VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase II executive summary: Solid-dose implants (SDIs)

March 2020

Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Solid-dose implants (SDIs)

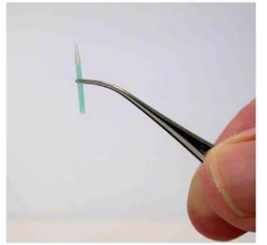
About SDIs

- SDIs **consist of vaccines (including antigens, adjuvants and excipients)** that have been **reformulated into a solid format**. This is typically **shaped like a needle** that is sharp and strong enough to be **implanted below the skin** and the dose it contains either dissolves immediately or is released slowly.
- In some cases, SDIs are contained in a **cartridge or cassette** for easy handling.
- An **applicator is used to propel the SDI into the skin** using a spring or compressed gas. The applicator might be separate and re-usable, or integrated and single use.
- SDIs could be regarded as an **alternative to microarray patches (MAPs)** as they should not have the reactogenicity of MAPs and possibly have a higher payload. But SDIs have other drawbacks such as the need for an applicator and being earlier in development than MAPs.

Stage of development

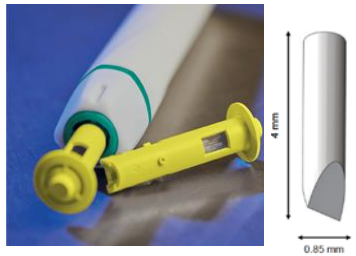
- SDIs are in a **very early stage of development**.
- **No clinical studies with vaccines have been published.**

Hirschberg HJHB, 2008 [a]



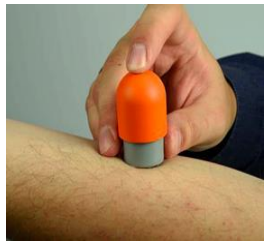
Separate, compressed gas-powered applicator (Bioneedle)

www.enesipharma.com [b]



Separate, spring-powered applicator (Implavax®)

Nemaura presentation [c]



Optional, separate applicator (Micropatch™)

[a] Hirschberg HJHB, van de Wijdeven GGP, Kelder AB, van den Dobbelsteen GPJM, Kersten GFA. Bioneedles as vaccine carriers. Vaccine. 2008 May 2;26(19):2389–97.
[b] https://www.enesipharma.com/technologies/platform/
[c] Nemaura presentation. Teriparatide microneedle patch for osteoporosis, December 2018. Presented during telecon 12 February 2019.

Summary of key insights (1/2)

Potential public health impact of innovation

Applicability to vaccines

- **SDIs could be applicable to most vaccines that are currently injected,** and could be viewed as an alternative innovation to MAPs, however:
  - **Vaccines will need to be reformulated** and there are few data on how feasible this will be;
  - Adjuvants might need to be removed, which **could reduce immunogenicity;**
  - The **limited payload of some SDIs** might make them unsuitable for some vaccines;
  - There are insufficient data to indicate which vaccines might be more suitable for use with SDIs rather than MAPs.

Public health benefits

- **Public health benefits** across vaccines may include:
  - **Resistance to heat exposure** and facilitating **use within the controlled temperature chain;**
  - **Easier to prepare/use**, allowing for **lesser trained staff** to administer the vaccines;
  - Single-dose presentation, potentially **reducing the missed opportunities** and **contamination risks** associated with multi-dose vials;
  - **Improved acceptability** to caregivers/parents based on **perceived ease of administration;**
  - **Improved safety** by **avoiding reconstitution errors** and avoiding **needle-stick injuries**.
  - Fewer components than needle and syringe delivery for lyophilised vaccines, **reducing the risk of stock-outs.**

Vaccine problem statements

- **SDIs could potentially address many of the top 5 problem statements for compatible vaccines** such as HPV, MenA, MR, IPV, rabies, TCV and yellow fever**,** particularly those related to:
  - **Heat stability** and **cold-chain requirements;**
  - **Safety issues**, including those associated with multi-dose vials and reconstitution;
  - **Ease of use.**

Summary of key insights (2/2)

Barriers to realise the innovation's potential impact

Costs

- The **commodity costs for SDIs are unknown but are very likely to be higher than for vials and N&S.**
- Delivery and distribution costs are also unknown and will depend on factors such as whether an applicator is required, whether it is reusable and whether it is distributed in the cold chain.

