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Update on pharmacist role in sterile compounding in hospital

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Abstract

Background: Sterile compounding, a critical aspect of pharmaceutical practice, involves the preparation of customized medications in a sterile environment. Pharmacists play a pivotal role in ensuring the safety and efficacy of compounded sterile products (CSPs), making their involvement integral to the healthcare system.

Objective: This article aims to describe the role of pharmacists in sterile compounding based on literature.

Method: Articles from Medline/PubMed, guidelines, reports, and databases related to sterile compounding have been searched and compiled. This review collected the qualitative data and identified the critical point for continuous quality improvement initiatives in sterile compounding.

Results: This comprehensive narrative review explores the multifaceted responsibilities of pharmacists in sterile compounding, drawing insights from various studies and databases. However, the study related to the pharmacist's role in sterile compounding practices is very limited. Recent articles that mention the pharmacist's role in sterile compounding commonly come from the guidelines or government documents. In general, CSP needs a commitment to comply with regulatory standards for achieving patient safety using the integration of technology and healthcare collaboration. Continuous professional development is a crucial contributor to keeping the quality of compounded sterile products.

Conclusion: The findings from various journals underscore the complexity of their responsibilities and emphasize the need for a holistic approach to ensure the integrity and safety of compounded sterile products in diverse healthcare settings.

Keywords: Pharmacist's role, patient safety, sterile compounding

1. Introduction

Sterile compounding is a specialized area within pharmaceutical practice that involves the preparation of customized medications in a sterile or aseptic environment to achieve free from any contaminations (USP, 2023). This process is crucial for patients who require medications that are not commercially available or need specific formulations tailored to the individual needs, such as intravenous admixture and parenteral nutrition (Hanifah *et al*., 2021). Compounded sterile products (CSPs) are typically injectable medications, intravenous solutions, or other sterile dosage forms which are under pharmacist's responsibility that should be (USP, 2023).

Pharmacists play a pivotal role in ensuring the safety and efficacy of medications, making their involvement integral to the healthcare system (Saseen *et al*., 2017). The pharmacist is the bridge between a physician/surgeon and patients who counsel and advise the

patient to maximize the desired effect of the drugs and minimize the untoward/adverse effects of the drug (Minor *et al*., 2019). In many types of health facilities, a pharmacist or drug expert is an individual who is engaged in designing, creating or manufacturing of a drug product, dispensing of a drug, managing, and planning of a pharmaceutical care plan also making sure the administration (Abdelaziz *et al*., 2016). They are experts in the activity and use of drugs, including their chemistry, pharmacology, and the formulation of medicines. They are the health care professionals who have the responsibility to give essential consideration to the patients and giving protection and providing safe and effective use of medicines (Islam *et al*., 2015). Pharmaceutical care is a comprehensive and patient-cantered approach in pharmacy practice that emphasizes collaboration among healthcare providers to optimize drug therapy outcomes (Tran *et al*., 2017). The concept has evolved since its initial definition by Hepler and Strand in 1990, which stated that pharmaceutical care is "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Helgesen *et al*., 2024). This definition highlights the pharmacist's role in ensuring safe and effective medication use while being accountable for patient outcomes. Therefore, pharmaceutical care represents a critical component of modern healthcare, where pharmacists actively engage in the therapeutic process alongside other healthcare providers to ensure safe, effective, and personalized medication management for patients.

However, sterile compounding is currently a new role in hospital compared to the non-sterile preparation. Health care facilities have applied various sterile medication to be prepared in hospital. Furthermore, the facilities also have a variety in function and complexity which determine different role of pharmacist. This review wants to know the pharmacist' roles and how they work in sterile dispensing unit based on regulation also the real work in hospital. This comprehensive narrative review explores the multifaceted responsibilities of pharmacists in sterile compounding, drawing insights from various journals and studies.

2. Method

The literature search was conducted using databases such as Google Scholar, PubMed, and Elsevier, which are published during 2016 to 2023. The keywords applied during the topic search process from relevant articles were "pharmacist", "role", and "sterile compounding". The studies were identified then categorized to answer the topics of regulation and the reason of sterile preparation also the works of pharmacist and the supporting factor to improve. Then,

the results of manual review were categorized as regulatory (13 studies) also pharmacist's role (20 studies). Supporting factors that were identified are including the technological advancement and interprofessional collaboration (33 studies).

