

VIPS Phase II executive summary: Barcodes on primary containers

March 2020

Barcodes on primary containers

About Barcodes

- Barcodes are symbols that **encode information** such as **product numbers, serial numbers, supplier data, batch numbers and expiry dates** which can be scanned electronically using two dimensional (2D) scanners, laser or mobile device cameras to automatically capture information.
- Barcodes **enable tracking and monitoring of vaccine products** in supply chains, providing information to manufacturers, transport providers, health facilities and other relevant parties involved in the logistics management systems, assuming the supporting infrastructure is in place.
- 2D barcodes can hold a significant amount of information and there is a possibility to **automatically import vaccination data into patient electronic medical records (EMRs)**.

Stage of development

- 2D Barcodes are **commercially available and are widely used on products globally across various industries including for products used in healthcare**. Many US and European vaccine suppliers provide 2D barcodes on primary containers, though not for the Gavi/UNICEF markets.
- **WHO currently recommends GS1 compliant barcodes for secondary and tertiary packaging** of vaccines containing the Global Trade Item Number (GTIN), vaccine expiry date and vaccine batch/lot number. **Gavi and UNICEF** recently announced that GS1 barcoding on vaccine **secondary packaging** will be a **requirement by 31 December 2021 to improve visibility and traceability of vaccines from manufacturer to beneficiary**.



Newswire.ca^a

2D barcode on primary container



PATH

Barcode on secondary packaging

^a <https://www.newswire.ca/news-releases/sanofi-pasteur-moves-national-immunisation-strategy-forward-with-new-bar-code-technology-509575151.html>

Barcodes have been prioritised for further analysis in VIPS Phase II over radio-frequency identification (RFID) tags for vaccine primary containers



Background

- At the June 2019 Steering Committee (SC) meeting, the SC suggested to **bundle barcodes and RFIDs together** as relatively similar innovations that could contribute to improving patient immunisation record-keeping, coverage, and safety monitoring once available on primary containers.
- During the VIPS Phase II evaluation, a decision was made to **prioritise barcodes** for vaccine primary containers over RFID tags following **desk research, expert interviews, and feedback and discussion with industry members** through the WHO/PATH Delivery Technologies Working Group.

Rationale for prioritisation of barcodes over RFID tags

- **RFID tags are substantially more costly** (Euro 0.10 to 0.20 per tag) and **more difficult to add to vaccine primary containers** and the data captured is also less accurate than 2D barcode labels.
- The **equipment to read RFID tags is more complex and expensive** and better suited to scanning higher levels of packaging (e.g., vaccine boxes on a pallet), while **barcodes are more appropriate for scanning individual vaccine primary containers** as would be done at health facility levels for patient record keeping.
- Vaccine manufacturers are **already adding barcodes at higher levels of packaging**, UNICEF and Gavi are mandating the use of barcodes on secondary packaging, and countries are using them for inventory, so **implementation of barcodes versus RFID tags on primary containers is expected to be more technically and economically feasible** and aligns with ongoing efforts.

Potential public health impact of innovation



**Applicability
to vaccines**

- Barcodes are **applicable to all vaccines**.



**Public health
benefits**

- Barcodes on primary vaccine containers **facilitate the ability of electronic health information systems to capture and utilise vaccine data at health facilities** providing vaccinations thereby helping to:
 - **Improve immunisation coverage** through more accurate patient recordkeeping.
 - **Improve acceptability to patients/caregivers** by improving correct administration, patient health records, and access to vaccines.
 - **Reduce vaccine stockouts** by facilitating tracking and tracing of vaccine products – though this benefit is mostly addressed through barcodes on secondary or higher levels of packaging.
 - **Improve safety** by reducing errors, helping to ensure the correct vaccine components are together, and facilitating AEFI tracking and product recalls.



**Vaccine problem
statements**

- Barcodes **address immunisation systems problems** rather than vaccine-specific problems.

Barriers to realise the innovation's potential impact



Costs

- Barcodes on primary packaging are expected to have a **minor impact on vaccine pricing** but will require **substantial investment by countries** to fully use them as part of electronic recordkeeping in health facilities.



