Stakeholder Perceptions of Pentavalent Vaccine (DTwP-HepB-Hib) in the Uniject™ Injection System

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Executive summary

Background and objective

Immunization is a proven tool for reducing deaths from infectious diseases, but getting vaccines to children in developing countries is a daily challenge. One potential way to improve coverage of basic vaccines is to combine several vaccine antigens into one injection that is delivered with an easy-to-use, single-dose, autodisable device. Pentavalent vaccine in the prefilled Uniject™ injection system[i] provides this format. To assess the readiness of stakeholders to accept this product presentation, we conducted interviews and discussion groups with health care workers, policy and procurement officers, and Expanded Programme on Immunization (EPI) managers in six countries.

Methods

We conducted semi-structured interviews with 151 health care workers and policy and procurement officers from Bangladesh, Cambodia, Kenya, Peru, Senegal, and Uganda. We also interviewed 61 EPI managers attending two World Health Organization (WHO) African Regional EPI meetings. Focus group discussions were also conducted in Peru with 69 decision-makers and end-users. Information on Uniject was presented to all participants. Product demonstrations were performed before the interviews and discussions. Participants had the opportunity to practice a simulated injection with Uniject.

Results

The majority of participants preferred a liquid pentavalent vaccine over a lyophilized formulation and a single-dose presentation over two-dose or ten-dose presentations. Policy and procurement personnel focused more on the purchase price and logistical impacts and preferred an autodisable syringe with a vial, whereas health care workers focused on qualities related to safety, ease of use, and patient compliance and expressed a preference for Uniject, which was perceived to save time and to simplify general immunization programmatic risks.

Conclusions and recommendations

Priorities of desired vaccine product attributes differ among country stakeholders. Building awareness of total systems costs and health outcome implications should help to align decision-makers and users of vaccine products. Overall, the introduction and demonstration of the Uniject injection system and the concept of pentavalent vaccine prefilled in Uniject was well received across different stakeholders; user acceptability was high based on ease of use, potential impact on safety with less risk of contamination, and less vaccine wastage.

The authors hope that this report will stimulate interest among a wide group of key stakeholders involved in vaccination with pentavalent vaccines.

[i] Uniject is a trademark of BD.

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Abbreviations

AD	autodisable
AFRO	WHO African Regional Office
CTC	controlled temperature chain
DTwP	diphtheria, tetanus, whole-cell pertussis
EPI	Expanded Programme on Immunization
FGD	focus group discussion
HepB	hepatitis B
Hib	*Haemophilus influenza* type B
HCW	health care worker
SSI	semistructured interview
WHO	World Health Organization

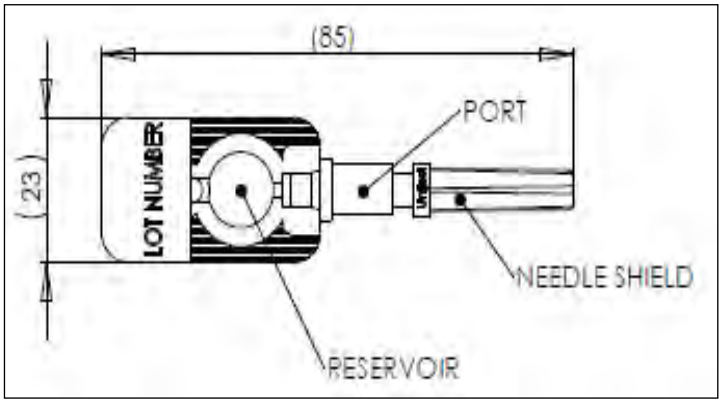
1. Introduction

The field of vaccines is developing at a swift pace, with the evolving vaccine pipeline offering tremendous advances to public health. Introducing these products poses challenges to current infrastructure and logistics, especially in developing countries, pressuring manufacturers to design vaccines that alleviate these complexities. The end results will inherently enhance public health programs, especially those of developing countries.

The Programmatic Suitability of Vaccine Candidates for Prequalification Working Group, the Immunization Practice Advisory Committee, and the Vaccine Presentation and Packaging Advisory Group, all run through the World Health Organization (WHO), are in place to help ensure that vaccines meet the needs and constraints of developing countries. Each of these three groups plays a critical role in vaccine recommendations (such as optimal dosing regimens, ideal formulations, presentation, and packaging) and has inputs into characteristics that facilitate access, minimize delivery errors, and maximize user compliance.

