

Insights from Field Introduction of “Smart” Syringes for Enhanced Safety in Voluntary Medical Male Circumcision Programs

Final Report

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Project IQ

Project IQ is a global cooperative agreement between Jhpiego and the US Centers for Disease Control and Prevention with a goal of providing comprehensive global TA to support safe, high quality VMMC programs. Areas of focus include: service delivery, standardizing quality management approaches, and improving the timeliness, accessibility, actionability, and quality of VMMC data.

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Background

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious adverse events including transmission of life-threatening infections. This harm is preventable. Safe injection practices are part of Standard Precautions, and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization (WHO), a safe injection is one that does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community.¹

The WHO is leading an initiative to transition global health systems to the exclusive use of safety-engineered syringes with both re-use prevention (RUP) and sharps injury prevention (SIP) features – which they also refer to as “smart” syringes – by 2020. The initiative calls upon donors to fund only smart syringes in all projects that involve administration of injectable medicines,^{2,3} such as the local anesthetic used for most voluntary medical male circumcision (VMMC) methods.

Both RUP and SIP features are intended to protect people from exposure to bloodborne pathogens. SIP features do this by protecting providers and clients from accidental injuries from used needles, while RUP features protect patients from deliberate or accidental re-use of syringes and/or needles, and “double dipping” needles/syringes into medication vials (“double dip”: enter with a needle and/or syringe already used to inject a previous client, potentially contaminating the vial with any bloodborne infection they carried).

Project IQ “smart syringe” pilots

Between 2015 and 2019, to help VMMC programs introduce smart syringes, Project IQ worked with service providers in selected countries to pilot multiple models of smart syringes meeting WHO quality standards and specifications for use in routine VMMC service delivery. This report summarizes provider and program manager feedback from using syringes with RUP features in Zambia, and syringes with both RUP and SIP features in Mozambique and Tanzania. The feedback in this document is intended to orient VMMC programs to smart syringes and help them plan for smart syringe introduction suited to local context.

Smart syringes 101

The International Organization for Standardization (ISO) uses three independent characteristics to categorize smart syringes, which are summarized below along with discussion of how these characteristics apply to VMMC procedures:

¹ CDC. Injection safety. Available: <https://www.cdc.gov/injectionsafety/index.html>

² WHO. WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings. Geneva, Switzerland; WHO: 2016. Available: <http://apps.who.int/iris/bitstream/10665/250144/1/9789241549820-eng.pdf>

³ WHO. Injection safety policy and campaign. Available: <https://www.who.int/infection-prevention/campaigns/injections/global-campaign/en/>

1. **Needle attachment (fixed or detachable)** – fixed needles are most commonly used for fixed-dose immunizations with small-body syringes ranging from .1 – 1.0 ml in capacity (ISO 7886-3). Fixed needles are permanently attached to the syringe and cannot be removed and replaced with a different gauge or length needle. In contrast, detachable needles are more commonly used with large-body/ISO 7886-4 syringes used for injecting medicines, including the local anesthetic used for most VMMC methods. This allows providers to use a large-gauge needle for drawing up medications to minimize effort and draw time; and a smaller gauge for injection to minimize pain and bleeding. (However, some large-body syringes up to 10.0 ml in capacity are also equipped with fixed needles.)

Application to VMMC procedure: VMMC services require a large-body syringe (e.g., 10 ml) to hold the necessary volume of anesthetic. Detachable needles are best suited to VMMC because providers will typically draw and inject medicine(s) using different needle gauges.

2. **Re-use prevention (RUP) feature (can be present or absent, and activation mechanisms can vary)** – an RUP mechanism prevents or significantly discourages re-use of the syringe and/or needle. Designs for this feature vary in their disabling mechanism and activation timing. The disabling mechanism may be “active” (requiring deliberate activation by the provider, for example by pushing a separate button); or may be “passive” (activating automatically, for example once the plunger is fully depressed). It also ranges from mechanically locking the plunger to physically breaking part of the syringe. For mechanisms that activate automatically, the activation timing may occur after a single injection, activating as the plunger is depressed so that it cannot be drawn back up; or it may allow for multiple injections and aspirations, only occurring once the plunger is fully depressed. The latter design is intended for uses where the syringe will be used to reconstitute the contents or to mix multiple drugs before administration. By allowing multiple aspirations, this type of RUP mechanism cannot completely prevent “double dipping” or re-use, but it is an accepted means for reducing those risks while preserving the necessary clinical function of the syringe.

