DERBY HOSPITALS’ NHS FOUNDATION TRUST
PROJECT FINAL SUMMARY REPORT

Purchasing for safety - injectable medicines

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1 Background

1.1 Patient safety is a high priority for the NHS, following a series of incidents leading to publication of an ‘Organisation with a Memory’ by the Chief Medical Officer in 2000. This was followed by ‘Building a Safer NHS’ which introduced a National Patient Safety Agency (NPSA) to oversee, research and implement patient safety solutions and develop a National Learning and Reporting system (NRLS).

1.2 Risks associated with the preparation and administration of injectable medicines have been known for a long time and controls on their preparation in place since the 1970s when a working party, chaired by Sir Alistair Breckenridge, recommended that drugs should only be added to infusion fluids within a controlled pharmacy environment, and that pharmacists should advise on stability and compatibility issues, as well as training ward staff.

1.3 Further guidance followed that distinguished between batch manufacturing, a licensable activity under statutory regulation of the Medicines Control Agency (now Medicines and Healthcare Products Regulatory Agency MHRA), and unlicensed dispensing under a section 10 exemption of the Medicines Act.

1.4 In the 1990s a series of failures resulting in the death of NHS patients led to a review of NHS aseptic manufacturing, resulting in the publication of ‘aseptic dispensing for NHS patients’ detailing recommendations by the Department of Health, to close the gap between licensed and unlicensed preparation of injectable medicines.

1.5 Medication errors remain a significant cause of medical error and in 2004, the Chief Pharmaceutical Officer published recommendations to improve medication safety. This reinforced recommendations for the safe handling, preparation and administration of injectable medicines, with recommendations to improve labelling, information and training.

1.6 Despite these recommendations, it is recognised that it is not always feasible or appropriate for all injectable medicines to be prepared in specialist pharmacy facilities and this prompted NHS Scotland to make recommendations for preparation of injections in near patient areas. These recommendations were largely based on risk assessment of the product and environment.

1.7 In March 2007, the NPSA published Patient Safety Alert 20, promoting the safer use of injectable medicines. Again, this focuses on risk assessment and makes clear recommendations to minimise clinical risk, through better technical information, clearer labelling, training and resources for healthcare staff. The alert recommends that the NHS implements a ‘purchasing for safety’ policy to promote procurement of standardised injectable medicine products with inherent safety features.

1.8 These themes are further picked up in ‘The Best Medicine’, published by the Healthcare Commission, following a review of medicines management in NHS Hospitals.
1.9 Following a review of medication incidents reported via the NRLS in 2006, data indicated a high incidence of errors in prescribing, preparing and administering injectable medicines with over 50% of all incidents reported occur during administration. Over half of incidents that lead to severe harm or death (0.2% of total reported) are related to injectable medicines. The NPSA published further recommendations to minimise these and other risks in May 2007.

1.10 Procurement of licensed 'ready to administer' injectable medicines is an ideal and offers opportunity for the NHS to work collaboratively with industry, national and commercial procurement hubs and regulatory agencies, and has been widely recommended following national guidance and work carried out to review availability and use of standardised products in the NHS.

1.11 Following ministerial approval, NHS PASA in collaboration with Pharmaceutical Industry, sought NHS Pilot sites to evaluate a 'purchasing for safety' strategy and clinical risk management solutions for injectable medicines. Derby Hospitals applied to be a pilot site in early 2007.

2 Introduction

2.1 Derby Hospitals is a progressive acute teaching hospital which achieved Foundation Trust status in July 2004. In 2006/7 medicines management in the Trust was considered to be good following review by the Healthcare Commission.

2.2 Management of injectable medicines is relatively advanced with both on-site pharmacy aseptic manufacturing (under MHRA Manufacturers specials license) and decentralised aseptic dispensing facilities. These serve to provide a range of standardised injectable medicines, which are ready to administer to patients.

2.3 A high level review (conducted as part of phase 1 baseline assessment) indicates that only approximately 12% of injectable medicines are actually prepared at ward level. 20% of injectable medicines are prepared by pharmacy services, and a further 26% reconstituted and administered by means of the simple, ‘closed’ Baxter Minibag plus™ system, at ward level; the remainder comprise standard ‘ready to administer’ infusion fluids.

