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Accidental exposure to hazardous drugs, reproductive toxicity risk and proper use of PPE in the hospital setting: evidence from an observational study

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Abstract. *Background:* Workplace safety in healthcare is crucial, especially regarding the handling of hazardous drugs, which pose significant risks due to their carcinogenic and teratogenic properties. This study focuses on the risks of reproductive toxicity associated with accidental exposure to hazardous drugs and assesses the effectiveness of personal protective equipment (PPE) in mitigating these risks. The COVID-19 pandemic has highlighted vulnerabilities in healthcare safety protocols. *Methods:* This observational cross-sectional study was conducted at the Azienda Ospedaliera Universitaria Policlinico di Palermo, involving healthcare personnel across various departments. Data were collected via an anonymous questionnaire administered through the hospital's intranet, focusing on demographics, exposure to hazardous drugs, PPE use, and health outcomes. The survey spanned six months, and statistical analyses, including Pearson Chi-square tests and multivariable logistic regressions, were employed, with a significance level set at 0.05. *Results:* The study revealed a significant lack of awareness among healthcare workers about non-antineoplastic hazardous drugs, with 61.7% of respondents unaware of these risks. The correct use of PPE was reported by 90.8% of participants, with nurses showing higher compliance than other categories. Despite these precautions, 6.45% of exposed workers reported difficulties in conception, though this association was not statistically significant (OR = 1.25, p = 0.802). *Conclusion:* The findings highlight the need for improved training and stricter enforcement of safety protocols regarding hazardous drug handling. While PPE use is widespread, the lack of awareness about non-antineoplastic drugs and reported reproductive issues suggest current measures

may be insufficient. The study advocates for implementing advanced protective technologies and continuous education to better protect healthcare workers and meet evolving safety standards.

Keywords: Hazardous Drugs, Reproductive Toxicity, Personal Protective Equipment (PPE), Healthcare Workers, Occupational Safety

Introduction

Workplace safety within the healthcare sector is crucial for both protecting workers from occupational hazards and ensuring the safety of patients. European and national regulations, including Italy's Legislative Decree 81/2008, establish stringent measures to prevent occupational accidents and diseases, emphasizing the use of personal protective equipment (PPE) and continuous training for healthcare personnel. The COVID-19 pandemic has further exposed vulnerabilities in the healthcare system, particularly in the area of worker safety, reinforcing the need for robust and effective safety management practices (1-2).

Hazardous drugs, defined by their carcinogenicity, teratogenicity, genotoxicity, organ toxicity, and reproductive toxicity, represent a significant risk to healthcare workers. European Union Directive 2022/431 and Regulation (EC) No 1272/2008 (CLP) set forth clear criteria for the classification of hazardous substances, requiring member states to implement protective measures by April 2024 (3). Italy's incorporation of these directives into national law through Legislative Decree 81/2008 has reinforced the necessity of risk assessment and the implementation of safety protocols for the handling of both oncological and non-oncological drugs (1). Healthcare workers face substantial risks when exposed to hazardous drugs via inhalation, skin contact, ingestion, or accidental needlestick injuries. These exposures can lead to acute effects such as dermatitis, respiratory irritation, and gastrointestinal disturbances, as well as chronic outcomes including neoplasms and reproductive toxicity (4). The importance of occupational safety in healthcare extends beyond the immediate protection of workers; it is integral to maintaining high standards of patient care. Approximately 12.7 million workers in the European Union are potentially exposed to hazardous drugs, with 7.3 million being nurses (5). These figures underscore the scale of the issue and the critical need for stringent management of occupational safety, particularly concerning the handling of hazardous drugs. Italian Legislative Decree 81/2008, which integrates European directives on workplace safety, mandates specific protections for healthcare workers dealing with hazardous substances, including strict protocols for the use of PPE (1). The COVID-19 pandemic has underscored the need for continual improvement in safety practices and risk management within healthcare. The