Application to VMMC procedure: Active mechanisms requiring *deliberate activation* by the provider were considered less desirable in this project. This is because any re-use for VMMC was considered most likely to be done immediately by the same provider re-entering the vial for more anesthetic, making it less optimal to rely on the provider for re-use prevention. If using a syringe with an active mechanism, provider training and supervision will be essential for motivating compliance with using the safety feature. Regardless of mechanism, the RUP feature needs to allow providers to 1) partially depress the plunger to expel excess volume or inject part of the anesthetic, without activating it, 2) aspirate the syringe with each move of the needle during anesthetic injection to ensure against injection into a vessel, and 3) in some programs, depress and withdraw repeatedly to mix lidocaine (lignocaine) and bupivacaine in the syringe. Thus, VMMC providers need RUP syringes with a mechanism that allows multiple aspirations and, if passive, only activates once the plunger is fully depressed.

3. **Sharps injury prevention (SIP) feature (can be present or absent, and activation mechanisms can vary)** – this feature adds protection from accidental needlestick injuries for the provider and others by blocking the needle after an injection is complete. For example, it may work by covering the needle with a sheath or cap, or by retracting it into the barrel of the syringe after the injection is complete.

Application to VMMC procedure: Accidental needle injury carries a risk for transmission of bloodborne pathogens, and prevention of needlestick injury is a universal precaution independent of a clients' serostatus for HIV, hepatitis, etc. Therefore, providers stand to benefit from smart syringe SIP mechanisms. The SIP feature must also be compatible with an appropriate RUP feature.

Note: While some available syringe models feature both RUP and SIP, others, including some summarized in this report, feature only one protection mechanism.

Further resources

- The WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings (Appendix 2, accessible here: <http://apps.who.int/iris/bitstream/10665/250144/1/9789241549820-eng.pdf>) offers detailed information about smart syringes. See pages 20-23 for tables describing different types of safety-engineered syringes available, their advantages, disadvantages and cost profile, as well as description and sample images of safety features.
- The WHO Department of Essential Medicines and Health Products Prequalification Team performance, quality, and safety catalog (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=42) provides specifications for smart syringe models prequalified for use in public health programs.

Procurement notes:

- Project IQ found that manufacturers had additional sizes and needle fixations (fixed vs. detached) of prequalified syringes available beyond what is listed online by WHO.
- WHO routinely updates its product prequalification, and therefore, products referenced in this report at the time of writing may differ from those posted in the WHO prequalification catalog at a later time.
- Implementers can weigh advantages of limiting their procurement to prequalified products, such as standardized public specifications, against disadvantages, such as limited options/limited competition.
- At present, implementers will have to do production selection and procurement on the organization level. Shared procurement mechanisms including US government supply chain systems may introduce RUP/SIP syringe options in future, potentially simplifying these decision.

Summary of syringe models introduced in Mozambique, Tanzania, and Zambia VMMC services

VMMC providers in the three participating countries introduced the models below within routine services, to develop and document experience with their suitability for use in VMMC programs. These models are prequalified except as noted below.

Model 1: Becton Dickinson (BD) [Emerald Pro](#) (Zambia)

Model 2: Helm Medical [Helmject](#) (Zambia)

Model 3: Hindustan Syringes and Medical Devices (HMD) [Kojack](#) (Zambia)

Model 4: DuoProSS Meditech *Baksnap* (Mozambique, Tanzania)

Model 5: Haiou [safety syringe](#) (Mozambique, Tanzania)

These models were selected to give providers a variety of clearly distinct syringe types that met the criteria for VMMC service delivery. See the table below for feature summaries for these models, and the WHO Department of Essential Medicines and Health Products Prequalification Team performance, quality, and safety catalog for detailed specifications.

Note:

- the BD *Emerald Pro* used in Zambia had a fixed needle, whereas the specifications indicate the needle is detachable.
(https://www.who.int/immunization_standards/vaccine_quality/e13_063_5ml_syringe_emerald_bd_v3.pdf)
- The DuoProSS *Baksnap* was among the products listed at the time of selection, but is no longer in the catalog.

