

# Pentavalent Vaccine in the Uniject™ Injection System: Health Care Waste Management Considerations

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## Executive Summary

### *Background*

Fully liquid pentavalent vaccines combining antigens for protection against the five potentially life-threatening childhood diseases (diphtheria, tetanus, pertussis, hepatitis B, and diseases caused by *Haemophilus influenzae* type B) are currently a component of national immunization schedules in over 70 countries. Using the Uniject™ prefilled injection system, a new presentation of fully liquid pentavalent vaccine is in development by Crucell. This is targeted for use in developing countries. To improve understanding of the impact on health care waste management (HCWM), PATH was funded by Crucell to conduct a quantitative and qualitative analysis of the differences between delivery of Quinvaxem® in BD Uniject™ and delivery of pentavalent vaccine in a vial using a syringe.

### *Methodology*

The quantitative and qualitative analysis compared the health care waste that would be produced by Quinvaxem® in BD Uniject™ with a liquid pentavalent vaccine in a vial administered with a SoloShot™ syringe as representative of standard syringes. The analysis focused on the weight and size of syringes, Uniject™, and vaccine vials of various sizes; the quantity of 0.5-mL syringes that would fit into 2.5-L and 5.0-L safety boxes; glass disposal; packaging reuse; waste management in campaign settings and during outreach vaccination; and the environmental impact.

Additionally, PATH conducted a literature search for systematic reviews and meta-analyses, primary research, and commentaries that examined HCWM, focusing on the programmatic effects of HCWM, specifically the volume of contaminated waste; ease of disposal; disposal cost and logistics; acceptability; and glass waste from vials.

### *Main findings*

The analysis identified the following advantages for BD Uniject™ as a presentation for Quinvaxem® over delivery of pentavalent vaccine via a vial and syringe: reductions in weight and volume of waste; elimination of glass waste; reduction of sharps/biohazardous waste; reduction in numbers of safety boxes; reduction of potential for packaging and syringe reuse; and lowered costs of consumables and equipment required for appropriate waste management.

These reductions lead in turn to a reduction in overall costs and resources; improved environmental impact through less incineration, open burning, and use of waste pits for vials; and overall facilitation of waste management in both campaign settings and outreach immunization activities.

### *Conclusions*

The proposed BD Uniject™ injection system for Quinvaxem® offers advantages over the presentation of fully liquid pentavalent vaccine in glass vials in combination with a standard autodisable syringe with regards to disposal and waste management.

Results from this analysis are corroborated by the existing literature on field use of several applications of the Uniject™ injection system. These advantages translate into cost savings and relevant operational elements that will positively impact use of Quinvaxem® in BD Uniject™ in low-income countries.

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## Abbreviations

AD	autodisable
CHW	community health worker
DTwP	diphtheria, tetanus, whole-cell pertussis
HCWM	health care waste management
HepB	hepatitis B
Hib	<i>Haemophilus influenzae</i> type B
PQS	Performance, Quality and Safety
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
WHO	World Health Organization

# 1. Background

Prior field analysis of the Uniject™ injection system prefilled with vaccines and other products suggests that Quinvaxem® in BD Uniject™ is likely to offer waste management benefits when compared with a single-dose glass vial of liquid pentavalent vaccine delivered as an injection with a 0.5-mL autodisable (AD) syringe. Crucell funded PATH to conduct a preliminary investigation assessing weight and volume of injection systems to help further the understanding of waste management differences between delivering Quinvaxem® in BD Uniject™ and delivering pentavalent vaccine in a vial using a syringe.

## 1.1. Pentavalent vaccine

Quinvaxem® is a fully liquid vaccine combining antigens for protection against the following five potentially life-threatening childhood diseases: diphtheria (D), tetanus (T), and whole-cell pertussis (wP; whooping cough), hepatitis B (HepB), and *Haemophilus influenza* type B (Hib). Quinvaxem® was codeveloped by Crucell and Novartis. Quinvaxem®, commercially available in single-dose vials, is currently a component of national immunization schedules in 35 countries. To support further the needs of Expanded Programme on Immunization processes and developing countries, Crucell has developed an alternative presentation of Quinvaxem® in a compact, prefilled, AD injection system (Uniject™).

## 1.2. The Uniject™ injection system

The Uniject™ prefilled injection system is a commercially available product, manufactured and marketed by BD, formerly Becton, Dickinson and Company.<sup>1-3</sup> The Uniject™ injection system is a compact, prefilled, AD injection system for intramuscular and subcutaneous delivery of medicines (Figure 1). The system delivers a premeasured dose of vaccine when the health care provider presses firmly on the prefilled reservoir. Once used, the injection system cannot be refilled or reused. The Uniject™ design offers fast, simple, and accurate injections, while the compact size allows for easy transport, storage, and disposal. Tamper-evident packaging facilitates safe, sterile injections.

