IMMUNISATION COALITION

9:00 am

Usability and acceptability of microarray patches for vaccination

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Acknowledgement of Country

We acknowledge the Traditional Custodians of the land on which we stand – the Turrbal peoples from the northside of the river and the Jagera peoples of the south side of the river. We pay our respects to Elders past, present and emerging.

Dance of the Dragonflies by Dharug artist Leanne Tobin.

Leanne's artwork reflects the vibrancy and traditional motions of the dragonflies as they move through their journey of life.

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Questionnaire

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Mentimeter

Learning Objectives

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- Describe microarray patches (MAPs) and understand their role in vaccine delivery.
- Understand the evidence to date about MAPs for use in vaccination.
- Identify factors that influence public and healthcare professionals' acceptance of MAPs.
- Explain the features of MAPs that enhance usability for healthcare professionals and the patient.
- Identify barriers and facilitators for MAP use in clinical settings compared with use at home.

Context and priorities

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.

Global

- The Vaccine Innovation Prioritization Strategy, a consortium including WHO, UNICEF, and Gavi, the Vaccine Alliance, recently ranked the development of Microarray Patches (MAPs) for vaccination as the highest global priority for achieving equity of vaccine coverage in low-income and middle-income countries.

Australia

Towards Australia's National Immunisation Strategy 2025-2030 Consultation Paper (Dept of Health and Aged Care)

- Technological advances may require significant adaptation in delivering immunisation programs and will always require deliberate efforts to *build trust in new technologies*. Communication with key stakeholders, including consumers, employers, community, and clinical groups, will continue to be essential to build confidence around new technologies.
- Opportunities for action: Preparing for assessment of emerging vaccine technologies and for the opportunities and challenges that adopting new technologies may present to existing immunisation programs and delivery.

[1]

Microarray patches for vaccination

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- Microarray Patches are a disruptive technology and innovation that can improve the accessibility and implementation of vaccination services globally.
- MAPs consist of ten to thousands of micro-projections applied to the skin by finger pressure or an applicator.
- MAPs penetrate the stratum corneum and deliver vaccine to the epidermal and upper dermal layer, rich in antigen-presenting cells.
- Dermal dendritic cells play a key role in intra-cutaneous vaccination due to their ability to activate an adaptive immune response, which is the role of adjuvants in commonly administered intramuscular (IM) vaccines (ie, hepatitis B, measles and polio).
- Several types of MAPs are currently in preclinical and clinical trials including biodegradable or **dissolvable**, **coated,** solid, hollow, hydrogel-forming, porous and hybrid.
- 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.

[2]

Background

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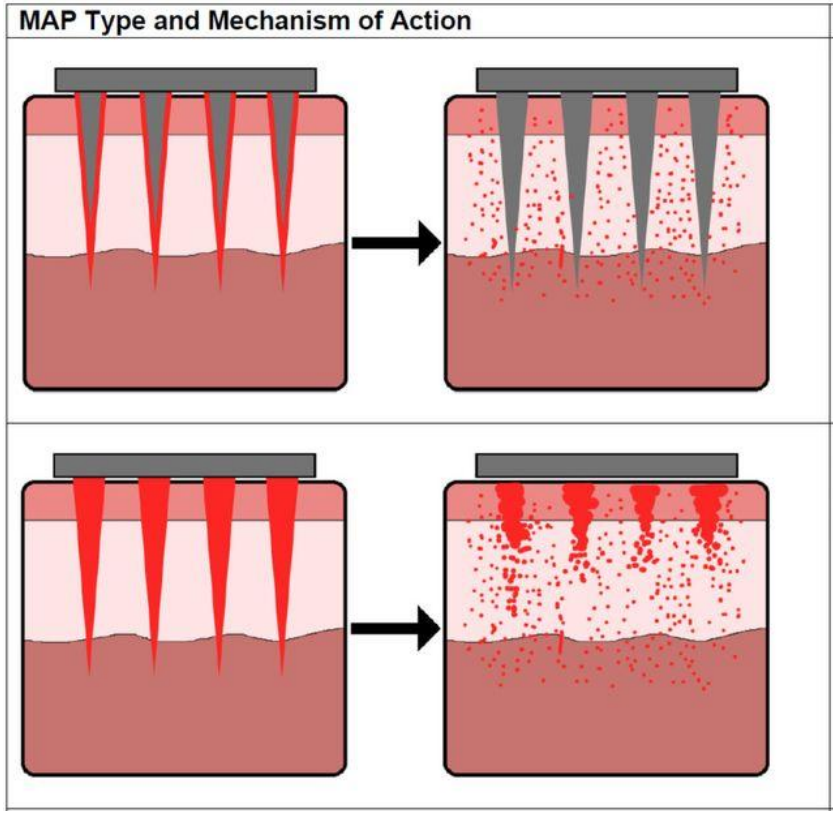
Types of patches (current human trials)

