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Sitaram Bhartia Institute of Science and Research

New Delhi

A Study to reduce the re-autoclave of medical instrument sets in the CSSD

By-

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PG/22/140

under the guidance of

Dr. Altaf Yousuf Mir

PGDM (Hospital and Health Management) 2022-2024



International Institute of Health Management Research New Delhi

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A STUDY TO REDUCE THE RE-AUTOCLAVE RATE AT THE CSSD

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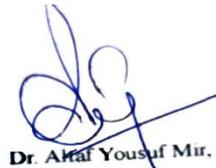
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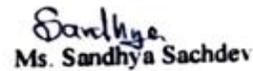
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Patient movement from OT to Wards Excel Training.

Strengths: Team oriented, flexible, Time management, Adaptable,

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ABSTRACT

Instrument sterilization at Sitaram Bhartia Hospital is done according to a strict protocol that includes several steps, ranging from pre-cleaning to storage, in the Central Sterile Supply Department (CSSD). Nevertheless, a 15% re-autoclave rate was found to be concerning after data from February, March, and April were analyzed. A thorough endeavor for quality improvement was started in order to deal with this problem.

Several factors, such as sets failing indicator tests, returning dry, or expiring unused, were identified by root cause analysis (RCA) as contributing to re-autoclave events. Commonly used packaging materials, like SMS sheets and medical grade paper, have shelf life that exceed the existing one-month limit, according to a subsequent study of the literature. A 45-day extension was thus allowed after attempts to increase the shelf life to 1.5 months were confirmed by successful culture tests.

Moreover, an extensive usage frequency analysis was carried out in recognition of the lack of a consistent protocol regulating set-packaging associations. Based on this data, a systematic approach was created, according to which packing materials with longer shelf lives were given to high-frequency sets and those with shorter shelf lives were given to low-frequency sets. Re-autoclave rates were significantly reduced as a result of this planned approach, eventually falling to 9%.

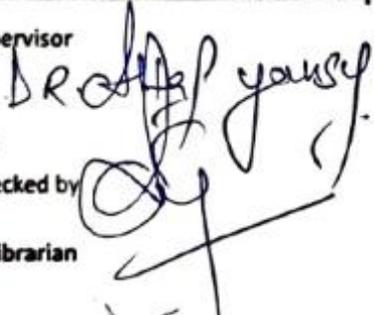
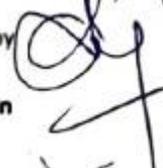
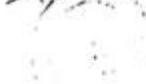
The efficacy of evidence-based treatments in streamlining sterilization procedures in healthcare settings has been proven by this project. The results provide a useful guide for improving sterilization procedures, patient safety, and operational effectiveness in CSSDs. In addition, reduced re-autoclave incidents resulted in higher CSSD efficiency, which reduced costs and saved up staff for other essential responsibilities.



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Yashwardhan

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LIST OF ABBREVIATIONS

S. No	LIST OF ABBREVIATIONS	FULL FORM
1	SBISR	Sitaram Bhartia Institute of Science and Research
2	CSSD	Central Sterile Services Department
3	RCT	Root Canal Treatment
4	ENT	Eye, Nose and Throat
5	OPD	Outpatient Department
6	ECG	Electrocardiography
7	GRS	Gender Reassignment Surgery
8	RCA	Root cause Analysis
9	OT	Operation Theatre
10	HDU	High Dependency Unit
11	ICU	Intensive care Unit
12	IPD	Inpatient Department
13	HCAI	Healthcare acquired infection
14	SAL	Sterility Assurance level
15	HAI	Hospital Acquired Infection
16	SBS	Sterile Barrier System
17	RMD	Reusable Medical Device
18	ETO	Ethylene oxide
19	PSBS	Paper based sterile barrier system
20	ISO	International Organization for standardization

21	FIFO	First in First out
22	NICU	Neonatal Intensive care unit
23	PICU	Pediatric Intensive care unit
24	LDR	Labor, Delivery and Recovery
25	SMS	Spunbond Meltblown Spunbond
26	LSS	Lean Six Sigma
27	EMR	Electronic Medical Record

ABOUT THE ORGANIZATION

The Sitaram Bhartia Institute of Science and Research was established with the goal of using research while benefiting society. The institute began as a health-focused organization and has now developed into one that excels at both patient care and medical research. The focus of its research is on health-related data collection, clinical practice translation of evidence-based guidelines, development of cost-effective interventions for better care, examination of factors influencing the onset of disease, and clinical guideline analysis based on medical literature.

The medical care services provided by the institute aim to provide treatment in compliance with globally recognized evidence-based principles. With this methodical approach, groups of medical specialists collaborate to fully attend to the requirements of patients and their families. The use of outcomes measurement in ongoing quality improvement and monitoring of healthcare is growing. The Sitaram Bhartia Institute upholds integrity in all its operations, which has led numerous patients to remark on how reliable the treatment received is. The facility is eager to make sure that each patient has a comparable experience and is excited about meeting new patients. With a focus on evidence-based medicine and world-class care, the Sitaram Bhartia Institute of Science and Research aspires to grow into a major medical facility. In order to better understand community healthcare needs and provide workable solutions to meet those needs, the institute seeks to construct well-designed research initiatives. By effectively addressing healthcare issues that could otherwise go unaddressed, it hopes to establish itself as a pioneer. The institute strives to establish cooperative agreements with top organizations across the globe and establish itself as a leader in health professional education. Donor organizations and private donors will recognize the institute's

significant contributions by kindly funding its programs. It would be widely acknowledged that the Sitaram Bhartia Institute is a representation of greatness in society.

Sitaram Bhartia is a multi-specialty hospital, having various departments dealing with the cases related to:

- **Anesthesiology:** Safe pain management is ensured before, during, and after surgery. The institute provides 24-hour onsite coverage by anesthesiologists. In addition to their role in facilitating safe surgeries, anesthesiologists offer post-operative pain relief, supervise care in the intensive care unit and recovery room, and provide epidural analgesia in the labor room.

- **Dental:** Sitaram Bhartia offers high-quality and safe oral care through an extensive range of dental services. The department is headed by Dr. Bindiya Bansal, a dental surgeon with 25 years of experience.

Common Areas of Treatment Dental Implants/ immediate implants, bone grafting surgeries, Gum surgeries, Smile make over procedures, Cosmetic filling, Diastema closure, Dental veneers, Teeth bleaching, Impaction surgeries, Sialo lithotomy, Single sitting, painless RCTs, Dental fillings, Dental tattoos, studs, Teeth extraction-surgical non-surgical, Artificial teeth replacement- partial, full mouth prosthesis

- **Dermatology:** With a combined experience exceeding 60 years, the dermatologists at Sitaram Bhartia are recognized experts in their fields. The department manages the care and treatment of common skin diseases and conditions such as psoriasis and eczema, while also offering specialized care for lesser-known disorders.
- **Diabetes & Endocrinology:** The Diabetes Centre at Sitaram Bhartia Institute of Science and Research stands as one of the pioneering centers in the city, providing extensive care and highlighting patient self-management. Each individual is assisted

in identifying their treatment objectives, selecting a treatment regimen, and acquiring the essential knowledge and skills for their daily management

