MAP Implementation Readiness Framework (MIRF)

Version 1.1

A LunaVax Framework for Assessing Readiness for Vaccine Microarray Patch (MAP) Introduction and Scale-Up

Samuel D. Okafor, PharmD
Founder & CEO, LunaVax

October 2026

LunaVax Discussion Brief No. 1

PROJECT FOUNDATION

The Vaccine Microarray Patch (MAP) Implementation Readiness Framework (MIRF) was developed to assess readiness for future MAP introduction and scale-up within immunization systems. It draws on three established implementation science frameworks: the Consolidated Framework for Implementation Research (CFIR),[1] which informed its readiness constructs; Proctor's Implementation Outcomes Framework,[2] which informed constructs such as acceptability and feasibility; and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework,[3] which informed the link between readiness and real-world implementation.

MIRF is intended as an initial discussion and planning framework. Its first planned application is in LunaVax's proposed Phase III effectiveness-implementation study of a needle-free measles-rubella microarray patch in Nigeria, subject to partnerships, approvals and funding. The proposed study would explore how baseline MIRF scores relate to implementation outcomes. Findings would inform refinements to domain scoring, readiness thresholds and future versions of the framework.

OVERVIEW

MAPs have emerged as a promising innovation that could simplify vaccine delivery, reduce cold-chain dependence and expand access in underserved communities.[4] Growing evidence supports their safety, immunogenicity and technical feasibility,[5,6] yet less attention has been given to the factors that influence successful introduction and scale-up within real-world immunization programs.

This discussion brief introduces the LunaVax MIRF, a tool informed by implementation science to support planning, pilot design, research, stakeholder engagement and policy discussions on MAP introduction. Early assessment can help identify opportunities, challenges and evidence gaps before broader implementation begins.

MIRF assesses five readiness domains:

- Acceptability
- Usability
- Operational Feasibility
- Workforce Readiness
- Institutional Readiness

Each domain is scored from 0 to 20 and combined into a 0–100 MIRF Readiness Index to guide planning across diverse immunization settings, with any domain scoring 0–7 flagged as a priority gap.

WHY READINESS MATTERS

Health innovations with strong clinical evidence have often faced challenges during real-world implementation.[7] In this brief, implementation readiness refers to the extent to which individuals, organizations, systems and implementation environments are prepared to support the adoption and integration of a new intervention. This builds on established readiness concepts in implementation science, including organizational readiness for change[8] and readiness for implementation within CFIR.[1] Readiness is often a critical determinant of whether a promising technology can be integrated, sustained and scaled within immunization programs.

Key readiness considerations include:

- Community acceptance and trust
- Ease of use for frontline health workers
- Workflow and system integration
- Workforce preparedness and training
- Documentation and accountability systems
- Operational and financial sustainability

For MAPs, these factors are likely to be central to successful introduction through routine immunization services, outreach and campaigns. Adoption may require changes to workflows, training, documentation and community engagement. Assessing these considerations early can help identify barriers and inform implementation planning.

INTENDED USERS

MIRF is intended for organizations involved in MAP introduction and scale-up, from product development to service delivery:

- Government and Public Health Agencies: Assessing preparedness for MAP introduction and scale-up within national and subnational immunization programs.
- Health Facilities and Service Delivery Teams: Understanding the workforce, training and operational requirements of MAP adoption.
- Researchers and Academic Institutions: Designing implementation studies, readiness assessments and human-factors evaluations.
- Global Health Organizations and Implementation Partners: Supporting program planning, community engagement, capacity building and field deployment.
- Vaccine Developers and Manufacturers: Identifying usability and implementation considerations during product development.
- Funders and Investors: Understanding implementation risks and scalability.

By providing a shared structure for assessing readiness, MIRF can help these stakeholders align efforts and set priorities before MAP introduction.