- **Solid-Coated**: typically contain various micro-projections made from biocompatible polymers or metals. These projections are coated with a layer of the antigen. The coating can be formulated to provide controlled release kinetics, ensuring the desired therapeutic effect over a specified duration

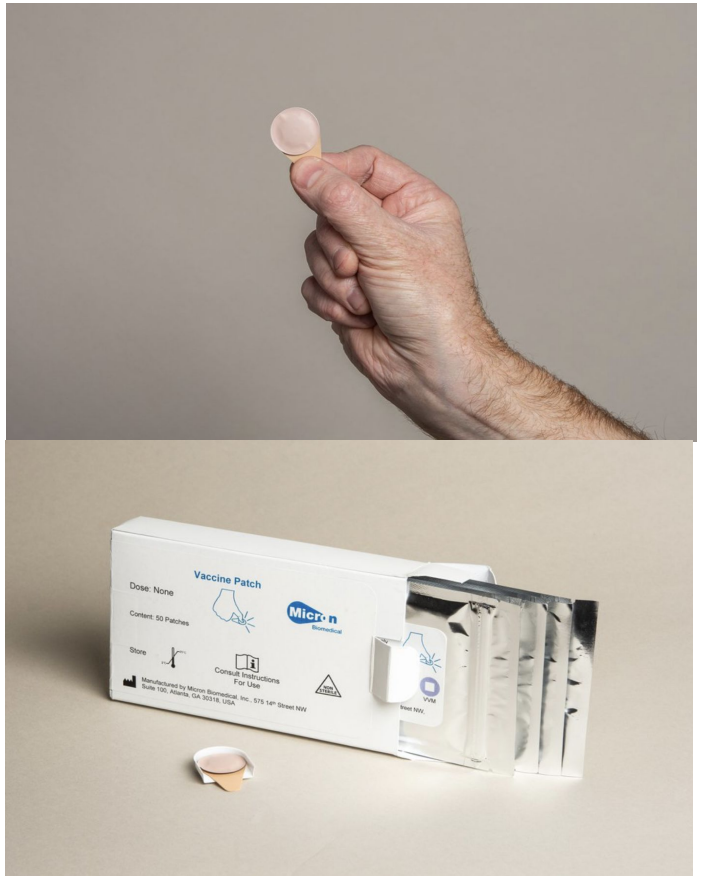
- **Dissolving**: typically feature microneedles or micro-projections fabricated from biocompatible and biodegradable polymers, such as hyaluronic acid, polylactic acid, poly(lactic-co-glycolic acid), or other natural polymers. These materials are formulated to degrade or dissolve upon contact with the skin, facilitating the release of the encapsulated drug or vaccine antigen payload.



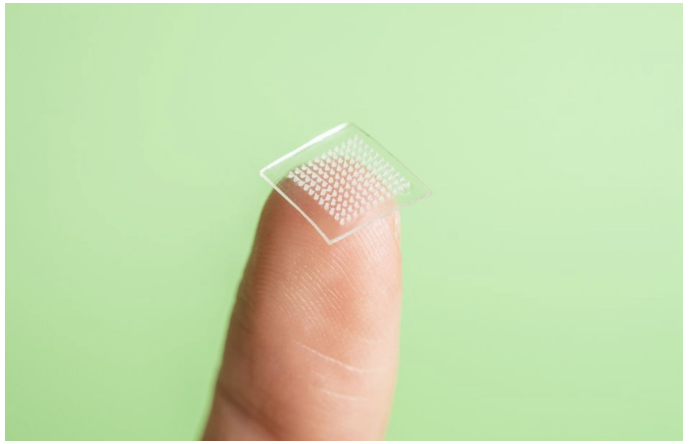
[2,3]

Examples of MAPs

Vaxxas Nanopatch prototype coated MAP. Photo: PATH/Patrick McKern.