Technology Readiness

- **SDIs are very early in development** (less advanced than MAPs). Major **technical challenges need to be addressed, some** vaccine-specific and some that apply to all vaccines in the areas of **formulation** and developing and scaling up **manufacturing processes.**
- As such, there is **still significant risk associated with their development.**

Commercial feasibility

- The **commercial feasibility of SDIs is uncertain**. The device costs and market potential are not known and vaccine manufacturers will need an incentive to adopt the technology.

Countries interest

- Based on the VIPS country interviews, there is **relatively little country-interest in SDIs at this point**. This might be due to lack of familiarity with the technology.

SDIs have a broad applicability to vaccines

	VIPS Phase II analysed vaccines	Vaccine Type	Presentation	Route
Vaccines **technically compatible** with SDIs and analysed in Phase II.				
Licensed vaccines	**Penta** (or DTP containing)	Adjuvanted inactivated subunit plus polysaccharide-protein conjugate	Liquid	IM[1]
	Hepatitis B (birth dose)	Adjuvanted sub-unit	Liquid	IM
	HPV	Adjuvanted sub-unit	Liquid	IM
	MR (or MCV)	Live attenuated	Lyophilised	SC[4]
	N. Men A (or N. Men A,C,W,Y,X)	Conjugate, adjuvant in diluent	Lyophilised	IM
	Polio, IPV	Whole inactivated	Liquid	IM or ID[6]
	Rabies	Whole inactivated	Lyophilised	IM or ID
	Typhoid, conjugate (TCV)	Polysaccharide-protein conjugate	Liquid	IM
	Yellow fever (YF)	Live attenuated	Lyophilised	SC
Pipeline vaccines	**Ebola** (rVSV-ZEBOV)[7]	Live vector	Liquid (FROZEN)	IM
	HIV (ALVAC prime only)[8]	Live recombinant virus	Lyophilised	IM
	Influenza (pandemic,VAL-506440)	Lipid nanoparticle, modified RNA	Liquid	IM
	RSV (Pre-F)	Recombinant protein	Lyophilised	IM
Vaccines **not technically compatible** with SDIs & not analysed in Phase II	**Rotavirus** (Oral)	Live attenuated virus	Liquid	Oral
	ETEC (ETVAX)	Whole inactivated organism	Liquid vaccine, lyophilised buffer and adjuvant	Oral
	HIV (bivalent subtype C gp120 boost only) [8]	Adjuvanted recombinant protein	Liquid	IM
	Malaria (RTS,S)	Adjuvanted recombinant protein	Lyophilised, liquid adjuvant	IM
	MTb (next gen.,VPM1002)	Live recombinant BCG	Lyophilised	ID

Applicability to vaccines

13 vaccines are technically compatible and have therefore been assessed with SDIs (out of 17 in scope) in Phase II.

Vaccine applicability:

- **SDIs** could potentially **deliver most vaccines currently administered by injection with N&S,** similar to MAPs. At this point, there is not enough data to indicate which vaccines might be more suitable for use with SDIs rather than MAPs.
- Vaccines **with adjuvants** are likely to have a **more challenging** development pathway.
- SDIs deliver vaccine SC and **might not be suitable for** vaccines that require **intradermal (ID) delivery.**
- Technical feasibility was assessed based on data, when available, and expert opinion. Key considerations included the natural route of infection, vaccine type, use of adjuvants and preservatives, and context of use.

Comparators:

To assess innovations against both 'best practice' and 'current practice', comparators were defined as:

- **SDV[2] presentation** and AD N&S[3],
- If available, the **MDV[4] presentation** commonly procured by LMICs.

[1] Intramuscular; [2] Subcutaneous; [3] Intradermal; [4] Single-dose presentation; [5] Auto-disable needle & syringe; [6] Multi-dose presentation; [7] At the time of the assessment, Ebola vaccine was not yet licensed and has been analysed as a pipeline vaccine; [8] 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.

