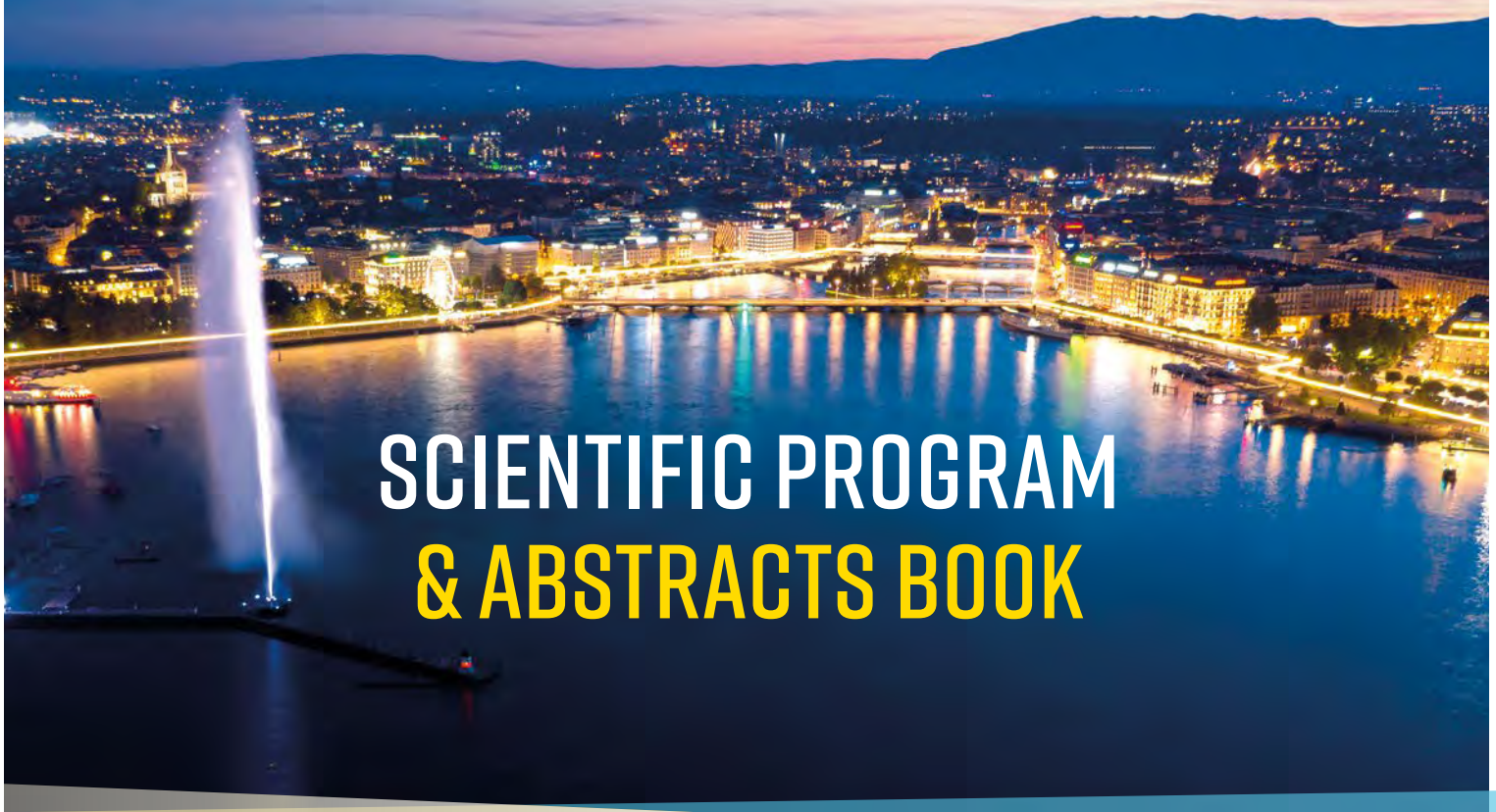
17TH / 20TH NOVEMBER 2021

CICG, GENEVA, SWITZERLAND

17TH ANNUAL DAYS OF THE SWISS SOCIETY OF STERILIZATION

21ST WORLD STERILIZATION CONGRESS



SCIENTIFIC PROGRAM & ABSTRACTS BOOK

GENEVA ALIVE CONVENTION BUREAU

Swisster 21

SGSV SSSH SSSO

Schweizerische Gesellschaft für Sterilgutversorgung
Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

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A WORD FROM THE SWISS ORGANIZING COMMITTEE

Dear Colleagues, Dear Sponsors, Dear Friends,

After a year 2020 marked by the Covid pandemic, November 2021 is the occasion to meet again for Swisster 21, the World Congress of Sterilization Sciences, which SGSV/SSSH/SSSO and WFHSS are pleased to organize in Geneva, from November, 17th to 20th 2021.

As Switzerland is a multilingual country, the organising committee will, for the first time, offer this world congress in 4 languages: English, German, French and Spanish.

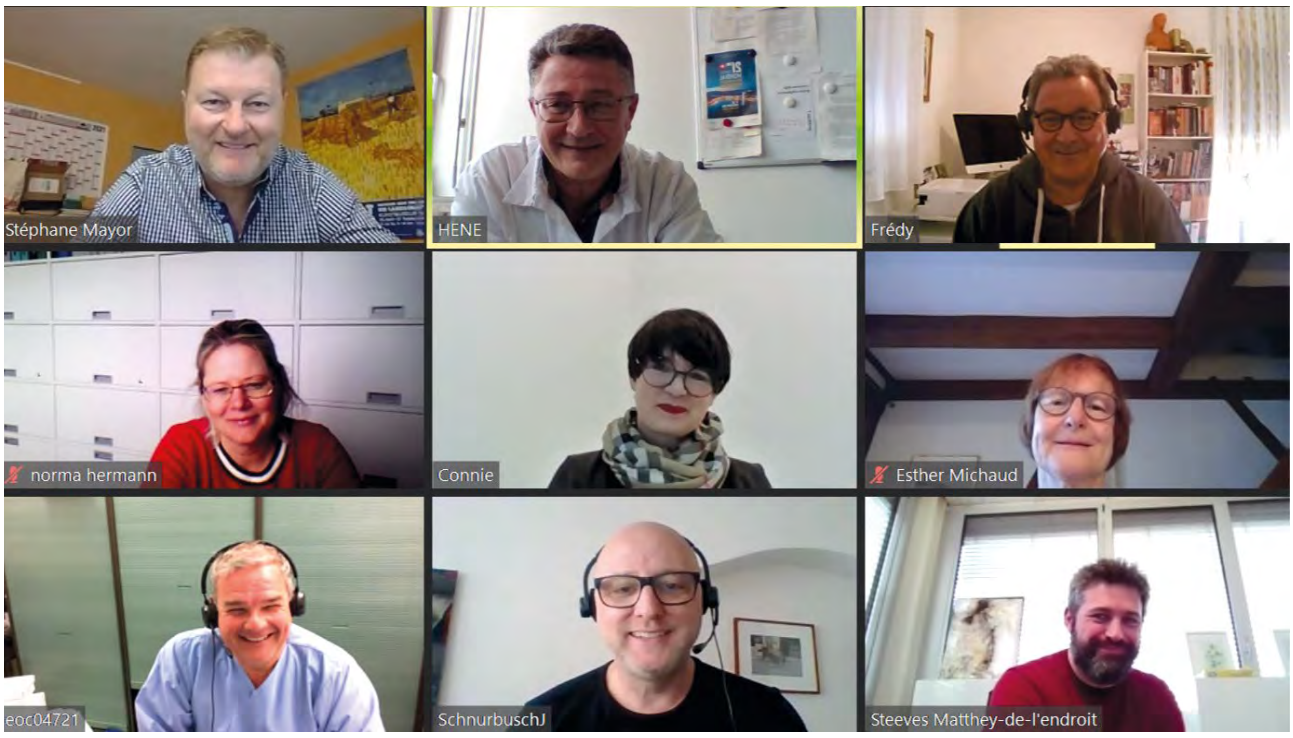
Simultaneous translations in these 4 languages and the organisation of the spaces at the Geneva International Congress Centre (CICG), Calvin's city and headquarters of many international organisations, will enable us to meet this challenge.

Debates, new technologies, research studies, experiences feedbacks, exchanges of views and satellite symposia will all be opportunities to demonstrate our resilience to the international health situation and to showcase the wealth of new ideas in the field of medical device reprocessing.

It will also simply be an opportunity for us to get together socially, as human relations are more than ever at the centre of current concerns.

The SGSV/SSSH/SSSO will be happy to introduce you to a part of Swiss culture and to prepare for you a slice of cantonal traditions and a fondue of conviviality.

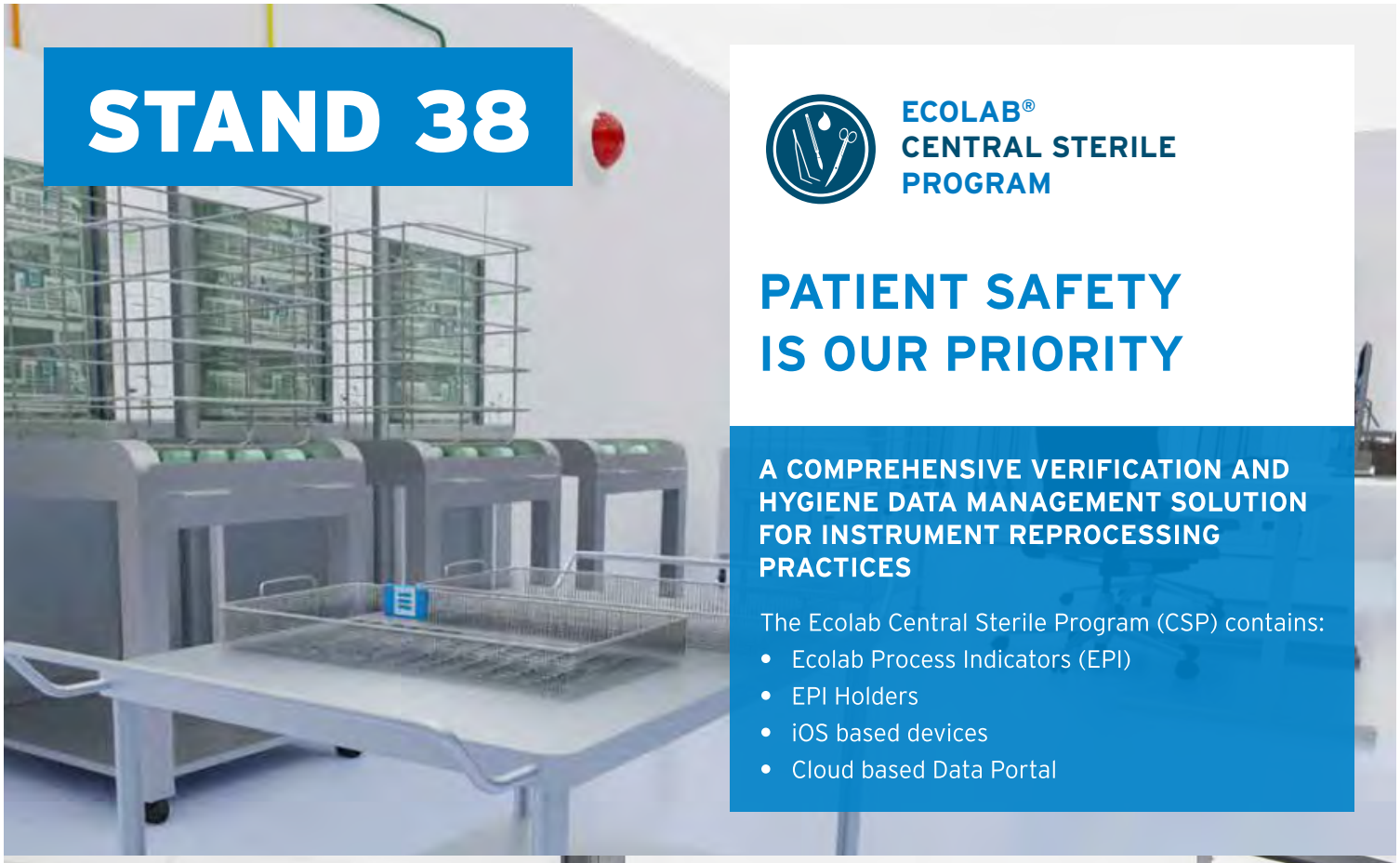
It is nice to see you in Geneva, to unite, all together, around the sciences of sterilisation, beyond the borders.



