DERBY HOSPITALS’ NHS FOUNDATION TRUST
PROJECT INITIATION DOCUMENT
PHASE 2 Report

Purchasing for safety - injectable medicines

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Documentation

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Pilot Plan – Phase Timings</td>
</tr>
<tr>
<td>B</td>
<td>Pilot Risk Register</td>
</tr>
<tr>
<td>C</td>
<td>Governance Chart</td>
</tr>
<tr>
<td>D</td>
<td>Communications Plan</td>
</tr>
<tr>
<td>E</td>
<td>Reference Materials</td>
</tr>
<tr>
<td>F</td>
<td>Executive Summary</td>
</tr>
<tr>
<td>G</td>
<td>Stakeholder Map</td>
</tr>
</tbody>
</table>
Contents

1. Background .................................................................................................................. 2
2. Introduction to the project ........................................................................................ 2
3. Pilot organisation and resource ............................................................................... 2
   3.1 Pilot acceptance 2
4. Governance and accountability ............................................................................... 2
   4.1 Performance monitoring and reporting 2
   4.2 Pilot team roles and responsibilities 2
   4.3 Collaborative Procurement Hub 2
   4.4 Industry stakeholders 2
5. Inputs and resources ................................................................................................ 2
6. Objectives .................................................................................................................. 2
   6.1 The objectives of the pilot are: 2
7. Scope (section 18.4) .................................................................................................. 2
8. Methodology .............................................................................................................. 2
   8.1 Phase 2 - implementation 2
   8.2 Methodology toolkit 2
   8.3 Cultural analysis 2
   8.4 Incident reporting & investigation processes 2
   8.5 Review of Phase 1 case studies and findings 2
   8.6 Phase 1 recommendations – for the Trust 2
   8.7 Procurement 2
   8.8 Questionnaire 2
9. Outputs ....................................................................................................................... 2
   9.1 PID and Executive Summary 2
   9.2 Communications plan 2
   9.3 Risk register 2
   9.4 Project plan 2
   9.5 Stakeholder map 2
10. Constraints ................................................................................................................ 2
11. Deliverables ............................................................................................................... 2
12. Benefits ...................................................................................................................... 2
   12.1 Benefits for patients 2
   12.2 Benefits for healthcare professionals 2
   12.3 Benefits for the procurement community 2
   12.4 Benefits for the healthcare industry 2
   12.5 Benefits for the pilot trust 2
13. Impacts ....................................................................................................................... 2
14. Risks and assumptions ............................................................................................ 2
15. Project acceptance .................................................................................................... 2
16. Project milestones – Phase 2 ................................................................................... 2
17. Quality ........................................................................................................................ 2
18. Phase 2 workstreams ............................................................................................... 2
   18.1. Introduction 2
   18.2. Methodology 2
   18.3. Outputs 2
   18.4. Workstream summaries 2
   18.5. Workstream evaluations 2
   19. Workstream recommendations 2
   Appendix A - Pilot project plan & phase timings 2
   Appendix B - Pilot risk register 2
   Appendix C – Governance chart 2
   Appendix D – Communications plan 2
   Appendix E – Executive Summary 2
   Appendix F – Stakeholder map 2
   Appendix G – Mini-questionnaire analysis 2
<table>
<thead>
<tr>
<th>Appendix No.</th>
<th>Title</th>
<th>Page</th>
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<tbody>
<tr>
<td>Hi</td>
<td>Evaluation of Needle-free systems (Pharmacy)</td>
<td>2</td>
</tr>
<tr>
<td>Hii</td>
<td>Evaluation of Needle-free systems (Nursing)</td>
<td>2</td>
</tr>
<tr>
<td>Hi iii</td>
<td>Evaluation of Bupivacaine Labelling and Information</td>
<td>2</td>
</tr>
<tr>
<td>Hi iv</td>
<td>Evaluation of Phenylephrine Labelling and Information</td>
<td>2</td>
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1. Background

1.1 The last few years have seen the issue of patient safety rise up the political agenda. In 2004, a National Patient Safety Agency (NPSA) & Design Council report stated that 'international research suggests that ensuring patient safety is becoming one of the most important challenges facing healthcare today, not just in the UK but worldwide'. The Government’s commitment to reducing medical errors was demonstrated in the 2000 publication: *An organisation with a memory*. This report – and the subsequent implementation plan: *Building a safer NHS for patients* - led to the establishment of the NPSA, and the principles set out have become pillars of the NHS quality and clinical governance agendas. One of the specific risks targeted for action in the latter document was ‘building safety into purchasing policy within the NHS’.

1.2 Human error is often implicated in medical mistakes. But ‘human beings make mistakes because the systems, tasks and processes they work in are poorly designed’. Consequently, the Department of Health has endorsed a design-led approach to patient safety in delivering safer products, services, processes and environments, and has recognised the interdependency between design and procurement. For safety solutions to be effective, design briefs and procurement decisions must be based on a detailed understanding of how staff and patients use – and sometimes misuse – these items.

1.3 In 2005, discussions involving Lord Warner, PASA and Baxter Healthcare resulted in a Ministerial submission, which recommended:

- more effective implementation of existing safety and procurement guidelines, thereby providing Trusts with the ability to take a more ‘systems based approach’ to purchasing, particularly in ‘high-risk’ areas, such as drug delivery and specialist therapies
- recognition of the need for a more formalised process between PASA, NPSA, the Healthcare Commission and the DH, which requires regular interaction relating to patient safety issues
- implementation and associated funding of pilot sites within the NHS to test ‘Purchasing for Safety’ benefits.

1.4 Whilst the procurement function has contributed to a number of initiatives designed to reduce medical errors, there has, to date, been no systematic, joined-up approach to purchasing for safety. This project is designed to address that issue by demonstrating that procurement can play a vital role not just in supporting but in *delivering* a key government policy. To do that, one major area with considerable scope to reduce risk to patient safety has been identified: injectable medicines.

1.5 The Pilot Trust places significant importance and emphasis on maintaining and delivering high standards of patient care. In particular, the Trust has been keen to address and improve patient safety with respect to Injectable Medicines. Analysis and reporting against clinical incidents and near misses has been conducted, which has included a focus on standardisation and centralisation of equipment; pharmacy-led production of ready to administer injectable medicine products and introduction of new pump technology and staff training for safer administration.

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1 NPSA. Design for Patient Safety: a design-led approach to tackling patient safety in the NHS. 2004
2 Prof Lucien Leape, Harvard School of Public Health, quoted in *Design for patient safety*, NPSA 2004
1.6 Having received Chief Executive support, The Pilot Trust has therefore applied to be one of the pilot sites for the project supported by PASA focusing on agreed areas within the Trust around Injectable medicines.

1.7 The timing of this project coincides with the recently published NPSA Alerts on improving medication safety in the NHS, in order to reduce the number of medication errors. Patient Safety Alert 20 promotes the safer use of injectable medicines.

1.8 The Cambridge University Engineering Design Council, Exodus and Atos Consulting were engaged by PASA to support the delivery of this Pilot.

1.9 A detailed Final Report for Phase 1 (ref: v2.0 31Jul2007 Pfs Derby Final Report Phase 1.doc) was compiled by the Pilot Trust. This Final Report was submitted to PASA for consideration by the project’s Programme Board. The conclusions and recommendations provided by the Pilot Trust following completion of Phase 1, will provide a basis for establishing the workstream approach for implementation and Phase 2 of the project.