**Figure 1. BD Uniject™ injection system.**



Photo: PATH

PATH licensed Uniject's underlying intellectual property to BD in 1996, and BD launched Uniject™ to pharmaceutical and biological producers the same year. Uniject™ has been used to deliver drugs and vaccines

in developing countries for over ten years<sup>1,4-8</sup>; user acceptability, safety, and efficacy have been demonstrated in a range of public health settings.<sup>9,10</sup> More than 73 million Uniject™ injection systems have been used to deliver drugs or vaccines. Over 5 million doses of HepB have been given to children at birth in Indonesia, and the United Nations Children's Fund (UNICEF) has delivered 8 million doses of tetanus toxoid (TT) in Uniject™ as part of the Maternal and Neonatal Tetanus Elimination program. In addition, Uniject™ has also been used for pharmaceutical applications such as for the administration of oxytocin.

### 1.3. Hazardous waste and its disposal

Between 10% and 25% of all medical waste is hazardous, and the majority of hazardous medical waste is infectious, meaning that it can transmit infections and may be harmful to health workers, the community, and the environment.<sup>11</sup> Injection equipment (e.g., needles and syringes) and other sharps waste are often exposed to blood-borne pathogens and, therefore, carry the greatest risk of disease transmission if reused or handled in an unsafe manner. This risk creates a significant public health burden. The World Health Organization (WHO) estimates that 21 million hepatitis B infections, 2 million hepatitis C infections, and 260,000 HIV infections are inadvertently caused by injections administered with contaminated needles and syringes each year.<sup>12</sup>

Proper segregation of medical waste into general waste, infectious waste, and sharps waste is the first step in preventing accidental injury and disease transmission. Once waste is properly segregated, it must be treated and disposed of in a safe manner according to facility and country policies for medical waste disposal.<sup>13</sup>

Immunization activities generate an enormous amount of medical waste that requires proper handling and treatment. Every year, an estimated 16 billion injections are administered. Not all needles and syringes are disposed of properly, creating a risk of injury, infections, and improper reuse.<sup>14</sup> Inadequate management of sharps and waste from immunizations can have a direct negative impact on the community and the personnel working in immunization services. In addition, if treated incorrectly, disposal of this waste can have direct and indirect health effects in the community and negatively impact the environment.<sup>15</sup>

## 2. Current Waste Management Practices

### 2.1. Training

Common training messages for safe handling of used syringes resulting from immunizations in facilities include the following:

- Place the safety box where the injections are given.
- Immediately dispose of the syringe in the safety box after injection.
- Do not recap syringes before disposal.
- Fill the safety box three-quarters full—do not overfill.
- Safety boxes should be filled only once and discarded immediately.
- In the event of a needlestick injury, report it to your supervisor and seek postexposure prophylaxis immediately.

PATH has developed a job aid for programs to use for trainings on safe disposal of Quinvaxem® in BD Uniject™. This is included as Appendix 4.

### 2.2. Final treatment and disposal

Incineration and burning are recommended treatments and final disposal options for safety boxes, with incineration at temperatures of over 800°C being preferable to minimize emissions.<sup>16</sup> Burning the safety box in a pit and then covering with a layer of dirt or disposing of the safety box in a sharps pit or infectious waste pit are also accepted practices. With the move to single-dose vials, glass quantities have increased, and the challenge of disposal has become increasingly problematic in low-resource settings.<sup>17</sup>

**Figure 2. A diesel-powered incinerator and infectious waste in Botswana.**



Photo: PATH

Infectious waste in health facilities may be incinerated, disposed of in pits or in the open, collected by specialized firms, or mixed with general waste.<sup>18</sup> However, in practice, many maternal and child health facilities lack small-scale incinerators so burn pits or burial are common. Budgets are often lacking funds for safe treatment and final disposal of infectious waste.



### 3. Literature Review

PATH conducted a literature search using PubMed for systematic reviews and meta-analyses, primary research, and commentaries that examined health care waste management (HCWM), including volumes, implications of glass disposal, and costs. Internal PATH reports were also assessed for prior evaluations of Uniject™.

As countries decide on the introduction of new vaccines, they weigh attributes related not only to immunogenicity but also to programmatic aspects such as vaccine doses wasted, ease of use, cold chain volume, and health care waste produced. A study conducted to evaluate the impact of introducing new vaccines revealed that countries prefer vaccines in ready-to-use formats, such as the case of single-vial liquid vaccine, as it simplifies the preparation process.<sup>19</sup>

The literature review PATH conducted focused on the programmatic effects of HCWM. The specific HCWM considerations that relate to BD Uniject™ were the volume of contaminated waste, ease of disposal, disposal cost and logistics, acceptability, and glass waste from vials.