WEDNESDAY 17 NOVEMBER

15.00	**OPENING OF THE REGISTRATION AND EXHIBITION**
18.00	**WELCOME CEREMONY IN THE PLENARY ROOM** *Christine Denis (WFHSS President), Hervé Ney (SSSH President)*
19.00	**WELCOME RECEPTION IN THE EXHIBITION AREA**

STAND 38



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THURSDAY 18 NOVEMBER

07.45 OPENING OF THE REGISTRATION AND EXHIBITION

07.45 VISIT OF POSTERS AND EXHIBITION

PLENARY ROOM

08.15 CONGRESS INTRODUCTION

08.30 SCIENTIFIC SPONSOR MEETING
OLYMPUS
The importance of documentation for safe endoscope reprocessing
Christoph Leutwyler, Dominique Luu Duc, Frank Bieger

09.00 SESSION 1 - WHAT'S NEW?
Moderator: Harry Oussoren (The Netherlands) & Hervé Ney (Switzerland)

09.00 CONFERENCE 1
Harmonised standards ?
The MDR and Brexit era – a brief update
Richard Bancroft (United Kingdom)

09.25 CONFERENCE 2
PCD: State of the art
Christine Denis (France)

09.50 CONFERENCE 3
HLD, liquid sterilisation: what is behind the words?
Lionel Pineau (France)

10.15 ROUND TABLE

10.30 COFFEE BREAK & VISIT EXHIBITION

10.55 SCIENTIFIC SPONSOR MEETING
BELIMED
The Journey towards the Smart CSSD of the Future
Philippe Heim, Markus Auly, Steve Sutton

12.00 SESSION 2 - WHAT'S NEW?
Moderator: Frédy Cavin (Switzerland) & Carolina Chiodini (Argentina)

12.00 CONFERENCE 4
A new way for pre-cleaning surgical medical devices using a bicarbonate solution under pressure with a machine Safe Clean Box STK 103-113 of Bicarjet
Tiziano Balmelli (Switzerland)

12.25 CONFERENCE 5
Three-dimensional printed medical devices: regulatory perspective on manufacturing and sterilization by healthcare facilities.
Mélanie Albert (France)

12.50 ROUND TABLE

13.00 LUNCH - POSTERS AND EXHIBITION

PLENARY ROOM

13h50 SCIENTIFIC SPONSOR MEETING
BBRAUN
Reinventing sterile goods supply - OR demand driven reprocessing
Massimo Fiamma, Andreas Heyer, Mirco Vitr

14.55 SESSION 3 - OT / CSSD
Moderators: Damien Berg (USA) / Stephane Mayor (Switerland)

14.55 CONFERENCE 6
Organizational audit to manage a conflict: feedback of a sterilization unit
Ingrid Jullian Desayes (France)

15.20 CONFERENCE 7
Management of loan equipment sets
Sigurd Vandendriessche (Belgium)

15.45 CONFERENCE 8
Interest in setting up a platform for dematerialized reservation and management of medical device loans
Laura Delassus (France)

16.10 ROUND TABLE

16.30 SCIENTIFIC SPONSOR MEETING
No translation provided
STERIS
Intelligent Environments - The future of hospital Connectivity & Workflow Solutions
Andrew Southcott, Mark Capel

17.00 COFFEE BREAK & VISIT EXHIBITION

17.25 SCIENTIFIC SPONSOR MEETING
NANOSONICS
Increasing patient safety by validating a reproducible method to reprocess ultrasound probes
Maja Decius, Jalel Ben Mesmia, Olivier Mazille

18.00 SESSION 4 - BEFORE REPROCESSING
Moderators: David Bellamy (Australia) & Jörg Schnurbusch (Switzerland)

18.00 CONFERENCE 9
What is the best Condition of Transportation between Operating Room and CSSD? - Results of a laboratory Study give a new Perspective
Gerhard Kirmse (Germany)

18.25 CONFERENCE 10
Can a humid storage environment of surgical instruments before reprocessing increase patient safety and durability of instruments?
Karin Bundgaard (Denmark)

18.50 ROUND TABLE

FRIDAY 19 NOVEMBER

07.45 | **OPENING OF THE REGISTRATION AND EXHIBITION**

07.45 | **VISIT OF POSTERS AND EXHIBITION**

PLENARY ROOM

08.15 | **INTRODUCTION**

08.25 | **SCIENTIFIC SPONSOR MEETING**
No translation provided
GETINGE
Improving efficiency in the CSSD, a Value Creation Partnership
Tore Evang, Miriam Bottinga ,Klas Rudbäck, Jean-Pierre Breysse

09.00 | **SESSION 5 - SCIENCE FOR STERILIZATION**
Duygu Percin (Turkey) & Esther Michaud (Switzerland)

09.00 | CONFERENCE 11
Plasma sterilization studies: the plasma as the unique sterilization agent
Joao Henrique Campos de Souza (Brazil)

09.25 | CONFERENCE 12
UV light-based reprocessing of flexible endoscopes without working channel in Oto-Rhino-Laryngology
Stefan Alexander Rudhart (Germany)

09.50 | CONFERENCE 13
Effect of fluid flow in cleaning hollow instruments
Daniel Robertson (The Netherlands)

10.15 | ROUND TABLE

10.30 | **COFFEE BREAK & VISIT EXHIBITION**

10.55 | **SCIENTIFIC SPONSOR MEETING**
No translation provided
STEELCO
360° overview of developments in instrument reprocessing
Andrew Cserey, Luigi Guarda, Elisa Basso

12.00 | **SESSION 6 - PROBLEM SOLVING**
Moderator: Norma Hermann (Switzerland) & Christophe Lambert (France)

12.00 | CONFERENCE 14
Air quality in the reprocessing unit for medical devices (CSSD): What should I do with unexpected results?
Marc Dangel (Switzerland)

12.25 | CONFERENCE 15
Swiss guide for the transport of contaminated or sterile reusable Medical Devices for CSSDs
Nicole Berset (Switzerland)

12.50 | ROUND TABLE

13.00 | **LUNCH - POSTERS AND EXHIBITION**

PLENARY ROOM

13h50 | **SCIENTIFIC SPONSOR MEETING**
BORER
Optimising the reprocessing process to reduce overhead costs where quality and cleaning efficiency matter: an experiment at the Weiden Clinic
Kordula Hoffmann, Dagmar Martini, Patrick Mausfeld-Lafdhiya

14.55 | **SESSION 7 - MONITORING OF STERILIZATION PROCESS**
Moderators: C.Denis (France) & S. Matthey-de-l'endroit (Switzerland)

14.55 | CONFERENCE 16
Can Hydrogen Peroxide Sterilization Chemical Indicators be used to estimate the sterilant dose delivered to instrument sets
Brian Kirk (United Kingdom)

15.20 | CONFERENCE 17
Choosing a PCD as a routine BD replacement?
Florian Gallais (France)

15.45 | CONFERENCE 18
Steam Sterilization Routine Monitoring: is it safe to use Type 5 Chemical Indicators as a substitute to Biological Indicators?
Matías Pilasi (Chile)

16.10 | ROUND TABLE

16.30 | **COFFEE BREAK & VISIT EXHIBITION**

16.55 | **SCIENTIFIC SPONSOR MEETING**
MMM
RUMED renovation during ongoing OR operation by using a temporary modular unit
Michael Glusow, Thomas Rauch

18.00 | **SESSION 8 - ACTUALITY**
Tillo Miorini (Austria) & Tiziano Balmelli (Switzerland)

18.00 | CONFERENCE 19
Traceability by RFID: back to the future? Experience at Geneva University Hospital
Hervé Ney (Switzerland)

18.25 | CONFERENCE 20
A Large Multicenter Study of Duodenoscope Contamination Rates after Reprocessing
Ross Segan (USA), L. Pineau (France)

18.50 | ROUND TABLE

20.00 | **CONGRESS DINNER**
(Registration mandatory)

SATURDAY 20 NOVEMBER

08.30	OPENING OF THE REGISTRATION AND EXHIBITION
08.30	VISIT OF POSTERS AND EXHIBITION
	PLENARY ROOM
09.00	**INTRODUCTION**
09.05	**SESSION 9 - QUALITY / RISKS** *Patricia Gutiérrez (Chile) & Cornelia Ingold (Switzerland)*
09.05	**CONFERENCE 21** **The requirements of Swiss Good Practice: Risk and Quality Management** *Norma Hermann (Switzerland)*
09.30	**CONFERENCE 22** **Like a Flight recorder: identification of risks in reprocessing medical devices** *Mélissa Giroux (Canada)*
09.55	ROUND TABLE
10.05	**SCIENTIFIC SPONSOR MEETING** **ASP** **The importance of Low Temperature Sterilization Validation & Compliance** *Philippe Destrez, Patrick Turner, Benjamin Fryer, Wouter Meert*
	PLENARY ROOM
11.05	**COFFEE BREAK & VISIT EXHIBITION**
11.30	**SESSION 10 - EDUCATION** *Hervé Ney (Switzerland) & Isabelle de la Charlerie (Belgium)*
11.30	**CONFERENCE 23** **Sterile Processing Technologist Federal Diploma, a new profession in Switzerland** *Frédy Cavin (Switzerland)*
11.55	**CONFERENCE 24** **Improvements to sterile processing - an essential part of any global surgery initiative** *Christina Fast (Canada)*
12.20	ROUND TABLE
12.35	**CLOSING CEREMONY** *Christine Denis (France) & Hervé Ney (Switzerland)*
	END OF THE CONGRESS