2. Introduction to the project

2.1 Over a quarter of NHS patients will receive intravenous therapy as part of their treatment, with over 90 per cent of patients passing through an acute hospital receiving IV fluid for re-hydration, to correct a biochemical imbalance or as a carrier for other medication. In 2003/4, the NPSA reported an annual adverse incident rate in the preparation, administration and delivery of IV therapy of more than 700. Of these, 80 cases resulted in the death of a patient. In 2007, NPSA published a report arising from incidents reported to the National Reporting and Learning System, which concluded that errors in prescribing, preparing and administering injectable medicines are common, with a high likelihood that these will reach patients. Over 50% of all incidents reported occurred during administration and over half of incidents that lead to severe harm or death (0.2% of total reported) are related to injectable medicines.

2.2 In 2004, the NPSA reported on the outcomes of a pilot study to determine the root causes of incidents involving infusion devices, where no fault with the equipment was found. The study identified a lack of competency-based staff training, together with unsystematic purchasing and management of devices as key factors contributing to infusion device incidents. This demonstrates a) that current purchasing practices can be part of the problem, and b) that purchasing cannot be tackled in isolation of the system as a whole. Lack of standardisation and poor usage and storage of equipment all contributed to the creation of latent system risks. Consequently, the NPSA recommended the reduction of incidents through standardisation and centralisation of IV device management. Further work by NPSA looking at injectable medicines has shown that the arrangements for their provision can also increase risks to patients.

2.3 It is recognised that a number of steps have already been taken to ‘purchase for safety’. The Pilot Trust has already completed some base-lining and has developed an Intranet based e-version of the Manchester Patient Safety Questionnaire, which was incorporated into the early assessment phase of this pilot project. Many other initiatives have also been implemented including pharmacy preparation of many injectable medicines from dedicated ‘near-patient’
pharmacy facilities. The Trust has a clear approvals process for the purchasing of equipment, and manages the training of its staff around medical devices. The Trust has previously undertaken activities to improve safety with injectable medicines, including development of guidance information on the Trust intranet. An effective formulary limits access to safe, clinical and cost-effective medicines.

2.4 The Pilot Trust has agreed to work in partnership with PASA, and to participate in this project – taking a system-wide and holistic view of patient safety in the area of injectable medicines. Working with a wide range of NHS stakeholders, as well as industry, the Trust will, via the project, seek to address the purchasing issues identified in numerous studies and reports. It will do so in the context of the system or environment into which changes are to be made, building on work that has previously been carried out, and recognising that effective design requirements are ‘a prerequisite to improvements in procurement and innovation practice’.6

2.5 This project supports the ongoing work undertaken by the Trust’s Clinical Effectiveness and Medicines Management Committees, and wider Trust objectives. The outcomes and deliverables of the Project will inform not only the Trust and PASA, but shall also provide information for other NHS Trusts as deemed appropriate by PASA.

3. Pilot organisation and resource

3.1 Pilot acceptance

a. The Pilot acceptance was secured by:
   b. Agreement from the Trust's Chief Executive
   c. Agreement by the Pilot Project Board and Pilot Sponsor
   d. Agreement by key stakeholders
   e. Sign-off by the Trust Project Board
   f. Sign-off by PASA (MET)

4. Governance and accountability

A Programme Board was established within PASA to monitor closely the progress of the pilot against their plan. This allowed for the rapid escalation and resolution of issues and risks identified by the Trust Pilot, to enable them to meet the project Gateways.

The Trust formed a Pilot Project Board, which met monthly and was co-chaired by the Trust Pilot Lead and the Pilot Facilitator (Appendix C)

4.1 Performance monitoring and reporting

Progress will be reported and performance monitored via the following mechanisms:

- monthly Trust Pilot Board meetings
- monthly PASA Programme Meetings attended by the PASA Project Manager to be chaired by PASA Programme Manager
• issues and risks log to be completed monthly by Trust Pilot Facilitator and discussed at the Trust Pilot Board meetings with significant or outstanding issues to be escalated by the Trust Pilot Facilitator to the PASA Programme Board and the Trust Pilot Sponsor to the Executive Board

• a Gateway review process, which will be established to ensure that minimum levels of attainment are reached before progressing to the next phase.

• monthly reporting by the Trust Pilot Sponsor of progress to the Executive Board

4.2 Pilot team roles and responsibilities

Pilot Project Sponsor – (Dr Kathy McLean, Medical Director)

The Project Sponsor shall have responsibilities for championing and overseeing the project at a high level, reporting progress to the Trust Integrated Governance Committee. They shall be responsible for high level ownership of the pilot and high level activities, including:

• Executive level communications, including media communications management and broad stakeholder engagement
• resolution of Trust issues or queries related to the pilot
• championing the pilot within the Trust
• provide and negotiate the necessary Trust resources
• removal of barriers and resolution of issues that cannot be resolved at steering group level
• key decisions affecting the pilot
• high level and corporate risk management
• attending the Pilot Project Board
• reporting to Trust Executive Board
• presenting project outputs/outcomes to stakeholders.

Pilot Manager and Lead – (Tom Gray, Chief Pharmacist)

The Pilot Manager and Lead shall be responsible for the day-to-day management of the project, reporting to the Project Sponsor. The Trust Pilot Lead shall be required to act as local change agent and be responsible for mobilising the resources at the Trust.

Duties included:

• attendance at all Pilot Board meetings
• chairing regular meetings between the Pilot Facilitators
• day-to-day management of the pilot risk register
• managing the Gateway process.
• achieving the objectives and deliverables specified in the Trust Project Initiation Document
• co-ordinating the project activities of Trust-based staff
• organising and maintaining records for project meetings as agreed with the Pilot Facilitator
• local implementation and embedding of agreed solutions and working practices
• managing the change associated with new ways of local working.
Pilot Facilitator – (Nancy Bavin, Management Consultant, Atos Origin)

An independent specialist shall be available to the Trust 1 day per week to drive the programme and to facilitate data collection and implementation. The Pilot Facilitator shall be responsible to the Pilot Board, in conjunction with the Trust Pilot Lead, for:

- achieving the objectives and deliverables specified in the local Project Initiation Document
- managing and driving the project plan
- reporting progress to the Pilot Board
- reporting progress to the Programme Board
- managing and mitigating risks associated with the pilot
- identifying, monitoring and resolving or escalating project issues
- co-chairing pilot team meetings with the Trust Pilot Lead

Other Pilot Project Team – (see Stakeholder Plan)
Dr Susanna Piggott (Consultant Anaesthetist)
Gill Ogden (Clinical Risk Manager)
Mark Cannell (Medical Devices Coordinator)
Anne Johnson (Assistant Director of Nursing)
Leslie Hancock (Professional Development Unit)

The pilot project team members are responsible to the Pilot Project Board, through the Pilot Facilitator and Trust Pilot Lead for carrying out tasks related to the project. These shall include:
1. attendance at Pilot Project Board Meetings and process workshops/focus groups – as required.
2. collection and verification of data to support analysis and process mapping activity
3. identifying, recording and evaluating ways of overcoming risks associated with the project
4. supporting management of change associated with the project
5. contributing to the activities of a project work streams as required by the Pilot Facilitator and Trust Pilot Lead.

4.3 Collaborative Procurement Hub

The Hub will:
- champion and promote the pilot programme across the region
- assist in the engagement of local stakeholders, especially clinicians, where appropriate
- facilitate the collection of data
- commit to implementing the outputs/recommendations as part of their work plan
- develop and embed best practice across the Hub.

4.4 Industry stakeholders

We will work closely with industry via the relevant trade associations (ABHI, ABPI and BGMA) and, in some cases, directly with individual companies, for example Baxter Healthcare, who have been instrumental in developing the project. Industry will be represented on the Steering Group.
5. Inputs and resources

Inputs will reflect the multidisciplinary nature of the project, as well as its local versus national focus.