3. Result and discussion

Pharmacists have experienced a very rapid shift in roles since the 1960s (Hanifah *et al.*, 2022). In terms of compounding, the role of pharmacists is very critical because there is no other profession that can competently replace it (Myers, 2013). Sterile compounding activities are clearly stated as part of pharmaceutical work in hospitals (Kemenkes RI, 2016). Pharmacists play a role starting from ensuring the quality of preparations, prescription screening, aseptic preparation, to ensuring the final quality of the product before being given to medical personnel and patients. In carrying out this role, pharmacists need to continue to update themselves with developments in knowledge, regulatory changes, and technological developments, as well as building a collaborative work culture with other health workers.

Based on the search strategy, research or writings on the role of pharmacists in sterile compounding are very limited. In fact, no articles can be obtained from a Google Scholar search using the keyword "pharmacist role in sterile compounding". New search process can be obtained with the keywords sterile compounding in hospital pharmacy. Writings that describe the role of pharmacists in sterile compounding are generally in popular or opinion articles. Meanwhile, writings on sterile compounding are mostly obtained from guidelines or articles which linked with technological developments, the importance of collaboration and continuous improvement.

3.1. Regulatory compliance and standards

One of the primary responsibilities of pharmacists in sterile compounding is ensuring strict adherence to regulatory standards. According to Smith *et al.* (2019), pharmacists must navigate and implement guidelines established by organizations such as the United States Pharmacopeia (USP), European Association Hospital Pharmacy (EAHP) and Institute for Safe Medication Practice (ISMP). Currently, USP 797 is a gold standard which is referred to by many countries for sterile compounding. As seen on **Table 1**, EAHP guide as how pharmacist engaged in sterile compounding, but USP 797 guides the detail standard of personnel, room and facilities, the procedure also the category of compounding sterile preparation which will be

basis of beyond used date (USP, 2023). Currently, the standard of BUD (beyond use date) is mostly referred to as USP. Compliance with these standards involves meticulous attention to detail, rigorous aseptic techniques, and continuous monitoring of environmental conditions to maintain the integrity of CSPs. Other guidelines like EAHP and ISMP address the general principles of safety and supporting system including the staff. From three guidelines emphasize the safety which are mostly influenced with the staffs mainly pharmacist (EAHP, 2023).

Table 1. The scope of standards for guiding sterile preparation

United State Pharmacopeia (USP) 797 last updated 2023	**European Association Hospital Pharmacy (EAHP) 2023**	**ISMP guidelines for sterile compounding and the safe use of sterile compounding technology last updated 2016**
Personal	The importance of compounding for addressing patient needs	Essential technology attributes
Facility	Engaging hospital pharmacists in the provision of personalized medication	Safe pharmacy processes
Category of CSP	Adjusting education and training to the increased need for personalised care	Safety gaps in three areas: automated compounding devices, IV workflow management systems, and IV robots.
Beyond use date	The involvement of hospital pharmacies in reconstitution practices	
Preparing, repackaging, labelling	The role of hospital pharmacists in the preparation and use of ATPMs	

3.2. Pharmacist' role in sterile compounding

To ensure the safety and efficacy of compounded sterile medication, pharmacist have to follow the guidance (Lam & Sokn, 2019). Pharmacists must adhere to strict regulations and guidelines set forth by regulatory bodies and other international standards. Compliance with these standards is critical to maintaining the quality and safety of compounded sterile products. Pharmacists play a key role in identifying and mitigating potential risks associated with sterile compounding. This includes assessing the risk of microbial contamination, human errors, and other factors that could compromise the integrity of compounded products (Whyte, 2004).

Pharmaceutical compounding is a critical aspect of pharmacy practice, involving the preparation of customized medications that requires a blend of scientific knowledge, technical skill, and regulatory compliance. Compounding pharmacists ensure that medications are tailored precisely to meet individual patient needs while adhering to stringent quality standards. This process typically includes combining, mixing, or altering drug ingredients to create formulations that are not commercially available or to modify existing medications to better suit patient requirements (Croft *et al*., 2018).

During preparation, all personnel must follow established protocols for aseptic technique, which involves maintaining a sterile environment to prevent contamination during the compounding process. Pharmacists are involved in quality assurance measures to guarantee the compatibility, stability and sterility of compounded products (Hanifah *et al*., 2022). This may include regular testing of air quality, equipment, and finished products to detect and prevent microbial contamination (Qadus *et al*., 2022). They must adhere to strict aseptic techniques to prevent microbial contamination during the compounding process (Ayalew *et al*., 2019). This includes maintaining a sterile environment, using appropriate personal protective equipment, and employing proper hand hygiene practices. Recent literature highlights the pharmacist's pivotal role in ensuring the quality and safety of compounded sterile preparations (CSPs). A study by Truong *et al.* (2020) emphasizes the need for continuous training and education for pharmacists engaged in sterile compounding to enhance their competencies and minimize the risk of errors. Furthermore, the pharmacist's role extends to regular monitoring and testing of compounded products. Frequent quality control assessments, including microbial testing and potency checks, are essential to guarantee the integrity of sterile medications.

