Limited sterile processing capabilities for safe surgery in low-income and middle-income countries: experience in the Republic of Congo, Madagascar and Benin

Olive Fast,1 Christina Fast,1,2 Dan Fast,1 Suzanne Veltjens,3 Zouliha Salami,3 Michelle C White3

ABSTRACT
It is highly difficult to perform safe surgery without sterile instruments, yet the capacity to adequately clean, disinfect and sterilise surgical instruments in low-income and middle-income countries is largely unknown. Sterile Processing Education Charitable Trust developed an assessment tool and, in partnership with Mercy Ships, evaluated the sterile processing capacity in 59 facilities in Madagascar, Benin and the Republic of Congo. This data-driven analysis paper illustrates how lack of sterile processing capacity acts as a barrier to safe surgical care. Our tool identified widespread lack of knowledge of techniques and resources needed for sterile processing. Only 12% of workers in Republic of Congo and Benin had sterile processing training and none in Madagascar. None of the hospitals surveyed met basic standards for cleaning, disinfection and sterilisation as defined by the WHO/Pan American Health Organization. Examples of poor practice included lack of cleaning supplies (basic brushes and detergents), incorrect drying and storage of surgical instruments, and inattention to workflow causing cross-contamination. Bleach (sodium hypochlorite) solutions, damaging to instruments, were used universally. In our experience, using an assessment tool allowed identification of specific gaps in sterile processing capacity. Many of the gaps are amenable to simple solutions requiring minimal resources and achievable by most hospitals. We recommend that stakeholders seeking to strengthen surgical health systems in low-resource settings incorporate sterile processing capacity assessments and training into their programmes.

BACKGROUND
Sterile processing capability is essential for safe surgical care

Without sterile instruments it is highly difficult to perform a sterile procedure. Therefore, proper sterile processing of surgical instruments is fundamental to surgical safety. Surgical instrument reprocessing comprises five fundamental steps: (1) cleaning and decontamination, (2) packaging and inspection, (3) sterilisation, (4) storage and (5) transportation. Cleaning and decontamination are the most important. Done properly, cleaning and decontamination can eliminate up to 99% of micro-organisms.1 Without
proper cleaning, bioburden on instruments is baked on in the sterilisation process, forming a protective layer for micro-organisms that survive to infect patients.

The 2009 WHO Surgical Safety Checklist requires confirmation of instrument sterility prior to starting surgery.\(^1\) Sterility is difficult to confirm in low-income and middle-income countries (LMICs) as sterility indicators are largely unavailable.\(^2\) Also, a paucity of evidence exists on the effectiveness of cleaning, decontamination and sterilisation of surgical instruments in LMICs. A recent pilot study reported universal deficiencies in 26 hospitals in nine LMICs and concluded sterilisation remains unconsidered and unsupported.\(^3\) Lack of trained sterile processing staff has also been identified as a barrier to patient safety.\(^4\)

In 2016, the WHO/Pan American Health Organization (PAHO) developed a manual for decontamination and reprocessing of medical devices in LMICs.\(^5\) However, country-specific data identifying local needs and context-specific solutions are scarce. This analysis paper describes our field experience assessing sterile processing capacity in three LMICs in collaboration with Ministries of Health. The data illustrate barriers that exist in achieving the 2016 PAHO guidelines,\(^5\) and thereby safe surgery.

Collaboration between Mercy Ships, Ministries of Health and Sterile Processing Education Charitable Trust

Mercy Ships is a non-governmental organisation offering free surgeries and training to local healthcare workers, including sterile processing staff. Mercy Ships visits countries at the invitation of the Head of State and works closely with the Ministry of Health to promote safe surgery. Sterile Processing Education Charitable Trust (SPECT) is a non-governmental organisation that provides education and training to sterile processing personnel in LMICs. SPECT’s work includes conducting hospital/healthcare centre assessments of reprocessing areas, providing education sessions, mentoring and consultation.

