

# First chemotherapy robot in use in London hospital

Compounding of a range of chemotherapy products is now being carried out by the world's first automatic compounder at Imperial College Healthcare NHS Trust. Ann Jacklin, chief pharmacist at the trust, explains how it works.

Since last month, compounding of all fluorouracil (5FU) products at Charing Cross Hospital, part of Imperial College Healthcare NHS Trust, has been carried out by a robot.

This marks the beginning of a new era for aseptic compounding and is expected to address capacity issues as well as improving the safety, accuracy and workflow of chemotherapy compounding.

The pharmacy departments across Imperial College Healthcare Trust currently prepare about 27,000 cytostatic doses each year, and production pressures are increasing (see the Background box, p40).

CytoCare, an automated compounding system owned by Health Robotics and distributed in the UK and Europe by B.Braun, was installed at Charing Cross Hospital about 18 months ago. Automated compounding of 5FU syringes began in November last year, and last month this was extended to 5FU infusions. Automated compounding of carboplatin and lower doses of cisplatin was expected to start as this issue of *The British Journal of Clinical Pharmacy* went to press.

## How it works

The CytoCare system prepares injectable solutions in a sterile environment. It comprises three laminar flow cabinets which provide a working environment that meets EU class A standards, and is designed to be kept in a room with a class B environment. The system takes up the same space as the laminar flow cabinets and isolators that were used previously in the trust's aseptic unit.

**Preparation** Pharmacy staff enter details of the patients' prescriptions into the system's computer and then load the robot with the drugs and containers required for production.



Health Robotics

The CytoCare unit takes up the same space as the laminar flow cabinets and isolators previously used

**Accuracy checking** The identity of each drug vial is confirmed by photorecognition software which does not rely on the presence of bar codes. Before compounding begins, the weight of the final container (e.g. syringe, infusion bag) is measured using a high precision scale.

**Compounding** The robot calculates the quantities of solutions that must be removed from each container, and mixes the products as required. The position of syringe plungers is read using a laser. Any powdered drugs are reconstituted and the system incorporates a device for shaking the vials to support dissolution. The final product is weighed again, and can then be unloaded by the technician and scanned to produce the final, patient-specific label. The whole production process takes two to three minutes for each product.

**Safeguards** The system includes safeguards to prevent cross-contamination, and contaminated air flow is contained using high-efficiency particulate air filters. The system also contains a hazardous waste container that seals automatically when full, to eliminate staff exposure to toxic waste.

## Vial sharing

A key benefit of the CytoCare system is that one vial can be used for a number of products. For manual compounding, the Medicines and Healthcare Products Regulatory Agency stipulates that product segregation must take place in units where compounders work alone — this means that the same vial cannot be used for more than one patient. This increases patient safety and prevents cross-contamination, but results in high levels of wastage of expensive drugs. With the CytoCare

system, partially full vials can be stored for future use. At Charing Cross Hospital, this alone has been estimated to save the trust £180,000 per year.

### Validity testing

Imperial College Healthcare NHS Trust is part of a consortium called the SafeChemo project — a market validation project, funded by the European Commission, to test new automated systems in chemotherapy. Two other pilot sites involved in the project are the General Hospital of Bolzano, Italy and the HS Pharmacy, part of Copenhagen University Hospital, Denmark.

Studies validating the safety and accuracy of CytoCare are now largely completed and the first results were released this month (see box on right).

To evaluate improvements in efficiency, process mapping is currently being analysed at each pilot site using a process improvement specialist. The HS Pharmacy in Copenhagen estimates that the 19 steps usually involved in compounding one product (from receiving the prescription through to the final product being dispatched) will be reduced to 8 steps.

Preliminary surveys of the views of aseptic staff have shown that almost 90% of them find the build-up of work at peak times stressful, over 70% worry about the risk of exposure to cytotoxic drugs, and almost 70% worry about repetitive strain injury. When asked whether they thought CytoCare will reduce their risk of exposure, about 50% agreed or strongly agreed, 30% disagreed or strongly disagreed, and 20% were undecided or did not answer.