Quality control in hospital compounding pharmacies is essential to ensure the safety and effectiveness of compounded medications (**Figure 1**). By employing thorough visual inspection methods and adhering to comprehensive QA protocols, pharmacists can ensure that compounded medications are safe and effective for patient use post-preparation. Any particles, discoloration, gas formation, or other visible changes indicate disqualification. Pharmacists should reject this product and evaluate to improve the quality.

To achieve patient safety in sterile compounding, pharmacists also significantly contribute to keep each step and aspect (Dalton & Byrne, 2017). According to a comprehensive review by Brown and White (2021), pharmacists play a crucial role in the entire process, from prescription assessment to the final administration of CSPs. They are responsible for conducting risk assessments, identifying potential sources of contamination, and implementing strategies to mitigate these risks. Ultimately, pharmacists are advocates for patient safety. They ensure that compounded medications meet the highest standards of quality and are free from contaminants, helping to prevent adverse effects and ensure positive patient outcomes (Aprilliano *et al*., 2023).

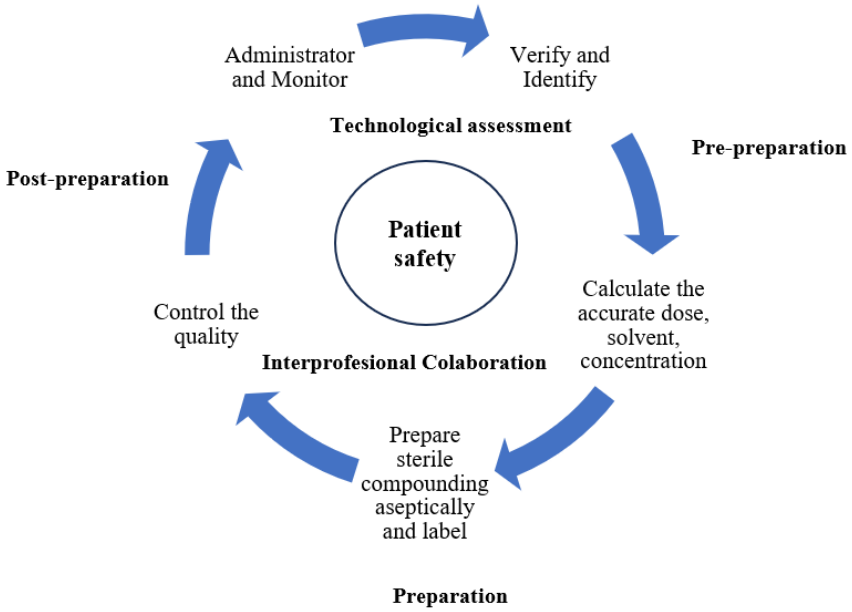

Figure 1. Pharmacist's role in sterile compounding

Moreover, pharmacists collaborate with other healthcare professionals to ensure that compounded products meet the unique needs of individual patients while aligning with therapeutic goals (Brown & White, 2021). This collaborative approach enhances patient safety by incorporating diverse perspectives and expertise, emphasizing the pharmacist's role as an essential member of the healthcare team. Pharmacists also collaborate with other healthcare professionals to ensure seamless integration of compounded medications into patient care plans (Alhamoudi & Alnattah, 2018).

To improve and meet high qualification as above, pharmacists are tasked with training and educating compounding personnel, including pharmacy technicians, on proper sterile compounding techniques. Continuous education is crucial to staying updated on best practices and emerging technologies in the field (Mill *et al*., 2021). Pharmacists are also responsible for maintaining thorough documentation of the compounding process, including ingredient measurements, environmental monitoring data, and quality control results. Accurate record-keeping is essential for traceability and accountability (Lee *et al*., 2023). Furthermore, Johnson and Davis (2020) emphasize the pharmacist's role in minimizing the risk of contamination during compounding processes. Pharmacists are instrumental in selecting sterile ingredients, ensuring proper storage, and employing appropriate administration techniques. This commitment to compliance not only meets regulatory requirements but also safeguards patients from potential harm and highlights the pharmacist's dedication to patient safety.

