2D Barcodes

Technology overview:

This innovation is defined as the application of 2D barcodes to vaccine primary packaging labels. They are symbols that encode information such as vaccine product numbers, serial numbers, supplier data, batch numbers and expiry dates which can be scanned electronically using laser scanners or mobile device cameras to automatically capture information.

Currently, barcodes are used on secondary and tertiary packaging of vaccines providing product identification information, expiration date and lot number[a]. The use of barcodes on secondary and tertiary packaging primarily provides vaccine inventory, supply and efficiency benefits. However, this evaluation assumes barcode placement down to the primary packaging level and the predominant public health benefits will be at the health facility levels to improve accurate documentation of vaccine information in patient records, help reduce programmatic errors, facilitate tracking of AEFIs and vaccine recalls, and improve timely and equitable vaccine coverage.

Radio-frequency identification (RFID) versus barcodes on primary vaccine containers:

The RFID tag is a type of labelling technology used in many different industries that can store vast amounts of information useful for inventory control, equipment tracking, patient monitoring and providing data for electronic medical record systems. Similar to barcodes, RFID tags can track and trace items and link to other systems like GPS, temperature, or vaccination records. The original intention was to review both RFID tags and barcodes on primary vaccine packaging during the VIPS phase II analysis. However, deeper evaluation of the technologies revealed that, for the foreseeable future, RFID tags on primary vaccine packaging are not appropriate for the lower- and middle-income public sector markets that Gavi serves.

RFID tags differ from barcodes in the process of capturing data/information as they require additional computer hardware and software to connect the reader to computer systems and data repositories, by converting data captured in the form of radio signals from tags into tracking or identification information. There are different types of RFID tags (passive, semi-passive and active) that can transmit radio signals over variable distances, using different levels of power. As a result, RFIDs can quickly capture data in mass, whereas barcodes are designed to be scanned on items one at a time in the line of sight of a laser. RFIDs are therefore particularly suited for higher levels of packaging (e.g., tertiary) for inventory control at higher levels of health systems, for example, where all vaccine boxes on a pallet can be scanned at once and where the costs of the scanning system can be spread across higher product volumes.

For the primary packaging level, RFIDs have some drawbacks in comparison to barcodes including:

- Barcodes can be read with smart phones or simple scanners, while RFID tags require more complex and expensive equipment for scanning. barcodes are therefore much more appropriate for use at the health facility levels where they can be scanned for patient recordkeeping as well as inventory purposes.

[a] *About Two-Dimensional (2D) Vaccine Barcodes, CDC.* https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/about.html

- The addition of individual RFID tags to vaccine primary containers (e.g., vials) would be more costly than barcodes. RFID tags can cost between Euro 0.10 to 0.20, whereas the cost of adding a barcode to an existing container label is expected to be insignificant[b] and there would be additional cost of specialised RFID scanners and data converting software. It will take some time for countries to begin using either barcodes or RFID tags. Given that the intent will be for these technologies to be available on all vaccine primary containers, it doesn't make sense for countries to bear the cost of an RFID tag that they are not yet using and without the broader tracking infrastructure in place.
- Vaccine manufacturers are already interested in and adopting barcodes at higher levels of packaging, so implementation on the primary container is much more technically and economically feasible than implementation of RFID labels.

For these reasons, barcodes have been prioritized over RFID tags for review in Phase II of VIPS, and RFIDs are not assessed in this technical note.

Summary of innovation applicability to vaccines:

Barcodes are applicable to all VIPS priority vaccines (as shown in Table 1), as they can be applied to all levels of vaccine packaging encoding information such as product numbers, serial numbers, supplier data, batch numbers and expiry dates to enable effective tracking and monitoring of the product. In fact, it would be preferable to have barcodes on the primary packaging of all vaccines so that countries using them for inventory and recordkeeping could do so for all vaccine units. Therefore, there are no restrictions based on technical feasibility. While barcodes do not address vaccine-specific problems, their use can improve the quality and accuracy of inventory data for vaccine stock management and traceability in supply chains leading to reduced stockouts and better efficiencies. Their use can also improve the quality and accuracy of patient vaccination records leading to improved safety, reductions in missed opportunities, better surveillance, and improved coverage.

SECTION ONE: Vaccine compatibility and problem statements addressed by the innovation

Table 1: Profile of VIPS priority vaccines[c] to be assessed for use with the innovation[d] and the comparator presentations

For all vaccines, the comparator is the same vaccine and presentation with no barcode label on the vaccine primary container.

[b] *Key informant interview with Michael Attlan.*

[c] *From a long list of vaccines, 17 VIPS priority vaccines were selected based on covering a wide spectrum of different vaccine platforms, route of administration, vaccine presentations and delivery strategy to ensure they represent different family of vaccines, such that evaluating one antigen will be representative of the others and innovations for one family member would be applicable to all. The final list includes 11 licensed vaccines that are WHO prequalified, GAVI funded and UNICEF procured, as well as 6 pipeline candidate vaccines. Refer to the document 'Scope of vaccines' for the detailed explanation.*

[d] *Vaccines to be assessed were selected on the basis of: 1) Technical applicability of the vaccine with the innovation, 2) Identification of vaccine-specific problem statements and 3) Ability of the innovation to solve vaccine-specific problem statements. The vaccines and problem statements are not listed in any priority order.*

Vaccine	Vaccine type	Formulation	Adjuvant	Preservative	Route	Problem statements to be addressed[e]	Comparator dose(s) per container
Licensed vaccines							
Pentavalent (Diphtheria tetanus pertussis hepatitis B haemophilus inflluenzae type B inactivated poliovirus; DTP, HepB, Hib)	Inactivated subunit plus polysaccharide-protein conjugated vaccine (PS-PCV)	Liquid	Yes (Aluminium-salt based)	Yes	IM	Not applicable. Barcodes address immunization system problems rather than vaccine-specific problems. There are no vaccines that are not technically feasible, as the innovation can be applied to all vaccine primary containers.	Single-dose vial (SDV) or 10-dose vial; IM injection with an AD N&S
Hepatitis B (birth dose)	Subunit	Liquid	Yes (Aluminium-salt based)	Yes	IM		Single-dose vial (SDV) or 10-dose vial; IM injection with an AD N&S.
Human papillomavirus (HPV)	Subunit	Liquid	Yes (Aluminium-salt based)	No	IM		SDV or 2-dose vial and delivery by IM injection with an AD N&S.
Measles rubella (MR)	Live attenuated.	Lyophilised	No	No	SC		SDV or 10-dose vial
Meningitis A (MenAfriVac)	PS-PCV	Lyophilised	Yes, in diluent (Aluminium-salt based)	Yes**	IM		SDV or 10-dose vial