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Presented by

Dr. Maja Decius
Internal hospital hygiene and hygiene laboratory Manager
University Medical Center Schleswig-Holstein (Germany)

Mr. Jalel Ben Mesmia
CSSD Strategic Manager
University Medical Center Schleswig-Holstein (Germany)

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HARMONISED STANDARDS? THE MDR AND BREXIT ERA - A BRIEF UPDATE OF ISO/TC 198'S STANDARDS AND ASSOCIATED ACTIVITIES

ORAL PRESENTATION

R. Bancroft

Science & Technical Director, STERIS
Chairman, ISO/TC 198
United Kingdom

AIM

Key words
Standards, harmonised standards, norms, MDR, medical device regulation

BACKGROUND

ISO has been drafting and publishing standards for decades; since the end of the 20th century, ISO has been working collaboratively with CEN to allow publication of global EN ISO standards. These standards, when adopted as European standards, can be harmonised to show how specific clauses can be used as a presumption of conformity to the legal requirements. The legal requirements for medical devices have changed recently as a consequence of the EU MDR/IVDR, as well as Brexit. As well as having to revise or adapt standards to maintain state of the art, these standards must also be revised to align with the new EU MDR/IVDR requirements. The consequences of the different regulatory framework in the UK as a consequence of Brexit will also have an impact on standards.

METHODS

ISO/TC 198 is responsible for 60 published standards, with 18 currently being updated. As well as work being conducted by the technical committee (TC) itself, much of the activity is within the TC's 14 working groups. The major areas of work currently underway are ISO/TS 5111 (water quality), ISO 11135 (ethylene oxide sterilization), ISO 11137 (radiation sterilization), ISO 17665 (moist heat sterilization), ISO 11138 series (biological indicators), ISO 11140 series (chemical indicators), ISO 11607 (sterile barrier systems), ISO 13408 (aseptic processing), ISO 15883 series (washer-disinfectors) and ISO 22441 (vaporized hydrogen peroxide sterilization). ISO/TC 198 also works closely with CEN/TC 204 and CEN/TC 102 to adopt most of these ISO standards as European (CEN) standards and liaison groups such as ISO/TC 210 and CEN/CLC/JTC3.

RESULTS

The key areas of development of these standards will be presented. A common area for many standards is the need to revise or amend to align with the MDR and/or the IVDR requirements so that the standard may be harmonised. The process of publishing a harmonised standard begins with the European Commission publishing a standardisation request (mandate) by way of a Commission Implementing Decision. This was published as M/575 earlier this year. M/575 lists 201 standards to be revised and 27 to be developed for alignment with the MDR, and 46 to be revised and 3 to be developed for the IVDR. Of the MDR standards, approximately 40 are directly connected to sterilization of medical devices and a further 15 that are indirectly connected.

-

World Federation for Hospital Sterilisation Sciences

PCD : STATE OF THE ART

ORAL PRESENTATION

C. Denis

France

The presentation reviews Process Challenge Devices (PCD) through their definitions and objectives as described in the ISO normative documents.

It includes an analysis of their place in routine operations and in process validation over the areas of cleaning, steam sterilisation and low temperature sterilisation.

We will address the question of the intellectual approach to the use of PCDs, what they are and what they are not.

User expectations on the standardisation of PCDs will be addressed in the conclusion.

HIGH LEVEL DISINFECTION, LIQUID STERILISATION, WHAT IS BEHIND THE WORDS?

ORAL PRESENTATION

L. Pineau

Eurofins Biotech Germande France

The "Spaulding classification" originally proposed in 1957 is still used to categorize a reused medical device (RMD) according to its intended use and the subsequent level of reprocessing required to render the RMD safe for reuse. However, changes have occurred over time, choice of sterilization and disinfection methods has increased, is more difficult, and subject to local interpretations

During this presentation we will go back to the definitions used worldwide to define terminal sterilization, non-terminal sterilization, sterilant, high level disinfection, describe the methods used to evaluate/validate the efficacy level reached after each treatment and highlight the safety levels provided by each method.

The example of flexible GI endoscopes will be used to illustrate the various approaches.

A NEW WAY FOR PRE-CLEANING SURGICAL MEDICAL DEVICES USING A BICARBONATE SOLUTION UNDER PRESSURE WITH A MACHINE SAFE CLEAN BOX STK 103-113 OF BICARJET (ITALY)

ORAL PRESENTATION

T. Balmelli[1]
A. Di Iorio[1]
V. Ziuliani[2]

[1]Societa Svizzera Di Sterilizzazione Ospedaliera - Biasca (Switzerland),
[2]Private - San Vito Al Tagliamento (Italy)

AIM

A new technology for pre-cleaning of dirty surgical medical devices as been tested in the sterilisation centre of «Centrale dei Servizi Industriali di Biasca» in the south of Switzerland.
The new technology is based on a mixture of sodium bicarbonate with water and compressed air.
This treatment could be assimilate to a conventional procedure by pre-cleaning by brushing but with better effectiveness because is possible to reach the most difficult part of de devices.
This method should substitute many manually preparatory operations such immersion in the ultra-sonic tanks end manual brushing without altering the geometry and functioning of the devices.
The test has been also defined the limits of the materials devices and in few cases of the constructions.
It was verify by biological laboratory also the effectiveness of the elimination of residual proteins before the mechanical washing process in thermos washer disinfectors.
Once the quality of the pre-treatment was tested, the research developed in the analysis and applicability of this technology in the daily treatment with the production staff.
First of all, the staff has been trained in the use of the machine, methods and controls, safety and maintenance provisions.
Workers' health specialist also verified even the job position.

METHODS

The most important part of our test, was to verify the impact on daily business, we defined three situations.
Three production employees, the first to loading, the second to the machine on cleaning, the third to unloading and preparation for mechanical washing.
Four production employees, the first to loading, the second to the machine on cleaning, the third and fourth to unloading and preparation for mechanical washing
Five production employees, the first and second to loading on two different lines, the third to the machine on cleaning, the fourth and fifth to unloading and preparation for mechanical washing on two different lines.

RESULTS

The results of our test is going in more than just one.
Most important, the first "configurations" with three employees has done the best organisation results in terms of effectiveness.
The second the staff had to be "persuaded" to use the machine.
The third was than at the exit of the disinfection far fewer devices had to be reprocessed.

CONCLUSIONS

In conclusion the new machine Safe Clean Box STK 103-113 could be a seriously opportunity to improve the quality of the pre-cleaning process for the delocalized sterilisation centres and with a several charge of devices.

THREE-DIMENSIONAL PRINTED MEDICAL DEVICES: REGULATORY PERSPECTIVE ON MANUFACTURING AND STERILIZATION BY HEALTHCARE FACILITIES

ORAL PRESENTATION

M. Albert[1]
S. Corvaisier[2]
L. Huot[1]

[1]Hospices Civils De Lyon, Pôle Santé Publique, Service Recherche Et Epidémiologie Cliniques - Lyon (France),
[2]Hospices Civils De Lyon, Stérilisation Centrale - Saint-Priest (France)

AIM
Surgeons increasingly request three-dimensional printed medical devices (3D-MD) in their healthcare facilities. These 3D-MD can be implants, accessories (cutting or drilling guide...) or anatomical models (surgeon training before surgery or template during surgery). The final application of each 3D-MD will determine the need to sterilize or not the 3D-MD. This process promises many advantages, but the regulatory framework remains poorly known and imperfectly understood, with a lack of practical and validated data on sterilization. The aim of this work was to make a state of the art of the available data and the responsibility of the hospitals and its actors wishing to manufacture, sterilize, and use 3D-MD.

METHODS
The Medical Device Regulation (MDR) 2017/745 was consulted. In absence of guidelines for sterilization of in-house 3D-MD, a bibliographic search was performed on PubMed and the Web of sciences database, using the following keywords: « sterilization » AND « three-dimensional print* » AND « medical device ».

RESULTS
The serial manufacturing of MD in hospitals does not appear feasible because of CE marking requirement, which is not mandatory for custom-made devices. Nevertheless, their production needs to respect the MDR with important specifications including a conformity declaration to the essential requirements, a statement of exclusive use to a particular patient or user, a post-production monitoring and the implementation of a quality system, especially in connection with the control and efficiency of manufacturing, washing and sterilization processes. There is no distinction between the different classes of custom-made 3D-MD (implants, accessories or anatomical models) in the MDR except for the quality system which needs to be certified by a notified body for class III implantable devices. Current data about sterilization of 3D-MD are still a work in progress. Twenty-four publications were selected: six of them concerned French practices. Sterility tests have been conducted on twelve materials and have shown the efficiency of steam sterilization or H2O2 sterilization without inoculation or after inoculation of S. epidermidis, E. coli, P. aeruginosa, E. faecalis or S. aureus. Regarding deformation tests after steam sterilization between 121°C and 134°C, results vary considerably according to materials, but also depending on the printed form or the printer used for the same material. H2O2 sterilization has been investigated in 7 articles and seems to cause less dimensional change in the studied materials.

CONCLUSIONS
A healthcare facility wishing to manufacture and sterilize 3D-MD must focus on mastering the entire process. To limit bioburden, the manufacturing place should be a controlled atmosphere area, and the characteristics of the inks known and controlled. Moreover, the efficacy of the sterilization process must be verified with tests of sterility and deformation. Considering the heterogeneity of the tests found in the literature, including the absence of inoculation with B. stearothermophilus while it is the indicator recommended by the European Pharmacopoeia, it will be necessary to work on appropriate and standardized procedures as a key point for a safe use in patients of in-house 3D-MD.

