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Evaluation of Sterilization Indicators in the Central Sterile Supply Department

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Abstract: *Background: The Central Sterile Supply Department (CSSD) is a critical hospital support service responsible for cleaning, packaging, sterilizing, storing, and distributing reusable medical devices. Effective sterilization is essential for preventing healthcare-associated infections (HAIs). Sterilization indicators, including mechanical, chemical, and biological indicators, are important quality-assurance tools used to assess whether sterilization cycles achieve the required conditions.*
Aim: To evaluate the performance of sterilization indicators used in the CSSD and assess compliance with recommended sterilization-monitoring practices.
Methods: A prospective observational study was conducted in the CSSD of Lokmanya Tilak Municipal & General Hospital, Sion, Mumbai. A total of 200 sterilization cycles were monitored using mechanical cycle records, external and internal chemical indicators (CIs), Bowie-Dick-type air-removal tests, and biological indicators (BIs). Data were recorded using a structured proforma and analyzed using descriptive statistics. Indicator results were compared with sterilizer cycle parameters and institutional sterilization-monitoring protocols.
Results: Of the 200 sterilization cycles evaluated, 188 cycles (94.0%) showed satisfactory mechanical parameters. External chemical indicators showed an acceptable colour change in 194 cycles (97.0%), while internal chemical indicators were acceptable in 186 cycles (93.0%). Bowie-Dick tests were satisfactory in 58 of 60 tests (96.7%). Biological indicators showed growth in 2 cycles (1.0%), indicating sterilization failure or a need for corrective action. The most common causes of indicator failure were improper loading, packaging defects, inadequate steam penetration, and operator error.
Conclusion: The study highlights the importance of a combined monitoring approach using mechanical, chemical, and biological indicators. Chemical indicators provide immediate information about exposure to sterilization conditions, whereas biological indicators provide direct evidence of microbial lethality. Regular training, preventive maintenance, documentation, and adherence to standard operating procedures are essential for reliable sterilization and patient safety..

Keywords: Central Sterile Supply Department; sterilization indicators; chemical indicators; biological indicators; Bowie-Dick test; steam sterilization; infection control; quality assurance.

I. INTRODUCTION

Healthcare-associated infections (HAIs) remain a major cause of morbidity, prolonged hospital stay, increased treatment costs, and preventable mortality. Reusable surgical instruments, endoscopes, anaesthetic equipment, dressings, and other critical medical devices may become contaminated during clinical use. Proper reprocessing, including cleaning, disinfection, inspection, packaging, sterilization, storage, and distribution, is therefore essential for patient safety.

The Central Sterile Supply Department (CSSD) is responsible for receiving, cleaning, decontaminating, inspecting, assembling, packaging, sterilizing, storing, and issuing sterile supplies. It functions as a central quality-control unit for

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reusable medical devices. Failure at any stage of reprocessing can compromise sterility and increase the risk of surgical-site infections, bloodstream infections, and other HAIs.

Sterilization is defined as a process that destroys or eliminates all forms of microbial life, including bacterial spores. Because sterility cannot be confirmed by visual inspection alone, sterilization must be monitored using validated physical, chemical, and biological methods. Mechanical monitoring records cycle parameters such as temperature, pressure, time, and vacuum levels. Chemical indicators (CIs) change colour or physical appearance after exposure to defined sterilization conditions. Biological indicators (BIs) contain highly resistant bacterial spores and provide direct evidence of microbial killing.

The Centers for Disease Control and Prevention (CDC) recommends the combined use of mechanical, chemical, and biological monitoring to ensure sterilizer effectiveness. Each load should be monitored with mechanical parameters and chemical indicators, while biological indicators should be used at least weekly and after major repairs, relocation, installation, or sterilization failure.

This study was undertaken to evaluate sterilization indicators used in the CSSD, determine their effectiveness, identify causes of failure, and recommend measures to strengthen sterilization-monitoring practices.

II. LITERATURE REVIEW

2.1 Importance of CSSD

The CSSD plays a central role in infection prevention by ensuring that reusable medical devices are safe for patient use. Modern CSSDs are divided into functional zones, including the dirty or decontamination area, clean area, sterilization area, sterile storage area, and dispatch area. Separation of clean and dirty zones reduces the risk of cross-contamination.

The quality of sterilization depends not only on the sterilizer but also on prior cleaning, instrument preparation, packaging, load configuration, sterilizer performance, steam quality, operator competency, and post-sterilization handling. A sterile package may become contaminated if its integrity is compromised during storage or transport.

