Storage and Handling of Vaccines

The Cold Chain

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Speaker Disclosure

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  – Dalhousie Pharmacy Endowment Fund

• Speakers Bureau/Honoraria
  – Dalhousie Continuing Pharmacy Education

• 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?

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

Is it Really a Problem?

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

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

Cold Chain Breaks by Reason Calendar Year 2009

- Power Interruption: 22.58%
- Equipment Problem: 61.85%
- Handling Error: 41.94%

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

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

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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
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

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

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

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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