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Speakers: Dr. Mirco Vitr, CEO IT4Process,
Andreas Heyer, Acting Partner Architecture- and Engineering Office,
Massimo Fiamma, Director Consulting B. Braun Supply Solutions

V-ST21003

ORGANIZATIONAL AUDIT TO MANAGE A CONFLICT: FEEDBACK OF A STERILIZATION UNIT

ORAL PRESENTATION

I. Jullian-Desayes

S. Guingand

C. Lamber

Centre Hospitalier Metropole Savoie - Chambéry (France)

AIM

In a context of professional burn-out and lack of acknowledgement towards headmanager, a diagnostic mission followed by a coaching has been proposed by the Centre Hospitalier Metropole Savoie establishment. Irregular flow and the lack of coordination and collaboration between professionals have been noticed by the audit society specialized in lean management. In this context, the aim was to propose solutions to improve the flow management and the process quality.

METHODS

Lean management reefers to a technique developed with the aim of minimizing the process waste and maximizing the value of the product or service to the customer, without compromising the quality. The lean management contains methods and tools used in industry to optimize the activity by the reevaluation of relevant activities with no added value, highlighting sensitive process and products by visual signals, identification of waste and bottlenecks by flow indicators. To this end, personalized interviews with the staff members (pharmacist, health executive, and sterilization operators), support services and customers (surgeons) have been led. Then, a working group has analyzed causes of dysfunctions and discouragements.

RESULTS

Each day, a production referent will be designated to conduct production tours (walking around) every two hours to control flows and bottlenecks. In case of a bottleneck, he can position a « fireman agent » to help the other staff members on this step of the process. Production referent and fireman are designated by the health executive each day. The health executive also conducts production tours every two hours at odds with the production referent in order to identify problems and potential improvement opportunities. Among these new tools to follow the activity, we use production indicators for each step of the process to manage bottlenecks, meetings with operating blocks members, care units, and biomedical engineer… Work schedule have also been adjusted with a better adequation between the staff and the activity flow.

CONCLUSIONS

After fifteen years of activity increase, the analysis of flows and unit dysfunctions have been required. These new tools to follow production, the involvement of staff members, and individual responsibility revalorization have revitalized the sterilization unit and the enjoyment in work. Staff satisfaction and results on performance improvements or the rate of non-conformities are regularly evaluated to adjust tools and actions.

MANAGEMENT OF LOAN EQUIPMENT SETS

ORAL PRESENTATION

I. De La Charlerie[1]
S. Vandendriessche[2]

[1]*Aster-Vsz - Namur (Belgium)*
[2]*Aster-Vsz - Brussels (Belgium)*

AIM

Facilitating sterile loan equipement in our hospitals through an industrial partner , we can provide a high quality sterile medical device to enable to work 24h. Even in smaller hospitals when our CSSD are closed we can continue to operate.
Aim for a more balanced work load for the CSSD workers whom at the moment receive at all hours loan euipement.
To comply with the MDR without the investment of extra resources.

METHODS

We outsource our loan sets, to an industrial partner who clean, desinfect and sterilise the medical devices for us.
The hospital sets remain the duty of the CSSD.

RESULTS

We have the kit available at the requested time and date.
We have no extra work with the input of our loan sets in our data base.
We have reduced the loss of instruments in OR and reduced the cost of the CSSD.
We have trays that comply with all the regulations and specifications as required in the good practises in Belgium, stipulated in law on 30.9.2020.
We have reduced stress levels from OR and CSSD because of late deliveries.
No need to invest in extra washers and sterilisers to complete the extra work.
We have extra time to do our normal duties.
We can concentrate on our instrumentsets without the need to constanly prioritsing our workload.
The OR knows in advance where to find and allocate the sets. Before hand it was a nightmare.
Waithing has been reduced by 40%.
Efficiancy has risen within the pharmacy for tracing implants and generating the bill for the patient afterwoods.

CONCLUSIONS

In our hospitals we're very pleased to work with this set up. It has given us an extra life line.
We have a difference between the Northern part of the country and the southern part of the country.
The Northern part is 100% pro for this concept. The southern part have some doubts, which is understandable.

INTEREST IN SETTING UP A PLATFORM FOR DEMATERIALIZED RESERVATION AND MANAGEMENT OF MEDICAL DEVICE LOANS

ORAL PRESENTATION

L. Delassus

J. Scholler

S. Wisniewski

B. Gourieux

Hôpitaux Universitaires De Strasbourg - Strasbourg (France)

AIM

The management of surgical equipment loans in health care institutions is a complex and time-consuming process involving multiple actors. The Pharmacy-Sterilization unit would like to set up a platform for the reservation and dematerialized management of surgical equipment loans. The aim is to evaluate the interest of this tool and to specify the scope concerned.

METHODS

A priori risk analysis of the lean circuit was carried out using the FMECA's method, with an assessment of the platform as a risk control element. A mapping of the medical device (MD) orders on loan made by the establishment in 2019 was carried out in order to evaluate the volume, and a daily query of orders on loan by the pharmacy was developed, making it possible to supply a support for monitoring ancillary equipment in sterilization. These data were compared with those obtained from the traceability software.

RESULTS

58 risks were identified on the loan circuit, 47% of which could be controlled using the platform. In 2019, 1229 orders MD on loan were placed, for 3172 lines. The surgical specialties most concerned are orthopaedics and traumatology (21%), ophthalmology (19%) and vascular surgery (13%). 9% of order lines are associated with ancillary equipment, mainly in orthopaedics-traumatology (67%). Over the period from November 2020 to March 2021, 106 loans with ancillary equipment were identified from the query. 85% of these were taken care of in sterilization. Conversely, 861 products were taken in charge for 209 loans according to the traceability software. 59% of these products relate to loans present in the tracking medium.

CONCLUSIONS

The implementation of a support for monitoring the surgical equipment loans in sterilization has enabled better visibility of future loans, although 41% of the MD taken in charge was not in the query. The completeness of this query was raised. Nevertheless, this figure should be put into perspective because some instruments are wrongly traced as loans (MDs undergoing trials, etc.). The implementation of a loan management platform would make it possible to harmonise the request procedures, to abandon manual traceability and to anticipate management of all ancillary equipment reservations. In view of the volume of implantable MD and the availability of ancillary equipment on loan, the deployment of the platform is initially envisaged for the surgery units with implants.

Although the management and follow-up support for the loan of surgical equipment in sterilization has enabled better anticipation of the activity, it lacks exhaustiveness. The implementation of a reservation and loan management platform would make it possible to harmonise the circuit and secure the flow of information between the various stakeholders. In the meantime, a real-time analysis of discrepancies between request and traceability will make it possible to improve completeness. This project was submitted to the institution's information system steering committee for validation.

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AD-210167-01-CT_A-MDR

WHAT IS THE BEST CONDITION OF TRANSPORTATION BETWEEN OPERATING ROOM AND CSSD? - RESULTS OF A LABORATORY STUDY GIVE A NEW PERSPECTIVE

ORAL PRESENTATION

G. Kirmse[1]

H. Biering[2]

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[1]Aesculap Ag - Tuttlingen (Germany),

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AIM

Minimizing the time between point-of-use care and processing in the is difficult to achieve under consideration of centralization of CSSD's. Looking around the world, there are various strategies avoiding drying of soil, corrosion and formation of biofilms. These range from dry transportation, to moist transportation using wet towels or sprays and to wet transportation. While point-of-use cleaning is demanded in all Guidelines around the world, it has to be admitted that soiled transportation is many times reality.
It will be important to know which maximum times can be accepted. The presentation will show results from laboratory studies to investigate the effect of different soils, transport conditions and waiting time on cleanability and corrosion of test devices.

METHODS

For laboratory tests stainless steel plates and process challenge devices (based on box locks) are contaminated with 100µl of various test soils, reflecting critical clinical soils. The test devices are stored in a simulate transport environment under various condition (dry, moist, various foam sprays, wet) for times from 1h to 72h, then cleaned and evaluated for corrosion (Berlin Blue dye test) and cleaning result (as BCA Protein test by elution).

RESULTS

As a first interesting finding all test soils were completely dried (showing no further weight difference) after 3h at room temperature. Moist storage conditions were able to slow down this drying process significantly while the drying with foam sprays was almost the same as in dry condition.
The cleaning results strongly depend on the test soil, some become harder or less reliable to clean. This was especially true for the mixture of sheep blood and iodine based disinfectant, which was therefore chosen as a "worst case soil".
The cleaning results between dry and moist storage showed no clear difference up to 3h waiting time but differences started at 6h and became really large at 16h and 24h wait. At 72h none of the storage methods produced reliable good cleaning results. While foam sprays produced good cleaning results in the protein test, the visual results were inferior to moist disposal.
The results on corrosion showed strong differences. In part of the test soils the corrosion attack continued even after the test soil was dry. Partly a significant corrosion attack could already be seen after one hour.

CONCLUSIONS

Similar to other areas the best solution has to be evaluated based on the individual situation and criteria of the hospital.
First it can be concluded that any larger amounts of soil and fluid (saline etc.) should be wiped off in the OR. With longer waiting times cleaning results can be improved with moist disposal but all methods have their challenges.
Additionally, it has to be considered, that any chemistry used during transportation has to be removed again and may interfere with the later cleaning process. Repeated use and subsequent effects were not part of the study.
Therefore clinical studies to evaluate the differences under clinical "real life" conditions have to performed.

CAN A HUMID STORAGE ENVIRONMENT OF SURGICAL INSTRUMENTS BEFORE REPROCESSING INCREASE PATIENT SAFETY AND DURABILITY OF INSTRUMENTS?

ORAL PRESENTATION

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AIM

According to national and international guidelines for infection control in healthcare, reprocessing sterilizable medical equipment is recommended to be initiated as soon as possible after completion of surgery. Furthermore, transport and storage of surgical instruments between theater and reprocessing site should occur in a humid environment (1,2). The main concern is that longer holding time and dry storage may result in deterioration of the instruments, i.e. inefficient cleaning using standard protocols and consequently higher susceptibility to corrosion.
However, the widely recognized recommendations for infection control primarily build on guidelines, procedural descriptions and consensus about 'best practices'. Evidence from systematic research is strongly warranted (3).
To produce evidence-based knowledge to the area of reprocessing by evaluating whether residual protein or corrosion increases due to storage environment (dry or humid). Furthermore, to evaluate the effect of holding time and number of treatment cycles on residual protein and corrosion.

METHODS

Protein residue was tested on 108 irrigation syringes and 108 forceps contaminated with human blood containing Enterococcus faecium (final concentration: 1.5*108 CFU/mL) and subsequently stored for 6, 12 and 24 hours at room temperature before reprocessing. Half of the items were stored dry and uncovered and the other half in a closed humid environment. Each instrument had the same holding time and storage environment during the test period. After 1, 25 and 50 reprocessing cycles, 6 instruments of each type, holding time and storage environment were examined for protein residues using SensoLyte's OPA protein quantitation method (4).
The same procedure was followed for 108 forceps which were examined for corrosion by visual inspection (stereomicroscopy) and scanning electron microscopy (5).