MR-MAP PRODUCT LANDSCAPE

MAPs consist of hundreds to thousands of microscopic projections coated with, or composed of, a dry vaccine formulation. When applied to the skin, the projections penetrate only the superficial skin layers and release the vaccine, after which the patch is removed. MAPs do not require reconstitution or syringes, may reduce cold-chain requirements and are generally perceived as less painful than injections.[4,9,10]

Two measles-rubella MAP (MR-MAP) candidates are among the most advanced vaccine MAPs in clinical development (Table 1).[5,6,11]

Table 1. Leading MR-MAP Candidates

	Micron Biomedical	Vaxxas
MAP Type	Dissolving patch with vaccine-containing projections	Solid patch with vaccine-coated projections
Application	Applied manually with thumb pressure; built-in indicator confirms adequate force	Applied using a single-use spring-loaded applicator
Wear Time	Approximately 5 minutes	Approximately 10 seconds
Application Site	Wrist	Deltoid or thigh
Clinical Status*	Phase 1/2 completed in The Gambia in adults, toddlers and 9-month-old infants	Phase 1 completed in Australia in previously immunized adults
Key Finding	Safe and well tolerated; immune responses comparable to subcutaneous injection in vaccine-naïve infants; strong caregiver preference for MAP	Safe and well tolerated, with immune responses comparable to subcutaneous injection

* As reported in published sources at the time of writing.[5,6,12,13]

Differences in application method, wear time and application site have direct implications for usability, health worker training and workflow integration. As more MAP products advance, readiness assessments will need to account for product-specific characteristics. MIRF is designed to support this across diverse MAP technologies and implementation contexts.

MIRF DOMAIN DEFINITIONS

Domain definitions are specific to MIRF. Acceptability and Operational Feasibility are adapted from Proctor's implementation outcomes.[2] Usability follows ISO 9241-11.[14] Workforce Readiness and Institutional Readiness build on organizational readiness theory[8] and CFIR.[1] Usability concerns the patch and its application; Workforce Readiness concerns staff and facility preparedness.

