Vaccine Quality Assurance Since the OIG

Getting Unsafe Equipment off the Road, Rules of the Road, and Driver's Ed

OIG Report Background

- **As part of its annual work plan, HHS Office of the Inspector General (OIG) assessed the extent to which selected Vaccines for Children (VFC) program providers and awardees adhered to CDC vaccine management requirements**
  - Storage equipment
  - Vaccine management
  - VFC program eligibility screening
- **OIG selected 45 VFC providers from the five largest VFC awardees for the sample**
- **Assessments conducted in April and May of 2011**

Report Findings: Accidents Do Happen

- **The report highlighted some areas for improvement and underscores the importance of maintaining a robust public health system**
- **Identified two types of findings:**
  - Storage and handling of vaccine
  - Program management issues
- **General recommendations from the report include:**
  - Ensuring vaccine storage and handling in accordance with VFC requirements
  - Enhancing processes for handling expired vaccines
  - Improving management of vaccine inventories
  - Ensuring oversight requirements

CDC's Approach

- **Formed an internal steering committee**
  - Responsible for identifying solutions to OIG recommendations and developing a set of activities and actions to address concerns raised in the report.
  - Comprised of CDC staff with expertise in immunization and storage/handling issues
    - included clinicians, health educators, health communicators, public health researchers and subject matter experts
- **Conducted an internal assessment**
  - Identified gaps in scientific knowledge, communication and education endeavors, and oversight/ accountability activities
- **Concentrated on potential solutions in policy, science and technology, education/training and accountability**

The Plan: Establishing the Foundation of Good Driving

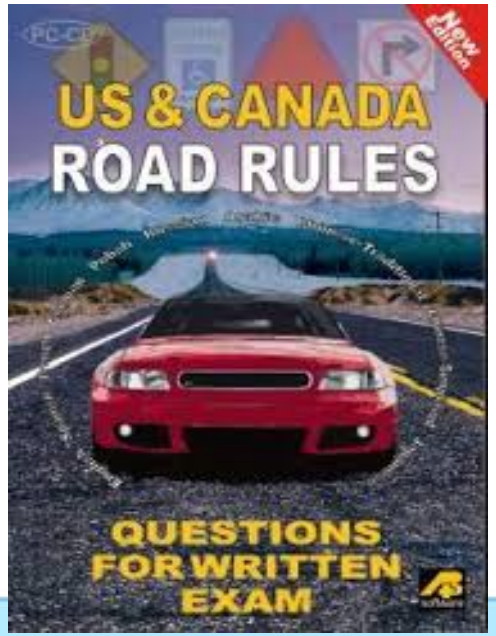
- **Mitigation plan submitted on 11/27/2012**
- **Strategy emphasized:**
  - Improved guidance (Getting rid of unsafe equipment)
  - Better review and oversight (Road rules)
  - Enhanced training and communications (Driver's ed)

Getting Rid of Unsafe Equipment – Improved Guidance on Storage and Handling

- **Revised recommendations on the equipment used for vaccine storage and temperature monitoring**
  - Standalone refrigerators and freezers – OR – use refrigerator only portion of combination fridge/freezer
  - No dormitory style refrigerators
  - Use a probe in glycol or other buffered set up
  - Digital data logger highly recommended
- **Updated Storage and Handling Toolkit**
- **Provided PPHF funding to select awardees to implement innovative temperature monitoring and vaccine storage solutions**
- **Commissioned studies with the National Institute for Standards and Technology to address knowledge gaps**

Establishing Road Rules – Better Review and Oversight

- **Revised guidance to awardees to address programmatic and oversight gaps**
- **Nationwide Training to address OIG findings titled "VFC in Action"**
  - Train-the-Trainer
  - Limited group size, held in regions
  - Interactive activities
  - Topics included: Storage and Handling,
  - Program Evaluation, Communications, and Problem Analysis
- **Reviewing and approving all awardee policies, procedures and training materials for providers**



Driver's Education – Enhanced Training and Communications

- **Created "You Call the Shots"**
  - Web-based training module for staff responsible for storage and handling
  - Emphasizes proper equipment, temperature monitoring requirements and stock rotation
- **Update Storage and Handling Toolkit**
  - Includes updated guidance for storage and handling and temperature monitoring equipment
  - Detailed guidelines, tools, and materials