Beyond the 17 vaccines analysed through VIPS, SDIs should be compatible with a range of other vaccines

**Pipeline vaccines*

Applicability to vaccines

VIPS vaccines assessed to be compatible with SDIs	Vaccine type	Other vaccines likely to be compatible with SDIs
HepB; pentavalent	Subunit, liquid, adjuvant	dT; TT; DTwP; DTaP; hexavalent; *non-replicating rotavirus; GAS; next generation malaria; CEPI vaccine platform (clamp); Shigella; ETEC*
HPV	VLP or inactivated virus, liquid, adjuvant	JE (inactivated); hepA; *non-replicating rotavirus; RSV*; *improved or universal influenza; influenza (pandemic)*
IPV	Inactivated virus, liquid	Influenza (seasonal); *RSV*
Men A	Polysaccharide-protein conjugate, lyophilised	Men ACWY(X)
MR; YF; *HIV (ALVAC viral vector prime)*	Live attenuated virus, lyophilised	MCVs; JE (live attenuated); dengue; influenza (seasonal); *CEPI vaccine platforms (live recombinant vectors); chikungunya, HSV; next generation malaria; RSV*
Rabies	Inactivated virus, lyophilised	*R&D Blueprint vaccines*
Typhoid	Polysaccharide-protein conjugate, liquid	Pneumococcal conjugate vaccine; Hib, Men ACWY (liquid); *GBS*; *Shigella*
Ebola	Live vector, liquid,	*CEPI vaccine platforms (rVSV); R&D Blueprint vaccines; HSV; next generation malaria; RSV*
Flu (pandemic)	Nucleic acid, liquid	*CEPI vaccine platforms (DNA, RNA), HSV*
RSV	Subunit, lyophilised	

Overview of SDIs public health benefits based on Phase II analysis

Comparator: MDV

Vaccine with an elimination agenda

Public health benefits

VIPS Criteria	Indicators	Penta	Hep B BD	HPV	MR	Men A	IPV	Rabies	TCV	YF	Ebola	HIV[5]	Influ-enza[6]	RSV[7]
Primary criteria – Health impact	Vaccine efficacy	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Vaccine effectiveness	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Ability of the vaccine presentation to withstand heat exposure	No data	Better	No data	No data	No data	Better	No data	No data	No data	No data	No data	No data	No data
	Ability of the vaccine presentation to withstand freeze exposure	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Primary criteria – Coverage & Equity impact	Number of fully or partially immunised (relative to target population)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Ease of use: clinical perspective based on product attributes	Better	Better	Better	Better	Better	Better	Mixed	Better	Better	Better	Better	Better	Better
	Ease of use: ability of a lesser trainer personnel to admin. / self-admin.	Better	Better	C. better	C. better	C. better	Better	C. better	C. better	C. better	C. better	C. better	C. better	C. better
	Ability to facilitate dose sparing	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Avoid missed opportunities and reduce vaccine wastage[1]	Better	Better	C. better	C. better	C. better	Better	Better	Better	C. better	Neutral	Neutral	Neutral	Neutral
	Acceptability of the vaccine presentation and schedule[2]	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better
	Potential to reduce stock outs[3]	Neutral	Neutral	Neutral	Better	Better	Neutral	Better	Neutral	Better	Neutral	Better	Neutral	Better
Primary criteria – Safety impact	Number of vaccine product-related AEFIs	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Likelihood of contamination and reconstitution errors	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better
	Likelihood of needle stick injury	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better
Primary criteria – Economic costs	Commodity costs of the vaccine regimen[4]	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Delivery costs of the vaccine regimen[4]	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
	Introduction & recurrent costs of the vaccine regimen[4]	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse	Worse
Primary criteria – Environmental impact	Waste disposal of the vaccine regimen[4] and delivery system	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better	Better

[1] Based on availability of the innovation in a single-dose presentation or multi-dose with preservative. The score would be neutral for all vaccines if the comparator was a SDV.; [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; [5] ALVAC prime; [6] VAL-506440; [7] Pre-fusion F protein

