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The Effectiveness of Ultraviolet Smart D60 in Reducing Contamination of Flexible Fiberoptic Laryngoscopes

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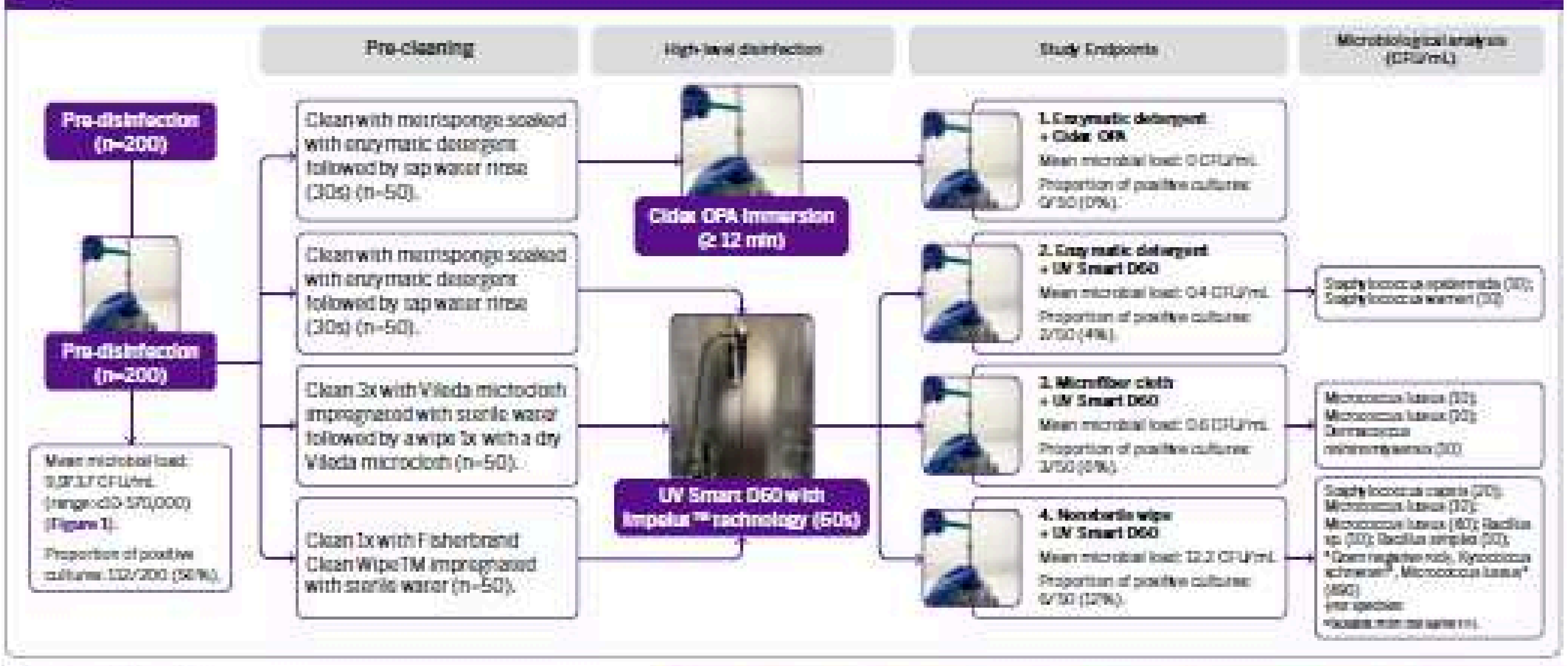
Introduction

- Flexible laryngoscopes (FFLs) are routinely exposed to the mucus membranes of the nasal cavity and pharynx.
- They are semi-critical instruments that require high-level disinfection (HLD)[1].
- Traditional disinfection methods include chemical immersion and automated endoscope reprocessors (AER).
  - Both processes use chemical liquid agents, which are toxic, require lengthy disinfection/processing times, and are incompatible with endoscope material[2-4].
  - These methods may be less suitable for large ENT settings that require rapid FFL turnover[4].
- **The aim of our study was to compare the bactericidal efficacy of various cleaning methods utilizing UV Smart D60 to a standard reprocessing method using Cidex OPA.**

Methods and Materials

- 200 FFLs were sampled after clinical use and another 200 after cleaning with 1 of 4 disinfection methods (**Figure 1**).
- Sample were vortexed (~2 minutes) and cultured on blood agar plates.
- If growth was detected, the number of colonies were counted and reported as colony forming units per mL (CFU/mL).
  - Positive post-sample cultures were gram-stained and bacterial identification was performed.
- We utilized a proprietary UV Smart D60 light machine with Impelux™ technology for UV disinfection protocols.
- Effective disinfection was defined as a bacterial count of <10 CFU/mL.

Figure 1. **An outline of each decontamination workflow.**



Results

- 112 of 200 FFLs had positive bacterial growth (56%).
- Mean microbial load pre-disinfection: 9,973.7 CFU/mL ±70,136.3 (range: <10 to 570,000 CFU/mL (**Figure 2**).
- Bioburden levels significantly decreased after each disinfection technique ($p<0.001$).
- There was no statisically significant difference between each disinfection group by proportion of positive cultures (**Table 1**) or mean microbial load (**Table 2**) ($p>0.05$).
- 13 bacterium were recovered on 11 FFLs (most common organism isolated was Micrococcus sp. (53.8%) (**Table 3**). None of the isolates had high-pathogenicity[6].

Figure 2. **Distribution of microbial burden after clinical use and after HLD.**

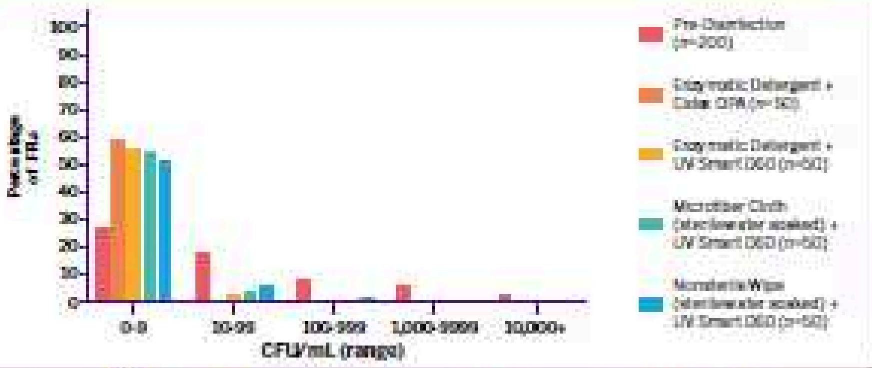


Table 1. **Mean microbial load and positive culture rate of each disinfection arm.**

Disinfection Protocol	Mean microbial load (CFU/mL)	Positive culture (%)[a]
Pre-disinfection	9,973.7	112/200[b] (56)
1. Enzymatic detergent + Cidex OPA	0	0/50[b] (0)
2. Enzymatic detergent + UV Smart D60	0.40	2/50[c] (4)
3. Microfiber cloth + UV Smart D60	0.60	3/50[c] (6)
4. Nonsterile wipe + UV Smart D60	12.2	6/50[c] (12)

[a]Pearson x2 test
[b]proportions did significantly differ from each other at p=0.05
[c]proportions did not significantly differ from each other at p=0.05

Table 2. **Pairwise comparisons of the mean log CFU of each disinfection arm (Dunn's test).**

Disinfection Protocol	Test-statistic[a]	p-value
Arm 1 vs. 2	-0.326	0.744
Arm 1 vs. 3	-0.489	0.625
Arm 1 vs. 4	-1.152	0.249
Arm 2 vs. 3	-0.163	0.870
Arm 2 vs. 4	-0.826	0.409
Arm 3 vs. 4	-0.663	0.507

[a]Kruskal-Wallis test with Dunn's correction for pairwise comparisons.

Table 3. **Frequency of bacterial organisms (n=13).**

Bacteria Species	Source	Frequency (%)
Micrococcus sp.	environmental, skin	7 (53.8)
Coagulase-negative **Staphylococci** sp.	skin	3 (23.1)
Bacillus sp.	environmental	2 (15.4)
Gram-negative rod, not specified	–	1 (7.7)

Conclusion

- Decontamination protocols with UV Smart D60 were as effective in removing contamination from FFLs as our traditional method of using Cidex OPA.
- We found UV disinfection to be faster, simpler, less toxic, and more resource-efficient, which will increase compliance with FFL disinfection in patient care settings and enhance healthcare worker and patient safety.

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References

1. [illegible]
2. [illegible]
3. [illegible]
4. [illegible]
5. [illegible]
6. [illegible]

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HOSPITAL STERILIZATION EFFECT ON PIECES OBTAINED BY 3D PRINTING IN ABS AND PLA

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OBJECTIVE:

To evaluate and analyze the possible effects of hospital sterilization by ethylene oxide (EO), hydrogen peroxide plasma (HPP) and saturated steam (SS) on ABS and PLA FDM 3D printing parts, and residue retentions on them.

METHOD: Prospective comparative study with intervention
PRINTING: Onshape and Ultimaker Cura software.
MACROSCOPICOBSERVATION:visualinspection.
MORPHOLOGICAL SURFACE OBSERVATION: scanning electron microscopy (SEM) at CNEA in 1x1x0.5 cm pieces.
RESIDUES EVALUATION FROM EO, ETHYLENE GLYCOL AND ETHYLENE CHLOROHYDRIN: residues evaluation was performed through gas chromatography and by INTI following its protocols. Measurements and observations were made on the pieces before and after their exposure to hospital sterilizationof SS,PPHy EO.

SS
Temperature: 134°C / 121° C
Exposure time: 10 min / 20 min
Drying time: 40 min / 15 min
Pressure : 2.00 bar Vacuum: -0.80 bar

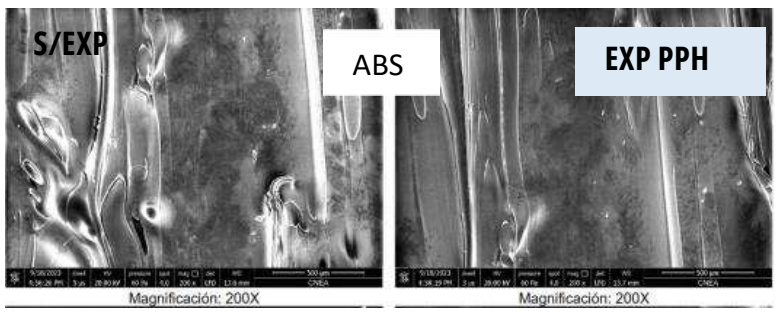
EO
Temperature: 52° C
Vacuum: -0.75 bar
Degassing pulses: 154
Total cycle time: 1189 min

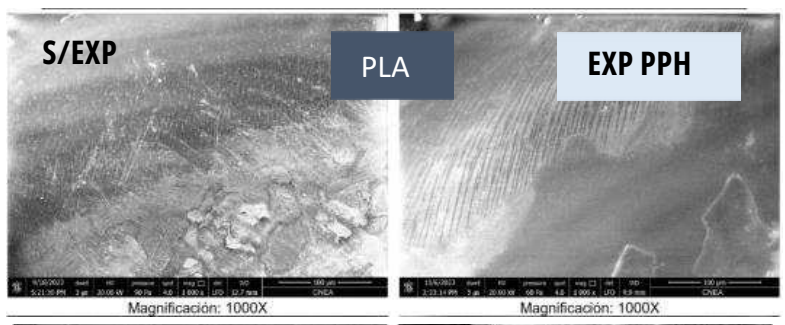
PPH
Flex: 42 min
Temperature: 75 °C
Pressure: 30 Torr
Plasma power: 500 W

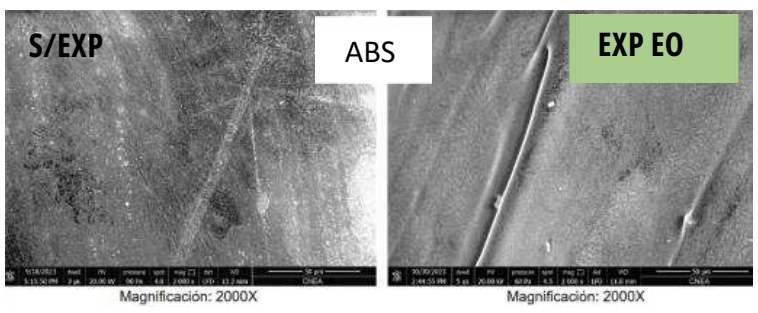
RESULTS:

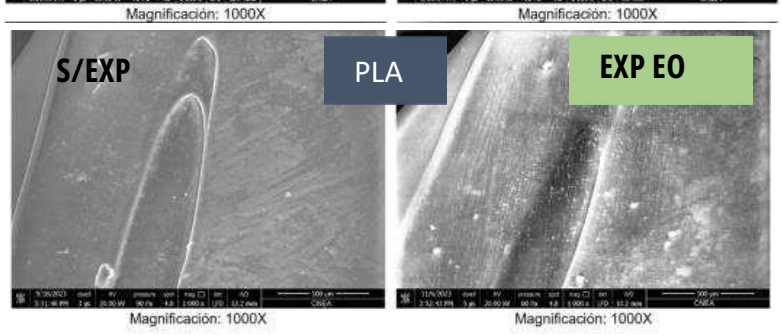
MACROSCOPIC OBSERVATION: deformation of the parts exposed to water vapor from autoclave.

MORPHOLOGICAL SURFACE OBSERVATION: Pieces with and without exposure to EO y PPH









EVALUATION OF EO, ETHYLENE GLYCOL AND ETHYLENE CHLORHYDRINE RESIDUES :

ACRYLONITRILE BUTADIENE STYRENE

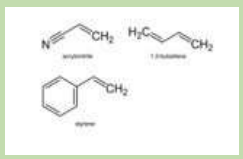
B)

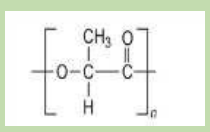
Muestra	Etilenclorhidrina (µg/g)	Etilenglicol (µg/g)
OT2459/03	< 10	17,3 ± 3,8

La curva de desorción de óxido de etileno tiene la siguiente expresión:

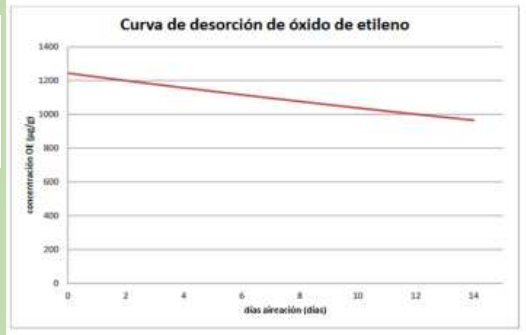
$$Conc_{OE}[\mu g/g] = C_0 \times e^{-kt}$$

donde: C_0: concentración inicial de óxido de etileno.
e : número de Euler (e ≈ 2,718281828459).
k : constante de desorción.
t : tiempo de aireación.





POLYLACTIC ACID



B)

Muestra	Etilenclorhidrina (µg/g)	Etilenglicol (µg/g)
OT2459/08	< 10	< 10

CONCLUSIONS:

According to the results, we conclude that the ABS and PLA pieces exposed to the SS cycles suffered deformation that was visible to naked eye, making impossible to sterilize them using this method. As soon as sterilization by EO, it is not recommended due to the high retention of EO and its residues and the difficult desorption of EO. PPH would be the sterilization method of choice for these parts. SEM verified the PPH smoothing effect on the surface similar to that described in other publications. We intend to carry out microbiological tests for more intricate models exposed to this method.

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STERILE PARAFFIN OIL FOR HOSPITAL USE: PACKAGING EVALUATION

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PARAFFIN OIL [CnH2n+2] Mixture of saturated liquid hydrocarbons, obtained from petroleum and purified F.A. VII Ed.

Features to consider:
Safety
Sustainability
Tamper-proof closure
Resistance

✓ *At the time of the analysis, no bibliography was found about comparison of hospital packaging for this product.*

ADVANTAGES	DISADVANTAGES
Reusable Inert	Fragile Very difficult to clean High water consumption

OBJECTIVE: To develop a hospital sterilization packaging for Liquid Paraffin (160ºC – 120 min) which must be non-toxic, economical, ecological and inviolable.

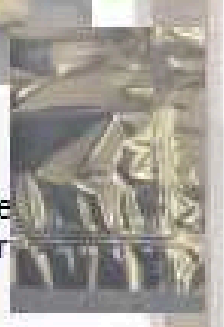
METHOD: Prospective comparative study. Alternative packaging to the traditional glass bottle was evaluated:

M1: ampoule bottle With rubber stopper and metal seal

M2: Polyester food sleeve

Polyamide sleeves (out of stock on the market)

For M2, a 3-strip continuous sealer (Yellow Pack- model M1000) was used. Temperature and sealing mode were evaluated. Medical grade paper was used as secondary packaging



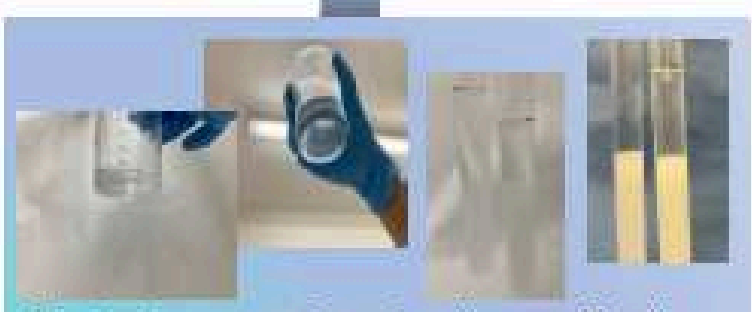
The purity tests did not show contamination of the sterile paraffin oil in polyester containers.
The 3 sealing bands on the food-grade polyester sleeves give the resulting container a tamper-proof seal.
In addition, the secondary packaging made of medical-grade paper allows the sterile condition to be safeguarded, the expiration date to be established and the hermetic seal of each unit to be evaluated.
The generation of weight and volume of waste was reduced and the consumption of water and chemicals required for washing in the event of reusing the traditional glass bottle was avoided.
A safe, economical and sustainable container was obtained.

CONCLUSIONS

For the hermetic closure of M2, the sealing temperature was between 220 and 222 ºC.
After sterilization, M1 changed its color. No changes were evident in M2.
After 4 hours at 0ºC, no opalescence was generated in M2 and CS, and the color change remained in M1.
When M1 and M2 were boiled with a mixture of 10 cm3 of paraffin - 96º alcohol equal parts, the alcoholic phase did not cause the litmus paper to turn for any sample.

RESULTS

PURITY TESTS were carried out according to F.A. VI.ED. In a refrigerator at 0º C (thermometer TB-IC 1020) for 4 hours,96º alcohol, Bunsen burner and litmus paper.



The tests were performed on the paraffin oil contained in glass and polyester containers, after sterilization in a dry heat oven (Cecar, model EPC:XXI) and were compared against a control sample (CS) without exposure.

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EARLY DETECTION OF BIOFILMS ON MEDICAL DEVICES SAVES LIVES

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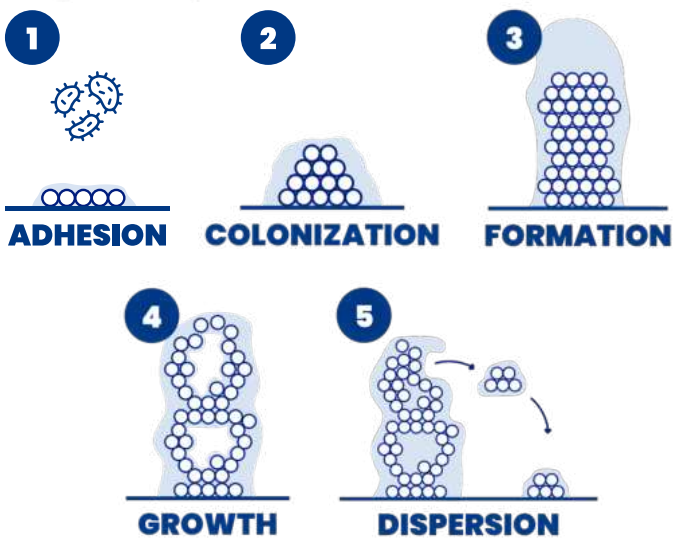
AIM

The majority of hospital-acquired infections are associated with the formation of bacterial biofilms on the surface of instruments, prostheses and other medical devices. This study aimed to identify, visualize, and remove bacterial biofilms on medical devices, address challenges in effective cleaning, and enhance washing practices. The goal was to develop and implement an early detection protocol for biofilms using new technologies for early detection and their subsequent removal.



METHODS

During 6 months of sampling, a descriptive, observational, prospective, cross-sectional study was conducted in the Central sterile supply department (CSSD). A protocol was drafted for the early detection of biofilms. The presence of biofilms is tested and visualized with the following products:
BIOZOOM (**ADOX** Argentina), a reactive oxygen agent formula, when applied to surfaces with the presence of microorganisms, produces a visible reaction in the form of white foam, facilitating the identification of contaminated surface. BIOZOOM PLUS, (**ADOX** Argentina) formulated with a specific dye that stains and improves the visualization extracellular polymeric substances (EPSs) of the biofilm.
If biofilm formation is seen, it is removed by washing with BIOFILMS REMOVER (**ADOX** Argentina). Once a manual cleaning of the Medical Device has been performed, focusing on the areas where biofilm formation was observed, the device is dried, and the detection process is repeated to verify its removal. If biofilm is detected again, the medical device is cleaned once more. If no biofilm is detected, the process continues with the steps to condition and sterilize the device."

