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Review of Medication Safety Protocols in Hospital Pharmacies: Evaluating Pharmacists' Roles and Best Practices in the Management of Advanced Therapy Medicinal Products

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Abstract

Background: The implementation of medication safety protocols in hospital pharmacies is critical to ensuring patient safety and minimizing the risk of medication errors. As healthcare systems increasingly adopt advanced therapies, the role of pharmacists in managing these medications becomes essential.

Methods: This review examines the best practices in medication safety protocols within hospital pharmacies, focusing on the contributions of pharmacists in the context of advanced therapy medicinal products (ATMPs). A systematic literature search was conducted across multiple databases, including PubMed, Scopus, and Web of Science, for studies published from 2013 to 2023. The analysis synthesized data on pharmacists' roles, interventions, and the impact of safety protocols on patient outcomes.

Results: The findings indicate that effective medication safety protocols, including thorough medication reconciliation, patient education, and active involvement in multidisciplinary teams, significantly enhance the management of ATMPs. Pharmacists demonstrated a pivotal role in monitoring medication use, addressing drug-related problems, and ensuring adherence to safety guidelines. The review highlighted a notable improvement in patient satisfaction and clinical outcomes associated with pharmacist-led interventions.

Conclusion: The study underscores the importance of robust medication safety protocols in hospital pharmacies for the safe administration of advanced therapies. The active participation of pharmacists not only improves medication management but also enhances overall patient care quality. Future research should focus on evaluating the long-term impact of these protocols on patient safety and healthcare outcomes.

Keywords: Medication safety, hospital pharmacy, advanced therapy medicinal products, pharmacist interventions, patient outcomes.

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1. Introduction

Innovative treatments involving gene and cell therapy (CGT) have transformative prospects for addressing illnesses and injuries via the use of changed nucleic acids, altered cells, or a combination of both [1]. The European Union (EU) designates these treatments as advanced therapy medical products (ATMPs) and classifies them into four categories: gene treatment medicines, somatic-cell treatment medicines, tissue-engineered medicines, and combination ATMPs [2]. The phrases "CGT," "ATMPs," and "regenerative medicines" are often used synonymously. The definitions and sub-classifications established by the United States and the European Union exhibit regulatory disparities between the two systems [3, 4]. CGT/ATMPs provide significant potential to alter the trajectory of impairment linked to several illnesses, including dementia, Parkinson's illness, cancer, and muscular dystrophy. These treatments have the potential to cure or reverse illnesses that are now untreatable or merely amenable to symptomatic management [5, 6]. Chimeric antigen receptor (CAR) T-cell therapy has demonstrated exceptional efficacy in the treatment of hematologic malignancies, and its advancements, in conjunction with other therapeutic modalities, have created significant opportunities for enhanced cancer therapies [7].

Nonetheless, the therapeutic use of CGT/ATMPs encounters particular obstacles owing to the intricate nature of these medicinal agents and the scarcity of clinical evidence [8]. The challenges encompass the necessity for procurement proficiency, cohesive logistics solutions, qualified personnel, completely traceable supply networks, focused on-site thawing and freezing apparatus and knowledge, information systems for prolonged patient monitoring, and optimized health financial and purchasing frameworks [9]. The effective clinical implementation of CGT/ATMPs significantly relies on the medical team's proficiency in delivering these services [10]. The effective and secure use of the intricate biological processes of CGT/ATMPs necessitates cooperation among a diverse medical team in a clinical environment, particularly in the dearth of substantial expertise.

Pharmacists are essential members of the hospital healthcare team, significantly contributing to the effective management of various diseases, including cancer, genetic disorders, autoimmune disorders, and rare diseases, which are prevalent treatment areas for patients undergoing CGT/ATMPs [11-15]. The fast rise in registered clinical studies and market-authorized goods globally is leading to a more prevalent acceptance of ATMPs for the alleviation or treatment of disorders in clinical practice [16, 17]. Marzal et al. [18] highlighted the essential function of pharmacists in guaranteeing the safe and effective utilization of CAR T-cell therapies, including medication manufacture, shipping and storage management, as well as participation in patient assessment, education, pharmacovigilance, and monitoring. The function of hospital pharmacists in the administration of CGT/ATMPs is increasingly acknowledged [18-20], however the data on this and its effect on patient results has not been comprehensively documented. This research aimed to collect empirical data about pharmacist interventions for patients receiving CGT/ATMPs and to synthesize perspectives and opinions on pharmacists' roles in ensuring the proper and safe use of CGT/ATMPs.