From 2013 to 2017, Mercy Ships was based sequentially in the Republic of Congo, Madagascar and Benin. As part of a larger project to strengthen the surgical healthcare system in each country,\(^6-8\) Mercy Ships collaborated with SPECT to assess sterile processing capacity and provide training to meet identified needs. In each country, the Ministry of Health gave permission for the assessments and training, and collaborated on identifying healthcare facilities, aiming to cover a range of facilities from university hospitals to healthcare centres. The Mercy Ships Institutional Review Board gave permission to analyse anonymised observational data by country.

ASSESSMENT OF STERILE PROCESSING CAPACITY

From 2013 to 2016 sterile processing capacity was assessed in 59 facilities (29 hospitals and 30 healthcare centres) in the Republic of Congo, Madagascar and Benin. These facilities undertake 79,935 procedures per year and serve a combined population of 4.07 million people. Details of the facilities are given in table 1.

Sterile processing capacity assessment tool

Since no tool was found in the literature, a paper survey tool was designed based on recommended standards\(^9\) (see online supplementary file 1).

The assessment survey was divided into four key areas:

1. workforce
2. workspace
3. reprocessing practices
4. testing of sterilisation equipment.

Reprocessing practices were subdivided into five components: cleaning and decontamination, packaging and inspection, sterilisation, storage, and transportation. All facilities received training and advice on sterile processing practices after the assessment. This analysis is largely focused on the cleaning and decontamination, as well as sterilisation aspect of reprocessing practices.

Observational data from operating rooms (ORs), maternal delivery rooms, decontamination areas and instrument processing facilities were collected. Semi-structured interviews (based on the survey tool) with hospital staff gave additional data.

LIMITATIONS IN STERILE PROCESSING CAPACITY

Workforce

Formal training is defined as having received education in the theoretical components of instrument reprocessing. In Benin and Republic of Congo, only up to 12% of staff were formally trained in instrument reprocessing, whereas in Madagascar none had formal training. In Benin, hospitals had trained staff but not health centres; larger hospitals used trained staff in sterilisation areas, but untrained nurses or students to clean and decontaminate instruments prior to sterilisation. In Madagascar staff had multiple responsibilities, including working in the morgue, undertaking dressing changes or working in laundry, and none had any formal training in sterile processing practices. Further details are shown in table 2.

Workspace

No facility surveyed had an adequate workflow whereby dirty instruments, surgical drapes and gowns are moved consistently from dirty to clean areas, and none provided personal protective equipment (PPE) to the workforce (see table 2). Dirty surgical instruments frequently came into contact with clean ones. Examples include the sink used to clean instruments was the same sink used by surgeons and nurses to ‘scrub’ prior to surgery; sterilisers were located in areas used for decontamination of instruments instead of being clearly separated. In some hospitals, it was evident that attempts had been made to create one-way flows of dirty to clean areas: one hospital had a dedicated decontamination room and a window through which nurses passed cleaned instruments for transfer to the sterilisation area.
### Table 1 Facility size and scope