Trust resources

The pilot team will be drawn from the selected focused clinical specialties, e.g. pharmacy, infection control and medical devices management, medical engineering, procurement, Anaesthetics, etc.

National resources

Inputs will be drawn from, amongst others: PASA, national category teams; academia; the Clinical Procurement Specialist Network; and specialist consultants.

6. Objectives

6.1 The objectives of the pilot are:

i) to demonstrate that strategic purchasing can reduce clinical risk associated with the administration of injectable medicines

ii) to learn lessons relating to the case of injectable medicines that will be of benefit to Trusts and Collaborative Procurement Hubs across the country

iii) to develop an approach that could serve as a model for addressing wider government policy issues through procurement.

6.2 The pilot objectives are closely aligned to the NPSA recommendations on improving medication safety in the NHS (March 2007). Including, but not limited to, reduction of patient risk via the following means:

a) colour, design and labelling of products

b) standardisation of devices, medicines and sets, and supporting training and protocols

c) centralisation of devices, medicines and sets

d) elimination/reduction of ‘open system’ medication in favour of pre-prepared products

e) elimination of injectables requiring complex calculation and dilution

f) double checking systems (e.g. bar-coding, electronic dose limiting software)

g) provision of written information by manufacturers for clinical staff.

By addressing the above areas, the Pilot Trust aims to:

- reduce the risk of errors (particularly user error) occurring
- alert users to possible dangers
- reduce the effect of use errors that occur.

6.3 Consideration will also be given to reduction of risk to staff, e.g. from needle stick injuries.
6.4 With this in mind, The Pilot Trust shall focus on:

A. standardising and centralising infusion devices
   A.1. review how purchasing and product selection decisions are made
   A.2. introduce or review process for evaluating the necessity for an infusion device prior to purchase
   A.3. identify the IV delivery system(s) that will minimise risk to patients and staff and promote procurement of products with inherent safety features
   A.4. determine the scope for reducing the range of infusion device types in use and, within each type, agree default configurations

B. identifying scope for rationalising medicine product ranges (e.g. by ‘dose-banding’ cytotoxics and antibiotics) and moving towards ready-to-administer or ready-to-use products wherever possible

C. developing an evidence-based ‘best practice/best value’ approach (practice and products) to IV drug delivery to optimise patient outcomes, system efficiency, user satisfaction, safety, cost-effectiveness and product use. This will include consideration of drug preparation in the clinical setting, delivery options, management of the intravenous access and monitoring of infusions throughout administration

D. ensuring stakeholder buy-in at local level through pro-active engagement and opportunities for input to decision-making from planning to implementation stage

E. delivering an agreed implementation plan that will support compliance with the recommended changes to products and practice

F. developing a process to measure the short, medium and long term outcomes (clinical and financial) of the implemented recommendations. This will include a means by which Trusts can demonstrate to commissioners their approach to patient safety.

7. Scope (section 18.4)

7.1 It is not possible, within the scope of this project, to include all departments, wards and clinical areas within The Pilot Trust. Therefore the Trust focussed on the following areas, and their respective processes and systems currently in place, arising from the findings and recommendations of phase 1:

7.1.1 Workstream 1 – Dose banding
Dose banding is a simple way of introducing standardisation to injectable therapy and products. Many medicines dosed by weight (e.g. aminoglycoside antibiotics) or Body surface area (e.g. cytotoxic chemotherapy) are suited to this approach. Dose banded products suit batch manufacturing and therefore purchasing for safety initiatives.

This work stream aims to work with the East Midlands ‘Re:Source’ Procurement Hub to identify suitable chemotherapy products for dose banding, develop a specification for the product, presentation (labelling and packaging) and logistics, to inform ‘purchasing for safety’ decisions.
7.1.2 Workstream 2 – Needle free systems

Needle-free systems are widely employed in the Trust for safe administration of injectable medicines and to reduce infection risks. Needle free systems are also available for the preparation of hazardous injections (e.g. cytotoxic chemotherapy), reducing the risk of operator injury and environmental contamination. Examples include the Teva ‘Tevadaptor’ system and Baxter ‘Chemo-Aide’.

This work stream aims to evaluate these products within specialist pharmacy aseptic dispensing services using qualitative techniques to rate ease of use, time saving, staff safety etc and to make recommendations for safe aseptic dispensing practice.

7.1.3 Workstream 3 – technical information / labelling

Information contained within injectable medicines packaging is highly variable and it is often difficult to extract the essential information for safe preparation and administration. There is a need to ensure that sufficient technical information is available to guide healthcare staff. In addition essential information (such as dose, range, route, method of administration) should be available on the outer pack.

This work stream aims to identify and evaluate essential information and optimise designs to reduce selection, preparation and administration errors. The work stream will adopt existing design schemes (e.g. Royal College of Anaesthetists’ critical care labelling scheme).

7.1.4 Workstream 4 – Barcodes

Barcodes contain essential information for the auto-identification of injectable medicines using appropriate technology. The development of matrix (2D and 3D) barcodes allows further information on product expiry and even patient name, dosing directions etc, to allow positive patient identification and reconciliation of product, patient and prescription.

This work stream will prepare a business case to support 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 will not allow evaluation within project time scales.

7.1.5 Workstream 5 – Designs for safety – infusion pumps

New technology and designs have come to market following publication of ECRI standards and development of software to set limits and track use, allowing a user log to downloaded for analysis. There is published evidence that these ‘guardian’ software systems prevent serious errors reaching patients. However, the interface often allows users to bypass these safety systems and they are may not be intuitive to use.

This work stream will focus on learning from errors recorded in the user logs, evaluating the impact of drug library and software limits on error reduction and developing a specification for manufacturers and procurement to optimise the user interface and key features for ‘purchasing for safety’ decisions.
7.1.6 Workstream 6 – Designs for safety – training

Training and assessment are essential to support the safe use of injectable medicine products and devices. Training is well established for nursing staff in safe administration of injectable medicines and use of infusion equipment; however, medical staff receive virtually no training in safe medicines practice associated with injectable medicines. There is also a widespread lack of understanding of second checking principles and practices, important safeguards in injectable therapy.

This work stream will focus on identifying the gaps in training and assessment of medical staff in Derby, identify methods for delivering this and evaluate training packages developed in South Manchester. The work stream will also identify / develop resources to support ward preparation of injectable medicines (e.g. posters, pocket guides etc).

7.2 In terms of product, all injectable medicines and the devices and consumables for their administration were in scope initially for Phase 1. Consideration was also shown to the systems and processes that supported the products and services, thus included (but was not limited to), packaging, labelling, use of colour and bar coding.

The umbrella of injectable medicines is seen to cover intraosseous, intravenous (push, infusion and combination) subcutaneous, intramuscular, epidural and intrathecal, intraarterial and intraocular administration. Administrations via the oral route are out of scope.

Products selected are:

Drugs for pre-prepared medicines will be identified as part of the workstream activity, based on risk profiles from Phase 1 and product availability.

7.3 In terms of process, the Trust’s pilot project shall encompass supply and storage, preparation and administration (including monitoring) of injectable medicines. Quality control shall also play an important role.

7.4 In terms of setting, The Pilot Trust, as far as possible, shall reflect the distribution of injectable therapies across the secondary care setting.
8. Methodology

8.1 Phase 2 - implementation

The implementation phase will address the issues identified during phase 1, prioritised according to urgency and ease of implementation. Because of the longer-term nature of some of the actions, it is likely that the plan will identify what can be achieved in the short, medium and long terms. It is important to stress that ‘quick fixes’ are not being sought; rather, we aim to encourage system-based improvements that are sustainable.

