American Academy of Pediatrics



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AAP Immunization Resources Storage and Handling Series Refrigerators, Freezers, and Vaccine Storage

The Centers for Disease Control and Prevention (CDC) offers <u>guidance on proper storage and handling</u> <u>of vaccines</u>, including recommendations on storage units for vaccines, in the <u>Vaccine Storage and</u> <u>Handling Toolkit</u>.

The American Academy of Pediatrics (AAP) has assembled some tips to help you choose the best equipment to meet the needs of your practice and keep your vaccine stock safe.

NEVER FREEZE REFRIGERATED-VACCINE

Silently freezing vaccine is the biggest threat to the potency and efficacy of your refrigerated-vaccine. It is impossible to visually detect whether a vaccine has been frozen. If such a vaccine is given to children, it may not prevent disease. Take precautions against freezing your vaccine by using the recommended equipment and properly setting up your refrigerator. For visuals of how to do this see the <u>CDC</u> <u>Vaccine Storage and Handling Toolkit</u> and the <u>EZIZ Preparing Refrigerators for Vaccine Storage</u>.

Key Points:

- Stand-alone refrigerator and freezer units are safest for storing vaccines.
- Medical- or pharmacy- grade refrigerators have electronic thermostats, audible door-ajar alarms, wire shelves, interior fans and ports to pass through sensor wires.
- Freezers are much smaller and can be manual or auto-defrost. They can have simpler analog thermostats, but should have a port for sensor wires. If picking a manual defrost unit, there should be a spare or second unit in the same office capable of holding the frozen vaccine while the defrost is completed.

CDC recommendations for stand-alone refrigerators and freezers

CDC strongly recommends replacing old, combination (domestic) units with stand-alone refrigerator and freezer units. Dual pharmacy-grade units with independent refrigerator and freezer compressors (not combo domestic units sharing a single compressor) are also excellent in offices where space is limited. Refrigerator/Freezer units can vary in size, from a compact, under-the-counter style to large, double-door units. The use of standard domestic combination refrigerator/freezer units is no longer appropriate, and many VFC programs may require their immediate replacement. The use of dormitory or bar-style refrigerator/freezers (small refrigerator units with interior freezer sections) has been banned for several years due to freezing vaccine risks.

CDC recommendations for stand-alone refrigerators and freezers (continued)

The characteristics of an appropriate refrigerator storage system include:

- ability to maintain within +/- 2°C of 5°C despite fluctuating ambient temperatures
- vaccine storage areas do not exceed the +2°C to +8°C +36°F to 46°F temperature range
- electronic / digital thermostat preset to <u>5°C (or possibly 4°C)</u>
- wire shelves with good interior circulation to minimize internal temperature variance to $\frac{+-2}{2}$ °C
- door ajar audible alarm and temperature excursion alarm
- enough extra room to hold the practice's vaccine stock, including flu vaccine at least 4 inches from the unit's walls
- certified continuous data logger with max/min displaying thermometer accurate to +/-0.5°C +/-1°F



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The characteristics of an appropriate freezer storage system includes:

- ability to store frozen vaccine not warmer than -15°C +5°F
- nor colder than -50°C -58°F
- \circ $\,$ room to store the year's largest inventory of Varivax, ProQuad and MMR II
- certified data logging max/min displaying thermometer accurate to +/-0.5°C
- automatic defrost or ability to defrost manually (practices using a freezer that needs to be defrosted manually will need a second freezer in which to store vaccine during the defrost process)

Half-liter drinking water bottles can be added to vaccine refrigerators to increase cold mass and thus stabilize temperature swings. Always cool water bottles in an alternate refrigeration unit before placing in a vaccine refrigerator. Chilled water bottles may be placed in empty shelves or the floor, but do not allow them to obstruct the air flow by touching the rear wall, nor should vaccines block the cover of the unit motor compartment. Typically, the air flow is down the rear walls from the circulating fan in the top and then back up the front.

Frozen water bottles may be placed in freezers to add cold mass. To help freezers retain their temperature longer in power outages, a <u>phase change material</u> -23°C -9°F capable of passively maintaining temperatures below -15°C +5°F is needed.

Types of refrigerator & freezers

Biologic-grade Full-sized Refrigerators

Biologic-grade ("medical"; "purpose-built"; "vaccine"; "blood-bank"; "laboratory") refrigerators are considered the best, most secure option for vaccine storage. These are the "gold-standard" in vaccine units and have electronic thermostats, wire shelving to improve circulation, small ports for the entry of a temperature probe wire and interior fans to equalize the temperature throughout. Manufacturers in this category offer a range of sizes and options to fit any clinic's needs. Size options include one-door and two-door bulk storage units, under-counter units and small point of service units to replace the disallowed dorm units. Units with glass doors help with inventory management. Keep in mind, biologic-grade units often require over a month to deliver. Some manufacturers will sell refrigerators classified as "biologic grade" with a mechanical or analog thermostat – avoid these. If purchasing a vaccine grade refrigerator, it should always have a "microprocessor controlled" or "electronic / digital" thermostat. These units are designed to run at approximately 5° C 41° F and rarely need any adjustment by the end-user. They are much safer than refrigerator units with analog dials.

