Introduction and Use of Reusable Instruments in Voluntary Medical Male Circumcision Programs

Orientation and Resource Guide

2nd edition: January 2022

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Acknowledgments

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Introduction to 2nd Edition

Due to the operational intricacy of high-throughput surgery in resource-limited settings, many voluntary medical male circumcision (VMMC) programs across East and Southern Africa have relied either partially or fully on single-use (disposable) surgical instruments. However, there are cost, waste management, environmental safety, quality, and supply chain challenges associated with single-use instruments. Additionally, program sustainability and health system capacity need to be improved. As a result, some VMMC programs may seek to transition some or all of their services to reusable instruments. There may be concerns that the transition will be complex and require time-consuming preparation and retraining of staff. To simplify the pathway to reusable instruments, this orientation and resource guide describes considerations for planning, operation, and maintenance of a reusable surgical instrument inventory, drawing from implementation experience of programs that always relied on reusables or previously made the transition. This document summarizes insights from available literature, safe surgery expert consultation, and partner program experience implementation, including feedback from frontline health workers and program managers.

Since the release of the original *Introduction and Use of Reusable Instruments in Voluntary Medical Male Circumcision Programs: Orientation and Resource Guide* in July 2017, additional experience with reusable instruments in VMMC programs has been shared and is reflected in this second edition. Significant updates include clarification of the infrastructure demands of the sterilization process; the addition of a subsection on decentralized and centralized (hub-and-spokes) processing approaches, with related updates to processing steps and additional figures; edits to instrument specifications (suture needle and scalpel) to reflect program changes; and additional guidance on preventing instrument mixing in settings where both disposable and reusable instruments are used. This document is not intended to serve as a procedure guide for instrument reprocessing. Programs can refer to the WHO's *Decontamination and Reprocessing of Medical Devices for Health-care Facilities* (available at: https://apps.who.int/iris/handle/10665/250232) for guidance on necessary equipment and activities for instrument reprocessing.

This is intended to be a "living" document that will be updated as more VMMC programs introduce reusable instruments. Feedback and additions are welcomed, particularly descriptions of challenges encountered and how they were addressed. Contributors will be recognized in later versions.

Purpose

To orient VMMC program managers and other technical and professional staff to the process of integrating reusable surgical instruments within VMMC programs.

What's New in this Second Edition

- Reframing of disposable vs. reusable comparison supporting transition regardless of program maturity and as an important step towards sustainability
- Subsection on decentralized and centralized reprocessing approaches including additional figures

- Greater detail on infrastructure and staffing needs for reprocessing
- Greater detail on reprocessing steps including updated figures and link to WHO reprocessing resource
- Edits to instrument specifications to reflect programmatic changes since last edition

Reusable Instruments for VMMC

Reusable surgical instruments are used in the vast majority of operating rooms in East and Southern Africa. They can typically endure an average of 150 cycles[*] before disposal, depending on the quality of the instrument steel. While this value can be used for forecasting, the timing of instrument disposal is ultimately determined not by the counted number of cycles, but by any deficiencies in function or ability to be adequately sterilized - for example, if the surface develops pitting or rust that cannot be removed.

Many VMMC programs began with single-use instruments because they considered this approach simpler for rapid scale up of service delivery. However, a transition to reusable instruments has several clear benefits for programs whether they are still scaling up or mature with a greater focus on sustainability. Some of these benefits include:

- Fewer resources are required long term to maintain adequate inventory of instruments to meet programmatic needs
- Significant savings on medical waste transport and disposal costs
- Reduced environmental impact of medical waste incineration and burial
- Majority of items that make up reusable kits can be procured locally through national supply chains
- PEPFAR Country Operational Plan guidance recommends prioritizing reusable instruments to reduce program costs
- Instruments made of high-quality reusable material, when used by well-trained providers, may improve surgical precision and tissue handling
- Build health system capacity and infrastructure and employ local personnel for sterilizer autoclave operation and maintenance and instrument inventory.

However, it's important to be realistic about the challenges of establishing or transitioning to reusable instruments. Recognition of these challenges will help a program plan their reusables program more deliberately. Some of these challenges include:

- Startup costs for instruments and sterilizing equipment
- Need for ongoing supply of sterility indicators and monitoring of reprocessing activities
- Training of instrument reprocessing staff
- Additional staff time for reprocessing activities
- Water and power needs where instruments are reprocessed
- Availability of qualified personnel to inspect and maintain sterilization equipment

[*] Based on programmatic experience with reusable instruments in VMMC.

This resource is intended to help programs plan and execute a transition to reusable instruments, not serve as a guide to instrument reprocessing. Although reprocessing is complicated, and a transition to reusuables can seem overwhelming, a stepwise, planned approach increases the likelihood of sustained success.

Preparation and Planning

Prior to starting or expanding use of reusable instruments, it's important for programs to consider the component steps of the entire reprocessing cycle including staffing, training, equipment installation and maintenance, ongoing supply needs such as packaging material and sterility indicators, and quality assurance. It's easy to focus on one component, such as procuring sterilizers, without having a comprehensive strategy for safely scaling up instrument reprocessing across a program. For programs that decide to completely or partially transition to reusable instruments, the following recommended steps will allow them to prepare for transition.

Procurement

First, ensure staff planning the transition understand local regulations or pre-existing agreements/contracts concerning medical instruments (e.g., any government tender policies, given the volume of surgical instruments procured for and used in hospitals). Communicate with ministry of health colleagues and national supply chain stakeholders to understand any specifications or preferences they may have concerning the quality of instruments used in public facilities or participation in national procurement quantification processes, if applicable.

Instruments

The following section summarizes considerations for individual partner-level forecasting, but some countries may participate in pooled procurement (e.g., procurement and supply management). If instruments will be acquired through pooled procurement, forecasting will be done according to that mechanism and is beyond the scope of this document. Participants in pooled procurement may wish to skip ahead to sterilizer procurement on p. 10.

1. Forecast instrument quantities for the program (see p. 23 for site-level instrument distribution). An 18-month forecast can help avoid stock outs during transition between funded program years.
    - For compatibility with annual funding cycles, this document recommends an annual procurement schedule, but programs may wish to elect an alternative schedule.
    - Instruments can be forecast in denominations equivalent to a full surgical instrument set (see Table 2 for reusable instrument set contents by surgical method), since they will be packed, sterilized, stored, and used as assembled sets. However, some programs have also found that certain instrument types – e.g., scissors – predictably wear out sooner than others, and they routinely buy extras of these to substitute in when they wear out. Alternatively, cutting

instruments that become dull, but do not break, can be sent locally for sharpening if this is available and preferrable.

- The following formulas can assist programs in forecasting the number of full-set equivalents to purchase for the first procurement, based on the anticipated annual VMMC volume (equivalent to annual performance target) and mean daily VMMC volume (equivalent to annual performance target divided by the number of operational days in the year). This forecast may need to be adjusted based on the proportion of procedures a program intends to do with reusable versus single-use instruments as it transitions over time.