Consequently, the long-term and some of the medium-term solutions will be delivered after the end of the pilot term; however, the pilot will set the Trust on a pathway for change and it will be important to have a follow-up evaluation at least 12 months after the conclusion of the pilots to measure the full benefits.

If appropriate, product trials/evaluations may be carried out during phase 2, in conjunction with the Centre for Evidence-based Purchasing (CEP) and the relevant suppliers (subject to ethics committee approval).

The project methodology design for Phase 2 shall include 5 main stages for each workstream. These are demonstrated in figure 1 below.

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Figure 1- project methodology
8.2 Methodology toolkit

- Phase 1 findings
- Task analysis techniques
- SWIFT (Structured What-If Technique) for hazard identification (relating to infusion devices in use, particularly the human and organisational factors).
- Root cause analysis tools and techniques
- Cost-benefit analysis (affordability versus value/quality/safety)
- Medical Devices Training Criteria (THOTH).
- Trust policies, processes and guidelines
- Trust clinical risk data and other relevant data related to the administration of injectable medicines.

8.3 Cultural analysis

Derby Hospitals NHS Foundation Trust has a positive safety culture as demonstrated in the response to the Manchester Patient Safety Framework. Over 4,000 evaluation forms were sent out with 990 returned (22%). Of those that returned forms, 54% of respondents rated the Trust as having a good or excellent safety culture – being proactive and integrated into strategy and daily activity - with only 3% of respondents rating this as poor. Some variation was seen across staff groups, and in response to the individual questions, although it is difficult to draw conclusions from these results.

However, even though systems and technology are in place to support practice, healthcare staff can become complacent and take systems for granted. Staff will often find shortcuts to get a job done more quickly in the pressurised care environment; such ‘custom and practice’ violations can lead to patient harm.

8.4 Incident reporting & investigation processes

Senior clinicians and managers have been trained in the use of Root Cause Analysis techniques and these are routinely used to investigate incidents with future moderate or high risk as well as develop learning from low risk incidents. Medication errors are routinely reviewed by the Trust Medicines Management Committee (reporting to Clinical Effectiveness Committee) and incidents involving medical devices and administration equipment to the Infusion Systems sub-committee. Incidents deemed to have a moderate or high potential future risk are reviewed and quality assured by the Trust Incident Review Group – a high level group including the Medical Director, Director of Nursing, Chief Pharmacist, Clinical Risk Manager, Complaints Manager and Trust Solicitor.

Promoting a safety culture is an ongoing necessity in any healthcare organisation, requiring ‘top-down’ promotion and ‘bottom-up’ reporting with constructive feedback on incidents, focussed and targeted interventions and promotional activities. This purchasing for safety initiative for injectable medicines has enabled the Trust to prioritise injectable medicines safe practice recommendations.
8.5 Review of Phase 1 case studies and findings

8.5.1 Case study: theatres and imaging

**Background:**
Theatres and Radiology areas are users of high risk injectable medicines (e.g. anaesthetics, contrast media).
Medicines management processes are subject to less scrutiny than other areas within the Trust due to restricted access and lack of daily clinical pharmacy services. Medication safeguarding processes are ad hoc and documentation is limited.

**Proposed Changes:**
1. Imaging - Use of pre-filled syringes in the operating theatres.
2. Theatres - Improved communication between departments.
3. Radiology - Improved documentation and reporting.

**Potential Benefit:**
- **Imaging -** Increased patient safety and reduced risk of errors.
- **Theatres -** Improved communication and reduced risk of medication errors.
- **Radiology -** Improved documentation and reduced risk of medication errors.

**Statement of Problem (Issue):**
1. Presentation of injectable medicines (storage, packaging, labelling, selection).
2. Incorrectly prepared products, lack of labeling, and incorrect rotation of stock.

**Area:** Theatres and Imaging, represented by General and Obstetric Theatres and X-ray.

**Pilot Site:**
Derby Hospitals NHS Foundation Trust.

8.5.2 Case study: chemotherapy

**Background:**
Cytotoxic chemotherapy is a high risk treatment, utilising potent injectable medicines that can cause harm on injection, spillage and mishandling. There are clinical risks to patients (e.g. radiation dose) and to staff (exposure due to mishandling, spillage). There are many controls in place for safe preparation and administration of cytotoxic chemotherapy and a proactive risk management culture.

**Proposed Changes:**
1. Introduce dose banding for further products (based on usage, stability, presentation etc.). Estimate 20% of total products.
2. Introduce standardised storage and handling procedures.
3. Introduce electronic patient administration systems.

**Potential Benefit:**
- **Imaging -** Decreased risk of exposure to harmful medicines.
- **Theatres -** Improved communication and reduced risk of medication errors.
- **Radiology -** Improved documentation and reduced risk of medication errors.

**Statement of Problem (Issue):**
1. Dose banding - to increase capacity for chemotherapy.
2. Lack of standardised storage (GSA).
3. Limited shelf life of pre-filled syringes.

**Area:** Cytotoxic chemotherapy preparation and treatment area.

**Pilot Site:**
Derby Hospitals NHS Foundation Trust.
8.5.3 Case study: maternity

Pilot Site:
Derby Hospitals NHS Foundation Trust

Area: Maternity Services

Background:
Maternity Services are key users of injectable medicines routinely. However, obstetrics can require use of complex epidural and other injectable medicines at short notice and in emergencies. There is some lack of standardisation of infusion equipment used in maternity areas (following risk assessment), although training is consistent. There is also lack of standardisation of drug products and national guidelines for use e.g. Synthrom products.

Use of extension lines and multiple connectors can lead to infection risks and errors due to administration via the wrong route. Inadequate labelling of injectable medicines and lack of accessible information can lead to preparation and administration errors, particularly when drugs are used in emergency situations.

Statement of Problem (Issue):
1. Standardisation of Synthrom products
2. Lack of standardisation nationally and locally use of different strengths of Synthrom pose a risk to patient safety
3. Lack of stability data to support pharmacy preparation / storage
4. Ward / Theatre preparation and storage – 7 Labelled / Checks / Arr
5. Extension lines / multiple connectors
6. ‘Dead space’ in extension lines could result in ‘bolus’ of drug and incompatibility if drugs mix in set.
7. Large lumen (high flow rate in emergency) increases dead space
8. Poor labelling and information
9. Inappropriate use of brand name on commercial products
10. Quality of information – small writing, unclear, inaccessible
11. Errors converting from concentration in ‘units’ to ‘ml per hour’

Proposed Changes:
1. Review national guidelines and rationalise strengths
2. Consider standard concentration and adjust dose by rate
3. Consider availability of pre-made special or commercial product
4. Consider pharmacy preparation of other injectable medicines
5. Consider standardised labelling by indication / administration
6. Review rationale for use of extension lines / connectors
7. Manufacturer to redesign extension sets to reduce ‘dead space’
8. Consider alternative large bore set with reduced ‘dead space’
9. Standardise extension sets across Trust
10. Standardised labeling of key information for administration
11. Improve clarity and accessibility to essential information for safe and effective preparation and administration (e.g. dose, range, route, preparation and administration method).