Clinical feedback

General

The majority of feedback on all models was positive. However, some providers highlighted isolated quality and usability issues, summarized here. Some issues can be addressed through training; others may lead programs to prefer an alternative syringe manufacturer or model. Overall, all models were felt to be acceptable for integration within VMMC programs once providers grew familiar and comfortable using them, without any specific models gaining greater provider acceptance than others. General issues identified included:

- *Unintentionally activating RUP mechanism*: The most common initial usability challenge, noted with all models, is unintentional activation of the syringe safety mechanism(s) before administration of local anesthesia is complete. This was addressed by giving providers adequate training and experience to grow comfortable with the safety features of the given syringe model so that they could adjust their grip to maintain efficient injection technique and minimize discomfort for the client while keeping the syringe functional through the steps of use.
- *Needle fixation, length, and gauge considerations*:
 - As described in the “Smart syringes 101” section, syringes with fixed needles are difficult to use in VMMC programs. The needle’s gauge can affect the procedure, as that needle must be used for both drawing up and injecting anesthetic. The larger the gauge, particularly if larger (lower number value) than 23, the more bleeding and client discomfort was observed. However, the smaller the gauge, the more time and force are needed to withdraw anesthetic from the vial. Bupivacaine is more viscous than lidocaine, so programs using lidocaine with bupivacaine may see force as a crucial consideration

- and find detachable needles particularly important. Project IQ found both needle fixation options were available in several models.
- Program providers are generally accustomed to using 3.81 centimeter (cm)/1.5 inch needles with Luer lock fittings. Some of the models piloted came with shorter needles or unique manufacturer needle fittings. Many providers are unaccustomed to using needles of this length and may require additional movements/aspirations/injections with the needle to complete a dorsal nerve block, and thus additional attention to aspirating/injecting without prematurely activating the safety mechanism. If included needles are short but have Luer lock fittings, programs can easily order a different needle length, either from the manufacturer or an alternative source, as long as the needle can still be fully retracted into the body of the syringe when the SIP mechanism is activated, and/or the activation feature does not depend on any unique properties of the manufacturer’s needle, though this adds complexity to the supply chain. In contrast, unique manufacturer needle fittings (unlike the common Luer lock fittings) allow less flexibility and could necessitate negotiation with the manufacturer to ensure the needle specifications are suitable for VMMC.
 - Unique manufacturer needle fittings may also introduce confusion if unintentionally comingled with non-matching syringes, and fail to attach securely to that syringe body and/or prevent the syringe from working. Alternatively, a standard Luer lock needle may fit on the body of a syringe designed for unique manufacturer needle fittings but might not function properly with the RUP mechanism, and the manufacturer would not be able to guarantee the safety of this use case.
 - Manufacturers may define needle gauge inconsistently (see model-specific feedback below), underscoring the benefit of testing samples prior to bulk order to ensure the supplies being provided function as desired.

Model-specific feedback*

Model	Safety mechanisms	Positive feedback	Negative feedback	Manufacturer price quote (subject to change)
Becton Dickinson (BD) <i>Emerald Pro</i> (fixed needle – 21 gauge; also available with detachable needle)	RUP: Locking gasket upon completion of injection (<i>passive mechanism</i>). SIP: None.	Generally found to be high quality.	Plunger was difficult for some providers to depress.	Unit cost: \$0.76 Minimum order: 1,000
Helm Medical <i>Helmject</i> (fixed needle – 21 gauge; also available with detachable needle)	RUP: Locking plunger upon completion of injection (<i>passive mechanism</i>). SIP: None.	Most providers able to use syringe comfortably after gaining experience.	Mixed feedback on overall syringe quality – providers reported it was more time-consuming to use than a conventional syringe, and that it was difficult to avoid prematurely activating the RUP mechanism while wearing gloves.	Unit cost: \$0.06 Minimum order: 800
HMD <i>Kojack</i> (detachable 23 and 21 gauge needles)	RUP: Locked/broken plunger upon completion of injection (<i>passive mechanism</i>).	Generally found to be high quality.	Some found RUP only activates when the plunger has been fully withdrawn prior to injection (so would	Unit cost: \$0.078 Minimum order: 100,000

