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Evaluation Of Modern Sterilization Practices In Multidisciplinary Healthcare Facilities, Laboratories, And Pharmacies And Their Impact On Healthcare-Associated Infection Control In The Kingdom Of Saudi Arabia

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Abstract
Sterilization remains a cornerstone of infection prevention and control within healthcare systems. This study evaluates modern sterilization practices across multidisciplinary healthcare facilities in the Kingdom of Saudi Arabia, including the pharmacy, laboratory, and physical therapy sectors, and their collective impact on healthcare-associated infection (HAI) control. Using a cross-sectional analytical framework, the research investigates sterilization standards, procedures, and levels of compliance within different healthcare disciplines. The findings indicate that variations in sterilization quality and validation processes significantly influence infection control outcomes. Centralized sterilization systems—when present—enhance consistency, traceability, and adherence to Saudi Food and Drug Authority (SFDA) and World Health Organization (WHO) guidelines. Conversely, resource constraints, limited training, and inconsistent audit mechanisms were identified as major barriers to achieving optimal sterilization standards. By highlighting the disparities and interrelations among pharmacy, laboratory, and physical therapy sterilization protocols, this study underscores the necessity of unified national policies and evidence-based quality assurance systems. Strengthening sterilization infrastructure and workforce competencies across all disciplines will be essential for advancing patient safety and reducing HAIs within the Saudi healthcare sector.

Keywords: Sterilization practices; Pharmacy; Laboratory; Physical therapy; Healthcare-associated infections; Infection control; Saudi Arabia; Multidisciplinary healthcare; Quality assurance; SFDA guidelines.

1. Introduction

The continuous progress in knowledge and technology among health practitioners has brought to the forefront serious issues regarding sterilization processes, particularly for medical instruments and other items designated as "critical devices" [1]. Sterilization processes are essential to producing, packaging, transporting, storing, and dispensing medicines, from the industrial scale to hospital pharmacy and laboratory levels. Contamination of sterile products can introduce pathogens, and the biological safety of medicines is an important topic worldwide [2]. Various sterilization techniques are employed, but independent validation of sterilization processes is essential at a laboratory level. The Saudi Food and Drug Authority (SFDA), an independent scientific and regulatory body, has set detailed guidelines for the pharmaceutical sector, including sterilization practices during pharmacological, pharmaceutical, and biological processing stages. Alongside the SFDA, the World Health Organization (WHO) defines sterilization procedures, instructional biological indicators, and ancillary equipment to be used in sterilizers [3].

In the Kingdom of Saudi Arabia, sterilization-related practices, objectives, methods, and compliance with local and international regulations (primarily the SFDA and WHO guidelines) fluctuate among different pharmacy, laboratory, and medical therapy sectors. The regional distribution of health facilities and available sterilization equipment types influence instrument sterilization methods (specifically procedure and bioburden) from one facility type to another, with the sterilization process generating and ensuring sterility according to the desired degree. Under the supervision of the Ministry of Health (MoH), all health facilities, including public and private hospitals and polyclinics, are organized into sectors and sub-sectors, with centralized sterilization units limited to multidisciplinary facilities. Centralized sterilization systems (manual or automated) fully control sterilization processes, allowing the generation of sterilization legends, infection-control audit trails, and effective monitoring of sterilization criteria and guidelines. A centralized system also facilitates alignment with a single sector or manufacturer, thereby standardizing procedures and consumables. Consequently, sterilization standards often follow national health regulations, including specific sterilizing agent and method-related requirements. [4]

2. Theoretical Framework and Standards for Sterilization

Sterilization is a physical, chemical, or biological process that effectively eliminates or renders all forms of viable micro-organisms, including bacterial spores [5]. Validation is the process of establishing evidence that a specific sterilization process consistently produces a sterile product. Biological indicators consist of specific micro-organisms, their spores, or suitable surrogates that are used to confirm the efficacy of a sterilization process. When subjected to validated sterilization processes under controlled conditions, they allow direct measurement of the lethal effect on the organism [6]. Proper sterilization practice aims to provide assurance that all sterile articles remain sterilized throughout the entire storage period until the point of use.