Vaccine manufacturers have indicated a willingness to improve product design, and they look to the WHO for guidance on the long-term requirements for vaccine delivery. Depending on the immunization setting and session size served, it may be preferable to have a multidose presentation in some situations and a single-dose presentation in other situations. Furthermore, there has been an increased demand for autodisable (AD) prefilled syringes and for vaccine formulations without preservatives (i.e., thiomersal). One option, which has existed for many years and has already been utilized for vaccine delivery, [1–10] is the Uniject device manufactured by BD, formerly Becton, Dickinson and Company. The Uniject™ injection system is a compact, prefilled, autodisable injection system for intramuscular and subcutaneous delivery of medicines (Figure 1). The system delivers a pre-measured dose of vaccine when the health care provider presses firmly on the prefilled reservoir. Once the dose has been delivered, the device cannot be refilled or reused. Uniject has been used to deliver drugs and vaccines in developing countries for more than ten years[1,4–10] and user acceptability, safety, and efficacy have been demonstrated in a range of public health settings.[9–10]

Figure 1: Uniject™ injection system



Dimensions in millimeters. A 0.5-ml Uniject™ injection system with a 23-gauge needle of one-inch length prefilled with water was used in the study.

Plans are in place to put a pentavalent (diphtheria, tetanus, whole-cell pertussis [DTwP]–hepatitis B [HepB]–*Haemophilus influenza* type B [Hib]) vaccine, a core component of the Expanded Programme on Immunization (EPI), in the Uniject™ injection system.[11] Given that a fully-liquid pentavalent vaccine in Uniject would be primarily implemented in national immunization programs in developing countries, it was deemed important to understand and know how such a vaccine presentation would be perceived by the stakeholders, that is, both the health care workers (HCWs) who would use the device, and the various policymakers and procurement personnel who would purchase the vaccine for use in their local EPI.

Therefore, PATH performed a series of interviews with the aims of obtaining feedback on the concept of a pentavalent vaccine in the Uniject™ injection system, determining stakeholder perceptions on a liquid pentavalent vaccine in the Uniject™ injection system versus other product formats (liquid or lyophilized in single-dose or multidose vials), and understanding potential barriers to its adoption.

In this paper, we examine the views of different stakeholders regarding perceptions of a pentavalent vaccine in the Uniject™ injection system and the factors that may influence its use in those developing countries where pentavalent vaccines are used as part of the local EPI. The findings may help to enhance our understanding of the perceived product benefits and challenges, as well as the differing preferences between purchasers and users, which may pose potential barriers to uptake of a pentavalent vaccine in this form.

2. Methods

PATH conducted in-country interviews and focus group discussions (FGDs) from August to December 2010 using a combination of qualitative and quantitative methods to gather information on stakeholder perceptions of pentavalent vaccine in Uniject. These studies were classified as non-human-subjects research by PATH's research determination committee; however, prior to the initiation of interviews, institutional and national ethical review board approvals were obtained in each country. We also surveyed EPI managers at two meetings in Africa during 2011.

2.1 Interviews

Semi-structured interviews (SSIs) were conducted in six countries across five regions to capture current practices and product perceptions in different environments. The countries were chosen for their diverse immunization practices and experiences with pentavalent vaccine. Bangladesh, Cambodia, Peru, and Senegal represented countries that currently use liquid pentavalent vaccine, while Kenya and Uganda represented countries using lyophilized pentavalent vaccines.

The SSIs were conducted with two target groups: EPI managers and HCWs with vaccine delivery experience, and ministry of health officials with policy and procurement authority. In total, there were 151 participants (from 16% Bangladesh, 14% Cambodia, 13% Kenya, 28% Peru, 15% Senegal, and 14% Uganda) divided into 102 EPI managers and HCWs and 49 policy and procurement officers. The interviews were conducted in English and were specifically designed for these two groups. Open, closed, and multiple choice questions approved as non-leading by an external third-party research firm were used to collect qualitative and quantitative responses. During the interviews, the interviewees were shown how to use the Uniject™ injection system and subsequently encouraged to simulate injection using a Uniject

filled with saline solution and injecting it into an orange. Questions pertaining to the use of the device were then asked.

