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

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

Section 1: Summary of innovation

1.1 Examples of innovation types:

Image source: Provided by PATH

1.2. Description of innovation:

Unsafe injections cause hepatitis B, hepatitis C, or HIV infections and can result in chronic disease or death (1). To reduce the risk of unsafe injection, the World Health Organization (WHO) Expanded Programme on Immunization called for the design of safer injection devices in the 1980s. In 1999, WHO, the United Nations International Children's Emergency Fund (UNICEF), and the United Nations Population Fund (UNFPA) released a joint statement supporting the use of autodisable (AD) syringes for immunization (2), and UNICEF started phasing out regular disposable syringes for immunization and replacing them with WHO prequalified AD syringes (3). The 1999 WHO/UNICEF joint statement highlights that AD syringes should be used for both routine immunization and mass campaigns (fixed dose immunizations) (2), and this was reaffirmed in a 2019 joint statement that also promotes the use of reuse prevention (RUP) syringes for reconstitution (4).

Safety syringes come in two types: RUP and sharps injury protection (SIP).[a] AD syringes are considered a specific subtype of RUP syringes, and RUP and AD syringes can both come with SIP features. **AD SIP syringes are the focus of this evaluation.** According to Gavi's Vaccine Innovations Lexicon, a SIP syringe is, "A single-use, disposable syringe 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. SIP syringes have an additional feature that helps prevent needle-stick injury and can increase the safety of immunisation delivery and disposal (5)."

Like AD syringes, AD syringes with SIP features can be used for routine immunization and mass campaigns for intramuscular, subcutaneous, or intradermal vaccinations. By 2012, International Organization for Standardization (ISO) standards were developed for SIP syringes (6). WHO also now recommends the use of syringes with SIP features for health care workers delivering intramuscular, subcutaneous or intradermal injectable medications to patients (6). The WHO Performance, Quality, and Safety (PQS) group is planning a consultation in 2019 to assess whether SIP features should be required for all immunization syringes (7,8).

[a] Unless specifically noted RUP syringes ordinarily refer to non-AD syringes used for reconstitution of freeze-dried vaccines and curative medicine (variable dosing).

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SIP syringes come in two subcategories - passive system and active. Passive systems are defined as SIP features that are automatically triggered after delivery and require no extra steps by the end user. Active systems require extra steps by the end user to activate. A couple of examples are contained in Table 1 below. A list of the current AD SIP syringes is available on the WHO's PQS catalogue (9).

1.3 Examples of innovations and developers:

Table 1.

Product name; Image	**Developer (place); website**	**Brief description, notes**
VanishPoint® retractable syringe  Image source:[b]	**Retractable Technologies**, Inc. (Little Elm, Texas) http://www.vanishpoint.com/	This device is classified as a passive system. The needle automatically retracts into the syringe.
BD Eclipse™ syringe  Image source: Provided by PATH	**BD**, Franklin Lakes, NJ https://www.bd.com/en-us	This device is classified as an active system and contains a needle shield that the user must push to cover the needle after use.

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

SECTION 2: Summary of assessment for prioritisation

2.1 Key benefits:

- AD SIP syringes may reduce the risk of sharps injury to patients, health care workers, and the community in low- to middle-income countries (10–12).

2.2 Key challenges:

- There are certain challenges related to the innovation, however they do not impact the assessment of innovation in phase I. Please refer to 2.3 (below) for challenges, which will be assessed in the phase II, when they are applicable.

2.3 Additional important information:

- The WHO Performance, Quality, and Safety group plans to require SIP features on both AD and reuse prevention syringes by the end of 2020.
- AD SIP syringes are more costly than AD syringes (13,14). For example, a 0.05 mL AD syringe without the SIP feature is priced at approximately $0.04 (15) compared to $0.065 for a similar size retractable AD syringe, i.e. an additional cost of $0.025, or 63% per syringe (16).
- May require proper training in proper use and disposal (17–19).

SECTION 3: Evaluation criteria

3.1 Health impact criteria

Indicator: Ability of the vaccine presentation to withstand heat exposure

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

Table 2.

Ability of the vaccine presentation to withstand heat exposure	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have features that may improve heat stability?	Neutral	The innovations are intended to be used with current vaccine formulations and presentations. They do not have any features that will improve (or reduce) heat stability.