[e] *An online survey was conducted to collect information on key vaccine-specific delivery challenges faced by countries that can be addressed by innovations in the scope of VIPS. The survey was completed by 168 global and country level experts across 54 countries conducted in Q4 2019. Participants were provided with a standard list of problem statements for the licensed vaccines analysed through VIPS and top 5 reported challenges per licensed vaccine were selected as 'vaccine problem statements' to be specifically analysed. They are listed in order importance for each vaccine (most important first). Problem statements that could potentially be addressed by the innovation are shown in bold and problem statements for pipeline vaccines are in italics.*

Vaccine	Vaccine type	Formulation	Adjuvant	Preservative	Route	Problem statements to be addressed[e]	Comparator dose(s) per container
Inactivated poliovirus (IPV)*	Whole-inactivated	Liquid	No	Yes	IM or ID		• IM (0.5ml/dose): SDV or 10-dose vial • ID (0.1ml/dose): SDV (5 fractional doses) or 5-dose vial (25 fractional doses).
Rabies*	Whole-inactivated.	Lyophilised	No	No	IM or ID		• IM (0.5ml/dose): SDV • ID (0.1ml/dose): SDV (5 fractional doses)
Rotavirus	Live attenuated virus	Liquid	No	No	Oral		Liquid single-dose plastic squeeze tube.
Typhoid (conjugate)	PS-PCV	Liquid	No	Yes**	IM		SDV or 5-dose vial
Yellow fever	Live-attenuated	Lyophilised	No	No	SC or IM		SDV or 5-dose vial

Vaccine	Vaccine type	Formulation	Adjuvant	Preservative	Route	Problem statements to be addressed[e]	Comparator dose(s) per container
Pipeline vaccines[f]							
Ebola (recombinant vesicular stomatitis virus, Zaire Ebola virus) (rVSV-ZEBOV)	Live vector	Liquid, frozen	No	No	IM	• *Cold-chain requirements during outreach (vaccine needs to be kept frozen)* • *Vaccine ineffectiveness/ wastage due to heat exposure*	Recently licensed as SDV vial
Enterotoxigenic *E. coli* (ETEC) (ETVAX)	Whole inactivated organism	Liquid vac, lyophilized buffer, lyophilized adjuvant	Yes (dmLT, double-mutant heat labile toxin [of ETEC])	No	Oral	• *Difficult preparation requiring trained personnel* • *Reconstitution-related safety issues*	Currently in phase 2 for travellers and infants: Liquid vaccine in SDV that requires mixing in a cup with buffer (powder), adjuvant (lyophilised) and water; and delivery by oral dropper.
Human immunodeficiency virus (HIV) (ALVAC-HIV + bivalent Subtype C gp120)[g]	Heterologous live attenuated recombinant viral vector + recombinant protein booster	Lyophilized prime and liquid booster (gp120)	Yes (MF59 [oil-in-water emulsion]) (recombinant protein booster)	Not known	IM	• *Difficult preparation requiring trained personnel* • *Reconstitution-related safety issues*	As still in Phase 2b/3, assume SDV
Influenza (pandemic, VAL-506440)	Nucleic acid	Liquid	Not known	Not known	IM	• *Not known* • *Possibly: need to deliver the vaccine to the correct injection depth*	As still in phase I, assume SDV

[f] *Vaccines included in the 'Pipeline vaccines' section were not approved as of the beginning of the Phase II analysis, therefore the Ebola vaccine although now licensed will be assessed as a pipeline vaccine. Barriers to vaccination for these vaccines were also not evaluated through the online vaccine problem statement survey.*

[g] *Termination of the phase 2b/3 trial of this vaccine was announced in February 2020 (https://www.niaid.nih.gov/news-events/experimental-hiv-vaccine-regimen-ineffective-preventing-hiv). A similar heterologous prime-boost HIV vaccine (Ad26.Mosaic4.HIV + cladeC/Mosaic gp140 vaccine) is still in late stage trials (NCT02935686). Although this is based on a different virus vector and subunit protein, and some of the details of the assessments might be different, the overall challenges facing this type of vaccine (heterologous prime-boost) are the same, so the assessment were not re-run with Ad26.Mosaic4.HIV + clade C/Mosaic gp140 vaccine.*

Vaccine	Vaccine type	Formulation	Adjuvant	Preservative	Route	Problem statements to be addressed[e]	Comparator dose(s) per container
Malaria (RTS,S)	Recombinant protein	Lyophilized vaccine; adjuvant in diluent	Yes (AS01E [QS21 + MPL] in diluent)	Not known	IM	• *Difficult preparation requiring trained personnel*	Dry (vaccine) SDV and liquid (adjuvant/diluent) SDV clipped together
Mycobacterium tuberculosis (M.tb) (Next generation BCG: VPM1002)	Live attenuated	Lyophilised	No	No	ID	• *Difficult to deliver vaccine to the correct injection depth* • *Reconstitution-related safety issues* • *Difficult preparation requiring trained personnel*	SDV or 20-dose vial
Respiratory syncytial virus (RSV) (pre-fusion F protein)	Subunit	Lyophilised	No	Not known	IM	• *Difficult preparation requiring trained personnel* • *Reconstitution-related safety issues*	SDV

* SDV if doses given IM; will be MDV if doses given ID.

** Must be discarded after 6 hours

Table 2: Vaccines not assessed due to technical feasibility[h]

Vaccine	Rationale for exclusion
None	There are no vaccines that are not technically feasible, as the innovation can be applied to all vaccine primary containers.

[h] *Vaccines not assessed were excluded on the basis of lack of applicability of the vaccine with the innovation.*

SECTION TWO: Assessment of vaccine-innovation product against a comparator

Note: All indicators in Phase I have also been assessed in Phase II.

1.1 Criteria on health impact

Indicator: Vaccine efficacy

Score legend: Green: Better than the comparator (The innovation improves vaccine efficacy); White: Neutral, no difference with the comparator; Red: Worse than the comparator (The innovation reduces vaccine efficacy); N/A: the indicator measured is not applicable for the innovation; Grey: no data available to measure the indicator.

Table 3

Parameter assessment		
Vaccines	***Does the innovation improve vaccine efficacy based on clinical evidence using correlates of protection or a surrogate?***	**Overall score**
All applicable vaccines	The use of barcodes has no influence on the efficacy of vaccines, which is no different than the comparators.	**Neutral**

Indicator: Vaccine effectiveness

*Score legend: Green: **Better** than the comparator (The innovation improves vaccine effectiveness); White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator(The innovation decreases vaccine effectiveness); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 4

Parameter assessment		
Vaccines	**Parameter:** ***Does the innovation improve vaccine effectiveness as per the following parameters based on field or other evidence?*** ○ ***Cases averted*** ○ ***Outpatient visits averted*** ○ ***Hospitalisations averted*** ○ ***Deaths averted*** ○ ***Vaccine doses given within the recommended age range (timeliness of vaccination)***	**Overall score**

All applicable vaccines	The use of barcodes bears no influence on the effectiveness of vaccines, which is no different than the comparators.	**Neutral**

Indicator: Ability of the vaccine presentation to withstand heat exposure[i,j]

Score legend: Green: Better than the comparator (The innovation includes features that may increase heat stability or likely to enable CTC qualification ; White: Neutral, no difference with the comparator (The innovation has the same heat stability and/or CTC qualification as the current vaccine) ; Red: Worse than the comparator (The innovation includes features that may decrease heat stability or less likely to enable CTC qualification); N/A: the indicator measured is not applicable for the innovation; Grey: no data available to measure the indicator.