Potential Benefit:
1. Rationalisation of product
2. Potential for single concentration, ready to use pre-filled product
3. Reduced risk of errors from mixing up similar looking syringes
4. Reduced cost through block NHS purchase agreement
5. National clinical guidelines for maternity services
6. Reduced administration complexity and fine selection errors
7. Reduced risk from inappropriate bolus of drug in ‘dead space’
8. Cost effective procurement and standardised training in Trust
9. Reduced risk of confusion, error and delay in treatment
10. Better availability of technical information for preparation
11. Clear information for safe administration of product

8.6 Phase 1 recommendations – for the Trust

8.6.1 Procurement

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

8.6.2 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 in future

8.6.3 Storage

- Review RHS medicines storage and preparation facilities and ensure designated area for medicines preparation conforms to best 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)
8.6.4 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

8.6.5 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

8.6.6 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

8.6.7 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

8.6.8 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

8.7 Procurement

A workshop held in May 2007, identified principles and practices from pharmaceutical procurement that should also be applied to the purchasing of medical devices and associated consumables. Development of a purchasing model - based on ease of use, standardisation, the procurement process, life cycle costing, information resources, communication and evaluation - will help with device selection.

These have been used in phase 2 workstreams in the development of a purchasing specification for dose-banded chemotherapy products and will form a key element of the NHS PASA procurement toolkit.
8.8 Questionnaire

Questionnaires will be used for the measurement of improvement through the workstreams, where appropriate, to establish evidence.

The staff survey conducted in August 2007 (Appendix G) provided valuable insight into staff attitudes and understanding of risk management issues relating to injectable medicines. Disappointingly only 232 staff (~5% of the clinical workforce) completed the online survey, due in part to technical difficulties and the short time scales for completion. 62% of questionnaires were completed by nurses and midwives, 12.5% by pharmacists and approximately 6.5% by doctors. 10.5% of respondents worked in Critical Care (ITU and Theatres), 8.5% in maternity services, 4.5% in Imaging and 3.5% in Oncology, pilot areas for the project. Nevertheless this represented a wide diversity of opinion about aspects of injectable medicine products and practice.

Analysis of the questionnaires highlighted staff awareness of the safe use of injectable medicines. It emphasised the need for a safer approach in the design and volume of injectable medicines and devices, supporting the selection of particular workstreams. Recommendations for Phase 2 workstreams, included:

- Dose banding and greater availability of standardised ready to administer injectable products. Whilst these are widely available for many products there is scope to extend the range further, and a need for aseptic dispensing when manufacturing is not considered economically viable. Facilities for aseptic preparation on wards are woeful and whilst some staff indicated that pharmacy could be unresponsive at times, most staff identified the lack of time they had for safe medicines preparation at ward level. Risks are mitigated by developing ward based pharmacy aseptic preparation / dispensing services, as at Derby Hospitals.

- Procurement of suitable ready to use injectable medicine products was considered a high priority by respondents although there was confusion as to who was responsible for this and the systems and processes supporting purchasing decisions – these will be addressed through phase 2 of the pilot.

- Needle free systems are considered an important method of safeguarding staff from inoculation accidents, and whilst widely adopted for administration of high risk medicines (e.g. chemotherapy) in many areas of the Trust, these are not currently utilised in the preparation of such high risk products. Use of plastic single-dose ampoules are welcomed and widely used in the Trust.

- Information and labelling were both identified as areas where improvements could be made, both in terms of product packaging and identification, but also technical information and instructions for preparation and administration.

- Barcodes were not specifically identified although recognition of the use of SMART technologies for positive patient identification and reconciliation of product with patient were both highlighted as important risk reduction measures.

- The questionnaire contains a wide range of recommendations for the safe and effective use of medical devices – from availability of clean, calibrated devices to recommendations for enhancements to user interfaces, security and functionality. The infusion device workstream will address many of these issues and concerns.

- Training also featured throughout the questionnaire with a need to improve this – making this more accessible, available to a wider range of staff and improving information to assist with the choice and use of medical devices used in injectable medicines administration.
9. Outputs

9.1 PID and Executive Summary

A project initiation document was developed between NHS PASA and the Pilot Trust to provide context to the purchasing for safety project (Phase 2), and to engage the support of Trust Executives and Associate Directors, by means of an Executive Summary.

A copy of the Trust Charter (Executive Summary) is included within Appendix E.

9.2 Communications plan

A communications plan covering the second phase of the project is included within Appendix D, and was developed incrementally to ensure that all stakeholders and interested parties were kept informed and the outputs of the project properly communicated and promoted.

Summary information was also made available to all Trust staff and wider NHS healthcare staff via a dedicated webpage on an extranet (nhs.net) server, available at: http://nww.derbyhospitals.nhs.uk/pasa/pasaindex.htm

9.3 Risk register

A project risk register was maintained by the pilot facilitator in order to escalate issues to the Pilot and Project Boards. A copy of this register is included within Appendix B.

Special attention was shown to the joint communications and media strategy between NHS PASA and the Pilot Trust, as a result of some local negative media attention in phase 1 of the project.

9.4 Project plan

A high level project plan was drawn up and managed by the Trust’s Pilot Lead to ensure that the project and the pilot remained on track. A chart showing the timing of the key phases of the project is included in Appendix A.

9.5 Stakeholder map

A stakeholder map, detailing the names of those Pilot Trust members who have been involved in the project is included within Appendix F.

10. Constraints

- Availability of Trust staff to lead the pilot
- Availability of Trust staff to attend workshops, interviews etc
- Availability of data required from the Trust
- Acceptance of pilot outcomes and the motivation and agreement to implement recommendations
- Ability to use expected purchasing savings on devices to offset potential increase in acquisition costs for inherently safer products.
11. Deliverables

For each workstream there will be:

- Cost-benefit analysis for key proposed actions and consistent method for assessing 'value' in patient safety terms, taking into account risk, benefits, total cost, affordability etc. This will help to make a case where acquisition costs are likely to increase.
- Revise current 'safety in use' criteria to be built into future procurements
- Final report with written up case studies
- Knowledge pack and toolset to guide other Trusts / procurement hubs (content to be agreed during phase 2)
- Methodology for evaluating progress and benefits against baseline / benefits tracking tool

12. Benefits

As in phase 1, a number of benefits can be identified from the project, which are summarised below:

12.1 Benefits for patients

Patient safety is paramount and this project has helped to raise awareness of the risks associated with injectable medicines. The project has highlighted a number of high risk processes which must be modified, as well as opportunities to enhance safety through use of better products (e.g. more standardisation and ready to administer products). Patient experience is also important and easily compromised by staff being too busy to clearly explain procedures and supervise the administration of injectable medicines.

12.2 Benefits for healthcare professionals

Health professionals involved in the focus groups and case studies from Phase 1 have benefited from the opportunity to review processes, products, devices and training in detail through brainstorming and structured interviews. A wide range of staff have participated in the online injectable medicines survey, reflecting on safe practice issues.

Despite the large number of products that are already provided by pharmacy in a ready to use form, and the widespread use of the Baxter Minibag Plus™ administration system, the project has identified a number of injectable medicines that could be presented in a safer or more convenient form and staff will benefit from more ready to administer products in the future.

Infusion devices have already been rationalised and staff benefit from greater availability of functional equipment through centralised equipment libraries. Whilst this has streamlined information and training in infusion devices and techniques there is opportunity for further work to maintain this and promote best practice in clinical areas. Some work has already been undertaken to rationalise consumable use in the Trust, although there is opportunity for further standardisation.

12.3 Benefits for the procurement community

Derby Hospitals have a strong reputation for cost-effective procurement of pharmaceuticals through the Trent Purchasing Consortium and now the East Midlands ‘Re:Source’ Procurement Hub.
Pharmaceutical procurement has always focussed on quality and increasingly on patient safety through, for example, review of packaging design and labelling. There are significant opportunities to rationalise procurement both nationally and regionally through commercial procurement hubs and to standardise products. It is essential that patient safety remains central to all procurement decisions, and must be built into purchasing specifications and subsequent contracts.