  Determine which of the following numbers is greater:

  Anticipated annual VMMC volume ÷ 150 *or* 2 x mean daily VMMC volume

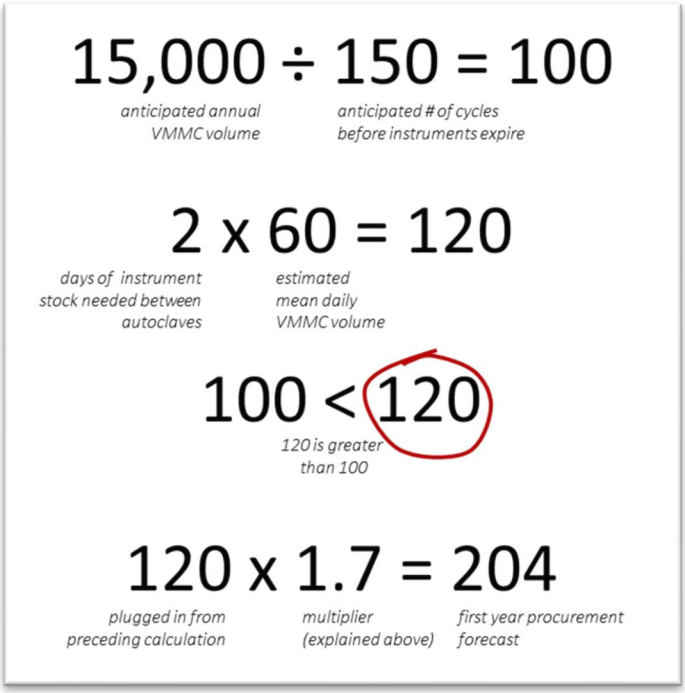
  Select the higher one of those numbers and multiply that number by 1.7. **This is your first-year procurement forecast.**

  An interactive calculator to auto-generate a procurement forecast is located at: http://project-iq-resources.jhpiego.org/vmmc-calculator/

  Further explained, this formula reflects the following considerations:

  - Based on the quality of instruments procured in current VMMC programs, instruments are expected to "expire" (see Quality Assurance section on p. 23 for signs of wear) after approximately 150 reprocessing cycles/uses.
  - Assumes instruments will be sterilized daily, but programs need at least enough full-set equivalents to cover twice the mean daily VMMC volume to ensure against demand surges or any lapse in sterilizer accessibility due to logistics or lack of power or water. They also need enough to cover the full annual target to account for stock expiration.
  - A certain proportion of instruments (+/- 10%) could malfunction out of the box or "expire" before 150 cycles. As a result, for the first year, an extra 20% of full-set equivalents should be procured.
  - An extra 50% of full-set equivalents should be purchased in case of delays in funding or procurement for the next year. This and the preceding bullet are the basis for the 1.7 multiplier.

  To illustrate, for a program with an annual performance target of 15,000 and mean daily VMMC volume of 60 (assumes 250 operational days per year), the calculation would be as follows:



This program forecast is 204 full-set equivalents for its first year.

Program planners may wish to consider the following modifications to these calculations:

- If instrument quality is high, instruments can endure well beyond 150 reprocessing cycles. If the supplier/manufacturer advises instrument life would last 1,000 reprocessing cycles, for example, programs would divide their anticipated annual VMMC volume by 1,000 rather than 150 when using the forecasting formula. Some programs have found instrument lifetimes to be much less than manufacturer's prediction. Especially during the initial period of use, it is important for programs to track the number of reprocessing cycles instruments can endure under local conditions to inform inventory management.
- Programs relying on high volume "campaign" periods to accomplish a high proportion of their performance targets in a short period of time can calculate their mean daily VMMC volume specific to the campaign period rather than an annual average in order to get a more accurate estimate of needs. This could result in considerable stock redundancy during periods of low demand/low volume but would assure sufficient instruments during high volume service delivery intervals.
- Programs using reusable instruments in a geographic area far from the sterilization point may wish to multiply the mean daily VMMC volume by a higher number when using this equation. For example, if they anticipate needing four days' worth of sterilized instruments to account for lengthy instrument round trip transport to and from the sterilization point, they should multiply the mean daily VMMC volume by four instead of two.

Note: In subsequent years, programs can adjust forecasts by factoring in the balance of unused instruments (if any). They would then modify buffer stock if they find the number of malfunctioning instruments is greater or lower than 20% used in the original forecast and projected targets for subsequent years. See p. 25 for inventory management, including site-level instrument distribution.

- Once the total instrument set forecast is calculated, determine the proportion of sets that will require forceps-guided complements versus dorsal slit/sleeve resection complements, if using the instruments prescribed in table 2 below. Alternatively, hybrid/universal sets could be ordered to obviate the need to estimate forceps-guided/dorsal slit breakdown.

2. Compile list and prices of the full complement of reusable items for a single instrument set (does not include consumables). The following is a sample list with average prices from VMMC programs currently using reusable instruments (prices vary based on instrument quality. The instrument mix used varies slightly between regions and programs.

Table 2: Illustrative instrument quantities and prices by surgical method

Item*	Quantity *Forceps-Guided*	Quantity *Dorsal Slit/ Sleeve Resection*	Price range
Sponge holding forceps **Length:** 33 cm		2	USD 5.00-7.00
Dissecting scissors Length: 13–15 cm		1	USD 2.50-6.00
Needle holder Length: 12–14 cm Working surface : 20 mm	1	1	USD 2.00-5.00
Suture scissors Length: 12–15 cm	1	1	USD 1.50-6.00
Hemostatic forceps (mosquito forceps), straight Length: 12–14 cm Working surface : 20–30 mm	4	4	USD 1.50-5.00
Hemostatic forceps (mosquito forceps), curved Length: 12–14 cm Working surface : 20–30 mm	1	1	USD 1.50-5.00
Hemostatic forceps cross clamp Length: 20 cm Working surface: 64 mm	1		USD 3.00-6.00
Artery forceps Length: 13–15 cm Working surface: 40 mm		2	USD 4.00-16.00
Tissue forceps (dissecting forceps), plain Length: 13 cm	1		USD 1.00-10.00

Working surface: 15 mm Serrated			
Tissue forceps (dissecting forceps), toothed Length: 13 cm Working surface: 15 mm Serrated		1	USD 1.00-10.00
Kidney dish	1	1	USD 6.00-10.00
Gallipot	1	1	USD 13.00
Mayo table/tray (quantity listed is per surgical bay)	1	1	USD 18.00-30.00

Source: Adapted from 2015 Supply Chain Management Systems VMMC Core Instrument List.
Note: Prices vary considerably by country and supplier. Price differences may reflect differences in quality, transportation costs, and/or other factors.

The following consumables/materials must also be purchased to complete a procedure set, regardless of surgical method:

Table 3: Consumables and other materials for VMMC procedures

Item	Quantity
Sterilization pouch, paper, muslin, or barrier cloth Minimum pouch size 33 cm x 50.8 cm; can also be used as the "tray" on top of the Mayo table during surgery (Figures 2 and 3 show instruments poststerilization in a sealed pouch and spread out prior to a procedure on a Mayo tray).	1
"O" drape- this can be made locally 80 cm x 80 cm with approximately 5 cm opening	1
Scalpel blade with handle/holder – IN DORSAL SLIT-ONLY SETTINGS THIS SHOULD BE OMITTED, AND REMOVED WHERE ALREADY PRESENT Disposable, retractable, and lockable Blade type 23 Total length: 11 cm	1
Gauze swabs 12 ply 100 x 100 mm	20
Gauze, petroleum jelly impregnated 1 ply 10 cm x 10 cm	1
Syringe 10 mL (Auto-disable/safety syringes recommended)	1
Needle 21 gauge 1.5 inches	1

Needle 24–25 gauge 1.5 inches	1
Suture, braided/absorbable, 4/0 Polyglycolic acid or chromic gut suture 75 cm Reverse cutting needle: 19 mm, 3/8 circle (meets PEPFAR COP20 and later guidance)	2
Gloves, surgical Sterile Default sizes (fit most providers): two pairs of size 7.0, one pair of size 7.5, and one pair of size 8.0	4
Gloves, prep/examination Sterile Default sizes (fit most providers): one pair medium, one pair large	2
Apron, disposable or reusable Plastic (similar quality to trash bag)	2
Shoe covering or clogs	2
Surgical face masks and surgical cap	2
Eye protection/goggles with ventilation to prevent fogging	2
Alcohol swabs Isopropyl alcohol 70% 1.25 inches x 2.5 inches	2
Surgical paper tape 12 mm 3 m in length	1

Source: Adapted from SCMS.