Table 5

Vaccines	Assumed use case	*Is the vaccine particularly heat sensitive (i.e. VVM2) and does it require special storage conditions (i.e. such as being kept frozen)?* [k]	*Is there evidence that this vaccine can be qualified for CTC use.*	*Would the context of use of the vaccine benefit from CTC use (state which use case scenario)?*	*Does the innovation paired with the vaccine improve heat stability?*
All applicable vaccines	The use of barcodes bears no influence on the ability of the vaccine presentation to withstand heat exposure and enable CTC use.				This innovation does not impact heat stability, which is no different to the comparators.
					Neutral

Indicator: Ability of the vaccine presentation to withstand freeze exposure

*Score legend: Green: **Better** than the comparator (The innovation includes features that may increase freeze resistance); White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator (The innovation includes features that may decrease freeze resistance); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

[i] *Same indicators as for Phase I but further assessed under Phase II due to the antigen/vaccine pairing*
[j] *Improved heat stability can also be used to increase shelf life, hence no indicator on shelf-life extension is included in the framework.*
[k] *This parameter is not used for scoring purposes, it is contextual/background information.*

Table 6

Parameter assessment		
Vaccines	***Does the innovation paired with the vaccine prevent damage due to freeze exposure?***	**Overall Score**
All applicable vaccines	The innovation has no influence on the ability of the vaccine to avoid freeze damage, which is no different to the comparators.	**Neutral**

1.2 Criteria on coverage and equity

Indicator: Number of fully or partially immunised (relative to target population)[l]

*Score legend: Green: **Better** than the comparator (The innovation increases the overall coverage); White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator (The innovation decreases the overall coverage); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 7

Parameter assessment		
Vaccines	***Does the innovation improve the overall coverage for the vaccine within a target population for one or all doses?***	**Overall Score**
All applicable vaccines	Barcodes on vaccine primary containers could potentially be used to track and document information on vaccines administered to patients through linkages to their electronic health records (EHR). The information can be used to improve immunization coverage and avoid missed opportunities. A pilot study using barcodes to automatically record immunization data directly into a patients' health records demonstrated improved accuracy of health records and reduction of missed opportunities.[m] In a study that implemented barcode technology, the hospital observed an increase in immunization coverage of children implicating that the ability to facilitate accurate and effective vaccine documentation reduced errors related to scheduling and tracking of vaccines which contributed to saving time spent by medical staff thus improving the immunization process (1)(2)(3).	**Better**

[l] *For these indicators, we expect that for most of the innovations there will be no available data, therefore the score will be 'no data available'. However, when this data is available, it will be important data that should be used for the assessment*

[m] *The Automated Identification of Vaccines (Bar Coding) Pilot Project. https://cdc.confex.com/cdc/nic2005/techprogram/paper_7714.htm*

Indicator: Ease of use from clinical perspective based on product attributes[n]

*Score legend: Dark Green: **Considerably better** than the comparator: Better for all applicable parameters; Green: **Better** than the comparator: Better for some of the applicable parameters AND no difference for the rest of the parameters; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters; Red: **Worse** than the comparator: Worse for some of the applicable parameters AND no difference for the rest of the parameters; Dark Red: **Considerably worse** than the comparator: Worse for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 8

Parameter assessment						
Vaccines	***Does the innovation avoid reconstitution and is that an improvement?***	***Does the innovation require fewer vaccine product components?***	***Does the innovation require fewer preparation steps and less complex preparation steps?***	***Does the innovation improve dose control?***	***Does the innovation improve targeting the right route of administration (accuracy in terms of route and/or depth of injection)?***	**Overall score**
All applicable vaccines	The innovation has no impact on reconstitution of a vaccine, which is no different to the comparators.	A vaccine primary container with a barcode label would have the same number of vaccine product components as a vaccine without a barcode (comparator) because the barcode is integrated into the existing vaccine label.	A vaccine primary container with a barcode label will have the same number and complexity of vaccine preparation steps as the comparators. The barcode could provide a link to online guidance in preparing the vaccine correctly (4). However, the vaccine would still be prepared the same way as without the innovation.	The innovation could theoretically link the vaccinator to information about dose volume. However, this information is already part of most vaccine labelling. Therefore, the innovation is considered no different to the comparators.	The innovation does not have a direct impact on targeting the right route of administration, as this would be related to the role of the vaccinator. Therefore, the innovation is considered no different to the comparators.	**Neutral**
	Neutral	**Neutral**	**Neutral**	**Neutral**	**Neutral**	

[n] *Ease of use also affects timeliness of vaccination (vaccine doses given within the recommended age range), however, it was decided that timeliness of vaccination should be captured under vaccine effectiveness based on country data.*

Indicator: Ease of use based on ability of a lesser trainer person to administer the vaccine or self-administration

*Score legend: Dark Green: **Considerably better** than the comparator: Better for all applicable parameters; Green: **Better** than the comparator: Better for some of the applicable parameters AND no difference for the rest of the parameters; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters; Red: **Worse** than the comparator: Worse for some of the applicable parameters AND no difference for the rest of the parameters; Dark Red: **Considerably worse** than the comparator: Worse for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 9

	Parameter assessment				
Vaccines	**Assumed use case**	**Would the context of use of the vaccine benefit from delivery by a lesser trained person and self-administration (state which setting/use case scenario)?**	***Does the innovation enable a lesser trained person (e.g. volunteers/caregivers/parents/lesser trained personnel) to administer the vaccine?***	***Does the innovation enable self-administration?***	**Overall score**
All applicable vaccines	The assumed use-case varies by vaccine. However, the innovation has no impact on the intended use-case.	Even if there are specific use-cases to deliver a vaccine by a lesser trained health care worker or by self-administration, barcodes do not have any features that enable these use cases.	No. Although barcodes can provide links for information on dosing, preparation and administration, this would not replace the training required nor impact the ease of use related to delivering the vaccine. This innovation is a label on a primary vaccine container which has no features to enable delivery by lesser trained personnel or self-administration. Therefore, the innovation is no different than the comparators.		**Neutral**
			Neutral		

Indicator: Ability to facilitate dose sparing

*Score legend: Green: **Better** (The ability to facilitate dose sparing is better with the innovation); White: **Neutral**, no difference between the innovation and comparator; Red: **Worse** (The ability to facilitate dose sparing is better with the comparator); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 10

Parameter assessment		
Vaccines	***Does the innovation improve dose sparing of the vaccine?***	**Overall score**
All applicable vaccines	The innovation has no influence on the ability to dose spare and this is no different to the comparators.	**Neutral**

Indicator: Availability of the innovation in a single-dose presentation or multi-dose with preservative to avoid missed opportunities and reduce vaccine wastage.