This will require good communication with healthcare professionals and clear specification for high quality, safe products. Increasingly medical devices and consumables are being targeted by procurement hubs and this is welcomed.

The project has identified a number of areas where national / regional procurement makes good economic sense and would bring significant patient safety benefits from this rationalisation (e.g. dose banding).

12.4 Benefits for the healthcare industry

The project offers the healthcare industry and local Trust opportunity to trial and evaluate new injectable medicine products and devices. Rationalisation and standardisation of the product range will ensure supply continuity to the NHS. Clear product specifications which focus on product safety and quality will encourage greater innovation in product design and business opportunity. The healthcare industry supplying this market will benefit from the opportunity to add value to their product offerings and to differentiate their products based on safety considerations.

A focus on simplification through clear labelling, effective product information, design and use of materials which are safe to handle and administer will encourage uptake from the NHS.

12.5 Benefits for the pilot trust

The pilot Trust has benefited from an increased focus and awareness of safety issues relating to injectable medicines. The project has clarified the extent of use and identified many areas of strength and opportunity as well as examples of poor practice and high risk.

The Trust has benefited from a closer working relationship with NHS PASA and access to researchers from the Cambridge Engineering Design Institute, as well as gaining experience in project methodology and the use of various analysis tools, from the project facilitators, Atos Consulting.

13. Impacts

- Patients – improved safety and reduced risk of adverse incident; better patient experience.
- Clinical staff – likely changes to administration protocols and practices for use of and administration of injectable medicines; increased emphasis on training and information.
- Suppliers – clarity around decision-making and rationale for product selection.
- Pilot hub – purchasing savings across participating Trusts; opportunity to roll out across the hub; reputation gain from leading the way in effecting a reduction in clinical risk through strategic purchasing.
• Trust – improved patient outcomes; improved patient and user satisfaction; reduced risk and cost of litigation; purchasing savings; better utilisation and management of equipment; standardised and simplified approach to administration of IV therapy.

• Purchasing and supply function – evidenced-based decision-making for purchasing; quantified savings opportunity.

• Wider Trust/CPH community – ability to learn from the Trust’s experience and benefit from best practice outputs.

• All – news ways of working, with safety and value as the common focus.

14. Risks and assumptions

A Risk Register for the pilot is at Appendix B. Risks will be monitored throughout the duration of the project and mitigating action taken where appropriate. Any significant (corporate) risks which cannot be managed by the project team will be escalated to the PASA Project Manager and Programme Board.

It is assumed that:

• The Trust will have an appropriate level of buy in from key stakeholders and the Pilot Sponsor

• The Trust will have sufficient staffing resources to undertake pilot activities to meet an agreed action plan

• PASA will supply some additional support and tools to manage the Pilot.

• PASA will supply Consultancy support 1 day a week to drive the pilot agenda and aid facilitation of focus groups and specialist interviews.

15. Project acceptance

Project acceptance is secured by:

• Agreement from the Trust’s Chief Executive

• Agreement by the Project Board and Project Sponsor

• Agreement by key stakeholders

• sign-off by Trust Project Board

• Sign off by PASA (MET)

16. Project milestones – Phase 2

The Project plan (appendix A) provides details of project milestones for each workstream.
17. Quality

Quality within the project will be assured by:

- following the principles of the PRINCE2 project management methodology with assistance provided by the Pilot Facilitator
- a robust governance structure that facilitates the rapid escalation and resolution of issues
- a risk assessment undertaken by the Trust pilot members. All Trust pilot members and stakeholders are obliged to register perceived risk with the Trust Pilot Board via the Risk Register. A Risk Register for the Trust Pilot will be maintained by the Trust Programme Manager/Pilot Facilitator.

Overall quality of the pilot will be assured by the PASA Programme Board and the Trust Pilot Board.
18. Phase 2 workstreams

18.1. Introduction

As described above the phase 2 workstreams were highlighted from key findings of phase 1 of the project. They were selected to cover a broad range of purchasing for safety benefits and clinical risk management issues.

Workstream Leads were members of the Trust Pilot Board or staff selected due to their expertise within the focus area. Workstream Leads were supported by a chosen workstream team, the Pilot Project Lead and Pilot Facilitator.

The workstreams were conducted over a period from October 2007 to February 2008, following the development of workstream briefs, which outlined the purpose, aim, objectives, milestones and measures. Progress was monitored at Pilot Board meetings through a summary action / progress plan and verbal reports (these are included within the attached workstream reports).

The following workstreams were conducted:

- Dose banding chemotherapy – developing a purchasing specification
- Needle-free preparation of high risk drugs – evaluating two devices
- Technical information and labelling – essential information for product selection / use
- Barcode technology – to minimise administration errors through positive identification
- Design of infusion devices – evaluation of user logs and software library / dose limits

Time constraints prevented the training workstream from progressing, although this remains fundamental to safe medicines practice with injectable medicines. The Trust provides systematic training for pharmacy and nursing staff, but medical staff receive little or no formal training.

18.2. Methodology

Each workstream conducted a series of tasks relevant to the workstream objectives. Brainstorm and focus groups were used to analyse safe practice issues and purchasing for safety opportunities and establish priorities for each workstream. A literature review was undertaken in each workstream to provide insight, context and to inform findings.

Where appropriate specifications were constructed to clarify requirements, guide design and establish procurement criteria. Limited evaluations were undertaken, in two workstreams, to test ideas and establish principles for safe practice with injectable medicines.

18.3. Outputs

Outputs consisted of a detailed workstream report according to the following template, which was agreed by the Pilot Board. These reports completed by the Workstream Lead form a key part of the phase 2 report to the PASA Project Board.

Evaluations are included within the report and include qualitative findings from detailed questionnaires designed by the workstreams, delivered and analysed by Exodus Research.

Further dissemination will be made through poster and oral presentations at national conferences, in addition to a national Purchasing for Safety report, from NHS PASA.
18.3.1. **Workstream reports** (See Annex 1)

- **Summary**
- **Background**
  - Phase 1 findings – summarising relevant findings from phase 1 report, including potential risks associated with current procurement practices and processes
  - Aim and key benefits – overall aim of workstream and expected key benefits
  - Workstream summary – from the workstream brief

- **Objectives** – specific objectives from the workstream briefs

- **Methods and measures**
  - Workstream design – design, setting, stakeholders, criteria for product selection
  - Evaluation(s) – methodology used for each evaluation (design, timescale etc)
  - Measures – quantitative and qualitative measures used for each evaluation and/or overall workstream; including clinical, financial, process and people measures as appropriate

- **Workstream outputs**
  - Literature review – relevant abstracts, existing national and local guidance
  - Focus groups – Summary of discussion and key findings from focus groups / brainstorm etc, and identifying proposals and recommendations
  - Evaluation(s) – Summary of key findings / results from any in-house evaluation(s)

- **Recommendations**
  *Detailed recommendations arising from the workstream, and related to the workstream objectives.*

- **Discussion**
  *Discussion of outputs and findings, relating these to the issues identified in phase 1 and phase 2 focus groups, published literature, national and local guidelines.*

  Discussion of the advantages and disadvantages of these risk reduction strategies, in terms of benefits, risks and associated costs.

  *Description of any Implications for Pharmaceutical Industry, PASA, MHRA, NPSA etc*

  Reflection on the methodology and measures, shortcomings and potential sources of error in reporting, any assumptions and challenges in undertaking the workstream.