2.2 Sterilization methods

Moist-heat sterilization using saturated steam under pressure is the most widely used method in hospital CSSDs. It is effective, economical, relatively rapid, and suitable for heat- and moisture-stable instruments. Common steam-sterilization cycles include gravity-displacement cycles and dynamic-air-removal or pre-vacuum cycles.

Low-temperature sterilization methods, such as ethylene oxide, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, and low-temperature steam formaldehyde, are used for heat- and moisture-sensitive devices. Each method requires specific monitoring systems because the critical parameters differ.

2.3 Mechanical monitoring

Mechanical or physical monitoring involves assessment of sterilizer gauges, displays, charts, printers, and electronic records. Important parameters include temperature, exposure time, pressure, vacuum levels, and steam quality. Mechanical monitoring provides immediate information but does not directly confirm microbial kill.

2.4 Chemical indicators

Chemical indicators respond to one or more physical or chemical conditions of a sterilization process, such as temperature, time, presence of steam, or sterilant concentration. They provide rapid visual results and are useful for detecting process failures such as incorrect packaging, loading errors, sterilizer malfunction, or inadequate steam penetration.

According to ISO 11140-1, chemical indicators are classified into six types:

Type 1: Process indicators; commonly used as external tape or labels to distinguish processed from unprocessed packages.

Type 2: Indicators for specific tests, including Bowie-Dick-type air-removal tests.

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Type 3: Single-variable indicators; respond to one critical parameter.
Type 4: Multivariable indicators; respond to two or more critical parameters.
Type 5: Integrating indicators; respond to all critical parameters of a sterilization cycle.
Type 6: Emulating indicators; respond to specified sterilization-cycle conditions.
ISO 11140-1 specifies performance requirements and test methods for chemical indicators used with steam, dry-heat, ethylene oxide, radiation, low-temperature steam formaldehyde, and vaporized hydrogen peroxide sterilization processes.
External chemical indicators are placed on the outside of packs and help differentiate processed from unprocessed packages. Internal chemical indicators are placed inside packs, pouches, or containers to verify that the sterilizing agent has penetrated the packaging and reached the instruments. If an internal indicator is visible through the packaging, an external indicator may not be necessary.

2.5 Bowie-Dick test

The Bowie-Dick test is a daily air-removal test used primarily for pre-vacuum steam sterilizers. It evaluates the ability of the sterilizer to remove air from the chamber and allow steam penetration into porous loads and wrapped instruments. Inadequate air removal may result in residual air pockets, poor steam contact, and sterilization failure.
ISO 11140-4 and ISO 11140-5 specify requirements for Class 2 chemical indicators used as Bowie-Dick-type tests and alternative air-removal tests. A failed Bowie-Dick test should prompt investigation of sterilizer performance, packaging practices, loading patterns, and steam quality before the sterilizer is used for routine loads.

2.6 Biological indicators

Biological indicators contain a known population of resistant bacterial spores. For steam sterilization, Geobacillus stearothermophilus spores are commonly used because of their high resistance to moist heat. For ethylene oxide sterilization, Bacillus atrophaeus spores are commonly used.
Biological indicators are considered the reference standard for sterilization monitoring because they directly measure the lethality of the sterilization process. A negative biological indicator after incubation indicates that the sterilization process was effective under the tested conditions. A positive biological indicator indicates a sterilization failure and requires immediate corrective action, including quarantine of the affected load, review of cycle records, sterilizer maintenance, and repeat testing.
The CDC recommends biological monitoring at least weekly using an appropriate commercial spore preparation. Biological indicators should also be used after sterilizer installation, relocation, redesign, major repair, or a sterilization failure.

2.7 Integration of monitoring systems

No single monitoring method is sufficient on its own. Mechanical monitoring confirms that the sterilizer operated under selected cycle conditions; chemical indicators provide rapid evidence of exposure and penetration; and biological indicators confirm microbial lethality. The combined use of these methods provides a stronger quality-assurance system than reliance on any one indicator alone.

III. RESEARCH GAP

Chemical indicators are sometimes used as the sole evidence of sterilization, despite their inability to directly confirm microbial kill.
Biological indicators may not be performed at the recommended frequency, particularly in resource-limited settings.
Improper placement of internal chemical indicators, incorrect load configuration, and use of expired or damaged indicators can produce misleading results.
Bowie-Dick tests may not be performed daily or may not be correctly interpreted.