Phase II confirms SDIs' broad potential public health benefits for a range of compatible vaccines

Public health benefits

Based on the assessment using VIPS primary indicators applied to SDIs with specific vaccines, SDIs can **potentially address many immunisation challenges for a range of compatible vaccines.**

- **Resistance to heat exposure** and facilitating **use within the controlled temperature chain** assuming the SDI formulation confers improved heat stability – *data supporting this have only been obtained with Hep B and IPV to date*.
- **Easier to prepare/use** allowing **lesser trained staff** to administer the vaccines, based on product attributes. SDIs score considerably better for vaccines that can be given to adolescents/adults because they **might enable self administration in these groups**.
- SDIs might **improve acceptance** as they are **perceived** as being better than needle and syringe for ease of administration[1].
- SDIs are a single-dose presentation, **reducing missed opportunities** due to reluctance to open a multi-dose vial. *Particularly relevant for vaccines with preservative-free multi-dose presentations such as HPV, MR, MenA and YF.*
- SDIs do not require reconstitution so the **risks of reconstitution-related errors and contamination are reduced**. *This is relevant for all lyophilised vaccines, such as MR, MenA, rabies, YF.*
- Fewer components, so should **reduce risk of stock-outs** *for lyophilised vaccines.*
- Needle-free delivery, **avoiding needle-stick injuries** *for all vaccines.*
- Sharps-free, so expected to **simplify waste-disposal** *for all vaccines.*

[1] Data from a developer's human factors study that did not involve actual injection of the SDI

Overview of the ability of SDIs to address vaccine specific problems identified in the VIPS Phase II country online survey[1]

Vaccine problem statements

Vaccine with an elimination agenda

	Penta	Hep B BD	HPV	MR	MenA	IPV	Rabies	TCV	YF	Ebola	HIV[3]	Influ-enza[4]	RSV[5]
Vaccine ineffectiveness/wastage due to **heat exposure**	2	2	4	1	3	2	2	1					
Vaccine ineffectiveness/wastage due to **freeze exposure**	1	1	1			1		5	3				
Cold chain requirements during outreach[2]	4	3	3	4	1	3							
Vaccine wastage or missed opportunities due to **multi-dose vial**[2]				1	2		4	2	1				
Reconstitution related **safety issues**[2]				3	4				2				
Reduced acceptability due to painful administration[2]	3	5	2			4	3						
Difficult preparation requiring trained personnel[2]		4	5				1	4					
Negative impact on the environment due to waste disposal practices[2]						5			5				
Needle-stick injuries[2]				5	5		5		4				
Contamination risk due to multi-dose vial[2]	5												
Difficult to deliver vaccine to correct injection depth[2]								3					

[1] Based on an online survey with 209 global experts and country-level stakeholders across 54 countries conducted in Q4 2019 – Q1 2020, top 5 challenges identified by countries per licensed vaccine were selected as 'vaccine problem statements' to be specifically analysed. Numbers in the table refer to the ranking order of top 1 to 5 problem statements. For pipeline vaccines, problem statements were defined by the VIPS WG. [2] Scoring based on product attributes. [3] ALVAC prime; [4] VAL-506440; [5]Pre-fusion F protein

No data available for assessment | No difference with the comparator | Better than the comparator | Considerably better than the comparator

SDIs have the potential to address many of the countries' top 5 vaccine problem statements for the applicable vaccines

Vaccine problem statements

The overlay of the top 5 problem statements by vaccines with the VIPS primary indicators assessment shows that **SDIs have the potential to address many top 5 vaccine problem statements for a broad range of vaccines:**