**Figure 3. Unsafe disposal of injection waste in Senegal.**



Photo: PATH

#### Volume of contaminated waste

A study evaluating single-dose versus multi-dose vials for immunization reported that the disposed volume of vials is approximately two to five times greater for single-dose vials; however, vial disposal does not present the same risk as sharps disposal.

Compared with single-dose vials with an AD syringe, prefilled AD devices decrease the total volume of contaminated medical waste by over 60%.<sup>20</sup> The study used the average packed volume per 0.5-mL AD syringe among the four suppliers and the volume of Uniject™ injection system as reported by BD. The volume of contaminated waste would be even less with Quinvaxem® in BD Uniject™, a presentation that contains about 25% less plastic than a standard AD syringe.

## Ease of disposal

Additional field studies have been conducted to evaluate different attributes of the Uniject™ injection system versus a standard needle and syringe. Among the attributes studied was the ease of disposal of the Uniject™ injection system. These studies evaluated various non-vaccine applications of Uniject™, including injectable contraceptives and oxytocin, as well as vaccine applications such as TT and HepB vaccines. The waste management considerations of all these applications can be extrapolated to the scenarios of use for additional vaccines in BD Uniject™, such as Quinvaxem®.

### *Sayana® Press<sup>1</sup>*

A waste management assessment conducted by PATH found that Sayana® Press generated 70% less waste by volume than the standard AD syringe (SoloShot™) with an empty depot medroxyprogesterone acetate vial.<sup>21</sup> Assessments showed that 2.6 times as many Sayana® Press fit into a 5.0-L safety box as standard AD syringes (500 compared to 195). Excluding the vial, use of Sayana® Press generated 39% less waste by volume than an AD syringe. Sayana® Press also occupied less than half the volume of the standard syringe and vial in distribution.

### *Oxytocin in Uniject™—Vietnam, Indonesia, Guatemala, and Honduras*

Various field operational studies conducted on oxytocin in Uniject™ for postpartum hemorrhage prevention have demonstrated high levels of acceptability among providers in regards to disposal of the Uniject™ injection systems.<sup>22</sup> In all these studies, providers have reported that it was easier to dispose of the Uniject™ injection system than needles and syringes.

## Disposal costs and logistics

In a study evaluating the use of Uniject™ for outreach immunization of the birth dose of HepB by village midwives<sup>5</sup> in which the HepB vaccine prefilled in Uniject™ was transported by health workers in an outreach carrier fitted with a small Uniject™ disposal box, 96% of midwives who participated in the study disposed of the Uniject™ correctly in the assigned cardboard disposal box. A cost-effectiveness analysis was conducted as part of the study, and the costs of disposal were considered to be about the same for Uniject™ injection systems as for standard disposable syringes. The cost of incineration per syringe varied greatly according to the amount of waste generated. The less waste generated, the lower the cost overall. However, the more the incinerator was used, the less the disposal cost per syringe.

Country studies that have included all of the cost components of waste management with medium-temperature incineration have indicated that the disposal cost per syringe ranges from US\$0.08 for routine health services alone to US\$0.02 when used for both routine services and immunization campaign waste disposal.<sup>23</sup> Based on this, it can be extrapolated that the cost of disposing Uniject™ has the potential to be less than that of disposing of needles and syringes, as Uniject™ generates less waste compared with needles and syringes. Also, the costs quoted do not include costs of final disposal of vaccine vials, which would not be applicable during immunization with a Uniject™-filled vaccine. With no formal disposal system methodology for glass vials, such costs are difficult to estimate. However, glass is increasingly becoming a burden to health systems that lack means of disposing of them.

## Acceptability

In a study that evaluated the performance, acceptability, and appropriateness of Uniject™ for an outreach immunization application of TT,<sup>4</sup> the TT prefilled in Uniject™ was stored, transported, and disposed of using a

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<sup>1</sup> Note: the Sayana Press product is formerly known as depo-subQ provera 104™ in the Uniject™ injection system.

small outreach carrier designed with a storage compartment and a small cardboard disposal box to reduce the risks of improper handling and disposal. Supervisors noted that the use of Uniject™ would simplify storage and distribution of vaccine supplies and injection equipment since it is a prefilled injection system. The study concluded that Uniject™ was reliable, easy to use, faster than a standard syringe, and well accepted by vaccinators, supervisors, and patients. Nevertheless, important operational issues such as ensuring a supply of outreach carriers and disposal boxes were critical for proper storage, transportation, and disposal.