2.4 Medical devices used for infusion therapy in the Trust have been standardised for several years, including establishment of centralised equipment libraries in 2004. Where possible devices incorporating smart technology (drug library, software limits, downloadable end-user logs) are used to maximise safety. Ongoing development of a plastics formulary has helped to ensure that consumable use is cost-effective and appropriate to the range of devices used.

2.5 The Chief Pharmacist is responsible for medicines management in the Trust, which is overseen by the Trust Clinical Effectiveness Committee. This is important in ensuring that the strategy and operational policy and procedures remain focused on patient outcomes.
2.6 The safe, clinical and cost-effective use of medicines is overseen by the Trust Drugs and Therapeutics Committee, and in relation to injectable medicines practice, by an Infusions Systems sub-committee. These committees reflect the multi-professional nature of medicines management, where the same standards should apply irrespective of discipline.

2.7 The Infusion systems committee takes a ‘system-wide’ view, developing policy and procedures for parenteral therapy, reviewing new equipment, training and other resources to support the safe and effective delivery of injectable medicines. Members of this committee together with other key staff formed the Pilot Board for this purchasing for safety project.

3 The project†

3.1 The project was conducted over 1 year from March 2007 to March 2008, in two key phases. The first, a review of safety culture and current practice with injectable medicines, based on literature review, analysis of incidents, and focus groups with practitioners. The second phase, involved taking forward workstreams to review and evaluate specific purchasing for safety recommendations, arising from phase 1.

3.2 The objectives of the project, as stated by NHS PASA:

3.2.1 to demonstrate that strategic purchasing can reduce clinical risk associated with the administration of injectable medicines
3.2.2 to learn lessons relating to the case of injectable medicines that will be of benefit to Trusts and Collaborative Procurement Hubs across the country
3.2.3 to develop an approach that could serve as a model for addressing wider government policy issues through procurement.

In addition for the Trust:

3.2.4 supporting implementation of NPSA recommendations for improving medication safety (e.g. relevant Patient Safety Alerts)
3.2.5 insight into use of injectable medicines in high risk areas (e.g. theatres)
3.2.6 introducing and evaluating new equipment and designs to improve safety of injectable medicines (e.g. needle-free preparation of high risk drugs)

3.3 The scope of the project covered a range of issues associated with injectable medicines, including:

3.3.1 colour, design and labelling of products
3.3.2 standardisation of devices, medicines, sets, and supporting training resources
3.3.3 centralisation of devices, medicines and sets
3.3.4 elimination of ‘open system’ medication in favour of pre-prepared products
3.3.5 reduction of injectable medicines requiring complex calculation and dilution
3.3.6 double checking systems (e.g. bar-coding, electronic dose limiting software)
3.3.7 provision of better written information by manufacturers for clinical staff

† See Project Initiation documents for Phase 1 (May 2007) and Phase 2 (Oct 2007) for detail
3.4 Based on incident data, risk assessment of injectable medicines used and the practice environment, the following clinical areas were chosen to analyse practice and evaluate possible risk reduction solutions:

- Cancer chemotherapy
- Theatres
- Imaging
- Maternity services

3.5 In addition to focus groups within these clinical areas, emphasis was placed on purchasing arrangements in the Trust, to identify learning from pharmaceutical procurement that could be applied to other procurement processes.

3.6 A survey was conducted with a wide range of clinical staff to evaluate the level of understanding of strategic management, policy and procedure and canvas opinion on risk issues associated with injectable medicines therapy.

4 Phase 1 findings‡

4.1 Cultural analysis, using the Manchester Patient Safety Framework, demonstrated a positive safety culture in Derby Hospitals, with over half the responses considering this good or excellent; only 3% of respondents rating this as poor.

4.2 Analysis of local incidents with injectable medicines further demonstrated that the Trust has a good reporting culture, and review of incident reporting data from the NPSA National Reporting and Learning System (NRLS) showed this to be typical of other large acute Trusts.

4.2.1 In common with national reporting, dose errors account for the most common medication errors in Derby Hospitals with over half of these occurring at the prescribing stage. In most cases these will be intercepted before they reach the patient, however, a third of these occur at administration and evidence suggests that up to 60% of these will reach the patient9.

4.2.2 Interestingly, risk assessment of those injectable medicines involved in incidents, using the NPSA risk assessment tool7, indicated that these are generally low risk, with most high risk products being prepared ready to use, by the Pharmacy Service.

