

# **The Secret Lives of Vaccines: The Alberta Experience**

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# Disclosures

- Irene Mazurenko is an independent consultant with no financial interest or conflict with the manufacturer of any product named in this presentation.
- Information in this presentation is based on work conducted for AHW; AHW has given permission to share the data provided.

# Why CC Policy?

- CC Guidelines in Immunization Manual
- Build on Influenza Immunization Policy
- Accountability
- AHW Role/AHS Role
- Process:
  - Literature Review
  - Canadian Environmental Scan
  - Data Analysis
  - Policy Development Framework

# Cold Chain

- Refers to the process used to maintain optimal conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client.
- +2° C to +8° C
- Protection from light for some vaccines.

# Why is cold chain important?

- Vaccines are sensitive biological products that may become less effective or destroyed when exposed to light or temperatures outside recommended range.
- Repeated exposures to heat results in cumulative loss of potency that is not reversible.
- Some vaccines experience an immediate loss of potency following freezing.
- Alum adsorbed vaccines, if frozen, can generate a severe local reaction.

# The Challenge

- It is not possible to look at a vaccine vial to determine if it has experienced temperature excursions.
- Clients receiving compromised vaccine may not be protected.
- Difficult to assess potency of mishandled vaccine.

# Are we shooting blanks?

- **If the cold chain break is not discovered, clients may be unknowingly susceptible to serious diseases.**
- You may need to revaccinate those who received a dose of compromised vaccine.
- You may have to explain to irate parents why their children must be revaccinated.
- There may be negative publicity.

# Wasted Cash?

- Vaccine wastage
- Cost of replacement vaccine
- Staff time
- Investment in vaccine/investment in equipment & staff training



# Interesting Research Findings

- Studies that measured freezing more frequently or with continuous monitoring were more likely to identify occurrences of vaccine freezing.
- Studies that measured longitudinal exposure to freezing from national stores to health clinics found that 75% to 100% of vaccine shipments were exposed to freezing at least once during distribution.

- Sites with on-site audits scored lower than those who completed self-assessments.
- Lack of thermometer and failure to maintain temperature log were major risk factors.
- Sites that corrected practices initially may not maintain optimal storage later.
- Nominating and educating a staff member to monitor temperature improved vaccine storage.

# Trends in Monitoring and Accountability

<b>Australia</b>	<ul style="list-style-type: none"><li>•National Vaccine Storage Guidelines</li><li>•Pharmacy Guild – 4 mandatory CC Standards</li><li>•Queensland – vaccine management audit</li></ul>
<b>New Zealand</b>	<ul style="list-style-type: none"><li>•CC Accreditation</li><li>•National audit program for childhood vaccines from national stores to clinics</li></ul>

## England

- Department of Health protocol National Patient Safety Agency
- NHS Sheffield includes vaccine transport and storage in IPC standards; audits

## US Vaccine For Children (VFC)

- Site visits by grantees
- Grantees must report vaccine wastage
- Thermometers with Certificate of Traceability and Calibration in all fridges
- Initial training and periodic review for grantee staff; content and dates documented
- Written routine and emergency storage and handling plans
- Small combination fridge/freezer unit with single door not acceptable for permanent storage

# Beyond the Basics

## California VFC (2009):

- Providers receiving > 10,000 doses annually must have “pharmacy grade” refrigerators.
- Bar fridges not acceptable at any time or duration.

## Oregon VFC (2011):

- Calibrated and certified continuous-tracking thermometers by all VFC providers.

