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Occupational Safety in Oncology Nursing: Findings from a National Survey on the Handling of Cytotoxic Substances in Germany

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***Abstract*– Background:** Oncology nurses in Germany are routinely exposed to cytotoxic drugs that are classified as carcinogenic, mutagenic and reprotoxic. Continuous or repeated contact, particularly in environments where containment systems and protective measures are inadequate or inconsistent, has been associated with incidence of adverse events, including malignancies, reproductive disorders, and genetic damage. Despite existing regulations in Germany and European directives, evidence suggests variability in protective practices and uneven implementation of guidelines. This study aimed to provide a comprehensive overview of training, protective measures, handling practices, and self-reported health outcomes among oncology nurses in Germany. **Methods:** A national cross-sectional survey was conducted by the European Biosafety Network in collaboration with the Konferenz Onkologischer Kranken- und Kinderpflege. The questionnaire captured demographics, awareness of guidelines, training frequency, availability of protective equipment, handling practices, occurrence of spills and leaks, reporting systems, and self-reported symptoms. **Results:** We received 1012 responses. The workforce was predominantly female (82.0%) and highly experienced, with 54.7% reporting over a decade of exposure to cytotoxic agents. While 60.7% indicated that refresher training was provided, one quarter reported receiving no such training. Familiarity with safety guidelines was inconsistent, with more than 40% unfamiliar or unsure. Access to basic PPE, such as gloves, was nearly universal (93.0%), but fewer than one-third (32.2%) reported access to closed-system transfer devices (CSTDs). Medical monitoring was absent in nearly two-thirds of institutions. Fluid leaks during administration were reported by 83.4% of respondents, with 10.6% describing them as occasional or frequent. A small but notable proportion (8.2%) reported symptoms associated with occupational exposure. Cross-tab analyses suggested cumulative exposure effects with a higher prevalence of symptoms among nurses with longer professional experience, and reduced leakage in settings using CSTDs. **Conclusion:** There are substantial gaps between regulatory standards and clinical practice in Germany. While variability in training, inconsistent access to advanced protective technologies, and limited surveillance measures leave oncology nurses vulnerable to unacceptable exposure levels. Greater standardisation, investment in closed-system technologies, and improved monitoring and reporting mechanisms are urgently needed to protect this workforce and align practice with international safety standards.

Keywords: Hazardous medicinal products, cytotoxic drugs, oncology nursing, occupational safety, protective equipment, Germany.

1. Introduction

Oncology nurses constitute one of the occupational groups most consistently exposed to cytotoxic chemotherapy drugs. These substances are classified as carcinogenic, mutagenic, and reprotoxic (CMR). Handling of these substances carries well-documented risks for healthcare workers. Reported adverse effects in healthcare literatures include acute symptoms such as nausea, dizziness, and dermatological reactions, as well as chronic outcomes including reproductive toxicity, genetic damage, and secondary malignancies [1,2]. Accumulating evidence indicates that even low-level, repeated exposure over time can result in measurable health consequences [3]. A 2024 systematic review further highlights that despite safety protocols, cancer nurses globally continue to perceive significant risks and experience barriers to safe handling in their daily practice [4].

To mitigate these risks, comprehensive occupational safety frameworks have been developed at both the national and

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international levels. In Germany, the *Technische Regeln für Gefahrstoffe* (TRGS 525) stipulate that employees handling hazardous substances must receive structured training, access to appropriate protective equipment, and, where applicable, health surveillance [5]. At the European level, Directive 2004/37/EC (Carcinogens, Mutagens and Reprotoxic Substances Directive), amended in 2022 (2022/431) to explicitly include hazardous medicinal products, requires Member States to ensure that workers are protected through substitution, closed-system technologies, and medical monitoring wherever feasible [6]. This has been further supported by the European Commission's 2023 guidance on the safe management of hazardous medicinal products, which emphasizes the hierarchy of controls [7].

