



SAFE CHEMO: AN EU-FUNDED ASSESSMENT OF TECHNOLOGY FOR ONCOLOGY COMPOUNDING

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SafeChemo is an EU-funded project to validate robotics and software for cytostatics compounding. Three European healthcare institutions will assess technology performance for 18 months. They have developed a joint protocol and defined outcome measures for efficiency, safety and human factors.

Background

As one in two men and more than one in three women will be struck by cancer during their lifetime, prescription of cytostatic agents is growing at a steady pace within healthcare institutions. Cytostatics compounding has become a major challenge for European hospital pharmacies, while awareness of operator and patient risks sharpens. Oncology compounding units across Europe are experiencing staffing problems, and it becomes increasingly difficult to recruit and maintain qualified personnel. This situation calls for the development and introduction of new automation approaches.

The SafeChemo Project

The European Union has an interest in supporting technology progress within the EU and in 2005 published an eTEN call for project proposals, to support companies developing solutions in eHealth. eTEN projects are aimed at providing funding for commercial companies working in partnership with healthcare providers to establish early

phase proof of principles. At the time of the call for projects a group of leading-edge industry players (BTC and Medarchiver) were developing a series of technological modules to address oncology compounding challenges (Table 1). These companies already had a strategic plan to install the early commercial products in a limited number of healthcare pilot sites and work in partnership with them to validate the product.

A consortium was therefore formed (Table 2), and the project outline for SafeChemo was developed as a combination of market research and a thorough validation of the proposed technological platform, to be performed by the three healthcare partners. A SafeChemo project outline was submitted to the European Commission in early 2007 and following a rigorous evaluation, the project was funded to take place over 22 months, starting from April 2007.

Validation approach

The challenges of applying automation

Table 2: The SafeChemo consortium

B. Braun Melsungen AG (G) – Project Coordinator
Region Hovedstadens Apotek - Capital Region Pharmacy (DK)
Kivex (DK)
Imperial College Healthcare NHS Trust (UK)
Biomedical Technology Consulting (I)
MedArchiver (I)
Azienda Sanitaria dell'alto Adige, Comprensorio di Bolzano - Bolzano Healthcare Trust (I)

to health care should not be underestimated, as barriers to the application of useful technologies lie in their actual performance within healthcare systems, and in their interaction with human factors. SafeChemo aims at aligning the products described in Table 1 and the problems encountered while compounding oncology infusions, to make sure that implementation and product development match user requirements.

The eTEN market validation approach provides us with a unique opportunity to look at some exciting new technology from a number of different perspectives, different skills and different approaches.

In August 2007 representatives of the three pilots met in London, with the goal of outlining the evaluation methods and performance criteria needed to generate research that is valid and reproducible in heterogeneous contexts. The assessment of the SafeChemo platform generated during

Table 1: Three software applications and a robot are being evaluated

Oncoplan CPOE: an oncology e-prescription module, including protocols management, interface to all available clinical data, automated calculation of doses, definition of all prescription details

Cytoplan: a production scheduling module, processing all incoming prescription data, dispatching prescription to multiple machines, organising production cycles

Cytocare: robotics for the preparation of injectable solutions in a sterile environment, allowing the automated compounding of drugs in final solutions, a highly precise check on drug, dose, volume and other relevant parameters, labelling of final preparations

Oncoplan MAR: a medication administration module, offering point-of-care verification of patient and dose to be administered.

Table 3: Safety – outcome measures

Filter integrity
Particulate testing
Microbiological cleanliness of the Cytocare chambers
Sterility of compounded solution
Sterility of partially used vials
Cross product contamination
Precision of preparation
Operator exposure
Risk of repetitive strain injury
Oncoplan/Cytoplan reliability data transfer
Oncoplan/Cytoplan reliability calculations
Reduced needle stick injuries
Correct vial recognition
Correct bag recognition
Final container labelling
Process step reduction as a measure to increase safety

Table 4: Efficiency – outcome measures

Process time – overall and by each process step
Process time – software
Reduced process steps/process optimisation
Cost of drugs
Cost of consumables
Documentation changes
Impact on “internal” error rates
Impact on “external” error rates
Skills mix
Process change in training and staff validation

Table 5: Human factors – outcome measures

Pharmacy staff views on CytoCare
Staff views on Oncoplan/Cytoplan – Pharmacy aseptic staff
Staff views on Oncoplan – Nursing
Staff views on Oncoplan – Medical staff
Patient views
Development of new roles for staff
Hospital Senior Managers’ views
Staff views – Pharmacy QC staff

this meeting includes an analysis of the current manual systems, in order to be able to compare performances, highlight differences and substantiate the business case.

The pilot sites agreed to evaluate the SafeChemo service under the following three domains:

- Safety
- Efficiency
- Human Aspects

For each of these evaluation domains a number of outcome measures were identified (Tables 3-5).

In order to adjust for potential local differences, the SafeChemo clinical partners agreed on a common, detailed experimental design for each one of the chosen outcome measures.

The first validation efforts started during the last quarter of 2007 with selected outcome measures, and are scheduled to progressively involve all assessment domains as the project evolves.

Dissemination

The three pilot sites will be sharing validation results throughout 2008 and will be reporting back to the EU via Quarterly Validation Reports, the Draft Pilot Results Report (May 2008) and the Final Pilot Report (January 2009).

In addition the pilots intend to disseminate findings widely over the course of the project. Results will be disclosed through symposia at international scientific meetings and publications in scientific journals.

Further information is available on www.safechemo.eu

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