Reducing the risks to nurses of working with hazardous cancer drugs

Freelance medical writer **Christine Clark** (cmclark@dermpharmacy.com) reports on the sixth annual online meeting held to discuss solutions to the risks encountered by nurses working with cancer drugs

Oncology nurses play a vital role in administering systemic anti-cancer therapy, but this comes with the ever-present risk of occupational exposure to hazardous drugs. Nearly 300 people joined the sixth annual webinar to discuss the results of research into the occupational exposure of nurses to hazardous drugs and the protective role of closed system transfer devices (CSTDs). The webinar, held on 24 April 2025, was organised by Aesculap Academia, the educational arm of B. Braun Medical Ltd. The earlier webinars in this series were reported in previous *BJN* Oncology Supplements (Clark, 2021a; 2021b; 2022; 2023; 2024).

The busy programme included presenting research findings on occupational exposure to cytotoxic agents, a study of the impact of CSTDs on surface contamination in clinical areas, a case study on implementation of closed systems for the administration of alemtuzumab and an extensive Q&A session.

Introducing the webinar, co-chair Naomi Clatworthy, Acute Oncology Nurse Consultant, Royal Devon University Healthcare NHS Foundation Trust, noted that an audience poll showed that 80% of respondents were 'very concerned' or 'concerned' about the health effects of exposure to systemic anti-cancer treatment (SACT). Co-chair Mark Foulkes, Nurse Consultant and Macmillan Lead Cancer Nurse, Royal Berkshire NHS Foundation Trust, commented that this 'shows the amount of concern' among nurses.

Exposure and health effects of hazardous drugs

Exposure to hazardous drugs remains a critical, ongoing concern in health care. Melissa McDiarmid, Professor of Medicine and Epidemiology, University of Maryland School of Medicine, traced its origins back to the chemical warfare agents used in the First World War. It was observed that mustard gas, an alkylating agent, caused lymphoid tissue shrinkage in animals, leading to its exploration for treating lymphomas. The alkylating agents became a regular part of cancer treatment in the 1960s and, by the 1970s, reports of second malignancies in treated patients began to emerge. This also raised concerns about the staff who handled the drugs.

In 1979, Falck et al demonstrated mutagenicity in the urine of nurses who mixed chemotherapy drugs (Falck et al, 1979). There was a clear dose-response relationship, with mutagenicity levels increasing throughout the working week and dropping during weekend breaks. This was 'the shot heard around the world', said Dr McDiarmid, and it triggered safe-handling efforts in the 1980s, leading to the development of guidelines by the American Society of Health-System Pharmacists (ASHP) and oncology nurses, and culminating in the comprehensive National Institute for Occupational Safety and Health (NIOSH) Hazardous Drug Guidance in 2004. The latest version was published in 2024 (Ovesen et al, 2024).

A hazardous drug is defined as an agent that is genotoxic, carcinogenic, teratogenic, or one that causes developmental or reproductive toxicity or serious organ toxicity at low doses. Importantly, newer drugs, including investigational new drugs, are also deemed hazardous if their structure and toxicity profiles resemble existing hazardous drugs. The International Agency for Research on Cancer (IARC) has classified many antineoplastics and even some antivirals and immune modulators as Group 1 carcinogens, meaning they are known human carcinogens.

Dr McDiarmid said that some colleagues think we have solved this problem and it is not a current issue; however, recent publications underline the commitment to safe handling. These include the International Society of Oncology Pharmacy Practitioners (ISOPP) *ISOPP Standards for the Safe Handling of Cytotoxics* (ISOPP, 2022), the European Trade Union Institute (ETUI) list of hazardous medicinal products (Lindsley and Musu, 2022), and guidance published by the European Commission (European Commission, 2023).

Recent studies reveal widespread environmental contamination; wipe-sampling studies consistently find drug residue on work surfaces in pharmacies and clinical areas. Contamination found on the surfaces of bags and syringes in pharmacy isolators can be carried to clinical areas. Studies also indicate that packaging from wholesalers can be contaminated, emphasising the need for glove use during unpacking.