3. Identify suppliers. There is a spectrum of instrument quality and cost, with prices increasing proportionate to steel quality (i.e., whether it is purified of contaminants, which can accelerate wear). All instruments should be solid stainless steel, not plated metal (plated means a layer of one metal type over another type). Surgical instrument manufacturers may sell products to a number of suppliers, which can result in a single instrument being branded and priced differently across suppliers even if the product is identical. When comparing prices, it is essential to collect detailed specifications to allow for accurate comparisons of quotes/bids, including how many reprocessing cycles the instruments can reasonably be expected to withstand and the material composition of the stainless steel.

4. Following are examples of regional suppliers used by VMMC implementing partners who have been satisfied with instrument price and quality. Suppliers are not typically the instrument manufacturers, but rather third parties. This list may serve as a starting point to solicit price quotes or samples:

   Dewal Surgical Co. http://www.dewalsurgical.com

   Asian Medical http://asianmedical.net

   Some VMMC countries also have local suppliers.

Instrument Quality

Stainless steel is composed of iron, carbon, chromium, nickel, manganese, silica, and many other metals in smaller quantities. The amount of each of these components depends upon the grade of stainless steel. Generally, the higher the chromium content, the more corrosion-resistant the metal is. There is no single standard measure for instrument quality, which makes it difficult to discern quality based on advertised specifications. Seventy-five percent of the world supply of traditional, handheld, stainless steel surgical instruments are produced in Germany and Pakistan. Many of the Pakistani instruments are first transported to Germany, where they often get final finishing and quality control. Suppliers and manufacturers may use industry marketing terms (e.g., operating room-grade) to describe any corrosion-resistant stainless steel instrument, but these terms are not regulated and should not be used as the basis for selecting suppliers or individual products. In the absence of formal clinical criteria for indicating instrument quality, the only ways to be sure of quality are to order samples to test or solicit recommendations from experienced programs (see list of suppliers informally recommended by implementing partners). For those testing samples, the following are qualitative indicators programs can use to help discern quality of samples:

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- Weight: Instruments should feel heavier than those used in the single-use kits to which providers are accustomed.
- Mechanical efficiency: The forceps hinge ("box lock") should open and close smoothly (without shifting of hinge bolt) and with ease (without sticking or clicking). Jaws of forceps should align. Tissue forceps should hold securely.
- Durability: While this indicator cannot be discerned immediately, if instruments show signs of wear (e.g., corrosion/rust, dull scissors; see full description of instrument wear in Quality Assurance section on p. 19) within 50 reprocessing cycles, they may be of inherently poor quality. Suppliers should also be asked to estimate the number of reprocessing cycles their instruments can withstand.

Sterilizers

There are multiple methods to sterilize reusable medical devices depending on setting and type of material. Steam/moist heat sterilization in an autoclave is the preferred method for heat stable items such as surgical instruments. Dry heat oven sterilizers are reportedly used in some VMMC settings although these tend to have smaller capacity with longer cycle times. Additional information on sterilization methods is available in the WHO's *Decontamination and Reprocessing of Medical Devices for Health-care Facilities* (https://apps.who.int/iris/handle/10665/250232)

1. Forecast number of new sterilizers needed at each service delivery or sterilization point; for mobile/outreach services, sterilization might not be performed onsite. Determine whether facilities have functioning sterilizers available for use by VMMC programs and procure extras as needed (see site specifications on p. 11 for additional planning considerations when introducing a sterilizer to a site). Sterilizer size/capacity is typically measured in liters, and an autoclave is typically anywhere from 20 L to 100 L in size. To illustrate the capacity by liter, a 75 L autoclave can sterilize 15 to 20 surgical instrument sets in a cycle. To maintain sterilized instrument supply and prevent unnecessary wear, it is strongly recommended that all instruments at least be cleaned, and ideally both cleaned and sterilized at the end of the day they are used (not left soiled overnight). Sterilizer capacity and availability (if shared with other services) should be considered to ensure there will be access to

sterilize a full day's instruments. If the sterilizer is small and/or site VMMC volume is high, several cycles may be required to process all instruments.

2. If new sterilizers are going to be purchased, determine specifications in consultation with Ministry:
    - Determine requirements: confirm which models can be registered by the Ministry, and which models existing biomedical engineers are trained to service, to ensure sustainable transition of machines.
    - Ministry staff experienced with models available in-country may provide important insights to inform model selection, e.g., one country's program has found clamp-topped autoclaves more durable than wheel clamp autoclaves.
    - Some Ministries register equipment procured to ensure ongoing maintenance of equipment is managed through the Ministry. Therefore, consulting on the process of registering equipment and maintaining equipment is important for sustainability of the program/equipment.

    There is a vast market of sterilizers, but this document refers to three types:

    - Conventional electrical sterilizers (most common) using steam (also known as an autoclave) or dry heat oven.
    - "Dual-power" sterilizerss can be powered by electricity or a propane tank and can thus be used in remote settings where electrical points are unavailable or unreliable.
    - Pending: Power-independent nitrogen dioxide autoclaves were being introduced in some military and other selected settings at the time of writing, but they have not been fully vetted in resource-limited settings.
3. Determine suppliers. Local governments will typically procure sterilizerss for facilities, so local suppliers should be available.

Single-Use Kits

Programs might consider retaining a central buffer stock of single-use kits to last up to three months to account for delays in reusable instrument delivery, long-term autoclave malfunction, or other unanticipated challenges. Staff should monitor the expiration of kit sterilization, prioritize using kits before they expire, and replace any unused kits that remain after that date (typically two years from date of assembly). Once a reusable instrument inventory is established, the utility of a single-use kit buffer stock is reduced but will vary by program (e.g., an implementer whose procurement timelines are lengthy or whose service delivery model includes campaigns in remote areas may wish to keep single-use kits in rotation long term).

Some programs have attempted to reprocess and reuse single-use kits. These instruments are susceptible to pitting over time, which can prevent sterilization, so are not appropropriate for repeated use.

Planning

Organization

There are at least two general approaches that programs can take to integrating reusable instruments, based on where those instruments will be processed. Planners should decide beforehand which approach or combination will work best for their program, based on site amenities and locations. This decision will affect equipment and supply purchasing decisions. These are illustrated in Figure 1.

Decentralized approach:
Each site using reusable instruments will perform all its own reprocessing. This approach may work best at 'static sites' or when campaign sites have reliable access to power (or are using alternative power sources), and enough VMMC volume to justify dedicating staff to processing; however, it could also apply at mobile outreach sites, if portable autoclaves are used and there is an appropriate water source and power available.

Centralized, or "hub-and-spokes" approach:
"Spoke" sites (typically, though not necessarily, smaller rural sites with fewer amenities) will send their used instruments back to a centralized "hub" site for reprocessing. Processed instruments are then returned to the spokes for repeat use. This approach may work best for time-bound activities, such as when spoke sites are being used during routine outreach or in a campaign and these sites do not have reliable access to power, or enough volume to justify dedicated reprocessing staff.

However, this approach does require a reliable two-way transportation plan, and it also requires that the spoke sites perform the first 1-2 steps of instrument processing, depending on how readily the used instruments can get to the hub reprocessing site. All spoke sites will have to pre-clean at the point of use. If they can then be picked up and transported back to the hub in without drying out, the manual cleaning step can be done at the hub site. At the spoke site, pre-cleaned used instruments should be stored in a leak-proof, hard-sided container and covered with a water-moistened towel to prevent drying of microscopic organic material on the instrument. If instruments are left to dry with blood and tissue in place, they are much more difficult, and potentially impossible, to clean on arrival at the hub site.
If instruments cannot be kept moist and transported back to the hub without drying out, they will need to be manually cleaned at the spoke site. A manufacturer-recommended detergent is needed to remove all visible soil, organic, and inorganic material in accordance with the guidance provided in the WHO decontamination and reprocessing of medical equipment in healthcare facilities manual. After cleaning, the instruments would then be rinsed and air-dried prior to transport back to the hub for packaging and sterilization.