S&H Communications/Training Research

- **Conducted research July 2013 to:**
  - Understand current end-user training
  - Identify training opportunities to improve S&H
  - Identify common problems related to S&H
  - Test S&H fact sheets
- **Study included 92 participants from physicians to medical assistants (everyone involved in S&H at the provider level)**
- **Research included in-depth interviews and focus groups**
- **Conducted in Atlanta, Chicago and Los Angeles**

Findings and Recommendations expected Fall 2013

Preliminary Results

- **There is a wide spectrum of training in terms of source of training, length, etc.:**
  - "Well, I went to school originally and they spoke about it [vaccine S&H], but…on the site, you're thrown into it" **(Implementer, Chicago)**
  - **"**The previous manager…just gave me tips and things that I needed to know about storage, but no formal training." **(Implementer, Chicago)**
  - "We have guidelines…and I feel like I should know the answer to that[where they come from], but I don't." **(Supervisor, Los Angeles)**
  - "I think MA when they come to be hired at Pediatric section, the RN trained them and I don't know." **(Doctor, Los Angeles)**
  - "Most of it [training manual] is based off CDC as far as basically what every immunization is, how to store it, how to give it, and what to do if it is expired." **(Implementer, Atlanta)**

Preliminary Results

- **Common storage and handling problems identified include training issues such as operator error and out of range temperatures:**
  - "…leaving the refrigerator open at the end of the day." **(Supervisor, Atlanta)**
  - "If vaccines get out of range…you need to get them back in-bounds…if they're too cold, you take them out for a while to adjust." **(Implementer, Atlanta)**
  - "[Take] whatever vaccines you're going to need for the day and …pull them out once instead of opening and closing that refrigerator, and having a second refrigerator, like a dorm-sized refrigerator, and just storing the daily ones there." **(Implementer, Chicago)**