RESULTS

Protein residues ranged from 21.8 to 28.1 µg (mean: 24.4 µg, sd: 1.3 µg) on the forceps and 21.5 to 54.0 µg (mean: 26.7 µg, sd: 4.9 µg) on the syringes. The analysis revealed no associations between storage environment and protein residue (PAdjusted=0.30, mean difference 95% CI: 0.48 [-0.42, 1.37]).
Stereomicroscopy showed areas with corrosion corresponding to 0-5% of the investigated surface area. The analysis revealed no associations between storage environment and corrosion (P=0.20).
Higher number of treatment cycles showed higher amount of corrosion. Instruments with 1 cycle showed corrosion ranging from none to 0.25% (mean 0.06%), 25 cycles showed corrosion between 0.25 and 5.0% (mean 0.52%), and 50 cycles showed corrosion between 0.25 and 5.0% (mean 1.45%) (P<0.001). In contrast higher number of treatment cycles showed lower amount of protein residue (PAdjusted<0.001). When investigating difference between corrosion and holding time, we found a lower protein residue concentration at 12 hours compared to 6 and 24 hours.

CONCLUSIONS

We found no evidence of an association between the presence of protein residue or corrosion and the storage environment before reprocessing was initiated. However, our findings confirmed previous research findings that a higher number of treatment cycles leads to a higher amount of corrosion. Thus, the cleanliness or the durability of the instruments seemed not to be affected by storage environment or holding time but instead by the sheer number of treatment cycles.

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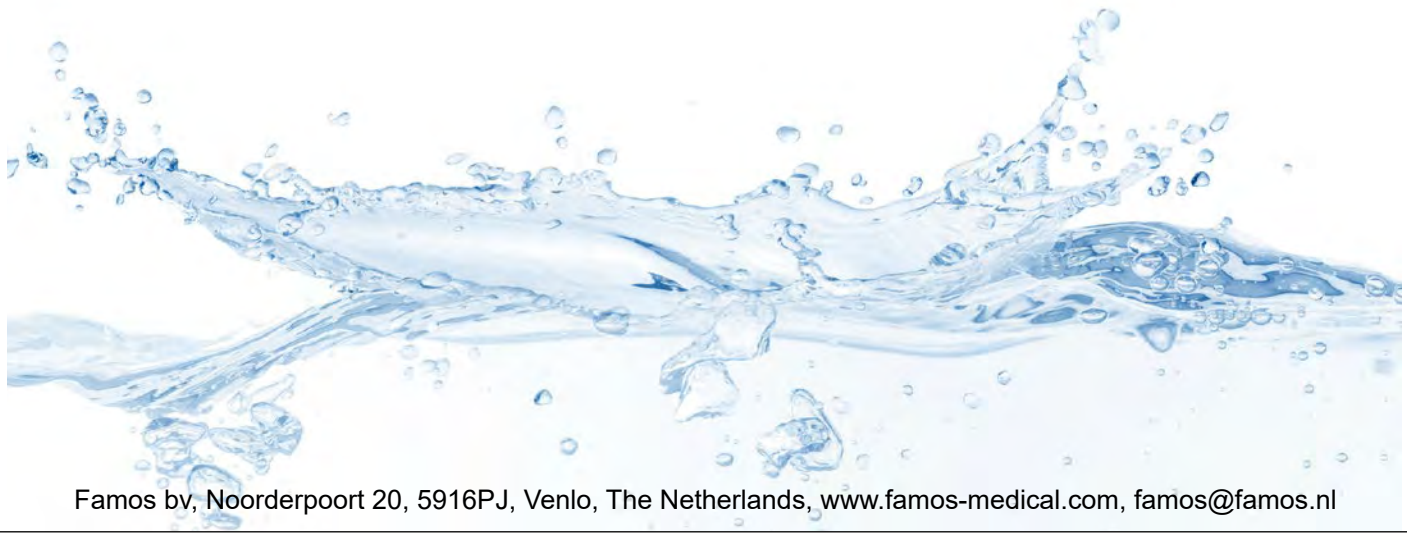

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PLASMA STERILIZATION STUDIES: THE PLASMA AS THE UNIQUE STERILIZATION AGENT

ORAL PRESENTATION

J.H.C. De Souza

Brazilian Health Regulatory Agency (anvisa) - Brasília (Brazil)

AIM

Despite the variety of technologies available to health services for the processing of health care products, the characteristics of each instrument are decisive in the choice of the most appropriate method. The plasma sterilization is a technology that draws a lot of attention for it congregates quickness, safety and effectiveness. In this work, we present a plasma source developed for sterilization studies at atmospheric pressure, where the plasma is exclusively responsible for the sterilization process. We used highly filtered ordinary air as the precursor gas. We present the characteristics of the plasma source, its performance in killing spores of G. stearothermophilus and preliminary results of the compatibility with non-woven fabrics used as packaging materials.

METHODS

Our plasma source is a Single Dielectric Barrier Discharge (SDBD) and was designed to work at atmospheric pressure. The discharge occurs between two coaxial cylindrical electrodes. The outer one was grounded and projected to fit the Petri dishes with the biological indicators next to the discharge. The precursor gas is HEPA-filtered ordinary air. We controlled the relative humidity of the precursor gas.
We exposed Petri dishes containing, at least, 107 CFU of G. stearothermophilus (ATCC 12977) spores for 2, 5, 10, 15, 20 and 40 minutes. After the plasma treatment, we applied the pour plate technique to count the viable cells. For each exposure time, we treated five inoculated Petri dishes. The counting of viable cells was made in triplicata.
To evaluate the compatibility with the non-woven fabrics, we placed the samples on Petri dishes and exposed to the plasma for 40 minutes. After the exposure, we analysed their integrity with a scanning electron microscope.

RESULTS

The average power of the system was 14.6 W. The decimal reduction time of viable spores, or D-value obtained was 8.40 minutes. We eliminated all the viable spores after 40 minutes exposure to the plasma. We observed a decrease of approximately 30% in the counting of viable cells, as the relative humidity of the air was raised from 20% to 60%. We did not find a significant contribution of the UV radiation for the sterilization process. We did not find relevant changes on the structure of the non-woven fabrics exposed to our plasma source.

CONCLUSIONS

We successfully developed a plasma source for sterilization studies, where the plasma is the only sterilization agent. We eliminated 107 CFU of G. stearothermophilus after 40 minutes of exposure. We associated this result to the positioning of the biological samples in our device and the low power of our system. We did not find a relevant contribution of the UV radiation to the biocidal process. We observed an important influence of the relative humidity of our precursor gas on the microbicidal capability of the plasma, which we associated to the changes in the concentration of reactive species produced from dissociation of the water molecule in plasma. We did not identify relevant changes on the structure of the non-woven fabrics exposed to our discharge, probably due to the positioning of the samples in our device.

UV LIGHT-BASED REPROCESSING OF FLEXIBLE ENDOSCOPES WITHOUT WORKING CHANNEL IN OTO-RHINO-LARYNGOLOGY

ORAL PRESENTATION

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AIM

Reprocessing of flexible endoscopes (FEs) is often expensive, time consuming and becomes increasingly complex, due to rising demands of hygiene. Surface disinfection by UV light is known for more than 120 years and has a wide application range nowadays [1]. To our knowledge, UV light disinfection has not been analyzed for the reprocessing of FEs in otorhinolaryngology (ORL) to date. After promising results in reprocessing of rigid ORL-endoscopes using ImpeluxTM UV-C light technology (UV Smart, Delft, Netherlands) the same method was tested for reprocessing of FEs without working channel in the present study [2].

METHODS

The tests were performed on non-channel FEs 2.5 × 270 mm, (KARL STORZ SE and Co. KG, Tuttlingen, Germany) with a plastic surface and a steerable tip. Disinfection consisted of mechanical precleaning for 15 seconds with a water-soaked tissue and 60 seconds exposure to UV-C in the box-based D60 UV system (UV Smart, Delft, Netherlands). 50 FEs were tested for bacterial contamination after transnasal flexible endoscopy before and after disinfection. Further 50 FEs were proofed on protein residuals after disinfection. The absolute effectiveness on germ reduction of the D60 UV system was tested on 50 stainless-steel test bodies and two control samples. The contamination on the test bodies consisted of approximately 8 × 107 colony-forming units (CFU) of Enterococcus faecium fixed by corn starch, bovine albumin and mucein, in order to simulate an organic contamination. Each endoscope or test body was disinfected separately after usage. Trypticase soy agar-based surface contact slides were used for sampling of the endoscopes and test bodies.

RESULTS

The FEs were contaminated with a high average value of 916.7 CFU (± 1057; 10 – 5500 CFU) after clinical usage. Variable bacterial flora was found on the FEs, including permanent mucosal flora bacteria, as well as potentially pathogenic bacteria (e.g. Klebsiella spp.). After reprocessing, an average contamination of 0.28 CFU (± 1.6; 6 x 1 CFU and 1 x 8 CFU) was found on 14% (n = 7) of the FEs. The remaining FEs were sterile. The bacteria detected on the FEs after reprocessing can all be attributed to the mucosal microflora (Coagulase negative Staphylococci, Micrococcus luteus, Bacillus spp. and Corynebacterium spp.). After reprocessing, all FEs were nearly protein-free (48 x 0 µg and 2 x < 1 µg). No further bacterial contamination (0 CFU) was found on the 50 standardized test bodies after reprocessing. The two control samples still were contaminated with 8 × 107 CFU, resulting in a germ reduction of about 107 for the reprocessed test bodies.

CONCLUSIONS

The ImpeluxTM UV-C light technology efficiently reduces bacterial contamination of FEs and might be useful in daily practice. Furthermore, it offers substantial financial and practical advantages to standard disinfection methods for FEs.

EFFECT OF FLUID FLOW IN CLEANING HOLLOW INSTRUMENTS

ORAL PRESENTATION

D. Robertson

Delft University Of Technology - Delft (Netherlands)

AIM

The cleaning of surgical instruments is a crucial part of the reprocessing cycle. Insufficient cleaning has been shown to lead to failure of sterilisation. Automated cleaning in washer-disinfectors have improved the repeatability of the cleaning process. Despite this, inspection after cleaning remains essential in monitoring the quality of the cleaning process. This quality control is far more difficult in hollow surgical tools like laparoscopic instruments, which contain complex geometries such as internal threading, diameter variations, as the internal surfaces cannot be inspected.
There are many parameters of the cleaning process and properties of the surgical instrument that influence the cleaning performance. The individual influence of these parameters is currently not well understood. In this pilot study, we aimed to investigate the relationship between the flow rate and removed mass fraction at different soaking times to get more insight in the effect of fluid flow on the cleaning of hollow instruments.

