wfhss
World Federation for Hospital Sterilisation Sciences

24TH WFHSS CONGRESS BRUSSELS

18-21 OCTOBER 2023

SCIENTIFIC PROGRAM

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WELCOME MESSAGE

Brussels, the capital of Europe and Belgium, will be the capital of sterilisation during the 24th WFHSS Congress.

The committees of the WFHSS, ASTER and VSZ invite you to discover the technological and scientific novelties, to exchange our practices and our ecological vision and to share our expertise during the scientific conferences and the exchanges within the exhibition space of the numerous and faithful industrialists.

Our congress will be exciting, enriching, friendly, welcoming and delicious... Belgian!

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24TH WFHSS CONGRESS

BRUSSELS

18-21 OCTOBER 2023

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24TH WFHSS CONGRESS BRUSSELS

wfhss World Federation for Hospital Sterilisation Sciences

19th OCTOBER 2023 Thursday

12:30 14:00 CET

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Championing **Safety** and **Sustainability** in Medical Device **Reprocessing**: Advancing Sterilization and Endoscopy Departments.

SYMPOSIUM Agenda

Introduce • Topic & Presenters
12:30h // 12:35h

Staying Safe and Outsmarting Infection: 2023 Review of Bacterial Resistance & Biofilm Formation

Healthcare Associated Infection & Antibiotic Resistance pose a major safety challenge to patients and hospital staff. This lecture will provide a review of what Sterilization Personnel should know about the state of HAIs in 2023 including the tactics organisms use to evade safety measures. These include the formation of biofilms and how bacteria evade antibiotic therapy. Armed with this information, the lecture will provide science-based recommendations for Sterilization Personnel on how they can safeguard patients, medical equipment, and themselves.

Ivan Salgo MD, MS, MBA | Chief Medical & Scientific Officer, ASP _____ 12:35h // 12:55h

Using evidence to build a high performance sterilization and HLD program

This lecture will present evidence, including case studies, to highlight factors that impact HLD and Sterilization department performance with respect to endoscope reprocessing in particular. Other areas of focus will include sharing best practices to improve quality and drive high performance in a reprocessing department, discussing the move toward sterilization, and developing benchmarks on how to adequately train and staff the department in order to elevate safety and drive down reprocessing failures.

Cori Ofstead, MSPH | CEO at Ofstead & Associates, Inc. _____ 12:55h // 13:15h
Frank Daniels, MSHA, MPH | MSHADirector, High-Level Disinfection & Sterilization at Virginia Commonwealth University

Sustainability and Economic considerations behind Medical Device reprocessing technologies

When considering which sterilizer is right for a particular setting, there is more to think about than the up-front costs of the sterilizer system itself. A comprehensive evaluation should assess longer-term costs and benefits of different options, including environmental considerations, in different settings. This presentation will cover an overview of climate considerations and carbon emissions healthcare, an introduction to health economic evaluation concepts, factors related to the sterilizer system, the instruments/devices being sterilizer and wrap up with how to use these concepts to evaluate different products.

Victoria McCreanor, MS, PhD | Hunter Medical Research Institute _____ 13:15h // 13:35h

Q&A Session _____ 13:35h // 13:50h

Conclusions _____ 13:50h // 14:00h

AD-230105-01-CT_A-MDR

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WEDNESDAY 18 OCTOBER

15.00 - 18.00	OPENING OF THE REGISTRATION AND EXHIBITION
	PLENARY ROOM - GOLD HALL
18.00 - 19.00	WELCOME CEREMONY
19.00 - 20.30	WELCOME RECEPTION IN THE EXHIBITION AREA

THURSDAY 19 OCTOBER

07.45 - 08.30	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION
	PLENARY ROOM - GOLD HALL
08.30 - 08.45	CONGRESS INTRODUCTION
08.45 - 10.30	**SESSION 1 - THE HORIZON OF THE FUTURE** *Moderators: David Bellamy and Christophe Lambert*
08.45 - 09.30	CONFERENCE 1 🇫🇷 **Revolutionizing Hospital Sterilization: Harnessing AI, Industrial Insights and Digital Transformation** *Paul Vanabelle (Belgium)*
09.30 - 10.00	CONFERENCE 2 🇬🇧 **The Power of Automation and State of the Art Technology to promote staff safety & efficiency** *Anita Cassell, Arlex Matulac (United States)*
10.00 - 10.30	CONFERENCE 3 🇬🇧 **Safety, cost and environmental effects of reprocessing single use medical devices: systematic review and meta-analysis** *Niamh Mcgrath (Ireland)*
10.30 - 11.00	COFFEE BREAK & VISIT EXHIBITION
11.00 - 12.30	**SESSION 2 - FLEXIBLE ENDOSCOPY** *Moderators: Harry Oussoren and Thomas Onsea*
11.00 - 11.45	CONFERENCE 4 🇫🇷 **Results of the study on the comparison of endoscope sampling and culturing methods** *Lionel Pineau (France)*
11.45 - 12.30	CONFERENCE 5 🇫🇷 **Automation to battle current endoscope reprocessing issues and missing field knowledge** *Martina Pinilla (Belgium)*

12.30 - 14.00	LUNCH - POSTERS AND EXHIBITION

	COPPER HALL	SILVER HALL	HALL 100	THE ARC
12.30 - 13.10	ASP Advanced Sterilization Products	MMM Group	matachana	Steelco
13.20 - 14.00		B BRAUN SHARING EXPERTISE	Honjo	GETINGE PASSION FOR LIFE

	PLENARY ROOM - GOLD HALL
14.00 - 15.30	**SESSION 3 - GREEN** *Moderators: Patricia Gutierrez and Krist Henrotin*
14.00 - 14.30	**CONFERENCE 6** **Green speeddating - Circular economy principles applied in the hospital - reduce medical waste** *Corinne Riekwel, Bart van Straten, Ron Op De Weegh and Joost van der Sijp (The Netherlands)*
14.30 - 15.00	**CONFERENCE 7** **Hygiene safety and resource savings in automated cleaning - A contradiction?** *Matthias Tschoerner (Germany)*
15.00 - 15.30	**CONFERENCE 8** **Surgical tray optimalization and standardization** *Mads Granlie (Denmark)*
15.30 - 16.15	COFFEE BREAK & VISIT EXHIBITION

	COPPER HALL	SILVER HALL	HALL 100
15.30 - 16.15	Belimed Infection Control	OLYMPUS	healthmark

	PLENARY ROOM - GOLD HALL
16.15 - 17.45	**SESSION 4 - CLEANING AND DISINFECTION** *Moderators: Christine Delebecque and Anja Huysmans*
16.15 - 16.45	**CONFERENCE 9** **Reprocessing dental handpieces : an hope for all and dental practices?** *Mireille Ferlita (France)*
16.45 - 17.15	**CONFERENCE 10** **Evaluation of a UVC-LED device for disinfection of medical instruments** *Hannah Siwe (Belgium)*
17.15 - 17.45	**CONFERENCE 11** **Influence of sodium bicarbonate pretreatment on final cleaning performance in a washer-disinfector** *Christophe Lambert (France)*

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FRIDAY 20 OCTOBER

08.00 - 08.15	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION

	COPPER HALL	SILVER HALL
08.15 - 09.00	KEN HYGIENE SYSTEMS	nanosonics

	PLENARY ROOM - GOLD HALL
09.00 - 10.30	**SESSION 5 - STERILIZATION** *Moderators: Hervé Ney and Sandrine Frédéric*
09.00 - 09.30	CONFERENCE 12 **Hospital Sterilization of 3D Printed Devices** *Randal Eveland (United States)*
09.30 - 10.00	CONFERENCE 13 **Monitoring of Steam sterilisation with PCDs** *Hugh O'Connor (Ireland)*
10.00 - 10.30	CONFERENCE 14 **A study of establishment and evaluation of a risk prediction model for steam sterilization** *Xin Zhao (China)*
10.30 - 11.15	COFFEE BREAK & VISIT EXHIBITION

	COPPER HALL	SILVER HALL
10.30 - 11.15	conf industries	Terragene

	PLENARY ROOM - GOLD HALL
11.15 - 12.45	**SESSION 6 - STANDARDIZATION** *Moderators: Harry Oussoren and Sigurd Vandendriessche*
11.15 - 11.45	CONFERENCE 15 **Dutch market agreement on standardized, automated and global sharing of CSSD information** *Jolanda Buijs, Jolyn van der Beek (The Netherlands)*
11.45 - 12.15	CONFERENCE 16 **Alignment of global medical device standards and their acceptability for regulatory purposes** *Richard Bancroft (United Kingdom)*
12.15 - 12.45	CONFERENCE 17 **ISO 22441 Standard for validation of the H_2O_2 sterilizers explained** *Philippe Destrez (France)*

12.45 - 14.15	LUNCH - POSTERS AND EXHIBITION

	COPPER HALL	SILVER HALL	HALL 100	THE ARC
12.45 - 13.25	STERIS	B|BRAUN SHARING EXPERTISE	Honjo	GETINGE PASSION FOR LIFE
13.35 - 14.15		MMM Group	matachana	Steelco

PLENARY ROOM - GOLD HALL

14.15 - 15.45	**SESSION 7 - QUALITY AND RISK MANAGEMENT** *Moderators: Damien Berg and Fredy Cavin*
14.15 - 14.45	**CONFERENCE 18** **Results of a study of insulation testing practices to improve healthcare facility testing practices and improve patients safety** *Cheron Rojo (United States)*
14.45 - 15.15	**CONFERENCE 19** **Surgical Instrument traceability in sterilization: legal obligation or necessity?** *David De Baets (Belgium)*
15.15 - 15.45	**CONFERENCE 20** **Patient safety through development of a surgical instrument tracking system with RFID** *Chankyung Park (Seoul)*
15.45 - 16.30	POSTER AWARDS SESSION
16.30 - 17.15	COFFEE BREAK & VISIT EXHIBITION
	CONGRESS DINNER

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Save the date

Thursday, Oct. 19th, 12:30 – 13:10
Satellite Symposium 1, ARC Room, Level 3
Focus on "Processes & Performance" in instrument reprocessing

Friday, Oct. 20th, 13:20 – 14:00 – ARC Room, Level 3
Satellite Symposium 2, ARC Room, Level 3
Focus on "People & Environment" in instrument reprocessing

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SATURDAY 21 OCTOBER

08.00 - 09.00	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION
	PLENARY ROOM - GOLD HALL
09.00 - 10.30	**SESSION 8 - RUMED DEPARTMENT** *Moderators: Carolina Chiodini and Wouter Meert*
09.00 - 09.30	**CONFERENCE 21** **Sterilization risk management in developing countries** *Hamid Zare Shah Mers (Iran)*
09.30 - 10.00	**CONFERENCE 22** **The development of the sterile processing profession through the years in Mexico and LATAM** *Livia Senties Zuniga (Mexico)*
10.00 - 10.30	**CONFERENCE 23** **Mental health in the department; lessons learned from the global pandemic** *Roel Beltran Castillo (Australia)*
10.30 - 11.00	**COFFEE BREAK & VISIT EXHIBITION**
11.00 - 12.00	**SESSION 9 - MASTERS OF DISASTERS** *Moderators: Tillo Miorini and Ines Harzallah*
11.00 - 11.30	**CONFERENCE 24** **How long does it take to build a humanitarian CSSD** *Bart Debeir (Turkije)*
11.30 - 12.00	**CONFERENCE 25** **Rebuilding a CSSD after a disaster** *Ali Hacchem (Lebanon)*
12.00 - 12.45	**FLAG CEREMONY**
	END OF THE CONGRESS

CONFERENCE 1
THE HORIZON OF THE FUTURE

REVOLUTIONIZING HOSPITAL STERILIZATION: HARNESSING AI, INDUSTRIAL INSIGHTS AND DIGITAL TRANSFORMATION

P. Vanabelle
(Belgium)

AIM

The objective of the presentation is to explore the possibilities of integrating artificial intelligence (AI) into the hospital sterilization process using methodologies used in the industry.

