

# Vaccine Quality Assurance Going Forward: “Engineering for Safety and Reliability, No Matter Who’s Behind the Wheel”

Claire Hannan, MPH  
Executive Director, Association of  
Immunization Managers (AIM)  
NVAC September 2013



# Objective

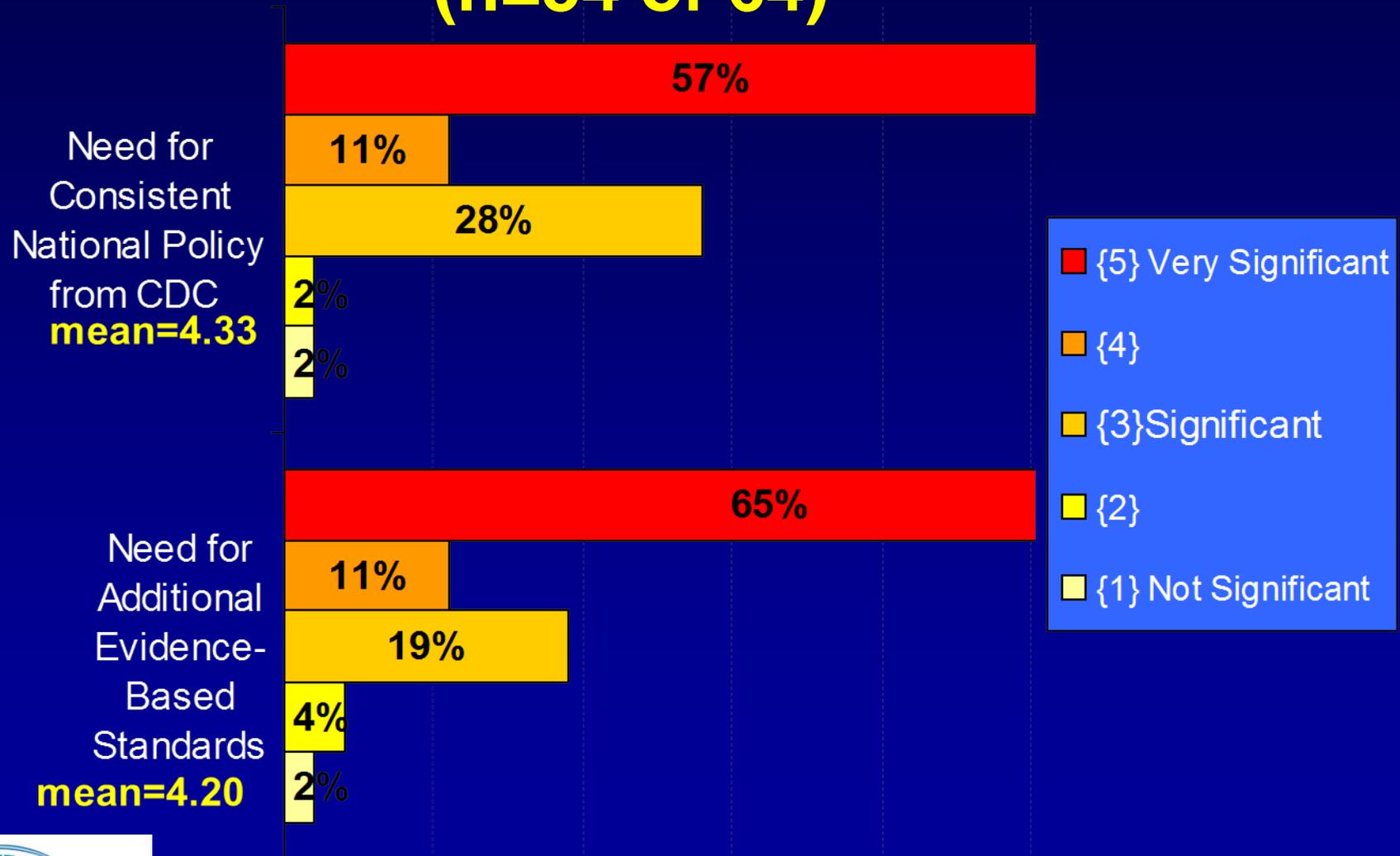


# **AIM Vaccine Storage and Handling Working Group (VSHWG), est. 2006**

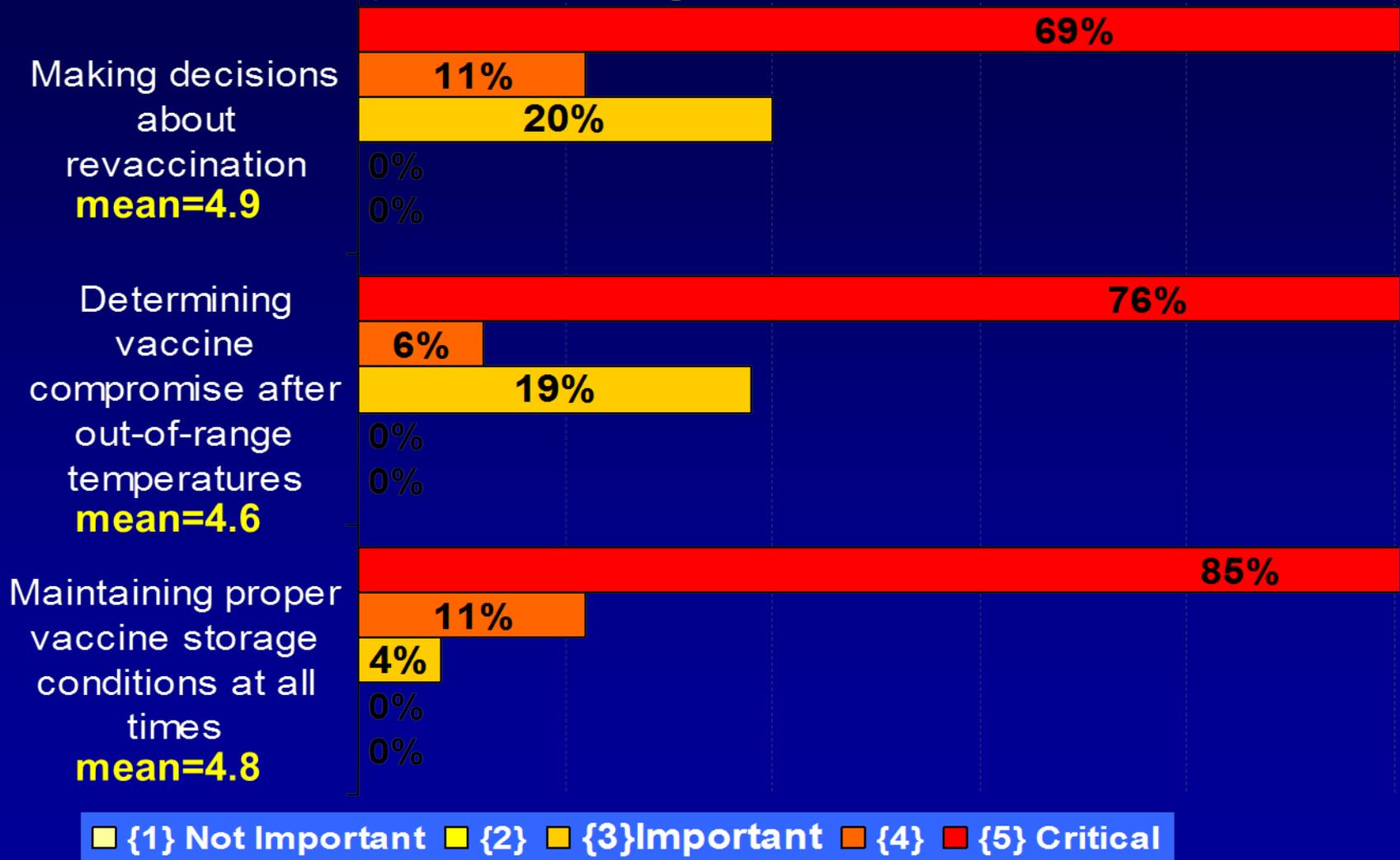
- **ACIP General Recommendations referred providers to state and local immunization programs for guidance on storage failures**
- **Members shared concerns, lack of reliable resources to guide decisions about storage failures**
- **Inconsistent manufacturer guidance about usability of vaccines following storage failures**
- **Absence of data to support decisions**
- **2008 survey of AIM members to gauge concerns**