2. Search methodology

A search was performed across four different databases (Scopus, PubMed, Science Direct, and Web of Science) for peer-reviewed literature published from 2013 to 2023 that illustrate the role of hospital pharmacists in managing modern advanced treatments and ATMPs.

3. Interventions by hospital pharmacists for patients undergoing CGT/ATMPs

The predominant interventions by hospital pharmacists for patients receiving HSCT were on medication delivery [21-30], prescription [23-30], and monitoring of medication use [26-30]. In these eight investigations, guidance and instruction were the predominant pharmacist services associated with

medication delivery. Pharmacists not only offered pharmaceutical and transplant instruction [24-30] but also provided medication counseling throughout patient admission and discharge [25-30] and actively delivered pharmacy guidance and instruction to other healthcare professionals [24-30].

The pharmaceutical treatment management process conducted by pharmacists included many implementation aspects, including the development of dosage management aids, compliance aids, individualized medication intake schedules, and standard dosing protocols [23, 26-28]. In addition to administration, they conducted reconciliation of medicines and recognized and addressed drug-related problems (DRPs) to enhance the use of each prescription medicine [24, 26-30]. Furthermore, pharmacists assessed and confirmed the prescriptions based on the intricate mix of drugs used by HSCT sufferers [23, 26, 27, 30].

As a part of the clinical team, the pharmacist cooperated with other healthcare practitioners to modify the prescriptions [30]. Pharmacists also engaged in the oversight of immunosuppressive therapeutic drugs, which delineated appropriate dose adjustments based on trough stages, organ activity, medication interactions, and toxicities [28]. Andrick et al. documented pharmacist interventions including the monitoring of post-transplant vaccination adherence, graft-versus-host illnesses and infections monitoring, as well as outpatient follow-up to enhance drug safety [29].

The interventions identified in the included studies are enumerated by speed: therapeutic drug tracking, decreased dose, patient awareness, immunosuppression administration, drug elimination, drug history examination, and graft-versus-host monitoring of diseases [23, 26, 29, 30]. Certain studies documented the identified Drug-Related Problems (DRPs) during treatments, mostly with safety and efficacy concerns [29, 30]. Responses indicating significant patient satisfaction were regarded as a key humanistic goal [24, 25, 29]. Zanetti et al. [30] showed a significant increase in patients' awareness and adherence. Furthermore, Alexander et al. [25] documented the favorable economic results of pharmacists in the management of bone as well as marrow transplant recipients, involving heightened discharge prescription income and reductions in pharmacist activity hours.

4. Essential functions of hospital pharmacists in CGT/ATMPs

The essential functions of hospital pharmacies in facilitating the efficient and secure utilization of CGT/ATMPs, as delineated in the 26 included studies, were summarized. This includes all six responsibility domains specified in the Basel Declaration. The literature on the role of hospital pharmacists in the management of CGT/ATMPs reveals essential components of interventions, including purchasing, impacts on recommending, preparation and distribution, administration, monitoring of medication use, human resources, training, and development, as well as additional measures beyond the Basel Declaration [31-56]. Thirteen studies documented the involvement of pharmacists in medical examination and validation of complicated advanced treatments and medical goods, including medication history assessment and concomitant therapy evaluation [32, 33, 36-40, 42, 44, 52-56]. Hospital pharmacists engaged in the pretransplant evaluation and validation of conditional regimens for patients undergoing HSCT, managed chemotherapy protocols and anti-infective treatments and identified and resolved drug-related problems (DRPs) throughout the transplant procedures [33, 37-42].

In the formulation administration for CAR T-cell treatments, pharmacists prioritize the incorporation of drugs for toxicity control (e.g., tocilizumab and siltuximab) and pursue approval of products for prescription additions. Hospital pharmacists, as members of a medical multidisciplinary team, were advised to interact with other healthcare practitioners to enhance the quality of prescription [32, 33, 40-43, 48, 56]. Four studies indicated that hospital pharmacists facilitated medication reconciliation to oversee regimen modifications at both the hospital and at home, including instances of remote oversight [36, 42, 43, 52].

