VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

# VIPS Phase II executive summary: Compact prefilled auto-disable devices (CPADs)

March 2020

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# Compact prefilled auto-disable devices (CPADs)

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## About CPADs

- CPADs are **integrated primary containers and injection devices prefilled with liquid vaccines**. They have features to **prevent reuse** and **minimize the space required for storage and shipping.**

Three CPAD subtypes have been assessed:

- **Preformed CPADs:** Squeezable polymer device, manufactured 'open' and supplied sterile and ready to fill/seal by the vaccine manufacturer.
- **Blow-fill-seal (BFS) CPADs:** produced, filled, and sealed in a continuous BFS process.
  - **Pre-assembled** (with needle attached) and **user-assembled** configurations are possible[1].
- **Other CPAD types:** Designs are in development leveraging prefilled syringe components.

## Stage of development

- One preformed CPAD, **Unject™, is commercially available**.
- Unject™ presentations of **Penta , HepB and TT vaccines were WHO prequalified** in 2006, 2004 and 2003 respectively. The pentavalent and tetanus toxoid products have been discontinued. Medroxyprogesterone acetate (similar to Depo-Provera) is also commercially available in Unject™.
- **BFS and other CPAD types are in design phases.**

[1] During the Phase I VIPS review, the Steering Committee suggested de-prioritising user-assembled BFS CPAD configurations because they have fewer potential benefits than all other CPAD types, due to the greater number of components and preparation steps, and risk of preparation and delivery errors and contamination.

drugdeliverysystems.bd.com [a]


Preformed CPAD (Unject™)

PATH

BFS CPAD (Apiject)

INJECTO™ [b]


Other CPAD (Easyject)



a https://drugdeliverysystems.bd.com/products/prefillable-syringe-systems/vaccine-syringes/uniject-auto-disable-pre-fillable-injection-system; b http://injecto.eu/easyject/

# Summary of key insights (1/2)

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## Potential public health impact of innovation

**Applicability to vaccines**

- **CPADs should be applicable to most or all liquid vaccines that are injected.**
  - Vaccine compatibility with the materials in the CPAD and stability in the device will need to be demonstrated.

**Public health benefits**

- **Public health benefits** across vaccines may include:
  - **Easier to prepare/use**, allowing **lesser trained staff** to administer the vaccines and with a **reduced risk of needle-stick injury**;
  - Single-dose presentation, potentially **reducing missed opportunities** and **contamination risks** associated with multi-dose vials;
  - **Improved acceptability** to caregivers/parents;
  - Fewer components **reducing stock-outs**, and a smaller **size simplifying waste disposal.**

**Vaccine problem statements**

- **CPADs could potentially address several of the top 5 problem statements** for Penta, HepB, HPV, IPV and TCV, particularly those related to:
  - **Ease of use** and **acceptability:**
  - **Difficult preparation.**



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# Summary of key insights (2/2)

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## Barriers to realise the innovation's potential impact

### Costs

- The **commodity costs for preformed CPADs** are **larger** than for vaccines in single- or multi-dose vials (SDV and MDV). Reduced costs for delivery and needle and syringe probably offset this increase for SDV (cost neutral), but not for MDV (net increase of ~$0.30 per dose).
- The costs for **BFS CPADs and other CPAD types are not known**.

### Technology Readiness

- Preformed CPADs have been **commercially available for at least 20 years.**
- **BFS and other CPAD types are early in development** and have manufacturing and technical challenges. However these devices utilise some existing manufacturing processes, so should be less complex than innovations with completely novel processes (such as MAPs or SDIs).

### Commercial feasibility

- Uptake of preformed **CPADs has been limited**. This is assumed to be due to purchasers being **unwilling to pay a higher cost**, and therefore **lack of incentives for manufacturers** to adopt the technology.

### Countries interest

- **Country interest** based on VIPS country interviews **in CPADs appears to be moderate** at this point, with an overall ranking of number 5 amongst the 9 tested.