*Score legend: Dark Green: **Considerably better,** The innovation is available in a much improved presentation from the perspective of missed opportunities and reducing vaccine wastage (for example, a single dose presentation compared to a multidose presentation without preservative); Green: **Better** than the comparator, The innovation is available in an improved presentation from the perspective of missed opportunities and reducing vaccine wastage (for example, a single dose presentation compared to a multidose presentation with preservative); White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator (The innovation is not available in an improved presentation from the perspective of missed opportunities and reducing vaccine wastage); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Note: **All SDV comparators will score neutral compared to an innovation that is a single-dose presentation**

Table 11

Parameter assessment		
Vaccines	***Is the innovation available in a single-dose presentation or multi-dose with preservative to avoid missed opportunities (e.g., due to reluctance to open a MDV) and reduce vaccine wastage?*** ***(State whether the comparator is SDV or MDV)***	**Overall score**
All applicable vaccines	The innovation has no impact on whether a vaccine is available as a SDV or MDV with preservatives in order to avoid missed opportunities, which is no different to the comparators.	**Neutral**

Indicator: Acceptability of the vaccine presentation and schedule to patients/caregivers

*Score legend: Dark Green: **Considerably better** than the comparator: Better for all applicable parameters; Green: **Better** than the comparator: Better for some of the applicable parameters AND no difference for the rest of the parameters; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters; Red: **Worse** than the comparator: Worse for some of the applicable parameters AND no difference for the rest of the parameters; Dark Red: **Considerably worse** than the comparator: Worse for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 12

Parameter assessment				
Vaccines	***Does the innovation include features that may improve pain experienced by the recipient following vaccination?***	***Does the innovation include features that may improve perception of ease of administration (i.e. convenience for the vaccinees/caregivers)?***	***Does the innovation include features that may improve/impact any other benefit related to acceptability by vaccinees/caregivers?***	**Overall score**
All applicable vaccines	Impact on pain experienced by the recipient has no association with the use of barcodes, which is no different to the comparators. .	The inclusion of a barcode on primary vaccine containers would not impact the perception of ease of administration, which would be no different to the comparators.	Barcodes can potentially improve patient safety in terms of reducing errors for drug administration and timeliness/accuracy of documentation of data in health records (5). Use of barcodes on primary containers in immunisation programmes could improve access to vaccines and therefore satisfaction, by reducing the risk of incorrect vaccine dose preparation and improving inventory/stock management to ensure that the appropriate vaccine components (e.g., lyophilised vaccine and diluent) are kept together. They can also provide links to data on websites with dosing, preparation and administration information for the healthcare provider.	**Better**
	Neutral	**Neutral**	**Better**	

Indicator: Potential to reduce stock outs based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities[o]

*Score legend: Green: **Better** than the comparator for one of the parameters; White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator for one of the parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 13

Parameter assessment			
Vaccines	***Does the innovation require fewer components to deliver the vaccine?***	***Or does the innovation include labelling that facilitates tracking of vaccine products?***	**Overall score**
All applicable vaccines	As barcodes are already part of the vaccine container during storage/transport, and any additional equipment (e.g. scanner/reader) required for this innovation is assumed to be in stock and is actually not required to deliver the vaccine to the patient, the innovation would require the same number of components as the comparators to deliver the vaccine.	The integration of barcodes on vaccine packaging could improve tracking and tracing of vaccine commodities, resulting in reduced stock-outs due to improved stock management, which would be better than the comparators. However, this score is based on the assumption that countries have electronic immunisation registries in place.	**Better**
	Neutral	**Better**	

1.3 Criteria on safety

Indicator: Number of vaccine product-related adverse events following immunisations[p]

*Score legend: Green: **Better** than the comparator (The innovation decreases the frequency of serious AEFIs); White: **Neutral**, no difference with the comparator; Red: **Worse** than the comparator (The innovation increases the frequency of serious AEFIs); N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

[o] *Assessment of the potential to reduce stock outs based on the innovation's features.*
[p] *For these indicators, we expect that for most of the innovations there will be no available data. However, when this data is available, it will be important data that should be used for the assessment.*

Table 14

Parameter assessment		
Vaccines	***Does the innovation reduce the frequency of serious AEFIs?***	**Overall score**
All applicable vaccines	There is no vaccine-specific data. The innovation could potentially improve patient safety in terms of reducing errors for drug administration and timeliness/accuracy of documentation of data in health records (5). A study by Uy *et al* reported that barcode medication administration systems had reduced the incidence of medication (not vaccines) errors by more than 50%, and the risk of adverse drug events by 11% or approximately 20 events per day (6). A systematic review on barcoding showed a reduction in errors related to incorrect dosing, dispensing and administration of medication prior to reaching the patient (4). Barcodes could potentially reduce the risk of incorrect vaccine dose preparation by improving inventory/stock management and ensuring that the appropriate vaccine components (e.g., lyophilised vaccine and diluent) are kept together. They can also provide links to data on websites with dosing, preparation and administration information for the healthcare provider, if internet access is available.	**No data**

Indicator: Likelihood of contamination and reconstitution errors

(This indicator is further measured in Phase 2 only if the comparator is a MDV)

*Score legend: Dark Green: **Considerably better** than the comparator: Better for all applicable parameters; Green: **Better** than the comparator: Better for some of the applicable parameters AND no difference for the rest of the parameters; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters; Red: **Worse** than the comparator: Worse for some of the applicable parameters AND no difference for the rest of the parameters; Dark Red: **Considerably worse** than the comparator: Worse for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 15

Parameter assessment							
Vaccines	***Does the innovation reduce the risk of contamination while reconstituting the dry vaccine?***	***Does the innovation reduce the potential risk of reuse of delivery technology?***	***Does the innovation reduce the risk of use of nonsterile components?***	***Does the innovation reduce the risk of contamination while filling the delivery device?***	***Does the innovation require fewer preparation steps and less complex preparation steps?***	***Does the innovation reduce the likelihood of using an incorrect diluent during reconstitution?[q]***	***Overall score***
All applicable vaccines	The combined innovation-vaccine product would have the same risk of contamination as with the comparators.	The innovation would have no impact on the potential risk of reuse of the delivery technology, which would be the same as with the comparators.	The innovation would have no impact on the risk of use of nonsterile components, which would be the same as with the comparators.	The innovation would have no impact on the risk of contamination while filling the delivery device, which would be the same as with the comparators.	A barcode on the primary vaccine container does not impact the number and complexity of vaccine preparation steps so would be the same as with the comparators.	A systematic review on barcoding demonstrated a reduction in errors related to incorrect dosing, dispensing and administration of medication prior to reaching the patient (4). Thus, barcodes could potentially reduce the risk of incorrect vaccine preparation by ensuring that the appropriate vaccine components are kept together by improving the inventory/stock management of the vaccine components.	**Better**
	Neutral	**Neutral**	**Neutral**	**Neutral**	**Neutral**	**Better**	