In 14 of the included studies, the pharmacists' intervention encompassed preparing and distribution processes, getting it, control, storage, and reconstitution of particular biological products or cytotoxic drugs, along with the preparation of dedicated premises and equipment. The majority of pharmacy practice

concerning medication administration discussed in this analysis was teaching and counseling directed at patients, caregivers, and other healthcare professionals [33, 35-40, 42-44, 47, 50, 55]. This primarily aimed to provide information on dose administration and instructions, treatment of side effects, major problems, and the pharmaceutical plan for admission and release.

Pharmacists additionally provided diverse medication management (MTM) services or performed MTM quality monitoring for patients to ensure the implementation and maintenance of superior pharmaceutical care. Documentation of physician orders and the use of the computerized order submission system by pharmacists were referenced in the seven-research considered [40, 42, 43, 48, 50, 53, 55]. Furthermore, pharmacists are committed to enhancing the quality and procedures of administration, including the assessment of medication adherence, the development of a pharmacist rotation model, and the establishment of research biosafety boards [36, 40, 43, 47, 48, 50, 51, 52].

Pharmacists documented patients' pertinent responses to therapeutic drug management (TDM), negative drug reactions, pharmacy rounds, and subsequent visits for purposes of monitoring [33, 35-40, 42, 44, 51-56]. The pharmacist implemented various tracking measures for HSCT patients to enhance care quality, including maximizing GvHD administration, facilitating post-transplant vaccinations, managing immunosuppressants or antibiotics, and monitoring the pharmacokinetics of renal and hepatic functions [33, 35, 37-39, 43, 44]. Pharmacists focused on monitoring and documenting cytokines release syndrome (CRS) and CAR T-cell-related encephalopathy sickness (CRES) while using CAR T-cell products [51, 52, 55, 56].

The involvement of pharmacists in the administration of CGT/ATMPs is intrinsically linked to the enhancement of their knowledge and abilities, mostly centered on staff training, staff recruitment, and core team development [31-33,35,37-40,42,45,46,48-56]. The training programs encompassed disease education, management of Advanced Therapy Medicinal Products (ATMPs), implementation and research (such as vehicle delivery, drugs compounding, quality assurance, legal framework, pharmacovigilance, biosafety, or risk evaluation), biological safety handling and shipping education, and measures training [31, 35, 45, 46, 50-53, 56]. Additionally, 13 studies [33, 35, 37-40, 42, 44, 47, 50, 53, 55, 56] indicated that pharmacists played a significant role in the formulation and execution of pertinent standards and operational standards (SOP), encompassing patient assistance programs, HSCT and supportive care directives, consensus guidelines and protocols, facility policies, and preparation and administration protocols [33, 37-40, 42, 47, 50, 53].

Regarding interventions outside the duty domains outlined in the Basel statement, five studies referenced the roles and competencies of hospital pharmacists as articulated in the HCT Clinical Pharmacist Role Description declaration established by ASBMT Pharmacy SIG, along with consensus recommendations pertaining to HSCT from the EBMT clinical pharmacists and clinical trials pharmacologist (CP/P) [33, 37-40]. Cooperative practice arrangements (CPA) were used to regulate pharmacists' interventions in therapeutic drug monitoring (TDM) among clinical pharmacy technicians and cooperating doctors [33, 34, 38, 39]. Financial interventions were also evaluated, including pharmacoeconomic analyses, pharmacy leadership participation in health system-level payer relations conversations, and the practices of product reimbursement and financial investigation processes [40, 48, 54-56].