Technology Readiness

- 2D barcodes are **ready for adoption** on the labels of vaccine primary containers. The **technology is well-established** and available on many products, though **mostly in HIC markets**.
- To implement, **WHO/UNICEF need to develop label standards and requirements** and **vaccine suppliers to UNICEF need to redesign labels** to accommodate barcodes, **potentially upgrade label printing equipment**, and seek **regulatory/WHO approvals** for label changes.



Commercial feasibility

- **Commercial feasibility is high** as many **manufacturers already supply barcodes on vaccine primary containers for non LMIC markets**, and **countries value and are implementing electronic recordkeeping for inventory and patient records**.
- It will take a **few years** though for manufacturers to update labels and **many years** for countries to build capacity to use this innovation on primary containers in health facilities.



5 Countries interest

- While **barcodes ranked 7th overall** (last) out of the 9 innovations in the VIPS country consultations, **decision-makers ranked them in 6th place**.



Barcodes on primary containers have applicability to all vaccines

Vaccines technically compatible with barcodes and analysed in Phase II

VIPS Phase II analysed vaccines	
Licensed vaccines	Penta (or DTP containing)
	Hepatitis B (birth dose)
	HPV
	MR (or MCV)
	N. Men A (or N. Men A,C,W,Y,X)
	Polio, IPV
	Rabies
	Rota (Oral)
	Typhoid, conjugate (TCV)
	Yellow fever (YF)
Pipeline vaccines	Ebola (rVSV-ZEBOV) ¹
	ETEC (ETVAX)
	HIV (ALVAC-HIV + bivalent Subtype C gp120) ⁸
	Influenza (pandemic, VAL-506440)
	Malaria (RTS,S)
	MTb (next gen BCG., VPM1002)
RSV (Pre-F)	

Barcodes are technically compatible with all vaccines including the 17 vaccines in scope of Phase II.

Comparator: No barcode on primary containers.

¹ At the time of the assessment, Ebola vaccine was not licensed and has been analysed as a pipeline vaccine.
² HIV vaccine consists of two different components: a virus vector for priming doses and a subunit protein plus adjuvant. The prime and boost were therefore assessed separately.

Overview of barcodes on primary containers public health benefits based on Phase II analysis

VIPS Criteria	Indicators	All Vaccines	
Primary criteria	Health impact	Vaccine efficacy	Neutral
		Vaccine effectiveness	Neutral
		Ability of the vaccine presentation to withstand heat exposure	Neutral
		Ability of the vaccine presentation to withstand freeze exposure	Neutral
	Coverage & Equity impact	Number of fully or partially immunised (relative to target population)	Better
		Ease of use: clinical perspective based on product attributes	Neutral
		Ease of use: ability of a lesser trainer personnel to admin. / self-admin.	Neutral
		Ability to facilitate dose sparing	Neutral
		Avoid missed opportunities and reduce vaccine wastage ¹	Neutral
		Acceptability of the vaccine presentation and schedule ²	Better
	Safety	Potential to reduce stock outs ³	Better
		Number of vaccine product-related AEFIs	Neutral
		Likelihood of contamination and reconstitution errors	Better
	Impact	Likelihood of needle stick injury	Neutral
		Economic costs	Commodity costs of the vaccine regimen ⁴
	Delivery costs of the vaccine regimen ⁴		Better
Introduction & recurrent costs of the vaccine regimen ⁴	Worse		
Environmental impact	Waste disposal of the vaccine regimen ⁴ and delivery system	Neutral	

Based on the assessment using VIPS primary indicators applied to vaccines, when barcodes on primary containers are used with electronic health information systems, they can contribute to **addressing the following immunisation challenges:**

- **Reduction in errors in recordkeeping** by using electronic capturing methods compared to inputting information manually.
- Improved quality of vaccination records resulting in **better coverage and prevention of missed opportunities especially when used with electronic health records** as countries can more accurately identify the immunisation status of individuals than with handwritten records.
- **Increased acceptability of vaccines** due to improved access and reduction in risks of use of incorrect components (e.g., lyophilised vaccine and diluent) due to better stock management.
- Improved traceability of vaccine commodities in the supply chain due to product specific information for tracking and tracing which can lead to **increased efficiencies in stock management and reduced stock-outs**. This is also a benefit of barcodes on secondary/higher packaging levels.
- Improved quality of surveillance systems to track AEFIs and conduct recalls and improved access to product data (e.g., through links to websites) resulting in fewer preparation errors and **better patient safety**.
- **Reduced delivery costs** due to time saved by healthcare workers on patient recordkeeping and inventory management due to increased speed of electronic capturing of data compared to manual data entry.

