Bundling devices

Use without innovation (i.e. vaccine and diluent in separate packaging)

Section 1: Summary of innovation

1.1 Examples of innovation types:

GSK's vial clip (1,2)

The bundling vial clip can be used between identical sized vials.

Bundling clip:

Bundling clip connecting two vials:

Use of bundling clip for vials in a secondary package:

Vaccine vial and diluent ampoule packaging combination (1)

As vials and ampoules have different diameters and heights, it is challenging to use the bundling clip to package them together. One approach is to use a moulded tray to package the different formats of the primary containers together.

Vaccine vial, diluent and syringe combination[a]

Vaccine vial and diluent packaging combination (1)

Individual cartons can also be used as a secondary packaging strategy to bundle a pair of vials (vaccine and diluent) together.

[a] https://cdn.vaccineingredients.net/wp-content/uploads/2017/03/hib-hiberix.jpg

Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

1.2. Description of innovation:

- Bundling devices allow vaccine components to be physically connected or placed together in the same secondary packaging to reduce the possibility of their separation and improve the likelihood of correct preparation and administration.
- Vaccine manufacturers adopt different packaging strategies to couple or bundle their vaccine products with diluents/buffers and/or reconstituting equipment as shown in table 1.
- There are multiple combinations in which the vaccine, diluent and / or devices can be bundled, some examples of combinations of vaccine primary packaging and devices include:
    - Vaccine vial and diluent vial;
    - Vaccine vial and diluent ampoule;
    - Vaccine ampoule and diluent ampoule;
    - Vaccine vial and sachet;
    - Vaccine vial, diluent vial, vial adapter, and reconstitution syringe;
    - Vaccine vial and prefilled syringe containing diluent;
    - Vaccine vial and dropper.

1.3 Examples of innovations and developers:

Table 1.

Product name; Image	**Developer (place); website**	**Brief description, notes**
 Image source: [b]	**GlaxoSmithKline** (GSK) has been using the bundling clips with some of their vaccines.	Bundling clips are used or have been used with GlaxoSmithKline's (GSK) Tritanrix™ HB+Hib pentavalent vaccine (WHO prequalified in October 2003 but currently discontinued) and their new Mosquirix™ malaria vaccine. (2).
 Image source: [c]	**Imojev** Live attenuated Japanese encephalitis vaccine Sanofi Hong Kong Ltd	1 vial (vaccine powder) + 1 vial (diluent) + 1 syringe + 2 separate needles stored together in a preformed tray.

[b] http://www.dewereldmorgen.be/images/cache/xl/2016/11/21/mosquirix.jpg
[c] http://www.hkapi.hk/images/drugs_images/Imojev%2001.jpg

Category: *Packaging and safety*

Innovation: *Bundling devices*

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Product name; Image	**Developer (place); website**	**Brief description, notes**
 Image source: [d]	**ACTHIB Vaccine** Sanofi Pasteur https://allmedtech.com/acvabsiviwid.html	5 single-dose vials with diluent for reconstitution packaged together in a secondary carton.
 Image source: [e]	**Hiberix** [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)] GlaxoSmithKline Biologicals	Preformed tray containing lyophilised vaccine, diluent and syringe
 Image source: [f]	**MENVEO** [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine] [g] Novartis	Meningitis A lyophilized conjugate vaccine component in a vial and the Meningitis CYW-135 liquid conjugate vaccine component in a prefilled syringe. Both are packaged together with needles for reconstitution and delivery in a preformed tray and secondary carton.

[d] https://cdn.vaccineingredients.net/wp-content/uploads/2017/03/hib-acthib-550x381.gif
[e] http://drugline.org/img/drug/11140_11222_1.jpg
[f] https://vaccineingredients.net/wp-content/uploads/2017/03/meningococcal-menacwy-menveo.jpg
[g] https://vaccineingredients.net/vaccines/meningococcal-menacwy-menveo

SECTION 2: Summary of assessment for prioritisation

2.1 Key benefits:

- Reduces errors in vaccine preparation, for example using an incorrect diluent to reconstitute a dry vaccine which can result in serious adverse events following immunization (AEFIs). The risks of incorrect diluent use could be greatly reduced if the vaccine and diluent were provided together, e.g. through the use of vial clips (1).
- Reduces mismatching and/or misallocation of vaccine components during distribution potentially reducing vaccine wastage and simplifies inventory processes (1).
- Helps ensure the availability of all the necessary vaccine components for healthcare workers to use for preparing and administering the vaccine, thus potentially reducing missed opportunities (1).
- Breakdowns in the separate supply chains at any level can result in poor stock and vaccine management leading to higher levels of expired vaccine or diluent stock (2). Pairing the vaccine and diluent together during the majority of its journey could eliminate the risk of the health facility storing expired diluents with unexpired vaccines or vice versa (1).

