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# Biologicals Management

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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



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# 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
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# 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

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# 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 (2005) and Addendum (2009)
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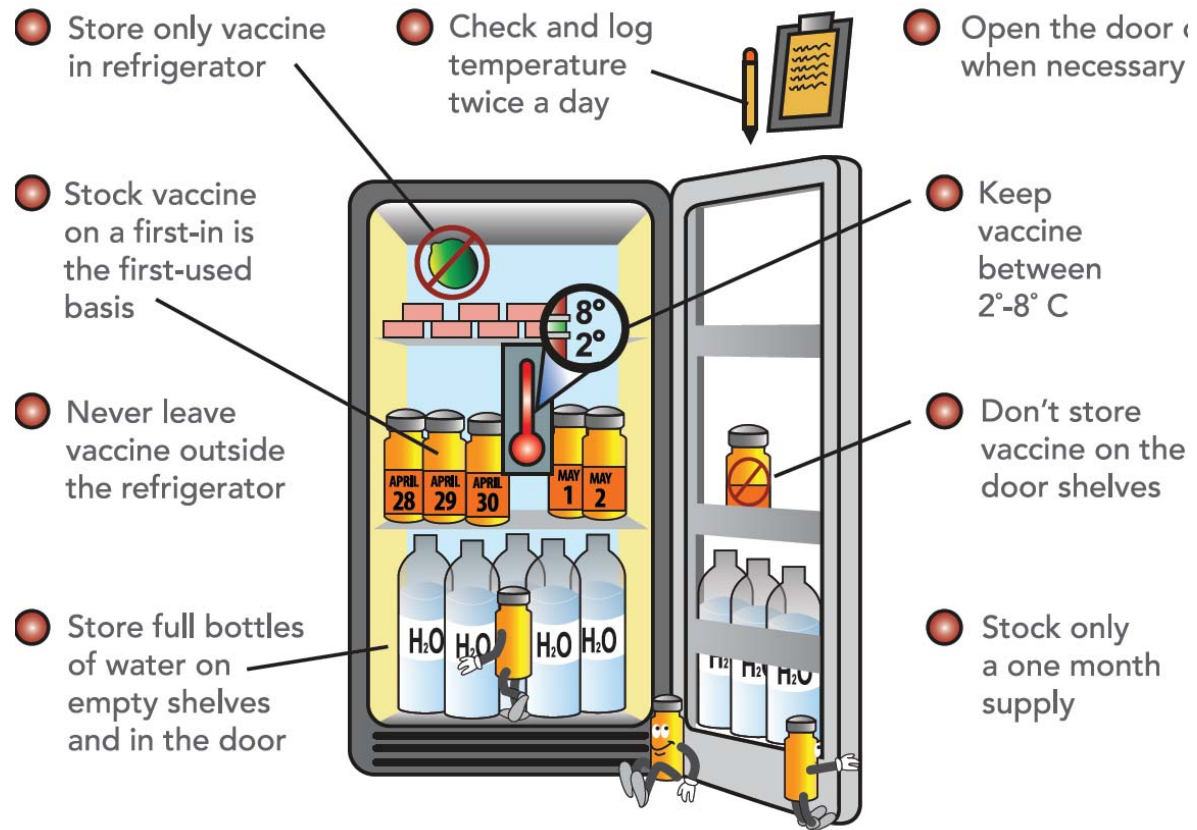
# Biological Product Monitors

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

Know your  
refrigerator !

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# VACCINE REFRIGERATOR



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# 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

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# 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.



