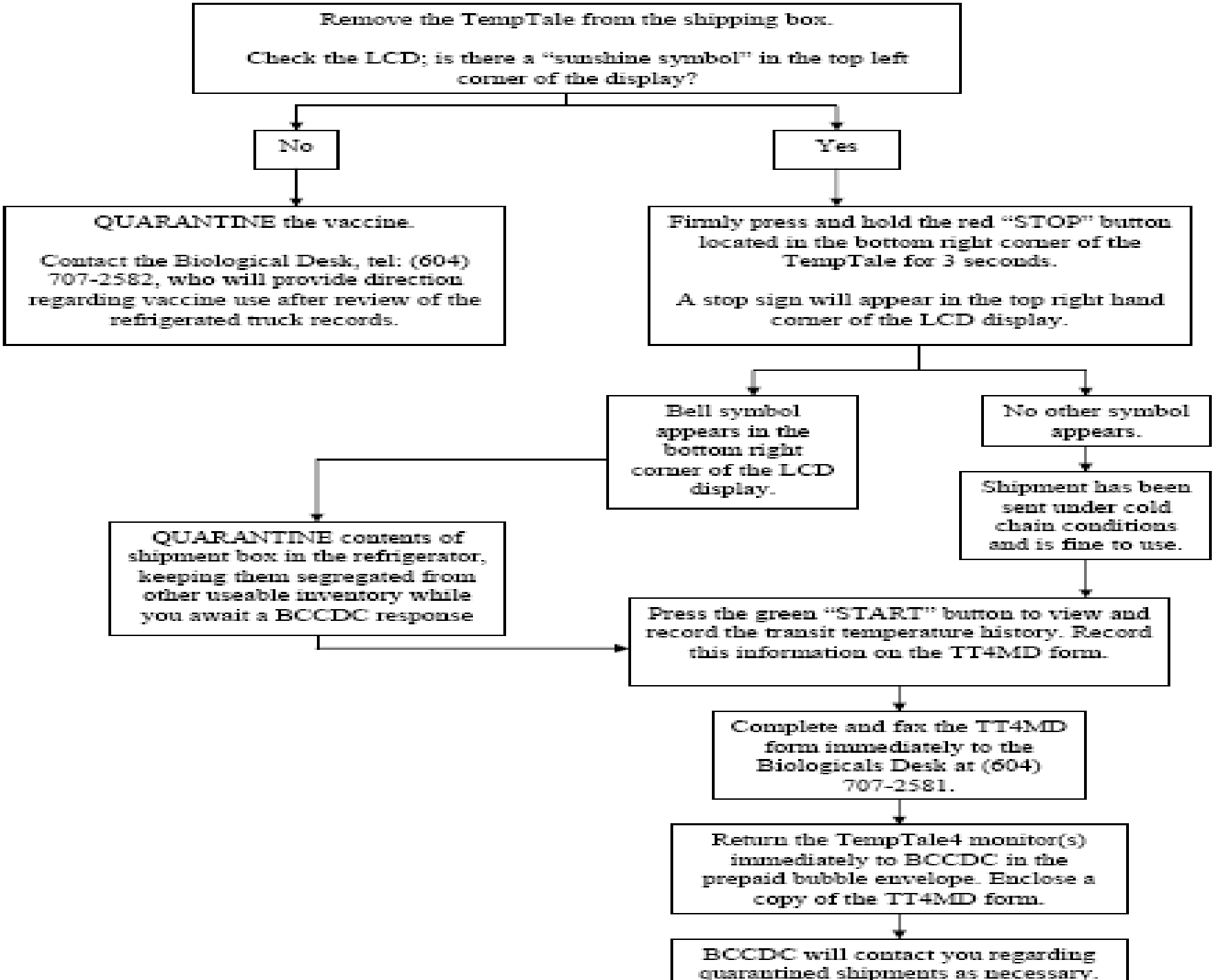
Unpack and refrigerate biological products immediately upon their arrival.

- 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




Remove the TempTale from the shipping box.
Check the LCD; is there a "sunshine symbol" in the top left corner of the display?
No
Yes
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.
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.
No other symbol appears.
QUARANTINE contents of shipment box in the refrigerator, keeping them segregated from other useable inventory while you await a BCCDC response
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.

TT4MD: 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: _____ Office Initials

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 ➡ [Store and segregate as per 5(g) – see reverse instructions] ☐ 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

(specify time unit of measurement)

Lowest Temp _____ Duration of Lowest Temp _____ minutes hours

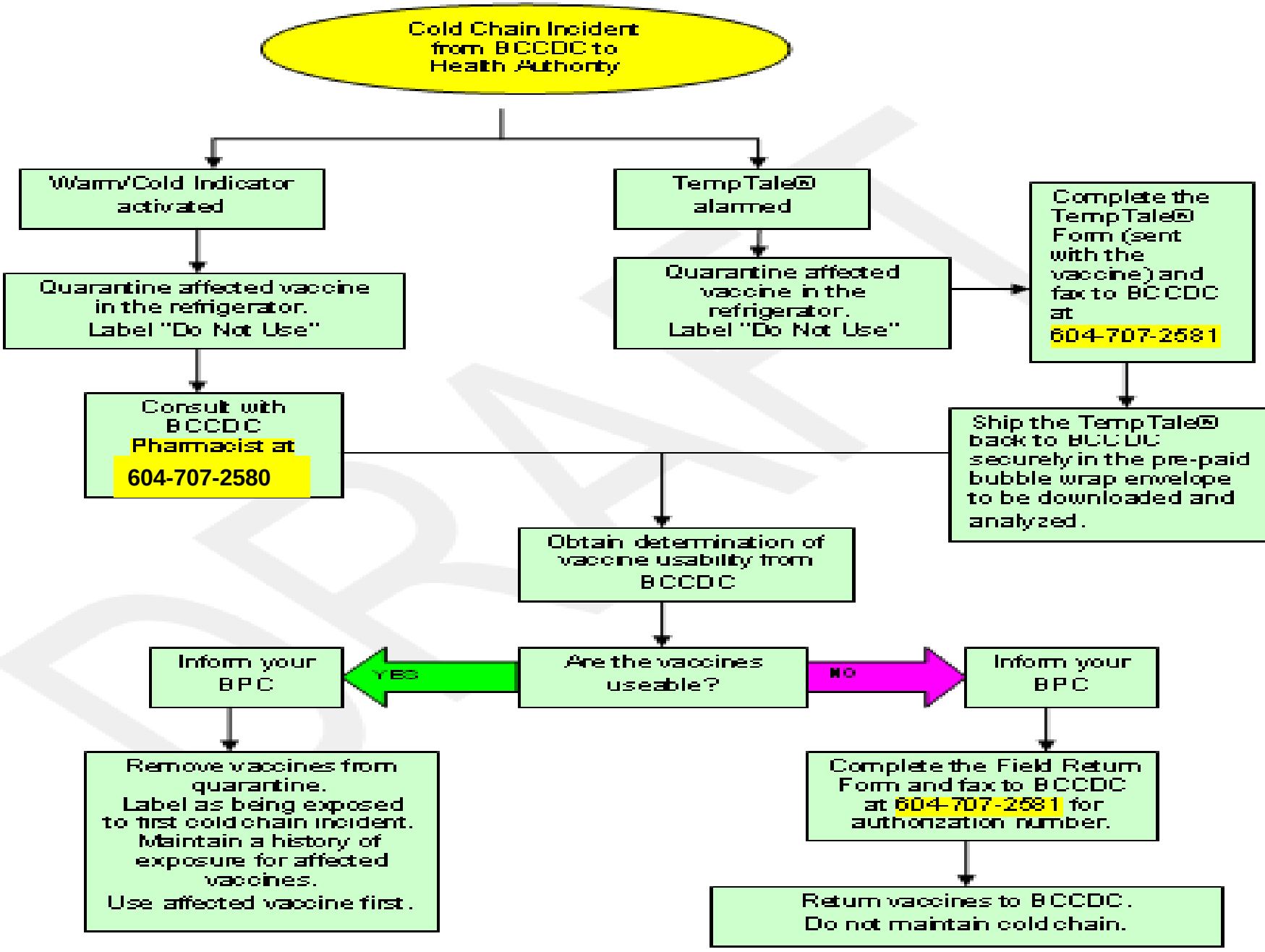
(specify time unit of measurement)

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



BC Centre for Disease Control

FIELD RETURN FORM

Health Unit:

Address:

Phone:

Fax:

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 Biologicals Return Requirements Form as per: Communicable Disease Manual.
http://www.bccdc.ca/NR/rdonlyres/74061D2E-4828-4A8C-BE6B-E551E8B2BC5A/0/Biologicals_return_and_redistribution_requirements_form.pdf

