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Oral Sessions

O_01

Contaminated endoscopes; to worry about, to ignore or to combat?

Margreet Vos[1]
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Session 1: Endoscopes, King Willem Alexander

Abstract not available.

O_02

The State of Endoscope Reprocessing – An American Perspective

Mary Ann Drosnock[1]
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Session 1: Endoscopes, King Willem Alexander

Biography:
Mary Ann Drosnock is the Senior Manager of Clinical Education at HealthMark Industries where she provides expertise on medical device reprocessing often presenting at conferences on effective reprocessing and infection prevention in endoscopy. Also, currently she is co-chair of AAMI Working Group 84, which is responsible for the ST91 national standard on flexible endoscope reprocessing and TIR99, which will address proper processing of ultrasound probes and dilators.
Previous to HealthMark, Mary Ann managed the Infection Control Program for Olympus America. There she had responsibility for Infection prevention & Device Reprocessing Functions. Prior to Olympus, MaryAnn worked as a pharmaceutical microbiologist and taught Microbiology courses at the college level.
MaryAnn has a B.S. in Biology and an M.S. in Quality Assurance and Regulatory Affairs. She is certified in Infection Control through APIC, as a Flexible Endoscope Reprocessor through CBSPD, is a Nationally Certified Registered Microbiologist and is an APIC fellow. Mary Ann also currently sits on the editorial board for AAMI BI&T journal and the PanAmerican Forum Journal.

The State of Endoscope Reprocessing – An American Perspective
Author: Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM), FAPIC

Aim: The aim of this presentation is to identify current requirements and trends in endoscope processing in the United States. These will be compared to European and world-wide recommendations to identify best practices for facilities to implement for process of flexible endoscopes. Adoption of these recommendations help to prevent endoscope-acquired infections.

Methods: As co-chair of AAMI WG84, which authors the ST91 document, the presenter will outline the current status of the document. ST91 is the US national standard for processing flexible endoscopes and has been widely adopted by facilities across the country since its initial release in 2015. ST91 gives comprehensive guidance and requirements for processing of all types of flexible and semi-rigid endoscopes in all healthcare settings. ST91 not only outlines the steps for how to process endoscopes, but also addresses staff training, competency, quality assurance steps, documentation requirements and sterilization considerations. Additionally, the program will stress the need for a quality system to be implemented in endoscope reprocessing per AAMI ST90, Quality Systems for Medical Device Processing.

Results: Current US Guidelines as well as US professional societies alike call for steps to be implemented to engineer quality into endoscope reprocessing through institution of a robust quality system. Aspects of a quality system to be include steps such as certification of employees, implementation of cleaning verification testing, process monitoring, tests, drying steps, endoscope surveillance cultures, proper device labelling, auditing processing steps, and proper transportation.

A quality management system (QMS) is defined as a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. Although ST90 is a

stand-alone standard, it is based on ANSI/AAMI/ISO 13485:2016 and follows the format of ANSI/AAMI/ISO 13485:2016. ISO 13485 is slowly gaining adoption by healthcare facilities around the globe. Adoption of ST90 by U.S. hospitals can be seen as a parallel event.

Establishment of a QMS is a very important step for health care facilities to standardize practice, provide quality products to customers and help in infection prevention by establishing and maintaining the highest-quality processes. Essentially, ST90 specifies minimum requirements for a QMS to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and non-manufacturer-related device failures. This standard provides the roadmap that facilities should use to establish a QMS that can maintain and deliver quality outcomes to its customers and patients.

An important part of a quality system is establishing and maintaining quality processes and equipment to ensure quality outputs. In order to achieve this high-quality process, equipment qualifications, also known as IQ/OQ/PQ, must be understood and followed. Although this concept has been around for years in other industries, such as pharmaceutical manufacturing, it has not been adopted in device reprocessing in healthcare settings as quickly. Now, with the release of ST90, the process of equipment qualifications for device reprocessing settings must be understood and implemented.

But taking this concept and applying it to endoscope processing by facilities employing manual processes can be conceptually difficult. How does this standard then apply to endoscope processing? What does the IQ/OQ/PQ concept look like for endoscope reprocessing and what would qualify to be performed in each of those categories?

IQ: Receiving the endoscope from the manufacturer, ensuring that all parts have come with the endoscope, that it has been installed correctly and is compatible with the video system, and that any calibration or maintenance schedules are known, etc.

Calibration/repair schedules may be established for the endoscope by the manufacturer, such as is the case with duodenoscopes, which must be returned at least annually to the manufacturer for maintenance. Beyond that, it is up to the facility to determine when an endoscope is returned to a repair vendor for maintenance. This may be determined based up facility policy, inspection results, cleaning verification results, and endoscope performance. An endoscope with an observed irregularity should not be used but should be inspected. If the irregularity is still observed after inspection, then it is recommended to contact the manufacturer.

OQ – These steps consist of initial checks inspection per manual, also known as the operational checks. These may be steps that a technical or even a biomedical engineer in a healthcare facility would perform.

It is recommended to perform all the preparation and inspection steps as outlined in the endoscope instruction manual for workflow, inspection of the scope, inspection of accessories, attaching accessories to the endoscope, inspection of ancillary equipment, connection of the endoscope and ancillary equipment together, and inspection of the endoscopic system as a whole. The entire device, including ancillary equipment and accessories should be identified and then assembled and tested as a system, including all the parameters to ensure that the device is operational during normal working situations. By doing this ahead of time, the facility can be assured of a safe and functional device for the first time that it is actually used on a patient.

Also, part of the OQ process is determining the devices and tests to be used for the inspection process of the flexible endoscope. For example, guidelines and standards call for the use of lighted magnification for inspection of endoscopes after the manual cleaning process. In addition, the facility should determine the product(s) to be used to perform cleaning verification testing on the

endoscope. Cleaning verification is performed after manual cleaning to test for residual debris. Inspection with lighted magnification and cleaning verification tests are critical steps in an ongoing quality processing procedure. Therefore, determining how these steps will be performed and the intervals is an important part of the OQ process.

PQ – These steps consist of the everyday checks and pre-procedure checks that should be performed every time that the endoscope is used. The pre-procedure checks are outlined in the instruction manual, not the reprocessing manual as mentioned previously and must be performed prior to every endoscopy procedure.

Another important process outlined in the pre-procedure steps is to check the instrument channel of the endoscope prior to each use with a compatible device for any obstruction or internal damage. This step is performed as follows:

- Straighten the insertion section of the endoscope.
- Insert a compatible accessory straight through the single use biopsy valve while closing its distal end and retracting it into the sheath.
- Confirm that the accessory extends smoothly from the distal end of the endoscope. Also, make sure that no foreign objects come out of the distal end.
- Confirm that the accessory can be withdrawn smoothly from the single use biopsy valve.

Examples of compatible accessory devices are properly-sized biopsy or grasping forceps. Remember that these should either be a new disposable device or a reprocessed reusable device. Other single-use devices exist to check patency of the channel, such as a blunt-end pushing device, which may also be utilized in the reprocessing area during the cleaning process. Cleaning brushes should not be used for checking the channel as their bristle flexibility can prevent an obstruction from being noticed as no resistance may be encountered during its utilization.

Also, within the confines of an IQ/OQ/PQ system, are additional steps that are performed routinely and when added into the process engineer quality into reprocessing. These steps are currently recommended in ST91 and ST79 as well as professional society guidelines and therefore should be implemented as part of the QMS for endoscopy. Examples of these quality processes are

- performing cleaning verification on regular pre-established intervals such as with each processing cycle or at least daily for all endoscopes that are used,
- enhanced inspection with lighted magnification and potentially a borescope,
- routine testing of equipment such as automated endoscope reprocessor (AER) for fluid flow through the connections,
- testing final rinse water quality checks in the AER,
- checking pressure outputs of leak testers, and
- performing microbial surveillance cultures on flexible scopes.

Conclusions: These guidelines stress that implementation of a robust quality system for endoscope process is necessary to help prevent endoscopy-acquired infections. Therefore, establishment of a QMS for processing departments is essential to releasing quality products to customers, which improves patient care and satisfaction and helps in infection prevention. Extending the implementation of a QMS to endoscope reprocessing allows for the same quality practices and processes and, therefore, better patient outcomes. Although the process of creating and implementing a QMS may seem daunting, the improvement in quality of care and practices makes the process worthwhile and extremely rewarding. ST90 (as well as ISO 13485) is the roadmap for how to establish a QMS for processing and its application to endoscope processing is a natural extension.

O_03

The Use Of Test Soils And Surrogate Devices To Validate Endoscope & Surgical Instrument Decontamination

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Session 1: Endoscopes, King Willem Alexander

Biography:
Richard Bancroft is the Science and Technical Director for STERIS Corporation. He has over 30 years' experience in sterilization and is a Registered Authorising Engineer (Decontamination), has a BSc Honours Degree in Applied Chemistry and is a Fellow of the Royal Society of Biology (FRSB). He is Chairman of the ABHI Sterilization and Microbiology Working Group, and has been involved in drafting of global sterilization standards for over 25 years, and is currently an active member of many standards committees. He is the convenor of ISO/TC 198 WG 6, convenor of CEN/TC 102 WG 7 and Co-Chair of AAMI/ST WG06. He was awarded the AAMI 2014 Standards Developer Award for his contribution to standards development.

Introduction:
Cleaning of reusable medical devices is influenced by four parameters - time, temperature, mechanical action and chemical action. These parameters cannot in practice be isolated and validated independently. In order to validate cleaning processes, test soils are used. Test soils, such as those given in ISO/TS 15883-5, are used to create worst-case soiling on reusable medical devices, in combination with surrogate or actual devices, to assist in the validation of washer-disinfectors used to reprocess these surgical instruments and medical devices. These requirements for test soils are currently being revised by ISO and have significant implications for the validation of cleaning processes for reusable medical devices, including surgical instruments and endoscopes.

Objectives/Discussion:
Test soils are typically proteinaceous in nature in order to recreate typical soiling from surgical procedures. Proteins are typically chosen as the marker of choice due to the fact that they are difficult to remove; higher temperatures during washing may denature and fix these proteins, making them more difficult to remove.
ISO is considering publishing values of certain substances, including proteins, as maximum limits for a device to be considered 'clean'. ISO is also proposing a new laboratory test method for acceptability of test soils to be used in cleaning validation studies. In order to quantify performance of these test soils, a test method has been developed using test pieces coated in blood and evaluated for residual proteinaceous soiling after subjecting to standardised immersion and elution conditions, which can be used with suitable medical devices or their surrogates to assess adequate cleaning.

Conclusion:
A consistent method for quantifying the performance of test soils has been devised. This method has been helpful for specifying test soil performance in the future and is currently being considered by ISO in the revision of ISO/TS 15883-5: 2005.

O_04

Medical Device Regulation; where are we, what can we expect and tips and tricks on what to do in our hospitals

Erik Vollebregt

Session 2: Legislation and Standards

Abstract not available.

O_05

WFHSS guidelines

Philippe Desterz

Session 2: Legislation and Standards

Abstract not available.

O_06

Eliminating Decontamination of Surgical Instruments with 0.5% Sodium Hypochlorite Solution: Implementing Evidence-Based Change in Low- to Middle-Income Country Sterilization Practices

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[1]*Sterile Processing Education Charitable Trust (SPECT), Calgary, Canada,* [2]*Jhpiego, Baltimore, USA,* [3]*Mount Royal University, Calgary, Canada*

Session 3: Cleaning and disinfection, King Willem Alexander

Biography:
Christina Fast is a sterile processing educator and the founder of Sterile Processing Education Charitable Trust (SPECT), a charitable organization focusing on providing education and mentoring to healthcare facilities in low- and middle-income countries. Partnering with international organizations, such as Mercy Ships, Assist International and LifeBox, SPECT has supported sterile processing best practices in 8 countries in Africa and 4 in Central America. Christina is published in the BMJ Global Health, AMIC Journal, and Surgical Infections. She was awarded 2018 Educator of the Year by IAHCSMM and in 2017 recognized as one of Calgary's top 40 under 40 to make a difference.

Aim: The aim of this collaboration is to discuss effective approaches to removing the use of 0.5% sodium hypochlorite as a pre-cleaning method for surgical instruments in low- and middle-income countries (LMICs). Over the past 30 years, LMICs have adapted national guidelines that include the recommendation to soak used surgical instruments in 0.5% sodium hypochlorite solution in efforts to protect health care workers (HCWs) from blood-borne pathogens in contaminated blood and body fluids. We conducted a thorough review of available literature and found no evidence that blood-borne infection rates are higher in HCWs who do not practice decontamination using 0.5% sodium hypochlorite compared to those who do. As sodium hypochlorite in concentrations > 0.05% has been recognized as corrosive to stainless steel, the 2016 WHO publication Decontamination and Reprocessing of Medical Devices for Health-care Facilitiesdoes not recommend its use on metal surfaces including surgical instruments. However, these guidelines are not yet adhered to in many LMICs where this practice persists.

Methods/Activity: Sterile processing practices at 20 hospitals in 2 African countries were assessed prior to a week-long training session provided by Sterile Processing Education Charitable Trust (SPECT) that included recommendations to remove 0.5% sodium hypochlorite from the instrument reprocessing cycle and proper use of personal protective equipment (PPE). Three to four months post training, assessments were again conducted at these hospitals to identify change in practice related to the use of 0.5% sodium hypochlorite.

Results: In Ethiopia, 8 out of 10 hospitals removed 0.5% sodium hypochlorite from their reprocessing practices following SPECT's training, but were subsequently required to use it again due to outdated national guidelines. Participants, being aware of the concern related to use of chlorine, paid attention to immersing instruments for no longer than 10 minutes, instead of longer periods as had been done previously. SPECT and Jhpiego worked with the Ministry of Health in Ethiopia to update national infection prevention and patient safety guidelines, and send a letter to hospitals authorizing them

to remove 0.5% sodium hypochlorite from their reprocessing practices. This provided participants with a valid response to accreditation concerns. In Tanzania 7 of 10 hospitals removed 0.5% sodium hypochlorite from their decontamination practice, while the other 3 decreased the time instruments were immersed to 10 minutes maximum. The Tanzanian government had updated their national guidelines prior to SPECT's training, but had not yet found a way to disseminate the changes to practice four months post training.

Conclusion: Updating national IP&C guidelines is needed throughout LMICs, where the current belief is that 0.5% sodium hypochlorite solution is effective protection against blood-borne pathogens for HCWs and patients. Additionally, Ministries of Health and hospital directors need to ensure programs and protocols are implemented for management of accidental exposure to blood-borne pathogens and are consistent with national post-exposure management guidelines. This includes ensuring HCWs have access to PPE and effective cleaning materials to prevent transmission of infection to workers and patients alike.

Keywords: Sodium hypochlorite, Instrument Processing

O_07

Elimination of prion protein in cleaning processes of medical devices in health care

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Session 3: Cleaning and disinfection, King Willem Alexander

Biography:
Dr. Matthias Tschoerner studied chemistry and microbiology at the Institute of Technology of Merseburg, the Università degli studi di Modena and the Martin-Luther University of Halle-Wittenberg and graduated 1994 a diploma degree in chemistry.
He completed the dissertation at the Federal Institute of Technology in Zürich and received the degree Dr. sc.nat. ETH in 1999.
Since 2000, he engaged with issues of the reprocessing of medical devices among others topics. First several years as head of research and development with emphasis on the development of cleaning and disinfection products in a private enterprise followed by an position as head of development at a service provider for processing highly complex medical devices.
In 2010, he joined the department of application engineering of the Chemische Fabrik Dr. Weigert GmbH & Co. KG in Hamburg. Since 2016 he leads the technical unit with application engeneering, analytics, R&D and microbiology.
Focuses are mechanical cleaning and disinfection procedures for medical, commercial, and industrial applications.
He is a member of various work groups of societies.

Pathogenic prion proteins have been known for several years as so-called "unconventional" pathogens and are causative agents of various transmissible spongiform encephalopathy (TSE) although for a long time the true character of the infectious agent was not well known. These include human diseases such as Creutzfeldt-Jakob disease (CJD), Gerstmann-Sträussler-Scheinker syndrome (GSS) or Fatal Familial Insomnia (FFI) and animal diseases such as scrapie in sheep and goats, Bovine Spongiform Encephalopathy (BSE) of cattle and Chronic Wasting disease (CWD) in north american deer species.
Transmission through social contacts was known in animals but in humans limited to very rare extreme burial rites (cannibalism).
With the "BES" crisis in the 1980's, the emergence of a new variant of Creutzfeldt-Jakob disease in UK in the 1990's is linked, which represents an oral transfer from species to species.
The transmissibility of various forms of spongiform encephalopathy through direct tissue transfer during surgical procedures and through contaminated instruments has been known for some time. Especially the proven high stability and persistence of the pathogens [1] highlights the special importance of the measures to avoid the transmission of pathogenic prion protein.

Therefore, specific treatment steps and procedures are recommended for the treatment of surgical instruments that may have had contact with tissues that are potentially contaminated with pathogenic prion protein. The aim is to reduce the potential pathogen load then to inactivate remaining infectivity and consequently to avoid iatrogenic transmission [2].
Different approaches exist in different countries. In France, instruments that might have had contact with risk tissues have to be processed by a cleaning process which has a proven inactivating effect on pathogenic prion proteins.

In Germany, these instruments are to be treated with 2 partially effective procedures, the cleaning in an alkaline environment with proven cleaning performance as one efficient method. Subsequently, the efficacy of the cleaning has to be checked during the validation of the processes.
This studie present the results of various experiments for the removal and for the complete inactivation of pathogenic prion protein.
The removability and the inactivation were investigated on the pathogenic prion proteins scrapie 263 K, BSE, and vCJD in vitro and in vivo.
The results show the difference between the reduction of the infectious load on an object by a good cleaning (removal) and the decontamination by complete inactivation of the prion protein.
With a good cleaning procedure in an alkaline environment, the infectivity can be securely reduced by up to 3.5 log. With a decontamination procedure with inactivation of the pathogen prion proteins the infectivity is reduced by 5.5 log.
Both methods can be established in the usual washer-disinfectors and routinely used for the reprocessing of medical devices.

[1] Gibbs CJ Jr1, et al, Transmission of Creutzfeldt-Jakob disease to a chimpanzee by electrodes contaminated during neurosurgery. J Neurol Neurosurg Psychiatry. 1994, 57, 757-8.
[2] Risk assessment for transmission of variant CJD via surgical instruments: a modelling approach and numerical scenarios. Economics and Operational Research Division Department of Health, December 2000, London, http://www.doh.gov.uk/cjd/riskassessmentsi.htm

O_08

Corrosion and Discoloration – an old but still pressing topic. New facts and strategies

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Session 3: Cleaning and disinfection, King Willem Alexander

Biography:
Dr. Gerhard Kirmse, born in 1966, studied Biomedical Engineering at the University of Berlin, Germany, and received his diploma in 1992. After several positions of international business development and quality management in Germany and in the USA he became Director of the Technical Competence Center at the Aesculap AG. Since more than ten years he is active in consulting for CSSDs.
He is doing research on reprocessing of surgical instruments, surface changes and process testing. He is member of several expert committees. Gerhard Kirmse completed his doctorate on "Influence factors on cleaning of instruments" (presented on wfhss 2014).

Introduction: Corrosion and discoloration of instruments until today create large amounts of damages in many hospitals. Central questions still seem to be difficult to answer:

- What is the risk associated with such effects?
- What should be the consequences?
- How can these effects be reduced with reasonable efforts?

Objective: New research results shall lead to better strategies in daily practice. The effects of pitting corrosion on cleaning performance were tested under standardized conditions and tests are also performed on clinical instruments.

Various process designs are tested under standardized conditions how far they can reduce effects of discolorations and corrosion.

Methods: Sizes of pitting corrosion holes on clinical instruments are measured by laser microscope. By the sizes revealed pitting corrosion with a standardized size is created electrochemically on test cylinders, made from stainless steel. These cylinders are contaminated with reactivated heparinized sheep blood, dried and cleaned by various methods.

The results of protein tests (OPA and ProReveal method) are compared between cylinders with and without pitting holes. Also clinical instruments with and without pitting corrosion are compared.

Cytotoxicity is tested by direct and indirect method on artificially created corrosion spots.

Furthermore sets of standard instruments with different surfaces were pre-treated with different conditioning processes and then repeatedly washed and sterilized by different processes, representing clinical standard procedures. The results are compared by macroscopic and microscopic surface condition and corrosion resistance (Prussian Blue test).

Results: The majority of pitting corrosions detected on clinical instruments have a size of 0.3 mm and below and a depth of 0.2-0.3mm. The results of protein tests were (depending on the cleaning

method) higher with pitting corrosion than without but not as bad as originally expected. It has to be noted that all pitting holes in this study did not have a "halo" around it. These "halos" were tested in an earlier study as (most of the times) a mixture of organics and corrosion products.

Cytotoxicity tests only showed a toxic results in massive corrosion spots.

It turns out that new instruments react more sensitive when brought into a process than aged ones. Pre conditioning based on alkaline cleaners and acids improves the situation and also using acids in the standard process. However it has to be noticed that variances can be seen even on the same type of instrument coming from the same production process.

Discussion and Conclusions: It can be concluded that corrosion definitely may have a negative influence on cleaning results and toxicity. However effects strongly depend on size and quantity. The corrosion resistance can be improved by pre-treatment processes and an adapted cleaning.

Based on these results it does not seem to be necessary to use magnification to inspect standard instruments for corrosion. An instrument with plainly visible corrosion should however be removed from service.

Further studies shall investigate if a further differentiation based on visual results or on results after secondary cleaning is possible.

O_09

Monitoring the efficacy of surface steam sterilization processes with temperature and pressure alone. Is this a valid approach?

Brian Kirk[1]
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Session 4: Sterilization, King Willem Alexander

Biography:
Brian Kirk is qualified as a Pharmacist. His post graduate studies include a Masters Degree in Pharmaceutical Analysis. His Doctoral research involved investigations into the application of computer technology for modelling the behaviour of chemical and biological indicators in steam sterilization processes and monitoring and controlling steam sterilizers; work for which he received the 1985 PDA annual award for best submitted paper. He worked for over 10 years in the UK NHS as a quality control pharmacist for a hospital pharmaceutical sterile supply manufacturing department gaining Qualified Person status as a result of this experience. He joined 3M Health Care in 1989 and held a number of responsibilities including product development and Technical services for sterilization supporting customers and business teams. Brian is a member of National(BSI), European(CEN) and International(ISO) standards committees responsible for chemical and biological indicators and steam, ethylene oxide and vH2O2 sterilizers and sterilization processes. Brian is the convenor of ISO TC 198 working group 3, moist heat sterilization. Brian has presented at national and international conferences, has published peer reviewed articles. He and is a registered UK AE(D). Brian is a visiting honorary lecturer at NottinghamUniversity and is a peer reviewer Journal of Hospital Infection.

Moist heat sterilization achieved by ensuring product, exposed to steam in a sealed chamber, is maintained at a specified temperature for a minimum period of time in the presence of moisture. Air trapped within the load and sterilizer chamber must be removed to allow rapid and even steam penetration. Failure to remove air can result in stratification in the chamber preventing steam contact or accumulation of air within the load creating pockets within lumen or porous materials preventing attainment of adequate moisture levels and therefore incomplete sterilization.
Temperature and time, are measured but moisture levels at the surface cannot. Tests are therefore prescribed which assess the efficiency of air removal using a challenge device which has a moisture sensitive detector. Standards also describe the estimation of steam saturation (moisture) using a theoretical calculation whereby measured temperature is compared with that calculated from pressure using steam table correlations.
Some are using this approach alone so Is T/P correlation a reliable method for determining the levels of residual air in a surface steam sterilization process? This paper presents results which inform the answer to the research question.

Experiments: Stage 1: Experiments were carried out in a steam exposure apparatus (resistometer) in which the residual air was increased by modification of the initial vacuum level. A fan was included in the test vessel to ensure homogeneity of the chamber conditions. Temperature and pressure measurements were recorded and the theoretical temperature calculated and statistically compared with the measured temperature using a paired t test.
In stage 2 experiments were carried out in a 360l test sterilizer. Residual air levels were gradually increased and T and P correlation calculated. In addition a standard test devices were included in the chamber to assess residual air levels.

In stage 3 a retrospective analysis of daily BDT results was carried out from two sterile service departments. Approximately 10% out of a body of ca 350 test results gave a fail based on estimation of residual air. T/P correlations were carried out and the pass and fail results compared statistically for significant differences.

Results: Results from stage 1 indicated that 18 % v/v of residual air would be needed to significantly disrupt the T/P correlation in measured and calculated data.
Results from stage 2 indicated that a residual air level of ca 1.0 L would cause a BDT failure but had no effect on T/P correlation which remained apparently valid.
The results from stage 3 indicated that there was no significant difference in the correlation of T/P measurements from processes which gave a satisfactory BDT and those which gave a fail.

Conclusions: The level of detectable air using T/P correlation far exceeds that which would cause a failure in a monitoring device used for a periodic test or included with sterilization loads. For this reason T/P correlation can lead to ineffectively processed loads being released into use. For this reason T/P correlation cannot be used as the sole measure of residual air in a surface steam sterilization process.

O_10

Validation and routine monitoring of steam sterilisers in hospitals

Remon van der Aa[1], M. Bartels[1], C. te Beest[1], J. Binnendijk[1], S. Dekker[1], J.P.C.M. van Doornmalen[1], M. van Hoof[1], J. Middelhoven[1], M.J. Meertens[1], S. Oostveen[1]
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Session 4: Sterilization, King Willem Alexander

Biography:
As Expert Sterile Medical Devices (DSMH)) responsible for total quality management accumulated on application of sterile medical devices, flexible endoscopes and associated equipment in health care processes. Development, implementation and control of the hospital internal tactical and operational policy deduced from legislation, regulations and strategic policy. President of the Material Advise Commission (MAC), member of Infection Commission, expert team Air Handling and Ventilation systems and expert team Cleaning Disinfection and Sterilization Devices. Also board member of the Dutch Society of Sterilization Experts (vDSMH)

Within a working party the value of a yearly physical validation of steam sterilizers for medical devices according to the standard ISO 17665-1 in 13 healthcare facilities was studied. A literature study was performed, followed by a survey of validation reports and analysis of collected data.
The standards [1,2] recommend a periodic validation program for surface steam sterilisers. In the country this is interpreted as a yearly validation[3], without any literature based rational or added value. Participants of the working party submitted results of the last five reported validation of one of their steam sterilisers located in their Central Sterile Supply Department (CSSD). A homogeneous dataset was acquired by limiting the results to tests specified in the standards and processes that are similar on all thirteen sterilisers. The dataset contains measurements of the 'air leakage test'[1], 'steam penetration test'[1], production processes at 134 and 121 °C with both 0% (empty) load and 100% (full) load. Also reproducibility, technical state and deviations were collected. This resulted in 13 included sterilisers with 64 validation reports, which results are categorised in table 1.

The results indicate that 7/13 (54%) sterilisers did not have any deviations from the standards over the last five validation and thus years. In case a deviation was recognised, the cause of the deviation was known by the 'owner' of the steriliser, e.g. deviations shown by measurements in phaco hand-pieces and in medical instruments made of polymer material.
Overall it was concluded that the countries interpretation recommendation of a periodic validation on yearly base is questionable. Many of the observations in validations were known before the validation was performed. The trends in validations of steam sterilisers indicated that, as long as the combination of steriliser, maintenance, process, load, loading pattern and wrapping does not change, the results of a validation are predictable. If the essential parameters (actual steam sterilisation conditions), measured in every process, are similar to those before maintenance, complete validation has no added value and it should be considered not necessary. It is advised to measure actual steam sterilisation conditions in every process.

[1] standard EN 285. Sterilization - steam sterilizers - large sterilizers, 2015.
[2] standard 17665-1. Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 2006.
[3] standard Dutch national guideline D6103b. Richtlijn validatie stoomsterilisatieprocessen, 2007

year of validation		2017	2016	2015	2014	2013
number of sterilisers		13	13	13	13	12
performed measurement	criteria					
air leakage test	EN 285	12/12	11/12	12/12	12/12	12/12
Steam penetration test	EN 285	13/13	13/13	13/13	13/13	13/13
134 °C standard process empty	ISO 17665	11/12	11/12	11/12	12/12	9/10
134 °C standard process 100 % load	ISO 17665	10/13	12/13	9/13	12/13	12/12
121 °C standard process empty	ISO 17665	6/6	7/7	6/7	8/8	8/8
121 °C standard process 100 % load	ISO 17665	5/5	6/6	4/6	7/7	7/7
reproducibility	-	9/9	9/9	7/7	7/7	7/7
technical state of the steriliser	criteria					
recorder/registration printer	EN285	13/13	13/13	13/13	13/13	12/12
temperature registration	EN285	13/13	13/13	11/13	13/13	12/12
pressure registration	EN285	13/13	13/13	12/13	13/13	12/12
temperature display	EN285	13/13	13/13	13/13	13/13	12/12
pressure display	EN285	13/13	13/13	13/13	13/13	12/12
indicating pressure gauge	EN285	12/13	12/13	11/12	11/12	10/11
reports reporting deviation		10	10	10	10	10
reported deviations in summary		9	13	9	15	1
proposed reported actions		2	1	4	3	1

Table 1: Categorised results of 13 steam sterilisers with 64 validation reports

O_11

Product families in steam sterilisation

Josephus P.C.M. van Doornmalen Gomez Hoyos[1,2], Ralph A.C. van Wezel[3]
[1]University of Technology Eindhoven, Eindhoven , the Netherlands, [2]Steelco SPA, Riese Pio X, Italy, [3]Catharina Hospital, Eindhoven, the Netherlands

Session 4: Sterilization, King Willem Alexander

Biography:
Josephus (in short Joost) is active in the field of decontamination of medical devices since 1995. Currently, he holds a position of Principle Scientist and a research position at the University of technology of Eindhoven. He performs and participates in research in decontamination. Some of the work he is involved in, has been published. Joost participates in Dutch, European and worldwide standardization committees and work groups. He is a frequently invited and appreciated speaker in conferences and universities.

Aim: The aim of this study is to identify product families in steam sterilization processes

Methodology: Sources used in this study were (university) libraries, internet and reports concerning steam sterilisation. This information has been extended with experimental work, for example [1-4]. (Because 5 references are allowed only 5 references are included in the reference list of this abstract).

Results: Steam sterilisation conditions are specified in the literature and standards as a specific degree of water vapour (Water Vapour Fraction, WVF), temperature (T) and time, for example 92 % WVF, 134 °C for 3 minutes. These conditions must be established on all location to be sterilised.

Three main products families could be identified with two subgroups were identified (table 1). These groups were based on the different phenomena to establish surface steam sterilisation conditions.

To define the groups further, the dimensions and the physical properties have to be taken into account. Amongst more these are the weight of the total load to be steam sterilised and the material to be sterilised.

The reference [2,3] demonstrates that the heavier the load, the longer the conditioning phase takes. The longer the conditionings phase takes the more time for diffusion. The more time for diffusion the better the steam penetration becomes. Consequently, heavy loads improve the steam penetration.

The dimensions of medical device for example channels [4] and physical properties such as capillary action (2,4] and heat transfer [5] will dictate how fast a device will warm up.]. The physical properties such as heat transfer and heat coefficients have to be taken into consideration for the product families, as well. This has consequences for the amount of condensate is formed in a process. In case of a thick-walled channelled device the condensate may block a channel and prevent steam penetration [2,4]. In such cases the orientation of the channel in the medical device may be of importance to drain the formed condensate [1].

Discussion: To identify the most difficult load the product families within a facility have to be qualified on the product families (table 1). Based on the dimensions and the physical properties the most difficult load can be identified and used to qualify a steam sterilisation process.

In the presentation the different physical phenomena the influence of dimension and physical properties will be explained with practical examples.

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Load type	subgroup	Driving phenomena	First approach calculation
Porous		Capillary action	Young-Laplace equation
Massive or non-hollow loads		Convection	Dilution factor
Loads with channelled medical devices	Thin walled channelled devices	Convection Diffusion	Coupled convection-diffusion equation
	Thick walled channelled devices	Convection, Diffusion, Condensation	Coupled convection-diffusion-condensation equation With vertical orientation of channel in device Coupled convection-diffusion equation

Table 1: Product families for steam sterilization. The qualification is made on physical mechanism to establish surface steam sterilization method. These mechanisms are capillary action, convection, diffusion and condensation [5].

O_12

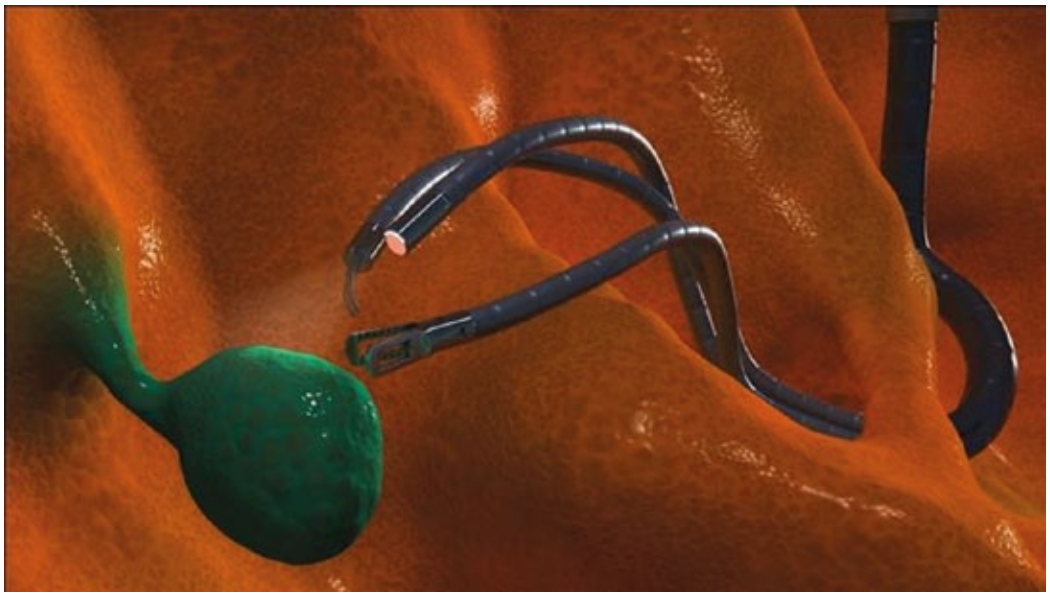
Bio-inspired medical devices

Paul Breedveld[1]
[1]*TU Delft, Delft, The Netherlands*

Session 5: Design of medical devices, King Willem Alexander

Biography:
Paul Breedveld studied Mechanical Engineering at TU Delft where he obtained his MSc and PhD degrees with honours. Extending his experience in space robotics to the medical field, he continued his research with developing ingenious surgical devices inspired by smart solutions in nature. Collaborating with academic hospitals, medical companies and biological research groups, the research within his group BITE (Bio-Inspired Technology) has resulted in a number of patents and spin-off companies. Being member of the BIOKON International Biomimetics Association, having received a number of prizes and awards, and being a leading researcher in a number of (inter-) national research programmes, his research was rewarded in 2012 with a prestigious Dutch VICI research grant on the development of dendritic devices for endo-nasal skull base surgery and in 2013 with an Antoni van Leeuwenhoek personal professorship at TU Delft. In 2016 he was one of the founders of the Painless Foundation: a Dutch initiative to find innovative solutions for patients with chronic and incurable pain.

As compared to man-made technology, nature follows alternative design pathways leading to smart and amazing solutions that can lead to great inspiration for technical applications. Within the Bio-Inspired Technology (BITE) group at Delft University of Technology (www.bitegroup.nl) we strive for the development of innovative surgical devices for minimally invasive surgery, catheter procedures and percutaneous interventions, drawing inspiration from extraordinary biological mechanisms and collaborating with a number of academic medical centres and companies. This presentation will give an overview of the developments within the BITE-group, combining research on the anatomy of squid tentacles, snakes and parasitic wasps with high tech manufacturing technologies such as 3D printing, leading to world's thinnest steerable instruments and snake-like surgical devices, some of which have been patented and commercialized. The presentation will also cover challenges with cleaning and sterilization with emerging new technologies in the OR.



Snake-like dendritic instrument moving through human anatomy.

O_13

Redefining visual inspection for medical devices

Stephen M Kovach[1]
[1]*Healthmark, Fraser, United States*

Session 5: Design of medical devices, King Willem Alexander

Biography:
My name is Stephen M Kovach I have been in the medical field since 1975 starting out as sterilization orderly and now am the Director the Director of Education for Healthmark Industries. I received my BS from Central Michigan University, with a Major in Biology in 1977.
I am active on the state and national levels of various organizations having held many positions. I am a voting member on various AAMI committees that set the standards in the USA for our profession. I have published many articles varying in subject matter from perfusion to the importance of cleaning surgical instruments.
I have spoken and presented at all levels from local to national and international on various topics relating to CSSD. I spoke in 1999 at the World Central Service meeting in Orlando, Florida on Parametric release. I was named by Hospital Purchasing News in 2007 as one of the 30 most influential people within the field of Central Service. I am proud to say "I have worked in the Heart of the Hospital- Central Processing".

Background: In 2015 Healthcare Purchasing News a publication in the United States in one of their articles made this statement on visual inspection.
"Visual inspection of surgical instruments following decontamination is a universal requirement for surgical instrument reprocessing. Despite the ubiquity of the practice, visual inspection technology has been slow to move into the digital age. In most sterile processing departments lighted desktop magnifying lenses are a common sight. However, the time has come for sterile processing departments to adopt better technology in order to give their technicians the best possible resources to keep patients safe".
It is now 4 years later and enhanced visual inspection with a borescope still is not the standards for examining hard to see places within various medical devices. We know that visual inspection is the most often specified technique for inspecting medical devices.
This statement of being "one of the most specified techniques" is supported by just reading any medical devices Instruction for Use (IFU). Here are just two examples taken from medical devices IFU. The first is from Aesculap and their IFU makes this statement on visual inspection "…inspection should be done just prior to sterilization. Inspect all instrument surfaces and individual parts for: Cleanliness of instruments, i.e. no debris, blood, tissue, etc. If not fully clean, repeat previous cleaning steps or properly dispose of the instruments…". The next is from the IFU for a STRYKER medical device and it states"…visually inspect the hand piece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary, to see the inner surface of the lumen. If soil remains, repeat the manual cleaning procedure, focusing on those areas…".
Thus, the most basic verification of the performance of a cleaning process is by carefully visually inspecting the cleanliness of medical devices with one's unaided eyes to inspect for defects in functionality, pitting, stains, imperfections on the medical device during its processing cycle and rejecting the medical device according to the medical devices IFU if any of these imperfections are found. This is the sometimes called the first Standard of Clean, "is the device visually clean".
Medical devices have become more and more complex over the years, and harder to inspect with just the unaided eye. Presently many Central Service Sterile Departments (CSSD) professionals are using basic magnification to help the unaided eye visually inspection of medical devices. This helps but many of these medical devices have lumens and channels that the unaided eye or basic

magnification cannot see into if the device is "visual clean".
In 2009 the field of enhanced visual inspection was born for CSSD. When the FDA issued an alert after investigating and outbreak at a Houston hospital concerning a dirty shaver and suggesting the use of some type of borescope be used to inspect these shavers
What has taking place since 2009 is that research is showing that the use of enhanced visual inspection with a borescope is revealing areas not explored before with the unaided eye and CSSD should start using this technology.

Aim: The aim of this abstract (oral presentation) will be to explore the evolution of visually inspection of medical devices with the naked eye to the present-day enhanced visual inspection tools (borescope) and show the need to use this new technology in everyday practice. Recent incidents of infections received by patients from dirty arthroscopic shavers have led to changes in how CSSD professionals visually inspect these medical devices. The manufactures of the shavers changed their Instructions for Use requiring the use of new tools to inspect their medical devices. Data and pictures will show how CSSD professionals are complying with the change to the Instruction for Use (IFU) on arthroscopic shavers and other medical devices.

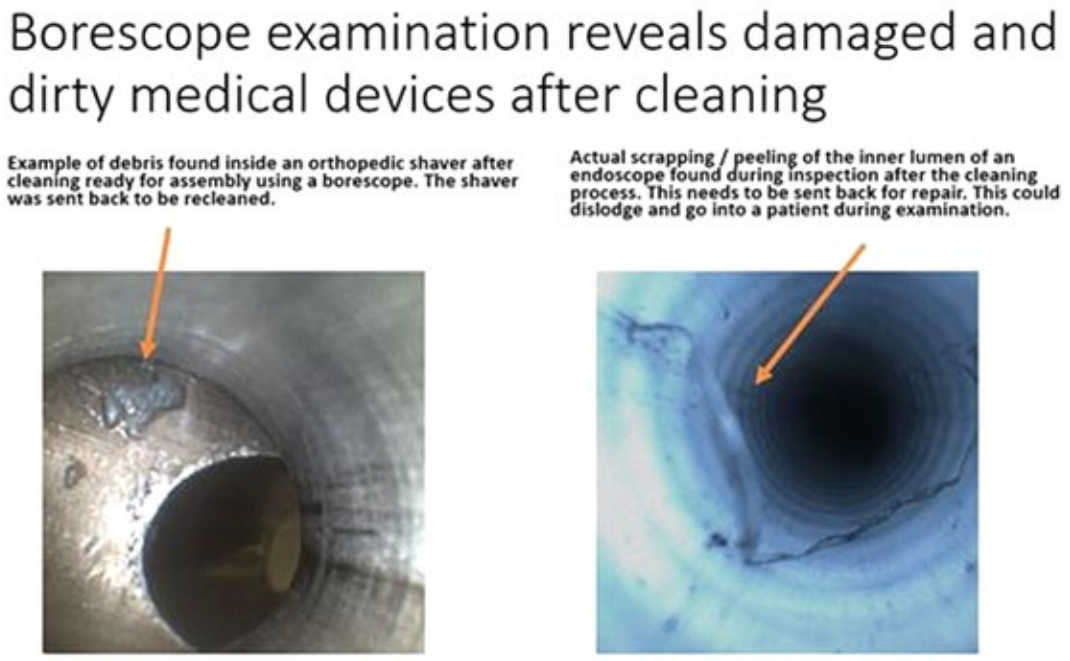
Method: Using survey results and actual pictures of medical devices being examined with a borescope in areas that cannot be seen with the unaided eye or other forms of visual inspection would otherwise be considered clean when they are actually dirty or damaged supports the need for this new technology.

