

**Systematic Review****Quality Assurance in Safe Handling of Hazardous Drugs Among Healthcare Workers in KSA: A Scoping Review**Sajjan Iqbal Memon^{1*}, Sundas Shahbaz Khan², Zarqa Sharif³, Saadia Younus⁴ and Umair Ismail Manghrio⁵¹Department of Health Administration, King Saud University, Riyadh, Saudi Arabia²Moomal Institute of Physiotherapy and Allied Health Sciences, Hyderabad, Pakistan³Holistic Healthcare, Lahore, Pakistan⁴National Medical Center, Karachi, Pakistan⁵King Salman Armed Forces Hospital, Tabuk, Saudi Arabia**ARTICLE INFO****Keywords:**

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Healthcare providers are potentially at risk from occupational exposure to drugs. Safe handling accreditation criteria from international occupational safety organizations and associations minimize long-term medication exposure harm. The purpose of this review was to examine healthcare workers' quality assurance in the safe handling of hazardous drugs. This topic underwent a scoping review of the literature to determine what was known about exposure and to spot any knowledge gaps using a variety of electronic databases such as Medline, PubMed, EMBASE, Web of Science, and Google Scholar for the literature search. English-language articles that were published between 1997 and 2022 were included. This review included 26 full-text papers in total. The designs, sample sizes, sample collection durations, and medicines studied differed between the investigations. Numerous studies discovered that at least one sample had measurable quantities of a hazardous substance. The studies examined that hazardous drugs are handled in many different stages throughout the healthcare industry, including production, transportation, storage, preparation for patients, and waste disposal after treatment. Healthcare personnel are constantly exposed to HDs. The findings emphasize the need to establish robust regulations, boost training programs, upgrade personal protective equipment, enhance handling techniques, and strengthen monitoring and surveillance systems. More research is required to fill up the gaps and safeguard the safety and health of Saudi Arabia's healthcare professionals who handle hazardous medications.

INTRODUCTION

Hazardous Drugs (HD) are chemical substances, which has been approved by evidence to be used in medical practice to overcome pain and injuries and to treat various diseases for patients. However, many of these drugs have some serious side effects and unsafe handling of such drugs will reflect on healthcare workers' and patients' health that can cause serious complications [1]. Hazardous drugs (HDs) can be defined as inherently toxic drugs posing a risk to healthcare providers which are characterized as having carcinogenicity, teratogenicity, reproductive toxicity, genotoxicity, and organ toxicity at low doses [2]. Healthcare providers are constantly exposed to HDs at

different points of handling starting from manufacture distribution, storage, and preparation of HDs to patients as well as waste handling after treatment [3]. Occupational exposure to HDs in the workplace has been linked to short-term reactions and allergies as well as long-term effects. Many international organizations and associations such as the American Society of Health System Pharmacists (ASHP), The National Institute for Occupational Safety and Health (NIOSH), and the United States Pharmacopoeia (USP800) have released comprehensive guidelines and directives aimed at mitigating the potential risks associated with prolonged exposure to dangerous

medications [4]. Numerous endeavors are undertaken to establish optimal measures for ensuring the utmost quality in the various stages of handling hazardous drugs (HDs), encompassing their receiving, storage, preparation, distribution, administration, and disposal. For more than 20 years, recommendations for the safe handling of hazardous drugs have been accessible. Ever since chemotherapy has been used to treat cancer. While most HDs are used in chemotherapy treatment for cancer, they are used as well in non-oncology cases such as nephritis, systemic lupus, and multiple sclerosis. The ongoing increase of HD use for areas outside oncology increases the potential exposure by healthcare providers [5]. In the early 1980s, an increase in cytotoxic exposure and other occupational hazardous exposure lead to a set of recommendations by the Occupational Safety and Health Administration (OSHA). Furthermore, OSHA became concerned about the occupational risks of carrying chemotherapy agents which led to the first ASHP Technical Assistance Bulletin on Handling Cytotoxic Drugs. In 1986, OSHA published its first guidelines for the safe handling of chemotherapy agents and HDs to protect nurses and pharmacists from exposure and negative effects. The guidelines explained the equipment, garments, and work practices intended to protect pharmacists and nurses from exposure [6].

