# Freeze-Preventive Vaccine Carriers

## Health need

When vaccines are transported from health centers to remote populations, temperatures inside vaccine carriers are often maintained with frozen ice packs, putting the vaccines at risk of freezing.[1,2] Many vaccines containing aluminum adjuvants are freeze sensitive and costly, including human papillomavirus, pneumococcal, liquid rotavirus, and cholera vaccines. If frozen, these vaccines lose potency and potentially leave vaccinated individuals at risk of disease. Freeze-damaged vaccines can also harm the reputation of vaccination programs and waste valuable health dollars.

To protect vaccines from freezing, World Health Organization (WHO) policy recommends the use of cool-water packs rather than frozen ice packs in carriers. If ice packs are used, they must be conditioned or allowed to warm from –25°C to 0°C. Conditioning is not an exact science, and freezing can occur even when vaccines are stored with conditioned ice packs. Thus, WHO has new Performance, Quality and Safety (PQS) specifications for carriers, requiring freeze-preventive features.

## Technology solution

PATH is addressing vaccine freezing at the periphery by redesigning existing carriers to be freeze safe. Even when used with non-conditioned ice packs, the freeze-preventive carriers will protect vaccines from temperatures less than 0°C, preventing freezing. By allowing the use of frozen ice packs, these carriers should simplify preparation and reduce training burden (in the long term).

## Current status and results

PATH developed the Freeze-Safe reference design for the first freeze-preventive vaccine carrier prequalified by WHO. In 2012, PATH and partners field tested a proof-of-concept design that used engineered phase-change material (PCM) as a freeze-preventive barrier to vaccines. In 2015, PATH refined the design to use water, a low-cost, readily available PCM, instead of engineered PCM. PATH laboratory tests showed that when used with frozen ice packs, these carriers prevented temperatures from falling to less than 0°C inside the vaccine compartment, preventing vaccine freezing. In 2016, PATH published the Freeze-Safe reference design to Research Disclosure, ensuring its global access, and in 2017, a carrier using PATH's reference design became the first freeze-preventive carrier to be WHO prequalified. This carrier will undergo field evaluations in early 2018.

PATH continues to collaborate with inventors and manufacturers, helping them to meet WHO PQS freeze-protection specifications and further optimize freeze-preventive designs.

1. Samant Y, Lanjewar H, Parker L, Block D, Stein B, Tomar G. Relationship between vaccine vial monitors and cold chain infrastructure in a rural district of India. *Rural Remote Health.* 2007;7(1):617.

2. Wirkas T, Toikilik S, Miller N, Morgan C, Clements CJ. A vaccine cold chain freezing study in PNG highlights technology needs for hot climate countries. *Vaccine.* 2007;25(4):691–697.

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**A vaccine carrier modified to be freeze preventive.**

**"Vaccines are sensitive to heat and freezing and must be kept at the correct temperature from the time they are manufactured until they are used."**

*Immunization in Practice: A Practical Resource Guide for Health Workers.* Geneva: WHO; 2004.

## Availability

For more information regarding this project, contact Pat Lennon at plennon@path.org.

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