- **Resistance to heat exposure,** facilitating **use within the controlled temperature chain** and **reducing cold-chain requirements** – assuming the SDI formulation confers improved heat stability. *Identified as an important problem for the **majority of the 13 vaccines assessed**.*
- Single-dose presentation, potentially **reducing missed opportunities** due to vaccine wastage or reluctance to open a multi-dose vial. *Identified as an important problem for vaccines in multi-dose presentations like **MR, MenA and YF**, as well as **rabies and TCV**.*
- **Reducing contamination risks** associated with the use of multidose vials. *Identified as an important problem for **preservative free vaccines in MDVs** and **pentavalent vaccine**.*
- No need for reconstitution, therefore **avoiding reconstitution errors.** *An important problem for **lyophilised vaccines (MR, MenA and YF)**.*
- **Easier to prepare/use**, saving time and allowing for **lesser trained staff** to administer the vaccines. *Identified as an important problem for **rabies, HepB, TCV, and HPV**.*
- SDIs are sharps-free, so **needle-stick injuries should be reduced,** *identified as the problem ranked #5 for **MR, MenA, rabies** and #4 for **YF*** and **waste-disposal** should be **simpler**, *also the problem ranked #5 for **IPV and YF***.
- SDIs have been **perceived** as being **easier to administer** based on the appearance of the device**,** which might improve acceptability. There are however, **no data on the pain associated** with vaccination with SDIs.

SDIs will likely have a higher cost than single dose vial (SDV) and multi-dose vial (MDV) alternatives

Costs

Commodity costs[1, 2]

Unknown, however likely to be higher than for SDV or MDV:

- There are **no data on the cost of goods (COGS)** or purchase price of an SDI.
- However, for combination products like SDIs, it is likely that the **COGS and procurement price will be higher** than for vaccines in SDVs and MDVs, **particularly if a separate applicator is required**.
- Previous studies have shown that for the comparators, the 'vaccine + vial' price is larger than the combined cost of delivery devices and safety boxes. **Therefore, the increase in 'vaccine + SDI' price is likely to outweigh savings in other commodity costs components.**

Delivery costs[1, 3]

Unknown. This will depend on SDIs' volume in the cold chain and vaccinator time for preparing and administering the vaccine:

- The **costs for storage and transport** in the cold chain is **unknown** due to lack of data on volume of SDIs, (which will be developer-specific).
- **Whether or not the separate applicator (if required) is distributed in or out of the cold chain will have a significant impact on the cold-chain volume.**
- The **impact on the vaccinator time costs is unknown**.

Introduction and recurrent costs[1]

Introduction costs due to training needs:

- **Training would be required** to introduce SDIs as is the case for any innovation.
- **No upfront costs for hardware**, recurrent or ongoing costs for SDIs.

[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;

SDI development is still early and faces significant challenges that will require substantial time, effort and investment to be overcome

Technology Readiness

Vaccine with an elimination agenda

VIPS Criteria	Indicators	Penta	Hep B BD	HPV	MR	MenA	IPV	Rabies	TCV	YF	Ebola	HIV[3]	Influ-enza[4]	RSV[5]
Secondary criteria	Technology readiness[1]													
	Clinical development pathway complexity	Low	Low	Low	Low	Low	Low	Low	Low	Low	Moderate	High	Low	Moderate
	Technical development challenges	High	Moderate	High	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	High	Moderate	High	Moderate
	Complexity of manufacturing the innovation	High												
	Robustness: multiple developers of the technology	No data	No data	No data	Not robust	No data	Not robust	No data	No data	No data	No data	No data	No data	No data
	Robustness: multiple suppliers/manufacturers of the vaccine	High	High	Moderate	Moderate	Not robust	Moderate	Moderate	Not robust	Moderate	Not robust	Not robust	Not robust	Moderate

- SDIs are at a **very early stage** in development. Although SDIs might be regarded as an alternative or back-up to MAPs, they are at an earlier stage and there is still significant risk in their development. To date there have been **no clinical trials** with SDIs containing vaccines.
- There are **significant challenges** facing the **technical development and manufacturing** of SDIs. Some issues are vaccine-specific but some, particularly manufacturing issues, apply to the platform overall.
- Novel manufacturing processes will need to be developed and be scalable.
- Based on limited data, the **number of** SDI developer–vaccine manufacturer **partnerships is believed to be low** (not 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 prime; [3] VAL-506440; [4]Pre-fusion F protein

SDI development is still early, and many key technical and manufacturing issues need to be addressed