2.2 Focus group discussions

Since recommendations for performing injections with Uniject do not include aspiration, FGDs were conducted in a Pan American Health Organization (PAHO) country (Peru) to understand product perceptions in a region where training and local practices often include recommendations to aspirate prior to administration. Five FGDs were conducted with participants from two groups: decision-makers (pediatricians, researchers, health economists, policy advisors, and members of the Technical Committee on Immunization) and end users (nurses, national EPI program HCWs, and coordinators). The regions and participants were chosen by the national EPI program manager based on availability. All FGDs were held in Spanish and were recorded for later analysis. In total, 33 decision-makers and 36 end users participated in the FGDs.

Prior to each FGD, participants were introduced to the concept of Uniject. Participants were then trained to use Uniject and asked to simulate injection of a vaccine using an orange. Following training, an experienced qualitative researcher facilitated the FGDs using a predetermined discussion guide. The discussion focused on the standard immunization practices in Peru (targeted at end users only), perceptions of the product, effectiveness of training, and factors involved in implementation of new technologies (targeted at decision-makers only).

2.3 Regional EPI managers' meetings survey

PATH also surveyed policy and procurement experts attending the 2011 WHO African Regional Office (AFRO) West EPI Managers' Meeting (Ouagadougou, Burkina Faso) and WHO AFRO East and Southern EPI Managers' Meeting (Harare, Zimbabwe). Sixty-one representatives from 28 African countries participated in the survey. A presentation on designing vaccines to meet country needs was given, during which specific questions related to product attributes and other related topics were asked. The participants were also given the opportunity to handle the Uniject™ injection system.

2.4 Data analysis

The information obtained from the SSIs, FGDs, and regional EPI managers' surveys was coded and analyzed in Microsoft Excel. Discrete and multiple-choice questions were evaluated to determine the frequencies and means of occurrences of selected responses. Key terms in responses to open-ended questions were coded and analyzed to determine response trends and outliers. Finally, data correlations were run to understand relationships between responses, participant role in immunization, years of experience, and country of origin. Analysis was focused to reveal the current level of knowledge and perceptions of policymakers, procurement personnel, and HCWs with vaccine delivery experience.

3. Results

We present the views and perceptions of participants from 34 developing countries regarding use of a pentavalent (DTwP-HepB-Hib) vaccine in the Uniject™ injection system. The findings of our investigations are presented in three sections: vaccine attribute preferences, stakeholder vaccine management priorities, and results from the FGDs.

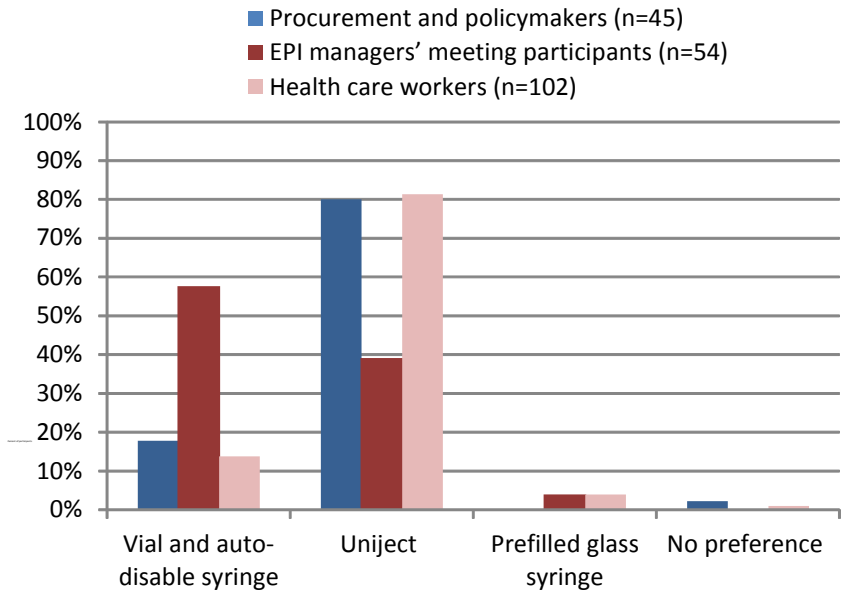
3.1 Vaccine attribute preferences

During the in-country interviews (SSIs) and EPI managers' meetings, participants were asked to indicate their pentavalent vaccine product presentation preference (vial and AD syringe, Uniject, prefilled glass syringe, or no preference), type (liquid, lyophilized, or no preference) and dose presentation (single-dose, two-dose, ten-dose, or no preference).