Competent Sterilization facilities should follow international standards, guidelines, and norms, such as the United Nations Economic Commission for Europe (UNECE) Directive, the Global Harmonizing System, the determination of a Sterilization Centre; the Good Manufacturing Practice, and Good Laboratory Practices, including the Saudi Commission for Health Specialties. These materials are intended to facilitate the formulation of national legislation. The above reference is one of the documents that provide guidance for determining a sterilization activity or processing on pharmaceutical products, ensuring that the practice of sterilization is conducive to protect the public dialogue practice of management and to preserve the quality and integrity of globally produced. [7]

Sterilization activities are one of the core elements that safeguard human health by maintaining the integrity and quality of sterilization products. Therefore, assessing how effective sterilization is indentifying the types of sterilization process employed.

3. Sterilization Practices in Laboratories

To obtain valid sterile products and to comply with certain regulatory requirements, laboratories typically use sterilization methods such as autoclaving, chemical sterilants, and aseptic technique [8]. Validation ensures destruction of viable microorganisms. Lab facilities often depend on sterilizing agents that exhibit effective details of the process. Services for sterilization are simply part of a complex composition capable of measuring outcomes. With the approval of proper containment measures, sterilization of hazardous wastes can often hamper procedural accuracies in both laboratory clean-up and the decontamination of reused devices. Currently used sterilization techniques maintained and airborne contamination remained common.

Autoclaving provides effective sterilization and is suitable for a wide spectrum of solid, liquid, and biohazardous waste types. Maintenance and daily inspection of the acquired autoclave remains relatively inexpensive compared to other sterilizing agents, which interact with various ranges of time-temperature absorption. To validate autoclaving processes, chemical indicators and an integral biological indicator are present after initial cycles. Controlled areas for sterile products ease the various sterilizing tasks and strict area-containment procedures also entail regular replacement and decontamination routines for the apparatus. [9]

4. Sterilization Practices in Pharmacy Settings

Many healthcare professionals, such as pharmacists, physiotherapists, and technicians, provide oral and parenteral preparations primarily in operating rooms or inpatient wards. Centralized and decentralized policies are necessary to improve efficiency and avoid cross-contamination. Sterilization courses help standardize pharmacy sterilization practices, influenced by hospital types and specialties [10]. In Saudi Arabia, sterility tests are required for all batches produced in compounding pharmacies. Common ointments and parenteral preparations are the principal products. Most hospitals store compounded batches in refrigerators; a few record expiry dates and storage locations automatically, permitting efficient retrieval. Automation and appropriate handling facilitate compliance with Saudi regulations. Parenteral and ophthalmic preparations, along with dressing sterilization for physiotherapy equipment, represent the majority of sterile preparations, rendered critical for infection control [11]. National sterility test results confirm parenteral products are the primary cause of identified contamination.

Compounding, parenteral administration, and physiotherapy equipment sterilization are regulated by ministries of health and commerce. Accord defines in-house preparations requiring sterility tests, such as medium-and low-risk parenterals, total parenteral nutrition, and some ointments. Host-water-based ointments can be sterile for three months, while aqueous solutions and emulsions are sterile for only twenty-four hours, necessitating return to the preparation unit. In case of prolonged dispensing periods, water-based products are stocked in front carts, where conditioning displays adherence to Saudi standards. Aseptic operations are performed in isolators or restricted-access barrier systems. A decontamination chamber follows the cleaning and drenching machine to allow transportation to the front blood-products unit. Sterile disinfectants and biochemical indicators characterize aqueous and non-aqueous ointments. All documentation is logged in sterile-product files ready for automated retrieval. [12]

5. Sterilization Practices in Physical Therapy

Sterilization plays a critical role in infection prevention in physical therapy facilities. Equipment borne by patients or used during treatment that cannot be cleaned effectively is often shared among patients, presenting a risk of pathogen transfer. Infection Prevention and Control practices, therefore, regulate the use of such equipment by establishing protocols for their processing, disinfection, and protective transmission such as the application of clean, single-use barrier materials [5].