VACCINES	Product Code (BCCDC Use)	LOT NUMBER	EXPIRY DATE (YYYY/MM/DD)	REASON	DOSES
DwPT/IPV/HB/Hib, Infanrix Hexa	INFANRIX				
DwPT/IPV/Hib, Pediacel	PEDIACEL				
DwPT/IPV, Quadracel	SPACE				
Haemophilus B Conjugate, ActHIB	TALL				
Hepatitis A, Vaqta pediatric	VAQTA0.5				
Hepatitis A, Vaqta adult	VAQTA1.0V				
Hepatitis B, Pediatric, (T-free), Recombivax-HB	RECOMB0.5				
Hepatitis B (Renal/Kidney Dialysis), Recombivax-HB	RECOMB-DYS				
Hepatitis B Vaccine, Recombivax-HB	RECOMB1.0				
Hepatitis B Vaccine, Engerix	HEPB10ENG				
HPV	HPV1				
Immune Serum Globulin, GamaSTAN	ISG-SD2.0				
Inactivated Polio, Imovax Polio	POLVACS				
Influenza Vaccine, Fluviral	FLUVIRAL				
Influenza Vaccine, Vaxigrip					
Measles, Mumps, Rubella, MMR II	MMR II				
Meningococcal C Conjugate, NeisVac-C	MENC0.5-NV10				
Meningococcal Conjugate A/C/Y/W-135, Menactra	MENOVAC				
Meningococcal Polysaccharide A/C/Y/W-135, Menomune	MOSS				
Pneumococcal Conjugate, Prevnar 7	PREVNAR10				
Pneumococcal Conjugate, Prevnar 13	PREVNAR13				
Pneumococcal Polysaccharide, Pneumovax23	PNEUV23				
Rabies Immune Globulin, HyperRab	RABIGH300TC2				
Rabies, Imovax Rabies	IMOVAX				
Rabies, RabAvert	RABAVERT				
Td Adsorbed	SOUND				
Td/IPV Adsorbed (adult)	ELEMENT				
Tdap Adsorbed, Adacel	ADCL5-0.5				
Tetanus Immune Globulin, Baytet / Hypertet	TIG250I				
Varicella Vaccine, Varivax III	VARVAX0.5-10				
Varicella, Varilrix	VARI2000I				
Other:					

Fax Form to: 604-707-2581

Name of Biological Products Monitor:

Biologicals Desk at BCCDC
1100-655 West 12th Avenue

Email: biologicals@bccdc.ca

Phone:

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

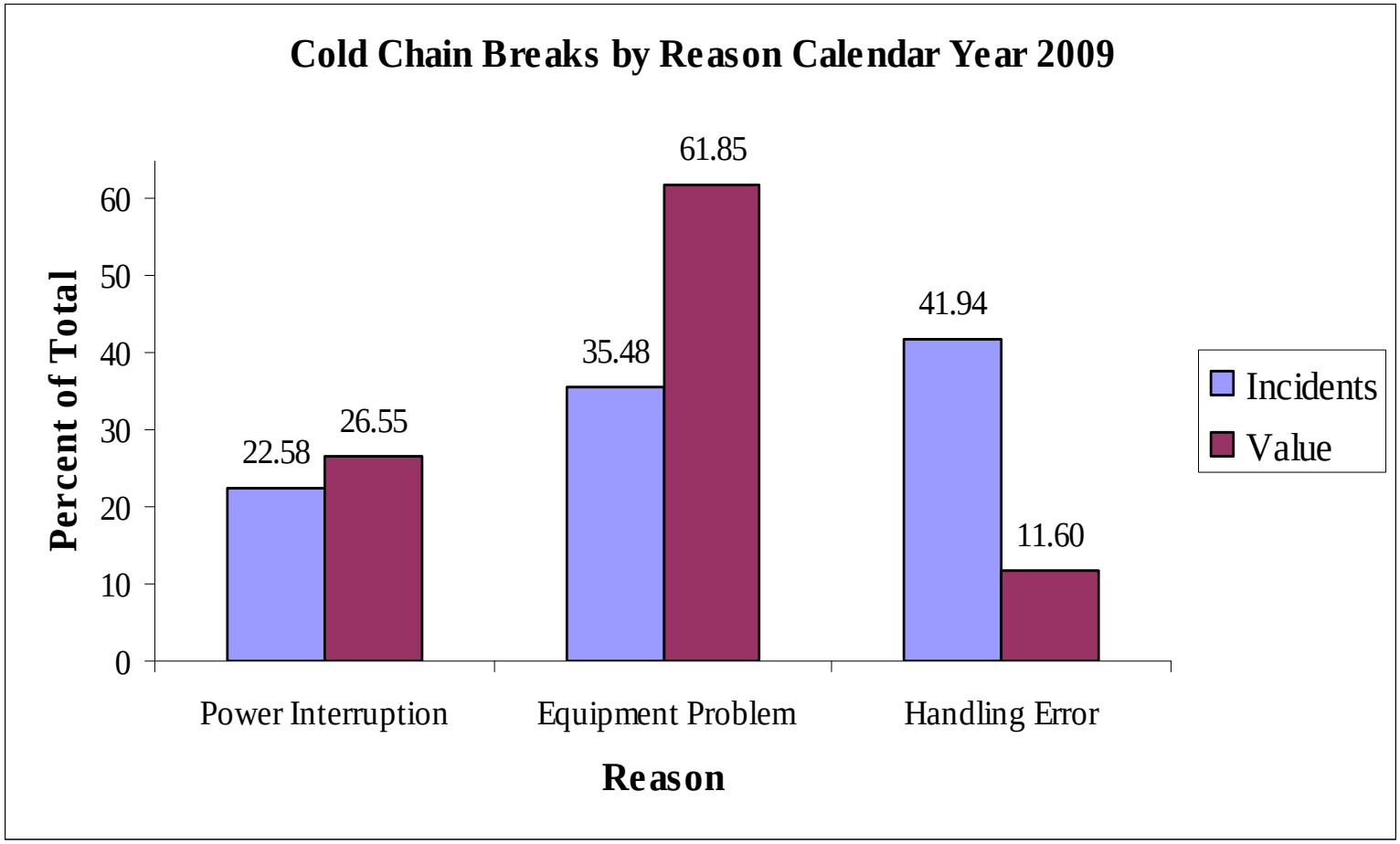
Section 1: Preventing and interpreting Cold Chain Breaks in the field

From: http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php

Preventing and interpreting CCB in the field

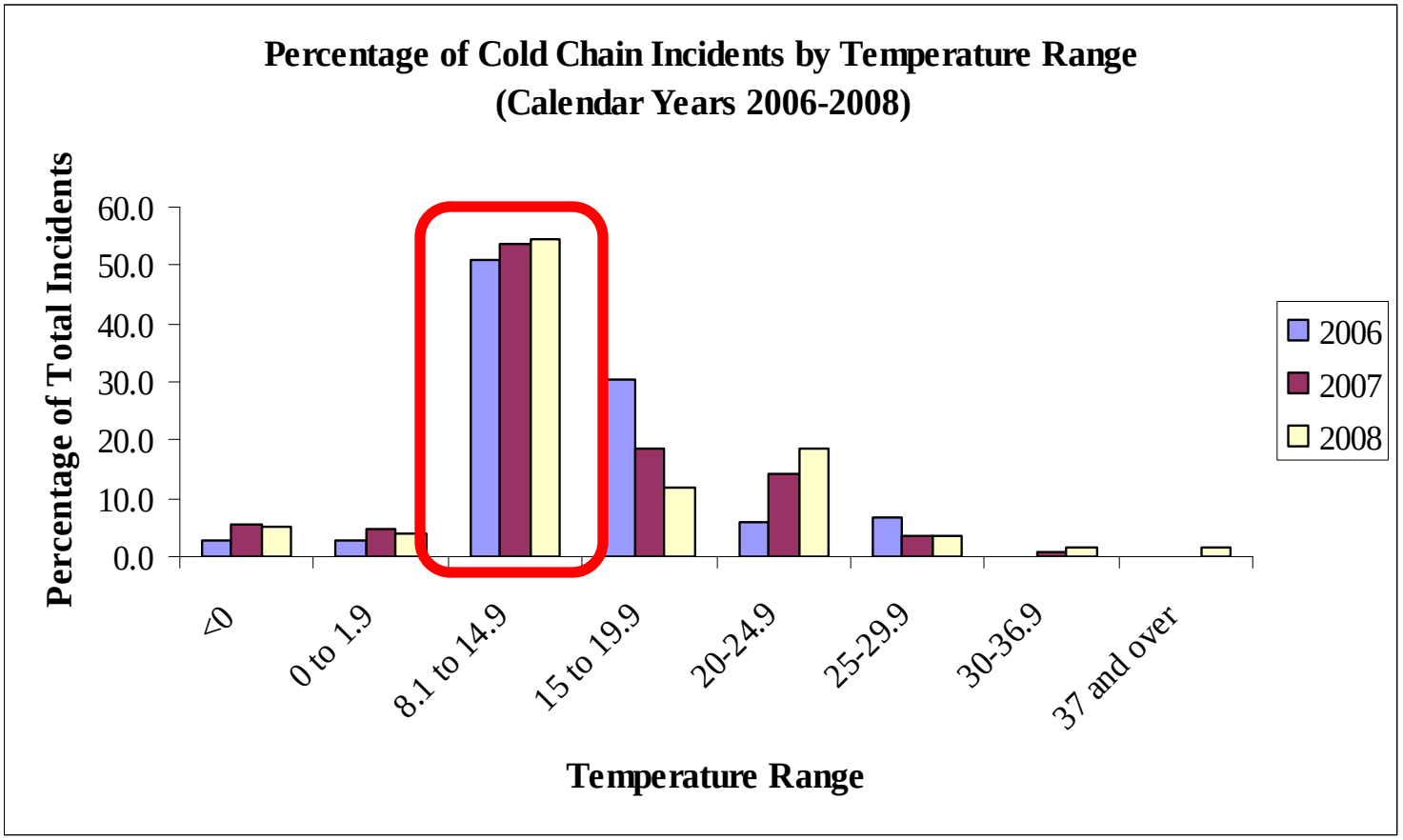
- Vaccine storage equipment evaluation and purchasing
  - Purchasing
  - Maintenance
  - Planning for equipment failure
- Vaccine storage practices
  - Temperature monitoring
  - Vaccine packing for transit (ambient temperature, mass clinics)
- Vaccine Stability Chart
  - Use
  - Reporting of decisions
- Reporting Cold Chain Breaks
  - Returning to BCCDC after a fatal break

