Plastic needles (for reconstitution)

Comparator: Reuse prevention reconstitution (RUP) needle and syringe (N&S) with metal needle

Section 1: Summary of innovation

1.1 Examples of innovation types:

Plastic hypodermic needle

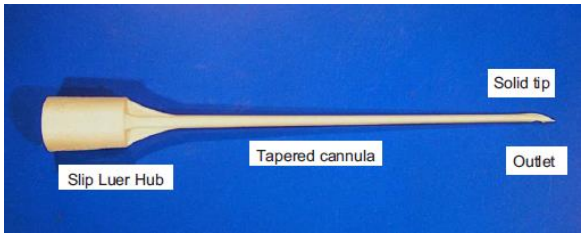


Image source: (1)

K Spike Reconsitution syringe

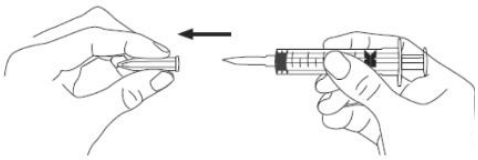


Image source: [a]

1.2. Description of innovation:

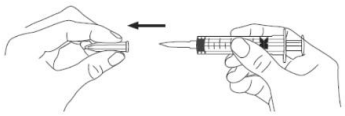
- Various designs and prototypes of polymer needles have been produced and tested in terms of functionality and comparability to metal needles (1,2).
- Plastic needles can be designed with a luer hub for attachment to a separate syringe or can be integrated into the syringe itself.
- Some polymer needle designs are intended to have sharpness similar to metal hypodermic needles and could be used to puncture vial stoppers as well as to penetrate the skin for parenteral injection. Some developers have focused on plastic needles that would be intended to be suitable only for use for accessing a vial. Other niches for plastic needles could include veterinary, pharmacy, or industrial purposes. This Technical Note (TN) is focused solely on vaccine reconstitution with plastic needles intended for vial access use, and not for injection, because of their potential safety benefits.
- At present, there are no commercially available reconstitution syringes with plastic needles. However, there are prototypes available and commercial products that could be adapted for this purpose.

[a] Courtesy of PATH, personal communication.

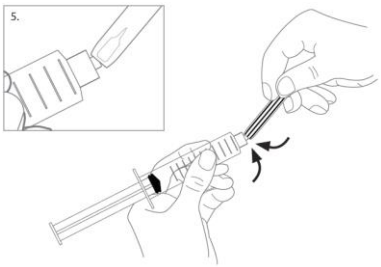
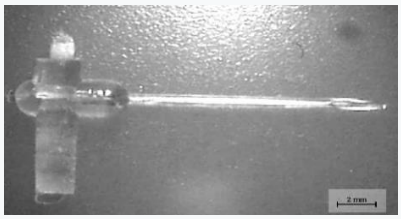
VIPS is a Vaccine Alliance project from Gavi, World Health Organization, Bill & Melinda Gates Foundation, PATH and UNICEF

1.3 Examples of innovations and developers:

Table 1.

Product name; Image	**Developer (place); website**	**Brief description, notes**
K Spike plastic reconstitution syringe  Image source: Star Syringe[b]	**Star Syringe** www.starsyringe.com No longer in active development.	A single-use disposable device composed of a plastic moulded syringe with integrated spike, which is inserted into the diluent and vaccine vial for reconstitution. The plastic needle was designed to be capable of penetrating a vial septum, but not skin. Several prototypes were developed for bench testing and evaluation by PATH. Prototypes were used in an assessment by health care workers in Oman in 2009 and in a clinical study in India in 2009-2010 under the WHO Measles Aerosol Vaccine Project (3). The device can be used to withdraw diluent from a vial or ampoule into the syringe, then the plastic spike needle is inserted into the vial containing lyophilized vaccine to empty the diluent and reconstitute the vaccine. However, due to lack of interest and collaboration by important stakeholders in the market the development of this technology has been put on hold.

[b] www.starsyringe.com

Product name; Image	**Developer (place); website**	**Brief description, notes**
K11 Rekon+  Image source: provided by PATH	**Star Syringe** www.starsyringe.com No longer in active development.	Prototype syringe with integrated plastic spike. After drawing up medication, the spike can be snapped off (using the syringe cap), leaving behind a luer connection. The plastic needle was designed to be capable of penetrating a vial septum, but not skin. Intended for use for accessing intravenous (IV) ports but could also be usable for reconstitution.
Polystyrene needle  Image source: (2)	**Georgia Tech** (Johnathan Colton's group)(2) Technology in design stage. Previous collaboration with SSB Technologies Pty Ltd and Telezon Ltd for strategic design input and funding.	Development of a variety of plastic needle prototypes based on different polymers, in particular liquid crystal polymer (LCP) which is durable enough to penetrate a vial septum and the skin.