5. Discussion

This review delineated the essential functions of hospital pharmacists in administering therapies for CGT/ATMPs and highlighted evidence of favorable results for patients receiving HSCT therapy. While empirical research on the involvement of hospital pharmacists in the management of ATMPs is insufficient, valuable insights might be obtained from their functions in HSCT. This research offers a detailed framework for interventions by hospital pharmacists on novel pharmaceutical items and complicated therapy, highlighting their essential role as vital members of the healthcare team. Pharmacists are progressively engaged in the application of revolutionary advanced medicines, and their function is receiving heightened acknowledgment from many stakeholders and professional organizations. The significance of pharmacological treatment in the realm of CGT/ATMPs is progressively becoming evident, likely

influencing patients' clinical, economic, and humanistic results positively. Measures are required to guarantee the competence of hospital pharmacists in alignment with established practice standards, therefore enhancing and reinforcing their responsibilities.

Hospital pharmacists play a crucial role in facilitating the effective and safe use of CGT/ATMPs. The measures by hospital pharmacists for HSCT patients described in this analysis mostly included prescription, administration, and monitoring, with less focus on procurement, preparation, and training. Pharmacists' documented HSCT interventions have demonstrated advantages for patient care concerning healthcare outputs (e.g., medication discrepancies and drug-related problems, immunosuppression administration, medication therapy management), clinical outcomes (such as adherence to medicine, immunosuppressant medication serum levels), humanistic outcomes (e.g., patient satisfaction and knowledge), and economic outcomes (prescription costs, pharmacists' time savings) [23-25, 27, 29, 30].

The significance of hospital pharmacists in HSCT, cellular treatment, gene therapy, and the management of ATMPs has been acknowledged by several stakeholders and professional organizations. The papers included in this review indicate that hospital pharmacists are tasked with facilitating the management and treatment of patients needing CGT/ATMPs via practices in procurement, prescription, preparation, administration, monitoring, and human resources development. Pharmacist interventions may be classified as CGT/ATMPs-based (e.g., purchasing administration and surveillance, transport and preservation, environmental and equipment evaluation, handling as well as delivery), direct-to-patient-based (e.g., patient education and counseling, identification and resolution of DRP and ADR, medical evaluation and peacemaking, TDM tracking and pharmacy rounds), and HCP-based (e.g., training and collaboration, process enhancement).

Furthermore, pharmacy departments are advised to recognize and collaborate with health-system stage payer relationships or insurance company executives [48]. In the United States, payer insurance for gene therapy may be categorized under medical benefits, pharmaceutical benefits, or both, and may include complex authorization procedures. Engaging with key payer decision-makers, especially prior to prospective FDA decisions, may improve HCP team members' comprehension of payer processes. Pharmacy leadership is advised to implement supervision mechanisms or approval processes at the executive level for the procurement of high-cost medications. When selecting medications from external specialty pharmacies, it is essential to evaluate the expenses of product management, and the dangers associated with storage, handling, and monitoring.

Patients pursuing treatments and medicinal goods in hospitals often presented with more severe medical illnesses, such as cancer or genetic disorders, necessitating intricate prescription regimens [15, 18]. Evaluating the whole medical and medication history of patients is deemed essential for providing guidance on Medication Therapy Management (MTM) and Therapeutic Drug Monitoring (TDM) for both prescribers and patients [57]. Through the assessment and confirmation of the justification for medication use, pharmacists were enabled to recognize and avert preventable adverse events (AEs) and adverse drug reactions (ADRs), as well as to oversee any unexpected drug-related problems (DRPs) for efficient treatment. Pharmacists' interventions in patient care included informing them about the risks and prevalent side effects of cell and gene therapy, such as graft-versus-host disease (GvHD) and infection following hematopoietic stem cell transplantation (HSCT), the incidence of cytokine release syndrome (CRS) and CAR T-cell-related encephalopathy syndrome (CRES) during CAR T-cell therapy, as well as associated toxicities and immunological risks [33, 35, 37-39, 43-45, 51, 52, 54-56]. Nevertheless, the creation of programs concerning the role of pharmacists in Advanced Therapy Medicinal Products necessitated more study to examine its impact on patient outcomes, therefore promoting doctors and patients to enhance the evidence supporting the adoption of pharmacist interventions.