	***No difference** to the comparator*

Indicator: Ability of the vaccine presentation to withstand freeze exposure

*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.*

Table 3.

Ability of the vaccine presentation to withstand freeze exposure	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have features that may improve freeze resistance?	Neutral	The innovations are intended to be used with current vaccine formulations and presentations. They do not have any features that will improve (or reduce) freeze resistance.

	***No difference** to the comparator.*

3.2 Coverage and equity criteria

Indicator: Ease of use[c]

*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 4.

Ease of use • *Assessment of the potential for incorrect preparation based on usability data from field studies (or based on design of innovation if field studies not available)* • *Assessment of the potential for incorrect administration based on usability data from field studies (or based on design of innovation if field studies not available)*	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Does the innovation avoid reconstitution and is that an improvement?	Neutral	The innovation, an AD SIP, would not be used for reconstitution. An RUP SIP would but is not the focus of this evaluation.
	Does the innovation require fewer vaccine product components?	Neutral	AD SIPs have the same number of components as the comparator; however, the devices may be larger or have a different configuration (for example, have a needle shield).
	[d]**Does the innovation require additional components or equipment (such as scanners or label readers)?**	N/A	
	Does the innovation require fewer preparation steps and less complex preparation steps?	Neutral	The preparation steps are unchanged from a user's perspective as the SIP components are integrated into the AD syringe.

[c] Ease of use can prevent missed opportunities resulting from the complexity of preparation and administration procedures. It could also impact the ability for lesser trained personnel to administer the vaccine (incl. self-administration). It can be assessed based on usability data from field studies (or based on design of innovation if field studies not available).
[d] This parameter is only assessed for RFID/barcodes, for all other innovations it is not applicable (N/A).

Category: *Delivery technology (not prefilled)*
Innovation: *AD sharps-injury protection (SIP) syringes*
Comparator: *AD N&S without SIP feature*

Ease of use • *Assessment of the potential for incorrect preparation based on usability data from field studies (or based on design of innovation if field studies not available)* • *Assessment of the potential for incorrect administration based on usability data from field studies (or based on design of innovation if field studies not available)*	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Does the innovation improve dose control?	Neutral	AD SIPs are similar to other AD syringes, therefore, no improvement in dose control over the comparator is expected.
	Does the innovation improve targeting the right route of administration?	Neutral	AD SIPs have similar properties to the comparator for targeting the right route for vaccine administration.

	No difference *to the comparator*

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Category: *Delivery technology (not prefilled)*
Innovation: *AD sharps-injury protection (SIP) syringes*
Comparator: *AD N&S without SIP feature*

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

*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 5.

Potential to reduce stock outs based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities • *Assessment of the potential to reduce stock outs based on the innovation's features*	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Does the innovation require fewer components?	Neutral	AD SIPs have the same number of components as the comparator; however, the devices may be larger or have a different configuration (for example, have a needle shield).
	Or does the innovation include labelling that facilitates product tracking and is it better than the comparator?	Neutral	The innovation has no features that would facilitate labelling or product tracking, similar to the comparator.

	***No difference** to the comparator*

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

*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 6.

Acceptability of the vaccine presentation to patients/ caregivers • *Does the innovation include features that may improve acceptability of vaccinees and caregivers*	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Painful or not painful	Neutral	One study showed that retractable syringes did not affect recipient pain in intradermal and intramuscular injections (20), and another found no significant pain from safety devices (21).
	Perception of ease of administration (i.e. convenience for the vaccinees/caregivers)	Neutral	Although vaccinees and caregivers would likely interact with the innovation similarly to the comparator, AD SIPs are generally considered easy to use, tolerated, and safe by patients (6).
	Any other tangible benefit to improve/impact acceptability to vaccinees/caregivers	N/A	

	***No difference** to the comparator*

3.3 Safety criteria

Indicator: Likelihood of contamination

*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 7.

Likelihood of contamination • *Risk assessment of potential for contamination based on design of innovation and on usability data from field studies*	Parameters to measure against a comparator	Score	Assessment
	Does the innovation reduce the risk of contamination while reconstituting the dry vaccine?	Neutral	An AD SIP would not be used for reconstitution. An RUP SIP (variable dose) could be used for reconstitution but is not the focus of this evaluation.
	Does the innovation reduce the risk of contamination while filling the delivery device?	Neutral	The preparation steps for AD SIPs are the same as the comparator.
	Does the innovation require fewer preparation steps and less complex preparation steps?	Neutral	The preparation steps for AD SIPs are the same as the comparator.
	Does the innovation reduce the potential risk of reuse of delivery technology?	Neutral	Both AD SIPs and the comparator traditional AD syringes, cannot be reused.
	Does the innovation reduce the risk of use of nonsterile components?	Neutral	No non-sterile components are involved in the use of the innovation or the comparator.