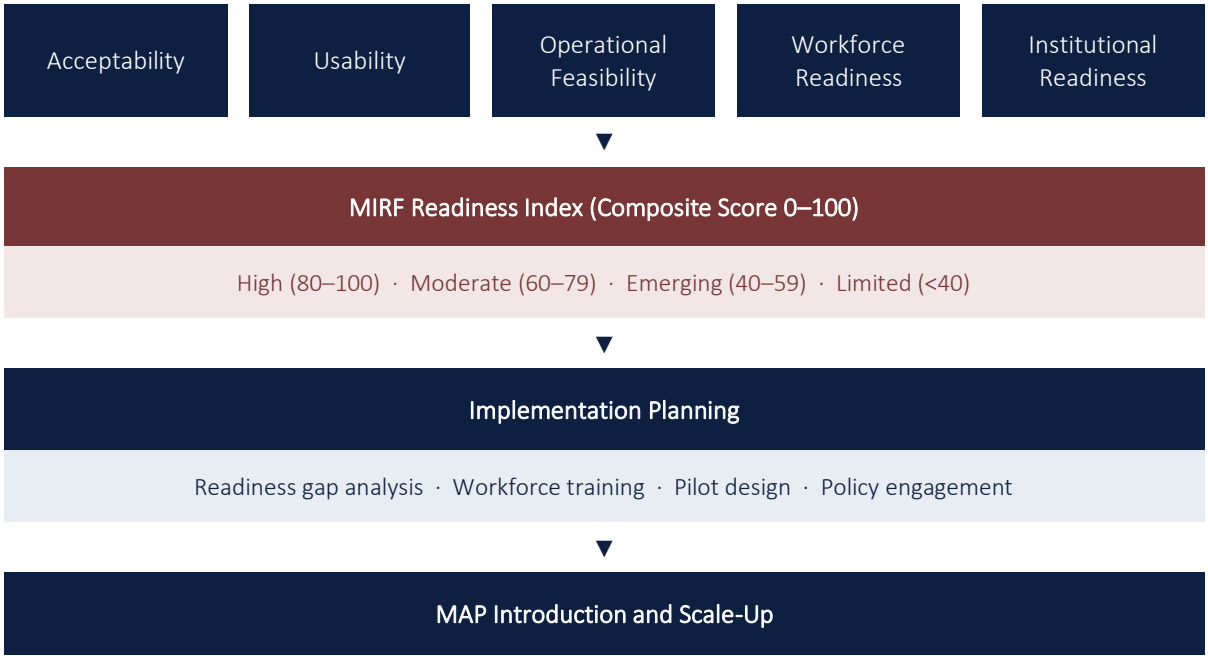
Table 2. MIRF Domain Definitions

Domain	Key Respondents	Definition	Considerations	Example Data Sources
Acceptability	Caregivers, communities, HCWs and CHWs	The degree to which intended users perceive or anticipate MAP vaccination to be agreeable, desirable and satisfactory	Trust in MAP technology; preference relative to injections; willingness to recommend MAP vaccination	Caregiver and community perception surveys, vaccine confidence indicators, health worker interviews
Usability	HCWs and CHWs	The extent to which intended users can correctly perform MAP administration with effectiveness, efficiency and satisfaction in their context of use	Ease of learning; intuitiveness of application; error prevention and correct application; suitability across health worker roles	Observed competency checklist and time to correct application during a standardized demonstration patch session; SUS[15]
Operational Feasibility	Facility leads, HCWs, CHWs and program managers	The extent to which MAP delivery can be successfully carried out within existing immunization systems	Fit with clinic and outreach workflows; resource and cost requirements; logistics and supply-chain readiness; digital infrastructure, where applicable	Facility capability assessment, workflow mapping, storage and supply-chain review
Workforce Readiness	Facility leads, HCWs, CHWs and program managers	The preparedness of the workforce and implementing facility to adopt, support and sustain MAP implementation	Leadership engagement; staffing capacity; training and supervision structures; implementation climate; perceived workload impact	Staffing and workload review, training and supervision records, structured interviews with facility leads
Institutional Readiness	Ministries of Health, implementing partners and program managers	The degree to which broader systems, stakeholders and institutions are prepared to support MAP deployment	Stakeholder engagement; policy alignment; documentation and information systems; implementation planning and governance	Policy and document review, stakeholder interviews, review of reporting and information systems

HCW: health care worker; CHW: community health worker; SUS: System Usability Scale.

Example data sources are illustrative and may be adapted locally. Baseline indicators are converted to domain scores using the MIRF User Guide (available on request during validation). When predicting implementation outcomes, define and measure readiness and outcomes separately to avoid circularity.

Figure 1. MIRF Overview



MIRF combines five readiness domains, assessed before implementation, into a composite readiness index to inform planning for MAP introduction and scale-up.

MIRF READINESS INDEX

The MIRF Readiness Index provides a structured approach for summarizing implementation readiness across the five framework domains. Each domain is scored from 0 to 20, yielding a composite score from 0 to 100. Higher scores indicate greater implementation readiness.

Scoring Methodology. Domain scores are based on predefined indicators drawn from structured interviews, surveys, observations and record reviews. Multiple sources of evidence may contribute to a single domain score, combined using the respondent selection, indicator definitions, conversion rules and weighting procedures in the MIRF User Guide. Standardized instruments such as the SUS are scored according to their published guidance before conversion to MIRF domain scores.

Categories apply equally to domain and total scores:

Table 3. Provisional MIRF Readiness Categories

Domain Score	Total Score	Category	Interpretation
16–20	80–100	High	Nearly all indicators met; few or no significant gaps
12–15	60–79	Moderate	Most indicators met; some gaps to address
8–11	40–59	Emerging	Some indicators met; important gaps to address
0–7	Below 40	Limited	Few indicators met; substantial preparation required

Any domain scoring 0–7 is flagged as a priority gap, regardless of the total score. Results should report all five domain scores alongside the total, as a strong total can mask a weak domain. Category ranges and equal domain weighting will be refined as field evidence accumulates.

Worked Example: Usability Domain. Each domain comprises five indicators, each scored from 0 to 4 (0 = not met; 1 = minimally met; 2 = partially met; 3 = largely met; 4 = fully met), giving a domain score from 0 to 20. This example uses a simulated-use demonstration with a non-antigen training patch.

Table 4. Illustrative Usability Domain Scoring

Indicator	Data Source	Score (0–4)
Correct application on first attempt	Observed competency checklist	3
Time to correct application	Timed demonstration session	4
No critical administration errors	Observed competency checklist	2
Perceived usability	SUS, converted to 0–4	3
Successful application by HCWs and CHWs	Observed competency checklist	3
Usability Domain Score		15/20 (Moderate)

MIRF Readiness Scorecard

Site or setting: _____ Date of assessment: _____

Assessed by: _____

Domain	Score (0—20)	Category	Priority Gap (0—7)	Notes
Acceptability			☐	
Usability			☐	
Operational Feasibility			☐	
Workforce Readiness			☐	
Institutional Readiness			☐	
Total MIRF Score	___ / 100			

MIRF Readiness Summary

Overall Readiness Category (select one)

☐ High ☐ Moderate ☐ Emerging ☐ Limited

Key Strengths: _____

Priority Gaps: _____

Recommended Next Steps: _____

MIRF IN PRACTICE: FIRST APPLICATION

The planned Phase III study, to be conducted by LunaVax Institute Nigeria subject to partnerships, approvals and funding, will apply MIRF across Lagos, Adamawa and Anambra states and the Federal Capital Territory, with assessment procedures tested in the preparatory pilot before baseline assessment at all sites. The study MR-MAP will be confirmed through partnership with a developer, and MIRF procedures will be adapted to its characteristics.