Results: The data shows compliance using a borescope for inspection of orthopedic shavers is not at 100 %. A survey taken in 2018 shows that out of 675 CSSD professional in the United States that responded to the survey that only 55% are using enhanced visual inspection on their orthopedic shaver; this was an increase from the results of the 2017 survey that had 887 participants respond and only 40 % were using enhanced visual inspection on their orthopedic shaver. Thus, improvement is being seen in using this technology for providing clean, functional and safe medical devices for the patient. While it should be at 100% for any CSSD reprocessing orthopedic shavers, progress is being made in using enhanced visual tools to inspect areas of medical devices that harbor possible tissue and damage that could not be seen before.
Actual pictures will be shared during the presentation showing concerns (tissue left in the shaver after cleaning) that can only be seen with enhanced visual inspection tools (see attached picture) like a borescope, supporting that these medical devices need to be inspected all the time 100%.
It is tissue like what will be seen in the pictures that caused the concern and recent incidents and infections with orthopedic shavers that supporting the need for all CSSD to have enhanced visual inspection tools in their departments. With out this new technology unclean medical devices will go undetected and patients will be harmed.
I will also explore the development of this new technology and investigate the internal workings of not only arthroscopic shavers, but other medical devices, such as endoscopes, by using actual pictures taken with a borescope of medical devices that need repair and would not have been discovered without this technology. It is said a picture is worth a thousand words, these pictures back up this statement.

Conclusion: The data presented supports why CSSD should put in place a practice guideline for visual inspection based on critical thinking skills, standards, guidelines, manufacturers IFU, their own risk analysis so medical device reprocessing professional can ensure all medical device are clean and functional.
Based on what has been presented we now have three steps to ensure a medical device is visual clean they are:
First and foremost, if it is visual dirty, you must re-clean it (unaided eye detection)
Second, the use of a Magnifying glass.
Third is enhanced visual inspection (Borescope, Flexible Inspection Scope, UBS microscope…) to be used in hard to see areas of a medical device like a lumen.

A CSSD should incorporating enhanced visual inspection as part of their Quality Management System (QMS); Inspection of medical devices with enhanced visual tools like a simple magnification or use of a borescope (flexible inspection scope) would now be part of their Performance Qualification (PQ) of every department. Remember that if a medical device is dirty "not visually clean" by whatever means used; send it back to be re-cleaned, how you do this is with your unaided eye and specific inspection tools, thus you can get to "Visual Clean" with the right tools and guidance document for your specific facility. These advanced enhanced visual inspection tools are the cutting-edge technology progressive CSSD's are using to deliver safe and ready to use medical devices for every patient. Bottom line is we want "To Keep it Clean".

Key Words: Visual inspection, Instructions for Use (IFU), Enhanced Visual Inspection, Inspection scope, borescope



Title: Redefining visual inspection for medical devices

O_14

Complex design of surgical instruments as barrier for cleaning effectiveness, favouring biofilm formation

Roel Beltran Castillo[1], Karen Vickery[3], Lilian Kelly De Oliveros Lopes[2,3], Anaclara Ferreira Vega Tipple[2], Evandro Watanabe[4], Huang Hu[3], Anand Kumar Deva[3], Dayana De Melo Costa[2,3]
[1]Adventist Health Care Limited Australia, Wahroonga, Australia, [2]Federal University of Goias, , Brazil, [3]Macquarie University, Sydney, Australia, [4]University of Sao Paulo, , Brazil

Session 5: Design of medical devices, King Willem Alexander

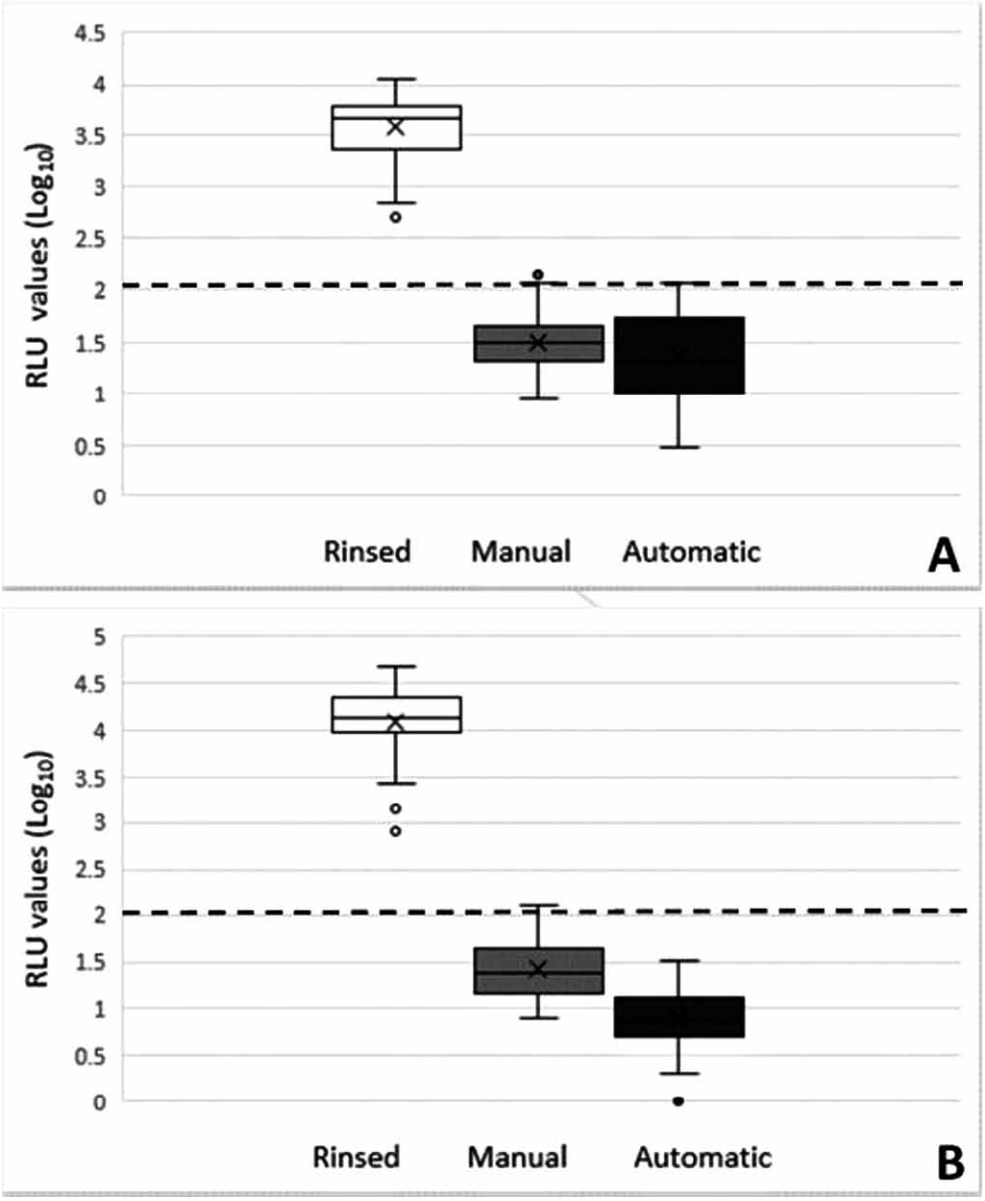
Biography:
Based in Sydney Australia, Roel migrated to Australia with a Science background. He started as a Reprocessing Technician at The Prince of Wales Hospital in 2007, moving to The Royal Prince Alfred Hospital in multiple capacities from CSSD Technician, Team Leader, Theatre/CSSD Coordinator until 2012. He commissioned a new CSSD at The Chris O'Brien Lifehouse he eventually managed and started Teaching in a part Time capacity at the New South Wales TAFE Randwick College - Sterilization Course. In 2015 he Lead the Reprocessing Team at the Macquarie University Hospital, provided outstanding staff engagement accreditation results and co-authored research publications in the field of CSSD. He is now currently Leading a Reprocessing Team of 27 at the Sydney Adventist Hospital, one of the biggest private hospitals in Australia.
He is passionate about CSSD compliance to standards, staff engagement, professionalization of the reprocessing role and sharing experience with the global community of dedicated invisible people who are the most critical component of surgical and procedural care of the patient.

Aim: Determine the cumulative effect of 20 cycles of contamination, cleaning (manual or manual followed by automated) and steam sterilisation on high-complex-design reusable surgical instruments (RSI) used for orthopaedic surgery

Methods: New flexible medullary reamers and depth gauges were contaminated by soaking in tryptone soya broth, containing 5% sheep blood and 109CFU/mL of Staphylococcus aureus (ATCC 25923), for 5 minutes. To mimic a worse-case scenario, RSI were dried seven hours and subjected to either a) rinsing in distilled water, b) manual cleaning or c) manual plus automated cleaning (gold standard), and steam sterilisation. The contamination, cleaning and sterilisation cycle was repeated 20 times. Adenosine Triphosphate (ATP) was measured after cleaning procedures, while microbial load and residual protein were measured following the 10th and 20th reprocessing, in triplicate. Scanning electron microscopy (SEM) was used to confirm soil and biofilm presence on the RSI after the 20th reprocessing

Results: Manual and manual plus automated cleaning significantly reduced the amount of ATP and protein residues for all RSI. Viable bacteria were not detected following sterilisation. However, SEM detected soil after automated cleaning, and soil, including biofilms, after manual cleaning.

Conclusion: Soil and/or biofilms were evident on complex-design RSI following 20 cycles of contamination and reprocessing, even using the gold standard method of cleaning. Although the depth gauges could be disassembled, biological residues and biofilm accumulated in its lumen. The current design of these RSI prevents removal of all biological soil and this may have an adverse effect on patient outcome.



Amount of residual soil (Adenosine Triphosphate) on the surface of reusable surgical instruments over 20 processing cycles on depth gauges (A), flexible medullary reamer (B) subjected to different cleaning regimes

O_15

Circularity as a new approach for sustainable instruments

Bart Van Straten[2], Tim Horeman[2]
[1]TU Delft, Dept. of Biomechanical Engineering, Delft, The Netherlands, [2]Van Straten Medical, Dept. of R&D, Utrecht/Nieuwegein, The Netherlands

Session 6: Continous improvement of the CSSD processes part 1, King Willem Alexander

Biography:
Request for dual presentation by Bart van Straten & Tim Horeman

Author bio Tim Horeman, The Netherlands
Tim Horeman MSc, PhD is Assist. Professor at TU Delft (Technical University Delft), researcher and Technology Director of MediShield BV, Technology Director of Surge-On Medical BV and involved with other technology start-ups. Tim received the first annual Athanasiou ABME Award at the Biomedical Engineering Society's (BMES). Furthermore, Tim received the Prins Johan Friso Engineering award in 2016 for his contribution to the development of medical technology and the improvement of patient safety.

Author bio Bart van Straten, The Netherlands
Bart van Straten MBA, MIT (European University/EU Business School), is General Manager at Van Straten Medical and researcher in the field of Circular Instrument Management and teacher. Bart is actively involved in the development of a multitude of medical devices that are currently used worldwide and considered as one of the founders of the concept of sustainable health care by means of circularity with surgical instruments.

Together with Tim Horeman, Delft University of Technology, department of BioMechanical Engineering, research is done in cooperation with Van Straten Medical in the field of sustainable surgery and circular instrument management.

Circularity as a new approach for sustainable instruments.
How a circular approach will provide cost benefits and sustainable benefits.

Background: Sustainability, in particular the Circular Economy, is gaining a growing interest within health care. Circularity is an economic system in which waste is minimized or even completely reused1 which can be achieved through maintenance, repair, reuse, remanufacturing, refurbishing, recycling, and upcycling. This is in contrast to a linear economy which is based on a 'take, make, dispose' model of consumption patterns[2].

Our work describes the results and opportunities of a circular approach including reusing hospital instrument waste, in particular surplus instruments and other stainless steel waste, as a basis for reuse in manufacturing of new medical products such as mesh baskets. The aim of this study was to show that cost savings can be realized for the hospitals by following a circular instrument repair and recycle approach. A project was initiated under the name 'Circular Instrument Management (CIM) ' and divided into two categories.

1. Minimizing instrument replacement, meaning prevention of instrument waste by repair instead of dispose in order to extend the life cycle of the instrument.
2. Recycling of the instrument -if it could not be repaired- by means of melting it into new raw material.

Feasibility of the second step was investigated by Van Staten Medical and observed by the Technical University Delft, department of biomechanical Engineering.

Methods: Van Straten Medical, a developer, manufacturer and global supplier of surgical products started to collect discarded instruments and stainless waste from four different hospitals during the period between 25 September – 12 December 2019. The collected material was separated by indication of material and use (e.g. 304SS used for trays or baskets and 316SS for surgical instruments) in two different containers. The routing, cleaning and transport costs were defined and compared with the revenue generated at the recycling company.

Results: A total of 1380 Kg waste was collected from four different hospitals during the period between 25 September – 12 December 2019. The disposable used instruments were disinfected on an external location. Some instruments needed to be separated on material specification. 95% of the waste consisted stainless steel that was completely recyclable. The remaining 5% consisted of plastic wrappings and protective caps, valves and aluminum labels/ tags. From the 1380 Kg, 50 Kg consisted of disposable stainless steel instruments. The cleaning and handling costs of disposable stainless steel instruments was calculated at 50 cents per Kg waste. 1230 Kg was found to be surplus stainless steel instruments and surplus mesh baskets. For all stainless steel material 0.8 euro was calculated per km per shipment for logistics and transport. Shipments were made with a total of 237,3 KM resulting in a standard prize of 0,138 euro per kilo for logistics and transport. All stainless steel waste, consisting of stainless steel 316 and stainless steel 304 was melted and recycled to sheet material. Despite the grade, 0.89 Euro per Kg was paid by the collecting metal recycle company. The sheet material was used to manufacture components for instrument mesh baskets and for stainless steel components used in instrument fixation[3].

Discussion: The aim is to realize cost savings for the hospitals due to lower instrument repair costs as opposed to replacement costs and minimizing stainless steel waste. 1.380 Kg stainless steel waste was collected that was turned into new raw material used to create sheet metal. The cost price to process non-surgical stainless waste is approximately 0,14 Euro per Kg recycled material and surgical stainless steel waste approximately 0,64 Euro. Compared with the revenues of 89 cent per Kilogram clean SS material it was demonstrated that this step in circular instrument management is feasible and even profitable. Furthermore, taking in account that hospitals often are confronted with additional costs for disposing their contaminated waste.

Circularity goes beyond reusing pure stainless steel waste as many of the instruments are build out of plastic and stainless steel materials. Our Study indicated that, to further facilitate efficient recycling, it is important that instruments are designed in such a way that disassembly is easy. In combination with regulations that allow reuse and recycle of modular instrument it should be possible to develop a new generation of SMART instruments that contain components that can be replaced, processed or reused easily. This approach can prevent unnecessary waste and reduce hospital costs related to disposable instrumentation and provide short term cost benefits, long term strategic opportunities and new profit pools in reverse cycle services.5.

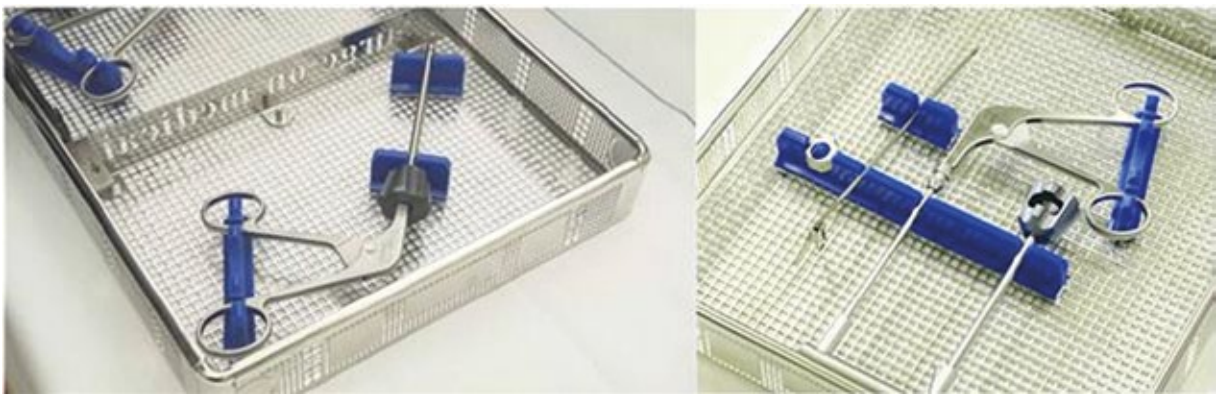


Figure 1. Modular Surge On Steerable punch, designed for assembly that allows replacement of parts. Punch is fixated in mesh basket made of sheet material made out of recycled stainless steel waste.

Designs for ease of disassembly but also instrument maintenance, repair, reuse, remanufacturing, refurbishing, recycling, and upcycling will contribute to the circular economy. Figure 1 shows the first steerable modular instrument that can be completely reused and reprocessed. This instrument can be taken apart for cleaning and sterilisation and maintenance. With recycling and ease of processing in mind, a design was established that contains cables for steering. In addition, parts that can potentially wear are made of stainless steel and can be easily replaced. This is in contrast to a linear economy which is a 'take, make, dispose' model of production. Further research is needed with regard to the design adjustments of the instruments. If an instruments is designed with the specification of ease of disassembly and (re)processing of separate components, the recycling and reprocessing to new raw materials will be simplified further.

The circular program changes the chain from 'make-use-throw-away' to 'make-use-reuse'. Special attention however, needs to be directed to the cleaning and disinfection of used disposable instruments. A proper procedure needs to be in place for the collection and transportation of contaminated instruments. Disinfection needs to be carried out before offering these instruments to a metal processor for melting the instruments.
A quality and risk management needs to be in place for circular instrument management. Meaning both for the process of the repair of instruments as well as for the reprocessing of instruments to new raw material. The ISO 14971 Risk Assessment may be considered as a standard procedure as well as the ISO 13485:2016 certification. Material certificates of the recycled new raw materials is a fundamental part within the Medical Device Regulations when using these materials for the manufacturing of new medical devices.

The first results of this test indicate that circularity as a business model could provide a basis for a new approach in surgical instrument management with cost savings and environmental benefits on the long run.
Further to be explained during a dual Oral Presentation by Tim Horeman and Bart van Straten.

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[3] Data on file. Waste collection at Maasstad Ziekenhuis, Rotterdam, Haaglanden MC, Den Haag, Van Straten Medical, NIeuwegein-Utrecht, VUmc, Amsterdam. Metal waste melted and reprocessed to sheet metal, supplied to Van Straten Medical for use in manufacturing of mesh basket and instrument fixation baskets.
[4] Comparison of refurbishment costs against replacement costs of a new instrument, on average 25% - 75% - price level 2019 Van Straten Medical.
[5] Towards the Circular Economy, Ellen Macarthur Foundation, Rethink the Future, Economic and business rationale for an accelerated transition; 2013

Keywords
Waste recylce; circularity; sustainable instruments; quality and risk management; instrument design

Submitted for WFHSS 2019 – request for dual oral presentation by
Tim Horeman
Bart van Straten

O_16

Measuring CSSD performance -what is good performance and what KPIs can we use to measure

Christine Denis[1]
[1]*WFHHS President*

Session 6: Continous improvement of the CSSD processes part 1, King Willem Alexander

Biography:
Dr Christine Denis Dr Christine DENIS is a PhD in Pharmacy and manager of the CSSD of Lille University Hospital (FRANCE).
She has been managing CSSDs for more than 20 years and has been the project leader of a super center of sterilization (STERINORD) opened in November 2013.
She has developed a large experience in production's organization, automation, validation, HR and quality management system.
Since 2014, she is the President of the World Federation for Hospital Sterilisation Sciences (WFHSS).

We all know that health expenses are increasing and must be controlled .We use to hear that health is priceless, but costly and the expenses' control must also apply to CSSDs.
But they are some differences between CSSDs and health care activities in a hospital: CSSDs are not profit-oriented, CSSDs' specificities are scarcely understood by hospitals' decision makers and top management.

It is often said than CSSDs are costly and do not generate any profit Mostly The Reprocessing costs of Reusable Medical devices are not well identified, though the benchmarking is not easy.
The lack of financial information regarding CSSDs participates (with other parameters) in the lack of recognition of our departments.

To improve this situation CSSD shall prove its efficiency , show that a production cost control is implemented, and demonstrate its internal and external performance.
It helps to prove its projects and investments' relevance. It covers the 2 main streams of a good steering = strategy and operationnal steering.

The presentation explains how the use of KPI (key performance indicators) can serve these objectives in CSDDs and shows a few examples of implementation.

O_17

CSSD design 101 / New Dutch guideline for design, construction and startup of a CSSD

René Vis

Session 6: Continous improvement of the CSSD processes part 1, King Willem Alexander

This Guideline applies to Central Sterilising Departments in hospitals, independent treatment centres and organisations that sterilise reusable medical devices for these parties. The Guideline also applies to other healthcare institutions and clinics that carry out extensive sterilisation activities independently. A Centralised Sterilising Department must consist of several, coordinated areas in which various activities take place that together form the full sterilisation process, spanning from the influx of used, loaners or new reusable medical devices to the delivery of checked, packed and sterilized medical devices. The recommendations and requirements set out in this Guideline also apply in case of renovation or modification of existing buildings.

The design of a CSD is very important for the quality of sterilised medical devices and their applications in patient care. It is essential to organise the design, realisation, verification and maintenance of this facility in a structured, process-based manner.

The guideline describes the minimal requirements per area or process step. Where the relationship between these areas or steps are critical for adequate and effective reprocessing. It also describes the different flows of products and staff members throughout the department. Per area is defined what the recommendations are in regards to air quality, finishing of floors and walls health and safety related issues including the implementation of national hygiene policies.

O_18

Challenging the six-hour recommendation for reprocessing sterilizable surgical instruments by identifying proportionality between protein residue and corrosion; and holding time

Karin Bundgaard[1,2], Erik Elgaard Sørensen[2,3], Head nurse Krister Ripadal[4], Biostatiscian Ann-Eva Christensen[5], Henrik Carl Schønheyder[3,6]

[1]Clinic for Neuro-, Head and Orthopaedic Diseases, Aalborg University Hospital, Aalborg, Denmark, [2]Clinical Nursing Research Unit, Aalborg University Hospital, Aalborg, Denmark, [3]Department of Clinical Medicine, Aalborg University, Aalborg, Denmark, [4]Sterile Centre and Clinic for Diagnostics, Aalborg University Hospital, Aalborg, Denmark, [5]Clinic for Diagnostics and Unit of Epidemiology and Biostatistics, Aalborg University Hospital, Aalborg, Denmark, [6]Department of Clinical Microbiology, Aalborg University Hospital, Aalborg, Denmark

Session 7: Continous improvement of the CSSD processes part 2, King Willem Alexander

Biography:

Karin Bundgaard, RN, MScN, PhD. Current employment as postdoc in clinical nursing at Aalborg University.
Research in this field has been presented at HIS conference 2018 in Liverpool as well as in the paper "Challenging the six-hour recommendation forreprocessing sterilizable medical equipment."

Background: At present, reprocessing of sterilizable medical equipment is recommended to be initiated within 6 h after completion of surgery, according to national and international guidelines for infection control in the healthcare sector (1). The main concern is that a longer holding time may result in deterioration of the instruments, i.e. inefficient cleaning using standard protocols for reprocessing and consequently more susceptibility to corrosion.

Aim: The aim of this study was to evaluate and challenge the 6-hour recommendation for reprocessing sterilizable medical equipment by determining whether residual protein increased proportional to holding time before reprocessing was initiated, and likewise whether an increase in corrosion was present on surgical scissors proportional to holding time.

Methods: Simple instruments, such as scissors and knife shafts, and more complex instruments with cavities, such as puncture cannulae, were tested. Instead of a surrogate ('test soil') we have used defibrinated human blood. The National Committee on Health Research Ethics has endorsed the use of human blood for research purposes conditional on the blood donor's informed consent. The blood was left to dry for 0, 3, 6, 9, 12, 24, and 36 h at room temperature before washing. Undiluted blood was lubricated on all surfaces of knife shafts and scissors, and puncture cannulae were flushed with blood. The instruments were washed in the washer-disinfector using the standard protocol. After washing, but before disinfection, the instruments were examined for protein residue using the o-phthaldialdehyde (OPA) method based on EN-ISO 15883-1: 2009 (2).
Corrosion resistance was tested using two qualities of surgical scissors, in order to include metals of different composition; all instruments were new at inclusion. One quality of scissors had a chromium content of 16%, and the other 12.5%. Fifteen scissors of each type were lubricated with blood on all sides and left to dry for 6, 12, and 24 h, following which, they were washed, disinfected, and autoclaved. After washing and disinfection, the scissors were inspected for visible signs of corrosion before being autoclaved. The process from contamination to end autoclaving was repeated in the

same way 50 times. Pairs of scissors of each quality subjected to each of the three holding times were tested for corrosion after 25, 35, and 45 reprocessing cycles, respectively. The remaining two scissors of each quality and holding time were retrieved after 50 reprocessing cycles. The individual scissors had the same holding time before reprocessing throughout the test period. The scissors were examined and evaluated using light stereomicroscopy and scanning electron microscopy (SEM). The degree of corrosion was assessed according to the ISO 4628-3 standard (3).

Results: Regardless of holding time and instrument type, all protein residues were below the consensus accepted threshold of 100 µg per instrument surface, with the lowest value at 14.0 µg and the highest value at 51.9 µg. Only three out of 42 values were >50 µg; the remaining 39 values were below 40 µg.
No correlation between holding time and the amount of protein residue was identified for the puncture cannulae. A non-significant slope of -0.37 (P = 0.09, 95% CI: 0.07, 0.81) was identified, and R2 = 0.216. The amount of protein residue on the contaminated puncture cannulae varied from 14.0 to 50.9 µg. One of the lowest and the highest values (14.3, 50.9 µg) were obtained from the samples with a holding time of 36 h. The 6 h values of 16.2 and 18.5 µg were higher than the 12 h values of 14.0 and 15.6 µg. Likewise, there was no correlation between holding time and the amount of protein residue remaining on the scissors. The observed slope was -0.21 (P = 0.11, 95% CI: 0.47, 0.06), and R2 = 0.196. Protein residue values for the scissors ranged from 33.7 to 51.9 µg. The two highest values were identified on the scissors with holding times of 0 and 6 h, and 51.9 and 50.3 µg, respectively. A weak correlation was found between holding times and protein residue for the knife shafts, with a slope of -0.08 (P = 0.01, 95% CI: -0.13, -0.02), and R2 = 0.431. The protein residue on the knife shafts ranged from 31.0 to 35.9 µg. However, due to the low variation in protein residues the correlation had no clinical relevance.
Stereomicroscopy showed surface areas with corrosion of the degree Ri 1 corresponding to 0.05% of the surface on 22 of 30 scissors. A comparison of the two qualities of scissors showed that the surface structure of scissors with 12.5% chromium was not entirely as smooth as the surface of scissors with 16% chromium. The scissors with 12.5% chromium also appeared to have small silicon embeddings (3 mm in diameter) and these scissors were therefore 'born' with small impurities in the surface. A higher incidence of corrosion was identified on scissors with 12.5% chromium, where 12 out of 15 scissors were affected, compared to 10 out of 15 scissors with 16% chromium. The light stereomicroscopy showed a weak tendency (no clear signs) toward less corrosive activity on scissors with 16% chromium and holding times of 6 or 12 h, compared to scissors with a holding time of 24 h. There was no clear tendency for the scissors with 12.5% chromium, where the same degree of corrosion was observed on the scissors with holding times of 6, 12, and 24 h. Pitting, indicating severe corrosion attack, was observed on four scissors with 12.5% chromium. These were the scissors with holding times of 12 h and 35 reprocessing cycles, 12 h and 50 reprocessing cycles, and two scissors with holding times of 24 h and 50 reprocessing cycles. It is possible that this pitting corrosion had already begun at inclusion and was caused by the quality of the scissors, not the holding time before reprocessing.

Conclusion: The present study provides evidence for no association between the presence of protein residue on three different types of surgical instruments and the holding time before reprocessing was initiated. Thus, the cleanliness of instruments after dry and uncovered storage seems to be independent of holding time before reprocessing. Furthermore, the study demonstrates that instruments may have holding times up to 36 h before reprocessing is initiated without exceeding the accepted upper limit of protein residue of 100 µg.
Instead of a surrogate ('test soil') we have used defibrinated human blood. Thereby use of a substitute for human blood was avoided. The human blood used in the study was not pretreated or cleaned, which means it may have been contaminated with both bacteria and medicine residues. This suggests that the cleanliness of instruments may be independent of holding times before reprocessing.
The study revealed distinct differences in the surface structure of the two qualities of scissors and the scissors with 12.5% chromium was observed to have small silicon embeddings (3 mm in diameter) in the surface. This finding emphasizes the higher incidence of corrosion identified on the scissors with 12.5% chromium and that pitting corrosion attacks were only observed in the scissors with 12.5%

chromium. These findings are in concordance with Rosenberg's claim that the corrosion resistance of the steel depends on the amounts and composition of its specific components (4).
The study thereby challenges the relevance of upholding the recommendation of a maximum wait of 6 h prior to reprocessing. The findings will potentially have an impact on the organization of reprocessing of surgical instruments in Denmark and internationally.

Acknowledgements: We are indebted to L. Heimann Larsen PhD and J. Lorenzen PhD for their advice.

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O_19

Meta analysis of ScopeControl data of 5 hospitals

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[1]*UMC Utrecht, Utrecht, The Nederlands*

Session 7: Continous improvement of the CSSD processes part 2, King Willem Alexander

Biography:
Experienced Clinical Physicist with a history of working in the hospital & health care industry. Skilled in Medical Physics, C++, Digital Imaging, Biomedical Engineering, and Cancer. Strong healthcare services professional with a Doctor of Philosophy (PhD) focused in 3D Image Processing and Visualisation from University of Amsterdam

Aim: The ScopeControl (DOVIDEQ Medical) is a device that measures the optical quality of endoscopes in the clean room of the sterilization department to determine whether the endoscopes still have sufficient optical quality to be used for the next surgery. When the lens quality drops below 70% or when the fiber transmission drops below 30%, the endoscope should be rejected and be checked by a technician. The device stores all measurement data like light (LT) and fiber transmission (FB), sharpness (FC), color correctness and view angles in a database.
Now that the ScopeControl has been in use in several hospitals for a couple of years, we want to see to what extent the data can be used for research questions such as:
- What is the average reduction in quality parameters such as light transmission through lens and fiber?
- If an endoscope fails, is it a gradual or a fast process?
- Is the degradation of an endoscope related to parameters such as degree of use, new or repaired, thickness/length, brand, hospital, or sterilization method?

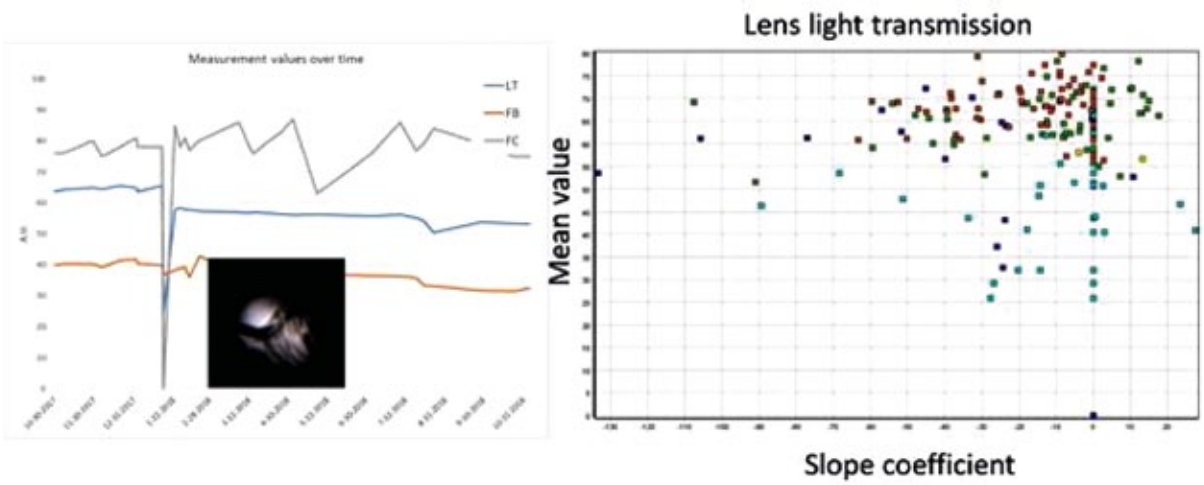
Methods: Measurement data of 5 hospitals was included in this study. For one hospital, this data could be linked to: 1) Endoscope repair/replacement. 2) Surgery data as the instrument basket number was also recorded during a ScopeControl measurement.

Results: A total of 47630 ScopeControl measurements were recorded in the period 2014-2018. To make the data useful, the following factors needed to be considered:
- Periods with no data because the ScopeControl was not available.
- Deviating measurements when the camera or sensor was defective.
- Registration of the measurement under an incorrect serial number.
- Missing basket numbers with a ScopeControl measurement as this was not enforced.

A special analysis tool was written in the C++ language to correct missing or corrupt data and enable comparison endoscope degradation over time between endoscope types, brands and hospitals.
Looking at the measurements, it appears that an endoscope deteriorates fairly slowly. On average it takes an endoscope about 8 years to drop below the rejection threshold. This degradation seems to be independent of length or thickness. On the contrary, often an endoscope suddenly breaks due to a lens or fiber breakage (See figure 1A). This makes the endoscope unusable at once.
The different LT, FB and FC graphs were analyzed further by determining five parameters of each graph:
1. Total number of days
2. Number of sterilization cycles
3. A start, mean and a slope coefficient by fitting a straight line.

In the software these values can be plotted against each other to search for distinguishable point clouds. A remarkable example was that the mean values of one endoscope type are clearly lower for one hospital (Figure 1B). This should trigger this hospital to investigate why the mean quality is lower.

Conclusions: The ScopeControl has delivered a lot of valuable measurements which potentially may reveal factors involved in the degradation of endoscopes. Benchmarking of hospitals, brands and types lie within reach.



A Breakage of a rod lens results in drop in LT and FC.
B Low mean value of LT graphs for the hospital with blue dots.

O_20

Residues after Reprocessing on Orthopedic Implants

Ludger Schnieder[1], **Klaus Roth**[1], Regina Miller[1], Gerald Mcdonnell[2], Mike Quin[2]
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Session 7: Continous improvement of the CSSD processes part 2, King Willem Alexander

Additive manufacturing, or 3D printing offers many advantages to medical device production. It also creates new challenges for the determination of biological safety. The printing process allows for matrixes to be layered in complex patterns within a device for various functions. The complex internal matrix poses a challenge to traditional extraction methods for the quantification of residues. Residual chemicals left on a device can pose risk for an immunocompromised patient by distracting the immune system, leaving a patient vulnerable to an increased risk of infection. Sterilization residues for certain sterilization modalities are routinely evaluated for residuals and have established acceptance criteria for patient safety evaluation. Other chemical compounds have limited or no evaluation in regards to patient risk from a toxicological perspective. In this study we will evaluate potential sources of chemical contaminant contribution within the supply chain and propose a method for the evaluation and acceptance criteria for determination of residual concentration.

R&D – When determining material compatibility, sterilant and manufacturing chemistries should be evaluated to understand the material interaction and propensity to contribute to chemical buildup of the residual. Although this practice is not a new one, the method we are proposing to detect and evaluate patient safety is an innovative method.

Method – Under vacuum conditions film like contaminations tend to desorb from their host surface. The speed of desorption depends on the temperature and the chemical composition of the contamination. A continuous monitoring of the gas released from the surface for a time of some hours using for example a quadrupole mass spectrometer allows the determination of the amount of material which was released from the surface and also provides a "fingerprint" of the chemical composition of the contamination, for example in the range of 45 to 200 atomic mass units. Although this is only a small range of masses the fragmentation of the desorbing molecules during ionization delivers a unique spectrum of masses. With the help of a database containing "fingerprints" of the relevant substances a very sensitive detection of residual amounts of chemical compounds can be performed.

Source – Many manufacturers use contract manufacturers to supply raw materials, portions or the entire final product. When sourcing contract manufacturers that reflect the expected level of quality it is crucial to set up a monitoring program with manufacturing residuals in mind. Although some raw materials used in the production of certain products may be evaluated for purity, it is not currently expected to evaluate all components or raw materials for residual manufacturing chemicals. Within this study the authors intend to demonstrate the potential impact of not implementing a routine monitoring program to evaluate product cleanliness.

Make – Devices intended to be implanted in a patient propose the largest risk to patient safety from a residual perspective. The residual manufacturing materials should be evaluated and monitored routinely to ensure patient safety.

Customer – Reusable medical devices processed for multiple patient use at a healthcare facility have the potential to see a buildup of detergents or lubricants. This residual buildup should also be evaluated for accepted levels to ensure patient safety.
Residual chemistry on materials or finished products affects all parts of Sterility Assurance (e.g., End to End Supply Chain, Industries). This project will challenge the audience to think differently and consider how residual chemistry should impacts device cleanliness and ultimately patient safety.

O_21

Spicing up your lectures on sterile supply: a blend of methods

Jan Huijs[1]
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Session 8: EDUCATION, King Willem Alexander

Biography:
Jan Huijs, owner of HEART Consultancy, based in the Netherlands. After working as a medical equipment engineer in Ghana, Africa for 7 years in the 1980's he started HEART Consultancy, a consulting agency focusing on sterilization of medical supplies and asset management for health facilities, focusing on the health services in the developing world. He presents training for users as well as technicians on sterilization of medical supplies in mainly developing countries since 1997. More recently workshops and lectures were also presented in several countries in the Middle East and Asia. He is author of the book "Sterilization of medical supplies by steam" which now has been translated into 9 languages. He has been doing research on sterilization of medical supplies in remote areas. Since 2014 he is honorary member of SVN: Sterilisatie Vereniging Nederland (Dutch Sterilization Association).

The provision of sterile goods is a crucial element in providing safe healthcare. However sterile supply tends to be a subject that is hard to grasp which deals with invisible life that needs to be removed and inactivated. Processes for cleaning, disinfection and sterilization are rather abstract. For understanding the steps of the sterile supply cycle, one meets questions in a wide range of scientific topics such as microbiology, physics, medicine, electrical and mechanical engineering and nowadays even information technologies. Questions range from: Where are these invisible micro-organisms? How can they spread? Why is surface tension of water impeding adequate cleaning? What are those non-condensable gases? Why is air in a steam sterilizer a problem? How to make steam at an adequate temperature to assure sterilization? Why the heck a vacuum is used for drying the load? What actually happens in that sterilizer? And knowing all these, how to make all this information available to a worldwide audience?

Training experience in the field: a need for blended learning
For a long time I have been presenting training sessions for CSSD staff and sterilizer technicians. Most of the time in Africa, however also in Asia, Middle east and recently also in the Netherlands. The traditional approach in training were the textbook and PowerPoint presentations based on the content of the book. However as time passed, the need for physical experiments was felt that bring the rather abstract topics closer to real life experiences. And with the Internet coming available in most corners of the world it was time to start making use of its potential.

Elements of blended learning: Methods of training/knowledge transfer
This demand lead to a blended approach of teaching in which a range of methods are used:

Textbook
A text book has been considered the backbone for any teaching program. Over the years a textbook on sterile supply was compiled which now covers the majority of the topics relevant to hospital sterile supply and remains being updated. At the moment the book is available in 9 languages; this year two languages are planned to be added. Especially for faraway locations postal charges have skyrocketed and therefore recently some editions became available as e-book.

PowerPoint presentations
Based on the content of the book a series of power point presentations were made and used during lectures. Where appropriate, the presentations are being adapted to the local reality where a course is presented.

Practical experiments
It is a known fact that the impact of actual physical experience in the real world is most effective in transferring and deepening knowledge. As sterilization is such an abstract topic, a number of practical experiments were introduced where students can participate. The experiments cover various aspects of the sterilization cycle. The main objective is to provide an additional layer of experience as compared to standard lecturing and/or reading. As much as possible the teaching aids are adapted to the reality of the participants. The used experiments do not claim to be complete and may be improved. Many of these experiments are very simple, low-cost and easy to apply.
Examples of practical experiments and demonstrations are related to microbiology using Petri dishes with culture medium. For demonstrations on infection prevention and cleaning/hand washing fluorescent powder and a UV light are used. For explaining and showing essential aspects of steam and steam sterilization a basic steam demonstration kit was developed based on a two litre Erlenmeyer flask, with a pressure gauge, a thermocouple with digital thermometer, a manual vacuum pump and a hot plate (See photograph). For verification of performance of sterilizers a basic kit was made that can be connected to the validation port of almost any sterilizer. It includes a pressure gauge and a dual channel thermometer with thermocouple entry. It allows real time measuring of temperatures in the chamber and centre of a load and helps demonstrating the crucial need of air-removal before sterilization. It also enables creating an air leak for simulating a failed process. The kit is used in combination with the standard textile Bowie and Dick pack. Students in groups run a correct and a fail cycle, while registering pressures and temperatures each minute of the process. Various additional practicals are done on manual and ultrasonic cleaning, packaging methods and more advanced sterilizer performance monitoring using various types of process challenge devices. Developing SOP's based on the actual situation in the department have also been included in practical workshops.