3.1.1 Product presentation

Four-fifths of HCWs (81%) and policy and procurement participants (80%) reported a preference for Uniject versus a vial with an AD syringe (Figure 2). HCWs commented that, compared to existing presentations, Uniject would be easy to use and store, would provide an accurate dose since measuring is not required, and offers less risk of air bubbles, contamination, and excess vaccine wastage. Policy and procurement participants commented that cold chain space may be compromised with Uniject when compared to multidose vials. However, 15 of 42 participants from Peru, a country in which standard immunization practices involve aspiration prior to vaccine delivery, reported a preference for a vial and AD syringe or prefilled glass syringe.

Figure 2: Preferred pentavalent vaccine presentation

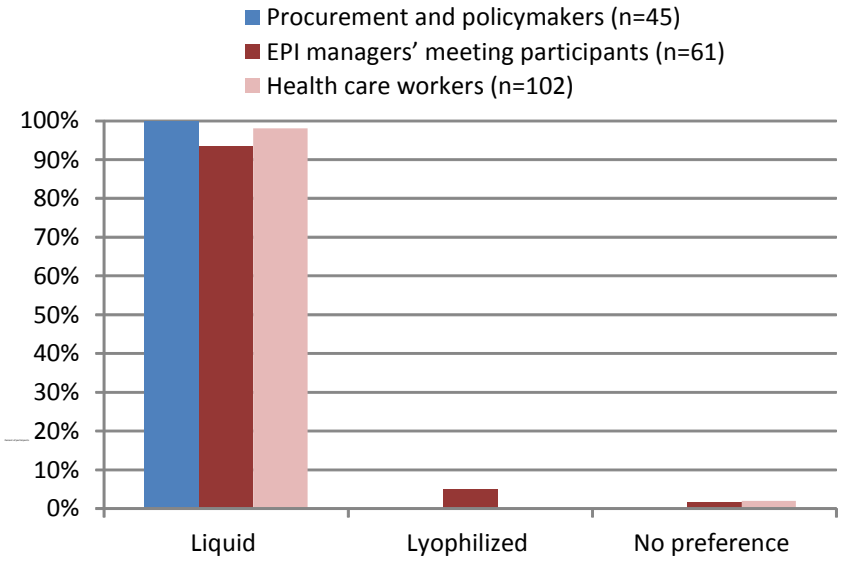


Of the 54 EPI managers responding, 57% indicated a preference for a vial with an AD syringe. A rationale was provided by 44% of those responding, whereby 13% indicated that this presentation would potentially require less space in the cold chain, 9% remarked that there would be no need to retrain HCWs, and 6% said that there would be less wastage, with other reasons (13%) being that it would be less expensive, safer, more durable, and/or offers the potential to be in a controlled temperature chain. A compact, prefilled, AD syringe, such as Uniject, was preferred by 39% of respondents. Of those, 75% provided a rationale with reasons that Uniject was easier to use (58%), easy to store (38%), safe and/or eliminated potential needle reuse or reconstitution mistakes (25%), and offered less vaccine wastage (4%). A few respondents (4%) preferred a prefilled glass syringe, with only one individual providing ease of use as a reason.

3.1.2 Vaccine type

All procurement and policymakers and 98% of HCWs stated a preference for liquid vaccine; 2% of HCWs expressed no preference (Figure 3).