Moreover, pharmacist interventions emphasizing collaborative practice and innovative pharmacy practices in larger settings were essential for enhancing the interprofessional role of hospital pharmacists, making it more significant and impactful [58]. The application of CPA fosters cooperation between pharmacists and doctors, allowing them to contribute their distinct skills to patient care and other health-related procedures

[33, 34, 48, 49]. The augmentation of pharmacist competency would advantage HSCT patients in alignment with the formulation and execution of the CPA framework [33, 34]. Innovative practice, primarily evident in pharmacists' leadership during the exploration, implementation, and standardization of services, involves the enhancement and reinforcement of existing roles, services, and practice models, alongside the creation of new roles within current practice environments [58, 59].

Delivering superior patient care within an efficient healthcare system would diminish healthcare expenses to enhance value [60]. In the creation and execution of hospital pharmacy services, it is deemed essential to examine measures that illustrate the value of pharmaceutical treatment. Value-based metrics are crucial in demonstrating the justification of resources to assist pharmacists in enhancing their services. Pharmacists can demonstrate the value-based influence on economic, humanistic, and clinical patient outcomes.

From an economic standpoint, favorable results are reflected in revenue growth and cost minimization. One pharmacy service is the coordination of discharged medicines, enabling pharmacists to contribute to the important care transitions for patients undergoing HSCT, who often manage a greater pharmaceutical load. Alexander et al. indicated that pharmacists in the ambulatory care environment at their healthcare institution in the United States were charged for clinical services via facility fees. Pharmacy services offered to HSCT patients generated more income via pharmacy billing, saved time for doctors, and facilitated outpatient pharmacy prescription referrals [25].

Moreover, drug treatment management conducted by qualified pharmacists via collaborative practice agreements and payment arrangements may be economically advantageous. Cell treatments, including HSCT procedures, often incur the greatest pharmaceutical expenditures and care intensity inside healthcare facilities. Pharmacists enhance cost control by optimizing the use of expensive pharmaceuticals, using medication use algorithms, and managing prescriptions, so allowing pharmacists and doctors to allocate more time to provide higher-value clinical services to a greater number of patients [34].

Pharmacists provide tailored education and consultation to patients, and their role in evaluating and confirming pharmaceutical information significantly enhances patient satisfaction with these services [25, 29]. Moreover, as significant healthcare providers, pharmacists may collaborate with multidisciplinary teams to alleviate doctors' burden, thereby reducing burnout and improving their satisfaction [25]. Patient outcomes, regarded as the paramount measure of value, are affected by several complicating circumstances, including the specific illness afflicting the patient, the existence of comorbidities prior to treatment, and discrepancies in pharmacological care resulting from diverse treatment management strategies.

Pharmacists should manage variables in medication management interventions for patients, encompassing medication reconciliation, education on medications and transplants, preparation of medication therapy, management of immunosuppression, prophylactic medication oversight, surveillance of graft-versus-host disease and infections, and adherence to post-transplantation vaccination protocols [29]. Pharmacists modify medication regimens based on changes in patients' clinical statuses, while monitoring follow-up appointments and time allocated to patients to convert these services into quantifiable patient outcome indicators, therefore providing high-value care.

Future initiatives must focus on the standardized management of CGT/ATMPs, achieving a scientifically valid and pragmatic equilibrium between safety and feasibility, to guarantee broad accessibility to these potentially transformational medicines or medicinal goods [28, 61]. Implementing established clinical practice standards and procedures effectively enhances the uniformity and quality of pharmaceutical practice. Several statements offering pharmacy practice management recommendations from international pharmacy organizations were referenced in the included studies, specifically the HCT clinical pharmacist role definition declaration (ASBMT pharmacy SIG) and suggestions for the role and skills of the EBMT CP/P involved in HSCT (EBMT Pharmacist Committee) [40, 62]. Consensus recommendations for designing questionnaires in intervention studies were derived from pharmacy practice administration and clinical supervision for COVID-19 in HSCT and cellular therapy patients [43], as well as guidance on the pharmacy handling of licensed gene medicines [43, 63].

The fundamental duties and capabilities of pharmacists outlined therein, together with particular pharmacy activities, may serve as educational resources for pharmacists to improve their practical skills and comprehension of specialized pharmaceutical services related to the management of CGT/ATMPs. Expert recommendations or consensus, thoroughly evaluated and debated by many stakeholders, provide a systematic reference for healthcare organizations aiming to establish or standardize pharmaceutical care procedures. This adherence to globally acknowledged standards facilitates the secure and efficient administration of sophisticated medicines.

