Injectable medicines: at the sharp end

In 2007 a UK trust joined an NHS project to review injectable medicine purchasing-for-safety initiatives. This article, the first in a series of three, discusses the project and makes recommendations.

Injectable medicines form part of routine medicines therapy within secondary care. Data from the UK’s National Patient Safety Agency (NPSA) indicate that incidence of errors in prescribing, preparing and administering injectable medicines is high; 50% of all medication incidents reported occur during administration, with more than half of the incidents that lead to severe harm or death (0.2% of the total reported) being related to injectable medicines.¹

Best-practice guidance for the NHS has long recommended that licensed, commercially manufactured injectable medicines should be procured by the NHS, and, where this is not possible, doses should be prepared in aseptic facilities, under the supervision of a pharmacist.² A lack of standardised licensed products and appropriate facilities in many UK hospitals results in injectable medicines being routinely prepared in wards and departments, under less than ideal conditions.³⁻⁴

In 2007, NPSA issued a patient safety alert to address these concerns, by requiring all NHS trusts to undertake an assessment of injectable medicines use and action improvements to reduce risks for patients and healthcare staff.⁵ The NHS Purchasing and Supply Agency (NHS PASA) invited trusts to join the project to demonstrate how a multidisciplinary approach could minimise risks associated with injectable medicines through “purchasing-for-safety” initiatives and other clinical risk management strategies.⁶

Derby Hospitals NHS Foundation Trust has a long history of aseptic manufacturing (under MHRA “specials” licence) and dispensing from decentralised satellite facilities, providing standardised ready-to-administer products. Only about 12% of injectable medicines are routinely prepared at ward level using syringes and needles; 20% are prepared by pharmacy services and a further 26% reconstituted and administered by means of a simple “closed”

---

Figure 1. Phase 1 of Derby’s injectables purchasing-for-safety review project
system (Baxter Minibag plus™), at ward level; the remainder comprise standard ready-to-administer infusion fluids. A new single-site hospital due to be completed at the end of this year further extends this opportunity with satellites on each floor, serving all general and specialist areas.

In preparation for this, and to address the actions recommended by NPSA, the trust was keen to review practice in the highest-risk areas, evaluate new equipment and designs, to reduce risk, and share best practice with the wider NHS.

**Methodology**

The project was conducted in three main phases over 12 months. Phase 1 involved a baseline assessment of the trust’s safety culture, incidents and process mapping by multidisciplinary focus groups in four high-risk areas: theatres, imaging, maternity and chemotherapy, as illustrated in Figure 1.

Pharmaceutical procurement and management of infusion devices were also reviewed to identify “best-practice, best-value” approaches to standardised management of injectable medicines across the trust. A survey of staff involved in injectable medicines therapy was conducted using an electronic questionnaire.

From this baseline assessment, key purchasing and practice recommendations were identified for the trust and the wider NHS (see Table 1), and six workstreams were designed to take these forward into phase 2 implementation, as illustrated in Figure 2.

**Discussion**

The pilot provided a comprehensive review of many aspects of injectable medicines practice and demonstrated that purchasing-for-safety initiatives, which support clinical risk management recommendations, can safeguard patient care. These need to cover the wide range of processes and tasks involved in practice and be applied consistently across professions to have maximum impact.

<table>
<thead>
<tr>
<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPSA patient safety alerts and design for safety guidance: W: <a href="http://www.npsa.nhs.uk">www.npsa.nhs.uk</a></td>
</tr>
<tr>
<td>NHS PASA Purchasing for safety W: <a href="http://www.pasa.nhs.uk">www.pasa.nhs.uk</a></td>
</tr>
<tr>
<td>Findings from each of the three pilot sites will be incorporated in a national NHS PASA “purchasing for safety for injectable medicines” report due in summer 2008</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 1. Some recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standardisation of drug products, infusion devices and consumables</td>
</tr>
<tr>
<td>• Rapid access to essential information for product preparation and administration</td>
</tr>
<tr>
<td>• Effective product labelling for safe selection, identification and product use</td>
</tr>
<tr>
<td>• Needle-free systems for preparation and administration of chemotherapy products</td>
</tr>
<tr>
<td>• Barcode reconciliation of medicines and auto-identification of patients</td>
</tr>
<tr>
<td>• Implementation of drug library and “guardian” software on infusion devices</td>
</tr>
<tr>
<td>• Development of information resources and structured training for medical staff</td>
</tr>
</tbody>
</table>
Phase 1 of the project identified several recommendations at each stage of the medicines use process for procurement, information, storage, preparation, checking, administration, training and documentation (see Table 1). Only about 5% of the clinical workforce completed the online questionnaire; nevertheless, this represented a wide diversity of opinion about aspects of injectable medicine products and practice. Analysis emphasised the need for a safer approach in the design and volume of injectable medicines and devices, supporting the selection of particular workstreams.

Standardisation is an important aspect of safe medicines practice and it is apparent that there is much work to be done across the NHS to address this and provide cost and volume benefits to the NHS and pharmaceutical industry. Recent publications illustrate the wide range of products and practices employed across the NHS, and mismatch with available NHS aseptic manufacturing capacity, as well as providing principles and risk management tools for addressing these inconsistencies.

Availability of licensed preprepared products will facilitate safe medicines practice. NHS manufacturers and clinical networks should agree national standards for critical and high-risk therapies and industry should be encouraged to apply for authorisations to bring licensed products to market, while national and regional procurement hubs ensure these remain affordable to the NHS. The highest-risk products must be prepared in dedicated pharmacy facilities by specialised staff, working to defined and assured standards. Aseptic dispensing should be moved as close to the patient as possible, to minimise delays and maximise input to the multidisciplinary team – ideally via satellite facilities.

Clinical engagement in the testing of products and recommendations and collaboration with industries are essential to ensure these are not only of high quality, but “fit for practice”. Purchasing and patient safety agencies, and regulators, must engage practitioners to enhance products, for example with regard to packaging and labelling, and ensure this is taken into consideration in future guidance.

The phase 2 workstreams developed a purchasing specification for dose-banded products, incorporating procurement, quality, clinical practice and other safety considerations. Evaluation of two needle-free devices for chemotherapy preparation and administration favoured a closed “generic” system usable with a range of syringe and infusion containers. A rotary card-index for information, product labels and a package insert were developed for use in theatre areas, for a product requiring complex preparation (phenylephrine) and one with multiple strengths (bupivacaine). These will be covered in future articles. Technological developments offer significant opportunities to “design-in” safety features, as default, such as a software library.

No single approach is likely to resolve all issues. It may be that a combination of approaches yields the best results. For example, using the well-established Royal College of Anaesthetists’ colour scheme (based on therapeutic class) assists selection of injectable medicines, with further use of design to differentiate between multiple strengths. As well as purchasing for safety for high-risk products, there are many opportunities for “purchasing-for-convenience” initiatives to supply routine, high-volume injectable medicines to the NHS, maximising efficiency, safety, convenience and cost.

Conclusions
The project has demonstrated the importance and value of collaborative working between NHS PASA, industry and NHS hospital trusts to ensure safety is built into product design, purchasing and implementation. Key recommendations have been identified for national development and implementation (such as dose banding and clearer product information and labelling) and for NHS trusts depending on local circumstances (such as product and device standardisation and management). A scorecard will be used to evaluate progress in implementing the recommendations over the longer term. Injectable medicines will remain at the sharp end of clinical practice, and health providers must actively embrace purchasing for safety and other clinical risk management initiatives in order to safeguard patient care.

The Derby Hospitals pilot team acknowledges the support and guidance of the NHS PASA team and project facilitation provided by Atos Consulting.

References