pandemic highlighted how inadequate PPE and insufficient preparedness could exacerbate stress and increase the risk of occupational hazards for healthcare workers (6). The implementation of preventive and protective measures, such as the use of hoods and Closed System Transfer Devices (CSTDs), is vital to ensuring the safety of personnel. Legislative Decree 81/2008 mandates the use of appropriate PPE and regular training to mitigate these risks effectively (1). Recent regulations, such as Directive (EU) 2022/431, have further emphasized the need for advanced protective measures, including the adoption of closed systems for handling hazardous drugs (3). These systems are designed to prevent contamination and reduce the exposure of healthcare workers to harmful substances. Additionally, continuous training and education for healthcare workers on the correct use of PPE and the handling of hazardous drugs are essential components of a comprehensive risk management strategy (7). The consistent application of safety measures, the ongoing training of healthcare workers, and the adoption of advanced protective technologies are essential to safeguarding the health and well-being of those working in the healthcare sector. This study aims to assess the impact of accidental exposure to hazardous drugs on hospital workers, focusing on the effectiveness of PPE in mitigating reproductive toxicity risks and ensuring compliance with safety regulations. The study's findings will inform future interventions aimed at enhancing workplace safety policies in healthcare settings.

Materials and Methods

The research protocol described in this study was reviewed and approved by the Ethics Review Committee of the University Hospital of Palermo. All participants involved in the study provided informed consent prior to completing the questionnaire, in accordance with current ethical guidelines. The study is of an observational cross-sectional type. The study population is composed of healthcare personnel of the Azienda Ospedaliera Universitaria Policlinico di Palermo, Sicily, Italy, one of the largest hospital facilities in the Sicilian region. A questionnaire was administered to all healthcare personnel of the Hospital through the Intranet platform of the company network. The questionnaire was not mandatory and guaranteed anonymity, in no way could the authors trace the identity of the interviewee. Participants were informed of the importance of the study through internal communications and information meetings, which emphasized the value of their participation in improving workplace safety and working conditions. The possibility of completing the questionnaire at any time during the data collection period was guaranteed, facilitating participation even for personnel with irregular shifts. To increase the response rate, periodic reminders were sent via email and information posters were placed in different areas of the hospital. The questionnaire was designed

to be completed in approximately 15-20 minutes, minimizing the impact on participants' working time. A specific questionnaire on exposure to hazardous drugs, adapted from the guidelines of the National Institute for Occupational Safety and Health (NIOSH), Employment Hazardous Drug Exposure Questionnaire. The questionnaire is divided into the following sections: demographic data, exposure to hazardous drugs, use of personal protective equipment (PPE), symptoms and health problems, awareness and knowledge of risks, accidental exposures. Data collection took place over a period of six months, from January 2024 to June 2024, divided as follows:

- Initial Phase (First month): Distribution of the questionnaire and initial information communications. In this phase, the focus was on raising awareness among staff about the importance of participating in the study;

- Intermediate Phase (from the Second to the Fourth month): Monitoring responses and sending reminders. During this phase, reminders were sent via email and information meetings were organized to further stimulate participation;

- Final Phase (Third month): Final data collection and closure of the questionnaire. In this phase, the focus was on reaching the last potential participants and solving any technical problems related to filling out the questionnaire.

Statistical analysis

For all qualitative variables, relative and absolute frequencies were calculated, categorical variables were analyzed with the Pearson Chi-square test. Logistic regressions were performed considering as dependent variables the correct use of PPE e independent variables: nurses, doctors or others. The level of statistical significance for the analyses was 0.05. The data were analyzed using the statistical software STATA, version 14 (8).

Results

The primary objective of the questionnaire was to examine various aspects related to exposure to hazardous drugs and their effects on workers' health. The topics covered included the frequency of exposure, risk perception, the presence of specific symptoms, and issues related to reproductive health. The collected data were analyzed to identify trends and correlations between the use of personal protective equipment (PPE) and the incidence of accidental exposures, as well as to evaluate the impact of exposure on conception difficulties.

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Sample description

The total number of respondents to the questionnaire was 233 workers, of whom 196 agreed to participate, and 37 declined. The distribution of participants was analyzed to obtain an accurate representation of the various operational units and professional categories involved.

The units analyzed included a wide range of hospital departments, including high-risk departments for exposure to hazardous drugs such as oncology, hematology, and nephrology (Table 1).

