

# INFORMATION TECHNOLOGY

## *Integrating IT for technical services*

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*This month's special feature continues with a discussion of a new IT system for the technical services departments at Great Ormond Street Hospital for Children*

**R**ational use of drugs can only be achieved when there is detailed information available upon which staff can base decisions and make recommendations. Although it has been relatively easy to gather this information from pharmacy dispensing systems, the same has not been true of hospital pharmacy technical services/production units. This was certainly the situation in the pharmacy department at Great Ormond

Street Hospital (GOSH) for Children and it is probably true to say that this mirrored the situation in many UK pharmacy departments.

Technical services within the GOSH pharmacy department comprises three production units: total parenteral nutrition (TPN), a centralised intravenous additives service (CIVAS), and cytotoxics. In 1998, each unit used a different computer system.

TPN formulation was performed using a piece of software written for the hospital in the 1980s. This software had not kept pace with the changes in parenteral nutrition formulation, especially with the new range of ingredients available for TPN compound-

ing. The functionality and ease of use of the system was poor and the documentation generated failed to comply, on a number of counts, with the requirements detailed in the standard reference sources.<sup>1-3</sup> As the formulating software was not integrated with the main pharmacy system, every bag compounded had to be issued subsequently to the patient using the pharmacy dispensing system.

CIVAS, which was introduced into the hospital in 1995, had undergone a large and steady increase in output. In 1996, the unit prepared 30,000 doses annually, by 1998 this had risen to over 60,000, with the unit operating a seven-day service. Systems intro-

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duced when the unit opened were not designed to cope with such a workload. The computer system used in 1996 was simply for label generation, with each label having to be edited so that information about the patients and their doses could be entered. A master worksheet was held for each product and details such as dose, dose volume and patient had to be manually entered. After a dose had been prepared, it was issued to the patient using the dispensary computer system. This way of working was labour intensive, and with so much manual entering and amending of worksheets and labels, the risk of errors occurring was high. It was generally believed that more staff time was spent generating documentation than was spent actually preparing patient doses.

The cytotoxics unit had a computer system which was more integrated with the main pharmacy system. Although patient information was recorded on the system, there was no active stock control, and the documentation produced by the system again failed to comply with the requirements in the standard reference sources.<sup>1-3</sup>

In order to meet the information needs of the hospital, and also to enable the technical services units to expand, a fully integrated pharmacy computer system was required.

In 1996/7 the GOSH NHS trust undertook a detailed review of the information needs of the pharmacy department and the hospital as a whole. A number of key requirements from a department-wide system were identified. These included:

- a fully integrated system covering all aspects of the pharmacy service; integration with the patient information management system (PiMS) and finance systems
- improved efficiency of financial control (stock management, ordering, invoice reconciliation, data transfer to finance, directorate expenditure)
- improved information (individual patient drug use and costs, disease category costs)
- a system which would be able to support further electronic patient record (EPR) developments within the hospital, in particular electronic prescribing

After a long and arduous tender process, the hospital opted for the purchase of the Ascribe pharmacy system.

## — IMPLEMENTATION STRATEGY

Selection of the system was finalised in December, 1998, with a "go-live" date fixed for August 2, 1999. Implementation of such a complex system was not straightforward and a great deal of effort was required from all the pharmacy department's 70 staff to ensure that the target

implementation date was achieved. Within the technical services departments, three key areas for successful implementation were identified: data entry, training, and validation and verification.

**Data entry** Data entry is an absolutely critical step in the process of setting up any new software system. With a complex pharmacy system, errors made in the entry of data may have far-reaching implications. These may present as errors in dose calculation, in stock control or in financial reporting.

Annex 11 of "Rules and guidance for pharmaceutical manufacturers and distributors"<sup>1</sup> gives clear guidelines on how data should be entered and the checks that should be made. With the installation of the Ascribe system at GOSH, all critical data entries were second-checked by a member of the quality assurance department.