Biologic-grade Freezers and Domestic Freezers

Freezers are easier to construct since they do not need a precise range – they just need to be always colder than --15°C +5°F. Freezers can be much smaller than what is normally used in a home. Although frost-free freezers are recommended, that feature is often found only in freezers much larger than what is generally needed. (Large

practices with <5 providers might consider a large 5+ cu ft freezer.) If not specially designed, freezers advertised as "frost-free" may warm up considerably above $-15^{\circ}C$ +5°F during defrost when the evaporator coils are heated to melt any frost or ice. Often it is less expensive to purchase two small manual defrost units and keep one as a "cold spare", than to purchase an appropriate auto-defrost unit. (The cold spare unit could hold the vaccine while the primary unit is being manually defrosted.) Be careful not to purchase more freezer than you need – vaccines containing Varivax are the only pediatric vaccines that require frozen storage, although MMR can be optionally stored frozen. Adequate freezers for 3 or 4 pediatricians can be as small as 1.5 cubic feet and cost as little as

\$250. If ordering a unit for under the counter, check the height of your countertop before ordering. Standard countertops are 36" high and may not be able to accommodate all freezers.



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Remember, small refrigerators and freezers can be sold as "counter top" or "built-in". That refers to the air circulation needed for cooling. "Built-ins" are able to exhaust waste heat out of the front of the unit.

Standard Refrigerators and Freezers and "Commercial Grade"

Standard domestic refrigerators and freezers are found in homes and appliance stores. Higher-end models are sometimes referred to as "commercial-grade," are most often used in the food service industry. They are not "biologic-grade". Currently, use of domestic refrigerator-only and freezer-only units is not prohibited, but future guidance may disallow them, as many VFC programs have done. Commercial food service refrigerators look very much like vaccine refrigerators, but there can be differences. Food service units are designed to rapidly cool large quantities of warm/hot food – and thus could get too cold (below 0°C 32°F) when the compressor turns on. In an emergency, it is possible for a domestic refrigerator-only unit to be used safely for vaccine storage with proper precautions. If used for VFC vaccine, you should consult with your local VFC.

Other Features and Alarms

Glass doors may help the practice with inventory control, but they lose heat much faster in a power outage. While a solid door unit may maintain an acceptable temperature for 2 hours without power, glass door units rarely go longer than 30 minutes. Having generator power is prudent if looking for a glass door unit.

Certified, continuous data-logging thermometers with a maximum and minimum display are required. <u>Read more about these</u>. It is also important to purchase a temperature monitor that can call, text, or otherwise notify several people if the unit has a temperature excursion. Best are those that will keep calling/notifying a list of staff until one acknowledges the notification with a response. Active notification could prevent nearly 80% of vaccine wastage due to temperature excursions.

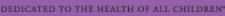
The refrigerator may come with an electronic digital display of temperature, but the VFC program will require a separate certified data logger in a glycol buffer.

Manufacturers and Distributers of Biologic-grade Units

The manufacturers and distributors below are a sample of some that you may wish to consider for safe vaccine storage in your practice. Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. If you are a manufacturer of equipment and wish to add or edit information below, please contact <u>immunize@aap.org</u>.

Aegis	http://www.aegisfridge.com
American Biotech Supply	http://americanbiotechsupply.com/find-a-dealer
Compact Appliance	http://www.compactappliance.com/on/demandware.store/Sites-Appliance-
	Site/default/Search-Show?q=american+biotech
Fisher Scientific	https://www.thermofisher.com/us/en/home/life-science/lab-
	equipment/cold-storage/vaccine-cold-storage-solutions.html
Follett	http://www.follettice.com
Helmer	http://www.helmerinc.com/
Lab Research Products	http://www.labresprod.com/
Migali Scientific Refrigeration	http://migaliscientific.com/
Panasonic Healthcare	http://www.panasonic-healthcare.com/us/biomedical
Powers Scientific	www.powersscientific.com
ThermoFisher Scientific	www.thermofisher.com/us/en/home.html

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Use the following to determine the appropriate equipment size for your practice

Refrigerator:

Offices generally have either one large central storage unit, or a bulk storage unit with smaller refrigerators at a nursing desk that maintains a few days-worth of supply. The advantage of the central-storage style is that there is just one unit to be inventoried, set up, and monitored. Disadvantages include crowding by staff when multiple vaccine administrators need to retrieve vaccines, and inefficiency of the vaccine administrator needing to leave the area to retrieve the vaccine. In a bulk-storage style, a very large unit could be placed out of the high-flow area and infrequently accessed. The vaccine administrator would pull mainly from a smaller unit near their vaccine preparation area and not need to walk to the central unit. The disadvantage is that there are more units to monitor and larger initial cost.

Sizing a unit is difficult. Consider getting something larger than what exists currently. If just starting out, consider visiting a practice of the size you hope to be and look at their vaccine storage units. Vaccines come in many varied and oddly shaped boxes, so just counting expected dosages is rarely helpful. Remember to factor in the space needed for FluMist and injectable Flu vaccine.

Freezer:

Freezers can be much smaller. Since only Varivax containing vaccine must be stored in it, a 1.5 cu ft unit can hold enough vaccine for 3 or 4 pediatricians. Generally it works best to have a second cold spare unit so units can be manually defrosted. If you have a cold spare and you get tight for room, the second unit, if set up with its own certified thermometer, can serve as an overflow unit as well. MMR can be stored frozen and most pediatricians store it in the freezer. Since only two visits (12m and 4y) require Varivax and MMR, the freezer can be placed in a less busy area of the office. Again, in selecting a size, base your needs on your current storage ability or visit another practice to see what works for them.

Special thanks to the Oregon Immunization Program for sharing material from their 2012 Refrigerator Guide and to the California Department of Public Health for sharing material from their Refrigerator Buying Guide!

One final suggestion: When ordering large refrigerators, measure all doors and entry ways and check unit dimensions to verify that the unit(s) you ordered can fit into your building and into the appropriate room. Have two different people measure at least twice. These units are often used in university labs and hospitals and are quite large and tall. When ordering, ask for and pay extra for "inside delivery". Otherwise, the shipping company (which is not who sold you the unit) may leave your new 500 pound refrigerator crated in a box in the parking lot.