Table 1. Distribution of respondents by gender and age

Variables		**N**	**%**
Gender	Female Male	113 121	57,65% 61,73%
Average age	Female Male	46,8 49,3	
Job	Doctor Nurse Other	122 72 39	52,36% 30,90% 16,74%
Susceptible subjects? (atopy, previous haematological alterations, pregnancy or breastfeeding, immunodeficiencies, etc)	Yes No	55 141	28,06% 71,94%
Conceiving difficulty	Yes No	10 186	5,10% 94,9%
Exposed subjects showed symptoms?	Yes No	144 59	70,94% 29,06%
Have you ever noticed unwanted weight loss?	Yes No	9 187	4,59% 95,41%
Have you ever come into physical contact with dangerous drugs?	Yes No	36 160	18,37% 81,63%
Do you always use PPE correctly/always follow safety rules during exposure?	Yes No	178 18	90,82% 9,18%

Awareness of Non-Antineoplastic Hazardous Drugs

The collected data revealed that 121 out of 196 workers were unaware of the existence of hazardous drugs belonging to categories other than antineoplastics. This finding highlights a concerning gap in the training and information provided to healthcare personnel. A detailed analysis of awareness distribution showed that a significant portion of the unaware workers were medical personnel, constituting 23.6% of the total respondents. Nursing staff also exhibited a significant lack of awareness, representing

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19.7% of the unaware group. Additionally, 8.6% of the respondents belonged to other professional categories within the hospital environment.

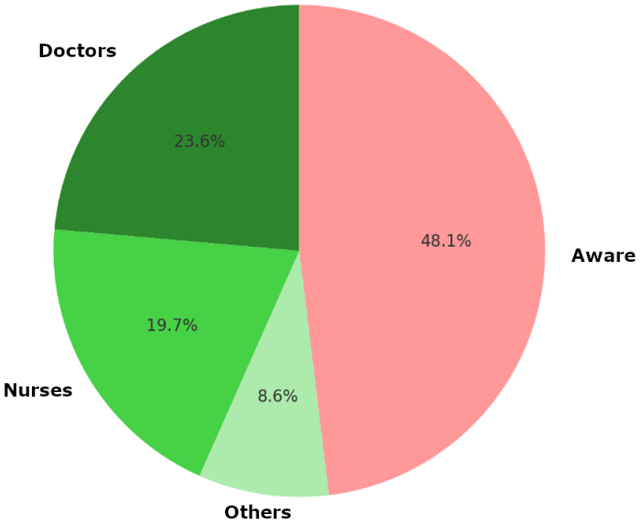

Figure 1. Distribution of awareness among Healthcare Personnel at AOUP. A detailed analysis of the sample indicated that awareness varied significantly among different operational units.

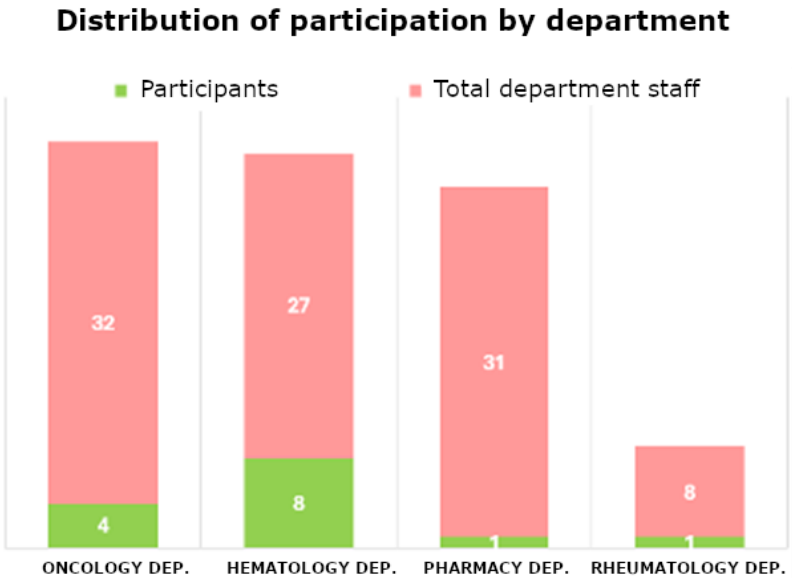

Figure 2. Oncology and pharmacy departments, where a higher sensitivity towards managing hazardous drugs would be expected, demonstrated a worrying lack of awareness. This suggests that even in high-risk departments, information about different categories of hazardous drugs is not adequately disseminated.