# Need for Better Evidence-Base and National Policy for Revaccination (n=54 of 64)



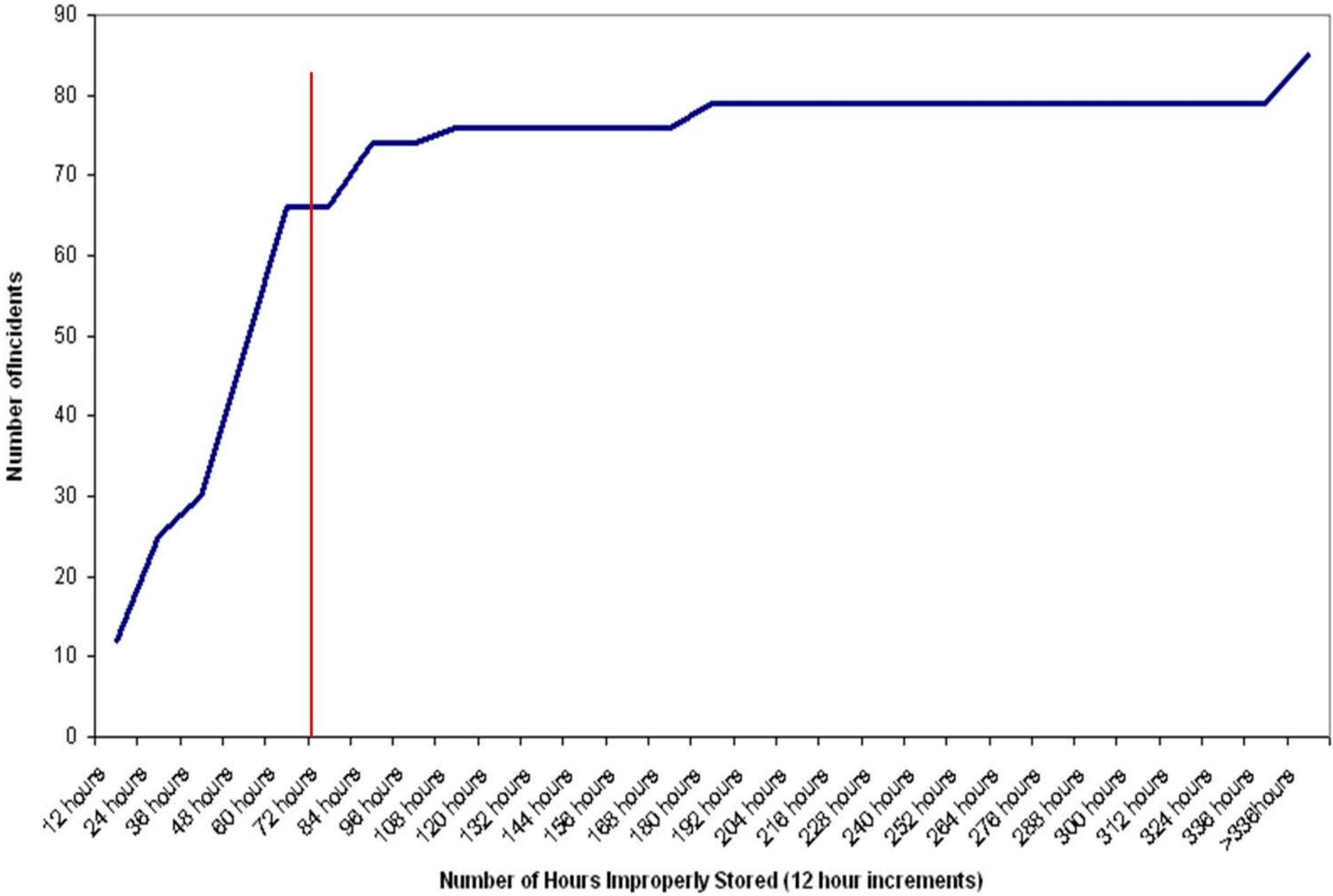
# Overall: How critical are these VSH issues to your program? (n=54 of 64)