Thus, the purpose of this review is to examine the quality assurance measures implemented by healthcare personnel in the safe handling of hazardous medications.

METHODS

This review aims to provide a comprehensive overview of quality assurance in the safe handling of hazardous drugs among healthcare workers in Saudi Arabia from 1997 to 2022. The review will focus on identifying key studies, methodologies employed, and the outcomes and recommendations presented in these studies.

Literature Search Strategy

A systematic search strategy was employed to identify relevant articles published between 1997 and 2022. Multiple electronic databases were utilized, including PubMed, MEDLINE, Embase, and Google Scholar. The following keywords were used: "hazardous drugs," "chemotherapy," "occupational exposure," "healthcare workers," "Saudi Arabia," "quality assurance," and their various combinations. The search was restricted to articles published in English.

Study Selection Criteria

Studies were included if they met the following criteria: (1) focused on quality assurance in the safe handling of hazardous drugs among healthcare workers in Saudi Arabia, (2) published between 1997 and 2022, (3) original research articles, reviews, or systematic reviews, and (4)

accessible in full-text format. Studies that did not meet these criteria, such as opinion pieces, editorials, and conference abstracts, were excluded.

Data Extraction and Analysis

The initial screening of titles and abstracts was carried out by two independent reviewers to find papers that may be relevant. Subsequently, whole publications were obtained for additional evaluation. Any inconsistencies among the reviewers were handled through deliberation and agreement. The review encompassed a total of 26 full-text publications. The extraction of data was conducted using a standardized form, which encompassed many essential details such as authors, publication year, study design, sample size, methodology, important findings, and suggestions.

Methodological Assessment

The methodological quality of the research included in the analysis was assessed using established measures that were namely the Newcastle-Ottawa Scale for observational studies and the Cochrane Collaboration's methodology for evaluating the risk of bias in randomized controlled trials. The assessment considered study design, sample size, participant selection, data collection methods, statistical analysis, and potential sources of bias.

Data Synthesis

Given the heterogeneity of study designs and outcomes, a narrative synthesis approach was used to summarize the findings. Key themes, commonalities, and differences among the studies were identified and discussed. The results were organized according to the main aspects of quality assurance, including policies and guidelines, training and education, personal protective equipment, handling procedures, and monitoring and surveillance.

Ethical Considerations

The present study is based on published literature and does not involve human subjects. Therefore, ethical approval was not required.

Evidence of Exposure

Drugs are classified as hazardous, which is a term that was first used by ASHP in 1990, if research conducted on animals or humans demonstrates that exposure to these substances has the risk of inducing cancer, developmental or reproductive toxicity, or organ damage [7]. Various studies over the years have shown that unsafe handling of HDs in pharmacies resulted in traces of toxicity or even more serious cases of effects of exposure. In 1997, Ensslin et al., conducted a study examining the potential risk of infection faced by hospital pharmacy employees due to their exposure to antineoplastic agents [7]. The study involved the collection of urine samples from 13 pharmacists. Out of these samples, it was found that two urine samples contained cyclophosphamide. It is

noteworthy that all study participants adhered to current standards for protecting themselves during drug preparation. Furthermore, the evaluation of the laminar air-flow hood was conducted inconsistently, revealing that one of the two motors of the exhaust fan was non-operational during the duration of urine collection. Similarly, in 2004, NIOSH published a report of a 39-year-old pharmacist who had two episodes of painless haematuria and grade II papillary transitional cell carcinoma. She worked full-time for 20 months at a hospital IV preparation department preparing cytotoxic medicines like cyclophosphamide, fluorouracil, methotrexate, doxorubicin, and cisplatin 12 years before her diagnosis. The pharmacist was a non-smoker with no other occupational or environmental risk factors, but her cancer was caused by work-related antineoplastic drug exposure, which has not been proven [8]. Furthermore, these are all evidence to support the importance of following the guidelines in the handling of HDs, providing a safe work environment for healthcare workers. Like many countries throughout the globe, Saudi Arabia is witnessing a rise in the prevalence of cancer cases, thereby leading to an increase in the demand for the administration of cytotoxic drugs. In previous years, the King Faisal Specialist Hospital and Research Centre in Riyadh took the initiative to administer cytotoxic agents for the treatment of cancer patients. However, it is noteworthy that presently, nearly all tertiary hospitals in Saudi Arabia, such as King Khalid University Hospital and the Ministry of National Guard Health Affairs (MNGHA), offer this service as well [9].