Healthcare personnel's awareness of the risks associated with non-antineoplastic drugs is crucial for ensuring workplace safety. Supporting the importance of these findings is the limited participation from departments where greater sensitivity towards the issue would be anticipated. The distribution of questionnaire participation by department reveals limited engagement in oncology, hematology, pharmacy, and rheumatology departments, which should have heightened awareness of the topic. Specifically, participation was 12.5% in oncology, 12.9% in hematology, 10.8% in pharmacy, and 25% in rheumatology. Moreover, the limited participation in departments where heightened sensitivity to the issue is expected underscores the importance of ongoing training and updates for personnel to ensure the quality of care and patient safety, without neglecting worker safety. This indicates that despite the anticipated sensitivity, there is a significant need to strengthen training and awareness strategies within healthcare facilities to improve the understanding and management of hazardous drugs.

Usage of Personal Protective Equipment (PPE)

The collected data indicate that the use of PPE, such as disposable gloves, varied among different professional categories.

As visible in Table 2, nurses reported more frequent use of gloves compared to doctors and other professional roles. Specifically, nurses reported using disposable gloves "always" in 82.26% of cases, "often" in 8.64%, "rarely" in 4.84%, and "never" in 4.84%. Doctors, on the other hand, used gloves "always" in 72.12% of cases, "often" in 16.67%, "rarely" in 5.56%, and "never" in 5.56%. Other roles reported "always" using gloves in 53.19% of cases, "often" in 7.69%, "rarely" in 15.38%, and "never" in 23.08%. This lack of participation may be due to various factors, including lack of time, perceived irrelevance of the questionnaire, or a general lack of awareness regarding the importance of managing hazardous drugs. While we acknowledge that the results may not be fully representative of the entire working population, the emerging indications remain relevant. Observing the row percentages, it is evident how frequently each category uses gloves. The column percentages, on the other hand, show which professional group is more represented in each practice of glove usage.

The Chi-square test was conducted to determine whether there is a significant relationship between the professional category (nurses, doctors, others) and the frequency of glove use. The Chi-square value obtained is 20.8067 with 10 degrees of freedom (chi2(10)) and the associated p-value (Pr) is 0.022, which indicates that there

is a statistically significant difference (at a 5% significance level) in the way different professional categories use gloves.

Table 2. Association between use of disposable gloves and job.

Use of disposable gloves	Nurses	Doctors	Others	Total
always	36.17%	53.19%	10.64%	100%
	82.26%	72.12%	57.69%	73.44%
often	16.67%	77.78%	5.56%	100%
	4.84%	13.46%	3.85%	9.38%
sometimes	33.33%	44.44%	22.22%	100%
	4.84%	3.85%	7.69%	4.69%
rarely	33.33%	66.67%	0%	100%
	1.61%	1.92%	0%	1.56%
never	15.79%	42.11%	42.11%	100%
	4.84%	7.69%	30.77%	9.90%
they are not provided to me by the employer)	50.00%	50%	0%	100%
	1.61%	0.96%	0%	1.04%
Total	32.29%	54.17%	13.54%	100%
	100%	100%	100%	100%
p-value = 0.022				

Table 3. The calculated Odds Ratios (OR) show a significant tendency for nurses to use PPE (gloves) compared to other categories (p < 0.05). Dependent variable: use PPE (gloves)

Job	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf. Interval]	
nurses	1 (base)					
doctors	2.935325	1.497951	2.11	0.035	1.079623	7.980685
others	5.522071	3.290316	2.87	0.004	1.717572	17.7537

Although the table indicates that doctors and other professionals have higher Odds Ratios compared to nurses, these data should be interpreted with caution. Nurses are used as the reference category with an Odds Ratio set to 1 (base), meaning that compared to nurses, the other categories are significantly less represented in the correct use of PPE.