Site selection. Under the proposed study design, sites would be selected using safety, regulatory and Good Clinical Practice (GCP) criteria defined in the study protocol, not MIRF scores. MIRF will be assessed at baseline at all sites, so it can be evaluated against implementation outcomes without influencing site eligibility.

Assessing usability before introduction. Because MIRF is designed for use before MAP introduction, usability will be assessed through a standardized demonstration session using a non-antigen training patch that matches the study product's design. This mirrors simulated-use approaches in MR-MAP human-factors research.[11] The study will also explore whether simulated-use scores predict usability and administration fidelity during real-world delivery.

Assessment and scoring. To support consistency across sites, MIRF assessments in the study are planned to be conducted by trained assessors independent of site staff, with completed assessments reviewed centrally before scores are finalized.

Addressing gaps before activation. Sites with priority gaps may receive targeted support, such as additional training or workflow adjustments, before activation. Baseline scores will be retained for analysis, and any remediation, including its timing and intensity, will be documented and considered when evaluating MIRF's predictive performance.

Beyond the study. Ministries of health, implementing partners and other stakeholders can apply MIRF across states, districts or facilities to identify strengths, gaps and priority investments before MAP introduction. Low scores indicate where support is needed, not settings to exclude.

PRIORITY RESEARCH QUESTIONS

Informed by 2026 Child Health and Nutrition Research Initiative (CHNRI) priorities for MR-MAP implementation research,[16] key questions include:

- How do caregivers and communities perceive MAP vaccination compared with injections?
- How do health workers rate MAP usability, and how often do administration errors occur in routine use?
- How does MAP delivery fit within existing clinic, outreach and campaign workflows?
- What training and supervision approaches best prepare different types of health workers, including community health workers?
- How should policies, documentation and information systems be adapted to support MAP introduction?
- Does baseline readiness, as measured by MIRF, predict implementation outcomes across sites and settings?

Together, these questions reflect MIRF's five readiness domains and its validation. Answering them will generate the evidence countries need to move MAPs from promise to practice.

IMPLEMENTATION CONSIDERATIONS

Before applying MIRF, organizations should consider the following contextual factors:

- Country-specific immunization policies and regulatory requirements
- Workforce structure and training models
- Cultural perceptions of vaccination and local language needs
- Urban, rural and hard-to-reach settings
- Resource availability and health system capacity

Data collection may be adapted locally, for example by translating tools, but domains and scoring should follow the MIRF User Guide, so results remain comparable.

FUTURE DIRECTIONS

MIRF is an initial contribution to MAP implementation science. Future work will focus on validating and refining the framework, including:

- Examining whether baseline scores predict outcomes, and which domains matter most
- Evaluating whether targeted remediation after baseline improves implementation outcomes
- Comparing simulated-use usability with real-world usability and administration fidelity
- Establishing content validity and scoring reliability, including agreement between assessors
- Refining domain scoring and category ranges based on field evidence
- Extending MIRF to campaign, outbreak response and community-based delivery
- Considering nutritional status, co-infections and other factors affecting vaccine response[11]

