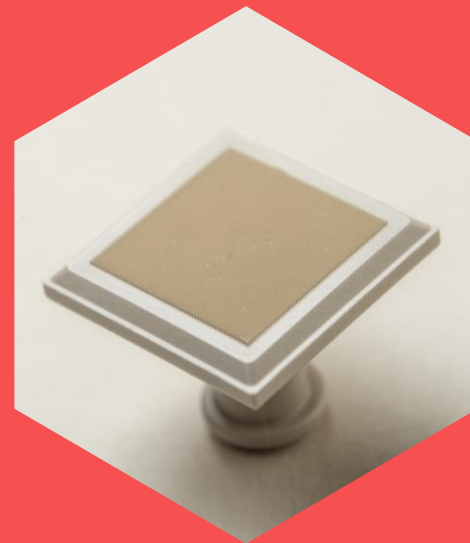


December 2022

Assessment of the acceptability and programmatic suitability of an HPV vaccine microarray patch in Ethiopia

REPORT



Abbreviations

CHWs	community health workers
EPI	Expanded Programme on Immunization
HCPs	health care providers
HPV	human papillomavirus
IM	intramuscular
MAP	microarray patch



Photo: PATH/Therese Blom Mason

Background and methods

PATH Center of Excellence for MAPs

- PATH Center of Excellence for Microarray Patch (MAP) Technology has been mobilizing efforts to accelerate the development of MAPs for critical vaccines and essential medicines and ensure that the MAP delivery technology platform can maximize its impact by meeting global public health needs.
- Its Scientific Advisory Group identified the HPV vaccine as a high-potential MAP application.
- Assessing health program and user needs of these applications in resource-constrained settings is one of the priority activities of the Center of Excellence.



Input from global stakeholders (1/3)

Human papillomavirus (HPV) vaccine programs in low- and middle-income countries face financial, programmatic, and social barriers to the introduction and sustainability of these programs. A MAP could offer potential advantages to address some of those barriers.



Photo: PATH/Patrick McKern

Source: PATH. Understanding user and program needs for the MAP technology. Seattle, WA: PATH; 2021.

5 https://media.path.org/documents/Understanding_User_and_Program_Needs_for_the_MAP_Technology.pdf.

Input from global stakeholders (2/3)

In 2020, we conducted interviews with global stakeholders who identified several ways an HPV MAP could address some of the programmatic barriers and improve the logistics for HPV campaigns:

- **Improve access and ease of use:** An HPV MAP that is easy to use and requires limited training could potentially remove the need for trained health care workers and reduce logistical and opportunity costs related to sending trained providers to schools. The pool of vaccine administrators could be expanded to include community health workers, pharmacists, school nurses, and school staff.
- **Heat stability:** The ability to store vaccines at a school for up to a week at ambient temperatures would improve the logistics for school-based immunization programs and could decrease the need for cold chain space at the point of administration.
- **Acceptability:** HPV is noted to cause injection site pain, which impacts acceptability and adherence to the second dose. A delivery method that causes less pain may improve uptake and community acceptance.

Input from global stakeholders (3/3)

Understanding the social and cultural context is also important to consider when exploring the MAP platform.

Stakeholders highlighted existing challenges: misinformation, rumors, vaccine hesitancy, community and social mobilization, and sustainable funding for community awareness and education activities. These issues have the potential to be exacerbated if a new technology is used.

Critical assumptions/unknowns: cost (vaccine and delivery) and cost-effectiveness, impact on cold chain, and regulatory pathway.



Photo: PATH/Rocky Prajapati



Photo: Suyash Dwivedi

OBJECTIVE

To assess the acceptability and
programmatic suitability of an HPV
vaccine MAP in Ethiopia

HPV vaccine program in Ethiopia

- HPV vaccine was piloted in Ethiopia in 2016 for 2 years, then introduced nationwide in December 2018.
- Current strategy: Gardasil (4-valent) 2 doses (6-month interval) in 14-year-old girls.
- Single cohort is due to vaccine shortage, with potential plans to expand when availability is not an issue.
- Delivery strategy: national campaigns approximately twice a year (particularly in January), mainly school-based, with community and health-facility component as needed.
- Schools are the major service delivery modality for HPV campaigns. School staff provide support in estimating targets, planning, advocacy, assent, and social mobilization activities with their respective schools.
- If girls are missed at 14 years of age, there is no catch-up strategy.

HPV vaccine campaigns and coverage

Month-Year	Cohort	HPV dose coverage
Dec-2018	1 st	HPV-1: 96%
Jun-2019	1 st	HPV-2: 94%
Oct-2019	2 nd	HPV-1: 97%
Jan-2021	3 rd	HPV-1: 92%
	2 nd	HPV-2: 82%
Jan-2022	4 th	HPV-1: 105%*
	3 rd	HPV-2: 83.4%

*In some rural districts, there's a local decision to vaccinate beyond the target group, which can result in coverage rates higher than 100%

Methods



- Stakeholder interviews following a semi-structured interview guide and accessing prototype samples.
- Data collection was conducted in June 2022, with a total of 19 participants.