In addition to formally adopting the previously described guidance, pharmacists could endorse best practices and offer essential clinical expertise and medication management while engaging in the development of guidelines and procedures within institutions and committees to enhance quality and facilitate enhancement [64]. Prescription management actions are crucial for the secure and efficient utilization of drugs and the attainment of adequate cost control [37].

Pharmacists contribute to hospital committees through their expertise in complex manufacturing standards for sterile products and biologics, hazardous medication regulations, drug storage and delivery assessments, adherence to risk management plans, third-party payer guidelines, health technology evaluations, and clinical decision support strategies. Pharmacists are adept at contributing to the formulation of organizational patient care protocols that integrate evidence-based medicine with optimal pharmaceutical practices [65].

6. Summary

Numerous insights and research from literature have shown the beneficial contribution of pharmacists in the treatment of CGT/ATMPs; nevertheless, there is still little information about the effectiveness of pharmacist-led strategies on patient outcomes. Utilizing the expertise of hospital pharmacists within multidisciplinary medical teams to establish a coordinated strategy that enhances pharmacy practice would more effectively address the management requirements of CGT/ATMPs. Furthermore, by further refining their advanced competencies, adhering to the most recent practice standards, and promoting quality and process enhancements, pharmacists will be more adept at ensuring the safe administration of pharmaceuticals and improving patient care quality.

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مراجعة بروتوكولات سلامة الأدوية في الصيدليات الاستشفائية: تقييم دور الصيادلة وأفضل الممارسات في إدارة المنتجات الطبية للعلاجات المتقدمة

الملخص

الخلفية :يعد تنفيذ بروتوكولات سلامة الأدوية في الصيدليات الاستشفائية أمرًا ضروريًا لضمان سلامة المرضى وتقليل مخاطر الأخطاء الدوائية. ومع تزايد تبني أنظمة الرعاية الصحية للعلاجات المتقدمة، يصبح دور الصيادلة في إدارة هذه الأدوية أمرًا أساسيًا.

المنهجية :تستعرض هذه المراجعة أفضل الممارسات في بروتوكولات سلامة الأدوية داخل الصيدليات الاستشفائية، مع التركيز على مساهمات الصيادلة في سياق المنتجات الطبية للعلاجات المتقدمة (ATMPs). تم إجراء بحث منهجي في عدة قواعد بيانات، بما في ذلك PubMed، Scopus، وWeb of Science، للدراسات المنشورة بين عامي 2013 و2023. وقد تم تحليل البيانات المتعلقة بأدوار الصيادلة، وتدخلاتهم، وتأثير بروتوكولات السلامة على نتائج المرضى.

النتائج :أظهرت النتائج أن بروتوكولات سلامة الأدوية الفعالة، والتي تشمل التدقيق الدوائي الشامل، وتثقيف المرضى، والمشاركة النشطة في الفرق متعددة التخصصات، تُحسّن بشكل كبير من إدارة المنتجات الطبية للعلاجات المتقدمة. لعب الصيادلة دورًا محوريًا في مراقبة استخدام الأدوية، ومعالجة المشكلات المتعلقة بها، وضمان الالتزام بإرشادات السلامة. كما سلطت المراجعة الضوء على التحسن الملحوظ في رضا المرضى والنتائج السريرية المرتبطة بالتدخلات التي يقودها الصيادلة.

الاستنتاج :تؤكد الدراسة على أهمية وجود بروتوكولات قوية لسلامة الأدوية في الصيدليات الاستشفائية لضمان الإدارة الآمنة للعلاجات المتقدمة. يساهم الدور النشط للصيادلة ليس فقط في تحسين إدارة الأدوية، ولكن أيضًا في تعزيز جودة رعاية المرضى بشكل عام. ينبغي على الأبحاث المستقبلية التركيز على تقييم التأثير طويل الأمد لهذه البروتوكولات على سلامة المرضى ونتائج الرعاية الصحية.

الكلمات المفتاحية :سلامة الأدوية، الصيدلية الاستشفائية، المنتجات الطبية للعلاجات المتقدمة، تدخلات الصيادلة، نتائج المرضى.