Professional organisations, including the European Biosafety Network (EBN), the Oncology Nursing Society (ONS), and the Konferenz Onkologischer Kranken- und Kinderpflege (KOK), further recommend the adoption of closed-system drug-transfer devices (CSTDs), the use of personal protective equipment (PPE) as standard practice, and the implementation of environmental and biological monitoring programmes [8]. Despite these frameworks, studies continue to identify significant gaps in compliance and practice variation across healthcare systems. Research indicates that many nurses do not consistently use PPE, that training may be irregular or insufficient, and that reporting of occupational accidents is incomplete [9]. Furthermore, the adoption of closed systems remains uneven, with barriers including cost, institutional policy, and awareness among clinical staff.

The German healthcare context, characterised by a predominantly female and ageing nursing workforce and a delivery model in which chemotherapy has historically been concentrated in inpatient hospital settings, presents specific challenges for the consistent implementation of protective measures. To date, there has been limited national-level data on how oncology nurses in Germany handle cytotoxic agents in practice, and to what extent regulations and guidelines are effectively translated into daily clinical routines. This study addresses that evidence gap by reporting findings from a nationwide survey of oncology nurses in Germany. This study aimed to provide a comprehensive overview of training, protective measures, handling practices, and self-reported health outcomes among oncology nurses in Germany to identifying both strengths and gaps in current practice.

2. Materials and Methods

Study design and setting: A national, cross-sectional descriptive survey was designed. The study was conducted between March and May 2025 by the European Biosafety Network (EBN) in partnership with the Konferenz Onkologischer Kranken- und Kinderpflege (KOK).

Participants and Recruitment: Participants were oncology nurses and related healthcare professionals engaged in the preparation, administration, or handling of cytotoxic substances. Recruitment was conducted via professional networks, oncology nursing associations, and institutional mailing lists across Germany. Participation was voluntary, and all respondents provided informed consent prior to beginning the survey. The targeted sample size was 1,000. Surveys were considered complete if the respondent provided full demographic data and completed at least 80% of the core survey items.

Survey Instrument: The questionnaire comprised multiple sections: demographics, training and guideline awareness, availability of protective measures, handling practices, experiences of exposure or accidents, and self-reported health outcomes.

To ensure reliability, items regarding exposure risks, PPE compliance, and safety behaviours were adapted from established, validated survey instruments used in oncology nursing research [10-14]. Content validity was established through a peer-review process involving independent subject matter experts in oncology nursing and occupational hygiene to confirm clarity, relevance, and alignment with current German occupational safety regulations (TRGS 525). The instrument included closed-ended questions, multiple-choice items, and ordinal scales to assess frequency (4-point scale: Never to Frequently) and process evaluation (3-point scale: Well organized to Not organized).

Data Collection: The questionnaire was hosted on SoSci Survey (SoSci GmbH, Munich, Germany), a secure online platform compliant with the General Data Protection Regulation (GDPR). No personal identifiers (e.g., names, IP addresses) were collected to ensure anonymity. Access to raw data was restricted to the research team.

Statistical Analysis: Data were exported into R Studio (R Foundation for Statistical Computing, Vienna, Austria) for analysis. Descriptive statistics (frequencies and percentages) were used to summarise demographic characteristics and response patterns. Open-ended questions were analyzed categorially to identify common themes in list types and symptom descriptions. Likert-type scale responses were aggregated to assess trends in safety perception. Crosstabulations and chi-square tests of independence were conducted to explore associations between key variables, including years of experience, workplace setting, and the use of protective technologies.

3. Results

Demographics: A total of 1,012 respondents provided complete demographic information. The age distribution was skewed towards older cohorts: 36.1% (n = 365) were aged 50 years or above, 28.0% (n = 283) were 40–49, 23.0% (n = 233) were 30–39, and 12.9% (n = 131) were 20–29. The sample was predominantly female (82.0%, n = 829). The majority of respondents identified as oncology nursing staff (61.4%, n = 621) and reported working in inpatient care settings (71.8%, n = 726), with smaller proportions in outpatient oncology care (11.9%, n = 120). Participants were highly experienced; 54.7% (n = 547) reported over a decade of experience with cytotoxic substances, while 7.3% (n = 73) had less than one year of experience.