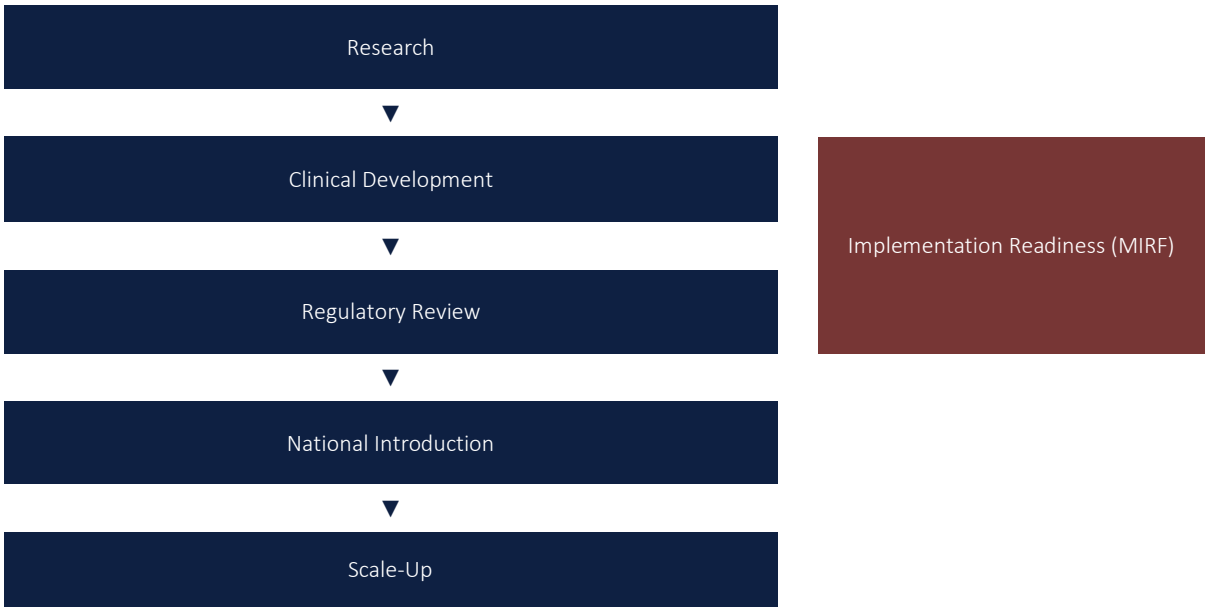
As evidence on MAP self-administration grows, MIRF may be expanded to assess readiness for caregiver-administered delivery, which could reduce reliance on trained health workers in remote and underserved settings. LunaVax welcomes collaboration with MAP developers, implementers and researchers applying MIRF, and their experience will inform future versions.

ALIGNMENT WITH GLOBAL MR-MAP PRIORITIES

MIRF responds to evidence needs identified by WHO's Product Development for Vaccines Advisory Committee (PDVAC). Its June 2023 meeting called for WHO Evidence Considerations for Vaccine Policy (ECVP) and implementation studies on health worker and caregiver experience, training and community health worker delivery. It also advised introducing MR-MAPs in clinics before campaigns, consistent with MIRF's initial focus.[11] An update to PDVAC in December 2023 emphasized that pre-implementation and operational research should inform Phase III design.[17]

The CHNRI exercise found that LMIC government respondents prioritized workforce and operational questions, such as vaccine administration and delivering MAPs alongside injections, reinforcing the need for health-system readiness, which MIRF assesses. With MR-MAPs anticipated by 2030,[16] early readiness assessment could help countries identify gaps and prepare for introduction.

Figure 2. MIRF within the MAP Development Pathway



Readiness assessment can begin alongside clinical development and regulatory review, so countries are ready for introduction once MAPs are approved.

CONCLUSION

Successful MAP introduction will depend not only on product performance but also on the readiness of communities, health workers, delivery systems and institutions. MIRF assesses this readiness across five domains, and its first application in LunaVax's planned Phase III study is intended to generate evidence on how readiness relates to implementation outcomes. As MR-MAP candidates advance, early investment in readiness could help countries prepare for timely, equitable and sustainable introduction.

Disclaimer

This framework is presented as a discussion and planning tool. It should not be interpreted as an official policy instrument, regulatory standard or implementation guideline. Validation is planned through LunaVax's pilot and Phase III study activities. References to WHO and other organizations do not imply their endorsement of MIRF. The views and conclusions presented are those of the author and do not necessarily reflect the views of Harvard Medical School, the Global Clinical Scholars Research Training Program or any affiliated institution.

Funding & Competing Interests

This work received no external funding. The author is Founder & CEO of LunaVax and Founder & Director of LunaVax Institute Nigeria, which will conduct the study in which MIRF is first applied.

Acknowledgment

The author acknowledges the Harvard Medical School Global Clinical Scholars Research Training (GCSRT) Program, Team 15 colleagues, faculty and program participants, whose discussions, feedback and diverse clinical perspectives helped inform the broader concepts reflected in this framework. MIRF was developed by Samuel D. Okafor, PharmD, Founder & CEO of LunaVax, independently of Harvard Medical School and the GCSRT Program, with input from the contributors and advisors listed below.

The author also thanks Sofiyat Bello and Daniel Adediran for their valuable feedback, and is grateful to Julie Lauffenburger, PharmD, PhD, for methodological input through the Harvard Catalyst Dissemination and Implementation Science consultation service.

