MEDICAL DEVICES AND HEALTH TECHNOLOGIES

Accelerating access to intradermal vaccine delivery devices

Background

Some intradermal (ID) injection delivery devices can improve the reliability of achieving the correct injection depth, increase vaccinator safety, and reduce training requirements. Despite the potential benefits, adoption of ID delivery devices with features for enhanced usability remains limited in low- and middle-income countries (LMICs).

PATH's multidisciplinary vaccine and pharmaceutical delivery team identifies, advances, and assesses primary packaging and delivery devices that have the potential to maximize safety and efficacy, expand equitable access, and minimize costs for immunization and essential medicines. For more than 20 years, PATH has worked to evaluate and advance ID injection technology options for use in resource-limited communities, including device development, test method development, clinical trials, regulatory and quality considerations, value propositions, and costing analyses.

The opportunity for intradermal delivery

Inequities in vaccine coverage persist globally among high-risk, marginalized, and hard-to-reach populations. ID vaccination is one potential solution to overcome access barriers and increase vaccine equity. Since the dermal layer of the skin contains a high concentration of immune cells that help recognize and respond to vaccine antigens, delivering some vaccines into this layer via ID injection can enhance immunogenicity. As a result, ID vaccination can enable dose sparing (e.g., one-fifth of the standard intramuscular [IM] or subcutaneous [SC] dose), which could:

- Reduce vaccine antigen costs (e.g., US$3.00 IM/SC versus US$0.60 ID).
- Stretch vaccine supply.
- Increase access.

In LMICs, ID vaccines are typically administered using an autodisable needle and syringe. ID vaccination is approved on-label for BCG, rabies, and COVID-19 (not introduced) vaccines as well as recommended through off-label World Health Organization (WHO) policy statements for fractional-dose inactivated poliovirus vaccine (fIPV) and mpox vaccine. ID delivery has also been evaluated for other vaccines, including those against yellow fever, influenza, hepatitis B, and human papillomavirus, with mixed results. One barrier to on-label use is the lack of incentives for vaccine manufacturers to undertake the clinical studies and regulatory submissions required to relabel their products for ID administration.

Another challenge to the uptake of approved or WHO-recommended ID regimens is that ID vaccination using an ID needle and syringe requires training and consistent technique. As such, a wide variety of alternative ID devices have been developed that are intended to make ID injections easier to administer correctly with minimal training and be more acceptable to vaccine recipients. Potential benefits of novel devices include:

- Improved injection consistency and lowered risk of needlestick injuries.
- Reduced training requirements for health workers.
- Expanded access through non-routine delivery strategies.

Compared to using IM needle and syringe, novel easy-to-use ID injection technologies are expected to come at a price premium. However, due to dose sparing, the total cost per vaccination may be reduced compared to using IM needle and syringe, especially for more expensive vaccines. Price sensitivity among procurers and country decision-makers is a key consideration for novel ID device adoption.

Understanding the feasibility and value of ID devices—and whether novel ID devices offer advantages compared to existing alternatives—requires evaluation of cost, usability, acceptability, programmatic fit, regulatory requirements, and market considerations. This type of comparative evidence and implementation guidance can help country- and global-level decision-makers determine when and how ID delivery approaches should be advanced, approved, and introduced.

ID injection device options

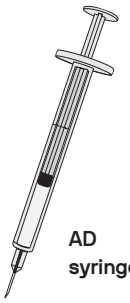
Technology overview

A range of technologies have been developed to facilitate ID vaccine delivery, each with different implications for usability, training requirements, regulatory pathways, and programmatic fit. ID injection devices can be prefilled or filled just prior to administration, which has implications for the clinical, regulatory, and policy requirements for regulatory approval and implementation. Four ID injection device subcategories are described below.

Fill-on-site devices

Autodisable ID needle and syringe

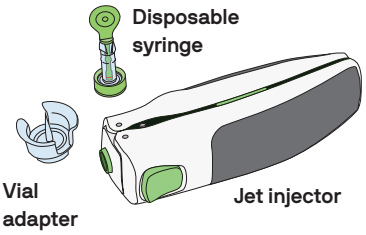
Traditional ID delivery uses an AD needle and syringe inserted at a shallow angle to deliver vaccine into the skin. This approach is already used for vaccines such as BCG, rabies, and fIPV in LMICs. AD syringes are widely available, are WHO prequalified, and have established regulatory pathways, but administration requires training and consistent technique.



AD syringe

Disposable-syringe jet injectors

Disposable-syringe jet injectors are needle-free devices that use a high-pressure liquid stream to deliver vaccine through the skin. These devices may improve injection consistency, reduce needlestick injuries, and simplify sharps waste management. One ID jet injector has regulatory approval and WHO prequalification and has been used for fIPV in LMICs.



Syringe-based hollow microneedle devices

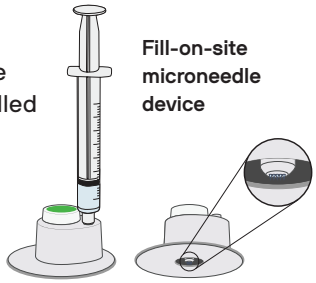
Syringe-based hollow microneedle devices use short needles designed to penetrate only the top layer of the skin. These devices attach to luer syringes and may allow administration using a technique more similar to IM injection, potentially reducing training complexity. Some platforms are in development, while others have received regulatory clearance in select markets.

Hollow microneedles on syringe

Fill-on-site or prefilled devices

Wearable hollow microneedle devices

Wearable hollow microneedle devices are adhesive-based platforms applied directly to the skin, which can be prefilled or filled just prior to administration. The hollow microneedles penetrate the top layer of the skin to deliver the vaccine, enabling simplified ID delivery. These technologies are still in development and may support easier administration in outreach or community settings.



Fill-on-site microneedle device

PATH's approach

With the aim of accelerating affordable access to crucial vaccines, PATH's multidisciplinary staff are evaluating the feasibility, value proposition, and regulatory pathway for advancing ID vaccine delivery devices in LMICs through support from The Rockefeller Foundation. Key focus areas are described below.

Assessing the value of ID delivery

PATH is evaluating how ID vaccine delivery compares with conventional IM delivery across a range of factors, including total cost of delivery, cold chain impact, and programmatic fit. These activities will consider the four device subcategories to help determine where ID injection devices may provide meaningful advantages and their role within the broader vaccine innovation landscape.

Stakeholder engagement with vaccine decision-makers, development partners, health workers, and technical experts in South Asia and globally will inform assumptions, identify implementation considerations, and ensure that analyses reflect real-world immunization program needs.

Advancing regulatory and policy pathways

PATH is synthesizing information on the clinical, regulatory, and policy requirements for introducing a vaccine administered with a novel ID delivery device (on label or via an off-label policy recommendation), focusing on the Indian market. The analysis will identify key evidence considerations for regulatory approval and policy adoption and explore opportunities to streamline pathways for future ID vaccines and delivery technologies. To understand the regulatory environment and evidentiary standards in India, PATH will host a product-agnostic expert group meeting.

Collaborate with us

PATH serves as a critical partner with end-to-end product development expertise to advance ID injection devices and fractional-dose strategies for LMICs to enable evidence-based decisions that maximize public health impact and value.

Interested in partnering with us or learning more about PATH? For general inquiries, connect with us at: innovation@path.org.

For ID device questions, please contact Collrane Frivold, PhD, MSPH at cfrivold@path.org.

PATH

PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges.

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