Training and Guidelines: Regarding ongoing education, 60.7% (n = 549) of respondents reported receiving refresher training on the proper handling of cytotoxic substances. However, 25.1% stated that no refresher training occurred, and 14.2% were unsure. Among those receiving refresher training (N = 236), the majority (72.5%) reported that it was provided annually. Familiarity with safety guidelines was reported by 58.6% (n = 528) of respondents, while 41.3% were either unfamiliar or unsure. Regarding workplace resources, 63.5% (n = 570) reported that an official list of cytotoxic substances was available at their facility, whereas 21.4% (n = 192) stated that no such list was available.

Protective Measures: Protective gloves were the most widely available form of personal protective equipment (PPE), reported by 93.0% (n = 756) of respondents. Special infusion sets were available to 76.8% (n = 624), respiratory masks (FFP2 or FFP3) to 63.3% (n = 515), and protective gowns to 57.1% (n = 464). Access to double gloves (40.5%, n = 329) and closed-system drug-transfer devices (CSTDs) (32.2%, n = 262) was lower. Regarding health surveillance, 64.3% (n = 520) reported that their institution does not conduct medical monitoring for employees exposed to cytotoxic substances. Only 17.4% (n = 141) indicated that such monitoring is in place. Similarly, environmental monitoring was limited, with 14.8% reporting surface contamination checks and 2.0% reporting biological monitoring. Figure 1 shows the availability of personal protective equipment (PPE) when administering cytotoxic substances.

Impacts and Accidents: 8.2% (n = 64) of respondents reported experiencing symptoms associated with cytotoxic exposure. The most common specific symptoms were skin reactions (13.1%), headaches (8.9%), and altered taste (6.5%). Regarding accident reporting, 57.3% (n = 441) indicated that occupational accidents were properly reported and tracked, while 35.8% (n = 276) were unsure and 6.9% (n = 53) stated that such accidents were not properly documented.
Fluid leaks from infusion systems or syringes were reported as occurring "rarely" by 66.6% (n = 522) of respondents, "occasionally" by 8.9% (n = 70), and "frequent" by 1.7% (n = 13). Only 16.6% (n = 130) indicated that leaks never occurred. Among respondents who reported "frequent" spills, 53.8% indicated that drugs were supplied prefilled, while 38.5% received non-prefilled medications.

Practices for the Handling of Cytotoxic Substances: The majority of respondents (95.3%, n = 758) reported that cytotoxic therapies are prepared in the pharmacy. While 79.9% indicated that therapies are foil-sealed and 78.1% stated they are prepared in bags, only 38.6% (n = 307) reported that therapies arrive already connected to infusion sets. Regarding administration devices, 78.6% (n = 619) of respondents reported using standard devices with Luer-Lock connections. By contrast, 19.4% (n = 153) indicated the use of additional protective components with a mechanical barrier, such as CSTDs. Figure 2 illustrates the different elements of proven cytotoxic therapy applications used. Users of standard Luer-Lock devices reported "occasional" leaks at a rate of 8.0% (n = 63), compared to 1.0% (n = 8) among users of closed handling systems with mechanical barriers. Figure 3 illustrate age distribution of “I don’t know” responses regarding awareness of cytotoxic substance lists (N = 115).

4. Discussion

The findings of this national survey reveal a workforce that is highly experienced but inconsistently protected against the risks of cytotoxic exposure. The demographic profile of respondents - predominantly female (82.0%) and aged over 40 - is consistent with the wider nursing workforce in Germany. From an occupational health perspective, this is critical, as gender-specific risks, particularly reproductive hazards, are an established concern when handling cytotoxic agents [3].

While most facilities provide initial instruction to new workers, the survey highlights a significant compliance challenge regarding ongoing education. One-quarter of respondents reported receiving no refresher training, and a further 14.2% were unsure of its provision. This gap has implications for both worker safety and institutional adherence to national guidelines (TRGS 525), which mandate regular instruction [5]. Furthermore, the fact that over 40% of respondents either reported inadequate accident reporting or lacked knowledge of the process suggests gaps in institutional transparency. A higher proportion of respondents which said they are not aware of a list of cytotoxic substances were over the age of 30. This uncertainty raises questions about whether healthcare staff are sufficiently engaged in safety procedures, as underreporting remains a persistent barrier to effective occupational safety in healthcare settings [9].