- **ENT:** The ENT department provides an extensive array of outpatient and inpatient services concerning ear, nose, and throat disorders. These services are delivered by a team comprising experienced and proficient doctors. Nasal Endoscopy, Audiometry foreign body removal from ear, nose and throat are some of the services offered by the hospital.
- **Gastroenterology:** The gastroenterology department is well-equipped to conduct diagnostic and therapeutic procedures for both the upper and lower gastrointestinal tract, including sigmoidoscopy and colonoscopy.
- **Nephrology:** With a dedicated Nephrology OPD, the facility conducts comprehensive evaluations of patients facing kidney-related issues like diabetic kidney disease, infections, acute and chronic renal failure, and renal hypertension. This evaluation includes clinical examinations, laboratory tests, and radiological assessments. Treatment options include dietary and lifestyle recommendations, medication when necessary, and patient education about peritoneal and hemodialysis, as well as counseling regarding renal transplant options. The center offers 24-hour emergency and planned dialysis services, covering hemodialysis and peritoneal dialysis. Moreover, it routinely performs modern endo-urological operations, including those utilizing laser technology.
- **Obstetrics & Gynecology:** The Obstetrics and Gynecology department caters to women from adolescence to post-menopause and has become the largest specialty at Sitaram Bhartia. Patients and their families consistently rate their care highly and express satisfaction with the services provided. A key focus of the department is to promote natural childbirth and reduce the caesarean section rate to medically

necessary levels. Gynecological services encompass treatment for fibroids, endometriosis, ovarian cysts, infertility, and uterine/ovarian cancer. The department is well-equipped to perform laparoscopic surgeries, hysterectomies, as well as hysteroscopy and colposcopy procedures.

- **Ophthalmology:** The ophthalmology department at Sitaram Bhartia is manned by a team of seasoned specialists who have received training from leading medical colleges in India. Comprising dedicated and proficient doctors, they possess the expertise to manage a wide array of medical and surgical conditions within the specialty.
- **Psychiatry & Psychology:** Led by Dr. Alok Sarin, a renowned psychiatrist, the psychiatry and psychology department at Sitaram Bhartia offers a broad spectrum of services. The psychiatry section provides outpatient consultation for adults and the elderly, while the psychology division extends its services to children and adults. Psychological assessments, support services, special education, and therapeutic programs are among the offerings, including tailored therapy sessions for children with special needs.
- **Radiology:** The Imaging Services Department at Sitaram Bhartia was established to deliver top-notch imaging solutions, aligning with the institution's commitment to comprehensive care. Equipped with cutting-edge facilities such as conventional X-ray units, Computerized Radiographic systems, dedicated Mammography and Dexa scan units, and advanced ultrasound scanners with Color Doppler capabilities, the department caters to a wide range of diagnostic needs. Offering round-the-clock emergency radiology services every day of the year, along with regular daytime services, it prioritizes safety and compliance, adhering to stringent radiation safety regulations. Services span from traditional X-rays and mammography to specialized

Dexa scans and ultrasound examinations, covering various body parts and functions. Additionally, the department extends cardio-pulmonary diagnostics, including ECG, pulmonary function tests, echocardiography, and 24-hour monitoring services for blood pressure and heart rhythm, ensuring comprehensive patient care.

- **Urology:** The Urology Department at Sitaram Bhartia Institute of Science and Research provides comprehensive treatment options for various urological conditions, including prostate enlargement, stone disease, male infertility, andrology, reconstructive urology, and urologic cancers. Led by Dr. (Col.) S.V. Kotwal, the department also offers Gender Reassignment Surgery (GRS), commonly known as sex-change operations, with an integrated team specialized in this field. The department routinely performs modern endo-urological operations, including procedures utilizing laser technology, ensuring advanced and effective care for patients.

INTRODUCTION

The Central Sterile Services Department (CSSD) is an established area in hospitals and other healthcare facilities where sterilization and other duties are performed on medical devices, equipment, and consumables. This makes it easier for medical personnel to use these instruments and tubes for a variety of aseptic procedures as well as for later use in the operating room of a hospital. The Central Sterile Supply Department (CSSD) delivers sterile supplies of surgical equipment, linen, dressing material, and other similar items to a hospital or healthcare facility's various departments, including labor rooms, minor OTs, HDUs, ICUs, emergency units, wards (IPDs), day care units, and outpatient departments (OPDs). As therefore, it is essential to make sure that every surgery is performed in a sterile setting and reduce possibility of infection spreading. ^[1]

Worldwide, healthcare-associated infections (HCAIs) affect hundreds of millions of patients annually, presenting a serious threat to public health. In order to stop the spread of these hospital-acquired illnesses throughout the hospital's many patient care departments, the Central Sterile Supply Department (CSSD) is essential. Patients and frontline staff feel more confident when they have access to clean, infection-free materials, which greatly raises their satisfaction levels. The medical equipment used in operating rooms and other healthcare settings has changed significantly over time. To properly reprocess these devices as they get more complicated, the Central Sterile Supply Department (CSSD) needs to keep up with technological developments. Many surgical and medical equipment and supplies are expensive and made to be reused. The hospital's CSSD is still an essential support area. Cleaning, processing, and sterilizing surgical instruments, treatment trays and sets, dressing supplies, linen, and rubber products like tubing are among its main duties. The CSSD also controls the controlled, economical, and effective use of the hospital's equipment resources.

To ensure a high degree of sterility, it also maintains standard operating procedures for sterilizing different items utilized in the hospital. The process of sterilizing something involves applying heat, chemicals, irradiation, high pressure, and filtration correctly in order to eradicate or kill any type of microbiological life, including spores. A sufficient and dependable supply of sterilized materials that are easily accessible for both normal and emergency use should be provided to all departments, with a few designated exceptions. Sterilization that is safe for bacteria is carried out in a controlled environment and for the least amount of money possible in the sterile supply department, which oversees this. Infections acquired in hospitals are considerably less common because to this procedure. To provide the best possible infection control, the hospital is committed to upholding the strictest standards of sterilization for all tools, equipment, and other materials. The CSSD's functions include receiving and processing used and unsterile supplies and sets, ensuring a continuous and bacteriologically safe supply, participating in the hospital infection control program, and advising and training the hospital administration on the suitability of supplies and equipment from a sterilization perspective. The CSSD should be conveniently located for its primary users, such as nursing units, labor rooms, and operating theaters. It is necessary to plan a CSSD with a minimum of 7 square feet per bed to allow for future expansion and growth. [2]

Workflow in CSSD

Receipt: Using stainless steel trolleys and a particular elevator, the material to be sterilized from various departments arrives at the area where it is received.

Cleaning: This function deals with the manual or mechanical cleaning of rubber and plastic goods, old equipment and materials, and washer-disinfectors, ultrasonic cleaners, jet glove washers, and dryers. Delivery trolley cleaning is also included. Syringes and needles, as well as different procedure sets for sternal punctures, venesections, paracentesis, aspiration,

catheterization, tracheotomies, suturing, dressing, biopsy, incision and drainage, aortography, cardiac resuscitation, gloves, IV fluids, treatment trays, operating room instruments, operating room linens, infusion fluids for renal dialysis, and occasionally linen from wards, are among the common items handled by the CSSD.

Assembling and packaging entails looking for breakages in glass objects and assessing the sharpness and damage of needles and equipment. The equipment is assembled and suitable sets are ready for usage by different departments following washing and drying. After that, the goods are sealed and packaged by hand or by a machine before being sterilized. Every pack needs to be appropriately labeled and documented, and records need to be kept up to date.