4.3 The staff survey indicated a wide diversity of opinion about aspects of injectable medicine products and practice, but given the poor return (approximately 5% of the clinical workforce) it is difficult to draw conclusions. Analysis of the questionnaires highlighted staff awareness of the safe use of injectable medicines, and emphasised the need for a safer approach in the design and volume of injectable medicines and devices. Recommendations arising from the survey supported the selection of particular workstreams in phase 2.

‡ Detailed findings are reported in the Derby Pilot Phase 1 Report, published July 2007
4.4 In addition to recommendations for standardisation of equipment and pre-prepared products, a broad range of issues were identified, applying to all stages of the medicines use process.

5 Recommendations are summarised below:

5.1.1 Procurement
- Off contract product evaluation and communication / alert process
- Standardisation of extensions sets, connectors etc & policy for use

5.1.2 Information
- Essential information label for high risk injectable medicines packaging
- Drug monographs for safe prescribing, preparation and administration of high risk products (with worksheet for complex preparation in clinical areas)
- Develop basic Trust injectable medicines guide (with focus on administration), pending publication of NHS Injectable Medicines Guide

5.1.3 Storage of medicines
- Review RHS medicines storage and preparation facilities and ensure designated areas for medicines preparation conform to practice standards
- Standardise medicines storage and stock levels within clinical areas, to maximise correct selection through positive identification; utilise supplementary labels on outer packaging to aid correct selection
- All medicines to be kept in original packaging in ALL clinical areas
- Removal of all expired, over stocked and ‘named-patient’ supplies regularly
- Emergency drugs in separate accessible ‘kit’ with consumables, diluents etc (i.e. Theatre emergency box)
- Limit storage of injectable medicine preparations in clinical areas to session (maximum 6 hours)

5.1.4 Preparation
- Regular audit of facilities / practices for preparing medicines in clinical areas
- Pharmacy preparation to focus on moderate and high risk injectable medicines, then high volume manufacturing and any remaining capacity for other ‘convenience’ products.
- ALL injectable medicine preparations to be clearly labelled with drug preparation details unless directly prepared and administered
- NO addition of injectable medicines to infusion fluids outside pharmacy service
- NO use of ‘open bowl’ techniques anywhere in Derby Hospitals NHS FT
- Dose banding for chemotherapy and other dispensed medicines where appropriate, and no commercially available product
5.1.5 Checking
- Second checking standard for preparation AND administration of intravenous medicines in ALL clinical areas. In process checks documented for high risk products (via worksheet) as appropriate

5.1.6 Administration
- Needle-free systems for ALL chemotherapy preparation and administration
- Labelling of all administration and extension sets (apart from standard peripheral IV lines), multiple lumens, using standardised labels
- Early development and adoption of barcode reconciliation for medicines
- Full implementation of drug library / guardian software limits in infusion pumps
- Evaluate Baxter Guardian™ software

5.1.7 Training
- E-Learning training, information resources and IV nurse champions
- Injectable medicines training for medical staff
- Maintain Trust wide register for induction and to prompt follow up training

5.1.8 Prescribing and documentation
- Incident reporting to be improved for reporting medication errors
- All medicines must be prescribed in Derby Hospitals NHS FT
- Prescribers aware that they are prescribing medicines with diagnostic tests
- All prescribing software to be fully validated and piloted before roll out

5.2 As well as the above recommendations for Derby Hospitals and other NHS Trusts (as appropriate), the following recommendations were made for NHS PASA, and other national agencies and regulators:

5.2.1 Procurement
- Commercial availability of dose banding for cytotoxic chemotherapy and other appropriate products against clear product specification
- Ready to administer products for Syntocinon, Contrast media, and other injectable medicines as appropriate (stability, volume etc)
- Safety issues core to purchasing decisions in commercial Procurement Hubs

5.2.2 Information
- Influence MHRA to change labelling guidelines to clearly display essential information on packaging (i.e. prioritise over license / licensee information)
- Support and input to the new NHS Injectable Medicines Guide regards commercial availability and purchasing for safety recommendations
5.2.3 Administration

- Medical devices should be designed with safety at forefront; current safety options are all too often buried under layers of menus instead of being offered as default primary choices
6 Phase 2 workstreams

6.1 Based on the outputs of phase 1, six workstreams were identified, and five taken forward in phase 2 of the pilot:

- Dose banding chemotherapy – developing a purchasing specification
- Needle-free preparation of high risk drugs – evaluating two devices
- Product information & labelling – essential information for product selection / use
- Barcode technology – for patient auto-ID and product reconciliation
- Design of infusion devices – evaluation of user logs and software safeguards

6.1.1 Time constraints prevented the training workstream from progressing, although this remains fundamental to safe medicines practice with injectable medicines. The lack of formal or consistent training for medical staff in aspects of injectable medicines a practice a particular concern.