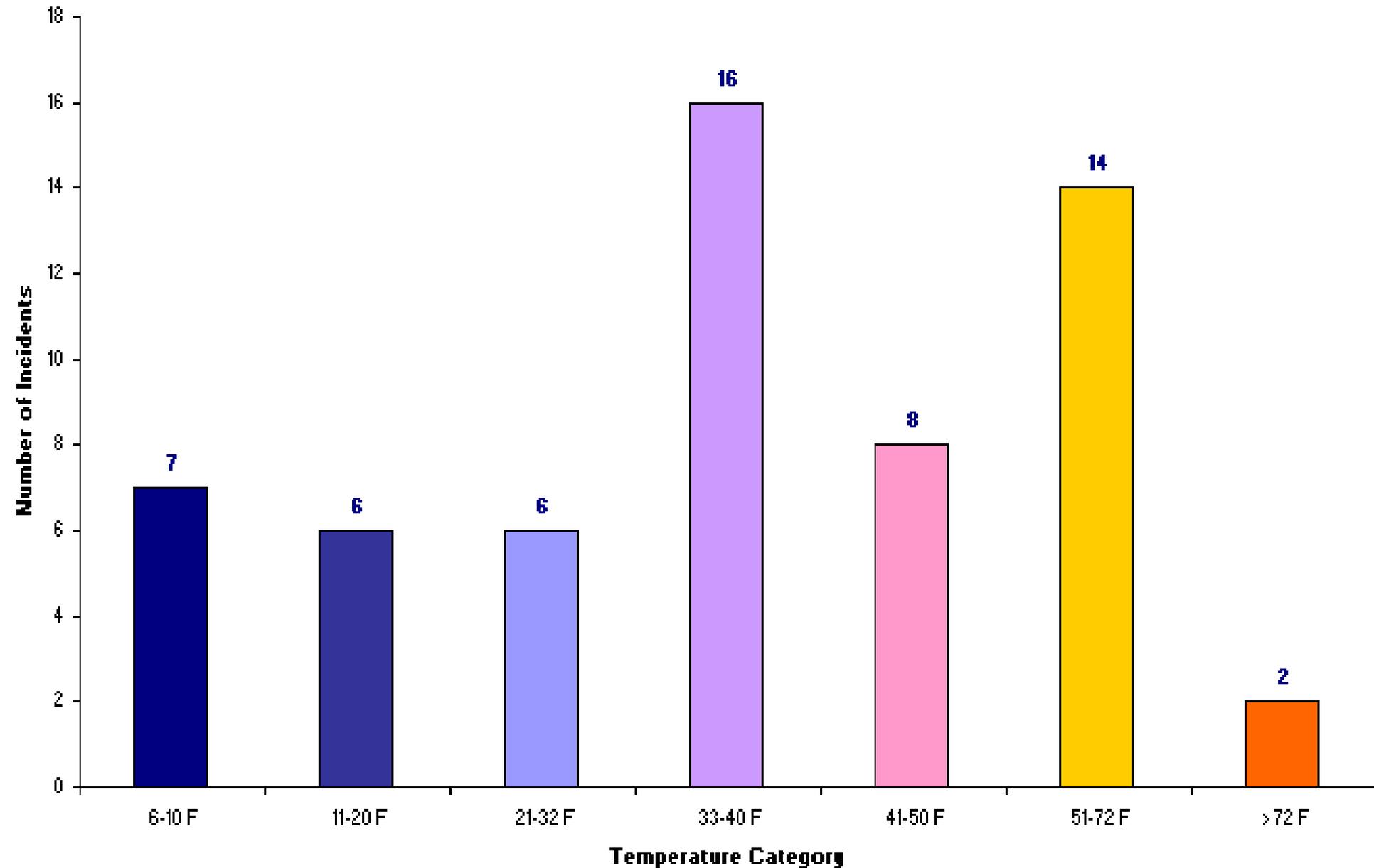
# 2009 AIM Study: Characterize Vaccine Waste Resulting from Storage Failures

- 8-week period (July – September)
- Participants reported characteristics of storage failures resulting in decision to waste vaccine
- 45 of 64 Programs participated (39 states)
- Total incidents reported = 318 (~40/wk)
  - 237 (75%) refrigerated vaccine incidents
  - 81 (25%) frozen vaccine incidents
  - 61 (19%) vaccine left outside a unit
  - 74 (23%) more than one temp excursion