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Product name; Image	**Developer (place); website**	**Brief description, notes**
Plastic hypodermic needle  Image source: [c]	**Telezon Ltd**	An Australian manufacturer of plastic needles composed of LCP[d]. Latest information suggests that Telezon's operations have closed down[e].
Micro Pin®  Image source: B. Braun[f]	**B. Braun** www.bbraunusa.com	Commercially available plastic spike dispensing pin with luer hub [g]. Used in hospital settings to access multidose vials without the use of a needle, generally for delivery of medication to IV lines.

[c] http://www.finnewsnetwork.com.au/CompanyReports/Telezon-Limited/0
[d] https://www.researchmoz.us/telezon-ltd-product-pipeline-analysis-2013-update-report.html
[e] Former ASX-listed company Telezon collapses into administration. https://www.smartcompany.com.au/finance/former-asx-listed-company-telezon-collapses-into-administration/
[f] www.bbraunusa.com
[g] https://www.bbraunusa.com/en/products/b0/micro-pin-non-ventedsingle-usedispensingpin.html

SECTION 2: Summary of assessment for prioritisation

2.1 Key benefits:

- Plastic needle designs that are intended to be capable only of penetrating vials would require very high forces to accidentally penetrate skin. This reduces the likelihood of needlestick injury to health care workers (HCWs), patients, and communities.
- Use of plastic needle syringes for reconstitution requires no changes to the presentation or licensing of vaccines.

2.1 Key challenges:

- Plastic needles that are intended to not easily penetrate human skin are likely to also require more pressure to insert and remove from a vial septum. This may reduce their usability and acceptability.
- Additional design and development work are required to incorporate a reuse prevention (RUP) feature (either by co-packaging the plastic needle with a RUP syringe or integrating it with a RUP syringe) and address other performance challenges.

2.3 Additional important information:

- Plastic needles can be burned or melted at relatively lower temperatures compared to the higher temperatures required for incineration of syringes with metal needles (2).
- Depending on the polymer material used, a syringe with a plastic needle can be compatible with existing recycling processes and practices, without first requiring separation of metal needles from plastic syringes (2).
- Alternative polymers such as LCP can enable increased sharpness and performance of plastic needles but are also likely to be more costly to produce.
- The cost of high-volume production of plastic needle syringes made of polypropylene, like the Star K Spike syringe, could be comparable with the costs of standard reconstitution syringes.
- Plastic needles have obtained regulatory clearance as medical devices. However, if plastic needle syringes do not meet the requirements of existing ISO standards for reconstitution syringes, new WHO PQS specification and verification protocols for the device could be required.
- Due to their thickness, plastic needles may increase coring of the septum, and/or failure of the septum to reseal after insertion, increasing the risk of leakage and contamination.

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	Plastic needle reconstitution syringes have no impact on the ability of a vaccine to withstand higher temperatures, which is no different to the comparator.

	***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	Plastic needle reconstitution syringes have no impact on the ability of the vaccine to withstand freeze exposure, which is no different to the comparator.

	***No difference** to the comparator*

3.2 Coverage and equity criteria

Indicator: Ease of use[h]

*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	Parameters to measure against a comparator	Score	Assessment
• *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)*	**Does the innovation avoid reconstitution and is that an improvement?**	Neutral	Plastic needle reconstitution syringes are intended for use to reconstitute dry vaccines in a vial, which is no different to the comparator.
	Does the innovation require fewer vaccine product components?	Neutral	Comparator reconstitution syringes are a single component, as they come with a preassembled needle or fixed (integrated) needle. Assuming that a plastic needle for vaccine reconstitution would similarly be preassembled or fixed to an RUP syringe, the number of components would be the same (vaccine, diluent, RUP syringe, delivery device).
	[i] **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	Assuming that the plastic needle would be preassembled or fixed to the RUP syringe, similar to the comparator, the number of steps for preparation would be the same.

[h] 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).
[i] This parameter is only assessed for RFID/barcodes, for all other innovations it is not applicable (N/A).

Category: *Packaging and safety*

Innovation: *Plastic needles (for reconstitution)*

Comparator: *RUP reconstitution N&S with metal needle*

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	Plastic needle reconstitution syringes are expected to be no different to the comparator in terms of dose control. Neither are used to deliver the dose to the patient.
	Does the innovation improve targeting the right route of administration?	Neutral	Plastic needle reconstitution syringes are expected to be no different to the comparator in terms of targeting the right route of administration. Neither are used to administer the vaccine to the patient.