Stakeholder type	n
National Expanded Programme on Immunization (EPI) managers	2
Low-coverage district	
District EPI manager	1
Facility-based health care providers (HCPs)	3
Community health workers (CHWs)	3
Teachers	3
High-coverage district	
District EPI manager	1
Facility-based HCPs	2
CHWs	2
Teachers	2
Total	19

Topics covered

- Successful HPV vaccination strategies
- Barriers to HPV vaccination
- Overview of MAP platform
- Perceived advantages and disadvantages of an HPV vaccine MAP
- Acceptability of an HPV vaccine MAP

Results

Results: Current program considerations

Most recent HPV vaccine district coverage rates, January 2022

Setting	HPV-1	HPV-2
High-coverage district	91%	86%
Low-coverage district	74%	47%

Theme



Insight





Potential upcoming changes to strategy

- Continue with 4-valent vaccine (no plan to switch to 9-valent).
- If global supply increases, cohort will expand to 9-14 year old girls.
- One-dose intramuscular (IM) schedule will be considered when the Strategic Advisory Group of Experts on Immunization/World Health Organization revises its position paper on HPV vaccination, beyond current endorsement.
- Technical Working Group would not approve a 2-valent vaccine (4-valent at minimum).



Results: Current program considerations

Theme	Insight
 Successful approaches	<ul style="list-style-type: none">• Integration with education sector through school-based vaccination campaigns plus outreach to out-of-school girls.• High enrollment in school.
 Main barriers to high coverage	<ul style="list-style-type: none">• Lack of operational funds (i.e., incentives for vaccinators, transportation and per diem costs).• Fear of injection pain and fainting.• Misconceptions/mistrust exacerbated by COVID-19 vaccine rumors.• Local unrest in some parts of the country.• Two-dose schedule.• Lack of awareness at community level.



Results: Current program considerations

Theme	Insight
 Main reason for dropout of second dose	<ul style="list-style-type: none">• School system related: transfer from primary to secondary school after first dose, poor tracing.• Dropout from school (relocation, marriage).• Refusal due to pain or local reaction after experience of first dose.• Hesitancy surging with COVID-19 vaccine (new negative beliefs and misconception that HPV vaccine was a second COVID-19 vaccine).
 Impact of COVID-19 pandemic	<ul style="list-style-type: none">• Interruption of 2020 HPV campaign.• Increased costs to run campaigns (personal protective equipment, sanitizer).• Fear of COVID-19 transmission.• Permanent dropout from school.• Increased rumors that led to mistrust and hesitancy for HPV vaccine.






Results: Current program considerations

Theme	Insight
 Community opinion of HPV vaccine	<ul style="list-style-type: none">• Some parents and girls readily accept the vaccine to get cervical cancer protection, but others have fears and misconceptions that include:<ul style="list-style-type: none">– Vaccine is a family planning drug that will harm female reproductive organs and lead to infertility.– It doesn't really protect against cancer.– It's toxic.– It's not needed until they initiate sexual activity.
 Stakeholder personal opinion of HPV vaccine	<ul style="list-style-type: none">• They all have a positive attitude toward the vaccine and acknowledge that it helps prevent cervical cancer and its associated sickness and death.

Results: Current program considerations

Theme	Insight
 Ways to improve coverage in low-coverage districts	<ul style="list-style-type: none">• Strengthen demand-generation activities, intersectoral collaboration, and incentives for outreach vaccinators.
 Low-coverage vs high-coverage districts	<ul style="list-style-type: none">• Factors associated with low coverage and missed second dose were described similarly in both settings.

Results: Perceived HPV MAP advantages

Attribute	Addresses main barriers?
 Usability <ul style="list-style-type: none"> Ease of use is highly appreciated as it would allow application by non-technical teams (CHW, school staff, etc.). 	Yes (<i>funding for outreach vaccinators; girls out of school</i>).
 Acceptability <ul style="list-style-type: none"> Decreased pain associated with application is highly appreciated as it would decrease fear of injection/syncope and increase acceptability. 	Yes (<i>fear of injection pain</i>).
 Thermostability <ul style="list-style-type: none"> Controlled temperature chain is not used in Ethiopia, but the option would be an appreciated MAP feature to use in hard-to-reach communities and to offer in temporary settings (markets). It would be useful if the MAP was stable for 7 days, like the length of a campaign (with a range suggested by stakeholders from 3 to 20 days). 	Yes (<i>funding for outreach vaccinators; girls out of school</i>).
 Injection safety <ul style="list-style-type: none"> Sharps safety would be an appreciated feature as it would reduce the likelihood of contamination and of needle stick injuries. 	No, but would ease logistics.
 Shelf life <ul style="list-style-type: none"> Increased shelf life would be an appreciated feature as it could help with shortage of vaccines. It would be useful if shelf life was 3 years (with range suggested by stakeholders from 1 to 5 years). 	No.