This finding is particularly relevant as nurses, who are frequently involved in activities requiring PPE, such as administering medications or handling biological materials, demonstrate a greater awareness and stricter adherence to safety practices. The higher compliance with PPE use among nurses may reflect not only the specific training and emphasis on personal protection within this category but also their more frequent exposure to high-risk situations that necessitate such protections. Although other professional categories may appear to have a higher tendency to use PPE, it is important to emphasize that nurses show more systematic and consistent adherence to PPE use making this category a model for best safety practices in the healthcare setting.

Difficulty in Conception

The analysis revealed that 6.45% of exposed workers reported difficulty in conception, compared to 4.85% of non-exposed workers. The calculation of the odds ratio (OR) for difficulty in conception showed a value of 1.35, indicating that workers exposed to hazardous drugs are 1.35 times more likely to experience difficulty in conception compared to those not exposed. However, the OR adjusted for age, sex and job role registered a value of approximately 1.25, which is not statistically significant ($p = 0.802$).

Discussion

The results of our study indicate a significant lack of awareness among healthcare personnel regarding non-antineoplastic hazardous drugs. This finding is concerning, especially considering that adequate knowledge of risks is essential for ensuring workplace safety. The existing literature supports the idea that continuous and targeted training is crucial for improving the management of hazardous drugs in healthcare settings (4). The use of PPE, such as disposable gloves, was more frequent among nurses compared to other professional categories. This result suggests a greater sensitivity among nurses towards personal protection, although there remains a need to enhance training for other professional roles (9). The lack of statistical significance in the relationship between exposure to hazardous drugs and difficulty in conception could be attributed to the small sample size and the complexity of factors involved, as highlighted by previous studies (10). An important study has demonstrated that, despite the use of protective measures such as gloves and closed system drug transfer devices (CSTD), healthcare workers are still exposed to cytotoxic drugs (11). This study, conducted by Hon and Motiwala (2022), revealed that 71% of the articles analyzed reported at least one sample with detectable levels of hazardous drugs in the

urine of healthcare workers. The finding that many urine samples contain traces of hazardous drugs despite the adoption of protective measures suggests that current safety practices may not be sufficient to completely eliminate the risk of exposure (11). Another study from 2014, aimed at evaluating the effectiveness of closed system drug transfer devices (CSTD) in reducing environmental contamination by chemotherapeutic agents such as Cyclophosphamide, Ifosfamide, and Fluorouracil, observed a significant reduction in contamination, with a 20-fold decrease in glove contamination after the implementation of CSTD (12). This clearly demonstrates the effectiveness of CSTD in reducing exposure to hazardous drugs, but it also highlights the need to continue improving and refining these technologies to ensure optimal protection. Biological monitoring through urine samples has proven to be a particularly effective method for assessing exposure to hazardous drugs. Hon and Motiwala's study further showed that 55% of urine samples from healthcare workers contained detectable levels of Cyclophosphamide, with a maximum reported concentration of 2.37 ng/mL (11). This study underscores the importance of biological monitoring as a tool for identifying exposure risk factors and evaluating the effectiveness of control measures. However, the variability in urine contamination results across different studies highlights the need to standardize sample collection and analysis methodologies to obtain comparable and reliable data (11). A similar study from 2018 found that 46.66% of subjects had positive urine samples for Cyclophosphamide and 16.66% for Ifosfamide, indicating that exposure can occur even when using PPE (13). This suggests that while PPE is essential to reduce risk, it cannot guarantee complete protection on its own and must be used in conjunction with other safety measures such as CSTD and safe work practices. The importance of training and educating healthcare workers as an integral part of exposure control strategies has been widely highlighted in the literature. Combined interventions, such as the use of closed system drug transfer devices, educational courses, and policy updates, have been shown to significantly improve worker safety. For example, educational courses that thoroughly explain the risks associated with hazardous drugs and the correct handling procedures can significantly reduce accidents and unintentional exposures (10). A meta-analysis conducted in 2007 showed a trend of reduced exposure to antineoplastic drugs among nurses over the years, with a 40% reduction in hospital surface contamination and a 30% reduction in positive urine samples between 1997 and 2007 (14). This positive trend is attributable to the adoption of better safety practices, the widespread use of CSTD, and the continuous training of healthcare workers. However, the study also emphasized that despite these improvements, exposure has not been completely eliminated, and further efforts are needed to ensure complete worker safety. In the UK, in 2005, the exposure of pharmacy technicians was examined and found that, despite control measures, there were still traces of Cyclophosphamide and Ifosfamide in the urine samples of workers (9),