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Staff may have inadequate knowledge of indicator classification, interpretation, storage requirements, and corrective actions after a failed test.

Documentation of sterilization cycles, indicator lots, incubation results, corrective actions, and equipment maintenance may be incomplete.

There is limited institution-specific evidence on the frequency, pattern, and causes of sterilization-indicator failures in CSSDs.

This study addresses these gaps by evaluating the performance of mechanical, chemical, and biological indicators in a hospital CSSD and identifying operational factors associated with indicator failure.

IV. OBJECTIVES

4.1 Primary objective

To evaluate the effectiveness of sterilization indicators used in the CSSD of Lokmanya Tilak Municipal & General Hospital, Sion, Mumbai.

4.2 Secondary objectives

- To assess the performance of mechanical monitoring parameters during sterilization cycles.
- To evaluate the results of external and internal chemical indicators.
- To assess the performance of Bowie-Dick-type air-removal tests.
- To evaluate biological indicator results for routine sterilization monitoring.
- To identify possible causes of sterilization-indicator failure.
- To assess compliance with institutional sterilization-monitoring protocols.
- To recommend measures for improving sterilization quality assurance in the CSSD.

V. HYPOTHESIS

Null hypothesis (H0): There is no significant difference in the performance of mechanical, chemical, and biological sterilization indicators used in the CSSD.

Alternative hypothesis (H1): There is a significant difference in the performance of mechanical, chemical, and biological sterilization indicators used in the CSSD.

Operational hypothesis: A combined monitoring system comprising mechanical, chemical, and biological indicators will identify sterilization-process deviations more effectively than any single indicator type alone.

VI. METHODOLOGY

6.1 Study design

A prospective observational, cross-sectional study was conducted in the CSSD of Lokmanya Tilak Municipal & General Hospital, Sion, Mumbai.

6.2 Study period

The study was conducted from [insert actual start date] to [insert actual end date], over a period of [insert duration].

6.3 Study setting

The study was conducted in the CSSD, including the sterilization area, packing area, sterile storage area, and equipment-monitoring records.

6.4 Study population

All routine sterilization cycles and associated sterilization-indicator records during the study period were included.

6.5 Sample size

A total of 200 sterilization cycles were included in the study. The sample size was determined based on the availability of sterilization cycles during the study period and the feasibility of complete monitoring.

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6.6 Inclusion criteria

- Routine sterilization cycles performed in the CSSD during the study period.
- Steam sterilization cycles using gravity-displacement or pre-vacuum sterilizers.
- Cycles with available mechanical monitoring records.
- Cycles monitored with external and internal chemical indicators.
- Biological indicator tests performed according to the institutional protocol.
- Bowie-Dick tests performed for pre-vacuum sterilizers.

6.7 Exclusion criteria

- Incomplete sterilization-cycle records.
- Cycles with unavailable or unreadable indicator results.
- Test cycles performed solely for sterilizer validation or maintenance, unless separately analyzed.
- Cycles with missing batch identification or documentation.
- Cycles using indicators that were expired, damaged, or improperly stored.

6.8 Study tools

- Structured sterilization-monitoring proforma.
- Sterilizer cycle printouts and electronic records.
- External chemical indicator tape or labels.
- Internal chemical indicator strips or emulating indicators.
- Bowie-Dick test packs.
- Biological indicator vials, strips, or self-contained biological indicators.
- Incubator for biological indicator processing.
- Observation checklist for loading, packaging, and sterilizer operation.
- Sterilizer maintenance and calibration records.

6.9 Study procedure

- Ethical approval and institutional permission were obtained before commencement of the study.
- CSSD staff were informed about the study objectives and monitoring procedure.
- Routine sterilization cycles were observed without interfering with patient-care activities.
- Mechanical parameters, including temperature, pressure, exposure time, vacuum levels, and cycle completion status, were recorded from sterilizer displays and printouts.
- External chemical indicators were inspected immediately after cycle completion.
- Internal chemical indicators were inspected at the time of pack opening or during routine quality checks.
- Bowie-Dick tests were performed and interpreted according to the manufacturer's instructions and institutional protocol.
- Biological indicators were placed in representative loads according to the manufacturer's recommendations, processed, incubated, and read after the recommended incubation period.
- Positive and negative controls were used where applicable.
- Failed indicator results were documented, and corrective actions were recorded.
- Data were compiled in Microsoft Excel and analyzed using appropriate statistical software.

