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MEDICAL DEVICES REPROCESSING:

BACK TO THE FUTURE

2024 WEBINAR SERIES #5

factsheet

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INTRO

Medical device reprocessing is a set of activities essential for healthcare systems response, answering to the needs of millions of procedures that are daily worldwide performed and contributing to the prevention of surgical site infections and other procedure-related infections, mainly endoscopy.[1]

Central Sterile Supply Departments (CSSDs) must adhere to rigorous standards to ensure quality, safety, responsiveness, efficiency, and sustainability, and are among the Joint Commission International's (JCI) top five most challenging requirements for 2022.[2,3]

Every day, tonnes of healthcare waste are produced worldwide, contributing to approximately 4-5% of greenhouse gas emissions.[4,5]
Implementing a holistic approach that integrates sustainability principles throughout the entire lifecycle of medical devices is urgently needed.[6,7]

The trend for single-use devices, due to concerns related to healthcare associated infections, is a problematic path that increases healthcare waste production, causes environmental damage to the planet and requires new approaches.[8,9]

IN THIS NEW ASP WEBINAR SERIES, MEDICAL DEVICE REPROCESSING: BACK TO THE FUTURE, THE FOCUS WAS ON THE TRENDS IN REPROCESSING THAT COULD CONSOLIDATE THE FUTURE OF PROCEDURES AND PROCESSES, AIMING HIGHER STANDARDS OF QUALITY, SAFETY AND ECONOMIC AND ENVIRONMENTAL SUSTAINABILITY.
OFF-SITE FACILITY REPROCESSING IS INCREASINGLY SEEN AS AN OPTION TO OVERCOME LIMITATIONS RELATED TO REPLICATION OF HIGH WORKING STANDARDS IN SMALL SCALE OPERATIONS, AS WELL AS REDUCING ADVERSE EVENTS, WHICH ARE CAUSED IN 80% OF THE CASES BY ORGANIZATIONAL ERRORS.[10,11]

However, this process must address several challenges to be successful, namely the logistics of transportation and the number of surgical sets and other devices, to satisfy the needs of medical professionals located elsewhere.[12]

The use of hydrogen peroxide is a major advance in reprocessing reusable medical devices. New ISO standards have been recently published to improve its implementation in a proper way.[13,14]

Reprocessing uro-genital and airway devices, such as endoscopes, presents an increasing challenge in maintaining high quality. Endoscopy is increasingly used as an alternative form of diagnosis and increasingly invasive treatment, which points to the need to reclassify endoscopes in the Spaulding classification.[15,16]

A number of problems related to incomplete decontamination have been identified that require process improvement in this area.[17-20]

Reprocessing technologies must also take into account economy and sustainability and support better lower costs. For example, efficient sterilisation methods with reduced water and energy consumption mean affordable money and less damage to equipment and the environment, contributing to sustainable healthcare systems and a greener environment.[4,5,21-23]

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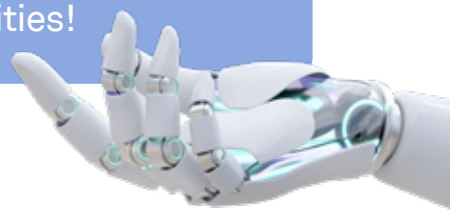
Topics to be addressed:

1. THE CHALLENGES BEHIND **OUTSOURCING YOUR MD REPROCESSING**
2. ISO 22441 - THE **NEW STANDARD** FOR H_2O_2 STERILIZATION
3. **INNOVATIONS** IN AIRWAY MEDICAL DEVICES REPROCESSING
4. **EVOLUTION** OF URO-GENITAL MD REPROCESSING
5. **SUSTAINABILITY AND ECONOMIC CONSIDERATIONS** BEHIND MEDICAL DEVICE REPROCESSING TECHNOLOGIES

"The final webinar was held as a Round Table, highlighting the key takeaways from each session. We thank you for your enthusiastic participation in this webinar series! The road ahead of us is full of opportunities!

CARLOS PALOS
ASP SUMMIT - SCIENTIFIC DIRECTOR



References

1. Global guidelines for the prevention of surgical site infection, second edition. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO 2. https://www.jointcommission.org/resources/news--and-multimedia/newsletters/newsletters/joint commission-online/april-19-2023/top-5-most-challenging-requirements-for-2022/. 3. The Joint Commission Guide to reprocessing reusable medical devices. JC, 2023. 4. Pichler P,Jaccard IS, Weisz U, Weisz H. International comparison of health care carbon footprints. Environ Res Lett. 14(6):064004. 7. 5. Health Care Without Harm, Arup. Health care's climate footprint. Health Care Without Harm; 2019. https://noharm-global.org/documents/health-care-climate-footprint-report. 6. Montesinos L, Checa Rifá P, Rifá Fabregat M, Maldonado-Romo J, Capacci S, Maccaro A, Piaggio D. Sustainability across the Medical Device Lifecycle: A Scoping Review. Sustainability. 2024; 16(4):1433. https://doi.org/10.3390/su16041433 7. Decontamination and Reprocessing of Medical Devices for Health-care Facilities, https://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf. 8. Keil M, Viere T, Helms K, Rogowski W. The impact of switching from single-use to reusable healthcare products: a transparency checklist and systematic review of life-cycle assessments. Eur J Public Health. 2023;33(1):56-63. doi:10.1093/eurpub/ckac174 9. Benedettini O. Green Servitization in the Single-Use Medical Device Industry: How Device OEMs Create Supply Chain Circularity through Reprocessing. Sustainability. 2022; 14(19):12670. https://doi.org/10.3390/su141912670 10. Relocating Sterile Processing Activities to an Off-Site Facility: Cost, Design, and Project Management Considerations April Cardone; Carolyn A. Grous,– AORN Journal, July 2020, Vol. 112, No. 1, pp 30-38. 11. Applying safety to quality: human error – https://ale.com/applying-safety-to-quality-human-error-traps. 12. Outsourcing or not outsourcing ? stérilisation magazine, page 10 111 # Été 2019 https://www.mobius.eu/app/uploads/Sourcing_STeMag111.pdf , October 2022. 13. Sterilization of healthcare products-low temperature vaporized hydrogen peroxide. Requirements for the development of a sterilization process for medical devices. ISO 22441:2022. 14. Rutala WA, Donskey CJ, Weber DJ. Disinfection and sterilization: New technologies. Am J Infect Control. 2023;51(11S):A13-A21. doi:10.1016/j.ajic.2023.01.004. 15. Rutala, W., Weber, D.. 2013. New Developments in Reprocessing Semicritical Items. American Journal of Infection Control. Elsevier Inc. pp. 560–566. https://doi.org/10.1016/j.ajic.2012.09.028. 16. Rational Approach _ Disinfection & Sterilization Guidelines_ CDC https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html. 17. Pyrek, K. M. August 10, 2018. Device-Related Infections: Patient-Ready Bronchoscopes Found to be Contaminated Despite Cleaning and Disinfection. Infection Control Today. https://www.infectioncontroltoday.com/view/devicerelated-infections-patient-ready-bronchoscopesfound be-contaminated; 18. Ofstead, C. L., Heymann, O. L., Quick, M. R., Johnson, E. A., Eiland, J. E., & Wetzler, H. P. (2017). The effectiveness of sterilization for flexible ureteroscopes: A real-world study. American journal of infection control, 45(8), 888–895. https://doi.org/10.1016/j.ajic.2017.03.016. 19. Center for Devices and Radiological Health. (2022d). UPDATE: Change in reprocessing methods with certain Karl Storz Urological endoscopes – Letter to health care providers. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/letters-health-careproviders/update-change-reprocessing-methods certain-karl-storz-urological-endoscopes-letter-health-care. 20. Food and Drug Administration (FDA). September 17, 2015. Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication. Retrieved June 8, 2023 from https://www.fdanews.com/ext/resources/files/09- 15/092115-safety-notice.pdf?1520852028 21. McCreanor, V., & Graves, N. (2017). An economic analysis of the benefits of sterilizing medical instruments in low-temperature systems instead of steam. American journal of infection control, 45(7), 756–760. https://doi.org/10.1016/j.ajic.2017.02.026. 22. Schafer B. Decreased number of repairs of rigid scopes as a result of low-temperature sterilization with H2O2 gas plasma. A field report form the Barmherzige Bruder Hospital in Trier, Germany. Central Serv 2009;17:194-6. 23. Skogas J, Marvik R. Measures taken to reduce damage and repair costs of rigid endoscopes during their handling and processing in surgical practice. Minim Invasive Ther Allied Technol 2003;12:76-81

THIS E-BOOK SUMMARIZES THE WEBINAR SERIES, HIGHLIGHTING THE RESULTS OF THE POLLS AND KEY TAKEAWAYS OF EACH WEBINAR.

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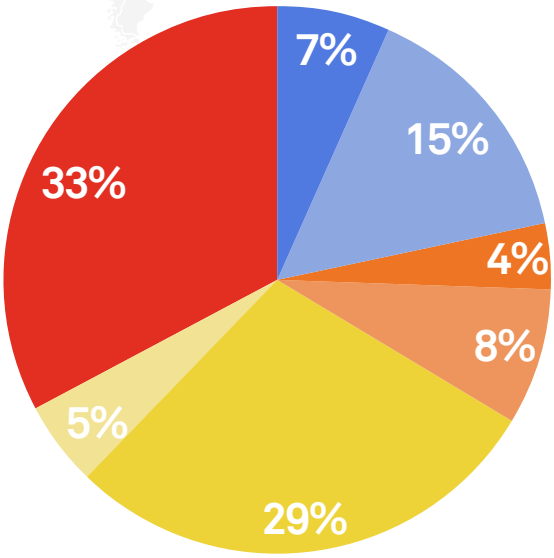
TOTAL
1312
REGISTRANTS

TOTAL
80
COUNTRIES REPRESENTED

TOTAL
764
QUESTIONS ANSWERED



Professions

- Clinical Sales / Production Specialist
- Decontamination Lead / Manager
- Healthcare Manager
- Infection Prevention & Control Specialist
- Nurse
- Physician
- Other

WEBINARS GLOBAL STATISTICS

THIS STATISTICS ARE AN INSIGHTFUL SUMMARY
OF OUR **ASP SUMMIT WEBINARS** ON THE
MEDICAL DEVICES REPROCESSING, **BACK TO THE FUTURE**

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2024 WEBINAR SERIES #5

BACK TO THE FUTURE

THE CHALLENGES BEHIND OUTSOURCING YOUR MD REPROCESSING

Dr. Elisabetta Anzanello

CONSULTANT FOR INTEGRATED SERVICES FOR INFECTIOUS RISK MANAGEMENT IN O.R.

ITALY

1st WEBINAR

INTRO

IN HEALTHCARE FACILITIES, WHETHER THEY ARE PUBLIC OR PRIVATE, THERE ARE MULTIPLE NEEDS IN TERMS OF SPECIALIZED HUMAN RESOURCES, MEDICAL EQUIPMENT AND OPERATIONAL SPACES.[1-10]

OFTEN OVERLOOKED BUT VITAL FOR PATIENT WELL-BEING, SOME SEGMENTS OF THE HEALTHCARE CHAIN STRUGGLE TO RECEIVE THE NECESSARY FINANCIAL AND PERSONNEL SUPPORT.[11]

THE POSSIBILITY OF RESORTING TO AN OUTSOURCING SERVICE WITH A LONG-TERM AND BROAD-RANGING PROJECT ALLOWS FOR THE RESOLUTION OF A PORTION OF THESE PROBLEMS, RECOVERING RESOURCES AND ACHIEVING BETTER PERFORMANCE THROUGH ECONOMIES OF SCALE. HOWEVER, IT IS ESSENTIAL TO CHOOSE THE MOST SUITABLE PROJECT FOR BOTH THE CURRENT AND FUTURE STRUCTURE.[12-13]

TOGETHER, WE WILL ANALYZE THE FUNDAMENTAL POINTS FOR THE DEVELOPMENT AND CORRECT IMPLEMENTATION OF AN OUTSOURCING SERVICE, ENSURING IT IS ALIGNED WITH THE NEEDS AND GOALS OF THE HEALTHCARE FACILITY.

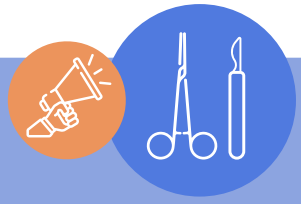
01. What is MD Reprocessing Outsourcing?

OUTSOURCING OF MD REPROCESSING IS THE DELEGATION OF MEDICAL DEVICE MANAGEMENT ASPECTS TO SPECIALIZED THIRD PARTY STRUCTURES EXTERNAL TO HEALTHCARE FACILITY

THIS MAY INCLUDE DEVICE REPROCESSING, DEVICE LIFECYCLE MANAGEMENT, MAINTENANCE, MATERIAL SUPPLY, AND LOGISTICS MANAGMENT. ADDITIONALLY, OUTSOURCING ENABLES HEALTHCARE ORGANIZATIONS TO ACCESS CUTTING-EDGE TECHNOLOGIES AND OPTIMIZED PROCESSES, FURTHER ENHANCING EFFICIENCY AND THE QUALITY OF SERVICES OFFERED.

THERE ARE VARIOUS APPROACHES TO OUTSOURCING IN MD REPROCESSING:

- Management of CSSD, in-house or external
- Management of CSSD including the supply of surgical instrument sets
- Management of CSSD with supply of surgical instrument sets and additional services such as surgical drapes and gowns, OR disinfection, and more.



ONE OF THE MAIN ISSUES IN THE OUTSOURCING OF MEDICAL DEVICES CONCERNS THE SAFETY AND QUALITY OF THE REPROCESSING PROCESS. SINCE MDS CAN COME INTO DIRECT CONTACT WITH PATIENTS AND DIRECTLY IMPACT THEIR HEALTH, IT IS OF VITAL IMPORTANCE TO ENSURE THAT THE REPROCESSING PROCESS OF MD IS CARRIED OUT SAFELY AND IN COMPLIANCE WITH THE HIGH STANDARDS OF QUALITY AND SAFETY REQUIRED.

WHY OPT FOR AN OUTSOURCING SERVICE?

- It is a non-core activity within hospital organization.
- There is a shortage of dedicated human resources for this task.
- Limited space availability within the hospital.
- An outsourcing provider may offer better economic management in a capital-intensive project.
- Outsourcing providers can organize a CSSD similar to a real MD production facility, adhering to the highest standards.

THIS APPROACH HAS GAINED POPULARITY OVER TIME, BECOMING A COMMON PRACTICE IN MANY HEALTHCARE FACILITIES WORLDWIDE.
THESE SERVICES CAN BE PROCURED THROUGH A PRIVATE PUBLIC PARTNERSHIP OR A DEDICATED TENDER PROCESS.

The main reason behind outsourcing MD reprocessing is the lack of human resources.

IMAGE SOURCE : by courtesy of Samiservice Shp , Trauma Center, Tirana

02. How to obtain the most appropriate service ?

WHAT IS LACKING IN HOSPITAL ORGANIZATION? IS IT AN ADEQUATE SPACE FOR CSSD, FUNDING FOR EQUIPMENT OR SURGICAL INSTRUMENTS, HUMAN RESOURCES, OR ANY KIND OF MATERIALS?

THIS TYPE OF ANALYSIS IS CRUCIAL FOR GAINING A CLEAR UNDERSTANDING OF THE POTENTIAL COLLABORATION WITH AN OUTSOURCER. THESE ARE THE MOST IMPORTANT INFORMATION TO GET IN ORDER TO DEFINE WHAT IS THE REAL NEED OF THE HEALTHCARE FACILITY:

- Number of surgical procedures separated by type and specialty in the last 3 years
- Evaluation of peak activity by surgical specialty
- Determine the number and positioning of O.R.s
- Assess the organization of operating rooms (OR)
- Analysis of the existing CSSD activity (number of sterilization units processed per year)
- Analysis of requests for reprocessing of MDs from other departments and their frequency
- Conduct an inventory of the surgical sets currently in use and those needed
- Identify non-OR medical devices that need to be reprocessed within the hospital.

EXPLORING THE OPPORTUNITY TO COLLABORATE ON THE PROJECT WITH OTHER HOSPITALS MAY ALSO BE WORTHWHILE.

- The available spaces and consequently the available pathways within the facility must be evaluated, together with the current equipment dedicated to sterilization process. This can result in an upgrade of the existing structure
- In addition, it is important to evaluate the future development plans of the surgical activity in order to properly calibrate the needs

IF THESE NEEDS CANNOT BE SATISFIED IN THE HEALTHCARE FACILITY, IT IS NECESSARY TO RELY ON A SPECIFIC EXTERNAL FACILITY. A GOOD SUPPORT FOR DECISION MAKING MAY COME FROM VISITING CSSD AND ANALYZING DOCUMENTATION COMING FROM THE POTENTIAL OUTSOURCERS.[3, 13-14]

Analysis of departmental equipment

- Assessments of the medical device reprocessing needs for the ICU, NICU, Emergency Room, and outpatient clinics.
- Verify the current equipment and ensure compatibility with CSSD standards and protocols, identifying gaps in equipment.
- Develop and implement strategies to manage CSSD workflows effectively, ensuring there are no urgent disruptions.
- Collaborate with departmental team to synchronize schedules and reprocessing cycles.
- Ensure proper packaging of reprocessed medical devices to maintain a safe shelf life.
- Establish guidelines and protocols for packaging based on the specific needs and use patterns of each department.

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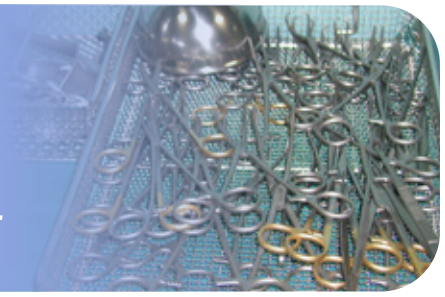
CHOOSING THE RIGHT OUTSOURCING SERVICE AND PROVIDER DEPENDS CLOSELY ON THE ABILITY TO ANALYZE AND EVALUATE BOTH THE NEEDS OF THE FACILITY AND THE CREDENTIALS OF THE PROVIDER.



Images: by courtesy of dr. E.Anzanello, Hospital QSUT Tirana, Albania

The hospital MD reprocessing needs assessment is crucial for gaining a clear understanding of the potential collaboration with an outsourcer.

THE MOST CRITICAL STEP IN THE IMPLEMENTATION PROCESS OF THE OUTSOURCING SERVICE IS THE DEFINITION OF THE NECESSARY EQUIPMENT AND FACILITIES FOR THE PROPER FUNCTIONING OF THE SERVICE, ACCURATELY DETERMINING THEM THROUGH A QUALITATIVE-QUANTITATIVE ANALYSIS.

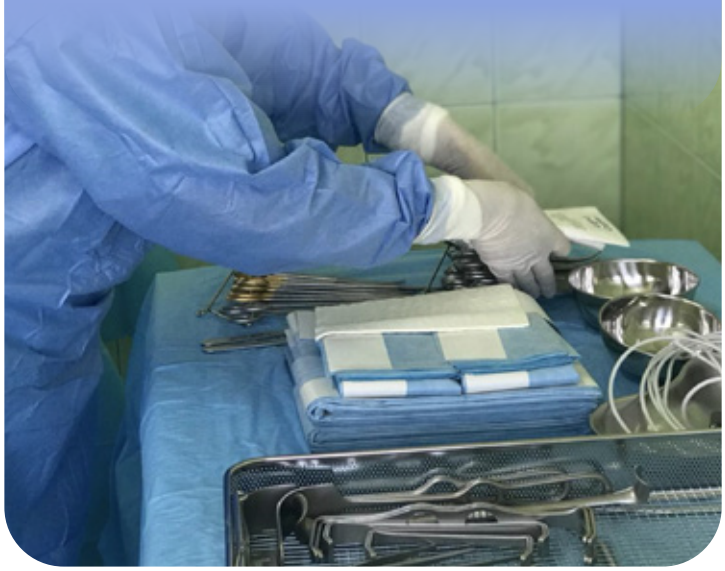


Image: by courtesy of dr.E.Anzanello, Krujie Hospital, Albania

03. Which are the stages of service development ?

PLANNING FOR THE CSSD INVOLVES:

- **Designating areas, procuring equipment, overseeing installation, arranging technical furnishings, and acquiring software and hardware, including single-use devices.**
- **Creating and organizing surgical instrument sets.**
- **Analyze and organize the MDs to be reprocessed for use in other departments to avoid critical issues.**
- **Logistics organization.**
- **Allocating human resources, scheduling shifts, and conducting training sessions.**
- **Establishing service and maintenance protocols.**
- **Conducting risk analysis and developing a disaster recovery plan.**

IN COLLABORATION WITH THE SURGICAL TEAM, EACH SINGLE PATIENT SET OF SURGICAL INSTRUMENTS MUST BE DESIGNED, SELECTING THE MOST SUITABLE SUPPLIERS ACCORDING TO SURGICAL NEEDS. BY STUDYING STATISTICS ON SURGICAL PROCEDURES, OPERATING ROOM SCHEDULING, AND PEAK ACTIVITY PERIODS, THE NUMBER OF COPIES OF EACH SURGICAL SET REQUIRED FOR SERVICE DELIVERY CAN BE DETERMINED.

THE PRELIMINARY RISK ANALYSIS, COMBINED WITH THE STUDY OF GATHERED INFORMATION, ENABLES THE ACCURATE ASSESSMENT OF THE NEED FOR ANY BACKUP SOLUTIONS THAT DO NOT REPLACE THE SERVICE BUT COMPLEMENT IT TO ENSURE CONTINUITY IN CASE OF NECESSITY RISK ANALYSIS AND DISASTER RECOVERY PLANS CAN EFFECTIVELY SUPPORT THE START-UP OF THE PROJECT BY GIVING CONFIDENCE TO HEALTHCARE PERSONNEL IN THE OUTSOURCING PARTNER.[3, 15-16]

One of the most important stages to take in consideration is Conducting risk analysis and developing a disaster recovery plan.

04. How to ensure an effective service

- Procedures in the Central Sterile Services Department (CSSD)
- Selection of appropriate materials and suppliers
- Procedures for use in the operating room (OR) for medical devices (MDs) and surgical sets.
- Procedures for use of reprocessed MDs in other hospital departments.
- Logistics and transportation adhering to both international and local standards and customers' needs.
- Implementation and management of dedicated Software systems for traceability.
- Acquisition and maintenance of Quality Certifications.

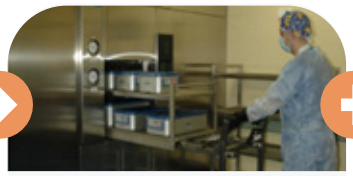
CSSD PROCESS

PROCEDURES

PROCEDURES IN THE CENTRAL STERILE SERVICES DEPARTMENT (CSSD) MUST BE CLEARLY DEFINED AND CONTINUOUSLY UPDATED TO GET BEST RESULTS.

OPERATORS

THE OPERATORS MUST HAVE A PERFECT UNDERSTANDING OF THE OPERATION OF THE EQUIPMENT AND THE TYPES OF CYCLES TO BE USED ON DIFFERENT MEDICAL DEVICES.



AREAS

THE OPERATIONAL SOFTWARE IS THE FOUNDATION ON TOP OF WHICH THE ENTIRE OUTSOURCING SERVICE MUST BASE ON. THE OPTIMAL SOLUTION SHOULD INVOLVE MANAGING THE ENTIRE SERVICE THROUGH THE SAME SOFTWARE ACHIEVING TOTAL PRODUCT TRACEABILITY. EVERY STEP OF THE PROCESS MUST BE RECORDED TO PROVIDE COMPLETE TRACEABILITY THAT ULTIMATELY TRANSLATES INTO A PRODUCTION LOT.

HUMAN RESOURCES

THE USE OF LOT TRACEABILITY ENSURES THAT PATIENTS WILL HAVE THE ABILITY TO KNOW EVERY STEP CONNECTED TO PRODUCTION FOR THE NEXT SEVERAL YEARS, AS WELL AS WITH ANY OTHER STERILE MEDICAL DEVICE AVAILABLE ON THE MARKET.[3, 15-16]

The implementation and management of dedicated Software systems for traceability its critical to ensure an effective service.

TRACEABILITY ON MD AND QUALITY CERTIFICATIONS ARE ESSENTIAL ELEMENTS TO OBTAIN A SAFE AND RELIABLE MD REPROCESSING SERVICE.

Images : by courtesy of dr.E.Anzanello, from CSSD Lushnjie and QSUT Hospitals, Saaniservice Albania, and Steritalia spa, Umbertide, Italy

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05. How to optimize the service?

IN ORDER TO OPTIMIZE THE SERVICE WE NEED TO ENHANCE COMMUNICATION CHANNELS AND IMPLEMENTING EFFICIENT METHODS FOR RAPID COMMUNICATION.

- Establishment of protocols between the Outsourcer and Hospital Management.
- Fostering team building between the OR staff and the Outsourcer, working collaboratively toward shared ethical outcomes.
- Enhance communication channels and implementing efficient methods for rapid communication.
- The operational Team must share protocols and operational procedures dedicated to operating rooms and departments
- For surgical instrument sets, before the service startup, it is important to jointly define the operational methods for managing the various needs may arise, whether they are modifications to the initial composition of the set, or the need for new or additional sets.
- Definition of documentation (on paper or software) for managing requests, movements, and all necessary activities.
- Clear definition of responsibilities and delineation of roles between all involved parties.

PROMOTING TEAM BUILDING BETWEEN THE OR STAFF AND THE OUTSOURCER, WORKING COLLABORATIVELY TOWARD SHARED ETHICAL OUTCOMES MUST BE AN OBJECTIVE.

THE IMPORTANCE OF INTEGRATING THE OUTSOURCER IN THE HEATHCARE FACILITY IS ESSENTIAL TO CREATE SMOOTH FLOWS WITHIN THE STRUCTURE AND ANTICIPATE ANY POTENTIAL ISSUES.[3, 15]

The key point is to remember that the common goal must be the patient's health, ensuring equal rights and safety for everyone.

WITHOUT ADEQUATE INTEGRATION BETWEEN THE HEALTHCARE FACILITY'S TEAM AND THE OUTSOURCER'S TEAM, THE PROJECT DOES NOT EFFECTIVELY FIT INTO THE ORGANIZATION.

Images : by courtesy of U.Staccini, former owner of Steritalia spa, owner of Tecnosanimed srl, Umbertide, Italy

Integration between outsourcer and healthcare team

Promoting team building between the OR staff and the Outsourcer, working collaboratively toward shared ethical outcomes.

he importance of integrating the outsourcer in the healthcare organization is essential to create smooth flows within the structure and anticipate any potential issues.

It shouldn't absolutely be perceived as an imposition of rules not shared by both parties, but rather, objectives should be proposed, discussed, and shared among representatives of both sides.

The key point is to remember that the common goal must be the patient's health, ensuring equal rights and safety for everyone.

By keeping these fundamental principles in mind, it is possible to implement a series of operational steps useful for achieving the objectives.

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Resume

THE OUTSOURCING OF MD REPROCESSING OFFERS VARIOUS APPROACHES, INCLUDING MANAGEMENT OF CSSD ALONE, MANAGEMENT OF CSSD WITH SUPPLY OF SURGICAL INSTRUMENT SETS, AND MANAGEMENT OF CSSD WITH ADDITIONAL SERVICES LIKE DRAPES AND GOWNS, OR DISINFECTION, ETC.

IDENTIFYING THE HOSPITAL'S NEEDS, SUCH AS SPACE, FUNDING, HUMAN RESOURCES, AND MATERIALS, IS CRUCIAL FOR POTENTIAL COLLABORATION WITH AN OUTSOURCER. THIS ANALYSIS INVOLVES EVALUATING CURRENT SURGICAL SETS, OR ORGANIZATION, AND IDENTIFYING NON-OR MEDICAL DEVICES NEEDING REPROCESSING.

OUTSOURCING IS CHOSEN DUE TO IT BEING A NON-CORE ACTIVITY, SHORTAGE OF RESOURCES, LIMITED SPACE, POTENTIAL FOR BETTER ECONOMIC MANAGEMENT, AND THE ABILITY OF OUTSOURCERS TO ORGANIZE CSSD EFFICIENTLY.

TO ACHIEVE THE BEST PERFORMANCE, IT IS ESSENTIAL PLANNING FOR THE CSSD ENTAILS DESIGNATING AREAS, ACQUIRING EQUIPMENT, ORGANIZING SURGICAL SETS, MANAGING LOGISTICS, ALLOCATING HUMAN RESOURCES, ESTABLISHING MAINTENANCE PROTOCOLS, AND CONDUCTING RISK ANALYSIS.

PROCEDURES AND UTILIZATION OF MDS AND SURGICAL SETS ARE ASSESSED IN OR AND OTHER HOSPITAL DEPARTMENTS, AS WELL AS IN THE CSSD. LOGISTICS MUST FOLLOW INTERNATIONAL STANDARDS FOR SAFETY, AND IT IS STRONGLY RECOMMENDED TO HAVE A SOFTWARE FOR TRACEABILITY AND MAINTENANCE OF QUALITY CERTIFICATIONS. EVERY DETAIL MUST BE ANALYZED AND EVALUATED BEFORE THE PROJECT START-UP TO AVOID CRITICAL ISSUES.

ESTABLISHING PROTOCOLS BETWEEN THE OUTSOURCER AND HOSPITAL MANAGEMENT, FOSTERING TEAM BUILDING, ENHANCING COMMUNICATION, AND DEFINING RESPONSIBILITIES ARE VITAL FOR EFFECTIVE COLLABORATION.

Take home messages

1. Carefully assessing internal needs helps obtain the best service.
2. Considering future operational developments of the facility also helps acquire a flexible service ready to adapt effectively to activ
3. Collaborating in the planning process in terms of methods and timing of service provision provides a comprehensive view of the final product and allows for precise service refinement.
4. Verifying the outsourcer's work through reliable operational software and inspections for certifications builds confidence in the safety of reprocessed MDs.
5. Working as a team with the outsourcer ensures the best performance through clear and consistent communication.

References:

1. World Health Organization, Decontamination and Reprocessing of Medical Devices of Healthcare facilities, ISBN 978 92 4 154985 pag. 14-15; 21-25; 30-69; 2. Le buone pratiche di sterilizzazione: Guida all'accreditamento delle centrali di sterilizzazione, E. Sesti, G. Finzi, U.L. Aparo, Terapia Moderna, Il Pensiero Scientifico Editore, ISBN 88-490-0162-2 pag.30,31 3. Linee Guida per l'accreditamento delle Centrali di sterilizzazione, G. Finzi, U.L. Aparo, G. Di Pietro, K. Kob, C. Lazzari, R. Li Donni, D. Pedrini, G. Pelissero, G. Sacco, S. Pili, E. Sesti, M.A. Vantaggiato, C. Verdeoliva, Edicom 2008 pag 38-42, 44-49, 53, 63-64, 83 4. ISO 13485 "Medical devices -- Quality management systems -- Requirements for regulatory purposes" 5. ISO 9001:2015 "Quality Management Systems - Requirements" 6. ISO 31000 "Risk management -- Principles and guidelines" 7. UNI CEI EN ISO 14971:2022 Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici 8. UNI EN ISO 17665-1:2007, Sterilizzazione dei prodotti sanitari. Calore Umido Parte 1: Requisiti per lo sviluppo, convalida e controllo di routine di un processo di sterilizzazione per MD 9. UNI/TR 11408:2011 Guida alla progettazione, allo sviluppo e al controllo del processo di ricondizionamento dei dispositivi medici riutilizzabili (DM) sterilizzabili mediante vapor 10. Qualità e sicurezza nei processi di sterilizzazione in outsourcing e costi della gestione integrata, Prof. F. Miroglio, SDA Bocconi. Oltre n. 15 11. La sterilizzazione – Modelli di servizio a confronto: l'Outsourcing, Prof. G. Paladino, Corso ANMDO 2006 12. Progettazione funzionale: Reengineering della centrale unica di sterilizzazione, E. Milani, P. Oliva, 18 Convegno nazionale AIIC 13. Linee guida per la convalida della sterilizzazione in ospedale –Procedure- G.I.S.I.O., Societa' Italiana di Igiene, Medicina Preventiva e Sanita' Pubblica, pg 102 14. La Sterilizzazione: Necessita' organizzative e standardizzazione dei Servizi, G. Finzi, M. Aporti, T. Campione, I Corso Nazionale ANMDO 28-29.04.2006, pp6-9 15. L'acquisto del servizio di sterilizzazione dello strumentario chirurgico, dr.sa P. Ferri, XIII Congresso AIOS, 24 ottobre 2015, pp 12-13 16. Vieri Lastrucci, Alberto Romolini, Martina Giusti & Niccolo' Persiani (2023) The impact of outsourcing operating theatre support services on hospital performances: the case of the largest university hospital of the Albania, Economic Research-Ekonomska Istraživanja , 36:1, 2199-2214, DOI: 10.1080/1331677X.2022.2097102

Sources:

Le buone pratiche di sterilizzazione: Guida all'accreditamento delle centrali di sterilizzazione, E. Sesti, G. Finzi, U.L. Aparo, Terapia Moderna, Il Pensiero Scientifico Editore, ISBN 88-490-0162-2 | Linee Guida per l'accreditamento delle Centrali di sterilizzazione, G. Finzi, U.L. Aparo, G. Di Pietro, K. Kob, C. Lazzari, R. Li Donni, D. Pedrini, G. Pelissero, G. Sacco, S. Pili, E. Sesti, M.A. Vantaggiato, C. Verdeoliva, Edicom 2008 pg 44-49, 53 | La Sterilizzazione: Necessita' organizzative e standardizzazione dei Servizi, G. Finzi, M. Aporti, T. Campione, I Corso Nazionale ANMDO 28-29.04.2006, pp6-9 | Linee guida per la convalida della sterilizzazione in ospedale –Procedure- G.I.S.I.O., Societa' Italiana di Igiene, Medicina Preventiva e Sanita' Pubblica, pg 102 | Linee Guida per l'accreditamento delle Centrali di sterilizzazione, G.Finzi,U.L.Aparo,G.DI Pietro,K.Kob,C.Lazzari,R.LiDonni,D.Pedrini,G.Pelissero,G.Sacco,S.Pili, E.Sesti, M.A.Vantaggiato,C.Verdeoliva, Edicom 2008, pg38-42 | L'acquisto del servizio di sterilizzazione dello strumentario chirurgico, dr.sa P. Ferri, XIII Congresso AIOS, 24 ottobre 2015, pp 12-13 | Linee Guida per l'accreditamento delle Centrali di sterilizzazione, G.Finzi,U.L.Aparo,G.DI Pietro,K.Kob,C.Lazzari,R.LiDonni,D.Pedrini,G.Pelissero,G.Sacco,S.Pili,E.Sesti,M.A.Vantaggiato,C.Verdeoliva, Edicom 2008, pg 83 | Vieri Lastrucci, Alberto Romolini, Martina Giusti & Niccolo' Persiani (2023) The impact of outsourcing operating theatre support services on hospital performances: the case of the largest university hospital of the Albania, Economic Research-Ekonomska Istraživanja, 36:1, 2199-2214, DOI: 10.1080/1331677X.2022.2097102 | L'acquisto del servizio di sterilizzazione dello strumentario chirurgico, dr.sa P. Ferri, XIII Congresso AIOS, 24 ottobre 2015, pp 12 | Linee Guida per l'accreditamento delle Centrali di sterilizzazione, G.Finzi,U.L.Aparo,G.DI Pietro,K.Kob,C.Lazzari,R.LiDonni,D.Pedrini,G.Pelissero,G.Sacco,S.Pili,E.Sesti,M.A.Vantaggiato,C.Verdeoliva, Edicom 2008, pg 63-64

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QUESTIONS & ANSWERS

WEBINAR SERIES #5

THE PURPOSE OF THE WEBINAR WAS TO HAVE A GENERAL OVERVIEW OF

"The Challenges behind Outsourcing your MD Reprocessing".

MODELS AND BENEFITS, HOSPITAL NEEDS ASSESSMENT, PROJECT AND SERVICE ORGANIZATION.

Attendees were asked to answer to several polls during this webinar.

WHY SHOULD I NEED AN OUTSOURCING SERVICE?

- 31% Specialisation and regulatory compliance
- 29% Cost efficiency
- 29% Resources savings
- 11% Flexibility

HOW CAN I GET THE RIGHT ONE FOR MY NEEDS?

- 56% Accurate hospital needs analysis
- 19% Analysis of the potential outsourcer
- 19% Costs/benefits analysis
- 7% New techonologies

HOW TO CREATE THE SERVICE?

- 49% Design and implement cssd
- 18% Surgical instruments sets creation
- 24% Risk analysis
- 9% Logistics

HOW TO GUARANTEE A SAFE AND EFFECTIVE SERVICE?

- 14% Software and traceability
- 29% Detailed procedures
- 47% Human resources and training
- 10% Certifications

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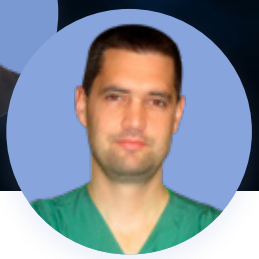
2024 WEBINAR SERIES #5
MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

ISO 22441 - THE NEW STANDARD FOR H_2O_2 STERILIZATION

Dr. Philippe Destrez
R&D EMEA, ASP, STRASBOURG, MONTESSON
FRANCE



Mr. Wouter Meert
PROCESS-PROJECT MANAGER CSSD, HEAD INSTRUMENT MANAGEMENT
UZ LEUVEN, BELGIUM

2nd WEBINAR

DR. PHILIPPE DESTREZ:

01. ISO 22441: the first standard dedicated to H_2O_2 sterilization

SINCE ITS INTRODUCTION IN THE EARLY 1990S, HYDROGEN PEROXIDE (H_2O_2) LOW-TEMPERATURE STERILIZATION (LTS) HAS EMERGED AS THE PREFERRED METHOD ON HEALTHCARE FACILITIES, SURPASSING TRADITIONAL OPTIONS LIKE ETHYLENE OXIDE AND FORMALDEHYDE DUE TO THEIR TOXICITY AND PROTEIN-FIXING PROPERTIES.

H_2O_2 LTS PERMITS CONVENIENT AND SAFE TERMINAL STERILIZATION OF HEAT SENSITIVE CRITICAL DEVICES THAT WERE OFTEN ONLY HIGH-LEVEL DISINFECTED.

H_2O_2 LTS PERMITS CONVENIENT AND SAFE TERMINAL STERILIZATION OF HEAT SENSITIVE CRITICAL DEVICES THAT WERE OFTEN ONLY HIGH-LEVEL DISINFECTED.

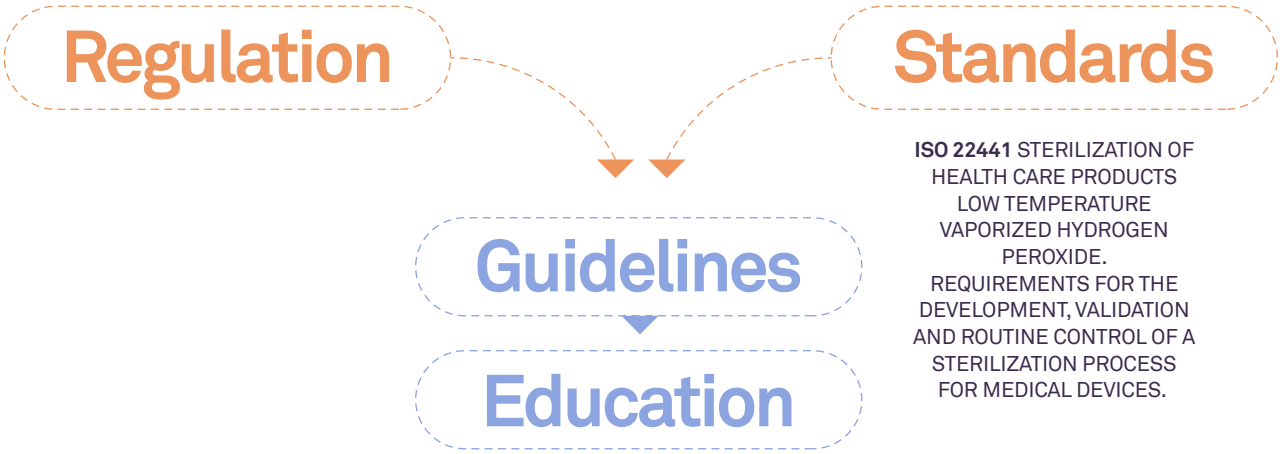
THE PUBLICATION OF **ISO 22441** MATERIALIZES THE SUCCESS OF H_2O_2 LTS. OTHER 2 STANDARDS FOR MANUFACTURERS OF H_2O_2 STERILIZERS (EN17180) AND H_2O_2 BACTERIOLOGICAL INDICATORS (ISO/AWI 11138-6) SHOULD BECOME AVAILABLE IN THE NEXT 2 YEARS.[1-3]

> **The publication of ISO 22441 materializes the growing success of H_2O_2 LTS.**

ISO 22441: H_2O_2 IS THE REFERENCE LTS MODALITY IN HEALTHCARE FACILITIES THROUGH THE WORLD.

IMAGE SOURCE : https://www.freepik.com/free-ai-image/people-hanging-out-with-robot_13231004.3.htm#fromView=search&page=1&position=22&uuid=e4c82f61-d5d0-4d80-af5d-13d0d74507bd

STANDARDS, GUIDELINES AND REGULATION:



ISO 22441 STERILIZATION OF HEALTH CARE PRODUCTS LOW TEMPERATURE VAPORIZED HYDROGEN PEROXIDE. REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

Source: 1. Courtesy of Philippe Destrez, Scientific Director ASP, Strasbourg - France

02. Contributions of medical devices manufacturers, sterilizers manufacturers and healthcare facilities

ISO 22441 IS A STERILIZATION PROCESS STANDARD FOR H_2O_2 LTS. IT COVERS ALL TASKS THAT CONTRIBUTES TO THE SAFE STERILIZATION OF MEDICAL DEVICES FROM EARLY DEVELOPMENT STAGES BY THE STERILIZER MANUFACTURER TO DAILY OPERATIONS BY THE HEALTHCARE FACILITY.

ISO 22441 HENCE CONTAINS REQUIREMENTS APPLICABLE TO THE STERILIZER MANUFACTURER, FOR STERILIZATION DEPARTMENTS BUT ALSO FOR MEDICAL DEVICE MANUFACTURERS.[4]

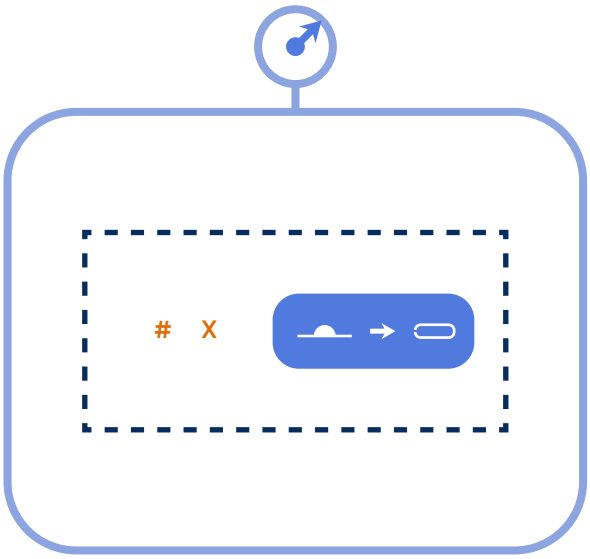
> ISO 22441 applies to sterilizer manufacturers, medical device manufacturers and healthcare facilities.

03. Partnership between medical device manufacturer and sterilizer manufacturer is key

MEDICAL DEVICE MANUFACTURERS MUST PROVIDE INSTRUCTIONS FOR REPROCESSING AND VALIDATE THE CLEANING PROCESS AND STERILIZATION CYCLES THAT THEY RECOMMEND.

GIVEN THE GROWING COMPLEXITY OF HEAT SENSITIVE MINIMALLY INVASIVE SURGERY DEVICE, VALIDATION MEANS STERILITY TESTS ON REAL DEVICES AND IN MOST CHALLENGING LOCATION IN THESE DEVICES. IT IS ALSO VERIFIED THAT THE DEVICE REMAINS FULLY FUNCTIONAL AFTER REPEATED REPROCESSING.

AS H_2O_2 CYCLES ARE SPECIFIC, STERILITY AND FUNCTIONALITY TESTS ARE OFTEN PERFORMED IN PARTNERSHIP WITH STERILIZER MANUFACTURERS.[5,6]



A NEW NORM: ISO 22441 VALIDATION:
MICROBIOLOGICAL PQ = 1 + 2 + 3 + 4 + 5 + 6

1. FOR EACH CYCLE
2. MOST CHALLENGING DEVICE WITH INOCULUM OR BI AT MOST DIFFICULT POSITION TO STERILIZE
   OR
   PCD (BI PCD) SHOWN TO BE EQUIVALENT
   NUMBER AND LOCATION ACCORDING TO MANUFACTURER GUIDANCE
3. IN PACKAGING
4. AT MOST CHALLENGING LOCATION IN MOST CHALLENGING LOAD
5. CYCLE PARAMETERS: AT LEAST P, T°C, T, VH_2O_2 (DIRECTLY OR INDIRECTY) WITHIN SPECIFIED TOLERANCE

Source:18 Courtesy of Philippe Destrez – R&D ASP: ISO 22441:2022 – Fig.6 Performance Qualification
Image: 5, Courtesy of Philippe Destrez – Advanced Sterilization Products – Research & Development

Complexity of minimally invasive heat sensitive medical device require thorough validation.

ALL H_2O_2 CYCLES ARE NOT EQUIVALENT.

04. The role of the healthcare facility

VALIDATION OF STERILIZATION PROCESSES ENSURE THAT ALL DOCUMENTATION AND CERTIFICATE WERE PROVIDED, THAT THE STERILIZER IS PROPERLY INSTALLED, OPERATIONAL, AND ABLE TO ACHIEVE CONDITIONS FOR STERILITY. ON SITE, PERFORMANCE QUALIFICATION (PQ) IS PERFORMED WITH WORST CASE LOAD AND BACTERIOLOGICAL INDICATORS. AS DETERMINATION OF AN H_2O_2 WORST CASE LOAD IS NOT EASY, CHALLENGE TEST PACK ARE MADE AVAILABLE. BI MIGHT BE REPLACED BY BI PCD THAT SIMULATE THE MOST COMPLEX DEVICES APPROVED FOR REPROCESSING.
FOR ROUTINE CONTROL AND MONITORING FAST READOUT BIS OR BI PCD SUPPORT PROCESS PARAMETER CONTROLS.[6,7]

BI-PCD CONFIRM WITHIN MINUTES THAT CONDITIONS FOR STERILITY ARE MET AT THE HEART OF THE MOST COMPLEX DEVICES.

Performance qualification is performed with worst case load and preferably BI PCDs.

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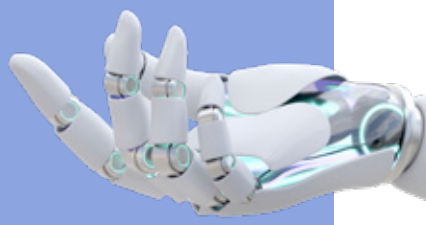
DR. PHILIPPE DESTREZ:

1. New ISO 22441 international standards materializes the success of H_2O_2 LTS;
2. Sterilization Process standards is applicable to sterilizer Manufacturers but also to Medical Device Manufacturers and healthcare facilities;
3. Partnership between sterilizer manufacturers and manufacturers of medical devices is key to overcome the growing material and geometrical complexity of modern heat sensitive devices;
4. Validation and control routine and monitoring can be performed with fast readout BI PCD that confirm withing minutes that conditions for sterility are met at the heart of the most complex medical devices.

Take home messages



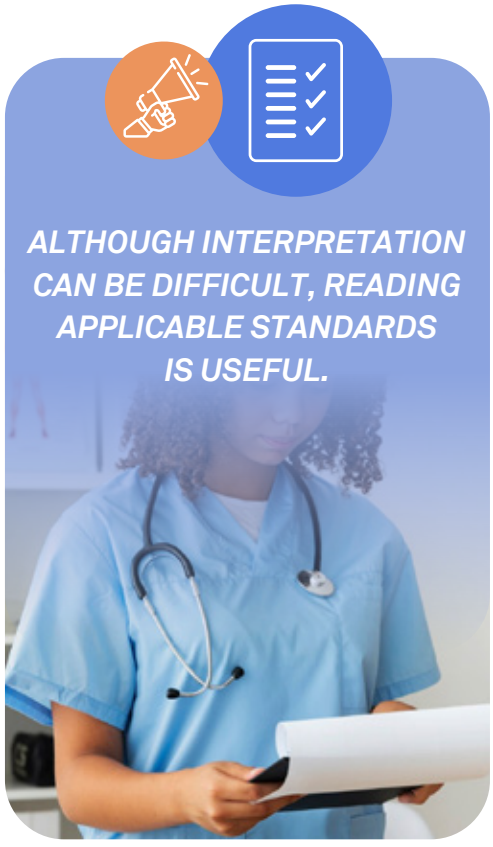
MR. WOUTER MEERT:

01. ISO 22441: the first standard dedicated to H_2O_2 sterilization

AN **ISO 13485** CERTIFIED CSSD IS OBLIGATED TO SHOW THE AUDITOR THEY HAVE A SYSTEM TO VERIFY IF NEW STANDARDS ARE AVAILABLE AND HOW THEY MAY IMPACT CURRENT PROCESS FLOWS.[8]

MEMBERSHIP IN A STANDARDS ORGANIZATION PROVIDES ACCESS TO UPDATED STANDARDS DOCUMENTS. FOR GUIDANCE ON PRACTICAL APPLICATION, CONSULT PROFESSIONAL ORGANIZATIONS LIKE THE WFHSS AND NATIONAL SOCIETIES, OR STERILIZER MANUFACTURERS.

> **Professional organizations, such as WFHSS or the national societies and sterilizer manufacturers, are helpful to understand practical implications of standards.**



ALTHOUGH INTERPRETATION CAN BE DIFFICULT, READING APPLICABLE STANDARDS IS USEFUL.

IMAGE SOURCE: https://www.freepik.com/free-photo/female-doctor-taking-notes-clipboard_12892240.htm#fromView=search&page=5&position=33&uuid=d9a7f05e-37a6-4eb8-93d0-c61c66237aec

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COMPLIANCE TO ISO 22441 PROCESS STANDARD

=

Sterilizer, BI and CI, packaging manufacturers

FOR COMPLIANCE TO APPLICABLE PARAGRAPHS OF ISO 22441 AND/OR OTHER STANDARDS

+

Medical device manufacturer

IN PARTNERSHIP WITH STERILIZER MANUFACTURER FOR STERILITY AND COMPATIBILITY EVALUATION OF MEDICAL DEVICES

+

Healthcare facility

FOR THE DEFINITION OF LOAD ACCORDING TO IFUS, SUPERVISION OF VALIDATION, ROUTINE CONTROL, LOAD RELEASE AND MAINTENANCE OF PROCESS EFFECTIVENESS

&

Applicable guidelines and regulation

FOR EXAMPLE FOR USE OF BI , BI PCD OR CI

Source: 1. courtesy of Philippe Destrez, Scientific Director ASP, Strasbourg - France

02. ISO 22441: Load Release

CONDITIONS FOR RELEASE OF LOADS REPROCESSED IN A H_2O_2 LOW TEMPERATURE STERILIZER WERE ALREADY DESCRIBED BY **ISO 14937**.[9] **ISO 22441** SPECIFIES THE CRITICAL PROCESS VARIABLES FOR VAPORIZED HYDROGEN PEROXIDE STERILIZATION: PRESSURE, TEMPERATURE, TIME, AND, IMPORTANTLY, HYDROGEN PEROXIDE CONCENTRATION. WHILE STERILIZER MANUFACTURERS DEFINE THE ACCEPTABLE RANGES FOR THESE CYCLE PARAMETERS, ISO 22441 MANDATES THAT BIOLOGICAL INDICATORS (BIS) AND CHEMICAL INDICATORS (CIS) COMPLY WITH RELEVANT STANDARDS. HOWEVER, THE SPECIFIC USAGE OF BIS AND CIS WITHIN STERILIZATION CYCLES IS DETERMINED BY USERS, GUIDELINES, OR REGULATORY BODIES.[10-12]

STERILIZER MANUFACTURER SPECIFY CYCLE PARAMETERS NEED TO BE USED TO RELEASE YOUR LOADS.

> **ISO 22441 specifies variables to be measured: pressure, temperature, time and H_2O_2 concentration.**

03. ISO 22441: Process Validation

VALIDATION IS KEY TO ENSURE THE STABILITY OF THE STERILIZATION PROCESS. **ISO 22441**[1] REQUIREMENTS ARE SIMILAR TO ISO 14937.[9] REQUALIFICATION IS COMMONLY REPEATED ANNUALLY AND AFTER MAJOR REPAIRS AND/OR RELOCATION. PERFORMANCE QUALIFICATION IS PERFORMED WITH THE WORST-CASE LOAD AND DEVICE OR MORE PRACTICALLY WITH A CHALLENGE TEST PACK AND A REPRESENTATIVE PROCESS CHALLENGE DEVICE (PCD).[7]

> ISO 22441 validation, based on ISO 14937 principles, maintains a consistent validation approach.

PERFORMANCE QUALIFICATION IS PERFORMED WITH THE WORST-CASE LOAD AND DEVICE OR MORE PRACTICALLY WITH A CHALLENGE TEST PACK AND A REPRESENTATIVE PROCESS CHALLENGE DEVICE (PCD).

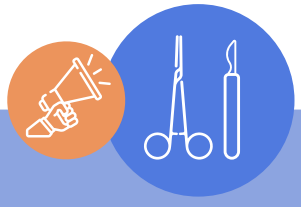
04. Medical Device (MD) compatibility and purchase of a new hydrogen peroxide (H_2O_2) sterilizer

THE NEW MDR 745-2017, APPLICABLE FROM MAY 2021, SIGNIFICANTLY CHANGED THE MEDICAL DEVICE LANDSCAPE. PRESSURE ON MEDICAL DEVICES MANUFACTURES (TO DEFINED AND VALIDATE REPROCESSING INSTRUCTIONS WAS INCREASED.[13]

WITH THE NEW **ISO 22441** STANDARD VALIDATING AN INSTRUMENT FOR HYDROGEN PEROXIDE BECOMES MORE CLEAR. ISO 22441 CLARIFIES WHAT IS EXPECTED FROM MDM.[9]

AS A FOOTNOTE, WHAT IF I WANT TO BUY A NEW HYDROGEN PEROXIDE STERILIZER?

AT THE MOMENT, THE STANDARD SPECIFYING MINIMUM FEATURES AND LEVEL OF PERFORMANCES TO BE PROVIDED BY H_2O_2 STERILIZERS (PREN 17180) IS STILL IN DEVELOPMENT **ISO 22441** HOWEVER CONTAINS KEY REQUIREMENTS AND CAN BE USED, AS WELL THE **ISO 14937**, FOR TENDERS SPECIFICATIONS.[6,9,13,14]



USE BOTH ISO 22441 AND ISO 14937 TO SUPPORT YOUR FUTURE TENDERS UNTIL THE EN 17180 IS PUBLISHED.

> With the new ISO 22441 validating an instrument for hydrogen peroxide becomes more clear. ISO 22441 clarifies what is expected from MDM.

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ISO 22441: INSTRUMENT COMPATIBILITY
BUYING A NEW HYDROGEN PEROXIDE STERILIZER

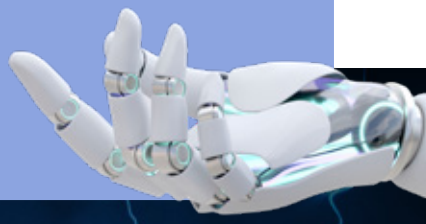
- MDR 2017-745
- IFU's
- General process validation instead of sterilizer specific

Source:20. Courtesy of Philippe Destrez – R&D ASP – ISO 22441 – Annex E.4

MR. WOUTER MEERT

Take home messages

1. Find for yourself the way to understand the content and impact of the new ISO 22441 norm on your CSSD
2. Use the new variables pressure, time, temperature and H_2O_2 concentration together if necessary with BI our CI to define your load releases
3. Defining a well thought out worst case for your hydrogen peroxide cycle validations builds in more safety in the process.
4. ISO 22441 will help you to safely connect new medical devices with your hydrogen peroxide sterilization process



References:

1. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html) 2. prEN 17180 Sterilizers for medical purposes - Low temperature vaporized hydrogen peroxide sterilizers - Requirements and testing (https://standardsdevelopment.bsigroup.com/projects/2017-02491#/section) 3. ISO/CD 11138-6 - Sterilization of health care products — Biological indicators, Part 6: Biological indicators for hydrogen peroxide sterilization processes (https://www.iso.org/standard/88921.html) 4. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Introduction, pag. vi, vii 5. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 4. Quality Management System, pag. 10-11; 6. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 8. Process definition, pag. 16-17; 7. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 9. Process validation, pag. 17-21 8. ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes (https://www.iso.org/standard/59752.html) 9. ISO 14937:2009 - Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/59752.html) 10. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 6. Process & equipment characterization , pag. 13-15; 11. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 10. Routine control, pag. 21-22; 11. Load release, pag. 22 12. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 11. Load release, pag. 22 13. 2017/745 - EN - Medical Device Regulation - EUR-Lex (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) 14. prEN 17180 Sterilizers for medical purposes - Low temperature vaporized hydrogen peroxide sterilizers - Requirements and testing (https://standardsdevelopment.bsigroup.com/projects/2017-02491#/section)

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QUESTIONS & ANSWERS

WEBINAR SERIES #5

THE PURPOSE OF THE WEBINAR WAS TO HAVE A GENERAL OVERVIEW OF

"ISO 22441 - The new standard for H_2O_2 sterilization".

ISO 22441,THE NEW STANDARD, RELEASING LOADS, EQUIPMENT VALIDATION, MD COMPATIBILITY

Attendees were asked to answer to several polls during this webinar.

WHAT IS YOUR KNOWLEDGE ABOUT THE NEW ISO 22441 STANDARD?

26%	I want to apply and wish to know more
45%	I've heard of it, but know very little
24%	None
5%	I know well ISO 22441

A NEW NORM, HOW DO YOU LEARN THE CONTENT?

34%	Reading it your yourself
41%	Training or symposium by the professional organisations
9%	Following trainings offered by manufacturers or validation institutes
16%	I wait until I really need to use the norm before learning about it

HOW TO VALIDATE YOUR PROCESS & RELEASE THE LOADS?

0%	Follow training by the professional organisations
11%	Following trainings offered by sterilizer manufacturers
0%	Following trainings offered by validation institutes
89%	Same as until now

HOW DO YOU CHECK THE COMPATIBILITY OF YOUR MEDICAL DEVICE WITH THE STERILIZATION PROCESS?

67%	I only use the IFU, if not there it's not compatible
14%	If the Representative of the MD Mfg say's it's compatible it's ok
14%	If the Representative of the sterilizer Mfg. says it's compatible it's ok
5%	I decide MD its compatible, based on my experience

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2024 WEBINAR SERIES #5

MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

INNOVATIONS IN AIRWAY MEDICAL DEVICES REPROCESSING

Mr. Olegs Tucs

ASSOCIATE SCIENCE LECTURER
TECHNOLOGICAL UNIVERSITY DUBLIN
DUBLIN, IRELAND

3rd WEBINAR

INTRO

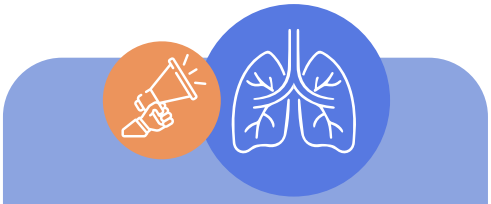
MEDICAL DEVICES USED IN AIRWAY MANAGEMENT, EXAMINATION AND TREATMENT ARE IRREPLACEABLE COMPONENTS OF MODERN HEALTHCARE EMPLOYED IN WIDE VARIETY OF INPATIENT, OUTPATIENT, EMERGENCY, AND CARE SETTINGS. CORRECT USE, MAINTENANCE AND BEST INSTRUMENT REPROCESSING PRACTICES ARE ESSENTIAL FOR PREVENTING HEALTHCARE ASSOCIATED INFECTIONS AND IMPROVING PATIENT OUTCOMES.

IN THIS WEBINAR, WE WILL DISCUSS COMMON TYPES OF AIRWAY DEVICES, EXAMINE HOW ARE THE DEVICES USED IN PATIENT TREATMENT, EXPLAIN WHY AIRWAY DEVICES CAN BECOME VEHICLES FOR TRANSMISSION OF PATHOGENIC MICROORGANISMS AND USE SCIENTIFIC EVIDENCE TO EXPLORE REPROCESSING CHALLENGES, DEVICE ASSOCIATED INFECTION OUTBREAKS, AND CHART THE WAY FORWARD TO SAFER, MORE SUSTAINABLE USE OF AIRWAY DEVICES WITH THE ULTIMATE GOAL TO ENSURE PATIENT AND HEALTHCARE WORKER SAFETY.

01. What are airway devices?

AIRWAY DEVICES ARE INSTRUMENTS USED TO ACCESS, EXAMINE, AND TREAT PARTS OF RESPIRATORY SYSTEM - NASAL CAVITY, LARYNX, AND BRONCHI. THESE INSTRUMENTS ARE USED IN EMERGENCY, OUTPATIENT, AND INPATIENT SETTINGS TO ENSURE AIRWAY PATENCY AND VENTILATION OF THE LUNGS, FACILITATE INTUBATION, ANAESTHESIA, CLINICAL INVESTIGATIONS, AND TREATMENTS OF DIFFERENT DEGREES OF INVASIVITY. EAR, NOSE, THROAT (ENT) SCOPES, LARYNGOSCOPES AND BRONCHOSCOPES ARE EXAMPLES OF AIRWAY DEVICES RANGING FROM SIMPLE RIGID MECHANICAL IMPLEMENTS TO COMPLEX FLEXIBLE INSTRUMENTS CONTAINING FIBRE OPTICS, ELECTRONICS, AND INTERNAL CHANNELS. TRADITIONALLY AIRWAY DEVICES ARE CONSIDERED SEMI-CRITICAL ACCORDING TO SPAULDING CLASSIFICATION AS THEY ARE SUPPOSED TO COME IN CONTACT WITH MUCOSAL EPITHELIUM OF THE AIRWAYS BUT NOT WITH STERILE BODY TISSUES.

IMAGE SOURCE:
https://br.freepik.com/fotos-premium/ilustracao-de-visualizacao-3d-da-anatomia-abrangente-do-sistema-respiratorio-humano_87965326.htm



EVEN THOUGH AIRWAY DEVICES ARE CLASSIFIED AS SEMI-CRITICAL, THEY ARE INCREASINGLY USED IN INVASIVE PROCEDURES ON VULNERABLE PATIENTS PRESENTING HIGH RISK OF INFECTION TRANSMISSION.

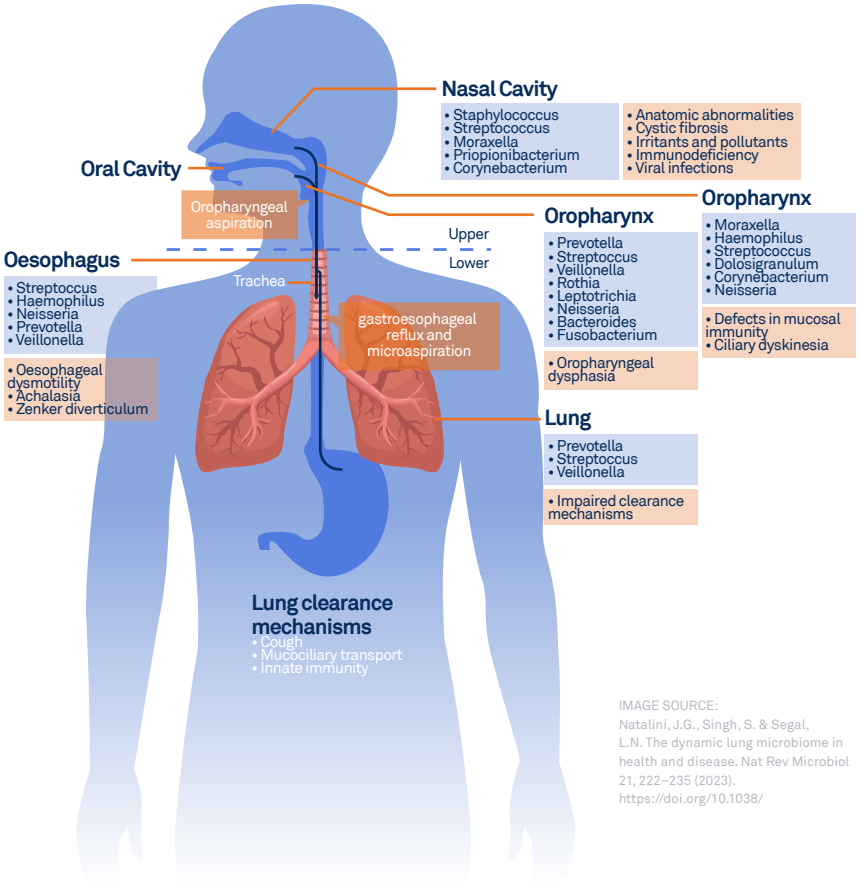


IMAGE SOURCE:
Natalini, J.G., Singh, S. & Segal, L.N. The dynamic lung microbiome in health and disease. Nat Rev Microbiol 21, 222–235 (2023). https://doi.org/10.1038/

Airway devices are diverse group of instruments used to examine and treat respiratory system issues, to ensure airway patency and facilitate intubation.

IN TODAY'S HEALTHCARE AIRWAY DEVICES ARE OFTEN USED IN INVASIVE PROCEDURES INVOLVING EXAMINATION OF DEEP BRONCHI, BREACH OF BLOOD VESSELS, BIOPSIES, AND MINOR SURGICAL INTERVENTIONS. INCREASING PREVALENCE OF RESPIRATORY PATHOGENS INCLUDING NOVEL VIRUSES AND ANTIBIOTIC RESISTANT BACTERIA COMBINED WITH USE OF AIRWAY DEVICES IN INVASIVE PROCEDURES ON VULNERABLE PATIENTS CREATES ADDITIONAL POTENTIAL FOR INFECTION TRANSMISSION AND ADVERSE OUTCOMES IN MEDICAL PROCEDURES.

TYPES OF AIRWAY DEVICES

NASAL SCOPES

NASAL ENDOSCOPES ARE INSTRUMENTS THAT ARE USED **TO EXAMINE THE NASAL CAVITY, SINUSES, PHARYNX AND LARYNX.**

IMAGE SOURCE:
https://clebermed.com/product/flexible-nasopharyngoscope/

LARYNGOSCOPES

A **LARYNGOSCOPE** IS AN INSTRUMENT FOR **EXAMINING THE LARYNX**, OR FOR INSERTING A BREATHING TUBE.

IMAGE SOURCE:
AORN Journal, Volume: 110, Issue: 1, Pages: 49-59, First published: 27 June 2019, DOI: (10.1002/aorn.12724)

BRONCHOSCOPES

A **FLEXIBLE BRONCHOSCOPE** ALLOWS FOR **DIRECT VISUALIZATION OF THE AIRWAYS** FROM THE ORAL OR NASAL CAVITY TO THE SUB-SEGMENTAL BRONCHI.

IMAGE SOURCE:https://www.olympus.com.au/medical/rmt/media/Content/-Content-MSD/Images/Product-Images/570-x-570/bronchovideoscope-bf-xt190-53214_ProductHero_GalleryThumb_352.png

02.Outbreaks associated with Airway devices

AS ESTIMATED BY THE FDA UP TO 500,000 BRONCHOSCOPIES ARE PERFORMED ANNUALLY IN THE USA WHILE IT IS ASSUMED BRONCHOSCOPES ARE UTILIZED IN A MILLION OR MORE PROCEDURES PER YEAR[1]. IN THE UK UP TO 2.8 MILLION PATIENTS RECEIVE GENERAL ANAESTHESIA AND MAYBE SUBJECT TO INTUBATION EVERY YEAR[2]. NUMBER OF NASAL ENDOSCOPIES DONE WITH THE USA MEDICARE & MEDICAID SERVICES SURPASSED 500,000 IN 2016 AS ANNUAL PROCEDURE NUMBERS INCREASED BY 9.3% OVER 15 YEARS[3].

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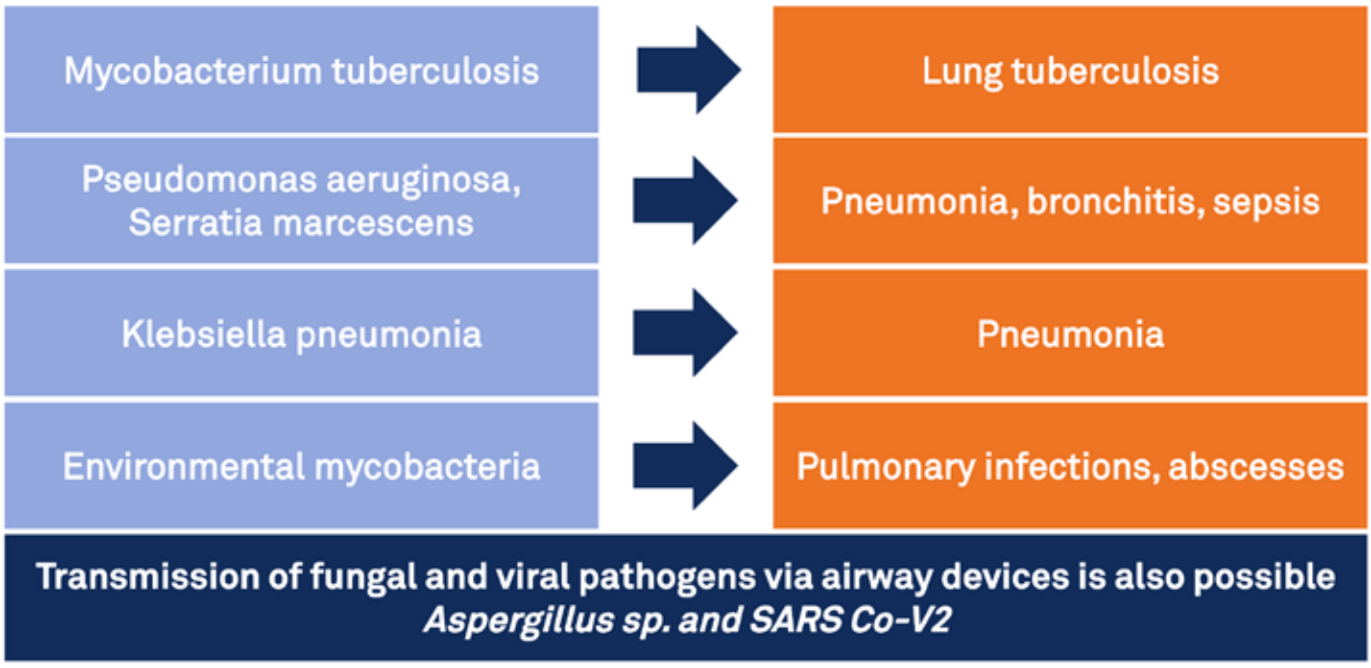
SUCH LARGE NUMBERS OF PROCEDURES INVOLVING AIRWAYS ARE INEVITABLY LEADING TO INFECTION TRANSMISSION AND INFECTION OUTBREAKS. FIRST REPORTS OF BRONCHOSCOPE-RELATED INFECTION TRANSMISSION WERE PUBLISHED IN 1978 JUST AS BRONCHOSCOPY WAS INTRODUCED IN ROUTINE CLINICAL PRACTICE[4]. SINCE THEN, NUMBER OF REPORTS ON INFECTION OR DEVICE CONTAMINATION ASSOCIATED WITH REPROCESSED FLEXIBLE BRONCHOSCOPES HAS BEEN STEADILY GROWING AND SURPASSED 200 IN 2017[5].

AIRWAY DEVICES CAN HARBOUR DIVERSE RANGE OF PATHOGENS FROM MYCOBACTERIUM TUBERCULOSIS CAUSATIVE AGENT OF TB TO PNEUMONIA AND SEPSIS INDUCING BACTERIA SUCH AS PSEUDOMONAS AERUGINOSA, KLEBSIELLA PNEUMONIA, SERRATIA MARCESCENS TO VIRUSES SUCH AS SARS COV-2 AND FUNGI SUCH AS ASPERGILLUS MOLD[6]. IT IS ESTIMATED THAT CROSS-CONTAMINATION RATE OF REUSABLE FLEXIBLE BRONCHOSCOPES IS AS HIGH AS 8.69% [7]. AIRWAY DEVICE ASSOCIATED INFECTION OUTBREAKS AFFECT VULNERABLE PATIENTS SUCH AS NEONATES AND ICU PATIENTS ESPECIALLY HARD[8].

ORGANISMS ASSOCIATED WITH AIRWAY DEVICE INFECTIONS



SOURCE:
Kovaleva, J., Peters, F. T., van der Mei, H. C., & Degener, J. E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clinical microbiology reviews, 26(2), 231–254. https://doi.org/10.1128/CMR.00085-12

Ofstead, C. L., Hopkins, K. M., Binnicker, M. J., & Poland, G. A. (2020). Potential impact of contaminated bronchoscopes on novel coronavirus disease (COVID-19) patients. Infection control and hospital epidemiology, 41(7), 862–864. https://doi.org/10.1017/ice.2020.102

AS NUMBERS OF AIRWAY ASSOCIATED PROCEDURES GROW AND AS MORE AND MORE OF THOSE PROCEDURES ARE PERFORMED ON VULNERABLE PATIENTS IT BECOMES INCREASINGLY IMPORTANT TO MINIMIZE THE CHANCE OF INFECTION TRANSMISSION VIA MEDICAL DEVICES AND THEREBY ENSURE POSITIVE TREATMENT OUTCOMES. EACH OUTBREAK AS TRAGIC AS IT MAY BE PRESENTS A LEARNING OPPORTUNITY AND A CHANCE FOR QUALITY IMPROVEMENT TO PREVENT SIMILAR EVENTS FROM HAPPENING AGAIN IN FUTURE. ENDOSCOPE SAFETY SHOULD BE PARAMOUNT FOR ALL PATIENTS, AND ESPECIALLY SO FOR THOSE PATIENTS WHO ARE MEDICALLY VULNERABLE.

Airway devices are used on millions of vulnerable patients worldwide and contaminated instruments have been involved in multiple healthcare associated infection outbreaks.

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03. Reprocessing options for Airway devices

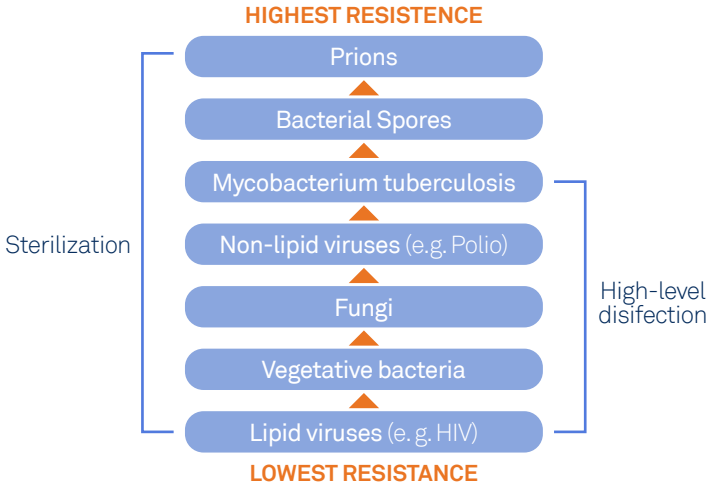
SAFE AND EFFICIENT DECONTAMINATION IS THE KEY FACTOR IN PREVENTING INFECTION TRANSMISSION VIA AIRWAY DEVICES. SINGLE USE BRONCHOSCOPES, ENT INSTRUMENTS AND LARYNGOSCOPES AS WELL AS SINGLE USE ACCESSORIES ARE MANUFACTURED IN CONTROLLED ENVIRONMENT IN LINE WITH INTERNATIONAL STANDARDS AND TERMINALLY STERILIZED USING ETHYLENE OXIDE OR IRRADIATION.

IF STORED AND USED IN ACCORDANCE WITH THE MANUFACTURERS' INSTRUCTIONS, RISK OF INFECTION TRANSMISSION VIA A SINGLE USE DEVICE IS EXTREMELY LOW. REUSABLE INSTRUMENTS ARE STILL WIDELY USED IN AIRWAY PROCEDURES AS THEY MAY BE PREFERRED BY CLINICIANS, ARE MORE ENVIRONMENTALLY FRIENDLY AND ARE A CHEAPER OPTION IF COMPARED WITH SINGLE USE INSTRUMENTS[9]. HOWEVER, RECENT RESEARCH SUGGESTS THAT REUSABLE BRONCHOSCOPES CAN ON AVERAGE COST MORE PER PROCEDURE WHEN COSTS OF TREATING HOSPITAL INFECTIONS ARE TAKEN INTO ACCOUNT[10].

MICROORGANISM RESISTANCE TO DISINFECTANTS AND STERILANTS

ENSURING THE MOST RESISTANT MICROORGANISMS ARE KILLED MEANS THAT LESS RESISTANT ORGANISMS ARE DESTROYED TOO.

Source: 17. CDC, 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/resistance.html



APPROACH TO REPROCESSING OF AIRWAY DEVICES IS BASED ON SPAULDING CLASSIFICATION FIRST PUBLISHED ALMOST 70 YEARS AGO[11]. MANUAL AND AUTOMATED HIGH LEVEL DISINFECTION FOLLOWING CLEANING REMAINS WIDELY ACCEPTABLE REPROCESSING STRATEGY FOR WHAT ARE CONSIDERED TO BE LOWER RISK SEMI-CRITICAL INSTRUMENTS. OUR UNDERSTANDING OF VARIETY OF PATHOGENS INCLUDING PRIONS, BACTERIAL ENDOSPORES, NON-ENVELOPED VIRUSES, AND BIOFILMS HAVE MASSIVELY IMPROVED SINCE THE TIME SPAULDING CLASSIFICATION WAS FIRST PUBLISHED. RECENTLY THERE BEEN NUMEROUS CALLS TO UPDATE AND REVISE SPAULDING CLASSIFICATION CONSIDERING INCREASED COMPLEXITY AND INVASIVENESS OF TRADITIONALLY SEMI-CRITICAL INSTRUMENTS, NOVEL REPROCESSING CHALLENGES AND DISCOVERIES OF NEW PATHOGENS[12,13]. AS FOR NOW AIRWAY DEVICES STRADDLE THE SEMI-CRITICAL/CRITICAL BORDER WITH MANUFACTURERS AND REGULATORS INCREASINGLY RECOGNISING IMPORTANCE OF STERILIZATION FOR REDUCING HEALTHCARE ASSOCIATED INFECTIONS.

High level disinfection is still an acceptable option for reprocessing reusable airway device while need for sterilization becomes more apparent as instruments get more complex, understanding of pathogens increases and procedures become more invasive."

REPROCESSING STRATEGIES OF AIRWAY DEVICES MUST REFLECT RELATIONSHIP BETWEEN USE OF INSTRUMENTS AND RISKS TO PATIENTS.

SINGLE USE INSTRUMENTS

NO REPROCESSING REQUIRED

Images source: Boston Scientific. https://www.medicaldevice-network.com/news/fda-boston-scientific-bronchoscope/

- LOW RISK
- HIGH COST
- LESS SUSTAINABLE

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REPROCESSING CYCLE OF REUSABLE SEMI-CRITICAL DEVICES

- PREPARATION FOR STERILIZATION INCLUDES CLEANING AND DISINFECTION
- BED SIDE PRE-CLEANING ESSENTIAL FOR REMOVAL OF GROSS SOIL AND SLOWING BIOFILM FORMATION
- LEAK TESTING WHERE APPLICABLE IS ESSENTIAL FOR ENSURING MECHANICAL INTEGRITY
- METICULOUS MANUAL CLEANING IS A FOUNDATION OF DECONTAMINATION SUCCESS
- DOCUMENTATION OF ADHERENCE TO THESE ESSENTIAL STEPS EACH TIME AN INSTRUMENT IS REPROCESSED MUST BE MAINTAINED

Source: HSE, 2019. Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities. https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-tandards-and-recommended-practices-for-the-operational-management-of-edu-s-qpsd-d-082-1-v1.pdf

HIGH LEVEL DISINFECTION (HLD) vs STERILIZATION

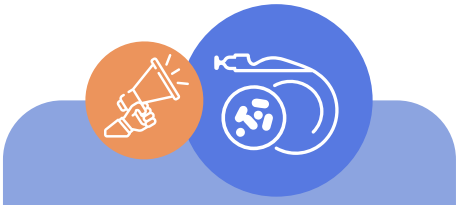
CONTAMINATED

CLEANED

DISINFECTED

STERILE

04. Barriers to proper reprocessing airway devices



STERILIZATION PROVIDES THE HIGHEST SAFETY MARGIN IN REPROCESSING OF MEDICAL DEVICES PROVIDED INSTRUMENTS ARE ADEQUATELY CLEANED PRIOR TO STERILIZATION.

IN THEORY REPROCESSING OF A REUSABLE MEDICAL DEVICE IS STRAIGHTFORWARD PROCESS WHICH RENDERS THE DEVICE SAFE FOR SUBSEQUENT PATIENT USE. IN REAL LIFE SITUATIONS PROPER CLEANING, DISINFECTION AND STERILIZATION ARE TAMPERED WITH BY MULTIPLE CHALLENGES. COMPLIANCE WITH REPROCESSING GUIDELINES AND GOOD DECONTAMINATION OUTCOME RELIES ON INSTRUMENTS BEING PROCESSED WITHOUT DELAYS BY COMPETENT, EDUCATED, PROPERLY SUPERVISED STAFF WHO UNDERSTAND RISKS OF INFECTION TRANSMISSION, DECONTAMINATION PROCESSES SUPPORTED BY ADEQUATE RESOURCES, AND DEVICES THEMSELVES BEING REGULARLY SERVICED AND PROPERLY MAINTAINED.

STAFF SHORTAGES, INSUFFICIENT RESOURCES, LACK OF TRAINING, LAPSES IN INSTRUMENT MAINTENANCE, CARELESS ATTITUDE ALL CREATE OPPORTUNITIES FOR MICROORGANISMS TO SURVIVE DECONTAMINATION BY FORMING BIOFILMS OR BY BEING PROTECTED BY RESIDUAL BIOBURDEN IN CASE OF INADEQUATE OR DELAYED CLEANING.

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SEVERAL STUDIES HAVE SHOWN THAT NON-COMPLIANCE WITH REPROCESSING GUIDELINES MAY LEAD TO ENDOSCOPE-RELATED HEALTH CARE-ASSOCIATED INFECTIONS, BUT EVEN COMPLIANT HIGH LEVEL DISINFECTION PROCESSES TURNED OUT INADEQUATE IN DECONTAMINATION OF FLEXIBLE ENDOSCOPES RESULTING IN INFECTION TRANSMISSION, INJURY AND DEATH[14, 15, 16].

Success of decontamination cycle depends on correct performance of every reprocessing step and on employing most suitable decontamination technique.

WHAT MAKES AN INFECTION HAPPEN?

- ONCE CONDITIONS ARE RIGHT THE 'PERFECT STORM' OF INFECTION HAPPENS
- PATHOGEN NEEDS TO BE TRANSMITTED TO A SUSCEPTIBLE HOST IN A SUITABLE ENVIRONMENT

SUSCEPTIBLE HOST

- IMMUNOCOMPROMISED
- NEONATE
- ELDERLY
- PREGNANT
- ICU
- CO-MORBIDITIES

FAILURES IN DEVICE REPROCESSING

- NON-COMPLIANCE OR INADEQUATE IFUS
- LACK OF EDUCATION
- INSUFFICIENT SUPERVISION
- LAPSES IN INSTRUMENT MAINTENANCE
- INADEQUATE ENVIRONMENTAL MONITORING

PATHOGENIC MICROORGANISMS

- PATIENT'S OWN FLORA
- ENVIRONMENTAL ORGANISMS
- HEALTHCARE WORKERS' FLORA

BACTERIAL BIOFILMS - ASSEMBLAGES OF MICROBIAL CELLS ATTACHED TO A SURFACE AND ENCLOSED IN A MATRIX OF EXOPOLYMERIC SUBSTANCES CAN BE RAPIDLY ESTABLISHED UNDER FAVOURABLE CONDITIONS SUCH AS PRESENCE OF MOISTURE AND BODILY FLUIDS ON USED INSTRUMENTS. THE ABILITY TO FORM BIOFILMS ALLOWS MICROORGANISMS TO SURVIVE UNDER CONDITIONS OF DRYING, CHEMICAL AND ANTIBIOTIC EXPOSURE[17]. PRESENCE OF BIOFILMS ESPECIALLY IN ENDOSCOPE CHANNELS INCREASES CHANCES OF DECONTAMINATION FAILURE. DOUBLE HIGH-LEVEL DISINFECTION AND LIQUID CHEMICAL STERILIZATION HAVE BEEN TRIALLED TO IMPROVE ENDOSCOPE REPROCESSING OUTCOMES, BUT SURVIVING MICROORGANISMS WERE STILL PRESENT ON THE INSTRUMENTS AFTER MODIFIED DECONTAMINATION[18]. ONLY LOW TEMPERATURE GASEOUS STERILIZATION WAS EFFECTIVE IN ELIMINATING PERSISTENT CONTAMINATION[19]. STERILIZATION PROVIDES THE HIGHEST SAFETY MARGIN IN REPROCESSING OF MEDICAL DEVICES PROVIDED INSTRUMENTS ARE ADEQUATELY CLEANED PRIOR TO STERILIZATION.

BEST OUTCOME FROM EVERY PROCEDURE

- ACCURATE RISK ASSESSMENT FOR PATIENT AND PROCEDURE
- ADEQUATE FACILITIES
- COMPETENT TEAM OF HEALTHCARE WORKERS
- SUITABLE TREATMENT
- FOLLOW-UP AND AFTERCARE

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Resume

DECONTAMINATION OF MEDICAL DEVICES INCLUDING AIRWAY INSTRUMENTS IS A HIGHLY REGULATED SECTOR. FOR THE BEST TREATMENT OUTCOMES EACH MEMBER OF A HEALTHCARE TEAM MUST FOLLOW RULES SET BY REGULATORY AUTHORITIES. HOWEVER, SOME OF THOSE RULES ARE BASED ON THE RISK CLASSIFICATION DEVELOPED OVER 70 YEAR AGO. FOLLOWING THOSE RULES IS HELPFUL IN MOST CASES, BUT IS NOT SUFFICIENT TO SAFEGUARD VULNERABLE PATIENTS WHO FACE POTENTIAL INFECTIONS DUE TO INADEQUATELY DECONTAMINATED COMPLEX INSTRUMENTS. IN LIGHT OF CHANGING PATIENT DEMOGRAPHICS, USE OF ADVANCED INSTRUMENTS, AND OUR KNOWLEDGE OF PATHOGENIC ENTITIES ADEQUATE RISK ASSESSMENT IN INSTRUMENT DECONTAMINATION DEMANDS NOT ONLY THE BEST PERFORMANCE OF EVERY STEP IN DECONTAMINATION CYCLE BUT ALSO ENSURING STERILITY - CONDITION WHEN THERE IS ZERO PATHOGENIC ORGANISMS PRESENT ON AN INSTRUMENT BEFORE IT COMES IN CONTACT WITH A PATIENT.

Take home messages

1. Airway devices are diverse group of instruments used to examine and treat respiratory system issues, to ensure airway patency and facilitate intubation.
2. Airway devices are used on millions of vulnerable patients worldwide and contaminated instruments have been involved thousands of incidents and infection outbreaks.
3. High level disinfection is still an acceptable reprocessing option but as our understanding of pathogens increases, procedures become more invasive, and instruments get more complex it becomes substandard.
4. Biofilms can rapidly grow on instrument surface in presence of moisture and once established pr… microorganisms from chemicals causing to disinfection failure.
5. Prions are the hardest to destroy pathogens which are present in airways and can be potentially transmitted with inadequately decontaminated instruments.
6. Success of decontamination cycle depends on correct performance of every reprocessing step and on employing most suitable decontamination technique.

References:

1. Ernst, A., Silvestri, G. A., Johnstone, D., & American College of Chest Physicians (2003). Interventional pulmonary procedures: Guidelines from the American College of Chest Physicians. Chest, 123(5), 1693–1717. https://doi.org/10.1378/chest.123.5.1693. 2. https://www.nationalauditprojects.org.uk/downloads/chapter27.pdf 3. Hur, K., Ference, E. H., Wrobel, B., & Liang, J. (2019). Assessment of Trends in Utilization of Nasal Endoscopy in the Medicare Population, 2000-2016. JAMA otolaryngology-- head & neck surgery, 145(3), 258–263. https://doi.org/10.1001/jamaoto.2018.4003) 4. Kellerhals S. (1978). A pseudo-outbreak of Serratia marcescens from a contaminated fiberbronchoscope. APIC, 6(4), 5–7.) 5. FDA MAUDE database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm 6. California Department of Public Health (CDPH). April 30, 2007. Inadequate Reprocessing of Semicritical Instruments: Recommendations for Reprocessing of Rigid laryngoscopes. Retrieved June 8, 2023 from https://www.cdph.ca.gov 7. Travis, H. S., Russell, R. V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. Journal of infection prevention, 24(3), 95–102. https://doi.org/10.1177/17571774231158203 8. Jørgensen, S. B., Bojer, M. S., Boll, E. J., Martin, Y., Helmersen, K., Skogstad, M., & Struve, C. (2016). Heat-resistant, extended-spectrum β-lactamase-producing Klebsiella pneumoniae in endoscope-mediated outbreak. The Journal of hospital infection, 93(1), 57–62. https://doi.org/10.1016/j.jhin.2016.01.014 9. Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. Journal of evaluation in clinical practice, 24(3), 528–535. https://doi.org/10.1111/jep.12904 10. Mouritsen, J. M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. Anaesthesia, 75(4), 529–540. https://doi.org/10.1111/anae.14891 11. Spaulding E.H. Chemical disinfection and antisepsis in the hospital. J Hosp Res. 1957; 9: 5-31. 12. N.J. Rowan, T. Kremer, G. McDonnell, A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability, Science of The Total Environment, Volume 878, 2023, 162976, ISSN 0048-9697, https://doi.org/10.1016/j.scitotenv.2023.162976. 13. McDonnell, G., & Burke, P. (2011). Disinfection: is it time to reconsider Spaulding?. The Journal of hospital infection, 78(3), 163–170. https://doi.org/10.1016/j.jhin.2011.05.002 14. Ofstead, C. L., Quick, M. R., Wetzler, H. P., Eiland, J. E., Heymann, O. L., Sonetti, D. A., & Ferguson, J. S. (2018). Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes. Chest, 154(5), 1024–1034. https://doi.org/10.1016/j.chest.2018.04.045 15. Epstein, L., Hunter, J. C., Arwady, M. A., Tsai, V., Stein, L., Gribogiannis, M., Frias, M., Guh, A. Y., Laufer, A. S., Black, S., Pacilli, M., Moulton-Meissner, H., Rasheed, J. K., Avillan, J. J., Kitchel, B., Limbago, B. M., MacCannell, D., Lonsway, D., Noble-Wang, J., Conway, J., … Kallen, A. J. (2014). New Delhi metallo-β-lactamase-producing carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes. JAMA, 312(14), 1447–1455. https://doi.org/10.1001/jama.2014.12720 16. Ross, A. S., Baliga, C., Verma, P., Duchin, J., & Gluck, M. (2015). A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant Escherichia coli. Gastrointestinal endoscopy, 82(3), 477–483. https://doi.org/10.1016/j.gie.2015.04.036 17. Yin, W., Wang, Y., Liu, L., & He, J. (2019). Biofilms: The Microbial "Protective Clothing" in Extreme Environments. International journal of molecular sciences, 20(14), 3423. https://doi.org/10.3390/ijms20143423 18. Gromski, M. A., Sieber, M. S., Sherman, S., & Rex, D. K. (2021). Double high-level disinfection versus liquid chemical sterilization for reprocessing of duodenoscopes used for ERCP: a prospective randomized study. Gastrointestinal endoscopy, 93(4), 927–931. https://doi.org/10.1016/j.gie.2020.07.057 19. Naryzhny, I., Silas, D., & Chi, K. (2016). Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. Gastrointestinal endoscopy, 84(2), 259–262. https://doi.org/10.1016/j.gie.2016.01.055

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3 webinar 2024

QUESTIONS & ANSWERS
WEBINAR SERIES #5

THE PURPOSE OF THE WEBINAR WAS TO HAVE A GENERAL OVERVIEW OF

"Innovations in Airway Medical Devices reprocessing".

AIRWAY DEVICES,OUTBREAKS ASSOCIATED,REPROCESSING OPTIONS, BARRIERS

Attendees were asked to answer to several polls during this webinar.

WHICH IS THE LARGEST EXPOSED SURFACE OF A HUMAN BODY?

- 71% Skin
- 11% Gut
- 18% Luns

HOW CAN PATHOGENIC ORGANISMS ENTER THE AIRWAYS?

- 92% Inhalation
- 4% All of the above
- 4% Carried on instruments

WHICH IS THE MOST CRITICAL STEP IN DECONTAMINATION CYCLE?

- 10% Disinfection
- 76% Cleaning
- 14% Sterilization

ARE THERE SPECIFIC GUIDELINES FOR REPROCESSING AIRWAY DEVICES IN YOUR COUNTRY?

- 25% Not sure
- 50% Yes
- 25% No

IN YOUR OPINION WHAT IS THE BIGGEST CHALLENGE TO SAFE REPROCESSING OF INSTRUMENTS?

- 29% Outdated guidelines
- 59% Inadequate training
- 6% Lack of resources
- 6% Not knowing how vulnerable is the next patient

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2024 WEBINAR SERIES #5

MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

EVOLUTION OF URO-GENITAL MD REPROCESSING

Eng. John Prendergast

AUTHORIZED ENGINEER (DECONTAMINATION) & SENIOR DECONTAMINATION ENGINEER
NHS WALES SHARED SERVICES PARTNERSHIP (SPECIALIST ESTATES SERVICES)
WALES, UNITED KINGDOM

4th WEBINAR

INTRO

HISTORICALLY STANDARDS USED TO DECONTAMINATE FLEXIBLE ENDOSCOPES HAVE PROMOTED HIGH LEVEL DISINFECTION AS THE ACKNOWLEDGED LEVEL. THIS STANDARD HAS ALSO INCLUDED ENDOSCOPES AND MEDICAL DEVICES USED IN THE PROVISION OF DIAGNOSTIC SERVICES USED WITHIN URO-GENITAL HEALTHCARE. SHOULD WE BE LOOKING AT DIFFERENT LEVELS DEPENDENT ON THE HIERARCHY OF RISK? ARE RISKS APPROPRIATE AND WHERE IS THE EVIDENCE OF HARM WITHIN THE URO-GENITAL FIELD?

SHOULD WE DETERMINE THE LEVEL OF DECONTAMINATION BASED UPON CLINICAL CONSEQUENCE AND IS THE CURRENT GUIDANCE ILLUSTRATED WITHIN SPAULDING OUTDATED? SHOULD WE LOOK AT DIFFERING STANDARDS OF DECONTAMINATION FOR 'HIGHER RISK' DEVICES SUCH AS URETEROSCOPES AND CYSTOSCOPES?

Are we doing enough to overcome known issues utilising such devices for patient activity?

Does this knowledge make us more accountable?

SHOULD WE EVOLVE INTO UTOPIA, 'STERILIZATION OF ENDOSCOPES'? DO WE UNDERESTIMATE THE RISK WHEN DECONTAMINATING SUCH MEDICAL DEVICES.

ARE RISKS APPROPRIATE AND WHERE IS THE EVIDENCE OF HARM USING ENDOSCOPES WITHIN THE URO-GENITAL FIELD?

IMAGE SOURCE:https://www.olympus.com.au/medical/rmt/media/Content/-Content-MSD/Images/Product-Images/570-x-570/bronchovideoscope-bf-xt190-53214_ProductHero_GalleryThumb_352.png

POLICY FOR THE LOCAL DECONTAMINATION OF REUSABLE EQUIPMENT ACCORDING TO THE SPAULDING CLASSIFICATION

Risk category	Recommended level of decontamination	Examples of medical devices
HIGH (CRITICAL) ITEMS THAT ARE INVOLVED WITH A BREAK IN THE SKIN OR MUCOUS MEMBRANE OR ENTERING A STERILE BODY CAVITY	STERILIZATION	SURGICAL INSTRUMENTS, IMPLANTS/PROSTHESES, RIGID ENDOSCOPES, SYRINGES, NEEDLES
INTERMEDIATE (SEMI-CRITICAL) ITEMS IN CONTACT WITH MUCOUS MEMBRANES OR BODY FLUIDS	DISINFECTION (HIGH LEVEL)	RESPIRATORY EQUIPMENT, NON-INVASIVE, FLEXIBLE ENDOSCOPES, BEDPANS, URINE BOTTLES
LOW (NON-CRITICAL) ITEMS IN CONTACT WITH INTACT SKIN	CLEANING (VISIBLY CLEAN)	BLOOD PRESSURE CUFFS, STETHOSCOPES

TYPES OF ENDOSCOPIC PROCEDURES

Types of endoscopes	Rigid endoscope example	Flexible endoscope example	Level of decontamination
INVASIVE - PASSED INTO NORMALLY STERILE BODY CAVITIES OR INTRODUCED INTO THE BODY THROUGH	ARTHROSCOPE LAPAROSCOPE CYSTOSCOPE	NEPHROSCOPE ANGIOSCOPE CHOLEDOCHOSCOPE	STERILIZATION BY STEAM OR A LOW TEMPERATURE METHOD E.G. GAS PLASMA
NON-INVASIVE -IN CONTACT BRONCHOSCOPE WITH INTACT MUCOUS MEMBRANE, BUT DOES NOT ENTER STERILE CAVITIES	BRONCHOSCOPE	GASTROSCOPE COLONOSCOPE BRONCHOSCOPE	HIGH-LEVEL DISINFECTION, E.G. IMMERSION IN GLUTARALDEHYDE, PERACETIC ACID, CHLORINE DIOXIDE

Source: WHO Guidelines for MD Decontamination & Reprocessing for Health-care Facilities (2016), Risk Assessment in Sterile Services, pag 22, Table 2

01.Endoscope, An everlasting problem?

HEALTHCARE HAS CHANGED SIGNIFICANTLY IN THE PERIOD SINCE SPAULDING WAS DEVELOPED, USE OF DIAGNOSTIC DEVICES, SUCH AS FLEXIBLE ENDOSCOPES, HAS BECOME A COMMON WHEN INVESTIGATING PATIENT AILMENTS. THE ABILITY TO VIEW AND TAKE BIOPSY RESULTS IN A FAST ASSESSMENT OF ILLNESS AND HOPEFULLY, RESULTING IN A BETTER PATIENT OUTCOME.

DEVICE MANUFACTURERS CONTINUE THE TECHNOLOGICAL EVOLUTION OF SUCH MEDICAL DEVICES. SUCH EVOLUTION PRESENTS BETTER PATIENT EXPERIENCES AND OUTCOMES, HOWEVER DO THEY COME WITH GREATER INFECTIONS RISKS? IS DECONTAMINATION CONSIDERED AS PART OF THIS DEVICE DESIGN? DO WE, AS AN INTERNATIONAL COMMUNITY, ADOPT INTERNATIONAL STANDARD OF PRACTISE OR DO WE INTERPRET RISKS TO DIFFERING LEVELS?

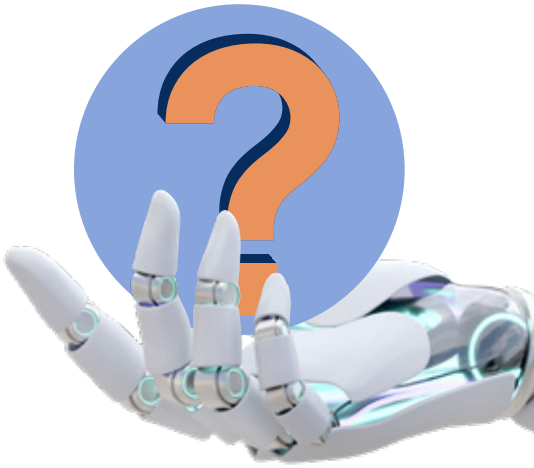

Image Ref - Flexible Ureteroscopes
Olympus America
Medical – October 2024

RISK

DIFFERENT TYPES OF FLEXIBLE ENDOSCOPES:

- OLONOSCOPES
- BRONCHOSCOPES
- GASTROSCOPES
- CHOLEDOCHOSCOPES
- DUODENOSCOPES
- URETEROSCOPES
- CYSTOSCOPES
- NEPHROSCOPE
- ENT SCOPES
- AND MORE!...

SUCH EVOLUTION PRESENTS BETTER PATIENT EXPERIENCES AND OUTCOMES, HOWEVER DO THEY COME WITH GREATER INFECTIONS RISKS?

Are Device manufacturers instructions appropriate for decontamination or do they not promote the best practise?

02.The evolution of Uro Genital Medical Devices

A UROLOGY ENDOSCOPY ALLOWS THE EXAMINATION OF THE URINARY TRACT USING A CAMERA ATTACHED TO A TUBE. THERE ARE TWO MAIN TYPES OF UROLOGIC ENDOSCOPY PROCEDURES:

- Cystoscopy
- Ureteroscopy

ONE OF THE MAJOR COMPLICATIONS OF A UROLOGIC ENDOSCOPY PROCEDURE CAN BE INFECTION. SUCH INFECTION CAN BE CAUSED BY MANY REASONS, BOTH EXOGENOUS AND ENDOGENOUS SOURCES. INAPPROPRIATE DECONTAMINATION CAN BE ONE OF THE PRIMARY SOURCES OF CROSS CONTAMINATION.

AS HEALTHCARE PROVIDERS WE MUST DO ALL WE CAN TO ENSURE DEVICES ARE REPROCESSED TO THE CORRECT STANDARDS. MANUFACTURERS INSTRUCTIONS PRESENT THE BASIC RECOMMENDATIONS FOR DECONTAMINATION; HOWEVER, THEY OFTEN DO NOT CONSIDER NATIONAL VARIATIONS, INTERPRETATIONS AND REQUIREMENTS.

INAPPROPRIATE DECONTAMINATION CAN BE ONE OF THE PRIMARY SOURCES OF CROSS CONTAMINATION.

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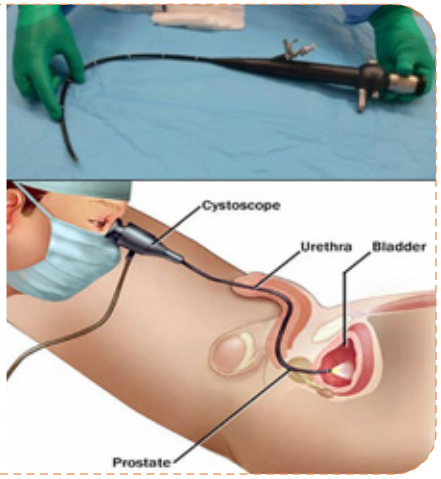
Cystoscopy

CYSTOSCOPY IS A PROCEDURE THAT ALLOWS YOUR DOCTOR TO EXAMINE THE LINING OF YOUR BLADDER AND THE TUBE THAT CARRIES URINE OUT OF YOUR BODY (URETHRA). A HOLLOW TUBE (CYSTOSCOPE) EQUIPPED WITH A LENS IS INSERTED INTO YOUR URETHRA AND SLOWLY ADVANCED INTO YOUR BLADDER.

CYSTOSCOPY IS USED TO DIAGNOSE, MONITOR AND TREAT CONDITIONS AFFECTING THE BLADDER AND URETHRA. YOUR DOCTOR MIGHT RECOMMEND CYSTOSCOPY TO:

INVESTIGATE CAUSES OF SIGNS AND SYMPTOMS.
DIAGNOSE BLADDER DISEASES AND CONDITIONS.
TREAT BLADDER DISEASES AND CONDITIONS.
DIAGNOSE AN ENLARGED PROSTATE.



Source: 4 -Cystoscopy - Mayo Clinic (October 2024) - https://www.mayoclinic.org/tests-procedures/cystoscopy/about/pac-20393694, visited on 20241018

Ureteroscopy

URETEROSCOPY IS A PROCEDURE TO ADDRESS KIDNEY STONES, AND INVOLVES THE PASSAGE OF A SMALL TELESCOPE, CALLED A URETEROSCOPE, THROUGH THE URETHRA AND BLADDER AND UP THE URETER TO THE POINT WHERE THE STONE IS LOCATED.

THE RATE OF INFECTIOUS COMPLICATIONS AFTER ENDOUROLOGICAL PROCEDURES IS STILL CONSIDERABLE AND ITS MANAGEMENT STILL CHALLENGING. **URINARY TRACT INFECTIONS (UTI) ARE NOW THE MOST COMMON COMPLICATIONS** AFTER URINARY STONE MANAGEMENT WITH SEVERAL SEVERE CLINICAL SCENARIOS, FROM POSTOPERATIVE FEVER (4.4%) TO UROSEPSIS (0.7%), **DESPITE ADEQUATE PERIOPERATIVE ANTIMICROBIAL PROPHYLAXIS.**

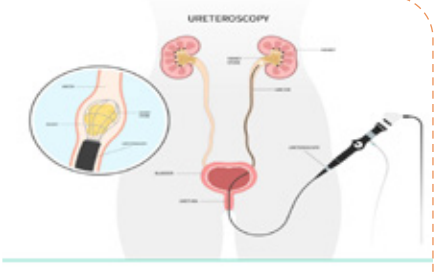


Image 1: https://medical.olympusamerica.com/products/flexible-video-ureteroscopes, visit on 2024/10/22
Image 2: Medfin (September 2024)
Source: Myths and realities: Infectious complications after endoscopic surgery of urinary stones, published on page 17 of the January/February 2020 edition of European Urology Today (EUT).
Link: https://uroweb.org/news/myths-and-realities-infectious-complications-after-endoscopic-surgery-of-urinary-stones, visited on 20241018

03. Show me the Evidence?

ARE OUR ASSUMPTION OF THE RISKS A REALITY? THAT'S AN ARGUMENT THAT IS OFTEN RAISED FROM CLINICAL TEAMS THAT MAY HAVE DIFFERING PRIORITIES (PATIENT RELATED MANAGEMENT). SHOW US THE EVIDENCE? ETHICALLY, IS IT INCORRECT NOT TO USE THE HIGHEST STANDARD OF DECONTAMINATION POSSIBLE?

THIS STUDY LOOKS AT SEVERAL HISTORICAL INCIDENTS THAT HAVE BEEN LINKED TO TRANSMISSION OF MICRO-ORGANISMS BETWEEN PATIENTS USING URO-GENITAL SCOPES. IN THESE INCIDENTS THERE ARE PROVEN LINKS TO DEVICES AS THE PRIMARY SOURCE OF THIS TRANSMISSION. SUCH INCIDENTS ARE PREVALENT ACROSS THE GLOBE, AND WE ASK, IS THE EVIDENCE PRESENTED THE TIP OF THE ICEBERG?

DO WE UNDERSTAND THE TRUE RISK AND THE CORRECT RATIO OF INFECTIONS BECAUSE OF DECONTAMINATION ACTIVITIES NOT BEING COMPLETED CORRECTLY?

DO WE UNDERTAKE ROUTINE SURVEILLANCE OF PATIENTS POST PROCEDURES?
DO WE MONITOR INTERNAL CONTAMINATION WITHIN SCOPES?

NEVER SAY

“THAT WON’T HAPPEN TO ME.”

LIFE

HAS A FUNNY WAY OF PROVING US WRONG.

Holistic strategy!
Can you see what is under the tip of the iceberg?

Source: https://www.linkedin.com/pulse/holistic-strategy--can-you-see-what-under-tip-iceberg-nordahl

ARE OUR ASSUMPTION OF THE RISKS A REALITY?

Is the Genie out of the bottle? Evidence is available to confirm the infection risks, are we doing enough to control?

04. Developing New Systems:

SHOULD WE LOOK TO REDEVELOP OUR DECONTAMINATION SYSTEMS IN THE SAME WAY WE HAVE ADAPTED TO ROBOTIC SURGERY? MUST THE DEVICE MANUFACTURERS CONSIDER THE PRINCIPLES OF DECONTAMINATION AND PUT GREATER EMPHASIS ON DECONTAMINATION PROTOCOLS?

SHOULD WE WORK TOWARDS STERILIZATION, WHICH INCLUDES URO-GENITAL ENDOSCOPES? IS STERILIZATION ACHIEVABLE? WHAT ARE THE OBSTACLES, AND CAN WE OVERCOME OR IS IT A CULTURE?

ARE SINGLE USE DEVICES AN OPTION? WOULD THIS CONTRADICT NATIONAL SUSTAINABILITY DIRECTIVES?

What do you want as a patient?
Single Use/Sterilized or Disinfected Device?

Source: SE, 2019. Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities. https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-s-tandards-and-recommended-practices-for-the-operational-management-of-edu-s-qpsd-d-082-1-v1.pdf

SHOULD WE WORK TOWARDS STERILIZATION, WHICH INCLUDES URO-GENITAL ENDOSCOPES?

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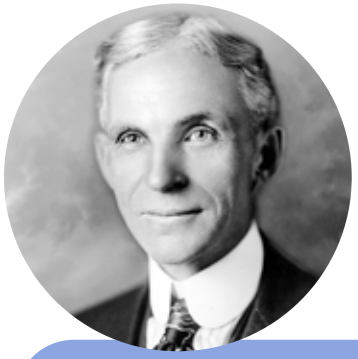
Resume

WE NEED TO DETERMINE THE RISK AND REACT APPROPRIATELY WITH PROCEDURE AND BIOBURDEN PRESENT WHEN USING URO-GENITAL ENDOSCOPES.
ADVANCEMENT IN URO GENITAL ENDOSCOPE TECHNOLOGY MUST INCLUDE BETTER DESIGNS (ROBUST) AND ENSURE DECONTAMINATION IS CONSIDERED AS PART OF DESIGN INNOVATION.

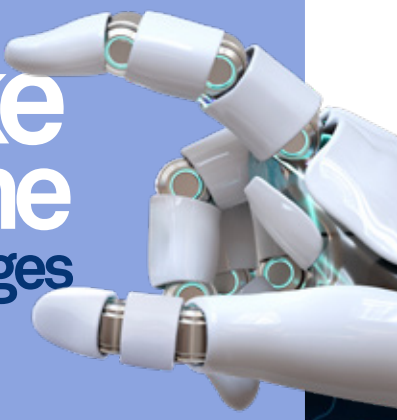
ADVANCEMENT IN REPROCESSING TECHNIQUES MUST BE CONSIDERED AND CHANGES ACCEPTED IN ACCORDANCE WITH EQUIPMENT AVAILABLE AND DEVELOPMENTS – EVOLUTION TOWARDS STERILIZATION MUST BE A PRIMARY CONSIDERATION.

USE OF SINGLE USE URO-GENITAL SCOPES SOLVE MANY OF THE ISSUES DISCUSSED IN CERTAIN AREAS OF HEALTHCARE, SINGLE USE DEVICE HAS MANY ADVANTAGES OVER RE-USABLE.
DOES SUSTAINABILITY DIRECTIVES PROVIDE AN OBSTACLE WHEN CHOOSING THE BETTER PATIENT OPTIONS? DECISION MAKING MUST BE BALANCED, AND ALL FACTS MUST BE ASSESSED WHEN CONSIDERING.



"If you always do what you've always done, you'll always get what you've always got."
Henry Ford

Take home messages



1. To conclude there are a combination of factors that can help reduce risks associated with Uro Genital endoscopic procedures (plus other types of endoscope).
2. Industry experts are now discussing whether Spaulding is appropriate within 2024.
3. We need to determine the risk and react appropriately with procedure and bioburden present.
4. Advancement in Uro Genital endoscope technology must include better designs (robust) and ensure decontamination is considered as part of design innovation.
5. Advancement in reprocessing techniques must be considered and changes accepted in accordance with equipment available and developments – Sterilization of reusables??
6. Sustainability and other factors are significant but must not be detrimental to patient safety.

References:
1. Dr. William Rutala, USA APIC 2016, SGNA 2017, AAMI 2017 | APIC Professional Advancement; Chapter 10 Review: Cleaning, Sterilization, Disinfection & Asepsis 2. Flexible ureteroscopes: a single centre evaluation of the durability and function of the new endoscopes smaller than 9Fr - PubMed (nih.gov) ttps://pubmed.ncbi.nlm.nih.gov/10992358/, visited on 20241018 3. Myths and realities: Infectious complications after endoscopic surgery of urinary stones, published on page 17 of the January/February 2020 edition of European Urology Today (EUT). Link: https://urowe-b.org/news/myths-and-realities-infectious-complications-after-endoscopic-surgery-of-urinary-stones, visited on 20241018 4. Cystoscopy - Mayo Clinic (October 2024) - https://www.mayoclinic.org/tests-procedures/cystoscopy/about/pac-20393694, visited on 20241018 5. Dr. William Rutala, USA SGNA 2017 - Duodenoscope and Endoscope Reprocessing: A need to shift from disinfection and sterilization

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4 webinar 2024

QUESTIONS & ANSWERS

WEBINAR SERIES #5

THE PURPOSE OF THE WEBINAR WAS TO HAVE A GENERAL OVERVIEW OF

"Evolution of Uro-Genital MD reprocessing".

THE FLEXIBLE ENDOSCOPE, HIERARCHY OF RISK, EVIDENCE, NEW DECOMTAMINATION SYSTEMS

Attendees were asked to answer to several polls during this webinar.

DECONTAMINATION OF URO-GENITAL ENDOSCOPES BASED UPON RISK. ARE WE ACHIEVING REQUIRED STANDARDS OF DECONTAMINATION?

- 14% Yes
- 71% No
- 14% I don't know

DOES YOUR INTERPRETATION AGREE WITH SPAULDING WHEN CONSIDERING RISKS DECONTAMINATING URO-GENITAL SCOPES PRIOR TO RE-USE?

- 23% Risks are not acknowledged, we often break the mucous membrane and sterile tissue?
- 23% Urgent review of Spaulding is necessary?
- 10% Yes - there is limited evidence of harm
- 43% Risks are not acknowledged, we often break the mucous membrane and sterile tissue?

ARE URO-GENITAL ENDOSCOPES A SOURCE OF HARM?

- 31% Yes, we should review systems to decontaminate
- 27% There are many uncertainties with such devices that elevate the risk
- 19% Yes, but clinical needs outweigh risks
- 12% Risks are no more than other clinical procedures
- 12% There is no evidence to confirm

SHOULD WE DETERMINE THE TRUE LEVELS OF CONTAMINATION?

- 3% We need robust monitoring systems in place to confirm the true picture
- 61% We should undertake routine patient surveillance post procedure
- 29% "Systems are fine we do not need more investigation (time/resource consequences)"
- 6% Evidence is Theoretical and not accurate

SHOULD WE AIM FOR STERILIZATION OF URO-GENITAL SCOPES (DEEMED HIGHER RISK)?

- 54% Yes, as a patient, you want a 'Sterilized' device!
- 39% Yes, where systems are possible.
- 7% I trust the decision made by the Clinical teams.

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2024 WEBINAR SERIES #5

MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

SUSTAINABILITY AND ECONOMIC CONSIDERATIONS BEHIND MEDICAL DEVICE REPROCESSING TECHNOLOGIES

Dr. Victoria McCreanor

ASSOCIATE DIRECTOR HEALTH ECONOMICS, HUNTER MEDICAL RESEARCH INSTITUTE, NEWCASTLE, AUSTRALIA

5th WEBINAR

INTRO

WHEN MAKING DECISIONS ABOUT INVESTMENT IN NEW TECHNOLOGY OR SERVICES IN HEALTHCARE, IT IS IMPORTANT TO CONSIDER A RANGE OF FACTORS. MAKING A DECISION BASED ONLY ON WHAT IS "CHEAPEST" OR "BEST" MAY BE SHORT-SIGHTED. OFTEN THERE IS MORE TO A PRODUCT OR SERVICE THAN WHAT YOU SEE UP FRONT.

Economic evaluation allows both costs and outcomes including effectiveness and environmental impacts to be considered together. Modelling can account for different time frames or uncertainty, to enable comprehensive understanding of the impact of different choices.

THE PRINCIPLES CAN BE APPLIED TO QUANTIFYING ASPECTS OF THE CARBON FOOTPRINT SUCH AS ENERGY, WATER USE AND WASTE.

IMAGE SOURCE:https://pixabay.com/photos/pills-tablets-stethoscope-ecg-1961431/

THE EVALUATION OF BOTH THE ONGOING COSTS AND OUTCOMES RELATED TO A NEW PRODUCT OR SERVICE IS IMPORTANT AS MANY COUNTRIES ARE NOW SPENDING CLOSE TO 10% OF GDP ON HEALTH. SPENDING MORE MEANS LESS MONEY FOR OTHER PUBLIC SERVICES INCLUDING EDUCATION, AND INFRASTRUCTURE SUCH AS ROADS. SPENDING MORE DOES NOT GUARANTEE BETTER OUTCOMES.

IF WE FAIL TO CONSIDER BOTH COSTS AND EFFECTS WHEN INVESTING IN NEW TECHNOLOGY, WE MAY INADVERTENTLY DRAW RESOURCES AWAY FROM OTHER SERVICES WHICH GENERATE GOOD OUTCOMES FOR PATIENTS OR THE HEALTH SYSTEM. A COMPREHENSIVE EVALUATION SHOULD ASSESS LONGER-TERM COSTS AND BENEFITS OF DIFFERENT OPTIONS, INCLUDING ENVIRONMENTAL CONSIDERATIONS, IN DIFFERENT SETTINGS.

THE PRINCIPLES BEHIND HEALTH ECONOMIC EVALUATION OF TREATMENTS AND SERVICES CAN BE APPLIED TO OTHER DECISIONS TO HELP UNDERSTAND THE COSTS AND CONSEQUENCES OF CHOOSING DIFFERENT TYPES OF STERILIZATION SYSTEMS.

01. Addressing the climate impact of healthcare

THE CLIMATE FOOTPRINT OF HEALTHCARE HAS BEEN ESTIMATED TO BE EQUIVALENT TO 4.4% OF GLOBAL NET EMISSIONS[1]. FIGURES VARY ACROSS COUNTRIES BUT ARE ESTIMATED TO BE 5.4% OF EMISSIONS IN THE UK, 5.1% FOR AUSTRALIA, AND 7.6% FOR THE USA(1). THE IMPACTS OF CLIMATE CHANGE ARE NOW BEING SEEN GLOBALLY. TRADITIONALLY, EVALUATION OF HEALTHCARE SERVICES AND TECHNOLOGY HAS NOT INCLUDED INFORMATION ABOUT CARBON EMISSIONS OR OTHER ENVIRONMENTAL FACTORS.

SUSTAINABILITY MEASURES SHOULD BE INCLUDED IN TECHNOLOGY ASSESSMENT BECAUSE EMISSIONS FROM HEALTHCARE HAVE A NEGATIVE EFFECT ON THE ENVIRONMENT AND THEREFORE ON HEALTH. LIFE CYCLE ASSESSMENT OF CARBON EMISSIONS WHICH INCLUDES RAW MATERIAL ACQUISITION (E.G., MINING), MANUFACTURING, USE AND DISPOSAL OR RECYCLING OF ITEMS, IS THE BEST APPROACH. WHILE THIS TYPE OF ASSESSMENT IS NOT ROUTINELY CARRIED OUT FOR HEALTH TECHNOLOGIES, WE DO HAVE SOME ESTIMATES OF CARBON EMISSIONS ASSOCIATED WITH KEY CONTRIBUTORS SUCH AS WATER AND ELECTRICITY USE.

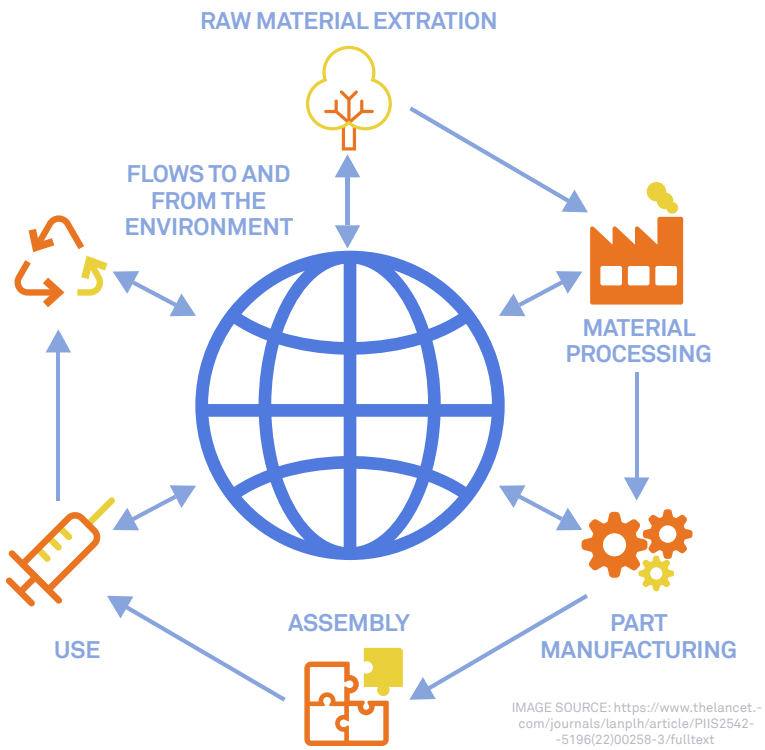

IMAGE SOURCE: https://www.thelancet.-com/journals/lanplh/article/PIIS2542--5196(22)00258-3/fulltext

The climate footprint of healthcare has been estimated to be equivalent to 4.4% of global net emissions.

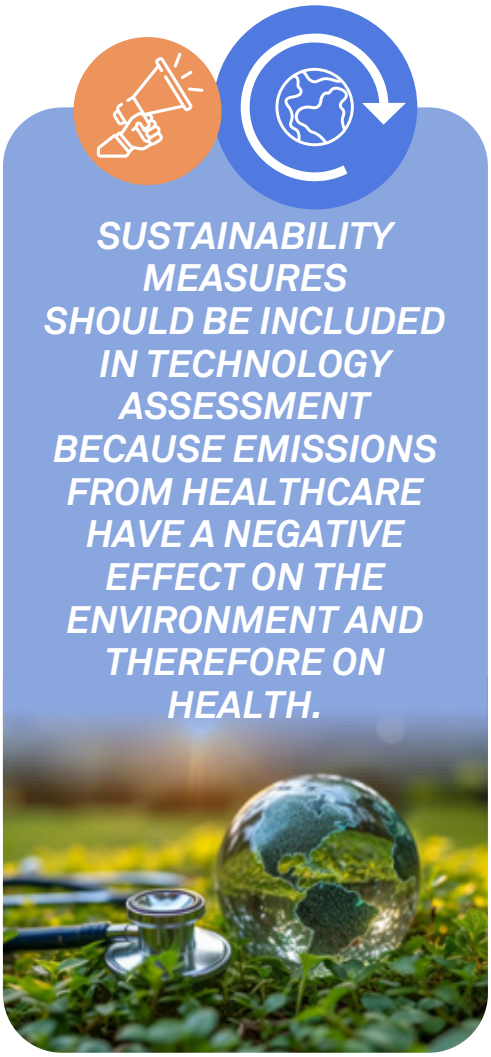

IMAGE SOURCE: https://www.freepik.com/free-ai-image/earth-day-celebration-concept_144428085.htm#fromView=search&page=1&position=2&uuid=0b8c1eee-cc23-4673-a080-a15d6a367dc0

02. Introduction to health economic evaluation

MANY COUNTRIES NOW SPEND 10% OR MORE OF GPD ON HEALTHCARE. SPENDING ON HEALTHCARE CANNOT CONTINUE TO INCREASE WITHOUT LIMIT, AND MUST BE CONSIDERED IN THE CONTEXT OF SPENDING ON OTHER IMPORTANT PUBLIC SERVICES. **FAILING TO CONSIDER BOTH COSTS AND OUTCOMES MAY MEAN WE ALLOCATE SCARCE HEALTHCARE RESOURCES IN WAYS THAT ARE INEFFICIENT AND INEQUITABLE.**
HEALTH ECONOMIC EVALUATION ENABLES THE CONSIDERATION OF BOTH COSTS AND HEALTH OUTCOMES.

Key factors in economic evaluation:

- **Benefits** of each option – effectiveness
- **Costs** related to each option
- Appropriate **timeframe**
- **Uncertainty** in estimates of costs and benefits – enables a more complex decision analysis

COMPARING BOTH EFFECTIVENESS AND COSTS OF DIFFERENT TREATMENTS, SERVICES, TECHNOLOGIES.

WHY NOT JUST USE THE "BEST" OR THE "CHEAPEST"?

WHAT YOU SEE UP-FRONT MAY ONLY BE PART OF THE STORY.

Failing to consider both costs and outcomes may mean we allocate scarce healthcare resources in ways that are inefficient and inequitable.

MANY COUNTRIES NOW SPEND 10% OR MORE OF GPD ON HEALTHCARE.

03.Sterilizer factors

THE KEY FACTORS TO CONSIDER WHEN EXAMINING THE COSTS AND CARBON FOOTPRINT ASSOCIATED WITH DIFFERENT STERILIZERS ARE: ENERGY CONSUMPTION, WATER CONSUMPTION, EFFECT ON OR DAMAGE TO INSTRUMENTS, DISPOSABLE OR SINGLE USE CONSUMABLE ITEMS.

WHEN THINKING ABOUT THE CARBON FOOTPRINT RELATED TO CONSUMABLES, IT IS IMPORTANT TO CONSIDER THE IMPACT OF THEIR PRODUCTION AND DISPOSAL, THE CHOICE OF REUSABLE VERSUS SINGLE-USE WRAPS, POUCHES AND TRAYS.

Increasing costs of electricity and water

THERE HAVE BEEN DRAMATIC INCREASES IN THE COST OF ELECTRICITY DUE TO THE WAR IN THE UKRAINE. USE OF ELECTRICITY IS THEREFORE ALSO COSTLY FROM A FINANCIAL PERSPECTIVE, AS WELL AS CONTRIBUTING TO THE CARBON FOOTPRINT. THE COSTS OF WATER ARE ALSO INCREASING AND IN SOME PLACES RESTRICTIONS ARE IN PLACE DUE TO DROUGHT CONDITIONS.

IN A WORLD AFFECTED BY CLIMATE CHANGE AND DROUGHT, AS WELL AS INCREASING ENERGY PRICES DUE TO WAR AND OTHER FACTORS, IT IS IMPORTANT TO MODERATE USE OF THESE RESOURCES WHERE POSSIBLE.

IMAGE SOURCE:https://justenergy.com/blog/how-to-calculate-your-carbon-footprint/

Electricity (€/MWh) 2020 vs 2022 (%)

ITALY 47,46€ - 441,74€ (931%)	GERMANY 34,98€ - 315,26€ (901%)	FRANCE 37,97€ - 400,95€ (1056%)

(MONTHLY ELECTRICITY PRICES IN SELECTED EU COUNTRIES 2020-2022; PUBLISHED BY BRUNA ALVES; AUG 23, 2022)

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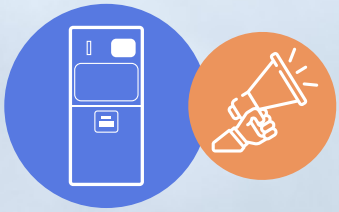
The key factors to consider when examining the costs and carbon footprint associated with different sterilizers are: energy consumption, water consumption, effect on or damage to instruments, disposable or single use consumable items.



IN A WORLD AFFECTED BY CLIMATE CHANGE AND DROUGHT, AS WELL AS INCREASING ENERGY PRICES DUE TO WAR AND OTHER FACTORS, IT IS IMPORTANT TO MODERATE USE OF THESE RESOURCES WHERE POSSIBLE.

IMAGE SOURCE:https://www.freepik.com/free-photo/earth-planet-hour-glass-global-warming-concept_17573717.htm#fromView=search&page=1&position=38&uuid=778a2a4f-ac43-4e41-9e16-f5ca94f433ec

04. Instrument factors

DIFFERENT STERILIZATION METHODS HAVE DIFFERENT EFFECTS ON MEDICAL INSTRUMENTS. IN PARTICULAR, INSTRUMENTS MADE OF PLASTICS, CORROSION-SUSCEPTIBLE METAL ALLOYS AND ELECTRICAL DEVICES ARE AFFECTED BY HIGH TEMPERATURE AND HUMIDITY. STEAM STERILIZATION MAY DAMAGE SUCH INSTRUMENTS MEANING THEY NEED TO BE REPAIRED OR REPLACED MORE FREQUENTLY. REPAIRS AND REPLACEMENT ALSO HAVE AN EFFECT ON CARBON FOOTPRINT BECAUSE OF THE ENERGY AND OTHER RESOURCE REQUIREMENTS NEEDED TO REPAIR INSTRUMENTS, MAKE NEW PARTS OR DEVICES.

Case studies in damage to endoscopes and cost of repairs:

A CASE STUDY ON THE FREQUENCY OF DAMAGE TO RIGID ENDOSCOPES WHEN A HOSPITAL CHANGED FROM USING STEAM TO A LOW-TEMPERATURE SYSTEM, SHOWED A **33% REDUCTION IN THE NUMBER OF REPAIRS AND A 58% REDUCTION IN THE NUMBER OF REPAIRS PER PROCEDURE.**[3,4]

Across 7 different studies of endoscope repairs, the average cost was $US 3,749.35 per repair. Substantial savings can be made by reducing the frequency of damage to instruments like endoscopes.[5,6,4,7–11]

- (LANDMAN J, LEE D, LEE C, MONGA M. EVALUATION OF OVERALL COSTS OF CURRENTLY AVAILABLE SMALL FLEXIBLE URETEROSCOPES. UROLOGY 2003;62:218-22.
- MAHAWONGKAJIT P, TECHAGUMPUCH A, AUKSORNCHAT K. EFFECTS OF BASIC ENDOSCOPIC HANDLING AND CARE TRAINING ON GASTROINTESTINAL ENDOSCOPY LOGISTICS. ENDOSC INT OPEN. 2022 JAN 14;10(1):E56-E61. DOI: 10.1055/A-1630-6403.
- SKOGAS J, MARVIK R. MEASURES TAKEN TO REDUCE DAMAGE AND REPAIR COSTS OF RIGID ENDOSCOPES DURING THEIR HANDLING AND PROCESSING IN SURGICAL PRACTICE. MINIM INVASIVE THER ALLIED TECHNOL 2003;12:76-81.
- SCHAFER B. DECREASED NUMBER OF REPAIRS OF RIGID SCOPES AS A RESULT OF LOW-TEMPERATURE STERILIZATION WITH H_2O_2 GAS PLASMA. A FIELD REPORT FORM THE BARMHERZIGE BRUDER HOSPITAL IN TRIER, GERMANY. CENTRAL SERV 2009;17:194-6.
- SUNG J, SPRINGHART W, MARGUET C, L'ESPERANCE JO, TAN YH, ALBALA DM, ET AL. LOCATION AND ETIOLOGY OF FLEXIBLE AND SEMIRIGID URETEROSCOPE DAMAGE. UROLOGY 2005;66:958-63
- CANALES B, GLEASON J, HICKS N, MONGA M. AN INDEPENDENT ANALYSIS OF FLEXIBLE CYSTOSCOPE REPAIRS AND COST. J UROL 2007;178:2098-102.
- STATHAM M, WILLGING JP. AUTOMATED HIGH-LEVEL DISINFECTION OF NONCHANNELED FLEXIBLE ENDOSCOPES: DUTY CYCLES AND ENDOSCOPE REPAIR. LARYNGOSCOPE 2010;120:1946-9
- INFLATION CALCULATOR: HTTPS://WWW.BLS.GOV/DATA/INFLATION_CALCULATOR.HTM)

33% reduction in the number of repairs and a 58% reduction in the number of repairs per procedure.

INSTRUMENTS MADE OF PLASTICS, CORROSION-SUSCEPTIBLE METAL ALLOYS AND ELECTRICAL DEVICES ARE AFFECTED BY HIGH TEMPERATURE AND HUMIDITY

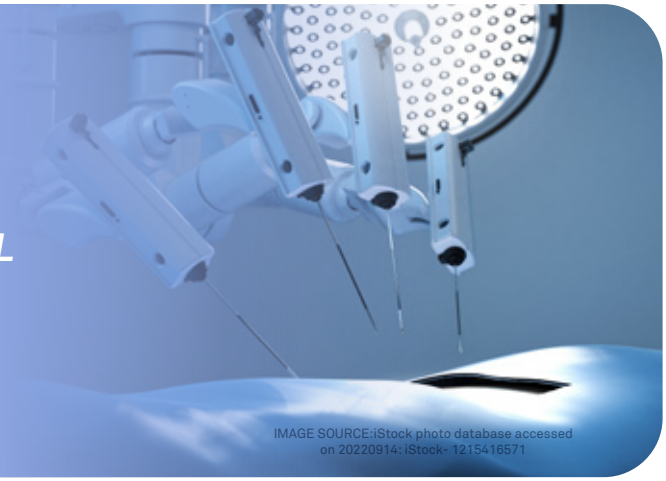


IMAGE SOURCE:iStock photo database accessed on 20220914: iStock- 1215416571

05. How to evaluate the economics in your context

WHEN EVALUATING DIFFERENT STERILIZATION OPTIONS, **IT IS IMPORTANT TO THINK ABOUT WHAT FACTORS ARE RELEVANT TO THE CONTEXT**.

MODELS CAN BE FLEXIBLE TO DIFFERENT INPUTS AND TIMEFRAMES AND INCLUDE MULTIPLE RELEVANT COSTS AND OUTCOMES. THEY CAN ALSO BE RUN MULTIPLE TIMES WITH NEW VALUES, TO INCORPORATE UNCERTAINTY IN ESTIMATES OF, FOR EXAMPLE, ELECTRICITY USAGE AND COSTS.

It is important to think about what factors are relevant to the context, for example, budgetary requirements for capital expenditure v. ongoing, local considerations – renewable energy, waste disposal, water.

Key context-specific factors:

- Relevant timeframe
- Instruments used
- Inflation – changing costs over time
- Budgetary requirements for capital expenditure v. ongoing
- Local considerations – renewable energy, waste disposal, water

MODELS CAN BE FLEXIBLE TO DIFFERENT INPUTS AND TIMEFRAMES AND INCLUDE MULTIPLE RELEVANT COSTS AND OUTCOMES

Carbon emissions from water and electricity

Category	Emission Factor	Source
WATER CONSUMPTION	0.132 KG CO_2/M^3	PARIS HOSPITALS[12]
ELECTRICITY CONSUMPTION	64.7KG CO_2/MWH	PARIS HOSPITALS[12]
	440.8 KG CO_2/MWH	GERMANY[13]
	256.2 KG CO_2/MWH	ITALY[13]
WASTEWATER TREATMENT	0.26 KG CO_2/M^3	PARIS HOSPITALS[12]

EXAMPLE MODEL EXAMINING COST AND CARBON EMISSIONS FROM WATER AND ELECTRICITY ONLY (OTHER FACTORS MAY BE IMPORTANT IN YOUR CONTEXT). IN THIS EXAMPLE, LOW TEMPERATURE REFERS TO HYDROGEN PEROXIDE GAS PLASMA STERILIZERS.

THIS EXAMPLE SHOWS THE HOW TO CALCULATE THE DIFFERENCE IN WATER AND ELECTRICITY CONSUMPTION PER M^3 BETWEEN A STANDARD 600L STEAM STERILIZER AND A 100L HYDROGEN PEROXIDE GAS PLASMA STERILIZER, AS WELL AS ASSOCIATED COSTS AND CARBON EMISSIONS.

SOURCE:Graphics: courtesy PhD Victoria McCreanor, Newcastle – Australia, 2024

References for the calculations

35. Cost of electricity in Germany. Electricity: https://www.statista.com/statistics/1267500/eu-monthly-wholesale-electricity-price-country/. **36.** Carbon emissions: Germany Climate impact checkup tool v3.3 https://healthcareclimateaction.org/checkup **37.** Waste water carbon emissions: https://www.eahp.eu/content/carbon-footprint-sterilisation-unit | **38.** Water cost in Germany: https://waterstatistics.iwa-network.org/graph/VG90YWwgQ2hhcmdlcyBmb3IgQ2FwaXRhbHMgKFVTJCk/100/2023 **39.** Currency conversion: https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-usd.en.htm **40.** Frequency and cost of repairs: Skogas J, Marvik R. Measures taken to reduce damage and repair costs of rigid endoscopes during their handling and processing in surgical practice. Minim Invasive Ther Allied Technol 2003;12:76-8 **41.** Cost of repairs: Schafer B. Decreased number of repairs of rigid scopes as a result of low-temperature sterilization with H2O2 gas plasma. A field report form the Barmherzige Bruder Hospital in Trier, Germany. Central Serv 2009;17:194-6. **42.** Cost of repairs: Sung J, Springhart W, Marguet C, L'Esperance JO, Tan YH, Albala DM, et al. Location and etiology of flexible and semirigid ureteroscope damage. Urology 2005;66:958-63

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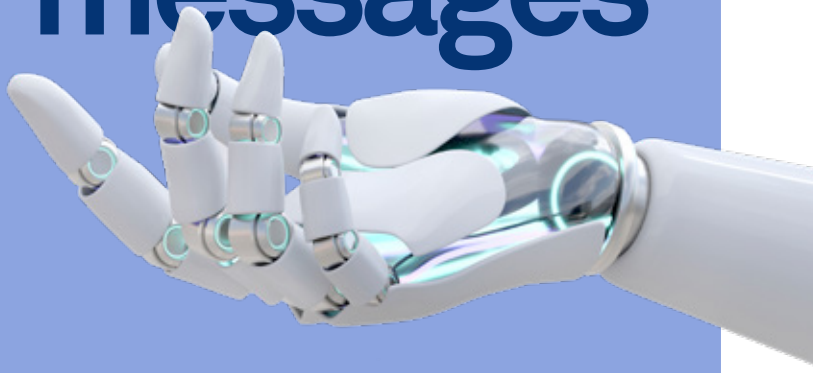
Resume

THERE ARE MANY FACTORS TO CONSIDER WHEN ASSESSING DIFFERENT STERILIZATION TECHNIQUES, THEIR COSTS AND IMPACT ON CARBON FOOTPRINT.

THESE FACTORS INCLUDING ONGOING ENERGY AND WATER REQUIREMENTS, COSTS AND IMPACT OF CONSUMABLES, STERILANT, TESTING AND MAINTENANCE, REQUIRE GREATER THOUGHT THAN WHAT MIGHT BE EVIDENT IMMEDIATELY. THE PRINCIPLES USED IN HEALTH ECONOMIC EVALUATION CAN BE APPLIED TO EVALUATE DIFFERENT OPTIONS IN DIFFERENT CONTEXTS TO ALLOW A MORE HOLISTIC DECISION-MAKING APPROACH AND MORE COMPREHENSIVE UNDERSTANDING OF THE ENVIRONMENTAL IMPACTS AND COSTS OF DIFFERENT OPTIONS.

Take home messages



1. Important to look beyond the up-front costs of the steriliz-er.
2. There are large differences in energy and water consumption: important in current environment.
3. Effect of different sterilizing processes on instruments important consideration (affects costs & carbon footprint).
4. Consumables/disposable items also contribute to carbon footprint.
5. Economic evaluation can be used to assess decisions your context.

References:

1. Health Care Without Harm, ARUP. Healthcare's Climate Footprint. 2019. 2. Statista. Average monthly electricity wholesale prices in selected countries in the European Union (EU) from January 2020 to September 2023 [Internet]. 2023. Available from: https://www.statista.com/ 3. McCreanor V, Graves N. An economic analysis of the benefits of sterilizing medical instruments in low-temperature systems instead of steam. Am J Infect Control. 2017 Jul 1;45(7):756–60. 4. Skogås JG, Mårvik R. Measures taken to reduce damage and repair costs of rigid endoscopes during their handling and processing in surgical practice. Minim Invasive Ther Allied Technol. 2003 Mar;12(1):76–81. 5. Landman J, Lee DI, Lee C, Monga M. Evaluation of overall costs of currently available small flexible ureteroscopes. Urology. 2003 Aug;62(2):218–22. 6. Mahawongkajit P, Techagumpuch A, Auksornchat K. Effects of basic endoscopic handling and care training on gastrointestinal endoscopy logistics. Endosc Int Open. 2022 Jan;10(1):E56-e61. 7. Schäfer B. Decreased number of repairs of rigid scopes as a result of low-temperature sterilization with H2O2 gas plasma: A field report from the Barmherzige Brüder Hospital in Trier, Germany. 2009 01;17:191–6. 8. Sung JC, Springhart WP, Marguet CG, L'Esperance JO, Tan YH, Albala DM, et al. Location and etiology of flexible and semirigid ureteroscope damage. Urology. 2005 Nov;66(5):958–63. 9. Canales BK, Gleason JM, Hicks N, Monga M. An independent analysis of flexible cystoscope repairs and cost. J Urol. 2007 Nov;178(5):2098–101; discussion 2102. 10. Statham MM, Willging JP. Automated high-level disinfection of nonchanneled flexible endoscopes: duty cycles and endoscope repair. Laryngoscope. 2010 Oct;120(10):1946–9. 11. U. S. Bureau of Labor Statistics. CPI Inflation Calculator [Internet]. 2023. Available from: https://data.bls.gov/cgi-bin/cpicalc.pl 12. Lemonnier J, Bottois C, Talon D. Carbon Footprint of a Sterilization Unit [Internet]. EAHP Congress 2021; 2021. Available from: https://eahp.eu/congress_poster_walk/carbon-footprint-sterilisation-unit 13. Climate impact checkup tool v3.3 [Internet]. Available from: https://healthcareclimateaction.org/checkup

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5 webinar 2024

QUESTIONS & ANSWERS WEBINAR SERIES #5

THE PURPOSE OF THE WEBINAR WAS TO HAVE A GENERAL OVERVIEW OF

"Sustainability And Economic Considerations Behind Medical Device Reprocessing Technologies".

CLIMATE IMPACT, HEALTH ECONOMIC EVALUATION, STERILIZER AND INSTRUMENTS FACTORS

Attendees were asked to answer to several polls during this webinar.

HOW MUCH DO YOU KNOW ABOUT THE CLIMATE IMPACT OF HEALTHCARE?

- 67% I'm really interested to know more about and what we can do
- 14% I've heard of it, but I don't know how I can contribute
- 14% None!
- 5% A lot… I'm an expert on climate impact!

HOW MUCH DO YOU KNOW ABOUT HEALTH ECONOMICS?

- 4% A lot… I am a health economist!
- 25% I know the words "health" and "economics", but not how they work together.
- 33% I've heard of health economic evaluation, but I don't know much about the details.
- 38% I've read about cost-effectiveness analysis, and I know the basics.

WHICH STATEMENT DO YOU AGREE WITH MOST?

- 26% Health outcomes are the most important. Costs shouldn't be considered when it comes to people's health.
- 33% Healthcare today is very expensive so understanding the costs is essential. We can only invest in new technology if it saves costs.
- 41% It's a balance. Just because something improves outcomes, doesn't mean we can afford to pay for it.

WHICH FACTORS ARE MOST IMPORTANT TO YOU WHEN THINKING ABOUT THE COSTS OF REPROCESSING MEDICAL DEVICES?

- 23% Consumable costs
- 46% Effect on equipment – avoiding need for replacement or repairs
- 23% Running costs – e.g. energy, water, maintenance, validation
- 12% The up-front cost of the sterilizer

WHICH FACTORS ARE MOST IMPORTANT TO YOU WHEN THINKING ABOUT THE ECONOMIC EVALUATION OF MEDICAL DEVICES?

- 75% Effects of sterilization on Medical Devices: damage, frequency of repairs, need for replacement, etc.
- 14% Medical Device Turnover
- 4% Thermo-labile Medical Devices
- 7% Thermosensitive Medical Devices

WHICH FACTORS ARE MOST IMPORTANT TO YOU WHEN THINKING ABOUT THE CARBON FOOTPRINT OF REPROCESSING MEDICAL DEVICES?

- 18% Chemicals and contamination
- 33% Effect of sterilisation on medical devices e.g. damage, frequency of repairs
- 15% Energy consumption in sterilisation/reprocessing
- 27% Reducing use of single use items and plastics
- 6% Water consumption in sterilisation/reprocessing

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2024 WEBINAR SERIES #5

MEDICAL DEVICES REPROCESSING:
BACK TO THE FUTURE

MODERATOR
Dr. Carlos Palos

AS FOR THE PREVIOUS WEBINARS, IT WAS A GREAT PRIVILEGE TO BE THE SCIENTIFIC DIRECTOR OF THIS EDUCATIONAL WEBINAR SERIES MEDICAL DEVICE REPROCESSING: BACK TO THE FUTURE. I WANT TO EXPRESS MY GRATITUDE TO ALL THE ATTENDEES FOR THE WILLINGNESS TO UPDATE YOUR KNOWLEDGE, TO THE SPEAKERS FOR THEIR HIGH-LEVEL TALKS, AND, FINALLY TO THE ASP UNIVERSITY FOR THE EFFORTS IN CONTINUOUS EDUCATION OF HEALTHCARE PROFESSIONALS.

Let's go back to the future!

Dr. Carlos Palos

ASP SUMMIT
SCIENTIFIC DIRECTOR

INFECTION CONTROL & ANTIMICROBIAL STEWARDSHIP
LISBON, PORTUGAL

THE 6TH **WEBINAR** TOOK PLACE ON JANUARY 2025, COUNTING WITH ALL THE SPEAKERS.

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Conclusion

IN THE 5TH ASP WEBINAR SERIES, MEDICAL DEVICE REPROCESSING: BACK TO THE FUTURE, HOT TOPICS WERE PRESENTED BY INTERNATIONAL EXPERTS AND DISCUSSED WITH THE ATTENDEES.

MEDICAL DEVICE (MD) REPROCESSING IS CHALLENGING, AND NEW ANSWERS ARE NEEDED TO CONTINUOUSLY IMPROVE SAFETY, QUALITY, EFFICIENCY AND SUSTAINABILITY.

OUTSOURCING MD REPROCESSING IS IN LINE WITH THESE PURPOSES AND IS SEEN MORE AND MORE AS AN OPTION. HOWEVER, IT REQUIRES CAREFULL ASSESSING OF THE NEEDS OF EACH ORGANIZATION AND A COLLABORATIVE PROCESS WITHIN THE ORGANIZATION AND WITH THE OUTSOURCER. ELISABETTA ANZANELLO COVERED THIS TOPIC ON THE FIRST WEBINAR.

HYDROGEN PEROXIDE STERILIZATION (H2O2), A LOW TEMPERATURE STERILIZATION PROCESS, HAS A NEW SPECIFIC STANDARD (ISO 22441) THAT MUST BE KNOWN AND UNDERSTOOD TO IMPROVE OPERATION AND HELP FACILITIES TO SAFETY INCLUDE NEW MEDICAL DEVICES IN THE H_2O2 STERILIZATION PROCESS. PHILIP DESTREZ AND WOUTER MEERT GAVE EXTENSIVE EXPLANATIONS ABOUT THIS NEW STANDARD IN THE SECOND WEBINAR.

THE REPROCESSING OF ENDOSCOPIC DEVICES BEYOND GASTROENTEROLOGY IS CHALLENGING AND MORE DEMANDING TO INCREASE SAFETY AND QUALITY OF CARE AND PREVENT HEALTHCARE ASSOCIATED INFECTIONS AND OUTBREAKS. THIS IS THE CASE FOR AIRWAY ENDOSCOPES (BRONCHOSCOPES, ENT INSTRUMENTS AND LARYNGOSCOPES) AND URO-GENITAL ENDOSCOPES (FLEXIBLE URETEROSCOPES AND CYSTOSCOPES). OLEGS TUCS AND JOHN PRENDERGAST COVERED THESE TOPICS ON THE THIRD AND FOURTH WEBINARS.

FINALLY, ENVIRONMENTAL AND ECONOMIC SUSTAINABILITY WAS COVERED BY VICTORIA MCCREANOR ON THE FIFTH WEBINAR, POINTING OUT THAT ORGANIZATIONS SHOULD LOOK BEYOND THE UP-FRONT COSTS OF STERILIZERS AND INCLUDE SEVERAL VARIABLES. A PROVISIONAL HOLISTIC MODEL FOR CALCULATION OF COSTS AND CARBON FOOTPRINT ASSOCIATED WITH DIFFERENT STERILIZATION PROCESSES WAS PRESENTED THAT CAN BE USED BY ORGANIZATIONS TO DECIDE WHICH TO SELECT.

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