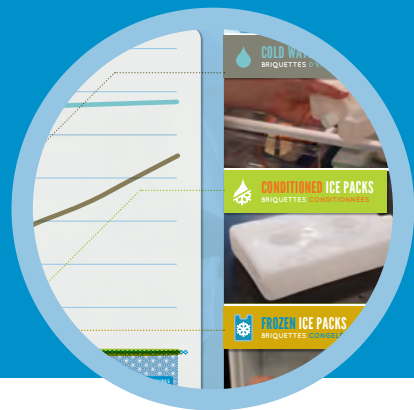


PREVENTING FREEZING IN COLD BOXES AND VACCINE CARRIERS



What you should know about freeze prevention:



Freezing vaccines is a widespread problem worldwide. Several studies over the last decade show that freezing conditions occur all along the vaccine supply chain and can compromise the potency of freeze-sensitive vaccines.^{1,2}



All vaccines containing an aluminum salt adjuvant are susceptible to freezing, including: diphtheria toxoid, tetanus toxoid, pertussis, liquid *Haemophilus influenzae* type b, hepatitis A, hepatitis B, human papillomavirus, liquid Japanese Encephalitis, liquid meningococcal, liquid pneumococcal, and liquid rabies vaccines.



Currently, there are several methods that may be used to keep vaccines within the recommended 0°C to +10°C when storing or transporting vaccines in cold boxes or vaccine carriers.

- **Frozen ice packs placed directly into a vaccine carrier will cause the internal temperatures of the carrier to drop below 0°C, exposing freeze-sensitive vaccines to damaging temperatures.**
- **The use of conditioned ice packs has long been recommended by the World Health Organization (WHO) to avoid freezing vaccines, however, conditioning is a process that takes time and advanced planning. Cold chain surveys have shown that this practice is difficult to enforce and is widely ignored.³**
- **Cool water packs are an excellent choice for preventing vaccine freezing when travel distances are short. This method requires refrigerator space and time to cool to a temperature between 2°C to 8°C prior to use. All performance, quality, and safety (PQS) prequalified cold boxes and vaccine carriers are tested for “cool life at +43°C,” which is the number of hours the carrier maintains temperatures below +20°C after being loaded with cool packs stabilized at +5°C for 24 hours.**
- **The controlled temperature chain is a choice for approved heat-stable vaccines labeled for higher temperature storage, used in certain situations. WHO is working with manufacturers to label vaccines according to their true temperature stability, which will allow countries to more easily adopt a controlled temperature chain approach when appropriate. In 2012 MenAfriVac™, a vaccine against Meningitis A, became the first vaccine to be licensed for use in a CTC. It can be used up to four days at up to 40°C.**



Efforts are underway to create freeze protection passive cold chain equipment. The WHO recently developed specifications for freeze-safe cold boxes and are in the process of developing specifications for freeze-safe vaccine carriers. New prequalified products will be listed in the PQS catalogue on the WHO website.

¹ Maa YF, Zhao L, Payne LG, Chen D. Stabilization of alum-adjuvanted vaccine dry powder formulations: mechanism and application. *J Pharm Sci* 2003;92(February 2):319–32.

² Chen D, Tyagi A, Carpenter J, Perkins S, Sylvester D, Guy M, et al. Characterization of the freeze sensitivity of a hepatitis B vaccine. *Hum Vaccines* 2009;5(1):1–7. In press.

³ WHO. *PQS Devices Catalogue: prequalified equipment for the Expanded Programme on Immunization*. WHO/IVB/11.08. Version 18 December 2012.



RELEVANT RESOURCES

RESOURCE TYPE	TITLE	ORGANIZATION
Video	Above zero: strategies to prevent vaccine freezing AVAILABLE AT: www.youtube.com/user/PATHprograms	WHO and PATH
Evidence brief	Innovative passive cooling options for vaccines AVAILABLE AT: www.path.org/publications/detail.php?i=2346 OR: www.who.int/immunization_delivery/optimize/resources/en/index1.html	WHO and PATH
Overview	Cool innovations for vaccine transportation and storage AVAILABLE AT: www.path.org/vaccineresources/details.php?i=1603 OR: www.who.int/immunization_delivery/optimize/resources/en/index1.html	WHO and PATH
Overview	Temperature monitoring for vaccine quality AVAILABLE AT: www.path.org/publications/detail.php?i=2055 OR: www.who.int/immunization_delivery/optimize/resources/en/index3.html	WHO and PATH
Guidance document	Use of MenAfriVac™ (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns AVAILABLE AT: www.who.int/immunization/documents/WHO_IVB_13.04_5_6/en/index.html	WHO
Photo book	Delivering MenAfriVac™ using the controlled temperature chain AVAILABLE AT: www.path.org/publications/detail.php?i=2308 OR: www.who.int/immunization_delivery/optimize/resources/en/index2.html	WHO and PATH
Video	Use of MenAfriVac™ in a controlled temperature chain AVAILABLE AT: www.youtube.com/watch?v=8BExyEJG5r0	WHO and PATH



WEBSITES OF ORGANIZATIONS WORKING ON THIS ISSUE

WHO PQS	http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/
PATH	www.path.org/projects/cold-chain.php
WHO	www.who.int/immunization/en/
United Nations Children's Fund Cold Chain Logistics Task Force	www.unicef.org/immunization/index_42071.html
Bill & Melinda Gates Foundation	www.gatesfoundation.org/What-We-Do/Global-Development/Vaccine-Delivery
GAVI Alliance	www.gavialliance.org