Are You Silently FREEZING Your Vaccines?

Upgrading To SAFE Vaccine Storage in Outpatient Pediatric Offices – Personal Confessions of a Refrigerator Geek!

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It is hard to imagine a more important function by a pediatric practice than safe vaccination. Vaccination is perhaps the single most frequent procedure we do – and we need to do it well! We as pediatricians must maintain the public trust of being the safest and best place to receive vaccines. Every child deserves to have fully potent vaccines! Hopefully this document will help you improve the mechanics of your vaccine storage. (*But remember, I am only sharing my personal opinions and this is not an official document of the AAP!*)

Who Oversees Vaccine Storage?

We all do! For private purchase vaccine, the pediatrician is obligated to know, understand and follow the principals of cold chain to ensure the full potency of each vaccine given. For those of us with VFC vaccines, the local VFC program will periodically inspect our record keeping, equipment, and our ability to follow the rules of the local VFC Grantee. In turn, the VFC Grantee must interpret and follow the recommendations of the CDC. VFC pediatricians all have contracts with the local VFC Grantee saying we will follow their directions exactly. In other words, we must follow the Grantee's interpretation of the CDC recommendations rather than the CDC directly – although in practice there may be very little difference between the two entities.

Deciding Style of Storage:

Outpatient pediatrics happens at a faster pace than most outpatient medicine. Since vaccination is much of what we do, it is important for office flow to carefully consider how vaccines are distributed within an office. There are two main themes for outpatient vaccine storage: 1) small point of care refrigerator units fed from a larger bulk storage unit, and 2) centralized storage using larger refrigerators. Both styles have pros & cons, with the deciding points being building layout, the number of providers being served, and if both VFC and private stock are required. (Having both VFC and private means you need two complete sets of vaccine! No routine swapping!)

Point Of Care with Bulk Storage:

Point of care (POC) refrigerators are relatively small (2.5 cu ft) under counter units that hold a limited supply of vaccines – both VFC and private. The goal is to have the unit at the counter where the nurse(s) prepares the vaccinations. The POC can be shared by one or two nurses. Generally there are just a few days worth of any one vaccine type, and that type is not replenished until completely used. This way any one dose does not spend more than a few days in a unit where the door is frequently opened. A nurse working at such a counter can go from chart work to having the vaccines in hand for a 4 year old well visit in less than 20 seconds! There is also less congestion in the halls and in front of the refrigerator from the other nurses. The disadvantage is more initial cost for the small units and the additional overhead of managing additional refrigerators.

Centralized Storage:

Centralized storage is the more common style of storage. The centralized refrigerators are placed so that all nurses can retrieve the vaccines they need from one or more larger refrigerators. The disadvantage is that the building must have sufficient space centrally located and the possible random congestion from all nurses converging throughout the day to a single spot. The normal patient traffic can occasionally interfere with the nurse traffic, slowing each other. But this is perhaps less expensive initially and has fewer refrigerators to maintain.

Refrigerator Characteristics:

Refrigerated vaccines are approved to be stored at 2-8C (with 5C as the target value). If a storage unit becomes warmer than 8C, the vaccine is either damaged (fully potent but now has a shorter shelf life) or destroyed, depending on the severity and duration of the warm excursion.

Although refrigerated vaccines may be somewhat tolerant of warmth, nearly all are considered destroyed if discovered to have spent any time in sub-freezing temperatures. With freeze risk, the issue is ANY exposure to sub-freezing temperatures rather than trying to determine the exact time spent below freezing. Whereas warmth may be a hand slap, freeze exposure is a chain saw!!

This extreme risk of freeze exposure makes some refrigerator designs much preferred for safety and ease of management. Vaccine refrigerators should be designed so no area available for vaccine storage can be less than 2C – ever!