	No difference *to the comparator*

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	Assuming that the plastic needle would be preassembled or fixed to the RUP syringe, similar to the comparator, the number of components would be the same (vaccine, diluent, RUP syringe, delivery device).
	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*

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	The plastic needle reconstitution syringes and the comparator are used for reconstitution purposes and are not used to deliver vaccines, therefore neither would have an impact on pain.
	Perception of ease of administration (i.e. convenience for the vaccinees/caregivers)	Neutral	Vaccinees and caregivers would not interact with the plastic needle reconstitution syringes and it is expected that their use would not impact the perception of ease of administration, which would be no different to the comparator.
	Any other tangible benefit to improve/impact acceptability to vaccinees/caregivers		

	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	The plastic needle reconstitution syringes would have the same risk of contamination as the comparator at the time of reconstitution, as this step relies on the aseptic practice applied by the vaccinator. It is expected that any commercial plastic needle would be proven to enable the septum to reseal after reconstitution.
	Does the innovation reduce the risk of contamination while filling the delivery device?	Neutral	The plastic needle reconstitution syringes and the comparator are not used to fill the delivery device; therefore they have the same risk of contamination.
	Does the innovation require fewer preparation steps and less complex preparation steps?	Neutral	The plastic needle reconstitution syringes would be expected to have the same number and complexity of vaccine preparation steps as the comparator.
	Does the innovation reduce the potential risk of reuse of delivery technology?	Neutral	The plastic needle reconstitution syringes and the comparator are not delivery technologies; therefore the risk is the same.
	Does the innovation reduce the risk of use of nonsterile components?	Neutral	It is expected that the plastic needle reconstitution syringes would have RUP features and be sterilised and handled with standard aseptic practice, which would be similar to the comparator.

	No difference *to the comparator*

Category: *Packaging and safety*

Innovation: *Plastic needles (for reconstitution)*

Comparator: *RUP reconstitution N&S with metal needle*

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.*

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?**	Better	The plastic needles under evaluation for reconstitution purposes are less sharp than the metal needles in standard reconstitution syringes so are less likely to cause needle stick injuries.
	Does the innovation use sharps for preparing and/or administering the vaccine and is that better than the comparator?	Better	The plastic needles contained in the reconstitution syringes under evaluation are less sharp than the metal needles in standard reconstitution syringes so are less likely to cause needle-stick injuries and less likely to be accidentally used to administer an injection.
	Does the innovation include an auto disable feature and is that better than the comparator?	Neutral	Standard reconstitution syringes are required to have RUP features. It is expected that a plastic needle syringe for reconstitution would also have an RUP feature.
	If the innovation uses sharps, does it include a sharps injury prevention feature and is that better than the comparator?	Neutral	Neither plastic reconstitution syringes or the comparator have sharps injury prevention features.
	Does the innovation reduce the risk of injury after vaccine administration?	Better	The plastic needle reconstitution syringes are less sharp than the metal needles in standard reconstitution syringes so are less likely to cause injury during handling and disposal.

	Better *than the comparator*

3.4 Economic costs criteria

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

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	The use of plastic needle reconstitution syringes does not impact the volume stored and transported in the cold chain since the same vaccine vial would be used, as with the comparator.
	Does the innovation reduce the volume per dose stored and transported out of the cold chain?	Neutral	It is expected that a plastic needle reconstitution syringe would have a similar volume per dose stored as transported out of the cold chain to the comparator.

	No difference *to the comparator*

[j] 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.

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 steps for the plastic reconstitution syringe would the same as for the comparator and so the time spent by the vaccinator is likely to be the same as the comparator.
	[k]Does the innovation have attributes that save time for staff involved in stock management?	Neutral	The innovation does not have any attributes that impact the time spent by staff on stock management.

	***No difference** to the comparator*

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.*

[k] 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. Plastic needle reconstitution syringes 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 could be applied to all dry formulation vaccines that require reconstitution with a diluent, or other two-component vaccines in glass vials that require mixing. MR and lyophilized presentations of MenACWY(X) are examples of two-component vaccines that could use a plastic needle for reconstitution.

Indicator: Ability of the technology to facilitate vaccine combination

Table 13.

Ability of the technology to facilitate novel vaccine combination • *Does the innovation facilitate novel combination vaccine products?*	**Assessment**
	The innovation has no impact on ability to facilitate vaccine combinations.

SECTION 4

4.1 Robustness of data:

Table 14.

Category	**Assessment**
Types of study	Formative usability and performance studies of prototypes. Manufacturer websites and brochures. Independent expert opinion.
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*	

Overall assessment:	*Low*	

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

Table 15.

Expert/type	Organisation/contact details	Notes
N/A	N/A	No interviews conducted.

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
Fatema Kazi	GAVI, the Vaccine Alliance fkazi-external-consultant@Gavi.org	Developed TN
PATH Medical Devices and Health Technologies Team Debra Kristensen Courtney Jarrahian Mercy Mvundura Collrane Frivold	PATH Debra Kristensen, Director Vaccine Technology Strategy and Policy dkristensen@path.org	Reviewed TN
Julian Hickling	Working in Tandem Ltd julian@workingintandem.co.uk	Reviewed TN

4.4 References:

1. Busillo E, Colton JS. Characterization of plastic hypodermic needles. J Med Device. 2009;3(4):41004.
2. Kim H, Colton JS. Fabrication and analysis of plastic hypodermic needles. J Med Eng Technol. 2005;29(4):181–6.
3. WHO, Of G, Measles THE, Vaccine A. Measles Aerosol Vaccine Project - Report To Sage. 2012;1–12.