Process simulations for sterilizers
Understanding the operation of sterilizers can be rather confusing, notably for the advanced sterilizers for porous loads and hollow instruments. A diagram alone does not clearly show what happens in a sterilizer as a process goes through its various phases. Based on the actual sterilizers as installed at the site where the training took place, process simulations were created based on the simplified piping diagram. During the simulation, the functioning of individual components and the flow of the various media (water, steam, condensate, compressed air) in relation to the process graph can be easily followed. The presentations also can be used during the practical workshops with the sterilizers in the department. This especially applies to sterilizers which do not have a graphical display, as is the case in many health facilities in the developing world.

E-Learning
The new media and the internet offer exciting new possibilities for knowledge transfer. For example student interaction, multimedia using text, sound, and film for movies and simulations. Moreover monitoring of students through on-line tests and assessments are easily integrated. And last but not least the material can be available to any location worldwide at any time on a device that also has massively reached the developing world: the smartphone. Especially countries in development where local training facilities and access to textbooks are limited but where smartphones have become widespread, this offers great new possibilities for upgrading the skills of staff. In collaboration with DTS, a Dutch developer of e-learning systems, since 2016 an e-learning platform was launched as supplement for training of staff of CSSD's in the Netherlands. It offers the theoretical part and ends with a practical evening at the vocational school which hosts the course. The training covers modules on micro-biology, infection prevention, cleaning and steam sterilization. The modules are based on the original textbook which thus can be used as a reference. In the mean time staff from a wide

range of hospitals in the Netherlands have followed the course and gained credit points of the Dutch Sterilization association (SVN) that has approved the course. At the moment an English version of the training is compiled, making it available to students worldwide.

Results

During the past more than 20 years, the textbook, PowerPoint presentations, process simulations and practicals were developed and have been used and field tested in 20 countries in Africa, Middle east and Asia and here in the Netherlands, and were received with great enthusiasm. Several thousand participants were involved in courses and workshops. The Dutch E-learning programme was implemented in the Netherlands in 2016 and was attended by 286 students from hospitals all over the country. There is a continuing demand from healthfacilities from all over the world to continue with the training activities .

Conclusion

The sterile supply cycle deals with ensuring safe sterile medical supplies by removing and inactivating invisible life. In order to achieve this, various methods and equipment is used. For teaching the use traditional textbooks and PowerPoint presentations has been common. However the abstract nature of procedures within the sterile supply cycle, make comprehension difficult. By making elements of the steps in the sterile supply cycle more visible it makes them more easy to understand and can help in creating more awareness of the presence of this invisible life, its behaviour and how to inactivate it. Using various teaching aids, several aspects of the steps in the sterile supply cycle can be demonstrated. The E-Learning programme provides a platform for studying independent of time and location and enhances studying with a wide range of multimedia tools such as animations, interactions, simulations, and student assessments etc. The blended approach of complementary teaching materials and methods thus can lead to deepening knowledge, enthusiasm for our profession and improved proficiency of the staff which ultimately leads to better patient safety.

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The book is also available in Spanish, French, Polish, Norwegian, Russian, Japanese and Turkish. For details refer to www.heartware.nl/books

Blended learning programme:
Bijscholing voor sterilisatiemedewerkers. (Blended learning refresher training for staff of the Sterile Services Department). It is hosted by the Summa College, Eindhoven, The Netherlands. Developed by Jan Huijs in collaboration with DTS, Oisterwijk, The Netherlands. E-Learning platform: eFront. For information visit: https://www.summacollege.nl/bedrijven-particulieren/cursussen/cursus-detail/bijscholing-voor-sterilisatiemedewerkers

Experiments with the steam demonstration kit greatly enhances a lecture as here during a workshop for CSSD staff and technicians in Kumba District Hospital, Cameroon (2008)

O_22

The Positive Impact of Social Media On Learning and Professional Growth Within the Global Sterile Processing Community

Hank Balch[1], Justin Poulin[1]
[1]*Beyond Clean, San Antonio, United States*

Session 8: EDUCATION, King Willem Alexander

Biography:
Hank Balch is the Co-founder and Principal Consultant of Beyond Clean. He began his career in instrument reprocessing as a frontline technician in 2009, and has served as an Instrument Database Specialist, Department Manager, and System Director for various SPD departments across the United States. Hank is an award winning Sterile Processing leader (2016 Healthcare Purchasing News "CS/SPD Department of the Year"), twice nominated for IAHCSMM President, founder of two state-wide IAHCSMM chapters, conference speaker, and well-known industry writer, blogger, and social media connoisseur. His work has been published in Becker's Hospital Review, Infection Control Today, Healthcare Purchasing News, Communique, Outpatient Surgery Magazine, AAMI BI&T Journal, SteriWorld, SVN: Parametric Release, and other publications across the globe. His passion is seeing frontline Sterile Processing professionals equipped to #FightDirty, every instrument, every time.

Aim: To demonstrate the existing value of social media tools and platforms to facilitate global networking, innovative education, and engagement of ideas to improve the Sterilization industry and frontline personnel.

Methods: Observations where made in the development of a USA-based, English language internet radio show discussing Sterile Processing topics with various subject matter experts around the world. Engagement data was gathered for the show from both national and international impact and reach analysis over an 18-month period. Statistics linked to continuing education credit delivery and audience-growth trends were captured during this period from form surveys and social media tools.

Results: From an initial podcast interview release in September 2017 which was downloaded in nineteen (19) countries around the globe, total engagement grew by February 2019 to encompass audiences in 125 countries on every continent with the exception of Antartica. Total international (non-US based listeners) comprised over 21% of content downloads, with the top ten geographic downloads including:

1) United States
2) Canada
3) Saudi Arabia
4) United Arab Emirates
5) Australia
6) United Kingdom
7) Philippines
8) India
9) Ireland
10) Qatar

Social media platforms connected with the podcast experienced a similar ten-fold growth during the observed 18-month period, with 33% of followers residing outside the USA. Over 13% of these social media platform followers listed English as a secondary language.

Conclusions: This presentation challenges the assumption that utilization of social media is inconsequential for the purposes of facilitating global engagement, collaboration, and networking within the Sterile Processing industry. Some view this category of (social) media as unprofessional and/or recreational by default, but this is an underestimation of the potential it has as a conduit for high-quality education and tangible networking on an international scale. If the internet as a whole represents the democratization of information to the masses, then social media in the service of the Sterile Processing industry represents the universal appreciation of scientific progress and the global hunger for knowledge and professional growth of frontline technicians. By leveraging social media in an innovative fashion, our industry can see tremendous growth in international collaboration and experience wide-scale dissemination of industry best practices in a manner and speed which far exceeds traditional methods.

Keywords: Social Media, Networking, Cross-Pollination, Global, Podcast

O_23

What can we learn from both worlds (debate on education in the USA and the Netherlands)

Damien Berg, Tom Pereboom

Session 8: EDUCATION, King Willem Alexander

Abstract not available.

O_24

Current status of CSSD development in China

Zhang Qing[1]
[1]*China Nursing Association Cssd Committee, Beijing, China*

Session 9: Miscellaneous, King Willem Alexander

Biography:
Zhang Qing, female, CSSD Manager of Peking Union Medical College Hospital, President of China Nursing Association CSSD Committee, Vice-president of Chinese Health Supervision Association Disinfection and Infection Control Committee, Vice-president of the Youth Committee of Chinese Preventive Medicine Association Disinfection Branch, Standing Committee member of China Medical Doctor Association Infection Management Committee, Member of the National Standardization Committee on Disinfection Technology and Equipment, Editorial Board Member of Chinese Journal of Nursing, and Editorial Board Member of Chinese Journal of Nursing Education.

Aim: China Nursing Association CSSD Committee (hereinafter refer to as CNACSSD) was founded in 2004, developing up to now, has 70 members, 50 young members and 210 expert members, covering 31 provinces, municipalities and autonomous regions of China. In 2009, National Health and Family Planning Commission of the People's Republic of China has published three industrial standards of Central Sterile Supple Department: WS310.1: Management Standard; WS310.2: Standard For Operating Procedure Of Cleaning, Disinfection And Sterilization; WS310.3: Surveillance Standard For Cleaning, Disinfection And Sterilization. Over the past decade, under the leadership of CNACSSD, with the full implementation of industrial standards, the deep development of professional training, and the extensive international communications, Chinese disinfection and supply profession has developed rapidly. Investigate the CSSD development status in Chinese hospitals, to provide scientific basis for achieving standardized management, organizing targeted professional training and practice, and balancing the development level of disinfection and supply profession in various regions of China.

Method: The special questionnaires designed by CNACSSD were used to do the investigation for 8 hot and difficult issues in the CSSD development, including the CSSD post setting and personnel status; the processing status of precise surgical instruments; the status of steam sterilization programs; the processing status of loan surgical instruments and implants, the processing status of ophthalmological surgical instruments, the status of CSSD basic topics, the application status of IFU and the assessment of personnel capability in CSSD. The questionnaire investigations were conducted in 651-1869 hospitals from 2013 to 2017.

Results: In terms of post setting and personnel status, the proportion of CSSD centralized management increased from 84% in 2013 to 93% in 2017; the proportion of hospitals with processing instruments scope covering general surgical instruments, rigid endoscopy instruments and special precise surgical instruments increased from 39% in 2014 to 47% in 2017. For the CSSD working time, up to 2017, 8-hour working time of CSSD is still practiced in more than 50% hospitals (24-hour standby). As the scope of processing instruments is expanding, an increasing number of hospitals begin to set up posts dedicated to rigid endoscopy instruments and loan instruments. According to the survey in 2017, the proportion of CSSD staff is mainly nurses, with 45% (843) hospitals having less than 20% workers, while 44% (823) hospitals having more than 70% nurses, efforts shall be made to develop specialized nurses and train skilled workers. The proportion of the CSSD managers with bachelor's degree or above has exceeded 60%. Surveys conducted in 2016 and 2017 for two consecutive years showed that 94% and 95% of hospitals have received WS310 training, but the

training mainly focuses on head nurses and nurses, while the training for workers is less. In terms of the processing status of precise surgical instruments, the survey results in 2017 showed that more than 20% hospitals did not take protective measures in the treatment of precise instruments. In terms of the processing status of the loan instruments and implant, the survey results in 2017 showed that the proportion of loan instruments processing is increasing in all levels of hospitals. 45% of the hospitals' loan instruments processing ratio reach to 10% or more of the total daily processing capacity of surgical instruments, but 8% of hospitals still have no special management system, and 20% of hospitals have no special processing procedure for loan instruments. According to the results of the survey in 2015 and 2017, in 4% of the hospitals, the loan instruments were taken out directly without any treatment, in 34% of the hospitals, the loan instruments were taken out directly after simple cleaning in the operating room without CSSD treatment. In terms of the status of steam sterilizing programs, 67% of the hospitals' sterilizers have no special sterilization procedures for super-large and super-heavy bags, and 57% of the hospitals' CSSD don't do the validation of the sterilization parameters and effectiveness when the load instruments were first received. In terms of application status of IFU, the proportion of domestic surgical instruments provided with standard IFU is 28% in 2016, while 7% in 2017. The proportion of foreign surgical instruments provided with standard IFU is 32% in 2016, while 14% in 2017.

Conclusions: For the development of disinfection and supply profession in China, in terms of personnel, should give full play to the role of specialized nurses in the instruments' management, improve the professional level of post personnel, enhance the precise technical operation of post personnel, and correctly grasp relevant laws, regulations, standards and norms. In terms of management, CSSD quality management system and evaluation criteria should be established, hierarchical personnel training and assessment system should be established, risk assessment and quality control should be strengthened, and team cooperation and innovation should be strengthened. In terms of technology, in view of the difficulty and quality requirements of cleaning, disinfection and sterilization of special surgical instruments, three technical guidelines have been compiled and published, namely, Cleaning and Sterilization Technical Operational Guidelines For Rigid Endoscopes, published in 2015, Cleaning and Sterilization Technical Operational Guidelines For Ophthalmic Surgical Instruments, published in 2016, and Cleaning and Sterilization Technical Operational Guidelines For Loan Surgical Instruments, published in 2017. The guidelines provide a basis for the standardized treatment of special surgical instruments with precise, precious, complex structure and diverse materials, and improve the processing quality of reusable surgical instruments. In terms of equipment, attention should be paid to the parameter validation and effectiveness evaluation of disinfection and sterilization, the method of cleaning and sterilization of new instruments and the validation of sterilization parameters, the method of cleaning and sterilization of loan instruments and the validation of sterilization parameters.

O_25

Energy-saving of steam sterilizer in the central sterile supply department

Jin Yun-yu[1]
[1]*The First Hospital Of Jilin University , Changchun, China*

Session 9: Miscellaneous, King Willem Alexander

Biography:
Ms. Jin is the chief nurse, engaged in nursing management for 15 years, engaged in disinfection supply center management for 10 years. He has won many management awards in China.

Aim: Steam sterilization is an energy-intensive process . The aim of this study was to reduce the energy consumption and save the cost of steam sterilizer usage in the central sterile supply department.
With the development of climate change and Global warming, there is an increasing attention in the environmental sustainability of health care[1]. Despite various of modes of sterilization, steam sterilization remains the commonest method for surgical items[2]. Meanwhile, steam sterilization is an energy-intensive process, each load require a lot of electricity, steam and water, also emissions extra $CO2$[3].
An idle sterilizer (standby) also consume energy, like electricity to maintain the control system of the sterilizer and steam to keep the jacket of the sterilizer warm.
Most medium- to large-sized hospitals in China equipped with several steam sterilizers and lack of normative management. These result in energy waste and inconformity the National sustainable development strategy. Furthermore, the study on energy-saving of steam sterilizer structure have been less reported domestically.
This study aim to address several things. First, find the active, idle or switched off time of the steam sterilizers during half of a year, and how much energy was wasted. Second, according to the first result, switch off some sterilizers when it is needed rarely, then count the electricity and steam use and the potential financial savings.

Method: This study was performed in the Central Sterile Supply Department (CSSD) at a third-grade class-A hospital in China. The CSSD owns six “Xinhua” steam sterilizers (Zibo, Shangdong, China). We examed the activity of all the sterilizers for half of a year, but excluded the following types of sterilizers, such as the immediate use steam sterilizers, table-top sterilizer and portable mode steam sterilizers.The hospital is capable of performing most types of surgery, with approximately 100,000 cases of surgery per year. The CSSD is responsible for the centralized management of all the reused items in the hospital. At the end of every sterilizer cycle, the monitoring system generate sterile reports automatically.
A steam sterilizer can be active, idle and off. Active cycles include standard sterilization procedures (132 °C sterilization cycle or 134 °C sterilization cycle) and auxiliary procedures (such as Warm Ups, Bowie Dick tests and quality testing procedures, etc.). What an example to “Xinhua” steam sterilizer, an active cycle need electricity, water and steam, and an idle sterilizer need steam and electricity. According to the Central Sterile Supply Department (CSSD) --Part 1: Management standard, the sterilization records should reserve above 3 years. We collected the sterilization reports from January to June, 2016, calculate the hours of active and off every day, thus get the result of the hours of idle. An energy-saving strategy was performed for the six steam sterilizers from January to June, 2017. All of the six sterilizers were used all day (from 06:00 to 01:00 h) on weekdays while three on weekends as conventional usage. But due to lower demand, it was necessary to only switch on three sterilizers

before 08:00 h and switch off three sterilizers on 15:00 h, and a fourth on 17:00 h at weekdays. At weekends, it was enough to switch on one sterilizer before 08:30 h, and switch off two sterilizers on 13:00 h. Then we calculated the hours that steam sterilizers were active, idle and off, and analyzed the potential reductions in energy and cost. In addition, the CSSD equipped two table-top sterilizers routinely for emergency items and these data was not included in the study.
Because of no reference about the energy consumption of the domestic steam sterilizer in China, we measured the average quantitative value of the electricity, steam, water consumption in an active cycle and an idle hours in the sterilizer factory with the help of engineers. This method takes the size of 1,500 liters of sterilizer as an example, different capacity sterilizer of the same brand can be proportionally converted.
All analyses were conducted using SPSS 18.0. Continuous data were analyzed for normality using the Kolmogorov Smirnov test. Because most distributions did not appear to be normal, most of data were reported as medians with interquartile ranges. Enumeration data were reported as frequencies (%). Differences between groups of continuous data were analyzed using the Wilcoxon signed-rank test for nonparametrically distributed data. All reported P values are 2-sided, and all comparisons attained statistical significance at $P < 0.05$.

Results: After implementation the switch-off strategy, sterilizers were idle for 10665 sterilizer–hours half of a year, reduced 5818 hours compared with formerly use. And we reduced electricity use by 2,910 kWh and steam use by 97,000 kg half of a year, resulting in financial savings of more than RMB ¥ 30,000 (17%).
From January to June, 2016, the data of sterilization cycles were 5,182, with 28 failed cycles. From January to June, 2017, a total data of cycles were 5,553, including failed cycles of 19. Table 1 shows the active sterilizer numbers of timing on 122 weekdays from January to June, 2016. We could see that the usage of sterilizers were different from time period obviously. There were one sterilizer active from 06:00 to 07:00 on only 3 of 122 weekdays and rarely more than one active sterilizer. Three of the sterilizers were active from 07:00 to 08:00 on only 8 of 122 weekdays. And after 15:00, three sterilizers active were only 7 of 122 weekdays and rarely more than two sterilizers active after 17:00. On weekends, it was enough for one sterilizer before 09:00 and after 13:00.
During weekends the idle hours of six sterilizers during low peak stage after performing energy-saving strategy compared with previous data. We could see how much difference in idle hours after new policy had been conducted ($P<0.01$). The idle hours of each period were decreased sharply. Each "Xinhua" steam sterilizer idle one hour will consume 16.56 kilograms of steam and 0.5 kWh of electricity, and the cost will be RMB ¥ 5. We needed to pay approximately RMB ¥ 60,000 for the steam and electricity consumption in half of a year at consuetudinary usage.
There was a significant difference of electricity, steam and finacial between before and after the policy. The idle hours of sterilizers were much more than active hours. The sterilizers were active for 4,221 (26.2%) h and idle for 11,871 (73.8%) h before the switch-off strategy. But after the policy, the sterilizers were active for 4,612 (43.2%) and idle for 6,053 (56.8%).We can see that the saving from such an approach after half of a year would be 97,000 kg, 2,910 kWh and approximately RMB ¥ 30,000.

Conclusion: The multistep switch-off strategy could reduce the consumption of energy and cost effectively, and could be applied to other similar hospitals.
Sterilization of the steam sterilizers existed high and low peak period. It was needed of all sterilizers in high peak period but not in low peak period. The idle hours might be longer if all of the sterilizers were switch-on and switch-off at the same time. The research about energy consumption and energy saving of steam sterilizer is lacking in China. So, it is important for the managers and staff of CSSD to pay more attention to their daily work and find the exited problem and adjust it to improve the quality of work and promote the development of the CSSD.
As the use of sterilizers are not continuous completely, it is hard to eliminate idle hours, but it is also useful to make some new strategy to reduce it. In addition, because of the fabric items are sterilized for the use of second day, may be we can sterilize the fabric items in night shift intensively, so it is able to switch off several sterilizers in day shift to reduce more idle hours. But this method is still in the stage of design and need further study.

Limitations of this study include lack of further research on other aspects except the switch-off policy. For example, As we know, the heat exchanger water of one "Xinhua" sterilizer need 17,000 liters every active cycle. Recycle and chill this water will achieve large water and finacial savings.

Keywords: sterilization, energy, sustainability, cost

Acknowledgement: This project was supported partially by the nursing scientific research fund of a third-grade class-A hospital in China.

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P_01

Spicing up your lectures on sterile supply: a blend of methods

Jan Huijs[1]
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Biography:
Jan Huijs, owner of HEART Consultancy, based in the Netherlands. After working as a medical equipment engineer in Ghana, Africa for 7 years in the 1980's he started HEART Consultancy, a consulting agency focusing on sterilization of medical supplies and asset management for health facilities, focusing on the health services in the developing world. He presents training for users as well as technicians on sterilization of medical supplies in mainly developing countries since 1997. More recently workshops and lectures were also presented in several countries in the Middle East and Asia. He is author of the book "Sterilization of medical supplies by steam" which now has been translated into 9 languages. He has been doing research on sterilization of medical supplies in remote areas.
Since 2014 he is honorary member of SVN; Sterilisatie Vereniging Nederland, (Dutch Sterilization Association)

The provision of sterile goods is a crucial element in providing safe healthcare. However sterile supply tends to be a subject that is hard to grasp which deals with invisible life that needs to be removed and inactivated. Processes for cleaning, disinfection and sterilization are rather abstract. For understanding the steps of the sterile supply cycle, one meets questions in a wide range of scientific topics such as microbiology, physics, medicine, electrical and mechanical engineering and nowadays even information technologies. Questions range from: Where are these invisible micro-organisms? How can they spread? Why is surface tension of water impeding adequate cleaning? What are those non-condensable gases? Why is air in a steam sterilizer a problem? How to make steam at an adequate temperature to assure sterilization? Why the heck a vacuum is used for drying the load? What actually happens in that sterilizer? And knowing all these, how to make all this information available to a worldwide audience?

Training experience in the field: a need for blended learning
For a long time I have been presenting training sessions for CSSD staff and sterilizer technicians. Most of the time in Africa, however also in Asia, Middle east and recently also in the Netherlands. The traditional approach in training were the textbook and PowerPoint presentations based on the content of the book. However as time passed, the need for physical experiments was felt that bring the rather abstract topics closer to real life experiences. And with the Internet coming available in most corners of the world it was time to start making use of its potential.

Elements of blended learning: Methods of training/knowledge transfer
This demand lead to a blended approach of teaching in which a range of methods are used:

Textbook
A text book has been considered the backbone for any teaching program. Over the years a textbook on sterile supply was compiled which now covers the majority of the topics relevant to hospital sterile supply and remains being updated. At the moment the book is available in 9 languages; this year two languages are planned to be added. Especially for faraway locations postal charges have skyrocketed and therefore recently some editions became available as e-book.

PowerPoint presentations
Based on the content of the book a series of power point presentations were made and used during lectures. Where appropriate, the presentations are being adapted to the local reality where a course is presented.

Practical experiments
It is a known fact that the impact of actual physical experience in the real world is most effective in transferring and deepening knowledge. As sterilization is such an abstract topic, a number of practical experiments were introduced where students can participate. The experiments cover various aspects of the sterilization cycle. The main objective is to provide an additional layer of experience as compared to standard lecturing and/or reading. As much as possible the teaching aids are adapted to the reality of the participants. The used experiments do not claim to be complete and may be improved. Many of these experiments are very simple, low-cost and easy to apply.
Examples of practical experiments and demonstrations are related to microbiology using Petri dishes with culture medium. For demonstrations on infection prevention and cleaning/hand washing fluorescent powder and a UV light are used. For explaining and showing essential aspects of steam and steam sterilization a basic steam demonstration kit was developed based on a two litre Erlenmeyer flask, with a pressure gauge, a thermocouple with digital thermometer, a manual vacuum pump and a hot plate (See photograph). For verification of performance of sterilizers a basic kit was made that can be connected to the validation port of almost any sterilizer. It includes a pressure gauge and a dual channel thermometer with thermocouple entry. It allows real time measuring of temperatures in the chamber and centre of a load and helps demonstrating the crucial need of air-removal before sterilization. It also enables creating an air leak for simulating a failed process. The kit is used in combination with the standard textile Bowie and Dick pack. Students in groups run a correct and a fail cycle, while registering pressures and temperatures each minute of the process. Various additional practicals are done on manual and ultrasonic cleaning, packaging methods and more advanced sterilizer performance monitoring using various types of process challenge devices. Developing SOP's based on the actual situation in the department have also been included in practical workshops.

Process simulations for sterilizers
Understanding the operation of sterilizers can be rather confusing, notably for the advanced sterilizers for porous loads and hollow instruments. A diagram alone does not clearly show what happens in a sterilizer as a process goes through its various phases. Based on the actual sterilizers as installed at the site where the training took place, process simulations were created based on the simplified piping diagram. During the simulation, the functioning of individual components and the flow of the various media (water, steam, condensate, compressed air) in relation to the process graph can be easily followed. The presentations also can be used during the practical workshops with the sterilizers in the department. This especially applies to sterilizers which do not have a graphical display, as is the case in many health facilities in the developing world.

E-Learning
The new media and the internet offer exciting new possibilities for knowledge transfer. For example student interaction, multimedia using text, sound, and film for movies and simulations. Moreover monitoring of students through on-line tests and assessments are easily integrated. And last but not least the material can be available to any location worldwide at any time on a device that also has massively reached the developing world: the smartphone. Especially countries in development where local training facilities and access to textbooks are limited but where smartphones have become widespread, this offers great new possibilities for upgrading the skills of staff. In collaboration with DTS, a Dutch developer of e-learning systems, since 2016 an e-learning platform was launched as supplement for training of staff of CSSD's in the Netherlands. It offers the theoretical part and ends with a practical evening at the vocational school which hosts the course. The training covers modules on micro-biology, infection prevention, cleaning and steam sterilization. The modules are based on the original textbook which thus can be used as a reference. In the mean time staff from a wide

range of hospitals in the Netherlands have followed the course and gained credit points of the Dutch Sterilization association (SVN) that has approved the course. At the moment an English version of the training is compiled, making it available to students worldwide.

Results

During the past more than 20 years, the textbook, PowerPoint presentations, process simulations and practicals were developed and have been used and field tested in 20 countries in Africa, Middle east and Asia and here in the Netherlands, and were received with great enthusiasm. Several thousand participants were involved in courses and workshops. The Dutch E-learning programme was implemented in the Netherlands in 2016 and was attended by 286 students from hospitals all over the country. There is a continuing demand from healthfacilities from all over the world to continue with the training activities .

Conclusion

The sterile supply cycle deals with ensuring safe sterile medical supplies by removing and inactivating invisible life. In order to achieve this, various methods and equipment is used. For teaching the use traditional textbooks and PowerPoint presentations has been common. However the abstract nature of procedures within the sterile supply cycle, make comprehension difficult. By making elements of the steps in the sterile supply cycle more visible it makes them more easy to understand and can help in creating more awareness of the presence of this invisible life, its behaviour and how to inactivate it. Using various teaching aids, several aspects of the steps in the sterile supply cycle can be demonstrated. The E-Learning programme provides a platform for studying independent of time and location and enhances studying with a wide range of multimedia tools such as animations, interactions, simulations, and student assessments etc. The blended approach of complementary teaching materials and methods thus can lead to deepening knowledge, enthusiasm for our profession and improved proficiency of the staff which ultimately leads to better patient safety.

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The book is also available in Spanish, French, Polish, Norwegian, Russian, Japanese and Turkish. For details refer to www.heartware.nl/books

Blended learning programme:

Bijscholing voor sterilisatiemedewerkers. (Blended learning refresher training for staff of the Sterile Services Department). It is hosted by the Summa College, Eindhoven, The Netherlands. Developed by Jan Huijs in collaboration with DTS, Oisterwijk, The Netherlands. E-Learning platform: eFront. For information visit: https://www.summacollege.nl/bedrijven-particulieren/cursussen/cursus-detail/bijscholing-voor-sterilisatiemedewerkers

Experiments with the steam demonstration kit greatly enhances a lecture as here during a workshop for CSSD staff and technicians in Kumba District Hospital, Cameroon (2008)

P_02

The evaluation of disinfection efficacy of levulinicacid for mycobacterium tuberculosis and safety toxicology assessment

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Biography:
Yang ,liu. Ph. D., Associate Professor, Master's Supervisor, Capital Medical University, Beijing China. Director of Epidemiology Research Department, director of Disease Prevention and Control department of Beijing chest Hospital, Capital Medical University. Research direction is Mycobacterium tuberculosis control and prevention, lung cancer and pulmonary tuberculosis molecular epidemiology research.

Aims: To observe the germicidal efficacy of levulinic acid plus sodium dodecyl sulfate (LVA-SDS)[1] for Mycobacterium tuberculosis(M.tb.) standard strain H37Rv and multidrug-resistant M.tb (MDR-TB) clinical isolates and to evaluate LVA safety. This study will provide a new method for the sterilization of M.tb.

Methods: H37Rv and MDR-TB in the logarithmic growth phase were first selected and ^{1} x 10^{5} CFU/ml bacterial suspension was prepared and used in the test. Dilution method[2] was used to observe whether LVA-SDS had germicidal efficacy on MDR-TB clinical isolates and MIC or MBC of LVA-SDS could be obtained. The concentration of disinfectants ranged from 0.325 ~ 0.0325 - 10 % ~ 1% (LVA-SDS). Control wells contained only bacterial suspension and water. Microtitre plate wells were seeded with 50 ul of the bacterial suspension, then adding 50 ul of disinfectant. Then the plates were sealed with perforated parafilm and incubated at 37 °C for 2~3 weeks. The plates were observed weekly to monitor the changes of their growth inhibition by visual examination and the optical density (OD) was tested in a spectrophotometer at 600 nm.
According to the 2002 China edition of the Technical Specification for Disinfection, animal experiment methods, such as the acute toxicity test, cumulative toxicity and skin irritation test, were used to evaluate the toxicology safety.

Results: The MIC and MBC of LVA-SDS for H37Rv and MDT-TB both were 0.075% LVA + 0.0075%SDS. The optimal killing concentration of LVA-SDS for H37Rv and MDT-TB isolates was 20%LVA+2%SDS and the suitable action time was 30min.
The maximum of the inactivation of the disinfectant on the acute toxicity test was LD50 > 5000 mg/(kg•bw). Cumulative toxicity test lasted for 28 days, and no death mice were founded. Skin irritation test showed that the integral scores of skin irritation were 0 and the LVA-SDS disinfectant had no irritation to the skin of mice.

Conclusion: The LVA-SDS disinfectant has a good bactericidal efficacy on H37Rv and MDT-TB isolates and LVA-SDS was a kind of non-toxic, no cumulative toxic and no skin stimulating disinfectant, which may be used to sterilize and prevent the transmission of Mycobacterium tuberculosis in the future[3].
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Key words: Mycobacterium tuberculosis; Levulinic acid; Sterilization; Safety

P_03

Thermolabile flexible endoscope cleaning and disinfection: Tips and tricks

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Biography:
He is an expert on medical sterile devices and expert on flexible endoscope cleaning and disinfection. He is the Honorable Secretary of SFERD, the working group that created the Professional Standard Handbook on Flexible Endoscope Cleaning and Disinfection in The Netherlands.

This Poster shows the results of 14 years of experience and contribution to the creation of the Professional Standard Handbook on Endoscope Cleaning and Disinfection. This manual is available in Dutch, English, Spanish and Russian language free of charge and can be downloaded on https://sferd.nl/downloads/ .

The Poster describes several Tips and Tricks that may support colleagues involved with endoscope cleaning and disinfection. The manual presents practical issues based on current legislation and guidelines. In addition the Poster describes suggestions as opportunities when endoscopes are replaces. It describes issues that may support you when incidents occur and you have to react in an effective mode.

The content of the poster then advises on which type of endoscopic disinfector is to be chosen in order to achieve optimal cleaning and disinfection and a patient-safe result.
Thermolabile flexible endoscope Cleaning and Disinfection: Tips and Tricks

P_04

A case study on Sterile processing leadership: Lessons learnt

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Biography:
Sterile Processing Lead

Aim: This presentation aims to share to the global reprocessing community the Australian experience in the challenges confronting individual health service organization in addressing expectations from our role as a support team in providing quality reprocessed medical devices on a timely manner that is worthy of patient use. The reprocessing professional's level of engagement in particular and the leadership required to motivate to motivate this, a critical aspect of this expectation. Lessons learnt, the historic challenges, persistent issues and moving forward as a team to deliver these expectations. What sort of leadership at least from this experience has been instrumental?

Methods: Observations gathered from 4 different hospitals during my lead provides a clear, short lived quality experience from 4 different team cultures. As a reprocessing technician, I was introduced to the role, taught, trained and moulded into a member of a team to deliver collectively as one, the results of which is greater than the individual sum of all, rather than an individual member trying to do my best and contribute as part of the whole. As a neophyte who doesn't have the knowledge let alone experience in reprocessing, the wide array of instrumentations to add, reprocessing for me was a simple step by step process, do your role to fill that part of the puzzle's missing piece. It didn't take long until it dawned to me that it wasn't as simple as that. The expectation is not a simple 2D geometric fit that will just fall in perfectly into measured edges; it wasn't that boring after all.
The human aspect in the technician is forgotten by mere protocol expecting compliance, programmed to follow procedures to the letter, ensure quality and timeliness is achieve of the processed products for its desired use. On the other hand, when we focus on people rather than the process and equipment, we realise that nothing can be done without those human hands, humans by nature social, caring and purpose driven.

Results: In my leadership roles, I have consistently shown respect, empathy, and care, earning respect that is crucial to the successful relationship with each staff and the team, showing that you care about their work or ideas. Lead by positive direction and build agreement among group members towards the accomplishment of a coordinated goal. Ultimately, leadership is not about who is in charge. It's about making sure your team stays focused on the goals, keeping them motivated and helping them be the best they can be to achieve those goals. This is especially true when the risks are high and the consequences matter, for example a wrongly processed medical device reused on a patient, what are the implications of this mistake?

Conclusion: People determine the success or failure of any venture. We need to cultivate a team of competent, confident individuals who can work well as a team. Therefore we can guide this team towards a well-defined vision by clearly communicating short and long terms goals, inspiring confidence and trust among colleagues.

P_05

"Are you "SHOCKING" your patients?"

Stephen M Kovach[1], Cheron Rojo[1]
[1]*Healthmark Industries, Fraser, United States*

Biography:
Stephen Kovach been in the medical field since 1975 starting out as sterilization orderly and now am the Director the Director of Education for Healthmark Industries. He received my BS from Central Michigan University, with a Major in Biology in 1977.
He is active on the state and national levels of various organizations having held many positions. He is a voting member on various AAMI committees that set the standards in the USA for our profession. He has published many articles varying in subject matter from perfusion to the importance of cleaning surgical instruments.
He has spoken and presented at all levels from local to national and international on various topics relating to CSSD. He spoke in 1999 at the World Central Service meeting in Orlando, Florida on Parametric release.He was named by Hospital Purchasing News in 2007 as one of the 30 most influential people within the field of Central Service. I am proud to say "I have worked in the Heart of the Hospital- Central Processing".

Are you putting your patient in danger!
Laparoscopic surgery has overtaken many abdominal and thoracic procedures. Between cholecystectomy, appendectomy, hernia repair, bowel resection and a range of other therapeutic and diagnostic (i.e., exploratory surgery) procedures, there are upwards of 7.5 million laparoscopic procedures performed annually worldwide.

It is no wonder with that many surgeries being performed that in November of 2018 the FDA issued a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery. Could this warning letter have been prevented if real quality management programs were in place? Could some of these injuries (burns to patients while undergoing surgery) been prevent.
Basically, burns happened in two ways to the patient. The first is called coupling it can be direct or capacitive.

Capacitive coupling occurs when two conductors of electricity are separated by a nonconductor. In electrosurgery, the conductors are the active electrode and the metal cannula, and the nonconductor is the insulation on the electrode. A serious burn can result from creation of a capacitor on the shaft of the instrument or an electrical charge which has transferred into the metal cannula even through intact insulation. Direct can occur when an active electrode accidentally touches a non-insulated metal instrument causing metal to metal sparking resulting in a patient burn.

Instrument insulation fails when the insulation on an electrode is cracked, worn down by frequent use, punctured by a sharp object or compromised by high voltage. Even a small break in insulation can leak substantial energy, causing unintended injury to organs and other tissue.

What can be done to help prevent any future burns to patients and stress the importance of following these solutions including addressing the Performance Qualification (PQ) part of a departments Quality Management System.

CSSD professionals have an obligation to prevent surgical burns. This poster is going to share survey results of CSSD professional in the United States asking them specific questions about what they are

doing to prevent surgical burns from insulated medical devices.
Manufacturers Instructions for Use along with peer reviewed articles will be used to support the current state of this concern, patients are getting burned.

The authors will than discuss why reducing insulation failure is more than just testing the insulation for breakage. The authors believe CSSD professionals need to look at the total process from start (from the surgeons and all perioperative team members) to finish (medical device reprocessing staff) using a Quality Management System (QMS). Remember that reducing the risk of insulation failure should be a team approach and if looked at in that way it can provided the institution with a better understanding of its process and provide the quality care, we all would want for our self's and our patients. The solutions are simple and if implemented surgical burns could be reduced to almost zero.

P_06

Case study: Correlation between the duration of a steam sterilisation process and the weight of the processed load

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Biography:
Nicole Lapanaitis is the Senior Technical Specialist for Sterilisation with 3M Medical Solutions Division. Nicole graduated from the University of New South Wales with a Bachelor of Science and Mathematics degree majoring in Microbiology and Immunology. She has also obtained multiple business-related certifications.
With over 20 years' experience, she has also worked as microbiologist gaining extensive experience in microbial test methods and development of quality management systems using risk based approach. This expertise has been combined to lead and drive evidence based practices in sterilisation.
Nicole is involved with sterilisation industry associations in both delivering education and undertaking cooperative research to assist the advancement of sterilisation practices and knowledge. She has shared and delivered these education and research outcomes as an invited speaker at various seminars, conferences and other international events and on a consultative level.
Nicole represents Medical Technology Association of Australia (MTAA) on the Australian Standards Committee responsible for national sterilisation standards in health service organisations. She is also the delegate on the international standard committee ISO TC 198 on various working groups.
Nicole has recently, as the first author, published this case study in Central Sterilisation Journal.

Aim: The aim of this case study was to research if a relationship between the weight of the load and the duration of a process could be identified in three sterilisers of the same brand, type and chamber size. An explanation for variations in steam sterilisation processes of similar sterilisers was also an interesting factor. There was a notion to also determine if different processes were identified and if a correlation between the duration of a process and the weight of the sterilised load is expected to be found.

Method: A case study was performed with a protocol using an independent data logger for time, pressure and temperature measurements. The devices were used across the similar brand, type and size of sterilisers. The data logger was placed in the same location within the sterilizer chamber above the drain. More than 700 datasets were acquired and analysed. The sterilising cycles were analysed in three phases, the conditioning, plateau and drying phase. There was also no required change to the process flow within the facility to acquire data.

Results: In total, 722 cycles were recorded across the 3 sterilisers over a 3-month period. It was expected that the three sterilisers would have similar processes. Although the number of control points and the structure of the processes contained the same components, over the three sterilisers, differences in the duration of the process phases were identified as shown in Figure 1. It was observed that the weight range of processed loads varied between approx. 5 kg to 90 kg. The validated load weight range was an empty load 0 kg, a mixed load 20 kg and an instrument load 64 kg. Included in the registered data were the types of complete trays in every load and the instruments that were packed in the trays, the numbers of trays in a load, and the materials of instruments. No correlation was found between the duration of the cycle or the with number of instruments or the

types of trays. Also, after analysis, no correlation or pattern was identified between the types of trays or instruments, other than the weight of the load.

Conclusion: It can be concluded that in this case study, the duration of a steam sterilisation process can be estimated with a linear trend line when the steriliser, its process and the weight of the load is known. It can also be concluded that sterilisers of the same model, make and size have different performances.
The results also indicate that the protocol applied in this case study may be used to find the trend line to predict the duration of steam sterilisation processes of other sterilisers and the effects of various weight ranges of loads.

		conditioning phase [s]	plateau period [s]	conditioning phase + plateau period [s]
steriliser 1	mean	1333	517	1836
	range	865 - 1696	472 - 546	1346 - 2184
	ratio (*max/min*)	1.96	1.16	1.62
steriliser 2	mean	1356	274	1603
	range	930 - 1692	267 - 323	1179 - 1914
	ratio (*max/min*)	1.82	1.21	1.62
steriliser 3	mean	1070	281	1332
	range	748 - 1312	252 - 330	1015 - 1571
	ratio (*max/min*)	1.75	1.31	1.55

Table 1: Average duration, the maximum and minimum of the conditioning phase, the plateau period and combination of both of the conditioning phase and the plateau period of the steriliser 1, 2 and 3.
The ration of the maximum and the minimum time of the phases (max/min) indicate a large variation in duration of the phases.

P_07

Compliance to bundles elements for processing medical devices

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Compliance assessment to activities included in medical devices processing should be a routine activity[1]. Healthcare acquired infection prevention traditional resources such as bundles (straightforward sets of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes in infection control) include different steps that require actions of greater or lesser complexity to be performed[2]. To apply bundles for CSSD is necessary to know if it is possible to comply and what it is needed for compliance for each bundle element. Studying reasons for professionals compliance to the medical devices reprocessing has not yet been carried out. Objective: To identify the compliance activities elements of bundles for Central Service Supply Department as well to evaluate the reasons for not compliance. Methods: a questionary about CSSD bundle element's (cleaning, overhaull, packaging, sterilization and storage) previously elaborated3 was answered by 47 nursing professionals that directly perform processing activities of medical devices. The reasons for not compliance were classified as socio adaptive (dependent on investments; team decisions) or technical actions (individual decision-dependent) elements. The Lickert scale in a 5 options ALWAYS-A, Almost always (AA), Sometimes(S), Almost never (AN), NEVER (N) was applied and the reasons for no compliance should be justified. Results and discussion: The professionals work in the morning (23%), in the afternoon (38%) and in the night (34%). From 825 answers to questions, 632 (76.6%) showed compliance. The difference between compliance (A/AA) and non-compliance (S/AN/N) was significant ($p<0.05$, ChiSquare=34.3548). There were 34 justified noncompliance answers (26 Socio-adaptatives, 8 technical). The structure items stand out. The different steps of the bundles may vary according to CSSD planning. Institutions with more resources have more infrastructure to develop the process with higher quality. The results of the categories show that the elements considered traditional are followed[3,4].