Contributors & Advisors

Timothy La Pine, MD
Senior Scientific Advisor, LunaVax
Neonatologist, Immunologist, Adjunct Professor of Pediatrics and Pathology, University of Utah; District Director, Rotary International Health & Service Committee

Olawale Salami, MD, DTMH, MBA
Clinical Trials & Regulatory Strategy Advisor, LunaVax
Head, Clinical Trials Unit, University of Global Health Equity (UGHE), Rwanda

Suggested Citation

Okafor SD. MAP Implementation Readiness Framework (MIRF): A LunaVax Framework for Assessing Readiness for Vaccine Microarray Patch (MAP) Introduction and Scale-Up. LunaVax Discussion Brief No. 1, Version 1.1. October 2026. Available at: https://lunavax.com/mirf

Version History

Version 1.1 (October 2026) is the first public release, following internal review of Version 1.0 (July 2026).

Copyright & Contact

© 2026 LunaVax. Licensed under CC BY-NC-ND 4.0. This publication may be shared for educational, academic, research and non-commercial purposes with appropriate attribution, but may not be modified or adapted.

Author: samuel.okafor@lunavax.com
Partnerships, developer collaboration and MIRF User Guide requests: partnerships@lunavax.com

REFERENCES

1. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
2. Proctor EK, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65–76.
3. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322–1327.
4. World Health Organization, United Nations Children's Fund. Measles-rubella microarray patch (MR-MAP) target product profile. Geneva: WHO; 2020. Available at: https://iris.who.int/handle/10665/330394.
5. Adigweme I, Yisa M, Ooko M, et al. A measles and rubella vaccine microneedle patch in The Gambia: a phase 1/2, double-blind, double-dummy, randomised, active-controlled, age de-escalation trial. Lancet. 2024;403:1879–1892.
6. Baker B, Bermingham IM, Leelasena I, et al. Safety, tolerability, and immunogenicity of measles and rubella vaccine delivered with a high-density microarray patch: results from a randomized, partially double-blinded, placebo-controlled phase I clinical trial. Vaccines. 2023;11(11):1725.
7. Giersing BK, Kahn AL, Jarrahian C, et al. Challenges of vaccine presentation and delivery: how can we design vaccines to have optimal programmatic impact? Vaccine. 2017;35:6793–6797.
8. Weiner BJ. A theory of organizational readiness for change. Implement Sci. 2009;4:67.
9. Prausnitz MR. Engineering microneedle patches for vaccination and drug delivery to skin. Annu Rev Chem Biomol Eng. 2017;8:177–200.
10. Rouphael NG, Paine M, Mosley R, et al. The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial. Lancet. 2017;390(10095):649–658.
11. World Health Organization. Meeting report: WHO Product Development for Vaccines Advisory Committee meeting on measles-rubella microarray patches (MR-MAPs), 21 June 2023. Geneva: WHO; 2023. Available at: https://cdn.who.int/media/docs/default-source/immunization/pdvac/pdvac-2023/final_mr_map_pdvac_meeting_report_june2023.pdf.
12. McAllister DV, Henry S, Prausnitz MR. Simplified drug and vaccine delivery using Micron's microneedle patch. ONdrugDelivery. 2018. Available at: https://ondrugdelivery.com/simplified-drug-vaccine-delivery-using-microns-microneedle-patch/.
13. Davies C, Taba M, Deng L, et al. Usability, acceptability, and feasibility of a high-density microarray patch applicator as a delivery method for vaccination in clinical settings. Hum Vaccin Immunother. 2022;18(4):2018863.
14. International Organization for Standardization. ISO 9241-11:2018. Ergonomics of human-system interaction — Part 11: Usability: definitions and concepts. Geneva: ISO; 2018.
15. Brooke J. SUS: a "quick and dirty" usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland IL, eds. Usability Evaluation in Industry. London: Taylor & Francis; 1996:189–194.
16. Sá Silva S, Ko M, Cherian T, et al. Priority implementation research for measles-rubella microarray patches identified using the Child Health and Nutrition Research Initiative methodology. J Glob Health. 2026;16:04141.
17. Zehrung D, Jarrahian C. Update on measles-rubella microarray patches (MR-MAPs). Presented at: WHO Product Development for Vaccines Advisory Committee meeting; 13 December 2023. Available at: https://cdn.who.int/media/docs/default-source/immunization/pdvac/pdvac-2023/6_update_on_mr-map_zehrung_and_jarrahian_131223.pdf.