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# CPADs apply to all liquid parenteral vaccines

Applicability to vaccines

| | VIPS Phase II analysed vaccines | Vaccine Type | Presentation | Route |
|---|---|---|---|---|
| Vaccines **technically compatible** with CPADs and analysed in Phase II. — **Licensed vaccines** | **Penta** (or DTP containing) | Adjuvanted inactivated subunit plus polysaccharide-protein conjugate | Liquid | IM[2] |
| | **Hepatitis B** (birth dose) | Adjuvanted sub-unit | Liquid | IM |
| | **HPV** | Adjuvanted sub-unit | Liquid | IM |
| | **Polio, IPV** | Whole inactivated | Liquid | IM or ID[6] |
| | **Typhoid, conjugate** (TCV) | Polysaccharide-protein conjugate | Liquid | IM |
| **Pipeline vaccines** | **Ebola** (rVSV-ZEBOV)[7] | Live vector | Liquid (FROZEN) | IM |
| | **HIV** (bivalent subtype C gp120 boost only) [8] | Adjuvanted recombinant protein | Liquid | IM |
| | **Influenza** (pandemic,VAL-506440) | Lipid nanoparticle, modified RNA | Liquid | IM |
| Vaccines **not technically compatible** with CPADs & not analysed in Phase II. | **MR** (or MCV) | Live attenuated | Lyophilised | SC[5] |
| | **N. Men A** (or N. Men A,C,W,Y,X) | Conjugate, adjuvant in diluent | Lyophilised | IM |
| | **Yellow fever** (YF) | Live attenuated | Lyophilised | SC or IM |
| | **HIV** (ALVAC prime only)[8] | Live recombinant virus | Lyophilised | IM |
| | **Malaria** (RTS,S) | Adjuvanted recombinant protein | Lyophilised, liquid adjuvant | IM |
| | **MTb** (next gen.,VPM1002) | Live recombinant BCG | Lyophilised | ID |
| | **RSV** (Pre-F) | Recombinant protein | Lyophilised | IM |
| | **Rabies** | Whole-inactivated | Lyophilised | IM or ID |
| | **Rota** (Oral) | Live attenuated virus | Liquid | Oral |
| | **ETEC** (ETVAX) | Whole inactivated organism | Liquid vaccine, lyophilised buffer & adjuvant | Oral |

**8 vaccines are technically compatible and have therefore been assessed with CPADs (out of 17 in scope) in Phase II.**

## Vaccine applicability:

- **CPADs could be applied to any liquid parenteral vaccine.**
- CPADs are likely to be most **useful** with vaccines that would benefit from an **easy-to-use single-dose presentation**, e.g. for outreach settings.
- Technical feasibility was assessed based on data, when available, and expert opinion. Key considerations included the natural route of infection, vaccine type, use of adjuvants and preservatives, and context of use.

## Comparators:

To assess innovations against both 'best practice' and 'current practice', comparators were defined as:

- **SDV[2] presentation** and AD N&S[3],
- If available, the **MDV[4] presentation** commonly procured by LMICs.

[1] Intramuscular; [2] Subcutaneous; [3] Intradermal; [4] Single-dose presentation; [5] Auto-disable needle & syringe; [6] Multi-dose presentation; [7] At the time of the assessment, Ebola vaccine was not yet licensed and has been analysed as a pipeline vaccine; [8] HIV vaccine consists of two different components: a virus vector for priming doses and a subunit protein plus adjuvant. The prime and boost were therefore assessed separately.

# Beyond the 17 vaccines analysed through VIPS, CPADs are likely to be compatible with a range of other vaccines

Applicability to vaccines

**Pipeline vaccines*

| VIPS vaccines assessed to be compatible with CPADs | Vaccine type | Other vaccines likely to be compatible with CPADs |
|---|---|---|
| HepB; pentavalent; *HIV (gp120 boost)* | Subunit, liquid, adjuvant | dT; TT; DTwP; DTaP; hexavalent; *non-replicating rotavirus; GAS; next generation malaria; CEPI vaccine platform (clamp); Shigella; ETEC* |
| HPV | VLP or inactivated virus, liquid, adjuvant | JE (inactivated); hepA; *non-replicating rotavirus; RSV*; *improved or universal influenza; influenza (pandemic)* |
| IPV | Inactivated virus, liquid | Influenza (seasonal); *RSV* |
| Typhoid | Polysaccharide-protein conjugate, liquid | Pneumococcal conjugate vaccine; Hib, Men ACWY (liquid); *GBS*; *Shigella* |
| *Ebola* | Live vector, liquid, | *CEPI vaccine platforms (rVSV); R&D Blueprint vaccines; HSV; next generation malaria; RSV* |
| *Flu (pandemic)* | Nucleic acid, liquid | *CEPI vaccine platforms (DNA, RNA), HSV* |