## Philadelphia VFC (2008):

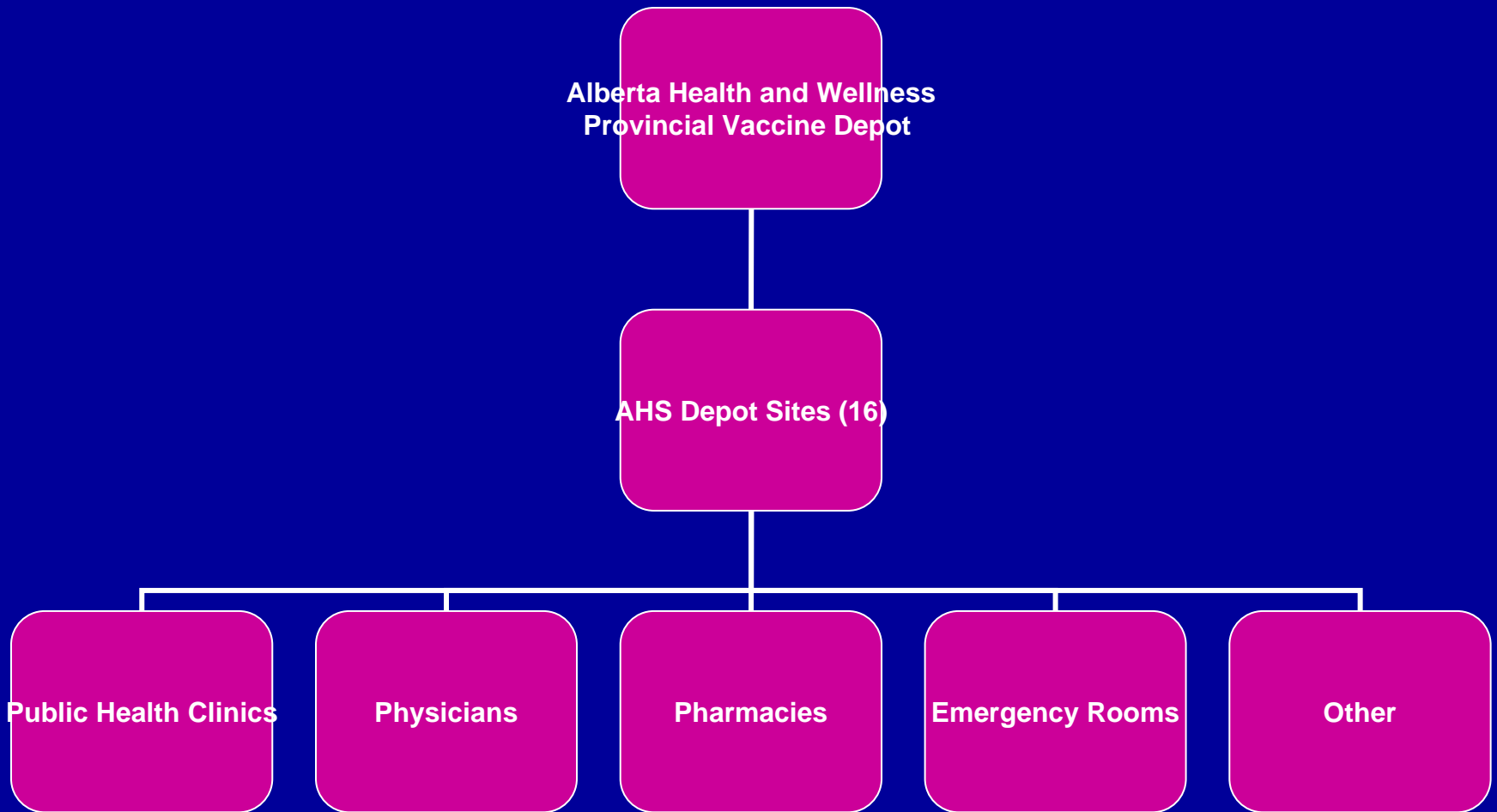
- 24 hour alarm if store \$15,000+
- Suspension if vaccine loss due to expiration or improper storage until wasted vaccine reimbursed
- Site inspection and 5 days of temperature recording before ordering vaccines
- Annual site inspections

# Canada

## Ontario

- Ontario Public Health Standards
- Vaccine Storage and Handling Protocol (2010) identifies minimum expectations.
- Boards of Health accountable for implementing standards and protocols.