RESULTS

During the analyzed period, a total amount of 2600 medical devices were tested for difficulty in cleaning by detecting the sectors where biofilms adhere. (laryngoscope handles, disinfection trays, harnesses, resuscitators, respiratory masks, suction jars, laryngeal masks, laparoscopic forceps, electrosurgical units, motors, orthopaedic cases, screw sets, laparoscopic trocars, resectoscopes, various instrument forceps, instrument handles, etc.). The Traumatology, Cardiovascular, and Neurology surgery areas presented the highest rates of surgical site infections. Therefore, the biofilm removal protocol was applied to all instruments and containers used in these surgeries. The protocol for removal and detection was applied to these. We document and protocol the cleaning procedures for all medical devices, including single-use ones (bipolar electrosurgical instrument a single-use instrument with vessel sealing and dividing capabilities, catheters, introducers, hemodynamic wires) to demonstrate their infeasibility for reuse. Highly porous medical devices such as resins, wood, and fabrics were assessed and found to encourage biofilm adhesion, making their removal difficult.

CONCLUSIONS

This early detection protocol for biofilms impacts on the improvement of cleaning practices for reusable Medical Devices and prevents the reuse of single-use Medical Devices where the cleaning cannot be guaranteed, benefiting patients by reducing associated complications and improving their quality of life. Biofilms pose a significant challenge due to their three-dimensional structure, which grants the bacteria within them a high tolerance to adverse conditions. This results in resistance to antibiotics or the body's immune system, leading to severe complications such as chronic infections, implant rejection, and reduced functionality of medical devices. For this reason, biofilms represent a major clinical concern, particularly in relation to hospital-acquired infections. In this way, health systems could reduce the high economic costs generated by infections associated with biofilms, due to hospitalization costs and prolonged antimicrobial treatments, while also preventing the sequels that this type of infection can cause in patients. Education and control are carried out every day at each reception by inspecting the cleanliness of Medical Devices. Therefore, we consistently strive to reduce unwanted incidents by emphasizing the continuous application of work protocols. The challenge lies in assessing the impact of the cleaning control protocol on surgical site infections.

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OR READY SAFETY MORE MOVING LESS

ROME CHOMRAK, BANGKOK HOSPITAL, THAILAND

Introduction

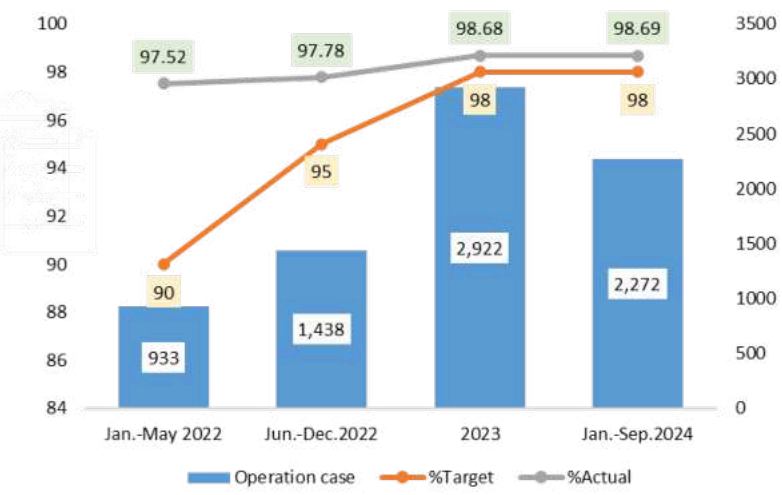
Surgical site infections (SSIs) can result in serious postoperative complications and significantly increase healthcare costs for hospitals. To lower infection rates during surgeries, preventive measures are essential, and a key factor is the design and performance of the HVAC (heating, ventilation, and air conditioning) system in the operating room (OR) and surrounding areas. Proper ventilation helps maintain a sterile environment, reducing the risk of infections.

Methods

The ventilation system in an operating room (OR) is designed to maintain positive pressure, typically 20 Pa higher than adjacent spaces, to prevent contaminated air from entering. This is achieved by controlling the air supply and extraction. Two common airflow patterns are used: mixing ventilation, which circulates air throughout the room, and unidirectional ventilation, where air flows in one direction. Unidirectional airflow is recommended for high- risk surgeries, like orthopedic procedures and organ transplants, to reduce the risk of surgical site infections (SSIs) by maintaining a sterile environment.

Results

The movement of objects and individuals inside the operating room (OR) greatly impacts airflow and the spread of pollutants. For example, when healthcare workers enter the protected area of unidirectional airflow, they can unintentionally bring in air from less clean areas, disrupting the airflow. Even routine actions like the bending movements of surgical staff can alter the unidirectional airflow, affecting the sterile environment and increasing the risk of contamination.



Year	Related SSI	Customer satisfaction
2021	0	4.19
2022	0	4.65
2023	0	4.74
Jan.-Sep.2024	0	4.87

Conclusions

The design and optimization of operating room ventilation systems are crucial for reducing the risk of surgical site infections (SSIs) and maintaining a sterile environment. Preventive steps should be taken to limit airflow disturbances during surgery. Key measures include maintaining positive pressure, selecting the right airflow pattern, and minimizing disruptions from movement inside and outside the OR. These actions are vital to ensuring patient safety and reducing the financial burden of SSIs. By adopting these strategies, hospitals can improve patient outcomes and enhance the overall efficiency of surgical procedures.

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BEHAVIOR OF NON-CONDENSABLE GASES DURING THE STERILIZATION PROCESS

Kharla Obando , Felipe Coros de la Piedra , Mabel Rios

Introduction

Currently, load release is performed through the physical parameters of the equipment, the approval results of chemical indicators (CI) and biological indicators (BI).
However, the presence of non-condensable gases (NCG) and their behavior during the sterilization process are not being considered.
A program was created with the average sterilization parameters obtained from a sample of 14 private healthcare institutions in Lima, Peru, to analyze the behavior of the CIs, BIs, and Process Challenge Devices (PCD) in the presence of NCGs and the critical sterilization variables.

Objectives

-Analyze the behavior of the chemical indicators (CI), biological indicators (BI), and process challenge devices (PCD) in relation to the critical sterilization variables and the non-condensable gases (NCG) during the sterilization process.

- Contribute information to users about the effect of NCGs in the sterilization process in order to establish correct parameters for load release.

Materials

1. **Temperature and Pressure Recorder (TPR):** The device enters the autoclave and records the internal behavior of the chamber. It is visualized in a program that graphs the behavior of the Pressure and Temperature variables. It has two temperature sensors and one pressure sensor.
2. **PCD:** These measure the proper removal of air and correct steam penetration in high-complexity devices to verify if the Critical Sterilization Variables are met. Different test complexities were used, varying in length and diameter. The tests meet and exceed EN 867-5, EN ISO 11140-1, EN 285 standards.
3. **Chemical and Biological Indicators:** We used Type 5 and 4 CIs in the load test. BIs were also used in a challenge device. One of the BIs contains a Type 5 indicator for immediate release.

Methods

A sample was taken from 14 clinics in Lima, Peru. The TPR device was used to record the behavior of various variables in each autoclave in the 134°C Program (Instruments).

Measured Variables:

- Air extraction time
- Heating time
- Sterilization time
- Drying time
- Number of vacuum pulses
- Number of trans-atmospheric pulses
- Vacuum level generated in each pulse (millibars)
- Steam level entering per pulse generated (millibars)

Test Program:

With the average variables measured in the 14 clinics, a test program was created with the following parameters:

- Number of Vacuum Pulses: 3
- Vacuum level in each pulse (millibars):
- 215, 217, 222
- Steam penetration level (millibars): 1265,
- 1245, 1799
- Number of trans-atmospheric pulses: 2
- Level (millibars): 1799 to 1157 and 1805 to 1151

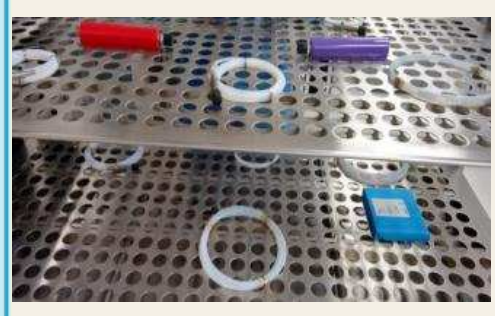
Sterilization Time: 652 minutes
Drying Time: 19 minutes

Results

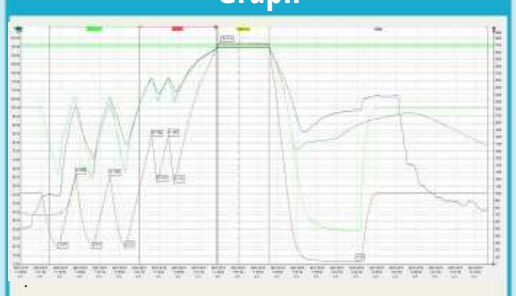
The indicators used produced the following results:

- **Type IV CI**: Turned.* **Type V CI**:
- Turned. **BI**: Negative result.
- **BI+CI+PCD**: The CI gave a non-
- approving result. The BI gave a negative result. A PCD was used. The BI contained a Type V indicator strip (Integrator). **PCD + CI**: None of the 7 challenge tests + chemical indicator
- was approved. 7 Helix-type PCDs according to EN-867-5 were used.

*Turned: At the point where they were placed, two or more critical sterilization variables were met.



Graph



Temperature and Pressure Behavior -Program at 134°C

PCD-No.	PCD-tube length [m]	Inner Diameter [mm]	HPR* [cm³]	Colour change of chemical indicator
1	1,5	2	30	
2	1,5	3	45	
3	1,0	5	50	
4	3,0	2	60	
6	4,5	2	90	
8	2,0	5	100	
9	3,0	4	120	

Result of Helix-type PCD

Conclusions

According to the results found in this study:
•PCDs were the only devices capable of detecting the presence of NCGs in the chamber
•We know that the critical sterilization variables are Time, Temperature, and Humidity, but NCGs must be considered for load release due to the complexity level of the instruments to be sterilized.
•The Bowie Dick test alone would not be sufficient to guarantee the absence of non-condensable gases during all sterilization processes performed throughout the day. It is necessary to use a PCD with a complexity superior to the load in each process.
•CIs provided more accurate results regarding critical sterilization variables and NCGs than BIs.
•For correct load release, the following must be considered: Validation, Calibration, Maintenance, and Proper Use of the equipment, as well as the correct use of CIs and PCDs.

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EN-ISO-11140,
EN-867-5,
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EN-ISO17665-1,
ANSI-AAMI ST79.

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World Federation for Hospital Sterilisation Sciences | Sociedad de Profesionales en Esterilización de Chile | Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos | Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

ADDRESSING THE ENVIRONMENTAL CONSEQUENCES OF ENDOSCOPIES : INTRODUCING ECO-FRIENDLY

GANDY AER

Ms.DORINA CURRI, INTERNATIONAL & MARKETING MANAGER

INTRODUCTION

Endoscopy is considered the third highest hazardous waste-generating department in a hospital. It is acknowledged that the reprocessing of reusable scopes is resource-intensive, consuming gallons of water per cycle, as well as disinfectants, detergents, and electricity daily. The aim of this abstract is to highlight the potential of GANDY – Automatic Endoscope Reprocessor devices, a comprehensive solution for endoscopic treatment, in significantly enhancing both environmental sustainability and financial efficiency within healthcare settings..

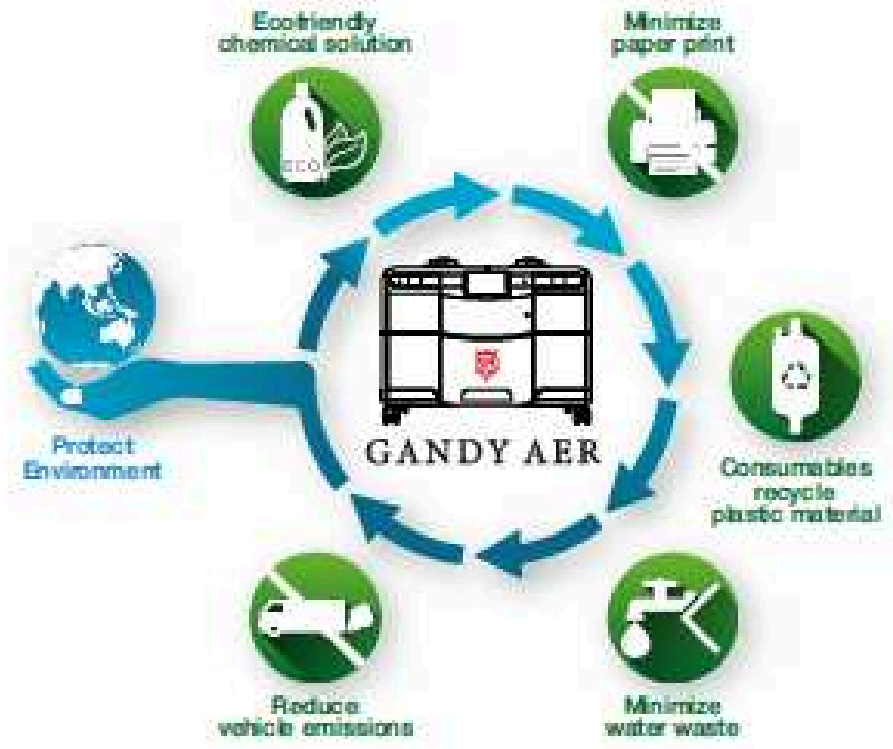
KEY WORDS

Sustainability Actions | Cleaning & disinfection | Automatic Endoscope Reprocessors

THE WASTE PRESENT IN THE ENDOSCOPE WASHERS IS CLASSIFIED AS:

1. **CHEMICAL WASTE:**
   This includes waste generated from use of detergents, disinfectants, and rinse aids in the cleaning and disinfection process.
2. **WATER WASTE:**
   Endoscope Washer disinfectors use water for cleaning, rinsing and flushing processes.
3. **ENERGY WASTE:**
   Endoscope Washer-Disinfectors requires electricity to operate and inefficient machines may consume more energy than necessary.
4. **SINGLE USE CONSUMABLES:** Some components of endoscope washer disinfectors, may be single use or require periodic replacement.

Introducing GANDY AER by Nuova Sb System srl innovative products stand as guardians of our environment, contributing to its prevention in the following ways:



1. The chemical solutions used in GANDY AER devices are eco-friendly, adhering strictly to the operating instructions outlined in the user manuals.

2. GANDY AER devices are designed to minimize water waste in each cycle. They are global frontrunners in efficiency, with remarkably low water consumption per cycle.

3. GANDY AER devices are equipped with a comprehensive traceability system, reducing the need for paper documentation throughout the entire cycle.

4. GANDY AER devices incorporate remote connectivity, allowing us to minimize outdoor activities. The reduction in physical travel not only decreases vehicle emissions but also helps protect the environment by reducing excess CO_2 emissions.

5. The consumables for GANDY AER devices are made from thermoplastic material sourced from components bearing the Ecological Conformity Mark, known as PLS.

CONCLUSION

The production strategy employed in the GANDY line is deeply influenced by PETE SEEGER's emphasis on sustainability and responsible production practices. We adhere to the priciple that if an item cannot be reduced, reused, repaired,rebuild, refurbished, resold, recyled or composted, then it warrants restriction, redesing, or removal from our production processed.

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Microbial Contamination of Final Rinse Water for Endoscope Washer Disinfector (EWD)

Authors: Sulisti Holmes[*], Robert Allan[*], Carol Colligan[**], Peter Hawkey[***]

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Aims:

- **To identify the cause of high bacterial Total Viable Counts (TVC) in final rinse water of EWD.**
- **To determine appropriate actions to resolve the issue.**

Introduction

Flexible endoscopes cannot withstand thermal processing. Therefore, they are mostly decontaminated using detergent and a high-level disinfectant, in an Endoscope Washer Disinfector (EWD or as known as Automated Endoscope Reprocessor). Endoscopes are subsequently thoroughly rinsed to remove chemical residues before being used on patients. The use of inappropriate quality of rinse water can reintroduce contaminants that affect patients. BS EN ISO 15883-4:2018 specifies the requirements for microbial and chemical quality of final rinse water.

National guidance such as SHTM 01-06 highlights the important to test and monitor rinse final water for endoscopes on weekly basis.

In 2020 the hospital observed the sudden rise in TVC results above the limit of 100 cfu/100 ml and the inconsistent results of TVCs of weekly samples taken from the EWD.

Method

A collaborative group consisting of the representatives from the hospital, the national body and the manufacturer/supplier was established to investigate the incident.

The group agreed an audit proposal to

- examine the current practice of maintenance and water sampling from Reverse Osmosis (RO) water treatment, water distribution system and EWD;
- identify critical points within the system;
- provide proposed corrective actions.

The unit had 2 identical models of EWD. Weekly TVC water sample test results taken from EWD, RO and distribution sampling points and break tanks were analysed.

Results

The pattern of TVC results taken from both EWD's, the water samples were almost identical. Three spikes (50-100 cfu/100 ml) were observed over a period of 16 weeks.

The audit findings indicated that:

- all Standard Operating Procedures had been followed by trained staff;
- laboratory accreditation for water testing was current;
- maintenance contract for the EWD and water treatment system was current;
- high TVCs were detected in samples of EWD rinse water and break-tanks, while TVCs for the RO and distribution system were zero.

The audit findings ruled out the water and distribution system, sampling, transport and laboratory as the reason for the high TVCs.

Reduced TVCs were seen following break-tank sanitization and/or change of the 0.2-micron filter. This was temporary as particulate material blocked the filter causing it to be bypassed.

All components that were in contact with the water appear to have been subjected to regular disinfection process, apart from the break-tank and tubing leading to the tank. The design of the pipe and break-tank within EWD was in an open circuit, exposed to the air resulting in bacterial ingress and growth (Figure 1a and 1b). There was no mechanism to inspect the level of cleanliness of the break-tank, nor to check if there was residual water left in the break-tank.

Drawing hot water from water treatment and distribution system during synchronisation might not always be effective, in the event of cold-water presence in the break-tank, or a high level of bacterial contamination in the tank/pipes.

Figure 1a. Break-tank and associated pipes

Figure 1b. Break-tank and associated pipes

Conclusions

Patterns of reduced TVC was observed after filter change and break-tank sanitization. The recurring increased of TVC counts was possibly attributed to the internal break tanks. Break tanks were not disinfected as part of the daily thermal disinfect cycle as they are not part of the thermal disinfect circuit which was not advised in the manufacturer's instructions.

The investigation led the manufacturer to develop a protocol to chemically disinfect break tanks. Since the protocol was implemented, TVCs in rinse water samples have been reduced to below the acceptable level of 10 cfu/100 ml1,2.

The disinfection of break-tank using high level chemical disinfection posed a risk to staff carrying out the procedure. In 2023, the hospital replaced the EWD with a newer model without break-tank. This provides greater assurance to patient and staff safety.

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Quality in the healthcare environment

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REDUCE THE DURATION NEEDED FOR COMPLETING THE EYE SET

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INTRODUCTION

The number of individuals receiving ophthalmic surgery has been rising in the period of 2021-2022 following the Covid-19 pandemic. Consequently, the utilization of Eye Set instruments and equipment has risen from around 3,664 cases to 6,321 cases, with an ongoing growth projected for 2023 at an average rate of 30 cases per day. It impacts the number of Eye Set tools and equipment currently in circulation throughout the system, which have only 81 sets.

AIM

To reviewing the processes involved in the preparation of Eye Set and to reduce the impact that will affect the demand for use to have enough circulating for use in eye surgery.

METHOD

1. Collect data: Record the daily Eye set return rate. Delivery time from the operating room such as Eye set wrapping reusable textiles issues, daily reusable textiles usage, and reusable textiles inspection time. 2. Team meeting: To examine the complete work process, from receiving the eye set from the operating room to cleaning, and preparing How to return items to the operating room to arrange full process management. 3. Meeting outcomes: Reusable textiles packaging requires multiple processes. Many sterile medical supply packaging materials utilize synthetic materials instead of reusable textiles. Sterile product production has been evaluated. Standardized physical, biological, and chemical sterilization. 4. Meeting with the team: Eye operating room nurses define the objective of affecting eye set wrap/pack materials and report test results. And will use Nonwoven instead of reusable textiles. 5. Start testing the new Eye set. 6. Evaluate test results to reduce wrapping time.

RESULT

Based on the New Eye set process testing, the results indicate that the incidence of unavailability is 0, indicating a successful outcome of the testing. For the duration testing, the Eye set procedure is taking approximately 7 minutes to complete for each package. By implementing a new packing procedure for the Eye Set and substituting the wrapping material with Nonwoven, the duration was significantly reduced to 0.39 minutes.

CONCLUSION

Management of incoming medical supplies and equipment for the purpose of sterilizing must maintain consistency in the level of patient service provided. The individuals concerned must utilize the provided information in order to attain suitable management. Efficiently managing valuable resources, particularly costly tools, requires the implementation of comprehensive guidelines that incorporate the entire system, beginning with strategic buying planning. The sterile medical supply team is responsible for the utilization, recycling, and upkeep of sterile equipment. Adapting operational procedures to accommodate the workload necessitates doing product testing on each occasion. It is important to take into account the satisfaction of the recipient of the position.

