American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccine Storage & Handling

Part I: Selecting & Purchasing Equipment

Today's Agenda

- Introduction
- Presentation
- AAP Resources
- Questions (please submit online)
- Adjourn

Today's Presenter: Graham Barden, III, MD, FAAP

- Completed Undergraduate Degree at Duke University, Medical Degree at Duke University Medical School, & Pediatric Residency at Vanderbilt University
- Member, Committee on Practice and Ambulatory Medicine (COPAM) since 2011; Member, Section on Administration and Practice Management (SOAPM) since 1998; Active Member, North Carolina Chapter
- Coastal Children's Clinic in New Bern, North Carolina

Why is Vaccine Storage Important?

"A common mistake that people make when trying to design something completely foolproof is to underestimate the ingenuity of complete fools."

From Douglas Adams in “Mostly Harmless”

Why is Vaccine Storage Important?

- When vaccines are exposed to inappropriate temperatures, their potency and efficacy can be diminished or destroyed, increasing the risk that vaccinated children will not get optimal protection against disease.
- Poor vaccine storage is very prevalent, even among pediatricians
  - A report by the Office of the Inspector General (OIG) published in June 2012 found that 76% of sampled VFC providers had vaccines that were exposed to temperatures outside of recommended ranges.

Why is Vaccine Storage Important?

- Pediatricians provide most vaccines to children in the United States (90%)
- Vaccines are one of the most successful intervention available in modern medicine, but in order to work, vaccines must be properly stored.
- If discovered that vaccines were stored improperly, your practice may need to notify patients to be revaccinated.

How Do You Keep Vaccines Safe?

Which in Pediatrics, is the same thing as saying…

How Do You Keep Your Patients SAFE?

How Do You Keep Vaccines Safe?

- Store them at 2-8° C
- Limit temperatures excursions!
- Freezing, even briefly, can destroy some vaccines without leaving evidence!
- Heat may shorten life span, and if exposure is long enough, destroy vaccines

How Do You Keep Vaccines Safe?

Reduce Risk that Vaccines will be Exposed to Temperature Excursions by having:

- Excellent Refrigeration Units
- Excellent Staff
- Excellent Thermometers*
- Rapid Notification of Problems*

*Covered in next webinar: Part II

CDC Recommendations

- The CDC makes Vaccine Storage and Handling Recommendations and Requirements
- State immunization programs must enforce the CDC's requirements and often choose to adopt the recommendations as well
- Currently these guidelines are available in the CDC Vaccine Storage and Handling Toolkit at: http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

CDC Recommendations

In 2012 CDC developed the following new recommendations regarding vaccines storage:

- Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator + freezer) or other units not designed for storing fragile biologics, such as vaccines, and…
- Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage, and…….