Figure 3: Preferred pentavalent vaccine type

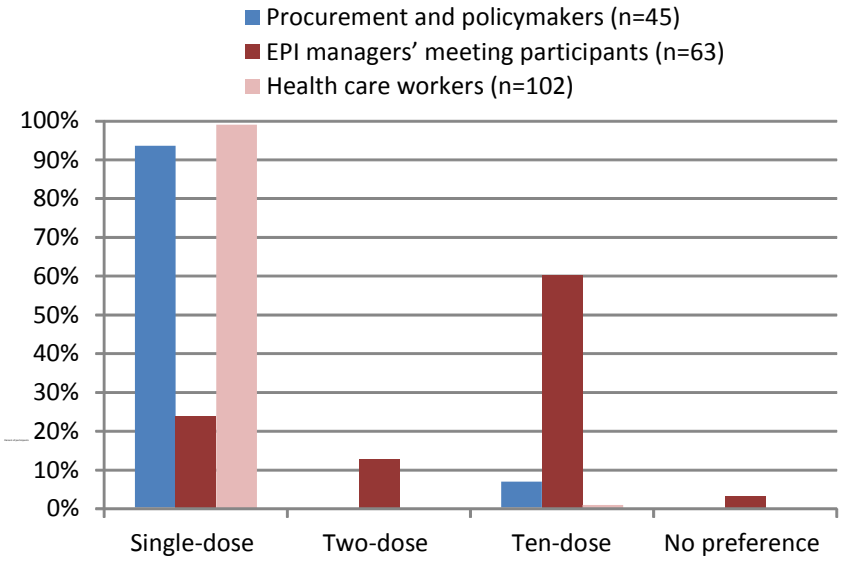


Of regional EPI managers, 93% reported a preference for liquid over lyophilized vaccine (5%) formulations, with 2% reporting no preference. Of those preferring a liquid formulation, 80% gave the following open-ended rationales for their selections: easy to use (45%), reduced storage volume and/or avoids reconstitution issues (24%), and saves time and/or causes less wastage (16%). Those preferring lyophilized vaccine gave the reasons that it would be more stable or that it was the vaccine originally introduced and therefore well known by immunization personnel.

3.1.3 Dose presentation

Most procurement and policymakers (93%) and HCWs (99%) indicated a preference for single-dose presentations; 7% and 1%, respectively, preferred ten-dose presentations, and none indicated a preference for a two-dose presentation (Figure 4).

Figure 4: Preferred pentavalent vaccine dose presentation



Of EPI managers, 24% reported a preference for single-dose pentavalent vaccine, giving the rationale that single-dose vials are easier to use (33%), HCWs are familiar with them (20%), and they offer lower vaccine wastage (20%), with further reasons being better stability, assurance of correct dose, allows child to be vaccinated without waiting, and/or it takes HCWs less time. A two-dose vial presentation was preferred by 13% of the participants, with the reasons being less vaccine wastage (40%), less storage space required (30%), standard size used in country (20%), and reduced cost (10%). The majority (60%) preferred a ten-dose vial size, commenting that a ten-dose presentation may require less cold chain space per dose (61%) and may be less expensive (18%); some participants had a perception of higher quality (3%). However, 37% of those preferring a ten-dose vial did not provide a rationale.

During the in-country SSIs, policy and procurement officers were asked to rank (1 = most important to 4 = least important) the following four vaccine attributes among different pentavalent vaccines: minimizing vaccine wastage, minimizing packaging volume, maximizing ease of delivery for HCWs, and minimizing time needed to prepare and deliver a vaccine (Table 1). Maximizing ease of delivery for HCWs was ranked as the most important criteria, followed by minimizing wastage, minimizing time needed for delivery, and finally minimizing packaging volume.

Table 1: Ranking vaccine attributes

	Procurement and policymakers (n=49)	Health care workers (n=102)	EPI managers (n=61)
Minimizing vaccine wastage	1	2	3
Minimizing packaging volume	2	4	2
Maximizing ease of delivery	3	1	1
Minimizing time to prepare and deliver a vaccine	4	3	5
Ability to use in CTC	Not asked	Not asked	4
Vaccine and syringe in an integrated device (i.e., Uniject)	Not asked	Not asked	6

Range was 1 = most important to 4 (or 6 for EPI managers) = least important
CTC = controlled temperature chain; EPI = Expanded Programme on Immunization

In contrast, HCWs ranked maximizing ease of delivery as the most important criteria, followed by minimizing vaccine wastage, minimizing time needed for delivery, and, lastly, minimizing packaging volume.