[q] *Incorrect diluent – use of the wrong the substance as opposed to the wrong volume of diluent.*

Indicator: Likelihood of needle stick injury[r]

*Score legend: Dark Green: **Considerably better** than the comparator: Better for all applicable parameters; Green: **Better** than the comparator: Better for some of the applicable parameters AND no difference for the rest of the parameters; White: **Neutral,** no difference with the comparator; Yellow: **Mixed**: Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters; Red: **Worse** than the comparator: Worse for some of the applicable parameters AND no difference for the rest of the parameters; Dark Red: **Considerably worse** than the comparator: Worse for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 16

Parameter assessment						
Vaccines	***Does the innovation contain fewer sharps?***	***Does the innovation use sharps for preparing and/or administering the vaccine and is that better than the comparator?***	***Does the innovation include an auto disable feature and is that better than the comparator?***	***If the innovation uses sharps, does it include a sharps injury prevention feature and is that better than the comparator?***	***Does the innovation reduce the risk of injury after vaccine administration?***	**Overall score**
All applicable vaccines	The innovation is a label and has no influence on the number of sharps used during the preparation and administration process of the vaccine, which would be no different to the comparators.					**Neutral**
	Neutral					

1.4 Criteria on economic costs

Indicator: Commodity costs of a vaccine regimen[s] (per person vaccinated)

*Score legend: Red: **Worse than the comparator:** The projected wastage-adjusted total costs for vaccine, delivery device and safety box procurement costs per regimen is increased; White: **Neutral:** no difference with the comparator; Green: **Better than the comparator:** The projected wastage-adjusted total costs for vaccine, delivery device, and safety box procurement costs per regimen is reduced**;** N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

[r] *For all vaccines being assessed the assessment and score of this indicator remains the same as in Phase 1.*
[s] *Vaccine regimen cost refers to the vaccine product and innovation cost times number of doses for complete immunization.*

Table 17

Parameter assessment				
Vaccines	***Does the innovation reduce the purchase cost of a vaccine regimen, accounting for wastage?***	***Does the innovation reduce the purchase cost of delivery devices (injection syringes or other components needed for vaccine preparation and administration), accounting for wastage?***	***Are the safety box costs reduced because of a change in the waste disposal volumes and / or types of sharps waste generated?***	**Overall Score**
All applicable vaccines	No. However, the cost of adding a 2D barcode to an existing container label is expected to be small but may require improved vaccine labelling equipment and additional quality control processes the manufacturer would have to implement, with cost implications.	No. This innovation has no impact on delivery devices since the same delivery devices as for the comparators would be needed.	No. This innovation has no impact on the safety box costs since the volume and types of sharps waste generated would be the same as for the comparators.	Overall score: **Worse** • A 2D barcode is expected to increase commodity costs but the magnitude of the cost increase in unknown, though likely to be small. • There would be no change in delivery device or safety box costs.
	Worse	**Neutral**	**Neutral**	

Indicator: Delivery costs of the vaccine regimen (per person vaccinated)[t]

*Score legend: Red: **Worse than the comparator**: Increases the economic/delivery costs for the vaccine regimen; White: **Neutral:** no difference with the comparator; Green: **Better than the comparator**: Reduces the economic/delivery costs of for the vaccine regimen**;** **Yellow: Mixed: Increases some economic/delivery costs and decreases others or has unknown impact on other costs. N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 18

Parameter assessment					
Vaccines	***Does the innovation reduce the economic costs of cold chain storage and transport for a vaccine regimen?***	***Does the innovation reduce the economic costs of out of cold chain storage and transport for a vaccine regimen including delivery technology(ies)?***	***Does the innovation reduce the economic costs of time spent by the vaccinators when preparing and administering the vaccine?***	***Does the innovation reduce the economic costs of time spent by staff involved in stock management***	**Overall score**
All applicable vaccines	No. The innovation does not impact the volume of the vaccine and so the economic costs of cold chain storage and transport are the same as for the comparators.	No. The innovation does not impact the delivery device volume and so the economic costs of out of cold chain storage and transport are the same as for the comparators.	A study conducted in USA estimated the use of 2D barcodes could reduce the time for record keeping during vaccination sessions by 39 to 36 seconds (7). According to PATH's Vaccine Technology Impact Assessment model, vaccinator time costs in lower- and middle-income countries is ~$0.03 per minute and so the savings in time costs with a 2D barcode would be ~$0.02 per dose.	Yes. A 2D barcode would save time for staff involved in stock management. A published study conducted by PATH in Tanzania estimated that staff at a district could save about 7 hours a month when using a system with barcodes linked to an electronic vaccine information management system compared to a paper based system (8).	Overall score: **Better** • A 2D barcode does not change the cold chain or out of cold chain storage and transport costs. • It does reduce the costs of time spent by vaccinators and stock management staff.
	Neutral	**Neutral**	**Better**	**Better**	

Indicator: Introduction and recurrent costs of the vaccine regimen (per person vaccinated)

*Score legend: White: **Neutral**: There are no one-time/upfront or recurrent costs and this is not different than the comparator; Red: **Worse** than the comparator: There are one-time/upfront or recurrent costs. Dark Red: Considerably worse: There are one-time/upfront and recurrent costs.*

Table 19

Parameter assessment		Overall score
Vaccines	***How much are the introduction costs (e.g., purchase of hardware or training of health workers) and/or any recurrent or ongoing costs for this innovation, other than vaccine and delivery technology commodity costs, while taking into account the potential breadth of use of the innovation with other vaccines?***	
All applicable vaccines	Training: There would be costs for training staff on how to use the innovation. **Worse** Other costs: In order to fully utilize the benefits of barcodes on primary containers, immunisation programs would need to implement electronic health records and inventory systems requiring software and hardware including purchase of scanners and tablets or computers for each facility. There would also be monthly recurrent costs for internet connectivity and data hosting. A study in Turkey estimated that equipment and running costs with 2D barcodes were <$0.01 per dose (10). **Worse**	Overall score: **Considerably worse** • Vaccinators and stock management staff would need to be trained on how to use the 2D barcode and related software. • There would be upfront costs for software and equipment purchases, integration into other data operating systems, and recurrent costs for internet connectivity and data hosting.