Sterilization: This procedure makes sure that supplies are made sterile so that patients can receive excellent care. To obtain the necessary sterility assurance level (SAL), it is done with steam sterilizers that run at particular temperatures and time cycles. Steam sterilizers have several advantages, such as quick heating and load penetration, complete microbial life elimination, and no residual toxicity. Downward Displacement, Pulsed Steam Dilution and Vacuum Assistance are several kinds of autoclaving machines available for use.

Storage: Sterilized goods are stored in this function, and distribution trolleys are given extra room. Every kind of sterile pack is kept in stock in the sterile storage section. To monitor the supply of materials and transport documentation, a computer terminal ought to be accessible at the conclusion of the processing path.

Issue and Distribution: The role includes supplying different hospital departments with sterile packages, dressings, linens, tools, and disposables. ^[3]

The significance of disinfection and sterilization has been brought to light by the concerning prevalence of hospital acquired infections (HAI) in Indian hospitals. Using sterilization techniques and disinfectants to achieve disinfection and sterilization is crucial to guaranteeing that surgical and medical instruments do not spread infectious microorganisms among medical personnel. A Centralized Sterile Supply Department (CSSD) backed by an automated laundry is one of the most widely recognized methods for preventing the spread of infectious diseases. Hospital-acquired infections remain a major concern in healthcare today, despite all precautions and technological breakthroughs. The goal of aseptic surgery is to eradicate all bacteria from equipment and bandages, preferably by subjecting them to pressured steam exposure. However, in everyday practice, this norm isn't always adhered to. Boiling water sterilization is an effective way to kill all viruses and vegetative bacteria, but it is not a reliable way to get rid of spores, especially those that cause pneumonia and tetanus. Proper storage of medical instruments after sterilization is also an important factor to be considered. By proper storage it is meant that the sterilized instruments should be kept in a clean zone, where there should not be any dirt particles present. The temperature and humidity in the clean zone should also be maintained at a particular and optimal level which will not let any microorganism or bacteria to grow under those conditions.

Before storing of medical instruments, it should be made sure that the instruments are packed properly, indicators are attached on it and are properly autoclaved. Only when the color of indicators change, we can say that the instruments are being autoclaved properly and the instruments are free from any contamination and infection is less prevalent through such sets. It should also be made sure that the instruments are double wrapped in the designated paper it is getting packed in.

Packaging and Wrapping Materials

Prior to sterilization, devices need to be wrapped. Effective sterilization, sterility maintenance, and aseptic removal of contents at the point of use are all made possible by the packing materials and processes that are intended to secure and protect the devices. International standards must be followed while selecting a material, which is determined by the suggested sterilizing technique.

The devices that need to be prepared and the sterilization method employed determine the kind and choice of wrapping material. Packaging needs to be chosen based on the sterilization technique.

General process for wrapping:

- Every package needs to have an identifying label with the contents, lot number, expiration date, and the operator's initials on it, as well as an exterior chemical indicator.
- Sterilization wrap, rigid reusable containers, and PSBS are the three types of sterile barrier systems (SBS) that can be used to package devices.
- The ability of each unique product to satisfy specified standards and criteria should be assessed when choosing a packaging solution.
- To guarantee that the item being packed is sufficiently covered, the wrapping material should be selected according to its appropriate size.
- Textile (linen) packs should not contain hollowware, reusable medical devices (RMDs), or dressings since drying the materials together can be challenging and compromise sanitation owing to temperature fluctuations.
- After only one use, single-use wraps ought to be disposed of in the proper healthcare waste stream.
- It is important to pack device bags carefully to avoid breaking fragile devices.

- Device packing trays need to have holes in them so that the sterility can be maintained.

TYPE OF PACKAGING

1. **Sterilization wraps:** Commonly used packaging materials for steam, dry heat, and ETO sterilization include bleached crepe paper and wraps made of cellulose and synthetic fibers. When the packs are kept dry and clean, these materials—which are permeable to air, steam, and chemical vapors provide an efficient barrier. Medical-grade paper is free of loose particles, but if the packs are opened by ripping, slicing, or cracking a fiber tear seal, particles could be discharged. The facility must utilize sterilization wraps in accordance with the manufacturer's instructions. It is not advisable to utilize double paper-based sterile barrier systems (PSBS) since it raises the possibility that steam won't get through the packing material (for more information, see ISO 16775). Furthermore, because paper-based sterile barrier systems absorb hydrogen peroxide vapor from the chamber and obstruct the cycle's ability to produce hydrogen peroxide plasma, they are not appropriate for use in the hydrogen peroxide plasma sterilization process.
2. **Reusable fabrics:** Steam sterilizers that use downward displacement or pre-vacuum can be used to sanitize hefty packs made of reusable woven cotton or cotton/polyester fabrics. But when it comes to acting as a bacterial barrier, they are less effective as compared to conventional sterilizing wraps. It is always recommended to utilize two layers of reusable materials with one layer serving as an inner wrap, or one layer of reusable fabric and one disposable sterilization wrap. The wrap becomes useless due to fabric flaws including holes and worn-out patches. Every outer wrap made of reusable fabric needs to be double-thick. While single-use sterilizing wraps perform better than reusable fabrics (cotton or polyester/cotton blends) as microbiological

barriers, reusable fabric wraps should retain their sterility for at least 7 days when stored in a clean, dry environment.

3. **Single-use Packaging:** Sterile devices must be designed, produced, and packaged in non-reusable packs and/or in accordance with the necessary protocols, as per medical device laws, to guarantee sterility. Single-use packaging is clearly preferred as the main container for sterile equipment. It is advised to double wrap any medical equipment used in the operating room. Sterility of the instruments packed in this type of instruments stay intact till at least 3 months when stored in a clean and dry environment.

The type of packaging to be used should be decided upon the frequency of use of that set and what all sets are compliant with what type of packaging material. ^[4]

LABELING OF THE PACKAGE:

To ensure safety and traceability, it is essential to check that packages are correctly labeled before sterilizing them. The following details need to be on the label:

1. Name of Product: Make sure you know exactly what is in the package. This facilitates accurate usage and prompt identification.
2. Name of Wrapper: Indicate the kind of wrapper that was applied. Understanding the compatibility of the packaging material with sterilizing techniques and preserving sterility depend on it.
3. Expiry Date and/or Sterilization Date: Provide the date of sterilization or the package's expiration. This aids in inventory management and guarantees that the product is used within its useful life.

4. The Word "Sterile" (if applicable): Make it clear that the instruments are sterile. This is essential to guarantee that sterile and non-sterile objects may be readily identified from one another.

5. Load Number: Give every sterilization batch a special load number. In the event that there are any problems with the sterilizing procedure, this enables tracking and tracing.

In order to guarantee patient safety, uphold appropriate sterilizing procedures, and enable effective inventory management, certain labeling standards must be met. ^[4]

STORAGE GUIDELINES:

Following are certain requirements that are needed to be followed while packaging of sets.