3.3. Technological advancements in sterile compounding

The landscape of sterile compounding has been significantly influenced by technological advancements. Lee and Chen (2018) highlight the use of automated compounding systems and robotics in their review, emphasizing how pharmacists embrace these innovations to improve precision and reduce the likelihood of errors. Automation not only enhances the efficiency of the compounding process but also contributes to increased accuracy in dosage calculations and product preparation (Fan *et al*., 2022). Furthermore, Fan found that technology-assisted workflow system (TAWS) in sterile compounding safety able to increase the ability to check, trace, and detect the errors also increase efficiency by reducing processing time (Fan *et al*., 2022). Automation of compounding tools proved the benefits of sterile preparation by reducing errors and processing time. Beyond the instrument for preparing, technological advancement for sterilization, sterilization control, and supporting tools like laminar air flow, personal protective equipment (PPE) is also significant to achieve patient safety.

To adapt with the advancement of technology, pharmacists, through ongoing training and education, integrate technology seamlessly into their compounding practices. This adaptability reflects their commitment to staying abreast of new developments, ensuring that patients receive CSPs prepared with the latest technological advancements, ultimately contributing to improved patient outcomes (Jean *et al*., 2020).

3.4. Interdisciplinary collaboration

Effective communication and collaboration among healthcare professionals are essential for successful sterile compounding. Brown and White (2021) underscore the pharmacist's role in interdisciplinary teamwork, emphasizing the importance of open communication with physicians, nurses, and other healthcare providers. This collaboration ensures that the entire healthcare team is aligned in providing safe and effective CSPs to patients. This study emphasizes the pharmacist's role within an interdisciplinary healthcare team. Interdisciplinary teamwork involves collaboration between professionals from different healthcare disciplines, such as pharmacists, physicians, nurses, and other specialists (Agomo *et al*., 2016). Effective communication is crucial for the success of sterile compounding. Open lines of communication between pharmacists and other healthcare providers ensure that everyone

involved in the patient's care is well-informed about the compounded sterile products (CSPs) being used (Mustikawati *et al*., 2023).

In their study, Garcia and Patel (2019) further elaborate on the necessity of interdisciplinary collaboration, emphasizing how pharmacists bring their unique expertise to the table. This collaboration extends beyond the compounding process, involving consultations with other healthcare professionals to tailor CSPs according to specific patient needs, medical histories, and treatment plans. This study highlights that pharmacists bring unique expertise to the interdisciplinary team. Pharmacists play a pivotal role in sterile compounding beyond the actual preparation of medications (Abdulghani *et al*., 2017). Pharmacists use their pharmaceutical knowledge to consult with other healthcare professionals, including physicians and nurses, to customize compounded medications according to specific patient needs. This involves considering individual patient characteristics, medical histories, and treatment plans (Kim *et al*., 2023).

The collaboration between healthcare professionals extends beyond the sterile compounding process. It involves ongoing consultations and discussions throughout the patient's treatment journey. The emphasis is on tailoring CSPs to meet the unique requirements of each patient. This patient-cantered approach ensures that medications are not only sterile and of high quality but also aligned with the individual patient's therapeutic needs (Jeyaraman *et al*., 2023).

3.5. Continuous professional development

The dynamic nature of pharmaceutical sciences requires pharmacists to engage in continuous professional development. Garcia and Patel (2019) emphasize the importance of ongoing education for pharmacists involved in sterile compounding. This involves staying abreast of new guidelines, technologies, and best practices, ensuring that pharmacists remain competent and capable of adapting to evolving standards.

Continuing education also plays a crucial role in addressing emerging challenges in sterile compounding. As highlighted by Garcia and Patel (2019), pharmacists who prioritize continuous learning are better equipped to navigate changes in regulations, incorporate new technologies, and implement best practices, ultimately contributing to the ongoing improvement of the sterile compounding process.

4. Conclusion

In conclusion, the pharmacist's role in sterile compounding is multifaceted and indispensable. Their commitment to regulatory compliance, patient safety, integration of technology, interdisciplinary collaboration, and continuous professional development collectively positions pharmacists as crucial contributors to the quality and safety of compounded sterile products. As the field continues to evolve, ongoing research, education, and collaboration are imperative to optimize the pharmacist's role in sterile compounding. The findings from various journals underscore the complexity of their responsibilities and emphasize the need for a holistic approach to ensure the integrity and safety of compounded sterile products in diverse healthcare settings.

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