Although procedural safeguards such as written instructions are widespread, the application of systematic environmental and biological monitoring is limited. The majority of respondents reported no medical monitoring or surface contamination checks at their workplace. This suggests that while basic administrative controls are in place, the surveillance systems intended to detect and mitigate long-term health effects are frequently absent. Analysis of leakage frequency by connection technology reveals a clear protective advantage associated with closed-system drug-transfer devices (CSTDs). Users of standard Luer-Lock devices reported "occasional" or "frequent" leaks at a significantly higher rate than users of closed handling systems with mechanical barriers. Given the established risks of cytotoxic exposure, these results suggest that the wider adoption of CSTDs could substantially reduce accidental exposure incidents in German oncology settings, aligning with European recommendations [6, 7].

The data indicates a correlation between years of professional experience and the likelihood of reporting exposure-related symptoms. The majority of reported symptoms, such as nausea and vomiting, were concentrated among those with over 10 years of experience. This pattern suggests that chronic or cumulative exposure over time may contribute to a higher prevalence of self-reported health issues among senior staff, a trend consistent with prior occupational health literature [1]. Conversely, uncertainty regarding

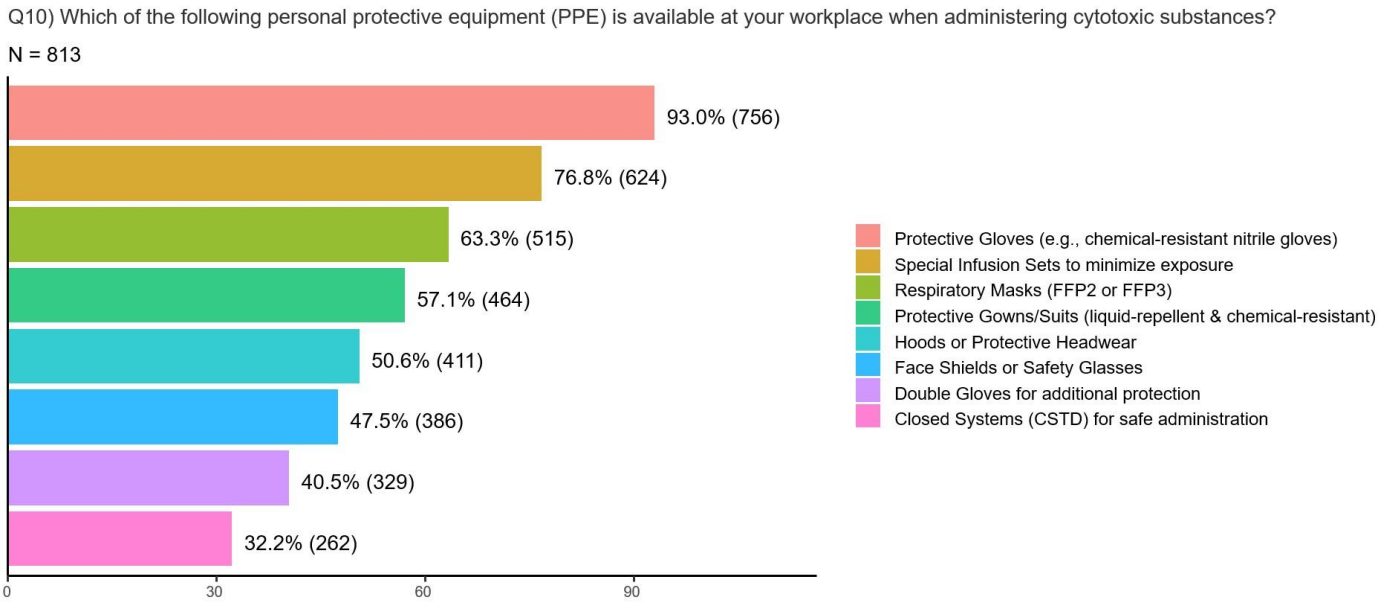

Figure 1. Availability of personal protective equipment (PPE) when administering cytotoxic substances.