6.2 The workstreams were led by members of the Pilot Board, supported by other specialist practitioners and managers, between October 2007 and February 2008.

6.3 Similar methodology was used as in phase 1 to review and evaluate recommendations – involving focus groups. A workstream brief was prepared for each workstream outlining purpose, scope, objectives, timescales and measures. Given the short timescales, progress / action reports were reviewed regularly at Pilot Board meetings.

6.4 The aims and main objectives are summarised below:

6.4.1 Dose banding

The work stream aimed to work with the East Midlands ‘Re:Source’ Procurement Hub to identify suitable chemotherapy products for dose banding, and develop a specification for the product, presentation (labelling and packaging) and logistics, to inform ‘purchasing for safety’ decisions.

6.4.2 Needle-free devices

The work stream aimed to evaluate two needle-free products for chemotherapy preparation and administration, using qualitative techniques to rate ease of use, time saving, staff safety etc and to make recommendations for safe aseptic dispensing practice.

6.4.3 Product information and labelling

The work stream aimed to identify and evaluate essential product information and optimise label, packaging and leaflet designs to reduce selection, preparation and administration errors. The work stream incorporated the existing Royal College of Anaesthetists’ critical care labelling scheme.
6.4.4 Barcoding

The work stream undertook an options appraisal to review the use of barcodes for the reconciliation, identification (of patients and products) and safe administration of injectable medicines. Technology limitations and delays to implementation of electronic prescribing and medicines administration did not allow evaluation within project time scales.

6.4.5 Infusion pumps

The work stream focussed on assessing commercial ‘pump needs analysis’ software, and identifying learning from data downloaded from end-user logs, to evaluate the impact of drug library and software limits on error reduction, and make recommendations to utilise this more effectively.

6.5 Work stream findings were documented in a report template, to include literature review, pertinent phase 1 findings, methods and measures, evaluation results, key benefits and recommendations.

7 Recommendations are summarised below:

7.1.1 Dose banding

Dose banding is a viable purchasing for safety initiative for many standardised products – a national approach and lead by NHS PASA would maximise the benefits and deliver greatest value to the NHS. Standardisation will reduce the range of products, facilitate national procurement and persuade industry to apply for marketing authorisation. A purchasing specification needs to address purchasing, logistics, quality and clinical risk management issues applying to the product, packaging and labelling. Customer care issues, supply and performance monitoring were also considered important aspects.

7.1.2 Needle-free systems

The ideal system will be entirely closed (including containment of drug vapours), be generic / compatible with a wide range of injection and infusion devices, easy to use for preparation and administration, supported by comprehensive sterility and stability data, and affordable. It was considered that health and safety, and regulatory agencies, could mandate use of needle-free systems for the preparation and administration of high risk drugs. National contracting by NHS PASA would ensure cost and volume benefits to the NHS and Industry.

7.1.3 Product information and labelling

In many cases product labelling and information currently falls short of the requirements of clinical practitioners and is recognised by the NPSA as a source of error and risk. The workstream demonstrated that regulatory changes need to be made to provide practitioners with essential product information and that this should be presented in a user-friendly, accessible way (e.g. using innovative label designs, clear technical information leaflets) to support safe injectable medicines practice.
Combining initiatives from RCOA and NPSA will assist practitioners with product identification, selection AND differentiation. These represent significant purchasing for safety and clinical risk management opportunities.

7.1.4 Barcoding

Barcoding technology offers benefits for patient safety and asset management, bringing safe practice, efficiency and accountability to a range of healthcare processes. A strategic approach to purchasing and developing a solution that covers all applications (e.g. asset tracking, stock management, auto ID of patients and reconciliation of drugs) is likely to be the most cost effective solution for the NHS, and represents an important purchasing for safety opportunity.

7.1.5 Pump design

There are significant purchasing for safety benefits that can be applied to medical devices, and opportunities to develop a purchasing specification, as well as better utilisation of safety features built into ‘smart’ pumps. Industry needs to do more to make these the default setting, user friendly and intuitive. ‘Pump needs analysis’ software has potential to support Trusts with standardisation of equipment, but further validation is needed. Dose limiting software and analysis of end-user logs offer valuable tools to improve safe use of devices to administer injectable medicines. These features should be built into national guidance and purchasing specifications.