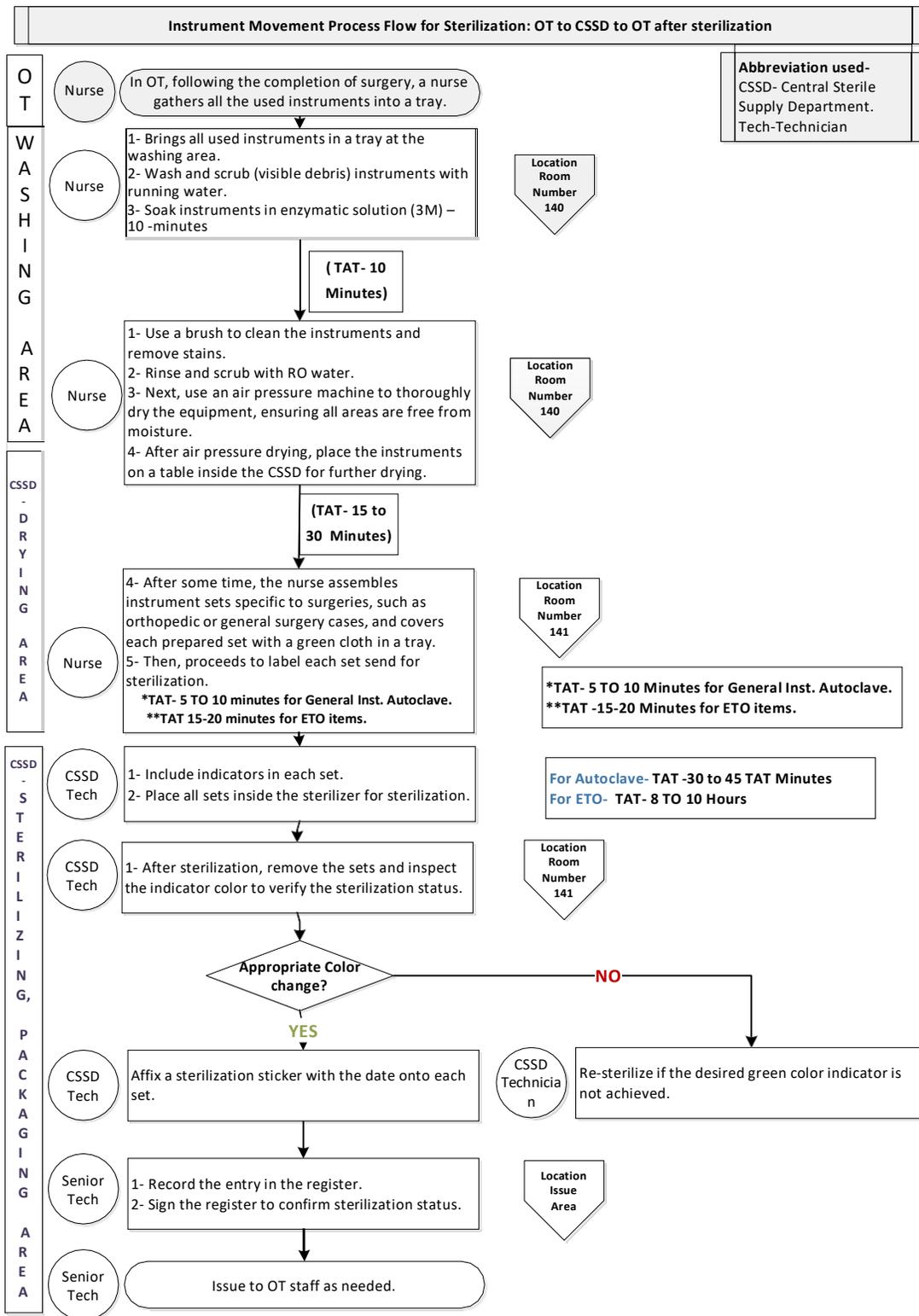
- Storage conditions for packaging materials should be between 18°C and 22°C, with a relative humidity of 35% and 70%.
- The integrity of the product depends on maintaining the proper balance of humidity and temperature.
- Packaging materials shouldn't be kept next to outside walls or other surfaces where the temperature might differ from the storage room's average.
- Shelf space for packaging products should be maintained at least 10 inches (28 cm) above the ground.
- To guarantee that packaging material doesn't go past its shelf life, it should be cycled according to the "first in, first out" principle. ^[4]

Proper compliance of all these guidelines regarding cleaning, packaging, labeling and storing of the medical instruments is necessary to increase the efficiency of CSSD department of any hospital as well as to reduce the Hospital acquired infection (HAI) caused because of non-sterility in the medical instruments used at the time of surgery.

CSSD AT SITARAM BHARTIA INSTITUTE OF SCIENCE AND RESEARCH

Sitaram Bhartia institute of science and research has an in-house CSSD department responsible for sterilizing instruments coming from different nursing wards, Labor and Delivery room (LDR), NICU, PICU, ICU, and from different Operation theatres (OT) in the hospital. Surgeries such as Ortho, urology, ENT, Eye, general surgeries, obstetrics and gynecological surgeries happens in the 3 OTs of the Hospital. Around 280 surgeries are done per month at SBISR and among these, orthopedic and gynecological surgeries are the most commonly performed surgeries. Central Sterile Services Department (CSSD), which is responsible for the sterilization of all surgical instruments is divided into three zones to ensure thoroughness and maintain high standards of safety. In the first zone, the "Dirty Area," nursing staff clean the surgical instrument sets upon their arrival at the CSSD. Next, in the "Autoclaving and Packaging Area," the instruments are sterilized and packaged by the CSSD manager and staff. Finally, in the "Clean Area," the sterilized instrument sets are stored in sterile storage rooms where the temperature is maintained between 15 and 25 degrees Celsius, and the humidity is kept at 40%. These conditions are crucial to preserving the sterility of the instruments. This organized approach and strict adherence to protocols ensure that all surgical instruments remain sterile, thus maintaining the highest standards of safety and efficacy for the surgical procedures conducted at SBISR.

Instruments from various nursing wards, labor and delivery rooms (LDR), NICUs, PICUs, ICUs, and operation theaters (OT) in the hospital are sterilized by the in-house CSSD department at Sitaram Bhartia Institute of Science and Research. In the hospital's three operating rooms, surgeries including gynecological, ENT, eye, orthopedic, and general surgeries are performed. Orthopedic and gynecological operations account for the majority of the approximately 280 surgeries that SBISR performs each month.



(Figure 1.0- Sitaram Bhartia Hospital's CSSD Workflow)

Upon arriving at the CSSD, nursing staff cleans the surgical equipment sets in the first zone, known as the "Dirty Area." The CSSD manager and employees then dry the instruments using

air gun and package the instruments, attach the indicator to these sets and put them in the autoclaving machine in the "Autoclaving and Packaging Area." Ultimately, the sanitized instrument sets are stored in sterile storage chambers in the "Clean Area," where the humidity is maintained at 40% and the temperature is kept between 15 and 25 degrees Celsius. The instruments' sterility must be maintained under these circumstances. The utmost levels of safety and effectiveness for the surgical procedures performed at SBISR are maintained because of this methodical approach and rigorous adherence to protocols, which guarantee that all surgical equipment remain sterile.

After the sets get autoclaved and get stored in the clean area. The Circulating Nurse in the OT picks every set that is required for the scheduled surgery and brings them in the OT after issuing them from the CSSD manager. The sets are taken into the OT with the help of sterilized stainless steel trolley. Proper care is maintained while transferring these sets from the CSSD. It's always advised to Circulating Nurse to handle sterile objects with caution. To maintain the item's sterility, it must not be pulled, crushed, and bended, compressed, or pierced the packing. Each object should be put through an integrity check before it is given out. It is the end user's obligation to visually check the packaging for integrity and labeling before opening and using a sterile item. It is made sure that sterilized items don't get used past their expiration date or if the sterilized packaging shows evidence of shredding, puncturing, or dampness in order to follow sterilization regulations. If these protocols are not followed properly, it increases the chances of HAI in the hospital. Therefore, proper check of all the process is maintained by the OT manager to increase the efficiency of the surgeries as well as the hospital.