Georgia Tech / Micron Biomedical prototype dissolving MAP. Photo: PATH/Patrick McKern.



Queen's University Belfast prototype sissolving MAP. Photo: PATH/Patrick McKern.

Administration of Microarray Patches

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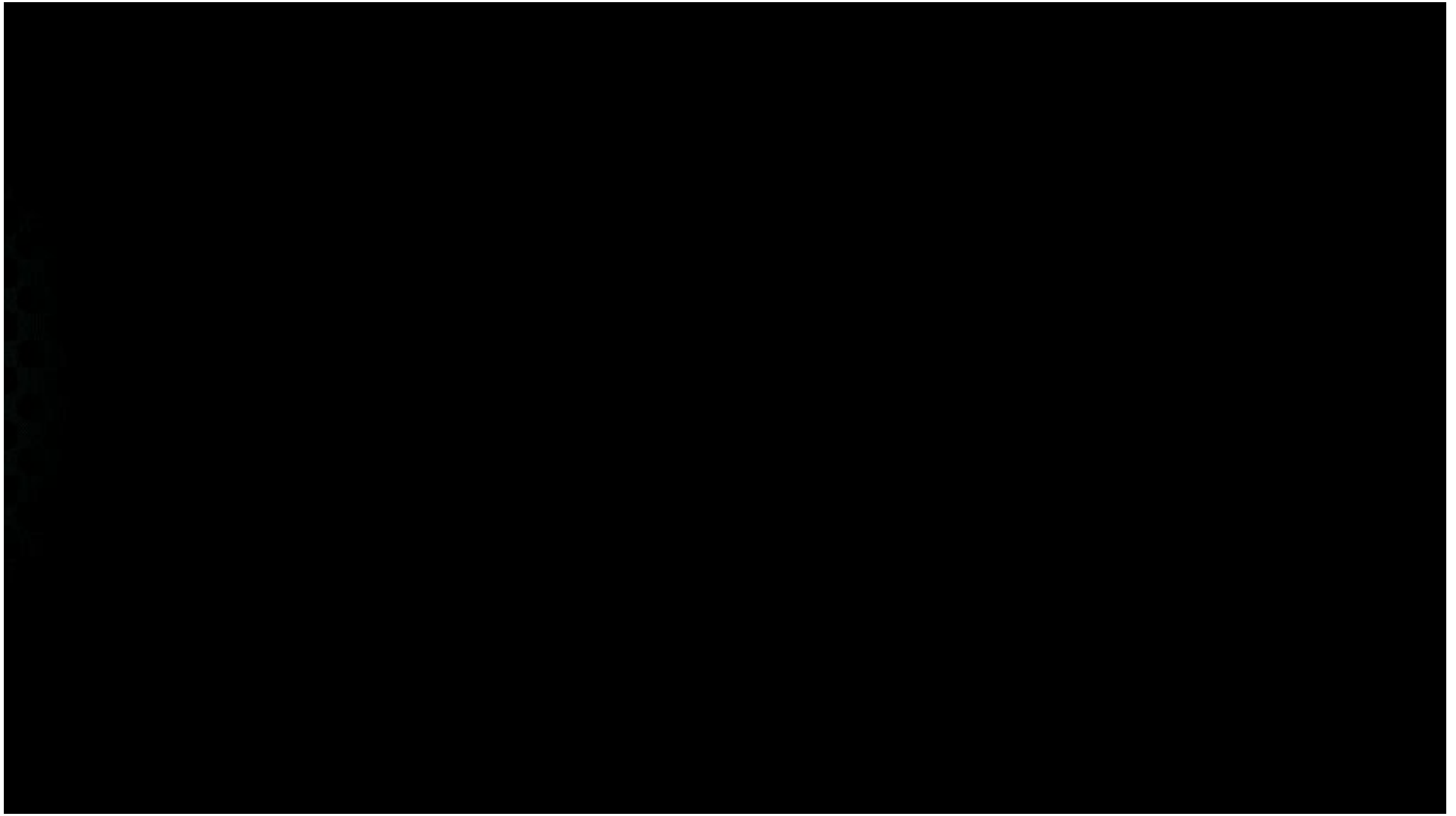

Evaluations and Clinical Research: Summary from PATH

- Evaluating the cost of manufacturing and delivering vaccines via MAP.
- Conducting economic evaluations with MAPs compared with delivery via standard methods.
- Conducting design and human factors evaluations to assess the usability, acceptability, and fit of MAPs for vaccine 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 pay for vaccine MAPs based on proposed product attributes.