¹ Based on availability of the innovation in a single-dose presentation or multi-dose with preservative; ² To patients/caregivers; ³ Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities; ⁴ per person vaccinated



Costs

Barcodes on primary containers will likely have higher total economic costs as their use requires systems in place in facilities for scanning and electronic recordkeeping

Commodity costs^{1, 2}

Commodity costs expected to increase slightly:

- The cost of adding a barcode to a primary vaccine container may increase the overall commodity cost of the vaccine, as manufacturers will need to redesign labels and may need to upgrade printing equipment and/or invest in additional quality control processes.

Delivery costs^{2, 3}

Delivery costs expected to reduce due to savings in time spent by vaccinators:

- Reduction in time spent by vaccinators and staff for patient record keeping and stock management of vaccines.

No cost savings or losses in the storage and transport of vaccines as barcodes do not impact the volume/size of the primary vaccine containers.

Introduction and recurrent costs¹

Increased introduction costs due to equipment and training needs, as well as recurrent costs:

- There would be upfront costs for **software development and purchase of scanners and computers for each facility**
- There would also be monthly recurrent costs for **internet connectivity and data hosting**.
- The above costs (except for the scanners) would be incurred as part of a broader effort than barcodes implementation, when a country is transitioning to electronic recordkeeping.
- Staff would require training on how to use barcodes.

¹ Of a vaccine regimen (per person vaccinated); ² Includes the purchase cost of a vaccine regimen and delivery devices (injection syringes or other components needed for vaccine preparation and administration) accounting for wastage, and safety box costs; ³ Includes costs of in and out of cold chain storage and transport for a vaccine regimen including delivery technology(ies), time spent by vaccinators when preparing and administering the vaccine and by staff involved in stock management;

2D barcodes are ready for adoption on vaccine primary containers



Technology Readiness

VIPS Criteria	Indicators	Penta	Hep B BD	HPV	MR	Men A	IPV	Rabies	Rota	TCV	YF	Ebola	ETEC	HIV ²	Influenza ³	Malaria	M. Tb ⁴	RSV ⁵	
Secondary criteria	Clinical development pathway complexity	No complexity (all vaccines)																	
	Technical development challenges	Low complexity (all vaccines)																	
	Technology readiness ¹ Complexity of manufacturing the innovation	Low complexity (all vaccines)																	
	Robustness: multiple developers of the technology	Not applicable (all vaccines)																	
	Robustness: multiple suppliers/manufacturers of the vaccine	Highly robust (all vaccines)																	

- **No clinical development is required.**
- **There is a low complexity** associated with adding barcodes to primary containers as the **technology is well established**. 2D barcodes are **used globally on primary containers of pharmaceuticals (including many vaccines)** and serial numbers (which add complexity) would not be required.
- **Some impact on vaccine production** is expected, e.g., for those manufacturers requiring higher quality printing equipment.
- **Barcode availability is unlimited**; they are obtained online from global standards organisations like GS1; therefore **supply** is therefore considered **highly robust**.

¹ VIPS assessment of the Technology Readiness criteria was informed by consultations with the WHO/PATH Delivery Technology WG for each innovation assessed under Phase II, as well as with consultations with regulators. ² ALVAC-HIV + bivalent Subtype C gp120; ³ VAL-506440; ⁴ VPM 1002; ⁵ Pre-fusion F protein.

