

Frequently Asked Questions on Microarray Patches (MAPs)

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What is a microarray patch (MAP)?

A microarray patch (MAP), also known as a microneedle patch, is an array of tiny microneedles attached to a bandage-like backing to enable a bandage-like application on the skin. Drugs encapsulated within these microneedles dissolve into the skin when the patch is placed on the skin, allowing for a noninvasive mode of drug administration.¹



MAPs can be manufactured in different geometries. Given their small sizes, the maximum drug dose that MAPs can hold is 1 mg or less, making them ideal for treatments that do not require high doses, such as vaccines, contraceptives, and pediatric drugs, or drugs with very high potency.² While there are several MAPs for both treatment and prevention in the research and development pipeline, no MAPs have been approved for use to date.³

How are microarray patches administered?

MAPs are easy to administer and cause little to no pain. They are simply placed on the skin like a bandage. Once administered, the microneedles on the patch pierce the skin to allow for greater absorption of the drug into the body without penetrating deep enough to stimulate pain receptors.

Who can administer MAPs?

MAPs can be administered by oneself; almost all health care providers, including community health workers; and even school staff. However, depending on national drug administration policies, only certain health care providers may be allowed to administer them in certain countries.



Example of a MAP, with an attractive graphic for kids, administered on the skin

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Types of MAPs

Coated MAPs are one of the more popular choices for vaccine delivery and have been evaluated with multiple vaccine platforms. Coated MAPs consist of a liquid solution and coating methods that allow vaccines to be dry coated to the tips of the microneedles at ambient temperatures.⁴ Once the patch is applied to the skin, the vaccine is deposited and penetrates the skin.

FIGURE 1: COATED MAP



Image source: Jovin J. Y. Choo, Christopher L. D. McMillan, Paul R. Young & David A. Muller (2023) Microarray patches: scratching the surface of vaccine delivery, Expert Review of Vaccines, 22:1, 937-955, DOI: 10.1080/14760584.2023.2270598

Dissolvable MAPs, unlike coated MAPs, are designed to dissolve in the skin completely. To ensure this, dissolvable MAPs are made of natural, biocompatible materials, and the desired drugs or vaccines are integrated together with the micro-projections by casting them in a mold filled with a dissolvable solvent and allowed to solidify.⁵ The resulting needles must be biocompatible, biodegradable, and mechanically strong enough to withstand the penetration of the skin while maintaining the safety, potency, and efficacy of the drug or vaccine.⁶

FIGURE 2: DISSOLVABLE MAP



Image source: Jovin J. Y. Choo, Christopher L. D. McMillan, Paul R. Young & David A. Muller (2023) Microarray patches: scratching the surface of vaccine delivery, Expert Review of Vaccines, 22:1, 937-955, DOI: 10.1080/14760584.2023.2270598

Hydrogel-forming MAPs are manufactured with polymers crosslinked with gelatin that rapidly swell upon insertion into the skin, releasing the drug into the surrounding microenvironment.⁷ These MAPs use a reservoir to store the drug — enabling higher volumes of drug to be administered —and must be left in the skin to deliver a larger dosage of the drug over an extended period. Hydrogel-forming MAPs can be sterilized prior to application, and unlike the dissolvable microneedles, they do not remain in the skin and are easily removed with very minimal damage to the skin.⁸

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FIGURE 3: HYDROGEL-FORMING MAP



Image source: Jovin J. Y. Choo, Christopher L. D. McMillan, Paul R. Young & David A. Muller (2023) Microarray patches: scratching the surface of vaccine delivery, Expert Review of Vaccines, 22:1, 937-955, DOI: 10.1080/14760584.2023.2270598

Potential Benefits of MAPs

Being absorbed directly into the skin and the bloodstream, MAPs will bypass first pass hepatic metabolism,⁹ a process wherein drugs administered orally experience extensive biotransformation in the liver, which often reduces their bioavailability. MAPs provide an excellent alternative to injectable drugs because they are non-invasive. Depending on the drug properties, MAPs could also improve bioavailability and maintain relatively constant plasma concentrations for several days with a single administration.¹⁰