### **Elimination of glass waste from vials**

The lack of glass waste from vials was another benefit of the Uniject™ injection system supported by the literature review. Vaccine vials are made out of thick glass requiring high-temperature incineration to destroy them.<sup>24</sup> This is a challenge in low-resource settings where resources for waste management are scarce. Without a glass vial, Uniject™ bypasses this logistical challenge and eliminates the added cost of glass disposal. Furthermore, Uniject™ does not emit toxic fumes such as those emitted by incineration of the rubber stoppers commonly found in disposable syringes.<sup>4</sup> In addition, Uniject™ contains only about 25% of the total amount of plastic found in standard disposable syringes.<sup>1,2</sup>

## 4. Study Design and Methodology—Comparative Analysis of Factors Impacting Waste Management

This section describes the waste management analysis to compare a future presentation proposed for Quinvaxem® (i.e., BD Uniject™ for Quinvaxem®, with a single-dose vial and syringe). Where applicable, the presentation is referred to as BD Uniject™ for Quinvaxem®, indicating that the study was performed with the Uniject™ injection system as adapted for future use with Quinvaxem®.

### 4.1. Objectives

The objective of this comparative analysis was to identify quantitative and qualitative differences in waste management attributes between BD Uniject™ for Quinvaxem® and a liquid pentavalent vaccine delivered using a single-dose vial and syringe in the context of both facility-based and campaign-based settings in regards to the following:

- Quantity and type of health care waste produced.
- Impact on safe containment options.
- Cost of disposal.

This information should be provided to decision-makers, donors, and collaborators on waste management considerations when considering vaccine presentation options for pentavalent vaccines.

### 4.2. Methodology

The quantitative and qualitative analysis compared the health care waste produced by BD Uniject™ for Quinvaxem® with a liquid pentavalent vaccine administered with a SoloShot™ syringe, as representative of standard syringes used in the field.

A comparative evaluation and analysis was conducted on the following:

- Weight and size of syringes, Uniject™, and vaccine vials of various sizes.
- Quantity of 0.5-mL syringes that fit into a 5.0-L safety box and into a 2.5-L safety box.
- Glass disposal.
- Packaging reuse.
- Waste management in campaign settings.
- Waste management during outreach vaccination.
- Environmental impact.
- Feasibility of using needle removers with Uniject™ injection systems.

To identify programmatic and cost implications for the introduction of Quinvaxem® in BD Uniject™ on HCWM systems, the following quantitative and qualitative data sources were referenced:

- PATH's HCWM expertise from the Making Medical Injections Safer project (2004 to 2010) funded by the US Centers for Disease Control and Prevention and the United States Agency for International Development and the HealthTech program funded by the United States Agency for International Development (1998 to 2009).

- Published and unpublished literature.
- Expert opinions from partners.

## 5. Results—Comparative Analysis of Factors Impacting Waste Management

This section describes the results of the waste management analysis to compare a future presentation proposed for Quinvaxem® (i.e., BD Uniject™ for Quinvaxem®, with a single-dose vial and syringe). Where applicable, the presentation is referred to as BD Uniject™ for Quinvaxem®, indicating that the study was performed with the Uniject™ injection system as adapted for future use with Quinvaxem®.

### 5.1. Size and weight of syringes and needles

Differences in the size and weight of BD Uniject™ for Quinvaxem® compared with a pentavalent vaccine in a single-dose glass vial with a plastic syringe are expected to impact management and costs of health care waste.

Weights and dimensions of Uniject™ injection systems and Soloshot™ syringes and needles are shown in Table 1.

**Table 1. Dimensions and weights of BD Uniject™ and Soloshot™ syringes.**

Measurement	Uniject™*	SoloShot™
Weight (single units) with packaging (g)	4.14 (filled)	3.59 (empty)
Weight (single units) without packaging (g)	1.17 (empty)	2.56 (empty)
Outside dimension (L x W x H, mm)	78 x 23 x 10	104 x 23 x 14
Length of needle (mm)	25	20
Volume—empty (cm <sup>3</sup> )	0.38	0.55

\*Individually packaged Uniject™ injection systems were used.

Table 2 summarizes the comparative weights for BD Uniject™ for Quinvaxem® and liquid pentavalent vaccine using a single-dose glass vial and syringe.

**Table 2. Weights of BD Uniject™, single-dose vials, and Soloshot™ syringes.**

Measurement	BD Uniject™ for Quinvaxem®	Liquid pentavalent vaccine in a 0.5-mL syringe		
		Single-dose vial, 0.5 mL*	SoloShot™ syringe	Total (single-dose vial + SoloShot™)
Weight (single units) with packaging (g)	4.14 (filled)	5.44 (filled)	3.59 (empty)	9.03
Weight (single units) without packaging (g)	1.17 (empty)	2.65 (empty)	2.56 (empty)	5.21

Both Uniject™ and the SoloShot™ IX injection systems are made up of common, syringe-grade plastic and stainless steel needles.

\* Source: Crucell.

## 5.2. Safety box requirements

Two sizes of safety box are commonly used, 2.5 L and 5.0 L (Figure 4). Depending on the setting (e.g., outreach, facility size, etc.), different safety boxes may be used due to varying volumes of injection devices.

