



# Advancing Safety and Efficiency in Hazardous Drug Management: Analytical Critique, Constraints, and Systematic Review Insights

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## Abstract

**Background:** The preparation and administration of hazardous drugs (HDs) in healthcare settings may have significant occupational risks to healthcare professionals. While robotic systems are increasingly deployed to mitigate exposure, the lack of explicit guidelines and worker satisfaction assessments highlights critical research gaps. Additionally, high documentary noise and limitations in study design compromise the reliability of evidence in occupational health investigations. **Methods:** This analysis reviewed literature on HD management, focusing on the safety and efficiency of robotic systems, systematic risk assessment, and worker satisfaction. Databases including Scopus and Web of Science were queried using targeted keywords in titles, abstracts, and keywords. Relevant studies were critically appraised for methodological rigor, limitations, and outcomes using established frameworks such as the STROBE statement and Arksey and O'Malley's scoping methodology. **Results:**

Findings revealed a lack of standardized protocols to minimize exposure risks during HD preparation and administration. Only two studies evaluated worker satisfaction related to robotic systems, primarily through electronic prescription usage. While integrating HDs into standardized management systems enhanced process safety and resource optimization, limitations in study designs hindered robust evidence generation. High levels of "documentary noise" from database searches and indexing inadequacies further constrained the review. Despite comprehensive search strategies, potential gaps in relevant literature persisted. **Conclusion:** The deployment of robotic systems for HD preparation offers promise in improving safety, but significant gaps remain in assessing worker satisfaction and exposure mitigation. Future research should focus on developing explicit safety guidelines, refining risk assessment methodologies, and improving database indexing to reduce documentary noise. Incorporating worker satisfaction assessments and adopting rigorous study designs are crucial to advancing occupational safety in HD management.

**Keywords:** Hazardous drugs, Occupational Health, Systematic Review, Robotic Drug Preparation, Worker Safety

**Significance** | This study provides critical gaps in hazardous drug safety, emphasizing worker exposure risks, systematic management, and database challenges.

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## Introduction

Concern regarding the safe handling of hazardous chemicals among healthcare professionals has been a persistent issue since

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Falck et al. (1979) identified heightened cellular mutagenicity in the urine of nurses exposed to cytostatic drugs. This landmark study underscored the occupational risks associated with handling hazardous substances in medical settings, spurring research and policy advancements aimed at mitigating these risks. The term "hazardous drugs" (HDs), initially associated exclusively with cytostatic agents, was first coined by the American Society of Hospital Pharmacists (ASHP) in 1990 and later adopted by the National Institute for Occupational Safety and Health (NIOSH) in 2004 (Bernabeu-Martínez et al., 2018; NIOSH, 2004). NIOSH's definition emphasizes the human health hazards posed by such drugs, including carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, and genotoxicity, as well as structural or toxicity similarities to other hazardous drugs.

In 2014, NIOSH introduced a classification system for hazardous drugs, dividing them into three categories: antineoplastic agents, non-antineoplastic agents with specific risk profiles, and drugs that pose reproductive risks primarily for pregnant or breastfeeding workers. This categorization provided a structured approach to understanding and managing chemical hazards in healthcare environments (Bernabeu-Martínez et al., 2020). Subsequent research has consistently highlighted the chemical dangers these drugs pose to workers, necessitating robust regulatory measures and technological interventions to enhance safety. Notable advancements include electronic prescribing systems, drug identification through coding mechanisms, and intelligent infusion pumps, all of which aim to minimize medication errors and improve overall safety in handling hazardous drugs (Shahmoradi et al., 2021).

The complex and multidisciplinary nature of handling hazardous drugs makes the process inherently prone to errors, posing significant risks to both patients and healthcare workers (Johnson et al., 2010). Recognizing these risks, global efforts have been initiated to establish guidelines for the safe use of HDs. However, achieving a universally accepted standard remains elusive. Adherence to clinical standards and the standardization of operational practices are critical for reducing variability and mitigating risks (Erce, 2016; Martínez Gabarrón et al., 2017).

Risk assessment serves as a cornerstone for managing and controlling the handling of hazardous drugs. Safety measures implemented in healthcare settings are often derived from such assessments, which provide insights into the perceived risks and exposure levels associated with HD management. Studies have advocated for integrating hazardous drugs into standardized management systems to enhance safety and efficiency (Bernabeu-Martínez et al., 2021). Despite the acknowledged importance of risk assessments, comprehensive evaluations remain scarce. To date, the Hazardous Drug Consensus Group has provided the only definitive

methodological framework for conducting risk analyses related to hazardous drugs (HDGC, 2017).