Cold Chain Incidents



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

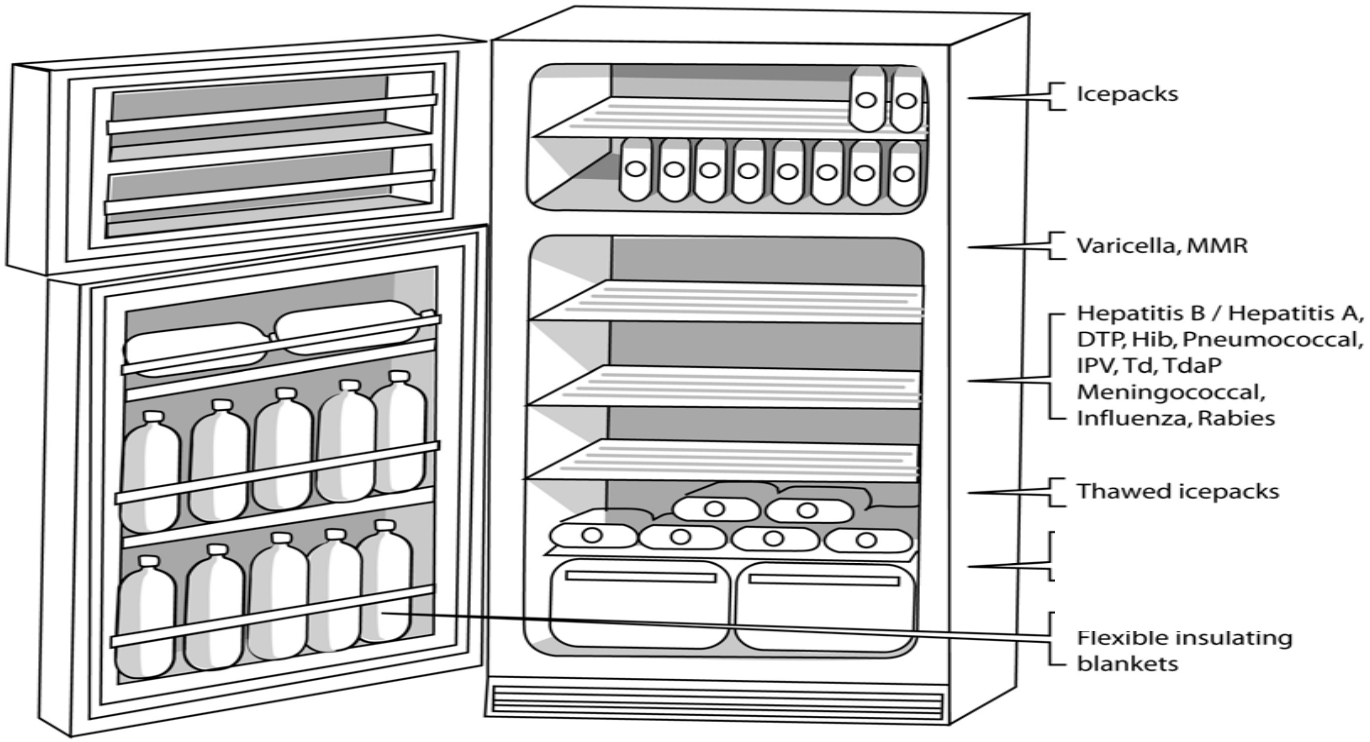
2) Defrost mechanism

3) Spatial temperature differential

4) Effects of changes in ambient temperature

5) Temperature recovery

Domestic Frost Free



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

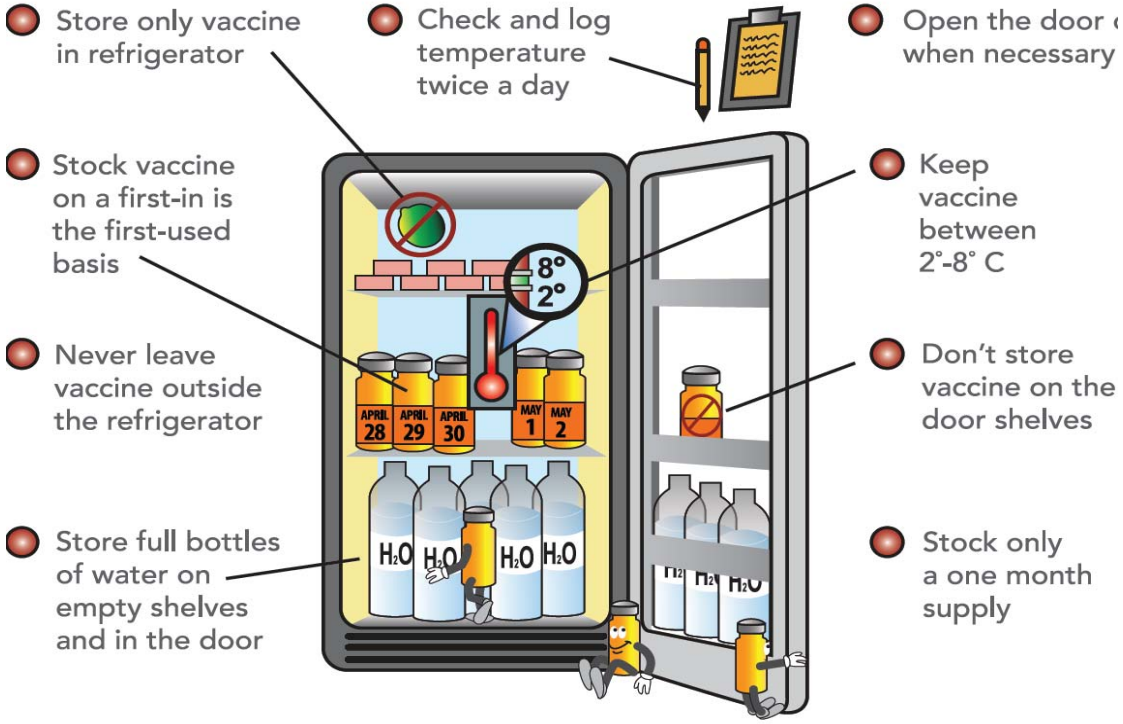
Fridge and thermometer maintenance:

- **Daily Maintenance Tasks**
- **Quarterly Maintenance**

- **Thermometer**
  - **calibration**

Vaccine Storage Practices:

Monitoring temperature



http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php

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)

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																														
°C Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
≥ 11°																														
10°					Take immediate action if temperature is in shaded section*																									
9°																														
8°																														
7°																														
6°																														
5°																														
4°																														
3°																														
2°																														
1°																														
0°					Take immediate action if temperature is in shaded section*																									
≤ -1°																														
Dial Setting of Fridge																														
Room Temp																														
Initials																														

Refrigerator temperature

Temperature Monitoring

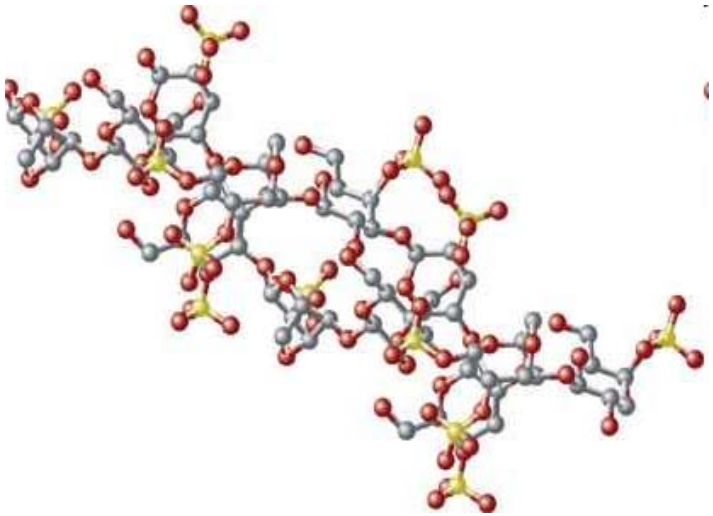
- **+2°C to +8°C is the recommended range**
- 0°C to +2°C: consider as “refrigerator conditions”
  - Thermometer accuracy (+/- 1° C)
  - “Worst case scenario”
  - Get fridge back in range quickly
  - **DO NOT FREEZE**

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.