The participants of the EPI managers' meetings were also asked to rank (1 = most important to 6 = least important) the order of importance of the same vaccine attributes mentioned above plus the following: ability to use the vaccine in a controlled temperature chain and whether the vaccine and syringe are packaged in an integrated device (i.e., Uniject), assuming the safety, efficacy and costs remained the same. For this group of participants, the most important attributes were maximizing ease of delivery for HCWs and minimizing packaging volume, followed by minimizing wastage and ability to use the vaccine in a controlled temperature chain. The least important attributes were minimizing time needed to prepare and deliver a vaccine, and having vaccine and syringe packaged in an integrated device (i.e., Uniject).

3.2 Stakeholder vaccine management priorities

To understand the importance of concerns related to vaccine management, participants of the SSIs were asked to evaluate how aspects of an immunization session would change (more, less, or same) if a pentavalent vaccine in the Uniject device were used instead of a pentavalent vaccine with a standard needle and syringe (Table 2). For all aspects (risk of vaccine contamination, risk of mistakes during preparation, risk of needlestick injury, problems with waste disposal, training required for administration, inaccuracy of dose injected, potential for improper needle reuse), between 53% and 100% of policy and procurement specialists and between 61% and 98% of HCWs ranked each aspect as "less."

Table 2: Perception of immunization programmatic risks and change offered by a pentavalent vaccine in Uniject compared to a pentavalent vaccine in a vial with an autodisable syringe

Immunization programmatic risk	EPI managers' concern rank[1] (n=61)	Perception of change offered by pentavalent vaccine in Uniject compared to vial and autodisable syringe								
		Policy and procurement officers[2] (n=43)			Health care workers[2] (n=102)			Pooled (n=145)		
		More	Less	Same	More	Less	Same	More	Less	Same
Vaccine contamination	1	2.3	88.4	9.3	3.0	94.1	3.0	2.8	92.4	4.8
Ability to maintain 2°C to 8°C cold chain[3]	2	-	-	-	-	-	-			
Mistakes during preparation	3	0.0	100.0	0.0	0.0	98.0	2.0	0.0	98.6	1.4
Needlestick injury	4	2.3	74.4	23.3	3.9	68.6	27.5	3.4	70.3	26.2
Problems with waste disposal	5	7.0	88.4	4.7	2.9	77.5	19.6	4.1	80.7	15.2
Training required for administration	6	34.9	53.5	11.6	20.6	61.8	17.6	24.8	59.3	15.9
Inaccuracy of dose injected	7	32.6	58.1	9.3	17.7	74.5	7.8	22.1	69.7	8.3
Potential for improper needle reuse	8	11.6	76.7	11.6	14.9	73.3	11.9	13.8	74.5	11.7

[1] From surveys at EPI managers' meetings in Africa
[2] Participated in interviews in six countries
[3] This question was asked only of EPI managers

However, 26% of participants believed that the risk of needlestick injury would likely be the same with Uniject, and 22% felt that inaccuracy of dose may be more likely with Uniject. This perception may reflect the lack of understanding that vaccine in Uniject is slightly overfilled allowing an accurate injected volume but leaving a small residue of liquid remaining in the device following administration. Fifteen percent of participants responded that waste disposal and 16% that training would be the same with Uniject, with 25% indicating that training would be more. Fourteen percent responded that there may be more potential for improper reuse with Uniject. Analysis of the results at a group level revealed that this overall trend in results was maintained for both HCWs and policy and procurement officers. Of interest is that 33% of policy and procurement officers and 18% of HCWs perceived that there would be a greater level of inaccuracy in dose volume following injection with Uniject.

Participants of the EPI managers' meeting were also asked to rank the same aspects of an immunization session, with the addition of one aspect: ability to maintain 2°C to 8°C cold chain. Participants were asked to evaluate the aspects based on their level of concern, with 1 being not concerned and 5 being very concerned. They selected risk of vaccine contamination and making mistakes during preparation as the most important factors. Risk of needlestick injury and problems with waste disposal and training requirements were ranked as the next most pressing concerns; inaccurate dose injections and the potential for improper needle reuse were ranked last.

3.3 Focus group discussions

Peru currently uses liquid pentavalent vaccine in a single-dose vial format as part of the immunization schedule. Two FGDs were held with decision-makers: one with members of the technical committee on

immunization (Lima, n = 21) and one with national EPI coordinators (Lima, n = 12). Three FGDs were held with HCWs: one with HCWs from Lima and Callao (n = 12), one with HCWs from Arequipa (n = 12), and one with HCWs from Chimbote (n = 12).