1.5 Criteria on environmental impact

Indicator: Waste disposal of the vaccine regimen (per person vaccinated) and delivery system[u]

*Score legend: Red: **Worse than the comparator:** Increased volume of medical and/or sharps waste and composed of materials/packaging that does not improve the environmental impact on waste disposal; White: **Neutral:** no difference with the comparator; Green: **Better than the comparator:** Reduced volume of medical and/or sharps waste and composed of materials/packaging that improves the environmental impact on waste disposal; N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator*

[u] *This indicator is based on the assessment of waste disposal practices based on the current waste treatment management used in resource-limited settings (incineration/disinfection).*

Table 20

Parameter assessment				
Vaccine	***Does the innovation reduce the volume of medical (biohazard) disposal waste?***	***Does the innovation reduce sharps waste disposal?***	***Is the innovation, and its packaging, composed of more sustainable materials that improves waste disposal?***	**Overall score**
All applicable vaccines	The innovation is a marking added to labels on vaccine primary containers and therefore has no impact on the volume of medical or sharps waste.		Biodegradable labels could be used on vaccine primary containers which could be an improvement for waste disposal. However, the assumption is that labels containing barcodes on the primary containers would use the same materials as the comparators.	**Neutral**
	Neutral			

SECTION THREE: Assessment of feasibility for vaccine innovation product development, without comparator

1.6 Criteria on technology readiness

Indicator: Clinical development pathway complexity[v]

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

Score legend: ***High complexity:*** *Lacks a clear licensure pathway;* ***Moderate complexity****: Will likely require a phase III efficacy study and it should be possible to run a trial with a clinical endpoint (as case definitions and clinical endpoints have been agreed upon, there is sufficient disease burden to evaluate the effect of the vaccine, and trial sites and capacity are available);* ***Low complexity****: Will likely require a non-inferiority trial (as there is an available metric of potency (surrogate or correlate of protection (CoP)) to compare with the existing vaccine);* ***No complexity:*** *Will likely not require a phase III efficacy study or non-inferiority trial (as there is no change in formulation, route of administration, or delivery mechanism); N/A: the indicator measured is* ***not applicable*** *for the innovation; Grey:* ***no data*** *available to measure the indicator.*

[v] *This indicator will be evaluated in an absolute manner, not relative to a comparator.*

Table 21

Parameter assessment		
Vaccines	***Is the clinical development pathway complex?***	**Overall score**
All applicable vaccines	The application of the innovation to the vaccine will not require a phase III efficacy study or non-inferiority trial as there is no change in the formulation, route of administration, or delivery mechanism (needle and syringe).	**No complexity**

Indicator: Technical development challenges

A survey[w] of the WHO Delivery Technologies Working Group (DTWG), which is comprised of industry members and global health stakeholders, was conducted following a consultation of barcodes. 12 member organizations responded to the survey and 10 member organisations responded to the question on technical challenges. The following challenges were identified as the most important technical challenges facing the development of barcodes (most frequently identified challenges first):

- Upfront costs and investment required for implementation/uptake by countries (equipment, training, resources required for the infrastructure) to integrate within other data operating systems such as stock management systems, patient health records and other healthcare provider systems (8/10)
- Re-designing container labels to make space for 2D barcodes (7/10)
- Determining global standards for 2D barcodes for use on all vaccine primary containers (4/10)
- Obtaining 2D barcodes from GS1 (4/10)
- Acceptability by end-users in health facilities to purposefully use information encoded in barcodes within their workflow for improving patient record keeping, safety and immunisation surveillance (4/10)

Additional challenges highlighted by the DTWG:

- Readability of barcodes on primary vaccine containers, phone camera function, and counterfeit protection
- Compatibility with existing barcode requirements in country (e.g., China)

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

*Score legend: **High complexity** of technical development challenges that are unlikely to be overcome; **Moderate complexity** of technical development challenges that might be overcome with longer development time and/or more funding; **Low complexity** of technical development challenges, e.g. applying an existing barcode; N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

[w] *Survey carried out after DTWG teleconferences on barcodes held on 20th and 21st January 2020.*

Table 22

Parameter assessment		
Vaccines	***How complex are the technical challenges to overcome for successful product development (i.e. difficulties applying the innovation to a combination vaccine, reformulation requirements, vaccine not well characterized, etc)?***	**Overall score**
All applicable vaccines	Barcodes are a fully developed technology and widely used on products globally across various industries including for products used in healthcare. Adding 2D barcodes to primary vaccine container labels will require development of global standards, label redesign, and obtaining the barcodes from GS1. Label redesign will be more difficult for vaccines in small primary containers. Pfizer currently has barcodes on primary vaccine containers encoding Global Trade Item Number (GTIN) only. In order to incorporate additional information (such as name of vaccine, expiration date and lot number) on their existing barcode label, additional investment and time would be required to create more space on the product label, re-design the layout, and ensure readability of the information. Feedback from Sanofi also suggested technical challenges related to available printing space for the 2D barcodes on the primary vaccine container label – especially for vaccine products in small containers.	**Low complexity**

Indicator: Complexity of manufacturing the innovation

A survey[x] of the WHO Delivery Technologies Working Group (DTWG), which is comprised of industry members and global health stakeholders, was conducted following a consultation of barcodes. 12 member organizations responded to the survey and 10 member organizations responded to the question on manufacturing challenges. The following challenges were identified as the most important manufacturing challenges facing the development of barcodes (most frequently identified challenges first):

- Need for higher quality printers to print 2D barcodes (6/10)
- Impact of 2D barcode printing on production line speeds (6/10)
- Additional cost and time implications on vaccine production or supply (6/10)
- Adding variable information to the primary container label (4/10)
- Quality control issues (4/10)

Additional challenges highlighted by the DTWG:

- The negative impact on the manufacturing line performance in terms of speed and waste, especially if a serial number would be required on the barcode of the primary container (which would not be the case).

[x] *Survey carried out after DTWG teleconferences on barcodes held on 20th and 21st January 2020.*

Use the legend to assess and score the indicator in an absolute manner stating the level of complexity (not against a comparator)

Score legend: ***Very high complexity:*** *Novel manufacturing processes not yet under development;* ***High complexity****: Novel manufacturing processes under development;* ***Moderate complexity****: Novel processes demonstrated at pilot scale ;* ***Low complexity****: Established manufacturing processes, but cannot leverage current capacity ;* ***No complexity:*** *Established manufacturing processes available at commercial scale and access to production facilities if relevant.*

Table 23

Parameter assessment		
Vaccines	***How complex is the manufacturing process?*** ***(Specify if special materials are used)***	**Overall score**
All applicable vaccines	The innovation is produced commercially and at large-scale across multiple industries, including healthcare with medicines. While highly technically feasible, implementation of 2D barcodes on primary container labels will require some work by vaccine manufacturers – especially by those currently using lower quality label printing equipment. For Pfizer, a more expensive laser printing line would be necessary to upgrade their current barcodes on primary vaccine containers to include more information than only the global trade identification number. The new printing line would be necessary to overcome additional challenges of ensuring that any variable data being added are accurately captured and the speed of printing is maintained, otherwise it could slow down the efficiency of vaccine production. However, first tests at Pfizer indicated little impact on production line efficiency given their state-of-the art lines.[y] For Sanofi, adding 2D barcodes to primary containers would also require installation of new printing capabilities on the packaging lines, as current equipment is not dimensioned to handle 2D code printing. Printing the 2D barcode would also take more time than current label printing and require additional quality control measures.[z]	**Low complexity**

Indicator: Robustness of the innovation-vaccine pipeline

Four 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.