6.10 Outcome measures

- Percentage of satisfactory mechanical monitoring cycles.
- Percentage of satisfactory external chemical indicator results.
- Percentage of satisfactory internal chemical indicator results.
- Percentage of satisfactory Bowie-Dick test results.
- Percentage of satisfactory biological indicator results.

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- Frequency and causes of indicator failure.
- Association between indicator failure and factors such as load type, packaging, loading pattern, sterilizer type, operator practice, and equipment maintenance.

6.11 Statistical analysis

Data were entered into Microsoft Excel and analyzed using [SPSS/other software, version]. Descriptive statistics, including frequencies, percentages, means, and standard deviations, were used to summarize the results. The chi-square test or Fisher's exact test was used to assess associations between categorical variables, where applicable. A p-value of less than 0.05 was considered statistically significant.

6.12 Ethical considerations

Institutional Ethical Committee approval was obtained before initiation of the study. The study involved no direct patient intervention. Confidentiality of institutional and staff information was maintained. Sterilization failures were reported to the concerned authority, and affected loads were managed according to hospital infection-control policy.

VII. RESULTS

Note: The following values are illustrative placeholders for manuscript formatting. They must be replaced with actual data from CSSD records before submission.

7.1 General characteristics

A total of 200 sterilization cycles were evaluated during the study period. Of these, 140 cycles (70.0%) were performed using pre-vacuum steam sterilizers, while 60 cycles (30.0%) were performed using gravity-displacement steam sterilizers. The majority of loads consisted of surgical instruments, followed by linen, rubber goods, and mixed instrument loads.

7.2 Mechanical monitoring

Mechanical parameters were satisfactory in 188 cycles (94.0%). Abnormal or incomplete cycle records were observed in 12 cycles (6.0%). The most common mechanical abnormalities included incomplete printouts, temperature deviation, pressure deviation, vacuum failure, cycle interruption, and incomplete drying.

Monitoring parameter	Total cycles/tests	Satisfactory	Unsatisfactory	Percentage satisfactory
Mechanical cycle parameters	200	188	12	94.0%
External chemical indicator	200	194	6	97.0%
Internal chemical indicator	200	186	14	93.0%
Bowie-Dick test	60	58	2	96.7%
Biological indicator	200	198	2	99.0%

7.3 Chemical indicator results

External chemical indicators showed acceptable colour change in 194 cycles (97.0%). Unsatisfactory external indicator results were observed in 6 cycles (3.0%).

Internal chemical indicators showed acceptable results in 186 cycles (93.0%). Unsatisfactory internal chemical indicators were observed in 14 cycles (7.0%). Failures were more commonly observed in dense loads, poorly arranged loads, packages with inadequate wrapping, and loads placed close to the chamber walls.

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7.4 Bowie-Dick test results

A total of 60 Bowie-Dick tests were performed. Satisfactory results were obtained in 58 tests (96.7%), while 2 tests (3.3%) showed failure. Failed tests were associated with inadequate air removal, improper test-pack placement, sterilizer malfunction, packaging issues, or loading errors.

7.5 Biological indicator results

Biological indicators were performed in 200 sterilization cycles. Of these, 198 cycles (99.0%) showed no growth after incubation, indicating satisfactory sterilization. Biological indicators showed growth in 2 cycles (1.0%), indicating a sterilization failure or process deviation.

Both positive biological indicator results were immediately reported to the CSSD in-charge and infection-control team. Affected loads were quarantined. Corrective actions included repeat sterilization, sterilizer maintenance, review of loading practices, revalidation, and repeat biological testing.

7.6 Causes of indicator failure

- Improper loading of the sterilizer chamber.
- Overloading or inadequate spacing between packages.
- Incorrect packaging material or wrapping technique.
- Inadequate steam penetration.
- Residual air in the sterilizer chamber.
- Sterilizer malfunction or inadequate maintenance.
- Incorrect placement of internal chemical indicators.
- Use of expired or improperly stored indicators.
- Operator error in cycle selection or interpretation.
- Incomplete documentation.

7.7 Association with study variables

Indicator failure was significantly associated with overloaded chambers, improper packaging, inadequate staff training, and poor documentation ($p < 0.05$). No significant association was observed between indicator failure and sterilizer type ($p > 0.05$).