CDC Recommendations

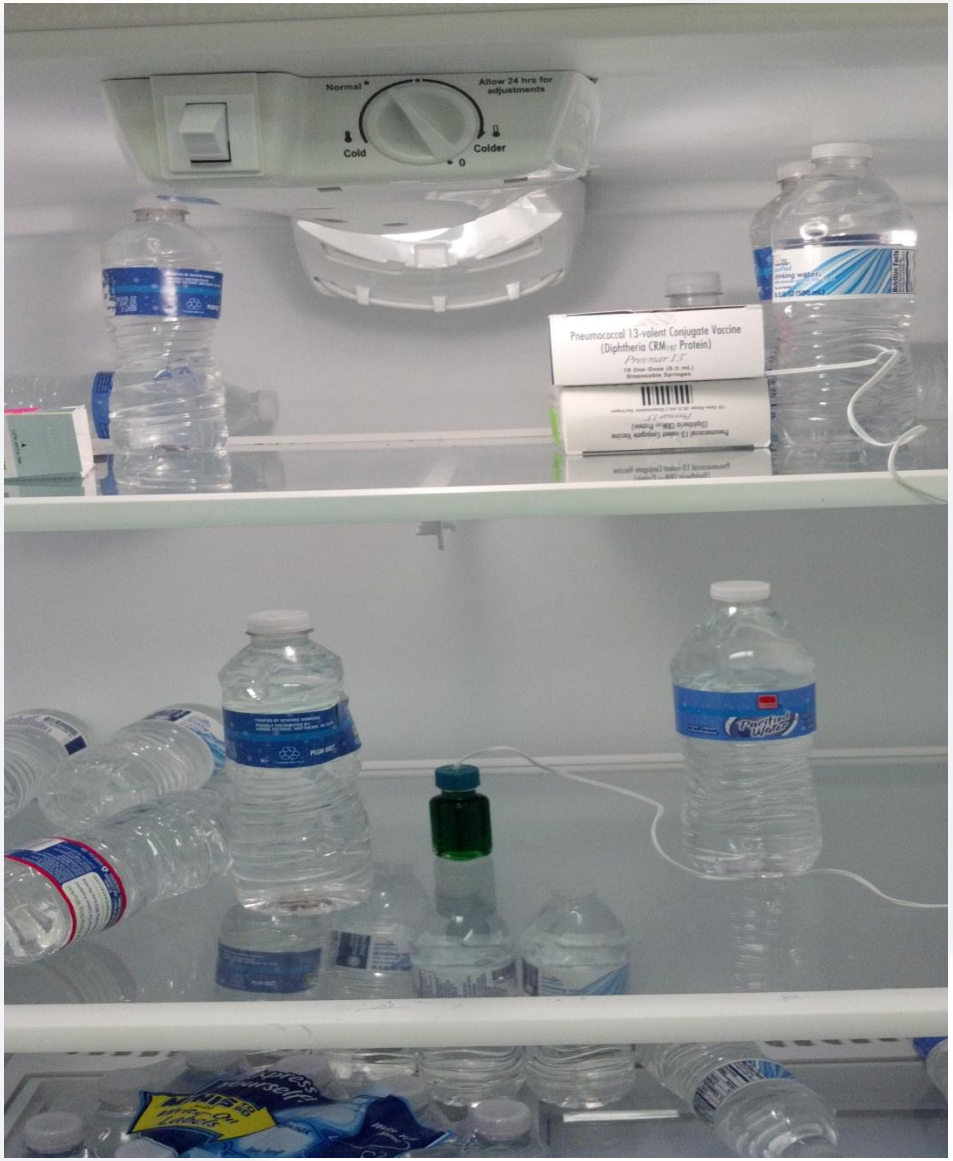
- They *ALLOW* combination domestic units if:
  1) Only the refrigerator section is used
  2) Top shelf is not for vaccine storage (frequently ignored advice)
     - drawers, doors and along the sides and back should also not be used for vaccine storage

This still may not create the ideal conditions for vaccine storage and are discouraged for use by CDC and AAP experts.