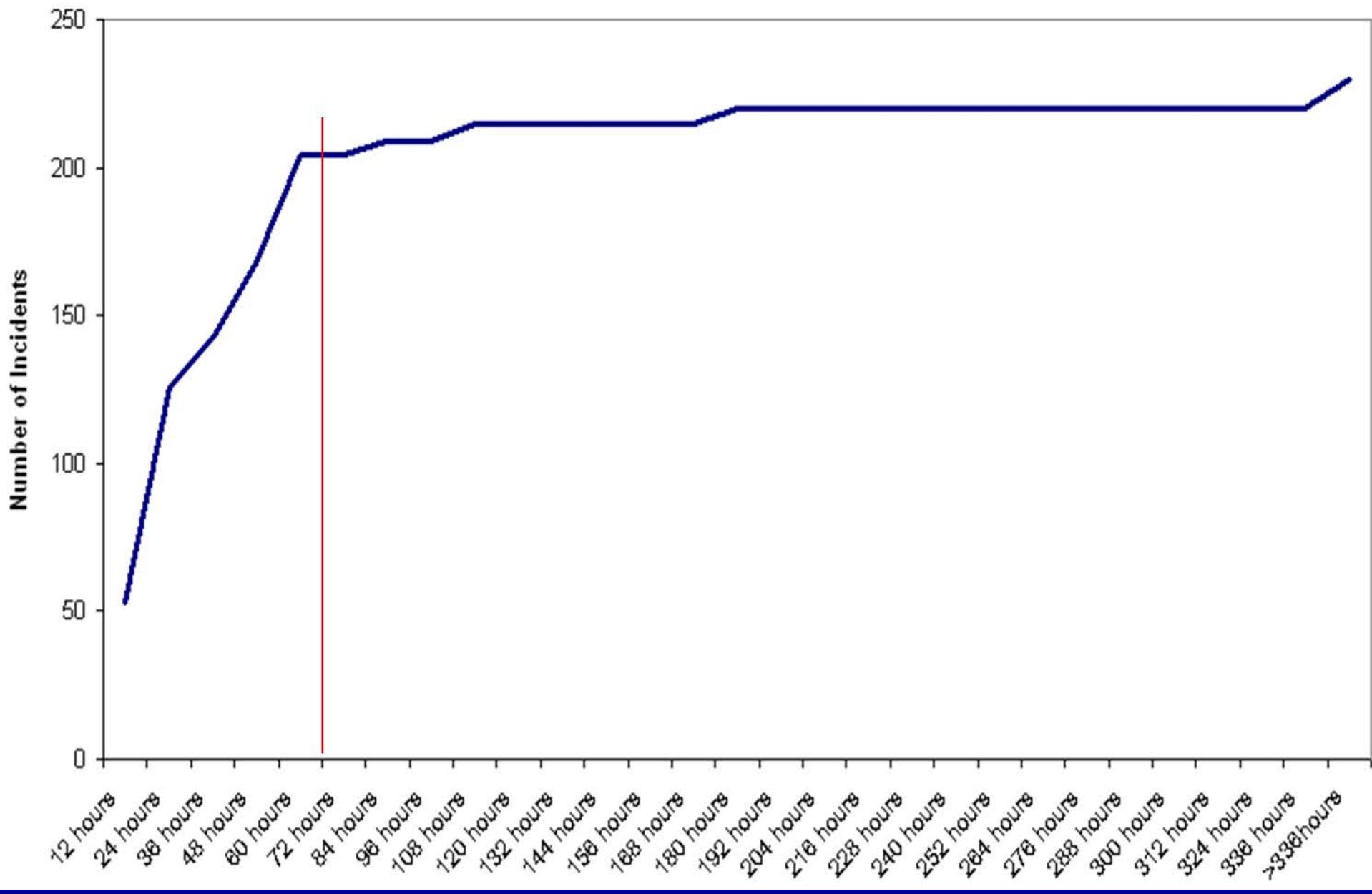
Cumulative Number of Frozen Vaccine Waste Incidents Reported by Duration of Improper Storage