Desirable features of a vaccine refrigerator include:

- Electronic or Microprocessor controlled thermostat the single most important characteristic of a vaccine refrigerator. Electronic thermostats rarely, if ever, lose calibration. All units are pre-tested and pre-set to 5C and need no end-user adjustment to maintain 2-8C throughout the entire unit. An adjustment should require a support call or technician on-site visit. If you need to adjust one, something is broken!
- 2) Interior fan for forced air circulation to minimize temperature variance within the unit. The fan runs continuously with or without the compressor running.
- 3) Wire or vented shelves. Solid surfaces such as the glass shelves found in home refrigerators (helps with spills) inhibit proper air flow and thermal mixing.
- 4) No closed compartments (like vegetable and meat bins) which also inhibit proper thermal mixing.
- 5) No space wasted on "door storage" which cannot be used for vaccine storage.
- 6) One or more ports (passageways) that allow the temperature probe wire(s) to enter the unit without disrupting the door seals (as would happen going in through the door.)
- 7) Door ajar audible alarms.
- 8) Digital display of the temperature used by the unit to activate the compressor. Most electronic refrigerators will display this temp as part of the thermostat unit, but understand the displayed temp is not the "official" temp of the unit or stored vaccine. The display shows an "air" temp not glycol buffered as required for official readings but can give a "heads up" as to when the door needs to be closed during an "inventory session".

Features to avoid in vaccine refrigerators:

- Analog thermostat. Often seen in home units, these units have a dial that is easily adjusted by hand. Markings often say "COLD....COLDER...COLDEST." It uses a bi-metal strip which can only be coarsely adjusted. Some refrigerators sold as stripped down pharmacy/medical grade refrigerators will have these. Although adequate for freezers, analog thermostats can "drift" making them not precise enough for safe vaccine storage.
- 2) Narrow, deep refrigerators. Horizontal shelf space is important for storing the many different vaccines needed for pediatrics. It is much easier to do inventory and check for expiry dates if each vaccine type can have its own row and is visible from the front.

Types Of Refrigerators

There are several broad classes of refrigerators, and the names are confusing. Roughly from Best to Worst:

- "Medical / Pharmacy / Purpose Built / Vaccine Refrigerators" are usually "refrigerator only" and with the Desirable Features listed above, are the refrigerators needed for vaccine storage! But - I have seen manufacturers list sub-par refrigerators as "value - pharmacy grade" with the older and cheaper analog dial thermostat. Don't be fooled – make sure they value your vaccines as much as you do! These should be set to 5C. When I use the phrase "Vaccine Refrigerator" I am referring to the subclass of this group with all of the Desirable Features above – especially the electronic thermostat!
- 2) "Dual Zone Medical / Pharmacy / Purpose Built / Vaccine refrigerators"- are appropriate for vaccine storage and are essentially an independent refrigerator attached to an independent freezer. The key difference between "dual pharmacy" & "combo domestic" refrigerators is that the dual unit has a separate evaporator (coils of tubing inside the unit that generate cold) for the freezer compartment and one for the refrigerator compartment. Evaporators are designed to produce either freezer temperatures or refrigerator temperatures. A standard combo domestic refrigerator uses the freezer evaporator to cool the refrigerator and thus risks freezing vaccine. Dual zone vaccine refrigerators are safer since they use an evaporator optimized for safely cooling the refrigerator section. These stacked units can be tremendous space savers in small offices, although be careful the freezer is not too large and the refrigerator too small. Size does matter!
- 3) "Twin Cooling" (Samsung) Domestic Refrigerators are a special class: These have completely separate refrigerator and freezer compartments with separate evaporators in each section and even door alarms and electronic thermostats. They are sold with the separate compartments as a way to keep freezer foods from tasting like refrigerator foods! (Remember in the usual domestic refrigerator, the refrigerator and freezer are open to each other.) They are technically "dual units" and not "combos" (see below) having two evaporators but sharing the single compressor. They are designed for home use and waste enormous space with closed bins and door storage and no circulating fan. While perhaps a reasonable choice for an emergency purchase, they are expensive and not as good as a vaccine refrigerator despite nearly the same cost. But they are available in local appliance stores if a temporary solution is needed. These and the freezerless refrigerators make an excellent choice in the employee break room. If continuously monitored with a certified thermometer, they could be put into immediate service as an emergency vaccine refrigerator if the real one fails (after, of course, removing all food!).
- 4) "Commercial Grade" generally manufactured for the food industry. They look good in stainless steel, have great wire shelves and possibly interior fans. They sometimes mention the ability to "rapidly cool" food – unclear if that involves air colder than 0C or just a high speed on the fan – but I am concerned the manufacturers are not sufficiently afraid of freezing a head of lettuce as you need to be for silently freezing vaccine! Without the electronic thermostat and probe ports, I would be afraid for routine vaccine use. The cost difference is minimal from a vaccine refrigerator – spend the extra few dollars and solve the problem!
- 5) "Refrigerator-Only Domestic Refrigerator" (or sometimes called "Freezer-less Refrigerators") refers to the classic "garage/utility quality" spare refrigerator. It has no freezer or ice compartment. May be forced air or "cold plate" (rear wall is a chilled metal plate cold enough to cool the unit) and has a dial analog (not digital) temp control. Solid door. It also has wire shelves which are good. This may be a reasonable temporary choice for a "I have to have one TODAY!!", but it is not a good long-term solution without the interior fan for circulation and digital thermostat for temp stability. But if you cannot wait several weeks for a vaccine refrigerator and emergency situations do happen these can be purchased for \$600 to \$800 from local appliance stores. The certified max/min thermometer should be placed in the coldest part of the refrigerator that can hold vaccines i.e., near the cooling plate or air vent. As with all vaccine refrigerators, a phone enabled monitor is strongly advised. This style is an