Given the inherent risks associated with handling HDs, identifying key phases and activities in the management process is vital. Implementing preventive measures to mitigate occupational exposure is equally crucial. Previous studies have explored the hazards and risks linked to HD handling, as well as the perceived severity of these risks (Bernabeu-Martínez et al., 2020; Ness et al., 2021). Standardizing practices based on risk-related factors can guide the development of coherent policies aimed at safeguarding worker health and enhancing safety in healthcare environments.

Technological advancements have facilitated significant improvements in managing hazardous drugs. Computerized systems have enabled healthcare facilities to collect extensive data on HD handling processes, generating valuable insights into current practices and potential hazards. Such analyses are instrumental in formulating preventive measures and ensuring process safety (Arksey & O'Malley, 2005; Wanden-Berghe & Sanz-Valero, 2012). Specialized computer systems have been developed to streamline the comprehensive management of hazardous drugs, aiming to reduce associated risks (Gayoso-Rey et al., 2020; Terkola et al., 2017).

This study aims to address gaps in the literature by analyzing existing scientific research to identify computer programs used in hospital pharmacies for managing hazardous drug exposure. This analysis seeks to provide a reference point for assessing the current state of worker safety and preventive measures in hospital pharmacy services. Additionally, it emphasizes the role of process computerization in mitigating risks associated with hazardous drugs. Employing a systematic methodological approach, this research aspires to contribute to the development of evidence-based strategies for enhancing safety in hazardous drug management.

## 2. Methodology

This study utilized a cross-sectional descriptive approach combined with a critical review of prior research on the management of hazardous drugs (HDs) within hospital pharmacy services. The methodological framework aimed to consolidate and analyze data on HD management interventions and the role of software in enhancing these processes.

To gather relevant literature, systematic searches were conducted in six electronic databases: MEDLINE (via PubMed), Embase, Cochrane Library, Scopus, Web of Science, and Medicine in Spanish (MEDES). Boolean operators and carefully selected keywords were applied to each database, ensuring a comprehensive retrieval of studies pertinent to HD management. The inclusion criteria were limited to studies published in English and Spanish, with a focus on interventions and technological advancements in hospital pharmacy services.

The study followed systematic review principles, with a strong emphasis on evaluating the quality of the selected publications. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist was used to assess methodological rigor and reporting standards, ensuring consistency and transparency in the analysis. The key interventions identified were classified into three primary categories: electronic prescription, preparation processes, and comprehensive management solutions. Electronic prescription systems primarily targeted the reduction of medication errors, particularly in antineoplastic drug management. The preparation processes category evaluated the effectiveness of gravimetric control software and robotic systems, while comprehensive management solutions were assessed for their ability to provide end-to-end oversight, traceability, and risk mitigation.

The analytical framework critiqued the evidence levels and recommendation grades using the Scottish Intercollegiate Guidelines Network (SIGN) criteria. Methodological limitations, such as inadequate bias mitigation and the absence of sensitivity analyses, were documented. Temporal trends in publication quality were also analyzed to identify progress in HD management research.

We have found certain challenges, including a limited number of recent studies, as evidenced by the low proportion of publications from the last five years. Additionally, high "documentary noise" due to database indexing limitations hindered the search process. The predominance of English-language publications potentially excluded valuable research in other languages.

As the study relied exclusively on secondary data from published literature, ethical approval was not required. All sources were appropriately cited to ensure academic integrity. Overall, the methodology highlights the critical need for updated, high-quality research in HD management, with a particular focus on comprehensive software solutions and enhanced safety measures for healthcare workers.

### 3. Principal Interventions Executed

This study consolidates critical information regarding interventions aimed at managing hazardous drugs (HDs) in hospital pharmacy services. It also reviews the software utilized in the management process, aligned with the goals of a systematic review (Hagger, 2012). The primary objective was to provide valuable insights to the scientific community and foster innovative solutions to protect healthcare workers.

Findings reveal that while software applications are predominantly employed for prescribing and manufacturing hazardous pharmaceuticals, especially antineoplastic agents, there is a lack of documentation on software that comprehensively oversees the

management of hazardous drugs within hospital pharmacy services.

The advent of new technologies, especially those derived from Web 2.0, has positioned the information and communication sectors as pivotal in the global economy. Consequently, studies emphasize that the future of these sectors hinges on the management and privacy of personal patient and consumer data (Palos-Sanchez et al., 2021). Additionally, mHealth applications have been identified as tools to anticipate patient behaviors, provide preventive advice, and monitor symptoms in home-care settings (Palos-Sanchez et al., 2021). However, the publications analyzed in this review exhibit obsolescence similar to earlier systematic reviews on occupational health and HD exposure (Bernabeu-Martínez et al., 2018; Domingo-Pueyo et al., 2016). The scarcity of studies published in the last five years highlights the urgent need for updated findings.