# Vaccine Distribution in Alberta



# Community Providers

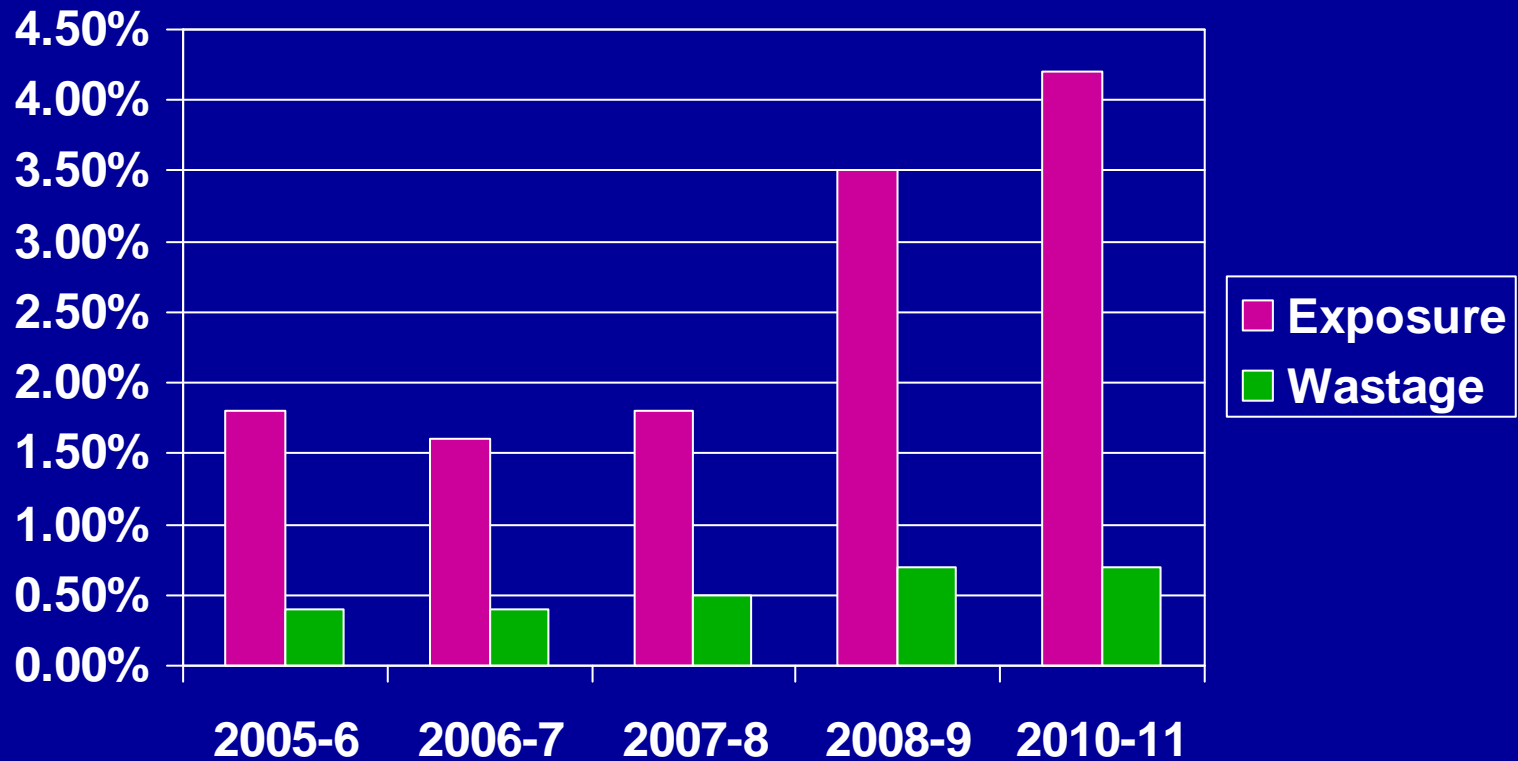
- Community providers (e.g. physicians, pharmacists) administered 35% of influenza vaccine in 2010/2011.
- Alberta's 5-Year Action Plan (Becoming the Best) outlines increased access to influenza by offering the vaccine in pharmacies and doctor's offices.
- AHS requires community providers to sign a vaccine agreement form which includes cold chain management requirements.
- No audits or inspections currently in place.



