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2024 WEBINAR SERIES #5

MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

INNOVATIONS IN AIRWAY MEDICAL DEVICES REPROCESSING

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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.

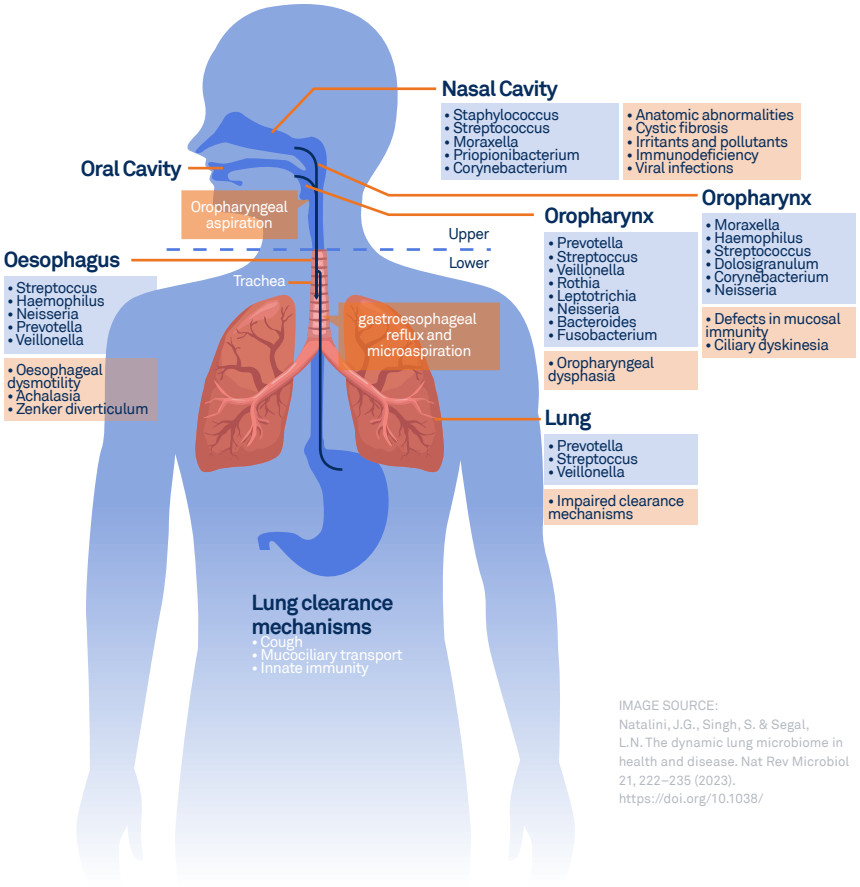

IMAGE SOURCE:
Natalini, J.G., Singh, S. & Segal, L.N. The dynamic lung microbiome in health and disease. Nat Rev Microbiol 21, 222–235 (2023). https://doi.org/10.1038/

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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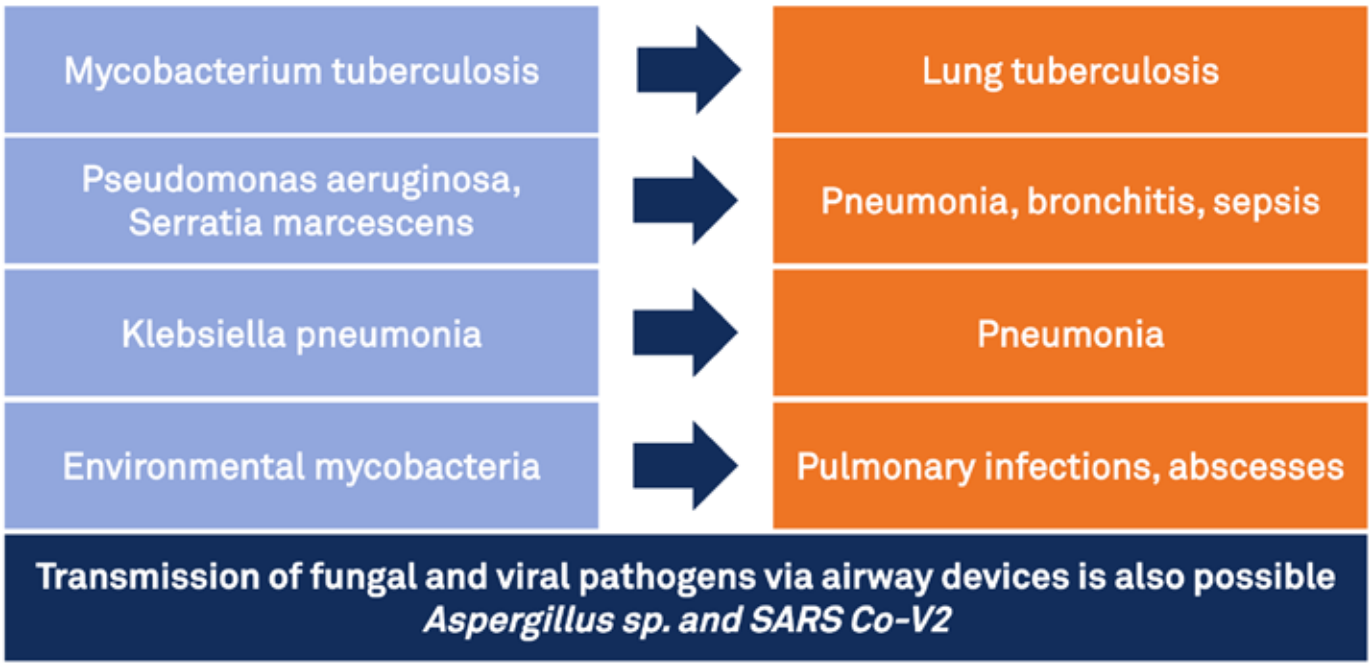
SUCH LARGE NUMBERS OF PROCEDURES INVOLVING AIRWAYS ARE INEVITABLY LEADING TO INFECTION TRANSMISSION AND INFECTION OUTBREAKS. FIRST REPORTS OF BRONCHOSCOPE-RELATED INFECTION TRANSMISSION WERE PUBLISHED IN 1978 JUST AS BRONCHOSCOPY WAS INTRODUCED IN ROUTINE CLINICAL PRACTICE[4]. SINCE THEN, NUMBER OF REPORTS 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 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. WE DON'T KNOW IF A DEVICE WILL BE USED ON A VULNERABLE PATIENT NEXT AND WE HAVE TO MAKE SURE EACH AND EVERYONE GETS THE SAFEST SERVICE.

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

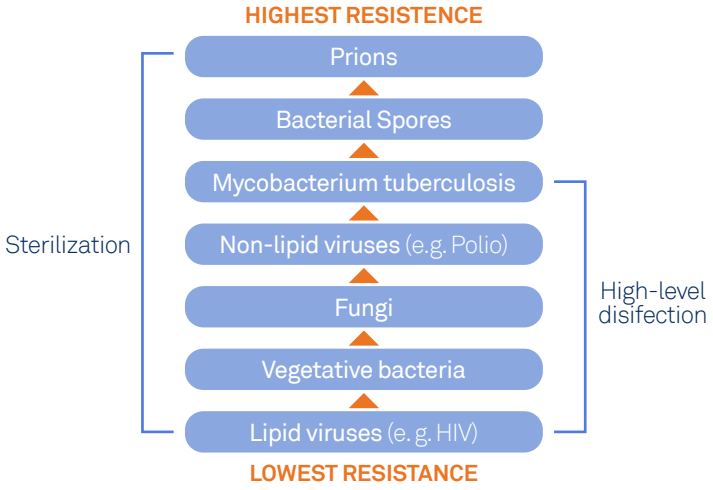
SAFE AND EFFICIENT DECONTAMINATION IS THE KEY FACTOR IN PREVENTING INFECTION TRANSMISSION VIA AIRWAY DEVICES. SINGLE USE BRONCHOSCOPES, ENT INSTRUMENTS AND LARYNGOSCOPES AS WELL AS SINGLE USE ACCESSORIES ARE MANUFACTURED IN CONTROLLED ENVIRONMENT IN LINE WITH INTERNATIONAL STANDARDS AND TERMINALLY STERILIZED 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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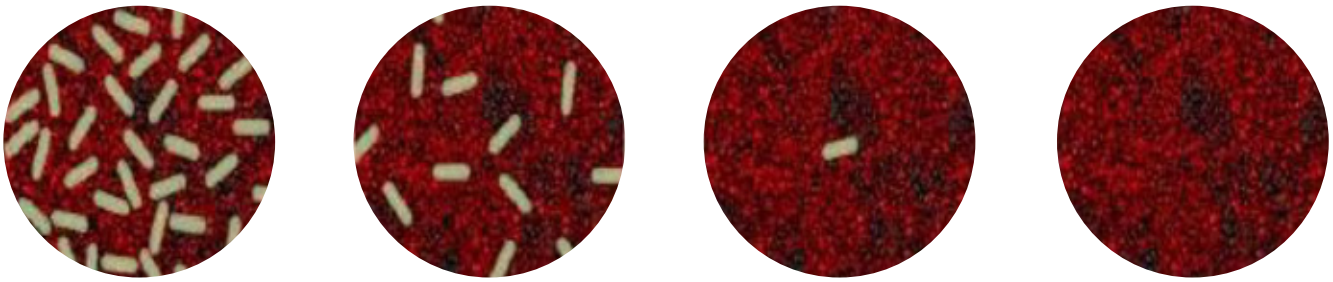
REPROCESSING CYCLE OF REUSABLE SEMI-CRITICAL DEVICES

- 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.

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