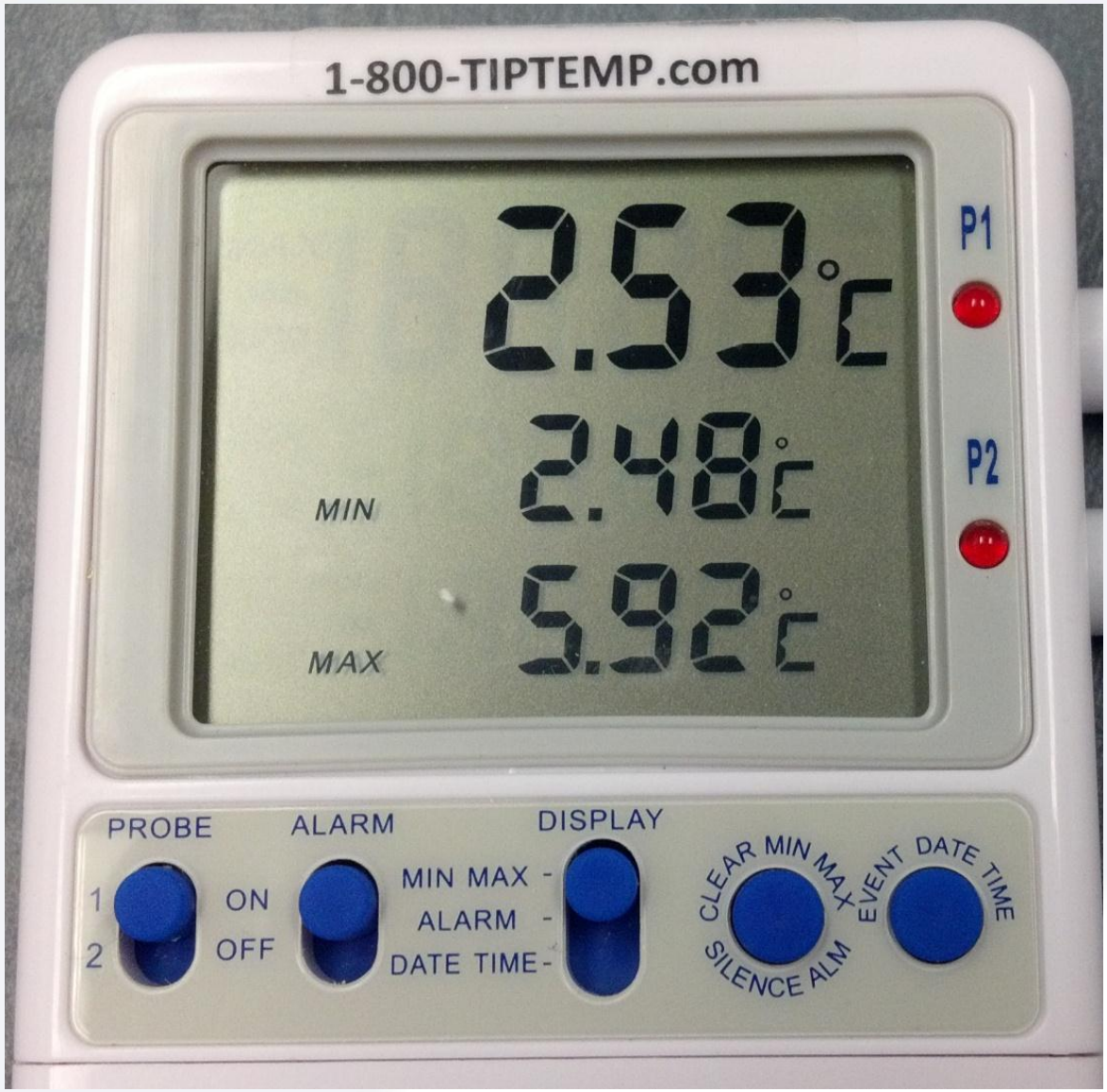
What is Wrong With Combo Units?

- They are cooled with freezing air from the freezer
- They have glass shelves that trap cold air and reduce air circulation
- Much of the space is not usable for vaccine storage
- There is no port for a thermometer wire to pass through

