



Safety in cytostatic compounding: the impact of automation

Alicia Tavella

A report of B Braun satellite symposium held on Thursday, 26 March 2009 at the 14th EAHP Congress, Barcelona, Spain.

The SafeChemo project (Eur J Pharm Prac. 2008;14(1): 83-4), carried out by a consortium of commercial companies and healthcare providers, set out to demonstrate the feasibility of robotic compounding of cytostatic drugs. This article reviews the challenges of safe cytostatic compounding and the benefits achieved with the automated system.

Technological solutions are highly effective barriers to patient harm, whereas other measures such as redesign of procedures, storage or labelling of medicines tend to have less impact in the long term, according to Ms Cathy Mooney (Director of Governance and Corporate Affairs, Chelsea and Westminster Hospital, London).

Medicines are recognised to be one of the highest risk areas and are always in

the top three most commonly reported incident types, she explained. Errors are costly both financially as well as in terms of reputation – and a good reputation is critical for a hospital today, she added. Reporting of errors is becoming more open in the UK and there are two key developments in this area. First, the National Patient Safety Agency has identified a list of “never events,” such as administration of chemotherapy by the wrong route, which should never happen if the correct preventative measures have been implemented. Second, incident reporting rates for individual hospitals are now published – although it requires great effort to persuade the public that a high reporting rate is good, she added.

Systems that rely on revised procedures and staff training tend to be weak barriers to harm and there are many other situations where harm could be avoided by using a technology-based approach, said Ms Mooney. One example was a situation where gentamicin was prescribed for neonates every 36 hours. It was given every 12 hours as a result of a transcribing error in the paper-based prescribing system. “There was no technological trigger to correct the prescribing,” said Ms

Mooney. Another example was a patient who was given albumin that was intended for the patient in the next bed. “A bar code check (of patient and product) could have significantly improved safety in this situation,” commented Ms Mooney.

Patients have a right to expect safe care and staff have a right to be protected in their work. In order to achieve these things we should invest more in technology, Ms Mooney concluded.

Safety challenges

The present manual system for preparation of cytostatic doses poses risks of exposure to cytostatic drugs, and repetitive strain injury (RSI) to the operators and risks of medication errors to patients, Ms AnnSofie Fyhr (Deputy Pharmacy Director, University Hospital of Lund) told the audience.

In Sweden some 340,000 doses of cytostatic drugs are made annually in 29 different hospitals. The majority (65%) are made in biological safety cabinets and the remainder (35%) are made in negative-pressure isolators. The most commonly prepared drugs are 5-fluorouracil, cyclophosphamide and cytarabine.



Professor Ann Jacklin



More than 400 participants attended

A recent survey in Sweden had found that the people involved in this type of work felt stressed by high workloads and experienced problems with finger and thumb grips. They also complained of problems with noise and felt they had poor job control.

Environmental contamination with cytostatic drugs is another important issue. The exterior surfaces of drug vials can be contaminated with cytostatics and this has been a particular problem with many drugs including cyclophosphamide, cisplatin and methotrexate. Another source of contamination can be leakage during preparation. In Sweden this problem is minimised by checking operator techniques when they are trained and then every three years using radio-labelled technetium as a tracer, explained Ms Fyhr. Studies of environmental contamination in pharmacies and on hospital wards have shown that low levels of cytostatic agents are found in many places. In one Swedish hospital the highest levels were found in patients' lavatories. For this reason the cleaning staff now wear protective gloves, noted Ms Fyhr. Research carried out in Denmark showed that the level of contamination was unrelated to the number of doses made.

In Sweden a computerised system is used to generate production protocols and labels. Pharmacists also have access to the computerised physician order entry (CPOE) system. In addition, prescriptionists double-check the six-digit drug identification number, the patient name, the drug volume, diluent, infusion set and label.

A computerised system is also used for error reporting. One important category of error is discrepancies between the order and the product that is finally delivered to the ward. Approximately 10 reports are received each month. Delivery errors are the most common followed by errors in labelling, dose, diluent and infusion sets. Between 1996 and 2008, 26 reports of serious adverse event have been logged. "Wrong drug" (11) and "wrong dose" (9) were the most common followed by "wrong pump system" (4) and "wrong label" (2).

Impact of automation

Use of CytoCare robot has increased

safety for the staff by reducing the risk of RSI, exposure to cytostatic agents and needle stick injury. In addition, excess workload and the resultant stress have been reduced and staff satisfaction has increased. Professor Ann Jacklin (Chief of Service Pharmacy and Therapies) described how the CytoCare robot had been introduced at the Imperial Healthcare NHS Trust.

A total of 29,500 doses of cytostatic doses are made each year in aseptic units in two hospitals (Charing Cross Hospital and Hammersmith Hospital).

Professor Jacklin emphasised the importance of providing the right product for the right patient whilst ensuring that microbial and particulate contamination are kept to the minimum and cross-contamination with other products is avoided.

Another important consideration is staff safety. RSI was identified as being a major risk for the trust and funding was provided for additional staff, she explained. Occupational exposure to cytostatic drugs, stress and heavy workloads and the ever-present fear of needle-stick injury are all things that worry staff and can make it difficult to recruit new staff.

The increase in day-patient and outpatient treatments has led to increasing demands for prepared doses of cytostatic drugs. Moreover, the service needs to be faster and more responsive to match current treatment schedules and expectations. "Doctors do not understand why we cannot make cytostatic doses at 8:00 pm," she said. However, until recently, the preparation processes were largely manual and highly regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA), and so there was very limited capacity for expansion.

Preparation of cytostatic doses had been centralised in the pharmacy for safety reasons and a number of other measures to reduce risks had been introduced. These include dose-banding, the use of standardised doses, purchase of ready-to-use products from the industry and the use of oral chemotherapy when possible. Although these measures were important for safety they made little

impact as the overall workload continued to grow.

"Automation was the next logical step," said Professor Jacklin. The CytoCare robot incorporates a number of important features including photo-recognition of ingredients, weighing of products to check accuracy, efficient disposal of waste and bar-code identification of final products. "It is exquisitely engineered and will work all day without meal breaks," she added.

Extensive validation testing was done and the MHRA gave its approval for use of the robot in principle in November 2008. Use of the robot started using a stepped approach, starting with a single product – 5-fluorouracil syringes – and progressively adding more products to take over more and more of the overall workload. "Once carboplatin and cisplatin are added, approximately 35% of the workload will be processed by the robot," explained Professor Jacklin.

One immediate benefit of the robot was the facility to share drug vials between patients. Previously this had not been possible because a separate process was required for each patient. The impact on staff safety has been considerable. The risk of RSI has been dramatically reduced and exposure to cytostatic agents has fallen. Stress for staff had also been reduced and because a lower level of training is needed to use the robot, staff flexibility has increased. The opportunities for needle stick injury have fallen from six to one per product and with the next upgrade the risks of needle-stick injury will be eliminated altogether.

In summary, Professor Jacklin said that the process is now more efficient and is delivered by staff who are less-pressured and more flexible.

Author

Alicia Tavella, MRPharms
Head of the Oncology Compounding
Department, and
Deputy Pharmacy Director
Azienda Sanitaria dell'Alto Adige
Comprensorio di Bolzano
4 Via Cassa di Risparmio
I-39100 Bolzano, Italy
alicia.tavella@asbz.it