The quality of included studies was assessed using the STROBE checklist. This evaluation revealed no significant temporal progression, which is consistent with earlier findings regarding the incremental adoption of quality standards (von Elm et al., 2008). Initial studies often lacked adherence to these quality requirements, as the STROBE checklist itself only began influencing research practices in 2004 (von Elm et al., 2008). Furthermore, many of the studies included in this review did not detail strategies to mitigate potential biases or conduct additional sensitivity analyses, contributing to lower overall quality ratings.

Based on the SIGN criteria, the level of evidence and recommendation grade of the included studies is consistent with previous findings (Harbour & Miller, 2001). Establishing a cause-effect relationship in intervention trials was challenging due to the inherent biases in certain study designs (Teufer et al., 2019). Occupational health and safety research often lacks high-quality evidence, partly due to the long-term nature of interventions and their outcomes (Barriocanal-Gómez et al., 2021). This study underscores the limited focus on HD management and control in existing literature.

#### 3.1 Predominance of American Studies and Language Considerations

The dominance of American research in systematic reviews is a well-documented phenomenon in the scientific literature. The robust infrastructure of U.S. universities, combined with substantial funding from public and private institutions, plays a significant role (Bernabeu-Martínez et al., 2020). Moreover, most reviewed studies were published in English, the prevailing language of scientific communication in healthcare (Sánchez-Moya et al., 2020). English-language journals also have broader representation in major bibliographic databases, increasing the visibility and citation potential of articles published in these outlets (Cohen et al., 2007).

### **3.2 Focus on Antineoplastic Drugs and Technological Interventions**

Most computer applications reviewed were centered on managing antineoplastic drugs. This focus is justified as these drugs are high-risk medications, with errors in their use posing significant risks to patient safety (Phillips et al., 2001). Antineoplastic agents are the second leading cause of medication error-related mortality (Phillips et al., 2001), necessitating their prioritization in clinical safety measures. The National Quality Forum has emphasized the enhancement of high-risk drug safety as a critical safety practice for universal adoption in hospitals (National Quality Forum, 2003).

Managing high-risk medications in hospitals is inherently complex, requiring interventions across all stages—packaging, storage, prescription, validation, preparation, dispensing, administration, and disposal (European Medicines Agency, 2015). Hospital pharmacy services oversee multiple phases, necessitating precise strategies to prevent errors and adverse outcomes. Technological advancements have introduced tools and programs to enhance medication safety and minimize human errors (Shamliyan et al., 2008). Meta-analyses have shown that electronic prescribing systems can reduce medication errors by up to 50% (Radley et al., 2013; Leape et al., 1995).

### **3.3 Prescription and Preparation Software**

The reviewed studies identified electronic prescribing as the most frequently utilized software, followed by applications for drug preparation. These findings align with evidence indicating that most drug errors in antineoplastic treatments occur during prescription, preparation, and administration phases (Escoms et al., 2019; Terkola et al., 2017). To address these challenges, technological solutions have been implemented to simplify and standardize protocols, automate calculations, and integrate checks to prevent unauthorized actions. For instance, software can issue alerts for dose variations or improbable prescription intervals, reducing the likelihood of human error (Radley et al., 2013). Additionally, gravimetric quality control and robotic processing systems have significantly reduced medication errors.

The emphasis on prescription software reflects a broader trend prioritizing patient safety over worker safety, possibly due to the lack of stringent worker safety regulations. Some reviewed studies also explored tools for quantitative and qualitative quality control of antineoplastic preparations, highlighting the challenges of achieving precise and safe preparation processes that minimize HD exposure among healthcare professionals. Robotic preparation systems offer partial solutions to manual processes, reducing exposure risks such as spills, aerosols, and needle sticks, while enhancing preparation traceability (Gayoso-Rey et al., 2020).

### **3.4 Gaps in Comprehensive HD Management Software**

Despite the availability of various technological interventions, the reviewed studies revealed a lack of comprehensive software capable

of managing all stages of the HD process, including traceability and risk reduction. Research on phases beyond prescription, such as preparation, dispensing, and disposal, remains limited. These stages are critical due to their complexity, associated risks, and costs (including labor, equipment, and materials). Hospital pharmacy services bear primary responsibility for these processes, which pose risks to both patients (e.g., preparation and administration errors) and workers (e.g., HD exposure).

### **3.5 Interventions and Outcomes**

Interventions involving electronic prescribing consistently demonstrated a reduction in prescription errors, particularly dosage errors. This reinforces the efficacy of electronic prescribing as a safety measure. In the preparation phase, studies highlighted the use of robotic processing systems and gravimetric control software, both of which improved preparation accuracy. These findings underscore the need for widespread adoption of such technologies to enhance preparation quality further (Terkola et al., 2017).