2.2 Key challenges:

- Although bundling vaccine vial and diluent primary containers in the same secondary packaging is expected to reduce mismatching errors, if the vials are removed from their secondary packaging the risk of incorrect diluent selection returns.
- As vials, ampoules and droppers differ in their dimensions and forms, the bundling of different shaped components together is challenging and would create more bulky packaging compared to the most efficient packaging configuration for each component separately.
- Bundling increases the packaging volume and leads to an increase in the cold chain costs because the other bundled components such as the diluent and syringes would be physically attached to the vaccine and hence stored and transported in the cold chain, as opposed to being shipped outside of the cold chain.

2.3 Additional important information:

- A bundling device or packaging strategy could be lower cost as could be implemented very quickly compared with supplying multi-component vaccines in integrated reconstitution technologies such as dual-chamber vials or dual-chamber prefilled delivery devices.
- As the application of a bundling clip to the vaccine vial and its diluent bears no impact on the aseptic filling procedure of the vaccine container, there would be no additional requirement for bridging studies to revalidate the containers.
- Since bundling is not currently an established process for all vaccines and vaccine manufacturers, the equipment and packaging process required for this step would need to be purchased, installed, and validated by the vaccine manufacturer.
- Bundling may increase the cost of the vaccine per vial, depending on the approach used. However, for a technology such as a bundling clip connecting two vials, this is expected to be be a minimal fixed cost per clip. With an increased number of doses per vial, the incremental cost of the bundling clip would decline, as the cost would be spread over a larger number of doses. Therefore, bundling multi-dose vials would have less potential impact on the price of vaccine per dose (2).

2.4 Evidence:

- A vaccine packaging study conducted with data from Kenya and Bolivia demonstrated that the effect of bundling vaccines significantly increased the volume stored in the cold chain at all levels of the supply chain (1).
- A PATH study on the total supply chain impact of bundling (for all vaccine formats, not just lyophilized) found that a 20 percent increase in cold chain capacity would be required if all lyophilized vaccines were bundled with their diluent (2).
- In 1987, AEFIs were reported due to the mistaken reconstitution of measles vaccine with a muscle relaxant compound stored in a vial that looked similar in size and shape to the diluent. Many more cases have been reported across various settings whereby errors made with reconstituting the vaccine with a wrong diluent have resulted in unnecessary deaths and serious AEFIs[h].
- In 2014, a muscle relaxant was mistakenly used to reconstitute a measles vaccine resulting in the death of 15 children in Syria (2).

[h] https://www.who.int/vaccine_safety/initiative/detection/managing_AEFIs/en/index4.html

Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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	Bundling devices (or the lack thereof) do not have an impact on the vaccine's 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	Bundling devices (or the lack thereof) do not have an impact on the vaccine's freeze resistance.

	No difference *to the comparator*

3.2 Coverage and equity criteria

Indicator: Ease of use[i]

*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	Bundling devices do not avoid the need to reconstitute lyophilised vaccines, but bundling physically connects the lyophilized vaccine to the correct diluent to reduce the risk of reconstituting the vaccine with the wrong diluent. Therefore, they reduce the chance for one type of reconstitution error (but not all). This is an improvement over separate packaging and distribution of the vaccine components.
	Does the innovation require fewer vaccine product components?	Neutral	Bundling ensures that vaccine components are provided together in a single package or joined with a clip. Because the vaccine is provided in the format, it does not change the number of vaccine product components that are required, or must be assembled, to deliver the vaccine per immunized individual.
	[j]Does the innovation require additional components or equipment (such as scanners or label readers)?	Neutral	No additional components are required relative to the comparator.
	Does the innovation require fewer preparation steps and less complex preparation steps?	Better	Because all vaccine components are provided in a single package, the preparation is less complex as the health worker does not need to search for separate items in the cold chain and in ambient temperature storage.

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

Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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	The use of bundling has no impact on dose control.
	Does the innovation improve targeting the right route of administration?	Neutral	The use of bundling devices has no impact on targeting the right route of administration.

	Better *than the comparator*

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

Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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?	Better	As the innovation enables the physical connection of vaccine components in the same primary packaging, this reduces the number of separate vaccine product components to track throughout the supply chain during distribution and storage, thus improving inventory management. This is better and reduces the logistic errors of tracking different components in the supply chain.
	Or does the innovation include labelling that facilitates product tracking and is it better than the comparator?	Neutral	Innovations that enable bundling of vaccine components do not impact labelling.