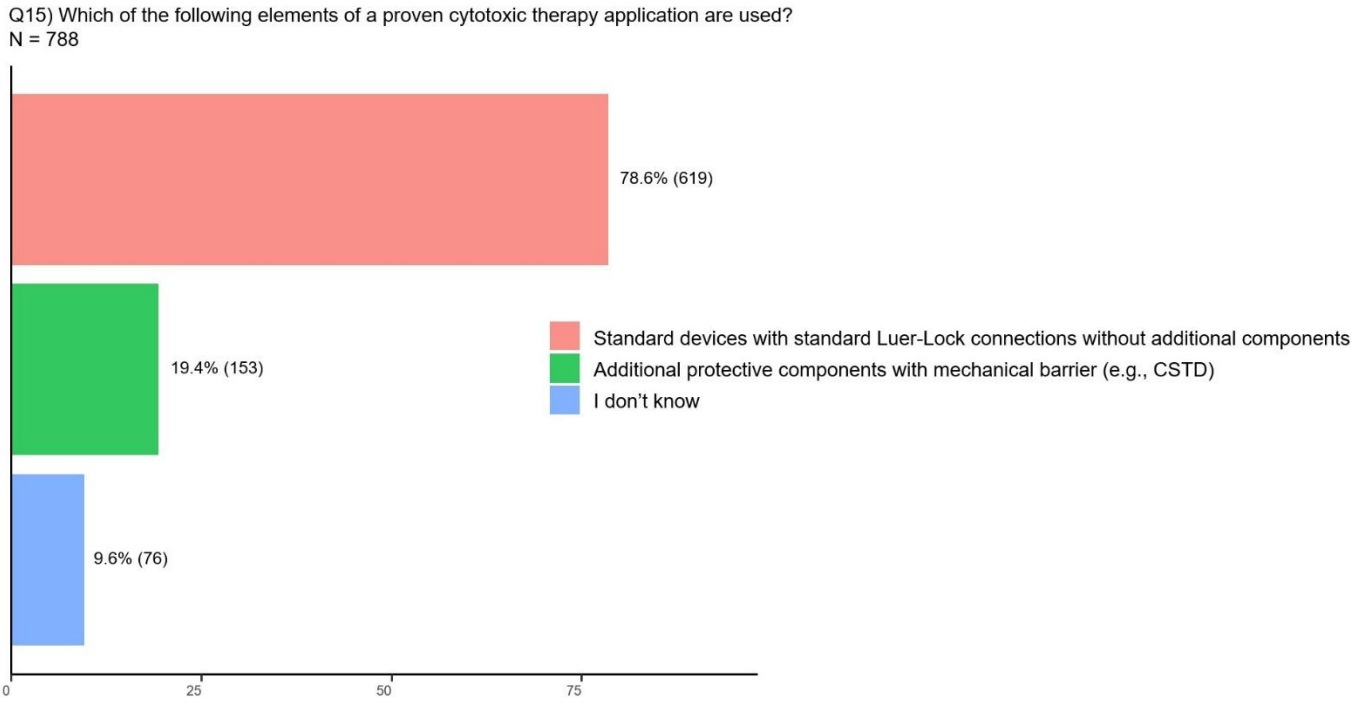

Figure 2. Elements of a proven cytotoxic therapy application used.

symptoms were highest among mid-career professionals, indicating a potential need for targeted education on recognizing occupational health impacts in this cohort.

A key strength of this study is its large sample size (N=1,012) and its focus on a specific national context following the implementation of new EU directives. The questionnaire provided clear insights into the practical reality of oncology nursing across Germany. However, limitations include the reliance on self-reported data, which may be subject to recall bias. Additionally, while the sample is large, it may not be fully representative of all outpatient settings, as the majority of respondents worked in inpatient care. Finally, the cross-sectional design allows for the identification of associations but cannot establish causality between reported practices and specific health outcomes.