The management of equipment and supplies requires coordination to maintain their adequacy. The sterile medical supply team must be capable of managing them effectively, ensuring they are fully prepared, promptly available, and meeting the satisfaction of the service user.

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SUSTAINABLE STRATEGIES IN MATERIAL AND STERILIZATION CENTERS: The awakening of a conscience

Innovation& Sustainability

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I ntroduc tion

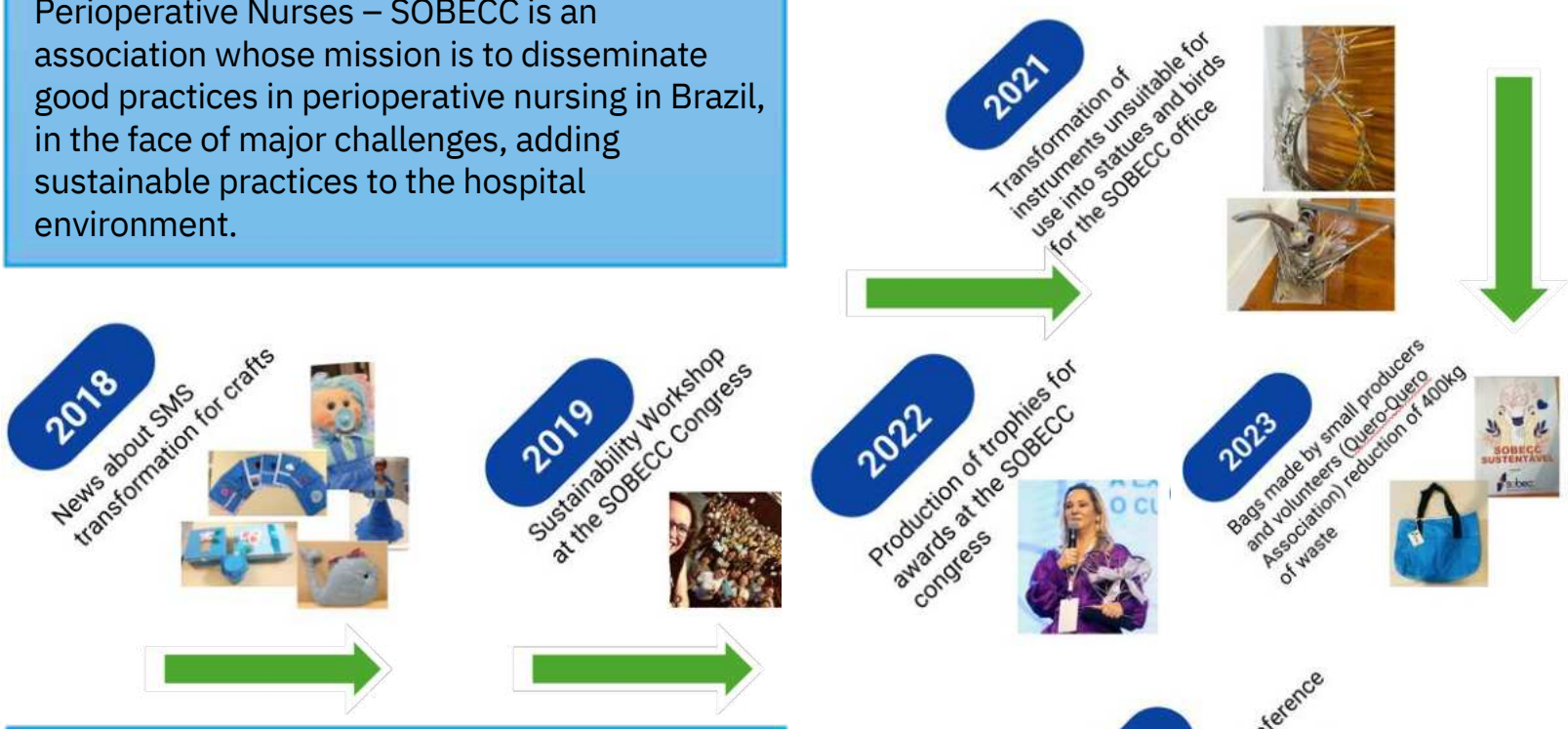
In health management, sustainability is the adoption of policies related to the adequacy of economic and environmental processes. In this sense, there are several challenges in the search for environmental efficiency and waste management1. In 2022, Brazil produced around 81.8 tons of waste, of which approximately 20% of hospitals2. This way, the use of materials that meet the requirements that can be treated, recycled or transformed into other products is of paramount importance for efficient environmental management within the health promotion process. The Brazilian Association of Perioperative Nurses – SOBECC is an association whose mission is to disseminate good practices in perioperative nursing in Brazil, in the face of major challenges, adding sustainable practices to the hospital environment.

Aim/ Purpose

Report SOBECC actions related to the use and transformation of materials and instruments unsuitable for use.

Methodology

Descriptive study, experience report type, based on the experience of actions carried out by SOBECC to transform SMS barrier systems and instruments unsuitable for use in new products: Bags, statues and trophies. This initiative occurred between 2018 and 2024, in Brazil.



D isc ussion

The reduction of 400kg of waste using discarded SMS barrier systems to prepare conference bags shows that it is possible to find solutions that transform the products used in hospitals. This practice contributes to the development of actions and policies that seek to reduce the impact of health on the environment. The creation of trophies using instruments, which were designed to discard metals, allowed useless pieces to be transformed into products that symbolize the recognition of the work of perioperative nurses and in addition to decorating corporate environments. Initiatives such as the proposals can contribute to improving hospital waste management at the national level.

Implications for Practice

Stimulating discussion at conferences and the transformation of discarded materials into new products is one of the first steps towards developing sustainable policies. It is important that each institution develops actions in favor of sustainability, especially in the area of health, which is responsible for a significant portion of waste generation for the environment.

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THE REPROCESSING OF SURGICAL ROBOTIC INSTRUMENTS

AIM

We aim to discuss the state of art end the main challenges in the reprocessing of robotic instruments, including cleaning, preparing and sterilization for different types of robotic technologies.

METHODS

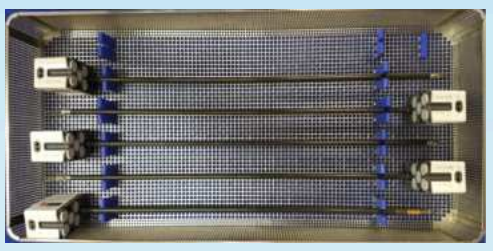
This is a review of the literature regarding the reprocessing of robotic instruments of different technologies.

RESULTS

Articles, manufacturers' recommendations, guidelines, and legislation were accessed to describe the reprocessing of robotic instruments. The robotic instruments have a complex design and conformation, with lumens smaller than 5mm in diameter, making access difficult for the mechanical removal of soil. They also have joints that favor the accumulation of organic matter, electric current circulation, and cannot be disassembled, which makes it difficult to access all surfaces of the material. Moreover, they present a limited number of reprocessing lives, previously validated by the manufacturer, seeking to guarantee the functionality and safety of the instrument's use. Due to these complexity and variety of instruments available on the market, the reprocessing of robotic instruments is based on the manufacturer's manual, using previously validated instructions made by the manufacturer. The cleaning step should start at the "point of use", that is, right after the surgery and still in the operating room. Mechanical cleaning is preferred (picture 1 and 2) but manual cleaning have been described. To clean any robotic medical device, the following should not be used: saline solution, acid solutions (pH<7), strongly alkaline solutions (pH>11), cleaning products based on hydrogen peroxide,
cleaning products based on bleach or rinsing aids. After cleaning, drying must be carried out with compressed air internally, only if it is possible to control the air pressure. A rigorous inspection should search for dirt, defects or damage to the tip or lens, light ports and fiber optic surfaces. A cleaning efficacy test should be carried out, especially in the lumens. Then, the articulated parts of the instruments must be lubricated in the places indicated by the manufacturers, and it is also suggested that a vapor-permeable protector is placed on the tip of the instrument (picture 3). Robotic instruments must undergo steam sterilization as gold standard, although some instruments have low-temperature claim. The standardization of quality indicators in the reprocessing of robotic instruments is still a challenge, as is the implementation of educational actions to maintain the level of quality in reprocessing due to the continuous updating of new technologies.

Picture 1 –Ultrasoniccleaning
Reference: author'sarchive

Picture 2 –Thermodeinfectioncleaning
Reference: author'sarchive



Picture 3 –Set for sterilizationprocess
Reference: author'sarchive

CONCLUSION

With the worldwide advance in robotic technology and consequently the growth of robotic surgery programs in healthcare institutions, monitoring the performance of reprocessing in these services is becoming increasingly necessary. This continuous monitoring must take place by measuring data through established metrics that are based on reliable and quality evidence, so that reprocesses are efficiently monitored, evaluated and improvements implemented. The main challenge will be to standardize quality indicators to measure the reprocessing of robotic medical devices by the CSSD.

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AUTHORS

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Managers profile of Central Sterile Supply Department in South of Brazil

Luciano Lemos Doro, Daniela Silva dos Santos Schneider, Vivian Lemes Lobo Bittencourt, Graciele Torezan, João Lucas Campos de Oliveira, Jeane Aparecida Gonzalez Bronzatti, Kazuko Uchikawa Graziano e Ana Maria Müller de Magalhães

In Brazil, the work at the Central Sterile Supply Department (CSSD) is carried out by the nursing team, made up of nurses and nursing technicians. However, only through adequate management can results be produced that contribute to the development of work and the growth of organizations. The quality of the final product is directly linked to the human factor involved in processing, whether operationally or managing the process in a systemic and responsible manner.

Objective

To describe the profile of the managers of CSSD in the state of Rio Grande do Sul (RS), Brazil.

Method

Descriptive, quantitative, study of random sampling based on data provided by the Regional Nursing Council, collected through online interviews from 12/2022 to 05/2023.

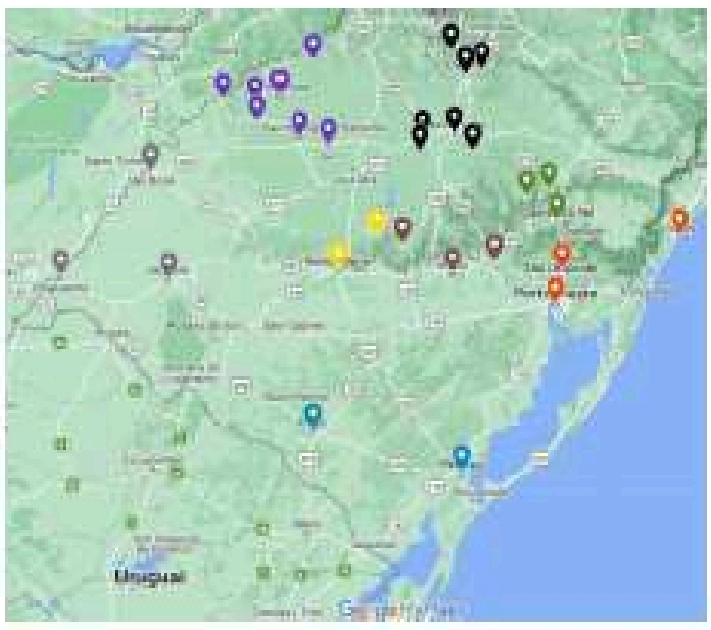

Figure 01 - Geolocation of the sample in the state territory. Rio Grande do Sul, Brazil, 2023

Results

Predominantly women (88.4%), the interviewees were between 24 and 70 years old, with a median time of 15 years of study and 16 years of working in The Central Sterile Supply Department. In addition, it was found that 60.5% of nurses take over other units besides the CSSD during their working hours.

Table 01: Sharing of CSSD Nurses among other units during their workday and association with hospital size. Rio Grande do Sul, Brazil, 2023

Hospital Size n=43	YES	NO	p*
	N(%)	N(%)	
Small	9 (90,0)	1 (10,0)	0.034
Medium	11 (68,8)	5 (31,3)	
Large	5 (33,3)	10 (66,7)	
Extra Large	1 (50,0)	1 (50,0)	
TOTAL	**26 (60,5)**	**17 (39,5)**	

*Pearson's chi-square test

Conclusion

The CSSD managers in Rio Grande do Sul are nurses, predominantly women, with professional maturity and specialists in various areas of knowledge, however, the specialization in areas different from the practice exercised in the CSSD as well as the difficulty in maintaining a nurse exclusively for this sector during the workday, can compromise patient safety.

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Sizing of Nursing Staff in Central Sterile Supply Department in South of Brazil

Luciano Lemos Doro, Daniela Silva dos Santos Schneider, Vivian Lemes Lobo Bittencourt, Graciele Torezan, João Lucas Campos de Oliveira, Jeane Aparecida Gonzalez Bronzatti, Kazuko Uchikawa Graziano e Ana Maria Müller de Magalhães

With technological advances in the surgical area, emphasizing minimally invasive procedures, the processing of medical devices has been facing new challenges. Among these challenges, the qualitative and quantitative adequacy of the nursing staff is undeniably essential for the quality of the processes developed, however, it is still a common difficulty to be faced by committed managers.

Objective

To analyze staffing and productivity in the Central Sterile Supply Department (CSSD) of hospitals in the state of Rio Grande do Sul (RS), Brazil.

Method

This is a descriptive and analytical study. The population (N=359) was made up of CSSDs from hospitals in RS. The random and stratified sample (N=43) came from data provided by the RS Regional Nursing Council.

Results

- The nurse is responsible for compiling the production: 69.7%
- The data comes from equipment records and occurs monthl: 72%, howerer only 48.8% had complete data to present.
- Higher productivity by nursing technicians in CSSD with an automated cleaning stage was noted, and this association proved to be significant ($p<0.05$).
- Most institutions had a real number of nursing professionals lower than that estimated by the institution's technical responsible nurse and this variation was from 11% to 83% for technicians and 25% to 75% for nurses.
- To carry out the personnel calculation, it was evident that 51.2% of the managers did not present information regarding service productivity.
- As provided for in COFEN/BR Resolution No. 543/2017, 72% stated that this is the calculation methodology used in your CSSD.

Conclusion

It was found that there are considerable differences between the estimated and the real regarding the number of professionals. The lack of productivity records, crucial for the calculation, was highlighted, which tends to lead to erroneous estimates, impacting the confidence of the method among senior management.

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COMPARISON OF STABILITY IN THE TRANSPORT OF BIOLOGICAL INDICATORS: A MARITIME, AIR, AND LAND ASSESSMENT

Process validation

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Methods

The monitoring of transport conditions used a datalogger calibrated for temperatures between -2°C and 60°C. In addition, bibliographic reviews of previous studies were used to check pressure and humidity. The study was conducted in comparison to retention samples under controlled temperature (18°C to 25.9°C) and humidity conditions (40% to 55% RH) in the storage environment.

Results

The batches underwent a series of tests aimed at evaluating the initial spore population, as well as the efficacy of the positive control and robustness against sterilization process failure simulations. A variation in results was observed; specifically, batch 21-220 recorded a success rate of 87.5% in the sterilization failure simulation, while batch 21-165 achieved a 100% success rate, suggesting effective sterilization.

The analysis of spore viability after submission to the different transportation methods revealed that land transport caused a minimal reduction in viability. In the case of air transport, there were significant temperature fluctuations, while sea transport was characterized by an increase in relative humidity. Despite these conditions, the effectiveness of the biological indicators remained unchanged.

Conclusions

The results indicate that, despite the variations in temperature, humidity, and pressure characteristic of the different means of transport, the biological indicators (BIs) preserve their ability to effectively monitor sterilization. This conclusion is based on data obtained through calibrated dataloggers and bibliographic reviews, demonstrating the resilience of BIs in the face of adversities encountered during transport. The analysis of the batches evidenced the stability of spore viability, confirming the minimal influence of these variations on the effectiveness of sterilization controls. Therefore, the robustness of BIs for safe transport by different means is confirmed, maintaining their integrity and functionality. By following the established guidelines, it is possible to ensure the arrival of the BIs at their final destination with their monitoring capacity preserved, assuring the quality and effectiveness of the sterilization processes employed.

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Innovation and automation of quality control processes in the production of biological indicators: A focus on Google tools.

Quality / Risk / Management

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Methods

The methodology involved recording the production orders generated by the ERP system in online spreadsheets and implementing a form accessible via QR code on production routes for the registration of quality control inspections at each stage of the production process. The spreadsheets were configured with formulas for alignment between goals, productivity, and quality, allowing for the automatic management of production order status through the sum of the quantity produced, reflecting the daily monitoring of goals. As a final element, simple programming in JavaScript was used to automatically generate certificates for the final product after each analysis conducted by quality control. The generated document contains all the analysis information, such as date and time, person responsible, parameters, and results obtained. The certificates are made available in PDF through an online platform where customers can follow the results via the product batch number they purchased.

Results

The main challenge lies in the management of production orders, quality control, and goal management, due to the limitations of the systems currently in use, which prevent the integrated and efficient management of data. The integration of online tools for automatic data compilation allowed for easy and accurate monitoring of results, as well as enabling the integrated analysis of real-time results. After the submission of the form, the data from the quality analysis were automatically compiled with the production orders and goals, allowing for precise management of data such as volumes produced, product traceability, analysis results, corrective and preventive actions, and productivity management. The analysis linked to the goals minimized the risks associated with potential failures in the production processes, with the achievement of the goals becoming visible only after the analysis was completed by quality control, ensuring compliance with all pre-established requirements before delivery to the customer, achieving 100% satisfactory results. The automatic generation of certificates was successful for 100% of the batches analyzed, simplifying the process and increasing transparency and reliability of results for customers.

Conclusions

The implementation of automating quality control processes in the production of biological indicators, using online tools, proves to be not only feasible but also effective for small and medium-sized enterprises. It enhances the ability to meet regulatory requirements and quality standards without the need to compromise the company's resources, thus establishing a new paradigm in quality management in the medical device industry.

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VALIDATION OF AERATION PROCESS IN REMOVAL OF ETHYLENE OXIDE RESIDUE IN MATERIALS FOR BIOLOGICAL INDICATOR PRODUCTION

Process validation

Paula Leonello Alvares E Silva 1 , Gabrielle Torres 1 , Isadora Aparecida da Silva Souza 1 , Estéfany Machado Da Silva 1 , Marcia Rodrigues 1 , Débora Sales 1 , Jonatas Montanucci 1

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Methods

Tests were conducted according to resolution RE2606 of 04/11/2006 to validate its efficacy and/or interference in the BI production process.

The parameters used in ethylene oxide sterilization were 2.4 kg of sterilizing mixture mass, 240 minutes of exposure time, sterilization temperature between 51°C to 55°C, and humidity of 40% to 49%, with and without aeration in a drying oven with air circulation at a temperature of 80°C for 12 hours.

Steam sterilization utilized a cycle of 121°C/30 minutes for sterilization and 20 minutes for drying. Validation was conducted through microbiological testing to verify material sterility and production of biological indicators containing *Geobacillus stearothermophilus* to assess interference of ethylene oxide gas residues on BI functionality.

Results

It was achieved 100% of sterility in both sterilization processes (figure 1).

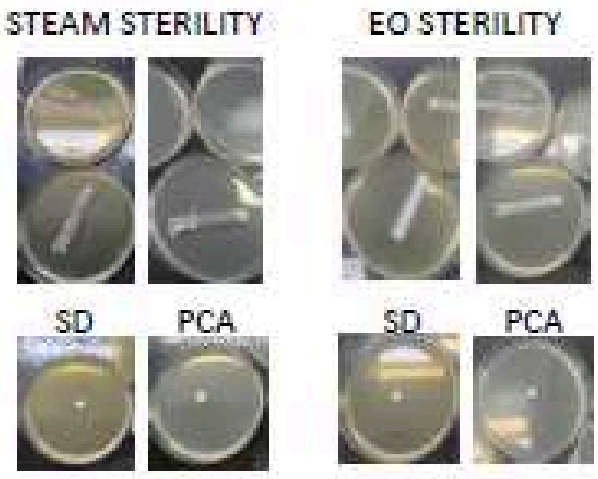

Figure 1. It was achieved 100% of sterility in both Steam and EO sterilization processes. Results of material culture on sabouraud ágar (SD) and Plate count ágarc(PCA)(figure 2).

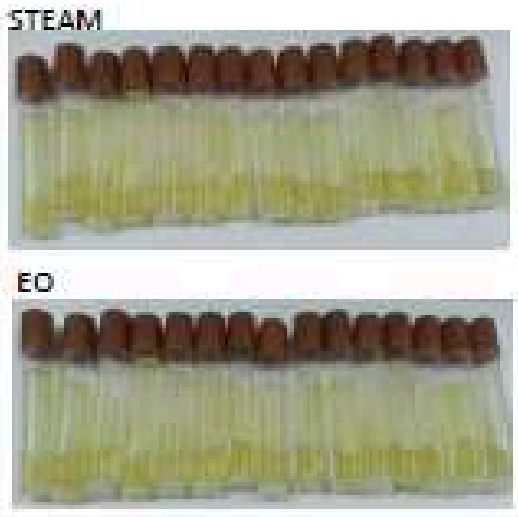

Figure 2. Biological indicators produced with EO-sterilized material With aeration, 100% bacillus growth was obtained, similar to steam sterilization.

Biological indicators produced with EO-sterilized material without aeration showed interference in bacillus growth, disqualifying them in the test. With aeration, 100% bacillus growth was obtained, similar to steam sterilization.