8 Discussion

8.1 The pilot has 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.

8.2 These need to cover the wide range of processes and tasks involved in injectable medicines practice and be applied consistently across professions to have maximum impact. Such an approach maximises the likelihood that errors will be prevented from reaching patients.

8.3 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 identify the wide range of products and practices employed across the NHS, and mismatch with available NHS aseptic manufacturing capacity10, as well as providing principles and tools for addressing these inconsistencies11.

8.4 Centralisation of equipment, preparation and / or procurement of ‘ready to administer’ products, and strategic management of policy and procedures are essential to maximise efficiency and ensure consistency.
8.5 Clinical engagement and testing of products and recommendations is essential for success. Process and outcome measures will ensure that products are not only of high quality, but ‘fit for practice’. Purchasing and Patient Safety agencies and Regulators must engage practitioners to enhance products e.g. packaging and labelling, and ensure that this is taken into consideration in future guidance.

8.6 No one approach is likely to resolve all issues and it may be that a combination of approaches yields the best results. For example, utilising 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.

8.7 Technological developments offer significant opportunities to ‘design-in’ safety features. The pump design workstream identified the value of dose limiting hardware and software limits, drug library selection and downloadable user logs to inform training needs. The needle-free workstream identified the characteristics of an ideal needle-free ‘system’ for the preparation and administration of high risk medicines.

8.8 Combination of technologies may well offer the best solutions and should be considered within any purchasing for safety initiative. For example, barcoding technologies should be developed for the range of auto-ID, tracking and reconciliation tasks undertaken in healthcare. Dose banded chemotherapy products could come combined with integral needle-free adaptors (that can connect to a wide range of infusion equipment). Smart pumps should allow the use of barcoding to transfer electronic prescription information for a specific patient, to automate settings, and minimise input errors.

8.9 However, over reliance on technologies will not prevent errors from occurring, and emphasis should be placed on basic medicines management – storage, handling, preparation etc. Best practice standards and competency assessment are essential for ensuring that staff are ‘fit for practice’. In particular, formal training in injectable medicines practice should be established for medical staff.

8.10 The highest risk products must be prepared in dedicated pharmacy facilities by specialised staff, working to defined standards, with full quality assurance and controls. Where possible aseptic dispensing should be moved as close to the patient as possible, to minimise delays and maximise input to the multi-disciplinary team, through decentralised ‘satellite’ facilities.

8.11 Availability of licensed pre-prepared products will facilitate safe medicines practice. NHS manufacturers and clinical networks should be encouraged to agree national standards for critical and high risk therapies and Industry encouraged to apply for authorisations to bring licensed products to market. National and regional procurement hubs must ensure that these remain affordable to the NHS.

8.12 As well as risk management, 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 e.g. IV flushes.
9 Conclusions

9.1 Overall the pilot has met the broad aims of the project, as described by NHS PASA, and Derby Hospitals, namely:

- to demonstrate that strategic purchasing can reduce clinical risk associated with the administration of injectable medicines
- to learn lessons relating to the case of injectable medicines that will be of benefit to Trusts and Collaborative Procurement Hubs across the country
- to develop an approach that could serve as a model for addressing wider government policy issues through procurement.
- supporting implementation of NPSA recommendations for improving medication safety (e.g. relevant Patient Safety Alerts)
- insight into use of injectable medicines in high risk areas (e.g. theatres)
- introducing and evaluating new equipment and designs to improve safety of injectable medicines (e.g. needle-free preparation of high risk drugs)

9.2 The project has demonstrated the value of working collaboratively across the NHS, both locally and nationally, and with commercial partners in developing and implementing purchasing for safety initiatives.

9.3 The project has provided further emphasis on the risks associated with injectable medicines and local practices, identifying weaknesses in local systems as well as reinforcing good practice in Derby Hospitals.

10 Acknowledgements

I would like to acknowledge the significant contribution of members of the Pilot Board and Workstream Leads who have given up valuable time to contribute to this pilot. Particular thanks to clinical staff and managers who have given up valuable time to share their experience, insight and expertise to inform the project findings. The pilot would not have been possible without the input, guidance and encouragement of the Project Lead and Atos Consulting, who have ensured that the objectives have been met.

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