METHODS

The sterilization process can be compared to many other processes found in the industry. In this area, the potential for using AI is revealed as part of a digital transformation process and in the establishment of action plans and digital roadmaps. The benefits and tools used to achieve this will be discussed. Some of these tools will be presented as well as how they introduce AI.
Artificial intelligence itself will be introduced. We will try to demystify this trendy topic and view it as a toolkit that will benefit operational excellence in and around the sterilization process. We will also see its implication in digital technologies that shape the industry of the future.

RESULTS

A series of use cases leveraging AI to improve operational excellence in hospital sterilization will be presented. These use cases are inspired by recent works and researches directly related to hospital sterilization or by similar experiences in the industry. Among them, we will present a digital twin for strategic, tactical and operational purposes, advanced techniques to accelerate the reconditioning stage, predictive maintenance of technological assets or even optimization of the extended sterilization supply chain.

CONCLUSIONS

In conclusion, hospital sterilization is similar to an industrial process and can benefit from good practices implemented in terms of operational excellence, digital transformation and use of AI. We show that there is numerous examples of AI-driven improvements that can be applied to hospital sterilization.

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Belimed Symposium
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Thursday, October 19
3:30 pm to 4:15 pm
in Copper Hall

- Planning and Design
- Washer-Disinfectors and Sterilizers
- Consumables
- Services
- Digitalization
- Training and Education

CONFERENCE 2
THE HORIZON OF THE FUTURE

THE POWER OF AUTOMATION AND STATE OF THE ART TECHNOLOGY TO PROMOTE STAFF SAFETY & EFFICIENCY

A. Cassell / A. Matulac / D. Connelly
Rwjbamabas Health - New Brunswick (United States of America)

AIM

Efficiency and staff safety are two very important aspects of a successful sterilization department. This study will look at contributing metrics from one hospital's antiquated sterilization department compared to its new, state-of-the-art department, specifically looking at the impact that the role of automation in technology plays on these areas.

METHODS

Data was collected using anonymous standardized surveys, retrospective review and direct observation using uniform audit tools for the following metrics: Trays processed per person per day, tray time in wash cycle, percent of trays being ultra-sonic cleaned, staff satisfaction, and staff safety as determined by leave of absence due to workplace injury. A two-year data collection period occurred for the «old» sterilization department, while a six-month collection period occurred for the «new» sterilization department`.

RESULTS

During this thirty-month data collection period, 547,500 trays were audited utilizing the facility's existing electronic instrument tracking system. The results showed that while occupying the «old» sterilization department, a technician completed an average of 16 trays per day, whereas, once in the «new» space, a technician completed an average of 25 trays per day; a 36% increase in productivity. This same tray audit revealed that in a given six-month period, on average, the «old» department was able to ultra-sonic clean 27,300 trays, or 30% of the total tray volume. Comparatively, the «new» department was able to ultra-sonic clean 72,800 trays in a six-month period, or 80% of the total tray volume for that period.
Additionally, this same tray audit demonstrated that the «old» department had an average tray wash cycle time of 35 minutes, compared to the «new» department, which had an average tray wash cycle time of 15 minutes, a 57% reduction intime. 158 surveys were collected, 12 removed, showed an overall 15% increase in staff satisfaction when looking at the questions: «how satisfied are you with your job;» «do you feel you have the necessary resources to complete your job;» and «how likely are you to recommend this institution?» During the two-year collection period in the «old» department, 2,190 days of work were missed because of leave of absence due to reported work place injury, or an average of three employees per day. In the six months of data collection in the «new» department, zero days ofwork have been missed because ofleave of absence due to reported work place injury; a 100% reduction.

CONCLUSIONS

It is apparent that the antiquated «old» sterilization department, consisting of Jess than 7,000 square feet ofworkspace was significantly Jess efficient than the «new,» state-of-the-art sterilization department consisting of more than 20,000 square feet ofworkspace.
Advancements in technology and automation have improved workflow and increased productivity, while reducing the rigorous impact this type ofwork has on the bodies of the staff. These advancements have also had a positive impact on staff satisfaction. It is necessary to develop more research in this area as this is only the findings of one hospital.

CONFERENCE 3
THE HORIZON OF THE FUTURE

SAFETY, COST AND ENVIRONMENTAL EFFECTS OF REPROCESSING SINGLE USE MEDICAL DEVICES: SYSTEMATIC REVIEW AND META-ANALYSIS

N. Mcgrath[1] / C. Waldron[1] / L. Keshtkar[2] / A.F.A.R.R. Farragher[1] / A. Burns[1] / A. Teahan[1] / J. Long[1]

[1] *Health Research Board - Dublin (Ireland)*
[2] *University Of Leicester - Leicesier (United Kingdom)*

AIM

To estimate the safety, financial costs and environmental impacts of reprocessing of the full spectrum of single use devices (SUDs) studied in the scientific literature, in line with European regulations and related approaches. To determine similarities and differences in the safety, costs and environmental impacts of SUD reprocessing by SUD type.

METHODS

In vitro (laboratory-based) and in vivo (human-based) study designs, carried out in OECD or EU member state countries were eligible for inclusion though only in vivo study designs were analysed following ail phases of the standard systematic review process. Searching was undertaken in four electronic databases and using supplementary search methods between July and September 2023. Title and abstract and full text screening, data extraction, quality appraisal and risk ofbias assessments were each independently completed by two reviewers, with disagreements resolved using consensus. Author conclusions of in-vitro studies were summarised and results of in-vivo studies were analysed using narrative synthesis, and meta analysis where appropriate. Results were reported by Medical Device Coordination Group (MDCG) 2021-24 device risk class.

RESULTS

We identified 33 in vitro studies examining 12 SUDs across five device groups spanning ail MDCG risk classes. Sorne endoscopie and laparoscopie devices (n=3 studies), internai fixator devices (n=l study) and certain cardiac catheter and cannula devices (n=7 studies) were recommended by study authors for reuse testing in humans. We identified 19 in vivo studies examining 16 SUDs across eight device groups spanning ail MDCG risk classes. No additional adverse safety events were reported for reprocessed external fixator devices (n=2 studies), ophthalmic devices (n=l study), endoscopie and laparoscopie devices (n=3 studies), implantable cardiac devices (n=4 studies) or cardiac catheter devices (n=4 studies), with conflicting results reported for major complications of cardiac catheter devices. Of two studies capturing indirect costs related to patient safety, one endoscopie and laparoscopie device study and one cardiac catheter device study each reported that savings were attenuated. The certainty of the evidence for ail primary safety and cost outcomes was very low. One study reported environmental impacts of reprocessing seven devices across risk classes I, Ha and IIb. Reprocessing of the seven devices slightly reduced global warming impacts, with the greatest benefits reported for deep vein thrombosis compression sleeves.

CONCLUSIONS

Overall, there is still insufficient evidence to establish the safety, cost-effectiveness, and environmental impacts ofreusing SUDs, and the amount ofavailable evidence differs by device type. External fixator devices and implantable cardiac devices (pacemakers and defibrillators) appear safe for reuse after at least one reprocessing cycle. However, the certainty in the evidence is very low. Reprocessing results in both direct and indirect cost savings (safety and device life cycle-related), and marginal savings diminish with subsequent reprocessing cycles. The certainty of the evidence for cost outcomes is also very low. SUD reprocessing has the potential to reduce global warming impacts, but may exacerbate human health impacts. High-quality randomised controlled trials, cost effectiveness studies, and environmental studies are needed in order to better understand the safety, costs, and environmental impacts of SUD reprocessing.

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October 19, 2023
13:20 - 14:00, Silver Room

Speaker: Linda Bodewes, Head of Operations, Sterinoord B.V.
Kevin Schröder, Senior Business Development Manager, Aesculap AG

Sustainable opportunities for hospitals – a comparison of sterile barrier systems

October 20, 2023
12:45 - 13:25, Silver Room

Speaker: Else de Ridder, Founder, Green Care Academy
Christian Nufer, Product Manager Sterile Technology, Aesculap AG

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CONFERENCE 4
FLEXIBLE ENDOSCOPY

RESULTS OF THE STUDY ON THE COMPARISON OF ENDOSCOPE SAMPLING AND CULTURING METHODS

L. Pineau
(France)

AIM

The objective of this study was to compare the efficacy of duodenoscope sampling and culturing methods recommended in France, Australia, Germany, Netherlands and United States of America (USA) by means of extraction efficacy comparison, while at the same time identifying key parameters that provide optimal microbial recovery.

METHODS

The duodenoscope sample extraction efficacy of each method was assessed using Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus as the test organisms along with the repetitive recovery method described in ISO 11737-1: 2018

RESULTS

The results obtained indicated mean overall bioburden extraction efficacy rates of 39%, 31%, 24%, 29%, 12% and 1% for the French, USA filtration, USA centrifugation, German, Dutch and Australian methods, respectively.

CONCLUSIONS

This study supports the need for a harmonized and standardized sampling and culturing method for flexible endoscopes, addressing main key factors that may influence the efficacy of the sampling and culturing method.