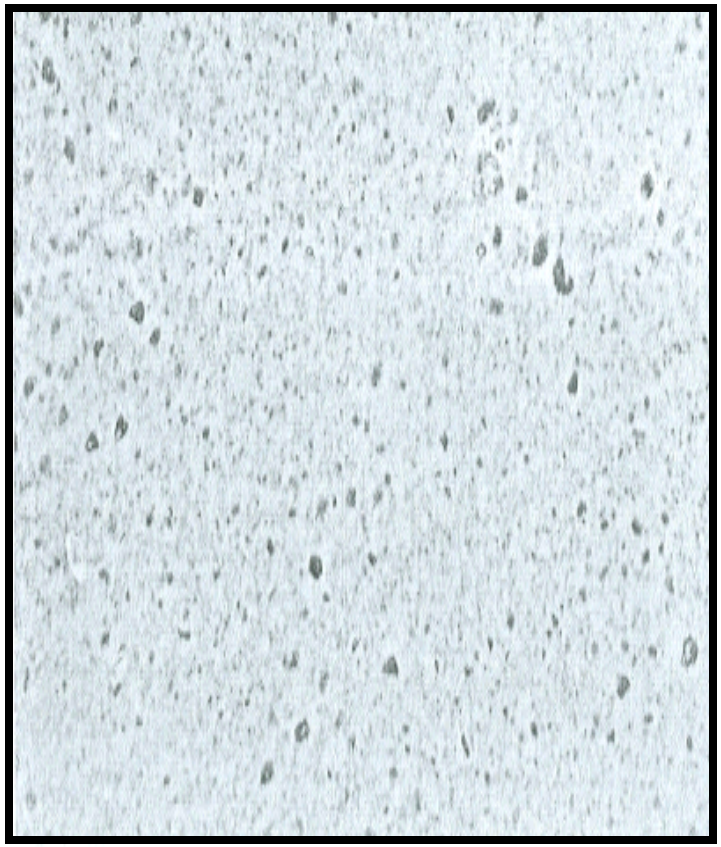


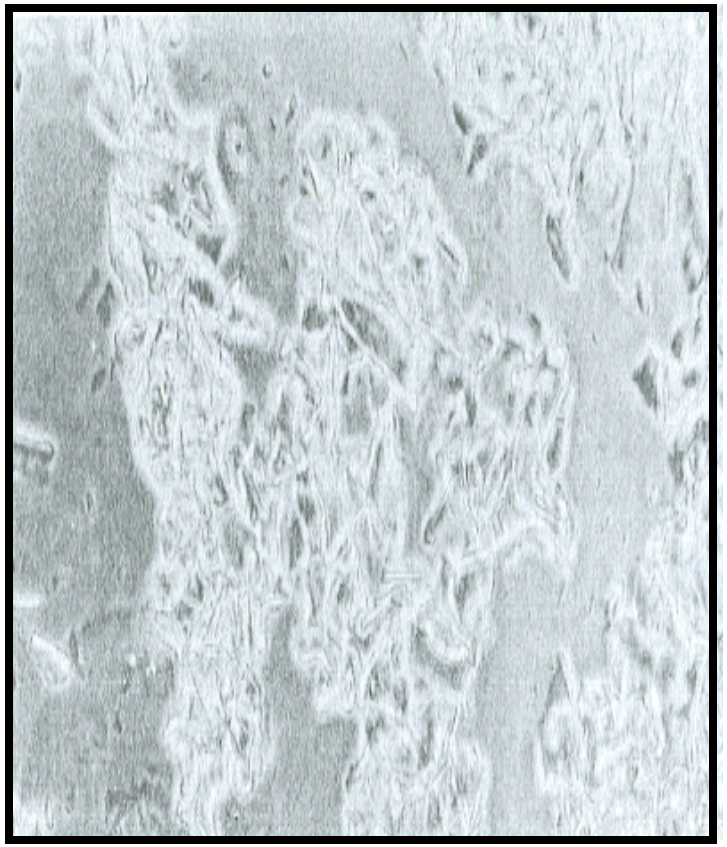
© WHO Turkey/2004/Gokhan

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

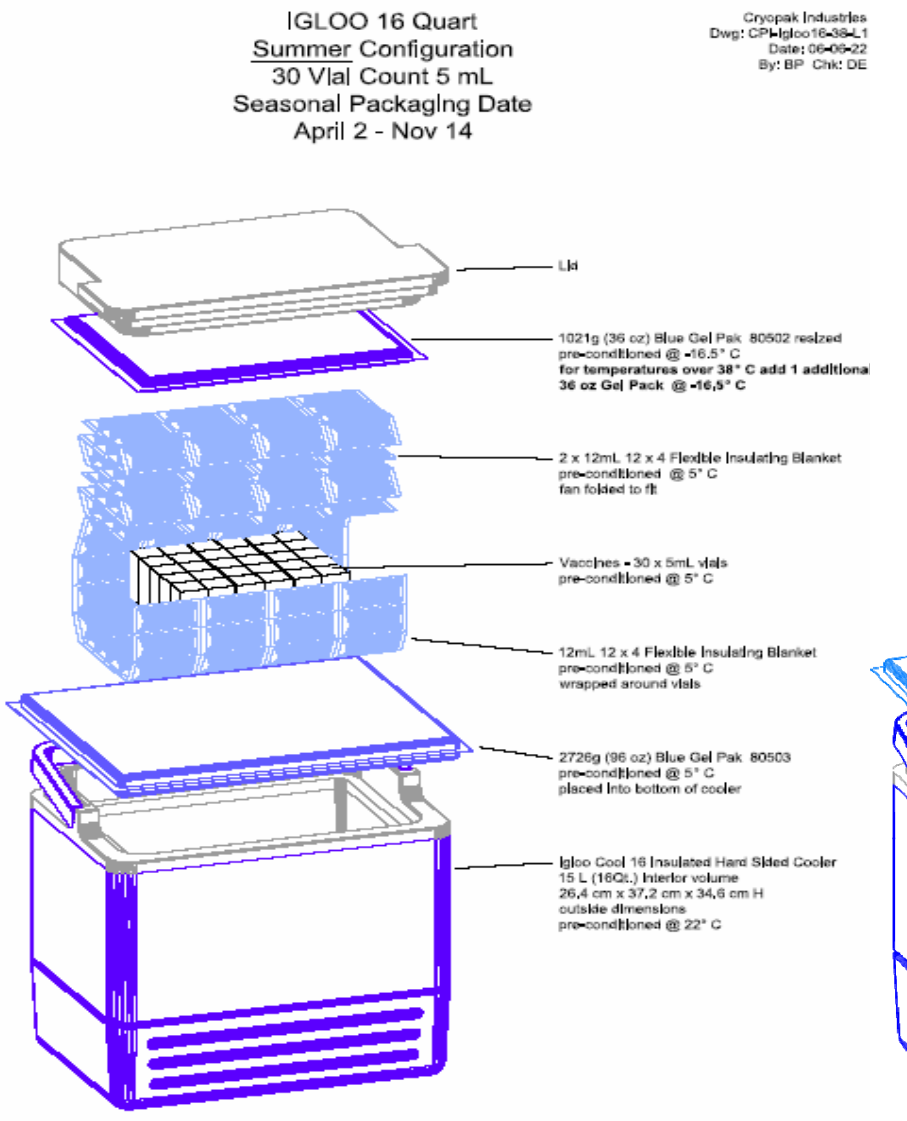


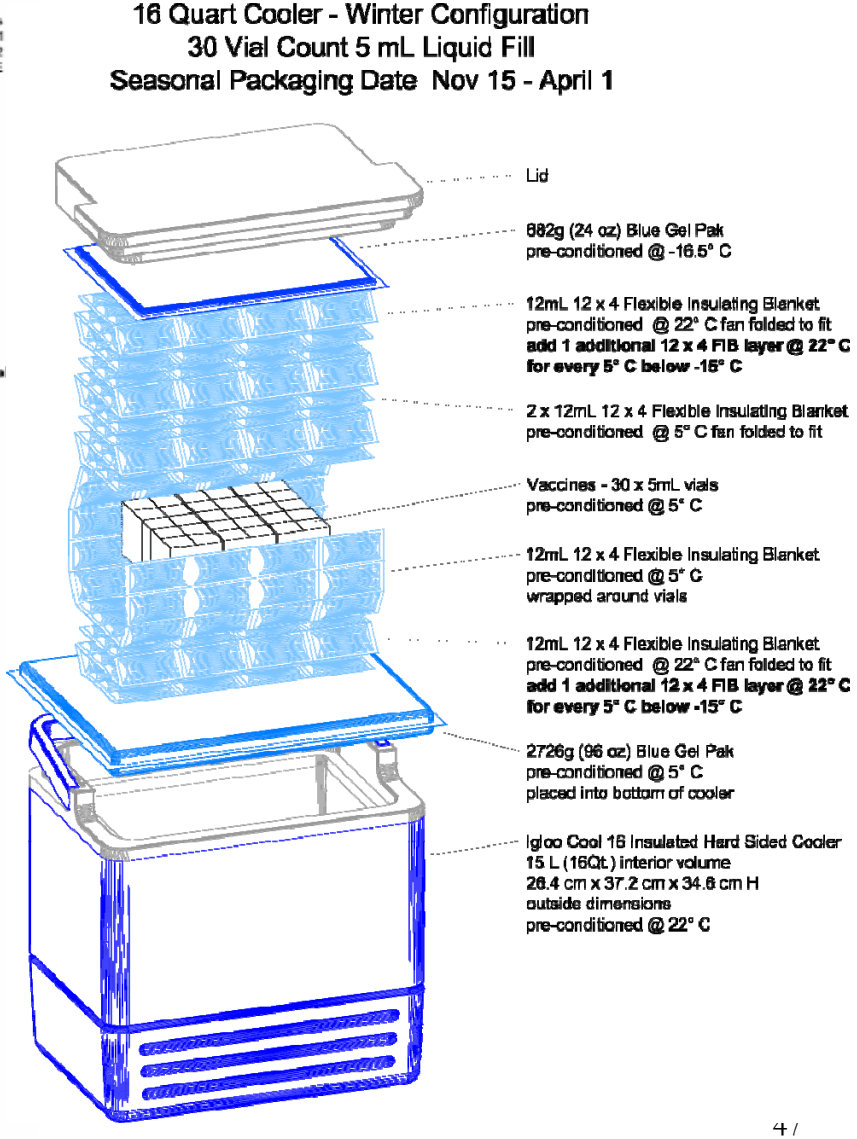


Packing for travel:

