# Storage and Handling of Vaccines

## The Cold Chain

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# Speaker Disclosure

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- Consulting
  - None

# Objectives

- Understand the importance of the cold chain
- Integrate National Storage and Handling Guidelines into practice
  - New National Guidelines are in progress so some things may change
- Respond appropriately to cold chain incidents

# What is the Cold Chain?


Picture from: http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/section1-eng.php#12

Maintenance of optimal conditions during the transport, storage, and handling of vaccines

Begins at the manufacturer and ends with the administration of the vaccine

# Why is the Cold Chain Important?

- Vaccines are damaged by exposure to excessive cold, heat &/or light

- Ensure use of effective product
  - ⇑ risk vaccine preventable disease
  - Loss of potency is cumulative
  - Remember that vaccines also have expiry date

- Public confidence in vaccines
  - Need to revaccinate people who have received a potentially ineffective vaccine

- Resource management
  - Supply chain ⇒ cancellation of clinics
  - Wastage & expense

Canadian Immunization Guide: http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-08-eng.php

# Is it Really a Problem?

- 17% to 37% HCPs expose vaccines to improper storage temperatures
  - Refrigerators too cold
  - Direct exposure to ice pack during during transport

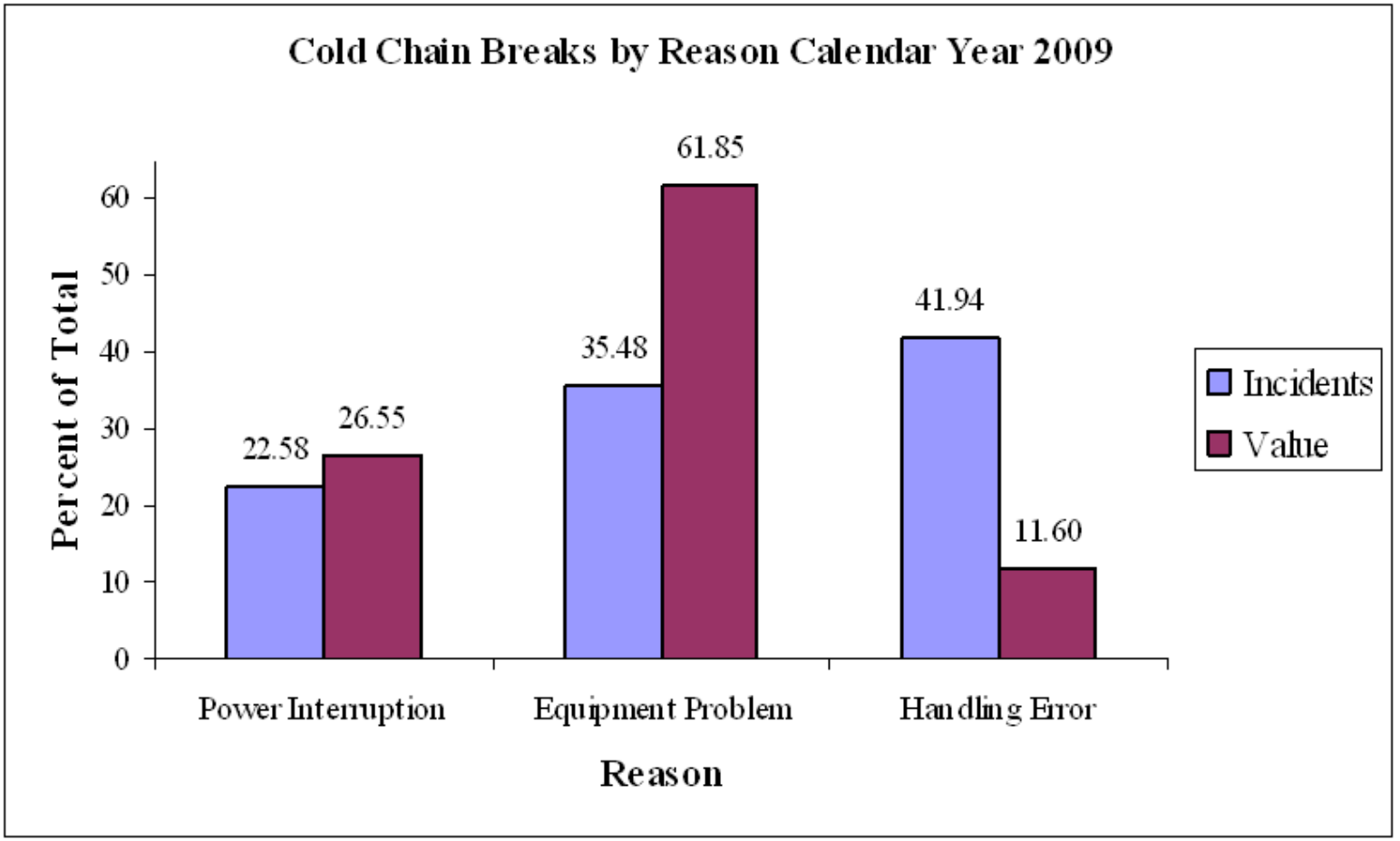
  - Refrigerators too warm
  - Problem with transport


Gazmararian JA, et al Am J Prev Med 2002;23(4):246–53 ; Bell KN, et al, Pediatrics 2001;107(6):1–6.