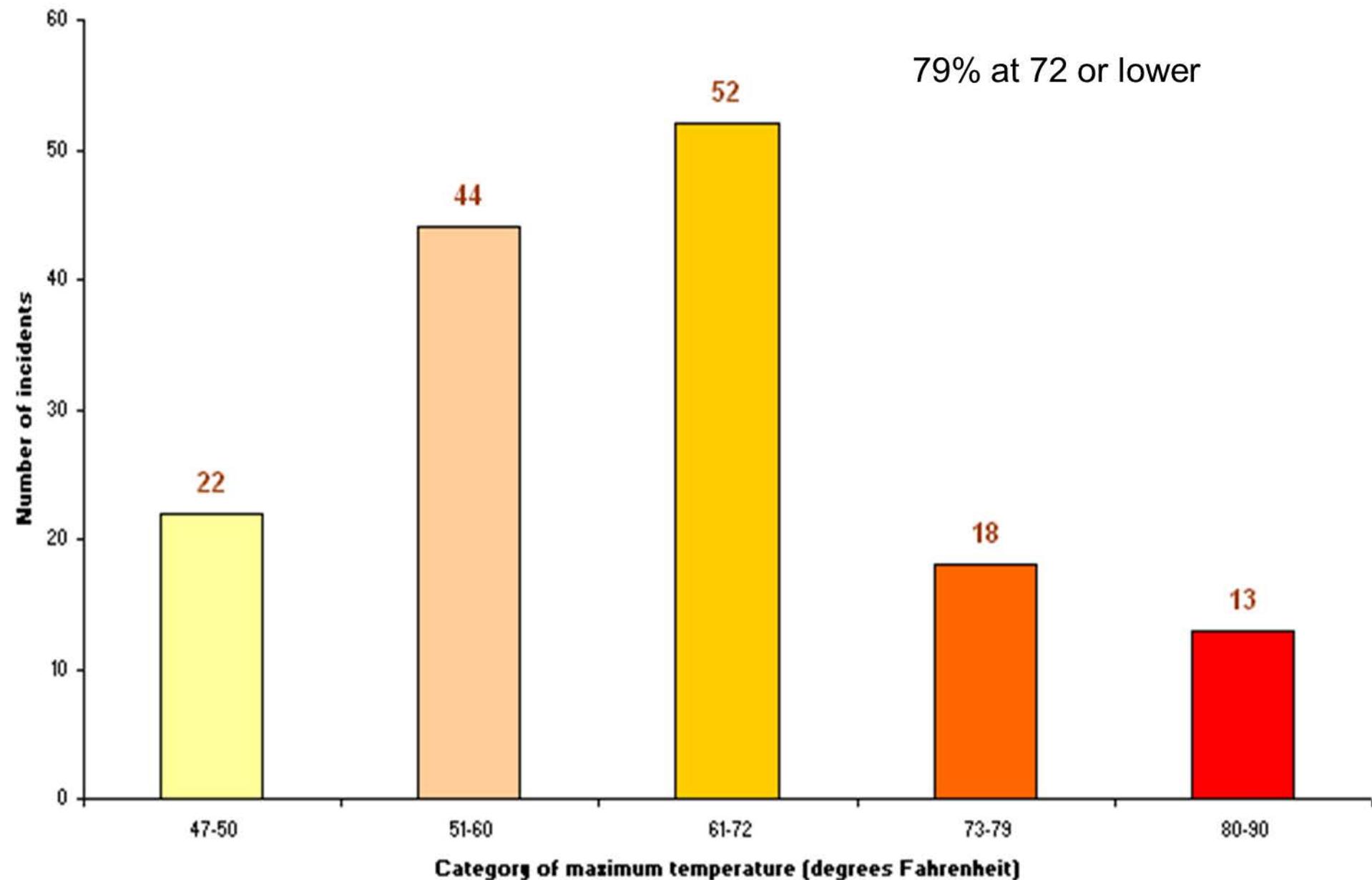
**Number of Incidents Resulting in Waste of Frozen Vaccine by Category of Maximum Temperature (Fahrenheit), AIM Vaccine Storage Survey, July 13-September 4, 2009 (n=64)**