The majority of participants revealed that aspiration prior to injection to prevent injecting a vaccine into a blood vessel is a very important consideration in Peru. The HCWs reported that aspiration is part of the curriculum in nursing schools and in ongoing immunization and general professional training provided to nurses. Participants were unaware that WHO recommendations advise that HCWs not aspirate before injection,[12] and some participants showed willingness to learn new techniques.

4. Discussion

This study provides qualitative insights into the preferred vaccine attributes from stakeholders in immunization delivery, policy, and procurement from more than 30 developing countries. The feedback gained presented an opportunity to reflect on the demand for specific vaccine product attributes.

The results revealed that there are differences in opinions between HCWs and policy and procurement officials. Health workers appear to be focused on ease of use, accuracy of dose, and reducing contamination risks and vaccine wastage; they believe that Uniject offers many of these advantages. Policy and procurement personnel, however, appear to be driven more by cost-reduction strategies including minimizing vaccine price per dose and cold chain storage, training, and transport costs. In order to address concerns such as the cold chain space requirements, innovations to Uniject and its packaging have been implemented to include a re-sealable plastic tray containing 20 units. This new packaging design ensures that the pentavalent vaccine in the Uniject device requires the equivalent amount of cold chain space, on a per-dose basis, as that required for single-dose vials.

The FGDs held in Peru gave insight into immunization practices in a country that currently uses the aspiration technique prior to vaccine delivery. It was revealed that aspiration is a critical component of vaccine delivery in this country and is still included as part of nurse training. Initially, the consensus was that there was reluctance toward Uniject, due to its inability to easily allow aspiration. In spite of this, national EPI participants in Peru expressed a strong interest in pentavalent vaccine in Uniject and were open to revising and updating the current guidelines on aspiration based on the recommendations of both the Centers for Disease Control and Prevention and the WHO, if additional scientific evidence were to be presented.

Together the interviews and FGDs among the HCWs and policy and procurement participants presented an opportunity to understand the perception of benefits and challenges related to pentavalent vaccine in Uniject. Although these groups are not representative of all EPI coordinators, vaccinators, or decision-makers, the opinions provided important data to inform continued product development and potential introduction of the product into low- and middle-income countries.

Overall, introduction and demonstration of the Uniject™ injection system and the concept of pentavalent vaccine prefilled in Uniject were well received by participants. However, the issue of aspiration was confirmed to be a potential barrier to adoption in the context of Peru, and potentially in other countries currently practicing this injection technique. Despite the controversy around aspiration, participants perceived pentavalent vaccine in Uniject as a positive alternative to pentavalent vaccine in a vial with

needle and syringe and indicated that they were willing to try this new presentation in the context of a pilot demonstration. Middle-income countries, such as Peru, also consider glass prefilled and retractable syringes as an alternative to traditional AD needles and syringes. However, the cost and volume benefits of Uniject may serve as convincing arguments for pentavalent vaccine in Uniject over glass prefilled devices and retractable syringes.

One of the limitations of this study was that 61 policy and procurement participants were attending the EPI managers' meetings that specifically highlighted concerns related to future cold chain constraints and introduction of higher price vaccines. As a result, participants may have been more apt to focus on these characteristics when completing the survey, potentially biasing the results from this group. Stakeholders mostly believed that pentavalent vaccine in Uniject reduces immunization programmatic risks; however, clear communication of the product's potential to lower system costs and ensure accurate and safe injection is recommended. Uniting policymakers and procurement officers with HCWs to understand and appreciate these qualities should increase acceptance and stimulate uptake of such innovative products and delivery devices.

5. Conclusions and recommendations

The findings enhance our understanding of the perceived product benefits and differing preferences between decision-makers and end users that may pose barriers to uptake.

Overall, the introduction and demonstration of the Uniject injection system and the concept of pentavalent vaccine prefilled in Uniject was well received across different stakeholders: user acceptability was high based on ease of use and potential impact on safety with less risk of contamination and less vaccine wastage.

The information elicited from this study will be useful for future decision-making, especially with regard to the uptake of new product devices. Increasing vaccine coverage still remains key to any immunization program, and a product that can help achieve this goal will be well-received by the immunization community.

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