Urine biomonitoring studies show that up to 60% of urine samples from exposed workers can be contaminated with the drugs they handle (Villa et al, 2021; Leso et al, 2022). This uptake leads to measurable biological effects. Studies, such as that by Roussel et al (2019), consistently demonstrate 'genotoxic biomarker insult', including increases in chromosomal aberrations and micronuclei, which are considered predictive of future cancer development, explained Dr McDiarmid. Specific research has linked handling alkylating agents to increases in chromosome 5 and 7 abnormalities, the same types of abnormalities seen in treated patients who develop second malignancies (McDiarmid et al, 2010).

Epidemiological studies have also shown increased relative risks for cancers (such as leukaemias and lymphomas) and spontaneous abortions in nurses and physicians handling these drugs (Skov et al, 1990; 1992; Hansen and Olsen, 1994; Petralia

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et al, 1999; Blair et al, 2001). The risk of spontaneous abortion for those exposed to anti-cancer drugs is twice as high, particularly early spontaneous abortions (Lawson et al, 2012).

Even newer therapies, including many targeted therapies, biotherapies and chimeric antigen receptor (CAR)-T-cell therapies, are increasingly recognised as reproductive toxicants or potential carcinogens, requiring hazardous drug-handling precautions, Dr McDiarmid said.

Managing the risks posed by hazardous drugs hinges on a comprehensive safe-handling programme using the hierarchy of controls:

- Engineering controls: physical barriers between the drug and worker, such as isolators and CSTDs
- Administrative controls: safe work practices, training and medical surveillance to monitor worker health and exposure. This also includes providing alternative duties for pregnant or breastfeeding individuals
- Personal protective equipment (PPE): gloves, gowns etc.

SACT syringes with CSTDs

The provision of SACT syringes with CSTD adaptors already connected (in the pharmacy aseptic unit) significantly reduces cytotoxic contamination during intravenous (IV) bolus administration, according to Louisa Knowles, Advanced Pharmacist for Technical Services, University Hospitals Birmingham NHS Foundation Trust. However, an audience poll showed that 80% of respondents do not receive SACT syringes with CSTDs already attached.

In the UK, SACT doses are usually prepared in pharmacy aseptic units in isolators that effectively separate the pharmacy workers from the hazards. CSTDs prevent the escape of drug droplets or vapour when hazardous drugs are transferred from one container to another, for example during preparation or administration. Their use therefore minimises the occupational exposure of nurses and pharmacy personnel to hazardous drugs, explained Ms Knowles.

According to the European Biosafety Network, the safe environmental threshold level is 0.1 nanograms (ng)/cm^2; below this level the drugs are not found in the urine of healthcare workers, Ms Knowles added.

Although a 2018 Cochrane review (Gurusamy et al, 2018) had concluded that the use of CSTDs was not associated with any reduction in occupational exposure, Ms Knowles found that she was frequently asked by nurses to provide cytotoxic injections with CSTDs already connected. NHS guidance recommending that CSTDs be attached by nurses on wards was considered to be outdated (NHS Pharmaceutical Quality Assurance Committee, 2018).

Ms Knowles undertook a study (Knowles, 2025) to determine whether adding a CSTD syringe adapter (Tevadaptor®, now Chemfort®) in the pharmacy aseptic unit reduced cytotoxic environmental contamination during IV) bolus administration.

Syringes of cyclophosphamide were prepared, 25 with standard caps and 25 with Chemfort Syringe Adaptor Locks. Cyclophosphamide was chosen as the test drug because it is commonly used and produces a colourless liquid, making spills less likely to be noticed than, for example, doxorubicin or epirubicin, which are red. Samples were collected from the syringe surface, the connect/disconnect point during administration and the nurses' gloves after administration. The samples were analysed using tandem liquid chromatography-mass spectrometry (LC-MS), with a detection limit of 7 picograms(pg)/cm^2.

The results showed a significant reduction in cyclophosphamide contamination with the Chemfort Syringe Adaptor Locks. On the syringe surface, 12 out of 25 standard capped syringes were above the safe limit (0.1 ng/cm^2), compared to zero with the Chemfort. On the connect/disconnect point, 19 out of 25 with standard caps were above the limit, compared to zero with the Chemfort. On nurses' gloves, 2 out of 25 with standard caps were above the limit, but zero with the Chemfort.