	No difference *to the comparator*

Indicator: Likelihood of needle stick injury

*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..*

Category: *Delivery technology (not prefilled)*
Innovation: *AD sharps-injury protection (SIP) syringes*
Comparator: *AD N&S without SIP feature*

Table 8.

Likelihood of needle stick injury	Parameters to measure against a comparator	Score	Assessment
• *Risk assessment of the presence of sharps during the process of preparing and administering the vaccine*	**Does the innovation contain fewer sharps?**	Neutral	Though AD SIPs shield or retract the needle after administration to mitigate the risk of needlestick injury, AD SIPs and traditional ADs have the same number of sharps.
	Does the innovation use sharps for preparing and/or administering the vaccine and is that better than the comparator?	Neutral	The preparation steps for AD SIPs are the same as the comparator and do not affect preparation.
	Does the innovation include an auto disable feature and is that better than the comparator?	Neutral	This is an evaluation of AD SIPs against traditional AD syringes, so by definition both the innovation and the comparator have an AD feature.
	If the innovation uses sharps, does it include a sharps injury prevention feature and is that better than the comparator?	Better	The innovation has SIP features whereas the comparator does not. This is better because AD SIP syringes either shield or retract the needle after administration, mitigating the risk of needlestick injury after administration and during disposal.
	Does the innovation reduce the risk of injury after vaccine administration?	Better	Based on a systematic review, there is moderate quality evidence that SIPs reduce needlestick injuries in the target population (6).

	Better *than the comparator*

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3.4 Economic costs criteria

Indicator: Total economic cost of storage and transportation of commodities per dose[e]

*Legend: Dark Green: **Considerably better** than the comparator: Reduces the volume per dose for applicable parameters; Green: **Better** than the comparator: Reduces the volume per dose for either of the applicable parameter, and there is no difference for the other; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Reduces the volume for one of the parameter, and increases the volume for the other parameter compared to the comparator; Red: **Worse** than the comparator: Increases the volume per dose for either of the applicable parameters, and there is no difference for the other; Dark Red: **Considerably worse** than the comparator: Increases the volume per dose for both parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 9.

Total economic cost of storage and transportation of commodities per dose	Parameters to measure against a comparator	Score	Assessment
	Does the innovation reduce the volume per dose stored and transported in the cold chain?	Neutral	There is no impact on the volume stored and transported in the cold chain since neither AD syringes or AD SIPs are stored in the cold chain.
	Does the innovation reduce the volume per dose stored and transported out of the cold chain?	Neutral	The volume of the SIP AD syringe will vary by manufacturer. The VanishPoint® 0.5 mL retractable AD syringe has a volume of 54 cm^3 per unit (22) while the Haiou retractable AD syringe has a volume of 29 cm^3 per unit (23). This can be compared to the volume of 0.5 mL non-SIP AD syringes from other manufacturers that have volumes ranging between 31 cm^3 and 43 cm^3 per unit (24,25). The volume of the Haiou 0.05 mL retractable AD syringe is 26 cm^3 per unit (16), and this is similar to the volume of a similar size AD syringe, which is approximately 30 cm^3 per unit (26). Given that the volume is dependent on the manufacturer and design of the syringe, and the range of sizes of SIP AD and AD syringes overlap, we score this as neutral.

	***No difference** to the comparator*

[e] The assessment of the indicator is volume-related and builds upon PATH's VTIA analysis. A directional estimation is made at this stage, and a better evaluation will be done in phase II with more antigen-specific data.

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Indicator: Total economic cost of the time spent by staff per dose

*Legend: Dark Green: **Considerably better** than the comparator: Reduces time for all applicable parameters; Green: **Better** than the comparator: Reduces time for either, and there is no difference for the other one; White: **Neutral**, no difference with the comparator; Yellow: **Mixed**: Reduces the time for one of the parameters, and increases the time for the other parameter; Red: **Worse** than the comparator: Increases the time for either of the applicable parameters; and there is no difference for the other one; Dark Red: **Considerably worse** than the comparator: Increases time for all applicable parameters, N/A: the indicator measured is **not applicable** for the innovation; Grey: **no data** available to measure the indicator.*

Table 10.