<table>
<thead>
<tr>
<th>Type of facility</th>
<th>Population served</th>
<th>Scope of surgical practice</th>
<th>Volume of surgery/year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pointe Noire, Republic of Congo, 2013</strong></td>
<td>2 million</td>
<td>Neurosurgery, orthopaedics, ENT, ophthalmology, obstetric and gynaecology</td>
<td>2000 surgeries</td>
</tr>
<tr>
<td>Referral hospital (n=2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Base hospital (n=2)</td>
<td></td>
<td>General surgery, trauma and caesarean sections</td>
<td>1000 surgeries</td>
</tr>
<tr>
<td>Antananarivo, Madagascar, 2014</td>
<td>1.4 million</td>
<td>Includes largest hospital and leading paediatric hospital in Madagascar</td>
<td>14,300 surgeries</td>
</tr>
<tr>
<td>University hospitals (n=11)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>District hospitals (n=3)</td>
<td></td>
<td></td>
<td>4,780 surgeries</td>
</tr>
<tr>
<td>Health centre (n=3)</td>
<td></td>
<td></td>
<td>720 surgeries</td>
</tr>
<tr>
<td>Cotonou, Benin, 2015</td>
<td>0.67 million</td>
<td>Largest government-funded hospital in Benin, main teaching hospital</td>
<td>17,600 surgeries</td>
</tr>
<tr>
<td>University hospitals (n=1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smaller government-funded (n=2)</td>
<td></td>
<td>General surgery and obstetrics</td>
<td>5,475 surgeries</td>
</tr>
<tr>
<td>Private hospital (n=2)</td>
<td></td>
<td>General surgery and obstetrics</td>
<td>4,020 surgeries</td>
</tr>
<tr>
<td>Zone hospital (n=6)</td>
<td></td>
<td>General surgeries, caesarean sections and obstetrics</td>
<td>4,440 surgeries; 3,200+ deliveries</td>
</tr>
<tr>
<td>Health centre (n=27)</td>
<td></td>
<td>Minor procedures and obstetrics</td>
<td>12,620 procedures; 14,500 deliveries</td>
</tr>
<tr>
<td>Total number of facilities (n=49)</td>
<td>4.07 million</td>
<td></td>
<td>79,935 (1,964 procedures per 100,000 population)</td>
</tr>
</tbody>
</table>

ENT, ear, nose and throat.

In the Republic of Congo use of PPE was almost non-existent. Some staff in one hospital wore gloves to clean instruments, but wore the same gloves into the OR, while removing sterile instrument packages and while turning water taps on and off. At another hospital masks were worn while cleaning instruments, but no protective gowns. In Benin conditions were better, as most sterile processing staff wore some form of PPE, including gowns, gloves, masks and footwear. At one hospital only gowns were worn with reusable rubber gloves. Rural healthcare centres were not assessed for PPE use. Some facilities in Madagascar had gloves available for staff but no other PPE.

**Surgical instrument reprocessing practice**

Instruments were inadequately cleaned and decontaminated due to lack of supplies (details given in table 3) at all facilities assessed. Examples include the following: few facilities had warm water, necessary to create suds that assist in removing bioburden from the instruments during cleaning. In the Republic of Congo, three hospitals used one worn fingernail brush for cleaning instruments, while the fourth hospital used a floor scrubbing brush. In one area, the staff members were required to purchase their own brushes. In another the brush was left to soak in formaldehyde (a high-level disinfectant that is carcinogenic) when not in use. In Madagascar, there was a general lack of cleaning supplies, high use of disinfectant prior to cleaning and lack of knowledge related to the importance of proper cleaning. In situations where autoclaves were functioning, the ability to adequately clean instruments, removing contaminated materials to allow steam to reach all surfaces, was lost due to a lack of basic cleaning materials, such as brushes, or knowledge of the importance of removing all bioburden from instruments to enable them to be sterilised. In Benin, most facilities had one or two brushes, although one hospital had only cloth rags for cleaning. Eight health centres had a worn brush for cleaning, two had a toothbrush, one used a sponge and another used a rag. Only one hospital had enzymatic detergent, instrument lubricant and
<table>
<thead>
<tr>
<th></th>
<th>Republic of Congo hospitals (n=4)</th>
<th>Madagascar hospitals (n=14)</th>
<th>Madagascar health centres (n=3)</th>
<th>Benin hospitals (n=11)</th>
<th>Benin health centres (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of workers undertaking sterile processing</td>
<td>17</td>
<td>67</td>
<td>16</td>
<td>34+</td>
<td>29+</td>
</tr>
<tr>
<td>Number of formally trained workers doing sterile processing</td>
<td>2 (12)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (12)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with PPE available*</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>Not assessed</td>
<td>0 (0)</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Number (%) of facilities with decontamination area separate from sterilisation area</td>
<td>1 (25)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (40)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Number (%) of facilities with clear workflow from dirty to clean</td>
<td>2 (50)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (18)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with restricted entry to sterilising area</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (10)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with infrastructure needed to support sterilisation†</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with reliable, clean water supply</td>
<td>4 (100)</td>
<td>14 (100)</td>
<td>3 (100)</td>
<td>11 (100)</td>
<td>27 (100)</td>
</tr>
<tr>
<td>Number (%) of facilities with reliable electricity supply</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*PPE, personal protective equipment, defined as gloves, mask and eye shield, and gowns.
†Defined as infrastructure required to support proper functioning of an autoclave, such as consistent electricity, distilled water, and regular maintenance.