Conclusion: It was compliance with most of the activities bundles elements. The reasons for the lack of compliance are related to investments needed for upgrade existing infrastructure. They are socioadaptative steps. The technical elements were knowledge and the filling that they do the job. It is needed investments to comply the bundles. It is suggested that these elements be used by the different institutions so that the processes can be improved as well as directing the necessary financial investments to the structure.

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Table–Compliance(Always,Almost Always) bundles elements for CSSD, 2019

Bundles	Questions	n	%
Clening1	1. Do you wear face shield or protective mask + glasses; waterproof long-sleeved apron; durable long-sleeved gloves; and closed shoe; cap clothing restricted to the area; hearing protection(use of Personal Protective Equipment -PPE) for the activity in this area?	43	91
	2. Do you discard detergent solution at each use of the ultrasonic washing machine and manual cleaning tubs?	21	47
	3. Do you do surface disinfection routine systematically carried out as per written protocol?	34	72
Cleaning 2	4.Do you use inputs (e.g., brushes) compatible for pre-cleaning (according to lumens, air and water pistols, flowing steam)?	45	96
	5.Do you use proper detergent for medical devices with record of opening date (enzymatic, alkaline,neutral, among others proper for MDP)?	46	98
	6. Do you use specific device for cleaning/drying of lumen items?	46	98
	7. Do you use purified water to rinse critical products.	23	53
Overhaull	8. Do you do annual visual acuity exam on 6/6 months basis?	25	54
	9. Do you verify cleaning and integrity of medical devices with a magnifying lamp or microscope for products with details of difficult visualization?	40	85
	10. Do you use medicinal compressed air pistol to complement drying in the area of inspection?	44	94
	11. Do you lubricate with standardized oil-free product to instrumental use of joints for better medical device performance?	36	77
	12. Do you follow protocol use test to verify the functionality of scissors and *clamps?*	33	72
Prepare;packing	13. Do you use PPEs (Mask, cap, and gloves) in the area of preparation and packaging area?	44	94
	14. Do you clean and disinfect surfaces according to an established routine?	38	81
Sterilization and storage	15. Do you believe that sterilization area has thermal comfort for the operator?	-	-
	16. Do you follow scheduled and record of cleaning equipment, as well as clean and preserved equipment?	38	81
	17. Do you verify of Sterile Barrier System (SBS) integrity before storing medical device pack and when at the moment of their distribution to the user units?	37	95
	18. Do you dispose medical devices stored so as not to damage SBS?	39	98

N=47 (100%)

P_08

Double manual cleaning versus automated cleaning for removal of biofilm of hinged surgical instruments

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Biography:
Graduation in Nursing from the Federal University of Goiás - FUG (2009). Master in Nursing from FUG (2012). PhD in Biomedical Sciences from Macquarie University, Sydney, Australia (07/2017) and PhD in Nursing from the FUG (09/2017), PhD in Cotutelle. Specialist in Prevention and Control of Healthcare Associated Infection - HAI from Federal University of São Paulo - UNIFESP (2014). Member of the Center for Nursing Studies and Research in Prevention and Control of Healthcare Associated Infection, Faculty of Nursing at UFG (2007 - present). Member of the Surgical Infection Research Group (SIRG), Faculty of Medicine and Health Sciences, Sydney, Australia (2014 - present). Research line: Prevention, control and epidemiology of healthcare associated infection and communicable diseases. Postdoctoral reseracher at FUG by the National Postdoctoral Program of the Coordination for the Improvement of Higher Education Personnel (CAPES).

Aim: To evaluate the efficacy of double manual cleaning (DMC) with enzymatic followed by alkaline detergent for removing biofilm on hinged surgical instruments compared to automated cleaning by washer-disinfector. Washer-disinfector cycles oftenly include a first wash with enzymatic detergent and second wash with alkaline detergent.

Methods: To simulate the worst contamination scenario, semi-hydrated biofilm of Staphylococcus aureus (ATCC 25923) was formed in vitro on haemostatic forceps, which were rinsed in distilled water and subjected to: Group 1 (n=5): soaked in sterile water for 5 minutes; Group 2-DMC (n=5): soaked in enzymatic for 5 minutes, brushed five times on each face, rinsed with filtrated water (0.2 µm), soaked in alkaline detergent for 5 minutes, brushed five times each face, rinsed with filtrated water (0.2 µm), and dried with sterile cloth. Group 3-DMC plus hinge inner bursching (HIB) (n=5): cleaned as in Group 2 and also HIB using a 2mm brush in both cleaning steps (Figure 1). Group 4-Automated cleaning (n=5): conducted in a washer-disinfector (including Pre-wash, Wash 1, Wash 2, rinse, thermal rinse, drying). Following, forceps were evaluated for microbial load, residual protein and biofilm by counting of colony forming units, protein assay (Pierce™ BCA Protein Assay Kit) and scanning electron microscopy, respectively.

Results: There was no statistically significant difference between microbial load and protein level contaminating the forceps subjected to DMC (Group 2) and positive control. DMC with HIB (Group 3) and automated cleaning (Group 4) significantly reduced the microbial load (reduction average 2.8Log10/P=0.038; 7.6Log10/P≤0.001, respectively), and protein level remaning (2.563µg/P=0.016; 1,453µg/P=0.001, respectively) compared to positive control. There was no statistically significant difference between DMC plus HIB and automated cleaning for all the tests performed. None of the cleaning methods completely removed biofilm/soil from the hinge internal region (Figure 1).

Conclusion: Automated cleaning had the best efficacy for removing biofilm. However, DMC plus HIB demonstrated to be an alternative cleaning method for sterilising units with manual cleaning structure only available, as is the case, mostly, in low/middle-income countries. It is important to consider

that automated neither any manual cleaning regimes were able to completely remove biofilm/soil from the forceps hinged area, and the amount of protein left after automated and DMC plus HIB was still 145 and 256-fold higher than recommended, 5µg/instrument side, thus 10µg/instrument, respectively. As cleaning is the most important step for the reusable medical devices reprocessing, efforts must be undertaken to improve cleaning in different social/economic realities/scenarios.

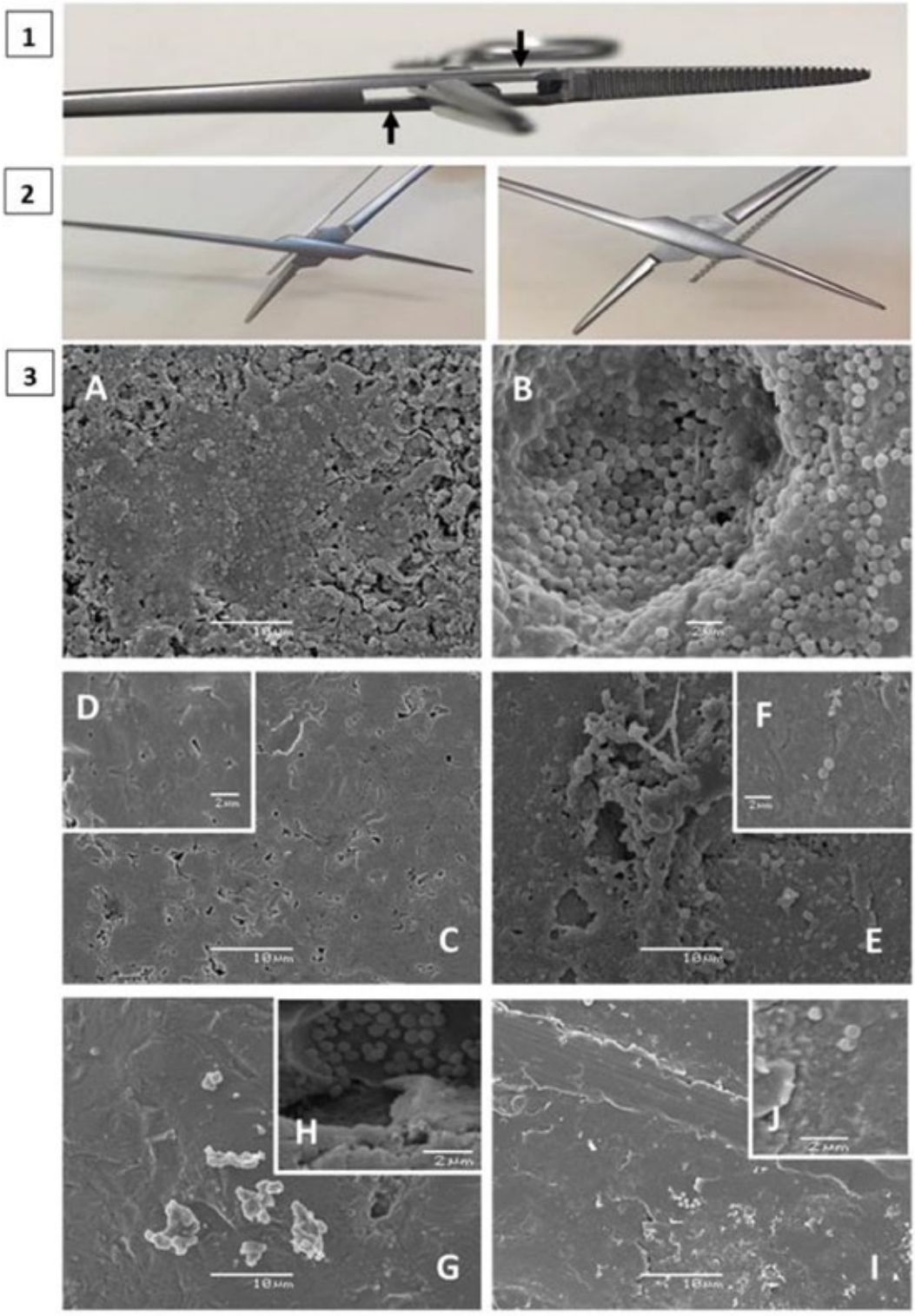

Figure 1. Haemostatic forceps inner hinge region (1) brushing (2), and microscopy images (3): A/B-Positive control; C/D-New forceps; E/F-Double manual cleaning; G/H-Double manual cleaning plus inner hinge brushing; I/J-Automated cleaning.

P_09

Adverse event reports in endoscope reprocessing

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Biography:
Mary Ann Drosnock is the Senior Manager of Clinical Education at HealthMark Industries where she provides expertise on medical device processing often presenting at conferences on effective infection prevention and reprocessing. Also, currently she is co-chair of AAMI Working Group 84, which is responsible for the ST91 national standard on flexible endoscope reprocessing and TIR99, which will address proper processing of ultrasound probes and dilators.
Previous to HealthMark, Mary Ann managed the Infection Control Program for Olympus America. There she had responsibility for Infection Prevention & Device Reprocessing Functions. Prior to Olympus, MaryAnn worked as a pharmaceutical microbiologist, managing quality control and R & D laboratories, and taught Microbiology courses at the college level to allied health professionals. MaryAnn has a B.S. in Biology and an M.S. in Quality Assurance and Regulatory Affairs. She is certified in Drug Development, Pharmaceutical Science, Infection Control through APIC, as a Flexible Endoscope Reprocessor through CBSPD, is a Nationally Certified Registered Microbiologist and is an APIC fellow. Mary Ann also currently sits on the editorial board for AAMI BI&T journal and the PanAmerican Forum Journal.

Failures in endoscope reprocessing continues to be a high-risk for healthcare facilities. Instances of missed steps, cross contamination, positive cultures, use error, and serious adverse patient events continue to be routinely reported in literature and directly to the FDA. This poster serves as a resource for facilities to:

- Review how and where to find adverse events and infection control reports related to incorrect processing of endoscopes so that facilities can learn from these events.
- Describe types of events that are typical in facilities that result in errors in reprocessing and potential patient infections
- Outline recent events that demonstrate continued issues with flexible endoscope reprocessing and how to prevent this from happening in your facility

Classification of Types of Reprocessing Events: There are many different types of events that can occur in facilities leading to adverse events and reprocessing incidents. These events can be classified into major categories as follows:

- Missed/abbreviated steps
- Not following the IFU
- Not following national standards (ST91)
- Use error
- AER malfunction
- Failure to visually inspect after cleaning and before use
- Failure to perform cleaning verification testing
- Microbial surveillance cultures positive
- Cross-contamination/Outbreaks

Next, examples of reported reprocessing events will be discussed to demonstrate how to research and find these types of topics.

What do we do with all this information? It is recommended that facilities routinely review the

information outlined in the processes above. This may be done quarterly or even biannually. When reviewing the report, it is helpful to perform a root cause analysis and determine what steps could be engineered into your facility's process to avoid such an outcome.

Next, look at current facility practice and determine if your facility is currently performing the step identified to mitigate the risk associated with the incident identified in step a. Review the current endoscope and accessory IFUs and national standards on the topic. Identify any gaps in procedure based on the report, IFU, and national standards.

Then, plan actions and follow-up to alleviate the risk of any gaps identified. Work with reprocessing staff, risk management and infection prevention to gain support for practice changes that have been identified. Perform training to staff and verify the new skills by competency assessment. Finally, audit endoscope reprocessing practices to ensure compliance to these changes and normal practices.

Conclusion: Improper reprocessing of flexible endoscopes and subsequent patient infection and adverse events continue to be an issue reported in industry and to the FDA. These reports are due to missed reprocessing steps, use error, inspection steps not performed, cleaning verification not performed, no microbiological sampling being performed and no patient follow-up after procedures. These errors can result in adverse events and serious patient injury, such as infections after endoscopy. Knowing where to find these reports, identify what went wrong during and how to apply the lessons learned in your facility is an example of quality steps that can be engineered into the reprocessing procedures.

P_10

Challenge of metropolitan sterilization society in Japan for providing better central sterile supply

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Biography:
Dr. Fukatsu is the director of Surgical Center and Central Supply Service, The Univeristy of Tokyo Hospital. He is a surgeon and has devoted to surgical research for preventing and treating postoperative complications during the last 30 years. He has established a new society for research and education in the field of sterilization.

Background and Aim: Central sterile supply department (CSSD) is a key division for providing adequately reprocessed devices to surgical center, wards and outpatient clinics. Although Japanese Society of Medical Instrumentation (JSMI) has established a system for certified registered central service technician and contributed to the education of CSSD staffs and securing the quality of their work for over 20 years, it is difficult for all staffs working for sterile supply to join JSMI conference and lecture due to geographical constraints and limited number of lectures. Therefore, many rural study groups have compensated the role of JSMI by delivering basic and new technique and knowledge on sterile supply to participants.
Here, we introduce various challenge of Metropolitan Sterilization Society (MSS), our CSS study group in Tokyo.

MSS Activity: MSS has been founded in 2011. Present executive members are 22 (4: faculty members of university hospital (3: medical doctors), 8: nurses, 9: CSSD staffs, 1: clerical staff of JSMI). The original aim of this society was to conduct training and to give lecture to persons who work at hospitals and clinics in Tokyo metropolitan area. However, once we shared the problems in CSSD, MSS has started making many other efforts to solve them.
MSS holds conference twice a year. Number of participants at each conference is 400-500. Each conference has specific theme which is determined referring to the results of questionnaire obtained at previous conferences. According to the answer to the questionnaire, participants wanted lectures on cleaning (28%), sterilization (21%), infection control (19%), guidelines (16%), validation (12%) and others (4%) at 15th conference in 2018.

The program of conference consists of 1) education lectures and symposium on basic and advanced technique and knowledge on CSS and 2) special lecture on new trend of CSS. We have added 3) basic lecture on infectious diseases since 2012, because Japanese CSSD staffs may not have good chance to obtain knowledge on infection control. Moreover, we have created 4) special discussion session on management of CSSD involving panelists and all participants since 2017. The discussion session themes were "How to evaluate quality and quantity of CSS work?" "How to let other hospital professionals appropriately recognize the CSSD?" "How to manage CSSD staffs?" and so on. Through the discussion, we try to make all participants think their work by themselves and find a new way to improve the quality and environment of work. During lunch time, 5) poster session is launched. We also publish official journal on cleaning and sterilization of medical devices through peer review system.

Conclusions: Future plan of MSS
We will make our MSS activity higher and more attractive. Without basic scientific accomplishment, no further development is expected in any fields of medicine. Though CSS task may belong to medical-related services, we will support basic research on cleaning, sterilization and management of devices for better CSS work and assurance of infection control. Collaboration with JSMI and other rural study groups is now developing.

P_11

A Series of nationwide surveys of actual sterility assurance practices among medical facilities in Japan

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Biography:
1993 Doctoral degree of medical science and a medical license
1995 Registered Anesthesiologist
1999 Board Certified Anesthesiologist
2007 Certified Sterile Service Technician
2013 Medical Device Information Communicator
2013 Certified Sterilization Specialist
2013 Certified Hospital Engineer

Work Experience:
2011 - Present Osaka Rosai Hospital
2009 - 2011 Osaka Kaisei Hospital
2001 - 2009 Fuchu Hospital
2000 - 2001 Osaka Rosai Hospital
1993 - 1999 Osaka Koseinenkin Hospital

Aim: A series of nationwide surveys in Japan revealed gaps in the quality of sterility assurance practices among the participating facilities. Based on the survey results, the Japanese Society of Medical Instrumentation (JSMI) developed their guidelines for sterility assurance in healthcare settings to improve the quality of sterility assurance practices. The objective of this study was to assess improvements in sterility assurance practices following the publication of the 3rd edition of the JSMI guidelines in 2015.

Methods: The fifth survey conducted in 2017 comprised 28 questions. The questionnaire was sent via postal mail in July 2017 to 1,623 facilities in Japan.

Results: A total of 558 completed questionnaires were received (response rate: 34.4%). Steady improvements in sterility assurance practices were observed (Table 1).

Conclusions: The large scale of this series of surveys in Japan is unprecedented, and a similar series of surveys has not been analysed in other countries. Compliance rates for some recommendations outlined in the recent guidelines for routine monitoring had improved in the 2017 survey. The findings suggest that the 3rd edition of the JSMI guidelines published in 2015 contributed to this improvement.

However, the survey results simultaneously highlighted several issues regarding sterility assurance practices. In some facilities, recommendations outlined in the recent guidelines for routine monitoring were not implemented. Surprisingly, validation tests were performed in only 31.3% of facilities, despite being clearly outlined in the recent JSMI guidelines. This low rate is likely due to a lack of laws or regulations concerning sterilization in medical facilities in Japan. Guidelines published by

academic societies play an important role in Japan and may differ from those in countries that have enacted strict laws or regulations. In clinical settings, sterility assurance practices depend on the honesty and effort of staff at the individual medical facilities.

We anticipate that the findings of this series of surveys will continue to contribute to improvements in the quality of actual sterility assurance practices in Japan. Moreover, the next edition of the JSMI guidelines should be revised to promote further improvements.

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Keywords: nationwide survey, actual sterility assurance practices in Japan

Table 1. Compliance for routine monitoring (%)

Recommendation in the JSMI guideline (2015)		2012	2017
Bowie-Dick testing every day		56.7	75.3
Cycle record of the physical monitors in every load	AC	82.7	83.4
	EO	79.2	79.2
	Plasma	87.5	84.6
CIs inside every package	AC	49.8	53.8
	EO	55.1	59.5
	Plasma	60.7	64.7
BIs every day	AC	63.3	76.2
every load	EO	74.5	76.4
every day	Plasma	80.9	78.8
Validation tests		–	31.3

JSMI: Japanese Society of Medical Instrumentation
CIs: chemical indicators, BIs: biological indicators,
AC: saturated steam, EO: ethylene oxide
Plasma: low-temperature hydrogen peroxide gas plasma

P_12

Investigation on the current status of autoclave steam sterilization procedure in the hospital CSSDs in China

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Aim: The purpose of the investigation is to understand the current status of the autoclave steam sterilization procedures in the central sterile supply departments (CSSDs) of hospital and to provide scientific basis for implementing standardized management as well as ensuring the effectiveness and quality of disinfection in Chinese healthcare facilities.

Method: We have surveyed the CSSDs in 726 hospitals with Grade B or above in 28 provinces by the questionnaire of the current status of autoclave steam sterilization procedures designed by the CSSD Professional Committee of the Chinese Nursing Association.

Result: The investigation among CSSDs in 726 hospitals has revealed that,(1) 71.63% of the surveyed CSSDs prolonging the exposure time in daily sterilization procedures, (2) 83.61% of the surveyed CSSDs following the manufacturers' recommended procedure parameters for cleaning, packaging, sterilization methods and sterilization cycles when handling loaner instruments, implants, power tools and precision instruments, and (3) for the over-size, over-weight and inseparable packages, 77.41% of the surveyed CSSDs extending the sterilization exposure time and drying time: in this part, mostly (38.29%) using 134°C and 10-12 min as sterilization cycle parameters, and mostly (35.61%) prolonging drying time to 10 min. Furthermore, 68.04% of the surveyed CSSDs who did not receive the sterilization instructions for instruments from manufacturers: in this part, 50.46% of the CSSDs chose to use the conventional cycle parameters, while 40.37% of the CSSDs extended exposure time of the sterilization cycles based on the individual experience. In addition, 25.76% of the surveyed CSSDs could not apply the sterilization methods and parameters indicated by manufacturers' instructions for the special equipment because of equipment limitations.

Conclusion: There are some problems in the sterilization process of loaner instruments in hospitals, which need to be further strengthened and standardized. As more and more medical instruments requiring extended sterilization procedures, CSSD should strengthen requiring medical device manufacturers provide sterilization methods and sterilization cycle parameters. CSSD should process medical instruments strictly in accordance with the sterilization methods and parameters provided by manufacturers. For specific sterilization procedures, appropriate indicators should be used to monitor the sterilization effectiveness and quality.

P_13

Survey of loaner instrument and implants processing status in 764 hospitals in China

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Aim: To explore the current situation of processing loaner instrument and implants in central sterile supply departments (CSSD) in domestic hospitals, in order to provide reference for the development of relevant regulations.

Method: A survey of loaner instrument and implants management was conducted in 764 hospitals.

Result: Totally, 2.88% of the surveyed hospitals did not have certain regulations of loaner instrument and implants management. In terms of post-duty settings, 44.37% of the surveyed hospitals did not set post for personnel of processing loaner instrument and implants, meanwhile, 16.23%, 17.15% and 50.65% of the surveyed hospitals could get loaner instruments and implants for elective surgeries 8 hours, 12 hours or 24 hours before the surgeries, respectively. Nearly 71.34% of the surveyed hospitals did not meet the requirements of reprocessing loaner instruments and implants after the surgeries, and 63.61% of the surveyed hospitals claimed that they had overweight packages of loaner instrument and implants, while 55.50% of the surveyed hospitals indicated that they could not obtain the IFUs of loaner instrument and implants from manufacturers.

Conclusion: We need to do a lot to improve the quality of medical care, such as developing and refining the regulations for the management, setting up specialized post for processing loaner instrument and implants, increasing the proportion of hospitals that have instructions for use (IFU) of loaner instrument and implants, and enhancing their compliance to follow manufacturer's instructions. All these things are necessary to ensure safety and reduce the risk of nosocomial infection.

P_14

Microbial surveillance testing of internal channels of flexible endoscopes

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Biography:
Kaumudi Kulkarni is the Manager of Research and Development at Healthmark Ind. in Michigan, USA. She has her Masters in Microbial Cellular and Molecular Biology from the University of Georgia, and a Masters in Microbial Genetics from India. She is a voting member at AAMI and ASTM and is also involved in the worldwide round robin testing of ISO protocols that impact cleaning of medical devices.
Kaumudi works with medical device manufacturers, sterile processing professionals, along with the FDA and other professional groups and organizations. She is also involved in developing various simulated use test soils used in cleaning validations, along with developing products that help improve patient care outcomes.

Aim: To demonstrate microbial surveillance testing of endoscope channels using traditional bacterial cultures and rapid gram-negative bacteria tests.

Background: Various standards organizations recommend that healthcare facilities consider implementation of microbial surveillance program for endoscopes, post high-level disinfection. In order to detect bacteria from internal channels of flexible endoscopes, the channels were extracted and tested with traditional bacterial petri-plate cultures and rapid gram-negative bacteria tests.

Methods: Samples:
- 90 internal channels of endoscopes from two endoscopy facilities from a multi-site healthcare system:
  At each endoscopy facility, instrument channels from 45 scopes were sampled with a total of 90 scopes being sampled between the 2 facilities:
  - 30 post manual cleaning
  - 30 post high level disinfection
  - 30 in storage
- 202 internal channels of endoscopes received in our laboratory from a third-party endoscope repair facility over the period of 1 year.

Methods used: Endoscope channel samples were flushed with sterile water and the sample extracts of each channel were divided to perform bacterial cultures using agar plates, and rapid gram-negative bacteria testing using enzyme-based technology. The two test methods were compared to check the level of agreement between each other.

Results: With both the sets of channels tested, the results for the rapid gram-negative tests and bacterial culturing correlated and showed a substantial level of agreement.

Conclusions: The results suggest that gram negative bacteria testing can be a useful rapid tool for post disinfection microbial surveillance of endoscopes. The gram-negative bacteria testing does not replace culturing, but it certainly can be used on a more frequent basis because of its quicker turnaround time as compared to traditional culturing.

P_15

Low temperature ozone sterilization technique using minimal amounts of water and electricity

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Biography:
Sandy Thill grew up in Luxembourg before starting her studies at the EPFL in Lausanne, Switzerland. She studied Life Sciences and Technologies and finished her Master in Bioengineering with a mention of excellence in 2017.
Her link with the start-up SteriLux began with her Master's Thesis. The work presented represents her research on ozone sterilization.
Present on the 14th and 15th JNSS and the 4th JIFS, the national sterilization conferences in Switzerland, respectively France, she became more and more familiar with the sterilization world in hospitals and the challenges still present in high-income countries.
Her main work at SteriLux consisted and still consists in characterizing and validating their patented low temperature ozone sterilization technology meeting the needs of a high quality sterilization in hospitals.

A swiss start-up has patented an ozone-based sterilization technology requiring minimal amounts of water and electricity.

Literature on ozone sterilization mainly focusses on ozone concentrations superior to 10'000ppm, whereas the present research focuses on significantly lower ozone concentrations (100 to 1'000ppm). This study aims to characterize the sterilization potential and efficiency of this new method for stainless-steel but also for heat-sensitive devices.

The ozone generation relies on UV light irradiation through a quartz inside a hermetically closed container. Oxygen present in the ambient air is transformed to ozone. In an environment saturated with relative humidity (i.e. >95%), ozone forms hydroxyl radicals, responsible for the sterilization. The process is reversed using another UV wavelength, leaving only H2O and O2 as by-products.

Characterization and validation microbial tests were conducted in accordance with ISO 11138-7:2019 using the overkill method. Geobacillus stearothermophilus spores are the most resistant organisms for ozone processes and are therefore used to prove a 12-log reduction (LR). An optical ozone measurement system was used to determine the ozone concentration.

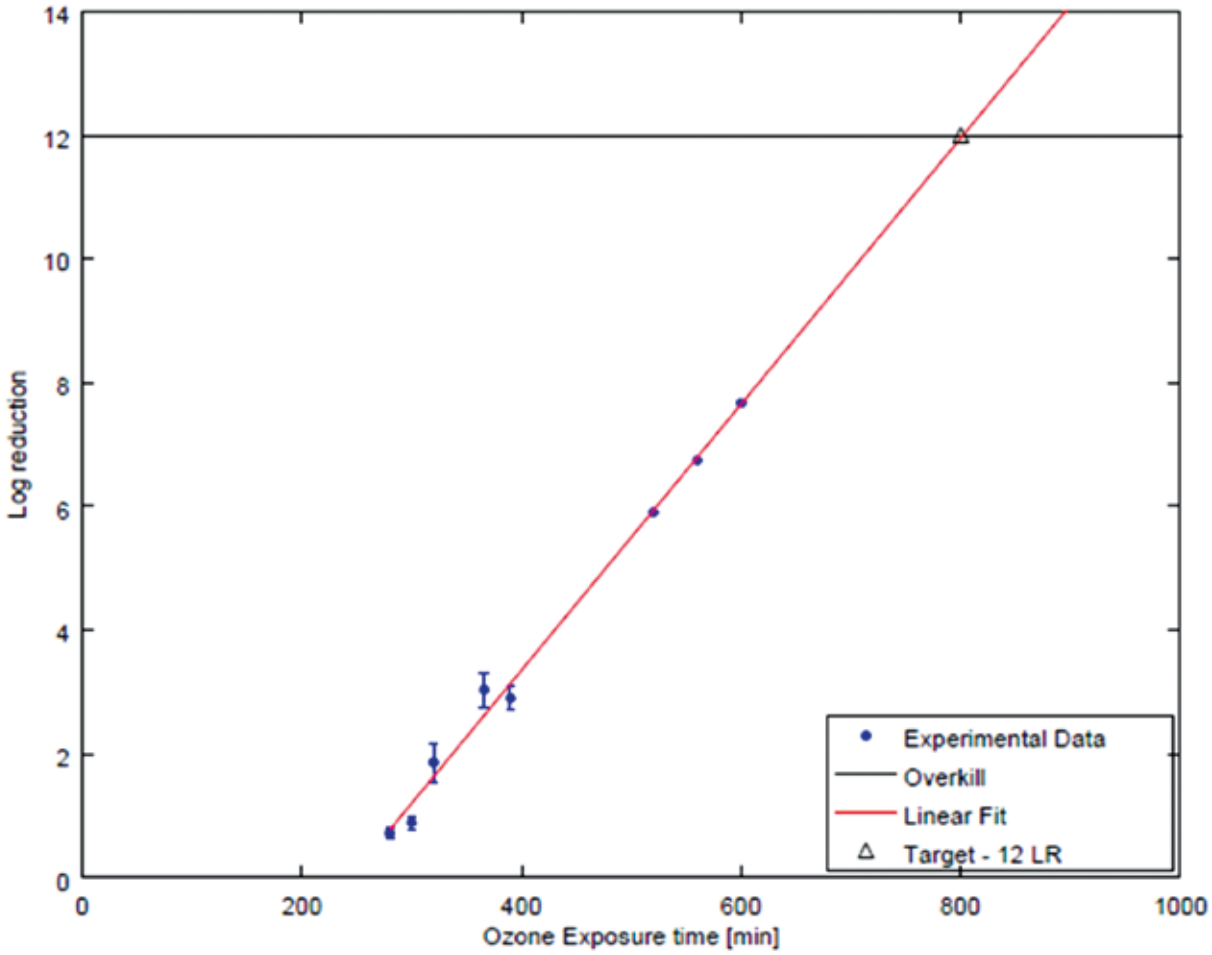
We extrapolated the results from survival curve and fraction-negative tests to demonstrate 12 LR. Figure 1 shows the first results of these tests and the extrapolation to 12 LR with a linearity matching the criterion (R2=0.9924>0.8).
The beginning of the bacterial decrease does not coincide with the start of the ozone exposure. This is due to a preconditioning phase consisting in ozone diffusion and increasing relative humidity inside the container to reach the conditions required for the actual sterilization.
Expressing the D-value in minutes was not consistent with the results. It was therefore expressed in dose defined as the integral of the ozone concentration over the exposure time (feasible according to ISO 11138-7:2019).

More tests performed at temperatures between 15°C and 35°C showed that a lower ozone dose is required to obtain sterility for higher temperatures, which is in line with the literature.

The materials to be sterilized have a crucial impact on ozone degradation. Materials such as stainless-steel are highly compatible with ozone. However, other materials, such as natural rubber or nitrile are degrading and degraded. Preliminary material compatibility tests performed on heat-sensitive and electronic medical devices, such as endoscopes, demonstrated feasibility of sterilization without altering device functionality.

This research demonstrates the sterilization efficiency of ozone-based technologies. Additionally, it shows their potential for low to high-income countries facing shortfalls of resources and increasing numbers of heat-sensitive devices.

Linear extrapolation of microbial results to 12 LR.



P_16

Effects of storage conditions on reprocessed chemical indicators

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Biography:
Director of the Central Sterile Supply Department of the Portuguese Institute of Oncology Francisco Gentil – Porto – Portugal for 13 years. Ms. in Biochemical and Clinical Chemistry and Ph.D. in Biomedical Sciences. Former Member of the board of Portuguese Association for Sterilization as such was member of the congress organization committee of the 12 World Sterilization Congress, (Estoril, Portugal, 2011). Since 2013, conducting courses on "Reprocessing reusable medical devices in Health Units" for operational assistants and nurses in several Portuguese Hospitals. From March 2015 to the present enrolled by Portuguese Quality Institute (IPQ) as National Expert for the following working groups: CEN/TC 102/WG/07 "biological and chemical indicators"; ISO/TC 198/TG 01 "Assurance of sterility"; ISO/TC 198/WG 04 "Biological indicators";ISO/TC 198/WG 06 "Chemical indicators". Since July 2017 member of the working group for the construction of the Portuguese guidelines on medical device reprocessing.

Keywords: Medical devices; Chemical indicators; Steam sterilization; Storage conditions.

Aim: It was observed that after the steam sterilized medical devices packages are kept for some time in the storage room, the color of the chemical indicators (CI) was sometimes different from the one present right after reprocessing of those packages, despite they still meet the expiration date. This causes a problem when sending the medical devices to the operating room, since nurses may think that the sterilization process was not satisfactory.
The main objective of this study was to evaluate the performance of several chemical indicators under the existing conditions in the storage room of our sterilization service.

Methods: Steam sterilization at 134°C and 121°C with holding times of 7 min and 20 min, respectively, were used as sterilization methods. Five different CI (kindly ceded by different manufactures) were tested. When presenting the results the samples were identified by roman numeration, since it was not our goal to compare different manufactures. Four different groups of packages, which mimic the most common types of packaging material used in our department were established, and the packages containing the CI were processed under the pre-determined conditions. After reprocessing, the packages were stored in the sterile storage room on shelves with different distances from the room's light source. Monitoring of the temperature and relative humidity of the storage room was performed. Over six months and once a week the visual color check of the indicators in the packages was registered.

Results: In the course of the experiment several CI changed their color depending on the storage conditions. The type of material used in packaging also seems to influence the performance of the chemical indicator. We could observe that CI packaging in two Polipropilen (PP) sheets, do not present color variation throughout the experience, no matter the sterilization conditions, nor the proximity of the light source. However, several CI packaging in: one PP sheet plus laminate paper/film pouch; laminate paper/film pouch; or two layers laminate paper/film present different colorations over time of experience, depending on light source proximity. In particular, the position of the package on the shelf or the proximity of the light source showed to be important factors.

Conclusions: The variations in CI staining seems to depend on: i) the type of packaging; ii) the proximity of the light source; iii) the time elapsed since the sterilization of the package.
The results obtained in this study highlight the importance of considering the particular type of packaging as well as the storage conditions of a sterilization service when purchasing CI.

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P_17

Generating improvements in the cleaning area of a material and sterilization centre

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Biography:
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Healthcare organizations are constantly expanding, becoming larger and more complex. The challenges of growing and expansion are not only related to infrastructure. Several processes are interconnected, involving patient safety goals and quality standards, which represent relevant challenges. Continuous improvement and risk monitoring must be adopted in healthcare organizations.

The Central of Material and Sterilization (CME) is a key department in the patient care chain, since it is the responsible for the processing of health products. The processing of materials should follow highly organized steps in order to minimizing risks involved in all stages of the process.
Our objective was to improve the quality of the processes in the purge area of the CME by means use of Healthcare Failure Mode and Effect Analysis (HFMEA). The tool was applied in a private nonprofit hospital located in Sao Paulo, Brazil.

Herein, a descriptive study design was used and an approach with research-and-action was applied. The research was divided into phases, according to the research action methodology: preparation and diagnostic, planning, action and final analysis. In the "preparation and diagnostic" phase we mapped the risks using the Healthcare Failure Mode and Effect Analysis (HFMEA) approach, in which fourteen failure risks were identified: three of critical level, five of high-level, two of moderate and four of low-level risk; additionally, twenty-two potential causes were identified. Based on preliminary results an action plan was carried out. Quality tools were used to implement the improvements that in the purge area. In the "final analysis" phase we reapplied the HFMEA to verify new risk scenarios of the purge area. The new results showed nine modes of failure: one of high risk, one of moderate risk and seven of minor risks, distributed in nine potential causes. There was a reduction of 36% reduction in risk situations as well as a modification in the risk levels: low risk situations raised by 75%, and moderate, high and critical risks reduced by 50%, 80% e 100%, respectively.

Our research shows how improvement measures taken according to critical ranking of mapped risks can increase the safety levels at a material and sterilization center.

P_18

Liposuction cannulae: screening of automated cleaning

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Introduction: Cleanliness of medical devices is considered the most critical step in materials reprocessing and, as point the literature, it is when failures most happen.[1] The cleaning process must reach the entire surface of the medical/hospital device, including recesses, joints and lumens (often narrow), in order to avoid bioburden and reduce microbial growth.[2] For patient safety, evidences shall be found to ensure the effectiveness of the cleaning process.[3]

Objective: To evaluate ultrasonic washer machine cleaning effectiveness in 4,00mm liposuction cannulae, by using a cannulae microscope device (Stericam), screening for dirt and performing microbiological analysis of Staphylococcus aureus ATCC 25923.

Method: Experimental study performed at the Central Sterile Services Department (CSSD) and at the Microbiology Laboratory of a Hospital Complex, located in Porto Alegre, RS - Brazil. The available study population consists in 22 units of 4,00mm liposuction cannulae, resulting in 14 units, after applying the following exclusion criteria: impregnated dirt, possible contamination and liposuction cannulae worn down. The data collection consists in nine steps: selection and identification of the liposuction cannulae unit; cleaning process with the ultrasonic washer machine; external and internal visual inspection; sterilization; inoculum of Staphylococcus aureus ATCC 25923 and Soil Test's impregnation; drying; post inoculum ultrasonic washer machine cleaning process; bacterial culture in Tryptic Soy Broth (TSB) and Plate Count Agar (PCA); and last, the liposuction cannulae microscope unit inspection with the Stericam.

Results: The research begins with 22 liposuction cannulae units of 4,00mm each, randomly selected, tagged and numbered from 1 to 22. However, cannula number 1 was disregarded as functional and excluded of the study. The second step consisted in performing the cleaning with the ultrasonic washer machine. In the third step, external and internal visual inspection have been performed in all studied units resulting in the exclusion of seven liposuction cannulae, constituting in the total of 14 samples for analysis. The sterilization step was necessary to ensure the cannulae just received Staphylococcus aureus inoculum. After the Stahylococcus aureus inoculum and Soil Test impregnation, the liposuction cannulae dried for 24 hours. After drying, the samples have been submitted to the ultrasonic washer machine for cleaning. The culture in TSB and PCA for bacterial growth determination has evidenced that all 14 cannulae samples presented viable bacteria and five of them have showed evidences of dirtiness after inspection with the Stericam.

Conclusion: It is not possible to ensure the cleaning efficacy of the 4,00mm liposuction cannulae using the ultrasonic washer machine, since the results of the study have presented bacterial growth and visible dirt after visual inspection (Soil Test).

Key-Words: Surgical Instruments, Contamination of medical equipment, Nursing.

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3. Alfa MJ. Monitoring and improving of effectiveness of cleaning medical and surgical devices. American Journal of Infection Control.2013;41:S56-S59

P_19

Meta-analysis of the cleaning effect of vacuum boiling washer in luminal devices

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Biography:
2014-2018 Bachelor of Nursing Medicine Peking University
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Objective: To systematically evaluate the cleaning effect of vacuum boiling washer in luminal devices.

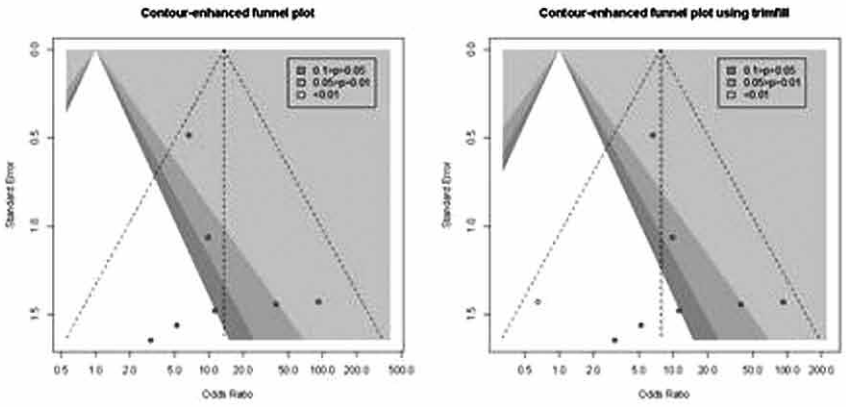
Methods: The databases such as CNKI, Wanfang Data, VIP, SinoMed, Science Direct, Web of Science, PubMed, Embassy and Cochrane Library were searched for the randomized controlled trials (RCTs) up to April 2018, comparing the cleaning effect of vacuum boiling washer versus non-vacuum boiling washer in luminal devices. Two reviewers strictly follow the inclusive and exclusive criteria for document selection, material extraction, and quality assessment. Then RevMan 5.3 software was used for Meta-analysis. R Programming Language was used for sensitivity-analysis. Contour-enhanced funnel plot was used to analyze publication bias.

Results: A total of 9 studies involving 1902 cases were enrolled in final with 951 cases in intervention group and 951 cases in control group. Meta-analysis showed that vacuum boiling washer could significantly improve the past rate with visual inspection (odds ratio(OR)=13.61,95% confidence interval(95% CI)=6.77~27.34,P<0.00001), the past rate with ATP biofluorescence assay(OR=10.91, 95%CI=4.30~27.68, P<0.00001) and the past rate with indicator discoloration (OR=4.72, 95%CI=2.81~7.93, P<0.00001), and reduce time consumption(mean difference(MD)=-21.76, 95%CI=-25.47~18.04, P<0.00001). Sensitivity-analysis showed that the overall results are stable and a single study does not have a significant effect on the results. Contour-enhanced funnel plot analysis showed that there is a certain degree of publication bias in the meta-analysis of the past rate with visual inspection and there is no obvious publication bias in other two indicators.