Vaccine Expiration Date:  
**1/08**

**Note:** Use **through January 31, 2008**. Do NOT use on or after February 1, 2008.

“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**



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# 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
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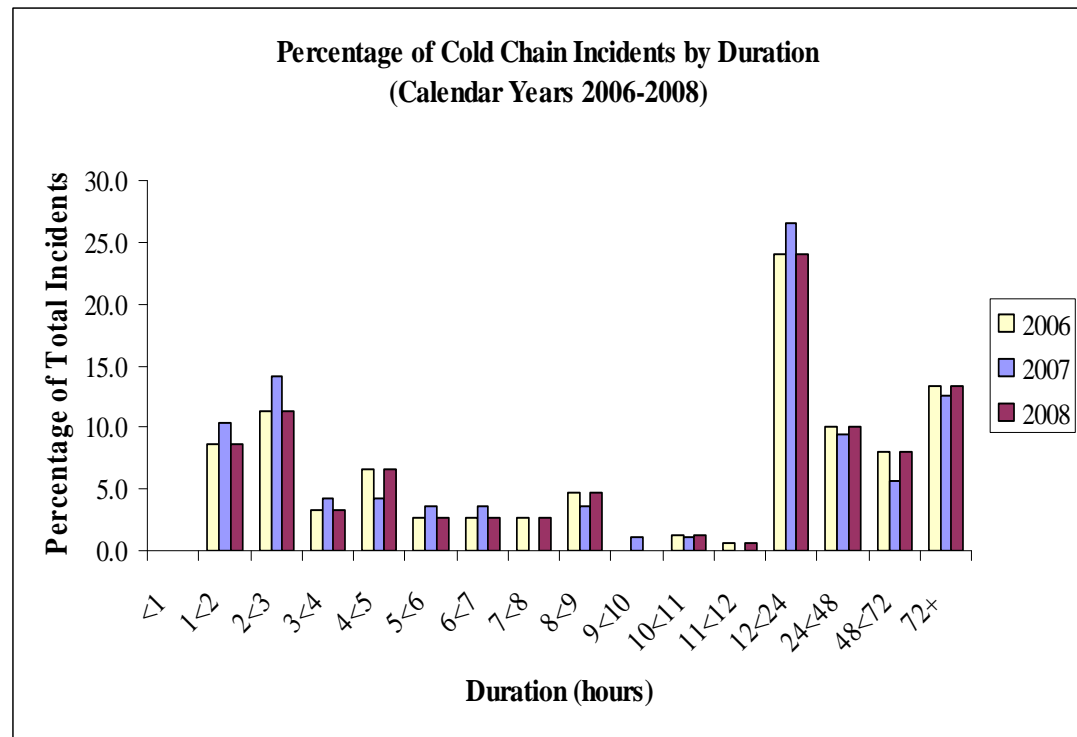
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# Biologicals Return and Redistribution Form

- 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
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# Duration of Exposures

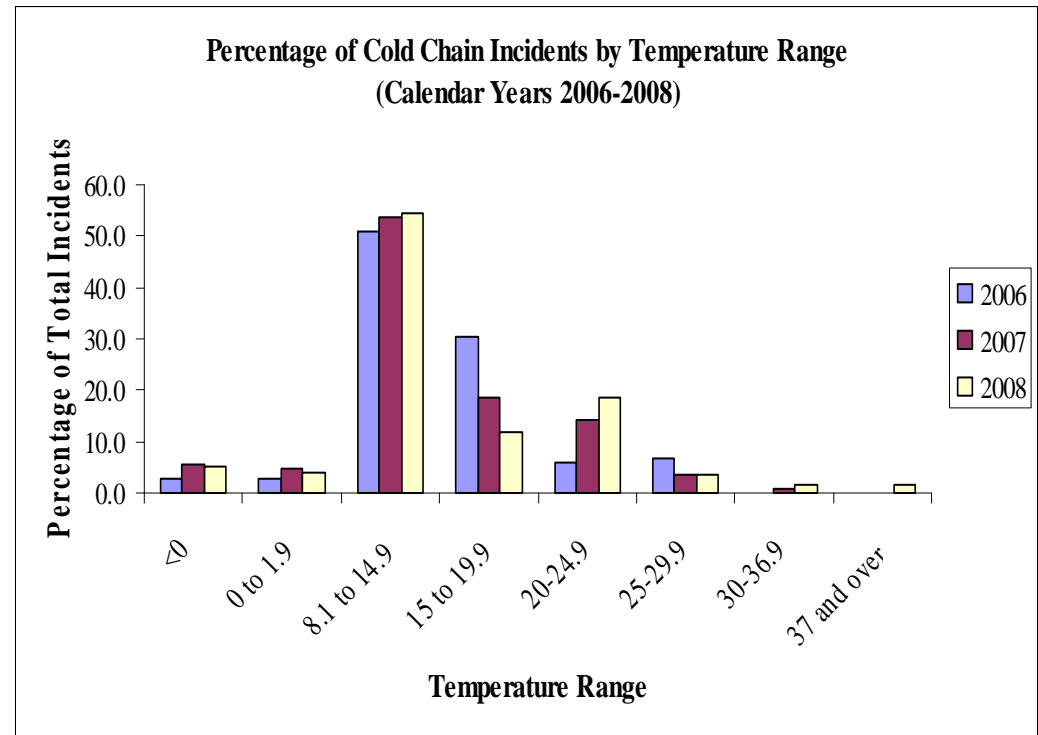
- Most cold chain incidents less than 72 hours