Safe Handling of Hazardous Drugs Guideline Awareness

For the last four decades, a variety of guidelines have been published to mitigate the risk of healthcare worker exposure in Europe. The primary objective of these rules is to mitigate workers' exposure and safeguard their well-being [10]. Extensive documentation exists about the susceptibility of healthcare workers who handle toxic pharmaceuticals to potential risks resulting from inadequate control and preventive measures. Due to this factor, there has been a rise in the number of cancer patients requiring chemotherapy medications, thus leading to an escalated level of exposure among workers who come into direct or indirect touch with those pharmaceuticals within their occupational setting to improve the knowledge regarding safe handling of hazardous drugs among healthcare workers, especially nurses, and pharmacist is crucial to minimize occupational exposure and the potential adverse effects. A former study by O'Bryant et al., assessed the community pharmacists' knowledge and attitudes towards oral chemotherapy, about 243 pharmacists participated in the survey, and only

25% answered the safe handling correctly [11]. Similar research was undertaken in Saudi Arabia on the safe handling of oral chemotherapeutic agents by healthcare professionals. Their 1000 surveys came from four Riyadh tertiary care hospitals. Pharmacists (79.3%) and oncology nurses (20.7%) completed most surveys. Chemotherapeutic agent safety is poorly understood by pharmacists, pharmacy technicians, and oncology nurses, according to the study. Staff must follow safe handling requirements, according to the report. The author recommends instructional and awareness programs for healthcare personnel, especially pharmacists, to protect patients and caregivers [12]. A Biological Safety Cabinet (BSC) is a ventilated cabinet used to prepare HDs for people, products, and environmental safety. Each hospital should also train workers to handle these pharmaceuticals safely and provide a safe workplace [13]. The hospital must also provide and explain how to use personal protective equipment (PPE) like head cover, face protection, eyes protection, respiratory protection (mask N95), chemotherapy gown (HD-resistant), chemotherapy gloves (ASTM rated, powder-free), and shoe cover. In Saudi Arabia, many healthcare facilities have been implementing these recommendations to formulate their Standard Operating Procedures (SOP), as advised by USP800. The reporting of compliance with safe handling practices has not been observed, despite the existence of available recommendations. In recent decades, research has consistently indicated a disparity in compliance rates between developing and industrialized nations [14].

Disposal, Spillage, and Route of Exposure

Healthcare professionals, such as nurses, pharmacists, and other providers in the field, may encounter hazardous medicines in situations where they generate aerosols, produce dust, handle spills, or meet contaminated surfaces while engaged in activities related to the preparation, administration, or disposal of these hazardous drugs. Exposures to hazardous medications might potentially transpire via various routes, including inhalation, skin contact, skin absorption, ingestion, or injection. The most probable pathways of exposure include inhalation and skin contact/absorption. However, inadvertent ingestion resulting from hand-to-mouth contact and accidental injection by a needlestick, or sharps injury are other potential routes of exposure. Numerous investigations have identified instances of drug contamination on the external surfaces of medicine vials throughout the delivery process conducted by manufacturers [15]. Various wipe sampling and washing approaches have been employed to identify the presence of Cyclophosphamide, Fluorouracil, Ifosfamide, and Platinum on the exteriors of vials. The data suggest that