### **3.6 Challenges in Implementation**

Healthcare professionals handling chemotherapy drugs face significant exposure risks during preparation and administration (Bernabeu-Martínez et al., 2021). Unlike patients who accept HD exposure risks as part of their treatment, healthcare workers should not be subjected to similar risks. Despite advancements in automation technology, manual preparation and dispensing techniques remain prevalent in many hospitals. Barriers to adopting automated systems include high costs and a lack of stringent regulations for employee safety. However, existing legislation promoting environmental safety provides a framework for broader adoption (Erce, 2016).

### **3.7 Recommendations for Future Research**

Given the gaps identified in current HD management processes, future research should prioritize developing software that encompasses all stages of HD management, from prescription to disposal. Comprehensive traceability systems are essential to minimize risks and improve safety outcomes for both patients and healthcare workers. Additionally, increased investment in automation technology and stricter worker safety regulations could facilitate broader adoption of advanced systems, reducing reliance on manual processes.

## **4. Analytical Critique**

A critical gap in the literature on the use of robots for hazardous drug (HD) preparation is the lack of assessment regarding worker exposure risk—one of the key motivations for adopting robotics. While mandatory quality standards exist for drug formulation, explicit requirements to mitigate healthcare professionals' exposure risks during HD preparation or administration remain absent (Bernabeu-Martínez et al., 2018). According to Bernabeu-Martínez



et al. (2020), integrating HDs into a standardized management system could enhance safety for patients and professionals, optimize resource use, and reduce process risks. Implementing systematic risk assessment methodologies and preventive strategies can help evaluate the likelihood and severity of adverse events.

Only two studies focused on worker satisfaction concerning computer program implementation, primarily through the lens of electronic prescriptions. Assessing worker satisfaction is essential, yet most selected studies neglect this aspect, highlighting a significant research gap (Bernabeu-Martínez et al., 2021; Shahmoradi et al., 2021).

### 5. Constraints

While rigorous reviews require high-quality studies with robust methodologies and follow-ups, this analysis incorporated all relevant studies to ensure comprehensiveness. The findings are constrained by the limitations of the included studies. Similar to other occupational health investigations, achieving a sample limited to robust designs with high evidence levels proved challenging (Falck et al., 1979; Teufer et al., 2019).

A notable constraint is the high proportion of non-relevant articles retrieved (relative to the included studies). This is attributed to indexing issues in databases like Scopus and Web of Science, as searches relied on querying titles, abstracts, and keywords (Bernabeu-Martínez et al., 2019). Such "documentary noise" is a common limitation in systematic reviews (Arksey & O'Malley, 2005; Gayoso-Rey et al., 2020).

Despite a comprehensive search, some relevant studies may have been overlooked. This limitation aligns with findings from earlier systematic reviews that emphasized the challenge of complete coverage in occupational health literature (Polovich, 2011; Chaffee et al., 2010). Addressing these constraints requires adopting refined search methodologies and improving database indexing systems to enhance the accuracy and relevance of systematic reviews (Wanden-Berghe & Sanz-Valero, 2012; Barriocanal-Gómez et al., 2021).

### 6. Conclusion

Among software developed for managing hazardous drugs (HDs), computerized prescription systems for antineoplastic medications were the most widely implemented at the hospital level. Notably, only one of the studies reviewed examined safety incidents affecting personnel handling HDs. Healthcare practitioners reported satisfaction with the integration of these systems into their workflows. While all studies prioritized patient safety as their primary objective, none assessed the risk of occupational exposure to HDs among employees. Consistent with Bernabeu-Martínez et al. (2018), leveraging information and communication technologies

can enhance the management of HD-related procedures, improving efficiency and reducing associated risks.

Despite advancements in robotics and standardized management systems, critical gaps persist in protecting healthcare workers from HD exposure. Incorporating systematic risk assessments and preventative strategies is essential to safeguard employees while ensuring procedural safety. Furthermore, worker satisfaction, often overlooked, warrants additional investigation to inform comprehensive policy development. Limitations in the current literature, including methodological shortcomings and database indexing inefficiencies, highlight the need for more robust research approaches in occupational health. Addressing these deficiencies through evidence-based practices and improved search methodologies will elevate safety standards, optimize resource allocation, and enhance the working conditions of healthcare professionals.

### Author contributions

R.M.A. conceptualized and supervised the study. T.I.A., A.A.A., H.A.A., and S.S.A. contributed to data collection, analysis, and drafting. A.Y.A., K.O.A., B.O.N.A., M.M.A., and T.G.T.A. supported methodology, validation, and manuscript review. H.B.B.A., A.H.A., M.M.M.A., S.S.A. (Saadi Saad Alanazi), A.H.M.A., H.D.T.A., M.A.B., and B.T.A. assisted with revisions, resources, and project administration. All authors reviewed and approved the final manuscript.

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### Competing financial interests

The authors have no conflict of interest.

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