What Is the Cold Chain?

Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency, increasing the risk that recipients will not be protected against vaccine-preventable diseases. The system used to keep and distribute vaccines in good condition is called the cold chain. The cold chain has three main components: transport and storage equipment, trained personnel, and efficient management procedures. All three elements must combine to ensure safe vaccine transport and storage.

The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider’s office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain.

*Vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°– 46°F [2°– 8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck.
Importance of Maintaining the Cold Chain

Vaccine Potency

Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Once potency is lost, it can never be restored. Furthermore, each time vaccine is exposed to heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.

Vaccine Appearance After Exposure to Inappropriate Storage Conditions

Some vaccines may show physical evidence of altered potency when exposed to inappropriate storage conditions, such as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look perfectly normal when exposed to inappropriate storage conditions. For example, inactivated vaccines exposed to freezing temperatures (i.e., 32°F [0°C] or colder) may not appear frozen and give no indication of loss of potency. Therefore, visual inspection of vaccines is an unreliable method of assuring potency.

Visual inspection of vaccines is an unreliable method of assuring potency.

<table>
<thead>
<tr>
<th>Properly stored vaccine</th>
<th>Improperly stored vaccine</th>
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<tr>
<td>Full Potency</td>
<td>Diminished Potency</td>
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Properly stored vaccine

Improperly stored vaccine

Visual inspection of vaccines is an unreliable method of assuring potency.
Burden of Cold Chain Failure

An estimated 17% to 37% of providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm.\textsuperscript{1,2} One study involving site visits showed that 15% of refrigeration units had temperatures of 34°F (1°C) or lower.\textsuperscript{2} Out-of-range temperatures require immediate action.

Loss of vaccine potency due to improper storage conditions is a costly mistake. Patients receiving vaccine with decreased potency caused by improper storage conditions may not be fully protected against the vaccine-preventable disease. In the General Recommendations on Immunization, the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP) state that mishandled vaccine doses should not be counted as valid doses and should be repeated unless serologic testing indicates a response to the vaccine.\textsuperscript{3} Recalling patients to repeat vaccine doses because vaccine has been stored improperly can damage public confidence in vaccines and in your practice.

Vaccines are also expensive. The vaccines needed for a single infant visit can cost $181 to $281 or more. For toddlers, vaccine costs jump to $198 to $338 or more per child. The vaccines needed for one child at school entry cost $111 to $188 or more.\textsuperscript{4} Avoid extra expenses by following procedures to maintain the cold chain.
**References**