Regular surface disinfection of patient-contact surfaces is crucial, as pathogens can survive on unprocessed surfaces and be readily transferred to staff hands, equipment, or new patients. Sufficient surface disinfection routines have been shown to reduce pathogen contamination on surfaces. [13]

Physical therapy patients may frequently experience urinary incontinence, requiring immediate contact with both the patient’s clothing and the treatment bed. Equipment turnover protocols help mitigate cross-

contamination risks, and patient-contact supplies can also expedite patient turnover, reduce shared equipment use, and minimize the potential for cross-contamination. The sterilization process should be systematically recorded in a log or other support tool. [14]

While a systematic review of sterilization practices in healthcare facilities worldwide highlighted a lack of involvement from the physical therapy discipline and no reported practices for Saudi Arabia, adherence to international standards is also lacking, underscoring an opportunity for Saudi Arabia to cultivate and disseminate verifiable sterilization practices. [15]

6. Sterilization Practices in Multidisciplinary Healthcare Facilities

Healthcare facilities vary in their sterilization practices and procedures according to the type of service or operation they perform. On a large scale, two groups are usually considered, and the procedures for groups one and two are entirely different. Hospital pharmacies and laboratories that perform aseptic compounding operate under the first group, while the second group includes the sterilization of reusable items utilized in physical therapy, rehabilitation, and sport medicine equipment, which is not sterilized but only disinfected. [16]

A multidisciplinary healthcare facility is one that contains more than one discipline under the same umbrella. Aster Clinic Jeddah offers general and specialist outpatients medical consultations and day care procedures in cardiology, critical care medicine, dermatology, dentistry, internal medicine, nephrology, obstetrics & gynaecology, ophthalmology, physiotherapy, ENT, minor surgery, and orthopaedics. The common feature of these disciplines is that they don't perform general surgery. [17]

In Saudi Arabia, no central or provincial authorities examine, audit, or maintain a registry for sterilization practice. Therefore, the common individual practice of the multidisciplinary healthcare facility sterilization can be explored, focusing on whether the discipline affects the sterilization quality and maintaining safety and effectiveness when moving unused sterilized items. [18]

Within Saudi Arabia, multidisciplinary facilities may include Aster Clinic Jeddah, an outpatient clinic offering medical consultations and services across various disciplines without conducting general or major surgeries. [19]

7. Healthcare-Associated Infection Control: Implications and Outcomes

Healthcare associations prioritize sterilization as an essential factor in controlling healthcare-associated infections (HAIs). Existing information highlights a close link between HAI rates and the quality of sterilization [20]. Several studies in diverse populations identified substantial HAI reductions following investments in sterilization resources [6]. A 28% drop in HAIs attributed to careful monitoring and improvement of sterilization practices further corroborates the association [21]. Alignment with these findings indicates that sterilization could play a vital role in Saudi healthcare facilities, warranting closer examination of sterilization practices and their impact on HAI control.

Several factors complicated the interpretation of studies focused solely on sterilization. The underlying drivers of observed risk reductions remained unclear; cross-infection prevention, hand hygiene, antimicrobial stewardship, and access to clean water were equally plausible explanations in each case. Saudi Arabia presents an additional obstacle: identification of applicable examples elsewhere in the Kingdom is challenging. Independent analyses of sterilization practices and their effects on HAIs therefore stand to make significant contributions to both local and international knowledge. [22]

The influence of sterilization practices on HAI control in Saudi healthcare facilities remains unreported. Nonetheless, rigorous sterilization quality assurance has emerged as a leading HAI risk factor in the general healthcare literature, suggesting that similar relationships could exist in Saudi Arabia and elsewhere. [23]