NEED FOR THE STUDY

To ensure patient safety and the efficient functioning of healthcare institutions, the Central Sterile Services Department (CSSD) must handle sterilization procedures with efficiency. One area of particular concern is the high re-autoclave rate, which not only pose a risk to patient health but also incur significant costs and strain on resources.

With a 15% re-autoclave rate in February 2024, the CSSD processed 2,632 instrument sets; 391 of those sets needed to be re-autoclaved. Of these, 318 were packed in casement cloth, 22 in single-use sealed peel packets, and 51 sets were packed in SMS (Spunbond-Meltblown-Spunbond) sheets. 397 sets required to be re-autoclaved out of 2,697 sets that were processed in March 2024, a somewhat lower re-autoclave rate of 13%. Of these, 298 were in casement cloth, 71 in SMS sheets, and 28 in single-use sealed peel packs. 342 instrument sets needed to be re-autoclaved out of the 2,412 sets that the CSSD handled in April 2024 at a re-autoclave rate of 14%. 49 sets were packaged in single-use sealed peel, 204 sets in casement cloth, and 89 sets in SMS sheets.

The data point to a recurring problem with re-autoclaving and raise the possibility that the packaging and sterilization practices in use today are insufficiently effective. The constant re-autoclave rates suggest that the causes of these high rates need to be thoroughly investigated. Inadequate packaging methods, failed sterilization cycles, or contamination during handling and storage are examples of potential contributing factors. The efficiency and safety of the CSSD's sterilization procedures can be enhanced by recognizing and resolving these problems.

For a number of reasons, re-autoclave rates must be decreased. By making sure that all devices are thoroughly cleaned and sterilized, it first improves patient safety. By eliminating the need for repeated sterilization cycles, which waste more time, labor, and materials, it also maximizes resource use. Thirdly, it reduces the expenses related to sterilization, such as

energy usage, equipment wear and tear, and sterilizing supply usage. Finally, it maximizes the use of human resources, freeing up employees to concentrate on other important duties rather than reprocessing instruments.

In order to lower the CSSD's re-autoclave rates, this study intends to examine and maybe alter the current sterilization protocols. The CSSD can improve the efficacy and efficiency of its sterilizing procedures by looking into the causes of high re-autoclave rates and putting targeted interventions in place. Safer patient care practices are also facilitated by this, which helps the healthcare facility by optimizing costs and resources. Improving sterilizing procedures requires addressing the high re-autoclave rates in the CSSD. This study aims to offer insightful information about the variables influencing re-autoclave rates as well as practical mitigation techniques. In the end, both patients and healthcare providers will gain from the effective lowering of re-autoclave rates, which will encourage safer and more sustainable healthcare practices.

LITERATURE REVIEW

Wendra Afriana, Febriyanti Zulyani, 2023- The research focused on areas such as patient flow, inventory management, and operational processes, resulting in improvements such as reduced patient wait times, lower inventory costs, and enhanced overall efficiency. The application of LSS fostered a culture of continuous improvement, promoting a more patient-centric approach and streamlined operations. This study contributes valuable insights for hospital administrators aiming to enhance healthcare delivery through systematic process improvement strategies. ^[5]

Youngsook, 2022 The World Federation for Health Sterilization Sciences conducted research aimed at improving management efficiency by verifying the expiration dates of sterilized products. They extended the expiration dates of sterilized sets after studying their environment. This adjustment resulted in a notable decrease in the re-processing rate, suggesting improved efficiency in sterilization processes. ^[7]

Joseph L, Rabindranath B, Ponnice F, Lee P, 2021 Through performance assessments using user satisfaction surveys and focused interventions, the project aimed to improve management in the Central Sterile Supply Department (CSSD). Dissatisfaction variables were identified in 2012 by a multidisciplinary team, and charge nurses participated in a baseline survey. The CSSD management received findings and recommendations from the Quality Management Cell. Subsequent polls conducted between 2014 and 2019 revealed a noteworthy rise in overall satisfaction, from 54% to 89%, with a p-value of less than 0.001. Other departments, such as laundry and radiology, were motivated to implement comparable procedures by the initiative's promotion of transparency and data-driven improvements. This study demonstrates how well-researched internal surveys promote ongoing quality enhancement. ^[9]

Lakhan P, Faoagali J, Steinhardt R, Olesen D, 2013: The paper addresses the controversy in Australian hospitals around the use-by date of sterile, reusable medical equipment. While shelf life has historically been determined by time, there is growing support for event-related determinations, in which sterility is preserved until a compromise event takes place. International and Australian standards offer rules for storage conditions and sterilizing processes. Sterilized things may stay sterile for up to 12 to 24 months, according to some small-scale research; nevertheless, the issue is complicated by the dearth of well-designed experimental experiments. In addition to providing an implementation algorithm, the paper lists the considerations hospitals should make when choosing between event-related and time-based shelf life. Sterility is ultimately dependent on effective sterilizing procedures, continuous observation, and suitable storage settings. ^[8]

Jeffrey R. Avansino, Adam B. Goldin, 2012- This literature review highlights the implementation of standardized operative equipment in a children's hospital for laparoscopic appendectomy, aiming to reduce costs while maintaining patient care quality. Results showed a 20% average reduction in supply costs per case, with no significant changes in operative time or patient outcomes. Surveyed healthcare professionals agreed that standardization improves cost-effectiveness and patient safety, though perceptions on efficiency and patient care varied by role. Potential annual savings exceeded \$41,000, supporting the efficacy of standardized practices in healthcare optimization. ^[6]

METHODOLOGY

AIM: To reduce the re-autoclave rate in the CSSD of Sitaram Bhartia Hospital.

Key Objectives: -

1. To decrease the re autoclave rate in the CSSD of Sitaram Bhartia Hospital
2. To investigate the causes of re- autoclave cases in CSSD.
3. To increase CSSD efficiency by decreasing the cost, manpower hours associated with re-autoclaving of medical instruments.

Research Design: - Prospective study design is used in the project with the aim decrease the re-autoclaving rate in the hospital.

Sample Size: - All the medical instrument sets sterilized in the CSSD of Sitaram Bhartia Hospital from February to June.

Data Source: - Data is collected from the CSSD registers and from the EMR.

Data Analysis: - Data is analyzed with the help of M S Excel.

Research Procedure: - The study was conducted in the Central Sterile Supply Department (CSSD) of the Sitaram Bhartia Institute of Science and Research. The initial phase involved a baseline study carried out in April, where data from February, March, and April were collected to understand the existing conditions. It was found that the re-autoclaving rate in the CSSD consistently ranged between 14-15% during these months. This high re-autoclaving rate indicated inefficiencies in the sterilization process, prompting the need for further investigation and intervention to improve the system.