excellent choice for a break room or lab refrigerator since it could serve as an emergency spare – if you always keep it monitored with a certified max/min thermometer and maintained in proper adjustment.

- 6) "Beverage Refrigerators" these often can look quite nice with a glass door but are generally cheaply built with no interior fan. They are built to cool products costing less than \$1 – not vaccines! I worry too much to try and make this work!
- 7) "Combo Domestic Refrigerators" refers to the refrigerator you can usually find in a local appliance shop or home. Combo domestic refrigerators have a freezer compartment (above or below) vented into a refrigerator section. The refrigerator section is cooled by freezer air being shunted into it at sub-freezing temperatures. These are extremely dangerous due to their tendency to have sub-freezing air strike vaccine boxes as it enters the compartment with vaccines. If the air drifts against a vaccine, it can silently be frozen despite the official thermometer reading normally. The risk is dependent on many unpredictable factors that change constantly how full the refrigerator is, whether or not vaccine is stored on the top shelf or near a freezer vent, the presence of circulation-defeating glass shelves, and no constant-flow air inside the unit. They also usually have analog thermostats which are not precise or accurate enough for vaccines. Although the CDC currently (2015) allows the use of the refrigerator section of a combo unit, I do NOT consider this class safe. Many individual VFC programs will not allow new combo units to be put in service or even old units that have experienced an excursion to be placed back in service. *I hope and anticipate there will be a mandatory retirement of these units soon*.
- 8) "12 Volt Car Refrigerators" for Transport although these are mentioned in the CDC Vaccine Storage and Handling Toolkit, I suspect they present a significant freeze risk. I have not tested these but would never trust it for transport. Passive cooling with conditioned frozen water bottles in a hardsided cooler is much safer than poorly characterized active cooling.

Additional Considerations with Vaccine Refrigerators

<u>Lead Time:</u> Often when ordering, the pediatrician is surprised it can take 2 to 6 weeks to receive the unit. You cannot wait until what you have breaks – you need to order now!

Size Matters! The best way to estimate what you need is to figure out how much storage space you now have and double it! Or triple it! Having extra space will allow you to take advantage of buying extra vaccine prior to a price increase. If you are just starting a practice, visit a similar sized practice and see what works for them. There is relatively little cost differential in the larger units, and I suggest purchasing the largest that your space will handle. For a two pediatrician office, a 23 cu ft has been adequate for us. And in our larger 4.5 doc practice, we have a 49 cu ft unit (but admittedly it has extra space). But because of the extra space, we do not sweat large flu shipments and were able to save \$9,600 in Prevnar costs by purchasing extra prior the 2015 \$16 price increase. The sq ft rating of refrigerators is usually outside dimensions – not useful storage space. For instance, I have an unused freezerless refrigerator billed as a "17 cu ft" refrigerator. If I measure the useful space that I can use in cubic inches and convert to cubic feet (WxHxD in inches divided by 1728 cu in/cu ft), I find that the three shelves provide only 6 cu ft and the floor area used to hold cold water mass has an additional 2.4 cu ft. To replace this refrigerator, I purchased a vaccine refrigerator advertized as "23 cu ft". When it arrived, I calculated how big the useful space was to store vaccine and I measured only 12.6 cu ft! Our 49 cu ft refrigerator measures 24 cu ft! If I count a makeshift shelf I added on the bottom (see below), it increases to 28.7 cu ft. I suspect all manufacturers do some similar magic with their cu ft rating - the usable inside dimensions seem to be approximately half of the advertized space.