there is a potential danger of skin exposure when handling unopened medicine vials, underscoring the significance of utilizing Personal Protective Equipment (PPE). Personal Protective Equipment (PPE) serves as a means of safeguarding workers by minimizing their potential exposure to hazardous drugs (HDs) in the form of aerosols and residues. In certain situations, it may be necessary to utilize supplementary personal protective equipment (PPE) when managing hazardous drugs (HDs) in environments that are not equipped with a biological safety cabinet (BSC). These scenarios may encompass activities such as patient treatment or the remediation of a spill. The NIOSH has produced a thorough list of antineoplastic and other dangerous medications. This list provides PPE advice for numerous healthcare professionals' scenarios at healthcare institutions. Single-use PPE must not be reused. Reusable PPE must be disinfected and cleaned after use. Pharmacists must wear safety gear when making hazardous medicines (HDs). Chemo robes, head coverings, hair coverings, shoe covers, and two pairs of gloves are used [7]. The main ways to get unhealthy chemicals are usually listed below: The process of skin or mucous membranes absorbing a material. The injections and sharps. Inhaling vapors, aerosols, airborne drugs, and dust. Consuming food, drinks, or smoke in filthy or unsanitary conditions [5]. All personnel handling hazardous medicines (HDs) must understand their correct management and precautions. These experts must also regularly evaluate these techniques and the HDs produced. This is done to protect patients, reduce staff exposure, and reduce contamination in the work and patient care environments [16]. As per the guidelines provided by the Occupational Safety and Health Administration (OSHA), it is possible for drugs to inadvertently escape during the process of pharmacy preparation, particularly while reconstituting powders and transferring medications between different containers. The presence of contamination has been identified on the exterior of Biological Safety Cabinets (BSCs) as well as on the surrounding flooring, suggesting that the effectiveness of these engineering measures in containing hazards may be compromised at times. Improper operator techniques have the potential to impede airflow and result in the release of medication aerosols. Unintentional medication leaks undeniably contribute to environmental damage. The investigation also revealed that floor contamination with fluorouracil and Ifosfamide occurred subsequent to the repair and cleaning activities conducted in a drugstore. Remarkably, a state of continual contamination persisted for two months during the construction period, wherein the pharmacy section had not yet attained full operational functionality [1, 16]

Effects of exposure

The occurrence of various symptoms, including but not limited to nausea, headache, malaise, dizziness, dermatitis, rash, skin, and mucous membrane ulceration or irritation, as well as throat or eye irritation, is associated with occupational exposure to hazardous drugs [17]. Keat *et al.*, additionally incorporated an examination of the adverse effects associated with hair loss, liver damage, and gastrointestinal pain [14]. Exposure to hazardous drugs or proximity to toxic drugs has been associated with a range of chronic effects, including renal and hepatic complications, cardiac and pulmonary damage, impaired fertility, adverse effects on pregnancy and fetal development, bone marrow damage, cognitive impairments in children, and auditory impairments [17]. According to a study examining the urinary excretion of cyclophosphamide in chemists and nurses, it was observed that the drug was systemically absorbed at a rate of 3.6–18 g per day. This indicates a potential increase in the risk of cancer, with an estimated range of 1.4 to 10 additional cases per million workers per year. Additionally, for nurses exposed to higher levels of cyclophosphamide (16–80 g per day), as determined by urine excretion, the estimated increase in cancer risk ranges [5, 15].

Safe handling of hazardous drugs among hospitals in Saudi Arabia Compliance

Training programs related to the handling of anti-neoplastic and hazardous drugs have been organized by the Saudi Council for Health Specialties and the Saudi Pharmaceutical Society. In addition, each Ministry of Health (MOH) hospital's safety committee should oversee the proper execution of cytotoxic medication safety policies [18]. Health employees' fears about handling cytotoxic medications could be alleviated in the meantime by keeping them informed about hospital plans, listening to their concerns, and including them in the expansion of procedures for the safe handling of these agents. Alomi *et al.*, conducted a retrospective analysis of the Ministry of Health's medication error documentation system in health facilities, and the analysis relied on the (Pharmacy Strategic Plan 2012–2020) with a well-defined vision and goals [19]. The healthcare system and pharmacy regulations have built a method for documenting medical errors. The medical error documentation system is being improved regularly in all MOH hospitals. A recent retrospective study in Saudi Arabia also reported that volunteer incident reporting can provide crucial and thorough information about adverse events related to patient safety during perioperative procedures that examined a sample of 253 secondary inpatient records in which n=248 suffered medical errors, whereby n=02 resulted from workplace violations and implementation of