CONFERENCE 5
FLEXIBLE ENDOSCOPY

CASE CHIREC HOSPITAL: AUTOMATION TO BATTLE CURRENT ENDOSCOPE REPROCESSING ISSUES AND MISSING FIELD KNOWLEDGE

M. Pinilla[1] / F. Cattoor[2] / A. Denidder[3]

[1] *Head Nurse Endoscopy-Chirec - Brussels (Belgium)*
[2] *Hospital Hygienist-Chirec - Brussels (Belgium)*
[3] *Pharmacist-Chirec - Brussels (Belgium)*

AIM

Recent study shows that appropriate manual cleaning of endoscopes reduces the number of microorganisms and organic Joad by 4-6 LOGS or 99,99%. (Puri 2017) This proves that HLD can only be reached with a decent pre-cleaning as this avoids the formation ofbiofilm. It's a complex and time-consuming job but essential in the cleaning process. If it's not clean, it cannot be made sterile. Still, several other studies show that the present reprocessing and process control procedures are often not adequate and safe.
One of the main reasons is the failing education of the staff, research claims. (Knight 2021) Both time-issues and the Jack of correct knowledge leads to current problematics conceming endoscopie infections. Manual cleaning is generally effective but difficult to control in practice. Hospital Chirec in Brussels bas made a comparison of the manual processes commonly used in hospitals to a semi-automated process.

METHODS

Hospital Chirec bas build «the center of excellence». A department that bas integrated automated cleaning solutions to optimize todays endoscope reprocessing game. Question now is: how have our work dynamics changed ever since?
Used tools:
1. Automated pre-cleaning / 2. Pass Through WD / 3. Drying cabinets / 4. Traceability

RESULTS

The preceived benefits of integrating automated solutions can be divided into the following points:

1 / Employee

Lower stress levels: increased work-comfort and time-management. Less staff needed.
c) Education: the user is easily guided through the entire cleaning & disinfection procedures. With ail devices easily communicating with each other, full traceability is also guaranteed.
d) E-leaming is integrated in the systems.

2 / Patient safety

Reduced contamination risk. Specifically, regarding the pre-cleaning:
Every (previously) manual cleaning step in the sink, is now performed automatically through a rigid software program. Because it is an automated, fixed program there is a certainty that ail steps are correctly performed procedure after procedure. Identically the same essentials steps automatically reoccur.
Recent white paper «DEMONSTRATING THE EFFECTIVENESS OF A SEMI AUTOMATED PRE-CLEANING PROCESS FOR FLEXIBLE ENDOSCOPES». shows
astonishing results after the integration of automated solutions. Therefore also being a topic we absolutely wish to cover during the oral presentation.

3 / Endoscopes

Less damage to the endoscopes was observed. Two main reasons:
- Leakage test is performed on a dry surface and full leakage test timing is respected. Also, the layer of the pre-cleaning device will not go down in case of found leakages, preventing even more internai damage.
- Full length of the endoscope is covered during pre-cleaning.

CONCLUSIONS

The integration of automated cleaning equipment not only benefits personnel but can also provide a great solution to the current contamination problem. Adequate pre-cleaning is of the utmost importance to achieve a safe, process-ready endoscope. Processes that achieve that goal are efficient and effective and can be widely implemented without much effort. A best practice example to be followed? Open for discussion.

REFERENCES / ACKNOWLEDGEMENTS

Puri P (2017) Hospital Infection Control Endoscopy, www.infectiousdiseaseadvisor.com/home/decision-support-in medicine/hospitalinfectioncontrol/endoscopy/?
fbclid=Iw AR08j9zWfBOPTbrORKWePHj72M6tx1cXiS4w0dKOF zNh8wn6TyBtna9OwEA#:-:text=Endoscopy related infections occur endogenously, from endoscopy personnel to patients Knight A (2019) Outpatient Surgery, https://www.aorn.org/outpatient-surgery/articles/enews-briefs/may-6 2021? utm_content=165756196&utm _medium=social&utm_source=linkedin&hss_ch annel=lcp- 464485#story

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CONFERENCE 6
QREEN

CIRCULAR ECONOMY PRINCIPLES APPLIED IN HOSPITALS TO REDUCE MEDICAL WASTE STREAMS

B. Van Straten, Dr.[1] / T.H.O.R. Horeman, Dr.[1] / C. Riekwel[2] / J. Van Der Sijp, Dr.[3]

[1] *Delft University OfTechnology - Delft (Netherlands)*
[2] *Delft University OfTechnology - Rolterdam (Netherlands)*
[3] *Delft University Of Technology - The Hague (Netherlands)*

AIM

The aim of our research is to set-up circular economy principles to reduce waste. Essential in this process is to work together with intrinsically motivated teams. Experiments were conducted to harvest different types of surgical waste and to reprocess it into new raw material and new medical devices.

METHODS

Four waste streams consisting ofpolypropylene wrapping paper, PET packaging, disposable instruments and surgical devices were collected from the Maasstad Hospital and HMC. A procedure was developed to safely collect and melt the waste streams. The influence of reprocessing methods was determined by a controlled tension test setup. A logistical and decontamination process was structured in the GreenCycl FieldLab to disinfect and reprocess the waste streams into raw material. A series ofproducts were made from the waste. Furthermore, gas and water, recovered from the CSSD were investigated with the perspective of making gas and water flows circular.

RESULTS

The logistical process for recycling medical waste consisted ofbags and containers which were transported. After arrivai the waste streams were disinfected using thermal disinfection machines and reprocessed by means ofmelting and granulation. The energy devices were disassembled after disinfection. The plastic waste was injection molded into new medical products. The material properties of ail four harvested waste streams are suitable to make new products. The strength until break of the reprocessed PP blue wrap was 37 MPa and 41 MPa for the PET. A set-up was made to recover gas and water from the thermal disinfectors, creating a buffer reservoir with the aim to reuse hot water for other purposes.

CONCLUSIONS

A safe and affordable process for collecting, disinfecting and reprocessing of medical waste is possible for multiple waste streams. The process was effective in disinfecting contaminated waste. The quality of injection molded products made from 100% recycled blue wrap and PET packaging is similar to ones made from 100% virgin. New products made from recycled medical waste can be used on the CSSD under the MDR regulation. Furthermore, collecting gas and heated water from the CSSD seems to have potential to reuse energy in a circular way.

REFERENCES / ACKNOWLEDGEMENTS

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CONFERENCE 7
GREEN

HYGIENE SAFETY AND RESOURCE SAVINGS IN AUTOMATED CLEANING - A CONTRADICTION?

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Chemische Fabrik Dr. Weigert Gmbh & Co. Kg - Hamburg (Germany)

AIM

The protection of our environment and the responsible use of resources are gaining increasing attention these days. Especially in the face of the current geopolitical situation, this is a particular challenge of great importance.
Innovative developments can contribute to environmentally friendly and resource-saving applications through increased efficiency. Modern cleaning processes can be one footstep that enables the savings potential to be passed on directly into routine.
The potential for saving resources in automated cleaning processes results on the one hand directly in reduced consumption of electricity, and on the other hand indirectly through shorter runtimes.

METHODS

New cleaning procedures enable it, for example, to lower the temperature in the automated cleaning stage by up to 20 °C from the 55 °C often used. In this case, the process chemistry will be dosed immediately after the water inlet at low temperatures without any disadvantageous foaming, exclusion of protein coagulation and indirect prolonged the effective cleaning time. This makes it possible to shorten the holding time from e.g. 10 min to 5 min, which significantly reduces both the process time and the energy consumption per batch.
Thus, opens up new possibilities for designing the process variables of a procedure for saving resources.
The prerequisite for the design of such resource-saving procedures is in full compliance with the hygienic requirements resulting from the regulatory and normative [1, 2] specifications and the recommendations of the professional societies.

RESULTS

In practical application, with a modern procedure for instrument processing in a standard washer-disinfector (15 DIN instrument trays), the power consumption could be reduced by up to 30 %, the water consumption by up to 20 %, and the batch time by up to 30 % in one batch compared to the previously used standard procedure.
For a medium-sized sterile processing department with 4 washer-disinfectors (WD) in 1- shift operation over 8 h and an assumed capacity of 8000 WD batches per year, this results in a significant savings potential as approx. 16,000 kWh of electricity. In addition to annual cost savings of several thousand euros in electricity also a significant increase in the WD capacity and water savings can be achieved in this way.
Examples ofresidual protein measurments are given to show that it is certainly possible to meet the hygienic requirements in practice with modem resource-saving procedures.

CONCLUSIONS

Improved performance characteristics ofprocess chemicals make it possible to modify machine processes beyond the established cleaning procedures and still ensure compliance with the required hygiene standards.
Applied innovative cleaning processes make it possible to optimise acknowledged standard procedures in instrument processing without having a detrimental effect on hygiene and patient safety.
The achieved small dosing quantities also reduce both the transport and storage costs and the consumption of resources in the production, packaging and transport of the process chemicals.

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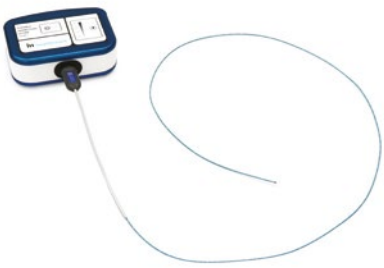

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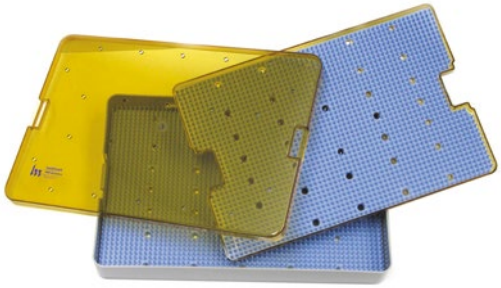

CONFERENCE 8
QREEN

SURQICAL INSTRUMENT TRAY OPTIMIZATION AND STANDARDIZATION AT A LARQE UNIVERSITY HOSPITAL

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AIM

The aim of this study is to describe the result of a surgical instrument tray optimization process across ail surgical departments in the largest University Hospital in xxx.

METHODS

This study was designed as a case study where data was extracted from an instrument optimization process covering ail Operating Rooms (ORs), and data from the Central Sterile Supply Departments (CSSD) production at xxx. The optimization process was based on a holistic view where instrument trays were aligned across surgical specialties. The optimization process consisted of a) Reduction in number of instruments. b) Consolidation or separation, where trays were divided or merged. c). Modulization, where modular trays for specific purposes were added, and d) Standardization, where commonly used instruments were standardized across all surgical specialties at the hospital.
Data was statistically processed and is presented in an overview of instruments and trays before and after the instrument optimization process. Workload was defined as average number of instruments processed in the CSSD per operation A linear regression comparing workload before and after the intervention was carried out for three ORs.