- **Conclusions**
  *Whether the overall aims of the workstream were met; the challenges of taking the workstream forward; next steps for the Pilot and Trust.*

- **Acknowledgements**

- **Appendices** – including the workstream brief, detailed findings of the brainstorm / focus groups and meeting notes, details of evaluation tasks and results.

18.3.2. **Questionnaires** used during evaluations to collate quantitative and qualitative staff responses and preferences (analysis undertaken by Exodus™ research).

18.3.3. **Dissemination** by means of written reports, oral and poster presentations and local and national conferences.
18.4. Workstream summaries

18.4.1. Workstream 1 – Dose banding

Lead: Peter Fox, Principal Pharmacist, Pharmacy Logistics, R&D

Dose banding is a simple way of standardising injectable therapy and products. Many medicines dosed by weight or body surface area are suited to this approach. Dose banded products facilitate batch manufacturing and purchasing for safety initiatives.

NHS aseptic manufacturing units have insufficient capacity to meet demand and the development of a procurement specification will encourage pharmaceutical industry to deliver dose banded products to a consistent standard to meet this growing demand for ready to administer products.

As well as freeing up NHS aseptic dispensing capacity, dose banding simplifies the provision of ready to administer products, by reducing dose variation, resulting in less errors and streamlining dispensing. The benefits include:

- reduction in patient waiting times through improved pharmacy workflows
- increased pharmacy capacity
- reduction of waste by avoiding incomplete use of vials when preparing individual doses and the ability to re-assign syringes if not used for a patient
- consistency for medical staff who may work on more than one site
- A reduced range of products required, which may result in reduced prices

Standardisation should bring about reductions in production costs at specials manufacturing units and, as demand becomes clearer, may convince the pharmaceutical industry to market fully licensed ready to administer products.

The workstream was conducted in collaboration with the East Midlands Procurement Hub ‘Re:Source’, and local Cancer Networks, making reference to local evaluation of dose banding and guidance from the Scottish Cancer Pharmacy Group.

The resulting specification was designed to address purchasing, logistics, quality and clinical risk management issues applying to the product, packaging and labelling. In addition customer care issues, supply and performance monitoring are also included.

In order to realise the true benefits such a specification needs to be promoted nationally and widely adopted. It is likely that a lack of agreement as to the products, and dose bands to be used, remains the biggest challenge to early implementation. There are opportunities to apply such an approach to rationalise other standard products (e.g. aminoglycoside antibiotics) and to utilise these standards within existing NHS aseptic manufacturing and dispensing units.

An evaluation of dose banded cyclophosphamide conducted in Derby in 2006, demonstrated that pharmacy preparation / dispensing time could be halved, freeing up valuable time and capacity for other patient specific preparation. Feedback from nursing staff was not formally evaluated but was largely positive, although identified that labelling and packaging needed to be improved to aid product selection and access.

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.
18.4.2. Workstream 2 – Needle-free systems

Lead: Amanda Hewitt, Chief Pharmacy Technician, Chemotherapy Services

Needle-free systems are widely employed in the Trust for safe administration of injectable medicines and to reduce infection risks. Needle-free systems are also available for the preparation of hazardous injections (e.g. cytotoxic chemotherapy), reducing the risk of injury to the operator and environmental contamination.

One of the main issues identified from Phase 1 of the project was the potential for needle stick injuries whilst aseptically preparing cytotoxic products. The aim of this particular workstream was to evaluate current local practice for cytotoxic preparation and also identify and evaluate needle-free devices, available on the market, for cytotoxic preparation and administration.

Anticipated benefits included:

- Safety for operators (eliminates the risk of needle stick injuries).
- Ease of use (with less manipulations required).
- Safer administration (decreases the risk of spillage).
- Reduced risk of cytotoxic exposure for both preparation and administration.
- Reduced preparation time.

Benchmarking indicated that current practice in Derby was in-line with other local units and that needle-free systems were not adopted locally. This was confirmed by literature review which relates to safe handling issues but without specific reference to needle-free systems, although closed drug transfer devices are recommended by the US National Institute for Occupational Safety.

Evaluation of two products (Baxter Healthcare’s ‘Chemoaide’™ / ‘Viaflo’™ system, and Teva Pharmaceuticals ‘Tevadaptor’™ system) was undertaken in the chemotherapy suite by a multi-disciplinary team of pharmacy and nursing staff. This involved both qualitative and quantitative self-analysis by means of a formal questionnaire, conducted by Exodus Research. The needle-free products were evaluated for one week, following introduction and basic training by industry representatives. The evaluations covered both use in the preparation and administration of cytotoxic chemotherapy.

The evaluation covered current practice, time taken, advantages and disadvantages for ease of use, operator protection, patient safety, and related incidents. The evaluations showed that staff preferred a needle-free system for preparation and administration of chemotherapy over use of needles / open systems. Significant patient / operator safety benefits were identified although ease of use / time was not a significant factor in choice. Cost and a lack of stability and sterility information were seen as limiting factors for uptake by NHS hospitals.

The ideal system would 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.

Whilst not wishing to put a price on patient or staff safety, systems currently available are relatively unaffordable. In order to minimise risk, regulatory and patient safety authorities should mandate the 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.
18.4.3.  Workstream 3 – Product information and labelling

Lead: Susanna Piggott, Consultant Anaesthetist

Information contained within injectable medicines packaging is highly variable and it is often difficult to extract the essential information for safe preparation and administration. There is a need to ensure that sufficient technical information is available to guide healthcare staff in the use of complex injectable medicines.

The Theatres and Imaging Focus Group identified the following risks arising in theatre which could lead to error with injectable medicines:

Lack of consistency in storage; distractions whilst preparing drugs for administration; lack of second checking; variability and unsuitability of drug packaging and information; some drugs supplied in doses far in excess of that required for clinical use; poor documentation; and inadequate staff training. Product labelling and information could offer possibilities for risk reduction through purchasing and were selected for further investigation by phase 2 workstream.

A multidisciplinary group involving medical, nursing, pharmacy and operating department staff reviewed packaging information supplied with injectable medicines and identified essential (mandatory and required) information for preparation, administration and storage that should be displayed on the primary (product vial) and secondary (outer packaging) containers.

The group focused on two high risk products - *phenylephrine*, a sympathomimetic drug, which is supplied in a dose 1000 times greater than that required for clinical use and requires complex dilution before use. *Bupivicaine* is a routine local anaesthetic for epidural use, but supplied in multiple strengths, and accidental intravenous injection has a very high mortality rate.

The focus group also looked at colour and design of the secondary container, incorporating the established Royal Collage of Anaesthetist’s (RCOA) critical care labelling scheme to aid product identification and selection, and design to differentiate between multiple strengths within a therapeutic family. New packaging and labelling were ‘mocked up’ and, together with a ‘Kardex’ style information system in similar design, evaluated by means of a questionnaire conducted by Exodus Research.

It is clear that 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 MHRA recognise ‘the potential for improving the layout of medicines labelling to aid clarity, to assist health professionals and patients to select the correct medicine and use it safely’; current regulations fail to deliver this.

A further focus group with representatives from NPSA and Industry, and a practice researcher from USA, reviewed opportunities to improve labelling and packaging through new draft NPSA guidelines for injectable medicines and innovative ‘peelable’ multi-layer labels providing information, product and record labels.

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 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.
18.4.4. Workstream 4 – Barcode technologies

Lead: Gill Ogden, Clinical Risk Manager

Barcodes contain essential information for the auto-identification of injectable medicines using appropriate technology. The development of matrix (2D and 3D) barcodes allows further information on product expiry and patient name, even links to dosing directions etc, to allow positive patient identification and safe administration through reconciliation of product, patient and prescription.