Conclusions

The validation allowed approval of EO sterilization parameters with aeration for 12 hours and implementation of this method in the BI production process (figure 2).

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VALIDATION OF SURGICAL-GRADE PACKAGING IN STEAM STERILIZATION OF MATERIALS FOR THE PRODUCTION OF BIOLOGICAL INDICATORS

Process validation

Isadora Aparecida Da Silva Souza, Gabriele Torres, Paula Leonello Alvares E Silva, Estéfany Machado Da Silva, Marcia Rodrigues, Débora Sales, Jonatas Renan Montanucci

2i Produtos Odontológicos E Médico Hospitalares S.a - Cambé (Brazil)

Methods

In this context, with the aim of validating the process, a study was conducted to verify the efficacy of the sterility of surgical-grade rolls from two different brands, applied to the articles used by the company for the manufacture of biological indicators. The tests were divided into three stages: sterilization of the materials, storage for 7 days, and microbiological analysis. The surgical-grade rolls used in the test were from brands A and B. The materials were separated by families (plastic, fabric, glass, paper, and culture media), and after sterilization and storage, sterility was checked using petri dishes with culture media (Sabouraud Dextrose and Plate Count Agar) and incubated at room temperature and 37°C for a period of 7 days.

Results

The results obtained were: for brand A, 25% contamination in plastics, 4% contamination in glass, 17% in papers, totaling 46% contamination. Brand B showed 100% sterility in all families.

Conclusions

Validation allowed the approval of the process using surgical-grade material from brand B, aiming to maintain compliance and efficacy of material sterilization for the production of biological indicators for 7 days.

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Ensuring Sterility in 3D Bioprinting and intraoperative 3D bioprinting : Challenges, Strategies & Innovations

Atila Nozari, BSc, MSc, PhD, PMP®
Solventum (fka. 3M Healthcare)

Abstract

The aim of this research is to investigate the challenges and strategies for maintaining sterility during intraoperative 3D bioprinting (IOB) during reconstruction surgeries. With the potential of IOB to revolutionize reconstructive surgery by enabling the direct printing of bioink layers onto injury sites, ensuring the sterility of bioinks, the bioprinter, and the integration of this technology into sterile surgical environments becomes paramount. This study seeks to investigate the effectiveness of current sterilization techniques applied to bioink components and the bioprinting equipment, and to develop new strategies to minimize contamination risks during the bioprinting process.

Methods

To investigate the sterility challenges of IOB, a two-fold approach was with bioinks and the air quality of the operating environment. employed. Firstly, a comprehensive review of existing literature and sterilization practices was conducted to understand current methodologies and their limitations. Secondly, experimental studies were designed to evaluate the sterility of bioink components (human adipose-derived extracellular matrix and stem cells and the bioprinting process itself. Sterility tests were performed on bioinks before and after bioprinting to assess the efficacy of sterilization methods. Additionally, the bioprinting environment's contamination levels were monitored to evaluate the risk during IOB. This included assessing the bioprinter's components that come into direct contact.

Introduction

Three dimensional (3D) bioprinting has been a powerful tool in patterning and precisely placing biologics, including living cells, nucleic acids, drug particles, proteins and growth factors, to recapitulate tissue anatomy, biology and physiology [1]. The application of 3D bioprinting to biological research has provided the tissue engineering community with a method for organizing cells and biological materials into complex 3D structures [2]. Figure 1. shows Schematic of 3D Bioprinting Scaffolds for clinical use, and sterility control section. An important component of bioprinting is the use of bioinks. Bioinks consist of biomaterials that can be used to encapsulate cells and incorporate biomolecules. Cell laden bioinks are hydrogel-based, as hydrogels have a high water content that is beneficial for cell survivability and shielding the cells from fabrication induced forces. The main properties of a bioink that need to be considered before printing include its viscosity, gelation and crosslinking capabilities. These properties can significantly affect print fidelity (construct stability and print deviation from the computer aided designs) as well as cell viability, proliferation and morphology after printing and compatibility for sterilization [3].
The main studied bioprinting techniques are: inkjet-based, extrusion-based and laser-assisted. Table 1. [4-9] provides brief examples of research for each technique. Maintaining sterility is a critical issue regardless of the printing technology used.

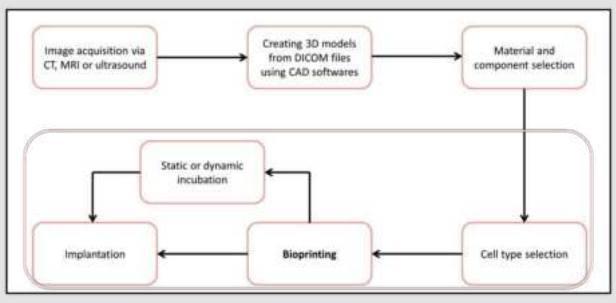

Fig. 1. Schematic of 3D Bioprinting Scaffolds for clinical use, and sterility control section.

Table 1. In vitro and in vivo studies. PU—poly(urethane), PCL—poly(caprolactone), PEG—poly(ethylene glycol), HUVECs—human umbilical vein endothelial cells, iPSCs—induced pluripotent stem cells, CM—cardiomyocytes, bMSCs—bone marrow-derived mesenchymal stem cells, ROB—rat osteoblasts, HUVECs—Human umbilical vein endothelial cells

Biomaterials	Cells	Results	Significance	Reference
Extrusion-based techniques				
Hyaluronic acid, Gelatin, Glycerol, Fibrinogen, PU	Human fibroblasts, Human keratinocytes	Subcutaneous implants in rats reduced wound area to <40% after 14 days. Regenerated skin tissue consisted of epidermis and dermis layers	Novel method to fabricate patient-specific tissue construct to reconstruct facial skin wounds	Seol, 2018 [4]
Alginate, Fibrinogen, PEG	HUVECs, iPSCs-derived CMs	Subcutaneous implants in NOD-SCID mice developed a vascular network and CMs exhibited maturation after 2 weeks	Demonstrates an advantageous printing design where extruded filament was composed of 2 different inks	Maiullari, 2018 [5]
PCL, Sodium alginate	Rabbit bMSCs, Rabbit chondrogenic bMSCs, Rabbit respiratory endothelial cells	Neocartilage and neovascularization in rabbits after 12 weeks of tracheal implantation	Demonstrates fabrication of an artificial trachea with two cell types via additive manufacturing	Bae, 2018 [6]
PEG, Laponite XLG, Hyaluronic acid	ROBs	Implanted into rat tibias, exhibited new bone formation after 12 weeks	Demonstrates benefit of extruding the scaffold support material and bioink separately, however combined into one printing process	Xinyan Zhai, 2018 [7]
Laser-assisted bioprinting				
Human Osseous Cell Sheets	HUVECs	Printed cell exhibits the formation of tubule-like structures within the biopaper after 21 days of culture	Demonstration of self-assembled cell sheets for the soft tissue regeneration	Kawecki 2018 [8]
Inkjet-based techniques				
Collagen, Thrombin, Fibrinogen	Neonatal human dermal fibroblasts and epidermal keratinocytes, Dermal microvascular endothelial cells	Printed scaffolds exhibited 17% better wound contraction after 6 weeks in nude mice	Positioning of microvascular endothelial cells on fibroblast/keratinocyte grafts seemed to be advantageous over commercially available fibroblast/keratinocyte grafts	Marchioli, 2015 [9]

Table 3 A summary of the advantages and disadvantages of sterilization techniques on suitable materials applicable to 3D printing

Sterilization Technique	Acvantages	Disadvantages	Suitable Materials
Heat dependant sterilization	Non-toxic and safe for the environment.	Requires high heat for long periods of time. Not suitable for majority of 3D printed materials due to inherent temperature sensitivities.	PGA, PLLA, PCL [11]
ETO	Suitable for heat sensitive materials.	Long sterilization time (>14 h). ETO is toxic and carcinogenic. Concerns regarding toxic residue on material remains.	ABS, PLA, PCL, PGA, PHB, PLLA, PLGA [12]
Hydrogen peroxide	Quick sterilization time (28–74 min). Suitable for heat sensitive materials.	Measuring hydrogen peroxide concentration during sterilization cycle in real time is difficult	PLA, PETG [13]
Peracetic acid	Suitable for heat sensitive materials. No possibility of contamination.	Cannot be used to sterilize in large batch. Can potentially induce change in structural and biochemical properties.	PLA [14]
Ozone	Suitable for heat sensitive materials.	Cannot be used to sterilize in large batch.	ABS [11]
Gamma ray	Cold method with a slight increase in temperature. High penetration ability. No toxic residue	Considerable health and occupational safety provisions are required. Can potentially induce structural changes	ABS, PCL, PGA, PLLA, PLA [12]

Results & Discussion

The preliminary literature review highlighted a gap in standardized sterilization protocols for bedside 3D printed materials and IOB. Table 2. [10] provides microbiological study and bacterial growth after 7 days. Table 3. [11-14] provides a summary of the advantages and disadvantages of sterilization techniques on suitable materials applicable to 3D printing & compatibility of materials with different sterilization modalities. 3D bioprinting however is currently limited in regards of sterilization modality application as it is directly bioprinted intraoperatively to the surgery site. Manufacturers and users rely on placing the 3D bioprinters within a bio cabinet (BSC) to address sterility. Aseptic techniques are employed to maintain a sterile environment within the cabinet by minimizing the introduction of contaminants. Maintaining absolute sterility within a BSC is very challenging due to the continuous airflow and potential for introduction of contaminants from the surrounding environment. Another method is utilizing methods to physically protect against contaminations, thereby ensuring the integrity of the 3D bioprinted constructs [15]. Literature review highlighted a gap in standardized sterilization protocols for IOB components and processes [1,4-8,16]. Experimental results showed that while traditional sterilization methods were effective for certain bioink components, they were less so for complex bioinks. These findings underscored the need for developing tailored sterilization techniques. Additionally, environmental monitoring revealed a significant risk of airborne contamination, emphasizing the necessity of enhancing sterile field protocols around the bioprinting area. Photocrosslinkable bioinks, such as gelatin methacrylamide (GelMA), hyaluronic acid methacrylate (HAMA), and poly(ethylene glycol), are common in bioprinting. There is a need for the development of new bioinks with rapid and stable crosslinking and the integration of advanced bioprinting modalities. Developing new materials such as tough hydrogels or integrating mechanically strong thermoplastics. In this regard bioprinting of soft bioinks can be coupled with thermoplastics [e.g., polycaprolactone (PCL) or poly(lactic-co-glycolic acid) (PLGA). Unliked 3D printed material, bioinks are not currently compatible with current sterilization modalities and they get sterile filtrated through certain size (for example 0.2 µm) sterile filter.

Table 2. Results of Microbiological studies

Sterilization Method	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Negative control
None (Control)	12 CFUs	4 CFUs	2 CFUs	4 CFUs	Neg.	Neg.
Gas Plasma	Neg.	Neg.	1 CFU	Neg.	3 CFUs	Neg.
Steam Heat	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EtO	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

CFU: Colony forming units. Neg.: negative result, no bacterial growth observed after 7 days.

Conclusion

The research confirmed the complexity of maintaining sterility during IOB, especially due to the sensitivity of bioink components and the open nature of the bioprinting process. It highlights the need for developing specific sterilization methods for bioinks and improving environmental controls to ensure a sterile operating field. Future work should focus on the optimization of sterilization protocols for various types of bioinks and the development of bioprinters designed to operate under strict sterile conditions. Further investigation into the integration of IOB within surgical procedures will be essential to address the practical challenges of implementing this technology in a clinical setting, ensuring that it can be safely applied to enhance patient outcomes in reconstructive surgery. • 3D Bioprinting is a powerful technology in tissue and organ fabrication. • 3D Bioprinting has gained significant interest in medicine and pharmaceutics. • Sterility of 3D Bioprinting material and process is extremely important. • Compatibility of 3D Bioprinting material with sterilization modalties need to be considered. • Standards and regulations need to be developed for assuring the sterility of the 3D Bioprinted material due to rapid advancements in IOB technologies.

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World Federation for Hospital Sterilisation Sciences | Sociedad de Profesionales en Esterilización de Chile | Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos | Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

An Australian Hospital Case Study - A Six Sigma Approach to Improving Surgical Implant Safety

Michelle Odayan & David Bellamy

Introduction:

Ensuring the sterility of orthopedic implants is paramount for patient safety and the prevention of infection4. This quality improvement project (QIP) aimed to address the risks associated with the reprocessing of surgical implant sets and to enhance sterilization processes. By applying Six Sigma principles, the project sought to reduce variation and improve overall process quality. A retrospective analysis of orthopedic trauma implant data from a New South Wales hospital was conducted, categorizing implants by usage and type. The focus was on data from 2012 - 2022 to assess implant utilization in trauma orthopaedic surgeries. The data from the electronic tracking systems was also included to monitor the frequency of reprocessing for each implant. The project was implemented in phases, involving perioperative stakeholders to refine processes, beginning with the removal of zero-usage implants and progressing to low, medium, and high-usage categories. As a result, implants were relocated to a revised storage system that streamlined management and retrieval, without compromising intraoperative safety. Enhanced tracking and the use of type 5 chemical integrators* further ensured quality assurance. The project also led to cost reductions by decreasing repeated reprocessing and exposure, thereby minimizing contamination risks.

Objectives:

Implement a QIP adapting Six Sigma principles to address risks associated with the continual reprocessing of surgical implants with a focused approach on orthopaedic implant sets utilised over a ten-year period (2012-2022) in a trauma hospital to:

1.Prioritise Implant Usage:
- Identify, deconstruct and prioritise the categorisation of orthopaedic surgical implantable items based on their usage frequency, ranging from zero usage to high usage implants in the orthopaedic sets.

2. Optimise Orthopaedic Implant Inventory Management:
- Remove all orthopaedic surgical implants that have been identified as zero usage implantable items from inventory from the data analysis 2012 - 2022.
- Repackage surgical implants in laminated sterilization pouches with a type 5 quality assurance chemical integrator indicator for surgical implants.
- Systematically categorise and store surgical implants in the new repackaging system in a designated theatre storage space.

3. Implement Systematic Categorisation of Implants into Individual Sterile Packaging:
- Prioritise and implement individually sterile packaged implantable items from low to high usage in identifiable laminated sterilization pouches.
- Systematically categorise and store individually sterile packaged items in the new storage system and allocated theatre space.

4. Implement a 5-year Shelf-Life Protocol:
- Develop a system to phase out implantable items with a shelf life exceeding 5 years to prevent the circulation and reprocessing of implants with expired shelf lives.

5. Enhance Traceability and Documentation:
- Replace old implants by implementing individual sterile packaging for implants with recorded date, lot number and a type 5 chemical indicator for traceability.

6. Ensure Correct Screw Utilisation:
- Implement a safety system to verify and ensure the correct use of implant screws for each patient to prevent the insertion of inaccurate or misplaced screws during surgical procedures.

7. Minimise Theatre Exposures from Aerosol Generating Procedures (AGP):
- Aim to decrease theatre exposure time to reduce contamination risks and biofilm development to surgical implants.

8. Prevent Accidental Implant Reuse:
- Develop an implant safety protocol to prevent accidental placement of screws back into the caddy and implement safety measures to ensure that once an implant/screw is used, it is not mistakenly reinserted.

9. Enhance Inspection and Quality Assurance Monitoring:
- Improve the inspection process to reduce fatigue and enhance overall quality assurance and monitoring in implant safety.
- Implement new protocol measures to increase the accuracy and effectiveness of quality assurance protocols for surgical implants.
- Implement CSSD/theatre education to update all stakeholders on the safe management of surgical implants and the adoption of the new implant safety system.

Methods

- Utilising Six Sigma principles to risk mitigate and improve patient safety outcomes, a retrospective analysis of orthopaedic implants used in a New South Wales hospital from 2012 to 2022,
- comprised of non-identifiable patient data, implant product code cross-referencing, temporal analysis, and a detailed iterative examination of the 2022 dataset.
- This analysis aimed to identify usage patterns of surgical implants that, despite being included in the inventory of loan sets/consignment sets, had never been utilised during the specified
- timeframe.
- Temporal analysis focused on dissecting the orthopaedic implant data specifically for the year 2022. Iterative analysis allowed for a detailed examination of trends and revealed insights into the
- utilisation patterns of surgical implants within the specified timeframe and were then able to be classified into 0 usage, low, medium and high usage categories.
- A time study was also conducted to determine the impact of time and labor costs within the sterilisation department during the cleaning and inspection phases to quantify the current practice versus best practice with the reprocessing management of implant sets.
  This was based on $34.33/hour for most of the sterilisation technicians to establish the costs against the high volume of trays/sets that represented the 71% of the identified 0 usage as well as the NSW Sterilisation Services Weighting Identification Tool.

Results

The 2022 non identifiable patient dataset findings are as follows:

- A total of 8165 implants were utilised for orthopaedic and trauma surgeries.
- 5566 different types of orthopaedic implants were identified in the analysis data.
- 71% of the implants were never used and underwent repeated reprocessing during the data period.
- 3953 items were identified as having zero usage and the cost impact to reprocessing was a saving of
- $881,190.10 per year once removed.
- Low usage category represented 1593 implants = 28.6%
- Medium usage category 11 types of implants = 0.2%
- High usage category 9 types of implants = 0.2%
- The QIP identified issues such as lack of systematic selection, absence of implant expiry dates, and repeated exposure risks during reprocessing.
  The instrument tracking system, when cross referenced with the implant product codes showed that the selected sku's out of the non-use category of implants not been used in over 13 years old and had undergone repeated sterilisation reprocessing during this time.
- Many of the implants did not have a traceable lot number to determine if the 5-year expiry had been exceeded There was no systematic rotation or replacement of the surgical implants, and the same type of implant can be distributed over 7 different sets. The same instrument product code was found in more than 7 orthopaedic caddy sets.

Set Number	Description	Usage in 2022	Total Usage Till Oct 2023	Processing Cost/Use (NSW Health Weighting Tool)	Total Processing Cost (2022)	Inventory Removal Savings	Net Cost After Removal
01161-01	AO Large Fragment Stainless Steel Set	16 times	13 times	$1767.50 (per process)	X 29 times =$51,243	$35,870.10	$15,273.90 (per year)
01668-02	Universal Small Fragment Set	68 times	65 times	$4360.00 (per process)	X 133 times $579,880	$405,916	$173,964 (per year)
01161-02	AO Large Fragment Stainless Steel Set	18 times	14 times	$1767.50 (per process)	X 32 times $56,560	$39,592	$16,968 (per year)
O1668-03	AO Large Fragment Stainless Steel Set	59 times	72 times	$4360.00 (per process)	X 131 times $571,160	$399,812	$171,348 (per year)
01668-01	Universal Small Fragment Set (2017)	215 times between 2017-2022		$4360.00 (per process)	Only one set until 2022		

Inventory Removal Savings = $881,190.10 AUD

- **360 screws – AO large fragment stainless steel set.**
- **931 screws – Universal small fragment tray.**

The weighting tool was used as a reflection of the current costs but does has some bearing on cost reflection. Most hospitals use a weighting of a $1.50, where as this hospital uses a lower estimate of $1.25. This costing could have a higher cost impact to other facilities. Overall, the project has contributed to a more efficient, safer impact to patient safety as well as preserving the burden of labor placed on the staff with the advanced complexity and dynamics of surgical instrumentation reprocessing.

Conclusions

The project's outcomes led to a comprehensive plan of action involving stakeholder engagement, removal of unused implants, and implementation of a new implant storage system. Findings indicated potential annual savings of $881,190.10 through removal of zero-usage inventory.
The project not only improved patient safety by minimising risks but also contributed to cost-effectiveness in sterilization processes. The implementation phase was a staged approach involving the systematic reorganisation of implant storage, ensuring sustainability through regular reviews and feedback from surgical stakeholders.
The project serves as a model for enhancing surgical implant safety, optimising inventory, and aligning practices with best practice standards, ultimately promoting patient surgical safety and healthcare operational efficiency.

Lot Number
Can be added to the label

Reference Number
For increased traceability

Expiry Date
As the date of sterilisation is known

References:

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Footnote: 3M™Attest Type 5 Steam Chemical Integrator used for internal pack control

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UNCUYO · FACULTAD DE ODONTOLOGÍA

Manual

Safe Practices In The Treatment Of Dental Instruments

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Aim

. Develop an application manual in the dental field, which contributes to the improvement of safe practices dentistry and that it is useful for professionals, assistants and related personnel, as well as for the training of students.

. Guarantee safe and functional devices to professionals, patients and society in general.

. Become aware and train the human resources and thus generate preventive awareness, which is a fundamental factor towards the cultural change

Introduction

When we talk about "sterilization" we immediately associate this terminology with the medical and hospital, pre-assuming that sterilization in primary care has less importance and less value than that performed in a hospital. The reality shows us just the opposite.

If we compare the percentage of hospitals versus primary care centers and other more small care center, we arrive at the conclusion, that there is a greater number of public or private healthcare centers, dental offices, clinics ophthalmological, aesthetic, veterinary, podiatrists, tattoo shops, etc., in which materials and instruments are handled surgical and are generally equipped with equipment, dry heat sterilizers and/or mini-claves for reprocessing the same.

This is why the need arises to develop a manual whose approach is aimed at providing a tool for its application in the dental field, reinforce work methodologies, and thus allow the user to acquire new strategies, which contribute to the improvement of safe dental practices.