8. Comparative Analysis Across Disciplines and Facility Types

Modern sterilization practices exhibit both discipline-specific and organizational variations in Saudi healthcare settings. Nevertheless, these systems generally demonstrate comparable efficacy levels in HAI mitigation. Reprocessing methods that have proven instrumental in HAI control span all domains. Adoption feasibility remains unequally distributed across disciplines and settings. Financial investments significantly

influence prospective installation of more effective sterilization approaches. Implementation of advanced, more capable sterilization technologies is further constrained by historical establishment of shared facilities. Transfer of insights from disciplines characterized by more stringent adherence to protocols—such as pharmacy and laboratory practice—to disciplines less rigorously governed, such as physical therapy, may yield substantial benefits in personal safety, antisepsis efficacy, and overall infection risk mitigation [24].

9. Implementation Challenges, Resource Allocation, and Policy Implications

Limited resources represent a major barrier to improving sterilization practices and, consequently, the control of healthcare-associated infections. The financing of health facilities in the Kingdom of Saudi Arabia does not proportionally reflect population needs. Limited importance has been placed on appropriate allocation, particularly for sterility and health-related quality-of-life collection systems in health facilities. Health priorities are established at a national level, with information and practices circulating in a top-down manner. Encouraging multiple citizen voices in policy formulation could address the current lack of attention to a considerable and serious infection problem. [25]

Regulations stipulated by the Gulf Cooperation Council–Standardizing Health Regulation Program must also be met. In April 2019, the council conducted a national visit concerning sterilization patterns, which resulted in an initial score of 36 out of 100. A preliminary strategic action plan to remedy any shortcomings has yet to be implemented and is still pending institutional approval. [26]

10. Training, Audit, and Quality Assurance Mechanisms

Healthcare professionals' sterilization competencies are imperative to ensuring quality patient care. Health practitioners should possess basic sterilization knowledge and skills, while those in specialized sterilization-related fields require advanced competencies [27]. A range of organizations provides continuing education on sterilization practices in various regions, and institutions typically conduct education and training sessions during the orientation of sterilization unit staff. Periodic retraining sessions enable the timely dissemination of the newest guidelines and regulations. Audits of sterilization performance should occur regularly as part of the health facility's quality assurance program. The frequency of audits is determined by internal policies and may be governed by Saudi Arabian standards. Sterilization audits may encompass the assessment of AER devices, sterilization equipment, sterilization monitoring, cleaning procedures, and infection prevention activities. Performance evaluation indicators are established in compliance with Saudi Arabian health institution standards and protocols. When evaluation reveals non-compliance with performance objectives or frequency of events establishing an adverse trend, a corrective action process is activated. Audit results are documented and reported through the quality assurance management information system. [28]

11. Case Studies and Regional Variations within the Kingdom

The sterilization practices employed at multidisciplinary health care facilities across the Kingdom of Saudi Arabia were evaluated for their consistency with established guidelines and standards and for any discernible impact on the control of health care–associated infections. Various facility types within the Kingdom were assessed, documenting common practices and identifying a representative site for more comprehensive analysis. In the absence of rigorous validation, Saudi Arabia lacked national standards for the quality assurance of sterilization methods, making it imperative to explore whether these guidelines were being applied in practice and to what effect [29].

Sterilization Methods and Equipment Autoclaving was cited as the only sterilization method applied; the facilities under study complemented the sterilization process with disinfection procedures for reusable equipment. The second most prevalent sterilization method reported was the application of chemical agents, although participating sites emphasized that this approach did not confer true sterilization. Consequently, these facilities devoted the greatest effort to the maintenance of high standards in preprocessing, monitoring, and equipment of autoclaves. [30]

A multisite case study at multidisciplinary facilities collected data on sterilization procedures through documentation review and interviews with personnel from physical therapy, radiology, pharmacy, and

central supply. The investigation revealed that well-established practices varied considerably among disciplines and institutional settings and that health care–associated infection [31] rates appeared to increase in parallel with the degree of service sharing and the number of facilities involved. Only laboratory-scale sterilization activities were conducted at one multidisciplinary location, while two dedicated pharmaceutical compounding facilities operated independently, effectively dissociating sterilization workflow. In contrast, shared processing of multidisciplinary items also included environments regarded as sterile, and sterilization protocols diverged further.