Benefits and Limitations

Benefits	Limitations
- Reduced pain score - Ease of use - Equivalent or improved immune response - Reduced sharps risk (no needle) - Enhanced thermostability - Potential reduced healthcare associated cost (i.e., cold-chain management) - Reduced clinical waste - Potential for trained lay people to administer - Potential for self-administration - Mass administration	- Limited vaccine compatibility and antigen loading - Complex manufacturing - Localised skin reactions (e.g., erythema) - Cost of development - Technical limitations (new technology) - Regulatory approval (currently not approved for human use)

[2,5–7]

Definitions

- **Safety** is described as a product's ability to eliminate or reduce the risk of potential hazards for intended use or foreseeable misuse. This includes adverse events following immunisation (e.g., pain, erythema or fever).
- **Usability** refers to the extent that a product can be used to achieve its desired goal effectively, efficiently and satisfactorily by users.
- **Acceptability** is the extent to which an intervention is received by a population and meets a population's and organisational setting's needs.

[2]

Safety and Adverse Events

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Study Type	Systemic Adverse Events	Local Adverse Events
RCTs - Influenza (x4+) – Healthy adults - MR (x2) – Healthy adults, paediatric - JEV (x1) – Healthy adults	Less common - Fever - Headache Rare - Fatigue - Cough - Sore throat - Diarrhoea - Myalgia	Common - Mild induration - Erythema Less common - Discolouration - Exfoliation - Site pain - Pruritus - Pigmentation Rare - Papular rash
Observational (e.g., excipient-coated [placebo]) - Healthy adults	Rare - Diarrhoea - Vomiting - Nausea - Headache	Common - Erythema Less common - Tenderness - Purpura - Oedema - Petechiae

[2,8,9]

Immunogenicity

- Phase I/II trials using Influenza, measles and rubella (MR), and Japanese encephalitis (JE).
- Equivalent or stronger immunogenicity in MAPs compared to injection across all studies.
- Similar immune response pathways.
- Healthy adults (18-57) [influenza, JE and MR] and children (infants and toddlers) [MR] across all studies on immunogenicity.

https://www.freepik.com/free-vector/fight-virus-concept_7466183.htm#query=immune&position=3&from_view=keyword&track=sph&uuid=d306cc0a-731d-4775-8d1f-b17455baad5d

[2,8]

Immunogenicity (Example Key Studies)

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Antigen Type	GMT (95% Confidence Intervals)	Seroprotection (%)
Influenza (H1N1) (Day 28)	MAP - 1197 (95% CI, 855– 1675) IM - 997 (95% CI, 703–1415)	MAP - 31/48 (65%) (95%CI, 60–78%) IM - 8/25 (32%) (95%CI, 15–54%)
Measles (Day 42)	MAP - 2182·9 IU/mL (1905·6 to 2500·5) SC - 1811·5 IU/mL (1480·6 to 2216·4)	MAP - 59/59 (100%; 94·0 to 100·0) SC - 59/60 (98%; 91·1 to 99·7)
Rubella (Day 42)	MAP - 268·2 IU/mL (228·3–315·0) SC - 234·3 IU/mL (95% CI 199·6–274·9)	MAP - 59/59 (100%; 93·9 to 100) SC - 60/60 (100%; 94·0 to 100)
Japanese Encephalitis (Day 42)	MAP (High-Dose) - 2·55 (Standard Deviation [SD]: 0·36) MAP (Low-Dose) - 2·04 (SD: 0·53) SC - 2·08 (SD: 0·47)	MAP (High-Dose) - 13 (100%, 75·3 to 100) MAP (Low-Dose) - 13 (100%, 75·3 to 100) SC - 13 (100%, 75·3 to 100)