Ms Knowles concluded that the addition of Chemfort Syringe Adaptor Locks to syringes during preparation (in the pharmacy aseptic unit) significantly reduced the level of environmental cytotoxic contamination during IV bolus administration and that it would be beneficial to do this routinely.

Future work should investigate other CSTDs, other final containers (such as infusion bags or intrathecal products), contamination in the pharmacy setting, and extended shelf-life data, Ms Knowles suggested

The challenge of alemtuzumab administration

An audience poll showed that 67% of respondents experienced challenges with SACT drugs with variable administration rates. A further poll showed that about 40% now used closed systems for administration of both bags and syringes. This reflected an increase in the use of closed systems since the webinar series started, commented Mr Foulkes.

The introduction of a closed administration system (using Infusomat® Spaceplus pumps and Chemfort CSTDs) for alemtuzumab infusion streamlined the process, saved time for nurses and safely reduced the infusion time for patients, according to Ann-Marie Hamilton, Senior Clinical Educator, and Sara Rush, Clinical Educator, from The Christie NHS Foundation Trust.

Alemtuzumab is a monoclonal antibody used for immunosuppression as part of fludarabine, melphalan and alemtuzumab (FMC) reduced intensity allogeneic transplant conditioning. It must be given very slowly because of the potential for reactions such as rigors, rashes, hives, hypertension and tachycardia. Patients receive pre-medication comprising methylprednisolone, paracetamol and chlorphenamine 1 hour before administration.

At The Christie Hospital, local safe administration policies require all administration lines to be primed with saline prior to connecting the infusion bag containing the drug. For infusions such as alemtuzumab, which must be given by an incremental administration rate, this results in long infusion times. According to the standard operating procedure (SOP) for alemtuzumab infusion, half-hourly observations are required, starting at the point of administration.

'Effectively we were carrying out observations for a patient who is receiving saline for nearly 2 hours,' said Ms Hamilton. This has been a long-standing point of contention, she added. Because the total infusion can take up to 6 hours, the effects of the pre-medications begin to wear off, making patients more prone to reactions. Typically, reactions occur late in the infusion process. Sometimes infusions could take so long that they did not finish until late evening, she said.

The opportunity for change arose when the ward replaced its old infusion pumps and

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the administration process was reviewed in detail. Key objectives were to reduce infusion and observation times, enhance patient experience and minimise staff exposure to hazardous drugs. This was all achieved by implementation of a closed system using B. Braun Infusomat Space Line giving sets in combination with Chemfort CSTD components (with membrane-to-membrane connections). Using the pump's automatic priming function allows priming of the giving set with SACT (in this case alemtuzumab). This system ensures that patients receive the drug as soon as the infusion starts and the risks of staff exposure to SACT are much reduced. Thus, a closed system is assembled and, when the infusion is complete, there is no need to despike bags or disconnect; and the tubing and empty bags are 'sealed' when discarded, therefore eliminating the risk of environmental contamination with hazardous medicinal products drops and vapours.

At The Christie Hospital a before-and-after study including 13 patients receiving alemtuzumab showed that priming of the administration set with the drug solution saved an average of 1 hour and 50 minutes per patient (a total of 19 hours and 10 minutes). Critically, 35 nursing observations were avoided, corresponding to a nurse-time saving of 4 hours and 40 minutes. If these numbers were extrapolated to alemtuzumab administrations for 1 year, patient infusion time would be reduced by nearly 79 hours. This would make the experience better and safer for patients, and would also increase chair capacity in the ambulatory care unit. In addition, 17 hours and 20 minutes of nurse time would be liberated.

The Christie Hospital is thought to be the first centre to use this method to prime the giving set safely with hazardous medicinal products. It is now being applied to other slow-running drugs, including obinutuzumab, rituximab, anti-thymocyte globulin (ATG), glofitamab, and intravenous immunoglobulin (IVIG).

The B. Braun Infusomat Spaceplus and Chemfort system

There were two main technical challenges in the project at the Christie Hospital: first, safe preparation of monoclonal antibodies (mAbs) in a clinical area and, second, priming of the giving set with a hazardous drug, Marius Nicola, Market Development Manager, B. Braun Medical, told the audience. Priming the giving set with a hazardous drug meant that the giving set had to be transformed from an open-ended to a closed device. There was then the question of how to fill the drip chamber and purge air from the (now closed) giving set, he explained.