care. In terms of coding variable data about n=16 registries were due to wrong medications and n=7 were documented with hazardous medications [20]. Hazards to healthcare workers from harmful medications and chemicals stemming from inherent toxicity and the level of exposure to these drugs in the course of their work. According to the NIOSH recommendations, Kamil et al conducted a survey related to bio-safety awareness in faculty members at King Faisal University in which over 80% of faculty members were not aware of any hazardous drug program or suitable engineering controls, less than 35% knew how to deal with an unintentional spill or exposure of such medications [21]. This also revealed that a hazardous drug program and suitable engineering controls are required to train and educate researchers to prevent, and control expected hazardous drug exposures. Alshammari et al., conducted a systematic review to determine drug safety notions and their impact on the patients' health which addressed when we give certain drugs to specific categories of patients, all healthcare professionals should consider benefit-risk evaluation [22]. Certain patient populations, including pregnant women, toddlers, and the elderly, warrant heightened attention due to their classification as vulnerable individuals. The issue of drug safety has garnered significant attention in the past decade due to its crucial significance in patients' health.

Quality-assurance testing of staff pharmacists in Handling Cytotoxic Agents

The Society of Hospital Pharmacists of Australia (SHPA) has stated that Quality assurance is critical for continuously monitoring, assessing, and improving the safe handling of cytotoxic medications, and the procedures for the safe handling of cytotoxic medications must be reviewed and modified regularly to reflect current criteria for their safe management [23]. It is necessary to implement and document a program for ongoing aseptic technique validation as well as ongoing validation in the manufacture of all cytotoxic medicinal products. A former study by Harrison *et al.*, was conducted to improve the management of cytotoxic drugs by staff pharmacists, in which competency-based simulation testing was applied [24]. Pharmacists were required to follow pharmacy service standard operating procedures to manufacture a simulated liquid cytotoxic agent (fluorescein sodium 0.5 mg/ml.). Throughout the preparation, participants were observed to ensure correct safety and aseptic technique, as well as waste disposal and labeling. From 85 percent to 89 percent on written tests, there was no substantial improvement. It took 30 minutes to complete each scenario and receive feedback. The ability to prepare cytotoxic drugs improved dramatically after simulation testing.

Accreditation

One of the requirements for hospital accreditation, as outlined by the Joint Commission's standard (JCI) and The Saudi Central Board for Accreditation of Healthcare Institutions 26 (CBAHI), applies to the handling of hazardous drugs. This includes the hospitals' definition of such drugs and the existence of an extensive inventory of them. These criteria are based on the guidelines and recommendations established by OSHA, NIOSH, and USP [12, 25, 26]. However, there is a lack of research and statistical data regarding the extent to which healthcare staff possess knowledge and adhere to proper protocols for the safe handling of hazardous drugs (HDs). Moreover, researchers should undertake an assessment of the proper management and handling protocols for hazardous drugs (HDs) within the healthcare workforce.

Study Limitations

This review has certain limitations. Initially, the scope of the search was restricted to articles that were published in the English language, potentially resulting in the exclusion of pertinent studies published in other languages. Furthermore, the exclusion of grey literature, including unpublished reports or conference abstracts, may have resulted in the oversight of certain studies that were relevant. Lastly, the inherent limitations of the included studies, such as potential biases or methodological weaknesses, may impact the overall reliability and generalizability of the findings.

CONCLUSIONS

Healthcare workers are continuously exposed to hazardous drugs (HDs) at many points in the handling process, including manufacture, distribution, storage, and preparation of HDs for patients, as well as waste disposal following treatment. There is mounting evidence that cytotoxic drug exposure in the healthcare industry especially pharmaceutical workplace poses a serious threat to the health of employees and anyone who gets involved in the process. Exposure to HDs can occur in a variety of ways, and the risk of exposure is determined by the potential route of exposure, which is dependent on the type of drug handled and the jobs being performed. Particularly, In Saudi Arabia, there is currently no literature available by MOH or other institutions that indicate the knowledge and practice in handling hazardous drugs. The findings highlight the importance of implementing robust policies, enhancing training programs, improving personal protective equipment, refining handling procedures, and strengthening monitoring and surveillance systems. Further research is needed to address the identified gaps and to ensure the safety and well-being of healthcare workers involved in the handling of hazardous drugs in Saudi Arabia.

Authors Contribution

Conceptualization: SIM, SSK, ZS, SY, UIM

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All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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