Finally, in circumstances where transport between hub and spoke sites may be interrupted but time is critical (like time-limited campaigns in remote areas), programs may consider keeping portable autoclaves for emergency use at spoke sites.

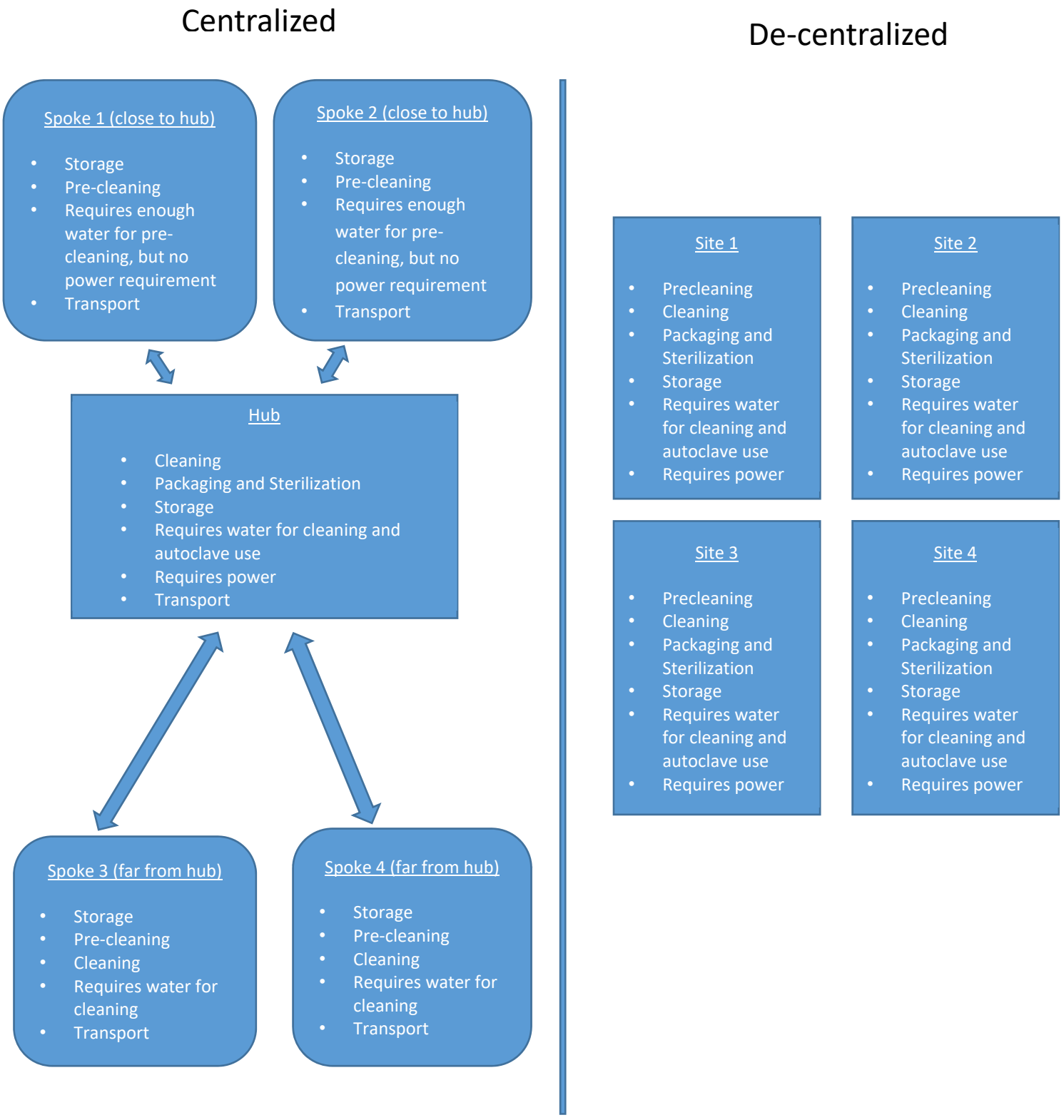


Figure 1: Decentralized and centralized (hub and spokes) potential systems for instrument processing across multiple sites

Staffing

All VMMC sites should have a designated infection prevention and control point of contact. Depending on the size of the site, this person may need to also serve as the designated reprocessing technician (small sites) or oversee and support the reprocessing technician (larger, busier sites). Any site which performs all steps of instrument reprocessing requires a designated technician (or VMMC provider trained on technician activities, if it is not possible to staff a technician) whose only duties are overseeing instrument inventory and reprocessing. A technician would be supervised by a site manager or equivalent senior clinical staff. At spoke sites where only the pre-cleaning and cleaning steps of instrument reprocessing are performed, it may not be possible to have a full-time designated individual. In this case, an individual would still need to be identified who is consistently responsible, and appropriately trained, for instrument cleaning and inventory management. This person may need to have other responsibilities as well although their scope of clinical responsibilities may need to be reduced to allow them time for instrument reprocessing and related activities. If the service volume is high at a spoke site, it may in fact be necessary to have a technician focus full-time on instrument management and cleaning. For the purposes of illustrating roles in this document, we specify activities that would be a technician's responsibility.

A technician's activities will include overseeing instruments' progression through the full cycle of reprocessing steps in place at their site including managing inventory and distributing sterilized instrument sets to the point of service (or into the transportation system for offsite points of service). Technicians at the hub site would need to be dedicated to instrument management and reprocessing full-time. Their responsibilities could include other unrelated tasks so long as their primary reprocessing activities can proceed in an unhurried manner. Instruments need to be tracked carefully to promptly detect quality/inventory issues. See Introducing and Maintaining Reusable Instruments on p. 16 for a full list of technician responsibilities. Supervisors should be allocated time to perform routine (monthly or quarterly) quality assurance/quality improvement, checking instrument quantities against inventory, and quality of random selection of instruments. See Quality Assurance on p. 23.

It is essential for all site staff to be oriented to the process of managing reusable instrument inventory so that they can support, but not stand in for, the trained technician. Providers may have grown accustomed to using single-use instruments and require time and coaching to get accustomed to using reusable instruments so that they can continue to operate confidently and efficiently. A proactive and thorough orientation will help prevent frustration and resistance associated with the transition to reusable instruments. This orientation should include:

- Differences between reusable and single-use instruments
- Reusable instrument life cycle (use → pre-cleaning → cleaning → sterilization → storage)
- Onsite instrument storage locations
- Implementer's chosen inventory system (including how instruments are moved from one location to another, including offsite sterilization, if applicable)
- How sterilizers work
- Types of sterility indicators, including how to interpret chemical/biological indicators
- Where providers should place used instruments
- Indicators of instrument wear or quality problems

- How to set aside and report a defective instrument in order to avoid reintroducing it into the inventory
- Other program-specific standard operating procedures (SOPs) to be followed

Site Specifications

Sites using reusable instruments must consider the following specifications:

- Instrument storage: A locking cabinet out of direct sunlight is highly recommended for instrument storage. When possible, a glass door will allow site staff to quickly assess when quantities are getting low. See p. 22 for more recommendations concerning instrument storage.
- Instrument flow: Instruments should generally flow from dirty to clean. This means the instruments are moved in a unidirectional fashion starting at point of use, with instruments from a later "cleaner" step never coming into contact or crossing paths with instruments from an earlier "dirtier" step. Physical separation between steps is best, such as cleaning in one room and packaging/sterilization in the next room, however, when space is limited, the steps may need to occur within a common space, keeping instrument flow in one direction and steps as physically separated as possible.
- Preparation space: Select a large area free from dust and contaminants to dry cleaned instruments prior to packaging and sterilizing
- Sterilizer space: Sterilizers should have dedicated space with ready access to necessary power and water supply. Sterilizer location must also be consistent with the "dirty-to-clean" unidirectional flow of instruments. Sterilizers can alternatively be located offsite if a hub and spoke model of centralized reprocessing is selected. Offsite sterilizers increase time and logistical burden associated with sterilization but they may be the best option based on infrastructure limitations and provide a cost or operational efficiency. Any time an offsite sterilizer is used, some stock of single-use kits can be helpful in reducing service interruption if transport of sterilized instruments is delayed.
- Power supply: Electrical sterilizers require a consistent electrical power supply either from the power grid or from a generator. Individual sterilizer power requirements will vary by machine, but if a site is subject to frequent power interruptions, a generator should be considered. Dual-power sterilizers require either electrical power or propane.
- Water supply: A steam autoclave will require clean water to operate. Distilled water is ideal, as it will optimize autoclave lifespan. Chemicals/impurities (sodium, magnesium, iron) in municipal water can adversely affect the life of an autoclave and manufacturer's instructions on water source should be followed.

Coordination with Other Services

In cases where sterilizers will be shared with other services and users (e.g., in a Ministry of Health facility), it is essential to define roles, responsibilities, and autoclave time allocations.

- If a technician hired by the VMMC implementer is managing inventory and sterilization for their own instruments, there should be an explicit agreement concerning the time they will be allocated to use the sterilizer. Storage space should also be clearly marked and locked to avoid pilfering/mixing by other services. Programs transitioning towards sustainability might adopt a more integrated model with minor surgery clinics.
- Any technicians associated with other services who also manage inventory and sterilization should be oriented to VMMC service delivery SOPs, to enable seamless coordination between services.
- Inventory mixing is a risk when VMMC programs share cleaning and packaging space, sterilizers, and/or technicians with other services. The simplest ways to prevent inventory mixing with other programs are to assign dedicated time for implementing partner staff to use reprocessing space and equipment; dedicate distinct storage space for VMMC instrument sets; mark instruments with acid-based etching (not vibrating engraving, which can damage instruments), surgical instrument identification tape, and/or use pouches and wrapping that are different in appearance from those used by other services and marked with "VMMC" (or equivalent country nomenclature), along with other standard particulars (e.g., date of sterilization).
- VMMC instruments can be packed and sterilized in the grouping in which they will be used, analogous to a kit or set. This will maximize efficiency for providers and help discourage repurposing of instruments to other services.
- Independent, regular quality assurance practices can help the VMMC programs ensure that irregularities in instrument stock or quality are promptly detected.
- If other services have been sterilizing and repurposing single-use VMMC instruments for their procedures, they may be dismayed by a VMMC program's decision to transition to reusable instruments. These expectations should be managed proactively.
- Benefits to facilities associated with introduction of reusable VMMC instruments include: access to new sterilizers (if applicable), reduced waste management burden for the site, and additional support for routine inspection and maintenance of autoclave machines.

Introducing and Maintaining Reusable Instruments

Reusable Instrument Cycle

Once preparatory steps are complete, including a decision on the order in which sites will transition to reusables, a program should integrate reusable instruments. In the first weeks, a program should keep backup supplies of single-use kits in case of problems with autoclaves and other challenges in the early phase of transition. Whenever single-use and reusable instruments are both in use, ensure a clear process is in place so that **single-use and reusable instruments do not mix.** The specific single-use and

reusable instruments available at a site should be carefully inspected and differences noted (e.g., in coloring, shape, or markings) that can help readily identify which is which.

Once in operation, the typical reusable instrument cycle is four stages, depicted in Figure 2, and each step is typically the responsibility of the technician.

Figure 2: Reusable Instrument Cycle and Top-Line Steps

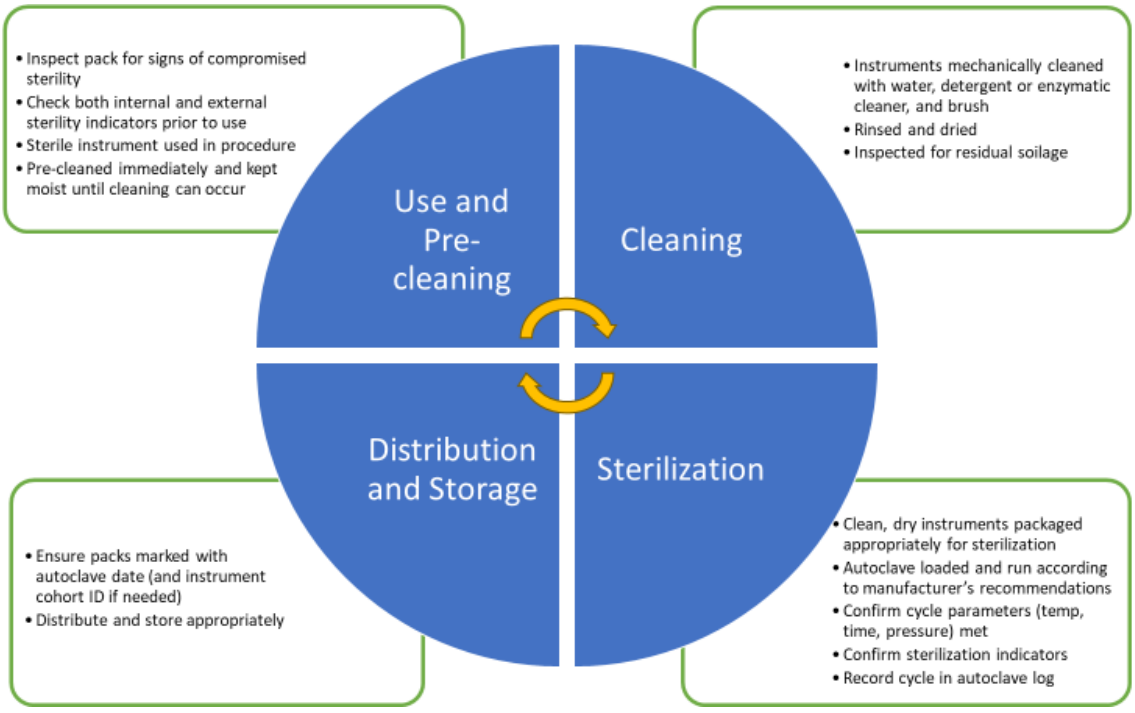
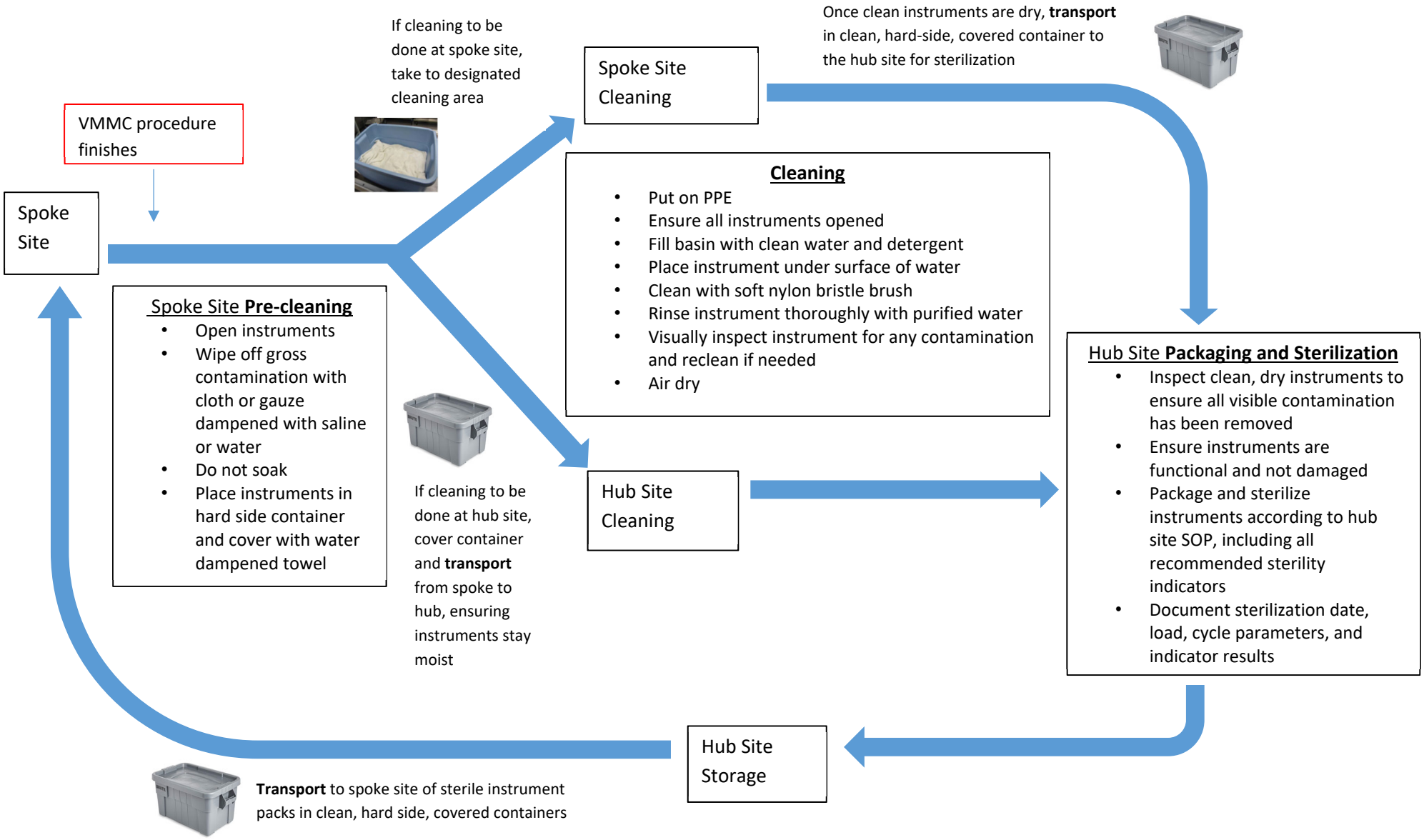