The most important aspects to take into account for the use, manipulation and reprocessing of instruments are also highlighted dental, contributing to preserving the safety of the professional, patients and third parties.

Methods Bibliographic review. Descriptive study.

Results
Obtaining a manual

Conclusions

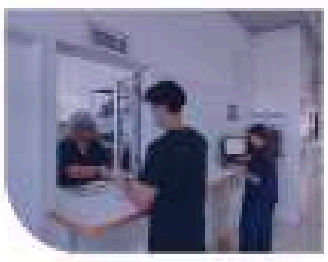
Due to the scientific and technological evolution that happens to us, we find ourselves immersed in the reality of being up to date with the latest developments.

It is worth highlighting the paradigm shifts in the unlimited and uncontrolled reuse of health instruments, to responsible reuse or even to the prohibition of using the instruments several times.

So it is essential to unify criteria that facilitate the execution of the processes, respecting their sequences, instructions of the manufacturer, current legislation, etc. through the development of operating procedures.

It is therefore, this manual aims to give practical advice and recommendations in clear and simple language, on good practices in the treatment of dental instruments and their processes in daily work; as well as highlight the importance and need for sterilization in oral health units.

That is to say, if we control the process, we control the final product.



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Reusable medical devices: Bridging the gap between manufacturer's IFUs and hospital practices using insights from processing validations

Alpa N. Patel, Katleen Peymen, Nelson Laboratories, LLC. 20 Nov 2024

Reprocessing validations: roles and responsibilities

Manuf.

Test lab

Manufacturers select and validate instructions for use of reusable medical devices

Users perform instructions

Problem statement

- Manufacturers validate their instructions, however users often have difficutly understandig the instructions and therefore create their interpretation.
- Validation process and challenges for a certain device not visible to users.

Reprocessing validation steps – Worst case conditions are applied

Devices are challenged to wost case contamination levels than clincal use

Devices are processed using steps ommitted From the IFU

Cleaning: protein, hemoglobin, TOC, etc.
Disinfection: 6 Log reduction of bacteria
Sterilization: SAL 10^{-6}

Evaluation of acceptance criteria

Common validation challenges

Cleaning

1. Removing detergent after cleaning

↓

Evaluate extensiveness of rinsing steps in IFU

2. Difficult to clean features

↓

Evaluate brushing/flusing steps in IFU

3. Effectiveness washer-disinfector program

↓

Evaluate extensiveness of manual pre-cleaning

Disinfection

1. Label claim disinfectant not sufficient for device

↓

Longer label claim IFU vs disinfectant claims?

2. Removing disinfectant

↓

Evaluate extensiveness of rinsing steps in IFU

Steam sterilization

1. Some devices/trays very challenging to dry

↓

Dry time IFU? 20 – 30 min is a common starting point, but for challenging devices up to 90 min

Conclusion

- Mutual communication between manufacturers and healthcare is warranted.

Reusable device → Manufacturer drafts IFU → Validation of IFU → Validation feeds back to IFU

Healthcare Facility Involvement

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DUODENOSCOPE CONTAMINATION

Where is the problem?

Lionel PINEAU PhD, Eurofins Hospital Hygiene, 13594 Aix-en-Provence, France

Introduction: Due to their complex design, duodenoscopes have been identified as a real challenge for people in charge of reprocessing them and several cases of infection transmitted by contaminated duodenoscopes have been reported. To reduce the risk of infection for patients, the FDA is supporting the transition from older fixed endcap duodenoscope models to newer models of duodenoscopes with disposable endcaps (1).

Olympus TJF Q190V

Pentax ED34-i10T2

Fujinon ED 580XT

Objective of the study: Even if endoscope manufacturers were ordered by the FDA to conduct postmarket surveillance studies to determine in real use situation, the contamination rate of their endoscopes after reprocessing, there is no data demonstrating that the design changes improve the reprocessing effectiveness,
The objectives of this study were to compare the contamination rates in real use situation of several models of reusable duodenoscopes and define what part of the duodenoscopes was contaminated (distal end or channels).

Method: A retrospective study of the results of 4222 duodenoscopes samples collected between 2018 and 2023 in 96 private or public hospitals in France was performed. Duodenoscopes were sampled and cultured using the reinforced sampling procedure published by the French ministry of health in 2018 (2). This method allows separate sampling of endoscope channels and distal end.

Results: The results of this retrospective study demonstrate that since the implementation of the reinforced sampling procedure in 2017, the mean contamination rate of duodenoscope remains stable and relatively high (around 14% of the duodenoscopes are at the action level) (see figure 1).

Figure 1: Evolution of duodenoscope mean contamination rate.

The post-reprocessing contamination rates of the three duodenoscopes models with removable end-cap (Olympus TJF Q190V, Fujinon ED 580 XT and Pentax ED 34i10T2) that were also included in the PMS study initiated by the FDA were comparable (between 11,4% and 12,7% of the endoscopes were at the action levels) (see figure 2).

Figure 2: Duodenoscope contamination rates.

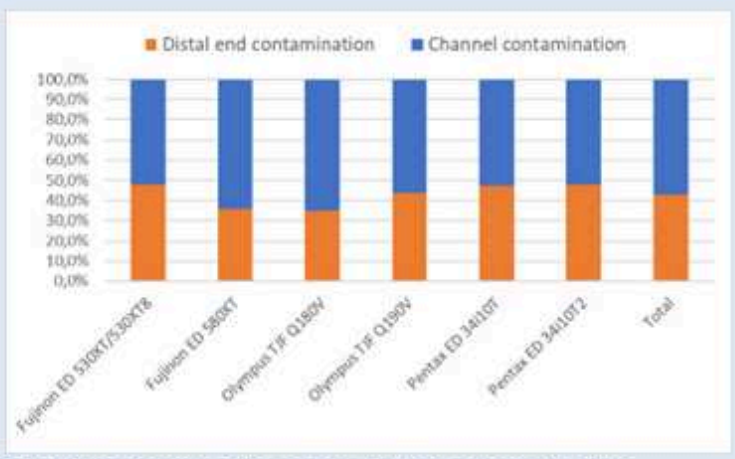

Figure 3: Duodenoscope channel and distal end contamination rates.

For the three duodenoscope models, for which a contamination was identified, contaminants are mainly recovered from the channels (between 52% and 64%). The analysis of the nature of the microorganisms isolated also confirms that when a contamination is found at the distal end, environmental contamination is the most probable root cause of microbial contamination in at least 80% of all cases (see figure 3).

Conclusion: The results of this study confirm that the contamination rates of the duodenoscopes with disposable endcaps are comparable to older fixed endcap duodenoscope models. For the new duodenoscope generation, the elevator does not seem to be the main issue, and the contamination is predominantly influenced by the channel contamination.

1. FDA. Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication. Available at: https://www.fda.gov/medical-devices/safety-communications/use-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication. Last accessed 11/10/2023.
2. FAQ N°2. Traitement des endoscopes souples thermosensibles à canaux. Available at: https://solidarites-sante.gouv.fr/IMG/pdf/dgos_faq_2_traitement_endoscopes_060819-2.pdf. Last accessed 11/10/2023.
3. Goyal Hemant et al. Gastrointestinal endoscope contamination rates – elevators are not only to blame: a systematic review and meta-analysis. Endosc Int Open 2022; 10: E840–E853.

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MANUAL REPROCESSING CHALLENGES IN VIEW OF OPERATORS LEGAL INTEGRITY AND PATIENT SAFETY BASED ON CURRENT REGULATIONS IN EUROPE. A ROLE MODEL FOR OTHER REGIONS?

Renz, S.* (2024)

Keywords

Manual Reprocessing, Hospital Associated Infections (HAI), Regulation (EU) 2017/745, MPBetreibV, Process Validation, Cleaning Guns, Brushes, Endoscope Drying, Final Rinsing

Legal Overview – Europe

"Medical device' means (..) also (..) products specifically intended for the cleaning, disinfection or sterilisation of devices (..)" (L 117/15, Regulation (EU) 2017/745 (MDR)). This has consequences for CSSD's. From washers / disinfectors via cleaning guns down to brushes: Every device which cleans a medical device has to be a medical device itself. It has to carry a CE sign. In Germany the legislator (MPBetreibV) demands the validation of reprocessing processes of medical devices.

The reprocessing process of devices like brushes or cleaning guns etc. has to be validated. The manufacturers need to provide a validated reprocessing manual. Operators using cleaning devices which are not single use or validated reprocessable to reprocess medical devices are liable to prosecution.

Patient Safety – Reprocessing

Despite technological advances, the number of reports of health care associated infections (HAIs) is increasing, not decreasing. The expert group Swissnoso reports that in Switzerland alone, about 70,000 people are newly affected each year. Every year, HAIs are responsible for 2,000 deaths (Ministry of Health (BAG), 2019). Previous inspections of the reprocessing of flexible endoscopes in hospitals revealed serious deficiencies in some cases (Moreno, R. (Swissmedic), 2019). Special attention must be paid to the treatment of hollow spaces. Only controlled reprocessed / new single use devices can properly reprocess (disinfect, dry etc.) medical devices.

Results

The additional requirements with regard to manual reprocessing represent additional work. This additional work is incurred by those responsible for the practice, in particular employees in CSSD / endoscopy, but also by medical device manufacturers. On the other side, the herein viewed strict regulations also suggest added value for hospital hygiene. Especially with regard to the challenges of manual reprocessing. It is essential for operators to identify nonconformities in both processes and equipment for manual reprocessing in order to not only being compliant with the regulations but also to increase patient safety to an acceptable level.

Case Examples For Nonconformities

Fig 1. Brush (Single use – multiple times used)

Fig 2. Cleaning gun *(not reprocessable, contaminated, oxidated)*

Conclusion

By extending the definition of the term "Medical device', the European legislator is addressing the relevance of hygiene in the reprocessing process and the associated fight against HAIs. Due to multiple reasons the current regulatory requirements are in general viewed critically by operators and medical device manufacturers. However if adhered to an added value for hospital hygiene can be assumed, at least for the parts considered here with regard to manual reprocessing.

Outlook – International

Regions outside of Europe (European Union) might need to orientate themselves towards the herein viewed EU regulatories regarding reprocessing with laws, or at least with recommendations in order to reach the same level of hygiene. Further scientific (possibly microbiological) studies can contribute to even greater international understanding.

*RfQ-Medizintechnik GmbH & Co. KG, Tuttlingen (Germany)

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Construction and validation of an instrument for event related sterility for health products

Vanessa Aparecida Vilas-Boas, Louise Assumpção Rondini, Thamiris Cavazzani Vegro Czempik, Ada Helena Melo Lorenzetti, Kazuko Uchikawa Graziano, Ariane Polidoro Dini

This work was supported by the Scientific Initiation Scholarship Institutional Program (PIBIC/Unicamp).

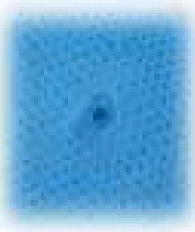
Descriptors: Sterilization; Time Factors; Validation Study; Nursing Assessment; Equipment and Supplies.

INTRODUCTION

Healthcare-associated infections constitutes a health problem. Surgical site infection is common and considered avoidable.[1]

Global Patient Safety Action Plan 2021-2030:

3.3	3.4
Infection prevention and control & antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines



Events related to maintaining the sterility of healthcare products → sterilized products remain sterile until an event or damage to the package integrity occurs.[2]

OBJECTIVE

Construct and validate an instrument to evaluate event related to the maintenance of sterility of processed health products by the Central Sterile Supply Department.

METHODS

Methodological Study

1st development of the instrument

2nd content validity by a judges' committee analysis[3]

- Content Validity Index (CVI) ≥ 0,80
- Content Validity Ratio (CVR) ≥ 0,80
- Modified Kappa ≥ 0,74[4]

RESULTS

Table 1 - Characterization of the judges' committee. Brazil, 2022.

Committee	Country/Region	Degree	Area of activity	Experience
Judge 1	Jamaica	Postdoctoral	Regulatory Agency	19 years
Judge 2	Brasil	Postdoctoral	Regulatory Agency	20 years
Judge 3	Brasil	PhD	Teaching/Research	07 years
Judge 4	Brasil	Postdoctoral	Assistance/ Teaching/Research	35 years
Judge 5	Uruguai	Master	Regulatory Agency/Research	20 years
Judge 6	Brasil	PhD	Assistance	03 years

After two committee evaluation, the stipulated grade was achieved at every item.

Figure 1 – First version of the instrument. Brazil, 2022.

Pre-test:

- thirty nursing professionals
- 86,67% good; 90% comprehensible

DISCUSSION

The sterility maintenance of a health product depends of several factors: packaging with antimicrobial barrier, hermetic sealing, storage and handling conditions → good practices by health institutions.

The adoption of event related sterility contributes for the reduction of waste, work load and processing costs.[4,5]

The instrument is available to use.[6]

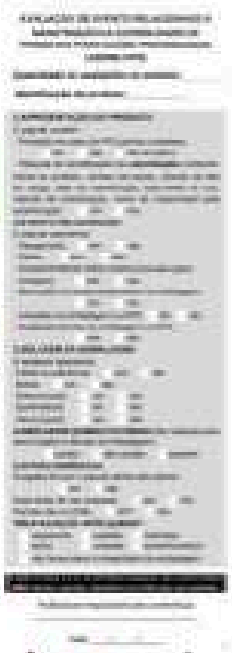


Figure 2 – Final version of the AERMS instrument. Brazil, 2023.

CONCLUSION

The instrument presented helps evaluating the package integrity and, consequently, the maintenance of sterility of the health product. It contributes for the paradigm translation, management e decisions making processes.

1. World Health Organization (WHO). [Internet]. Genebra: WHO. 2021. 2. Link T. AORN J. 2020;112(3):248-260.
3. Terwee CB, et al. Qual Life Res. 2018;27(5):1159-1170.
4. Yusoff MSB. Education in Medicine Journal. 2019;11(2):49–54.
5. Da Cruz AR, et al. J Health Manag. 2022;24(2):203-212.
6. Vilas-Boas VA, et al. Rev. Bras. Enferm. 2024;77(4):e20240021.

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Health products storage instrument validation study for nursing evaluation

Louise Assumpção Rondini, Renata Cristina Gasparino, Ariane Polidoro Dini, Suzimar de Fátima Benato Fusco, Rafael da Silva Marconato, Vanessa Aparecida Vilas-Boas

This work was supported by the Scientific Initiation Scholarship Institutional Program (PIBIC/Unicamp).

Descriptors: Sterilization; Time Factors; Validation Study; Nursing Assessment; Equipment and Supplies.

INTRODUCTION

The actual Global Patient Safety Action Plan defends the infection prevention and the safety of medical devices.[1] Audit and risk assessment instruments can help identifying processes and managing indicators.

Events related to maintaining the sterility of healthcare products[2,3]

- Packaging
- Handling
- Sealing
- Storage conditions

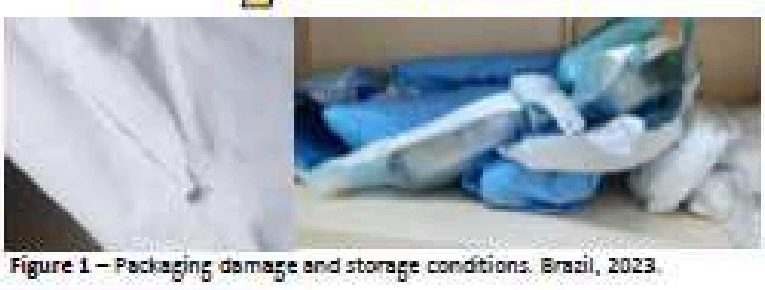

Figure 1 – Packaging damage and storage conditions. Brazil, 2023.

OBJECTIVE Construction and validation of an instrument for internal auditing of the storage location from the Central Sterile Supply Department (CSSD), having as principle aspect the event related sterility and the health risk analysis.

METHODS

Methodological Study

1st development of the instrument

2nd content validity by a judges' committee analysis[2]

- Content Validity Ratio (CVR) ≥ 0,80
- Modified Kappa ≥ 0,74[4]

Health risk evaluation through criticality: Essential, Necessary or Recommended[4]

RESULTS

Judges' committee analysis:

16 (invited) → 9 (consent) → 7 (1st round) → 5 (2nd round)

The first version was meant to be applied at the assistance units and at the CSSD. After two rounds, the final version of the instrument was decided to be applied only in the CSSD.

Figure 2 – Final version of the auditing instrument. Brazil, 2023.

Pre-test:

- Sixty one nursing professionals invited
- Seventeen answered (27,86%)
- 82,35% good; 94,11% accordance with the values of practice

DISCUSSION

Lack of:

- Evidences about relationship between storage and sterility maintenance;
- Professionals' knowledge about storage and regulations;[5]
- A risk map is being developed based at the Healthcare Failure Mode and Effect Analysis (HFMEA);[6]
- Studies about hands hygiene at CSSD.

CONCLUSION

The adequate conditions of storage is essential for preventing events to occur. This study contributes to the development of the packaging integrity assessment plan.

1. World Health Organization (WHO). [Internet]. Genebra: WHO. 2021.
2. Terwee CB, et al. Qual Life Res. 2018;27(5):1159-1170.
3. Vilas-Boas VA, et al. Rev. Bras. Enferm. 2024;77(4):e20240021.
4. Yusoff MSB. Education in Medicine Journal. 2019;11(2):49–54.
5. Oliveira AC de, et al. Ver. SOBECC. 2014;19(4):188-94.
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PROCESSABLE OPTICAL HEATING SYSTEM: SUSTAINABILITY AND PATIENT

Alexandre Nardi[3], Ana Maria Muller Magalhães[1], Daniela Santos Schneider 1,2, Jermanno Xavier[3], Laura Zigue[2], Liege Lunardi[2], Mateus Coccaro[2]

1. School of Nursing at the Universidade Federal do Rio Grande do Sul (UFRGS); 2. Hospital de Clinicas de Porto Alegre (HCPA); 3. FAMI Medical Technology

IIn minimally invasive surgery (MIS), the surgical structure is visualized through optical scopes.

These optics frequently experience blurring caused by temperature differences between the human body and the optical equipment.

This issue can disrupt the procedure, potentially leading to extended surgical and anesthetic durations.

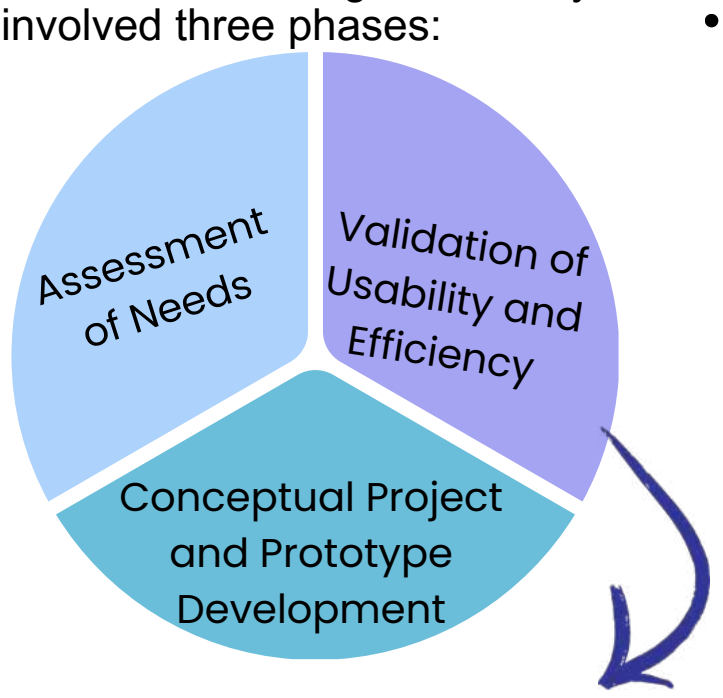
AIM

Develop a heating system for sustainable optical defogging in laparoscopic procedures.

METHODS

HOSPITAL DE CLÍNICAS PORTO ALEGRE RS + FAMI

This methodological study involved three phases:



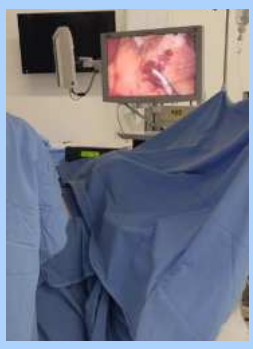
and was applied to 82 minimally invasive surgical procedures

Project and Prototype:

- Heated at least 80% of the optical body,
- Low-cost and sustainable,
- No disposable inputs required,
- Steam sterilizable, easy to use, and efficient.

Usability:

- Maintained optical temperatures between 38-40ºC
- Adjustments improved system performance by minimizing environmental factors



RESULTS

Assessment of Needs:

- Identified difficulties in maintaining optical visibility,
- Existing solutions did not support controlled heating,
- Disposable products increased costs.

CONCLUSIONS

The development of this optical heating and defogging system has resulted in a sustainable, efficient, and processable product that significantly reduces downtime in laparoscopic surgical procedures.

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THE DEVELOPMENT OF STANDARDS: WHAT IS NEW FOR THE CSSD?

The sterile processing department is a service that faces a constant increase in regulation, due to its crucial role in preventing healthcare-associated infections. The development of increasingly technological and complex medical devices requires the implementation of stricter regulations to ensure patient safety. This implies that standards must evolve at the pace of new technologies and medical devices. Therefore, it's essential to stay up to date on the latest regulations and guidelines applicable to DPE.