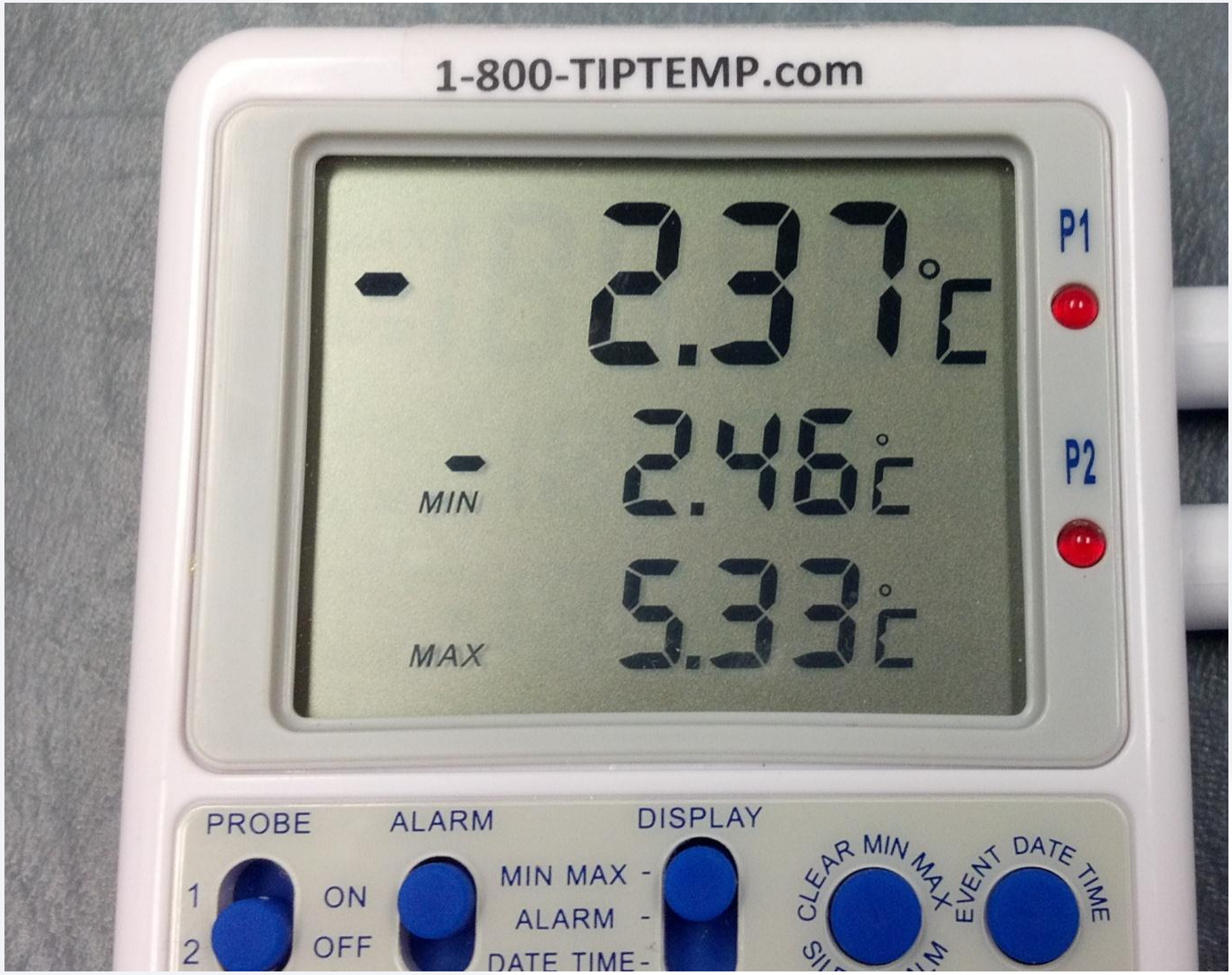
Demonstration Of Top Shelf Freeze



Middle Shelf Glycol Buffered Probe



Top Shelf Glycol Buffered Probe



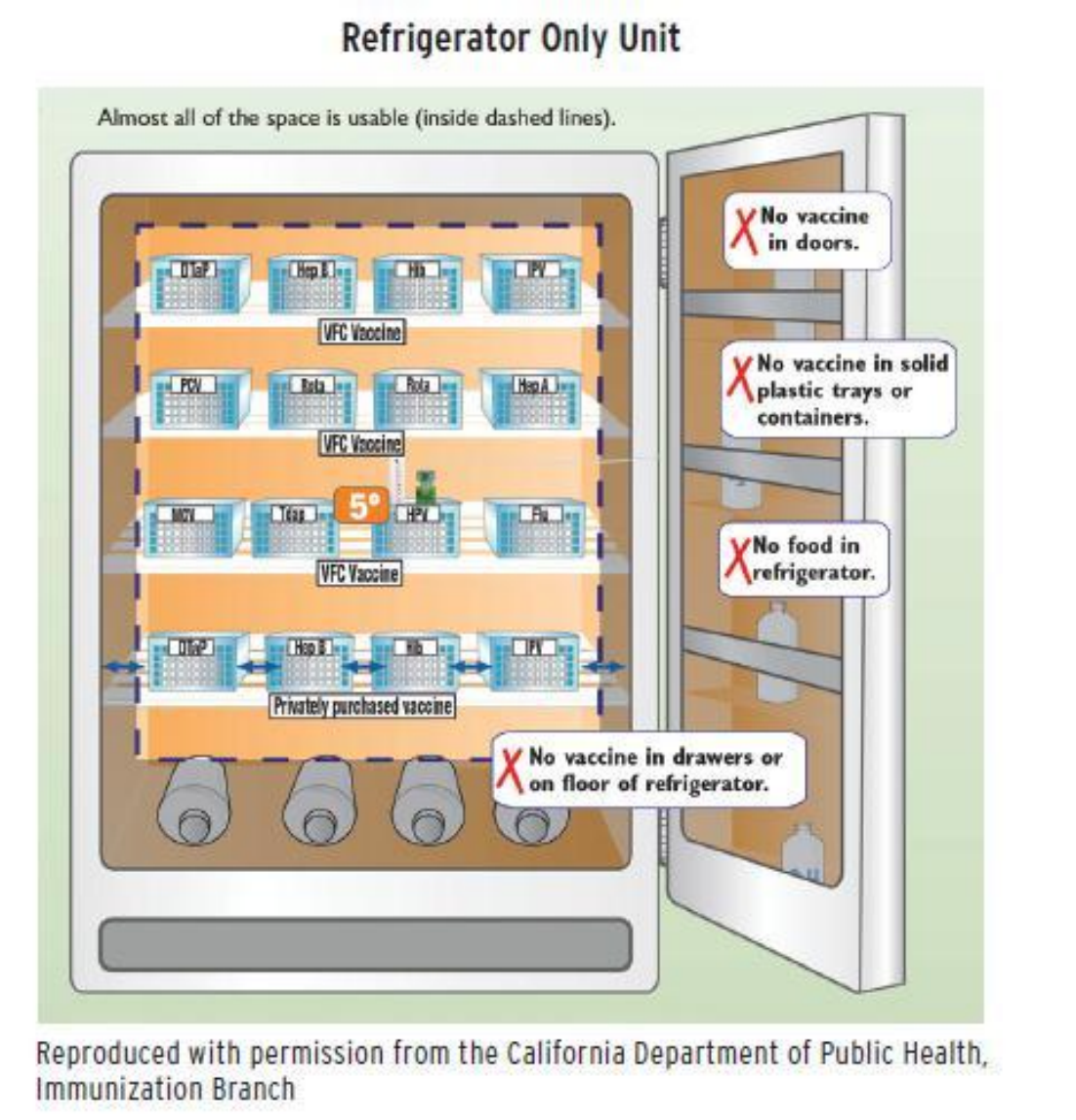
Why replace your domestic combination unit?

- To protect vaccine potency
- To protect investment in vaccines (often $15,-$40,000 per provider)
- To decrease risk of freezing (and thus destroying) refrigerated vaccine.
- Storage space is likely inadequate & stand-alone units can hold much more vaccine than combination refrigerators.
- Biologic-grade refrigerators have internal circulation fans, and wire shelves which greatly reduce the variation in temperature and allows for storage throughout the unit.

A biologic-grade refrigerator is ideal

- Also known as medical-grade, or pharmacological-grade
- These are designed for vaccine storage. They are designed to maintain a very precise and narrow temperature range (within 1-2 C) throughout
- Circulating fans and wire shelves allow temperature to remain even and maximize useable space
- Controlled by electronic / microprocessor thermostat, not mechanical dial

A biologic-grade refrigerator is ideal



Reproduced with permission from the California Department of Public Health, Immunization Branch

Biological-Grade

- Electronic digital thermostats
- Visible Digital Temperature Displays
- Adjustable Wire Shelves
- Interior Circulating Fans
- Ports for Temperature Probes
- Door Ajar Alarms
- Options for “glass” or “solid”doors
- Wide range of sizes
- Optional locks for security

Biological-Grade

- These may not be available immediately, plan 2-4+ weeks to receive this equipment
- Measure carefully to ensure the unit will fit in your space
  - Especially pay attention to doorway measurements
  - Strongly recommend paying extra to have the unit delivered into your office, rather than just to the parking lot.

Alternatives for vaccine storage

1) Stand-alone (Freezer-less) Domestic Refrigerators

2) Twin Cooling Dual Domestic Refrigerators

Stand-alone (Freezer-less) Refrigerators

- Minimal shelving in the doors, no ice maker, wire shelves and generally a cold plate on the back wall to cool the refrigerator.
- Least costly alternatives to combination units at $600 to $900 depending on size.
- Analog thermostat that requires adjustments and careful monitoring.