While most vaccine MAPs would still require cold chain — albeit at higher temperatures than currently available vaccines, for example, 2-8°C instead of -20°C - most other MAPs would not require cold chain and complex distribution systems because they are heat stable.¹¹ Thanks to this heat stable nature, MAPs have the potential to increase equitable access to health care as they can be stored in decentralized health facilities in rural and remote areas. This will curb and prevent stockouts and enable health programs to meet people where they are.¹² Their heat-stable nature also allows for rapid deployment during outbreaks, in wars zones, in humanitarian crisis regions, and in communities of refugees and displaced persons.13

Depending on the type of microneedle technology employed, MAPs could also address barriers relating to providing immunization, in the case of vaccine MAPs, and treatment in health settings only by allowing house-to-house delivery, self-administration, and delivery by postal mail.¹⁴ This will eliminate the need (and associated inconvenience and costs) to travel to these health facilities for subsequent doses and increase adherence.

Vaccine MAPs will address vaccine wastage where only a portion of vaccine doses in a vial are used before its expiration, usually within hours and situations where health care personnel turn down patients because there are too few patients to open a whole vaccine vial.¹⁵

As MAPs do not require needles for drug administration, no special disposal procedures would be necessary, averting risks of needle contamination. Needle phobia and needlestick injuries will also be averted, potentially increasing acceptability.¹⁶

Vaccine MAPs will reduce workload and free up health care providers, including by eliminating additional preparation steps, such as reconstitution of the lyophilized (freeze-dried) vaccine and vaccination; increase the number of people that could be vaccinated in a single session;¹⁷ and JUNE 2024

enable health care providers to focus on other tasks. In addition, the use of MAPs would result in the expansion of the pool of vaccine administrators over time to potentially include, for example, school staff.¹⁸

Given that lower-level health care providers are often present in health care facilities 24/7, MAPs for treatment and immunization could be administered anytime they are needed.¹⁹ This is a major win for immunization programs because it could potentially allow all newborn vaccines to be administered to all newborn babies any time before they leave health facilities.

Given their skin application, vaccine MAPs have the potential to enhance immune responses using a smaller vaccine dose²⁰ and elicit a more robust immunological response because the dendritic cells within the dermis captures bacteria, viruses, and other foreign invaders and teaches the immune system how to fight them off.²¹

While the above desired product characteristics are appealing, achieving all of these in a single MAP is technically not feasible with the MAPs on the research and development pipeline today; currently, each of them presents some, rather than all, of the above characteristics.

Potential Disadvantages of MAPs

As with the introduction and adoption of any novel technology, MAPs will not be accepted overnight. In parallel with MAPs research and development, there is the need to study community perceptions around their effectiveness to inform mass scale social mobilization and outreach and engage with communities, health providers, policymakers, and other stakeholders to provide basic information on the benefits of MAPs and address questions and concerns.²² The unit cost of manufacturing MAPs will be high. In the specific case of measles and rubella vaccine MAPs, it has been estimated that MAPs will cost more than the current needle and syringe vaccine.²³ However, this higher cost could potentially be offset by savings in reduced vaccine wastage, logistics, vaccine service delivery costs, and broader health and economic gains from improved and equitable immunization coverage and fast-tracking diseases elimination.²⁴

Scaling up the manufacturing capacity of MAPs involves substantial investments, including building an automated pilot line and developing good manufacturing practices, all of which require significant financial investments to build novel manufacturing equipment and production facilities.²⁵

In the case of vaccine MAPs, sterility requirements for regulatory approval may need to be clarified because end filtration used for most vaccines during fill and finish may not be possible.²⁶ Terminal sterilization of some MAPs also may not be possible because antigens may be sensitive to heat, radiation, and other methods of sterilization.²⁷ Hence the need for upfront investments to acquire aseptic/sterile input materials and control an aseptic process.²⁸ However, some MAPs to deliver drugs may be able to be terminally sterilized, reducing the complexity of the manufacturing process.

Given that a MAP constitutes a combination product — namely, the drug and the device — which would require adherence to design controls, national regulatory authorities might have different review approaches. In addition, Critical Quality Attributes for MAPs are unique, requiring novel testing methods and their justification to regulators.²⁹

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ENDNOTES

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