<u>Linear Shelf Space:</u> Horizontal shelf space is important for organizing vaccines and helping with accurate inventory. Extra shelves can trade the unused vertical space between shelves for valuable horizontal space. Rows of vaccine boxes can have gaps between them for ventilation and to more easily do inventory. Just remember if you are also using VFC vaccine, you will need to have room for two complete sets of vaccine stock. I recently added up the linear size of the 21 vaccines we stock, added a half inch for spacing, and came

up with 7 feet of required shelf space per vaccine set! Pediatricians with private and VFC will need up to 14 feet of shelf space for each vaccine box to have its own row!

<u>Measurements:</u> I cannot stress enough that Vaccine Refrigerators can be very large! They are frequently taller than what our doors are built to accommodate. Although a single door refrigerator can be tilted to pass a doorway, the double door large refrigerators do not tilt easily! Remember, these units are built for commercial and hospital labs – large spaces with large doors. Measure three or four times with at least two different people before you decide to order. Having your refrigerator stuck in the parking lot is not useful!! For the large units, inquire about "White Glove" delivery or "Inside Delivery". That makes the shipping company uncrate and deliver the unit where you want it – and not leave it in the parking lot!

<u>Doors – Sliding or Swinging?</u> The vaccine refrigerators also have the option of glass sliding doors or swinging doors as is found on standard domestic refrigerators. I think this is a personal preference. We chose the swinging doors. Be warned that unlike domestic refrigerator doors, vaccine refrigerators may be built with a fixed hinge side – not reversible. If it is to sit in a corner, you do not want to go "past" the unit to open the door – you generally want it to open from the side you most often approach.

<u>Doors – Glass or Solid?</u> Vaccine refrigerators give the choice of glass see-through doors or solid doors. The solid doors have the advantage of being more insulated. So if you live in a power outage area or are prone to losing power during storms, solid doors may be better. In fact, with solid doors in a power outage, you can put conditioned frozen water bottles on the top shelf (15 or more half liter frozen water bottles) and prolong the time of 2-8C to a day or more. Glass doors may give an advantage when doing inventory and knowing where to reach for a vaccine.

<u>Where Does the Heat Go?</u> Refrigerators have to pull heat from the vaccine compartment and dump it outside. The heat can be dissipated through small frontal grates, out the rear, or even through the walls radiantly. You should not put a vaccine refrigerator flat against a wall or in a tight closet if there is not room to dispel the compressor heat. Our 49 cu ft unit needed to sit recessed in a shallow hall closet, but the heat was dumped to the rear. We were able to remove a section of sheet rock so that the heat could dissipate into the space above the refrigerator. This can be a problem for small refrigerators and freezers. These are often placed in closed spaces under nurse work desks. For these Point Of Care small refrigerators/freezers, be careful to note whether or not the refrigerator dumps heat to the lower front (front breathing), through the sides via radiant heat, or out the rear. Units need about 4 inches of clearage between themselves and walls to work properly.

<u>Extra shelves:</u> Inquire about purchasing extra shelves. We often need more linear space than height between shelves. Look at your current vaccine boxes and measure what the spacing will require for double stacking the boxes on at least some of the shelves. Manufacturers will sell extra shelves but often this add-on is not listed. The bottom floor is often open and may be wasted space. Although it is usually not appropriate to set boxes of vaccine on the floor (the compressor may be below and the floor the warmest spot, not the coolest), I have tested my large units and found that I can lay a large number of pre-chilled half liter water bottles on the floor and cover with cheap wire shelving from a hardware store. As long as you first test that area of the refrigerator with a data logger, that should be an excellent place to safely store unusually large flu shipments.