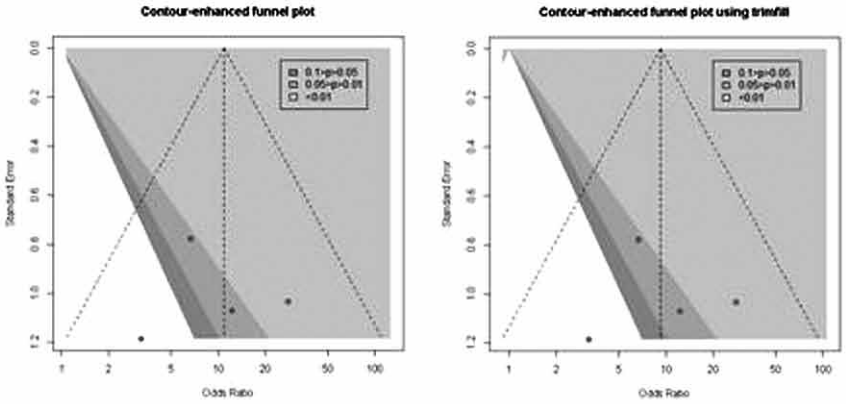
Conclusions: Vacuum boiling washer can significantly improve the cleaning quality, reduce the time consumption and improve the working efficiency. It also provides a clinical basis for the use of vacuum boiling washer in the hospital.

Key words: Vacuum boiling washer; Luminal devices; Cleaning effect; Meta-analysis

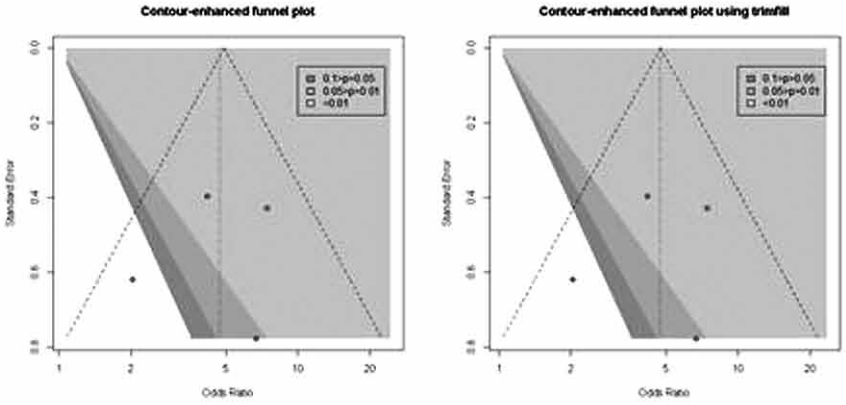
Contour-enhanced funnel plot



A past rate with visual inspection



B past rate with ATP biofluorescence assay



C past rate with indicator discoloration
Contour-enhanced funnel plot

P_20

Investigation of residual formaldehyde on flexible endoscopes after low temperature steam and formaldehyde sterilization

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Biography:
Belongs: Osaka University Hospital

Biography: Graduated Osaka University of Commerce in 2000; Joined the Osaka University Hospital in 2012 as technician of CSSD; April 2017-Deputy General Manager, Central Sterile Supply Department
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Background and Purpose: Ethylene oxide gas (ETO) is the current agent of choice for low temperature sterilization of medical instruments at health care facilities in Japan. There are some significant disadvantages associated with the use of ETO which include workplace environmental safety concerns and prolonged sterilization time due to the required aeration step. A preliminary review of other options included consideration of Vaporize Hydrogen Peroxide (VHP) sterilization along with low temperature steam and formaldehyde (LTSF) sterilization. We determined that some flexible endoscopes cannot be sterilized with VHP due to their narrow luminal structure, but found that LTSF sterilization was an effective alternative method. As residues of sterilizing agents are a common concern with low temperature sterilization methods, we measured the residual formaldehyde on flexible endoscopes after LTSF sterilization in order to determine whether LTSF-sterilized endoscopes could be used in clinical settings. This investigation of residuals is detailed in this study. If residuals were found to be within acceptable limits, this in turn would enable a change in sterilization method from ETO to LTSF.

Method:
- The distribution of temperature in the chamber of the LTSF sterilizer was measured during no-load operation. As formaldehyde is more volatile at higher temperatures, we assumed that the elimination of formaldehyde would be easier at the highest-temperature position (HP) and more difficult at the lowest-temperature position (CP).
- Olympus BF-P40 flexible endoscopes (insertion part: working length of 550 mm, tip outer diameter of 4.9 mm) were used as test objects. They were put in sterilization containers and placed on the HP and CP positions in the sterilizer chamber.
- These test objects were removed from the chamber immediately after sterilization. Each test object was placed in a specially designed glass tube (outer diameter: 15mm, length: 550 mm) with 50 mL of 0.2 M sodium hydroxide solution. The tubes were tightly sealed. In each glass tube, the insertion part of approximately 550 mm from the tip was immersed in the solution for 16 hours for extraction.
- The amount of residual formaldehyde was measured using chromotropic acid absorption spectrophotometry according to EN14180 Annex D.

Results: The amount of residual formaldehyde was 25.2 ± 22.5 µg (mean ± standard deviation) at the HP position and 61.3 ± 18.20 µg at the CP position.

Conclusion: We conclude that LTSF-sterilized flexible endoscopes can be used in clinical settings as the amount of residual formaldehyde measured in this study was 1/100th of the amount reported in the Netherland's RIVM Report 710401018 (1992), which is referred to in Annex E of EN14180.
In order to fully validate LTSF sterilization for use in clinical settings, the sterilizability and suitability of all products and packaging materials and the persistence of the sterilizing agent should be validated for any daily-use products that would be subject to sterilization. For these studies, the validity of the method for extracting residual formaldehyde needs to be more robustly established.

P_21

The perceptions of contractors regarding the current state of the management of surgical instruments on loan in Japanese hospitals

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Biography:
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Nikkei-Service Co.,Ltd.(2001-2019)
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- Area Manager of Nikkei-Service Co.,Ltd (2016-2019)
Osaka University Hospital central supply service (2019-)
Member of JSMI(Japanese Society of Medical Instrumentation)

Background: A survey conducted by the Ministry of Health, Labour and Welfare in Japan in 2017 revealed that most hospitals in Japan are relatively small with the most common number of beds ranging from 50 to 99 (24.8% of the total number of hospitals). Only 0.6% of Japanese hospitals have 900 or more beds and no more than 4.9% of all Japanese hospitals have 500 or more beds. In mid- to large-sized hospital facilities, medical instrument outsourcing has been increasing. In a 2018 medical services survey, the percentage of hospitals that outsource cleaning and disinfection of instruments was 35.3%, demonstrating an increasing trend compared to a 20.7% rate of outsourcing in 2009. As outsourcing becomes more common, there are many issues in in-hospital equipment cleaning services, which need to be addressed by the contracted outsourcing companies in order to efficiently manage the increased number of surgical instruments on loan (SIL). As many of the staff of outsourcing companies work part-time only, stricter control of outsourcing procedures is required to ensure instruments are properly tracked and cleaned in a timely manner.

Aim: To report on the perceptions of contractors regarding the current state and issues of SIL management in Japan.

Methods: Ten years have passed since Osaka University Hospital started using SIL, in 2010. We examined the changes in cleaning rates of surgical instruments prior to the implementation of SIL compared to the results due to improved procedures implemented over the past 10 years.

Results:
1. Changes in cleaning rates
At the commencement of the study period, in 2010, cleaning was carried out only for frequently used SIL. Monthly cleaning rates for instruments at the time of delivery varied widely from 42% to 92%. A policy was then implemented with the goal of cleaning all SIL. This resulted in a significant improvement with the cleaning rates of instruments delivered within a designated time frame improved to 89% to 100% in 2019. Importantly, although our goal was to clean all SIL, we could not clean instruments before use if they were delivered outside of business hours. Thus, overall cleaning rates before use ranged from 58% to 78%.
2. Improvement of SIL management procedures
Key issues involved in the efficient management of SIL include ensuring confirmation of the number of SIL delivered and reducing the number of non-standard surgical instruments introduced by physicians in their practice that require cleaning. With respect to confirming the of number of SIL, we moved from

a paper-based method of confirmation to a tablet computer (iPad) in order to enhance visibility and identification of instruments. However, we could not reduce the number of non-standard instruments introduced by doctors.

Conclusions: The management of SIL is a common global issue. In Japan, outsourcing of cleaning and disinfection has increased and outsourcing contractors make an effort to implement efficient procedures. However, to achieve overall success in managing this issue, it is necessary to achieve a reduction in the number of non-standard surgical instruments brought into the hospital system by physicians.

P_22

The efficacy of ultrasonic cleaning in stainless steel and polyvinyl chloride (PVC) using different detergents

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Biography:
She graduated in Nursing at University of Sao Paulo, Nursing School of Ribeirao Preto in 2002. She got her Master in Sciences in 2010 at University of Sao Paulo. She got her PhD in Sciences at University of Sao Paulo in 2015. She is currently a post doctoral research fellow at University of Sao Paulo.

Aim: To evaluate the efficacy of ultrasonic cleaning in stainless steel and PVC materials using different detergents.

Methods: Stainless steel and Polyvinyl Chloride (PVC) tubes (185mm length X 5mm diameter) were immersed in 200mL in Human Albumin (20% - Grifols™) and Soil Test (2g - Browne™) per 4 hours. Then, the samples were rinsed in tap water and cleaned ultrasonically (Medsafe™) in deionized water for 5 or 15 minutes without detergent (control group) and with different detergents (enzymatic, alkaline, disinfectant detergent, and neutral – experimental groups). After ultrasonic cleaning each sample was rinsed in tap water and a protein residue test (Getinge Assured™) was done, swirling the test swab all over the surface (instrument surface test) and inside the lumen (instrument lumen test), and then inserting the swab in the test tube. The higher the level of contamination of protein, the darker and faster the color changes to blue.

Results: Table – Results of protein residue test for sample type, detergent, and time.

Conclusion: The increasing complexity of medical devices makes reprocessing an increasing challenge for Sterile Processing Departments. Cleaning is a critical step and should be monitored, because residues can compromise sterilization and disinfection, and put patient safety at risk. There are several kinds of detergents released for use in the market, and is not always easy to decide which one to choose. The method used in our experiment showed to be a simple method to compare the cleaning efficacies of detergents and may be used as a first stage in benchmarking cleaning efficacy of detergents. Also, our experiment allowed evaluating the cleaning efficacy of the ultrasonic washer in two different times, comparing the surface and the lumens. The disinfectant detergent showed significantly more failures compared with the others detergents. Also, there were more failures with 5 minutes cycles compared with 15 minutes cycle. Lumens showed more failures than surfaces, confirming others studies.Surprisingly, the only water group showed to be effective to eliminate protein residues from PVC in the 5 minutes cycle.

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Table – Results of protein residue test for sample type, detergent, and time.

Detergent	Sample	n	Time	Protein residue test	
				Surface	Lumen
Only water	Stainless steel	5	5'	0/5	4/5
		5	15'	0/5	0/5
	PVC	5	5'	0/5	0/5
		5	15'	0/5	1/5
Neutral	Stainless steel	5	5'	0/5	0/5
		5	15'	0/5	0/5
	PVC	5	5'	0/5	1/5
		5	15'	0/5	0/5
Alkaline	Stainless steel	5	5'	0/5	1/5
		5	15'	0/5	0/5
	PVC	5	5'	1/5	0/5
		5	15'	0/5	0/5
Multi-enzymatic	Stainless steel	5	5'	1/5	0/5
		5	15'	0/5	1/5
	PVC	5	5'	0/5	2/5
		5	15'	0/5	1/5
Disinfectant detergent	Stainless steel	5	5'	5/5	5/5
		5	15'	3/5	3/5
	PVC	5	5'	2/5	4/5
		5	15'	0/5	5/5

P_23

Medical device anodization compatibility with hydrogen peroxide sterilization

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Biography:
Roger Vu is a R&D Senior Scientist at Advanced Sterilization Products with over 10 years of experience in disinfection and sterilization of medical devices. Roger has had roles in product development and research within the scope of medical device processing. He has supported sterilization validations for numerous devices with many device manufacturers. He earned a master's degree in Molecular Microbiology and Immunology at the University of Southern California, Keck School of Medicine.

In order to achieve compatibility with sterilization processes, material selection is particularly important when designing medical devices. In addition to the primary base materials used for the construction of common medical devices, consideration should also be given to secondary materials used to enhance the devices. Specifically, anodization is a critical material component that can dictate device compatibility if incorrectly specified for the device design. This material component was evaluated to better understand compatibility with STERRAD® hydrogen peroxide sterilization. Organic anodization colorants, or dyes, are widely used for decorative finishes. The porous anodized aluminum is simply dipped in a dye bath, and over time, dye is absorbed into the surface. All dyes fade to some degree, over time, as a result of bond cleavage within the organic molecule. This cleavage can occur as a result of UV irradiation, chemical oxidation or a combination of both.1 An oxidative environment, such as hydrogen peroxide sterilization, can fade anodized coatings that are colored with organic dyes.1 To address the issue of fading with some anodized aluminum products, inorganic electrocoloring techniques were evaluated by Reliant Aluminum Products. In Electrocoloring, the part is immersed in a second electrolysis tank following initial clear anodization. The second electrolysis tank typically contains specific metal salts, such as stannous sulfate, for coloring. The coloring effect is believed to be due to the deposit of extremely small crystals or particles, such as metal or oxides, in the pores of the electrolytic oxide film. Such deposits can lead to coloring or shading due to the optical effects of absorption.1 This type of inorganic electrocoloring resists oxidation and bleaching from hydrogen peroxide sterilization cycles better than organic methods. There is an increasing number of available sterilization processes and systems which utilize oxidization processes or strong oxidizers for sterilization, including: ozone, chlorine dioxide, hydrogen peroxide, peracetic acid. Due to the similarity of technology between commercially available hydrogen peroxide sterilizers, we would expect comparable compatibility results with anodized surfaces. Therefore, medical device manufacturers should use care in selecting materials and designing components and devices, remaining aware of how materials may interact with various sterilizing processes.

P_24

Medical Device lubricant and adhesive compatibility with hydrogen peroxide sterilization

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Biography:
Roger Vu is a R&D Senior Scientist at Advanced Sterilization Products with over 10 years of experience in disinfection and sterilization of medical devices. Roger has had roles in product development and research within the scope of medical device processing. He has supported sterilization validations for numerous devices with many device manufacturers. He earned a master's degree in Molecular Microbiology and Immunology at the University of Southern California, Keck School of Medicine.

In order to achieve compatibility with sterilization processes, material selection is particularly important when designing medical devices. In addition to the primary base materials used for the construction of common medical devices, consideration should also be given to secondary materials used to enhance the devices. Specifically, lubricants and adhesives are critical material components that can dictate device compatibility if incorrectly specified for the device design1. These secondary materials were evaluated to better understand their respective compatibility with STERRAD® hydrogen peroxide sterilization. There is an increasing number of sterilization processes and systems, that are either on the market or being developed, which utilize oxidization processes or strong oxidizers for sterilization, including: ozone, chlorine dioxide, hydrogen peroxide vapor, peracetic acid. Powdered lubricants of graphite, boron nitride, and Teflon® were demonstrated to be compatible with 100 hydrogen peroxide sterilization cycles. No degradation was found for any of the samples. In contrast, incompatible molybdenum disulfide, tungsten disulfide, niobium diselenide, and tungsten diselenide lubricants showed signs of degradation after 11-13 cycles.2 Hydrogen peroxide compatible lubricants should be used in medical device design and manufacturing to enhance device compatibility. Some adhesives evaluated had minor affects during hydrogen peroxide sterilization, but many demonstrated good compatibility.1 Some high-temperature-curing epoxies that use small amounts of catalytic curing agents showed better compatibility than room temperature curing epoxies. An example was imidazole-cured resins. Imidazole curing agents cure largely by homopolymerization, with relatively low proportions of curing agent to resin, leading to relatively low levels of amine cross-linkages.1 Adhesives that use large proportions of amines as curing or cross-linking agents tended to be incompatible.1 Due to the similarity of technology between commercially available hydrogen peroxide sterilizers, we would expect comparable compatibility results of lubricants and adhesives between the sterilizers. Based on the above, thinking about how materials may interact with various sterilizing processes should be thought of when selecting materials and designing components and devices.

P_25

Sterilization of flexible endoscopes

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[1]*Advanced Sterilization Products, Irvine, USA*

Biography:
Roger Vu is a R&D Senior Scientist at Advanced Sterilization Products with over 10 years of experience in disinfection and sterilization of medical devices. Roger has had roles in product development and research within the scope of medical device processing. He has supported sterilization validations for numerous devices with many device manufacturers. He earned a master's degree in Molecular Microbiology and Immunology at the University of Southern California, Keck School of Medicine.

Reusable medical devices are cleaned manually and/or in an automated system such as in a washer disinfector according to the device manufacturer's recommendations. Then, they are subjected to the healthcare center's terminal process such as terminal sterilization or high-level disinfection (HLD) depending on the Spaulding classification. Cleaning reduces the bioburden and removes foreign material that interferes with terminal processes.1 Cleaning should be done promptly after use as foreign matter and soiled organic material may dry onto instrumentation. Sterilization is a validated process used to render a product free of all forms of viable microorganisms.2 HLD is a process that kills all microbial pathogens but not necessarily high number of bacterial spores.2 Reprocessing of reusable medical devices is regarded as a process that renders devices safe with low risk to patients, some exceptions exist, such as flexible endoscopes. Many infection outbreaks have been associated with endoscopes. The fact that most types of endoscopes can remain contaminated after HLD reprocessing indicates that the margin of safety with endoscope reprocessing is minimal or non-existent3, due largely to endoscope design complexity4, insufficient cleaning5, and biofilms inside their channels6. Since sterilization provides a higher microbial kill compared to HLD process, it is expected to significantly improve the margin of safety, provided sufficient cleaning. Therefore, unless contraindicated, it is preferred to sterilize semicritical devices rather than high-level disinfect them7; however, this is often impractical. The challenge with sterilization is mainly due to the material compatibility limitations8 where they are not compatible with most sterilization modalities, including steam and vaporized hydrogen peroxide. Although ethylene oxide is compatible, it is not practical due to slow turnaround times.9 Hydrogen peroxide sterilization is relatively fast but not compatible with most current endoscopes, mainly due to the use of a lubricant inside the endoscopes that reacts with hydrogen peroxide and corrodes the endoscope from inside out when processed a few times with vaporized hydrogen peroxide sterilizers.10 In summary, in order to potentially provide a higher standard of care by reducing infection rates, new endoscope designs need to be made easier to clean with more robust materials that are compatible with fast low temperature sterilization technologies.

P_26

Nurse challenges in the implantation of good practices material and sterilization centre: patient safety

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Biography:
Enfermeira graduada pela Universidade Federal do Pará, Especialista em Administração de Enfermagem nos Serviços de Saúde pela Universidade Federal do Pará; Especialista em Enfermagem de Centro Cirúrgico, Centro de Esterilização e Recuperação Pós-Anestésica pela Faculdade Inspirar; Mestre em Gestão Pública pela Universidade Federal do Pará; Docente nas disciplinas Centro Cirúrgico e Centro de Material e Esterilização nas Faculdades Pan Amazônica e Faculdade Paraense de Ensino em Belém do Pará-Brasil.

Objective: To identify the challenges faced by the nurse of the Material and Sterilization Center (CME) in the processing of articles regarding the safety of the surgical patient.

Methodology: Descriptive, exploratory, qualitative approach, carried out with nurses from Material Center and Sterilization of a Public Hospital of Belém-Pará, Brazil, from August to September 2018. The project was approved by the Research Ethics Committee of the Paulista University (UNIP) under the number CAAE 96056918.3.0000.5512. For data analysis, the Bardin content analysis was used.

Results: Two important categories were found: Challenges of the Implementation of Good Practices of Processing of Health Products; and professional training as a factor for patient safety. The most outstanding challenges were the lack of physical structure, associated with insufficient human resources, equipment without maintenance, and the lack of protocols, which do not comply with RDC 15/2012, which determines in Brazil the implementation of good practices in CMEs. With reference to the importance of Training, the research contributors emphasized that the team should be trained in patient safety, since only then will they be prepared to do the processes properly.

Conclusion: The study made it possible to identify the challenges in the implementation of good practices faced by the CME nurses and among these challenges are the human and material resources management, perceiving the need for adjustments and implementation of improvements in the sector, especially respect to the difficulties with the scarcity of material resources, inadequate equipment, including those specific to the CME, such as autoclaves, washing machines, thermo-dynestrictors, generating in the professionals feelings of dissatisfaction, fatigue and resilience[1] therefore the nurse's role will reflect and directly influence the work of the CME team to the quality of the safe practice of the surgical patient[2]. It was concluded that the work developed in the CME is of great relevance in relation to infection control, especially those related to surgeries. These results can contribute to the understanding of the difficulties, which is the first step towards the change of culture in relation to the Good Practices of Processing of Health Products.

Keywords: Nursing; Sterilization; Patient safety

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2. Moriya, GAA; Takeiti, MH. Rev. SOBECC, São Paulo, p.1-2

P_27

Nursing protagonism in the health product cleaning process: patient safety

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Biography:
Graduada em Enfermagem pela Universidade Federal do Pará; Licenciatura Plena pela Universidade Federal do Pará; Especialista em Administração de Enfermagem nos Serviços de Saúde pela Universidade Federal do Pará; Especialista em Centro Cirúrgico, Centro de Material e Recuperação Pós Anestésica pela Faculdade Inspirar; Mestre em Gestão Pública pela Universidade Federal do Pará. Docente na Faculdade Pan Amazônica (FAPAN) e Faculdade Paraense de Ensino (FAPEN), nas disciplinas Centro Cirúrgico e Centro de Material e Esterilização.

Objective: to analyze the importance of the nursing team in the process of cleaning products for health in relation to patient safety.

Methodology: field research, exploratory, descriptive, qualitative, with nursing professionals from the Material and Sterilization Center (CME) of a Public and Teaching Hospital of Belém, state of Pará, Brazil. The research was approved by the Research Ethics Committee of the Paulista University (UNIP) under the no. 2,893,760, CAAE no. 95250718.0.0000.5512.

Results: They were divided into categories: Cleaning Process and patient safety; Work process; Professional qualification. In the CME, as a result of this research, the cleaning of Health Products (PPS) is performed manually by the nursing team, and considered the primary stage, to guarantee the effectiveness of the next stages of the sterilization process, avoiding that products used in the vehicles of contamination. Regarding the work process, it was evidenced that the protocols were not known and outdated, as were cleaning accessories and insufficient personal protective equipment (PPE) to perform the procedure. Regarding training, the results show that there is training, especially when new and complex materials are received, but without a set period. Another important result in the research was related to structural problems, difficulties in maintaining established routines that are lost with time and failures in internal communication. The actions developed by the nursing team in the CME are directly related to the safety and protection of the patient, thus, the adoption of safe practices during the processing of articles influence positively in the control of infections and surgical complications, mainly the cleaning stage, considered one of the most important in the processing of articles.

Conclusion: The study made it possible to analyze the importance of the nursing team in a more important stages of product processing, which is cleaning, and that despite all the challenges and difficulties, the team is aware of its role in the safety of the patient and to reduce these difficulties the elaboration of a Standard Operating Procedure (POP) is indispensable for the involvement of those responsible for the execution of the tasks, as well as the analysis of each step in order to verify which is the easiest and most efficient to be followed (1). In the studied institution, the process of cleaning products for health is performed manually, it is pointed out that this form of cleaning has limitations, being recommended automated cleaning, allowing greater control of process parameters and reproducibility, in addition to minimizing occupational risks (2). For this reason, continuing education becomes very important for the acquisition of new knowledge and skills in each process within the CME, bringing assurance and safety in the sterilization, making indispensable the qualification of the employees (3).

Keywords: Sterilization Center. Nursing. Sterilization.

References:
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P_28

Neutralizers used to determine the bactericidal activity of disinfectants in a qualitative suspension test

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Biography:
Soohee Kim is currently a researcher at Veterinary Drugs and Biologics Division, Animal and Plant Quarantine Agency(Goverment Agency).

In South Korea, the protocol of evaluation of bactericidal activity of disinfectants is followed by APQA(Animal and Plant Quarantine Agency) and this method is the qualitative suspension test which results are expressed as 'growth' or 'no growth'. The objective of this study was to compare the bactericidal activity of fourteen commercial disinfectants against Salmonella Typhimurium using Dey-Engley neutralizing broth instead of 5 % horse serum(in nutrient broth) as neutralizing sol. Test organism was Salmonella Typhimurium strain(ATCC 14028). The concentration of bacterial inoculum was 2.7×108 cfu/mL and the value of optical density was 0.178 at 600 nm by using a spectrophotometer. The assay was done according to APQA Approval test in duplicate. Disinfectant is considered bactericidal if there is growth in less than one positive out of five tubes tested. In both neutralizers, six out of fourteen commercial disinfectants showed growth in five out of five tubes, while the other eight disinfectants no growth in five tubes. In conclusion, the test results for determining the efficacies of fourteen commercial disinfectants were the same in both neutralizers.

P_29

Performance evaluation of the microbial barrier in surgical apron sms x fabric 100% cotton

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Biography:
Enfermeira. Gerente Administrativa da Associação Paulista para o Desenvolvimento da Medicina. Pós-graduação em Administração Hospitalar. Especialização em Segurança do Paciente. Especialista em Enfermagem Pediátrica/Neonatal.

Objective: Preventing the microbial contamination of the operative wound is the main function of the surgical apron, besides the protection of the medical team. Made with 100% cotton fabric in some countries such as Brazil, its use still generates controversy over the efficiency of the barrier against microorganisms. Therefore, our aim was to compare the performance of surgical aprons in new cotton fabric and used with disposable surgical apron in SMS medical grade when subjected to bacterial filtration test.

Method: In this comparative study, we used 10 SMS aprons, 10 in 100% cotton new fabric and 10 used several times. We cut out 4 samples of 10 cm2 of all aprons, in a total of 120 samples that were subjected to the bacterial filtration efficiency test, according to ABNT NBR 14873. The tests were carried out in a laminar flow chapel in an accredited microbiology laboratory. The aprons consisting of a fabric, besides this assay, were also tested in moist environment, simulating the intraoperative reality.

Results: The Aprons in SMS presented compliance with bfe 97.30%, according to the manufacturer's report. The new fabric aprons were non-conforming, with dry performance 80.8% and in humid environment 54.5%. All the aprons in fabric with different uses presented non-conformity with values of 72.7% and 35% dry and in wet environment, respectively.

Conclusion: The difference in performance between the fabric and SMS aprons was proven, and the non-conformity of new and used fabric aprons was demonstrated in all tests. For marketing, reports are required from all aprons manufacturers in SMS. On the contrary, it is not requested from fabric fabricators, barrier efficiency reports against pathogens. Thus, the migration of the fabric to the SMS is mandatory in order to ensure the safety of the surgical patient. We emphasize that managers, as responsible for analyzing the cost-benefit of materials for the hospital institution, have the duty to decide for the product with safe performance and in compliance with current legal norms. Studies developed in several countries indicate that the values spent with nosocomial infection outweigh the investment in materials of proven quality. We consider the results obtained as definitive, in order to support the decision to replace the fabric of the surgical environment, due to the risk that it represents to our patients. Scientific evidence bases this assertion, distances us from dangerous empiricism and elucidate long-term doubts about the use of fabric in the components of surgical apparel.

Keywords: Protective clothing, Microbial Barrier, Surgical infection

P_30

Viable and non-viable particles: imminent danger in the operating room

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Biography:
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Objective: The movement of microorganisms in the air uses suspended particles and these contaminants end up settling on the surfaces, producing a potential risk of contamination. Aiming to substantiate this theoretical basis, to discuss clean room classification in hospitals and to demonstrate the direct relationship between the amount of non-viable particulate matter with the bioburden, we developed a study at the CSSD and Operating Theater of a Public Hospital in São Paulo, Brazil.

Method: Using a Milipore Air test equipment, we performed air collection on Petri dishes containing specific culture medium for bacterial and fungal growth, at various points in two operating rooms, preparation rooms and storage of sterile material. Simultaneously, particle counter air samplings were performed using the methodology established at NBR ISO 14644-3: Clean rooms and associated controlled environments - Part 3: Test methods.

Results: In the operating room, the overall mean particle size of 0.5 micron was approximately 1,500,000 with the presence of the Micrococcus luteus, Staphylococcus sp and Baciclus sp bacterias; There was no fungal growth. There was growth of the same bacteria and Cladosporium fungi in the preparation and storage rooms of sterile material, with the overall mean particulates 4 million and 3.5 million, respectively.

Conclusion: We did not find specific cleaning class norms for the studied areas, so a correlation with the pharmaceutical industry. The areas were classified as ISO 8 with acceptable particulates up to 3,520,000 / m^3 of air. The data obtained show that clean rooms usually have low levels of microbial contamination. In the preparation and storage rooms we found a greater number of non-viable particles, bacteria and fungi. We believe that high fiber detachment, due to the handling of textiles in these areas, was a determining factor for this result, proving the existence of linearity between the elements: the greater the amount of particulate matter the greater the bioburden. Although the identified microorganisms have low pathogenicity, studies indicate that there is a strong relationship between air contamination and surgical wound, resulting in infection. The literature describes that each non-viable particle can carry up to 5 viable particles and their precipitation directly on the surgical incision, the deposition on the instruments and / or the medical staff's clothing can lead to its contamination. We suggest periodic measurement of particulates in critical hospital areas for control, as well as defining their classification based on a history of results. Also, this study aims to provoke reflections on the use of low fiber detachment clothing; acquisition of unidirectional laminar flow ventilation systems and restriction of the number of people in the operating room. The direct impact of these actions will certainly reduce the potential risk of surgical site infection and reduce health care costs.

Keywords: Clean Room, Aerial Contamination

BRAZIL. National Health Surveillance Agency. Quality Guide for Air Treatment and Enviromental Monitoring Systems in the Pharmaceutical Industry. 2013.
ABNT NBR ISO 14644 –3: Clean rooms and associated controlled environments - Part 3: Test methods.

P_31

Clinical efficacy comparison of a manual-specific enzymatic detergent versus three non-specific enzymatic detergents for surgical instrument cleaning

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[1]Xin Tai General Hospital, Taipei, Taiwan, [2]Fu Jen Catholic University Hospital, New Taipei City, Taiwan, [3]Yeezen General Hospital, Taoyuan City, Taiwan

Biography:
Miss Liu is a register nurse and has worked in operation room over than 18 years. She also has two-year experience of head nurse of CSSD in a regional hospital in Taiwan.

Aim: The objective of this study was to compare the cleaning efficiency of a manual-specific instrument detergent, Prozyme Active(M) with three non-manual-specific detergents, Low Foam Ultra Rapid Multi-Enzyme Cleaner(X), Premium with APA(Y), and Aniosyme Synergy 5 Enzyme Detergent(Z), in order to optimize the manual cleaning process under manpower shortage.

Methods: A specific kind of orthopedic tray and bowls and kidney basins used at the same operation were reprocessed in this study. Three categories of instruments were recruited and described in chart 1. Randomized 90 instruments (30 items for each category) for each detergent group were cleaned respectively by well trained staff who complied strictly the standard of process which was modified from the DGSV manual cleaning guideline1. The study design was showed in chart 1.

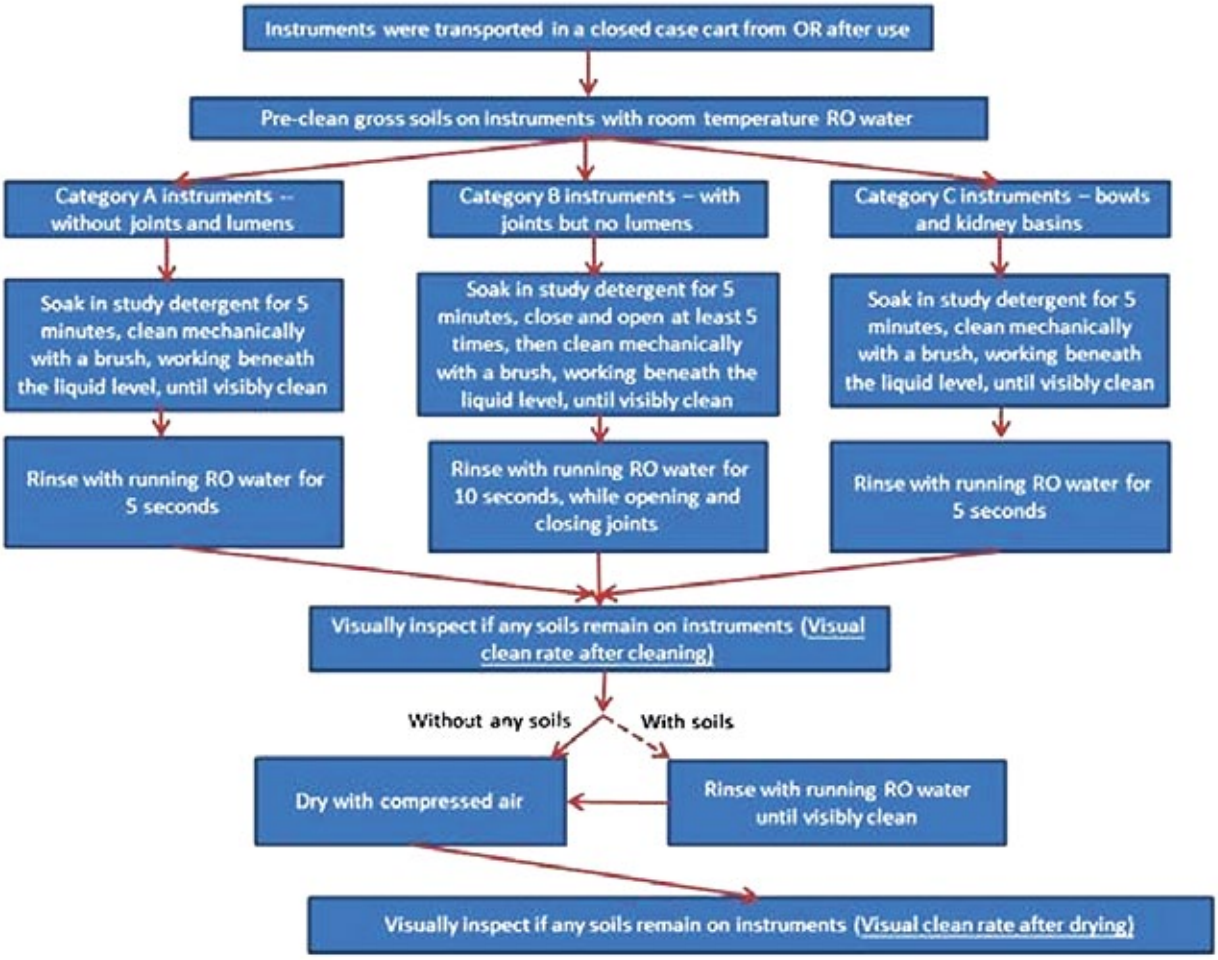
Results: Totally 360 instruments were tested. (1) Visual clean rate after cleaning: All instruments cleaned with detergent M were without any soil or residue after cleaning. The visual clean rate was 100%. However, for instruments cleaned with detergent X, Y and Z showed significantly low ($p<.05$), which were 67.8%, 48.9%, 20.0%, respectively. All visible soils were foams and looked like detergent residues. (2) Visual clean rate after drying: 87 instruments (96.7%) reprocessed with detergent M were soil free after drying, which was significantly higher ($p<.05$) than other detergent groups. However, the visual clean rate after drying of detergent X group was the lowest (15.6%) and had statistical significance($p<.05$) when compared to other groups. For detergent Y and Z groups, the visual clean rates were 54.4% and 55.6%. All visible soils were white and greasy-feeling residues, which could be removed by scrubbing.

Discussion and conclusions: The study results showed the manual-specific detergent (M) had much better cleaning efficacy under the same duration of rinse time. In contrast, instruments cleaned with non-manual-specific detergents (X, Y and Z) had much more residues after cleaning and drying and needed to be further rinsed and/or re-cleaned. This study confirmed the application of the manual-specific detergent in this unit regarding the time saving with superior cleaning quality.

References:
1. DGSV: Guideline for validation of manual cleaning and manual chemical disinfection of medical devices.
2. Detergent M: Deconex® Prozyme Active (Borer)
3. Detergent X: 3M™ Low Foam Ultra Rapid Multi-Enzyme Cleaner (3M)
4. Detergent Y: Endozime® Premium with APA (Ruhof)

5. Detergent Z: Aniosyme Synergy 5 Enzyme Detergent (Anios)

Chart 1. Study design



P_32

Improving the quality of endoscope cleaning by multiplex process

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Biography:
Medical laboratory scientist of infection control.

Introduction: Cleaning is an important process in endoscope reprocessing. Endos-copic Retrograde Cholangiograohy and Pancreatography (ERCP) is a high risk of infection. That's why CDC suggested using EO gas for sterilization. But according to some study, using EO gas for sterilization cant avoid the bacteria growth on the scope, so the true and important process for reprocessing is cleaning.

Material and method: in this study, we collected 60 ERCP samples after cleaning. And we spread three groups, the first group was using the re-used brush, the second group was using a disposable brush, and the third group was using a disposable brush with multiple processes. After cleaning, we used the ATP to test the quality.

Result: In the first group, the average of ATP was 347 RLU, and the passing ratio was 55%. In the second group, the average of ATP was 86 RLU, and the passing ratio was 80%, then in the third, the average of ATP was 27 RLU, and the passing ratio was 95%.

Summary: In this study, we found the disposable brush can improve the quality, but not only one step can improve the quality of reprocessing. By using multiple processes, the quality can be better. And the p values between each group were < 0.05

P_33

Influences of residual moisture remaining in instruments on vaporized hydrogen peroxide sterilization process

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Biography:
· *Chief examiner Central Sterile Supply Department, Koshigaya Municipal Hospital*
· *CSS (Certified Sterilization Specialist) by JSMI (Japanese Society of Medical Instrumentation)*
· *MDIC (Medical Device Information Communicator) by JSMI*
· *a Member of Metropolitan Sterilization Society*

Background: The continued development of new surgical methods and technologies has resulted in reusable medical devices that are more complex and present greater reprocessing challenges. In addition to cleaning and sterilization, proper drying of instruments has become more difficult because of complex structures such as narrow lumen devices as well as more heavy and complex designs such as orthopedic power tools. Insufficient time available for drying between cleaning and sterilization, especially for loaner instruments, increases the possibility of moisture remaining on/in instruments that are placed in the sterilization chamber.

We conducted a series of experiments to determine the effect of residual moisture on sterilization efficacy on a number of surgical instruments.

Methods:
1. 1mL, 2mL, or 10mL of sterile water was placed in stainless steel petri dishes and packaged in separate sterilization pouches. Each package was processed in a vaporized hydrogen peroxide sterilizer. Each volume of water was tested 4 times, and the number of cycle cancellations was recorded.
2. Observation windows in the chamber door allowed observation of the effects of the cycle vacuum on the water in the petri dishes. The effects of the process on 2mL and 10mL samples in canceled cycles was photographed.
3. The temperature profiles of the processes for the 2.5mL and 10mL samples of sterile water, as well as processes containing no water, were recorded by data loggers and compared.
4. Baseline data for processes that did not cancel was obtained by running 3 replicate cycles containing no water, and 3 replicate cycles with 1mL water samples.

Results:
1. All four cycles cancelled in the presence of 2mL and 10mL water while only one out of four cycles cancelled in the presence of 1mL water.
2. Water boiling followed by freezing was observed and recorded for both 2mL and 10mL before the cycle was cancelled.
3. The minimum temperature for the 2.5mL and 10mL water samples was dropped to less than -8 degree centigrade. The processes without water had a minimum temperature of 26 degree centigrade.
4. Condensation of hydrogen peroxide was observed during the first three sterilant injections, out of the four in each process. This phenomenon was observed in all three tests performed.

Conclusion: This study suggested the possibility of a sterility failure because of residual moisture remaining in instruments. Residual moisture or condensation of hydrogen peroxide could result in insufficient exposure to the sterilant.

While most vaporized hydrogen peroxide sterilizers will automatically cancel the cycle if water is present, this study implies that a small amount of water may not trigger the auto-cancelation and may lead to a sterility failure. Thus sufficient drying time between cleaning and sterilization is very important.