STANDARD

ISO defines a standard as a document that provides rules, guidelines, or characteristics for activities or their results. The Association for the Advancement of Medical Instrumentation AAMI defines a standard as a consensus document that provides guidelines, specifications, requirements, or characteristics for products, materials, processes, and services. AAMI standards are developed to ensure that health technologies and medical devices are safe, effective, and managed and used safely.

- ISO 15223-1:2022; Medical Devices- Symbols to be used with information to be supplied by the manufacturer. Part 1- General requirements. ISO 22441:2022
- Sterilization of Health care products - Low temperature vaporized hydrogen peroxide - Requirements of the development, validation and routine control of a Sterilization Process for Medical Devices ISO/IDS 11135:2023; Sterilization of Health care Products - Ethylene Oxide- Requirements of the development, validation and routine control of a Sterilization Process for Medical Devices ISO 17665:2024; Sterilization of Health care products -Moist heat- Requirements of the development, validation and routine control of a Sterilization Process for Medical Devices

GUIDELINES FOR PERIOPERATIVE PRACTICE 2024 ED & 2025 PRE-ORDER:
Includes a chapter for:

- Sterilization
- Sterile barrier systems
- Cleaning and process of flexible endoscopes
- High Level Disinfection
- Cleaning and care of surgical instruments

- ANSI/AAMI ST98:2022; Cleaning validation of health care products - Requirements for development and validation of cleaning process for medical devices
- ANSI/AAMI ST108:2023; Water for the processing of medical devices
- ANSI/AAMI ST24:2024; General-purpose ethulene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities.

MEXICO

·PROY-NOM-045-SSA2-2024, Para la vigilancia epidemiológica, prevención y control de las infecciones nosocomiales.
·PROY-NOM-137-SSA1-2024,Etiquetado de dispositivos médicos.
·PROY-NOM-240-SSA1-2024, Instalación y operación de la tecnovigilancia.
·PROY-NOM-241-SSA1-2024, Buenas prácticas de fabricación de dispositivos médicos.

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SIMULATION-BASED TRAINING FOR MATERIAL PACKAGING IN THE MATERIAL AND STERILIZATION CENTER

S. Jesus [1], J. Campos [2], L. Ferreira [2], L. Reis [2], C. Silva [1].
[1]National Cancer Institute - Rio de Janeiro (Brazil), [2]Federal University of Rio de Janeiro (Brazil)

AIM

Material packaging is a critical aspect of the daily operations in the material and sterilization center, demanding skilled professionals to execute the technique with precision. Simulation, a versatile teaching strategy applicable in various settings, including hospitals, can significantly enhance the efficiency and practicality of the material and sterilization center's operations.

OBJECTIVES

This study aims to propose training based on Rapid Cycle Deliberate Practice (RCDP) simulation for material packaging and evaluate professionals' performance.

METHODS

Methodological study: Simulation training for packaging materials using crepe paper or non-woven sheets (SMS). An instrument was constructed with folding standards based on AORN, AAMI, and the Pan American Health Organization guidelines.

MATERIAL PACKAGING STEPS	YES	NO
Step 1 - Open and position the sheet of crepe paper or SMS diagonally on a rigid surface		
Step 2 - Position the material in the center of the sheet		
Step 3 - Position the chemical indicator inside the material		
Step 4 - Fold the proximal flap and then fold the tip		
Step 5 - Fold the right side flap and then fold the tip		
Step 6 - Fold the left side flap and then fold the tip		
Step 7 - Fold the distal flap and then fold the tip leaving it outside		
Step 8 - Close the material with zebra tape (type I chemical indicator)		
Step 9 - Attach the identification label to the material		

Image 1 – Pre-test and post-test Instrument (the authors)

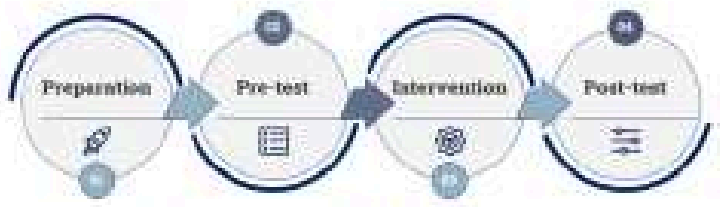

Image 2 – Training Steps (the authors)

Image 3 – Principles of RCDP (the authors)

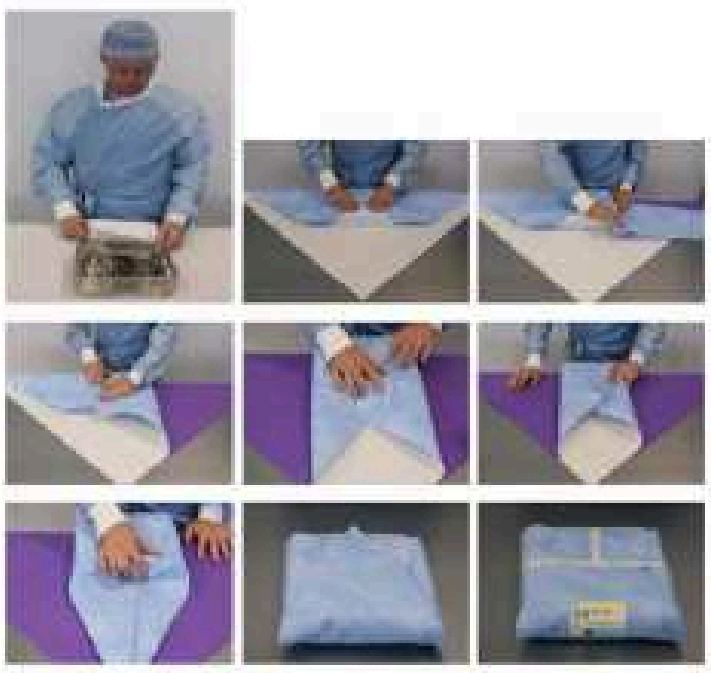

Image 4 – Material packaging steps (WHO, 2016)

CONCLUSIONS

The nurse manager of the material and sterilization center can utilize simulation training with the RCDP and the assessment instrument to train professionals. This will help identify the most challenging stages and require more attention and reinforcement during training. Rapid cycle deliberate practice can be implemented in the material and sterilization center for all stages of material processing.

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25th wfhss CONGRESS

โรงพยาบาลศิริราช ปิยมหาราชการุณย์

25th wfhss CONGRESS

20-23 NOV 2024 SANTIAGO-CHILE

EVERYONE KNOWS

PROJECT OWNER : Miss Nanthipha Sirijindadirat, Miss. Pawitree sukket, Miss Kalyarinthaphas Somboonsap /and CSSD SIPH team

Policy:Loaner Instrument management

The procedures should include the following:

1.Ensuring loan instruments are properly decontaminated prior to use, that the company supplying have an indemnity agreement if required, and the set(s) of instruments are uniquely identified to ensure traceability.

2.All loan devices must only be used by staff who have been trained adequately in the use of the equipment. Adequate user instructions should be available to allow for the safe use of the device.

3.All loaned devices being returned to a manufacturer/supplier must be cleaned /decontaminated prior to release.

4.All loaned devices must be delivered a minimum of 24 hours prior to use to allow for reprocessing before use. If the devices have been reprocessing by the suppliers, the supplier must provide documentation that decontamination has been performed.

5.A comprehensive delivery note/checklist (received and returned) should be performed between the suppliers and receivers.

6.The recall procedure should include assessment of client/patient/resident risk and a procedure

Background Proposal

the number of incidents Delivery of loaner tools in time for the procedure / postponing surgery cases

Sirirajpiyamaharajkarun Hospital (SiPH) has used the Implant and Loaner which must be imported from outside. and there are many companies Recording may not be complete at times because the company officials did not record or incorrectly recorded and the CSSD staff do not know the use of the tool in advance. Therefore, sometimes the operating room staff do not know the delivery of the equipment. Implementation of process sterile tools It takes time to track down the tools. causing sometimes the equipment to be dropped that will be used in surgery or tool not found causing the postponement of the surgical case

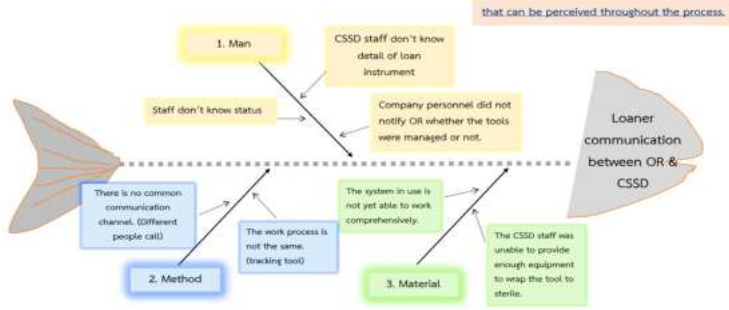
The Central sterile supply department (CSSD) has solved the problem to work conveniently more quickly and reduce postponement of surgical cases due to unavailability of tools reduce tool tracking problems can't find tools dropped, lost, such problems. directly affect the patient undergoing surgery

Objectives

In order to minimize surgical delays in patients requiring the use of loaner equipment, and to reduce the communication time between departments, efforts are being made to ensure that the loaner equipment is readily available and functioning properly, aiming for zero delays. This initiative also aims to streamline communication processes between different units for more efficient coordination.

Tool: Fish Bone Diagram

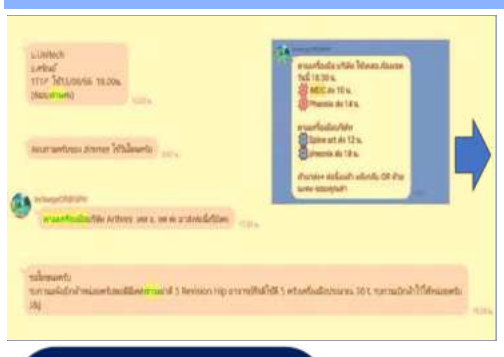
Summary of 3 main reasons that will be used to make improvements in Phase 1Failed to check Loaner tool status.Officers do not act the same.There is no clear communication channel that can be perceived throughout the process.



Methodology

In the first cycle of the PDCA (Plan-Do-Check-Act) process, there has been a transition from manually recording data in logbooks to inputting information through Google Forms. Additionally, notifications are now sent via Line Notify to a dedicated group to alert operating room staff and infection control personnel. This aims to keep them informed about the status of equipment, facilitating easier monitoring compared to the traditional method of recording in logbooks

In the second cycle of the PDCA (Plan-Do-Check-Act) process, it was identified that the Line Notify system, which provided a one-time notification, did not allow for continuous monitoring of tool status throughout the entire process. The inconsistency in notifications led to a realization that there were time gaps in searching for information. As a response to this, a "Web Application" has been developed. This application is designed to enable staff from the company, operating room personnel, and infection control staff to conveniently and swiftly check the status of loaner equipment in each case. The information is presented in a dashboard format, allowing real-time monitoring and immediate access to critical data.



Result

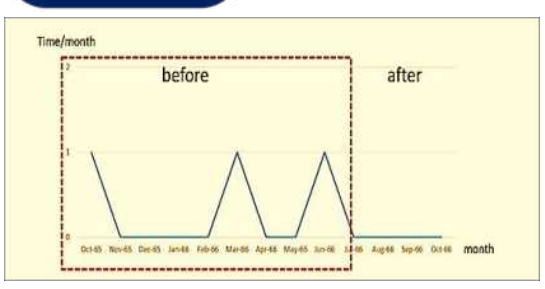
After implementing the Web Application, staff from all departments can easily and quickly check the status of loaner equipment, streamlining operational processes. Checking the dashboard reduces work time and helps prevent surgical delays. Additionally, it has contributed to increased satisfaction ratings between departments.

1.The satisfaction score for using the Loaner Equipment Status Tracking Application is equal to or greater than 4 out of 5.

2.The goal is to reduce the occurrence of incidents where loaner equipment is not delivered on time for surgeries or causes surgery postponement to zero incidents.

3.The objective is to decrease the time spent on searching or verifying loaner equipment information for surgeries at SiPH to zero minutes.

Result



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World Federation for Hospital Sterilisation Sciences

Sociedad de Profesionales en Esterilización de Chile

Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos

Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

IMPROVEMENT AND IMPLEMENTATION OF CENTRAL STERILE SUPPLY DEPARTMENT TRAINING PROGRAMAFTER 2 YEAR AT VIETNAM NATIONAL CHILDREN'S HOSPITAL

Dang Thi Thu Huong1, Dang Thi Mai Chinh1, Nguyen Bui Toan Thang1, Tran Quang Nghia1, Tran Minh Dien1

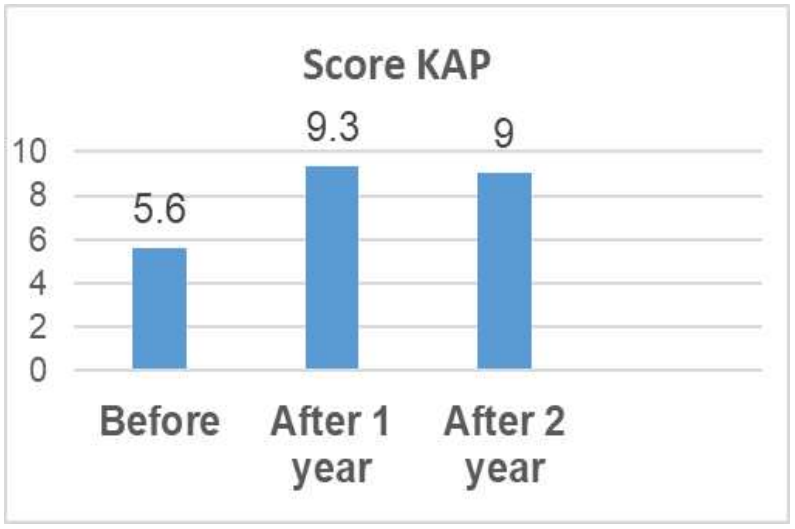
1. Vietnam National Children'S Hospital;.

Corressponding author: Dang Thi Thu Huong

Aims: to evaluate methods to improve the training system and improve learning efficiency and job satisfaction of CSSD staff and to evaluate the results of continuous training course at the VNCH after 2 year of implementation.

Methods: Acombined quantitative and qualitative study was conducted on a total of 100 trainee participating in a training courses during the year period from 2022 to 2024.

Results: A total of 100 trainees, nursing (36/100), CSSD (25/100); Housekeepers (22/100), other staff 17% (17/100)



**(p value =0.000, p≤0.01)*

Evaluation content	Pre-training N = 68	Post-training N = 68	p
Independently and confidently handle problems at work	3.8 (0.69)	3.8 (0.58)	< 0.001
Sharing experiences between colleagues	3.9 (0.75)	3.6 (0.57)	< 0.001
Colleagues trust your ability to handle work	4.2 (0.8)	4 (0.57)	< 0.001
Completeassignedtasks	4.4 (0.74)	4.1 (0.6)	< 0.001
Improve efficiency in the workplace	4 (0.71)	3.9 (0.54)	< 0.001
Total	4.2 (0.71)	3.8 (0.58)	< 0.001

The results of the assessment of the ability to apply knowledge of the training program have more than 80% of the students rated at 4 (*on the Likert scale from 1 to 5 with: Likert 1: very poor; Likert 2: poor; Likert 3: Average; Likets4: Good; Likert 5: Excellent*).

Conclusion: The training program changed the KAP of medical staff after 2 year. The results are evaluated in terms of the trainee's ability to apply knowledge after training.

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SURGICAL PLANNING BASED ON REAL MATERIAL AVAILABILITY – INTEGRATION BETWEEN TRAZINS AND SELENE SYSTEMS

[2]Rubio L.[1], Rico G.[1], Cousillas N.[2], Martínez C.[2], Úbeda S.[2], Úbeda A.

1. Los Arcos del Mar Menor General University Hospital - Murcia, Spain 2. Gestión y Trazabilidad del Instrumental Quirúrgico S.L. - Barcelona, Spain

INTRODUCTION

Surgical instruments are a key and decisive factor in the success of a surgical procedure. It is mandatory to keep the instruments in an optimal state of quality, to guarantee patient safety.

The Los Arcos del Mar Menor General University Hospital in Spain has a complete inventory of surgical instruments, with instrument-level marking and a comprehensive maintenance plan, as well as the state-of-the-art Trazins WS traceability system, which guarantees the registration of all processes, thus increasing patient safety.

Furthermore, to ensure patient safety, it is also necessary to allow time enough between the use of each instrument tray, so that it can be properly reprocessed, ensuring thorough cleaning, disinfection, and sterilization of the instruments.

Nevertheless, the lack of information on the available instruments when surgical programming is carried out, means that on many occasions it is not possible to correctly reprocess the instruments, making it difficult to maintain the instruments and generating conflict situations between the Surgical Department and the Reprocessing Unit of Medical Devices.

OBJECTIVES

Implement an application that facilitates the planning of surgical interventions based on the real-time availability of materials, in a straightforward manner and without the need to pre-parameterize the type of instrument tray used for each intervention.

METHODS

At Los Arcos del Mar Menor General University Hospital in Murcia, Spain, the integration between the SELENE and TRAZINS computer systems facilitates the coordination between surgical scheduling and material availability.

1. TYPIFICATION OF INSTRUMENT SETS IN TRAZINS WS

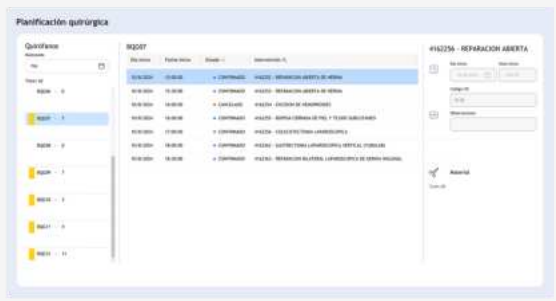
Specific functionality of the TRAZINS WS computer system, designed to optimize available resources. It allows grouping the instrument trays that can be used for the same type of intervention.

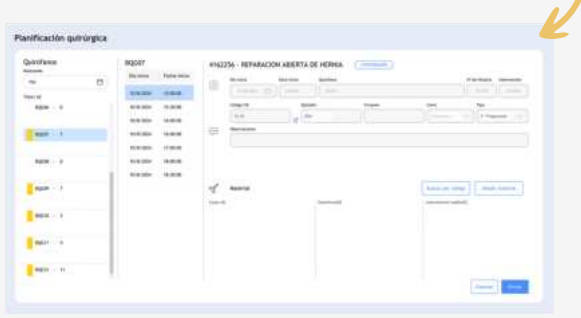
2. SET TYPE ASSOCIATION – CIE CODE

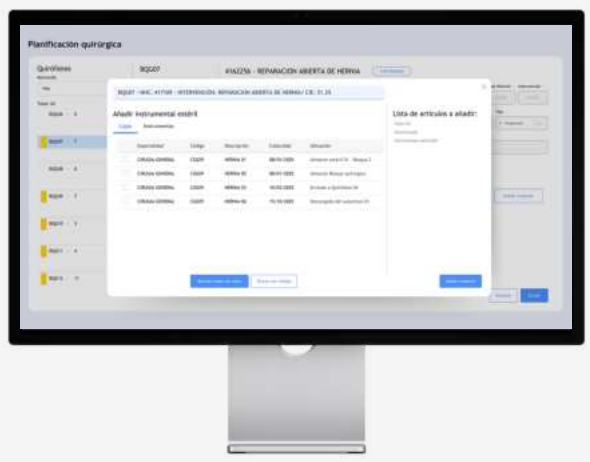
Development of a learning system based on the information about the trays used in different surgical procedures. This information is recorded in SELENE and retrieved in TRAZINS through integration.

3. AVAILABLE MATERIAL INFORMATION

Surgical scheduling is done in SELENE and retrieved in TRAZINS WS via integration. TRAZINS WS displays the available sets according to the type of intervention, sorted by their expiration date.







DISCUSSION

Interoperability between the computer systems that manage surgical planning and instrument traceability can significantly help in this regard by enabling scheduling based on the actual availability of surgical sets.

Interoperability between systems allows for the following:

- Organization of work in the Reprocessing Unit according to the surgical schedule, with programming available directly from TRAZINS WS.
- Real-time information on material availability in the Surgical Department, based on the scheduled type of intervention. This information is available directly from SELENE.
- Optimization and standardization of the available instrument trays, providing statistics on their usage and using algorithms that distribute the workload evenly, thus balancing the frequency of use and contributing to extending their lifetime.

SET ANALYSIS LOS ARCOS HOSPITAL

910	Sets	15.477	Instruments
275	CIE codes performed	175	Types of sets

CONCLUSION

This software solution can be an effective solution for surgical planning issues in hospitals, transforming an innovative idea into a practical tool that significantly improves operational efficiency, being able to integrate with the existing medical history system, thus facilitating the work of staff and reducing the complexity of surgical planning in the centers.

With this new solution, surgical interventions can be planned based on real availability of the material, through a machine learning system that allows determining the necessary sets in each procedure without the need for previous parameterization by the user, thus automating the process and reducing the possibility of error.

HOSPITAL UNIVERSITARIO LOS ARCOS DEL MAR MENOR

TRAZ INS

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World Federation for Hospital Sterilisation Sciences

SPECH Sociedad de Profesionales en Esterilización de Chile

INDE Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos

Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

Barriers and facilitators to event-related sterility: a qualitative approach for nursing professionals

Vanessa Aparecida Vilas-Boas, Louise Assumpção Rondini, Kazuko Uchikawa Graziano, Maria Cecília Bueno Jayme Gallani, Milena Pavan Serafim

Descriptors: Sterilization; Shelf Live; Nursing.