**Figure 4. 5.0-L and 2.5-L safety boxes.**



Photo: PATH

Table 3 summarizes the comparative quantities of BD Uniject™ for Quinvaxem® versus 0.5-mL SoloShot™ syringes that can be contained in the two sizes of safety boxes. Approximately 2.6 times and 2.4 times as many BD Uniject™ for Quinvaxem® injection systems will fit into 5.0-L and 2.5-L safety boxes, respectively, compared to 0.5-mL SoloShot™ syringes. Further details are given in Appendix 1.

**Table 3. Comparison of numbers of BD Uniject™ for Quinvaxem® and 0.5-mL SoloShot™ syringes contained in safety boxes (PATH, 2011<sup>21</sup>).**

Safety box size	BD Uniject™ for Quinvaxem®	SoloShot™	Empty safety box weight
5.0 L	500	190	11.9 oz
2.5 L	180	75	7.0 oz

Table 4 summarizes the estimated safety box requirements for 500 syringes with 1-inch needles based on the capacity information in Table 3.

**Table 4. Anticipated safety box requirements per 500 0.5-mL syringes with 1-inch needles: BD Uniject™ for Quinvaxem® compared to SoloShot™ syringes.**

	5.0-L safety box		2.5-L safety box	
	Number needed	Total cost (US\$)*	Number needed	Total cost (US\$)†
Number required per 500 BD Uniject™ for Quinvaxem®	1	0.90	3	2.37
Number required per 500 SoloShot™ syringes	3	2.70	8	6.32

\* Cost estimate is based on a base quote of US\$0.90 received in December 2012 plus shipping costs (range for shipping costs is 20% to 100%).

† Cost estimate is based on a base quote of US\$0.60 received in December 2012 plus shipping costs (range for shipping costs is 20% to 100%).

Thus, for a given number of syringes, approximately 3 and 2.7 times as many 5.0-L and 2.5-L safety boxes, respectively, would be required for 0.5-mL SoloShot™ syringes compared to BD Uniject™ for Quinvaxem®, providing clear cost savings. Associated cost savings would also include reduced international shipment costs, given that fewer boxes would be needed to ship a given number of doses in Quinvaxem® in BD Uniject™. Possible containment options for Quinvaxem® in BD Uniject™ are described in Appendix 2.

As an example of potential cost savings for incineration, a program in which 100,000 children are vaccinated with Quinvaxem® in BD Uniject™ would result in 200 filled, 5.0-L safety boxes, with fuel costs to incinerate the waste estimated at US\$70. The corresponding number of vaccinations using pentavalent vaccine delivery with glass vials and syringes would result in approximately 526 5.0-L safety boxes filled with syringes, and incineration costs of US\$183.

### 5.3. Glass disposal

Liquid pentavalent vaccines are packaged in single-dose, 0.5-mL glass vials, as well as in multi-dose presentations of 2- and 10-dose vials. The preference in many countries for single-dose vials results in increasing quantities of glass vial waste. Though the empty vial is not considered infectious waste, it still requires disposal. It is not uncommon to find glass vials in safety boxes, adding weight and occupying valuable space intended for sharps. Glass vials, if not crushed, fill up sharps pits quickly. Space for pits is limited, especially in busy peri-urban health centers in many countries, where the volumes of injections are likely to be high.

**Figure 5. Disposal pit for glass vials in Mozambique.**



Photo: PATH

BD Uniject™ for Quinvaxem® would eliminate the need for a glass vial. Glass has become increasingly problematic to dispose of in low-resource settings. Glass does not melt in medium-temperature, small-scale incinerators or by burning and can quickly fill waste pits. The explosions caused by incinerating sealed vials cause serious damage to the refractory liners of incinerators. Glass can melt in a high-temperature incinerator, blocking the grate and partially encapsulating needles. Not treating the vial leaves it exposed in garbage piles for potential inappropriate reuse. By avoiding glass vials by using Uniject™, pressure is reduced on the waste



management system through elimination of the need to crush or sterilize glass vials; this also significantly reduces the rate at which waste pits fill. More information about glass disposal is included in Appendix 3.

## 5.4. Packaging reuse

Quinvaxem® in BD Uniject™ will be packaged in a tray containing 20 injection systems, reducing the amount of packaging waste that results from wrapping each individual syringe. The blister packs currently used for many standard syringes present a potential risk of reuse—the packaging could be collected, filled with a used, non-AD syringe, resealed, and sold as a new syringe.<sup>25</sup> As the packaging for Quinvaxem® in BD Uniject™ is still under development, the volume of packaging that will be produced was not evaluated.

**Figure 6. Potential Quinvaxem® in BD Uniject™ packaging format.**



Photos: Johnson and Johnson Company

## 5.5. Waste management in campaign settings

BD Uniject™ for Quinvaxem® is expected to facilitate safe management of waste in community-based distribution. Since BD Uniject™ for Quinvaxem® is significantly smaller than standard AD syringes, more injection systems will fit into a safety box or an improvised container. This allows for smaller or fewer safety

boxes or containers, as well as less waste to contain, transport, treat, and dispose of, thereby simplifying the disposal logistics.