METHODS

The influence of fluid flow speed and soak time on the removal of the test soil on smooth stainless steel tubes was studied. We designed a test setup which consisted of a surgical instrument model mounted in a reservoir. This was connected with silicone tubing to a pump and a flow sensor. The instrument model was a stainless steel tube with an internal diameter of 9 mm that was split lengthwise so that the internal surfaces can be inspected. A test soil consisting of egg yolk prepared according to the guidelines of ISO 15883-5, was deposited on a portion of the model using a mask. The test soil was dried and then weighed before and after cleaning to find the removed mass fraction. We applied flow rates of between 0 and 8 L/m and varied pre-soaking times between 0 and 10 minutes.

RESULTS

The results of this study showed that the removed mass fraction increases significantly for flow rates up to 7 L/min, above this, the removed mass fraction stagnates. The removed mass fraction increased when comparing no soaking time to 5 minutes soaking, however between 5 minutes and 10 minutes soaking no significant difference was found.

CONCLUSIONS

This study shows the effect of flow rate on the cleaning performance and it can be concluded that for adequate cleaning of hollow medical instruments the shear stress induced by the flow rate should be taken into account. The results in this study will be used as a benchmark to follow-up studies where we will further study other effects in the cleaning process such as the influence of instrument geometries, and properties such as oscillating flows, and detergents. In future, understanding the influence of these parameters can be of help in the cleaning monitoring and validation of automated washer-disinfectors as well as in improving cleanability when designing surgical instruments.

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AIR QUALITY IN THE REPROCESSING UNIT FOR MEDICAL DEVICES (CSSD): WHAT SHOULD I DO WITH UNEXPECTED RESULTS?

ORAL PRESENTATION

M. Dangel

M. Von Rotz

S. Tschudin Sutter

University Hospital Basel-Infection Control - Basel (Switzerland)

AIM

According to the Swiss agency for therapeutic products (swissmedic), reprocessing of medical devices must be performed in rooms fulfilling air quality standards as defined by the clean room class ISO 8 requirements outlined in the European norm EN ISO 14644-1 and endorsed by the Swiss Standards Association. To assure that these requirements are met, measurements of room temperature, humidity, particle numbers and size distribution as well as bacterial counts in air samples are performed twice yearly. Bacterial and fungal counts exceeding the recommended threshold defined by the ISO 8 usually correlate with elevated air particle counts.

Objectives: We repeatedly measured elevated bacterial counts in the context of non-elevated air-particle counts during our routine air quality surveillance of one of our institution's sterilization units. We aim to report these discrepant results and discuss potential implications.

METHODS

We report measurements of air quality indicators routinely measured at both sterilization units of the University Hospital Basel, Switzerland from April 2018 through April 2021. The sites of measurement were standardized (40 sites in unit A and 24 sites in unit B). Each sterilization unit is divided into a production and a storage site. Air particle measurements were performed using LASAIR III particle counter. Bacterial and fungal counts were measured by culturing air samples (160 litres collected with MAS 100 Microbial Air-Sampler) on blood agar and Sabouraud agar plates. Results were interpreted as defined by the swissmedic (threshold for bacterial counts 200 CFU/m3).

RESULTS

During the study period, 472 air samples were collected (14 routine and 2 follow-up measurements) at 64 sampling sites. Temperature, humidity (between 32.1-38.4%) and particle number requirements were met throughout the study period while bacterial count thresholds were exceeded in 13.3% of all samples. Air quality requirements were more frequently met in unit B, 98.4% [mean 42 CFU/m3] as compared to unit A 79.2% [mean 132 CFU/m3].

Samples with elevated bacterial counts revealed bacteria considered as skin flora in 19.7% and gram-negative bacteria (i.e. Pseudomonas oryzihabitans, gramnegative rods) in 1.4% in unit A. Several site-inspections of unit A were inconspicuous. As an immediate measure, disinfection with ultraviolet light (UVC) of the entire unit was performed. After one-time UVC disinfection, no more moulds (not reported here in more detail) were detected in the follow-up measurements for 18 months, while bacterial count thresholds were repeatedly exceeded.

CONCLUSIONS

Our results indicate that bacterial thresholds defined by the swissmedic may be exceeded, despite all other air quality indicators being met. The source of persisting detection of elevated microbial counts in unit A could not be detected so far, despite extensive investigations. UVC-disinfection may serve as a complementary short-term intervention to reduce microbial counts but source investigation is needed for sustainable quality assurance. Our study reveals an important knowledge gap as reports on discrepant results between different air quality indicators are lacking, as is guidance on how to proceed in this context.

SWISS GUIDE FOR THE TRANSPORT OF CONTAMINATED OR STERILE REUSABLE MEDICAL DEVICES FOR CSSDS

ORAL PRESENTATION

N. Berset

SSSH Committee (Switzerland)

Guide suisse pour le transport des DMx réutilisables souillés ou stériles pour les centrales de stérilisation

Swiss guide for the transport of contaminated or sterile reusable Medical Devices for CSSDs.

The transportation of soiled and/or sterile reusable medical devices (DMx) reprocessed for different customers by an external sterilization facility or by an in-house CSSD can have an impact on patient safety.

The objective of these new Swiss guidelines on Transport is to provide essential information and to help the entities that transport reusable MDs to implement state-of-the art knowledge and technologies.

In this particular context, which requires specialized and uncommon knowledge in the field of reprocessing of reusable MDs, the objective is to ensure that there is no risk of contamination, either of the environment or of the sterile MDs, during transportation. The Transportation Guidelines aim at helping you implement the various processes required to transport medical devices safely.

It makes particular reference to European requirements such as EU Standards and the European Agreement for the Transport of Dangerous Goods by Road as well as Swiss laws and ordinances. For training and certification of the staff in charge of transporting reusable MDs, safe transport must be ensured.

There is a chapter on the equipment required as well as real-life examples drawing upon the Swiss experience in this field.

The main risks associated with transport often come from mechanical stress and variations in temperature, humidity and dust. Identification and maintenance information of the means of transportation should also be taken into account. The process is validated with installation qualification, operational qualification and performance qualification. All these elements are included in several chapters of the Guidelines.

Last but not least, before transportation, a risk analysis must be done to guarantee optimal distribution, which means that each risk must be evaluated according to its severity, occurrence and detectability

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CAN HYDROGEN PEROXIDE STERILIZATION CHEMICAL INDICATORS BE USED TO ESTIMATE THE STERILANT DOSE DELIVERED TO INSTRUMENT SETS

ORAL PRESENTATION

B. Kirk

Brian Kirk Sterilization Consultancy Group Ltd - Castle Donington (United Kingdom)

AIM

Some sterilization processes are judged effective if the load is exposed to defined conditions of process variables. In steam sterilzation a time and temperature combination is applied in the presence of moisture. Other processes rely on the application of a defined dose of sterilizing agent. In irradiation a dose of ca25kGy is applied . Dose is a derived value calculated from the intensity of the sterilizing agent and time of exposure. Different combinations of radiation intensity and exposure time can be used to deliver equivalent doses. Sterilizing aqueous solutions in sealed containers can also determine an integral of temperature and time, Fo, giving an equivalent heating time at 121.1oC. In this respect Fo is equivalent to dose, temperature being analogous to intensity. Vaporized hydrogen peroxide sterilization(VH2O2) is used for processing heat sensitive medical devices. Sterilizers report exposure conditions as a «dose» of VH2O2 applied by integrating the area under the VH2O2 concentration and exposure time curve(AuC-mg.s/L).
The colour change in plastic tokens (CIs) are employed to assess absorbed dose in irradiation sterilization. Moving front CIs have been calibrated to estimate Fo and are therefore «dosimeters». This report investigates if the colour change in CIs can be calibrated against delivered VH2O2 dose and then used to estimate the dose delivered to the contents of medical device instrument sets (MDIS).

METHODS

A number of CIs were exposed to VH2O2 in an exposure apparatus to establish their performance. This created a large cohort of data allowing plots of the response of CIs, expressed as colour coordinates, a*,b* or E, against the exposure dose(mg.s/L). Regression analysis established the relationship between colour change and exposure dose.
In a second stage CIs were placed within MDIS which were then exposed to VH2O2 sterilization processes. CI colour change was measured and used to estimate the delivered dose to the MDIS.

RESULTS

When the measured colour change of CIs was plotted against the dose of exposure either linear or logarithmic best fit regression curves were observed with good correlations(R2>0.95). This suggested measured colour change on a CI would be a means of estimating the dose of VH2O2 delivered to an MDIS. When the colour change observed in CIs included in MDIS was used to estimate the dose of VH202 delivered, large differences between that measured in the sterilizer chamber and the estimates were observed. Possible reasons might be due to the localised conditions found within the MDISs being different to chamber conditions. These are explored further in the presentation.

CONCLUSIONS

Analysis of previously published results showed that the colour change of a CI correlated to the exposure dose of VH2O2. Calibration curves were created which were then used to estimate the dose of VH2O2 delivered to MDISs. Differences were observed between the measured dose reported by the sterilizer and that estimated from the CI colour change. The reasons for these differences might be due to the local conditions occuring within MDIS being different to those measured in the chamber and the reasons are considered further in the presentation.

CHOOSING A PCD AS A ROUTINE BD REPLACEMENT?

ORAL PRESENTATION

F. Gallais

L. Machuelle

H. Mouton-Sclaunich

A. Ozenne

M. Laurent

Rouen University Hospital - Rouen (France)

AIM

The relevance of the BD test and the place of the PCD (Process Challenge Device) in the validation of the sterilization process in autoclave is today at the heart of the scientific debate.
How do you ensure that saturated water vapor penetrates all the medical devices?
The use of PCD seems to be the most widespread solution to date in hospitals, but nevertheless requires some prerequisites: determination of the worst case load and comparison of the detection limits with a BD test (test Bowie & Dick).
Thus, we have tested different PCDs on the market (Goubanne®, BD Sterisense®, Helix GKE®, Helix StericlinTM) under the worst sterilization conditions.