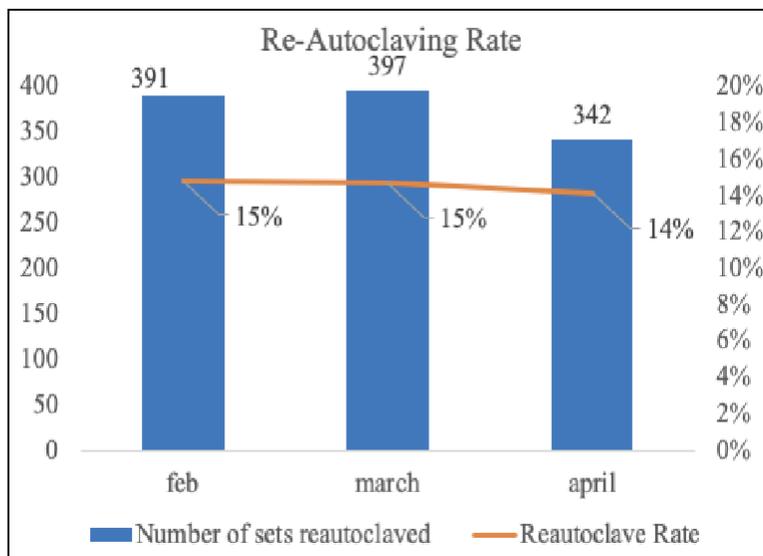
The primary objectives of the research were to decrease the re-autoclaving rate, increase the efficiency of CSSD operations, and reduce the costs associated with re-autoclaving. A comprehensive literature review and root cause analysis (RCA) revealed several issues within the CSSD: there were no standardized protocols for packaging instruments, the shelf life of sterilized sets was shorter (30 Days) than standardized expectations (90 Days), and the CSSD

was understaffed, leading to failures in following the First-In, First-Out (FIFO) principle. These problems guided the formulation of specific interventions.

To address these issues, several changes were implemented in May. Firstly, a standardized list was created for sets that are not frequently used, ensuring they were packed in materials that provide a longer shelf life. Protocols were established to determine the appropriate packaging for each instrument type. Additionally, selected sets were sent for culture testing after 45 days to verify that sterility was maintained over time, thereby ensuring the effectiveness of the new packaging protocols. Nurses were also given training to rigorously follow the FIFO principle within the CSSD, aiming to ensure that older sets were used first, thus reducing the likelihood of sets being re-autoclaved due to exceeded shelf life.

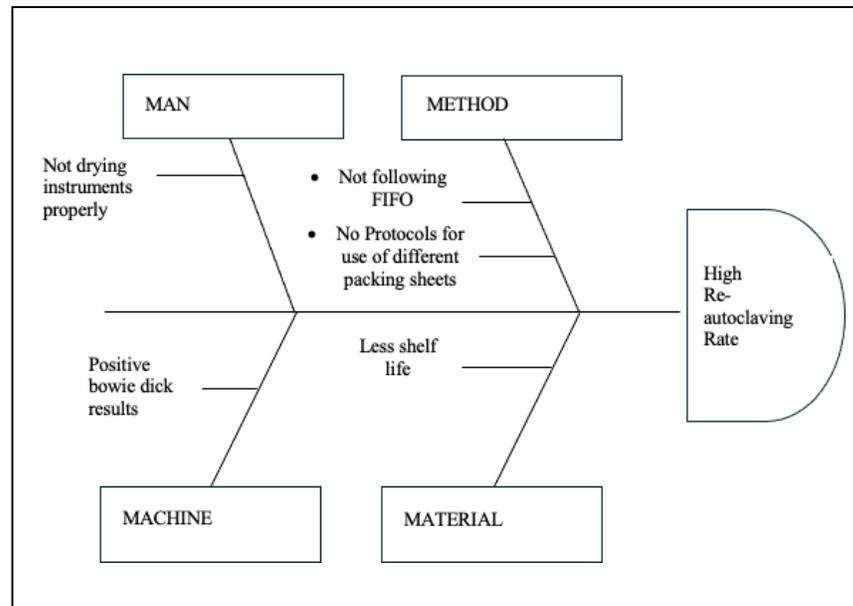
In June, a thorough analysis was conducted to evaluate the impact of these interventions. This involved comparing the re-autoclaving rates before and after the interventions taken in the CSSD.

RESULTS



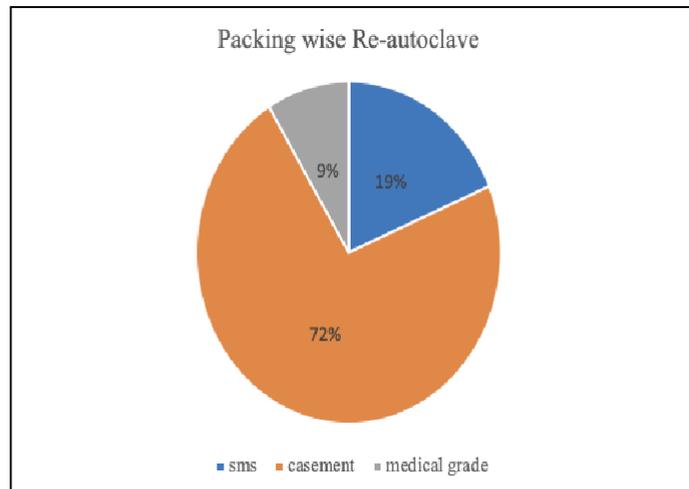
(Figure 1.1- Re-Autoclaving Rate/Month)

This graph plots the number of sets that are re-autoclaved monthly along with the related re-autoclave rates for the months of February, March, and April. The graph's main axis shows how many sets are re-autoclaved each month. Re-autoclaving 391 sets in February led to a minor increase to 397 sets in March and a subsequent decrease to 342 sets in April. Re-autoclave rate expressed as a percentage is shown on the secondary axis, where it is 15% in February and March and then drops to 14% in April. With a minor decline in the quantity of re-autoclaved sets and the re-autoclave rate in April, the data shows a high re-autoclave rate over the course of the three-month period. This high re-autoclave rate not only reduce the efficiency of the CSSD but also raises some questions on the higher possibilities of spreading of Hospital acquired infections because of un-sterility of the medical instrument sets. Cost associated with sterilizing these medical instrument sets such as electricity cost, water cost, packing paper cost, laundry cost and indicators cost can be reduced if proper protocols and changes are implemented in the CSSD which will directly lead to increased efficiency and less workload on the manpower.



(Figure 1.2- Root cause analysis for High Re-Autoclave Rate)

The high re-autoclave rate in instrument sterilization operations can be attributed to multiple important reasons, as revealed by the analysis of the Fishbone Diagram. Problems with manpower, including not drying instruments thoroughly before autoclaving, cause damp conditions when opened, which means the sterilization is not sufficiently done and must be repeated. When all previous sets must be re-autoclaved to guarantee adequate sterilization due to a positive Bowie Dick indicator result, machine-related issues occur. An increase in re-autoclaving events and irregular sterilization cycles are the results of methodological flaws such as noncompliance with FIFO principles and the lack of standardized packaging processes. Another contributing factor in the issue is the compromise of sterilization efficacy caused by the use of packing materials with shorter shelf life than required by standard specifications. Reducing re-autoclaving incidents and guaranteeing consistently dependable instrument sterilization require addressing these complex challenges through enhanced protocols, training, and material management techniques.



