VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Autodisable sharps-injury protection syringes

June 2019

Gavi The Vaccine Alliance

World Health Organization

Bill & Melinda Gates foundation

PATH

unicef

Autodisable (AD) sharps-injury protection (SIP) syringes

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About AD SIP syringes

- AD SIP syringes are **single-use, disposable syringes** with a **mechanism that covers the needle after use to reduce the risk of accidental needlestick injury**.
- Mechanisms include **retraction of the needle into the barrel after injection or a needle shield**.
- Some syringes have **SIP features that are automatically activated** and **others require extra activation steps by the end user.**

WHO [a]

A VanishPoint® retractable syringe (Retractable Technologies, Inc.)

PATH

BD Eclipse™ syringe (BD, Franklin Lakes, NJ) with needle shield

Stage of development

- AD SIP syringes are **commercially available**.
- A list of the current AD SIP syringes is available on the World Health Organization's (WHO's) Performance, Quality, and Safety (PQS) catalogue[b].

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[a] http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/LinkPDF.aspx?UniqueID=f3025136-636d-4139-9773-fdbf824276e1&TipoDoc=DataSheet&ID=0

[b] WHO. PQS catalogue website. Category E008 auto-disable syringe for fixed dose immunization page. http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=37. Accessed April 4, 2019.

Autodisable (AD) sharps-injury protection (SIP) syringes scorecard

Comparator: AD needle and syringe (N&S) without SIP feature

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Quality of evidence: Moderate

VIPS Criteria		Indicators		Priority indicators - Country consultation		
				RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral			
	Coverage & Equity impact	Ease of use [a]	Neutral	+	+	++
		Potential to reduce stock outs [b]	Neutral			
		Acceptability of the vaccine presentation to patients/caregivers	Neutral		+	+
	Safety impact	Likelihood of contamination	Neutral			+
		Likelihood of needle stick injury	Better			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Neutral	+		
		Total economic cost of the time spent by staff per dose	Neutral	++	++	+
		Total introduction and recurrent costs [c]	Neutral			
Secon-dary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All parenteral vaccines are 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)

Autodisable (AD) sharps-injury protection (SIP) syringes: Assessment outcomes

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KEY BENEFITS

- **May improve safety:**
  - Since AD SIP syringes either shield or retract the needle after administration, thus they **reduce the likelihood of needlestick injury** and **transfer of bloodborne pathogens** to patients, health care workers, and the community after vaccine administration.
- **Antigen applicability:**
  - **Broad applicability** as AD SIP syringes can be applied to **all parenteral vaccines**.

KEY CHALLENGES

- Although the volume of AD SIP syringes varies by manufacturer, there is a **potential risk that the innovation could have a larger out of cold chain volume** than a traditional AD syringe which could increase the overall storage and transport costs.

Autodisable (AD) sharps-injury protection (SIP) syringes: Rationale for prioritisation

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- AD SIP syringes are **recommended to be prioritised** for further analysis under Phase II. Although the added benefit of AD SIP syringes is singularly focused on **improving safety, this is a key feature with high potential public health value.**
- **Additionally, WHO recommends use of syringes with SIP features** for health care workers delivering injectable medications to patients and the WHO Performance, Quality, and Safety group plans to **require SIP features on both AD and reuse prevention syringes by the end of 2020**.

Additional important information to be analysed in phase II (if prioritised for Phase II)**:**

- How best to align with and provide complementary value to WHO's evolving recommendations and requirements regarding AD SIP syringes for immunisation.