New label standards will need to be created for the UNICEF market and some effort and investment needed to include barcodes on vaccine primary container labels¹



Technology Readiness

Regulatory	Technical	Manufacturing
<ul style="list-style-type: none"> • WHO/UNICEF label standards incorporating 2D barcodes on vaccine primary container labels will need to be developed that align with all relevant national regulatory authority (NRA) standards. • Vaccine manufacturers will need to seek NRA and WHO prequalification approvals for label changes. 	<ul style="list-style-type: none"> • Labels will need to be redesigned to make room for a GS1 compliant 2D barcode; greater difficulty expected with fitting the 2D barcode on smaller containers with smaller labels. GS1 can electronically issue 2D barcodes to vaccine manufacturers. • Vaccine manufacturers supplying vaccines to UNICEF/Gavi are in the process of adding barcodes to secondary vaccine packaging to help with tracking inventory. • To use barcodes on primary packaging, health facilities will need scanning equipment as well as the computers, software, and internet connectivity required for electronic health and inventory records. Some countries are building these systems now, but the process will take many years for other countries. 	<ul style="list-style-type: none"> • Some vaccine manufacturers will require higher quality printers to print 2D barcodes as they require more precise printing than text. • The addition of 2D barcode printing could minimally affect production line speeds and may require additional quality control measures.

¹ It is assumed that serialisation will not be required on primary containers.



Commercial feasibility

The commercial opportunity for barcodes in LMICs is significant

VIPS Criteria	Indicators	Penta	Hep B BD	HPV	MR	Men A	IPV	Rabies	Rota	TCV	YF	Ebola	ETEC	HIV ¹	Influenza ²	Malaria	M. Tb ³	RSV ⁴
Secondary criteria	Commercial feasibility	Country stakeholders' interest based on evidence from existing data																
		Potential breadth of the target market																
		Existence of partnerships to support development and commercialisation																
		Known barriers to global access to the innovation																

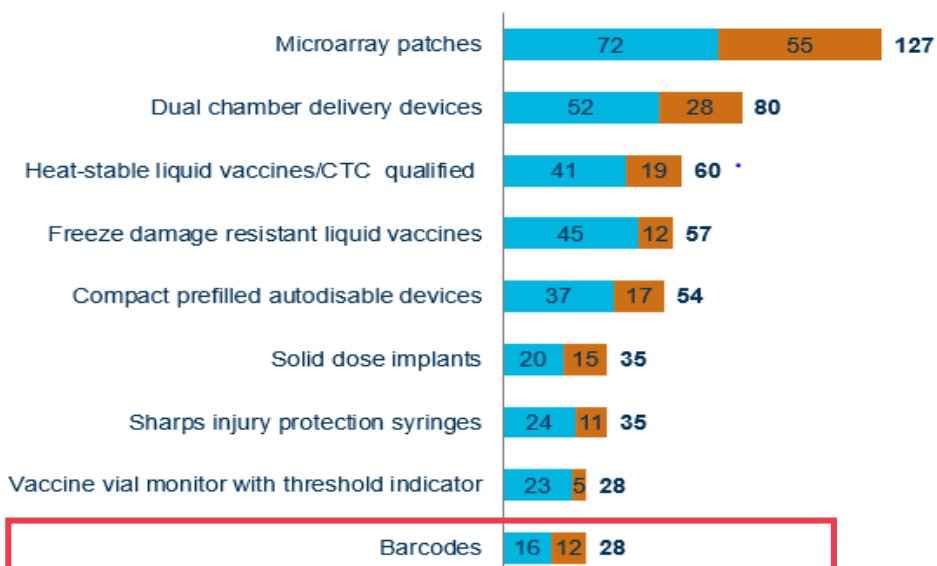
- **Demonstrated country interest**
 - At least **4 LMICs are proactively piloting introduction of barcodes on secondary packaging** along with electronic inventory systems and **many countries are adopting electronic immunisation registries** that could benefit from the ability to enter data by scanning primary container barcodes.
 - **Turkey has successfully used barcodes since 2010 on all pharmaceuticals and packaging levels**, including vaccine primary containers, and all their vaccine suppliers have complied with their request for barcodes on labels.
- **Large target market and significant interest from vaccine manufacturers in supporting development and commercialisation**
 - **Large market** (both HIC and LMIC) as barcodes are applicable to all vaccines and are widely used on products globally.
 - **Some vaccine manufacturers have moved forward with barcodes on primary packaging to meet the demand from particular countries** and/or to comply with their national regulatory authorities (e.g., GSK, Merck, Sanofi, and Wyeth/Pfizer).
 - **4 out of 5 vaccine manufacturers responding to the Delivery Technologies Working Group survey are interested in applying 2D barcodes to vaccine primary containers for LMICs** in the future with one specifying that the **approach should be phased** (with higher packaging levels first). The manufacturer that is not interested has capability but stated that they comply as required by customers.
- **The likely pathway to inclusion of barcodes on the primary containers** of existing and future vaccines is through a WHO/UNICEF labelling requirement.