Funding: This work was supported by the Fund to support teaching, research and extension (FAEPEX nº 2497/21).

INTRODUCTION

The sterility maintenance of health products depends **good practices** of work among all the processing stages. However, studies have identified a **lack of care** with sterilized health products[1].

Understanding the factors underlaying the lack of compliance in the adoption of new regulamentations for verifying the sterility of health products, becomes fundamental to propose interventions that will be able to promove the expected behavior of nursing professionals enfermagem[2].

OBJECTIVE

To explore the motivations and barriers to implementing the event-related sterility to healthcare product among nursing professionals.

METHODS

Design: Qualitative study of inductive and descriptive approach, based on the theory of planned behaviour (TPB)[3].
Location: Public Hospital - Central Sterile Services Department (CSSD), Surgical Centre, Neurology Ward and Emergency Unit.
Sample: Nurses and Nursing technicians.

Data collection: October 2021 - September 2022
Analyses: Thematic analysis
Ethical aspects: Approved by the Research Ethics Committee (Resolution No. 466/2012).

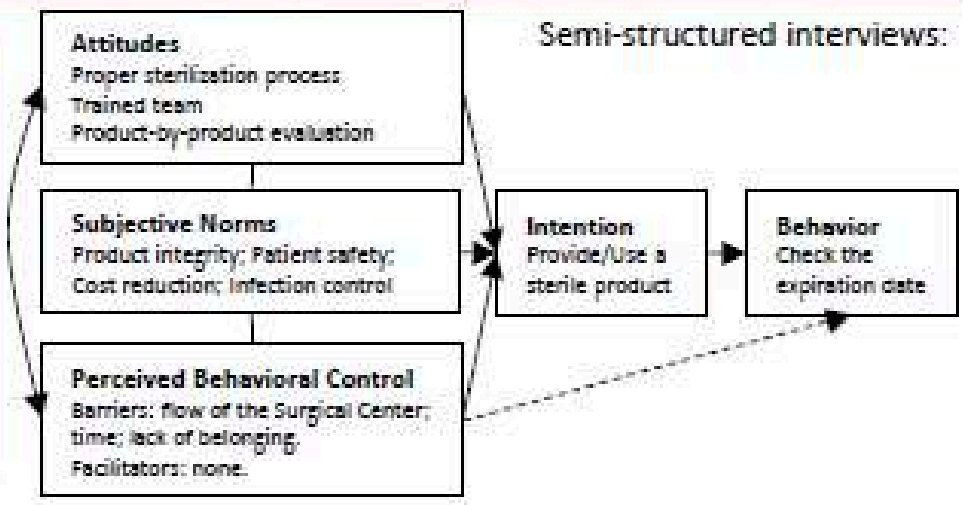
RESULTS

Systematic observation:

- Failures to check the integrity of the packaging
- Improper handling
- Improper storage
- Related events

There are protocols written on CSSD, but they do not cover the concept of event-related sterility.

Semi-structured interviews:



DISCUSSION

Nursing plays a fundamental role both in the processing of healthcare products and in their use by patients[4].
There is concern about monitoring the sterilization expiration date, but data on package integrity inspection does not appear.

CONCLUSION

- Construction of instruments
- Package integrity assessment plan
- Development of education strategies

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25th wfhss CONGRESS

Optimizing Tray and Instrument Inventory

Sterile Processing Department
How'dy Villano, CRCST - Program Administrator
Cedars Sinai Medical Center, Los Angeles

Background

Sterile Processing Department is known as the Heart of the Hospital here at Cedars-Sinai Medical Center. We manage multiple service lines across seven floors of operating rooms. Each floor containing a minimum of six rooms, with the maximum number reaching up to 13. On average, there are about 120-130 cases per day. We process 1000 trays per day and about 25,000 per month. Given this high volume, optimizing and maintaining adequate inventory of trays and instruments becomes crucial for ensuring patient and the success of our daily operations.

Projects and process improvements implemented in 2023

The year 2023 saw significant project developments, key process improvements and the application of new devices that matched the industry standards.

Improvements included:

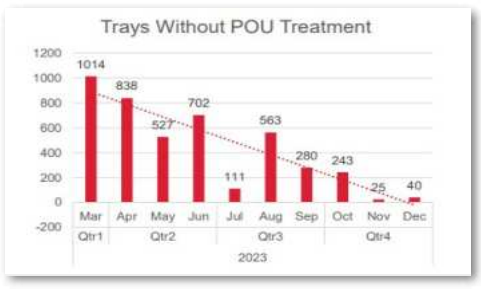
- Ortho Consolidation and Optimization Projects
- Streamlined new instrument requests by using QR Code
- Laser etched barcodes for tray labeling
- OR and SPD Point of Use Cleaning improvement collaboration
- Implementation of new inspection devices that matched the industry standards
- Developed model for predicting capital budgetary needs

Actions

- Ortho Consolidation and Optimalization Project: Collaborated with surgeons to combine sets that are frequently used together and optimize instrument to only include what is used.
- Streamlining instrument request by using QR code: Created a digital form that can be filled out by scanning a QR code that automatically populates in a instrument request tracker.
- Laser Etched Barcode for Tray Labeling: Moved away from sticker barcodes to metal laser etched labeling system.
- OR and SPD POU Cleaning Improvement Collaboration: Teamed up with the OR staff in improving POU cleaning by providing education, conducting audits with Periop Nurse Managers and presenting data collected using our tracking system scan points to Epidemiology/Infection Prevention Team.
- Implementation of New inspection devices that matched the industry standards: Provided the SPD staff with new inspection devices such as borescopes, insulation testers, and EndoCams.
- Developed model for predicting Capital Budgetary needs: Used real time data by running a report on usage exceeding inventory, gathered through our tracking system and created a predictive model of our capital budgetary needs.

BEFORE

Prior to Consolidation and Optimization Knee Trays



AFTER

After Consolidation and Optimization Knee Arthroplasty Tray

Consolidation vs Optimization of Trays

Consolidation and optimization are both strategies aimed at improving efficiency and effectiveness but differ in focus and approach.

Consolidation:

- Definition : Consolidation involves combining multiple trays into a single set.
- Focus : Streamlining trays by reducing redundancy and complexity of sets. This could involve merging multiple sets into one due to similarity of instruments or service line.
- Goal: The primary goal of consolidation is to lessen tray inventory and avoid having multiple of similar sets.
- Example: Combining Minor, Plastic and Mastectomy trays due to similarity of instruments and purpose of the trays.

Optimization:

- Definition : Optimization involves making the best possible use of resources by determining what is actually used and needed in the tray by the surgeons during procedures.
- Focus: It focuses on fine-tuning existing trays by using real information gathered from observing procedures and even information provided by OR staff including Surgeons and Surgical Techs.
- Goal: The primary goal of optimization is to save cost, enhance productivity and effectiveness of a tray by including what is needed vs what is perceived as necessary.
- Example: Gathering information from Surgical Techs and Surgeons on what is being used from 3 different trays to create a single simple and effective set.

Results

- Ortho Consolidation and Optimization Project:
  - √ Total Shoulder Retractor Tray, Bankhart Retractor Tray, Stone Shoulder Instrument Tray, and Hawkins Bell Retractor combined and optimized to create Shoulder Retractor Tray. This reduction eliminated the reprocessing of 5,716 instruments annually, which equates to $7659 annual savings.
  - √ Klapper Knee Tray, Major Ortho Tray, Penenberg Knee Tray, Rajaee Knee Accessory, and Spitzer Knee Tray combined and optimized to create Knee Arthroplasty Tray. This reduction eliminate the reprocessing of 112,254 instruments annually, which equates to $150,420 annual savings.
- Streamlining customer instrument request by using QR code
  - √ Implementation of QR code technology for instrument requesting enhanced efficiency, accuracy and traceability, ultimately contributing to improved patient care and operational effectiveness in SPD. 1,068 instrument requests have been processed in the new system, with demonstrated customer satisfaction.
- From Sticker Barcodes to Laser Etched Metal Labels
  - √ Moving from sticker barcodes to metal laser etched ones led to increased durability, longevity and improved sterilization compatibility of our tray labeling system. 1,563 instrument sets have been laser etched to date. The missing instrument frequency has reduced from a peak of 32,167 to 892 in a 1 year time frame.
- OR and SPD collaboration improving POU cleaning practices led to
  - √ Safer surgical procedures, higher quality of instrument reprocessing and even helped avoid damaging of instruments in turn helping save cost in the long run. This also provided an opportunity for SPD and OR collaboration, improving relations between the 2 departments. POU compliance has improved from a peak rate of 1,014 down to 40 occurrences of non-compliance.
- Implementation of new devices such as borescopes, insulation testers, and EndoCams
  - √ Introduction of borescopes, insulation testers, and EndoCams helped the SPD staff conduct a more thorough and improved inspection process, early detection of instrument damage and minimized risk of contaminated items making it to the OR. The number of pro-active repairs increase by 40%.
- Developing a predictive model
  - √ Deployment of a predictive model for predicting capital budgetary needs enabled the organization to leverage real-time data, improve resource planning and foster a culture of continuous improvement and innovation.

Conclusions

In summary, the initiatives implemented in 2023 have yielded significant benefits across our operations. Consolidating orthopedic trays, streamlining instrument requests with QR codes, transitioning to laser-etched metal labels, and collaborating on POU cleaning have all led to cost savings, improved efficiency, and enhanced patient . Introducing new inspection devices and developing a predictive model for budgetary needs further exemplify our commitment to innovation and excellence. These efforts reflect our dedication to continuous improvement and optimizing patient care.

What's next?

2024 will continue with optimization projects branching out to other service lines and specialties. We will focus on Data driven solutions and search for more opportunities of collaboration between OR and SPD such as Dr. Preference Card clean up project and other similar endeavors.

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World Federation for Hospital Sterilisation Sciences
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Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

Sterilant Residuals on Medical Devices Following Sterilization

Shresha Manohar M.Sc., Keyvan Nowruzi PhD.

Advanced Sterilization Products
33 Technology Dr., Irvine CA 92618

Introduction

Hydrogen peroxide gas plasma (HPGP) sterilization systems are widely used to sterilize heat-sensitive medical devices and instruments, such as endoscopes, surgical tools, and delicate plastic components. Per, ISO EN 109931, removing residues is essential for safety, material preservation, and overall cleanliness of medical device that have direct or indirect contact with the patient's body during intended use1. In HPGP sterilizers, decomposition of hydrogen peroxide (H2O2) to O2 and H2O occurs spontaneously by exposure to 'Plasma', providing serious advantage of safety - for the 'Sterilizer Operator' (environment) the contents of the load and ultimately ensuring a safer environment for patients2. Chemical sterilization methods, offer various strategies to remove sterilant residuals from the sterilization chamber and load3. Some sterilizers in market that use VHP, employ physical removal of chemical sterilant by vacuum3. This study aims to determine the effect of varying treatments of plasma and vacuum has on material sterilant residuals and the H2O2 vapor emissions post vaporized hydrogen peroxide processing.

Method

A HPGP sterilizer was configured to remove hydrogen peroxide using either plasma or vacuum (no plasma). To evaluate residual H_2O_2 on processed materials, quantification was performed according to ISO EN 10993-174. Polyurethane (PU) and Radel coupons (1.5 cm x 3.5 cm) were pre-conditioned overnight at 18°C/50% RH before being processed through customized cycles, each cycle consisting of two exposure phases with one injection per phase, applying plasma or vacuum (no plasma) during pre-exposure and/or post-exposure phases. Ten coupons per cycle were processed, and post-processing, H_2O_2 residues were extracted and analyzed via spectroscopic calibration in triplicate5.

To evaluate H_2O_2 vapor emissions post-processing, the area around the sterilizer was monitored using ChemDAQ Steri-Trac® sensors. Two sensors were placed above the chamber door, and data was tracked on a Micro Center TW700 Winbook tablet. Sterilization cycles using plasma or vacuum (no plasma) were tested with both an empty chamber and a 50lb. load, with peak average H_2O_2 vapor levels recorded at the end of two cycles.

Results

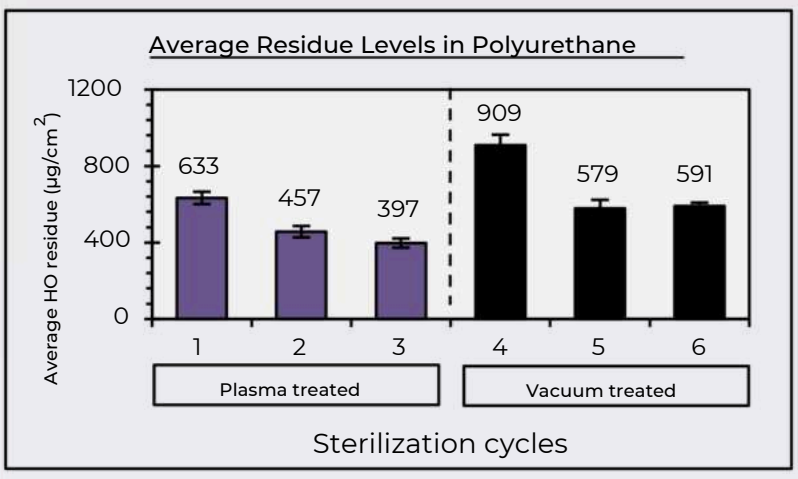
H_2O_2 process residues: Table 1

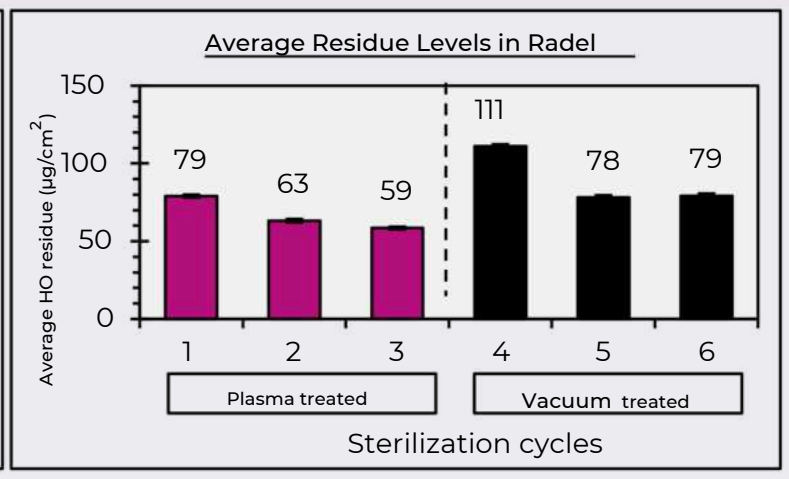
- Average H_2O_2 residue amounts ranged from 909 µg/cm^2 to 59 µg/cm^2 for material coupons. The average H_2O_2 residues from cycles that used plasma are 29% lower in PU and 25% lower in Radel compared to cycles that used only vacuum (no plasma)5.
- **Cycles 1 and 2** had similar pre-exposure conditions, but in Cycle 2, the extended plasma during the post-exposure phases resulted in a 27% lower residual level in PU and 20% lower in Radel.
- **Cycles 2 and 3** had similar post-exposure, but in Cycle 3, the extended plasma during pre-exposure phase resulted in a 13% lower residual level in PU and 6% lower in Radel.

In summary, the more time exposed to plasma correlated to lower residuals whereas the more time exposed to vacuum did not always correlate to lower residuals

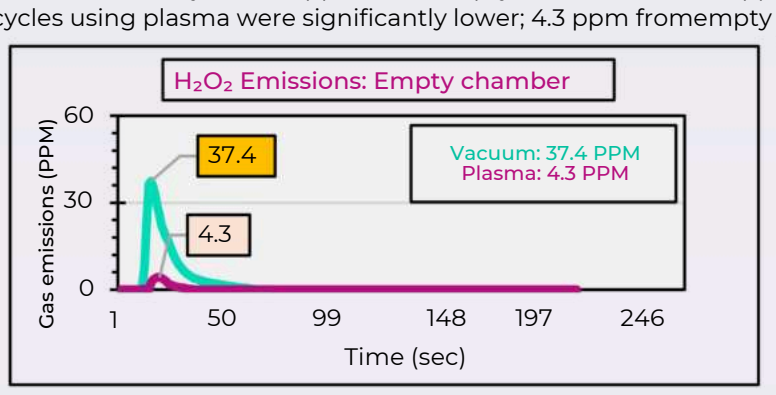
Table 1: Average H_2O_2 Residue (µg/cm^2) for material coupons processed through prototypical cycles

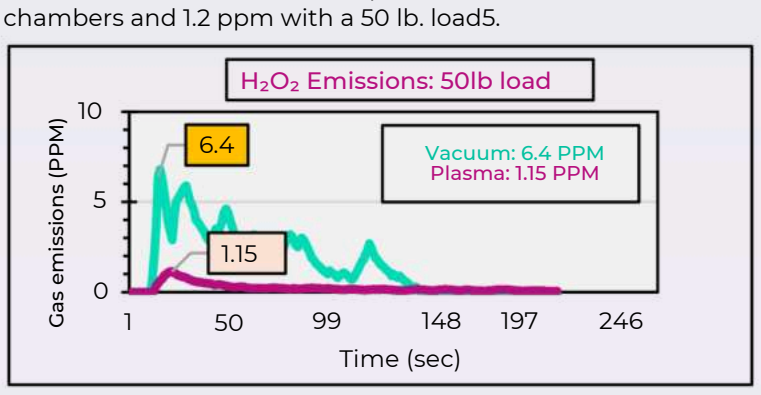
Cycle No.	Treatment	Sterilization cycle phase			Average H2O2 Residue (µg/cm2)	
		pre-exposure	Post exposure 1	Post exposure 2		
		Time (min.)	Time (min.)	Time (min.)	Polyurethane	Radel
1	Plasma	3.3	3.7	3.7	633 ± 32	79 ± 1
2		3.3	7.2	7.2	457 ± 30	63 ± 1
3		6.6	7.2	7.2	397 ± 24	59 ± 1
4	Vacuum	3.3	3.7	3.7	909 ± 55	111 ± 1
5		3.3	7.2	7.2	579 ± 45	78 ± 1
6		6.6	7.2	7.2	591 ± 18	79 ± 2





H_2O_2 Vapor Emission: Cycles with vacuum (no plasma)release significant levels of peroxide vapors when the chamber door is opened after thesterilization cycle; 37.4 ppm from empty chambers and 6.4 ppm with50 lb. load. The H2O2 vapors released after sterilization cycles using plasma were significantly lower; 4.3 ppm fromempty chambers and 1.2 ppm with a 50 lb. load5.





Conclusion

- Plasma treatment has been shown to be more effective than vacuum-only (no plasma) treatment in lowering H_2O_2 residuals on materials.
- H_2O_2 emissions from the chamber after a plasma sterilization cycle are significantly lower compared to a vacuum-only (no plasma) cycle, with approximately 8 times less emissions from empty chambers and 6 times less with a 50lb. load. This makes plasma a safer and more efficient alternative6.
- Plasma technology stands as an available and effective tool in HPGP sterilization to achieve better residue control and minimizing exposure to both workers and the environment2,6.

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The shelf life of sterilization of health products used in health care

Elizangela Silva Wieler[1]

Introduction: This study presents the importance of Material Sterilization Centers (MSC) and the sterilization process, advances in technology, advanced techniques for cleaning, preparing and storing materials, clothing and the sterilization expiration date of materials used in health care and the processes that guarantee the efficiency of the unit, in addition to the types of packaging and best practices adopted, according to the requirements of Resolution No. 15, published by Anvisa in 2012, which provides for good practice requirements for the processing of health products and other measures.

Objectives: The sterilization validity period of materials used in health care and the processes that guarantee the efficiency of the unit, presenting the types of packaging and the most appropriate practices to guarantee validity and avoid possible storage failures, demonstrate the importance of the sterilization validity period used in the health area and discuss the types of packaging, storage and validity period of hospital medical items processed in the materials and sterilization center (CME), present storage specifications, deadlines and processes.

Method: A bibliographic review of publications available in Pubmed, Scielo and Google Academics was performed using the following descriptors: health products OR sterilization OR sterilization OR sterile material AND CME. Thirty-six publications were found, and the exclusion criteria were: full text; 10 years of publication; and abstract. Eleven publications relevant to the topic remained and were analyzed and discussed.

Results: The material is not contaminated by storage time but by events that damage the packaging and sterility should be related to the events and not to the time as incorporated in the Recommended Practices of the Association of Perioperative Registered Nurses (AORN). The following fundamental processes were identified: purging – washing and decontamination of the area; cleaning that can be automated by washer-disinfectors; decontamination to eliminate microbes; disinfection and destruction of microorganisms; sterilization; storage and distribution; packaging for sterilization. Events harmful to the patient may be linked to the loss of integrity and functionality due to numerous or inadequate processing.

Conclusion: The validity of medical-hospital articles is linked to the quality of the packaging and storage location of the health products and to the efficiency of the processes carried out by the Material and Sterilization Centers (MSC). The packaging for storing the materials determines their shelf life, keeps the contents sterile after reprocessing and ensures the integrity of the material for use. The processes of reception, cleaning and disinfection, preparation of health products with cleaning inspection, assessment of completeness, functionality and selection of sterile barrier are of great importance against infection. Hospital infections are the result of inadequate practices and failures in the work process. The physical location should allow a continuous and unidirectional flow in order to avoid the crossing of contaminated and sterilized health products.