Rust remover to care for instruments. Instruments received soaking in bleach (sodium hypochlorite) solution from the OR were washed with laundry soap and water, and then on occasion rinsed with tap water and either left to air-dry on a towel or dried by hand. All facilities surveyed used bleach solutions to clean and decontaminate instruments, which is no longer recommended. Laundry soap, mixed with bleach, was used to clean instruments in all four facilities in the Republic of Congo. Following cleaning, facilities soaked the instruments for variable lengths of time (5–45 min) without rinsing following the bleach soaks. At times the instruments were placed on a towel to dry and other times they were wiped down with a green surgical drape—once noted to have been used for a previous procedure. In Benin, the process for decontamination in the larger centres involved soaking instruments in a bucket of bleach solution in the OR, then sending them to the decontamination room. In Madagascar conditions reflected what was observed in the other two countries.

Testing of sterilisation equipment

The results of functionality testing for sterilisation equipment found in the facilities assessed are shown in table 4. Of the autoclaves tested 20%–75% were functioning compared with 64%–100% of dry heat sterilisers.

Autoclaves

Each hospital assessed in the Republic of Congo had non-functioning autoclaves. Of the eight functioning autoclaves, three were used exclusively to sterilise cloth. One hospital had only a small table top autoclave functioning, while another had two dry heat sterilisers and three small autoclaves in use. A fourth hospital was using a 2-month-old autoclave to sterilise instruments; however,
Table 3  Sterile processing practice

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>Republic of Congo hospitals (n=4)</th>
<th>Madagascar hospitals (n=14)</th>
<th>Madagascar health centres (n=3)</th>
<th>Benin hospitals (n=11)</th>
<th>Benin health centres (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) of facilities with warm water easily available</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with various sized brushes and sponges available for cleaning</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with appropriate detergent*</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Number (%) of facilities with clean clothes for drying instruments</td>
<td>2 (50)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>6 (60)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Decontamination

| Number (%) of facilities using bleach solution prior to cleaning† | 4 (100) | 14 (100) | 3 (100) | 11 (100) | 23 (100) |
| Number (%) of facilities using three-sink method‡ | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

*Appropriate detergent defined as enzymatic or liquid soap with a pH between 7 and 10.18
†Use of bleach is no longer recommended. 9 10
‡Three-sink method defined as two separate containers with warm, soapy water for decontaminating and cleaning, and a third with distilled water for rinsing.15

4 months later it was found to be non-functional. Two of the seven functioning autoclaves found in Madagascar were used only for sterilising cloth materials, while two others could not be used as employees did not have the passwords required to operate them. Of the remaining three, two passed biological indicator testing and one failed. In Benin, autoclaves at two hospitals were non-functional 4 months following assessments. A third hospital did not have an autoclave, but used a dry heat steriliser.