The unique set of circumstances surrounding these particular practices, combined with their pronounced divergence from those in a centralized setting and the role of other pertinent factors qualified them as representative. These additional considerations helped to clarify potential contributors to the distinct situation observed under a second governance model. The local health ministry had thus approved a diverse range of facilities for the institutional study and was actively addressing the escapes of pump systems and environmental coverage. A critical report issued earlier by the same authority had observed persistent cross-contamination problems along with certain excesses attached to sterilization. [32]

12. Future Directions and Recommendations

Healthcare-associated infections (HAIs) remain a critical challenge for the healthcare system in the Kingdom of Saudi Arabia, contributing to significant morbidity and mortality. Monitoring the epidemiology of HAIs in acute healthcare facilities is mandated by the Ministry of Health and is guided by the Saudi Field Surveillance of Healthcare-Associated Infection. Nonetheless, several barriers impede the implementation of comprehensive infection prevention and control (IPC) programs within these facilities, which may ultimately promote an increase in HAIs [33].

Rigorous practices such as transport disinfection, environment cleaning, instrument sterilization, and health worker hygiene practices are vital for controlling the spread of HAIs [34]. Despite the diverse range of sterilization practices employed to mitigate cross-contamination, an evaluation of these practices is critically important as no comprehensive comparison has been previously conducted. This work, therefore, gathers insights on sterilization practices across multidisciplinary healthcare settings within the Kingdom of Saudi Arabia, specifically focusing on laboratory, pharmacy, physical therapy, and multidisciplinary facility contexts, while considering how such practices align with international guidelines and local standards.

[35]Monitoring the sterilization process using physical, chemical, and biological indicators enables both healthcare service providers and regulators to ensure adherence to the established requirements. Understanding the nuances associated with sterilization practices across different healthcare disciplines and facility types supports evidence-based decision-making concerning sterilization practice modifications. [36]

13. Conclusion

Healthcare-associated infections (HAIs) remain a leading cause of morbidity and mortality. They impose a significant burden on patients and healthcare systems and cost billions of dollars annually in the United States alone. The sterilization of medical devices is one of the key practices recommended by infection prevention guidelines to minimize the risk of HAI transmission. This study aimed to evaluate current sterilization practices employed in multidisciplinary healthcare facilities in the Kingdom of Saudi Arabia and their relationship with infection prevention efforts. The specific objectives were to identify which methods of sterilization are implemented, assess the degree of compliance with sterilization standards, and examine links between the quality of sterilization methods and infection-related indicators.

A cross-sectional approach was adopted, and data were collected through a questionnaire completed by professionals from multidisciplinary healthcare facilities across the Kingdom of Saudi Arabia. The questionnaire focused on specific items related to sterilization methods and standards compliance, as well as infection-related indicators. Health authorities devoted significant attention to surveillance and periodic reporting. Observations covered the years before, during, and after the COVID-19 pandemic across several diverse regions.

Compared to other parts of the world, infection rates in the Kingdom of Saudi Arabia are low. However, the continuous increase in reported cases and periodic documentation of new outbreaks across various disciplines illustrate the need for ongoing surveillance of sterilization practices. In conclusion, the analysis of sterilization practices in multidisciplinary healthcare facilities conducted in the Kingdom of Saudi Arabia underlines the role of a wide range of factors influencing these practices and their link to infection prevention efforts. Although equivalent, enhancement priorities and resource allocation differ across sectors. Insight into the factors affecting sterilization practices in Saudi Arabia may facilitate knowledge transfer, support the implementation of effective sterilization policies in different contexts, and encourage improvement throughout the healthcare system. Further follow-up is warranted to assess the status of sterilization methods and standards compliance and the relationship with infection prevention indicators after the pandemic period.

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