# Overview of CPADs public health benefits based on Phase II analysis

*Comparator: MDV*

Vaccine with an elimination agenda

**Public health benefits**

| VIPS Criteria | | Indicators | Penta | Hep B BD | HPV | IPV | TCV | Ebola[7] | HIV[8] | Influenza[9] |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary criteria | Health Impact | Vaccine efficacy | Neutral | No data | No data | No data | No data | No data | No data | No data |
| | | Vaccine effectiveness | No data | Better | No data | No data | No data | No data | No data | No data |
| | | Ability of the vaccine presentation to withstand heat exposure | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral |
| | | Ability of the vaccine presentation to withstand freeze exposure | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral |
| | Coverage & Equity impact | Number of fully or partially immunised (relative to target population) | No data | Better | No data | No data | No data | No data | No data | No data |
| | | Ease of use: clinical perspective based on product attributes | Better | Better | Better | Better | Better | Better | Better | Better |
| | | Ease of use: ability of a lesser trainer personnel to admin. / self-admin. | Better | Better | Better | Better | Better | Better | Better | Better |
| | | Ability to facilitate dose sparing | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral | Neutral |
| | | Avoid missed opportunities and reduce vaccine wastage[1] | Better | Better | C. better | Better | Better | Neutral | Neutral | Neutral |
| | | Acceptability of the vaccine presentation and schedule[2] | Better | Better | Better | Better | Better | Better | Better | Better |
| | | Potential to reduce stock outs[3] | Better | Better | Better | Better | Better | Better | Better | Better |
| | Safety impact | Number of vaccine product-related AEFIs | Neutral | Neutral | No data | No data | No data | No data | No data | No data |
| | | Likelihood of contamination and reconstitution errors | Better | Better | Better | Better | Better | Better | Better | Better |
| | | Likelihood of needle stick injury | Better | Better | Better | Better | Better | Better | Better | Better |
| | Economic costs | Commodity costs of the vaccine regimen[4,5] | Worse | Worse | Worse | Worse | Worse | Worse | Worse | Worse |
| | | Delivery costs of the vaccine regimen[4,6] | Worse | Worse | Worse | Worse | Worse | Worse | Worse | Worse |
| | | Introduction & recurrent costs of the vaccine regimen[4] | Worse | Worse | Worse | Worse | Worse | Worse | Worse | Worse |
| | Environmental impact | Waste disposal of the vaccine regimen[4] and delivery system | Better | Better | Better | Better | Better | Better | Better | Better |

[1] Based on availability of the innovation in a single-dose presentation or multi-dose with preservative. The score would be neutral for all vaccines if the comparator was a SDV; [2] To patients/caregivers; [3] Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities; [4] per person vaccinated; [5] Score is relevant to preformed CPADs, no data available for pre-assembled and other CPADs; [6] Score is relevant to preformed and pre-assembled CPADs, no data available for other CPADs
[7] rVSV-ZEBOV [8] bivalent subtype C gp120 boost only; [9] VAL 506440

# Phase II confirms CPADs potential public health benefits for liquid parenteral vaccines

Public health benefits

Based on the assessment using VIPS primary indicators applied to CPADs with specific vaccines, CPADs can **potentially address several immunisation challenges for a range of compatible vaccines.**