P_34

Efforts to reduce scalpel blade contamination in used surgical instruments

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Biography:
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2012.4~2017.10 - The University of Tokyo hospital, Supply Center, Research Associate
2017.11 ~ - The University of Tokyo hospital, Surgical Center, Assistant Professor

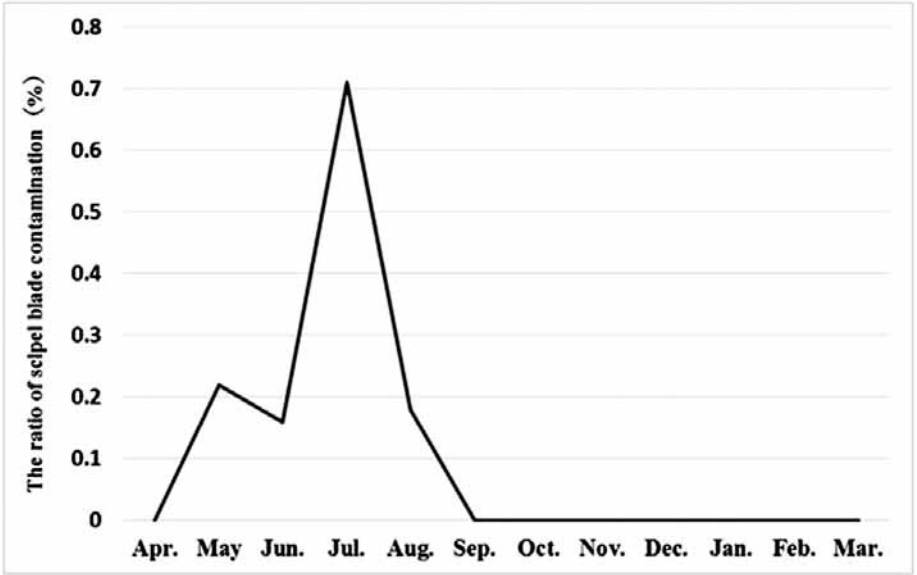
Purpose: Reusable surgical instruments are cleaned after use.
The contamination of the scalpel blade used in the operation into a used instrument may lead to injury of the cleaning staff.
In this study, we examined whether changing the postoperative surgical instrument counting procedure by nurses would be useful in reducing the contamination of scalpel blades into used instruments.

Methods: From April 2017 to March 2018, a total of 6,487 operations were analyzed. The study period were divided into the first half (the first 6 months, 3291 cases) and the second half (the following 6 months, 3196 cases). Regarding the disposal of the scalpel blade after surgery, in the first half, it was done by the scrub nurse alone. In the second half, it was done by the scrub and circulating nurses checking at the same time (double check). After that, the frequency of scalpel blade contamination in used instruments were compared between the first and second half.

Results: The frequency of scalpel blade contamination in used surgical instruments was 7 cases (0.21%) in the first half, but 0 case (0.00%) in the second half.

Conclusions: When the scalpel blade is discarded after the operation, the double check by the scrub and circulating nurses prevents the scalpel blade from being mixed into the used surgical instrument. It may be useful for medical safety because it contributes to reducing cleaning staff injury.

The frequency of scalpel blade contamination in used surgical instruments



P_35

A study on introduction of SPSM for evaluating reliability of sterilization processes

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Biography:
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Adjunct Professor of Shenzhen University.
Member of the Standing Committee of the Guangdong CSSD association.
Vice President of CSSD chapter of Guangdong Provincial Hospital Nurses Association.
Deputy Director of the CSSD Committee of Shenzhen Nursing Association.

Objective: By measuring 4 key parameters of steam sterilization process (equilibration time, sterilization temperature band, holding time, and sterilization temperature uniformity) under daily condition, sterilization process safety margin was calculated to evaluate reliability and reproducibility of A steam sterilization process in a quantitative and feasible approach. A preventive maintenance in early stage through prospective risk analysis to avoid most of possible sterilization failures can now be performed.

Methods:
1 Chose #2 sterilizer (Type MST-9615 HS2) currently in use where this study was performed. Main settings of chosen P1 cycle are: Sterilization temperature 134°C, sterilization time 5 minutes. Seven calibrated temperature sensors were placed inside packs located at previously defined locations. An additional temperature sensor was placed adjacent to the sterilizer control sensor. P1 was run with daily random loads and measurements of four critical variables were recorded. It repeated 30 batches.
2 Four key process parameters were measured and the results were evaluated against EN285.
3 Calculated safety margin. Currently there are no relevant definitions in international standards regarding the use of "safety margins" concept to evaluate sterilization process. Referring the calculation widely used in industry, we use the definition of "Sterilization Variable Safety Margin (SVSM)" and "Sterilization Process Safety Margin(SPSM)" as below:
SVSM%= ABS (Target Value –Measured value) / Target value .
SPSM%= Min (All specific 4 SVSMs).
4 A BI PCD was placed above chamber drain. A class five CI was placed in each of test packs.

Results:
1 All CIs and BI PCDs showed passed results.compliance to requirements of EN285 cannot be given.
2 SVSMs results (average and range): SVSM of equilibration time : 94.9% [86.7%-100.0%]; SVSM of sterilization temperature band: 67.3% [60.3%-71.0%]; SVSM of holding time: 72.0% [71.1%-72.8%]; SVSM of sterilization temperature uniformity: 83.1% [59.5%-93.0%]. Compliance of all 30 test runs to EN285 can be clearly confirmed.
3 SPSM result (average and range) : 66.8% [59.5%-71.0%]. (Results are shown in Figure 1).
4 Introduction of SPSM showed actual value of four key parameters exceed 66.8% of required value on average. This SPSM as overall indicator can therefore be used to quantify the reliability of the sterilization process.

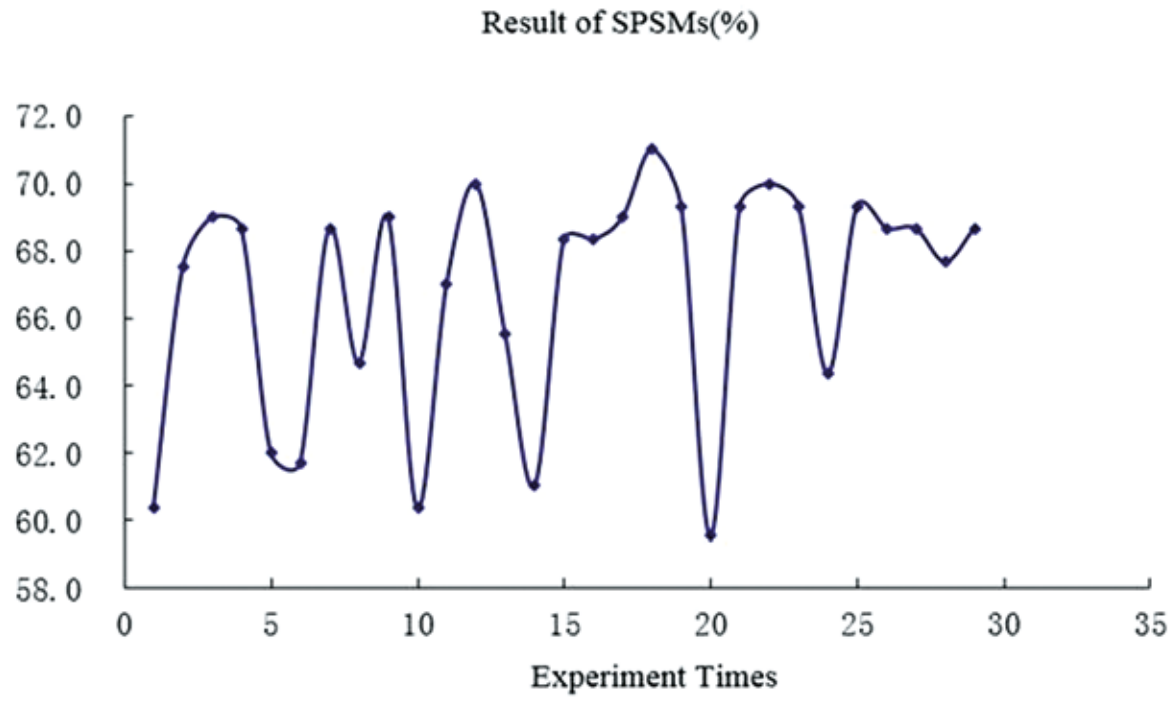
Conclusion:

1 The fundamental change in assessment of "quality" of sterilization process: CIs and BIs are non-quantitative methods and naturally cannot provide precise information. Introducing the concept of "safety margin" to quantify the reliability and reproducibility of sterilization processes in healthcare sector:

1.1 In this study, the average value of SPSM 66.8% was chosen as benchmark of SPSM for P1 program of #2 sterilizer. acting as an evaluation criterion of effectiveness of subsequent sterilization process tests. Whenever there is a situation in which SPSM of subsequent sterilization process is lower than the reference value, or SPSM of multiple tests fluctuate widely, it is a clear warning.

1.2 Generating a SPSM trend curve of a specific process based on the SPSM values calculated in every subsequent test can be realized, and be used for forward-looking risk analysis while gradually reducing the degree of dependence on CIs and BIs.

Fig. 1 Result of SPSM of P1 program



P_36

Study on the cleaning quality of the medical apparatus and instrument by using STF cleaning inspection card test

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Biography:
Huang Meihua, chief nurse, head nurse, vice president of the Central Sterile Services Department Professional Committee of Shenzhen Nursing Society. She has been working as the head nurse in the central sterile services department of Shenzhen Children's Hospital for 19 years. She has considerable experience and specializes in the various processes including cleaning, disinfection, packaging, sterilization, distribution, information management. She is the lecturer of the Shenzhen Central Sterile Services Department Professional Training Seminar that is held annually by the Shenzhen Central Sterile Services Department Professional Committee.

Objective: There was a test for residual protein by STF cleaning inspection card reaction after cleaning medical apparatus and instrument, to detect the effective evaluation of cleaning effect of medical apparatus and instrument.

Methods: 840 of surgical instruments were randomly divided into two groups. They were washed by normal cleaning and cleaned by soaked in muti-enzyme detergent. Cleaning effect were checked by using eyeballing, magnifying glass, lustration test and STF cleaning inspection card test on the contaminated surgical instruments respectively. In the same time, to evaluate the cleaning results.

Results: There were 23 positive cases(23.0%) that examined by direct eyeballing, 25cases(25.0%) by magnifying glass, 31 cases(28.2%) by lustration test paper, 35 cases(31.8%) by STF cleaning inspection card test ,which all took place in 420 cases normal cleaning group; but in 420 cases muti-enzyme detergent group, 7 positive cases(7.0%) that examined by direct eyeballing, 8 cases(8.0%) by magnifying glass, 10 cases(9.1%) by lustration test paper, 14 cases(12.7%) by STF cleaning inspection card test. ($p<0.05$).

Conclusion: There are all certain to have some clinical value that the cleaning effect of medical apparatus and instrument were evaluated by using eyeballing, magnifying glass, lustration test and STF cleaning inspection card test. It is obvious to have a high sensitivity that the residual protein was checked by test, especially the clinical significance.

P_37

Implementation of a business continuity Plan: Sterile processing department case of a University Hospital

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Biography:
Dr Laffite Maeva

Introduction: Grouping and centralizing a French Sterile Processing departments (SPD) in large hospitals facilities make them vulnerable. In order to ensure continuity of care in case of a failure or damage, french regulation requires the implementation of Business Continuity Plan (BCP).

The aim of this work is to describe the implementation of a BCP in the SPD of our University Hospital Center (UHC) and to present the major points of consideration

Methods: First, the work consisted in mapping the risks. Risks were identified. For each step of the sterilization process, their criticality rankings were assessed and the means of control were identified and evaluated. Based on this risks analysis and their impacts, we defined how to ensure the business continuity management and set up staggered procedures.

Results: By mapping we identified and prioritized 124 potential risks. When they may cause a partial or complete interruption of the activity, risks have been analyzed. In order to ensure the continuity of key activities, the transfer of part of the medical devices (MD) and staff from the damaged hospital to a contracted rescue establishment was the strategy. The way this deportation was organized and the related quality documents were described and drafted, then evaluated using two real-life exercises carried out between our UHC and the rescue establishment. In this way, it was possible to adjust the defined organizations, and to highlight the critical points of this approach. Among them: the ability of the rescue establishment to absorb the activity of the damaged hospital, how to match schedules to its activities, the impact on the deadlines for providing MDs and therefore the surgical schedule of both establishments.

Conclusion: The drafting and implementation of the BCP allowed defining how to treat risks and to adopt the necessary measures to maintain key activities of our SPD. These are specific to each hospital, its activities and its environment. To us, these simulations highlighted the impossibility of relocating all our activity to the rescue establishment. This implies to define, at the institutional level, which are the essential surgical activities to be eligible for this deportation.

P_38

Analysis on the present situation of sensory evaluation of cleaning effect of soft instruments

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Biography:

Yiqin Zhou, female, born in August 1985, with a bachelor's degree, graduated from Chiang Mai University, Thailand, in March 2012. From July 2012 to February 2018, he served as the teaching team leader of the central sterile supply department of the First Affiliated Hospital of Kunming Medical University. From 2014 to 2016, she was awarded the title of "three educations" and undertook the teaching task of elective courses of Kunming Medical University. From April 2018 to now, she has worked in the central sterile supply department of Fuwai Cardiovascular Hospital, Yunnan Province. From 2016 to 2018, the first author published many papers; participated in the compilation of three monographs as the editorial committee; won one utility model patent and participated in three utility model patents; two papers were exchanged as wall newspapers by the 14th and 15th National Development Forum of Sterilization and Supply Center held by the Chinese Nursing Society.

Objective: To analyze the soft instruments in medical fabrics used in hospitals, which mainly refer to surgical clothing, surgical cover sheet, surgical cave towel, which can block water, bacteria and air, wearable and foldable facial materials with two-way protective function, through cleaning quality of soft instruments. Sensory evaluation finds problems, improves cognition, and controls the safety and effectiveness of its cleaning and disinfection effect.

Methods The quality control teams of 10 central sterile supply department in hospitals were selected to investigate the sensory evaluation status of cleaning quality of soft instruments by issuing questionnaires, and the problems of cleaning quality were found.

Results: The survey results showed that 10 hospitals, 6 of which entrusted third-party washing institutions, 4 hospitals washed themselves in the hospital, there was no significant difference between the two ($P > 0.05$). In 10 hospitals, 6 hospitals that could accurately grasp the sensory quality evaluation criteria of soft ware cleaning were used as research group, and 4 pairs of criteria. The quality of sensory cleaning of soft instruments in the study group was higher than that in the control group, and the difference was statistically significant ($P < 0.05$).

Conclusion: In the process of quality control of cleaning soft instruments, hospitals should raise awareness, strengthen supervision and management, prevent and control nosocomial infection, and ensure patient safety.

P_39

Automation of different computer queries within French Institute of sterilization

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Biography:
French Pharmacist, work on Amiens Sterilization

Aim: Traceability in sterilization is an essential element allowing to have all the information of the process at any time. The collected data is of significant size and its analyzes is time-consuming. The use of an automatic query and distribution tool makes it possible to target the information sought, to save time and to transmit the information efficiently.

Methods: In order to carry out this type of operation, it is necessary to have a traceability software (Ecosoft® edited by MMM), an automatic query software, and a computer scientist mastering the database and its functioning.
A working group has been set up with computer scientists and pharmacists in order to target the information sought, to formulate queries and to test the results.

Several queries have been put in place with automatic mailing to the various actors involved:
- Daily query indicating the list of non-sterile reusable medical devices at 6:00 am, sent to the chiefs of operating blocks and pharmacists.
- Daily query indicating the list of missing or «to be checked» instruments by package at 8:00 am, sent to the chiefs of operating blocks, to operating room nurses and pharmacists.
- Daily query indicating machine defects at Day - 1 sent to pharmacists.
- Daily query indicating the production status at 5:00 pm and 7:00 pm sent to pharmacists.
- Monthly billing indicating the invoices for external hospitals sent to pharmacists and financial services.

Results: This tool has made it possible to optimize our methods of work and communication. The operating blocks have thus the necessary information on the equipment before the first operation. Decision-making is thus faster, helping to reduce organizational stress and to improve the quality of life at work.
It also allowed us to have a global view of our activity and to improve our action plans. In the span of 3 years, we decreased the number of adverse events reports by 3 and the number of missing instruments by 3.
This system will allow us, in the long term, to adapt and prioritize the management of certain packages according to the time of day and the expected volume to be sterilized.

Conclusion: The implementation of this system has had a very positive result on our hospital because communication is an essential element between the sterilization unit and the operating blocs. Likewise, the automation of this system made it possible to anticipate and solve faster the problems related to our activity.

P_40

Establishment of a global policy to reduce missing instruments in a French hospital centre

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Biography:
I'm a French Intern Pharmacy, who work on Amiens Sterilization

Aim: The impact of missing instruments in sterilization packages has long been underestimated. The cost represents 1% of the annual hospital sterilization budget1. This may cause the cancellation or reprogramming of some operations.
It is essential for our unit to make this circuit as secure as possible and to implement corrective measures to improve upon the situation.

Methods: The data presented here comes from a big-data query of the Ecosoft© (MMM) software. They were filled by the sterilization technicians during the packaging process. they control the status of each instrument with a computerized listing: validating the conformity or non-conformity of the instruments with justifications (broken, missing etc.).
We compared the percentage of missing instruments (relative to the computerized listing) from January 2018 to July 2019.
Noting that the sterilization packages that did not have a computerized listing or were loaned by a pharmaceutical company, were not taken into account into this study.

Results: The policy of reducing the missing instruments started in January 2018. A technician was in charge of the computerization of the listings. On April, the management employee of the orthopedic block joined-in to help the technician during the packaging stage. Considering the fact that the orthopedic sector represents around 40% of the sterilization activity and have the highest missing instruments rate (7%). Later this year, the second orthopedic management employee trained the technicians with the packaging of instruments of the department.

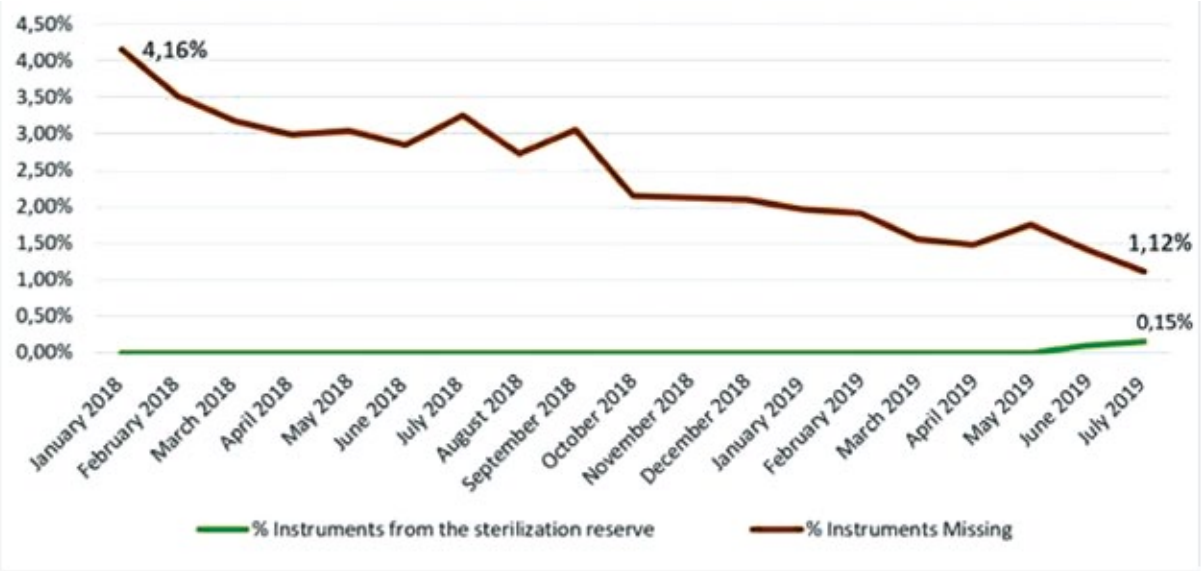
A reserve in a clean zone with the main missing instruments was also created (determined via computer requests). Finally, we reduced the overall number of instrument references by 15%.
Moreover, a non-conformity function: «Instruments from the sterilization reserve», was added to the Ecosoft software to highlight the work of technicians.

Thanks to all these measures, the number of missing instruments decreased by 371% in the space of 19 months satisfying the operating blocks (cf Graph).

Conclusion: Management of the missing instruments of the operating packages is a crucial issue from an economical and human standpoint, ensuring an optimal quality for the patients. Our example is applicable in other institutions. Knowing that we reached the average of missing instruments of other international establishments[1].
This cooperation with the management employees of operations blocks, the optimal use of computer tools and the good training of sterilization technicians are key.

1 : Daumas C. « Instruments de base manquants dans les boites: une réalité dure à digérer »

Graph representing the percentage of instrument missing according to the different actions implemented



P_41

Discussion on cleaning methods of ophthalmic instruments contaminated by adhesives

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Biography:
Li Juguo, nurse, quality control officer of central sterile supply department of the second affiliated Hospital of Kunming Medical University, has been engaged in disinfection supply specialty for more than 8 years. She is familiar with all kinds of surgical instruments and is good at the disposal of precision and complex instruments and the quality control of disinfection supply specialty. She has edited 3 monographs and 2 patents for invention of utility models.

Purpose: Discussing the cleaning methods and effects of ophthalmic instruments contaminated by adhesives.

Method: Divide the ophthalmic instruments contaminated by adhesives into two groups, and the contrasted group is cleaned with ultrasonic cleaner and fully automatic cleaning disinfector. The experimental group adds 3% hydrogen peroxide solution cleaning on the basis of the control group. Test method, use the protein residue cleaning test rod to test the cleaning quality of two groups of instruments.

Result: The qualified rates of cleaning in the experimental group and the contrasted group are 95% and 75% respectively. The cleaning qualified rate of experimental group is obviously higher than the contrasted group, and the difference has statistics significance ($P < 0.01$).

Conclusion: The cleaning quality of ophthalmic instruments contaminated by adhesives cleaned with 3% hydrogen peroxide solution is obviously improved contrasted with the non-users.

P_42

Competence investigation on insulation testing on electrosurgical instruments and needs analysis of training for CSSD stuff

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Biography:
Wang Xu, Deputy Director Nursing teacher, member of the 27th Disinfection supply Nursing Professional Committee of the Chinese Nursing Society; standing Committee member of the Hospital Disinfection and Sterilization Branch of the Disinfection and infection Control Committee of the China Health Supervision Association; member of the Logistics Management washing Disinfection Section of the China Hospital Association; editorial Committee of the Journal of Integrated traditional Chinese and Western Medicine Nursing (Chinese and English); expert of the Disinfection supply Project Group of the Western Nursing Union; Director of Yunnan nursing society and vice chairman of disinfection supply management committee of hospital association; published more than 20 papers, published five monographs as the first editor-in-chief, participated in two guides and obtained two patents for utility models.

Aim: This paper is to investigate the competence of insulation testing on electrosurgical instruments, to analyse the needs of training, and also to strengthen the effectiveness of monitoring the insulation testing of electrosurgical instruments for CSSD stuff, providing a reference for the nursing safety training.

Method: Take 180 CSSD stuff from 36 hospitals as the research objects and utilize "self-assessment form of the competence on insulation testing on electrosurgical instruments and the needs of training" to conduct the investigation.

Results: The self-assessment score of competence on insulation testing on electrosurgical instruments from CSSD stuff is (3.10±0.42), including four latitudes which are Attitude, System, Cognition and Skills with each of the latitude score (3.31±0.55, 2.80±0.63, 2.74±0.68, 3.03±0.36) respectively. Based on the survey of training needs for CSSD stuff, the top 3 ranked training needs are trace management record of insulation testing on electrosurgical instruments (93.89%), disposal procedures for insulation damage of electrosurgical instruments (92.78%) and adverse events caused by leakage of electrosurgical instruments (80.55%).

Conclusion: The competence of insulation testing for CSSD stuff is at a low level by overall. The competence could be improved by analysing the needs of training, establishing systematic training system and taking effective training action, ensuring the safety of patients and medical personnel.

Key words: electrosurgical instruments, insulation testing, competence, influence factor

P_43

Comparative study of ATP fluorescence test and protein residue test for cleaning monitoring effect

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Biography:
He Jianhua, He has been engaged in disinfection supply major for more than 9 years, familiar with the regional layout of disinfection supply centre, operating procedures, special equipment operation and common high and low temperature sterilization failure analysis, regional teaching work, as sterilization and packaging area leader. 3 monographs, 2 patents for invention and utility model.

Objective: To explore the cleaning monitoring methods which are currently widely used, we compare ATP fluorescence test and protein residue test to find which method is more accurate for monitoring of cleaning quality.

Methods: A mixture of Escherichia coli and serum was uniformly lay out on 150 vascular forceps for 8 hours. After the soils on the surface of the instruments were completely dried, the instruments were then cleaned and disinfected by the same way. After that, the cleaning quality of these instruments will be inspected by ATP fluorescence test and protein residue test respectively.

Results: Using ATP fluorescence test, the number of qualified instruments was 139, while the number of unqualified instruments was 11, and the pass rate was 93%. Using protein residue test, the number of qualified instruments was 124, while the number of unqualified instruments was 26, and the pass rate was 83%. There was a statistically significant difference between the two methods ($X2=6.04$, $P<0.05$).

Conclusion: After experimental comparison and biological culture verification, it was found that both of the two test methods can be used for routine cleaning quality testing. Each of the two methods cannot contain the other one, and it is best to use the two methods together.

Key words: ATP fluorescence test; protein residue test; cleaning effect monitoring

P_44

Three cleaning methods on medical cleaning brushes: A comparison of their decontamination effect

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Biography:
As a research member, I have participated in the application of National Natural Science Foundation Project and Scientific Research Project of Henan Province for many times. Up to now, I have five years of clinical work experience, and I am passionate about disinfection supply.

Objective: To explore the decontamination effect of different cleaning methods on medical cleaning brushes, and to provide reference for the terminal cieaning of cleaning tools in the Central Sterile Supply Department.

Methods: Three groups (with 30 in each group) were established according to the different methods of cleaning: conventional cleaning, standard cleaning and standard cleaning plus ultrasonic cleaning. After washing, the RLU values were determined by the ATP bioluminescence method, and the SPSS 22.0 software was used to analyse the variance among these methods.

Results: There was a huge difference between the conventional cleaning group and the other groups($p<0.05$).The difference between the standard cleaning group and the standard cleaning plus ultrasonic cleaning group was statistically significant ($p<0.05$). The change before and after the standard cleaning plus ultrasonic cleaning group was the largest, 1207.03 ± 473.23, compared with the conventional cleaning group, the difference was statistically significant ($p<0.05$).

Conclusion: Standard cleaning and ultrasonic cleaning with auxiliary cleaning have a good cleaning effect on medical cleaning brushes. The standard cleaning plus ultrasonic cleaning was obviously better than the conventional cleaning.

P_45

Survey and analysis of the status of performance testing of pressure steam sterilizers

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Biography:
Chen Li, nurse, engaged in disinfection supply professional work for 7 years, responsible for disinfection supply centre quality inspection and management for five years, is currently the quality inspection department of Yunnan Ziqing Medical supplies Service Co., Ltd., and is fully responsible for the quality management of medical fabric washing and disinfection. With the first author published 4 professional papers, participated in 3 monographs, participated in the invention of a utility model patent.

Objective: To understand the current status of temperature, pressure and time parameters of pressure steam sterilizer monitored by temperature and pressure detector, and to provide basis for further standardization of physical performance testing of pressure steam sterilizer.

Method: The physical performance of the pressure steam sterilizer was tested by temperature and pressure detector in the joint measurement and testing technology department, and the results were analysed.

Result: 42 sterilizers in 14 medical institutions were tested with small load and full load respectively. Among them, the qualified rate of small load was only 11.90%, the qualified rate of full load was 42.86%, and the cumulative qualified rate was only 27.38%.

Conclusion: The qualified rate of physical performance test results of pressure steam sterilizer is low, the sterilization quality cannot be effectively guaranteed, and there are great potential safety hazards. Medical institutions at all levels should pay attention to the physical performance testing of pressure steam sterilizers, find out potential safety hazards in time, and provide safety guarantee for the effective supply of sterile articles in hospitals.

P_46

A new proposal of identification system for surgical instruments using 920MHz passive RFID tag

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Biography:
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2010, Professor, Department of Human Environment, Shonan Institute of Technology
1993, Associate Professor, Department of Information Engineering, Shonan Institute of Technology
1986, Assistant, Department of Radiology, National Defense Medical College
1984, Assistant, Tokyo Denki University

Surgical instruments should be identified in before and after of operation to reduce the vestigial remnant and to manage their history of usage. In the present, two-dimensional symbol system is being used. In this method, hand-operation is necessary. Hand-operation gives rise to the human error. Automatic identification system for surgical instrument is hoped to eliminate the error. Wireless identification is useful, since the hand-operation is unnecessary. HF band RFID system is proposed for surgical instruments identification. This system cannot identify the large number of surgical instruments in bulk, since its identification area is small in principle.

In this study, new compact UHF band passive RFID tag is proposed to identify the surgical instruments. The tag is sized 5.5mm×2mm×2mm in typical. Its weight is less than 0.01g. It is light enough to mount on the surgical instruments. Heat resistant of the new tag is over 150°C. The tag can be applied for operation for BSE patient, since the new tag can be adapted to high temperature sterilization.
New low-intensity antennae are proposed in the system. The antennae named RECOPIC are set in identification box. RECOPIC is developed by TEIJIN LIMITED. The box is 550mm×360mm×80mm in size. The antennae cannot radiate an electrical field strong enough to interfere with medical equipment in principle. Two antennae are set to inside of ceiling. Another two are set to bottom. Vertical interval is set to 35mm. Horizontal intervals of two antennae on the ceiling and the bottom are set to 10mm. Maximum reader power is set to 1W (upper limit in Japanese law). Electrical field intensity level is evaluated as preparatory experiment to ensure electric safety. Measurement points are set 10mm and 100mm from top of the box. The electric field intensity is managed within safety level using these antennae.

In the post-op identification, the instruments can be put on the metal mesh tray in bulk. The tray is 390mm×300mm×15mm in size. Maximum amount of instruments is designed 50. The 50 instruments put on the metal mesh tray in bulk. New compact UHF band passive tag is attached on each instrument. The tray set on to the centre of the low-intensity antennae. The instruments were identified in 10 times. Output power of the RFID reader is set to 1W. Amount of identified tag and required time length were measured in each trial. In the experimental results, 50 instruments are identified perfectly. All instruments are identified in all trials in around 2 seconds. It is enough to reduce the work load of surgical nurse for management of the surgical instruments.
Proposed new UHF band tags could be identified on metal mesh tray. The price of the new UHF band passive compact RFID tag in the study is approx. 0.1€. The measured electrical field intensity outside of identification box is kept safety level for medical scene. It is described that the proposed UHF band passive RFID system is useful for identification of surgical instruments in the operating room.

P_47

Design and application of new tube instrument cleaning brush

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Objective: To design and manufacture a new type of luminal instrument cleaning brush and to explore its cleaning effect.

Methods: A total of 400 luminal instruments were selected from the operating room from May 1, 2018 to June 30, 2018. They were randomly divided into experimental group and control group, with 200 pieces in each group. When the control group was manually cleaned, the enzyme solution was soaked and washed with a traditional brush. After the enzyme solution was soaked in the experimental group, a new type of tube instrument cleaning brush was used for washing. Both groups used a 5x magnifying glass test, a white gauze test and adenine nucleoside triphosphate bioluminescence assay compares the cleaning quality of the two sets of instruments and records the brushing time of the instrument.

Results: The quality of washing in the experimental group was higher than that in the control group. The difference was statistically significant ($p<0.001$); the brushing time of the experimental group was (2.57±0.36) min, which was shorter than that of the control group (5.55±0.73) min. The difference was statistically significant ($t = 16.27$, $p < 0.001$).

Conclusion: The new tube instrument cleaning brush is easy to use and cleans the inside of the lumen more effectively, which effectively improves the cleaning quality of the lumen device, saves the brushing time and improves the working efficiency.

P_48

Effect of different loading methods on adsorption of hydrogen peroxide concentration and injection pressure during packaging materials

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Objective: To investigate the effects of different loading methods on the adsorption concentration of hydrogen peroxide and the pressure during sterilization injection during low temperature plasma sterilization.

Methods: Sixty-five 45*10*5cm3 empty silicone instrument boxes recommended by Johnson & Johnson were selected. Three were made of 100cm2 non-woven double-layer packaging; three were made of Tyvek 60*20cm2 paper-plastic bag single-layer packaging. The three packages to be sterilized in the non-woven package were placed on the upper shelf of the sterilizer, and the special Guard was placed on the lower shelf, which was set as the control group; the experimental group was reversed. The load is 70%, and each is 20 pots. Immediately after the sterilization, the aseptic bag was used to adsorb the concentration of hydrogen peroxide, and the pressure of each pan was recorded according to the physical printing paper.

Results: The adsorption concentrations of the sterile bag of hydrogen peroxide in the control group were 13.745±3.754 and 8.065±4.599, respectively. The hydrogen peroxide adsorption concentrations of the two materials in the experimental group were 11.120±4.187 and 8.205±4.181, respectively. The differences between the groups were statistically significant ($P < 0.05$). The adsorption of non-woven fabrics in the control group and the experimental group was found to be 13.745±3.754, and the adsorption of non-woven fabrics in the experimental group was observed. The concentration was 11.120±4.187, and the difference was statistically significant. The pressure (torr) of the control group was 9.121±0.243, and the pressure of the experimental group was 9.410±0.188. The difference was statistically significant ($P < 0.05$).

Conclusion: Tyvek material packaging has less adsorption to hydrogen peroxide and is more suitable for low-temperature plasma sterilization of hydrogen peroxide. In the mixed loading, the sterile package of Tyvek packaging is placed on the upper layer, and the sterile package of non-woven packaging. Placed on the lower layer, the sterilization is smoother and the sterilization quality is more guaranteed.

P_49

Validation of automated cleaning of robotic tweezers in barrier washer-disinfector

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Biography:
- *Coordinator of the Santa Catarina Hospital Material CSSD,*
- *Specialist Material and Sterilization Centre - CSSD*
- *Specialization in Processing Level I Sterilized Products by DGSV (German Sterilization Society) and IAHCSMM (International Association of Central Health Service Management Material)*
- *Member of SCIH and CPPS Committee*

Objective: To validate the automated tweezers cleaning process for robotic surgery in a barrier washer-disinfector.

Method: Experience report conducted in a CSSD (Central Sterile Services Department) of a large private hospital located in the city of São Paulo, Brazil. In this experience report, eight decontaminated, semi-reusable robotic tweezers used for up to 10 times for the Da Vinci Xi® (Intuitive Surgical Inc., Sunnyvale, CA, USA) Surgical System were used, being 2 large needle driver, 1 monopolar curved scissors, 2 prograsper forceps, 1 maryland bipolar forceps, 1 fenestrated bipolar forceps and 1 cardiere forceps, the tweezers were impregnated with Washer Disinfector Test Soil, rack-mounted in a barrier washer-disinfector, 12 temperature sensors were placed on the washer chamber along with the tweezers, subjected to the washer-disinfector programs with the following phases: prewash with enzymatic detergent, wash alkaline detergent, rinse, thermo disinfection at Temp. 90°C for 5 minutes, and rinse. To detect the effectiveness of the automated cleaning process, the surface adenosine triphosphate (ATP) test was used, where the post-cleaning recovery analysis, the approval of up to 50 relative light units (RLU) and visual inspection with 10x magnifying glass were parameterized.

Result: The ATP test was performed on all tweezers with results below of 20 RLU´s, and absence of dirt on the visual inspection with the 10X magnifying glass, where the service opted to validate in addition to manual cleaning, automated cleaning in barrier washer-disinfector, ensuring reproducibility, minimizing occupational risk, increasing evidenced process safety through cleaning test and subsequent visual assessment proving to be more effective and zero loss of robotic tweezers.

Conclusion: Robotic surgery is considered an evolution of minimally invasive laparoscopic surgery with numerous benefits for the patient, such as decreased pain, blood loss during the procedure, shorter hospital stay and postoperative discomfort. In another hand, there is the challenge of the used tweezers, since they are of complex conformations, with inaccessible internal spaces which cannot be disassembled for processing. For an effective and safer result, the recommendations of the manufacturer and supplier of the technology were analysed separately, where both did not propose relevant methodologies to evaluate the cleaning, this is due to the little evidence in the literature of the robotic forceps cleaning efficiency, even though it is still a focus for the surgical procedure, which enabled us to perform this study.

Keywords: Validation, Cleaning Process

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Vinci Xi® Instruments – Reprocessing Instructions EndoWrist®, Single-Site®, e Stapler

P_50

Value design of productive chain process on the CSSD – central sterile service department

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Biography:
- *Coordinator of the Santa Catarina Hospital Material CSSD,*
- *Specialist Material and Sterilization Centre - CSSD*
- *Specialization in Processing Level I Sterilized Products by DGSV (German Sterilization Society) and IAHCSMM (International Association of Central Health Service Management Material)*
- *Member of SCIH and CPPS Committee*

Objective: To implement the value flow map on the CSSD (Central Sterile Service Department) using Lean methodology.

Method: Descriptive study, performed at the CSSD (Central Sterile Service Department) of a large private hospital located in the city of São Paulo, Brazil, in which a Lean management tool was applied to survey problems (improvements that could be made). For the mapping of the current process and projection of a sustainable flow, to organize the process the value flow map was considered as a strategy to systematize the flow of: Receiving, cleaning, preparation, sterilization, storage and distribution. At each stage improvement opportunities were analyzed and implemented to build the future scenario of the production chain.

Result: The value chain flow was designed to strengthen the proposed objectives, in line with the addition of new practices to influence the change of the mindset in the dynamics of the operational process of the team working at the CSSD - Central Sterile Service Department, 30 new actions were implemented through the analysis of the value chain flow, where the expected results from the implementation of this methodology, made it possible to highlight major impacts of process and indicator improvements, in addition to reducing waste of consumables and time in the processes.

Conclusions: The use of the Lean methodology in the implementation of the value stream map made it possible to design a clear and visual process by making targeted efforts and adding value to the needs of customers supported by the CSSD (Central Sterile Service Department). Among the actions one of an important impact was implemented in the cleaning area, where the preparation of the baskets of instruments that would be exposed to cleaning was reevaluated minimizing rework due to the automated process being more effective avoiding return of the medical devices with organic matter to the cleaning area, in the preparation area the reorganization of Surgical boxes on shelves properly identified by specialty enabled the preparation of the material according to the surgical schedule, flowing and eliminating the causes of delay and quality problems, totaling the reduction of waste through a structured and agile process. Thus, avoiding large losses such as overproduction, reprocessing of materials, eliminating waste, improving operational flow and performing procedures that concern the continuity of care. The participation of the entire multidisciplinary team was one of the determining factors for process adherence and strengthening a highly reliable organizational culture.

Key words: productive chain, CSSD

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P_51

Microbiological analysis of hoses of washer-disinfectors used for processing gastrointestinal endoscopes in use in clinical practice

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Biography:
Graduated in Nursing from the Pontifical Catholic University of Goiás (1983), Master's degree in Nursing from the Federal University of Rio de Janeiro (1991) and PhD in Nursing from the University of São Paulo (2000). Currently, a Full Professor at the Faculty of Nursing of the Federal University of Goiás (FUG). Leader of the research group NEPIH (Center for Nursing Studies and Research in Prevention and Control of Healthcare Associated Infections), registered with CNPq. Supervisor in the Postgraduate Program in Nursing at the Faculty of Nursing at FUG and in the Postgraduate Program in Health Sciences at the Faculty of Medicine at FUG, master and doctorate levels. Experience in teaching, research and extension in the field of infection prevention and control, acting on the following subjects: Standard Precautions, biohazard for healthcare workers and biosafety measures, reusable medical devices processing, CNPq researcher, Member of the National Commission for the Prevention and Control of Healthcare Associated Infections - CNIRAS and member of the Commission for Infection Control of the Faculty of Dentistry of FUG, since its creation in 1998.

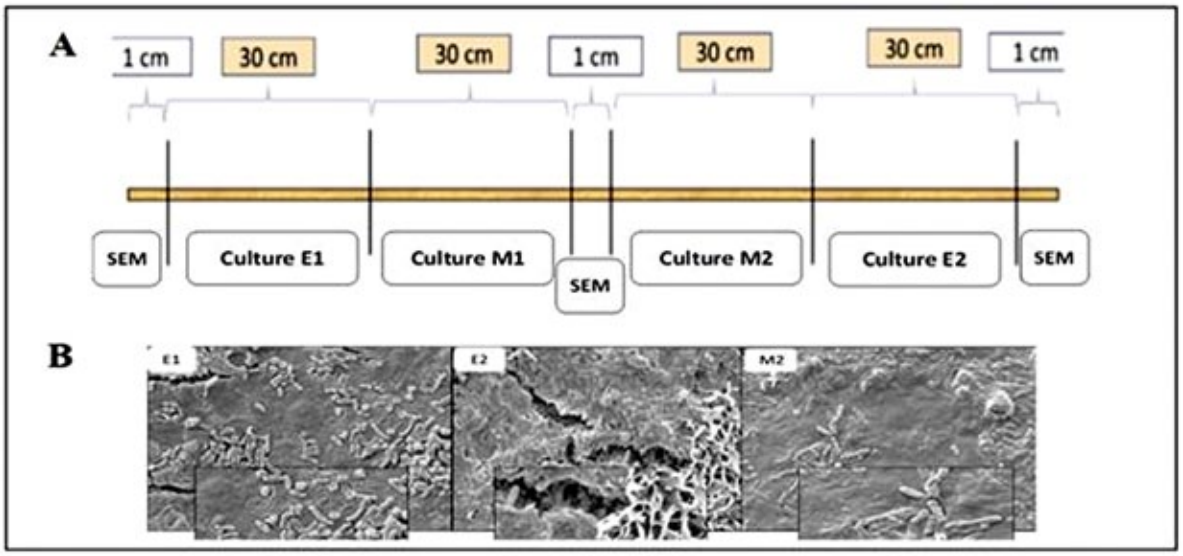
Aim: To evaluate the microbial load and the presence of biofilm in hoses of washer-disinfectors used for processing gastrointestinal endoscope in use in clinical practice.