	Better *than the comparator*

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Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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	Bundling has no impact on administration of the vaccine and perceived pain of administration.
	Perception of ease of administration (i.e. convenience for the vaccinees/caregivers)	Neutral	Same as above
	Any other tangible benefit to improve/impact acceptability to vaccinees/caregivers	Better	Serious injuries and deaths from vaccine/diluent mismatches are rare, but when they occur they can be widely publicized and shake caregivers' confidence in vaccines and immunization programs. Bundling could reduce these errors and lead to increased acceptability of vaccination.

	Better *than the comparator*

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Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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	Parameters to measure against a comparator	Score	Assessment
• *Risk assessment of potential for contamination based on design of innovation and on usability data from field studies*	**Does the innovation reduce the risk of contamination while reconstituting the dry vaccine?**	Neutral	The use of bundling devices has no impact on the risk of contamination during the process of reconstitution, filling the delivery device and in terms of preparing the vaccine for administration.
	Does the innovation reduce the risk of contamination while filling the delivery device?	Neutral	
	Does the innovation require fewer preparation steps and less complex preparation steps?	Neutral	
	Does the innovation reduce the potential risk of reuse of delivery technology?	Neutral	The common scenario is to have vial/vial bundles for which the risk of re-use and use of sterile components would be no different to the comparator. It should be noted that if there is potential to bundle vaccine vials/diluents with delivery device (e.g. oral syringe) or other components (e.g. vial adapters) then the risks would be reduced as each time the vaccine can be delivered with new available delivery devices/components.
	Does the innovation reduce the risk of use of nonsterile components?	Neutral	

Neutral	***No difference** to the comparator for vial/vial combination*

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Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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 • *Risk assessment of the presence of sharps during the process of preparing and administering the vaccine*	**Parameters to measure against a comparator**	**Score**	**Assessment**
	Does the innovation contain fewer sharps?	Neutral	Bundling does not impact the vaccine components used or the process of preparing and administering the vaccine.
	Does the innovation use sharps for preparing and/or administering the vaccine and is that better than the comparator?	Neutral	
	Does the innovation include an auto disable feature and is that better than the comparator?	Neutral	
	If the innovation uses sharps, does it include a sharps injury prevention feature and is that better than the comparator?	Neutral	
	Does the innovation reduce the risk of injury after vaccine administration?	Neutral	

	***No difference** to the comparator*

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3.4 Economic costs criteria

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

*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?	Worse	Bundling increases the volume stored in the cold chain as the vaccine is now stored with the diluent and/or devices that are typically not stored in the cold chain (2).
	Does the innovation reduce the volume per dose stored /and transported out of the cold chain?	Better	Bundling reduces the volume stored out of the cold chain because the diluent and/or devices are now stored in the cold chain.

	***Mixed** for the comparator*

[k] 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.

Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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?	Better	With bundling, the vaccinator saves time that would have been spent matching the vaccine and diluent.
	[I]**Does the innovation have attributes that save time for staff involved in stock management?**	Neutral	There are no attributes of the innovation that would impact the time spent by staff involved in stock management.

	***Better** than the comparator*

[I] 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.

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Category: *Packaging and safety*

Innovation: *Bundling devices*

Comparator: *Use without innovation (i.e. vaccine and diluent in separate packaging)*

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.*

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. Similar to the comparator, there are no anticipated upfront or recurrent costs for bundling devices.

	***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 vaccines that have more than one component required for preparation and delivery. This innovation can be used for packaging dry vaccines and their diluents to improve safety. Bundling reconstitution and delivery devices is also possible. MR is an example of a two-component vaccine that could benefit from bundling. ETEC is another potential candidate vaccine.

Indicator: Ability of the technology to facilitate novel vaccine combination

Table 13.

Ability of the technology to facilitate novel vaccine combination • *Does the innovation facilitate novel combination vaccine products?*	**Assessment**
	No. Bundling of vaccines is a secondary packaging strategy and has no influence on vaccine formulation.

SECTION 4

4.1 Robustness of data:

Table 14.

Category	Assessment
Type of study	The majority of the data has come from two PATH technical reports (1,3) 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*	All the data assessed has been for vaccine applications

Overall assessment:	*Low to Moderate*	

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 and reviewed the TN
PATH Medical Devices & Health Technologies Team Debra Kristensen Courtney Jarrahian Mercy Mvundura Collrane Frivold	PATH Debra Kristensen dkristensen@path.org	Reviewed the TN
Julian Hickling	Working in Tandem Ltd julian@workingintandem.co.uk	Reviewed the TN

4.4 References:

1. Optimize. Vaccine packaging study Bundling lyophilized vaccines with their diluents and harmonizing their packaging. 2013.
2. PATH. Technology Report : Vial Bundling Clip. An overview report on vial bundling clips to prevent reconstitution errors.
3. PATH. Technology Report: Vial Bundling Clip. An overview report on vial bundling clips to prevent vaccine reconstitution errors.