## 5.6. Waste management during outreach vaccination

As task shifting occurs and community health workers (CHWs) increasingly take on immunization responsibilities, the small size of BD Uniject™ for Quinvaxem® and the simplicity of managing its waste will be an advantage during outreach immunization. Vaccinators and CHWs who may be required to travel to homes or health outposts on foot or via local transportation may find BD Uniject™ for Quinvaxem® simpler to dispose of than a glass vial and AD syringe. Regardless of whether the injection waste needs to be transported back to the health facility for final disposal, there will be less waste to manage. Smaller safety boxes or durable biohazard waste containers could facilitate BD Uniject™ for Quinvaxem® waste containment in field settings because of its small size.

## 5.7. Environmental impact

The environmental impact that might result from residual vaccines leaching into the environment from glass vials has not yet been documented. Unlike a glass vial, the plastic reservoir containing in BD Uniject™ for Quinvaxem® can be incinerated, thereby eliminating risks of environmental contamination from the vaccine. It is unknown whether there is an environmental risk from incineration of residual vaccine, though the risk would be no different than from incineration of a syringe used for pentavalent vaccine.

## 5.8. Needle removers

An option for containing, disabling, and treating used needles are electric and manual needle removers. While not common practice for disabling needles, needle removers have been piloted and introduced into various countries,<sup>26</sup> including India, where they are now the national standard of care. The three most widely evaluated manual needle-remover devices are made by BMDi, Balcan, and BD.

Results from bench testing of the BMDi, Balcan, and BD needle removers with Uniject™ injection systems showed that these devices are not compatible with Uniject™.<sup>26</sup> The BMDi needle remover does not accommodate insertion of the Uniject™ hub, which is slightly wider than a standard hub. The Balcan needle remover allows insertion of Uniject™ but requires an unreasonable amount of force to cut the hub and needle. The Uniject™ hub is too large to enter the insertion hole of the BD hub cutter.

Consequently, it is not recommended to use needle removers for disposal of BD Uniject™ for Quinvaxem®. Instead, the injection system should be placed immediately in a safety box or appropriate sharps container until final treatment and disposal according to local safety guidelines.

## 6. Case Study: Kenya

Data from the comparative analysis (Section 5) have been applied to scenarios used in Kenya to demonstrate the impact a reduction in injection waste volume can have on the HCWM system. The information used in this section was gathered as part of PATH's HCWM project, which is funded by the US Centers for Disease Control and Prevention under the President's Emergency Plan for AIDS Relief and is based on communication with Fred Okuku, Project Director of the Kenya HCWM Project (February 2013). For a district-level facility in an urban setting, patient volumes are high and space is limited. The majority of health facilities rely on old, small-scale incinerators that are not operating well. Some facilities are receiving support to install newer, diesel-powered incinerator units. While these units operate more efficiently and produce fewer harmful emissions, they require a significant amount of fuel. For example, at one district hospital, their incinerator uses 500 L to 600 L of diesel per month at a cost of US\$630 to US\$756.

In December 2012, the hospital used 600 L of diesel to burn 2,220 kg of health care waste. Of the 2,220 kg load, safety boxes accounted for 150 kg. This equates to 40.5 L of fuel to destroy all of the sharps. With a cost of 110 Kenyan Shillings (ksh) per L, this equates to US\$51 per month, representing a significant sum for resource-constrained facilities.

**Figure 7. Safety boxes filled with used sharps awaiting treatment and disposal in Kenya.**



Photo: PATH

As noted, in urban settings space is limited, so storage and disposal can be a challenge. In Kenya, transport of health care waste is limited and disposal on site in a facility is the prevalent practice. While safety boxes can be destroyed through incineration, the glass vials that are used for traditional vaccine administration are not easily destroyed and are often seen piled up in storage rooms or in disposal pits outside in the absence of collection systems or options for treatment and recycling. Use of Quinvaxem® in BD Uniject™ will eliminate glass waste, which is important for facilities overwhelmed by traditional vaccine waste streams.

**Figure 8. Glass waste from a health facility in Kenya.**



Photo: PATH

## 7. Conclusions

The proposed BD Uniject™ injection system for Quinvaxem® offers comparative advantages to other presentations of fully liquid pentavalent vaccine with regard to disposal and waste management attributes. These include both single-dose or multi-dose glass vials in combination with a standard AD syringe. Through this comparative analysis, the following advantages were identified:

- Reduction of waste produced in both weight and volume.
- Elimination of glass waste.
- Reduction of sharps/biohazardous waste.
- Reduction in numbers of safety boxes required for safe disposal of waste.
- Potential reduction in cost and resources (e.g., safety boxes and fuel for destruction) required for safe disposal of waste.
- Facilitation of waste management in campaign settings.
- Facilitation of waste management in outreach immunization activities.
- Reduced potential for packaging and syringe reuse.