RESULTS

As presented in Table 1, the average reduction in unique instruments across the hospital was 31% (19%-55%). Sorne disciplines made significant changes to their tray structures, while others primarily reduced the number of instruments in their existing trays. The total number oftrays increased by 8%, however the reduction in total number of instruments was 15%.
Reduction in workload in the CSSD was calculated based on data from gynecology, urology, and obstetrics/ pediatrics. This amounted in a reduction in workload between 9,5% to 12.2%, none ofwhich were statistically significant.

CONCLUSIONS

This study underlines the complexity of instrument tray design, where no research to date have shown how a reduced usage of instruments can be ensured across all surgical departments at a large University Hospital. The approach combining methods used at xxx showed how interdisciplinary groups of experts in an iterative design process made it possible to redesign instrument trays with a significant reduction as a result. Furthermore, the data suggests that it is possible to convert the reduction of instruments per tray and across several surgical disciplines into a reduction in workload in the CSSD. Thus, it provided opportunity to decrease wasted resources cleaning unused instruments in the CSSD.

CONFERENCE 9
CLEANING AND DISINFECTION

REPROCESSING DENTAL HANDPIECES : AN HOPE FOR ALL AND DENTAL PRACTICES ?

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[2] *Chu De Nantes, Technical Services (France)*

AIM

Our group in partnership with industrial partners, conducted a project aiming at developing a solution enabling our CSSD to wash, disinfect and lubricate 400 dental handpieces (DHP)/d from our Dental Care Center. We won the specialjury award at the 2018 SFSS conference and an innovation award in our hospital in 2021. Since 5 years this special washer/disinfector (WD) is able to efficiently reprocess the internai and extemal surfaces. We wish to share our experience with others professionals who stmggle to improve DHP washing, disinfection and lubrication.

METHODS

Hospital must comply with regulatory standards in operational and performance Qualifications. Internai and extemal soiling tests must be done on a regular basis. The qualification tests must also indicate the absence ofmoisture and the presence of traces of lubrication. We think about loading and unloading DHP : it must be done with minimal efforts. It was a problem when dental market is so poor. In 2013 there was no WD with 52 DHP with specific connections in a load carrier. To reduce costs, we started with an existing Miele 7882CD WD. This project required multiple skills, knowledge in mechanics, industrial automation and engineering.

RESULTS

In 5 years we developed two identical WD. Every year the compliance in accordance with ISO 15883 standard was achieved for TD Vario cycle (55°C - 5 min; 93°C 5 min), items of cleaning , disinfection drying and also lubrification. The cleaning products and their concentration are identical to our others WD. The cycle lasts 1h30. Tt is performed 6 cycles/d [6 am -21 pm]. Traceability is done by the supervision software and the WD ticket. 315 PIDs are processed on average/d [52-478]. After sterilization, no soi! is found. Usual technical problems have occurred. There were few reports of lubrication defects. 60 Sterilization operators have been trained and use the WD with satisfaction and without additional manipulations. The cycle lasts 1h30. It is performed 4 cycles/d.

CONCLUSIONS

Few professional are aware that treatment of DHP is difficult and can be dangerous for patients (infection) when it's non-compliant. No lubricate DHP might cause bums to patients. Our «home» solution exists to compensate for a lack of the market. Today, we know that these machines « 4 in I» have proven their efficiency and reliability. But we see areas for improvement (maybe compressed air lubricate installation, time etc). Together _all the professional (dentists, industrials, CSSD) can bring their experience and knowledge to improve the reprocessing of DHP. For this purpose, training of dentist students is also important. The experience of CSSD can provide a new opportunity for ail professionals who want to take care ofDHP. Now, we want to design a new modular machine to satisfy more professionals. We hope re-engaging ourselves in the same collaborative dynamic because collaborative approach works and satisfies users. Together we have to show that more quality is possible to preserve patients health. And you ?

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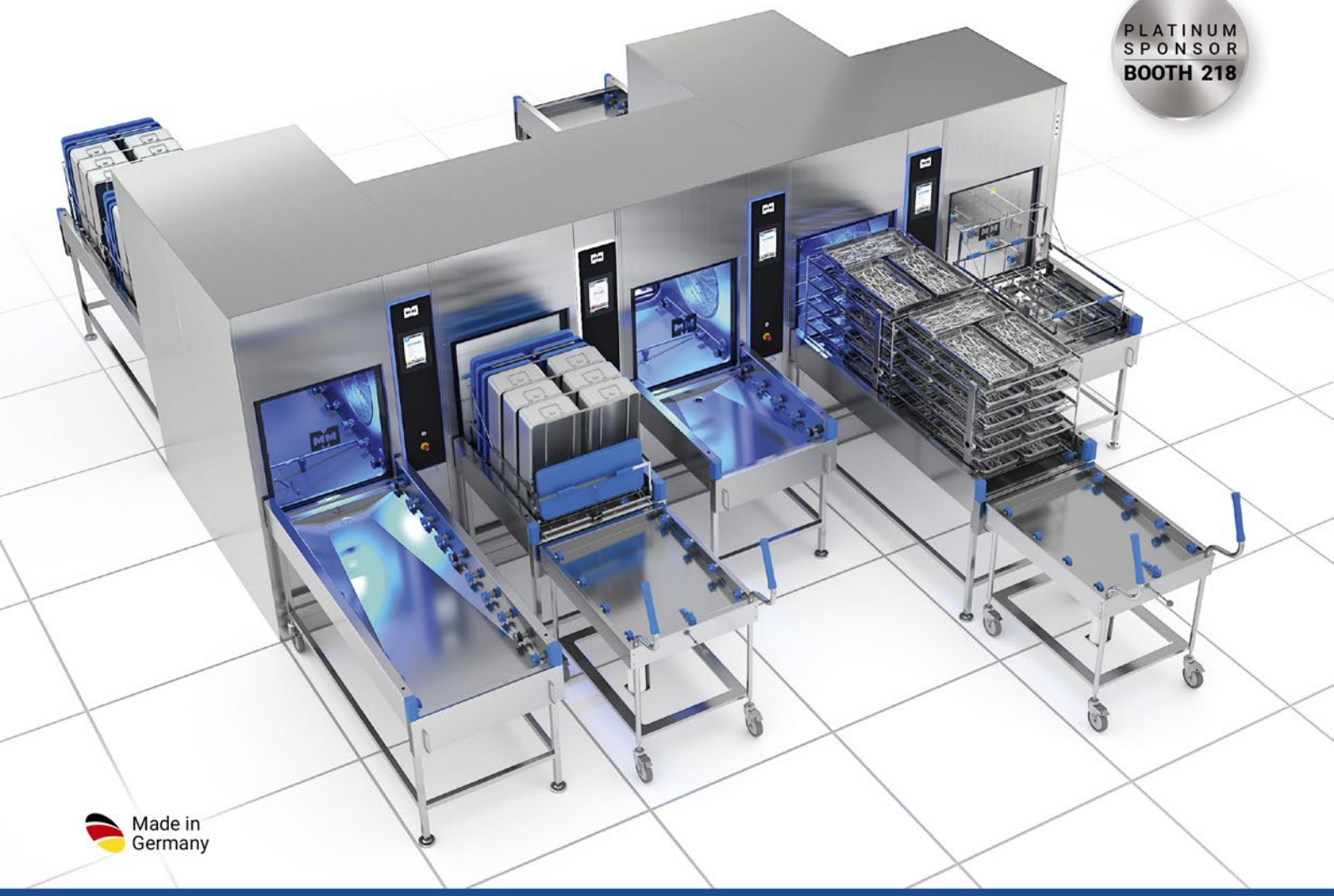

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CONFERENCE 10
CLEANING AND DISINFECTION

EVALUATION OF A UVC-LED DEVICE FOR DISINFECTION OF MEDICAL INSTRUMENTS

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AIM

Infection prevention and contrai is an important discipline to combat nosocomial infections. A variety of methods is available to ensure adequate disinfection of medical instruments. Despite the existence of many reprocessing guidelines and protocols, there are still various limitations and remaining challenges which include error prone manual disinfection, microbial resistance towards biocides, high environmental burden of disinfectant wipes and chemicals, and complex medical instruments for which there is no suitable disinfection solution. Innovative technologies such as UVC disinfection might provide an answer to some of these challenges. Our first objective is to test the efficacy of an ultraviolet C (UVC)-light emitting diode (LED) device for disinfection of a contaminated surface. As a second objective, we aim to evaluate the effectiveness of the device for disinfection of medical instruments, with a focus on those instruments for which there are shortcomings using the current disinfection protocols.

METHODS

To test the efficacy of the UVC-LED device, we contaminated a petri dish with a droplet containing Staphylococcus aureus ATCC 25923, which we subjected to a 5-minute disinfection cycle. A positive contrai was prepared in parallel. Bacterial load was collected in saline, quantified as colony forming units/mL and the log reduction was determined. Surveys were conducted in 14 departments of a Flemish hospital to inquire about medical instruments which generate difficulties with existing disinfection protocols. Six parameters, specifically correctness and duration of execution of protocol, impact of protocol on lifetime of instrument, cost of instrument, frequency of use and risk of healthcare-associated infection, were used to identify those instruments for which there is a high need for an alternative disinfection strategy. Medical instruments were tested as described above but the method of contamination and collection was optimized in an instrument-specific manner.

RESULTS

We observed complete reduction of the bacterial Joad on a petri dish, corresponding to a more than 9 log10 reduction. The survey identified 28 medical instruments of which 13 had
a high need for an alternative disinfection protocol. As proof of concept, four of these were selected for further investigation, which includes hand and angle pieces, orthodontie pliers, nose sensors and laryngoscope blades. The level of disinfection of medical instruments varied from no to complete bacterial reduction depending on the instrument.

CONCLUSIONS

We demonstrated with S. aureus that the UVC-LED device has high disinfecting ability on a standard surface and has great potential as a sustainable disinfection method. The results obtained on medical instruments showed that the shape may influence the efficacy of disinfection. This, combined with the desired level of disinfection of the instrument, should be considered when using the device as an alternative disinfection technology.

CONFERENCE 11
CLEANING AND DISINFECTION

INFLUENCE OF SODIUM BICARBONATE PRETREATMENT ON FINAL CLEANING PERFORMANCE IN A WASHER-DISINFECTOR

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AIM

In many countries, there is no pre-treatment before instruments used in operating rooms (OR) are sent to the sterilisation unit. In Germany, dry transport is recomrnended by the DGSV [1]. In France, pre-treatment by immersion in a detergent-disinfectant is recommended in order to avoid drying of the soils. «BICARMed®» is a pretreatment equipment using a pressurized sodium bicarbonate jet. After use in the OR, the soiled instruments are treated manually in a close enclosure.
The aim ofthis study is to evaluate the interest ofthis method to facilitate and improve the quality of the final cleaning and compare it to the pre-treatment by immersion.