METHODS

The determination of the worst case is done in 3 steps:

- Search for the most restrictive packaging: container, non-woven paper, paper-plastic bag, ULTRA® bag
- Determination of a minimum cycle with the lowest possible pretreatment
- Determination of the most constraining load: empty, full or full load of lumen instruments

An on-board sensor is placed in the core of the load (without sterilization packaging) in order to obtain the reference values of pressure and temperature of the sterilization chamber
The sensitivity of the PCDs is evaluated using 2 types of leakage compared to different paper and electronic BD tests (test BD Stericlin, Test BD/PCD StericlinTM, Test BD 3MTM):

- Air pressure leak (door seal)
- Leakage at sub-atmospheric pressure (direct air injection into the autoclave)

The pressures and temperatures recorded by the PCDs are compared to the values recorded by the on-board sensor.
Once the sensitivity of the PCDs was measured in worst case, the same leakage conditions were reproduced on a standard BD cycle (134°C- 3min30) with paper and electronic BD tests to compare the detection capacities of the tests.

RESULTS

The worst case is defined as a PCD packed in a container, regardless of the composition of the load with minimum cycle (5 pre-vacuum at 200mbar)
The packed PCD is systematically in error whatever the type of leak and the level of leakage.
The 3 PCDs systematically indicate the same measured pressure. They do not give identical results concerning the measured temperatures.
BD tests are not systematically in error according to the type of leak with a great variability of sensitivity for the colorimetric devices.

CONCLUSIONS

The worst case finally indicates that the composition of the load does not significantly influence the sensitivity of a PCD. Nevertheless, a PCD packed in a container is more sensitive than a standard BD test.
The PCD on the market have a good sensitivity. They are equivalent in accuracy on pressures but not on temperatures. Thus, when choosing the PCD, it is necessary to take into account the configurations (materials, tube length)
Thus, we recommend not to rely on BD tests (random results due to non-detection of residual air and not representing a real load), but to test the autoclaves daily with a PCD in container.

STEAM STERILIZATION ROUTINE MONITORING: IS IT SAFE TO USE TYPE 5 CHEMICAL INDICATORS AS A SUBSTITUTE TO BIOLOGICAL INDICATORS?

ORAL PRESENTATION

M. Pilasi

Inde And Dgsv - Santiago (Chile)

AIM

Chemical Indicators (CIs) and Biological Indicators (BIs) are used in many countries to evaluate sterilization processes. Some local recommendations requires the use of BIs under certain situations, (e.g., for implants release). ISO 11140-1 clearly states that Type 5 CIs are designed to be equivalent or to exceed the performance of BIs described in ISO 11138-1. Despite of this, some recommendations do not allow to replace BIs with Type 5 CIs.

In 2005, Schneider et al. compared the performance of BIs and Type 5 CIs under sub optimal conditions, concluding that only BIs were able to detect failures when, for example, exposed to superheated steam conditions. However, not all the indicators were exposed to the exact same conditions. Also at that time, the technology of CIs was not as well as developed like it is nowadays.

The aim of this study is to check in practice if Type 5 CIs can detect failures in the same level as BIs do, confirming what is written in ISO 11140-1 and therefore be a safe and cost-effective alternative for users all around the world.

METHODS

A hospital steam sterilizer was used to test the indicators. Cycle parameters can be freely programmed and changed as the service password was available for this study.

Type 5 CIs and G.stearothermophilus strips with a population of 105 and a D121 value of 1,6 minutes were exposed to a marginal sterilization cycle within different PCDs.

A set of 9 PCDs with different steam penetration characteristics were used. PCDs are numbered 1 to 9, being number 1 the easiest to penetrate and number 9 the most difficult one.

The marginal cycle is a 3 minutes @134ºC program where the vacuum pulses are adjusted to modify the air removal performance and therefore intentionally leave Non-Condensable Gases (NCG) inside some PCDs.

BI strips and Type 5 CIs were used together in the same position within the PCD to expose them to identical conditions.

Type 5 CIs were evaluated immediately after removing them from the PCDs while the BIs after incubation as per the manufacturer`s instructions.

3 repetitions of the marginal cycle were executed exposing all the 9 PCDs containing the CIs and BIs.

A control group cycle with a higher air removal performance was used.

RESULTS

For all the 3 repetitions of the marginal cycle, Type 5 CIs showed a clear "fail" result always in a less challenging PCD in comparison to that PCD where the BIs showed a growth (fail) result for the same cycle.

CONCLUSIONS

The results suggest that in fact Type 5 CIs are more demanding than BIs under the presence of NCG, exactly as mentioned in ISO 11140-1, and therefore they can be a safe and cost-effective alternative for BIs. Nevertheless, it`s important to remark that sterilization processes must be validated according to ISO 17665 and proper routine monitoring must be defined only during the process validation.

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RFID TRACKING: BACK TO THE FUTURE? EXPERIENCE OF THE UNIVERSITY HOSPITALS OF GENEVA

ORAL PRESENTATION

H. Ney

Swisster 21
Expert sterilization HUG
SSSH President
Switzerland

The evolution of European regulations on medical devices creates the possibility of using each medical device's unique identifier to track them during reprocessing in CSSDs.

After several years reorganizing surgical operating platforms with laser data matrix codes specific to each MD, the idea was to take an interest in the latest technological developments associated with RFID.

The 3 objectives of the evaluation of the proposed solution are the following: - What are its technical impacts?

- What are its functional impacts?
- What are its organizational impacts?
- Is the financial aspect an obstacle or an opportunity?

The Caretag® solution was made available to the CSSD team. The scope of the study is voluntarily restricted to the recomposition stage for comparability purposes.

Tests for soiling, Tag resistance, ergonomy, reading time, user feedback are among the key points identified.

Two key questions arise in terms of traceability of the "on-instrument" recomposition:

- Does it contribute to ensuring the safety of the reprocessing process?
- Doesn't its systematic implementation require the use of different methods to ensure its completeness if necessary?

Despite the speed at which it is possible to scan an RFID support, it is worth remembering the specific nature of the context, i.e. the diversity of surgical devices.

Is this back to the future, or an avant-garde solution still in the making?

A LARGE MULTICENTER STUDY OF DUODENOSCOPE CONTAMINATION RATES AFTER REPROCESSING

ORAL PRESENTATION

R. Segan[1]

L. Pineau[2]

[1]Olympus Cooperation Of The Americas - Center Valley, Pa (United States)

[2]Eurofins Biotech Germande - Marseille (France)

AIM

It is estimated that over 650,000 patients in the United States undergo Endoscopic Retrograde Cholangio-Pancreatography (ERCP) annually. Several outbreaks of infections associated with duodenoscopes have been reported in recent years. Following clinical procedures, duodenoscopes are reprocessed using manual cleaning, automated cleaning, and high-level disinfection, according to the manufacturer's Instructions for Use (IFU). To date, the contamination rates of duodenoscopes following the reprocessing procedure has not been investigated in a large-scale, multicenter, real-world study. As part of this study, we have assessed the contamination rates of duodenoscopes following reprocessing, as part of the Post Market Surveillance (PMS) studies ordered by the US Food and Drug Administration (FDA).

METHODS

Sampling and culturing of the duodenoscopes after reprocessing were conducted according to the FDA and CDC's "Duodenoscope Surveillance Sampling and Culturing – Reducing the Risks of Infection." High Concern (HC) organisms (i.e., organisms more often associated with disease) were defined as all Gram-negative rods, Staphylococcus aureus, Staphylococcus lugdunensis, Beta-hemolytic Streptococcus, Enterococcus sp., and yeasts. The contamination rate of duodenoscope with ≥1 CFU of HC organisms after reprocessing was investigated.

RESULTS

859 samples from newer model duodenoscope and 850 samples from older model duodenoscopes, collected from 16 sites, were assessed. 35 samples (4.1%) from the newer and 56 samples (6.6%) from the older model were contaminated with HC organisms. The HC organisms detected were classified as Gastrointestinal 45.4%, Human-Origin (predominantly oral/nasal/dermal) 16.7%, Environmental 24.1%, Waterborne 13.0% and Unidentified 0.9%.

CONCLUSIONS

Contamination rates published in the literature vary greatly, with studies reporting HC organism contamination rates of 0.2% to 15%. This difference in the reported contamination rate depends on the definition of HC organisms, the cutoff value of the number of colonies detected, and the sampling/culturing methodologies. The detected HC organism contamination rates were lower than the 15% reported by Rauwers 2018, which uses almost the same sampling and culture method criteria as this study but has higher rates than those reported by several other publications. A broader high concern organism definition may have contributed to this high concern rate, as many authors focused on fewer species of organisms. Although the relationship between endoscopic contamination and the occurrence of infections remains unclear, in order to reduce HC organism contamination after reprocessing, it is essential to improve the IFU and human factors for the reprocessing procedure. Appropriate training programs should be also be provided.

THE REQUIREMENTS OF SWISS GOOD PRACTICES: RISK AND QUALITY MANAGEMENT

ORAL PRESENTATION

N. Hermann

Head of CSSD at Inselspital, Bern, Switzerland

The Swiss Good Practices for MD reprocessing is a reference document on MD reprocessing for healthcare establishments in Switzerland. Swissmedic also uses these requirements as a basis for inspections of CSSDs in medical institutions.

Swissmedic is the licensing and control authority for medicines and medical devices in Switzerland. The institute guarantees that only high-quality, safe and effective therapeutic products are available in Switzerland - an important contribution to the protection of human and animal health.

The first Good Practices for MD reprocessing were published by Swissmedic in 2004. There was a strong need for harmonised rules and clear indications for MD processing. Let us not forget that at the end of the 90's, a new disease was terrifying the CSSDs: the new variant of the Creutzfeldt-Jakob disease.

This situation called for a change in the legal requirements and also highlighted the need for a reference document with clear guidelines such as the Good Practices for MD reprocessing.

The healthcare sector and the field of medical devices are constantly evolving, so CSSDs must keep up with those changes. In 2016, during the review of Good Practices for MD reprocessing in 2016, SN EN ISO 13485 was used as reference. All CSSDs that chose to go in this direction at the time were already close to meeting the requirements of this standard in 2016.

In the meantime, standards have changed significantly, especially in the medical device sector, which means CSSDs have had to introduce and maintain an effective quality assurance system. This is also true for risk management. To some, this still seems too abstract and far removed from our daily work.

However, our new version of the Good Practices for MD reprocessing requires it, and as past practice has proven, it forces us to go in the right direction.

How else can CSSDs identify and assess risks or define and implement risk reduction measures? This presentation aims to shed some light on this subject.