Methods: Cross-sectional study conducted at an Endoscopy Center of a large public hospital in the Midwest region of Brazil. Flexible hoses made of translucent Polyvinyl chloride (PVC) with polyester braids, measuring approximately 1 cm x 130 cm (diameter x length), from two washer-disinfectors were collected (removed) following aseptic technique after one, three and 12 months in use, totaling six hoses. The collected hoses were replaced with new ones with the same specifications. Each hose collected was cut in seven fragments (Figure 1), using sterile scalpel blades, and subjected to analytical tests to determine the microbial load by culture and presence of biofilm by Scanning Electron Microscopy (SEM). SEM was performed on the fragments of the hoses in use for 12 months. For the microbial culture, tryptic soy broth (TSB) was inserted into hoses fragments of approximately 30 cm (E1, M1, M2 and E2) (Figure 1), which were sonicated for 10 minutes. TBS was filtered through a membrane (0.22µm), placed onto nutrient agar and incubated for up to 48 hours at 35°C. Following, Colony Forming Units (CFU) were counted and the bacteria colonies were classified according to Gram' stain. For SEM, fragments of 1 cm from the ends and the middle of the hoses (Figure 1) were fixed with 2.5% glutaraldehyde and dehydrated at increasing concentrations of ethanol.

Results: Bacterial growth was detected for all fragments of all the hoses evaluated (n = 12) and most of them were gram-negative rods. The bacterial load averages in hoses in use for one, three and 12 months were 54, 641 and 103 CFU, respectively. Bacterial load of 7/8 hose fragments evaluated after 12 months in use and 2/8 fragments of hoses evaluated after 3 months in use was >103 CFU. For the hoses in use for 1 month, the highest bacterial load was 137 CFU. Thick biofilms were detected in the hoses in use for 12 months (Figure 1).

Conclusion: High microbial load and presence of biofilm were detected in hoses of washer-disinfectors used for processing gastrointestinal endoscope in use in clinical practice, which may compromise the processing quality of these medical devices, mainly due to the risk of equipment (re) contamination during the final rinsing step, thus posing a risk to the patient safety.

Figure 1. Hoses cutting scheme (A) and Scanning Electron Microscopy (SEM) images, of hoses inner (B). Soil and biofilm composed of rod/bacillus (E1, E2, M2) and cocci (E2) shaped bacteria.



P_52

Application of RCA to reduce the risk of fiber optic bronchoscope reprocessing

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Dongmeili was born in China,i am a lead nurseworking inCSSD.
Lianglisheng was born in China,he is a doctor with carrying out pain diagnosis and treatment.

Background: The fiber optic bronchoscope has the characteristic of complicated structure, long and narrow lumen, special material, no high temperature resistance, more processing flow, and increased difficulty of cleaning and disinfection. In this study, root cause analysis was used to analyze the existing cases, and the true causes of unqualified cleaning and disinfection for fiber optic bronchoscope were summarized, and targeted circumvention measures were established to provide reference for peers in dealing with endoscopy.

Methods: The RCA group was set up to analyze five cases from positive microbiological culture of bronchoscopy (GB15982 qualification standard ≤ 20cful/piece) in 2018 in the disinfection supply center of Yantai Yuhuangding Hospital affiliated to Qingdao University. According to the 80 / 20 principle, The main causes of culture positive bronchoscopy in the 5 cases were as follows: the clinical users did not preprocess in place and did not recover the secretions in time, leading to the drying of secretions, the damages of bronchoscopes were not found due to the check before cleaning was unappropriate, the choice of cleaning brush was unaccurate; the cleaning tools were not cleaned and disinfected in time, resulting in secondary pollution, and so on. In view of the above reasons, the planned maintenance system of fiber optic bronchoscope was formulated, the weak parts in the reprocessing process of bronchial soft endoscope were perfected, the operation standards were refined, and the personnel training was strengthened.

Results: From January to June in 2019, 1793 high-level sterilized bronchoscopes were treated in the department, and there were no positive cases of microbial monitoring.

Conclusions: Base on the analysis of the positive cases of microbiological monitoring in fiber optic bronchoscope with high-level cleaning and disinfection, the defection in the cleaning and disinfection treatment to fiber optic bronchoscope were continuously improved, which greatly reduced the risk and rate of unqualified fiber optic bronchoscope reprocessing.

P_53

Inactivation of Endotoxins at low temperature condition utilizing innovative gas phase sterilization system

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Biography:
The author specialized in Gene & Cell Medical drug development, and organizing GMP compliant cell processing facility, and also have engaged as clinical specialist in internal medicine, Gastroenterology.

It is vital to address the continuing concern that endotoxins can have in the manufacturing and quality control of medical products and devices, dry-heat sterilization is generally the preferred method for rendering heat-stable materials free of endotoxin. But there are limitations to the effective approaches available to inactivate bacterial endotoxin, especially at low temperature. We have developed innovative technology as gas phase sterilization system based on a catalytic reaction mechanism by use of methanol to generate mixed biogas, exhibiting remarkable performance of nucleic acid decomposition as well as sterilization, and already reported it at the 18th World Sterilization Congress at Bonn. Here we will present recent findings of additional remarkable function of this system exhibiting inactivation of bacterial endotoxin at low temperature around room temperature. Standard endotoxin indicators 2,000 EU/vial (2K-ET) (Charles River Laboratores, CRL) were used for the experiments, and endotoxin concentrations were determined by Endosafe®-PTS™ instrument including disposable PTS™ cartridge FDA (0.05-5 EU/mL) (CRL). 2K-ET vial was directory exposed to mixed biogas in apparatus for 60 min at 37 or 60°C, and endotoxin concentrations were measured using 2K-ET samples dissolved in 1mL endotoxin-free water. After biogas exposure for 60 min., endotoxin concentration levels were remarkably reduced to 6~11 %, and its effect suggests temperature dependent; 83.3±4.7 EU/mL at 37°C (n=3), 46.0±0.85 EU/mL at 60°C (n=3), control sample (non-exposure): 725±23.5 EU/mL (n=3). Thus, this innovative gas phase sterilization system revealed to exhibit interesting performance of endotoxin inactivation at low temperature as 37°C Although this advantageous function is expected to be widely useful and have high potential in the public health and pharmaceutical industries in the future, it is still necessary to develop the reduction performance into 3-Log reduction.

P_54

Quality and risk management in Croatian CSSD

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Biography:
Snjezana Busancic, RN,BN,MN,QM living and working in Dubrovnik, Croatia. Supervisor in Dubrovnik General Hospital CSSD and lecturer on University of Dubrovnik Nursing Study. President of Croatian Nursing Council of Dubrovnik-Neretva Country, member of Croatian Nursing Council Committee and Dubrovnik General Hospital Quality Committee. Active participant in many professional training. Organiser and manager of many nursing professional training in Dubrovnik-Neretva Country. Published: Malignant disease of prostate node, Communication skills with children and adolescents, Physiological factors that determinate efficiency of study.

Aim: Central Sterile Supply Department (CSSD) plays a key role in providing the items required to deliver quality patient care. The main task of CSSD is to provide an equally quality and safe medical devices. CSSD Quality Management (QM) ensure quality levels for the product and service they produce as well as that these levels are consistently attained. So it was important to as to determine is there establish QM in CSSD in Croatia.

Methods: A research was conducted in a several CSSD in Croatia in July 2019. For research purposes was created an original questionnaire. Respondents were CSSD staff, various degree of education. The data were processed by IBM SPSS Statistics for Windows ver.20.0. and descriptive described in absolute and relative frequencies.

Results: Cleaning and disinfection are 44,44% carried out in accordance with the written recommendation CSSD supervisor, 38,89% according Standard Operating Procedure (SOP) and per 8,33% by oral instruction or the way staff consider the best. Sterilization process in 41,67% is done according written recommendation CSSD supervisor, 38,89% according SOP, 13,89% by oral instruction and 2,87% the best considered way of CSSD staff. Storage of sterile device is 47,22% carried out in accordance with the written recommendation CSSD supervisor, 30,56% according SOP, 16,67% according oral instruction and 5,56% by way they considered the best.
Medical devices are reprocessing in 44,40% by users oral instruction and equipment maintenance is done only in case of failure in more than 42,00%.

Conclusions: In order to produce quality and safe medical devices in Croatian CSSD it is very important to establish appropriate QM. QM will ensure quality levels for product as well as these levels are consistently attained. Considering of conducted research in just some of Croatian CSSD for relevant data it is necessary to take research in all Croatian CSSD.

Keywords: Quality Management, Standard Operating Procedure, Central Sterile Supply Department, Sterilization

P_55

Improved cleaning with enzymes

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Biography:
John W. Howell received a Bachelor of Science degree in biology from the University of Nebraska in 1997. Shortly thereafter, he began his career in industry by joining Sybron Biochemicals (Salem, VA) which was acquired by Novozymes A/S (based in Copenhagen, Denmark) and rebranded as Novozymes Biological Inc. which manufactured a variety of microbial solutions for cleaning applications. John started in the R&D group developing microbial-based detergents and investigating numerous supportive technology platforms including Bacillus spp. mediated inhibition of bacteria and fungi.

In 2013 he joined Novozymes enzyme-based business where he is the technical lead in developing and transforming the market for enzymatic based medical device reprocessing detergents. He and his team at Novozymes work to educate the industry on sustainable biotechnology and how enzyme technology can have a positive impact and improve cleaning outcomes.

This study aimed to compare the efficacy of different detergent formulations in cleaning various medical instruments. Surgical blades containing dry clinical soils were soaked in different detergent solutions for 10 minutes, and then rinsed with water. Pictures and fluorescent images of the blades were taken before and after cleaning. Under visual analysis, an optimized enzymatic detergent outperformed a non-enzymatic and a standard enzymatic detergent, leaving no visual residue in the blades tested. Subsequent fluorescent analysis confirmed this outcome. The optimized enzymatic detergent leaves no fluorescent residue after washing, while some fluorescence can still be observed in the blades washed with a standard enzymatic detergent. This optimized formula was obtained by the utilization of next generation enzymes and increased dosage compared to the standard enzymatic detergent. In conclusion, optimized enzymatic detergents can be obtained by utilizing the right enzyme, at the proper dosage and cleaning parameters. The resulting formulas can provide improvement over "industry standard" cleaning guidelines which can improve rewash rates, decrease waste and costs to hospitals, and improve patient outcomes.

P_56

Acquisition of integrated system for centralized processing equipment for medical device

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Biography:
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Coordinator of the Medical Device Processing Committee of the FMUSP Clinical Board,
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Member of World Forum Hospital Sterile Supply Executive Committee - WFHSS - Management 2014/2019
Member of the Global Relationship Committee of the Association PeriOperative Register Nurse - AORN - 2018/2019 Management.

Introduction: The Central Sterile Supply Department (CSSD) is the area of the hospital responsible for processing medical devices (MD) and has a specific physical plant with unidirectional flow and physical barriers to ensure quality control MD processing steps in all areas.
The Ministry of Health, through resolution RDC 15/2012, established the requirements of good practices for the processing of MD, and for the operation of services that perform centralized MD processing, aiming at the safety of the patient and the professionals involved.

Objective: To acquire the integrated system of equipment for centralized processing of medical devices.

Method: This is a descriptive research on the type of experience report of the actions taken to acquire an integrated system of centralized MD processing equipment from a large, specialized and public hospital located in the city of São Paulo.
The new CSSD project was designed to incorporate high technology into the MD cleaning, disinfection, sterilization, storage and distribution processes, with modern physical facilities, based on current scientific recommendations and legislation.
Consideration must also be given to maintaining the sustainability of the area and the safety of work processes, use of reverse osmosis deionized water in all processes, centralization and automation of the chemical disinfection process of endoscopes and echocardiography probes, control and monitoring. peer-to-peer traceability at all processing steps.
The integrated system of equipment for centralized MD processing, in which all equipment is of automated discharge barriers consisting of: 03 automated endoscope reprocessors; 04 thermo disinfectants, 01 car wash; 03 cannulated ultrasonic washers; 03 tracheal dryers; 06 thermal sealers; 05 pressure saturated steam autoclaves. Also it includes the process traceability system, solutions dilution system and reverse osmosis water treatment system.

Results and Discussion: The acquisition of 100% of all items of the integrated system of equipment for centralized MS processing was carried out by means of the international trading mode held in

October / 2018. It consists of a specific equipment system for rational, centralized and integrated execution of all stages of MS processing.

Conclusion: All equipment of this system are compatible with each other and have full integration with the computer system network of the Hospital.
The wide range and quantity of components that have been purchased from the same brand will facilitate general use and reduce maintenance costs for the entire system.

hospital management, sterilization

P_57

Comparison of the shelf life sterility of medical instrument sets and storage between central supply

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10 April 1987 Bachelor of Nursing Scienc, Chulalongkhon University
29 August 2008 Master Of Business Administration, Dhurakij Bundit University
AWARDS: APSIC CSSD Center Of Excellence Program (2013-2014) Gold Award
CSSA position: President of Central Sterilizing Services Association(Thailand)

Problems and Causes: The procedures in the past found that during transportation expensive lens get damaged. The broken packages are found after delivery. The equipment is not able to be used. Sometimes, the equipment is delivered to wrong receivers in wrong department. Allergy Center also uses this kind of tool. According to the tool cleaning processes, sometimes, there is water stain or dirty sport on the equipment. This equipment cannot be used efficiency. The department who get this equipment cannot use them to the patients or they are not satisfied with the equipment quality. Sometimes, they get damaged. The department needs to spend more cost and time to procure and maintenance the new equipment instead of the old ones.
Development Activities: to improve for the most efficiency working procedures in the department for the user impression, clean equipment usage following KAIZEN principal. KAIZEN is to change working procure to the better one by following reducing, stop, and changing with clear indicators.

Target: To reduce the number of damaged equipment and unclean equipment, or receiving uncompleted equipment after hand over and delivery to Central Sterile Supply Department
6. Indicators: Target:
1. The numbers of equipment which are not clean and not ready to be used. ≤ 3 topics/ month
2. The numbers of returned equipment and instrument are not complete or not correct. And the equipment are not ready to be used. ≤3 topics/ month
3. The numbers of equipment that damaged and lost after delivery to Sterile Medical Supplies Department. ≤3 topics/ month

Action:
1. Preparation of lens container to prevent equipment on delivery from damage.
2. Stickers usage as a sign to equipment segmentation between, ear nose and throat center, allergy center and other department, this is to prevent wrong equipment delivery
3. Meeting session between ENT Center and Central Sterile Supply Department every two months to make working plan, problem solving discussion, and setting team to taking care of equipment usage.
4. Officers training to additional skills and focus on problem solving and document preparation about equipment checking and to use equipment carefully and also to increase working productivity.

Result Measurement:
1. Summary of performance (first period)
During November 2017-September 2019, result measurement process can be conducted by incident report in hospital and response from other departments. The result was found in the good direction. The working procedure is controlled and efficiency. The number of damaged equipment is decreased. The users are impressed and use the equipment without problems between departments.

Project Summary: There is preparation of lens container to prevent any damages from instrument transportation and to improve working procedure. This is to make it easier to control, follow up, and inspection and follow up report about damaged equipment. Also, it is about the development of work training to department officers to gain more working skills and efficiency.

The value of inspecting means to develop efficiency of working procedure for service person and user get instrument safety

P_58

The value of inspecting Ear Nose, and Throat (ENT)

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[1]*Central Sterilizing Services Association Of Thailand, Thailand*

Biography:
Nanthipha, Pattaraporn, Nalinee, Saharat and CSSD team of CSSD Sirirajpiyamaharajakarun hospital, Thailand

Problems and Causes: The procedures in the past found that during transportation expensive lens get damaged. The broken packages are found after delivery. The equipment is not able to be used. Sometimes, the equipment is delivered to wrong receivers in wrong department. Allergy Center also uses this kind of tool. According to the tool cleaning processes, sometimes, there is water stain or dirty sport on the equipment. This equipment cannot be used efficiency. The department who get this equipment cannot use them to the patients or they are not satisfied with the equipment quality. Sometimes, they get damaged. The department needs to spend more cost and time to procure and maintenance the new equipment instead of the old ones.

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Target: To reduce the number of damaged equipment and unclean equipment, or receiving uncompleted equipment after hand over and delivery to Central Sterile Supply Department Indicators
1. The numbers of equipment which are not clean and not ready to be used≤ 3 topics/ month
2. The numbers of returned equipment and instrument are not complete or not correct. And the equipment are not ready to be used≤3 topics/ month
3. The numbers of equipment that damaged and lost after delivery to Sterile Medical Supplies Department. ≤3 topics/ month

Action:
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P_59

New technologies for improving hygiene control of borrowed instruments

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Head of AMTA Sanatorium Sterilization.
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Postgraduate Professor of Buco Maxilo Facial Surgery of the Dentistry degree at Maimonides University, Argentine.
Associate Professor: Sterilization and Biosafety chair. Specialization Career of Hospital Pharmacy of the ISALUD University. Argentine.
Director and teacher in sterilization courses at the College of Pharmacists and Biochemists of the Federal Capital. Argentine
Author of the Book: "Strategic Sterilization", several articles and posters.

Objective: The main objective of this work was to assess the cleanliness of the Hospital's borrowed surgical instruments at the time of their return and to decrease the number of scheduled surgeries that are canceled due to their dirtiness, by using new technologies for hygiene control.
When the borrowed material does not pass the cleanliness control, a non-conformity is recorded in the traceability system. If the instruments have to be washed at the hospital to avoid the cancellation of a surgery, the Institution concerned is penalized.

Methods: During 6 months of sampling, each container received, as well as one instrument inside it, were visually examined using a magnifying glass and a gauze with alcohol. The material that did not present visible dirtiness was analyzed through a surface protein quantification method, by using Chemdye PRO1 MICRO system, along with Bionova MINIPRO auto-reader incubator. The system was validated using PRO1VT (Terragene, Argentina). The swabbing method and the acceptance limit (5 µg- instrument side) were taken from HTM 01-01 recommendations. The results were traced through Bionova traceability software. A Dirtiness Rate (DR) was generated in order to perform a temporary statistical monitoring (dirt material/received material * 100).

Results: During the analyzed period, a total amount of 3348 containers were received. 219 were rejected (6.5%) due to visible dirt remains (N= 10; 22%) or to protein remains (N= 209; 78%). The temporary data analysis revealed that the DR was reduced by 50% (from 9.32% to 4.62%), despite the amount of received material was doubled.
This lead to maintain the net quantity of instruments' cleaning processes at the Hospital, demonstrating the usefulness of adding new technologies to hygiene monitoring and the imposition of penalizations.
As a reference, one of the Institutions reduced its Dirtiness Rate from 26.47% to 0%. The surface protein detection and quantification system allowed the detection of instruments with non-visible dirt, and also to have traceability over institutions responsible for their cleaning.

Conclusions: The application of hygiene controls and their qualitative and quantitative results generated processes improvements in the Sterilization Central, leading to a radical reduction in the cleaning processes within it. Although there are still some rejected receptions for some institutions, many of them are from new suppliers of the Hospital, and therefore a permanent cleaning control of the borrowed containers is required. Having a surface protein detection system made it possible to ensure the correct cleanliness of the instruments, not a minor issue when it comes to sterilization. The incorporation of a traceability system allowed the assessment of every Institution and the establishment of a work methodology by documenting all different episodes arising daily.

P_60

A risk-based approach for validation of reprocessing instructions for medical devices

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02/2015: Strategy and sales at Valitech
08/2013: Aviation consultant at ALG S.A. / Indra Business Consulting
11/2011: Consultant, Analyst at Arthur D. Little GmbH
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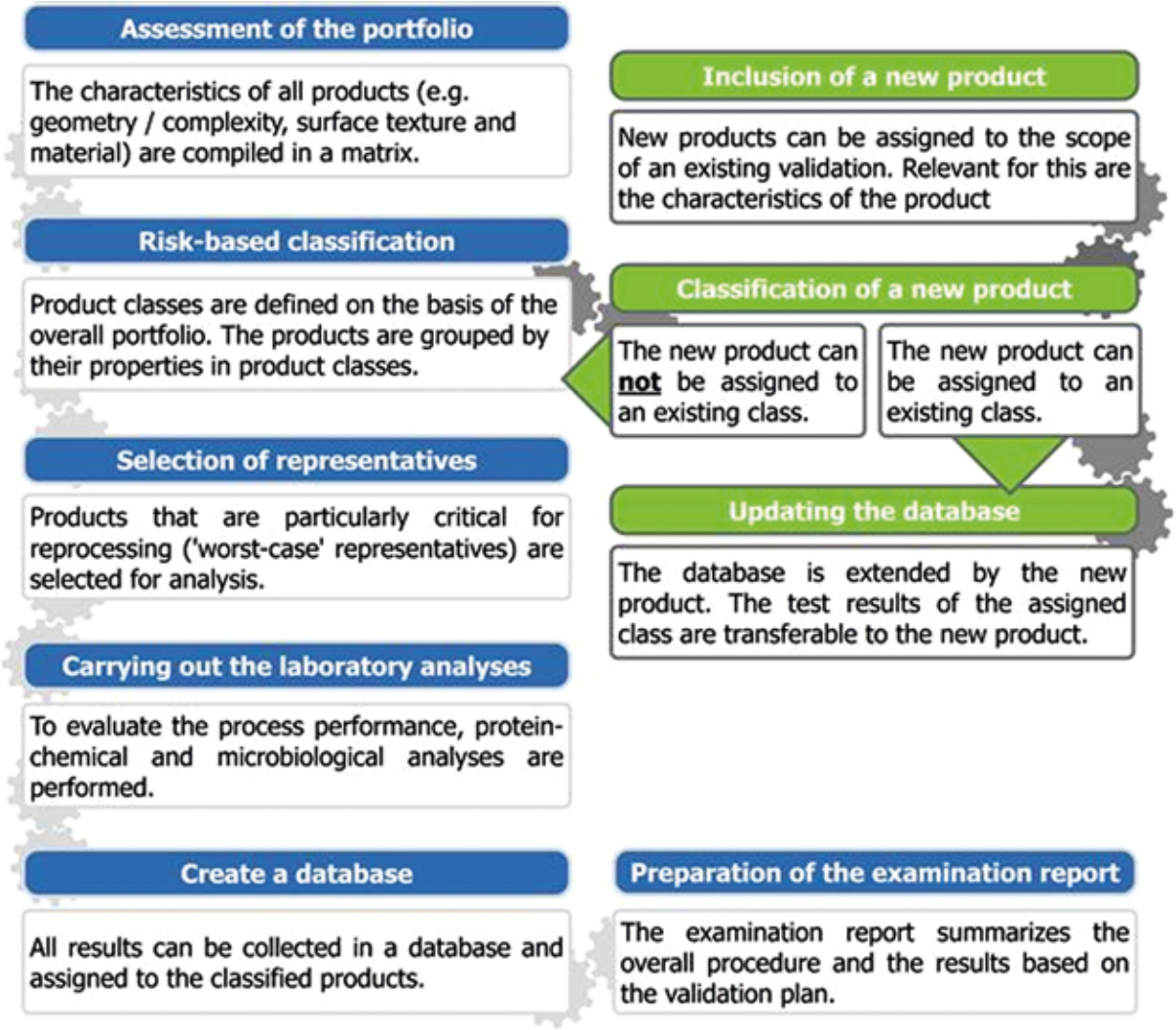
Hygienic reprocessing of medical devices is of high importance for manufacturers, operators and patients. Therefore detailed user manuals containing reprocessing instructions need to be provided to those who use these devices. The requirements for these instructions are described in the new Medical Device Regulation and international standards, such as EN ISO 17664, and they are more rigorously monitored by certification bodies. The validation of reprocessing instructions guarantees, that the reprocessing procedures described are effective and reproducible.

Laboratories carrying out the validation effort need to fulfill certain requirements and need to be experienced in setting up a validation concept (Figure: Risk-based concept for the validation of reprocessing instructions), covering a potentially large number of different instruments from a single manufacturer. Depending on the reprocessing procedures they need to be familiar with a variety of national and international regulations and standards, describing procedures and laboratory methods.

It has shown to be beneficial to follow a risk-based approach in order to avoid examining every single aspect with each instrument, potentially creating redundant analysis results. In order to plan the validation and the documentation, the laboratory works closely with the manufacturer. The medical devices which need to be covered in the validation are classified based on predefined critical criteria, such as the field of application, the potential degree of contamination, their material or geometric properties. Additionally, the applicable standards, describing reprocessing methods or test soils, have to be identified. Then, 'worst case' scenarios with representative instruments from critical classes are defined. The validation plan describes the exact steps of the classification, the 'worst case' definition and the type of necessary documentation. For analysis, chemical (oPA, BCA) or microbiological methods (E. faecium, G. staerothermophilus) are typically applied. Naturally, the laboratory carrying out the analysis must have its methods well implemented and validated.

The description of the methodological approach and the results of the analysis are summarized in a validation report. Setting up a database containing the classification data of the instruments and results of all analyses carried out, enables the manufacturer or laboratory to evaluate future instruments based on their reprocessing-critical properties. If these properties have already been tested with previous similar instruments, then previous results may be applicable, reducing the amount of redundant work. Hence, the manufacturer prioritizes additional validation needs based on a risk evaluation of newly marketed instruments and can avoid redundancies as well as reduce cost to an optimal level.

Figure 1: Risk-based concept for the validation of reprocessing instructions for medical devices according to EN ISO 17664.



P_61

Technical analyse of wipes in intermediate level disinfection: are they an alternative to semi-automated disinfection?

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Background: Endocavity probes are semi-critical medical devices (MD) in the Spaulding classification. In March 2019, at the request of the health ministry, the French Hospital Hygiene Society (SF2H) published new guidelines for the disinfection of endocavitary ultrasound probes. The instrument disinfection is upgraded to Intermediate level disinfection (ILD) to prevent HPV infection.
Several ILD processes exist: the semi-automated ANTIGERMIX® (UV-C) and TROPHON® (H2O2) and manual process by immersion in a disinfectant product. The use of disinfectant wipes specific for ILD associated with a protective sheath is a possible alternative to immersion.
The University Hospital is equipped with a TROPHON®. The time of a disinfection cycle is 7min. In practice, with an estimated number of 70-80 acts per day, the resources available are not enough. The implementation of wipes use appears as an easy alternative to set up.
The aim is to evaluate the compliance of wipes with SF2H new guidelines and make a choice according to the pratices in medical ward.

Material et methods: To reach an intermediate level of disinfection, the manufacturer of the disinfecting wipe must claim compliance with the following European standards: bactericidal activity EN16615, fongicidal activity EN 16615 EN 13624 and EN 14562, mycobactericidal activity EN 14348 and EN 14563, virucidal activity EN 14476. We analyse 6 wipes products of 5 differents manufacturers: TRISTEL (Duo ULT and Trio), ANIOS, Dr. WEIGERT, FRANKLAB and THX medical. Wipes validation is performed by analysing feasibility, level of disinfection and estimating contact time and cost.

Results: The results are presented in the following comparative table.

Discussion and conclusion: THX MEDICAL wipes are not retained for further test because they do not meet the intermediate disinfection standards. The others wipes are conform to the European Standards. TRISTEL DUO ULT and TRIO, ANIOS, Dr. WEIGERT and FRANKLAB wipes are going to be tested in the different departments. The final choice, if the use of wipes is retained for disinfection of endocavitary probes, will be according to the feasibility, the global time and the cost in real use comparing to TROPHON®.

Comparative table of disinfectant wipes

	Activity	Standards	Contact time	Cost
TRISTEL TRIO ® Tristel	Bactericidal activity Fongicidal activity Mycobactericidal activity Virucidal activity Sporicidal activity	EN 13727, EN 14561, EN 16615 EN 13624, EN 14562, EN 16615 EN 14348, EN 14563 EN 14476, EN 16615 EN 14347, EN 14561	30 sec 30 sec 30 sec 30 sec 30 sec	+++
TRISTEL DUO ULT® Tristel	Bactericidal activity Fongicidal activity Mycobactericidal activity Virucidal activity Sporicidal activity	EN 13727, EN 14561, EN 16615 EN 13624, EN 14562, EN 16615 EN 14348, EN 14563 EN 14476, EN 16615 EN 14347	30 sec 30 sec 30 sec 30 sec 30 sec	++
WIP'ANIOS Clean UP + solution Sporactiv® Anios	Bactericidal activity Fongicidal activity Mycobactericidal activity Virucidal activity Sporicidal activity	EN 13727, EN 16615 EN 13624 EN 16615 EN 14348, EN 16615 EN 14476, EN 16615 EN 13704, EN 16615, ASTM 296-715	30 sec 1 min 3 min 30 sec, 3 min (PV) 2 min	++
WIPES MEDIPAL 3 IN 1 Dr Weigert	Bactericidal activity Fongicidal activity Mycobactericidal activity Virucidal activity Sporicidal activity	EN 13727, EN 16615, EN 13697 EN 13624 EN 16615 EN 14348 EN 14476, EN 16615 EN 13704	1 min, 2 min, 2 min 2 min 1 min 2 min 2 min	+
VIRO'WIPES 150 Franklab	Bactericidal activity Fongicidal activity Mycobactericidal activity Virucidal activity	EN 13727, EN 16615, EN 13697 EN 13624, EN 16615 EN 14348 EN 14476	5 min, 2 min, 5 min 10 min, 2 min 10 min 10 min	+
CLEANISEPT® WIPES FORTE MAXI THX Medical	Bactericidal activity Virucidal activity Sporicidal activity	EN 13704, EN 16615 EN 14476, EN 16777 EN 13704	2 min 2 min 2 min	+

P_62

Comparison of two active principles of flexible endoscope disinfection: Peracetic acid and carbon dioxide

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Biography:
Giovana A. A. Moriya is the supervisor of the surgical center of Hospital Infantil Sabara. She is the current president of Brazilian Society of Surgical Center Nurses, Anesthetic Recovery and CSSD (SOBECC).

The healthcare environment as well as the medical devices used in procedures can function as reservoirs and transmission devices for pathogens, so many publications have emphasized the importance of high-quality cleaning and disinfection, as well as choosing the most suitable method for that goal. Semi-critic medical devices require a minimally high level of disinfection. Because many of them are thermo-sensitive, chemical methods must be used. Strict adherence to current guidelines is necessary as more outbreaks have been associated with inadequately cleaned or disinfected endoscopes undergoing high level disinfection than any other medical device. Attention should be paid to the choice of the most suitable endoscope disinfection methods because even using the same pre-cleaning process and following the manufacturers' guidelines, there are discrepancies in the daily practice of the methods usually employed, as well as determining the choice of how to verify the efficacy of the cleaning and disinfection.

Objective: To compare the antimicrobial efficacy of two formulations of active ingredients of chemical disinfectants in semi-critic medical devices in a medium-sized pediatric hospital in the city of São Paulo, Brazil.

Method: This was a cross-sectional field study with a quantitative approach. The sample consisted of 3 flexible endoscopes, which have irrigation and suction channel, used in pediatric procedures identified as I, II, and III. Endoscopes I and II were pediatric and had a diameter of 2.8 mm and endoscope III was neonatal and had a diameter of 2.2 mm. To verify the efficacy of cleaning and disinfection, bioluminescence adenosine triphosphate (ATP) chemical tests were performed before manual cleaning and after disinfection with test-products each time the flexible endoscopes were used and processed. The test-products used for high level disinfection were: product A - 0.20% (w/w) liquid peracetic acid ($C_2H_4O_3$), product B - liquid Chlorine dioxide (ClO_2), stabilized in a 7% aqueous solution. Both were tested for 30 days. For each test-product, the following sequence of procedures were performed: pre-cleaning, manual cleaning with enzymatic detergent solution and mechanical rubbing with soft bristle brush and then automated process on proprietary equipment (including leakage, rinsing and drying testing). Prior to each manual cleaning procedure, the amount of RLU was checked by ATP test and after completion of complete disinfection.
Results: A total of 41 flexible endoscopes were processed in 30 days with product A: 20 endoscopes I, 17 endoscopes II and 4 endoscopes III. With product B, 14 flexible endoscopes were processed: 5 endoscopes I, 4 endoscopes II and 5 endoscopes III. Product A, before manual cleaning, resulted 20 to 8626 RLU, and after disinfection, 0 to 31 RLU. Product B, before manual cleaning, resulted 245 to 6243, and after disinfection, 2 to 76 RLU.

Conclusion: Antimicrobial efficacy of the two formulations is confirmed in Endoscopes I, II and III when using automatic processors and adhering to all processing steps, including pre-cleaning, leak testing and manual cleaning.

P_63

Is it possible to have good results in the management of orthoses/prostheses/special materials using dedicated team strategies and operational efficiency?

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Biography:
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Introduction: In the management of health facilities, one of the key points is related to specific materials used in surgical procedures, especially orthoses, prostheses and special materials (OPSM). Once there is a great variety of products, the assertive management needs to be concerned about patients' safety, business relationships, operational efficiency, confidence and economic credibility of the institution. Professionals in a private hospital in São Paulo, Brazil, carried out a feasibility study for having an administrative team dedicated to OPSM management processes, with the purpose of improving operational efficiency at the Sterilization Center. (SC) and the level of service provided in this area. Objective: Demonstrate the results of an OPSM management project, after having hired a dedicated administrative team, and the operational flow.

Method: This is an experience report, developed in an extra-large, where more than 2,000 surgical procedures are performed every month. Initially, it was carried out the mapping of all phases of the processes involving OPSM and a calculation of the average time spent by professionals in administrative activities related to OPSM. It was necessary to hire ten administrative professionals for: receiving and returning of materials; invoice control; collection and control of spare parts; and materials organization. These activities had been, until then, performed by professionals of the nursing team. Then, the flow of administrative processes was redesigned in order to optimize time and collect data for this purpose. Routines and scales, which are monthly rotated, have been elaborated, so that professionals are able to master all areas and processes, covering all work periods, making it possible to meet the demand, with the presence of team members at all times.

Results: After data collection, a basis to compare and monitor the evolution of the team over a period of one year was obtained. The Hospital had an average of 2,400 surgeries/month, out of which 750 used OPSM. Analyzing the average time for receiving materials, this time was 28 minutes per patient in the beginning of the study, ie, 350 hours/month only with OPSM receiving. As the team's performance curve improved, this time was reduced to 12 minutes per patient, ie, 150 hours/month. It is noteworthy that these times were previously spent by the SC team. It was also possible to verify the evolution of the tax process, with an average of 930 invoices/month, issued by the SC. Initially, the average time for issuing the invoices was 120 hours after the procedure. By using the team strategy, this time was reduced to 3 hours after the surgical procedure.

Conclusion: One year after the implementation of the team work, it was possible to measure the improvement of processes involving OPSM. In relation to assistance, there has been greater

availability of nursing team for assistance, due to the reduction of events with materials and the improvement of service level. As for the administrative area, there has been a reduction of approximately 97% of the time for issuing invoices, providing greater agility in the capital turnover generated by procedures using OPSM.

P_64

The impact of medical waste management in the Surgical Environment (SE)

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Biography:
Director of the Brazilian Society of Surgical Center Nurses, Center for Sterilization and Anesthetic Recovery
PhD Professor, School of Health Sciences, Hospital Israelita Albert Einstein

Introduction: Health waste currently presents a problem regarding its final destination, since it is necessary to ensure the correct disposal at the source and the reduction of environmental impacts. Surgical Environment (SE) is a sector within the hospital that generates said waste, therefore, it is prudent that we take a careful look at the work processes of this environment. Thinking about the awareness of the professional and the responsibility to properly manage health waste, there was concern to discuss this issue.

Objectives: Revisit the mapping and classification of waste generated within SB; define the correct form of waste segregation at source and propose the elaboration of work flows for specific health residues.

Method: Is an experience report, developed in a private, extra-large institution located in the city of São Paulo, Brazil. Initially, a literature review was conducted, in particular, norms, manuals and resolutions pertinent to the concepts of health waste management, interfacing with SE practices and focusing on studies that analyze proposals for improvements in sustainability issues that encompass this concept. The first step was to establish the division of the SE into areas in order to classify the waste generated by the inputs that are used to perform the work processes. After that, it was possible to remap and set the areas to provide the correct disposal at the source. In parallel, there was a need to elaborate flows for the so-called special residues, which include surgical explants, instruments that will no longer be used and instruments with electronic components that have a limited number of uses. In this work, it was decided to divide the waste generated in the SB into two groups: "common waste" and "special waste", based on the need for specific documentation for disposal. The common waste group is made up of those that can be disposed of directly in the sector, in a specific location, to be sent to temporary storage, within the institution, without the need for specific documentation. The special waste group is composed of those who need differentiated care. These actions serve as guides to assist in the awareness of health professionals as active agents in this work environment.

Results: Following the movement to revisit the areas that make up the SE, there were points of improvement regarding the updating of the waste disposal policy generated there, as well as the elaboration of flows for special waste, which require differentiated attention disposal of such waste includes: Surgical Explant Disposal, Surgical Explant Return, Disposable Instruments Disposal, Electronic Component Disposal, and Reuse Limit; at source, according to the rules and laws in force in the country.

Conclusion: It is possible to direct the professionals working in the SE, facing the issue of health waste management, facilitating the understanding on the subject and provided with guiding tools for professional action in a conscious manner in the disposal of waste generated in the sector. As a continuation of this work, it is necessary to periodically monitor the actions implemented, as a guarantee commitment to sustainability.

P_65

Simultaneous cleaving of viral capsid and DNA. A fast way to screen for virucidal efficacy

Alex Sava[1]
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Biography:
Alex has over 25 years experience in discovering and developing of disinfection and sterilisation methodologies, including Nanosonics process, enzymatic prion deactivation and many others. With particular interest in developing environmentally sustainable disinfection protocols with reduced carbon footprint and chemical/packaging waste.

Every couple of months, new viral strains are reported in the media. This prompts requests to hospital infection control specialists to confirm virucidal efficacy of instrument reprocessing cycle (IRC) against the emerging virus.

As there are no reliable cell-based assays for the infectivity of even the most notorious viruses (HIV, Hep B), let alone emerging viruses, the answers are not straightforward. The current broad virucidal claim is supported by cell culture-based virucidal assays (eg ASTM1053 or EN16777) on three viral strains that date back to the 1950's. Extrapolating the ASTM1053-validated virucidal efficacy to emerging viruses is quite risky when taking the sophisticated resistance mechanisms employed by these viruses into account.

Since virus are essentially DNA (or RNA) genomic strands enveloped in a protein capsid, until the early 2000s there was a consensus that merely damaging viral capsid was equivalent to the loss of virus infectivity. Recently more and more data indicate that viruses may reproduce from the viral genome alone [1-3]: Due to a multitude of reasons - from a compromised immune system to dysregulated endocytosis - viral nucleic acids can be taken into human cells, evading the cell's immune sensing mechanisms.

The above data (quite rightfully) is creating concern amongst hospital staff over the safety in exposure to reusable instruments that might harbour intact viral genome. As reported at 2018' WFHSS - DNA of Hepatitis B survives throughout some instrument reprocessing cycles. Similarly, DNA of HIV persists intact through certain common chemical disinfection cycles. Uncertainties about the infectivity of the intact viral genome in the current prone to litigation environment have already resulted in the lengthening of IRCs - for example, A0=600 was increased to A0=3000 in washer disinfectors due to possibility of HBV survival.

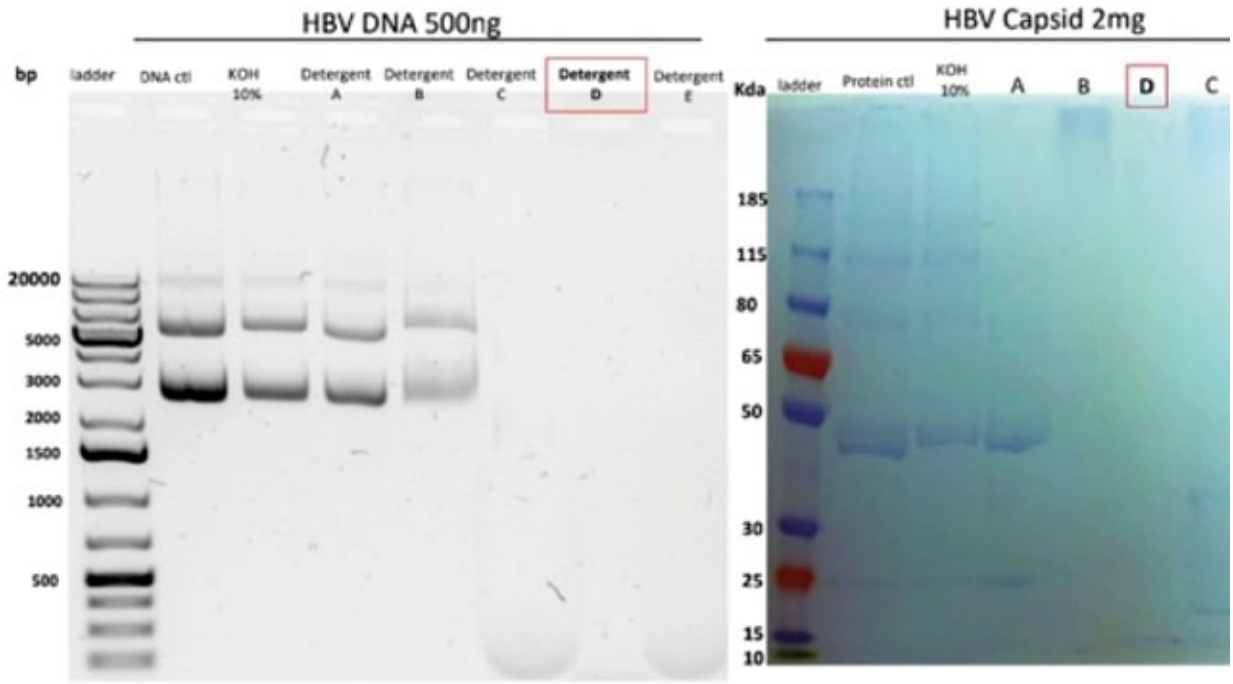
We present a fast, reliable and inexpensive screening for virucidal efficacy. The virucidal efficacy corresponds to the concurrent denaturation of both viral DNA/RNA and capsid proteins. Therefore the virucidal capacity of a disinfectant can be reliably resolved upon challenging with the viral loads characteristic of an active phase of chronic viral infection - ~20,000 IU per mL (or 105 copies/ml) and screening for both biological components. If both capsid protein and DNA are cleaved, the disinfectant or IRC posses the desired complete virucidal activity.