METHODS

After use in the OR, the instruments are randomly divided into 2 arms. Arm A: pre-treatment by immersion in a detergent-disinfectant (n=539 instruments); Arm B: pre-treatment with sodium bicarbonate (n= 555 instruments). At the end of each pre-treatment, the instruments were cleaned in a qualified WD. The monitoring and contrai of the efficiency of each washing cycle was assessed by a washing indicator positioned on the baskets in accordodance with the NF EN 15883-5 standard. The residual contamination after washing was visually assessed and evaluated by a semi-quantitative colorimetric method. For this, each basket of clean instruments was immersed in a blue colorant (five minutes) and then rinsed. The intensity of the blue stains (from II to 15) and the surface area in mm2 were observed. The statistical test used in this study is the x2.

RESULTS

The percentage of soiled instruments after cleaning varies from 14.3 to 74.1% in arm A and from 4.2 to 60% in arm B. Statistical analysis shows that the percentage of soiled instruments after cleaning in WD was on average higher in arm A (44.7%; n= 241) than in arm B (19.8%; n= 110) (x2 test, p-value < 0.001). Contaminated areas and color intensity were also higher in arm A The proportion of instruments with low level of contamination (intensity 1) were significantly different between the two arms (x2 test; p-value = 0.040). The proportion of intensity 2 to 5 was higher in arm A. The contaminated surfaces vary from 3 to 156 mm^2 in arm A and from 3 to 60 mm^2 in arm B.

CONCLUSIONS

The results ofthis study demonstrate the effectiveness ofpre-treatment with pressurized sodium bicarbonate as compared to pre-treatrnent by immersion. This improvement can be observed in the quality of the final cleaning. This technology can make an indisputable contribution to the quality ofmedical device reprocessing process in countries that practice dry transport without prior pretreatment. The implementation ofthis practice in the operating room can save the use of detergents-disinfectants and minimize the risk of corrosion attributed to them.

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CONFERENCE 12
STERILIZATION

HOSPITAL STERILIZATION OF 3D PRINTED DEVICES

R. Eveland / K. Ant\oga / A. Meyer / L. Tuscano
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AIM

Advancements in 3D printing are revolutionizing the medical device industry, allowing medical professionals to create patient-specific devices within a hospital quickly and economically. Applications vary widely from non-surgical uses such as prosthetics, dental restorations and anatomical models for pre-surgical training and patient education, to surgical uses such as cutting guides for orthopedic procedures and anatomical models used intraoperatively, to implants. For hospital professionals creating 3D printed devices for surgical use within a hospital, the emerging technology is a true tuming point as they take on the role of a medical device manufacturer. A patient-specific 3D printed device's path to a surgical suite includes collection of patient imagery, translation ofthat imagery into a printable mode!, printing and print verification of the mode!, sterilization, and then surgical use. Currently, steam is a common sterilization method used; however, not ail materials are compatible with the high temperatures of steam sterilization. This research will evaluate, following low temperature hydrogen peroxide sterilization, that 3D printed devices for surgical use are sterile, biocompatible, and materially compatible to ensure safe surgical use.

METHODS

Research was conducted to evaluate and subsequentially qualify a low temperature vaporized hydrogen peroxide (VHP) process within a hospital sterilizer to allow for sterilization of hospital-produced, single-use, 3D printed surgical guides and anatomical models for surgical (non-implant) use. Severa! commonly used 3D printed materials were evaluated after sterilization in a low temperature vaporized hydrogen peroxide sterilizer.

RESULTS

The materials were verified as sterile via an overkill approach after a lxl0E6 challenge with the most resistant organism for vaporized hydrogen peroxide, Geobacillus stearothermophilus spores. Biocompatibility has been established in accordance with ISO 10993 principles. Material compatibility was demonstrated through dimensional analyses as well as evaluation of 3D printed samples by ASTM methods following worst-case hydrogen peroxide sterilizing agent exposure.

CONCLUSIONS

While some studies have focused on separate elements of sterilization on 3D printed devices (e.g., sterility or material compatibility), this research has evaluated ail elements for commonly used materials with one technology; vaporized hydrogen peroxide.

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CONFERENCE 13
STERILIZATION

MONITORING OF STEAM STERILISATION WITH PCDS

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AIM

Steam sterilisation is worldwide the most applied sterilisation method. Steam sterilisation conditions are specified in the literature [I]. To release loads after a steam sterilisation process the steam sterilisation conditions it bas te be ensured that steam sterilisation conditions are met before use in a procedure on patients. Before a steam steriliser is taken into production the steam sterilisation conditions in the sterilizer chamber have to confirmed during a Performance Qualifications. The PQ has to be performed for ail applied combination of the steriliser, process, loading, loading pattern and Sterile Barrie System.

METHODS

Measuring the NCGs in a steam sterilizer is not trivial. Therefore, most often conditions are confirmed with temperature measurements in the steriliser chamber and in a Joad with additional indicators. These indicators are most often chemical or biological indicators or a theoretical temperature calculated out of the pressure is used to qualify the steam composition in a process. Recent developments demonstrate that it is possible to representatively measure the NCGs during performance qualification and validation.
Unfortunate; the physical methods for measuring the NCGs in the load is not yet a common, widely and commercially available method. In this study it will therefore not be further addressed. This results that performance qualification are based on pressure and temperature measurements and often in combinations with biological or chemical indicators, at this moment.These combination of tests were perfonned in a Medical Device testing !ab and Hospital Clincal conditions

RESULTS

The literature specify steam steril isation conditions. To evaluate if steam steril isations conditions in de chamber and the load are satisfied, commercially available indicators are used in practice. However results of commercially available biological, chemical and physical based indicators demonstrate a variation in results and accuracy ofthese indicators. A doser inspection on the daims of these indicators show that these indicators were developed to comply with standards and not so much or better indirect to the literature . The test processes specified in the standard to test an develop indicators for steam sterilisation are based on pressure measurements and not the steam sterilisation parameters: the temperature, the steam composition and time. As a result the indicators based on these methods are disastrous indicators: if a fail is indicated by these indicator it will be a large fail.
That this was common practice was because no better method was available at the time that the standards first standards for steam sterilisation were developed, the 1960s. While the medical devices were developed, e.g., for minimal invasive surgery, and technology progressed, e.g., Computational Fluid Dynamics (CFD) calculation methods and new sensors, the standards for steam sterilisation remained using the technologies of the 1960s.

CONCLUSIONS

Alterantive methods oftesting steam quality are required, the results are open for discussion and scrutiny but the author condudes that consistent,reliable and robust «parametric release» is not assured or guaranteed with traditional histrorical Process Challenge Device methodology.

REFERENCES / ACKNOWLEDGEMENTS

Joost van Doornmalen, Dr Celine Herra

CONFERENCE 14
STERILIZATION

A STUDY OF ESTABLISHMENT AND EVALUATION OF A RISK PREDICTION MODEL FOR STEAM STERILIZATION

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AIM

This experiment is an attempt to establish a sterilization risk prediction mode!, by applying criteria stricter than sterilizer contrai system , to intervene in sterilization pracess at early stage ofrisk thus pravide «invisible contrai» ofsterilization quality, instead ofreacting only when alarm is triggered.
It eliminates the risk offailure much earlier and allows CSSD to manage the sterilizer in a praactive and predictable manner.

METHODS

1 / Set praactive intervention condition

Our CSSD analyzes alarm logic of in-use sterilizer and operation history, sets following conditions that trigger early intervention when examining every batch document:

1.1 - Time of each Pre-vacuum pulse 2: 8 minutes (sterilizer criteria is 15 minutes)
1.2 - Sterilization phase:
1.2.1. Either temperature < 134,2°C (sterilizer criteria is 134°C)
1.2.2. Deviation of two temperatures or pressures at same moment> 0.6°C or 60 mbar (sterilizer criteria is 1°Cor 100 mbar)

2 / Contrai group:

The operation data of 4 sterilizers and CSSD itself from August 2021 to April 2022.
CSSD verifies very batch document, contacts service only when unexpected alarms occurred.

3 / Experimental group:

Operation data of same sterilizers and CSSD from May 2022 to January 2023, after implementation of risk prediction mode1.
CSSD contacts service to arrange investigation whenever parameter(s) reached above set waming values. However the sterilizer continues running before service measures are taken.

4 / Compare indicators:

Qualification rate of sterilization pack Rate of sterilizer in praper operation Rate of CSSD overtime
Rate of delayed delivery.

RESULTS

Totally 8257 batches were investigated.
After implementation, the reduction rate of sterilizer downtime reached 98.9%, from 339.39h to 3.58 hours, which is really significant.
Our CSSD basically did no spend time on unexpected failure because the overtime dropped from 279.5h to zero.
The proper operation rate ofsterilizer increased 9.4%, from 91.37% to 99.98%.
The rate of delayed delivery also significantly reduced by 40.6%, from 59.38% to 18.75%. There were no sterilization packs needed to be re-sterilized.
Ali these reduced CSSD's reliance on scarce resources from service provider for handling unexpected failures.
Performance improvements of one sterilizer was also observed.
Mean value of sterilization temperature and temperature fluctuation increased from 134.2°C to 134.4°C and decreased from 1°C to 0.6°C, improving sterilization reliability and stability.
Mean value of the highest temperature of sterilization temperature band decreased from
135.2°C to 135°C, reducing damage to instruments caused by continuously exploring to high temperature.

CONCLUSIONS

1 / Change CSSD management concept, establish a new sterilization risk prediction mode! to significantly improve sterilizer operation efficiency.

2 / The step-by-step establishment of a sterilization risk prediction mode! is feasible and propagable.
The first step ofthis exploration is to determine the intervention conditions based on our sterilizers' alarm logic and operation data specifically.
As understanding and analysis ofthis new model deepens, next step will further optimize those conditions through evidence-based decision making approach. The future
outcome will be expected to improve both reliability of sterilization process and economic efficiency ofCSSD management.
This study shows the concept has wide feasibility and may apply to most CSSDs

CONFERENCE 15
STANDARDIZATION

DUTCH MARKET AGREEMENT ON STANDARDIZED, AUTOMATED AND GLOBAL SHARING OF CSSD INFORMATION

Jolyn van der Beek[1] / Hans Lunenborg[1] / Kees van der Meulen[2] / Jolanda Buijs[2]

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AIM

The purpose of the abstract is to share the developments in the Dutch market related to the Uniform Dataset agreement made with the Dutch associations- of medical device suppliers, healthcare institutions, healthcare professionals, GS1 and individual suppliers. To inform colleagues all over the world and to see if we can all work together to a worldwide use of the agreed on global standard use of product data exchange related to the cleaning, disinfection and sterilization processes.