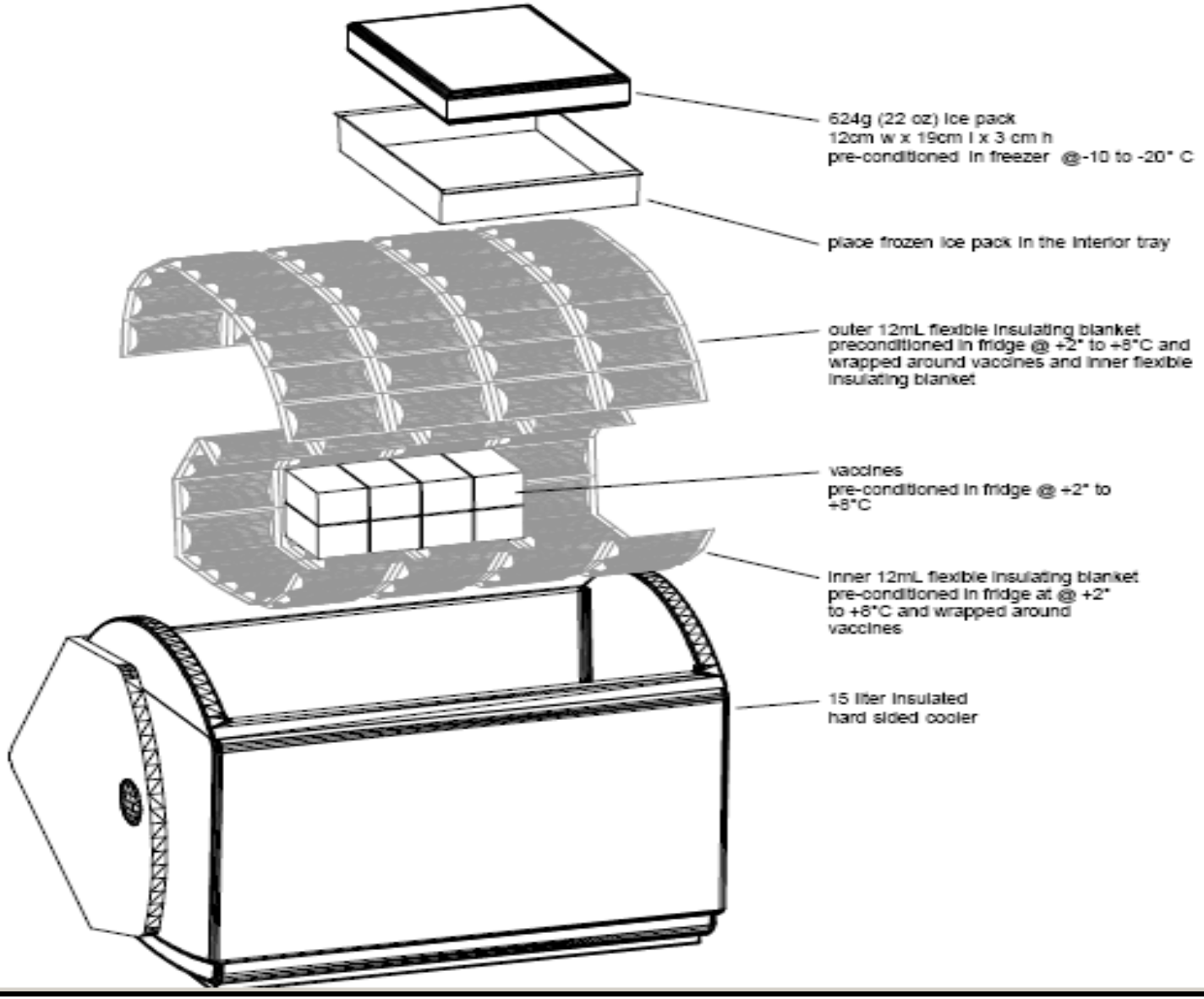
- Use of tested coolers and thermometers key
- Ambient temperature important (seasonality)

Summer vs. Winter



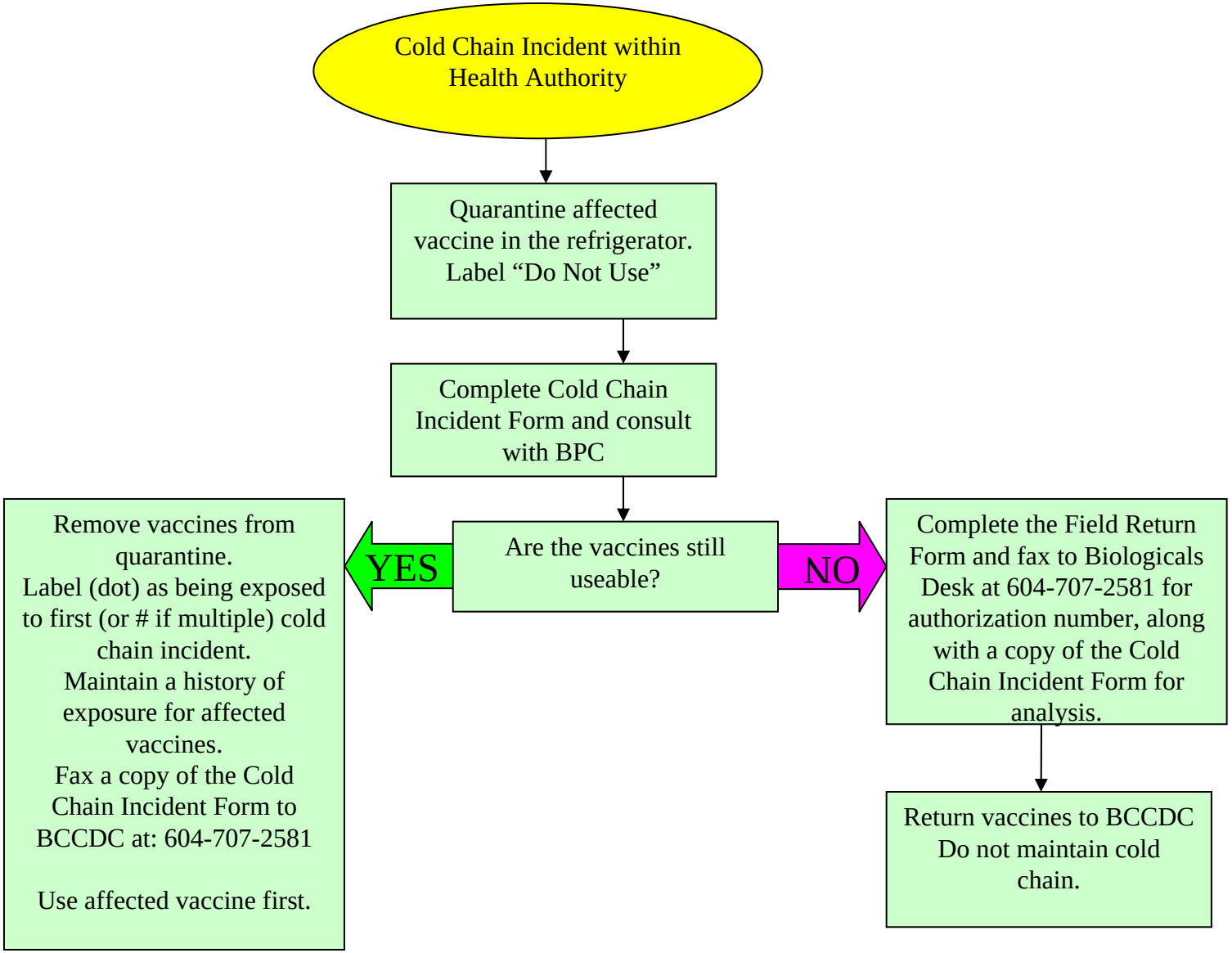


Packing an Insulated Cooler



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
Are the vaccines still useable?
YES
NO
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.
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.

PRODUCT	EXPOSURE DURING COLD CHAIN INCIDENT			REFERENCE
	< 0° C	> + 8° C to ≤ +25°C	> +25° C	
GlaxoSmithKline				
Boostrix	Do not freeze.[1]	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.	[1]Product monograph Feb 2008 [2]PWGSC contract E60PV-07PERT/002/PH, April 2007 Annex C.
Engerix B	Do not freeze.[1]	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]	Stable at +37°C for 7 days.[1]	[1]Product monograph Sept 2008 [2]GSK TagALERT® monitor interpretation provided to Ministère de la Santé et des Services Sociaux du Québec from GSK, May 2009
Fluviral	Do not freeze. [1]	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.	[1]Product monograph Jun 2008 [2]Information obtained by BCCDC from GSK, Sept 2008
Havrix	Do not freeze.[1]	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]	Stable at +37°C for 3 weeks.[1]	[1]Product monograph Oct 2008 [2]Information obtained by Saskatchewan Ministry of Health from GSK, Apr 2009
INFANRIX hexa	Do not freeze. [1]	Unreconstituted vaccine is stable at +25°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.	[1]Product monograph Jul 2008 [2]PWGSC contract E60PH-08HEXA/001/PH December 2008, Annex D.

Vaccine Stability Chart Interpretation

- **Boostrix®** (data is different because of sources of information)
  - Product monograph- 8 hours at 21º C
  - Contract clause- 2 weeks at 25º C
    - Use the more generous of the two statements
- **Engerix®**
  - 7 days at 37ºC (single exposure)
  - Multiple exposures totaling 24 hours at 25ºC

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.