- **Vaccine effectiveness.** Timely administration of *HepB birth dose* has been shown to be better with out of cold chain distribution in Uniject compared with out of cold-chain distribution in vials.
- **Easier to prepare/use** allowing **lesser trained staff** to administer the vaccines, based on product attributes.
- CPADs are a single-dose presentation, **reducing missed opportunities** due to reluctance to open a multi-dose vial. *This is particularly relevant for vaccines with **preservative-free multi-dose presentations such as HPV**, or that have to be **discarded at the end of an immunisation session such as TCV**.*
- CPADs have been found to be **more acceptable** than needle and syringe (*for HepB birth doses*) by caregivers.
- CPADs are prefilled and single component, so should **reduce the risk of stock-outs** *for all vaccines.*
- Because CPADs are prefilled, there is no need for the additional step of withdrawing vaccine from a vial, so the **risk of needle-stick injury is reduced**.
- Due to their small size, **CPADs are expected to improve waste-disposal.**

# Overview of the ability of CPADs to address vaccine specific problems identified in the VIPS Phase II country online survey[1]

**Vaccine problem statements**

| Vaccine with an elimination agenda | Penta | Hep B BD | HPV | IPV | TCV | Ebola[3] | HIV[4] | Influenza[5] |
|---|---|---|---|---|---|---|---|---|
| Vaccine ineffectiveness/wastage due to **heat exposure** | 2 | 2 | 4 | 2 | 1 | | | |
| Vaccine ineffectiveness/wastage due to **freeze exposure** | 1 | 1 | 1 | 1 | 5 | | | |
| **Cold chain requirements** during outreach[2] | 4 | 3 | 3 | 3 | | | | |
| Vaccine wastage or missed opportunities due to **multi-dose vial**[2] | | | | | 2 | | | |
| Reconstitution related **safety issues**[2] | | | | | | | | |
| **Reduced acceptability** due to painful administration[2] | 3 | 5 | 2 | 4 | | | | |
| **Difficult preparation** requiring trained personnel[2] | | 4 | 5 | | 4 | | | |
| **Negative impact on the environment** due to waste disposal practices[2] | | | | 5 | | | | |
| **Needle-stick injuries**[2] | | | | | | | | |
| **Contamination risk** due to multi-dose vial[2] | 5 | | | | | | | |
| **Difficult to deliver vaccine** to correct injection depth[2] | | | | | 3 | | | |

[1] Based on an online survey with 209 global experts and country-level stakeholders across 54 countries conducted in Q4 2019 – Q1 2020, top 5 challenges identified by countries per licensed vaccine were selected as 'vaccine problem statements' to be specifically analysed. Numbers in the table refer to the ranking order of top 1 to 5 problem statements. For pipeline vaccines, problem statements were defined by the VIPS WG. [2] Scoring based on product attributes. [2] Scoring based on product attributes. [3] rVSV-ZEBOV; [4] bivalent subtype C gp120 boost only; [5] VAL 506440

No difference to the comparator | Better than the comparator

# CPADs have the potential to address several countries' top 5 vaccine problem statements

Vaccine problem statements

The overlay of the top 5 problem statements by vaccines with the VIPS primary indicators assessment shows that **CPADs have the potential to address several of the top 5 vaccine problem statements for several vaccines:**

- **Overcoming poor acceptability due to painful administration**. CPADs have been found to be preferable to needle and syringe by caregivers and have high acceptability with vaccinators. *Acceptability was identified as a problem for four of the five vaccines assessed (**penta, HepB, HPV and IPV**).*
- **Easier to prepare/use**, saving time and allowing for **lesser trained staff** to administer the vaccines. *Identified as an important problem for **HepB, TCV, and HPV**.*
- Single-dose presentation, potentially **reducing missed opportunities** due to vaccine wastage or reluctance to open a multi-dose vial. *This was identified as a problem for **TCV**, which has a 5-dose presentation that contains preservative, but unused vaccine is recommended to be discarded at the end of a session.*
- **Reducing contamination risks** associated with the use of multidose vials. *Identified as an important problem for pentavalent vaccine.*
- Due to their small size, **CPADs are expected to improve waste-disposal.** *Identified as a problem for **IPV**.*