Figure 3 illustrates the potential division of reprocessing steps between spoke and hub sites in a hub-and-spokes model.

Figure 3: Potential divisions of instrument processing steps between hub and spoke sites



Specific actions associated with each stage in the cycle are as follows. This text is meant to provide a general overview but does not contain enough detail to serve as an SOP. Full instructions on instrument processing in resource-limited settings are available in the World Health Organization guidance on Decontamination and Reprocessing of Medical Devices for Health-Care Facilities, available at: https://www.who.int/infection-prevention/publications/decontamination/en/.

Pre-cleaning

- Immediately after use, instruments should be pre-cleaned. This means removing gross soil by wiping with a damp cloth.
- Do not soak instruments in saline as this can cause damage. **Do not use chlorine solution or disinfectants for pre-cleaning**, as it is corrosive to instruments. Once all gross soil has been wiped off, instruments should be covered with a water-moistened towel or sprayed with a commercial product specifically designed for this purpose. Instruments are then taken to a designated area for cleaning.
- If pre-cleaning is being done at a spoke site, the pre-cleaned instruments should be returned to the hub without being allowed to dry out (e.g., ensure covered with a damp towel). The processing technician at the hub site should re-inspect instruments for defects.

Cleaning

- Clean instruments manually using water with detergent or enzymatic cleaning product and brush then rinse thoroughly. Mechanical cleaning equipment such as ultrasonic cleaners or automated washers may be used instead of manual cleaning although this equipment is not widely available in resource limited settings.
- Allow instruments to dry, typically air dry but can be manually dried with clean, non-linting cloth
- Visually inspect each instrument after cleaned and dried to ensure all visible contamination removed prior to packaging
- If while cleaning, the technician notes a defective or malfunctioning instrument, he or she should set it aside and dispose of it according to waste management SOPs (see p. 27 for waste management resources) and log it in the site inventory.
- If single-use instruments are also being used at the service delivery point and contain "single use only" markings, check instruments for marking and set aside any single-use instruments. If single-use instruments are being used but are unmarked, the technician should monitor instrument quality carefully to detect single-use instruments.
- Note: Waste management processes will remain the same for bio waste, sharps, and other consumables.

Table 4: Types and use of sterilization packaging materials

Sterilization Method	Packaging Material Requirements	Acceptable Materials
Steam autoclave	Should allow steam to penetrate.	Paper Plastic Cloth

		Paper peel packages Wrapped, perforated cassettes
Dry heat	Should not insulate items from heat. Should not be destroyed by temperature used.	Paper bags Aluminum foil Polyfilm plastic tubing Wrapped, perforated cassettes
Unsaturated chemical vapor	Vapors should be allowed to precipitate on contents. Vapors should not react with packaging material. Plastics should not make contact with sides of sterilizer.	Wrapped, perforated cassettes Paper Paper peel pouches

Source: https://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization.htm

Packaging and Sterilization

- Place full instrument set in sterilizer-safe pouch/wrapping or tray, ensuring forceps are open-jawed to allow hinges to be fully sterilized. (See Table 4 for examples of sterilization packaging materials.)
- A chemical indicator should be placed among the instruments, inside the package, and on the outside of each package if the internal indicator is not visible through the package.
- Place pouches or alternative packaging in autoclave.
- Start cycle and monitor to ensure machine is operational.
- Once cycle is complete, check indicators (see sidebar) to confirm sterilization.
- Inspect instrument packs. Check to ensure no tears in pouches, if applicable; notify supervisor if there is visible condensation (may be a sign of wear on rubber seal of autoclave door) or corrosion (a sign of wear on instruments).
- Mark autoclave logbook/register.

Sterilization Indicators

Physical Indicators

- Time, temperature, and pressure gauges built into autoclaves: For each sterilization cycle, these readings should be observed and verified prior to unloading the sterilizer and documented in the autoclave register (see Appendix 3 for a sample register).
- In hospitals or other locations with large, freestanding autoclaves (unlikely in most VMMC settings), autoclaves may produce an indicator printout.

Chemical Indicators

- Chemical indicators (CIs) change color or show movement during the sterilizer cycle to verify that some or all sterilization parameters were met.

- CIs should be used on the outside and inside of all sterilized packages. Indicator tape is an example of an external CI that indicates whether a package was run in the sterilizer. Internal CIs are used to ensure the sterilant penetrated the packaging system.
- If using a dynamic air removal (prevacuum) sterilizer, an air removal test should be run daily.

Biological Indicators

- Biological indicator (BI) monitoring is the gold standard for sterility assurance [Centers for Disease Control and Prevention, 2003, 2008], as BIs contain bacterial spores that are highly resistant to sterilization (more resistant than the bacteria on instruments).
- BI monitoring is completed by running a BI in the sterilizer with a load. If all spores in the BI have been killed, the BI will indicate sterilization has been achieved. Each BI works differently, and the manufacturer instructions for use provide details on how to use and read the indicator.

