

Reconstitution Technologies

Health need

Many obstacles must be overcome before a vaccine or medication can be safely delivered to a child in a developing country. Delays in transit and temperature extremes can potentially spoil products en route. In addition, some vaccines and medications are dried (e.g., lyophilized) and must be reconstituted with a diluent before use, which can cause challenges. Besides adding extra preparation steps, diluents are often stored and transported outside of the cold chain, separately from the vaccine or medication with which they will be paired. A special reconstitution syringe is also required—adding cost, an extra item to transport and track, and medical waste. Even if everything arrives on time, together, and at the right temperature, there is plenty of room for error if a drug is used without the appropriate diluent or if the reconstitution process is not performed using sterile devices, which can lead to disease transmission. Mistakes can also result from multiple reconstitution steps, increasing supply wastage.

For the reconstitution of vaccines and medications to become safer and more economical, reconstitution processes must be simplified. Novel prefilled reconstitution technologies that keep a dried product and its diluent together offer many advantages over current systems, such as ensuring storage at the same temperature and a streamlined mixing process of the two parts. The selective and strategic introduction of vaccines and essential medicines using integrated reconstitution devices therefore represents a promising means of eliminating reconstitution errors, reducing supply wastage, improving ease of use, and decreasing the impact on medical waste disposal systems.

Technology solution

PATH has examined a variety of reconstitution technologies to see if they are suitable for use in developing countries. Five such technologies were evaluated by health workers in Andhra Pradesh, India. Results were favorable; the health workers felt that the devices better enabled them to deliver safer injections and caused less wastage. They also provided extensive input on device design and usability. Hilleman Laboratories has also developed an integrated reconstitution and administration device for oral delivery of their thermostable rotavirus vaccine, which is in development.

Current status and results

PATH continues to advocate for and support the development of low-cost, prefilled reconstitution technologies for use with dried vaccines and medications. Our goal is to enable the selective and strategic availability and introduction of dried vaccines and essential medicines in a low-cost, integrated format to reduce the mortality and morbidity rates from reconstitution-related adverse events. We are currently assessing how specific features of integrated reconstitution devices impact stakeholders all along the supply chain. As part of this effort, we are also facilitating interactions among users, device developers, vaccine manufacturers, and public health experts. At every point, we aim to ensure that the technology is safe, affordable, and sustainable.



PATH

A simpler process for the reconstitution of vaccines and medications.

“An easy-to-use integrated reconstitution technology may have the potential to significantly improve the safety of vaccine reconstitution and reduce the risk of contamination. The use of a dry formulation may offer the added benefit of increased vaccine thermostability.”

Birgitte Giersing, PhD, Initiative for Vaccine Research, World Health Organization

Availability

For more information regarding this project, contact Darin Zehrung at dzehrung@path.org.

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