Microarray patches for delivery of vaccines and essential medicines

**Background**

Microarray patch technology has the potential to foster untold gains in access, efficacy, and adherence for vaccines and essential medicines. PATH is working to accelerate the development of this innovative delivery technology platform to address critical public health needs.

PATH is collaborating with microarray patch (MAP) developers, vaccine and drug manufacturers, and other global stakeholders to evaluate and advance a range of MAPs at varying stages of product development, with the aim of improving access and equity in the delivery of vaccines and essential medicines in resource-constrained settings.

**Health need**

**Vaccines**

Globally, the prevention of measles, rubella, typhoid fever, influenza, and COVID-19, among other infectious diseases, could be accelerated with vaccines that are easier to store, transport, and deliver. Additionally, vaccines that are thermostable, easy to use, and needle free, have the potential to improve programmatic suitability in resource-constrained settings. This is critical for easing logistical challenges and expanding vaccine coverage and public health impact in routine, campaign, and outreach immunization scenarios.

**Essential medicines**

A self-applied long-acting contraceptive product would provide additional choices to women seeking family planning. HIV infection can be prevented and treated with antiretroviral medications, but for infants and small children, adherence to daily oral doses can be challenging. Therefore, new drug presentations and safe delivery methods are needed to ensure access and use by all who need them.

**Technology solution**

MAPs, also known as microneedle patches, consist of microscopic projections that deliver vaccines or pharmaceuticals once applied to the skin. Contact with the skin’s moisture initiates the delivery process. As shown in Figure 1, some MAP designs have solid projections coated with a dry formulation of a vaccine or drug (a), while others have dissolvable projections formulated with the active ingredient itself (b). Still others have projections that serve as a conduit, transferring drug from a solid drug reservoir in the MAP through the skin (c). For each of the designs, applying pressure to the MAP enables the projections to penetrate the outermost layer of the skin with less pain than a traditional needle and syringe injection. Some platforms also require an applicator for delivery, which can be an integrated component or separate device.

**Advantages of MAP delivery**

Using MAP delivery offers the potential for:

- **Increased thermostability** for reducing cold chain.
- **Self-administration or easier delivery** by lesser-trained health care workers.
- **Reduced wastage** and missed opportunities for vaccination due to single-dose presentation.
- **Safety benefits** by eliminating the risks of needlestick injury or improper reconstitution typically associated with needle and syringe.

Several studies have shown that MAPs may also be formulated for long-acting, sustained delivery of some vaccines and medications such as contraceptives to...
reduce administration frequency. For vaccines, the technology platform can also access unique immune cells in the skin to induce a potent immune response (allowing for potential dose sparing and increased supply).

Approximately 100 research organizations and health technology companies are developing MAPs for various indications across the world. However, only a fraction of these products is focused on high-priority health areas specific to low- and middle-income country markets.

PATH and partners—through collaborative efforts to integrate key stakeholder feedback into product development and collect data needed for regulatory approvals and implementation—are committed to accelerating the development, introduction, and uptake of MAPs for disease areas that disproportionately burden people in these countries.

Current status and results
PATH’s multidisciplinary staff are focusing on key activities to help accelerate sustainable access to MAPs for priority health needs, including in the following areas.

Evaluations and clinical research
- Evaluating the cost of manufacturing and of delivering vaccines and essential medicines via MAP; conducting economic evaluations to determine the value and socioeconomic and public health impact compared with delivery via standard methods.
- Conducting human-centered design and human factors evaluations to assess the usability, acceptability, and programmatic fit of MAPs for vaccines and drugs for use in country health programs.
- Testing the thermostability of MAPs to understand potential storage requirements.
- Conducting clinical research to compare the safety, efficacy, and acceptability of MAP delivery with standard delivery methods.

Paving the way for introduction
- Identifying and facilitating product development pathways for MAPs—including the relevant clinical, regulatory, manufacturing, and program introduction activities.
- Engagement with country and regional stakeholders to understand decision-making considerations for vaccine introduction and presentation switches and assess willingness-to-pay for vaccine MAPs based on proposed product attributes.

Engagement opportunities
Through PATH’s Microarray Patch Center of Excellence, and membership in the Vaccine Innovation Prioritisation Strategy (VIPS) Alliance, we are working to increase equitable access to improved presentations of vaccines and pharmaceuticals in low- and middle-income countries through the MAP technology platform. To learn more, see the following resources.

• Newsletter: Subscribe to our newsletter to receive updates on PATH’s work and that of MAP researchers around the world.
• MAP resources page: For more information on PATH’s work on MAPs including resources published by the Center of Excellence, go to https://www.path.org/programs/mdht/mapresources/.
• VIPS site: For more information on the VIPS Alliance, the technologies evaluated, and the MAP Action Plan, go to https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy.
• Target product profiles: To review and provide input on MAP target product profiles, go to https://www.path.org/resources/microarray-patch-target-product-profiles-tpp/.

Addresses United Nations Sustainable Development Goal 3.B: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines.