

BACK TO THE FUTURE

THE CHALLENGES BEHIND
OUTSOURCING
YOUR MD REPROCESSING

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ITALY1st

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 MANAGEMENT. 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.



IMAGE SOURCE : by courtesy of Saniservice S.p.A. - Trauma Center, Tirana

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

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:

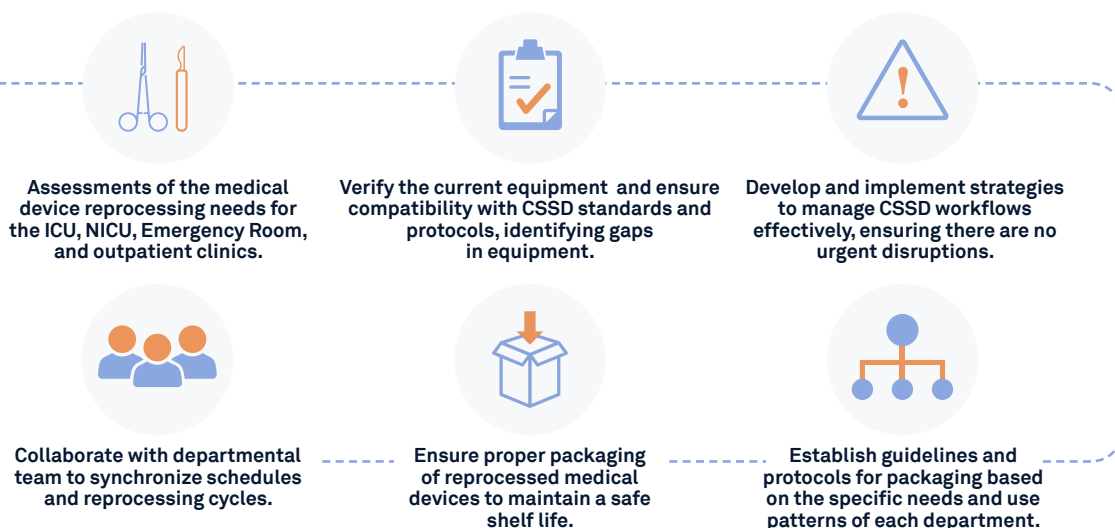
- Number of surgical procedures separated by type and specialty in the last 3 years
- Evaluation of peak activity by surgical specialty
- Determine the number and positioning of O.R.s
- Assess the organization of operating rooms (OR)
- Analysis of the existing CSSD activity (number of sterilization units 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



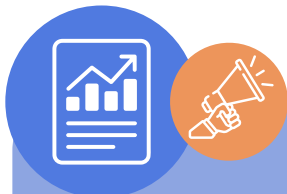


CHOOSING THE RIGHT OUTSOURCING SERVICE AND PROVIDER DEPENDS CLOSELY ON THE ABILITY TO ANALYZE AND EVALUATE BOTH THE NEEDS OF THE FACILITY AND THE CREDENTIALS OF THE PROVIDER.



Images: by courtesy of dr. E. Anzanello, Hospital OSUT 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.

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

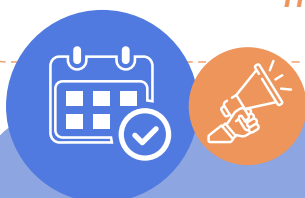
THE OPERATIONAL SOFTWARE IS THE FOUNDATION ON TOP OF WHICH THE ENTIRE OUTSOURCING SERVICE MUST BASE ON. THE OPTIMAL SOLUTION SHOULD INVOLVE MANAGING THE ENTIRE SERVICE THROUGH THE SAME SOFTWARE ACHIEVING TOTAL PRODUCT TRACEABILITY. EVERY STEP OF THE PROCESS MUST BE RECORDED TO PROVIDE COMPLETE TRACEABILITY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



05. How to optimize the service?

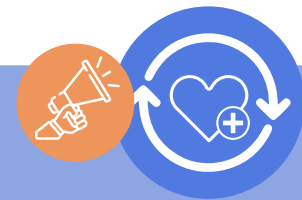
IN ORDER TO OPTIMIZE THE SERVICE WE NEED TO ENHANCE COMMUNICATION CHANNELS AND IMPLEMENTING EFFICIENT METHODS FOR RAPID COMMUNICATION.

- 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 HEALTHCARE 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.



The 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.

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.

- 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.

Take
home
messages



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