[8–11]

Acceptability

- Participants preferred MAP over needle and syringe in four studies.
- Many HCPs wanted MAPs in their clinical practice and expressed willingness to administer.*
- Many unvaccinated individuals would be willing to receive an influenza vaccine via MAP.
- MAPs considered more convenient than needle and syringe.
- Self-administration was more acceptable in clinical settings.
- Trained lay administration was viewed favourably, but HCPs were more cautious.
- Wear times of less than 30 seconds were acceptable.*
- Participants reported that MAPs would be useful in children and needle-phobic clients*
- Potential mass administration*

[12–16]

Acceptability

Settings

Clinical settings

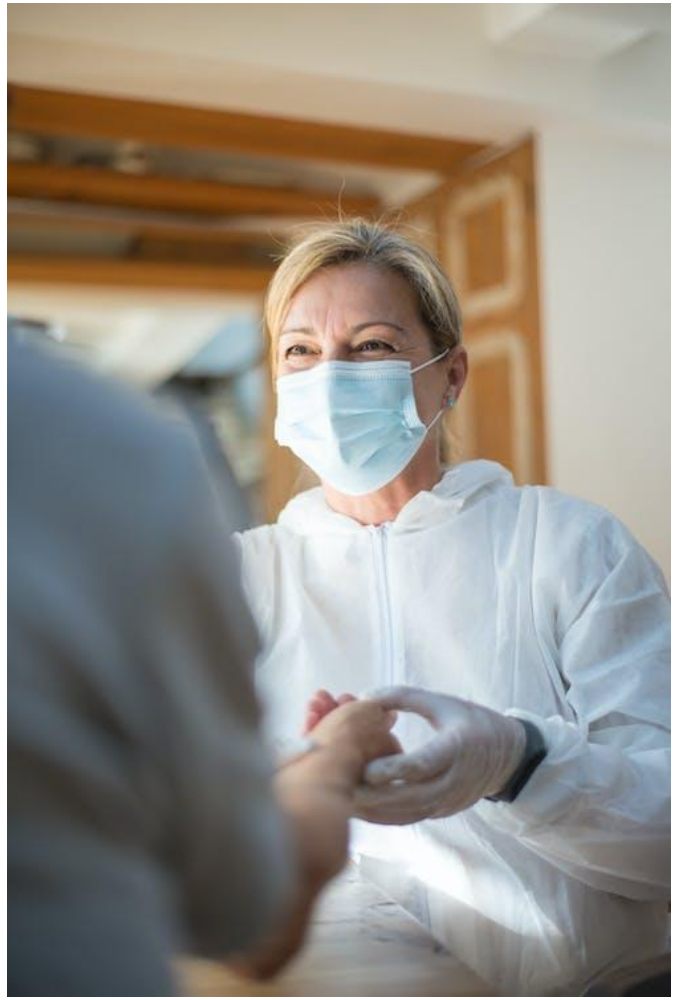
- Highly acceptable among General Public and HCPs*
- Healthcare professional administration highly acceptable
- Trained laypeople or Community Health Volunteers
- Mass administration
- Reduced clinical waste

At home (self-administration)

- Lack of access to medical support
- Documentation on AIR*
- Clinical waste*

Cost

- Cold-chain management
- Reimbursement / coverage
- Low-income earners



https://www.pexels.com/photo/woman-wearing-face-mask-and-gloves-8949835/

[5,16,17]

Usability and Performance

- Ease of use among general public and HCPs*
- IFU – illustrative pamphlet and video demonstration*
- Older adult – dexterity, capability following instructions
- Wear times from current trials range from 10 seconds to 8 hours
- Visual indicator was suggested by General Public* but considered unnecessary among HCPs
- Most felt it would be easy to administered to children, but some HCPs had mixed responses

[5,8,11]

Future Research / Direction

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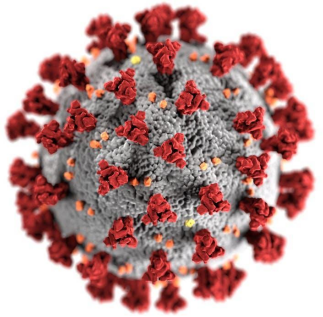
Additional Target Vaccines

- Rabies
- COVID-19
- HPV
- Hepatitis B (birth dose)



Other Priorities

- Long-Acting HIV Pre-Exposure Prophylaxis
- Contraception

[4]

Timeline to Regulatory Approval

- The Microneedle Array Patch (MAP) Regulatory Working Group (RWG) aims to inform, guide and define the regulatory science of the MAP dosage form.
- This group aims to expedite the clinical translation of the technology to benefit stakeholders, including product developers, regulatory authorities, public health bodies and end-users.