Technology Readiness

Regulatory	Technical	Manufacturing	Vaccines
• **Clinical development:** For licensed vaccines, phase III bridging studies with immunogenicity endpoints should be sufficient. For novel vaccines, the same (clinical) endpoints would be required as for needle and syringe (N&S) or other delivery methods. • **Biocompatibility** of the dissolvable delivery components will need to be assessed. • **Removal of adjuvant** means the vaccine may be considered as “new” from a regulatory point of view. • **Usability studies** might be required, particularly if depth of delivery is critical.	• **Adjuvants.** It might not be possible to incorporate adjuvants into SDIs. If these are absent, immunogenicity might be reduced. • **Formulation:** SDIs need to be formulated to have sufficient structural integrity to penetrate the skin but be able to dissolve in SC tissue. Slow-release or residual implant material might result in granuloma formation. • **Quantity of vaccine required:** Some SDIs have limited payload capacity, which might be insufficient for some vaccines.	• **Developing a cGMP manufacturing process:** Aseptic manufacture will be required. The manufacturing processes (including assembly and packaging) will be novel and unique and need to be developed, tested at pilot scale and scaled up. • **Quality control:** Novel methods for in-process controls and process validation will be required, and possibly novel assays for product release. • **Manufacturing time per unit:** The process will need to operate at commercial scale and be competitive with the process for other delivery methods, e.g. vials and N&S.	• **‘Best’ vaccines** from a development/manufacturing perspective may be **IPV**, and **live attenuated viruses** (e.g. MR, YF) due to the amount of antigen required and the absence of an adjuvant. • **Other currently-lyophilised vaccines** might be suitable. • **SDIs** deposit vaccine SC, so **might not be suitable for** vaccines that require **ID delivery,** e.g. **VPM1002 (next gen Mtb) and BCG. Dose-sparing using ID** delivery for fractional doses of **IPV and rabies** vaccines **might not be possible.**

The commercial opportunity for SDIs in LMICs is highly uncertain and developers and manufacturers will need an upside to create partnerships

Commercial feasibility

VIPS Criteria	Indicators	Penta	Hep B BD	HPV	MR	MenA	IPV	Rabies	TCV	YF	Ebola	HIV[1]	Influ-enza[2]	RSV[3]
Secondary criteria: Commercial feasibility	Country stakeholders' interest based on evidence from existing data	No data												
	Potential breadth of the target market	Large	Large	Large	Large	Moderate	Moderate	Small/ Moderate	Small/ Moderate	Moderate	Small	Large	Small	Large
	Existence of partnerships to support development and commercialisation	No known interest	No known interest	No known interest	Moderate	No known interest	No known interest	No known interest	No known interest	No known interest	No known interest	No known interest	No known interest	No known interest
	Known barriers to global access to the innovation	No data												

- **No data were found to indicate interest in using SDIs from country stakeholders.** This might be due to lack of familiarity with the technology; SDIs are at a very early stage in development.
- **Market potential and uptake for SDIs in LMICs** is **highly uncertain** and will likely need to be driven by a **dual-market in HICs**, at least at the beginning:
  - Financial attractiveness of SDIs will be determined by the **value proposition in HICs.**
  - **Cost of goods** compared with N&S & vials is **unknown** but is likely to be higher for SDIs. This may drive the choice of initial use case for SDIs in LMICs.
- **Partnerships to support further early development and commercialisation will be required:**
  - Eventually, **agreement between vaccine manufacturers and SDI developers** will be needed regarding responsibility for release of the final combination product, royalty sharing and liability during clinical testing.