# Storage Conditions for Vaccines

- Fridge stable
  - +2° C to +8° C
  - Aim for +5° C
- Frozen
  - ≤ -15°C
- Some vaccines are light sensitive
  - Keep in original packaging
- Diluents
  - Be familiar with specific storage conditions for diluents

# A Few Common Reasons for Cold Chain Breaks




Courtesy of Brittany Deeter - BCCDC

# What Makes for an Effective Cold-Chain?

- People
  - Proper training
- Equipment
  - For both storage and transport
- Policies, Procedures & Protocols
  - Every day and “What to do if … happens”

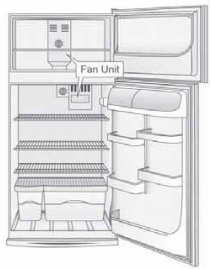
# People

- Anyone who handles and/or administers vaccines should:
  - Understand importance of cold-chain
  - Use best practices
  - Be familiar with policies & procedures
  - Be familiar with urgent protocols
  - Understand their responsibility

National Storage & Handling Guidelines, 2007

# Equipment

- Refrigerator
  - Purpose built
  - Domestic
    - Know your refrigerator
      - Temperature zones – store vaccines in certain areas only
      - Air vent location – keep vaccines away to prevent freezing
      - How does ambient temperature impact internal temperature?
    - No bar fridges


National Storage & Handling Guidelines, 2007

# Equipment

- Organizing the refrigerator

Thermometer – mid-compartment not on freezer floor



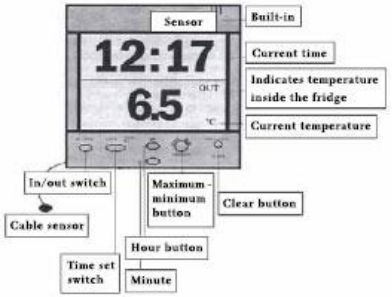
Remove deli & vegetable/fruit crisper drawers

Thermometer placement – middle shelf in fridge

NationalGuidelines for storage & handling of vaccines, 2007.

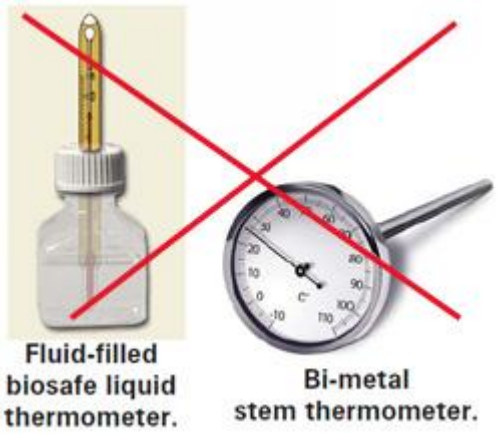
# Equipment

- Multiple Types of Thermometers
  - Data loggers – ideal – real time continuous monitoring
  - Strip monitors – sometimes for transport
  - Chart recorders
  - Min-Max thermometers
  - Digital thermometers
    - Some may have min-max feature



# Equipment

- Thermometers
  - Not appropriate
    - Household thermometers
    - Bi-metal stem thermometers
    - Fluid-filled biosafe thermometers (AKA bottle)




Picture from http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/10600.asp?student_id=

# Temperature Monitoring

- Record twice daily
  - Current temperature
  - Minimum and maximum refrigerator temperature
  - If out of range
    - Calibrated thermometer – assume thermometer is correct
    - Protect vaccine if temperature noted out of range

- Contact local Public Health and/or vaccine manufacturer if exposure outside recommended range

# Temperature Monitoring

**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° | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Refrigerator temperature 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Courtesy of BCCDC

# Policies, Procedures & Protocols

- Routine storage & handling
  - Includes temperature monitoring
- Shipping vaccine between sites
- Protecting vaccine during clinics
- Urgent/emergency storage & handling

# Routine Storage & Handling

- Staff education
  - 1 lead + backup
  - limit access for untrained personnel
- Place in designated refrigerator/freezer immediately upon receipt
- Post storage/handling guidelines prominently
- Rotate stock according to expiry date
- Separate products with similar packaging
- Alternate storage