LIKE A FLIGHT RECORDER: IDENTIFICATION OF RISKS IN REPROCESSING MEDICAL DEVICES

ORAL PRESENTATION

M. Giroux

Adjointe Au Directeur Des Services Professionnels Et À La Directrice Générale Adjointe - Saint-Louis (Canada)

AIM

In Canada, more than 250,000 users contract a hospital-acquired infection;
Surgical site infection is the second most common hospital-acquired infection;
77% of post-operative deaths are related to infection;
Costs of $1.6 billion to $3 billion in U.S. currency annually. 30,000 to 60,000 CAN$/ISO (ICSP 2019).
During the 4th year of surveillance (2019-2020), a total of 4694 MDR-related adverse events were reported as of June 15, 2020. Of these, 4206 (90%) were incidents and 488 (10%) accidents, including 4% (with a risk of infection).
Among incidents: 90% were related to the level of a breakage in the reprocessing chain, especially in the assembly and packaging.
A joint request was adressed to ASSTSAS to assess ergonomic stresses in the medical device reprocessing unit of the CISSS Monteregie-Est.
Several workers had localized physical discomforts in the back, shoulders and upper limbs.
The objectives were: to identify the musculoskeletal stresses present and mentioned by day, evening and night workers at the medical device reprocessing unit and endoscopy, also,to propose ways to reduce constraints in the short to medium term.

METHODS

Anticipated challenges
• Collaboration of teams: sense of common purpose sometimes lacking at individual team levels ($/hour).
«Managing a project entails mobilizing around a shared goal and ensuring its sustainability.»
• Professionals' lack of time / multiple duties / lack of specialized staff.
• Dearth of information at the beginning and during the process; lack of visibility «kills»:
«What is the point of trying hard if you do not see the impact of your work?»
• Meticulous approach
• Audits
- Training of Operating Room and MDRU staff
- Conduct a survey of stakeholders
- MDRU staff to visit the Operating Room
- Assistant to update an Excel spreadsheet of AH-223 MDRU-SOPs;
- Create a dynamic tool for incident/accident management.

RESULTS

Increase in AH-223 returns;
Integrating a patient partner into the project;
Perform small-scale PEEAs (e.g., The Steril-Peel workstation).
Assessing the costs of non-quality at the URDM.
Decrease accident/incident in URDM
Workers in health

CONCLUSIONS

It is imperative that we prevent adverse events from recurring, that we implement various pre-emptive measures, including training staff, drafting or updating procedures and policies, introducing traceability systems for MDs, creating tools to foster quality (mapping) and providing monitoring and analysis of MDR incidents/accidents through an action plan.
All these preventive measures foster a safety culture and ensure continuous process improvement in the interest of quality and sustainability.

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STERILE PROCESSING TECHNOLOGIST FEDERAL DIPLOMA, A NEW PROFESSION IN SWITZERLAND

ORAL PRESENTATION

F. Cavin

SGSV/SSSH/SSSO Switzerland

INTRODUCTION

At the WFHSS Congress 2008 in Milan, I presented the situation of the training in MDR in Switzerland and the project to create a new profession with a 3-year apprenticeship.

The conclusions were:

- The implementation of a new profession with a federal certificate of competence is becoming a necessity.
- There is still a long way to go, as we still need to clarify a few things to get there.

What has happened since then?

HISTORY

- 2007 - 2008 Survey on MDR practices at the request of the authorities
- 2009 - 2010 Collaboration with a company specialised in the steps necessary to create a new profession, prepare the preliminary dossier and obtain the first green light from the authorities.
- 2010 SGSV/SSSH/SSSO joins ODASanté (umbrella organisation for healthcare professions in Switzerland).
- 2011 - 2012 Conducting a needs analysis for the new profession and obtain the second green light from the authorities.
- 2013 - 2016 A commission was set up to develop the training requirements, including the curriculum and the training plan and to choose the name of the new profession.
- 2017 - 2018 Implementation in the three language regions was finalised with the designation of training centres, drafting the training manual and of course materials, training the trainers in companies, and selecting the teachers.
- 2018 A first group of trainees started their training in each of the three language regions.
- 2018 - 2021 Adjustments were made to correct the detected imperfections and the certification procedure was finalised with the drafting of the oral and written exams.
- 2021 30 trainees obtain the Federal Diploma
  17 in the German part, 10 in the French part and 3 in the Italian part
- 2021 Design of a preparatory course for the certification procedure for people who have been working in CSSD for at least 5 years.

OBJECTIVES OF THE PRESENTATION

- Explain the design process of competence-based training according to the following system
- Describe the strengths and weaknesses of the training.
- Present the ideas and actions that will have to be put in place to make the training sustainable.

IMPROVEMENTS TO STERILE PROCESSING - AN ESSENTIAL PART OF ANY GLOBAL SURGERY INITIATIVE

ORAL PRESENTATION

C. Fast[1]

O. Fast[2]

[1]Sterile Processing Education Charitable Trust (spect) - Calgary (Canada),

[2]Mount Royal University - Calgary (Canada)

AIM

Disparities in surgical care are a significant contributor to global health inequities, especially in low-resource settings where surgical site infections are a major cause of morbidity and mortality. Efficient sterile processing (SP) practices play an essential role in the success of any global safe surgery initiative yet are often overlooked. This presentation discusses the work done by SPECT in partnership with global organizations to support continuous improvements in surgical care and SP practices.

METHODS

Aggregate data has been compiled from work conducted over a 10-year period, from 2011-2021, using a quality improvement design. A retrospective approach to data analysis was taken to summarize findings from assessments of sterile processing practices in healthcare facilities across 14 countries in Sub-Saharan Africa, South East Asia and Central America.

RESULTS

Findings from an analysis of the aggregate data identified a common absence of knowledge related to sterile processing, a need for access to equipment and resources, and a lack of understanding of the implications for health care workers and patients alike of possibilities for improvements. Continuous education and training, as well as advocacy, demonstrated visible improvements in many aspects of sterile processing practices. Opportunities for further improvement with increased attention to the details of sterilization were found to exist.

CONCLUSIONS

Common barriers related to sterile processing practices exist in countries globally. Some of these challenges can be addressed with education and training. Increased attention, however, to international standards, as well as supporting local health care workers and administrators with adequate resources, is needed to see continued improvements.

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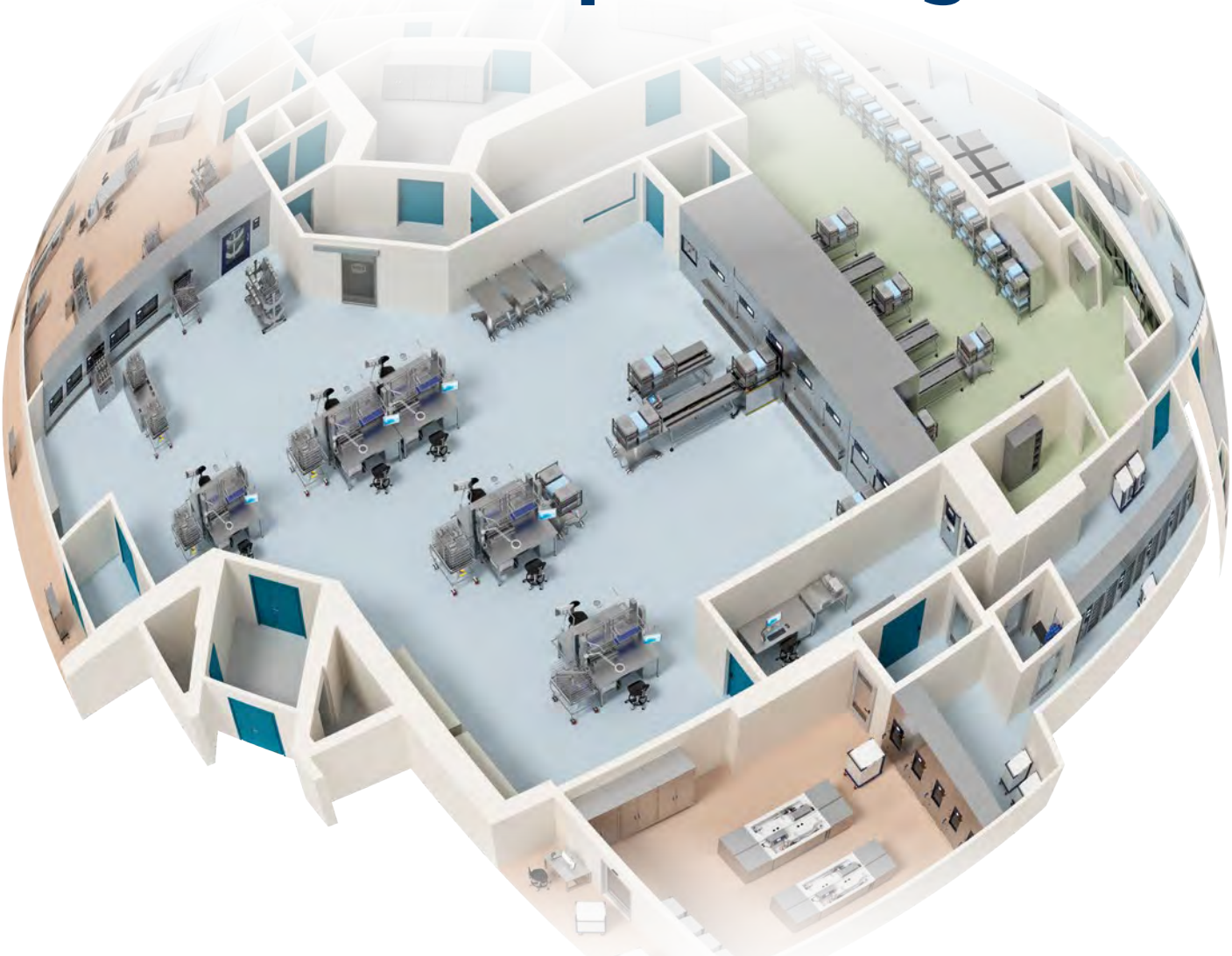

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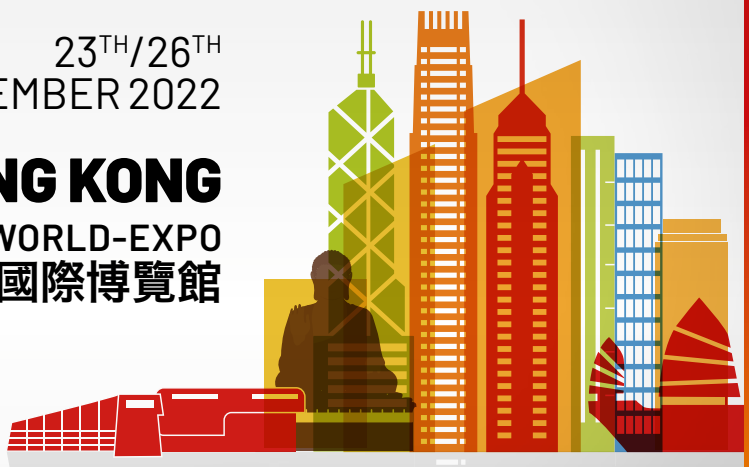

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