Twin Cooling Dual Refrigerators

- Only domestic units with a totally separate cooling mechanism for the refrigerator and freezer sections
- Refrigerator-only coils reduce the risk of freezing for the refrigerated vaccine (Models without ice makers are preferred.)
- Electronic thermostat for increased accuracy of temperatures and less drift over time
- Generally available on the same day at local retailers, but at a comparable cost to biologic-grade refrigerators
- Space usage is not ideal. Glass shelves block air circulation and are designed with lots of unusable door storage
- Has not been tested by NIST

Freezers

- CDC recommends a stand-alone freezer
- The freezer section of a combination unit is disallowed by CDC guidance.

Freezers

- Freezer management can be less precise in temperature regulation since they just have to be “colder than -15° C” (5° F)
- Although it is nice to have digital thermostats on freezers, it is not as important as in refrigerators. However, the small freezers are cheap enough that two can be purchased to help with manual defrosting – the “cold spare” can safely hold the vaccine as the main freezer is defrosted.

Defrosting Freezers

- The CDC currently recommends an “auto-defrost” freezer.
  - That feature is difficult to find in freezer-only units and generally quite expensive.
  - Freezers with manual defrost analog controls are acceptable and the small 1.1 to 1.5 cu. ft. models are inexpensive (between $200 and $300).
    - Purchase 2 and use one to store vaccines while you manually defrost the other
- Maintenance of frozen temperature is especially problematic with defrost cycles. These cycles require warming of the freezer above the recommended temperature range of -15C to -58C

Storage Space in the Office

- Before purchasing new vaccine storage units, assess the clinical space available and work-flow characteristics of your practice.
- You may select one of two broad styles of vaccine storage:
  - **bulk storage with smaller point of service (POS) refrigerators** in the clinical area, and
  - **centralized storage** with one or more units.

Bulk storage with smaller point of service (POS) refrigerators

- Bulk storage refers to having a large one- or two-door refrigerator placed either in or out of the clinical area.
- The point of service (POS) refrigerators can be small and located at a nurses' work station where vaccine will be prepared.

Bulk storage

Advantages

- Clinical staff have easy access to vaccines during their busy day
- With a POS and bulk storage, the cumulative effect of the temperature variation is potentially less.

Disadvantages

- Potentially greater cost* of the smaller POS refrigerators (approximately $900) plus the bulk storage unit
- More units that need temperature monitoring

Centralized Storage

- Centralized storage refers to having one or more main refrigerators that store all of your practice's vaccine.
  - Each dose is retrieved from that unit.
  - If space allows, you may have one large double-door refrigerator or two smaller units
    - One for VFC vaccine
    - One for private stock vaccine
  - Remember, VFC and private vaccine, even if stored in the same unit, should be kept separate and labeled

Centralized Storage

Advantages

- Potentially less cost and fewer monitored units

Disadvantages

- Increased walking distance to a central unit
- Potential for a traffic jam when more than one clinician needs vaccines
- Frequent opening and closing of the door

Under the Counter Units

If you use an under the counter unit, determine where it discards waste heat and make sure there is adequate ventilation

Choosing a Refrigerator

You will need to determine:

- Size:
  - The easiest way to pick a refrigerator size is to consider what you currently have and assess your inventory and practice population needs.
  - Estimate how much room you currently have and how much you would rather have.
  - Study the published dimensions and compare to actual measurements of what you have
- Plan for delivery – “Inside Delivery” a must!
- Time for set up and temperature stabilization

AAP Resources

- AAP Immunization Web Site: http://www2.aap.org/immunization/index.html
- AAP has information sheets to help locate biologic-grade refrigerators: http://www2.aap.org/immunization/pediatricians/pdf/VaccineStorageRF.pdf
- AAP Vaccine Storage and Handling PediaLink course: http://bit.ly/vaccinestorage

Questions???

Thank You for Joining Us!

Next SOAPM-PPMA Webinar:

Vaccine & Storage Handling Part II

Mid-July, 2014

Thank You for Joining Us!

If you have any questions or ideas for future webinar topics:

Jose Lopez, Manager,

Practice Management

847/434-4089 or jlopez@aap.org