METHODS

The agreement has been formed by a working group existing out of Dutch associations- of medical device suppliers, healthcare institutions, healthcare professionals, GS1 and individual suppliers. A steering committee of representatives of both the supplier and hospital side follows the implementation and use of the uniform dataset closely and keeps close contact with the involved organizations to help the members of the associations to comply with the agreement.

RESULTS

The first result is an agreed product dataset to be shared via the Global Data Synchronisation Network (GDSN) standard and the corresponding declaration of intent endorsed by the involved organizations. The agreed dataset contains attributes related to product identification, training/education on the safe use of the medical device, cleaning- disinfection- and sterilization processes, instructions for use (IFU), legal documents such as CE-certificate, EU declaration of conformity.

Ninety-five percent of the Dutch hospitals use GDSN to receive standardized product data. Enterprise Resource Planning (ERP) and Electronic Health Records (EHR) providers automatically process product data from GDSN into internal systems using FTPS (XML) or API (JSON). The next step is to use the data for the instrument tracking systems.

CONCLUSIONS

The use of a worldwide standard for the exchange of information related to the medical device and related cleaning, disinfection and sterilization processes reduces the administrative burden related to use of Excel files and other manual PDF formats for the data. The supplier can share the associated legal documents and data attributes worldwide with all hospitals, through which the hospitals have the data directly available for internal processes in the CSSD. International suppliers have the data available and can share the same data with hospitals in other countries, which will help our community worldwide in having the data available directly, digitally, and automated. This also contributes to more efficiency in the desired data for legal purposes, such as the European Medical device Regulation (MDR).

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CONFERENCE 16
STANDARDIZATION

ALIGNMENT OF GLOBAL MEDICAL DEVICE STANDARDS AND THEIR ACCEPTABILITY FOR REQULATORY PURPOSES

S. Colburn[1] */ R. Bancroft*[2]
[1] *Us Fda - Maryland (United States of America)*
[2] *Steris, Chair, Jso/tc 198 - Leicester (United Kingdom)*

AIM

Barriers to global trade can be minimised by uniform technical standards. The World Trade Organisation (WTO) stipulates that international standards take precedence over national standards, because international standards can be used to align national standards.
International consensus standards are preferred because they are crowd-sourced from experts around the world and developed in a transparent and inclusive manner, which means that these standards reflect an agreement across borders that their technical content is best suited to ensure patient and public health.
Despite global agreement that international consensus standards are ideally suited to medical device development, manufacture and regulation (Vienna Agreement between CEN and ISO, Dresden Agreement between CENELEC and IEC and International Medical Device Regulators Forum's and Global Harmonization Working Party's focus on regulatory convergence around standards, pressures to modify or create regional versions of standards frequently lead to an array of national versions of standards, obviating the benefits of relying upon the original consensus standards in global commerce. The goal is to discuss the unintended consequences ofregulatory inconsistencies that could lead to a global break down of uniform technical standards.

METHODS

In Europe, the MDR was enacted in 2017 with a three-year transition, which was extended in 2023.
The transition to the MDR means many European standards harmonised to the former MDD and AIMD need to be harmonised to the MDR. The European Commission's Standardisation Request, M/575, lists 201 standards that need modification to be harmonised, with a deadline of May 2024. At the beginning of 2023, we have 16 standards hannonised to the MDR and 10 standards to the IVDR.
Many standards are European adoptions of international standards from ISO and IEC; in US, many standards that are recognized in FDA's Recognized Consensus Standards Program are US adoptions of international standards from ISO and IEC.
Changes to the main text of these standards in order to make them acceptable for harmonization or recognition could have consequences for global alignment ifthese changes are not globally acceptable.

RESULTS

Changes will be needed to standards due to MDR implementation.
Historically, this has required minor amendments to a standard's European annexes and/or European foreword addressing the presumption of conformity.
Occasionally, changes are needed to the core text of the standard and therefore require a new edition; in this instance, if the standards are European adoptions of international standards, these modifications must be consensus-accepted by ISO or IEC in order to maintain global alignment.
In a worst-case scenario, standards with almost identical title, scope and content could exist as different regional and international standards.

CONCLUSIONS

To facilitate global harmonization, any change to a consensus-developed standard should be considered an improvement to its technical content or to its utility for regulatory purposes. Ail actors involved in the preparation, implementation and use of standards should be aware of the global consequences of these actions, however well intended.
Global alignment of the technical content of standards benefits the standard user by simplifying conformity with regulatory requirements and thereby reducing costs and ultimately improving patient safety.
This study shows the concept has wide feasibility and may apply to most CSSDs

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CONFERENCE 17
STANDARDIZATION

ISO 22441 STANDARD FOR VALIDATION OF THE H_2O_2 STERILIZERS EXPLAINED

Philippe Destrez
(France)

Since its creation in the early 1990's, hydrogen peroxide (H2O2) became the most popular low temperature sterilization (LTS) technology in hospitals across the world. However no dedicated international standard existed. H_2O_2 LTS was hence covered by generic standard ISO 14937. ISO 22441, published in August 2022, is progressively adopted as the reference process norm for H_2O_2 LTS.
The presentation explains the place of ISO 22441 in the medical device reprocessing normative framework as well as its relationships with complementary H_2O_2 standards that remain to be published.
After reminding the role of the various stakeholders to obtain a compliant sterilization process, the paragraphs of ISO 22441 are commented with a particular focus on process validation aspects.
Presentation concludes that compliance to a sterilization process standard requires the implication of sterilizer manufacturer, medical device manufacturer and healthcare facility.

CONFERENCE 18
QUALITY AND RISK MANAGEMENT

FINDINGS OF AN INTERNAL AUDITING STUDY OF INSOLATION TESTING PRACTICES TO IMPROVE HEALTHCARE FACILITY TESTING PRACTICES AND PATIENT OUTCOMES

C. Rojo
Healthmark Industries - Henderson (United States of America)

AIM

The aim of the study was to identify how common insulation testing failures and malfunctions are in insulated medical devices used in healthcare facilities.

METHODS

A study was performed via auditing of random laparoscopie insulated trays and bipolar insulated forceps using an insulation tester with variable power settings and a variety of adapters. An enhanced inspection microscope was used to evaluate the damage identified with the insulation tester and other visible damage observed. Concurrently, a qualitative survey question was administered to operating room personnel asking if they had experienced events such as arcing of electrical current during a procedure. Additionally, the United States Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database were searched for adverse events on insulation failures reported within the same timeframe to demonstrate that there is a significant patient risk.

RESULTS

A retrospective cross-sectional 12-month study was conducted from May 2021 to April 2022 at 41 healthcare facilities. Of the total 365 instruments that were tested, 210 showed failures on insulation testing or inspection with 14 facilities showing a failure rate of 75%-100% of ail devices tested. The study also identified that insulated bipolar forceps had the highest failure rate with 26 facilities having a 75%-100% failure rate for those devices. Respondents to the survey question answered as follows for experiencing malfunction such as arcing from the insulation of the instrument during a surgical procedure during their career: Yes 42.24% (28/66), No 54.55% (36/66), and NIA 3.03% (2/66).
During the MAUDE database search, two documented reports were obtained showing the instrument arced resulting in skin blisters, and another where a portion of the liver was burned.

CONCLUSIONS

The study identified numerous failures in insulation integrity found in patient-ready instruments and trays awaiting assembly, which is a clear patient safety risk. These failures highlight the need for improved internai testing practices, audits, and continuing education on insulation testing practices. A robust quality system consisting of a high-quality insulation testing program will decrease adverse events in the patient population and healthcare staffrelated to stray electrical energy in insulated devices, which can cause burns, fires, shocks, and even death.

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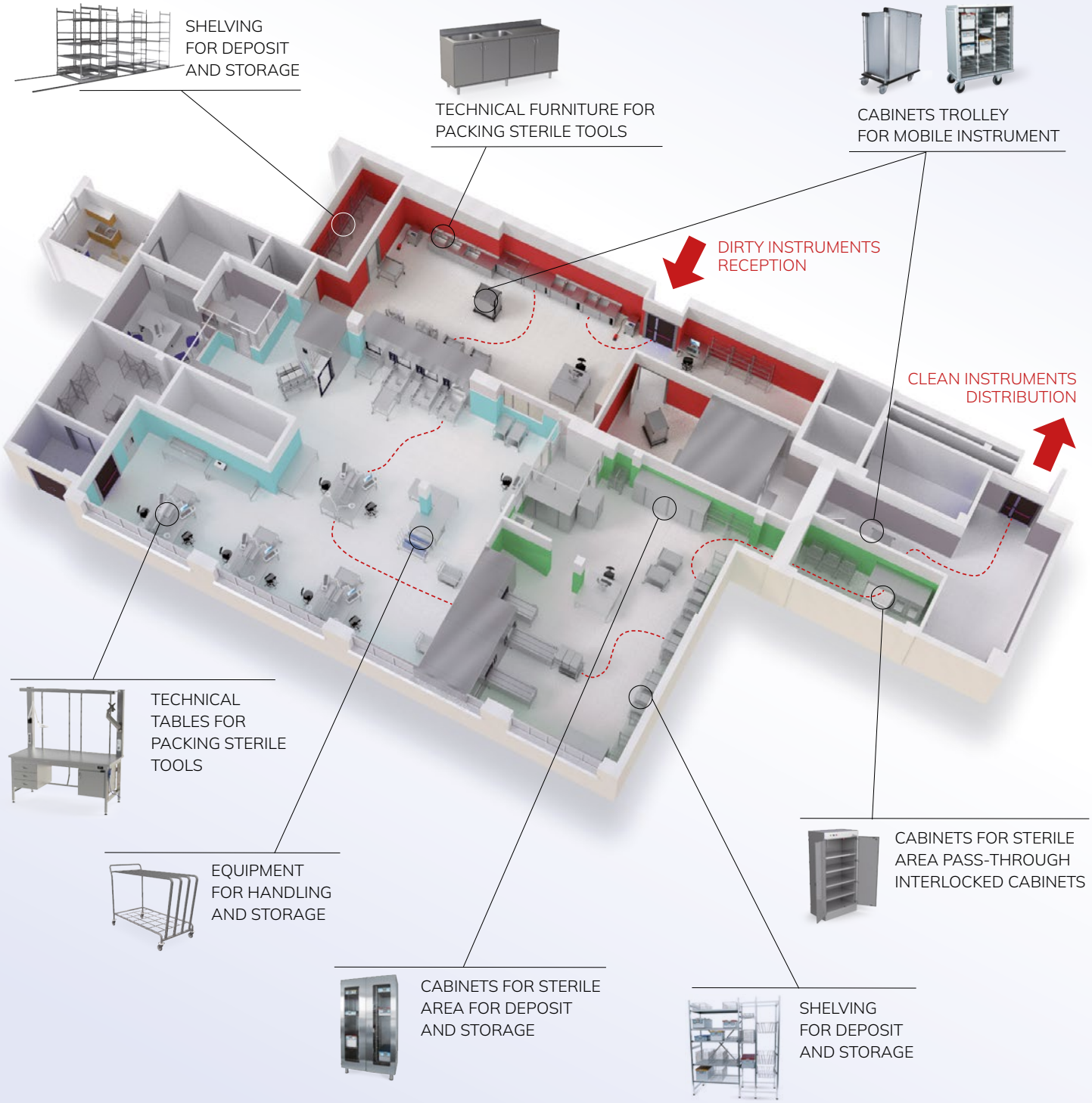

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CONFERENCE 19
QUALITY AND RISK MANAGEMENT

SURGICAL INSTRUMENT TRACEABILITY IN STERILIZATION: LEGAL OBLIGATION OR NECESSITY?