Materials Testing Preliminary Results

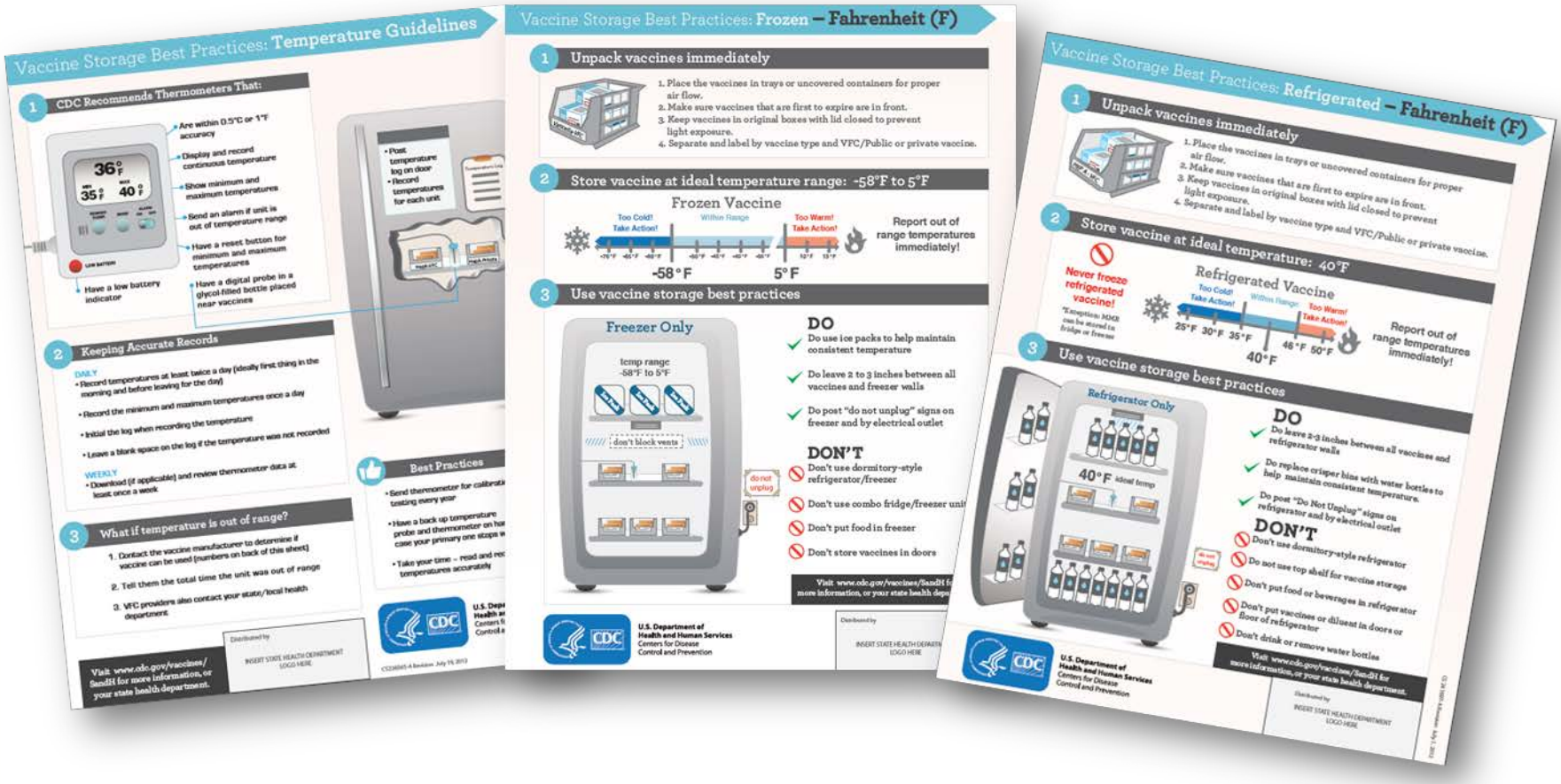
- **Respondents did not understand or were unaware of requirements and recommendations.**
  - "One thing I'm surprised about the water bottles, because I really never knew that you can store water bottles in the refrigerator. I guess the purpose of it is to keep the temperature controlled." **(Implementer, Chicago)**
  - "You just guess [how long a unit has been out of range]. Because you aren't there all night, we'd just say approximate." **(Implementer, Los Angeles)**
  - "I like the description about unpacking vaccines, because we've had an issue in my office where vaccines were delivered late. My front office staff member got it, put the flu vaccines right in the freezer." **(Physician, Atlanta)**

Next Steps: Revise Materials

- **12 fact sheets as part of suite of materials. Four are in final draft :**
  - Temperature Monitoring
  - Refrigerated Vaccine Storage
  - Froze Vaccine Storage
  - Off Site Transport and Handling
- **Easy to understand, plain language**
- **Incorporate quizzes to facilitate learning/comprehension**
- **Available in English and Spanish / Fahrenheit and Celsius**

Initial 4 fact sheets expected distribution late 2013

S&H Fact Sheets Tested



Ongoing Activities

- **CDC continues to improve vaccine storage and handling through Storage and Handling Coordinating Workgroup**
- **Interagency agreements with NIST in FY 2013 and 2014 to examine:**
  - Optimizing vaccine temperature monitoring—protocols and equipment for continuous temperature monitoring
  - Storage of frozen vaccine
  - Emergency vaccine transport for frozen and refrigerated vaccine
  - Optimizing thermal ballast for refrigerators and freezers
  - Temporary storage containers/ units

Ongoing Activities (cont.)

- **Developing standards for vaccine storage units**
  - Drafting an MOU with NSF International to develop standards for vaccine storage units (refrigerators and freezers)
  - Units can then be certified as meeting the standards
  - Will assist providers in identifying vaccine storage units that will meet their needs
  - Process could later be adapted to assess future technologies proposed to address vaccine storage/handling concerns

Key Takeaway Messages

- **Improving the VFC program based on the Inspector General's report is a shared responsibility**
  - CDC
  - Grantees
  - National Partners
  - VFC provider offices
- **Submission of Mitigation Plan does not mean we have fixed all the problems**
  - Continuous improvement process
  - Diligence is necessary
- **Continued partnership is the key to maintaining and improving stewardship**

Discussion