Table 4  Steriliser functionality

<table>
<thead>
<tr>
<th>Sterilisation</th>
<th>Republic of Congo hospitals (n=4)</th>
<th>Madagascar hospitals (n=14)</th>
<th>Madagascar health centres (n=3)</th>
<th>Benin hospitals (n=11)</th>
<th>Benin health centres (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) of facilities using a functioning floor model autoclave to sterilise instruments</td>
<td>2/4 (50)</td>
<td>2/14 (14)</td>
<td>0/3 (0)</td>
<td>7/11 (63)</td>
<td>0/23 (0)</td>
</tr>
<tr>
<td>Number (%) of all floor model autoclaves found that are functional</td>
<td>5/10 (50)</td>
<td>4/20 (20)</td>
<td>N/A</td>
<td>9/14 (65)</td>
<td>N/A</td>
</tr>
<tr>
<td>Number (%) of facilities using a functioning table top autoclave to sterilise instruments</td>
<td>3/4 (75)</td>
<td>0/14 (0)</td>
<td>0/3 (0)</td>
<td>4/11 (36)</td>
<td>5/23 (22)</td>
</tr>
<tr>
<td>Number (%) of functional table top autoclaves</td>
<td>3/7 (42)</td>
<td>N/A</td>
<td>N/A</td>
<td>10/12 (83)</td>
<td>6/6 (100)</td>
</tr>
<tr>
<td>Number (%) of dry heat sterilisers functional</td>
<td>1/1 (100)</td>
<td>22/33 (73)</td>
<td>2/3 (67)</td>
<td>18/28 (64)</td>
<td>17/26 (65)</td>
</tr>
<tr>
<td>Number (%) of facilities using pressure cookers to sterilise instruments</td>
<td>0/4 (0)</td>
<td>2/14 (14)</td>
<td>0/3 (0)</td>
<td>0/11 (0)</td>
<td>7/23 (30)</td>
</tr>
<tr>
<td>Number (%) of facilities using a dry heat steriliser</td>
<td>1/4 (25)</td>
<td>13/14 (93)</td>
<td>2/3 (67)</td>
<td>8/11 (72)</td>
<td>12/23 (52)</td>
</tr>
</tbody>
</table>

N/A, Not applicable;
Dry heat sterilisers

Of 31 dry heat sterilisers identified (of which 64%–100% were functional), the recommendations for times and temperatures were only adhered to in 10 facilities. Times used varied from 15 min to 3 hours, while temperatures varied from a low of 97°C to a high of 200°C. Frequently the dry heat steriliser temperature settings and length of processing time were insufficient to sterilise instruments. Furthermore, as numerous temperature gauges and timers were broken, the staff were unable to determine when the appropriate temperature was reached to begin the sterilisation process, therefore were not able to identify when to put instruments in or how long the instruments had been at the correct temperatures.

In Madagascar, of the six that failed chemical indicator testing, four were at a large hospital and were new. Testing with higher temperatures resulted in chemical indicators passing for all four dry heat sterilisers. Both external and internal chemical indicators failed with a newer dry heat steriliser as the door was damaged and would not seal properly.

In Benin, 2 of the 18 functional dry heat sterilisers failed chemical indicator tests. Other issues identified with the 18 being used included the temperature gauge on one being broken, so instruments were placed in the dry heat sterilisers for 1 hour. Two dry heat sterilisers were placed on a charcoal fire and kerosene stove, respectively, due to lack of electricity. At a third healthcare centre, staff were unaware of how to use the dry heat sterilisers, and in another, stones were placed against the door to keep it closed.

In some facilities where autoclaves and dry heat sterilisers were both functioning, containers holding instruments were inappropriately used. Autoclaves require instrument containers to be vented to allow steam to enter the container, thereby sterilising the instruments, whereas heat from dry heat sterilisers can penetrate closed containers. Containers without venting were inappropriately used in autoclaves in some facilities. Also, in Congo and Madagascar there were seldom ways of identifying instruments sterilised from those awaiting sterilisation. Storage and transport of instruments was also inadequate. In one observation, an OR nurse entered the decontamination area to collect sterilised instruments for the next surgery. She saw a box sitting on the counter and picked it up to take into the OR. It was a box that had just been prepared for sterilisation, but not yet processed. In other situations, we identified workers opening the box containing sterilised instruments in the decontamination room and then taking it to the OR for the next surgery.