	SIP: none.		not activate if less than 10cc originally drawn up), but not found to be a universal problem.	
DuoProSS Meditech <i>Baksnap</i> (detachable 23 and 21 gauge needles)	RUP: Plunger is pulled back then snaps off for disposal (<i>passive mechanism</i>). SIP: Pulling plunger back retracts needle into barrel of syringe. (<i>active mechanism – requires provider to pull back plunger after injection</i>). Sometimes termed 'syringe with retractable needle'.	Generally found to be high quality.	23G needle was thicker than 23G size program was accustomed to using. ¥	Cost estimates variable.
Haiou retractable safety syringe	RUP: Plunger is pulled back then snaps off for disposal (<i>passive mechanism</i>). SIP: Pulling plunger back retracts needle into barrel of syringe. (<i>active mechanism – requires provider to pull back plunger after injection</i>).	Generally found to be high quality.	- Unique needle fitting not convenient if a change to needle length/gauge is needed because it is not available on local market. - Providers disliked having to manually activate SIP feature. Some providers forgot to snap plunger off after retracting, and thus had difficulty fitting the syringe into sharps disposal container. † - Short needle required more injections than standard syringe/needle. - 23G needle was larger than typical 23G size. ¥	Cost estimates variable.

* All model-specific comments represent the viewpoints of the individual providers and do not represent the opinion of Jhpiego or CDC.

† Comments on manual activation of SIP and plunger snap of Haiou were not reflected in provider feedback to Thermofisher *Baksnap* syringe, though because the mechanism of action is the same for both models, these considerations should apply for both models as well.

¥ Feedback from Mozambique only. Tanzanian providers did not experience this issue .

Program management feedback

General

Smart syringes can be integrated into programs with minimal disruption, but the following considerations will ease the transition:

Procurement: If not participating in pooled procurement/supply chain, prior to selecting a syringe model for introduction in a given program, ensure the manufacturer can comply with your organization's procurement policies and regulations. Project IQ encountered challenges with select vendors due to payment terms that conflicted with organizational policies (vendor requesting full prepayment) and manufacturing/shipping timelines and locations which were slow or inconvenient for implementers in sub-Saharan Africa. Manufacturers with nearby regional distribution centers can help expedite shipment, reducing the risk of stockouts due to delivery delays. Inexpensive, high-quality products with high minimum orders may be optimal for large programs or those using pooled procurement mechanisms. Smaller programs procuring separately may prefer products with smaller minimum orders. Ordering samples prior to bulk procurement ensures specifications meet program expectations.

Orientation/training: Smart syringes are designed for use with little or no instruction. However, in a high-throughput, high-efficiency program like VMMC, there may be a need to manage providers' and supervisors' expectations so they understand smart syringe injections can require several additional minutes until providers grow accustomed to the change in technique. Our introduction exercise revealed providers were accustomed to working with such efficiency that smart syringe acceptability was only assured with dedicated orientation and training time to allow providers to confidently maintain their previous speed of service. For this reason, supervisors may wish to first accustom themselves and/or a small group of senior providers/trainers to using the syringes so they can mentor others; summarize the manufacturer instructions for use (IFU), introduce a job aid (consider including an informal mobile phone video) if the manufacturer's is insufficient or nonexistent, and oversee practical use without time pressure in five clients per provider, or until providers are confident.

Additionally, every new product should be thoroughly piloted not only to accustom providers to it but to identify any unexpected variations before large purchase commitments are made. Providers sometimes perceived unexpected variations in product characteristics, e.g., between countries. These can include not only features unique to the product, but generic attributes like needle length and gauge.

Way Forward

Numerous smart syringe options exist, each with its own combination of features and design elements. This pilot project highlights some important questions to consider when choosing a product for use at scale, including (but not limited to):

- Does the syringe/needle combination prevent only reuse, only sharps injury, or both?
- Does the syringe come with a fixed needle, detachable needle, or no needle?
- If the needle is detachable, does the syringe require a custom needle supplied only by the manufacturer, or can it use any needle with the same standard fitting?
- Are the needles used with the smart syringe different in any detrimental way from the conventional ones currently in use (e.g., are the needles shorter or thicker)?
- Does the syringe function differently in any detrimental way from those currently in use (e.g., harder to pull back, awkward grip)?
- What is the additional cost and how easy is the procurement process?

Smart syringes require proper use, and often require provider activation (such as pulling the plunger back to cover the needle), to be effective. Bypassing these safety features is possible with improper use (such as not expelling the last bit of local anesthetic so the RUP feature does not activate, then accessing a multi-dose vial again).

Provider input is vital during the selection process, to identify unexpected product issues and increase buy-in. Consider narrowing to 2-3 options, based on which products have the features deemed most important, and introducing these across multiple locations and providers for a few months before committing to a full-scale supply chain.

After selecting and procuring smart syringes, an education/mentoring plan using the manufacturer's or locally devised material is recommended to ensure consistent and proper use.