PRODUCT	EXPOSURE DURING COLD CHAIN INCIDENT			REFERENCE
	< 0° C	> + 8° C to ≤ +25°C	> +25° C	
GlaxoSmithKline				
Boostrix	Do not freeze.[1]	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.	[1]Product monograph Feb 2008 [2]PWGSC contract E60PV-07PERT/002/PH, April 2007 Annex C.
Engerix B	Do not freeze.[1]	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]	Stable at +37°C for 7 days.[1]	[1]Product monograph Sept 2008 [2]GSK TagALERT® monitor interpretation provided to Ministère de la Santé et des Services Sociaux du Québec from GSK, May 2009
Fluviral	Do not freeze. [1]	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.	[1]Product monograph Jun 2008 [2]Information obtained by BCCDC from GSK, Sept 2008
Havrix	Do not freeze.[1]	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]	Stable at +37°C for 3 weeks.[1]	[1]Product monograph Oct 2008 [2]Information obtained by Saskatchewan Ministry of Health from GSK, Apr 2009
INFANRIX hexa	Do not freeze. [1]	Unreconstituted vaccine is stable at +25°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.	[1]Product monograph Jul 2008 [2]PWGSC contract E60PH-08HEXA/001/PH December 2008, Annex D.

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)

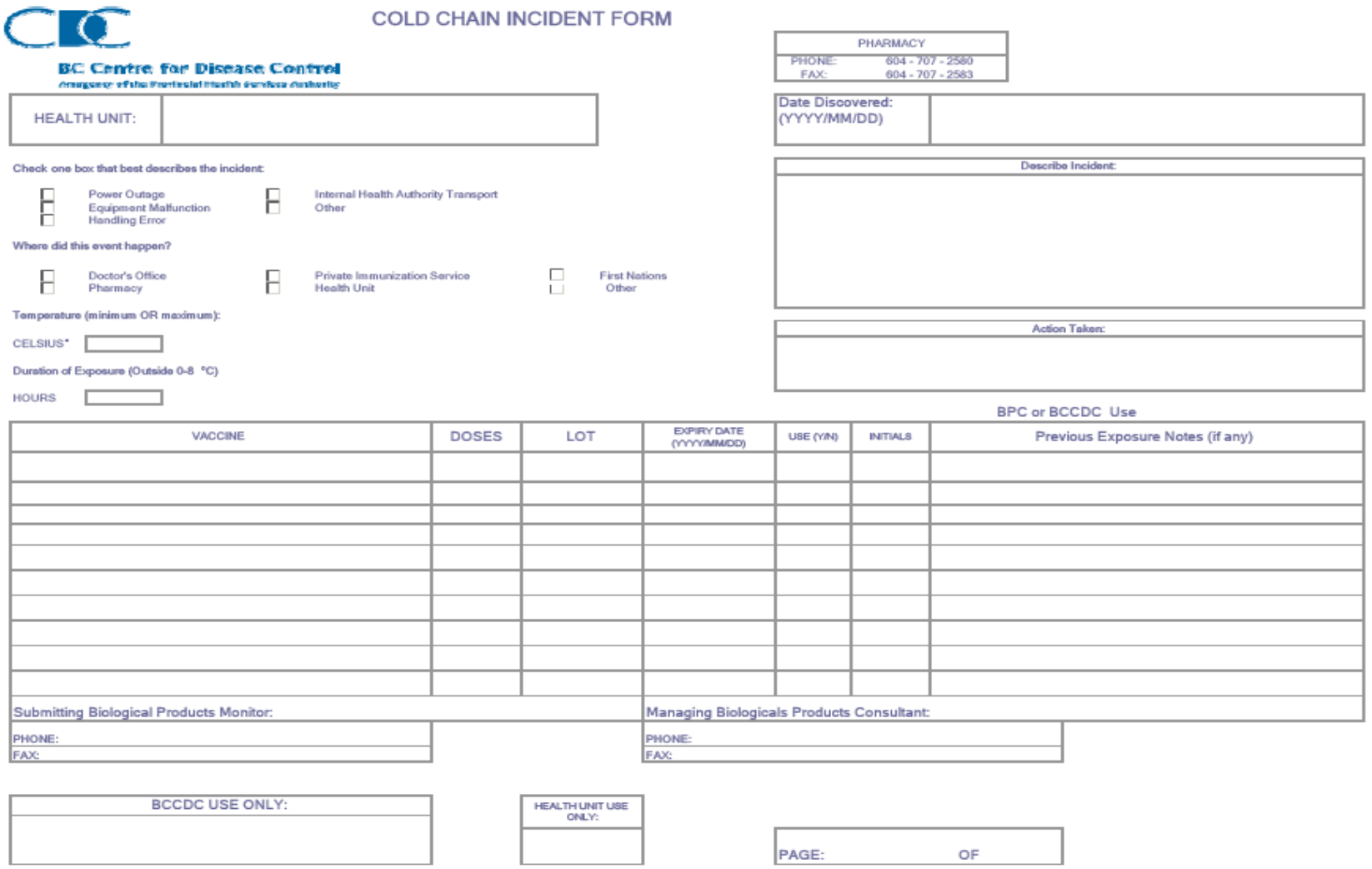
Vaccine Stability Chart Interpretation

- 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



BC Centre for Disease Control

COLD CHAIN INCIDENT FORM

PHARMACY	
PHONE:	604 - 707 - 2580
FAX:	604 - 707 - 2583

HEALTH UNIT:	

Date Discovered: (YYYY/MM/DD)	

Check one box that best describes the incident:

- ☐ Power Outage
- ☐ Equipment Malfunction
- ☐ Handling Error
- ☐ Internal Health Authority Transport
- ☐ Other

Where did this event happen?

- ☐ Doctor's Office
- ☐ Pharmacy
- ☐ Private Immunization Service
- ☐ Health Unit
- ☐ First Nations
- ☐ Other

Describe Incident:

Temperature (minimum OR maximum):

CELSIUS* ☐

Duration of Exposure (Outside 0-8 °C)

HOURS ☐

Action Taken:

BPC or BCCDC Use

VACCINE	DOSES	LOT	EXPIRY DATE (YYYY/MM/DD)	USE (Y/N)	INITIALS	Previous Exposure Notes (if any)

Submitting Biological Products Monitor:	Managing Biologicals Products Consultant:
PHONE:	PHONE:
FAX:	FAX:

BCCDC USE ONLY:

HEALTH UNIT USE ONLY:

PAGE: OF

Completing field return forms:

BC Centre for Disease Control

FIELD RETURN FORM

Health Unit:
Address:
Phone:
Fax:

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 Biologicals Return Requirements Form as per: Communicable Disease Manual.
http://www.bccdc.ca/NR/rdonlyres/74061DCE-4826-4A8C-BE6B-E551E652BCDA/0/Biologicals_return_and_redistribution_requirements_form.pdf

VACCINES	Product Code (BCCDC Use)	LOT NUMBER	EXPIRY DATE (YYYY/MM/DD)	REASON	DOSES
DaPTdPWHBHib, Infanrix Hexa	INFANRIX				
DaPTdPWHib, Pediacel	PEDIACEL				
DaPTdPV, Quadracel	SPACE				
Haemophilus B Conjugate, ActHIB	TALL				
Hepatitis A, Vaqta pediatric	VAQTA0.5				
Hepatitis A, Vaqta adult	VAQTA1.0V				
Hepatitis B, Pediatric, (T-free), Recombivax-HB	REDOMB0.5				
Hepatitis B (Renal/Kidney Dialysis), Recombivax-HB	REDOMB-DYS				
Hepatitis B Vaccine, Recombivax-HB	REDOMB1.0				
Hepatitis B Vaccine, Engerix	HEPB10ENG				
HPV	HPV1				
Immune Serum Globulin, GamaSTAN	ISG-SD2.0				
Inactivated Polio, Imovax Polio	POLVACS				
Influenza Vaccine, Fluviral	FLUVIRAL				
Influenza Vaccine, Vaxigrip					
Measles, Mumps, Rubella, MMR II	MMR II				
Meningococcal C Conjugate, NeisVac-C	MENC0.5-NV10				
Meningococcal Conjugate A/C/Y/W-135, Menactra	MENCVAC				
Meningococcal Polysaccharide A/C/Y/W-135, Menomune	MOSS				
Pneumococcal Conjugate, Prevnar 7	PREVNAR10				
Pneumococcal Conjugate, Prevnar 13	PREVNAR13				
Pneumococcal Polysaccharide, PneumoVax23	PNEUV23				
Rabies Immune Globulin, HyperRab	RABIGH300TC2				
Rabies, Imovax Rabies	IMOVAX				
Rabies, RabAvert	RABAVERT				
Td Adsorbed	SOUND				
TdIPV Adsorbed (adult)	ELEMENT				
TdaP Adsorbed, Adacel	ADCL5-0.5				
Tetanus Immune Globulin, Bayset / Hypertet	TIG250I				
Varicella Vaccine, Varivax III	VARVX0.5-10				
Varicella, Varitrix	VARI2000I				
Other:					

Fax Forms to: 604-707-2581

Name of Biological Products Monitor:

Biologicals Desk at BCCDC
1100-655 West 12th Avenue
Vancouver BC V5Z 4R4

Email: biologicals@bccdc.ca
Phone: 604-707-2582

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 **Month and Year:** January 2008

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufac-turer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconsti-tution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
01/2/08	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
01/9/08										1	1
01/15/08	LST	✔	Pneumovax 23	Merck	M	0395B	2/15/09	N/A	5	3	3
01/22/08										1	2
01/29/08										0	2
								Vaccine Totals	7	5	2 ††

* 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"

Physical Stock Check (In Doses)	2
Difference ("Balance" minus "Physical Stock Check")	0
Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock records for vaccine providers. Contact program staff for information. If stock records **are not** available from the state or local health department immunization program, this stock record may be used (see Stock Record in the Resources section for a blank version).