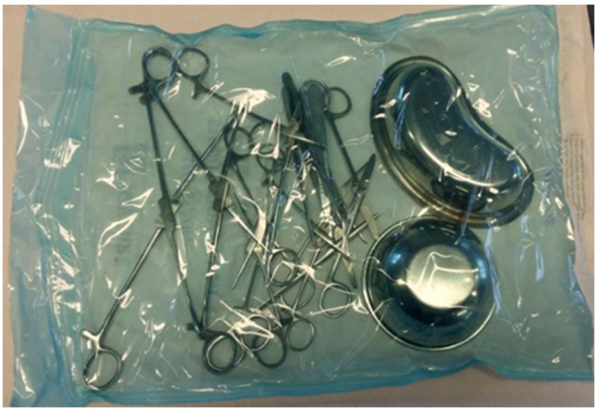
Source: https://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm

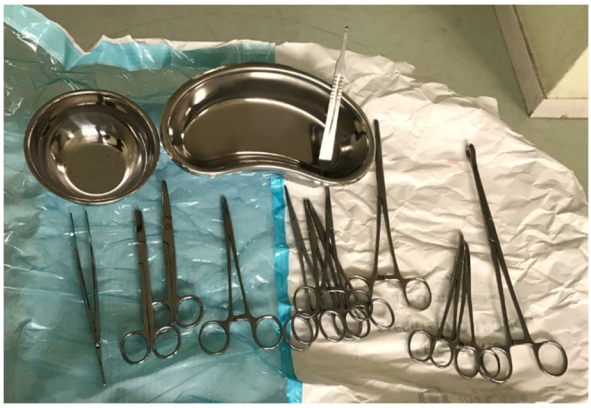
Storage

- Sterilized packages should be stored in a manner that reduces the potential for contamination (i.e., clean, dry, and temperature- and traffic-controlled areas elevated above the floor and away from walls).
- Sterilized items should remain in pouch/wrap until they are needed for use.
- Date and mark packages to denote the instrument "cohort" and program (if autoclave is shared with other services).
- Organize according to shelf-life practices (first in, first out), accounting for expiration of sterility, which will vary based on method of packaging/storage.
- Note: Some facilities have switched to event-related practices. This approach recognizes that the product should be considered sterile until some event causes the item to become contaminated (e.g., a package becomes torn or wet), not based on how much time has elapsed since sterilization.
- Lock cabinet when not in use, if possible.
- Complete inventory tracking update.

Figure 4: Instruments in sterilization pouch

Figure 5: Instruments on opened sterilization pouch, on Mayo tray





Distribution

- All packages containing sterile items should be inspected before use to ensure sterile barrier integrity and dryness. Any package that is wet, torn, dropped on the floor, or damaged in any way should be recleaned, repackaged, and resterilized.
- Place packages at service delivery point (surgical bay) for the start of services at the beginning of each day.
- Maintain stock of approximately 10 packages per bay, replenishing throughout the day.
- If, while in use, a provider notes a defective or malfunctioning instrument, he or she should set it aside and alert the technician so that it can be properly disposed of and logged in the site inventory.
- Soiled (i.e., post-procedure) surgical instruments should be pre-cleaned at point of use by wiping with damp gauze to remove gross contamination. They must be kept moist with a damp towel (but not left immersed) to prevent drying of blood and transported to the designated cleaning area.

Quality Assurance

Supervisors should be allocated time to perform routine (monthly or quarterly) quality assurance/quality improvement, checking instrument quantities against inventory and checking quality of random selection of instruments. The following are recommended steps for performing quality checks to identify signs of wear in a random sample of instruments (unless otherwise noted by an asterisk, instruments showing signs of wear can continue to be used if the provider is comfortable using them but should be discarded and replaced as soon as feasible):

- Hinges
  - Stiffness when opening/closing jaws
  - Loose screws must be tightened/repaired prior to use

- *Cracks in hinge: Blood can enter the crack and is difficult or impossible to clean. Remove immediately.

- Ratchets
  - *Ratchets fail to hold
- Jaws/teeth: Instrument may continue to be used with any of the following signs of wear so long as it securely holds tissue. If it cannot hold tissue, discard.
  - Misalignment between tips/jaws/teeth (tip distal to handle)
  - Visible gap between jaws when closed
  - Chipped/dulled teeth (if applicable)
  - Burrs
  - Worn edges
- Surface
  - Dents
  - *Spots and stains that do not come off after sterilization
  - *Corrosion/rust
  - *Difficult to clean/visibly unclean
- Scissor blades
  - *Dull spots or chips on cutting edge of scissors: There are tissue-simulating products that should be used to test surgical scissors for sharpness.

Sterilizer Preventive Maintenance and Repair

As with any machine, programs should plan for routine preventive maintenance and repair of sterilizers, e.g., schedule service for autoclaves before high volume seasons or campaigns, or annually for sites with more consistent volumes. As discussed in the sterilization indicator box on p. 21, there are several ways to monitor sterilizer performance. When a technician identifies signals of poor performance, repair or replacement must be coordinated.

For newly purchased sterilizers, vendors will typically issue a time-limited warranty covering repairs and training for the technician and/or other staff. Once the warranty expires, repairs and training are no longer their obligation. Programs may wish to explore MOH willingness to have the implementer contract MOH technicians on a temporary basis to manage repairs.

While not essential, the following maintenance activities can extend instrument life:

- Enzymatic antiseptics can be used to periodically remove protein remnants, but cost-benefit is questionable.

- Chemicals/impurities (sodium, magnesium, iron) in water can adversely affect cleaning and the life of an instrument. If possible, programs should use distilled water in autoclaves and ensure adherence to manufacturer's instructions for use concerning appropriate water qualities.

Inventory Management

Site-Level Distribution

Programs procure instruments in bulk and must then determine the proportion of instruments going to each site. While each context will have its own considerations, a conservative approach would be to allocate twice the number of instrument sets needed for a day's operation (i.e., twice the average daily site VMMC volume), plus 20% buffer stock for malfunctioning instruments. Undistributed instruments can be stored centrally or regionally and distributed based on site needs.

Instrument Cohorts: An Example from Mozambique

As the first instrument procurement arrives and enters circulation, the program will need to monitor the wear and track the quantity of instruments in circulation to ensure safe instruments are available in adequate supply for VMMC. A program in Mozambique assigned instruments to a "cohort" as they were introduced. For example, any full instrument sets introduced in August 2017 would be in the Aug17 cohort. Cohort quantities are logged in the site-level instrument inventory, and the cohort assignment is marked for easy tracking in storage and subsequently in use. When possible, the program uses a single cohort in any given day (or week, if possible) for ease of tracking. Cohort tracking loses its precision if individual instruments malfunction or show signs of wear earlier than the rest of the cohort because a new instrument will need to be introduced to replace the defective/expired one (see Replacing Instruments, below), and it will be "fresher" than the rest of the instrument set. As individual instruments from a cohort are removed from use, the date of removal is recorded and the useable lifespan of instruments at that site will become clear. This information can guide inventory management.