Although disposal of Uniject™ injection systems used for vaccination sessions with Quinvaxem® is easier than disposing of vials and syringes used for vaccination sessions with other pentavalent vaccines, immunization programs still need to budget adequately and plan for waste management and final disposal of Quinvaxem® in BD Uniject™. Waste management and final disposal requires consumables and equipment that are commonly used in immunization programs. Though resources and access to these technologies may be limited, there is no need to add new technologies or procure technologies that are specific to Uniject™.

Results from this analysis are corroborated by the existing literature on field use of several applications of the Uniject™ injection system. These advantages translate into cost savings and relevant operational elements that will positively impact use of Quinvaxem® in BD Uniject™ in low-income countries.

## Appendix 1. Capacity of Safety Boxes With BD Uniject™ for Quinvaxem® and SoloShot™ Syringe and Compaction of Contents

### Capacity

To improve understanding of the safety box requirements for BD Uniject™ for Quinvaxem®, the number of used BD Uniject™ for Quinvaxem® injection systems and also the number of used SoloShot™ syringes that fit in two sizes of safety boxes were counted:

- 5.0-L safety box.<sup>28</sup>
- 2.5-L safety box.<sup>29</sup>

The 2.5-L and 5.0-L safety boxes are the standard safety boxes commonly used in the field.

**Table 5. Safety box specifications.**

Safety box size	WHO PQS approved/available through UNICEF	Weight empty	Quantities	
			BD Uniject™ for Quinvaxem®	SoloShot™
5.0 L	Yes	11.9 oz	500	190
2.5 L	Yes	7.0 oz	180	75

WHO PQS: World Health Organization Performance, Quality and Safety

UNICEF: United Nations Children's Fund

For each of these tests, the safety box was gently shaken after insertion of two-thirds or three-quarters of the used syringes to fill to the three-quarters fill line. These results were achieved both times they were tested; however, they are subject to variation based on individual user technique and represent a best-case scenario. In addition, it was found that the larger box footprint (5.0 L, 6.125 inch square compared to 2.5 L, 4.625 inch square) was more conducive to compaction of Uniject™ injection systems in the box.

### Compaction

The compacting patterns for Uniject™ and SoloShot™ syringes deposited in safety boxes were assessed. Pictures were taken before and after shaking. Figures 9 and 10 show that the larger box footprint (5.0 L, 6.125 inch square compared to 2.5 L, 4.625 inch square) was more conducive to compaction of Uniject™ injection systems.



Figure 9. Uniject™ compacting orientation in different size safety boxes.



Photos: PATH

Figure 10. Soloshot™ compacting orientation in different size safety boxes.



Photos: PATH



## Appendix 2. Containment Options for Quinvaxem® in BD Uniject™

When considering introduction of Quinvaxem® in BD Uniject™, there are two primary sharps containment options—safety boxes (existing or purpose made) and improvised containers. Safety boxes are the recommended practice and are widely used. When safety boxes are not available, improvised containers (e.g., durable cardboard boxes, bleach bottles, and other hard plastic bottles) are commonly used.

### *Safety boxes*

Safety boxes procured through global programs are generally selected from among those that have passed the WHO Performance, Quality, and Safety (PQS) standards.<sup>27</sup> The boxes prequalified through PQS are available in 15-, 10-, 5-, and 2.5-L sizes. The type most commonly procured for clinics is the 5.0-L disposable cardboard safety boxes. Pricing varies depending on manufacturer and quantity but ranges from US\$0.68 to US\$1.00 per box. Some countries produce their own safety boxes—most of these have not been submitted for PQS prequalification.

PT MediBest (Indonesia) designed and produced a 0.5-L safety box for use by midwives administering HepB in Uniject™ in Indonesia (Figure 11).

**Figure 11. PT MediBest 0.5-L safety box and Uniject™ carrier from Indonesia.**



Photo: PATH

Because of their small size, 2.6 times and 2.4 times as many BD Uniject™ for Quinvaxem® injection systems fit into 5.0-L and 2.5-L safety boxes, respectively, as a standard AD immunization syringe.<sup>21</sup> This means that a program may require one-third the amount of safety boxes when procuring Quinvaxem® in BD Uniject™ instead of traditional pentavalent vaccine presentations. Being smaller and lighter, less waste is produced, thereby simplifying waste handling, transport, treatment, and disposal.

### *Improvised containers*

Where appropriate safety boxes are not available, particularly in community-based distribution settings, programs have found alternatives to protect vaccinators, CHWs, patients, and the community from accidental needlestick injury.