Based on VIPS country feedback¹, there is moderate & little interest in barcodes on primary containers from decision-makers & immunisation staff respectively in comparison to other innovations

Feedback from in-person country interviews

Innovations' ranking



Perceived benefits

- Potential to improve the ability to track or have information about vaccines,
- Saves health care worker time;
- Makes monitoring of AEFIs or recall of vaccines easier;
- Improves stock records;
- Improves legibility of labels.

Perceived challenges

- Higher equipment requirements;
- Impact on overall cost;
- Immunisation staff: complexity and time to use the technology, and availability of internet power;
- Decision makers: feasibility of barcodes at service-delivery level, training needs.

- Decision makers ranked barcodes as #6 and immunisation staff ranked it as #9 in terms of having the greatest potential impact to address their immunisation programme's challenges. The overall rating is #7 (last with VVM-TIs).
- The low rating by immunisation staff may be due to lack of familiarity with electronic systems for patient records and inventory and/or greater interest in innovations affecting vaccine delivery.

¹ Based on in-person interviews conducted in Q4 2019-Q1 2020 with 55 immunisation staff and 29 decision makers across 6 countries to gather feedback on the 9 innovations under final evaluation



However, the online survey shows a different picture in terms of interest to transition to use of electronic systems for both vaccine inventory and patient record keeping

Additional feedback from VIPS online survey

In the **VIPS online survey**, the vaccine-specific problem statements related questions were not relevant for barcodes. Thus **two additional questions** were asked to countries on **interest and use of electronic systems for vaccine inventory** and **electronic patient record keeping**, to inform **country interest and readiness** to capture the **benefits of barcodes on primary containers**.

- **93% respondents** (out of 55 participants from 25 countries) and **91% of respondents** (out of 99 participants from 40 countries) reported that **a transition from a paper-based system to an electronic system for inventory vaccines and for patient record keeping respectively would benefit their immunisation program**.
- **57% of respondents** (out of 129 participants from 49 countries) and **22% of respondents** (out of 127 participants from 49 countries) stated that their country **already uses electronic systems for vaccine inventory and for patient record keeping respectively**.

Potential impact of VIPS prioritisation

What could VIPS do to accelerate development of barcodes on primary containers for LMICs

Risks of not prioritising barcodes through VIPS

- There is an opportunity to **build on the ongoing work** to incorporate barcodes on secondary packaging for Gavi/UNICEF markets and **gain synergies** by **setting standards** and **sequenced timelines for both simultaneously**.
 - This would give both industry and countries time to prepare and would help ensure eventual primary container barcode availability for countries that are ready to implement. While the availability on vaccine labels would be mandatory to ensure clarity and consistency for manufacturers, the use in countries would not be and countries that are not ready to implement could defer use of barcodes.
- If barcodes were to be prioritised by VIPS, beyond the above, stakeholder inputs would be sought to identify follow-up activities that would have the **greatest impact on accelerating** their availability. These could include:
 - **Convening a new or harnessing an existing barcode working group** that includes representation from global stakeholders, donors, the vaccine industry, and GS1 to **reach consensus on plans and implementation timelines for vaccine products**;
 - **Preparing updated WHO/UNICEF primary packaging labelling standards** that include barcodes and are compatible with national regulatory authority requirements;
 - **Assisting countries with implementation** research and documentation of the value proposition **once the innovation is available**; and
 - **Development of guidance for countries** on implementation, equipment requirements, and ensuring compatibility with health information systems based on implementation research results.

- **Barcodes on secondary packaging benefit are focused on vaccine inventory issues.** Delays in the availability of barcodes on primary containers will mean that countries will be unable to incorporate their use into emerging electronic health information systems and reap the coverage/equity, safety, and timesaving benefits.
- **Loss of an opportunity to advance a “low hanging fruit”** and to synergise with the ongoing work to incorporate barcodes into secondary vaccine packaging.