### Background

The demand for ready-to-use injectable chemotherapy products is increasing as the number of cancer patients rises. This trend looks set to continue, with estimates from the World Health Organisation that cancer cases will increase by 50% by 2020.<sup>1</sup>

As well as a greater number of NHS patients, changes to the rules on paying for additional private care in England (see *The British Journal of Clinical Pharmacy* 2009;1:9) are likely to increase the number of private cancer patients. If NHS trusts cannot meet the demand for the supply of chemotherapy products they will lose business to other providers.

It is a challenge to increase capacity while ensuring patient safety and decreasing risk to the operator.

Dose calculation errors, prescription errors, and cross-contamination during IV compounding can all have fatal consequences.<sup>2</sup>

Pharmacy staff manually preparing chemotherapy risk exposure to cytotoxic drugs through inhalation, ingestion and skin contact.<sup>3</sup> Repetitive strain injury is a common problem for staff who manually compound drugs, and can cause problems with litigation and having to fund extra staff.

### Validation results

Preliminary validation results from the three CytoCare pilot sites were announced this month. These included tests for filter integrity, particulate contamination, microbiological cleanliness, sterility of prepared doses, sterility of partially-used vials, precision of preparation, correct vial recognition, accuracy of final container labelling and software reliability. CytoCare passed all elements of these tests.

For example, sterility of the compounded solution and partially-used vials was measured by adding tryptone broth to the syringes or vials and incubating them for 7 days at 20–25°C and

then for another seven days at 30–35°C. No microbial growth was observed.

Filter integrity was measured using the cold di-octyl phthalate (DOP) test. Cold DOP generators produce an aerosol at room temperature, with particles ranging in size from 0.2 to 1.2 microns. The aerosol was introduced to the unit and light scattering (due to particle concentration) was measured using a photometer at the inlet and outlet of the unit. The maximum permitted particle penetration is 0.01%. The maximum recorded concentration in the CytoCare tests ranged from 0.0002% in the loading area to 0.001% in the back of the compounding area.

### Next steps

The impact of the CytoCare system on aspects such as the accuracy of compounding, patient waiting times, staff time and MHRA requirements will be evaluated as part of the SafeChemo project, and results are expected to be published towards the end of this year.

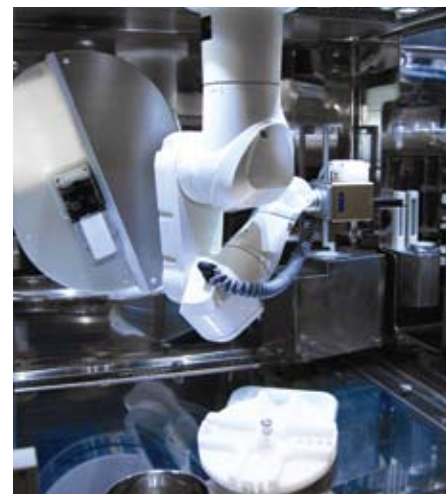
The next step for Imperial College Healthcare NHS Trust is to use CytoCare to prepare 5FU and cisplatin preparations for the other hospital sites in the trust, starting with Hammersmith Hospital. This will then be extended to the production of other cytotoxics as these are validated.

A future plan for the trust is installation of another product from Health Robotics — the 'IV station'. This is an automated compounding system designed for non-hazardous intravenous drugs, so would be suitable for ward-

based use, for example. The system is still under development, and an audit is currently being undertaken to assess the potential for the IV station to be used in the acute renal unit Imperial College Healthcare NHS Trust.

### References

1. Mason HJ, Blair S, Sams C, Jones K, Garfitt SJ, Cuschieri MJ, Baxter PJ. Exposure to antineoplastic drugs in two UK hospital pharmacy units. *Ann Occup Hyg* 2005; 49(7):603–610.
2. US Food and Drug Administration. Consumer Update: The special risks of pharmacy compounding. May 2007. Available at [www.fda.gov](http://www.fda.gov) (accessed 10 February 2009).
3. Stewart BW, Kleihues P (Editors). *World Cancer Report*. Lyon; IARC Press: 2003.



Cytocare's robotic arm prepares the vial for compounding

Health Robotics