Any container used as a sharps container should be shaped so that a health worker is not at risk of needlestick injury when placing the device in the container. The container should be puncture and water resistant; be able to be safely held to prevent needlestick injury while inserting the used syringe; be stable when on a flat surface; have a means of closing for transport; and preferably not made of polyvinyl chloride plastic, which generates toxic emissions if burned or incinerated. They should be returned to the health facility to be buried or burned.

**Figure 12. An improvised sharps container in Tanzania.**



Photo: PATH

## Appendix 3. Challenges with Glass Disposal

For disposal of glass vials, WHO recommends<sup>30</sup>:

- Dispose of capped or uncapped vials into a protected pit. To reduce the volume, crush them once into the pit.
- Boil or steam sterilize sealed vials, then send them to the municipal waste stream or landfill.
- Uncap vials, rinse them with water and a 0.5% chlorine solution, then send them to the municipal waste stream or landfill.
- Vials can be reused—uncap the expired ones and clean them with water and a 0.5% chlorine solution, boil them, or steam sterilize them according to the existing facilities on site. The clean empty vials can be used to contain small quantities of medicine (e.g., ointment or gentian violet) or even sold. Reuse or recycling has the advantage of controlling the quantity of waste produced.

Crushing glass vials requires a purpose-made glass crusher, something not widely available or commonly considered in many health facilities. A vial crusher is an added expense and an added task for busy, resource-strapped health facilities. Some experts have recommended sterilizing glass vials prior to crushing, something that would add even more time and expense. Crushing glass safely requires equipment not available at most facilities, so vials amass in waste heaps around health centers. This can be problematic in facilities with limited space and invites inappropriate reuse. Furthermore, it may make the facility appear to be poorly managed. BD Uniject™ for Quinvaxem® eliminates the need to manage the waste resulting from glass vials for multiple vaccines.

**Figure 13. Example of a vial crusher in Mozambique.**



Photo: PATH

Some facilities with significant quantities of injections/glass vial waste have improvised solutions, such as the vial crusher above. Fabricating a glass crusher requires commitment and effort as there are a great number of vial crushers that can be commercially purchased. The example in Figure 13 was made using a steel weight on the end of a metal rod inside a large pipe. The pipe is set over a sharps pit, so the crushed glass can be pushed right into the pit without handling broken glass. When the hammer is removed, however, there is a risk of glass shards falling outside the pit. Médecins Sans Frontières has developed a design for a vial or ampoule crusher which is very similar though it has the safety feature of a loading chute, which prevents the metal hammer from being withdrawn while reloading the crusher box with vials.

## Appendix 4. Guidelines for Safe Disposal of Quinvaxem® in BD Uniject™

### Using a sharps container effectively

- Do not recap Quinvaxem® in BD Uniject™ before disposal.
- Place the Quinvaxem® in BD Uniject™ in the sharps container immediately after use.
- Ensure the sharps container is placed within reach of every vaccinator's workstation.
- Eliminate the need to carry used Quinvaxem® in BD Uniject™ injection systems before disposal by appropriate placement of containers.
- Do not overfill the sharps containers.
- Sharps containers should be filled only once and disposed of when full.

### Treatment and final disposal of filled sharps containers

**Autoclaving.** By using pressurized steam to heat the waste to a temperature of at least 121°C, autoclaves can disinfect infectious waste without causing airborne emissions that are created when waste is burned. Steam disinfection is an efficient method of treating medical waste because the moisture increases heat transfer and penetrates the waste load more effectively, reducing the time needed to achieve disinfection. After being autoclaved, the waste may be shredded and/or transported off site for disposal in a secure area.

**Incineration.** Incineration can completely destroy syringes by burning at temperatures above 800°C. The high temperatures kill microorganisms and reduce the volume of waste to a minimum. Properly functioning incinerators ensure the most complete destruction of syringes and produce less air pollution than burning at lower temperatures. Sharps containers can also be destroyed by commercial or public incinerators.

**Burning in metal drum or protected hearth.** Burning in a metal drum or protected hearth is another way to dispose of used syringes. Sharps containers can be placed in a metal drum. When the drum is full, fuel can be poured in, the waste ignited, and the materials burned until the fire goes out. The remains should then be buried. Care must be taken that filled drums are not accessible to the public.

**Burying debris after burning.** The remains of sharps containers should be buried after burning. Bury debris in a pit at least one meter deep in a controlled area for burying waste, where people do not have access and will not dig to plant crops or establish latrines.

**Open burning.** Open burning in a pit is the least preferred option for contaminated sharps such as the Uniject™ injection system. However, if open burning must be done, workers should adhere to the following:

- Fence off and clear the area in which open burning takes place.
- Warn people to stay away and avoid smoke and fumes from the fire.
- Carry the waste to the site just before burning.
- Burn the waste in small, designated areas.
- Prevent animals or people from accessing the site.
- Make sure the fire is completely out before leaving the site.
- Prevent waste from scattering and littering the surrounding areas.
- Bury the remains.

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