# When Cold Chain Breaks Happen

- Cold Chain breaks are reportable to AHW.
- AHW makes recommendations as to whether vaccine can be used and corrective measures to be taken.
- If compromised vaccine has been administered, consultation with the OCMOH.
- AHW maintains data base of cold chain breaks.

# Cold Chain Exposure as a Percentage of Vaccine Distributed



# Number of Incidents by Size of Vaccine Loss

2010-2011

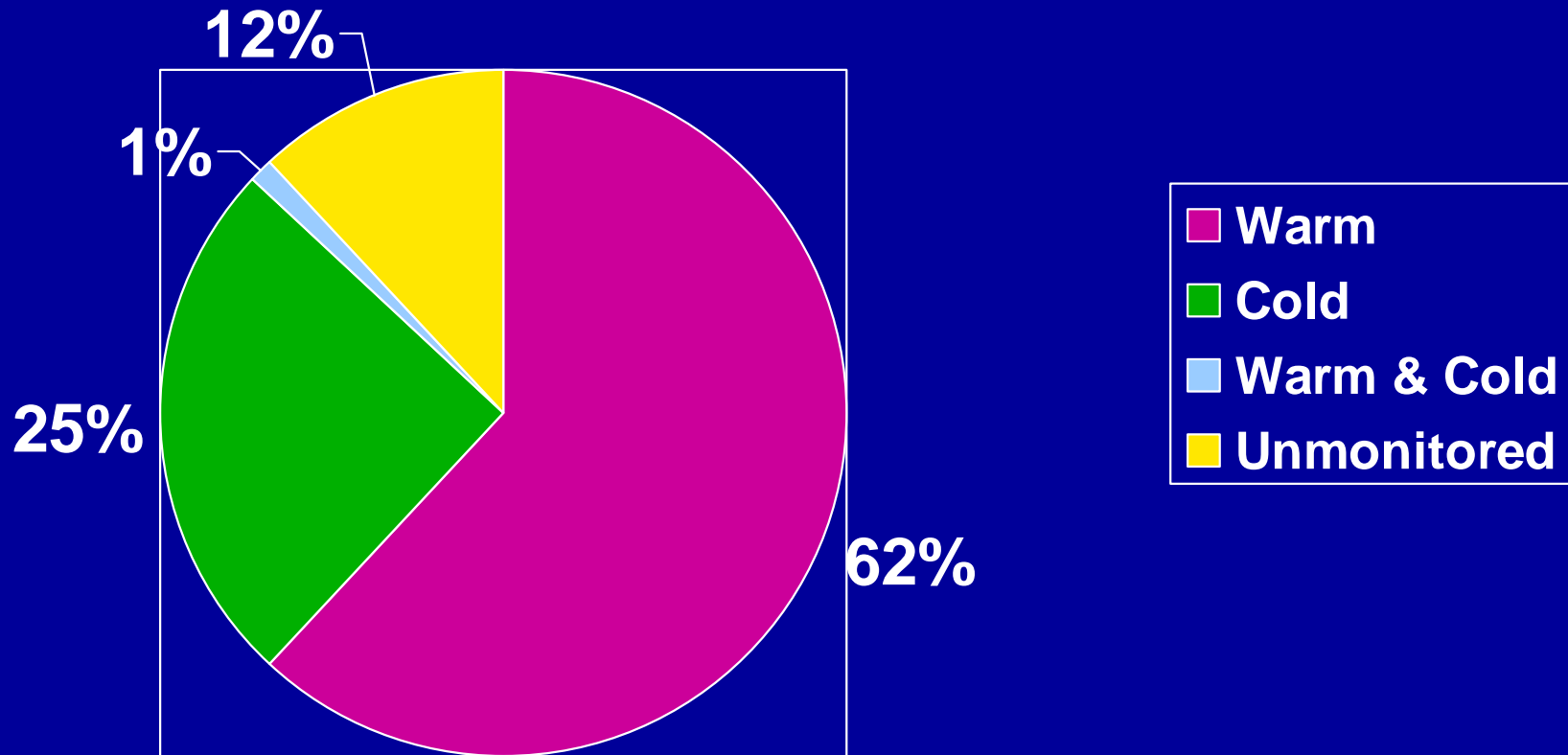


# Impact of Large Cold Chain Breaks

- All cold chain breaks matter.
- In regards to vaccine loss:
  - Incidents <\$500 contribute 9% of total vaccine loss