<u>Where is the Cooling Air Flow?</u> Vaccine refrigerators have an interior fan that constantly runs. Most have it in the top of the unit and it pulls the warmer top air up and forces it through the evaporator coils to cool the air and then forces the cool air down the rear inside wall of the unit. If vaccine boxes slide back and touch the rear wall, the cooling flow is disrupted and the temperature in the unit may drift from uniform. Usually the wire shelves have an upturned lip that catches the bottom row of vaccine boxes – be sure the next rows do not slide back! Understand where the air flows – do not block the air as it leaves the coils – that is a potential freezing or near-freezing risk for the box doing the blocking! The vaccine boxes should be 2 inches from the rear walls – especially being careful not to obstruct the cooling flow.

<u>How Do You Repair It?</u> If repairs are needed, first check with the manufacturer. But remember that the restaurant industry also has large refrigerators and the service people that work on those units will be happy to service yours.

Freezer Characteristics:

Freezers are MUCH simpler than refrigerators. They just need to keep Varivax, Varivax-containing vaccines and Zostavax less than -15C at all times. This is primarily a "one-sided restriction" – never get warmer than -15C! (You don't want to get colder than -50C either, but none of the freezers we can afford will get that cold! The -50C max cold does rule out using dry ice for transport since that that can cause damage at -79C)

Staying colder than -15C is much easier to do than trying to stay within a 2-8C range! MMR can be stored in a refrigerator or freezer. Most VFC Grantees recommend freezer storage for MMR due to its increased (relative to the other vaccines) sensitivity to warm excursions.

<u>Size:</u> Before I realized how little freezer space we needed, I bought a 5 cu ft manual defrost freezer with an electronic thermostat as a bulk storage unit in addition to a 1.1 cu ft freezer cube placed closer to the nurses. It The bulk unit is mostly empty in our 4.5 pediatrician office. We could easily get by with a pair of 1.1 or 1.5 cu ft freezers as we do at our smaller satellite offices.

<u>Manual Defrost:</u> With very small freezers, it is almost impossible to have an automatic defrost freezer and not have the compartment get warmer than -15C during the defrost cycle. When we used combo domestic refrigerators, the freezer would routinely get up to -10C or even -5C with the auto-defrost cycle (which essentially warms the coils enough to melt any accumulated frost.) Merck's package insert reflected this and used to say, "Any standard home freezer with an average temp of -15C is adequate for storage." The PI changed a few years ago and now states, "Varivax should be stored between -50C and -15C" which is interpreted as never warming above -15C. There is only one small freezer I know of that can maintain a -15C or colder during defrost. It is in a dual unit, not a stand alone, (American Biotech Systems, PH-ABT-RFC-16A) and does so by using -20C phase change material to cool the unit as the defrost happens. It is perhaps cheaper if we just purchase small manual defrost freezers. The problem is you need a place to put the vaccine when you are defrosting the unit every few months so you should purchase two small freezers – either use them both as a distributed vaccine supply or keep one as a cold spare filled with frozen water bottles to help with an emergency transport if needed. These small units are in the \$250 to \$350 price range.

<u>Temperature Probe Port Required!</u> The biggest nuisance of the small manual defrost freezers is manually defrosting them! If you try and run the required probe though the side of the door, you will gap the magnetic seal and let in moist humid air – and frost up the inside quickly. Small manual units all need a probe port to allow passage through the side or rear of the refrigerator without compromising the door seal. It is possible to "drill your own" probe port if you purchase a cheaper \$250 model without an integral port. But be warned these units dump their heat through the side walls of the freezers and you may hit one of the coils with pressurized coolant and destroy the unit.

<u>Analog controls are adequate!</u> Since freezers have only a one-sided temperature requirement, the simple dial analog control is fine. Unlike the refrigerator getting too cold, a warm freezer is likely to merely shorten the shelf life of the Varivax, not destroy it. If you do have a warm excursion above -15C, you must call the VFC grantee for VFC vaccine and the Merck for the private. Remember, this Varivax arrives in your office at +2C, so Merck has a tremendous amount of data for warm excursions.

<u>Defrost – When? Or – How Much is Too Much Ice?</u> There are two issues with a manual defrost unit: is the ice encroaching on the door seal (big problem), and is the ice interfering with the cooling of the unit? Be careful to manually remove any ice near the door seals. I would mechanically knock off any ice within 1 inch of the door opening. Ice in that location can slowly push on the door seal until the door pops open and can ruin the

vaccine. It is hard to say how much ice is too much ice – but the more ice, the more inefficient the cooling of the cavity becomes and the more stress on the compressor – even if the certified thermometer says it is fine. To defrost the unit you need to have a second freezer with a certified thermometer on the premises so that the vaccine can be transferred to that unit. This is why these should be purchased in pairs! The units are small enough to be carried to a large sink and warmed with a hair dryer until all ice is gone. Of course the vaccine cannot be replaced until the thermometer verifies the temperature is <-15C.