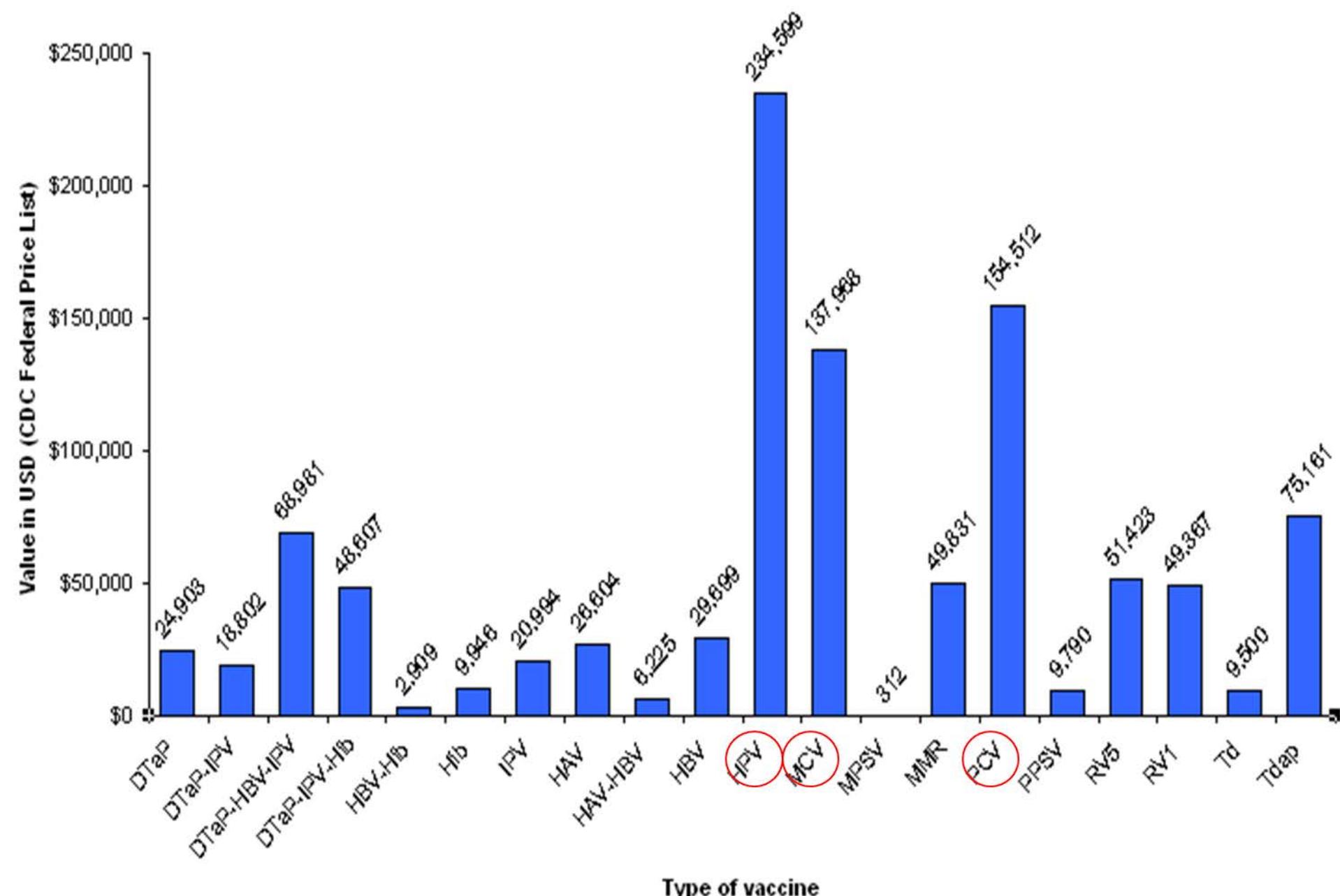
Cumulative Number of Incidents Resulting in Refrigerated Vaccine Waste by Duration of Improper Storage, AIM Vaccine Waste Study, July 13-September 4, 2009



**Number of incidents resulting in refrigerated vaccine waste, by category of maximum temperature (Fahrenheit), AIM Vaccine Storage Study July 13-September 4, 2009 (n=149)**



Value of each type of publicly-funded vaccine wasted, AIM Vaccine Waste Study July 13 - September 4, 2009 (total value \$1,032,498)



# CDC Action: Evidence Based Guidelines

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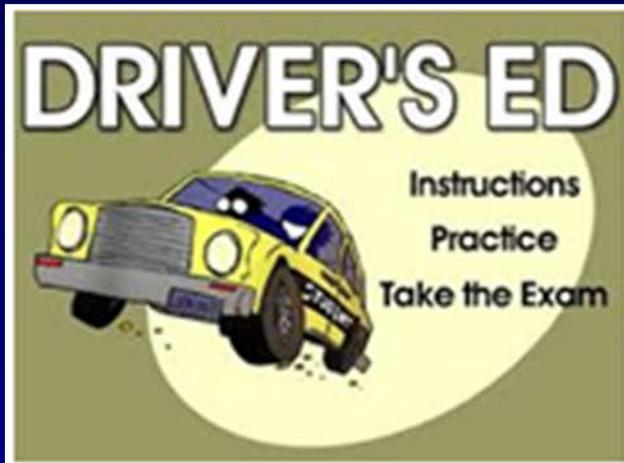
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# CDC Action: Training



## Immunization: *You Call the Shots*

**Navigation:** Comments | Glossary | Exit | Back | Next

**About Hib Vaccine**

Hib vaccine is categorized as a polysaccharide conjugate vaccine, which is a type of inactivated bacterial vaccine. It is made by joining a piece of the polysaccharide capsule that surrounds the Hib bacterium to a protein carrier. This joining process is called conjugation. Conjugating a protein carrier to a piece of the polysaccharide capsule from a Hib bacterium creates an effective vaccine.