  - Incidents \$500 - \$5000 contribute 13% of total vaccine loss
  - Incidents \$5000+ contribute 78% of total vaccine loss

# Type of Exposure by Percentage of Vaccine Discarded

2010-2011



# Duration of Excursion

2010-2011

< 17 hrs	? Overnight	212 incidents
18 – 40 hrs	? Weekend	49 incidents
41 – 64 hrs	? Long Weekend	17 incidents
65 – 72 hrs		8 incidents
3 - 14 days		35 incidents
> 15 days		7 incidents
Unknown		37 incidents
	Total	365 incidents

# How Can Monitoring Make a Difference?

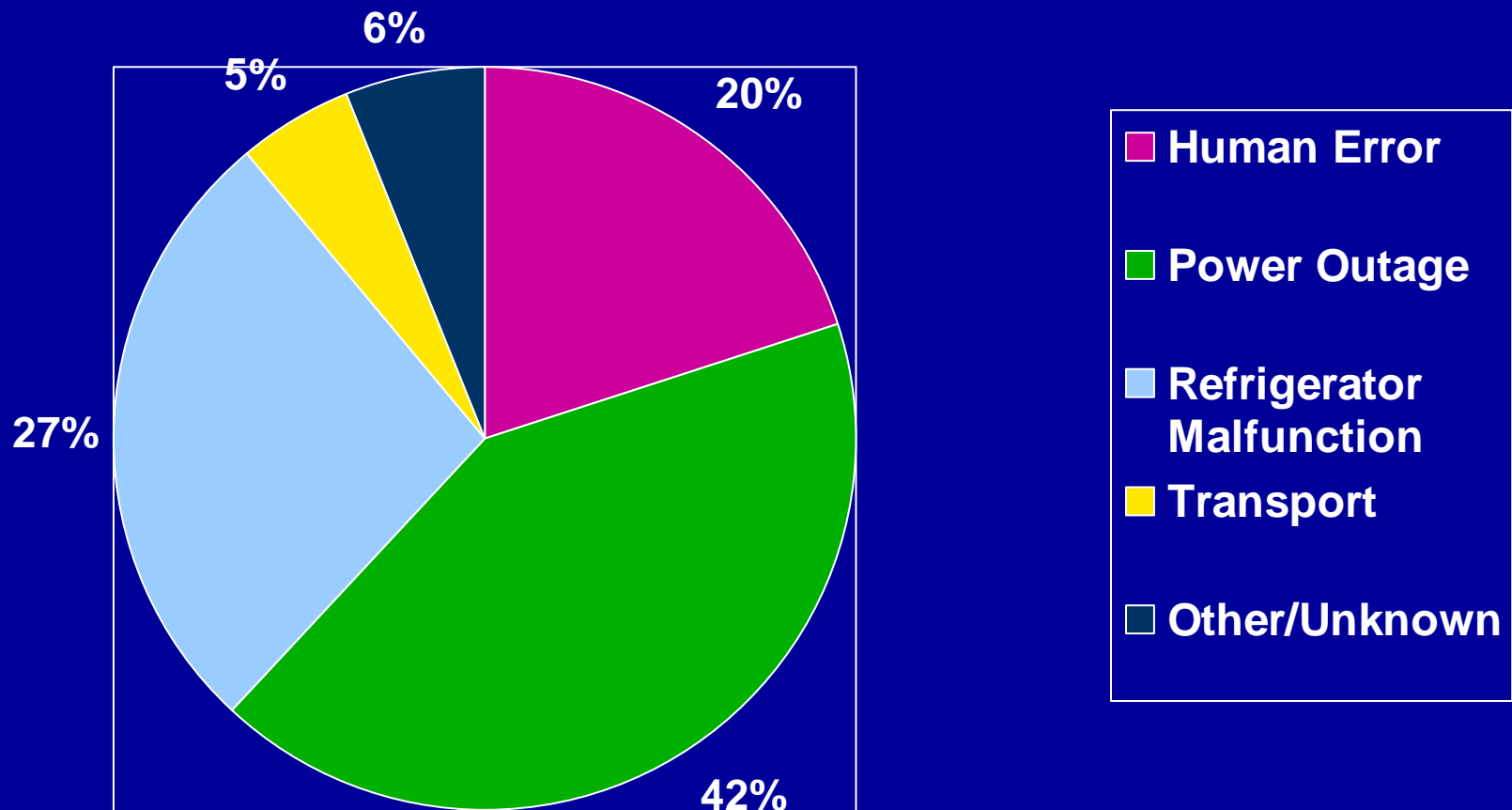
- Even a broken clock is right twice a day