O. Willième
Care-Nam - Namur (Belgium)

AIM

CARE-NAM is a brand new sterilization platform established at 1, 6 and 35 km respectively from the hospitals it serves around the city of Namur in Belgium. This sterilization will open its doors in autumn 2024. After a first challenge of dimensioning calculation that we presented to you at WHFSS 2022, we discuss the place of surgical instruments or RMD (Reusable Medical Devices) and the obligation or necessity to trace them but also the pitfalls to avoid when engaging in this approach.

METHODS

Under the Regulation (EU - European Union) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, the traceability obligation concems Class III devices but Member States encourage (Art 27, paragraph 9) and may require healthcare facilities and professionals to record and retain, preferably by electronic means, the UDI (Unique Device Identifier) provided to them. Therefore, there is no requirement to register, only advice, to be implemented by May 26, 2025 (subject to legislative change)
When a facility combines the processing ofMRDs from several different hospitals, each with their own history and specificities, it is necessary to be able to track each set and each instrument by individual traceability, in the interest of patients, user professionals, the hospitals themselves and above ail to strengthen the quality system of the sterilization platfonn.

RESULTS

With this in mind, we have studied and tested different means of identifying and recognizing DMRs and we propose to share with you this information, the limits of each identification and reading system, the good and bad decisions that could impact on the management of this traceability and on the capacity of each sterilization service concerned to commit to this path, for the benefit of efficient management accounting and the confidence of agents, but above all, for the benefit of the quality and safety of care

CONCLUSIONS

Individual traceability of instruments processed in the sterilization department is strongly recommended by the authorities, but becomes a necessity when a sterilization platform takes in DMR from different sources. The preparation and implementation ofthis traceability is an important quality assurance challenge. The choices made will determine the quality of the products and of the work, the cost of the project and its sustainability.

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CONFERENCE 20
QUALITY AND RISK MANAGEMENT

PROMOTING PATIENTS SAFETY THROUGH THE DEVELOPMENT OF A SURGICAL INSTRUMENT TRACKING SYSTEM WITH RFID TECHNOLOGY

C. Park / Y. Im / S. Kim / H. Won / S. Mo / J. Park / E. Gil / S. Jung / S. Kim
Seoul National University Bundang Hospital (Korea)

AIM

1 / Problem analysis

(1) The standardized surgical instrument reprocessing process (request, cleaning, packaging, sterilization, release) is not computerized
(2) The use history of surgical instruments is unknown

2 / Key Indicators and Goals

(1) Reduced the average number of errors per month from 10.3 per month to 4 per month when requesting sterilization of surgical instruments used in the operating room to the central supply part
(2) Improved job satisfaction of operating room nurses using the tracking system from 51.05 points to 80 points

METHODS

1 / Development and use of surgical instrument tracking program
2 / Development and installation ofRFID equipment linked with surgical instrument tracking program

RESULTS

1 / Key indicator evaluation summary

(1) Reduction in sterilization request errors (current level of 10.3 cases per month—-> reduced to 2.1 cases, 18.4% exceeded the previous target)
(2) Improvement in nurse satisfaction (current level 51.05 points —-> 80.25 points improvement, achievement of exceeding 0.25 points compared to the previous goal)

2 / Business improvement effect

(1) It is possible to manage the use history of surgical instruments, so that appropriate measures can be taken when problems occur in the surgical instruments or sterilization process.
(2) It is possible to check the reprocessing status and inventory of surgical instruments, so it can be used for preparing and managing surgical instruments necessary for surgery.
(3) The validity period of ail surgical instruments can be checked in real time, soit can be used for surgical instrument management.
(4) It is possible to check the work status of cleaning and sterilization equipment and personnel in the central supply part, so it can be used to improve work efficiency.
(5) It is possible to check the frequency of use of surgical instruments, so it can be used for surgical instruments management.
(6) Improving job satisfaction of operating room nurses

CONCLUSIONS

Through this activity, a surgical instrument tracking system was equipped, and potential transmission of infection was prevented through the management of the use history of surgical instruments, and appropriate follow-up measures were taken according to the occurrence of problems, thereby laying the foundation for enhancing patient safety. In addition, it is now possible to use it for management work that can maximize work efficiency through real-time status checking of equipment and personnel. The Jack of quantitative evaluation tools to show the effect of the system construction is a feature ofthis activity, but the part that can be used for various QI activities in the operating room and central supply department based on data obtained through the surgical instrument tracking system is encouraging. The remaining task is to expand the application of the tracking system to ail surgical instruments in the future and to have a system that can automatically input the use history in the operating room.

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CONFERENCE 21
RUMED DEPARTMENT

STERILIZATION RISK MANAGEMENT IN DEVELOPING COUNTRIES

H. Zare Shah Mers / F. Abdi
Researcher - Tehran (Iran)

AIM

Identifying major challenges in sterilization in developing countries can help them to reduce costs of challenges and improve health quality.

METHODS

Literature review / Experimental research / Observational research / Survey research / Case study / Quantitative research

RESULTS

Inadequate infrastructure: Many healthcare facilities in developing countries may lack the necessary infrastructure to support effective sterilization practices. For example, they may not have access to reliable electricity, clean water, or adequate storage facilities for sterilized equipment. This can make it difficult to maintain the sterility of equipment and supplies.

Limited access to quality equipment and supplies: Healthcare facilities in developing countries may have limited access to quality sterilization equipment and supplies. This can include items like autoclaves, sterilization pouches, and disinfectants. In some cases, healthcare facilities may have to rely on outdated or ineffective equipment, which can compromise the effectiveness of the sterilization process.

Insufficient training and capacity-building: Healthcare personnel in developing countries may not have received sufficient training in sterilization practices, or may Jack the necessary skills and knowledge to effectively implement these practices. This can include issues like improper cleaning and disinfection procedures, inadequate monitoring and documentation, and poor equipment maintenance.

Cultural and social factors: Sterilization practices may be perceived differently in different cultures, and social factors such as religious beliefs can impact their adoption and effectiveness. For example, in some cultures, using alcohol has some limitations. Or understating of sterilization and cleanness may be very different with global norms. Specially in dental operations.

Limited resources: Healthcare facilities in developing countries may be operating with limited resources, which can make it difficult to implement effective sterilization practices. For example, they may not have the staff or funding needed to conduct regular monitoring and quality control measures, or to purchase necessary equipment and supplies.

CONCLUSIONS

Education and training: One of the most important methods for managing sterilization risks is educating healthcare workers and other relevant personnel about proper sterilization techniques. This can include training on how to properly use sterilization equipment, as well as educating them on the importance of sterilization in preventing the spread of infection.

Standard operating procedures (SOPs): Developing and implementing standardized procedures for sterilization can help ensure that healthcare facilities are following best practices. SOPs should outline the steps for sterilization, including pre-cleaning, packaging, and proper use of sterilization equipment. These procedures should be regularly reviewed and updated as necessary.

Quality control: Establishing quality contrai measures can help ensure that sterilization procedures are being properly followed. This can include regular testing of sterilization equipment and monitoring of sterilization cycles to ensure that they are achieving the desired level of sterilization.

Equipment maintenance: Proper maintenance and repair of sterilization equipment is essential to ensuring that it is functioning properly. This can include routine cleaning, calibration, and repair of equipment as needed.

Record keeping: Maintaining detailed records of sterilization procedures and equipment maintenance can help ensure accountability and facilitate monitoring and evaluation of sterilization practices over time.

CONFERENCE 22
RUMED DEPARTMENT

THE DEVELOPMENT OF THE STERILE PROCESSING PROFESSION THROUGH THE YEARS IN MEXICO AND LATIN AMERICA

L.Sentíes
México (Mexico)

AIM

To share the development of sterile processing in the last 25 years that has changed the department's perspective from not valued to being considered a key piece of the surgical team.

METHODS

Retrospective review of the changes in the last 25 years.

RESULTS

- Changes in equipment, infrastructure and processes
- Commitment to the profession
- Pride in working in the department
- Industry and manufacturers involvement
- The individuals working in the CSSD are recognized as professionals who are an integral part of the medical surgical team
- The CSSD is no longer an unknown place

CONCLUSIONS

- In the last 25 years there has been a renewed focus on the **Sterile Processing Department** and Instrument Processing
- The pandemic reinforced the essential contributions and the important role played by the CSSD within healthcare organizations
- Without the dedication of the SP professionals to cleaning, decontaminating, disinfecting, and sterilizing devices and instruments used in the OR, it would be impossible to provide infection-free patient care
- **Sterile Processing really matters!**

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- From 12:45 to 13:05, Friday, Oct. 20, Subject: *Behind the scene: The digital heart of CSSD*, by Ms. Sofia CAO
- From 13:05 to 13:25, Friday, Oct. 20, Subject: *A step further to a "lights-out" CSSD: MoovinTech automatic packing solution*, by Mr. Ken XU

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CONFERENCE 23
RUMED DEPARTMENT

MENTAL HEALTH IN THE REPROCESSING COMMUNITY: A RETHINK ON CREATING A SUPPORTIVE WORK ENVIRONMENT, LESSONS LEARNT FROM THE GLOBAL PANDEMIC

R.B. Castillo
Sydney Adventist Hospital - Sydney (Australia)

AIM

There is an increasing need to develop strategies supporting healthcare workers' well-being and mental health to work productively [1]. This case study aims to share amongst global colleagues an increased awareness of the reality that confronts every person in a team that provides consistent, high-quality reprocessed items in support of patient care, that this shared experience may provide a better understanding of how we can confront this specific challenge that is seldom discussed in a global stage. We may find it helpful to cope with increasing stress in the workforce.