(Figure 1.3- Packaging wise Re-autoclaved sets)

Based on the kind of packing sheets used, the distribution of sets needing to be re-autoclaved is shown in the pie chart. It shows that casement sheets, which have a short shelf life of seven days, are used to package a large 72% of the sets that require re-autoclaving. 9% of the sets, on the other hand, are packaged in medical grade sheets and 19% of the sets are packed in SMS sheets, both of which have a 30-day shelf life.

Sets that are not utilized frequently but are nonetheless packaged in casement sheets are identified by interviewing circulating nurses in order to address the high re-autoclave rate connected with casement packing sets and are shifted to SMS sheets packaging in order to provide them longer shelf life and to reduce the number of times it gets re-autoclaved with being getting utilized. The shelf life of the SMS and medical grade paper sets were also being proposed to increase to 45 days to decrease the re-autoclave rate for sets packed in medical grade paper and SMS. After 45 days, culture samples of both SMS and medical-grade paper were successfully sent and tested, ensuring that the prolonged shelf life would not impair sterilizing efficacy (Figure 1.4&1.5).

Based on this, the extension was allowed. The total sterilizing operations are to be improved and the frequency of re-autoclaving is to be decreased with this method

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LABORATORY INVESTIGATION REPORT

Patient Name : Mr. HOSPITAL INFECTION CONTROL	Age/Sex : 11 Year(s) 4 Month(s) / Male
UHID : SBID.272944	Order Date : 28/05/2024 10:58
Episode : OP	Mobile No : 9842111111
Ref. Doctor : Self	Facility : SBISR
Registration_No : 272944	
Address : C/O SITARAM BHARTIA INSTITUTE OF SCIENCE AND RESEARCH , ,New Delhi,DELHI, 0	

Microbiology

TEST NAME	RESULT
Sample No : 0700054067	Collection Date : 28/05/24 11:01 Ack Date : 28/05/2024 11:04 Report Date : 30/05/24 10:25
Culture and Sensitivity (Pyogenic) - Any specimen (automated)	
Sample Type- Any Specimen	
Nature of specimen.	Swab from single Instrument in medical grade paper
Date of reporting.	30/05/2024
Final report.	Final report: No growth obtained in aerobic culture
Interpretation - Sterility is maintained.	
Comment	
Date of sterilization- 13/04/2024	
Date of expiry- 12/05/2024	
-The specimen submitted is processed for culture by conventional method on standard sterile culture media and incubated aerobically at 370C for up to 48 hours.	
-If any significant growth of pathogenic bacteria is indicated during the period of incubation, the isolated organism is further processed for identification by automated VITEK-2 ID & AST system /standard conventional biochemical tests and antimicrobial sensitivity testing is done by automated VITEK-2 ID & AST system/ Kirby Bauer disk diffusion method.	
-The testing & interpretation of antimicrobial sensitivity is done as per the latest CLSI/EUCAST guidelines and reported accordingly.	
Note- Administration of antibiotic prior to specimen collection may inhibit the growth of pathogenic bacteria.	
All the culture reports should always be correlated with relevant clinical & laboratory findings before consideration of treatment.	



Page 1 of 2



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Reg office: Block No. 1E, 216 Acharya Jagdish Chandra Bose Road, Kolkata, West Bengal -700017

(Figure 1.4- Culture report for sets packed in Medical Grade sheet after 45 days)

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LABORATORY INVESTIGATION REPORT

Patient Name : Mr. HOSPITAL INFECTION CONTROL	Age/Sex : 11 Year(s) 5 Month(s) / Male
UHID : SBID.272944	Order Date : 05/06/2024 13:29
Episode : OP	Mobile No : 9842111111
Ref. Doctor : Self	Facility : SBISR
Registration_No : 272944	
Address : C/O SITARAM BHARTIA INSTITUTE OF SCIENCE AND RESEARCH , ,New Delhi,DELHI ,0	

Microbiology

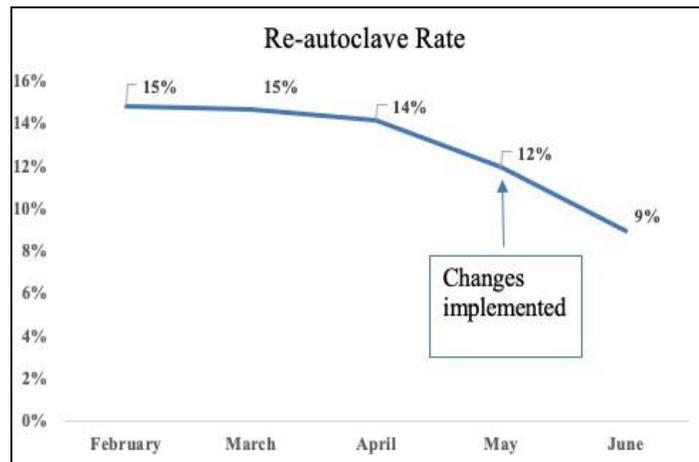
TEST NAME	RESULT
Sample No : 0700055031	Collection Date : 05/06/24 13:32 Ack Date : 05/06/2024 13:33 Report Date : 07/06/24 10:37
Culture and Sensitivity (Pyogenic) - Any specimen (automated)	
Sample Type- Any Specimen	
Nature of specimen.	Culture swab - OT (MLS Set)
	SMS sheet
Date of reporting.	07.06.2024
Final report.	
Date of sterilization: 22/04/2024	
Date of expiry : 21/05/2024	
Final report: No growth obtained in aerobic culture	
-The specimen submitted is processed for culture by conventional method on standard sterile culture media and incubated aerobically at 37°C for up to 48 hours.	
-If any significant growth of pathogenic bacteria is indicated during the period of incubation, the isolated organism is further processed for identification by automated VITEK-2 ID & AST system /standard conventional biochemical tests and antimicrobial sensitivity testing is done by automated VITEK-2 ID & AST system/ Kirby Bauer disk diffusion method.	
-The testing & interpretation of antimicrobial sensitivity is done as per the latest CLSI/EUCAST guidelines and reported accordingly.	
<i>Note- Administration of antibiotic prior to specimen collection may inhibit the growth of pathogenic bacteria.</i>	
<i>All the culture reports should always be correlated with relevant clinical & laboratory findings before consideration of treatment.</i>	
End of Report	
 Dr. Vrushali Vishwas Patwardhan M.D. Consultant Microbiology	




24 hrs. Emergency, Laboratory, Radiology Services | Ambulance Service | Blood Storage Facility | ICU | HDU
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(Figure 1.5- Culture report for sets packed in SMS sheet after 45 days)



(Figure 1.6 - Re-Autoclave rate before and after changes implemented)

The improvement attained is clearly seen in Figure 1.6 that compares the rate of re-autoclaving medical instrument sets before and after putting certain improvements into place. The re-autoclave rate in February, March, and April initially ranged from 14–15%. Re-autoclave rate decreased by 3% to 12% in May, during the transition period when modifications were being planned and implemented progressively.

A notable improvement was seen after the improvements were fully put into place, which included giving the Central Sterile Services Department (CSSD) a comprehensive list of sets to pack in SMS sheets (which have a longer shelf life) rather than casement sheets (which have a shorter shelf life), and increasing the shelf life of medical grade and SMS sheets from 30 to 45 days. The re-autoclave rate dropped to 9% by the middle of June. This decline demonstrates how well the adjustments made to improve packing procedures and increase shelf life worked, ultimately resulting in a significant drop in the frequency of re-autoclaving.