# Currently available CPADs have a higher cost than SDV and MDV alternatives; cost of new CPAD types is unknown

Costs

## Commodity costs[1, 2]

**Higher for existing preformed CPADs, but unknown for new types in development:**

- Previous cost of goods (COGS) analysis found that a preformed **CPAD could increase cost of vaccine purchase (per dose) by ~$0.07 compared to an SDV and by ~$0.30 compared to an MDV.** The significance of these changes will depend on the cost of the vaccine itself.
- Costs of BFS and other CPAD types is unknown.
- **COGS estimates are preliminary and exclude some key costs[4]** and so magnitude of cost differences may be larger.
- All **CPADs will reduce costs of purchasing N&S.**
- **Preformed and BFS CPADs will reduce safety box costs due to their smaller size**. The total **savings in delivery device** and safety box costs will be **~$0.04 per dose.**
- The volume of other types of CPADs is unknown, but the reduction in purchase costs of N&S will outweigh the possible increase in safety box costs due to larger size.

## Delivery costs[1,3]

**Reduced compared to SDV, but increased compared to MDV for existing preformed CPADs:**

- Due to smaller storage and transport volumes and faster preparation time, **delivery costs for preformed and preassembled BFS CPADs are expected to be lower than SDV (by < $0.02 per dose). They are likely to be higher than MDV (by ~$0.02)** due to their larger size per dose.
- There are no data on storage volume or preparation time for other CPAD types, so the delivery cost impact is not known.

## Introduction and recurrent costs[1]

**Introduction costs due to training needs:**

- **Training would be required to introduce CPADs** as would be required with any innovation.
- No upfront recurrent or ongoing costs for CPADs.



[1] Of a vaccine regimen (per person vaccinated); [2] Includes the purchase cost of a vaccine regimen and delivery devices (injection syringes or other components needed for vaccine preparation and administration) accounting for wastage, and safety box costs; [3] Includes costs of in and out of cold chain storage and transport for a vaccine regimen including delivery technology(ies), time spent by vaccinators when preparing and administering the vaccine and by staff involved in stock management; [4] Markup is not included in the COGS – this would account for R&D and regulatory costs and profit.

# Preformed CPADs are commercially available, BFS and 'other CPAD types' require further development

**Technology Readiness**

| VIPS Criteria | Indicators | Vaccine with an elimination agenda | Penta | Hep B BD | HPV | IPV | TCV | Ebola | HIV[2] | Influenza[3] |
|---|---|---|---|---|---|---|---|---|---|---|
| Secondary criteria | Technology readiness[1] | Clinical development pathway complexity | Low | Low | Low | Low | Low | Moderate | High | Low |
| | | Technical development challenges: preformed and other CPAD types | Low | | | | | | | |
| | | Technical development challenges: pre-assembled BFS | Moderate | | | | | | | |
| | | Complexity of manufacturing the innovation: preformed and other types | Low | | | | | | | |
| | | Complexity of manufacturing the innovation: pre-assembled BFS | Moderate | | | | | | | |
| | | Robustness: multiple developers of the technology | Not robust | Not robust | No data | No data | No data | No data | No data | No data |
| | | Robustness: multiple suppliers/manufacturers of the vaccine | High | High | Moderate | Not robust | Not robust | Not robust | Not robust | Moderate |

- One preformed CPAD is currently available (Uniject), and fill/finish technologies exist. **Each vaccine candidate must be validated for stability** in a CPAD container and **manufacturing lines need to be installed**.
- **BFS is a widely used aseptic pharmaceutical filling method,** but some **key development and manufacturing challenges** need to be addressed to apply this technology to CPADs. These include incorporation of an autodisable feature, avoiding fluid path leakage, and ensuring the container is sufficiently squeezable to expel a full dose.
- The 'other CPAD formats' are still in development but can likely **leverage some components and filling equipment from conventional prefilled syringes**, so technical and manufacturing challenges are potentially low complexity.
- A HepB CPAD is currently prequalified and used in Indonesia.. **No other vaccine manufacturer/CPAD developer partnerships** are known.