# Routine Storage and Handling

- Protocols for:
  - Temperature monitoring
  - Equipment maintenance & repair
  - Vaccine storage
  - Response to storage & handling issues
  - Receiving, packaging and transporting vaccine
  - Inventory management
  - Disposal

# Vaccine Transport

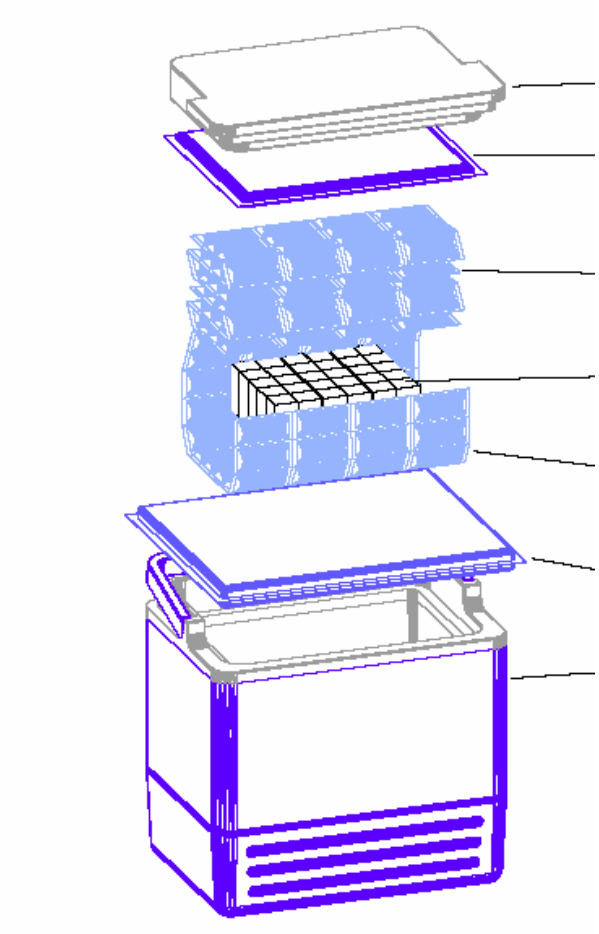
- Summer and winter configurations
  - Check with local Public Health office for dates in individual jurisdictions
  - Summer (Nova Scotia)
    - Early April to Mid-November
  - Winter (Nova Scotia)
    - Mid-November to End March

Nova Scotia Immunization Manual, 2013

# Example of Summer Configuration

Check with your local Public Health office for recommended configuration

Condition cooler with frozen gel 5-30 min prior to packing cooler



Cooler lid

36 oz frozen gel pack (-16.5°C)

2 x refrigerated 12 mL flexible insulated blankets in fan folded position

Vaccine – maximum of 30 x 5 mL vials

Wrapped in 1 x refrigerated 12 mL flexible insulated blanket

96 oz refrigerated Gel (5°C)

***16 quart Igloo Cooler***

Don’t forget the temperature monitor

Nova Scotia Immunization Manual, 2013

# Vaccine Transportation


Courtesy of BCCDC

# Protecting Cold-Chain in Clinic Setting

- Ensure potency of vaccine
  - Minimize number of times cooler is opened during immunization
  - Record temperature
    - Before leaving office
    - Arrival at clinic (but before begin immunizing)
    - Q3H during clinic
    - Completion of clinic (but before transport)
    - Upon return to office

Nova Scotia Immunization Manual, 2013

# Urgent and Emergency Situations

- Think ahead
  - Predictable power disruptions
- Who
  - Responsible individuals
  - Staff availability
  - Important telephone numbers
    - Power company
    - Alternate storage facility
    - Manufacturers

- Where
  - Alternate storage
    - Appropriate monitoring
    - Agreements with other facilities (hospitals etc)
- How
  - Transportation considerations
  - Which vaccines if can’t transport all

# Cold Chain Breaks

- Contact public health
  - Complete cold-chain incident report

- Quarantine affected vaccine under proper storage conditions
  - Is vaccine still usable?


Yes

Remove from quarantine

Label as exposed - with date

Use first

Multi-dose vials

No

Dispose as per protocol

# Suspect Frozen Vaccine?

- Freezing most important problem
  - Too close to freezer compartment in fridge
  - Too close to ice packs in insulated coolers
- Fridge stable vaccine (+2-8°C) cannot be used if frozen
- Diluent should not be used if frozen

Bulletin of the World Health Organization

# Validation of the shake test for detecting freeze damage to adsorbed vaccines

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*Bulletin of the World Health Organization* 2010;88:624-631. doi: 10.2471/BLT.08.056879

## Introduction

- http://vimeo.com/8389435

# Review of Objectives

- Defined and outlined importance of the cold chain
- Reviewed National Storage and Handling Guidelines
  - New National Guidelines are in progress so some things may change
- Reviewed response to cold chain incidents