Figure 1. Attaching a Chemfort Syringe Adaptor Lock to a giving set patient connector (top). Making the loop back to the SACT bag by connecting to a Chemfort Connecting Set port (bottom). This loop allows priming the giving set with the drug, without risk of spillage and drops

B. Braun Infusomat Spaceplus technology, together with the Chemfort portfolio of CSTDs, provided the solutions. The Chemfort system prioritises ease of use with a linear connection and disconnection that gives an audible click when properly connected, ensuring the operator knows the system is securely closed. Chemfort's vial adaptors incorporate Toxi-Guard® technology, which automatically equalises pressure within the vial. This technology uses two membranes: a 0.2-micron membrane to maintain drug sterility by locking out air contaminants, and a charcoal cloth with active carbon to lock in hazardous drugs, thereby protecting both staff and medication. The portfolio includes adaptors for vials, syringes, intravenous bags and a Luer lock connector.

'So we transform any needle-free connection into a membrane-to-membrane device,' said Mr Nicola. Moreover, its low residual volume makes it suitable for small volume administrations, such as subcutaneous injections, he added.

In order to prime the B. Braun Infusomat Spaceplus primary giving set with the SACT solution, a Chemfort Syringe Adaptor Lock is attached to the giving set patient connector, converting it into a closed system. The primary giving set is then loaded into the pump and connected back to the SACT bag's secondary line via a Chemfort Connecting Set port (see *Figure 1*).

The automatic priming feature on the B. Braun Infusomat Spaceplus pump is then used to prime the line and purge air. Starting the infusion is a simple matter of selecting the drug from the inbuilt drug library. In future, this method could be applied to other drugs, reducing infusion time and saving nursing time, Mr Nicola suggested.

This type of approach can tackle a number of key challenges, namely prevention of occupational exposure to hazardous drugs, prevention of microbial contamination and elimination of avoidable delays in the administration of SACT. It may even help to relieve capacity pressures in pharmacy aseptic units.

These measures align well with NHS objectives of improving safety, patient satisfaction, productivity and workforce safeguarding, Mr Nicola emphasised. B. Braun supports implementation through a team of some 12 experienced clinical therapy specialists, who have years of NHS implementation experience. There is also a growing list of published data from institutions such as University College Hospital and The Christie Hospital. 'So you don't have to reinvent the wheel – just reach out to your colleagues and they can help,' he concluded.

Discussion

The discussion that followed highlighted varying practices, ongoing debates and the crucial need for evidence-based guidelines and improved staff awareness.

Wipe testing and contamination monitoring

Wipe-testing (swab-testing), while not a legal requirement in the UK or the USA, is recommended professional practice. Dr McDiarmid suggested that such testing should be performance driven, and initiated

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when new products, practices or equipment are introduced.

For NHS pharmacy aseptic units, Royal Pharmaceutical Society guidance recommends regular residue monitoring for drugs, including cytotoxics, at least annually, to verify cleaning efficacy (Beaney, 2016). Although this type of testing is often not performed in areas where nurses prepare drugs on wards, it was noted that, when open systems are used, contamination will invariably be detected. Mr Nicola commented that wipe-testing before implementation of a closed system will invariably give positive results. He suggested that it can be useful to validate effectiveness and good procedure after implementation of closed systems.

The role of CSTDs and implementation challenges

The adoption of closed systems for hazardous drug handling is seen as a way forward, but their widespread implementation faces significant hurdles. Addressing the question 'Why doesn't UKONS [UK Oncology Nursing Society] just tell people what to do?', Mr Foulkes explained that if they were to mandate closed systems this could have 'massive cost implications for hospital trusts'. There would be 'pushback' and a demand for robust supporting evidence.

He acknowledged that the meta-analysis sponsored by UKONS (Gurusamy et al, 2018) had failed to demonstrate robust evidence for CSTDs but this may have been due to the Cochrane methodology employed. Another UKONS-sponsored project is looking at how nurses' attitudes to SACT have changed over the years. When asked to comment on the practice of preparing mAbs in clinical areas, UKONS issued a strongly worded position statement to members, saying that it should be undertaken only on an emergency (short-term) basis and that closed systems must be used.