- Min/Max versus continuous recording
  - Was a weekend excursion really a 1 hour excursion?

# Percentage of Discarded Vaccine by Cause of Cold Chain Break

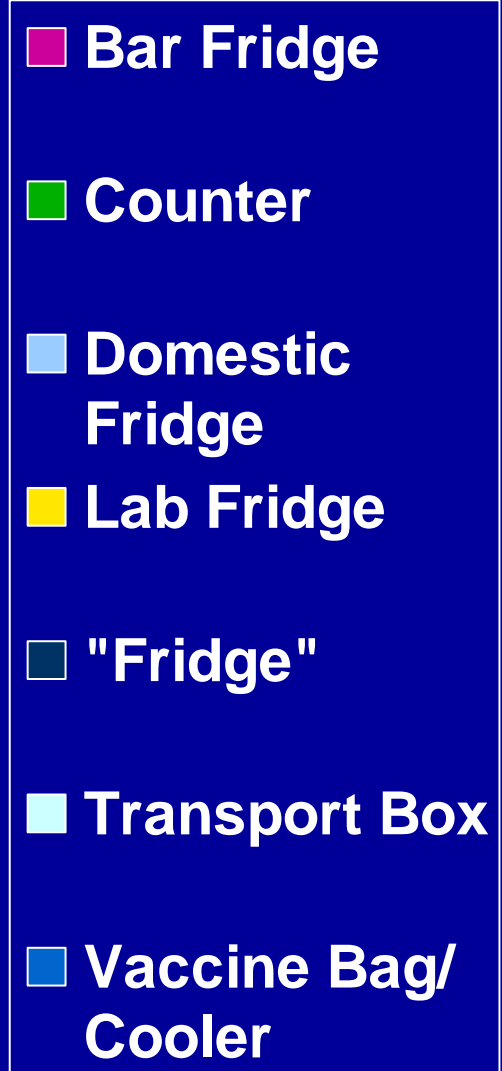
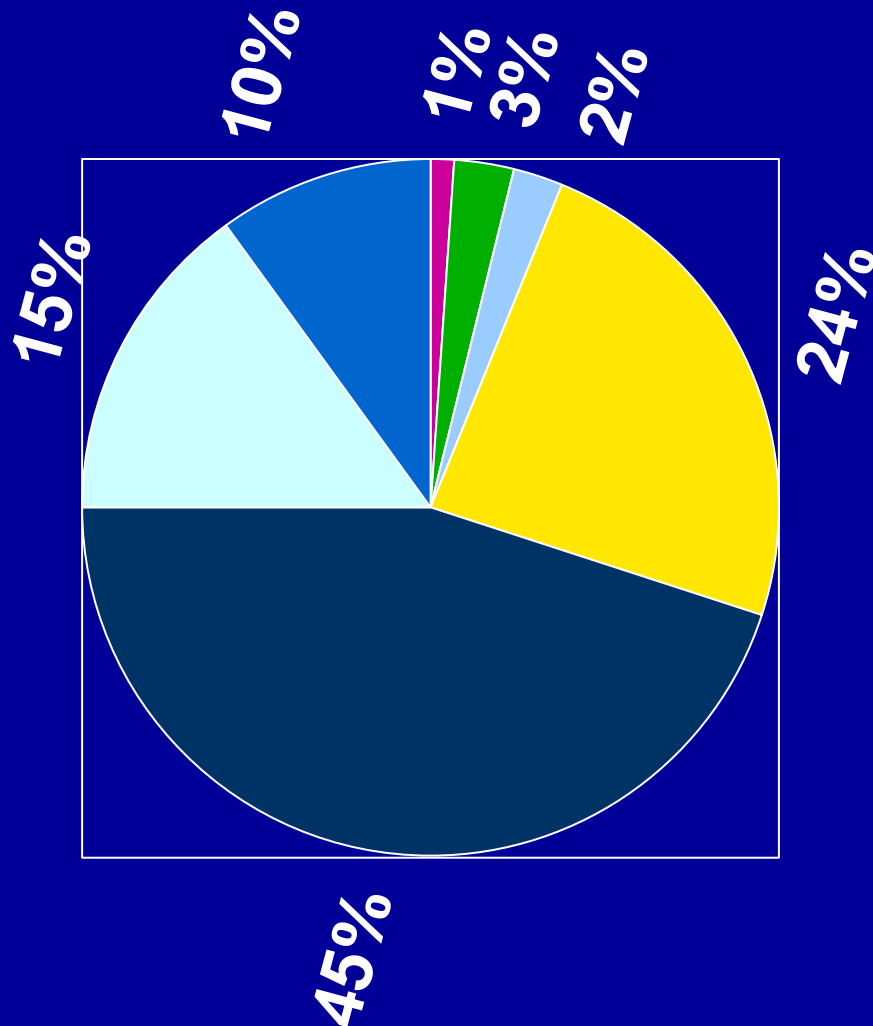
2010-2011





# Percentage of Discarded Vaccine by Storage Unit

2010-2011



# What can go wrong?

- A. How much can be lost in a vaccine bag?
- B. Lab Fridges can malfunction.
- C. Just recording the temperature is not enough.
- D. Alarm systems can fail.
- E. Anything can happen during transport.
- F. Power outage – a matter of when, not if
- G. Repeat exposures

# What is preventable?

- Some cold chain breaks are not preventable (refrigerator failure, power outage).
- Some cold chain breaks are preventable (human error)
- Vaccine loss, however, may be prevented:
  - Stock management
  - Appropriate temperature monitoring
  - Continuous temperature recording
  - Monitored alarms
  - Power back-up
  - Trained staff
  - Procedures in place
  - Contingency plans

**“...the majority of medical errors do not result from the individual recklessness or the actions of a particular group – this is not a “bad apple” problem. More commonly errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.”**

“To Err is Human: Building a Safer Health System” 1999 IOM Report

# Patient Safety Framework

## Elements of safety management:

- Proactive identification of risks
- Effective reactive response
- Learnings from review of adverse events
- Evaluation of implemented recommendations

# Policy Approach

- Consistent standard across Alberta
- Maintain cold chain break reporting
- Right equipment and procedures in place
- Incremental implementation
- Focus on education, preventing problems, and quality assurance
- Support role and responsibilities of AHS

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What are your challenges?