Keywords: health products; sterilization; sterile material

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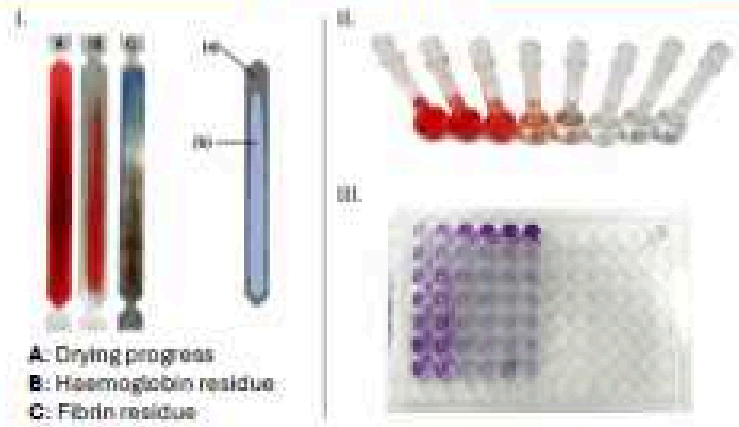
Influence of drying time on the removal of blood from medical devices

B.R. Wulff, S. Lohse, M. Tschoerner
Chemische Fabrik Dr. Weigert GmbH & Co. KG, Hamburg, Germany

Introduction

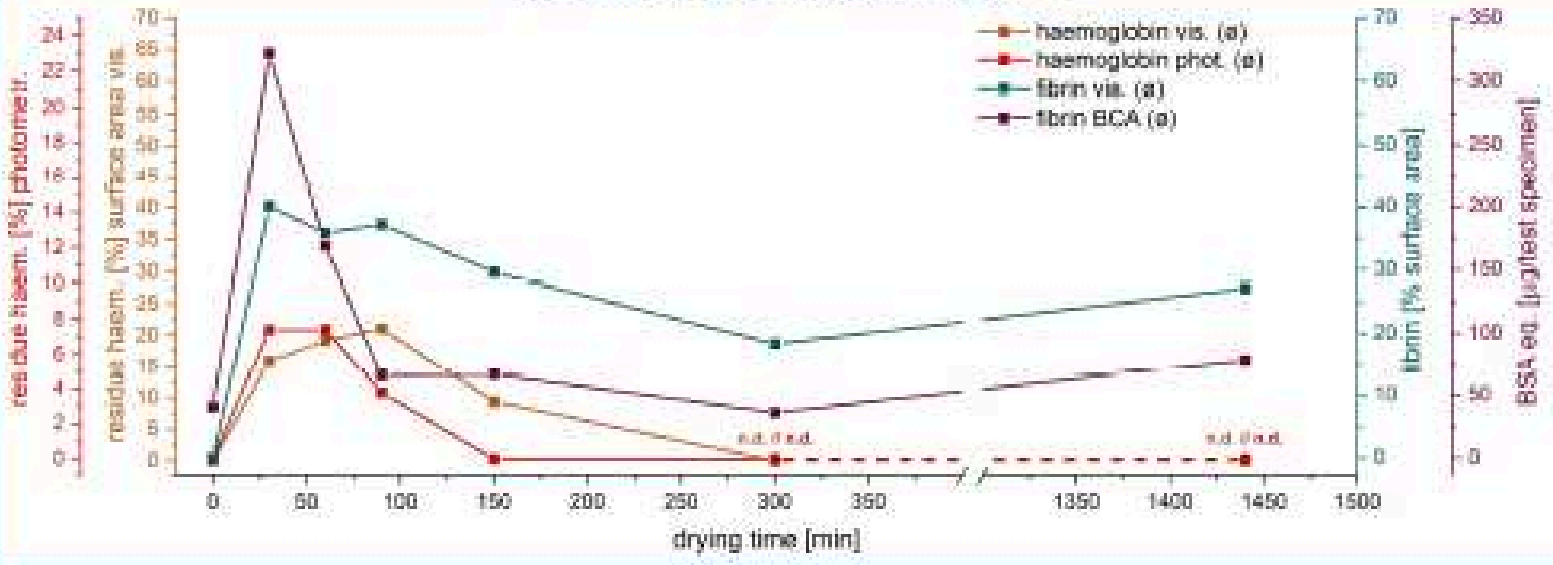
- When processing surgical instruments after use in the operating theatre, the safe removal of blood and blood-containing contaminations is an essential task
- There are several recommendations concerning the ideal timeframe for cleaning medical devices based mainly on practical experience
- So far, few systematic studies on the influence of the drying time of blood residues before reprocessing surgical instruments have been conducted
- In this study we investigated the effect of different drying times on the subsequent cleaning result in the removal of blood

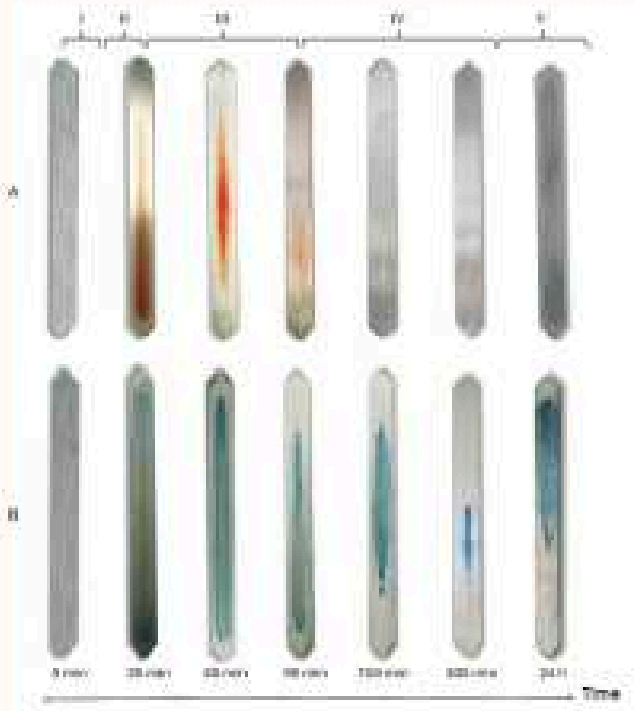
Methods



- Stainless steel plates contaminated with sheep's blood were used as samples in immersion bath experiments
- Protein residues were quantified spectroscopically (BCA, haemoglobin) and visually using the integrals of the contaminated surface

Results and Discussion





- The amount of both haemoglobin and fibrin residues remaining after the cleaning experiments was found to be significantly dependent on the drying time of the blood specimens (A: haemoglobin, B: fibrin / residual protein)
- The highest amount of protein residues remained after a drying time of 30 min to two hours, while directly after contamination or after longer resting periods the blood could be removed more easily
- Based on the data obtained, it can be deduced that there are standing times that are favourable for reprocessing and also times when the blood residues are particularly difficult to remove
- Due to the simple geometry of the samples, the experiments only allow conclusions about superficial contamination with blood, in case of joints, channels or other more complex geometries both drying times and drying dynamics may vary

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STERILE PAPER-PLASTIC BARRIER SYSTEM FOR PRESSURE STERILIZATION

by
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Original scientific paper

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The sterile paper-plastic barrier system is used for packaging final sterilized medical equipment to protect sterilized items.The sterilization medium in the autoclave is saturated vapor . The pres sure exerted by saturated steam influences the expansion of the gas in the paper-plastic sterile barrier system and may cause the sterile barrier system to be collapsed. There is a correlation between the rate of pressure variation in the chamber of the pressure sterilization equipment and the coefficient of gas expansion of the sterile paper-plastic barrier system.The paper-plastic sterile barrier systems used in hospitals are factory tested according to GB/T 19633 and YY/T 0681 stand ards and the quality can satisfy the needs for preparing sterile barriers. Although part of the parameters of the preparation process are recommended by the manufacturer, the clinical use of instrument packs to meet the needs of a single procedure always results in large and heavy instrument packs. Paper-plastic wrapping bags are available in sizes that allow the wrapping of larger and heavier plastic surgery instruments.

The top of the paper-plastic sterile barrier system resembles an arch once it has been inflated, its surface tension can be approximately calculated by the Young-Laplace equation .

$$\sigma = \frac{1}{4} D(p_{\text{in}} - p_{\text{out}}) \quad (1)$$

When the surface tension is larger than the tensile strength of the bag, breakdown occurs. A larger curvature radius leads to a larger surface tension, so the flat surface is easy to be broken under the inflation pressure or an external force.

According to the gas state equation:

$$p_{\text{in}} V = \text{R}T \quad (2)$$

where R is the molar gas constant, T – temperature inside the bag, and V – the inflated air vol ume of the bag, eq. (1) becomes:

$$\sigma = \frac{1}{4} D\left(\frac{\text{R}T}{V} - p_{\text{out}}\right) \quad (3)$$

Equation (3) implies a small volume is peculiarly prone to breakdown.

Pressure change during the inflation and the exhaust is illustrated in fig. 1, during the inflating process, the pressure increases with time, while an opposite process occurs during the exhausting process. When the inflating process stops, the pressure keeps unchanged until ex haust. During the exhausting process, the surface tension is released partially, and some part of surface become more plat, so it is more prone to breakdown as shown in fig. 1(b)

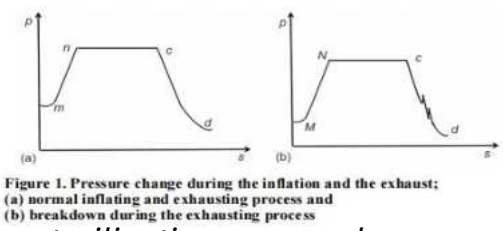

Figure 1. Pressure change during the inflation and the exhaust; (a) normal inflating and exhausting process and (b) breakdown during the exhausting process

During the pressurized steam sterilization process,heavy surgical instruments in paper-plastic packages were repeatedly subjected to a bag break after sterilization. Through interrogation experiments, it was found that the ambient tempera ture validated paper-plastic packaging IS011607-2-2006 Final Sterilised Medical Device. Packaging Part 2: Confirmation Requirements for Forming, Sealing and Assembly Processes were all satisfied, but the burst test validation method for paper-plastic packaging for high temperature and high pressure environments was not incorporated. Considering that the test ing of paper-plastic packaging is at standard atmospheric pressure at ambient temperature, the addition of burst testing of the equipment air inlet rate and the gas expansion coefficient of the paper-plastic aseptic barrier system will better enable the function of the aseptic barrier in special environments.

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Examination of ophthalmic phaco handle using borescopes and adenosine triphosphate (ATP) tests: a single-center observational study

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Aim

Cataract surgery is one of the most voluminous surgical procedures in ophthalmology, and the ophthalmic phaco handle is an essential instrument. If not disposed of properly, trace amounts of detergents or chemical contaminants that can be well tolerated in other body cavities may lead to serious consequences when they enter the eye, with the development of Toxic Anterior Septal Syndrome (TASS). To evaluate the value of current reprocessing procedures and borescopes in the visual inspection of phaco handle by performing borescopes visual inspection and adenosine triphosphate (ATP) tests of phaco handle.

Methods

The study was conducted in a large tertiary care general hospital where all ophthalmic surgical instruments, including phaco handle, were centrally disposed of by the sterile processing department (SPD) within the healthcare facility after use. A total of 41 phaco handles were subjected to two examinations.

Results

Borescope examination revealed that 56.1% of the phaco handles had foreign material in the lumen or a variety of structural damage, including corrosion, rust, green lint, and discoloration. In particular, pitting corrosion of varying degrees was found in 24.4% of the perfused lumens, mainly at the interface, in the middle of the lumen, and at the outlet, in the form of flakes. However, the cleaning quality of all handles in the ATP bioluminescence test was judged to be satisfactory.

Conclusions

This study demonstrated the value of a borescope in the visual inspection of phaco handles, visualized structural damage inside the lumen, and helped us to improve our current cleaning procedures. For example, informing ophthalmic nurses to promptly use sterile distilled or deionized water to rinse the inside of the handle lumen, prohibiting sterile towels containing textile fibers from being laid on the table surface by sterile supply staff, and promptly repairing or discontinuing the use of handles with internal structural damages, all of the above measures have further ensured patient safety.

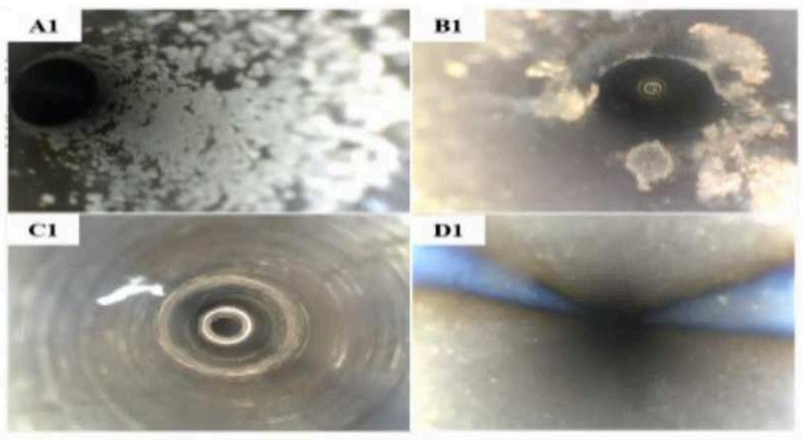

Fig. 1 Phaco handle borescopes results

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Creating a Paperless Environment for the Sterile Supplies Unit

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INTRODUCTION

The Sterile Supplies Unit (SSU) at the Hong Kong Children's Hospital is responsible for managing sterile items and providing sterilization services to all sectors of the hospital. As the Hong Kong government will implement Municipal Solid Waste Charging which will charge all sectors in Hong Kong based on the quantity of waste disposal, the SSU embarked on a mission to collaborate with the government and implement waste reduction policies. By adopting waste reduction measures, the SSU team aimed to significantly decrease waste output and create a more sustainable working environment.

ANALYSIS & ASSESSMENT

Below were information collected for assessment,
- record retrieval times
- storage capacity
- staff feedback from surveys and interviews

The primary cause identified was the heavy reliance on paper records, which resulted in a complicated workflow, inefficient record retrieval and limited storage space.

- Waste generated by disposal of unused papers
- Old records occupying valuable storage space
- Potential loss of crucial documents
- Time consuming in recording, distributing and tracing records for reprocessing items

METHODS

STRATEGY FOR CHANGE

INTERVENTION

① Integrating and documenting information of all reprocessing items in wards during preparation;

② Step-by-step implementation in four distinct phases since January 2023 instead of one-time change;

③ Pilot to selected wards by phases for new workflow and record keeping system;

④ Sufficient training with demonstration materials online for staff, nurses and ward users;

⑤ Regular supervision and review during and after the change process.

Phase 1 (1Q2023)
Enhanced workflow for plasma sterilization and requisition processes: An electronic template of requisition form was created for users to replace the paper form ordering.

Phase 2 (3Q2023)
Converted 90% of daily routine records for sterilizers, washers and validation tests into electronic version within the SSU.

Phase 3 (4Q2023)
Disposal of all old records kept in warehouse after scanning and storing in server.

Phase 4 (1Q2024)
Implementation of an electronic ordering system in collaboration with Cluster Central Sterile Supply Departments (CSSDs): All items (include disinfection / sterilization and ward-specific-items) could be ordered by the electronic CSSD ordering system.

RESULTS

- 75% ↓ Record Retrieval Time
- 40 File Boxes (30 x 23 x 24cm) Storage Space Utilization
- ALL Paper Requisition Forms Converted Into E-version
- HIGH Staff & User Satisfaction Level

CONCLUSION

The project successfully diminished excessive waste generation at source. It simplified and systemized workflow that reduced human errors and ensured standard sterilization services provided. Further improvement will be enhanced through regular reviews and feedback from concerned parties.

The transition to electronic record-keeping system cannot be accomplished at one stroke. It requires phase by phase practice and modification in between, as users need adaption period to be acquainted with the new workflow and system. Different opinions may be received from stakeholders. Adequate communication with concerned parties should be ensured in order to come up with the best solution, achieve consensus and optimize the outcomes.

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Sterile Supplies Unit

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World Federation for Hospital Sterilisation Sciences

Sociedad de Profesionales en Esterilización de Chile

Instituto Nacional de Esterilización y Reprocesamiento de Dispositivos Médicos

Sociedad Chilena de Enfermeras de Pabellones Quirúrgicos y Esterilización

A study of implementing a centralized leasing management model in the reprocessing of flexible endoscopes

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KEY WORDS:

Flexible endoscopy; centralized leasing management model; equipment turnover; delayed return rate

AIM:

Refine the management of flexible endoscopes, to reduce operating costs, ensure reprocessing quality, meet the needs of clinical use, and supply timely and effectively.

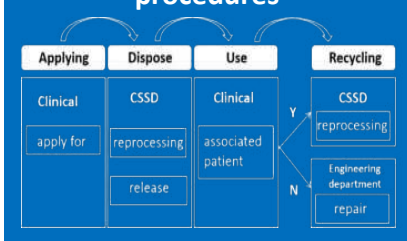
METHODS:

1. Set up a flexible endoscope centralized leasing management center led by Engineering department and CSSD.

2. Established a new management system with five functions: asset management, cleaning and disinfection, maintenance, quality control and maintenance, and leasing operation.

3. The period from November 2021 to May 2022 was the experiment period implementing new centralized leasing management model. The period from May to October 2021 was the control period.Collected operation data and compared the results before and after its implementation. Meanwhile the number of staff and flexible endoscopes , and reprocessing flow of flexible endoscope all remain unchanged.

Application and return procedures



Timing statistical from tracking system

Maintenance module of tracking system

4. Add rental billing module and endoscope maintenance module to existing instrument tracking system.

4.1 The tracking system automatically records the lease duration, starting with "release time" and ending with "Return acceptance time". Thecharging period is set at 0-4h, 4-8h, and more than 8h. The longer the time, the higher the rent.

4.2 With the endoscope maintenance module, all endoscope failures are recorded and the root causes are determined by the ME department together with endoscope manufacturer. The clinic department shall be responsible for the maintenance only when the damage is due to its own fault, rest of them are handled by CSSD.

5. Evaluation indicators:

5.1 Turnover rate of endoscope: Effective number of endoscope deployment / (total number of endoscope × total number of days)×100%, where the effective number of endoscope deployment was the total number of endoscope deployed by Leasing Center during study period. Total days are total number of days during study period.

5.2 Rental time: The time from the issuance of each flexible endoscope to time of return.

5.3 Delayed return rate: Number of delayed returns / total returns ×100%, where delayed return is defined when the rental time is more than 4 hours.

5.4 Average maintenance time: Total maintenance time / total maintenance times x 100% .

5.5 Time from end of disinfection till clinical use.

5.6 Timely supply: The time from receiving the order to final release should not be more than 2 hours.

5.7 Overtime hours of CSSD endoscope reprocessing staffs.

Table 1

Indicator	Control Group (May-Oct.2021)	Experiment Group (Nov.2021-May 2022)	Rate of Improvement
Totalpieces offlexible endoscopefor circulation	4	4	
Total timesof circulation	246	362	
Average rental time	227 min	102 min	55%
Total cases ofdelayed return	112	41	63%
Total cases of maintenance	3	4	
Total days of maintenance	125	51	59%
Average maintenance time	41.6 days /piece	12.6 days/piece	70%
Average duration from completion of disinfecdtion steptill clinic use	147 min	72 min	51%
Number of user (Clinic department)involved	10	13	30%
Case oflong time delivery(longer than2 hours after order)	19	0	100%
Total OT hours of flexibel endoscope reprocessing staff	19h	7h	63%
Total OT hoursof staffs at Decontamination Area	126h	118h	
Overtime proportion offlexibleendoscope reprocessing staffs of CSSD	15%	6%	60%

RESULT:

*1.*Service condition of endoscope: Table 1

*2 .*Turnover rate of endoscope： Figure 1

3 . Rental time of flexible endoscope： Figure 2

4. Statistical resuits： Table 2

Figure 1

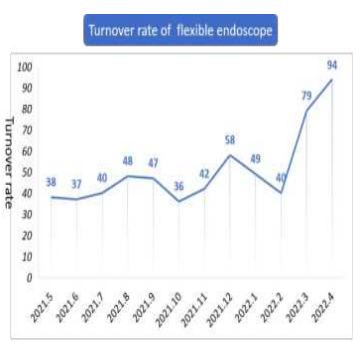


Figure 2

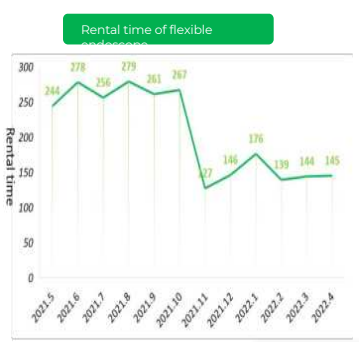


Table2

	Control Group	Experiment	Z/X²	p
averag useing time(min)	264	144.50	-2.882	<0.05
rate of delayed return(%)	45.53	11.33	90.98	<0.05
rate of overtime(%)	15	6	5.35	<0.05

CONCLUSION:

The study shows the new management model，developed based on practical problems we encountered, can shorten the time from soft endoscopic treatment to clinical use,can achieved significant improvement in a high quality and cost-effective flexible endoscope circulation.

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