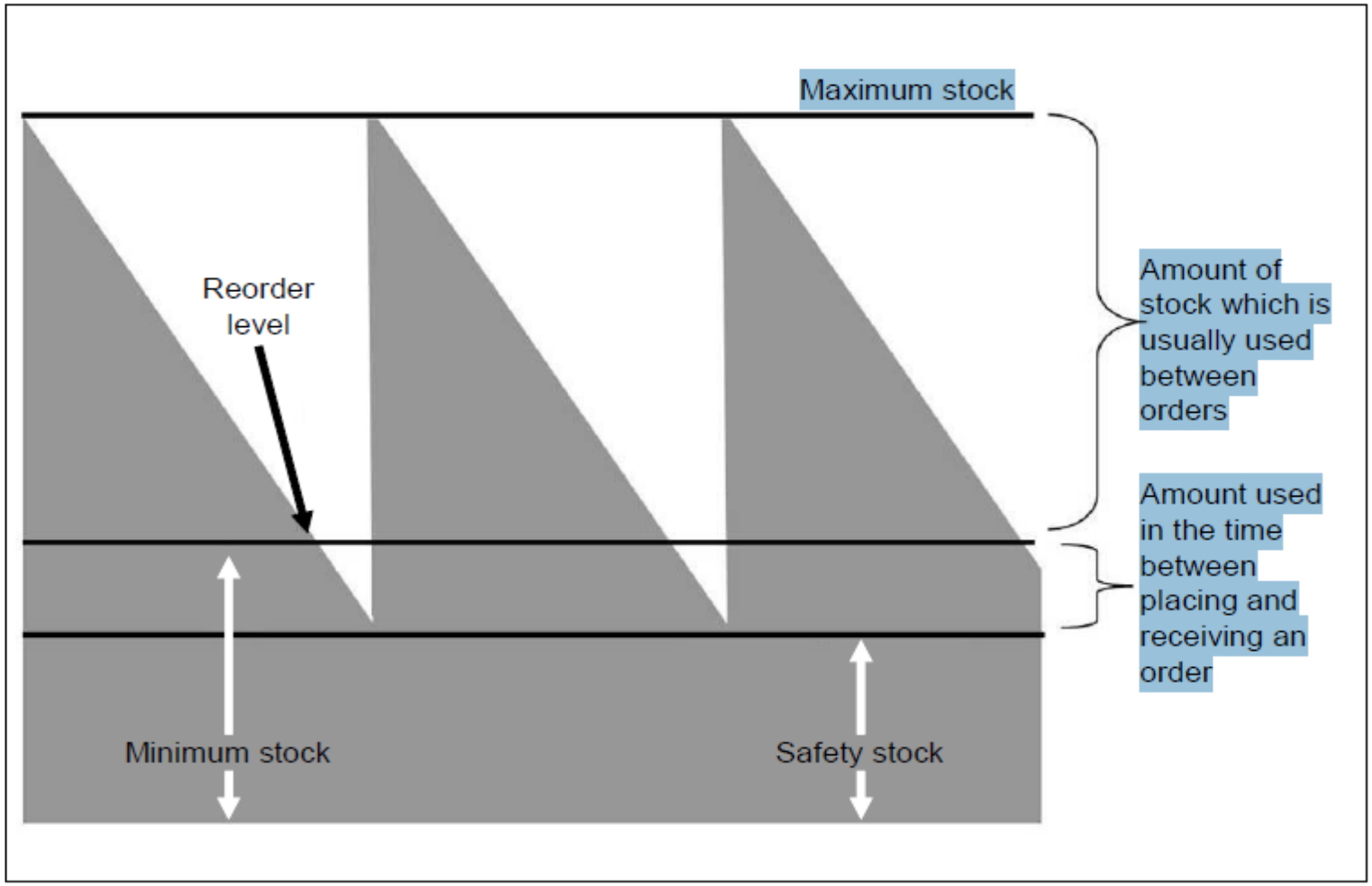
Inventory Management Tool- example

RICHMOND HEALTH DEPARTMENT BCCDC INVENTORY May 1 - May 28, 2009

PRODUCT NAME	CODE NAME	UNIT DESCRIPTION	MONTHLY INVENTORY IN UNITS: UNITS ON HAND	ORDERED	TOTAL	MONTHLY DISTRIBUTION IN UNITS: RHD	DOCTORS	OTHER	RETURNS TO DISTRIBUTOR	WASTAGE IN UNITS: CODE1 EXPIRED	CODE2 FRIDGE FAILURE	CODE3 DAMAGED PRODUCTS	UNITS ON HAND	returns
Tetanus Immune Globulin	BAYTET-S	1 x 1 dose syringe	0	0	0								0	0
Td/IPV Adsorbed	ELEMENT	5 x 0.5ml vial	12	0	12		3						9	0
Hepatitis B t free	RECOMB 0.5	1 x 0.5 ml vial	285	216	501	65	186						250	0
Hepatitis B	RECOMB1.0	1 x 1 ml vial	40	0	40	9							31	0
Hepatitis B - Engerix	RECOMB1.0	1 x 1.0 ml vial	0	0	0								0	0
Hepatitis B	RECOMB 3.0	10 x 3.0 ml vial	0	0	0								0	0
Hepatitis B	RECOMB1.0	10 x 1 ml Vial	48	0	48	30	2						16	0
Hepatitis B (KD)	RECOMB-DYS	1 x 1.0 ml vial (40mcg)	4	5	9	4							5	0
Hepatitis B (KD) Engerix	RECOMB-DYS	1 x 1.0 ml vial (20mcg)	0	0	0								0	0
**Influenza (Split)	FLUVIRAL	1 x 10 dose vial	46	0	46								46	0
Influenza Virus Vaccine	INFLUVAC	10 x 0.5 ml syringe	0	0	0								0	0
DT/IPV	GLEN	5 x 0.5ml amps	0	0	0								0	0
Hepatitis A	VAQTA1.0	1 x 1 ml vial	0	0	0								0	0
Hepatitis A	HAVRIX 1440	1 x 1 ml vial	27	20	47	2	23						22	0
Hepatitis A	VAQTA0.5	1 x 0.5 ml vial	14	0	14								14	0
H1N1	H1N1	1 x 10 dose vial	0	0	0								0	0
H1N1 (Non-Adjuvanted) - Pregn	H1N1	1 X 5 dose vial	0	0	0								0	0
H1N1 (Non-Adjuvanted) 10-64yr	H1N1	1 x 10 dose vial	0	0	0								0	0
Human Papiloma Virus	HPV	1 x 0.5 ml single dose vial	633	288	921	541							380	0
Immune Serum Globulin	ISG-SD2.0	1 x 2 ml vial	0	0	0								0	0
Meningococcal	MOSS10	1 x 10 dose vial	0	0	0								0	0
Measles, Mumps, Rubella	MMR II	10 x 0.5 ml vial	56	20	76	21	26						29	0
Meningococcal	MOSS	1 x 1 dose vial	0	0	0								0	0
Miningococcal A/C/Y/ W-135, Menactra	MENCVAC	1 x 0.5 ml dose vial	6	0	6								6	0
Miningococcal A/C/Y/ W-135, Menactra	MENCVAC	1 x 0.5 ml dose syringe	0	0	0								0	0
Inactivated Polio IPV	OCEAN	5 x 0.5 ml amps	0	0	0								0	0
Inactivated Polio, Imovax	POLVACS	10 x 0.5ml x 1 dose syringes	1	0	1	0.5	0.5						0	0
Inactivated Polio, Imovax	POLVACS	1 x 0.5 ml dose syringe	37	50	87	45							42	0
DaPT/IPV/HIB/HEPB	INFRANRIX-HEXA	10 x 0.5 ml single doses (syringe + vial)	69	0	69	5	23						41	0

Apr 1 - Apr 30 | **May 1 - May 28** | May 29 - Jun 25 | Jun 26 - Jul 23 | Jul 24 - Aug 20 | Aug 21 - S

Inventory control systems: Minimum, Maximum and Safety Stock Levels



BC Centre for Disease Control
An agency of the Provincial Health Services Authority

BIOLOGICALS ORDER FORM

HEALTH UNIT	EMAIL TO: biologicals@bcodc.ca	ORDER DATE (YYYY/MM/DD):
	BIOLOGICALS DESK PHONE: 604-707-2582 FAX: 604-707-2581	Sender Name & Phone:

SHIP TO:

NOTES:

STANDARD VACCINES: Approved by:	BASE ORDER [1]	DOSES ON HAND [2]	DOSES REQUIRED [3]
DaPT/IPV/HB/Hib, Infanrix Hexa, 10 doses per box			
DaPT/IPV/Hib, Pediacel, 5 doses per box			
DaPT/IPV, Quadracel, 5 doses per box			
Haemophilus influenza type b, ActHIB, 5 doses per box			
Hepatitis A, pediatric, Vaqta			
Hepatitis A, adult, Havrix 1440			
Hepatitis B, infant, Recombivax-HB			
Hepatitis B, dialysis, Recombivax-HB			
Hepatitis B, grade 6/adult, Engerix B or Recombivax			
Human PapillomaVirus, grade 6 and 9 girls, Gardasil			
Inactivated Polio, Imovax Polio, 10 doses per box			
Influenza, Fluviral, 10 adult doses per vial			
Influenza, Vaxigrip, 10 adult doses per vial			
Measles, Mumps, Rubella, MMR II, 10 doses per box			
Meningococcal Conjugate C, Neisvac, 10 doses per box			
Pneumococcal Conjugate 13, Prevnar, 10 doses per box			
Pneumococcal Polysaccharide 23, 10 doses per box			
TdaP, Adacel, 5 doses per box, Grade 9			
Td Adsorbed, 5 doses per box			
Td/IPV Adsorbed, 5 doses per box			
Varicella, Varilrix, 10 doses per box			