- The RWG has parallel work streams that aim to:
- (1) define the MAP dosage form (delivery platform);
- (2) identify and understand MAP critical quality attributes
- (3) develop standardised validated test methods to evaluate the quality of finished MAP products and/or the development of pre-clinical prototypes;
- (4) inform the microbiological requirements for MAP products.

[4]

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MAP studies from our team

MAP studies from our team

Usability, acceptability, and feasibility of a High-Density Microarray Patch (HD-MAP) applicator as a delivery method for vaccination in clinical settings

- **Background:** We aimed to ascertain whether professional immunizers (PIs) and other healthcare workers (HCWs) in Australia, a High-Income Country (HIC), found the HD-MAP applicator usable and acceptable for vaccine delivery.

- **Methods:** This feasibility study recruited PIs and HCWs to administer/receive simulated HD-MAP administration, including via self-administration. We assessed usability against essential and desirable criteria. Participants completed a survey, rating their agreement to statements about HD-MAP administration. A subset also participated in an interview or focus group. Survey data were analyzed using descriptive statistics, and interviews were transcribed and subject to thematic analysis.

- **Davies C**, Taba M, Deng L, Karatas C, Bag S, Ross C, Forster A, Booy R, Skinner SR. Usability, acceptability, and feasibility of a High-Density Microarray Patch (HD-MAP) applicator as a delivery method for vaccination in clinical settings. Hum Vaccin Immunother. 2022 Nov 30;18(4):2018863.

MAP studies from our team

- **Results:** We recruited 61 participants: 23 PIs and 38 HCWs. Findings indicated high usability and acceptability of HD-MAP use across both groups by a healthcare professional or trained user and for self-administration with safety measures in place. Most administrations met essential criteria, but PIs, on average, applied the HD-MAP for slightly less time than the required 10-seconds, which the HCWs achieved. PIs perceived safety concerns about home administration but found layperson self-administration acceptable in an emergency, pandemic, and rural or remote settings.

- **Conclusions:** Participants found HD-MAP administration usable and acceptable. Usability and acceptability are likely to be improved through end-user education and training.

- **Davies C**, Taba M, Deng L, Karatas C, Bag S, Ross C, Forster A, Booy R, Skinner SR. Usability, acceptability, and feasibility of a High-Density Microarray Patch (HD-MAP) applicator as a delivery method for vaccination in clinical settings. Hum Vaccin Immunother. 2022 Nov 30;18(4):2018863.

MAP studies from our team

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Perceived safety, usability, and acceptability of microarray patches for vaccination: a mixed methods study

Berger MN, Davies C, Harmer-Ross J, Mathieu E, Shaban RZ, Bag S, Skinner SR

- **Introduction:** Vaccination plays a crucial role in public and population health. Microarray patches (MAPs) could enhance vaccine uptake through reduced pain, no needles, improved thermostability, and self or lay administration. We aimed to investigate the perceptions of MAP vaccination among the general public and healthcare professionals (HCPs) aged 18 years and older.
- **Methods:** This was part of a project to validate a scale measuring MAP vaccination's safety, usability, and acceptability. Surveys and semi-structured interviews were conducted online in Australia, Canada, United Kingdom, and New Zealand. 7-point Likert scale items were dichotomised from “strongly disagree” to “strongly agree” and analysed using descriptive statistics (e.g., means and confidence intervals (CI)). Interviews were transcribed verbatim, coded, and analysed using thematic analysis.