Other methods

We found 14 health centres in Benin without either an autoclave or dry heat steriliser; six did not have electricity, and nine used pressure cookers. Eight of the pressure cookers were functional and heated with gas, electricity, charcoal or kerosene. Two centres had electric pressure cookers that were not being used. Five of the pressure cookers that were not functional due to broken gauges were used to boil instruments instead. One healthcare centre with no means of steam sterilisation placed instruments in a box filled with water that was placed on a rack over a gas stove, where they boiled the instruments for an hour. In Madagascar only 8 of 29 healthcare centres had electricity; therefore, they either immersed instruments in a bleach solution or boiled them prior to use.

**LACK OF STERILE PROCESSING CAPACITY AS A BARRIER TO SAFE SURGICAL CARE**

Our assessment of 59 facilities in three countries shows that deficits in sterile processing workforce, practice and functional equipment are acting as barriers to safe surgical care. No facility achieved WHO-recommended standards for surgical instrument reprocessing. There was a lack of knowledge of current sterilisation theory with universal use of outdated practices (using bleach solutions), known to be harmful to instruments.

**Prevention of surgical site infection**

While numerous factors contribute to surgical site infections (SSIs), one of them is failure to sterilise reusable medical devices. High standards for instrument reprocessing in high-income countries (HICs) mean that studies identifying unsterile instruments as a cause for SSIs are rare. However a systematic review of healthcare-associated infections emphasised the cost-effectiveness of implementing standards for sterilisation and decontamination to counter high infection rates in LMICs. SSIs are the most common type of healthcare-associated infection identified in LMICs, impacting up to one-third of surgical patients. LMICs have a higher percentage of SSIs than HICs, with rates ranging from 1.2% to 70%, compared with 1.2%–5.2% in HICs. That none of the 59 facilities in our survey were able to adhere to even basic WHO standards for sterile processing means that none of the 79,935 annual surgical procedures in the facilities assessed occur under sterile conditions, putting patients at risk of infection. This highlights that a fundamental step in surgical safety, sterile technique, cannot be achieved. If sterility is compromised, then other initiatives such as timing of administration of prophylactic antibiotics are unlikely to achieve maximum efficacy in the fight against SSIs.

**Preservation of surgical instrument quality**

The provision of good-quality surgical instruments is a current area of focus for improving surgical safety in LMICs. Our assessments show that if new instruments were donated to the hospitals in our study, instrument quality would deteriorate rapidly due to lack of proper care. All three countries in our study were following outdated guidelines now known to damage surgical instruments. Previously the PAHO recommended decontaminating instruments by soaking them in a 0.5% bleach solution immediately after surgery. However, this practice is no longer recommended as hypochlorite corrodes...
instruments causing them to rust; is inactivated by body fluids and blood rendering it ineffective, further posing a risk to healthcare workers who transport surgical instruments in the disinfectant, believing the items safe to handle; and increases the risk of microbial resistance.\(^2\)

Lack of appropriate cleaning supplies also damages surgical instruments. Cleaning requires adequate resources: warm water, brushes, clean clothes, sponges, enzymatic detergent and distilled water.\(^2\) Some or all of these were missing in most of the facilities assessed. Laundry detergent, the most common detergent used, contains water softeners and components that damage instruments. Enzymatic detergents, made specifically for cleaning surgical instruments, were unavailable in Benin and Republic of Congo. A local source was found in Madagascar, but the business lacked clients. Brushes were often limited and frequently too large to adequately remove bioburden. Ongoing use of instruments not adequately cleaned results in bioburden being baked onto instruments in the sterilisation process, which successfully allows microbes to survive under a coat of blood and body tissue, which increases the risks for patients and decreases the functionality of the instruments.