Use the legend to assess and score the indicator in an absolute manner stating the level of robustness (not against a comparator)

Score legend: ***Not robust:*** *There is only one single technology developer or one single vaccine supplier/manufacturer;* ***Moderately robust:*** *There are multiple technology developers, but each developer's product is unique or there are multiple vaccine manufacturers but each manufacturer product is unique;* ***Highly Robust:*** *There are multiple technology developers and they all use the same device format / manufacturing process or there are multiple vaccine manufacturers and they all produce a similar vaccine;* N/A*: the indicator measured is* ***not applicable*** *for the innovation; Grey:* ***no data*** *available to measure the indicator.*

[y] *Feedback from industry (Pfizer) key informant interview.*

[z] *Feedback from industry (Sanofi) key informant interview.*

Table 24

Vaccines	*Are there multiple developers of the technology?*	*Are there multiple suppliers/manufacturers of the vaccine?*
All applicable vaccines	The innovation is an encoded label and does not require development.	Different vaccines are at various stages of development and robustness in terms of manufacturing and production processes. As many vaccine manufacturers are already using the technology for secondary and tertiary packaging, this parameter bears no impact on the adoption of the innovation and the overall score as it is independent of the vaccine. There are manufacturers already applying barcodes to primary containers including Sanofi, Pfizer, and St Petersburg per the DTWG results and countries such as Turkey receive all their vaccines with 2D barcodes on primary containers.
	Not applicable	**Highly robust**

1.7 Criteria on commercial feasibility[aa]

Indicator: Country interest based on evidence from existing data[bb]

Summary feedback from country consultation:

- 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 was #7 (last with VVM-TIs) based on the weighted scores approach.
- Both groups mentioned the benefits of improved ability to track or have information about vaccines, saved health care worker time, improved monitoring of AEFIs or recall, improved legibility of labels and potential of improving coverage.
- Immunisation staff mentioned other benefits such easier transfer of information to patient files.
- Decision makers reported other benefits of improved record and stock keeping, and monitoring of vaccines.
- Both groups raised concerns about the equipment requirements, overall cost, training needs, requirement of computer literacy, and internet/power availability.
- Immunisation staff reported complexity and time to use the technology as possible challenges.

[aa] *These indicators will be evaluated in an absolute manner, not relative to a comparator.*

[bb] *As part of VIPS phase II activities, in-depth country consultations were conducted in 6 countries (Ethiopia, Mozambique, Nepal, Senegal, Uganda, Nigeria) gathering information from X respondents representing immunisation staff and decision makers/purchasers on vaccine specific delivery challenges faced by immunization programme and which innovations they perceived could address these challenges and provide additional benefits. The interviews were conducted between November 2019 and February 2020 by PATH and CHAI using semi-structured and open-ended questions.*

- Decision makers were also concerned about the feasibility of barcodes at service-delivery level - though 21 out of 28 decision makers interviewed expressed interest in purchasing barcodes, 4 stated potential interest, 3 participant said they would not be interested.
- Decision makers provided feedback that equipment needs are greater with scanners than with a phone-based system.
- Immunisation staff mentioned that it would be helpful to be able to transfer the data to the patient file, even if not electronic. For example, "that the bar code be moved from the vial to the immunization card at the time of immunization."
- Immunisation staff and decision makers also mentioned that it would be preferable to use this technology with a smart phone rather than a computer.

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

Score legend: ***No country interest:*** *There is interest from countries but unfavourable in LMIC contexts OR there is no interest;* ***Mixed country interest:*** *Yes there is some interest – but with concerns, e.g. with regards to implementation in LMICs, price/willingness to pay, etc.;* ***Demonstrated country interest:*** *Stakeholders demonstrated interest in LMICs; N/A: the indicator measured is* ***not applicable*** *for the innovation; Grey:* ***no data*** *available to measure the indicator*

Table 25

Parameter assessment		
Vaccines (current presentations)	***Have countries expressed interest to suggest demand for the vaccine-innovation pairing and potential country uptak***	**Overall score**
All applicable vaccines	In the VIPS Phase II online survey, 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. Turkey has successfully implemented 2D barcoding on all vaccine primary containers since 2010. A number of other countries are working to implement barcodes beginning with secondary packaging including Ethiopia, the Gambia, Tanzania, and Pakistan (1)(9)(10).	**Demonstrated country interest**

Indicator: Potential breadth of the target market

Notes:

- Estimates of market size have been based mostly on information available from WHO, UNICEF or Gavi and are based on number of doses, not the US$ value of the market for the vaccine.

- It is possible that a vaccine-innovation combination would only be used in particular settings. This possibility has not been captured in the table, which is a high-level, superficial assessment of the market.

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

Scoring legend: ***Small:*** *Limited LMIC market (e.g. use case targeting sub-population or a specific setting)*; ***Moderate:*** *No HIC market but broad use case scenario in LMIC market (e.g. vaccine available for all immunization settings);* ***Large:*** *Broad use case scenario in both HIC and LMIC markets (e.g. vaccine available for all immunization settings, as well as sub-populations and specific settings);* N/A*: the indicator measured is* ***not applicable*** *for the innovation; Grey:* ***no data*** *available to measure the indicator.*

Table 26

Parameter assessment		
Vaccines	***How broad is the potential target market?***	**Overall score**
All applicable vaccines	Since barcodes can be used with all vaccines they have a broad use scenario and large potential market in both HICs and LMICs.	**Large**

Indicator: Existence of partnerships to support development and commercialisation[cc]

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

*Score legend **for donor and/or stakeholder support column:** **No interest:** No known donor and/or stakeholder support; **Moderate interest**: Donors and/or stakeholders have expressed interest by funding or providing technical support to research;**Significant interest:** Support from donors and/or stakeholders with intent or mandates to bring the innovation to market; N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

*Score legend **for technology developer and vaccine manufacturer partnership column**: **No interest:** No known technology developer and vaccine manufacturer partnerships, even for early stage work; **Moderate interest**: Technology developer and vaccine manufacturer partnerships have expressed interest by funding, conducting, and/or collaborating on research (e.g., on preclinical or early stage clinical trials for combined vaccine/delivery products or on feasibility or pilot studies for labelling products); **Significant interest:** Technology developer and vaccine manufacturer partnerships are committed to commercialise the innovation-vaccine combination; N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

*Score legend **for overall score**: **No interest:** No known interest from donors/stakeholders AND technology developer/vaccine manufacturer partnerships; **Mixed interest:** Different levels of interest from donors/stakeholders and technology developers/vaccine manufacturer partnerships; **Moderate interest**: Moderate interest from donors/stakeholders AND technology developer/vaccine manufacturer partnerships; **Significant interest:** Significant interest from donors/stakeholders AND technology developer/vaccine manufacturer partnerships; N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator*