[1] VIPS assessment of the Technology Readiness criteria was informed by consultations with the WHO/PATH Delivery Technology - WGI, as well as with regulators.
[2] bivalent subtype C gp120 boost only; [3] VAL 506440

# BFS and other CPAD types leverage existing manufacturing technologies, but require custom adaptations

Technology Readiness

| Regulatory | Technical | Manufacturing | Vaccines |
|---|---|---|---|
| • **Clinical development**. For licensed vaccines, phase III non-inferiority or bridging studies with immunogenicity endpoints are expected to be sufficient. However, for novel vaccines, the same (clinical) endpoints would be required as for N&S or other delivery methods.<br>• CPAD typically requires specialised **filling equipment** that will need to be **validated**. | • **Stability:** Compatibility with CPAD materials and production processes must be demonstrated for each vaccine. Moisture vapor/gas barrier properties of materials must be adequate for long term storage, or a secondary containment barrier (e.g. foil overwrap) will be needed, which will impact the storage volume.<br>• **Autodisable feature:** For novel CPADs, an autodisable feature compliant with ISO standards must be incorporated.<br>• **Functionality**: Leakage, squeezability, and complete dose expression (delivery) are design challenges for preformed and BFS CPADs. | • **Filling/sealing:** Equipment for Uniject, BFS, and prefilled syringe filling has been developed but must be installed by a manufacturer. Access to pilot-scale filling can be a barrier.<br>• **Aseptic production:** Manufacture of some CPADs will require development of custom aseptic processes, such as assembly of needle hubs to the BFS container.<br>• **Quality control and inspection:** Custom methods for in-process controls and process validation are required.<br>• **Filling line capacity:** BFS offers the potential for higher throughput filling capacity than other CPAD types. | • **Any liquid parenteral vaccine** is a feasible candidate for CPAD delivery from a technical perspective.<br>• Concerns have been raised about the stability of vaccines during the BFS manufacturing process due to potential exposure to heat, but examples of **several types of vaccines** (e.g. live attenuated viruses and subunit antigens) have been tested and **found to be stable when filled with BFS.** |

# To date, commercial uptake of CPADs in LMICs has been limited

Commercial feasibility

| VIPS Criteria | | Indicators | Penta | Hep B BD | HPV | IPV | TCV | Ebola | HIV[1] | Influenza[2] |
|---|---|---|---|---|---|---|---|---|---|---|
| Secondary criteria | Commercial feasibility | Country stakeholders' interest based on evidence from existing data | No data | Mixed interest | No data | No data | No data | No data | No data | No data |
| | | Potential breadth of the target market | Large | Large | Large | Moderate | Small/ Moderate | Small | Large | Small |
| | | Existence of partnerships to support development and commercialisation | Moderate interest | Moderate interest | Mixed interest | Mixed interest | Mixed interest | Mixed interest | Mixed interest | Mixed interest |
| | | Known barriers to global access to the innovation: Preformed CPAD | No known interest | | | | | | | |
| | | Known barriers to global access to the innovation: BFS and others | No data | | | | | | | |

- Despite being commercially available for at least 20 years, **CPAD uptake has been limited**. **Three vaccine products have been WHO prequalified in Uniject, but two of these were subsequently withdrawn.** Penta was discontinued due to **manufacturer specific production line issues.** Tetanus toxoid was discontinued due to **uncertain demand and countries' unwillingness to pay the price premium for a single dose product in a CPAD.** No market shaping was attempted for these products. **Hep B birth doses continue to be produced and used in Uniject, but only for the Indonesian national market** (thus the mixed interest)**.**
- The future **market potential and uptake for CPADs in LMICs** is **uncertain**. A key barrier is assumed to be **purchasers' willingness to pay a higher cost** for a CPAD presentation, so there has been **no incentive to vaccine manufacturers** to adopt the technology**.**
- Other barriers are the need for funding for product development, the investment required to scale-up manufacturing, a perceived lack of market potential and only modest interest from stakeholders.