DISCUSSION

The results of our study highlight how crucial it is to improve sterilizing procedures in healthcare settings in a systematic manner. Significant inefficiencies in the sterilizing process are highlighted by the high re-autoclave rate of 14–15% in the first three months of the investigation. Using tools like the Fishbone Diagram, we were able to pinpoint several important causes of these inefficiencies, such as problems with staffing, machinery breakdowns, poor procedure, and improper use of packaging materials.

The manpower-related issues, specifically the under-drying of instruments prior to autoclaving, which resulted in moist conditions and weakened sterilization was an important concern. This problem emphasizes the necessity of rigorous training and adherence to stringent procedural guidelines to guarantee adequate drying and safe handling of instruments.

Positive Bowie Dick indicator findings indicated the presence of machine-related issues and the need for routine sterilization equipment calibration and maintenance. By taking these precautions, you can lessen the frequency of sterilization cycles by ensuring the autoclaves' dependability and efficacy.

The re-autoclave rate was made worse by procedural mistakes such as neglecting the FIFO principles and an absence of consistent packaging procedures. Sterilization process integrity and workflow efficiency are enhanced by the implementation of standard operating procedures and strict adherence to FIFO principles.

The results obtained after the intervention showed a significant improvement; by mid-June, the re-autoclave rate had decreased to 9%. The observed decrease indicates to the effectiveness of the improvements that were put in place, such as improved packing techniques and longer shelf lives for packing materials. The improvement that has been

observed is consistent with the research that has been studied and highlights the significance of standard procedures and ongoing quality improvement in healthcare settings. For instance, the research conducted in 2023 by Wendra Afriana and Febriyanti Zulyani showed how the implementation of Lean Six Sigma (LSS) techniques could greatly improve operational operations, resulting in shorter wait times for patients and cheaper inventory costs. Similarly, standardizing operating equipment can save expenses and increase patient safety without sacrificing the quality of service, according to Jeffrey R. Avansino and Adam B. Goldin (2012).

The effectiveness of our interventions is also similar to findings from Youngsook (2022), wherein increased sterilization process efficiency was attained by confirming and increasing the expiration dates of products that had been sterilized. Additionally, Joseph L. et al.'s (2021) discussion of the use of user satisfaction surveys and performance assessments proved helpful in our situation, showing how data-driven adjustments can result in significant increases in quality and efficiency.

Our research indicates that significant improvements can be achieved in sterilizing operations by addressing complicated issues with improved protocols, training, and material management strategies. In addition to increasing operational effectiveness, lowering the re-autoclave rate also enhances patient safety and resource efficiency. In order to ensure that healthcare facilities can maintain high standards of sterilization while optimizing their processes and resources, future research should continue to examine and develop these solutions.

CONCLUSION

The objective of this research was to determine and address the reasons behind the high rates of re-autoclaves in the Central Sterile Services Department (CSSD) at Sitaram Bhartia Hospital. Several important concerns were identified by the preliminary analysis, including inefficient packaging procedures and materials, machine-related issues, and poor instrument drying. These elements aroused concerns about the possibility of hospital-acquired illnesses and higher operating costs in addition to increasing the re-autoclave rate.

Considerable progress was made with focused interventions. Among the major adjustments were:

- **Changing to Longer Shelf-Life Packing Materials:** As SMS sheets have a longer shelf life than casement sheets, the frequency of re-autoclaving was essentially decreased. An analysis revealed that a significant percentage of sets that were re-autoclaved were originally enclosed in casement sheets.
- **Extending the Shelf Life of Packaging Materials:** Re-autoclaving was further avoided by giving SMS and medical-grade paper sets a 45-day shelf life after successful sterility testing.
- **Increasing Compliance and Protocols:** Methodological errors that led to the high re-autoclave rate were addressed by better implementation of FIFO principles and increased adherence to sterilization protocols, which included thorough instrument drying.

Re-autoclave rates significantly decreased as a result of these treatments; they went from 14–15% in February, March, and April to 12% in May and then to 9% by the middle of June. By reducing the risk of hospital-acquired infections, this reduction not only reduced the cost of

operations but also improved the efficiency and dependability of the CSSD's sterilization procedures, improving patient safety.

However, the lack of time was an important constraint to the study. The 45-day shelf life extension that is now in place, while successful, may be extended to 90 days as literature suggests. An even higher decrease in the re-autoclave rate is anticipated as a result of improved compliance with the new protocols brought about by more time for thorough testing and gradual implementation.

In conclusion, there have been notable operational improvements in the CSSD at Sitaram Bhartia Hospital because of the methodical identification and resolving of the primary factors causing high re-autoclave rates. To sustain these improvements and ensure uniform, dependable sterilization of medical equipment, it will be essential to implement these improved methods and material management approaches going forward. This study emphasizes how crucial it is to continuously evaluate and adjust sterilization procedures in order to uphold high standards for the provision of healthcare services. Further studies should concentrate on the potential advantages of extending the shelf life of packing materials to 90 days, as well as the effects of higher compliance over an extended duration.

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ANNEXURE:

List of the sets identified to be less frequently used and started to be packed in SMS

Packaging

INFREQUENTLY UTILIZED SETS		
S.No	Set Name	Department
1	Ortho Laminectomy Set	Ortho
2	THR set	Ortho
3	Arthroscopy New Set	Ortho
4	Amputation Set	Ortho
5	Bone Holding Set	Ortho
6	Broken Screw Set	Ortho
7	Ortho 4.5MM basic set	Ortho
8	LCP instrument	Ortho
9	DHS set	Ortho
10	External Fixator Set	Ortho
11	Ortho 3.5 mm Screw Plate Box	Ortho
12	DCP/LCP tabular plate Box	Ortho
13	Ortho 4.5 mm Screw Box	Ortho
14	Hand reamer set	Ortho
15	Biopsy Set	Emergency
16	Aspiration	Emergency
17	Garbed Syringe Set	Emergency
18	Cut Down Set	Emergency
19	Catheterization Set	Emergency

20	Towel Clip	Emergency
21	ENT set	Emergency
22	Tennaculum	Emergency
23	Sims Speculum	Emergency
24	Cervical Biopsy Forceps	Emergency
25	Uterine Dilator	Emergency
26	Major Surgery 1st set	General Surgery
27	Major Surgery 2nd set	General Surgery
28	Vascular Surgery set	General Surgery
29	Craniotomy set	General Surgery
30	Tracheostomy set	General Surgery
31	Thoracic surgery set	General Surgery
32	Tuboplasty set	General Surgery
33	Septoplasty set	General Surgery
34	Myringoplasty set	General Surgery
35	Tonsillectomy set	General Surgery
36	Eye Instrument 1st set	ENT
37	Eye Instrument 2nd set	ENT
38	New Eye instrument set	ENT
39	MLS instrument set	ENT
40	Antrum set	ENT
41	Oral Biopsy set	ENT
42	Septoplasty Set	ENT
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44	Tonsillectomy Set	ENT
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46	Curator	IVF
47	Cuscus	IVF
48	A V retractor	IVF
49	Chattel Forceps	IVF
50	Uterine Sound	IVF
51	Tenaculum	IVF
52	Mangles Forceps	IVF
53	D&C Set	LDR
54	McDonald Stitch	LDR
55	Outlet forceps	LDR
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57	IUI set	LDR
58	PPH set	LDR
59	Narrow Cuscus	LDR
60	Cut-down set	PICU
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