VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Intradermal (ID) Devices

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

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Intradermal (ID) Devices

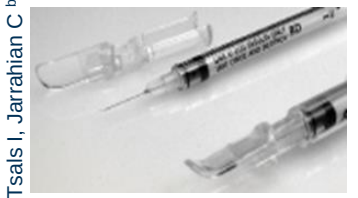
About ID Devices

- ID devices and delivery devices **used to inject vaccines into epidermal and dermal layers of the skin**. They **have been developed to improve the ease and accuracy of ID injections** which are given at an acute angle to the skin to deposit the vaccine just below the surface (Mantoux technique).
- ID devices are grouped into three sub-types for this assessment:
  1. **Needle hubs and syringe adapters (with needles)** that fit onto the end of luer syringes. They have an integrated short needle or needles (typically less than 1.5 mm) that only penetrate the skin to the depth of the dermis.
  2. **Syringe adapters (without needles)** that attach to standard Bacille Calmette-Guerin (BCG) or insulin syringes with needles are designed to control the angle & depth of needle penetration.
  3. **Field-filled ID syringes** that resemble a standard syringe but incorporate some form of needle (e.g. plastic needle) for filling and a short (less than 1.5 mm) needle for injection.

www.nanopass.com

Needle-hub

Tsals I, Jarrahian C [b]



Syringe-adapter
(without needle)

www.cugh.org [a]

Field-filled ID syringe.
Star intradermal safety device

Stage of development

- Some ID devices have **received regulatory approval as medical devices** e.g. 510(k) in the USA or CE mark in Europe. One ID adapter and one needle-hub are available commercially.
- ID devices are not combination products and **might not require approval with a specific vaccine** from a named manufacturer.
- Several other devices are in **very early stage of development** and most/all of the devices in development **do not include auto-disable (AD) features**.

[a] https://www.cugh.org/sites/default/files/TS01.2_Zehrung.D.pdf
[b] Tsals I, Jarrahian C, Snyder FE, Saganic L, Saxon E, Zehrung D, et al. Clinical performance and safety of adapters for intradermal delivery with conventional and autodisable syringes. Vaccine. 2015 Sep 8;33(37):4705–11.

Intradermal (ID) devices scorecard

Comparator: Bacille Calmette-Guerin (BCG) autodisable (AD) needle and syringe (N&S) , using Mantoux technique

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Quality of evidence: Low to moderate

VIPS Criteria		Indicators	Sub-types			Priority indicators - Country consultation		
			ID needle-hub	ID adapter	ID syringes	RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	Neutral	Neutral	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral	Neutral	Neutral			
	Coverage & Equity impact	Ease of use [a]	Worse	Worse	Worse	+	+	++
		Potential to reduce stock outs [b]	Worse	Worse	Worse			
		Acceptability of the vaccine presentation to patients/caregivers	Better	No data	Better		+	+
	Safety impact	Likelihood of contamination	Worse	Worse	Worse			+
		Likelihood of needle stick injury	Worse	Worse	Neutral			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Considerably worse	Neutral	Neutral	+		
		Total economic cost of the time spent by staff per dose	Neutral	Neutral	Neutral	++	++	+
		Total introduction and recurrent costs [c]	Neutral	Neutral	Neutral			
Secondary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All parenteral vaccines are potential candidates					
		Ability of the technology to facilitate novel vaccine combination	No					

* RI : Routine immunisation

++	Given significantly more importance
+	Given more importance
	Kept neutral

[a] Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration
[b] Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities
[c] Total economic cost of one-time / upfront purchases or investments required to introduce the innovation and of recurrent costs associated with the innovation (not otherwise accounted for)

Intradermal (ID) Devices: Antigen applicability

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- ID devices could be **applied to any vaccine that can be delivered intradermally,** but **vaccines formulated with adjuvants are less likely to be suitable**.
- Examples of currently available vaccines that have been demonstrated to be compatible **with ID delivery include**: **BCG, rabies, yellow fever, meningococcal conjugate vaccines and IPV**.
- The **live recombinant BCG 'next-generation' TB vaccine should also be suitable**.
- ID devices may be **most relevant as a dose-sparing strategy**, to reduce the impact of supply or cost constraints.

Intradermal (ID) Devices: Assessment outcomes

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KEY BENEFITS

✚✚ Potential to **increase acceptability:**

- Injections with some ID devices are **perceived as less painful.**

- ID devices are **designed to serve as aids to improve injection accuracy** (i.e., obtaining the appropriate angle and depth of injection) and therefore their use could **potentially expand the number of HCWs** available to deliver ID injections **in a campaign setting.**

KEY CHALLENGES

- **Rated lower than the comparator on some aspects of coverage and equity:**

✚✚ May reduce **ease of use**:

  - Existing data **do not verify that the devices improve accuracy of ID injections** among trained HCWs.
  - May increase **risk of missed opportunities** due to **more components and more steps to prepare.**

- Potential to **increase stock-outs** due to more components (additional needles for filling, or separate syringe hubs, or separate adapters for fitting onto a syringe).

- **May negatively impact safety:**

✚ Some ID-device designs could potentially **increase the likelihood of contamination** and **needle-stick injuries** due to additional preparation steps and lack of AD features.

✚ **May increase out of cold chain volume and storage and transportation costs** due to more components.

- **Limited applicability** since vaccines formulated with adjuvants are less likely to be suitable.

✚✚ Important attribute for at least 2 settings or for the 3 settings based on the country consultation (see slide 3)

✚ Important attribute for campaigns or routine facility-based immunisation based on country consultation (see slide 3)

Intradermal (ID) Devices: Rationale for prioritisation

- ID devices are **not recommended to be prioritised** for further analysis under Phase II given **their limited benefits.**
- While they do improve acceptability in comparison to standard BCG syringes using the Mantoux technique and may reduce training requirements, they come with **many tradeoffs including added complexity and additional components that could negatively impact coverage and equity and safety**. The ID needle hub also has **negative impacts on storage and delivery costs.**