MAP studies from our team

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Perceived safety, usability, and acceptability of microarray patches for vaccination: a mixed methods study

Berger MN, Davies C, Harmer-Ross J, Mathieu E, Shaban RZ, Bag S, Skinner SR

- **Results:** In the survey group, 403 general public and 184 HCPs responded. We interviewed 27 participants (12 general public and 15 HCPs). The general public and HCPs perceived MAPs as safe and efficacious, with means of 5.00 (95% CI: 4.85-5.14) and 4.92 (95% CI: 4.71-5.12) respectively. The general public (mean=5.58, 95% CI: 5.46-5.70) and HCPs (mean=5.75, 95% CI: 5.59-5.92) perceived MAPs as usable. Lastly, the general public (mean=5.49, 95% CI: 5.37-5.61) and HCPs (mean=5.30, 95% CI: 5.12-5.50) perceived MAPs as acceptable. Thematic analysis revealed that MAPs could be safe in clinics, including self-administration. HCPs were concerned regarding possible adverse events at home (i.e., anaphylaxis). HCPs demonstrated interest in incorporating MAPs in their clinical practice. Most participants felt that MAPs would be easy to use due to their “straightforward” instructions. All participants mentioned that MAPs would be advantageous for children and needle-phobic individuals.
- **Conclusion:** Overall, the general public and HCPs perceived MAPs as safe, user-friendly, and well-received. MAPs as alternatives to needle and syringe vaccination could gain considerable acceptance among key users. This could particularly improve reaching priority populations and areas with limited resources.

MAP studies from our team:

Vaccine microarray patch self-administration: A preliminary study in older adults

- **Introduction:** We assessed the safety, usability, acceptability, and performance of the High-Density Microarray Patch (HD-MAP) in older adults.

- **Methods:** This study was a single-centre, open-label, single-arm intervention in healthy older adults aged 50+. HD-MAPs were applied by a trained user and self-administered. Application sites were compared for skin response, usability, and acceptability. Participants received one excipient-coated HD-MAP to the volar forearm (FA) and the upper arm (UA) administered by a trained user. Participants then self-administered an HD-MAP to the FA and UA. Each administration was video recorded. Participants completed an online questionnaire and semi-structured interviews. Analyses were undertaken using descriptive statistics. Interviews were coded in NVivo 12 and subject to thematic analysis. The study occurred from 8 September 2021 to 15 February 2022 in Brisbane, Australia.

MAP studies from our team

- **Results:** Of 44 participants, 43% (n = 19) were male, and 57% (n = 25) female. The HD-MAP was well-tolerated, with no serious adverse events. The increase in transepidermal water loss following participant self-administration was similar to that observed for trained user administration. Fluorescent dermatoscopy confirmed that HD-MAPs engaged with the skin surface and that self and trained user administrations were similar. Most participants found the HD-MAP applicator easy to use. Most participants preferred vaccination by HD-MAP should its efficacy be proven equivalent to intramuscular injection (IM). Participants reported high levels of acceptance of the resulting marks on the skin. For most participants, self-administration of the HD-MAP at home, without supervision, was highly preferable for its convenience and ease of use.

- **Conclusion:** In this study, HD-MAPs were safe in older adults, and the performance was effective, regardless of administrator. Older adults preferred the HD-MAP for its ease of use and convenience of self-administration. This vaccine delivery method shows promise for future implementation for this population.

MAP studies from our team

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Usability testing of the high-density microarray patch for vaccination of adults

Primary objectives: to evaluate the usability and acceptability of the HD-MAP applicator, including its Instructions for Use, and document the frequency of use errors and deviations when participants use the device without assistance.

- Study participants from metropolitan and regional will be recruited:

1) immunisation nurses, GPs, pharmacists, and
2) self-administering lay people without vaccination experience.

- An observer will video record participants using the device and process the footage post-acquisition, using an observation checklist to record the incidence of any use errors.
- Data will be further collected via an interview and a demographic instrument.
- Participant hand strength will also be assessed.

Conclusion

Potential benefits of MAPs

- MAPs have been immunogenic, well tolerated, easy to use, and acceptable
- Reduced burden on healthcare professionals and resources (lay / self-administration and time-saving)
- Convenience and mass administration (role in possible pandemics / endemics)
- Reduced pain and enhanced thermostability

Challenges of MAPs

- Safety of unsupervised self-administration
- Accuracy of documenting (if administered at home without provider)
- Confidence in new technology
- Unclear timeframe to regulatory approval

[2,4-7]

Questionnaire

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Mentimeter

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