

Automating the preparation of chemotherapy in a UK Pharmacy department

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Automated solutions for preparing individual doses of chemotherapy are starting to be marketed in Europe. CytoCare, an automated solution for preparation of individual patient doses of chemotherapy was installed at Charing Cross Hospital, UK, in January 2007

The benefits of using automated systems in a dispensary setting is well recognised, however until very recently the use of automation in aseptic preparation has been limited to automated pumps used in the preparation of parenteral nutrition and batches of other products. Automated solutions for preparing individual doses of chemotherapy are starting to be marketed in Europe. In January 2007 the pharmacy department at Charing Cross Hospital (part of Imperial College Healthcare NHS Trust, London) took delivery of a CytoCare, the first installation of its kind in the UK and one of the first in the world.

What is CytoCare?

CytoCare comprises three enclosed laminar flow cabinets fitted together: a materials transfer area, a materials store and a compounding area. There is a six-axis robotic arm situated in the compounding area. The arm withdraws doses of cytotoxic drugs from single or multiple vials, and transfers these doses to final containers. The system supports the full range of vial sizes currently on the market from which cytotoxic doses are prepared. A range of final containers can be prepared including infusion bags, 3ml, 10ml and 60ml syringes and elastomeric infusion devices (if pre-filled with saline).

The system has its own camera for vial recognition and a weighing scale to confirm each dose has been prepared accurately. Partially used vials are stored in the compounding chamber so they can be used to prepare any further doses of that drug required during a compounding session.

Anticipated benefits

We believed the use of this automated system would reduce the risk of repetitive strain injuries, minimise operator exposure to cytotoxics, decrease the risk of compounding errors occurring (eg, wrong drug, wrong diluent, wrong volume) and allow us to train and validate staff to prepare cytotoxics much more expediently than if being trained to use an isolator or work in a laminar flow cabinet.

Vial sharing is not approved by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for the manual preparation of individual patient

doses by solo operators. As the system allowed us to vial share using solo operators we believed it would deliver significant cost savings particularly when preparing high cost cytotoxic doses.

Project management

A business case was prepared based on these perceived benefits, particularly cost savings, and was approved by the Trust's Executive Board in October 2006. At this point a Project Board was set up to oversee the installation, validation and operational use which initially consisted of the chief pharmacist, the pharmacy lead for aseptic services and the quality assurance manager.

As the project progressed a larger Project Team was established which included other senior staff from the aseptic unit and QA. The project team met weekly to ensure the project remained on track.

Installation and validation at Charing Cross Hospital

CytoCare provides a class A compounding environment and we felt it should be treated like any other laminar flow cabinet and therefore installed it in a class B room. At the time of our initial interest in CytoCare, the aseptic unit at Charing Cross was being rebuilt. The rebuild was delayed until a decision on the CytoCare business case was made. As this was successful, the size of one of the class B rooms was increased to house the automation, and the air handling had to be adjusted to provide additional air supply to the room.

Following delivery of the system, the project team spent time becoming familiar with it and working with the manufacturers to understand fully how it worked. In May 2007 our original system was replaced with a new enhanced model with some of the improvements being based on the comments made by the project team at Charing Cross. It became very obvious when we began testing the new machine that the main chamber got extremely hot (up to 37°C) very quickly. Further work with the manufacturers resulted in a cooling unit being provided to keep the main chamber at a temperature below 25°C; once this was resolved we were able to begin our validation work.

We did have some product failures initially due to lower than expected fill volumes relating to air ingress

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into syringes, as would be expected with the first installation of its kind, but close collaboration with the manufacturer has meant that these have been resolved such that we are now in operational use.

Our validation work was carried out as part of the SafeChemo project; an EU sponsored project involving three hospitals (Charing Cross, Bolzano in Italy and Copenhagen in Denmark). The aim of the SafeChemo project was to carry out a market validation of CytoCare. On top of the traditional validation work the project also examined efficiency and human aspects related to CytoCare, full details can be obtained at www.safechemo.com.

After confirming the software was Good Automated Manufacturing Practice (GAMP) compliant, the validation work included the following:

- Recognition of ingredients.
- Sterility of final products and operator validation.
- Sterility of partially used vial.
- Physical monitoring.
- Cross product contamination.
- Precision of preparation.
- Validation of the internal balance.

Our main concern right from the moment we first saw CytoCare was how we would clean it. It is fitted with ultraviolet (UV) lights and these provide a key part of the cleaning schedule. UV lights are not something we routinely use in the UK for sanitising clean room equipment and we were surprised at their effectiveness. We have had very good results for microbiological cleanliness which demonstrate that our concerns over cleaning and maintaining an aseptic environment were misplaced. The validation work was completed and based on this, the system was approved for use in principle by the MHRA in November 2008 and we began preparing live doses for administration to patients from 10th November.

Prior to going live we produced over thirty standard operating procedures relating to the use and maintenance of the robot. We also briefed nursing staff in our oncology day care as using CytoCare meant they were presented with syringe labels that were different to those they were used to. Most importantly we briefed all nursing staff that as we would be moving to weight as our measure of preparation accuracy and there is variation in the graduations of syringes some doses may appear to have a slightly different volume in the syringe than indicated on the label.

Operational Use

The project team decided to take a phased approach to operational use:

- Phase 1 : Solution into a syringe.
- Phase 2 : Solution into a bag.
- Phase 3 : Powder into a syringe.
- Phase 4 : Powder into a bag.
- Phase 5 : Other containers.

This decision was based on the complexity of preparing each dose making the simplest doses, in terms of preparation, first. A list of drugs which were suitable



Figure 1. The CytoCare robotic arm in operation

for preparation using CytoCare and which fitted each of these phases was produced and a decision was made initially to go live with one product, 5 fluorouracil (5FU), in syringes.

The reason for choosing 5FU was that it had high usage within the Trust, was cheap and was routinely prepared in advance. In January 2009 we moved to phase 2 and began preparing 5FU in bags and since then moved on to preparing bags of both cisplatin and carboplatin. So far we have prepared 338 syringes and 170 bags using CytoCare.

We have been able to lower the skill level of staff we can use to compound cytotoxics. We have started to train one of our pharmacy assistants, who were not previously trained to manually compound, to use CytoCare. We have found that it is both quicker and simpler to train staff to operate the CytoCare than to train them to manually compound. Our next steps, as reliability of operational use improves, will be to look at introducing further drugs based on the phased approach described above with paclitaxel and etoposide likely to be the next candidate drugs.

We have also been able to reduce the level of physical cleaning required on a daily basis. When we first began using the robot we took a "belt and braces" approach to our cleaning. As we have gathered more data over the past 2.5 years we have realised this is not necessary and as result we have stepped down the programme of the clean we carry out on CytoCare. On a daily basis cleaning now takes one person 10 minutes, the weekly clean takes around 30 minutes and monthly takes 2 people around 1 hour.

Conclusion

Our experiences so far would suggest that there is indeed a place for CytoCare within hospital aseptic services. We believe it will reduce repetitive strain injuries, improve operator safety, reduce errors and lead to increased efficiency. In hospitals where vial sharing is not current practice, it should also deliver significant cost savings. ■