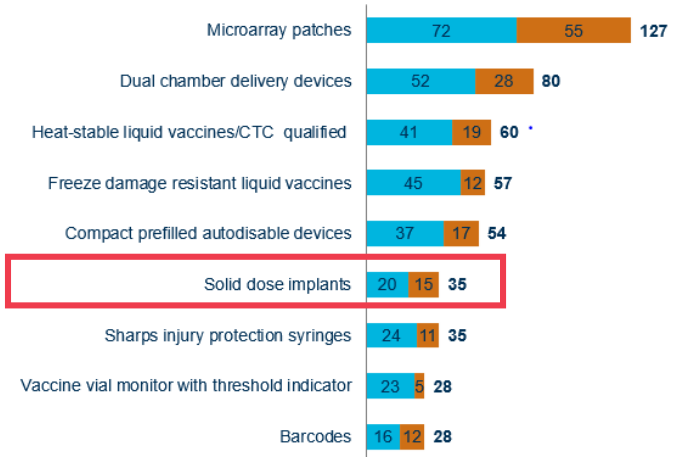
[1] ALVAC prime; [2] VAL-506440; [3]Pre-fusion F protein

Based on VIPS country feedback[1], there is relatively little country interest in SDIs

Countries interest

Feedback from in-person country interviews

Innovations' ranking



- SDIs are rated **overall #6 amongst the 9 tested**, i.e. for their potential impact in helping address immunisation programme's current challenges, but **#8 by immunisation staff and #5 by decision makers** (based on a weighted score approach).

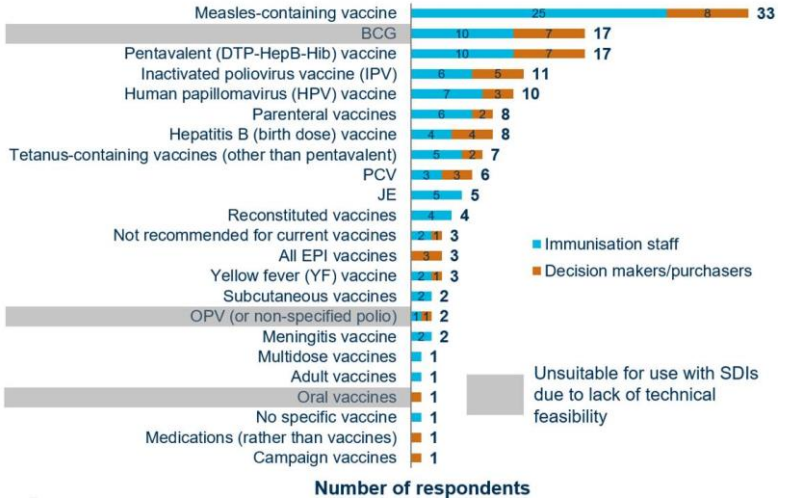
Perceived benefits

- Make **preparation, administration** & **logistics** of vaccines **easier and faster;**
- **Increase acceptability** to recipient/caregivers, e.g. less painful;
- **Save time** of immunisation, improve safety by **reduced needle-stick injuries** and improve **waste disposal**;
- Decrease **vaccine wastage** due to single dose presentation and reduce **contamination risk.**

Perceived challenges

- **Immunisation staff: Time** required, **complexity of the technology, acceptability to patients/ caregivers,** specifically for SDIs with applicator**, and need for community sensitisation;**
- Impact on **cold chain volume** and **cost;**
- **Training.**

Vaccines' ranking for SDIs



[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

Potential impact of VIPS prioritisation

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

What could VIPS do to accelerate SDIs development for LMICs	Risks of not prioritising SDIs through VIPS
If SDIs were to be prioritised by VIPS, **stakeholder inputs would be sought to identify follow-up activities** that would have the **greatest impact on accelerating** SDI development. These could include: • **The creation of partnerships between developers, manufacturers and possibly donors/funders,** to facilitate access to vaccines. • **Push-funding (possibly) to support development of the technology**. In particular, clinical proof of concept is needed for SDIs. • **Developing an innovative pull-funding mechanism** (possibly, in the longer term). • **Country and cost analyses** to provide clarity on use-case scenarios in LMICs.	• There might not be an immediate downside. **SDI developers might continue but not favour LMIC products.** • SDIs are early-stage/high risk and products have a long lead time. **Additional delays might not be significant** viewed in that context. • Vaccine **manufacturers might de-prioritise working with SDI developers**, reducing access to vaccines and delaying programmes. • **SDIs could be a back-up or alternative technology to MAPs**. Despite the points above, if non-prioritisation were to have a negative impact on SDI development, it **might reduce the number of technology options available.**

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