Results: Perceived HPV MAP disadvantages



Wear time

- Most stakeholders considered that a wear time of some minutes would be acceptable and that it would not lead to new barriers, but a few thought that such time would need to be supervised and could become a barrier.
- Maximum wear time should be one minute (with some stakeholders suggesting between 5 to 30 minutes as well).



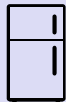
Schedule

- While some stakeholders thought a schedule requiring more doses than the current IM schedule would be acceptable given MAP advantages, many thought more doses would increase dropout rate and lead to supply shortage.
- Preference would be for one dose.



Temporary skin changes

- The majority of stakeholders thought this potential side effect would be acceptable when providing adequate information to recipients.
- A couple of stakeholders were concerned it could become a barrier, associated with misconceptions and causing anxiety.



Cold chain volume

- Some stakeholders said it would be acceptable if volume of MAP was a bit larger than current vial because of the advantages MAP offers, but several others said it would increase barriers by requiring additional storage capacity. Current volume for 4-valent vaccine in Ethiopia is 15 cm³/dose (10 single-dose vials per box).

Results:

Value of HPV MAP and expected acceptability (1)

“I think parents and adolescents will accept and prefer the MAP after briefing them on the benefits of this new technology compared to IM injection for HPV vaccine.”

– Community health worker, low-coverage district, Ethiopia



Results: Value of HPV MAP and expected acceptability (2)

- **National level:** Stakeholders didn't think that the MAP would increase coverage given current IM success, and that more evidence would be needed. They envisioned that the current HCPs and maybe the CHWs would be trained to use the MAP. They were concerned about acceptability by the community and rumors that could hinder implementation.
- **District level:** In stark contrast to national level, district program managers and facility-based health workers thought that MAPs would increase coverage and minimize hesitancy, seeing great value in a MAP presentation. They envisioned that in addition to current use (HCPs in schools and fixed posts), the MAP would allow integration of more temporary locations (cinemas, mosques, markets, youth friendly services, etc.) by other non-technical users. They would feel comfortable applying the MAP, and expected acceptability by other potential users, caregivers, and adolescents.
- **Community level:** CHWs and teachers would feel comfortable applying the MAP and expected it to be acceptable to other potential users, caregivers, and adolescents.

Results: Expected HPV MAP concerns and other recommendations from community level

- CHWs and teachers thought that the new technology could give rise to misconceptions such as being a microchip or a family planning method to control population growth.
- They emphasized the importance of social mobilization activities to inform caregivers and adolescents in order to avert mistrust from a new technology.
- They recommended to create a single-dose presentation to minimize dropouts.

Limitations

This is a qualitative study that gathered the opinions of relevant stakeholders at national, district, and community levels, but it cannot be deemed to be representative of the context for all of Ethiopia.

There was no discussion of cost of an HPV MAP in comparison to IM administration during this assessment, but cost is known to be a key factor in decision-making processes of ministries of health and funders.

Stakeholders were able to handle real prototypes that were inside a small transparent plastic bag, but it wasn't possible during this assessment to give them an opportunity to do a mock application, which could have led to different perspectives.

Conclusions

Conclusions (1)

- Overall, the results from this assessment suggest that **an HPV MAP would be an acceptable and programmatically suitable option** for the current HPV vaccination program in Ethiopia.
- **This assessment identified similar input from Ethiopia stakeholders** as was expressed by the global stakeholders, both in terms of programmatic advantages and concerns.
- In spite of its relatively high national coverage for first dose with IM administration, **there is need to increase coverage in certain low-coverage districts** and for dropout of second dose. The latter could be less relevant if a one-dose policy is implemented in the near future in Ethiopia.

Conclusions (2)

- Per some of the main barriers to high coverage identified by stakeholders:
 - The **ease of use of an HPV MAP could reduce programmatic operational costs** (transport, per diem) needed to mobilize facility-based HCPs to schools if school-based staff could administer a thermostable HPV MAP.
 - Additionally, **an HPV MAP could increase access for those adolescents that drop out from school** if CHWs and other non-technical staff could apply it, which was highlighted as a reason for dropout of the second dose, in particular.
 - Moreover, **the less painful administration of an HPV MAP could reduce adolescents' fear of injection pain** that was also identified as a main barrier for high coverage.

Conclusions (3)

- As with any new vaccine or delivery mode, **the introduction of an HPV MAP would need to be accompanied by appropriate social mobilization** to avoid mistrust and misconceptions around the new technology.
- The potential **cost and cost-effectiveness** of an HPV MAP should also be explored to inform country decision-making.
- **Desired attributes of an HPV MAP in terms of wear time, schedule, thermostability, shelf life, and cold chain volume were described by stakeholders**, in order to make the technology more suitable programmatically.

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