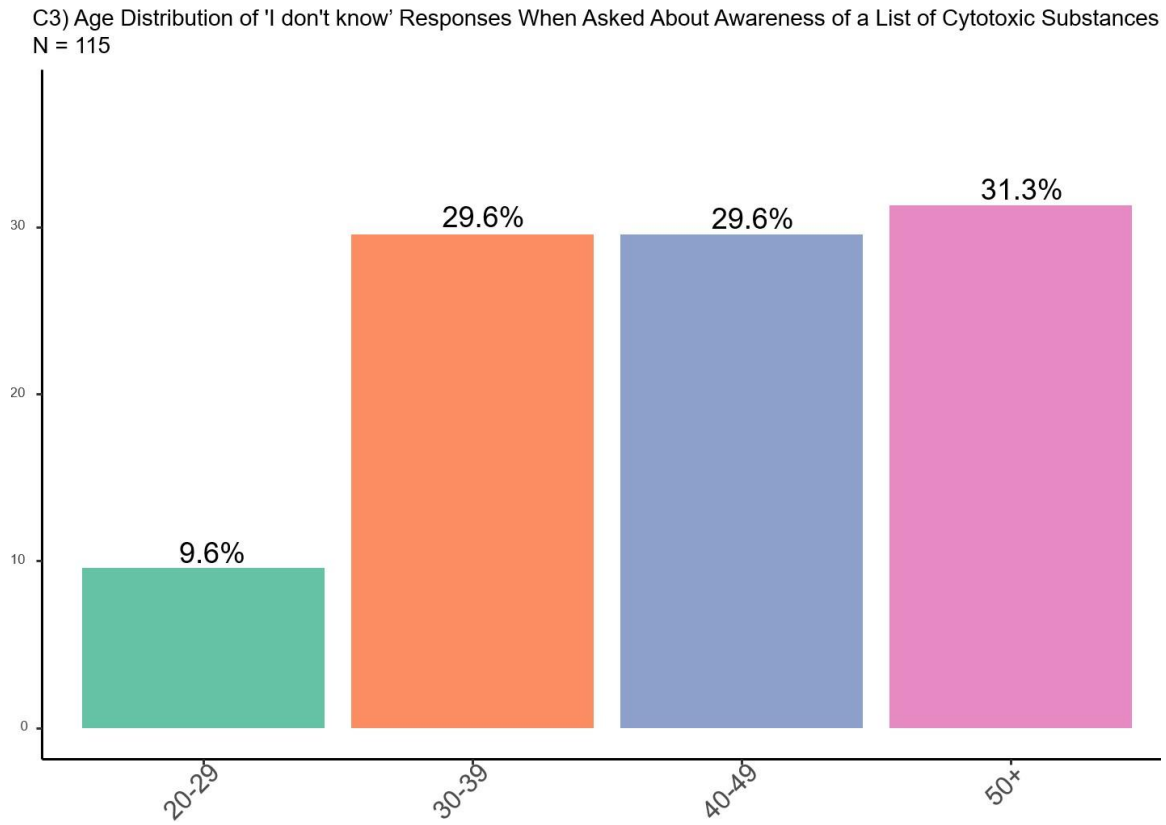

Figure 3. Age distribution of "I don't know" responses regarding awareness of cytotoxic substance lists.

5. Conclusion

This national survey highlights a significant gap between regulatory safety standards and clinical reality in German oncology care. While procedural safeguards such as written instructions are common, the implementation of technical controls - specifically closed-system drug-transfer devices (CSTDs) - and systematic medical surveillance remains inadequate. The persistence of leakage events, even among experienced staff, confirms that current practices are insufficient to prevent exposure. To protect the health of the oncology nursing workforce, it is essential to enforce the mandatory implementation of closed-system technologies and establish standardized, regular monitoring protocols in line with EU Directive 2022/431.

Conflict of Interest: This project was conducted by the European Biosafety Network (EBN) in partnership with the Konferenz Onkologischer Kranken- und Kinderpflege (KOK). The management of the project was funded through a transaction with Equashield; however, the study itself was independently designed, implemented, and analysed by the EBN and KOK. To ensure academic integrity and non-commercial oversight, all data collection and interpretation were peer reviewed by two additional independent experts in the field with no financial incentive. While industry funding supported the administration of the project, no sponsor had influence over the study design, data analysis, or final manuscript content.

Author Contributions: Josh Cobb and Loïc Frémond coordinated the overall project design, data analysis, and manuscript preparation on behalf of the European Biosafety Network (EBN). Prof. Dr. Patrick Jahn contributed to the survey design, dissemination, and interpretation of results as a representative of the Konferenz Onkologischer Kranken- und Kinderpflege (KOK). All authors contributed to drafting and revising the manuscript, approved the final version, and agree to be accountable for all aspects of the work.

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