Replacing Instruments

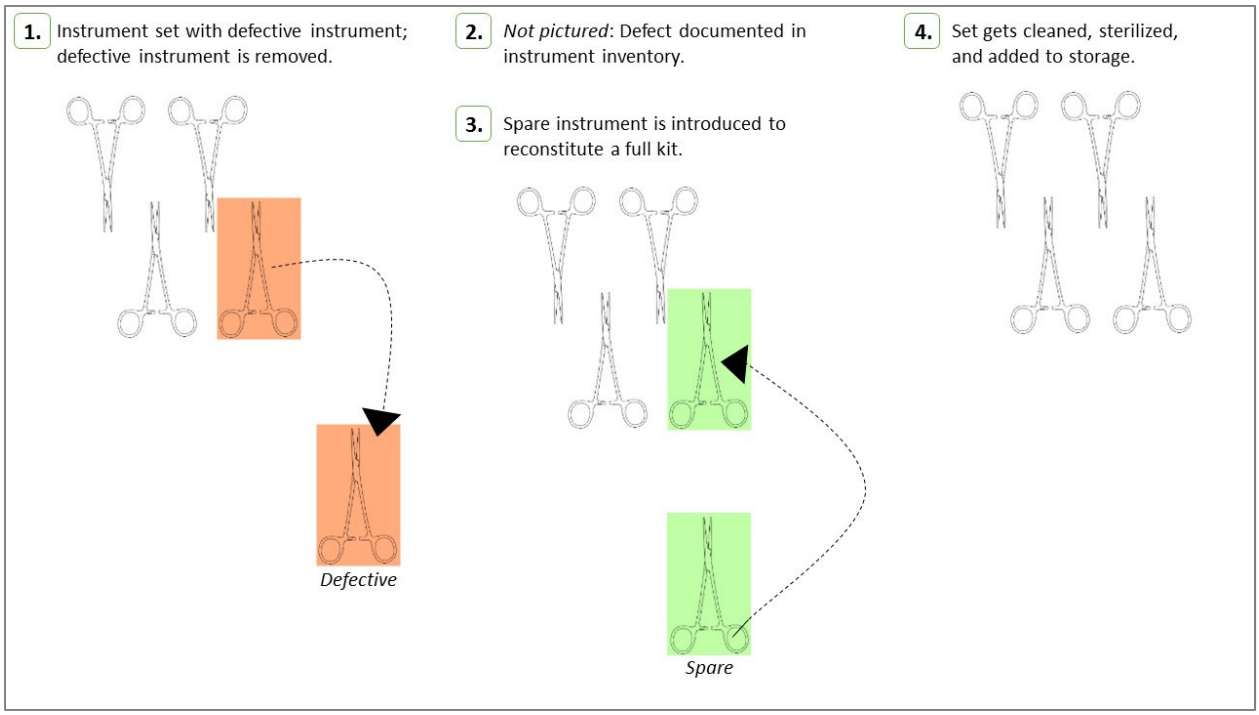
Occasionally, one or more instruments in any given reusable instrument set will malfunction or show signs of wear before the rest of the instruments. For this reason, the 20% instrument buffer stock from the procurement should be stored separately (i.e., all surgical scissors in one box instead of as part of assembled sets), unsterilized, and in their original packaging to replace malfunctioning/expired instruments.

This suggested process of replacing an instrument works as follows:

1. When an instrument malfunctions/expires, the provider or technician (whoever notices the defect) should put the instrument aside.

2. The type of instrument, type of defect/wear, and instrument cohort are documented in the instrument inventory.
3. A spare/replacement instrument is taken out of its original packaging and added to complete the instrument set.
4. The complete instrument set is cleaned, sterilized, and added to storage using the "first in, first out" shelf-life storage practice (or event-driven process, if used). (The other instruments in the set may not have been used since the last sterilization, but they are nonsterile because it was opened for inspection.) This process is illustrated in Figure 6 (next page).

Figure 6: Replacing instruments



Site-Level Instrument Inventory

Site-level inventory should track the number of active instrument sets, malfunctioning/expired instruments, and the inventory of spare instruments in the buffer stock. Programs have had success performing site-level instrument inventory on a monthly basis. See **Appendix 1** for a sample monthly site-level inventory tool. If a specific instrument repeatedly demonstrates quality issues, the program may

wish to explore an alternative supplier for that item. If the instrument cohorts expire faster or slower than anticipated, future instrument forecasts may be adjusted accordingly. The site-level inventory should be completed by the technician, with careful review by his or her supervisor. An editable Word version is also available.

Program-Level Instrument Inventory

A program-level inventory will allow managers to track the aforementioned trends in aggregate. This exercise is helpful when conducted on a quarterly basis. See **Appendix 2** for a sample program-level inventory tool. An editable Word version is also available.

Autoclave Register

Registers allow the program to track the performance and use of an autoclave. See **Appendix 3** for a sample autoclave register. An editable Word version is also available.

Waste Management

In general, transitioning to reusable instruments should decrease waste burden by significantly reducing metal instrument waste without substantially affecting the production or management of biohazardous and general non-hazardous waste. At the end of their useful life, reusable instruments can be managed in the same way as disposable instruments, treated as sharps or non-hazardous metal waste as appropriate.

See waste management recommendations in the following resource documents for relevant principles, infrastructure requirements, and best practices. These may be considered alongside other national or local waste management standards to arrive at an appropriate waste management SOP. Once determined, that SOP should be communicated and incorporated into quality assurance and improvement activities.

- World Health Organization healthcare waste management reference material: https://www.who.int/publications/i/item/9789241548564
- Ackerson, Scott, Layloff, Tom, Pahl, Nicole, and Ranade, Britta. 2016. Supply Chain Management System: Waste Management Plan. Available at: https://www.ghsupplychain.org/sites/default/files/2019-07/scms_vmmc_wasteguide.pdf

Appendix 1: Quarterly Site-Level Instrument Inventory Tool

SAMPLE MONTHLY SITE-LEVEL INSTRUMENT INVENTORY AND INSTRUMENT RETIREMENT LOG TOOL

Item	**In storage**	**In use**	**Defective/malfunctioning/ worn/missing** *(include details in retirement log)*	**Awaiting disposal per waste management SOP**	**Total individual instruments available for use** (*in storage + in use*)	**Total set equivalents of this instrument available for use** (*total individual instruments available/# per set*)
Core kit items (adapt based on composition of set in program)						
Kidney dish (1/set)						
Gallipot (1/set)						
Needle holder (1/set)						
Suture scissors (1/set)						
Hemostatic forceps, straight (4/set)						
Hemostatic forceps, curved (1/set)						
FG complements (adapt based on composition of set in program)						
Hemostatic forceps cross clamp (1/set)						
Tissue forceps, plain (1/set)						
DS complements (adapt based on composition of set in program)						
Artery Forceps (2/set)						
Tissue forceps, toothed (1/set)						
Dissecting scissors (1/set)						

	Total available	**Total required**	**Total needed from stock/procurement** (“total required” minus “total available”)	**Notes** (including notes on spare individual instruments not currently part of ‘sets’)
Core set equivalents				
FG complements				
DS complements				

INSTRUMENT RETIREMENT LOG

Date	Instrument type	Reason no longer in use (e.g., defective, stained broken, worn, missing)	Notes

Appendix 2: Program-Level Instrument Inventory Tool

SAMPLE QUARTERLY PROGRAM-LEVEL INSTRUMENT INVENTORY TOOL

District	Complete sets available		Complete sets required for full operation		Sets needed from stock/procurement ('sets required' minus 'sets available')		Individual instrument needs to complete additional sets*
	FG	DS	FG	DS	FG	DS	
Province 1							
District 1							
Site A							
Site B							
Site C							
District 2							
Site A							
Site B							
Site C							
Province 2							
District 1							
Site A							
Site B							
Site C							
District 2							
Site A							
Site B							
Site C							
District 3							
Site A							
Site B							
Site C							
District 4							
Site A							
Site B							
Site C							
TOTALS							

*Use if requesting a box of a single type of instrument rather than full sets – use only if very disproportionate quantities are in stock on site, e.g., no remaining scissors, but the rest of kit contents are in good supply

Appendix 3: Autoclave Register

SAMPLE AUTOCLAVE REGISTER

Load	Date	Content of packs (mark FG or DS kit, other contents, and/or instrument cohort)	Number of packs	Number of cycles (>1 indicates sterilization had to be repeated)	Cycle time (for final cycle, if >1 cycles performed)			Maximum temperature during sterilization	Maximum pressure during sterilization	Problems incurred (e.g., sterilization indicator shows incomplete sterilization)	Technician performing sterilization
					Start Time	End Time	Duration				
Load 1											
Load 2											
Load 3											
Load 4											
Load 5											
Load 6											
Load 7											
Load 8											
Load 9											
Load 10											
Load 11											
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