Using the above method we screened some of the Australia-marketed medical instrument detergents. We found that many of these detergents (even with prion deactivation and 'digest all biological matter' claims) are completely ineffective in cleaving DNA and have poor efficacy

in denaturing capsid proteins. Promisingly at least one detergent (detergent D) demonstrated an impressive ability to cleave both DNA- and capsid protein during 10 min at 40C cycles.

This clear DNA and capsid protein denaturation correlates well with the virucidal efficacy tested as per ASTM1053

Hep B simultaneous denaturing of capsid and DNA by medical instrument detergents



P_66

Comparison of the shelf life sterility of medical instrument sets and storage between central supply store department and any department

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Biography:
Head of CSSD, Chonburi Cancer Hospital
Comparison of the shelf life sterility of medical instrument sets and storage between Central Supply Store Department and any Department in Chonburi Cancer Hospital
Koragot Vicheantheab
Chonburi Cancer Hospital, Central Supply Store Department ,Thailand 20000

Determining the duration shelf life sterility of medical instrument that are not suitable while medical instrument remain sterile, causing unnecessary resources to be rebuilt. This research, therefore, compares the sterile retention period in the central dispensing unit with various departments in the hospital using 576 sets of sterile tools that are sterile according to standardized procedures. And 64 swab culture samples to confirm sterility before the experiment. After that, divided into 2 groups by collecting in the central dispensing unit and various departments in the hospital and randomly sampling the culture in each group, 64 sets in each 4th week, 5th week, 6th week and 7th week respectively. Data were analyzed using descriptive statistics.

The research found that the toolset stored in various units of the hospital showed 2 sets of bacteria in 5th week ,and 6th week respectively. The toolset stored in the central dispensing unit was not detected for 7 week.

The research recommends that the management or relevant departments determine the period of sterilization conditions of medical instrument sets in various departments of the hospital for at least 4 weeks.

Keywords : shelf life sterility, medical instrument ,Central Supply Store

P_67

Jet in time

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THE EFFECTS OF THE "JET IN TIME" MODEL OF RECEIVING AND DELIVERING MEDICAL EQUIPMENT, CENTRAL STERILE SUPPLY DEPARTMENT (CSSD)
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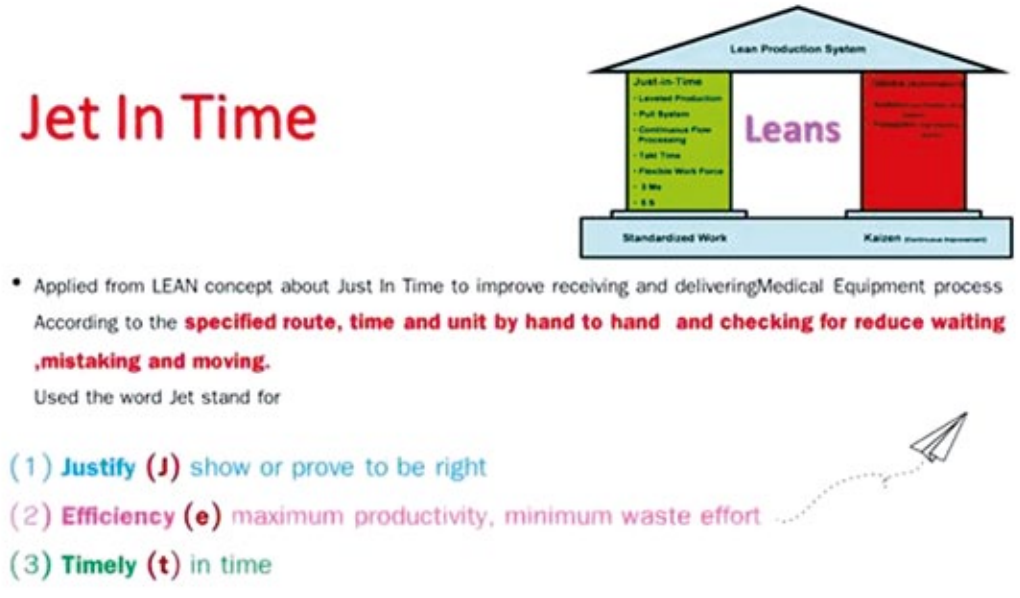
Vachira Phuket Hospital, Thailand

The Central Sterile Supply Department (CSSD) is responsible for making sterile medical equipment to distribute to the patient units in the hospital. Accuracy, efficiency in terms of ready for use, and timely manner of receiving and delivering sterile medical equipment lead to patient safety and satisfaction of the personnel. This was a one-group, pre-test and post-test quasi-experimental study conducted in a medical center in Southern Thailand. The purposes were to compare between the traditional model (pre) and the Jet in Time model (post) if there were the differences in (1) the effect of receiving and delivering medical equipment with regard to accuracy, efficiency in terms of ready for use, and timely manner; (2) the personnel's compliance of the receiving and delivering medical equipment protocol; and (3) the personnel's satisfaction. The sample was the personnel involved in the delivery process including the ones from the patient units and the CSSD. Demographic data were analyzed by using descriptive statistics. The differences of the outcome variables between the groups were compared by using the Chi-square statistics and paired t–test depending on the level of measurements of the variables.

The study showed that receiving and delivering medical equipment using the Jet in Time model was more accurate and timely than that of the traditional model ($p < .05$), except that of efficiency-ready for use. The personnel's compliance to the protocol increased significantly ($p < .05$) and they were more satisfied with the Jet in Time model than the traditional model ($p < .01$).

Key words: Receiving and Delivering Medical Equipment



P_68

Performance improvement for sterile storage management

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Biography:
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The study aims to determine guidelines for an appropriate improvement in inventory management and to increase the performance for sterile storage management of the Central Supply Sterile Department in Srinagarind Hospital. The study showed that problems with a lack of sterile storage management efficiency. The original system has been run with a combination of experience and estimation. For the study methodology, through interviews with management, units of user, members, data analysis was carried out in the form of a Fish Bone Diagram; SWOT analysis; and a pairing of weaknesses, strengths, opportunities and threats in order to formulate the strategic management plan. The sterile medical supply inventory was classified according to ABCD Analysis to obtain supply demand forecasting. A forecasting approach through the Smoothing Technique, reorder point and safety stock were applied to this study using risk analysis as determination criteria. , with an availability of 99.96 %. According to 2016 and 2017 fiscal year reports on remaining supplies, the resulting annual expenditure on unused items was 2,541,927.00 bath and 1,258,731.00 baht respectively, with a decrease of 1,283,196 baht or 50.48 %. An expense comparison was examined between the original inventory and the revised inventory, for which the waste decrease totaled 71,762.57 baht per year.

Keywords: Inventory Management, ABCD Inventory Analysis, Reorder Point.

Tows Matrix - Strategies

TOWS MATRIX			SO Strategies	WO Strategies
	Opportunities (O)	1.The medical school is funded in recognition of its contribution and excellence. 2.Hospital's management scheme facilitates the unit's operations	S3O1: Implement IT program to develop efficient inventory management.	W1O2: Improving the performance for sterile storage management . W5O1 Create awareness and participation to use products efficiently . W1T2: Change the provisioning operation by using the outsource.
			ST Strategies	**WT Strategies**
	Threats (T)	1.Limited funding from the government 2.The ever-changing nature of medical technologies necessitates regular updates on equipment.	S1T1: Changing and selecting a new purchasing. S1T2: Following a new technology trends of treatments.	W1T2: Change the provisioning operation by using the outsource.

P_69

Study in the time delay of temperature of loaner instruments in sterilizers with different pulsations

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Biography:
Yuan Yuan, head nurse of disinfection supply center, Friendship Hospital Affiliated to Capital Medical University, was born in November 1960,CHINA. Member of the Sterilization and Supply Committee of the Chinese Nursing Association; Vice-Chairman of the Sterilization and Supply Committee of the Beijing Nursing Association; Member of the Sterilization and Supply Center of Primary Medical Institutions of the Sterilization and Infection Control Committee of the Chinese Health Supervision Association; Member of the Regional Sterilization Management of the Nursing Equipment and Materials Branch of the Chinese Medical Equipment Association Members of the Committee.

Objective: To test the delay time of loaners by using temperature and pressure detectors and to explore the impacts on the temperature rising delay for loaner instruments in different pulsating forms of sterilizers.

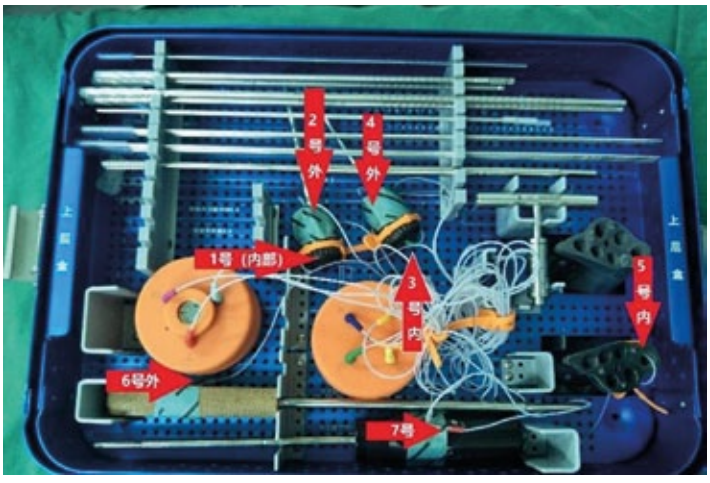
Methods: Temperature and pressure detectors were used to measure temperature and time parameters of different parts of loaner instruments in sterilizers with different pulsations.

Results: The loaner instruments with special material and complicated structure are prone to and more obvious in temperature rising delay in the sterilizers with three-atmospheric pulsations. However, the temperature rise delay on the surface of metal tube devices consisting of compositive material can be minimized by using sterilizers with 8 pulsations. The delay in temperature rise of inside compartments of instruments made of compositive material occurs in sterilizers with both 3 and 8 pulsations, but greatly improved when sterilizers with 8 pulsations were used.

Conclusion: Compared to 3 pulsations, sterilizers with 8 pulsations require less time period for sterilization of general loaner instruments, but instruments with special materials and complex structures need much longer time for rising temperature in order to a successful sterilization. Therefore, people should pay more close attentions to such delay and enable to avoid the potential risks of sterilization failures.

Key words: Loaner instruments, Temperature rising, Pulsations

Placements of probes of temperature and pressure detector



P_70

Lean Process of Dental instrument in CSSD by Kaizen concept

Nantipa Sirijindadirat[1]
[1]*Siriraj Piyamaharaj Karin, Thailand*

Biography:
Nanthipha, Pattaraporn, Nalinee, Saharat and CSSD team of CSSD Sirirajpiyamaharajakarun hospital, Thailand

CSSD provide disinfection and sterilization instrument & medical devices for the whole hospital follow international standard guideline. Dental department is 2nd of 5 tops customer's CSSD and dental instruments so many dedicated and complicated instrument. Reusable medical equipment/ devices must be thoroughly inspection, preparation before packing and sterilizing for ready to use and patient safety. Inspection process for malfunction and damage instrument before packing is important process. The CSSD had the function to control the sterilization of Medical Devices. Kaizen is an approach to creating continuous improvement based on the idea that small, ongoing positive changes can reap major improvements. Kaizen is core to lean manufacturing, or The Toyota Way. It was developed in the manufacturing sector to lower defects, eliminate waste, boost productivity, encourage worker purpose and accountability, and promote innovation.

In the same way of Sirirajpiyamaharajakarun Hospital a study was undertaken from January 2018 to June 2018 to compare October to December 2017 look at how. The result of the analysis focused on 5 topics:
1. Still remain in CSSD stock
2. The instruments are out of order after the sterile procession
3. The instruments are not matching with tagging and sticker names
4. The instruments have been disappearing after the sterile procession
5. The amount of occurrence reports

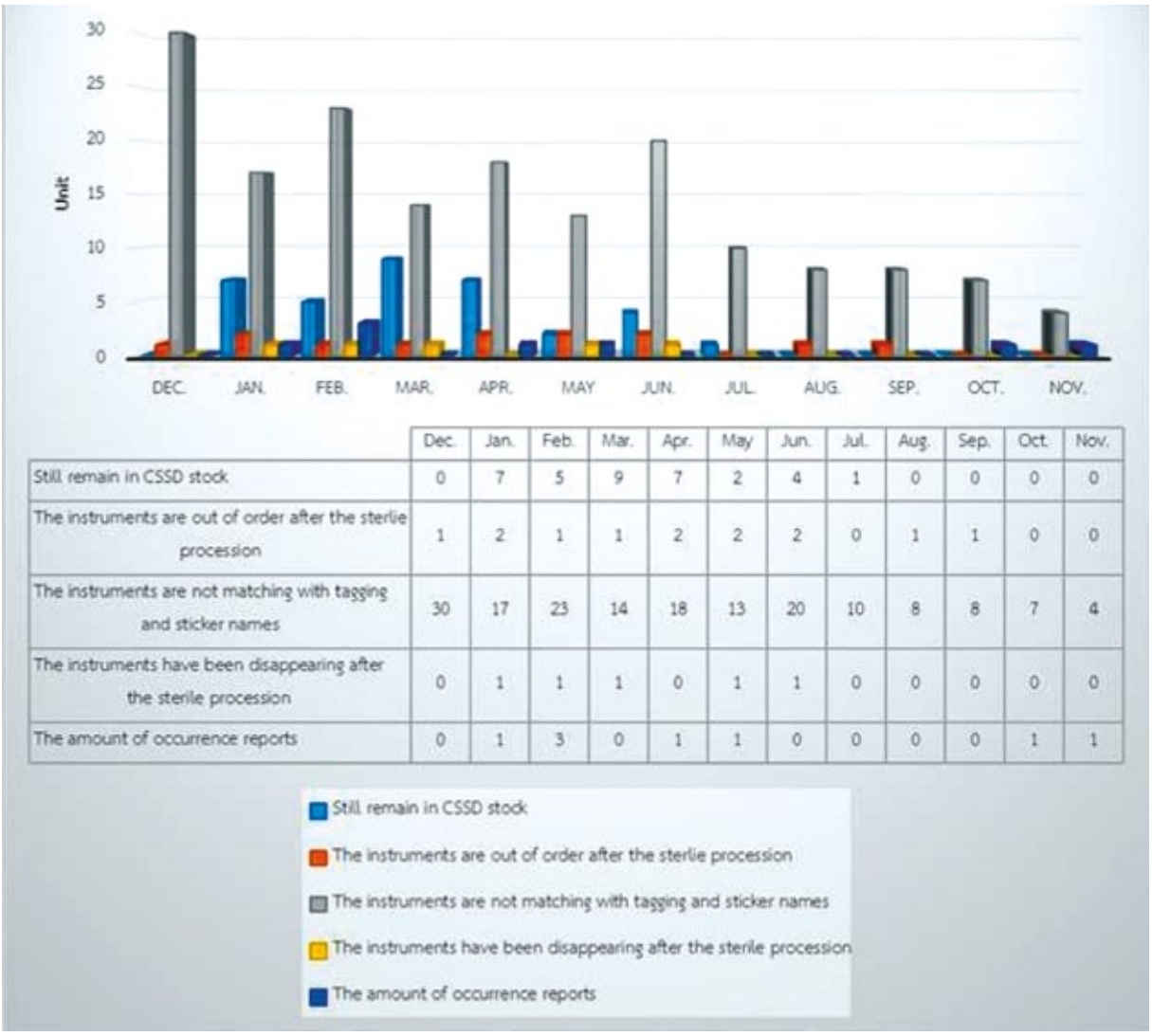
As a result of this study a decision was made to come up with a solution to this costly issue of re-sterilization and lost services because of no instrument.

Objective
1. To reduce the stock out and the amount re-sterilization < 5unit/ month
2. To reduce dental instruments lost = 0
3. To complete delivery and instrument ready to used >95%

Methodology
1. Re-organization and provide well training special dental instrument and QC staff double check before packing.
2. Create innovation basket for separate each dental instrument and tagging label. Staff at decontaminated area is assembled and separate dental instruments into innovation basket before the next process.
3. Staff in clean area are easy to packing and reduce human error.

Result and Conclusions: As a result of this Sirirajpiyamaharajkarun Hospital for 6 months :
The stock out and the amount re-sterilization is reduce average 5 pcs/m. , Dental instrument lost is lesser than before and complete delivery and instrument ready to used average 98.3%.This result was

reported at dental committee was achieve target.The committee discuss ways of solving this. result was report dental committee



	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.
Still remain in CSSD stock	0	7	5	9	7	2	4	1	0	0	0	0
The instruments are out of order after the sterlie procession	1	2	1	1	2	2	2	0	1	1	0	0
The instruments are not matching with tagging and sticker names	30	17	23	14	18	13	20	10	8	8	7	4
The instruments have been disappearing after the sterile procession	0	1	1	1	0	1	1	0	0	0	0	0
The amount of occurrence reports	0	1	3	0	1	1	0	0	0	0	1	1

P_71

Central sterile service department: building a positive reality in the midst of a restrictive reality

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Biography:
Graduated in Nursing from the Federal University of Goiás (2002), Master's degree in Experimental Biology from the Federal University of Rondônia (2009) and PhD student in Nursing from the Federal University of Goiás (2019). Currently, a Adjunct Professor at the Faculty of Nursing of the Federal University of Rondônia (UNIR). Deputy leader of the LAPECS (Health Care Research Laboratory) research group, registered with CNPq. Experience in teaching, research and extension in the area of infection prevention and control, acting on the following subject: reusable medical devices processing.

Aim: To evaluate the quality of reusable medical devices (RMD) reprocessing in Central Sterile Service Departments (CSSD).

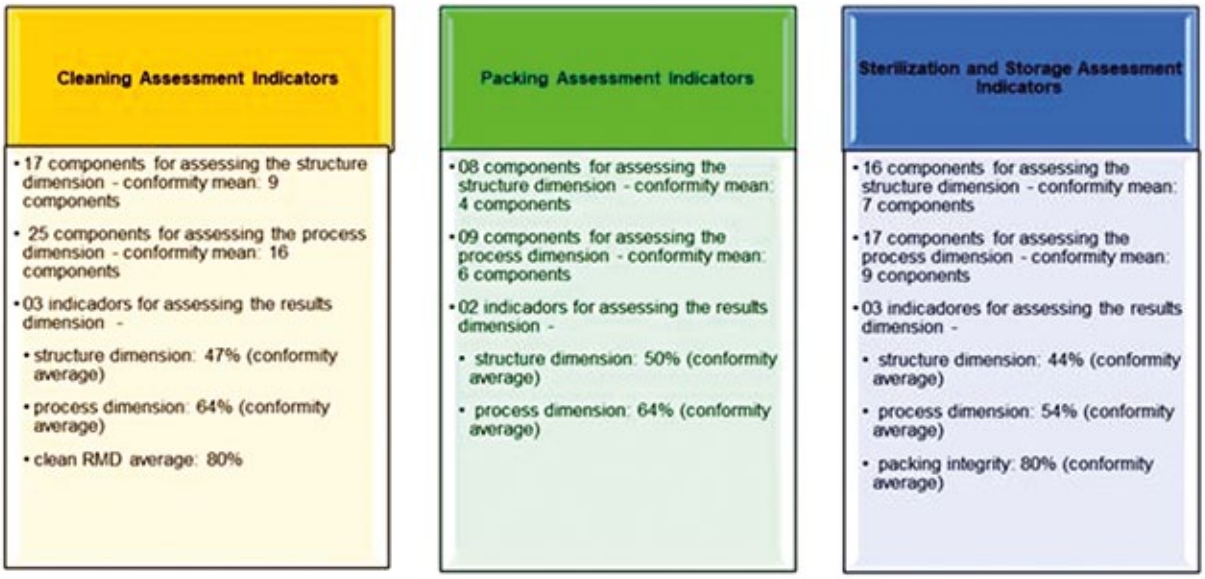
Methods: Evaluative research of intervention based on Appreciative Investigation carried out in CSSDs of the four largest hospitals of a state of the Western Amazon, North region of Brazil. Quality assessment was performed through structure, process and outcome indicators, in three interrelated phases: phase 1 - situational diagnosis using the quality indicators; phase 2 - group mapping; phase 3 - Appreciative Investigation workshop to build a joint planning. Figure 1 shows the aspects evaluated by the quality assessment indicators. Study participants were healthcare workers from the CSSD, the Hospital Infection Control Commission and the Patient Safety Center. The research project was approved by an Ethics Committee (protocol: 58757316.6.0000.5300).

Results: Three CSSD were centralized and one semi-centralized, with exclusive nurses, as manager, in two units. For the four CSSD, the structure indicator compliance ranged from 44 to 50% (average 49%) and the process indicator from 54 to 64% (average 61%). The result indicator for the cleaning step (assessed by ATP and protein swab tests) ranged from 75 to 94% (average 80%). Three units performed manual cleaning only and one manual and automated cleaning. The CSSD workers mapped profile was: over 55 years, female, complete high school and working time at CSSD from 1 to 5 years. Overall, driving forces were higher than the restrictive forces, and the restrictive forces were focused on the physical structure. In the appreciative workshop, for building a joint planning, the experiences and perceptions prevailed over the quality indicators. Some proposed and ongoing actions: adequacy of hand hygiene supplies, consult the hospital engineering team for the analysis of architectural projects, strengthening of communication between the CSSD and their leaders, training for all CSSD workers, and review the CSSD standard operational procedures and routines.

Conclusions: The structure indicators showed more non-conformities than the process indicators throughout the processing steps at the four CSSD. The result indicator for cleaning and packing integrity obtained the best rates. Evaluation using CSSD-specific indicators directed efforts, saved time and aggregated evidence. The association with group mapping, also specific to CSSD, and appreciative planning allowed the object to be contemplated in various dimensions and possibilities. However, it is still a challenge to establish the quality indicators in clinical practice as a routine.

Appreciative intervention showed to be a tool to boost this goal.

Figure 1. Step 1 - Quality assessment indicators for reusable medical devices (RMD) reprocessing at Central Sterile Service Departments.



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Exposure to biological material related to reusable medical devices cleaning

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Biography:
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Aims: Identify the incidence of Central Sterile Service Department workers exposure to biological material during reusable medical devices (RMD) cleaning, profile the accidents and victims, and establish the factors associated with accidents with biological material during RMD cleaning.

Method: Cross-sectional analytical study. Data collection was performed from January to June 2019, through the Brazilian records of compulsory notification of accidents with biological material, from the Occupational Health Reference Center, located in the Midwest region of Brazil. The study population was CSSD workers who reported accidents with biological material from January 2006 to December 2018. Data were analyzed using the R-3.6.1 program for windows. Descriptive statistics was used to estimate the chance (odds ratio - OR) of percutaneous accidents during RMD cleaning. Confidence interval of 95% and $p < 0.05$ were considered for the univariate analysis.

Results: A total of 10,674 accidents with biological material were reported, of which 524 occurred during RMD cleaning (4.9%). The nursing team was the group with the largest number of accidents (n=324; 68.9%). For this group, percutaneous exposure was predominant (n=445; 84.9%), with needles (n=127; 28.5%), slides/lancets (n=82; 18.4%), glassware (n=26; 5.8%), and others. Blood and blood fluids were the biological material involved in 350 (66.8%) cases. Most of the victims were vaccinated for HVB (n=453; 86.4%). Regarding the Anti-HBs, 121 workers (23.0%) had no protection against HBV. The source-patient was known in 137 (33.8%) cases only. At the time of the accidents, 364 (69.4%) were not using all the personal protective equipment recommended. The risk of percutaneous accident during RMD cleaning was 1.34 (p=0.02214; 95% CI).

Conclusion: The RMDS cleaning step showed to be a critical moment for the CSSD workers' safety and health, as the findings of this study pointed to the high risk of accidents with biological involving blood and percutaneous material. These characteristics qualify the severity of these exposures

and the chances of illness for the victims, as it may result in the transmission of pathogens of epidemiological importance. In addition, it is worthy to highlight the low adherence to protective barriers by the workers, as most of them did not have the recommended personal protective equipment. Overall, this study evidenced the importance of basic actions for prevention and control of exposures to biological material, such as continuous and permanent workers educational training, administrative measures to ensure the workers safety during their activities, and monitoring the processes that generate these injuries.

P_73

Approach towards a design method to appropriately modularize surgical robots for sterile reprocessing

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Biography:
2009-2014: Bachelor of Science in Mechanical Engineering, RWTH Aachen University; Specialization: Design Engineering
2014-2016: Master of Science in Development and Design Engineering, RWTH Aachen University
2016 - Today: Research Assistant at the Chair of Medical
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Introduction: Robot manufacturers tend to either provide drapes to cover sensitive parts that cannot be reprocessed or take charge of complex reprocessing procedures themselves. But what if the robot could be modularized in a way that sensitive parts (which are usually the most expensive) were systematically separated from non-sensitive parts that are easy to reprocess? We aim to develop a method that supports the design of cost-efficient robotic systems with a focus on the usability in the surgical context of use regarding the entire use cycle of surgery and reprocessing of modules.

Methods: In mechanical design, most modularization approaches start with an existing product in order to optimize the manufacturing process. By contrast, our approach is based on an analysis of requirements and functionality with the following generic steps:
1. Establish a generic function structure that contains all universal and application-specific functions of a potential robot.
2. Elaborate a requirements list including all constraints, conditions and dependencies, e.g. for cleaning, disinfection, sterilization and (re)assembly in the operating room and central reprocessing department.
3. Create functional modules by mapping functions to requirements to reveal similarities and assess their compatibilities with requirements.

We exemplified the approach by two existing systems (A+B) developed at our institute (Theisgen2018) regarding functional similarities and resulting drivers for modularization.

Results: System A is a miniaturized navigated robot entirely composed of autoclavable parts and meant to dynamically guide a tool e.g. a burr in space. The system is equipped with five motor-encoder-gearbox combinations for five degrees of freedom (DOF) which can be autoclaved up to 100 times. System B is a four DOF system with different kinematic structure and workspace requirements to position a static drill guide according to an image based plan. We were able to substitute four motor-encoder-gearbox combinations by only one and put all sensitive parts into a single universally applicable drive module. All applications-specific modules, e.g. the kinematics, are passive and can therefore be reprocessed or designed as disposables. Both systems are highly modular with components fitting into one sterilizing basket of 85mm height (DIN 58952-2) and can be efficiently mounted during surgery. For System B only 5 mounting steps are required.

Conclusion: The suggested modularization approach supports a systematic system design. Using a generic functional structure (step 1) could help to reveal modularization potential, e.g. by using

the drive module of system B as a module of system A and other systems with similar functions and requirements. Eventually, mapping hygienic requirements to functional modules and define design limitations may lead to module separations on the physical side and help to find new so called module drivers (Erixon1998) for modularization from a hygienic perspective.

References:

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Theisgen, Lukas; La Fuente, Matías de; Radermacher, Klaus (2018): Modular design of versatile surgical mini-robots. In Current Directions in Biomedical Engineering 4 (1), pp. 411–414. DOI: 10.1515/cdbme-2018-0098.

P_74

Necessary for the relationship between hospital staff and contractors

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Biography:
CSS (Certified Sterilization Specialist) by JSMI (Japanese Society of Medical Instrumentation)

Introduction: The establishment and maintenance of a good relationship between hospital staff and contractors may be mentioned as an important item in the evaluation of the business level of the central material sterilization room. This time, I will announce the significance and ideas for it based on my experiences.

[Significance of good relationship between contractors and hospital staff]
In japan, there is a medical-related service mark system as a mechanism that shows the ability to perform commissioned work appropriately according to the type of business. However, just because a contractor has received this certification, it does not necessarily mean that the proper business can be completed. In order for a contractor to fully utilize its power, it is essential to build a trusting relationship with the hospital staff who is the contractor. Based on past experience, points necessary for establishing and maintaining a good relationship between hospital staff and contractors. In the past, I was worried about human relations with hospital staff, but now I can maintain good relations and realize my contribution to medical care while working hard.

[What the contractor needs to gain trust in the hospital]
Based on past experience, points necessary for establishing and maintaining a good relationship between hospital staff and contractors.

1. Study session
   Explains how long it takes to recycle the used surgical instrument
   Explanation of the meaning and importance of sterilization assurance
   Explanation of contract between contractor and hospital
   Clarified the part that was only vaguely understood by nurses until now
2. Making materials that quantify the amount of work
   The number of times the sterilizer is operated, the number of times the cleaning machine is operated, and the number of surgical instrument regeneration processes in the central material sterilization room are quantified and reported on a monthly basis.
3. Meeting with central material sterilization room staff
   Meeting is held twice a month.
4. Meeting with surgical staff
   Meeting is held once a month
5. Investigate if there is something you do not understand
   Newly purchased surgical instruments read and respond carefully to the package insert. We will collect information from distributors, manufacturers, washing machine manufacturers, sterilizer manufacturers, etc., and work with the staff at the central material sterilization room to find the best recycling method. Discuss various arrangements with the doctor who uses the surgical instruments in question. When something goes wrong, we always investigate the cause and collect and analyze scientific data. As a result, if necessary, we will review the work content and strive to improve operations.

[At the end]
A good relationship of trust between hospital staff and contracted staff is indispensable for the central material sterilization room to function well. To the end, it is necessary to have good daily communication and each contractor's staff must fully understand the contents and significance of the work.

P_75

Evidence-based practice of safety margin measurement for periodic testing of steam sterilizers

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Biography:
Aiqin Chen is the CSSD manager of Sun Yat-sen University Cancer Center(SYSUCC). She holds a Bachelor of nursing degree from Sun Yat-sen University. She is responsible for the management and technology study of cleaning, disinfection, sterilization and supply of SYSUCC, with 8 years of clinical nurse experience, 7 years of Medical Oncology & Hematology Department management experience, 10 years of CSSD management experience. Her articles were posted on both the 18th and 19th world sterilization congresses.
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Object: Introduce the safety margin into the performance evaluation of steam sterilizer for quantitative analysis.

Method: Determine the safety margin of 4 critical variables and overall sterilization process, based on physical measurements of a specified number of test runs of identical sterilization program on the same sterilizer. Further the mean value and 95% reference range of each safety margin are calculated, namely sterilization variable safety margin (SVSM) and sterilization process safety margin(SPSM). The correlation between 4 SVSMs and SPSM were defined.

Results: Mean value of them are 89.88% (SVSM of Equilibration time), 73.25% (SVSM of sterilization temperature band), 76.01% (SVSM of holding time), 83.41%(SVSM of temperature uniformity) and 73.09% (SPSM). The 95% reference range of them are 76.88-102.88(SVSM of Equilibration time), 70.99-75.51(SVSM of sterilization temperature band), 73.70-78.33(SVSM of holding time), 72.60-94.22(SVSM of temperature uniformity) and 70.58-75.61(SPSM). The coefficient of variation of them are 7.38(SVSM of Equilibration time), 1.57(SVSM of sterilization temperature band), 1.55(SVSM of holding time), 6.61(SVSM of temperature uniformity) and 1.76(SPSM).

Conclusion: The quality of sterilization process can be quantified by introducing safety margin concept. During routine sterilization practice in the CSSD where this study was conducted, more prospective settings for the quality management guideline of pack inspection, utility inspection, and sterilization loading control etc. can be implemented by referring to SPSM indicator in order to minimize the occurrence of sterilization failure.

Description of the discreteness of each safety margin

Table 1 Description of the discreteness of each safety margin

	Equilibrium Time Safety Margin (%)	Sterilization Temperature Range Safety Margin (%)	Duration Safety Margin (%)	Temperature Uniformity Safety Margin (%)	Sterilization Process Safety Margin (%)
Mean value	89.88	73.25	76.01	83.41	73.09
Standard deviation	6.63	1.15	1.18	5.51	1.29
Range	26.67	2.08	3.89	21	5.33
Variable coefficient	7.38	1.57	1.55	6.61	1.76
Reference range (95%)	76.88-102.88	70.99-75.51	73.70-78.33	72.60-94.22	70.58-75.61

P_76

How to avoid pitting corrosion on surgical instruments?

Ina Haacke[1], **Delphine Haase[1]**, Matthias Tschoerner[1], Karina Wesemann[1]
[1]Chemische Fabrik Dr. Weigert Gmbh & Co. KG, Hamburg, Germany

Biography:
Delphine Haase, Applications Engineering neodisher

A damage which is often seen on surgical instruments is corrosion on stainless steel surfaces. The cause could be the used water for reprocessing, physiological saline solution, rests of blood or other ingredients containing chlorides remaining on surgical instruments.

The praxis of wet disposal is frequently used for the transport of the used instruments from the place of use to the central department for decontamination, control/maintenance, packing and sterilization. For this purpose, an appropriate foam spray may be applied to the instruments after the end of the surgeries.

However, the wet disposal increases the risk of corrosion due to damp conditions during longer periods.

A foam spray with corrosion stop and a self-acting pre-cleaning can be used to avoid this problem. Several foam sprays from the field have been tested for their corrosion inhibition properties according to standard laboratory methods and to a publication of the Working Group Instrument Preparation (AKI) [1]. Here, the sprays were applied alone and in a mixture with sodium chloride or blood on test plates made of stainless steel.

The results show very different outcomes for the corrosion inhibition performance of the tested foam sprays. One foam spray with new technology shows respectable corrosion inhibition properties in the presence of physiological saline solution.

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P_77

ATP, easy as 1, 2, 3

Paul Caesar[1]
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Biography:
Since 1991 I am working as an infection control practitioner (ICP) in the field of infection control in hospitals. Mainly in large teaching hospitals and a university medical centre but also in dentistry. I also did some projects on infection control in Tanzania.
Since an outbreak of M. chelonei in a hospital, due to inadequate working automated endoscope washers in 1992, I did some research on reprocessing flexible endoscopes and building on experience on risks due to the use flexible endoscopes and their reprocessing. As expert on medical devices and reprocessing endoscopes, I also give lectures on this subject, and developed an course on cleaning and disinfection of flexible endoscopes for hospital care workers working in reprocessing medical devices. Did a lot of audits on reprocessing flexible endoscopes and some consultancies. I've developed on of the two main education programs for infection control practitioners in the Netherlands and still am a guest lecturer in this program. I am chair of the Dutch Platform of Endoscope (reprocessing) Experts. Nowadays I'm working in a teaching hospital and in an organization of nursing homes, bridging the infection control gap between them.

Aim: The purpose of this study was to evaluate the use of a simple and easy to use test like Adenosine TriPhosphate (ATP) bioluminescence, as a daily quality marker in controlling the cleanliness of FES after reprocessing and prior to subsequent patients.

Methods: In 2 hospitals (M, T) ATP bioluminescence was performed using the HYGIENA Sure Plus System®, using Ultrasnap swabs and Channel Testing Sponges (Ø 4mm; Ruhof®), conform manufacturer´s IFU and instruction.
In hospital M ATP swabs and microbial samples of 30 patient used duodenoscopes (Olympus TJF-160VR) were taken of all channels after 1) manual cleaning and finishing an EWD cycle, or 2) after this process followed by a drying stage (complete reprocessing, CRP). ATP swabs of 92 patient used FES in hospital T were taken from the biopsy channel after CRP. A new introduced duodenoscope (Pentax ED34-i10T2, with a single patient use sterile disposable elevator cap (DEC™) was monitored by ATP and microbial samples from the biopsy channel and tip after patient use and CRP. ATP results were defined in Relative Light Units (RLU).
Cut off values were based on findings from different hospitals and earlier studies. FES were regarded clean if ATP results were 0-50 RLU after the manual and EWD stage, or <15 RLU after CRP (passed)
Microbial samples were taken from the tip of the FES (swab) or by filling and flushing channels (0,9% Sodium Chloride (NaCl); 10 ml/biopsy channel). All samples were determined conform local laboratory protocols.
Cut off value for a microbial clean FES was based on the nationwide accepted Professional Standard Handbook on Endoscope Cleaning and Disinfection (SFERD) when results of samples from a channel were < 20 CFU/20ml, or when no growth was detected from the swab of the tip.

Conclusion: Although there were some slight differences in outcome of RLU in duodenoscopes in hospital T and M, our total number of results confirms the outcome of other studies on using ATP as a simple tool to demonstrate the cleanliness of FES. Based on our results we recommend implementing ATP testing after CRP, prior to an endoscopic procedure as a reliable, standard, routine - 'easy as 1, 2, 3' - tool for controlling cleanliness of FES. Introducing this, quality in reprocessing FES can be improved for only a few euros (or dollars) more, providing more safety for every patient undergoing an endoscopy.

NB Medeauteur: M van Ark

P_78

How clean is your manual cleaning process? Do you know?

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Biography:
Ms Norlidah Othman is a Nurse Unit Manager of Epworth Richmond Hospital Melbourne, Australia. She received her Nursing Degree from the University of Southern Queensland, Australia and her Master in Health Administration from Monash University, Australia.
She started as a qualified perioperative registered nurse from Singapore in 1984 and continued to progress in her career as CSSD Manager overseeing Parkway Healthcare CSSD (Gleneagles and Mt Elizabeth), Singapore, from year 2000 to 2005. She was one of the key people in the planning of offsite Supercenter CSSD in 2003.
In late 2005, she relocated to Melbourne when she was headhunted by Royal Melbourne Hospital to manage the CSSD department. Between 2013 and 2014 she was involved in researching evidence-based processes for CSSD in collaboration with Infection and Prevention Department in Monash Health. The studies were published in the American Journal of Infection. She also currently an experienced teacher and assessor for the last 10 years with various Registered Training Organisation mainly teaching Sterilisation, Nursing and Health Allied courses.

Using UV marking (fluorescent liquid) can demonstrate cleaning process required and increase the understanding of the manual cleaning by the CSSD technicians.

Introduction: Effective manual cleaning is integral for successful disinfection and sterilisation. Human intervention is imperative in this manual process. 1-2

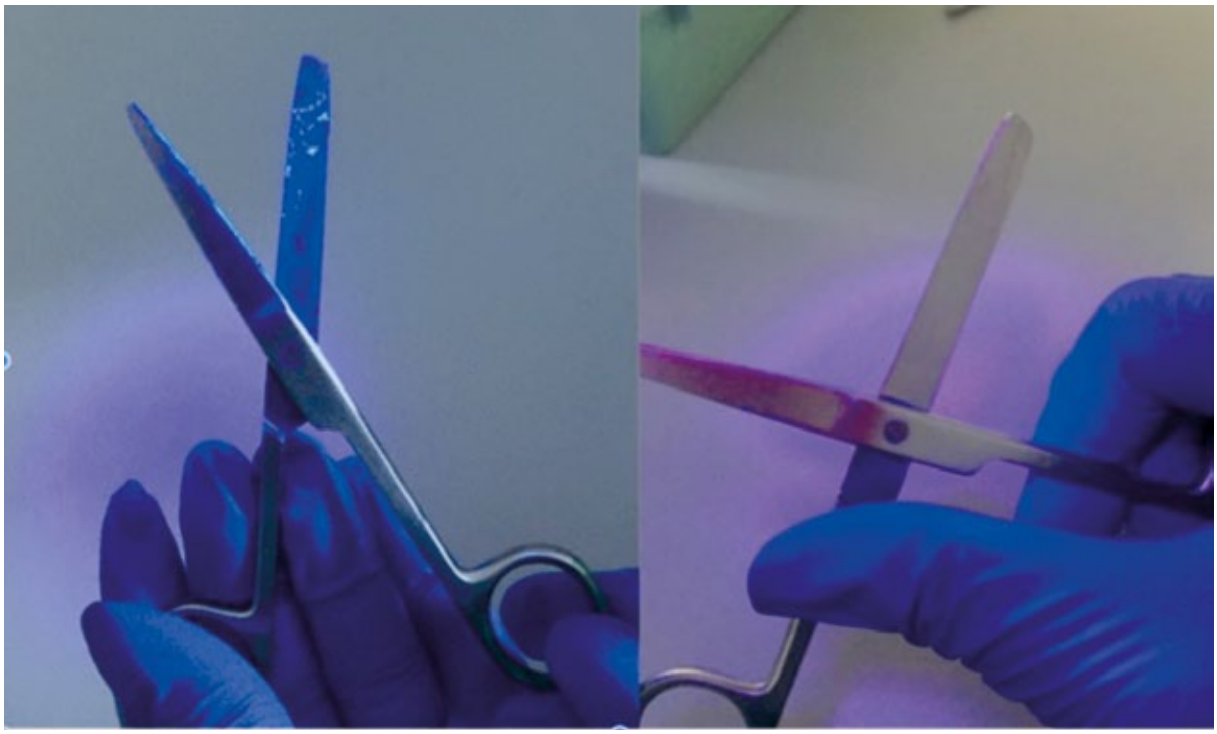
Aim: Providing visual evidence for the instrument technician performing this task to demonstrate easily the missed areas especially grooves and hinges.

Methods:
- Use 0.1ml fluorescent liquid marker. Rub the liquid on to the surface of the instrument.
- Twenty-three technicians participated in the test of their competency in manual washing of a random instrument.
- After the instrument was washed and dried, it was reviewed under the ultraviolet torch light. The ultraviolet light demonstrate if the instruments had been cleaned thoroughly by the removal of all the fluorescent liquid.

This method followed a simple study conducted on non-lumen endoscope published previously.

Results: Of 23 technicians, only 5 succeeded in removing the fluorescent marker completely.
Conclusion: This simple method to check competency and can be easily used to improve accountability and commitment to achieve excellence in CSSD. Designed as an education awareness tool.

Left- After manual cleaning with residue of fluorescent fluid.
Right - After manual cleaning and completely free from fluorescent fluid.



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