suggesting once again that the effectiveness of control measures depends not only on the technology used but also on adherence to safety procedures and continuous worker training. Biological monitoring through urine samples has proven to be a particularly effective method for assessing exposure to hazardous drugs. A 2015 study found that 55% of urine samples from healthcare workers contained detectable levels of Cyclophosphamide, with a maximum reported concentration of 2.37 ng/mL (15). The variability in urinary contamination results across different studies highlights the need to standardize sample collection and analysis methodologies to obtain comparable and reliable data (15). Additionally, the study by Hon et al. (2015) revealed that the use of PPE and environmental control measures, while helpful, does not always completely prevent exposure to hazardous drugs, as evidenced by detectable levels of Cyclophosphamide in workers' urine (16). This suggests that exposure may occur through inadequately controlled routes, such as dermal absorption or surface contamination. Finally, a 2022 study highlighted the need to standardize biological and environmental monitoring methods, including clear criteria for interpreting results, in order to improve the ability to assess and manage risks associated with hazardous drug exposure in healthcare settings (15). This is particularly important given that the lack of a standardized exposure limit further complicates risk assessment and the implementation of effective control measures.

Study Limitations

The main limitation of the study is the small sample size, which may have limited the ability to detect significant differences. Additionally, the analysis did not account for additional variables such as lifestyle, exposure to other substances, or pre-existing medical conditions, which could have influenced the results. Future studies with larger samples and a more detailed analysis of these factors could provide a more comprehensive understanding of the issues related to hazardous drug exposure.

Conclusions

Our study aims to emphasize the importance of adopting preventive measures and enhancing staff training on the use and handling of hazardous drugs. The literature review clearly demonstrates that exposure to hazardous drugs poses a significant risk to healthcare workers. Despite advances in control measures, such as the use of closed system drug transfer devices and PPE. and the growing adoption of biological monitoring. there are still significant challenges to be addressed. Future research should focus on developing standardized guidelines for biological and environmental monitoring. as well as evaluating the long-term effects of exposure to hazardous drugs. Only through a sustained commitment to research and the adoption of advanced safety measures will it be possible to adequately protect the health of

healthcare workers. It is crucial that healthcare institutions recognize the urgency not only of implementing the recommendations of the decree but also of developing new regulations to safeguard the health and safety of healthcare workers. Preventive measures include the implementation of Closed System Drug-Transfer Devices (CSTDs) and other safety technologies to reduce the risk of exposure. It is also essential to intensify the continuous training of healthcare personnel on best practices for the safe management of hazardous drugs. This can include specific training programs, workshops and refresher courses. Healthcare institutions might consider implementing specific and detailed continuous training programs for healthcare personnel, covering best practices for the safe handling of hazardous drugs. Such training should be mandatory and integrated into the professional development plans of healthcare staff. Moreover, healthcare institutions should regularly monitor and evaluate the effectiveness of the implemented safety measures, making necessary adjustments based on feedback and new scientific evidence. Healthcare institutions must work towards developing new regulations that address emerging needs in the global healthcare context. This may include revising existing guidelines, adopting international standards and promoting a culture of workplace safety. Our work is not intended to be merely an academic analysis, but it aspires to serve as an incentive for tangible change. Through the analysis of data collected at the Azienda Ospedaliera Policlinico of Palermo, we aim to contribute to the existing literature and offer insights for a revision of safety policies, in line with European directives and emerging needs in the global healthcare context. The adoption of preventive measures and the intensification of staff training are fundamental elements for improving workplace safety. It is vital to recognize and address the inadequacy of existing recommendations, working towards increasingly advanced standards of prevention and safety. With this spirit, we hope that the healthcare sector can evolve towards cutting-edge safety practices, ensuring a safe and healthy working environment for all healthcare personnel.

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