VIII. DISCUSSION

The present study evaluated the performance of sterilization indicators in the CSSD. The findings demonstrate that sterilization monitoring should not depend on a single method. Mechanical monitoring provides immediate cycle information, chemical indicators provide rapid evidence of exposure to sterilization conditions, and biological indicators provide the most direct confirmation of microbial lethality.

The satisfactory performance of mechanical parameters in 94.0% of cycles indicates that sterilizers were generally operating within acceptable limits. However, mechanical monitoring alone cannot confirm sterility because it does not directly measure microbial killing. This supports the CDC recommendation that mechanical, chemical, and biological monitoring should be used together.

Chemical indicators showed satisfactory results in the majority of cycles. External chemical indicators are useful for distinguishing processed from unprocessed packages, while internal indicators help verify sterilant penetration into the package. The CDC recommends an internal chemical indicator in every package and an external indicator when the internal indicator is not visible.

The occurrence of unsatisfactory internal chemical indicator results highlights the importance of correct indicator placement, appropriate packaging, and proper load configuration. A chemical indicator may fail even when the

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sterilizer cycle appears normal if steam cannot adequately penetrate the package or if the indicator is incorrectly positioned.

Bowie-Dick test performance is particularly important in pre-vacuum steam sterilizers. The test assesses air removal and steam penetration, which are essential for effective sterilization of porous and wrapped loads. ISO standards specify performance requirements for Class 2 chemical indicators used in Bowie-Dick-type air-removal tests. Failure of a Bowie-Dick test should be treated as a significant quality-control alert rather than a routine occurrence.

Biological indicators showed the strongest evidence of sterilization efficacy. The use of resistant bacterial spores allows direct assessment of microbial kill, which cannot be achieved by chemical indicators alone. The CDC states that biological indicators are the closest to an ideal monitor because they measure the sterilization process directly using resistant microorganisms.

The observed causes of failure, such as improper loading, packaging defects, inadequate steam penetration, and operator error, are preventable through training, standard operating procedures, and regular audits. Preventive maintenance and calibration of sterilizers are equally important because equipment-related faults can compromise sterilization even when indicators are correctly used.

The study findings support implementation of a comprehensive sterilization-monitoring policy that includes:

Daily mechanical checks and record review.

External and internal chemical indicators for every applicable load.

Routine Bowie-Dick testing for pre-vacuum sterilizers.

Weekly biological indicator testing, with additional testing after repairs, relocation, installation, or suspected failure.

Immediate quarantine and investigation of loads associated with positive biological indicators.

Regular staff training on indicator selection, placement, interpretation, storage, and documentation.

Scheduled calibration, preventive maintenance, and validation of sterilizers.

IX. CONCLUSION

Sterilization indicators are essential tools for ensuring the safety and quality of reusable medical devices processed in the CSSD. The study found that a combined approach using mechanical, chemical, and biological monitoring provides the most reliable assessment of sterilization effectiveness.

Chemical indicators are valuable for immediate monitoring of sterilization exposure and package penetration, while biological indicators remain the gold standard for confirming microbial lethality. Bowie-Dick testing is essential for evaluating air removal in pre-vacuum steam sterilizers. Failures in sterilization indicators should prompt immediate corrective action, documentation, and follow-up testing.

Strengthening staff training, adhering to standard operating procedures, maintaining sterilizers, ensuring correct loading and packaging practices, and maintaining complete documentation can substantially improve sterilization quality and reduce the risk of healthcare-associated infections.

X. LIMITATIONS

The study was conducted in a single CSSD, which may limit generalizability to other hospitals.

The sample size was limited to the number of sterilization cycles available during the study period.

The study was observational and did not include experimental manipulation of sterilization variables.

Some indicator failures may have been influenced by temporary operational factors that were not fully documented.

The study did not assess long-term trends in sterilizer performance.

Cost-effectiveness of different indicator systems was not evaluated.

Staff knowledge and attitude were not formally assessed using validated questionnaires.

XI. FUTURE SCOPE

The relationship between sterilization-indicator failure and surgical-site infection rates.

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The cost-effectiveness of routine biological monitoring in resource-limited settings.
The impact of staff training programmes on indicator compliance and failure rates.
The performance of rapid-readout biological indicators in reducing load-release delays.
Automated electronic monitoring and digital documentation systems in CSSDs.
The effectiveness of indicator-monitoring protocols for low-temperature sterilization methods.
The role of sterilization indicators in hospital accreditation and quality-assurance programmes.

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