**Workforce**

Our assessments show the shortage of trained sterile processing staff (12% in Republic of Congo and Benin, and less than 1% in Madagascar) is a barrier to safe surgical care. The WHO’s standard operating procedures recommend that staff have formal qualifications in sterile processing, as well as education/training and competency assessments.\(^2\)

**Sterile processing practice**

Of the three parts of surgical instrument reprocessing (cleaning, decontamination and sterilisation), cleaning and decontamination are the simplest to do, the most important in preserving instrument quality and can remove up to 99% of micro-organisms.\(^5\) Yet our results show this is largely overlooked. Improper cleaning and decontamination are a barrier to safe surgery as they cause instrument deterioration and fail to remove bioburden from instruments even when placed in a functioning autoclave. Rearranging work spaces so that cleaning occurs in a separate area to patient contact, using a simple three-bowl method for cleaning (including brushing)\(^2\) and decontamination, and correctly drying and storing instruments should be achievable with minimal resources in most hospital settings. Therefore, this became the focus for most of our training in the majority of facilities.

Prior literature has focused on autoclaves,\(^3\) seemingly as a panacea to improve sterile processing capabilities. Yet our results show the infrastructure required to support proper functioning, such as consistent electricity, distilled water and regular maintenance, is absent. There is a lack of knowledge concerning which type of instrument containers (vented or closed) should be used in dry heat sterilisers versus autoclaves. Furthermore biological and chemical indicators, used in HICs to verify that instruments are adequately sterilised,\(^12\) were unavailable in facilities assessed. Lack of indicator testing prevents confirmation of instrument sterility, a key step on the WHO Surgical Safety Checklist.\(^3\)

While dry heat sterilisers are commonly used in LMICs, especially by healthcare centres, and in our experience were more likely to function than autoclaves (64%–100% vs 20%–75%), they are no longer used in HICs due to inconsistent provision of heat and extended sterilisation times.

**CONCLUSION**

This data-driven report highlights the lack of sterile processing capacity in three LMICs and discusses how the deficit acts as a barrier to safe surgical care. To improve knowledge and standards, LMICs require training and support.\(^4\) Adjusting patterns of workflow and focusing more resources on cleaning and decontamination should be achievable at most hospitals as should the proper storage of reprocessed instruments, quality and inventory controls. However, other issues are more complex, such as supply of PPE, enzymatic detergents and infrastructure to support the use of autoclaves. A concerted effort by governments and international organisations will be required to address these issues. From our experience, we suggest the following recommendations to others involved in improving surgical safety in LMICs:

1. Basic sterile processing practice should be integrated into national and subnational surgical capacity building programme.
2. Our assessment tool (online supplementary file 1) could be used to assess sterile processing capacity and identify areas for simple improvements.
3. Simple methods, essential for cleaning and decontamination, such as the three-sink method, use of brushes and warm soapy water, require minimal resources and should be taught by stakeholders engaged in improving surgical safety.
4. Workflow patterns with clear progression of devices from dirty to clean areas and correctly drying and storing instruments should be achievable and must be encouraged.
5. The practice of soaking surgical instruments in bleach solutions should cease as it is ineffective, damages instruments, increases microbial resistance and is an unnecessary expense.

**Contributors** OF, CF, DF and MCW conceived and designed the study. OF, CF, DF, ZS and SV acquired the data. OF, CF and MCW contributed to data interpretation and analysis. OF and MCW wrote the first draft of the manuscript, and all authors were involved in critical revision of the article and approved the final version for publication.

**Funding** SPECT and Mercy Ships Canada received funds from Grand Challenges, Canada (grant number S6 0482-01-10).

**Competing interests** None declared.

**Ethics approval** Reviewed by Mercy Ships Institutional Review Board.

**Provenance and peer review** Not commissioned; externally peer reviewed.
Data sharing statement There are no additional unpublished data.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

REFERENCES