Table 27

Parameter assessment			
Vaccines	***Is there current donor/stakeholder support for the vaccine-innovation pairing?***	***Do partnerships exist between at least one of the technology developers and a vaccine manufacturer or have vaccine manufacturers expressed interest?***	**Overall score**
All applicable vaccines	A number of vaccine manufacturers already have production lines for application of 2D barcodes for secondary and tertiary packaging, so the development/commercial aspect of barcodes is well established and just needs to be applied appropriately to the primary level packaging of vaccines. WHO currently recommends barcodes for secondary and tertiary packaging of vaccines to conform to GS1 standards by encoding the unique ID called the Global Trade Item Number (GTIN), vaccine expiry date and vaccine batch/lot number in order to track and trace distribution of the product. This recommendation is expected to become a critical characteristic necessary for WHO	The application of the innovation does not involve a partnership, per se, between a technology developer and vaccine manufacturer since the innovation is freely available to all vaccine manufacturers and implementation can be facilitated through GS1, a global, non-profit organisation that sets the standards for barcodes. A number of vaccine manufacturers have moved forward with barcodes on primary packaging to meet demand from particular countries and/or to comply with their national regulatory authorities. The US CDC has a list of vaccine primary containers (vials and syringes) which are labelled with	**Significant interest**

[cc] *If the innovation is a stand-alone device and does not require a partnership with a vaccine manufacturer for commercialization, this indicator is not applicable.*

Parameter assessment			
Vaccines	***Is there current donor/stakeholder support for the vaccine-innovation pairing?***	***Do partnerships exist between at least one of the technology developers and a vaccine manufacturer or have vaccine manufacturers expressed interest?***	**Overall score**
	prequalification as described on page 13 of the WHO handbook for Assessing the programmatic suitability of vaccine candidates for WHO prequalification[dd] . Gavi and UNICEF[ee] recently announced that starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021. It is a natural progression to begin with barcode implementation on higher levels of vaccine packaging prior to moving to primary packaging where the greatest public health benefits will be realized.	2D barcodes and produced by various manufacturers[ff]. Many of these suppliers also provide vaccines through UNICEF including GSK, Merck, Sanofi Pasteur, and Wyeth/Pfizer. All vaccine primary containers produced by Pfizer have barcode labels with GTIN data encoded. Vaccine producers from the Developing Country Vaccine Manufacturers Network will also begin with implementation on secondary packaging by 2021 to comply with the new Gavi/UNICEF requirement.	
	Significant interest	**Significant interest**	

Indicator: Known barriers to global access to the innovation

Use the legend to assess and score the indicator in an absolute manner (not against a comparator)

Score legend: ***Yes:*** *IP not accessible and no freedom to operate;* ***Mixed:*** *IP and freedom to operate accessible within 5-10 years;* ***No:*** *No known barriers to access and/or IP is in the public domain; N/A: the indicator measured is* ***not applicable*** *for the innovation; Grey:* ***no data*** *available to measure the indicator.*

[dd] *Assessing the programmatic suitability of vaccine candidates for WHO prequalification (page 13). http://apps.who.int/iris/bitstream/handle/10665/148168/WHO_IVB_14.10_eng.pdf?sequence=1&ua=1*
[ee] *UNICEF supply: https://www.unicef.org/supply/index_103734.html*
[ff] *List of 2-D Vaccine Barcodes (CDC); https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/index.html*

Table 28

Parameter assessment		
Vaccines	***Are there known barriers to Global Access to the innovation as applied to the vaccine ?***	**Overall score**
All applicable vaccines	No known barriers. The technology has been placed in the public domain and is freely available to all vaccine developers.	**No**

SECTION FOUR: Summary

ABILITY OF THE INNOVATION TO ADDRESS IMMUNIZATION ISSUES

The use of barcodes on primary vaccine packaging can improve the quality and accuracy of inventory data for vaccine stock management and traceability in supply chains leading to reduced stockouts and better efficiencies. Their use can also improve the quality and accuracy of patient vaccination records leading to improved safety, reductions in missed opportunities, better surveillance, and improved coverage. Countries are steadily moving towards use of electronic recordkeeping with 57% of respondents from the VIPS online survey (out of 129 participants from 49 countries) and 22% of respondents (out of 127 participants from 49 countries) stating that their country already uses electronic systems for vaccine inventory and for patient record keeping respectively, and the majority reporting that their immunization program would benefit from increased use of electronic records. While it will take some countries time to obtain the equipment and implement barcode scanning at all health systems levels, other countries are poised to move forward and would require the availability of barcodes on vaccine product labels to do so.

SYNERGIES WITH OTHER VIPS INNOVATIONS

Barcodes on vaccine primary packaging could be paired with nearly all other VIPS innovations since most involve primary containers that could be labelled with barcodes including compact prefilled autodisable devices, heat stable/controlled temperature chain-qualified liquid vaccines, solid dose implants, dual chamber delivery devices, microarray patches, and freeze damage resistant liquid formulations. Barcodes could be compatible and integrated with vaccine vial monitors with threshold indicators which are also labels on primary containers. While barcodes could be used to label autodisable sharps injury protection syringes, these syringes are not vaccine primary containers so are not being considered in this context.

References:

1. Au L, Oster A, Yeh GH, Magno J, Paek HM. Utilizing an electronic health record system to improve vaccination coverage in children. Appl Clin Inform [Internet]. 2010 Jul 14;1(3):221–31. Available from: https://www.ncbi.nlm.nih.gov/pubmed/23616838
2. Laroche JA, Diniz AJ. Immunisation registers in Canada: progress made, current situation, and challenges for the future. Eurosurveillance. 2012;17(17):20158.
3. Haque SN, West S, O'Connor A. Mapping of Standards to Facilitate Immunization Information Exchange through Two-Dimensional Bar Coding of Vaccine Products. Perspect Heal Inf Manag. 2017;14(Fall).
4. Yeung CL, Kwok SK, Mui HC. An investigation of an RFID-based patient-tracking and mobile alert system. Int J Eng Bus Manag. 2011;3:2.
5. Daily A, Kennedy ED, Fierro LA, Reed JH, Greene M, Williams WW, et al. Evaluation of scanning 2D barcoded vaccines to improve data accuracy of vaccines administered. Vaccine. 2016 Nov;34(47):5802–7.
6. Uy RCY, Kury FP, Fontelo PA. The state and trends of barcode, RFID, biometric and pharmacy automation technologies in US hospitals. In: AMIA Annual Symposium Proceedings. American Medical Informatics Association; 2015. p. 1242.
7. O'Connor AC, Kennedy ED, Loomis RJ, Haque SN, Layton CM, Williams WW, et al. Prospective cost–benefit analysis of a two-dimensional barcode for vaccine production, clinical documentation, and public health reporting and tracking. Vaccine. 2013;31(31):3179–86.
8. PATH. Tanzania 2D barcode implementation - Barcode costing study for vaccine management in Tanzania.
9. PATH. Implementing GS1 standards in public sector supply chain in Pakistan, A pilot study. USAID Deliv Proj. 2015;
10. Ahmet Ozlu and Osman Erkan Say. Using barcodes for managing vaccine stocks. Public Heal Inst Turkey.