Staff are encouraged to challenge unsafe practices within their own organisations, commented Ms Clatworthy. The Royal College of Nursing and other groups are currently formulating position statements on the handling of hazardous drugs, she added.

Staff training

There is a clear consensus that current training and awareness around hazardous drug handling needs significant improvement, with more emphasis on safe handling, SACT administration and educating staff about potential long-term side-effects. Staff should also be informed about the evidence for long-term risks associated with SACT handling.

Staff who are breastfeeding should avoid mixing or administering SACT. Suitable tasks for breastfeeding staff should be identified in advance by managers so that there is no confusion when the situation arises, said Dr McDiarmid. Furthermore, staff who are not SACT-trained should not deliver immunotherapy, because it requires specialist skills to ensure patient and worker safety, Mr Foulkes confirmed.

Personal protective equipment

Goggles are not routinely worn for preparation of mAbs in clinical areas in the USA, according to Dr McDiarmid.

Regarding PPE, British law specifies standards for the thickness of gloves, aprons and appropriate masks for handling SACT, said Mr Foulkes. Despite this, there are large variations and a lack of standardised practice across different areas. Although full gowns are not typically used in the UK, aprons are common. Concerns were also raised about staff not using any PPE, or even gloves, in some settings, highlighting a critical safety gap.

A question about precautions when preparing infliximab prompted comments about the wider issue of identifying hazardous products. Dr McDiarmid advised staff to double-check the manufacturer's data sheet. In the early days, mAbs were felt to be low risk because their high molecular weight (more than 500 Daltons) could prevent absorption through the skin, but this is not true for mucous membranes or cuts, she explained. Highly lipid-soluble drugs could also be absorbed more easily via those routes, she added.

Other important safety considerations include:

- Exposure monitoring: there is no single device to monitor overall staff exposure to multiple hazardous drugs – staff could handle up to 40 different drugs in one week. Current methods are drug specific and look at specific areas, for example air in the breathing zone or hotspots on gloves
- Laundering uniforms at home is not recommended, unless full gowns are worn for SACT administration (and removed afterwards)
- Spiking and despiking of chemotherapy bags at the bedside is generally discouraged, unless absolutely necessary.

Conclusions

This meeting was the sixth in a series designed to examine the risks for nurses of exposure to hazardous drugs and the measures that can be taken to mitigate them. There was general recognition that nurses are exposed to hazardous drugs during administration and disposal of SACT and also during preparation of mAbs at ward level. Several conclusions can be drawn from the presentations:

- Appropriate provisions for risk management and ongoing monitoring of staff should be implemented
- Risk management measures should follow the hierarchy of controls and use the strongest available methods first, that is: start with engineering controls such as CSTDs
- The long-term effects of exposure to monoclonal antibodies are as yet unknown but CSTDs should be used when they are prepared on wards in order to minimise the risk of exposure
- A study showed that the provision of SACT syringes with CSTD syringe adaptors already connected (in the pharmacy aseptic unit) significantly reduces cytotoxic contamination in the clinical area during IV bolus administration (Knowles, 2025)
- The implementation of the closed systems, B. Braun Infusomat Spaceplus pumps, Cyto-Set Airstop® dedicated sets and Chemfort CSTDs for alemtuzumab administration, saved time for nurses and patients and freed up chair capacity in the day unit.

Ultimately, the goal is to foster a culture of healthy respect for hazardous drugs, encouraging continuous learning and the creation of safer working environments. **BJN**

Declaration of interest: This article is based on presentations and discussion at the webinar held on 24 April 2025 by Aesculap Academia (the educational arm of B. Braun Medical). The presenters Louisa Knowles and Sara Rush received honoraria

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Research Skills for Nurses and Midwives

By Sue Dyson and Peter Norrie

This book aims to provide nurses and midwives with a sound theoretical knowledge base for understanding, critically appraising and undertaking research in all areas of health service provision. A comprehensive insight is provided into philosophies, methodologies and methods relevant to health care, using examples from both professions.

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