## — A thorough and detailed validation programme is essential for new pharmacy computer systems which will be performing complex calculations

**Training** Training is essential as a new computer system will only ever be as good as the staff who use it. If staff are not trained properly in its use, there may well be serious consequences. Again, these can present as errors in dose calculation, stock control or financial reporting. Time must be set aside for the initial training of staff, and also for the on-going training of staff as new versions of the software are made available. At GOSH, temporary staff were employed to enable key members of the department to be released for training. These trained staff were then responsible for training the other staff in the department.

**Validation and verification** Validation is a key component of good manufacturing practice. Just as a new manufacturing process needs to be validated to demonstrate that it continuously delivers the expected result, so does a new computer system. This is particularly important when calculations are performed and the output used to give detailed information about the preparation of dosages.

The guide to good automotive manufacturing practices (GAMP)<sup>4</sup> is now being recommended by the Medicines Control Agency as the standard to be used when

introducing new technologies. Although much of the document is concerned with the design of new computer-controlled systems, the document also gives guidance on the implementation of these systems.

The guide identifies three key stages of validation which are:

- installation qualification (IQ) — the system has been installed as specified
- operational qualification (OQ) — the system works as specified
- performance qualification (PQ) — the system in its normal operating environment produces a product of acceptable quality

Annex 11 of "Rules and guidance for pharmaceutical manufacturers and distributors"<sup>1</sup> also details some of the key standards required for a computer system used in the preparation of medicinal products. Some guidance is also available in the soon to be published third edition of "Quality assurance of aseptic preparation services".<sup>2</sup>

A validation strategy and procedure were developed in the pharmacy for the testing of all parts of the Ascribe computer system.

The Ascribe system can be viewed as modular in design, and in the GOSH technical services department the modules are TPN and CIVAS/cytotoxics. There are many similarities between the CIVAS and cytotoxics modules and for the purposes of installation they were treated as just one module.

## — TPN

The TPN module of the Ascribe software had been installed in the pharmacy department during 1998, in advance of the rest of the pharmacy system. The hospital uses a number of standardised TPN regimens which act as a starting point for the formulation for individual patients. When a patient starts on TPN, it is prescribed in accordance with the trust's TPN protocols, with adjustments made to reflect the patient's requirements (for example, fluid and electrolyte balance). Each of these unique GOSH regimens had to be entered onto the systems database.

**Training** Staff have to undergo a detailed training programme before they are authorised to use the system for the formulation of regimens. This is because the formulation of a TPN regimen is a critical step in the preparation of the product. Systems are in place to check worksheets and labels before compounding proceeds, but these may not detect every error made in the formulation of the regimen. Staff are trained in the use of the software by an authorised trainer, followed by the successful completion of the formulation of a number of sample prescriptions. These sample prescriptions are of

increasing complexity, and have been designed to test the user's understanding of all areas of the system's functionality. Members of staff have only two opportunities to formulate all regimens correctly. If this is not achieved, a full re-training has to be undertaken.

**Validation** The validation (operational qualification) of the TPN module consists of product database validation and system output validation.

**Product database validation** A product that has been incorrectly set up in the TPN database can have potentially fatal consequences for patients. For this reason, the decision was taken that every product in the database would be checked for accuracy using "first principles". A print-off from the product database was taken for every TPN raw material on the system. Three senior staff members then checked this data for accuracy (for example, for glucose 50 per cent, this would involve checking that the energy content of the solution determined using first principles matched that contained in the systems database).

**System output validation** The output from the system performs a number of functions. It gives detailed instructions to the TPN staff on how to compound the solutions; it instructs the nursing staff on how to administer the solutions; it gives detailed information to the hospital nutrition team (clinicians, specialist nurses, dieticians and pharmacists) of the contents of the patient's regimen. All this information is of critical importance, and it was decided that as with the product database, all outputs from the system should be verified by three senior staff. For every standard TPN regimen which had been loaded on the system, the accuracy of the printed output was checked again from first principles.