Total economic cost of the time spent by staff per dose	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have attributes that can save time for the vaccinator in preparing and administering the vaccine?	Neutral	The preparation and administration steps are unchanged from a user's perspective as the SIP components are integrated into the AD syringe.
	[f]Does the innovation have attributes that save time for staff involved in stock management?	Neutral	AD SIPs do not have any attributes that would save time for staff involved in stock management.

	No difference *to the comparator*

3.5 Introduction and other recurrent costs criteria

Indicator: Total economic cost of one-time/upfront purchases or investments required to introduce the vaccine presentation and of recurrent costs associated with the vaccine presentation (not otherwise accounted for)

*Legend: White: **Neutral**: NO there are no one-time/upfront or recurrent costs and this is not different than the comparator; Red: **Worse** than the comparator: YES there are one-time/upfront or recurrent costs.*

[f] [f] This parameter only applies to barcodes and RFID to capture the benefits for stock management processes, not based on the number of components, but the specific features of the innovation.

Table 11.

Total economic cost of one-time/upfront purchases or investments required to introduce the vaccine presentation and of recurrent costs associated with the vaccine presentation (not otherwise accounted for)	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Are there one-time upfront costs that will be incurred for use of this innovation or recurrent costs that will be incurred for use of this innovation?	Neutral	No. AD SIPs do not have any upfront or recurrent costs. As with any innovation, vaccinators may need to be trained. However, we are not including training costs as part of the assessment in this phase.

	No difference *to the comparator*

3.5 Secondary criteria on potential breadth of innovation use

Indicator: Applicability of innovation to one or several types of vaccines

Table 12.

Applicability of innovation to one or several types of vaccines • *What vaccines/antigens does the innovation apply to, based on technical feasibility?*	**Assessment**
	This innovation can be applied to all parenteral vaccines and will be independent of presentation (i.e. will be compatible with single- or multi-dose vials). An example on the VIPS priority antigen list is pentavalent vaccine.

Indicator: Ability of the technology to facilitate vaccine combination

Table 13.

Ability of the technology to facilitate vaccine combination	Assessment
	AD SIPs are a delivery device and do not impact the ability to combine vaccines.

SECTION 4

4.1 Robustness of data:

Table 14.

Category	Assessment
Type of study	The majority of the data have come from WHO's guidelines on the use of safety engineered syringes, which includes a systematic review of the case for SIPs (6). A few studies found a reduction in needlesticks in general but were unable to show direct cause and effect (that is, a correlational effect versus a direct effect). This has been combined with expert opinion.
Inconsistency of results	There are too few comparable studies to assess inconsistency of results.
Indirectness of comparison • *Indicate the setting in which the study was conducted (low, middle or high income setting);* • *Comment if the data is on non-vaccine application of the innovation*	Most of the data assessed has been for SIP applications and not AD SIP applications for vaccine administration specifically. Likewise, most studies were focused on outcomes for health care workers (not patients) in high-income settings.

Overall assessment:	*Moderate*	

4.2 List of technical experts, manufacturers and/or technology developers interviewed for inputs:

Table 15.

Expert/type	Organisation/contact details	Notes
Amardeep Singh Chahal Manufacturer	BD Amardeep_Singh_Chahal@bd.com	
Rajiv Nath Manufacturer	Hindustan Syringes & Medical Devices hmduk@hmdhealthcare.com	

4.3 List of technical experts, manufacturers and/or technology developers that have reviewed and provided feedback/input to the technical notes (TN):

Table 16.

Reviewers	Organisation/contact details	Notes
Joe Little	PATH jlittle@path.org	Developed and reviewed TN
PATH Medical Device and Health Technology Team Debra Kristensen Courtney Jarrahian Mercy Mvundura Collrane Frivold	Debra Kristensen dkristensen@path.org	Reviewed TN
Fatima Kazi	Gavi Fkazi-external-consultant@gavi.org	Reviewed TN
Julian Hickling	Working in Tandem Ltd julian@workingintandem.co.ul	Reviewed TN

4.4 References:

Peer-reviewed publications of primary data, systematic reviews, other reports:

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