[Click here to learn more about the history of Hib vaccine and Hib vaccines.](#)

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**Indications for Vaccination**

ACIP recommends routine hepatitis A vaccination for all children 12-23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at subsequent visits. Consider opportunities for vaccinating children and adolescents, such as entry into elementary, middle school, or day care, or during healthcare visits for other reasons.

[Click here to learn more about hepatitis A vaccine and other routinely recommended vaccines.](#)

**Modules**

- Understanding the Basics: General Recommendations on Immunization
- Diphtheria, Tetanus, and Pertussis
- Polio
- *Haemophilus influenzae* type b (Hib)
- Influenza
- Hepatitis A

**Description**

*You Call the Shots* is an interactive, web-based immunization training course. It consists of a series of modules that discuss vaccine-preventable diseases and explain the latest recommendations for vaccine use. Each module provides learning opportunities, self-test practice questions, reference and resource materials, and an extensive glossary.

The course is available free of charge on the CDC Vaccines and Immunizations website at: <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>.

**Audience**

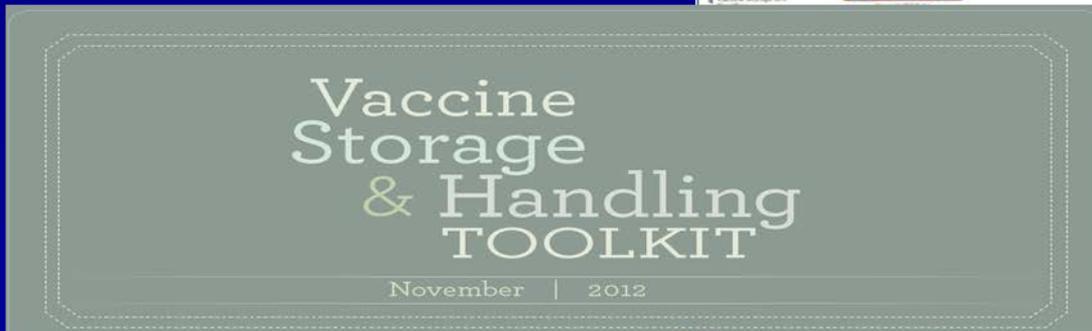
The course is intended for nurses, nursing students, medical assistants, pharmacists, and other health professionals who provide immunizations.

Questions or comments about the course may be e-mailed to [nipinfo@cdc.gov](mailto:nipinfo@cdc.gov).

Immunization: *You Call the Shots* was developed through a Cooperative Agreement between the Centers for Disease Control and Prevention (CDC) and the Association for Prevention Teaching and Research (APTR).

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**Next**



# What Next? Better Engineering



Going Driverless



OTO: KAREN BLEIER/AFP/GETTY IMAGES

# **New Opportunities for Innovative Solutions**

- **Digital data loggers (now)**
  - **Great advance, continuous temperature data**
  - **Many more identified temperature excursions of questionable significance**
  - **How will we respond?**
- **Alarm systems (now)**
  - **Some internet based, not widely used yet**
- **Storage units purpose-built for vaccines and their special needs (now and future)**

# **New Opportunities for Innovative Solutions**

- **Expand FDA licensed recommended refrigerated temperatures beyond 2-8C?**
  - Reduce unnecessary waste due to current 2-8 standard?
- **Visual quality indicators on packaging?**
  - WHO uses vaccine vial monitors for warm temperatures
  - Freeze threshold indicators
    - Most common US clinic problem resulting in waste
    - Temperatures in different parts of storage units vary: freeze damage of a particular package may not be detected by thermometer
  - New technology? Electronic indicators
  - Potential boost to consumer and provider confidence

# Conclusion

- **Are there groups capable of developing, or already using, engineering solutions that could reduce the effort currently necessary to ensure consistent, correct vaccine management in all settings?**
- **Engineering solutions have the potential to make it easier to maintain the desired level of quality and reliability of immunization delivery to all ages in all settings in the U.S.**