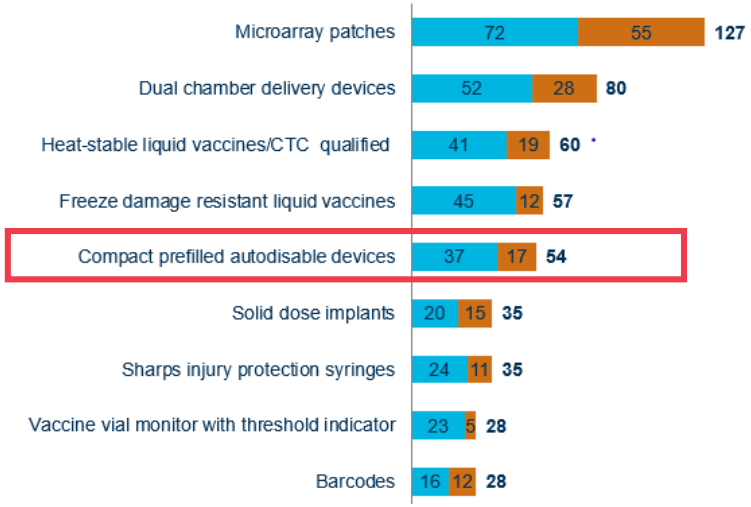
[1] Bivalent subtype C gp120 boost only; [2] VAL 506440

# Based on VIPS country feedback[1], there is moderate interest in CPADs

Countries interest

## Feedback from in-person country interviews

### Innovations' ranking




- **Immunisation staff** ranked CPADs as **#5 and decision makers #4** in terms of having the greatest potential impact to address their immunisation programme's challenges. **The overall rating is #5 amongst the 9 tested**.

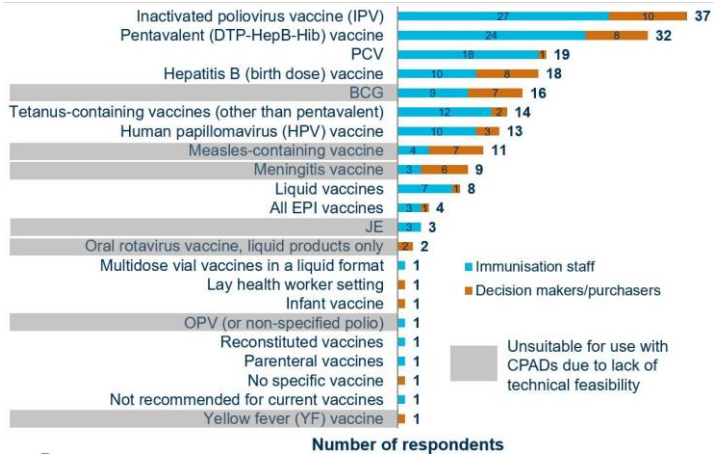
### Perceived benefits

- Make **preparation, administration** and logistics of vaccines **easier and faster; save health care worker time;**
- Reduce **vaccine wastage** and **risk of contamination,** improve **delivery of the correct dose;**
- **Increase acceptability** of vaccines;
- Enable delivery of vaccines **outside health facility** and by **lesser trained personnel to deliver** vaccines.

### Perceived challenges

- Overall impact on **cold chain volume**
- **Time required and complexity** of the technology use**, training requirement;**
- Decision makers: **increase in overall cost and price per dose;**
- **Need for community sensitisation; acceptability;**
- Risk of **not delivering full dose** and **packaging /integrity of the seals; waste disposal.**

### Vaccines' ranking for CPADs




[1] Based on in-person interviews conducted in Q4 2019-Q1 2020 with 55 immunisation staff and 29 decision makers across 6 countries to gather feedback on the 9 innovations under final evaluation

# Potential impact of VIPS prioritisation

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## What could VIPS do to accelerate CPADs development for LMICs[1]

If CPADs were to be prioritised by VIPS, stakeholder inputs would be sought to identify follow-up activities that would have the **greatest impact on accelerating** CPAD development. These could include:

- **Coordinating ongoing and future efforts to ensure that products meet LMIC needs, clarify priority vaccines for packaging in CPADs,** and possibly accelerate product availability through push funding.
- If buyers' **unwillingness to pay a premium for CPADs is the main obstacle,** then **clear signaling that this issue will be addressed** as well as **market shaping activities** including **a procurement mechanism** will be needed**.**

## Risks of not prioritising CPADs through VIPS

- While novel CPAD design efforts are ongoing and are unlikely to be affected, **commercialisation and scale-up of priority LMIC vaccines in CPADs is unlikely to occur** without greater resources and attention.
- Vaccine **manufacturers may see no incentive to adopt CPAD presentations for LMIC markets without market-shaping incentives.**



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