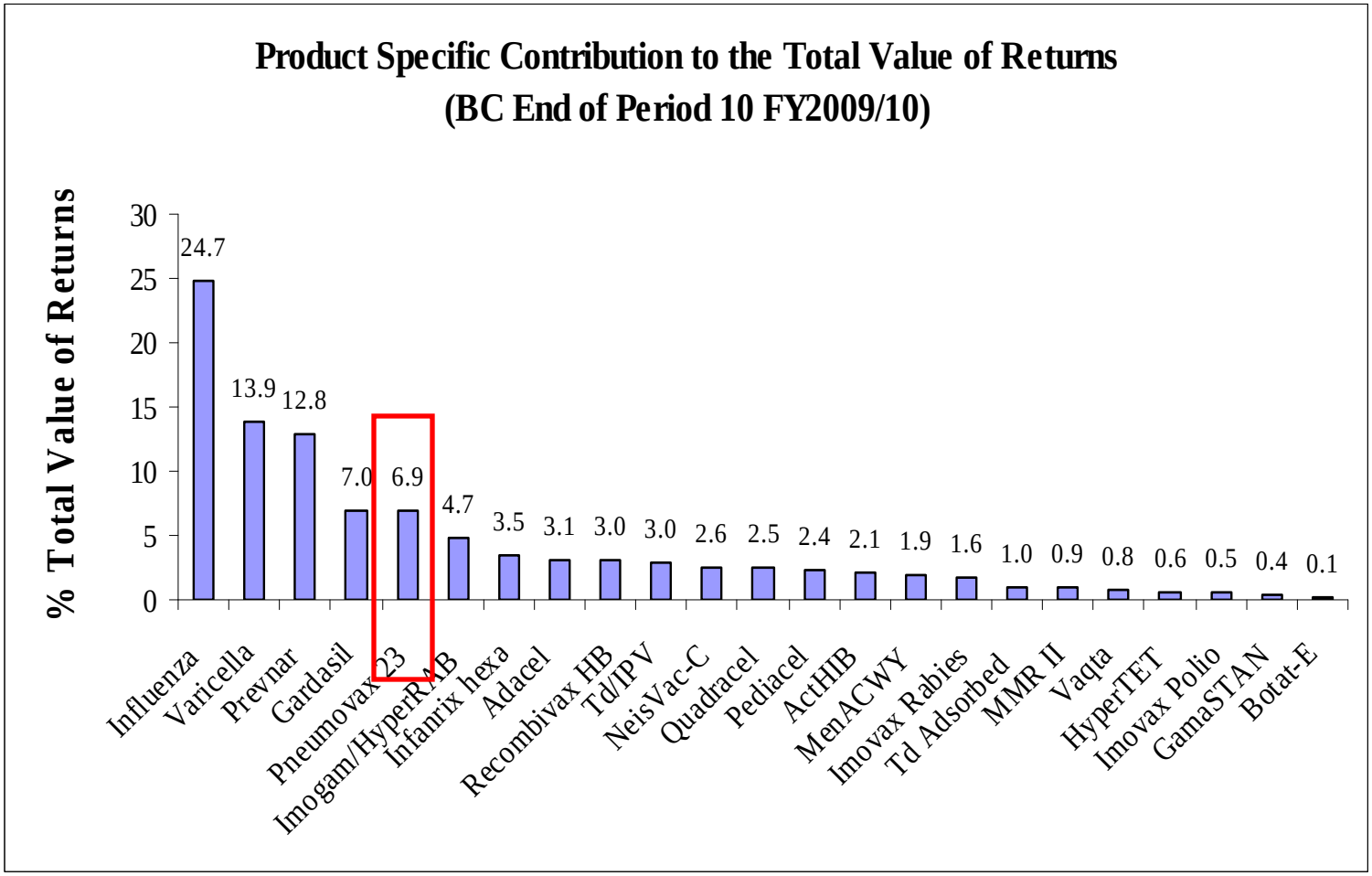
NON-STANDARD VACCINES: Approved by:			
Immune Serum Globulin, Gamastan, 2 ml per vial			
Meningococcal conjugate, A/C/Y/W - 135, Menactra			
Meningococcal polysaccharide A/C/Y/W - 135, Menomune			
Tetanus Immune Globulin, Hypertet			

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:

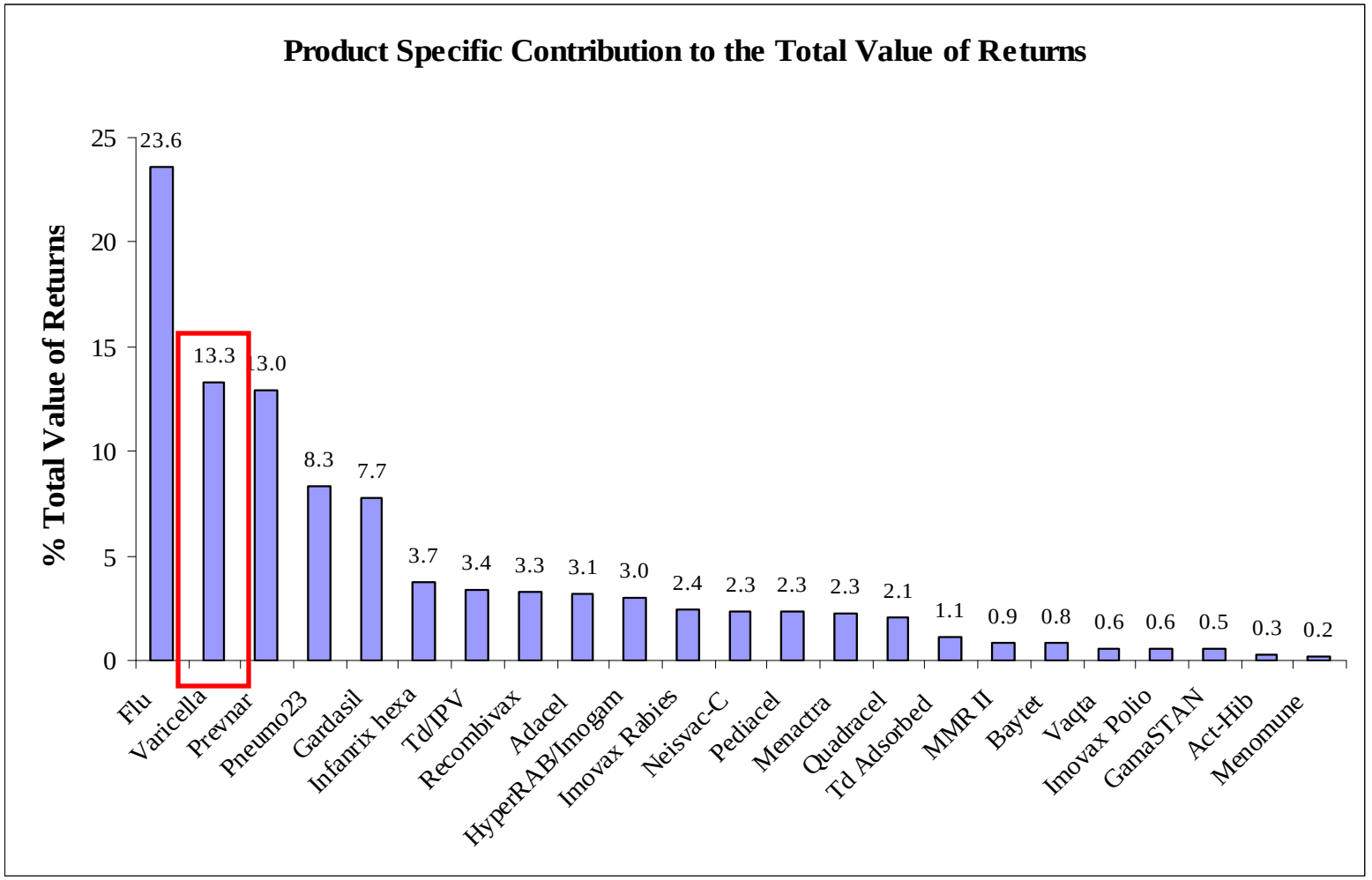


Expiry

Expiry

- 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:



Inventory management

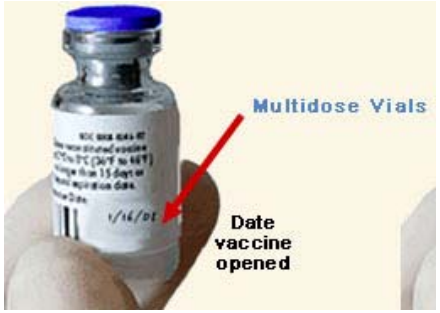
- "First in, first out" management vs. "earliest expiry first out"
- Check expiry date on the last business day of the month

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.

"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

Excellence Program
2010 Silver Level Recipient

BC Centre for Disease Control
AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

BIOLOGICALS RETURN AND REDISTRIBUTION REQUIREMENTS FORM

NOTE: A FIELD RETURN FORM (http://www.bccdc.ca/imm-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 _____

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