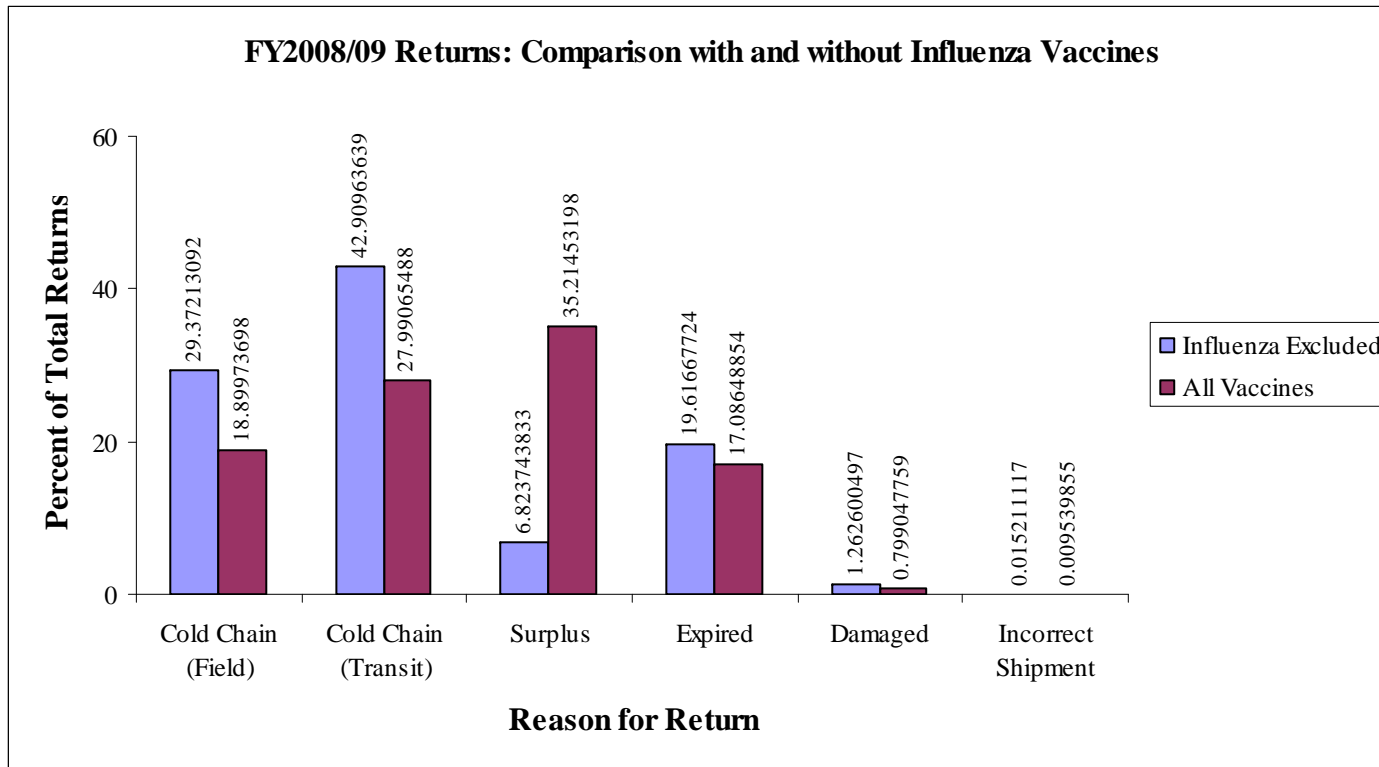


# Temperatures

- Most incidents < 25°

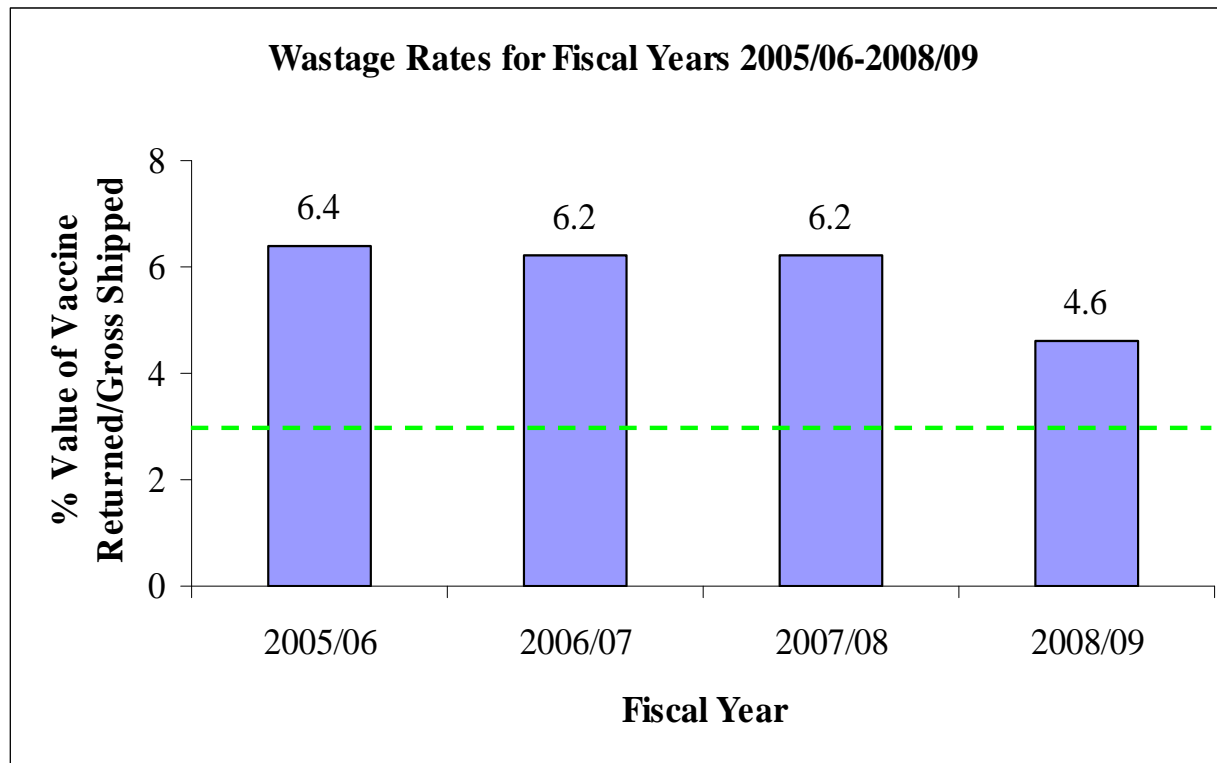


# Returns by reason



# Vaccine wastage

- Wastage goal: 3%



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# Next Steps

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

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