METHODS

Reprocessing departments must comply with numerous standards and guidelines, and policies, procedures and systems based on instructions for reprocessing (IFU) must be in place; staff certification of competencies must be up to date, and preventative equipment maintenance and validations must be current, there must be quality assurance monitoring and continuous improvement, ail evidence of the expected quality of processed items provided to the surgical, medical, and nursing team.

Behind the quality product, however, are individuals with the power of the human touch that provides an opportunity to add toits value. The social person in each ofus requires support from every team member to sustain our psychological well-being.

We have asked individual staff consent in our department in this case study under the condition of anonymity. Most staff have agreed to share their exceptional circumstances so global colleagues in the reprocessing profession can see through the experience. Sorne team members decided to share photos and their persona(experiences as we individually struggled as a team throughout the pandemic.

RESULTS

It is clear at the start that most of the team seemed to realise the direct impact of their well being towards expected outcomes. Still, as we progressed through the pandemic, communication played an important role during the pandemic. Three distinct characteristics resulted in this case study as we discussed our experience: Communication initiated «care in action» for every ill team member to be helped by most, if not ail, the other team members. We also interviewed staff and consistent coping mechanisms like seeking help - this created mini-groups within the team that eventually helped each other out as a response mechanism to whoever became ill.

Increasing their sense of humour through daily conversation in the workplace helped in some ways; getting away from social media was a collective strategy as the news was ail sad and greatly impacted one's self-esteem, according to senior staff.

Because healthcare workers tend to be more focused on patient care [2], reprocessing technicians included, self-care was the least used strategy during the pandemic as most of the team also care for their families. This exposed vulnerability to increased sadness.

CONCLUSIONS

Even before the pandemic, there were no established guidelines for reprocessing departments to cope with the psychological demands of the expected delivery of support to
patient care areas. However, we can rely on lessons leamt from the collective strategies in our reprocessing team.

CONFERENCE 24
MASTERS OF DISASTERS

HOW LONG DOES IT TAKE TO BUILD A HUMANITARIAN CSSD

CONFERENCE 25
MASTERS OF DISASTERS

REBUILDING A CSSD AFTER A DISASTER

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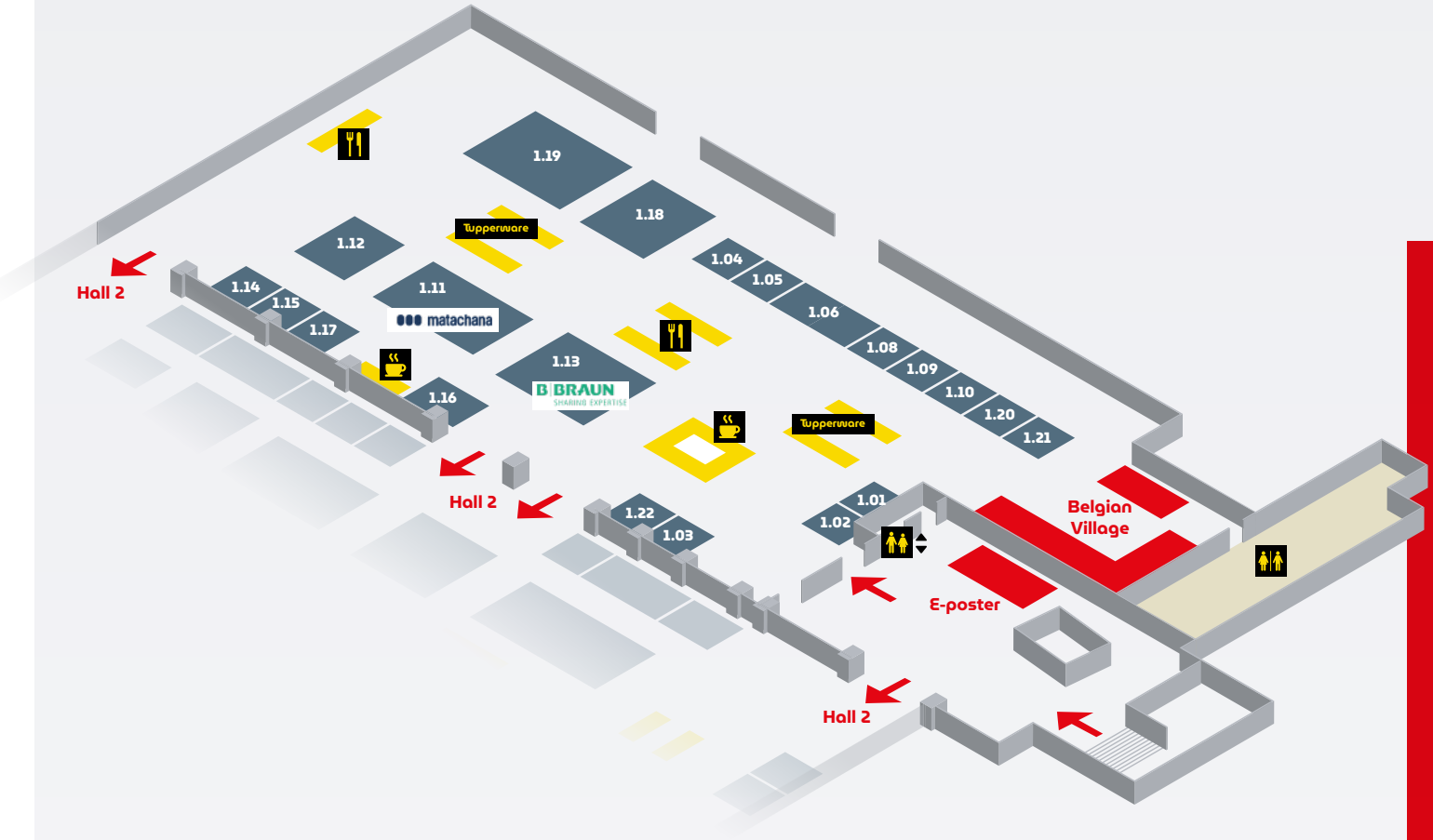

1.01 / PARASURE
1.02 / 2D SURGICAL
1.03 / CHILI 2024
1.04 / RENZ FOR QUALITY
1.05 / INNOVATION MEDICAL
1.06 / BELINTRA
1.08 / ENTRHAL
1.09 / PHARMALABEL
1.10 / WARM SURGICAL
1.11 / MATACHANA
1.12 / FAMOS
1.13 / B.BRAUN
1.14 / CHAMBER
1.15 / DOVIDEO MEDICAL
1.16 / HAWO
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1.18 / HONJOMED
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1.21 / TONON MED
1.22 / KEN HYGIENE

PLAN DE L'EXPOSITION

LEVEL -2 / HALL 2

2.01 / DRWEIQERT
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2.04 / STERISTAR
2.05 / QANDUS
2.06 / EBRO XYLEM
2.07 / WARWICK SASCO
2.08 / LAOKEN
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2.13 / CBM
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PLAN DE L'EXPOSITION

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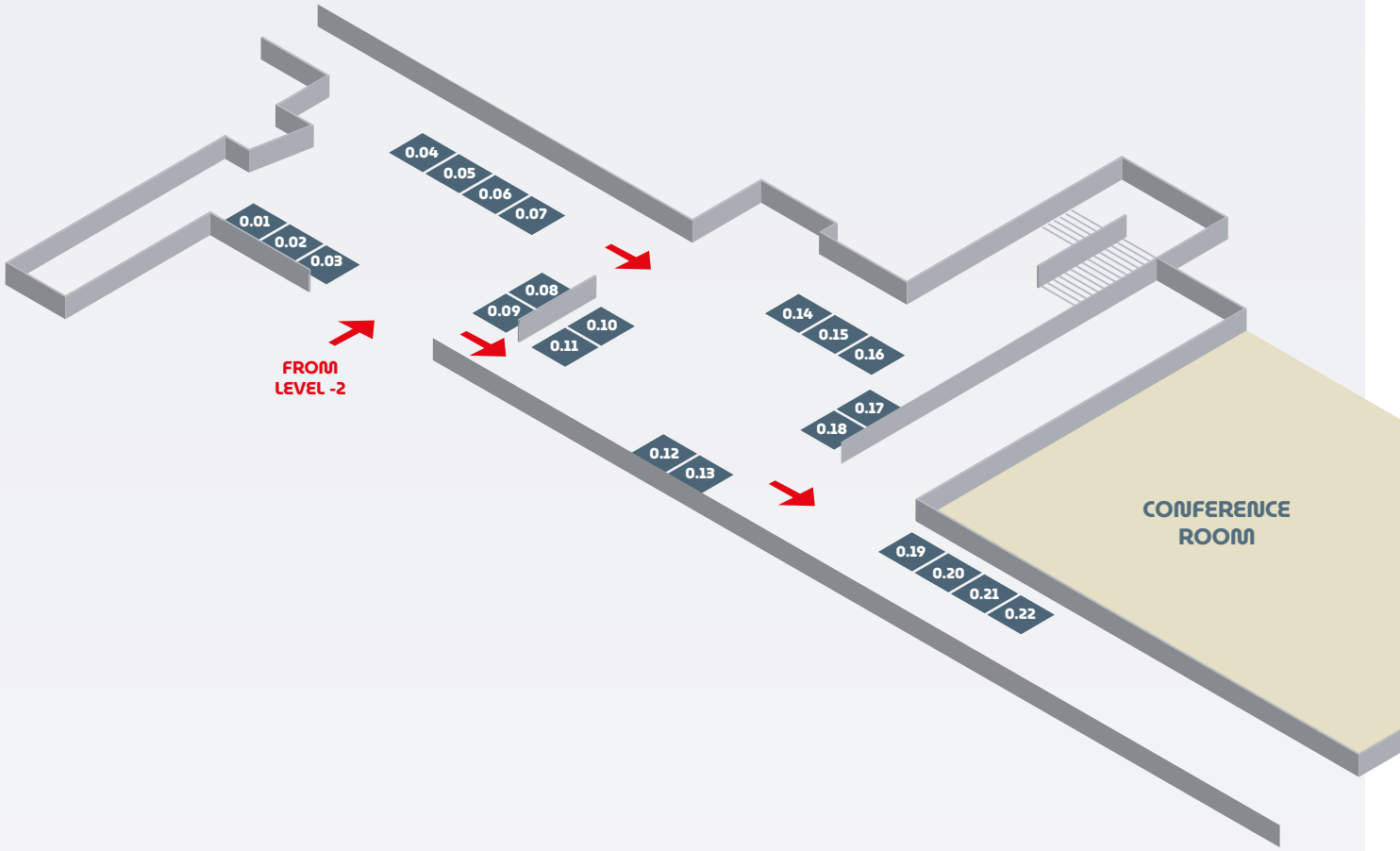

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0.06 / ASANUS
0.07 / REMEDA
0.08 / GKE-GMBH
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