<u>But I Really Want a Larger Freezer</u> – Many come in larger "under counter" sizes and the nice ones have the electronic thermostats and digital temperature read outs. Remember to be careful about where the heat dumps out of the under counter units so that they have proper ventilation. These units may get colder to -28C but none of the freezers we are likely to purchase get anywhere near the lower limit of -50C for Varivax. By getting colder at -28C and by having extra room, you can store the -20C Phase Change Material in unused portions of the freezer and provide excellent "cold mass". Cold mass in the way of frozen water bottles is not very helpful at -15C. Ice has little specific heat capacity (but it is more than "air" so frozen water bottles in empty space is better than nothing, just not a lot better!) The phase change material requires a lot of heat to go from frozen to melted at -20C and thus can help stabilize a powerless freezer for Varivax.

MONITORING!

Monitoring is absolutely required but beyond the scope of this paper. A Max/Min Data logger is required, but I also insist that people purchase a standalone phone enabled monitor in addition to the certified thermometer! Phone enabled means it will call you (voice) if it suspects a problem. Some units will text and email, but I need an old fashioned voice phone call to get my attention at 2 am! My favorites to do this job are SENSAPHONE (available on Amazon) and TemperatureGuard (http://temperatureguard.com/). Both can notify you by phone of power outages and temperature excursions. I have had to make several trips back to the office for doors not being quite closed and power. The TemperatureGuard can graph your data over time using certified thermometers and store the values on your network as well as send email and text. The Sensaphone is not nearly as sophisticated and just calls to alert you of an alarm. Both can share a fax line and do not need a dedicated line, and can respond with the current temperature if you call the devices! My current favorite data logger is a two probe unit that comes with a 2 year certification and relatively small glycol bottles w/ probes for buffered temperature values. It can record data from both probes every minute for a year before it overwrites. I recommend setting it for every two minutes (plenty fast) and to overwrite if its memory is full – but that will be two years! The data can be automatically downloaded by sticking a thumb drive in the USB port. It can be viewed here: https://traceable.com/products/thermometers/6431.html.

Where can I go on the internet to see what refrigerators and freezers I can pick from?

The two vaccine refrigerator manufacturers at the 2015 NCE are: <u>http://www.migaliscientific.com/products/vaccine-storage/</u> and

http://www.americanbiotechsupply.com/Products/Refrigerators/Pharmacy-Refrigerators.aspx

Both of these companies build excellent units in a wide range of sizes and I have experience with both. But pay attention to the measurements! You can occasionally have the wheels removed to get through a door, but you need to plan for it and the mover needs a special dolly that can grip the lower lip and become its "wheels"!

The best local advice might be your local VFC Grantee. In North Carolina, our Immunization Branch wants to be involved from the start and in fact wants to approve purchases before they are made, to insure adequate size, quality and function. They do not allow anyone to purchase new domestic refrigerators. The market obviously changes too quickly to list all of the manufacturers, but a quick conference with Mr. Google asking about Vaccine Refrigerators or Pharmacy Refrigerators should yield many to choose from.

Where can vaccine refrigerators and freezers be purchased? If your office has a relationship with Cardinal, McKesson, Henry Schein & Medline, you should contact them. I have seen some surprisingly favorable prices (like \$2600 for a solid door 23 cu ft unit). Having a knowledgeable salesman walk in your building and help advise you on possible solutions can be very valuable. They can work out a quote including shipping and give a good idea when to expect the unit. Worth the effort to ask!

How about freezers? Freezers are simple and small enough to order from Amazon or http://www.compactappliance.com/medical-freezers/. Remember to buy a pair!

And if you still do not know what to do, you can always email me (or find me on SOAPM) and I'll do my best to get you out of a Domestic Refrigerator Mess!

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The AAP's Vaccine Storage and Handling Guidance is available through http://tinyurl.com/AAPVaccines

or the official url:

https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/vaccine-storage-and-handling-guidance.aspx