Vaccine Stabilization

Health need

Maintaining cold chains to store and transport vaccine is a challenging task in many developing countries. The potential for heat to damage vaccines is highest in areas where power outages or gas shortages prevent refrigerators from operating or where vaccine must be transported over long distances to reach remote populations. Vaccines containing an aluminum adjuvant are also sensitive to freezing. Accidental freezing can occur when vaccines are placed too close to the walls of ice-lined refrigerators, the evaporator in certain refrigerators, or the frozen ice packs inside insulated transport carriers. Inadvertent exposure of vaccines to damaging temperatures has been well documented in both developed and developing countries. When health workers suspect a vaccine is temperature damaged, the vaccine is often discarded—at great cost to the immunization program. When temperature damage goes unnoticed, children may receive ineffective vaccine.

Technology solution

Thermostable vaccines will improve the effectiveness and efficiency of immunizations by preventing temperature damage to vaccines, reducing vaccine wastage, and decreasing logistical and equipment requirements as well as the costs of vaccine transportation and storage, especially at the periphery of the cold chain. Thermostable vaccines will also facilitate coverage gains by enabling vaccine delivery in remote areas beyond the reach of the existing cold chain. Additional benefits, such as improved vaccine safety and superior product formats, are also possible depending on the stabilization methods used.

Current status and results

PATH is researching several methods to improve the thermostability of vaccines of importance to developing countries such as vaccines for measles, hepatitis B, diphtheria-tetanus-pertussis (DTP), *Haemophilus influenzae* type B (Hib), *Shigella*, enterotoxigenic *Escherichia coli*, meningococcal, rotavirus and pandemic influenza. Research is being conducted in collaboration with vaccine producers, vaccine development projects, technology companies, laboratories, and universities. Achievements include:

- Development of a method to protect vaccines containing an aluminum adjuvant from freeze damage and advancing its application to pentavalent (DTP-hepatitis B-Hib) vaccine through formulation development, analytical method development, preclinical work, laboratory-scale production, and stability studies. PATH's vaccine freeze-protection technology is in the public domain so that vaccine manufacturers worldwide can use the approach.
- Identification of a technology to improve the heat stability of hepatitis B and Hib vaccines and demonstration of its compatibility with the above method to obtain a heat- and freeze-protected hepatitis B vaccine product.
- Marked improvements in the stability of hepatitis B and meningococcal A vaccines through reformulation involving glass-forming sugars plus other excipients and processing via spray drying.

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Thermostable vaccines improve vaccine effectiveness and ease logistics.

"...heat-stable vaccines and combination formulations can simplify and improve drug and vaccine delivery while expanding the reach of modern medicine to millions more who could benefit."

Daar AS, Thorsteinsdóttir H, Martin DK, et al. Top 10 biotechnologies for improving health in developing countries. *Nature Genetics*. 2002;32:37.

Availability

For more information regarding this project, please visit our web site at http://www.path.org/projects/vaccine-stabilization.php or contact Debra Kristensen at dkriste@path.org.

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