## ■ CIVAS/CYTOTOXICS

A great deal is expected from an integrated pharmacy system which is able to manage such a complex operation as the preparation of drugs for intravenous administration. In order to perform these tasks, a large amount of data relating to the product needs to be entered onto the system database. This can initially appear daunting.

Documentation generated by the system includes worksheets and labels. Any errors made in the entry of the critical data required by the system will result in errors appearing in the documentation, stock control or pricing. There is no simple way for staff to be trained in the setting up of CIVAS drugs on the Ascribe system. Speed comes with the experience of setting up many drugs, and with this experience comes the knowledge of short-cuts and trouble-

shooting. Over a period of time, members of staff will come to know which data field is responsible for a particular piece of information and how that information is used by the system. Once this is known, errors in set-up can be rapidly corrected.

Within data entry, one also needs to consider the design of worksheets and labels. The Ascribe system gives the user some degree of freedom in worksheet and label design. However, once again, a good understanding of how the system operates is required in order to get the most out of these freedoms. This understanding only comes from the experience of using and experimenting with the system.

**Training** Training of staff to use the Ascribe CIVAS/cytotoxics module is quite straightforward. The system has a broad functionality, and moving from a cumbersome system which required staff to perform calculations and manually enter data onto worksheets to the Ascribe system was quite an easy transition to make. Staff still needed to be trained in the operation of the system, and to demonstrate that they could use it properly. Training procedures were therefore developed and incorporated into the training protocols of the pharmacy department. These required staff to generate correctly a set number of worksheets and labels for products, and to issue the correct quantities of raw materials.

**Validation** The output of the system has to be checked thoroughly. As the system permits a move away from the labour-intensive process of checking every calculation, the initial validation process needs to be rigorous. Validation of the cytotoxics and CIVAS modules was a two-fold process. First, screen prints were obtained for each of the products being prepared, and these were checked. Second, sample prescriptions were entered onto the system for each product and all outputs (worksheets and labels) were checked and authorised by the quality assurance team.

## ■ LESSONS LEARNED

Our experience has demonstrated that the best way to achieve safe implementation is through having a member of the department dedicated to the task of introducing the new system. This person will quickly become proficient in the operation of the system, and be able to identify where data has been inputted incorrectly. An approach where a number of members of the department are all involved in separate parts of the implementation while continuing to perform their normal duties does not work.

The introduction of a new pharmacy computer system is not easy. Where the system is multifunctional and will be

performing complex calculations, a thorough and detailed validation programme is essential. The introduction of the new computer system at GOSH has been successful. It has resulted in the elimination of manual keying in of data by staff, time saving (as worksheets and labels are all generated by the system) and a reduced risk of dose calculation errors, and ultimately, an improved skill-mix across the department.

The introduction of any new technology should inspire and enthuse staff. New software means that an opportunity is presented for the review of entrenched systems of working, some of which may have only become established due to the limitations of the old technology.

When drawing up statements of need, and writing specifications for new software systems, a distinction should be made between what is essential and what is only desirable, and what is an absolute necessity from "go-live" and what can be introduced at a later date.

All staff involved in the procurement process for a new system should be encouraged to "think big" and consider how their departments or units could operate in five to 10 years time, and the software required. Nevertheless, both suppliers and users should accept that these are future requirements. Users should not expect a supplier to be able to deliver everything immediately, likewise suppliers should be promoting their systems based upon currently available functionality, not what may be available on the "go-live" date. Suppliers and users of systems should look to the future and work together on developing the system, but both must manage the expectations of the other.

The new pharmacy system at GOSH is just one small, but important, part of the trust's overall EPR strategy. Through the introduction of the system, all members of the pharmacy project team have gained very useful skills and experience that can be used across the trust in the implementation of future EPR projects.

## REFERENCES

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