Most medication errors occur at the point of administration and half the medication errors that lead to harm or death occur with injectable medicines. Whilst only 4% of errors involve patient identification, errors made during administration are more likely to result in harm as there are fewer opportunities to identify and rectify them.

Current reconciliation systems involve independent double checking, although the checking process is often misunderstood and poorly applied. Double checking is not routinely practiced in some theatre areas where the same individual can be responsible for prescribing, preparing and administering injectable medicines with no independent checks. Barcoding has been successfully used for positive patient identification and to reconcile medicinal and blood products with the patient prescription and administration record.

The workstream aimed to develop a business case and outline specification supporting barcoding for a wide range of applications, including patient identification, reconciliation of products, asset tracking etc, and building on work already being conducted within the Trust. An options appraisal supported working with a preferred supplier to develop or source such a technical solution.

A focus group involving nursing staff within Surgical Services identified opportunities to reduce risk in the injectable medicines preparation and administration process using barcoding, and identified key benefits as:

- Increased efficiency of stock management (including direct ordering for non stock drugs)
- Safety checks against product, patient record and the patient at the preparation and administration stages

Issues and risks were identified including the need for training and authentication, and the lack of machine readable barcodes on some products. Importantly staff considered that the use of barcode readers must be a natural part of the process and not an extra ‘chore’, to minimise the risk of workarounds.

An ideal system will cover a wide range of healthcare auto-identification issues and interventions. Most commercial products are designed to address one particular issue and such an approach would involve multiple different systems, resulting in complexity and integration issues. A subsequent meeting with GS1 confirmed this strategic ‘umbrella’ approach would be of greatest benefit to a complex, multi-faceted organisation such as the NHS.

Barcoding technology offers significant 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 is likely to be the most cost effective solution for the NHS, and represents an important purchasing for safety opportunity.
18.4.5. Workstream 5 – Pump design for safety

Lead: Mark Cannell, Medical Devices Coordinator

New technology and designs have come to market following publication of ECRI standards and development of software to set dosing limits and track use, allowing download of user logs for analysis. There is published evidence that these ‘dose limiting’ software systems prevent serious errors reaching patients. However, the interface often allows users to bypass these safety systems and they may not be intuitive to use.

The workstream was identified from issues raised by the focus groups in phase 1 of the project, which identified that, as well as a lack of familiarity and training, errors occurred due to complex menu choices and pump availability in the Trust was a significant concern. The workstream conducted in collaboration with Baxter Healthcare, validated a pump needs analysis and analysed end user logs using a bespoke health informatics tool.

The Trust standardised volumetric infusion devices in 2003-4 and has since introduced a standard PCA pump and syringe driver devices, in line with national recommendations. Some of these pumps incorporate smart technology in the form of hardware and software limits, drug library selection and auto-setup options. However, the interfaces appear somewhat counter-intuitive, invariably discouraging the use of the safety software by burying under levels of menu functions, instead of it being an “opt-out” function.

Centralised equipment libraries have been established on both sites, with a marked reduction in the unavailability of equipment and benefits in terms of tracking and maintenance of infusion equipment.

Pump logs from 191 Baxter Colleague™ volumetric infusion devices, representing an average of 4,700 hours of battery life and 70 hours end user activity were analysed. Data demonstrated that batteries were utilised only 3% of the time with limited deep discharges (that can lead to pumps entering a ‘failsafe’ mode, shutting down and leading to sub-therapeutic treatment). The analysis showed that pumps were only utilised around 60% of the time. Analysis of end user logs showed that Guardian safety software has not been implemented and dose mode (as opposed to rate setting mode) only utilised 17% of the time. There are significant opportunities to improve pump safety through initialisation of these features, making use of the standardised injectable medicine infusions used across the Trust.

The pump needs analysis predicted a significant increase in the number of infusion channels required, which is contrary to the utilisation findings above. This may be due to the different methodology applied in these tools. A more accurate assessment of the findings would refine these tools and could provide objective guidance to the purchaser.

Dose limiting software and analysis of usage logs offer valuable tools to improve safety of injectable medicines. However, these must be readily accessible and reports easy to interpret with clear recommendations. New pumps should incorporate ‘smart’ technologies and further national guidance is awaited from NPSA.

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 these safety features within Derby and other NHS Hospitals.
18.5. Workstream evaluations

Questionnaires were developed for the two workstreams that involved product evaluation and design; needle-free systems and product labelling & information. The results from these questionnaires were collated and analysed by Exodus Research and are summarised below:

18.5.1. Workstream 2 – Needle-free systems

Evaluation of pharmacy preparation using needle-free devices showed that staff considered these safer than current practice using needles. Needles were considered quick and easy to use, but could involve complex manipulation and carry a risk of needle-stick injury. The Baxter ChemoAide™ device was also considered quick and easy to use but carried a risk of spillage. Operators noted that contamination of the vial and adaptor occurred and the price was a disadvantage. Operators were divided in their opinion that this device represented value for money. Teva’s Tevadaptor™ was found considerably easier to use and this together with its safety considered the greatest advantages. Contamination was still considered the greatest risk, although it was considered value for money by participants. Neither of these devices represents a truly closed system.

Evaluation of chemotherapy administration using these systems, clearly favoured one device as a result of a number of problems, resulting in spillage, contamination and wastage. Nursing staff already use a needle-free administration system (Baxter Clearlink™) so were aware of the benefits of this approach, however this was not closed in that products still needed to be ‘opened’ to connect to the Clearlink™ adaptor. As expected, needle-stick injury and contamination were considered the greatest risk with needle-dependent administration. The majority found the ChemoAide™ system more difficult to use and contamination was considered the greatest risk, with spillage occurring on at least one occasion. Tevadaptor™ was considered much easier to use and the safest system.

18.5.2. Workstream 3 – Product information and labelling

Participants represented Anaesthetists, theatre Nurse Practitioners and Operating Department Practitioner, who evaluated product information and mock-up labelling for Bupivicaine and Phenylephrine products (as described elsewhere in the report). With Bupivicaine, staff found the current labelling made it easy to select between strengths, and information presented generally helpful. The new design was preferred and information clearer and safer with some innovative features (e.g. strength on inner surface of flap, use of ‘colour coding’ etc). Evaluation of the product information was not so clear cut, with staff referring to a range of different sources for information, although overall the new design was considered safe and with advantages over existing sources. The proposed information ‘Kardex’ was popular and considered a good single source of summary information but should be colour linked with the drug (therapeutic class).

Phenylephrine was used less frequently, although required more complex manipulation. Participants found the current labelling and packaging clear, aiding dose selection. Whilst information on the new label design was satisfactory, users had more difficulty distinguishing between strengths, and at least one respondent felt that the ‘colour coding’ was a disadvantage in selecting the correct vasopressor. Nevertheless some of design features were considered beneficial for safety (e.g. font size, colour, dilution warnings etc). Overall the majority preferred the new packaging and labelling design.

9 in 10 respondents did not refer to the information leaflet, surprising given the complex dilutions required for therapeutic use – largely due to familiarity with the product. Staff preferred the new information leaflet, with some reservations, and the ‘Kardex’ was considered a useful resource.
19. Workstream recommendations

The phase 2 workstreams have identified a number of recommendations for NHS Trusts, NHS PASA, NPSA, MHRA and Industry – these are summarised below:

19.1. Workstream 1 – Dose banding

- The specification developed by the Re:Source NHS Collaborative Procurement Hub is used to tender for the provision of ready to use chemotherapy products.
- Hubs and Cancer Networks work together to standardise dose banding schemes to reduce the number of products required.
- The Pharmaceutical Industry is encouraged to produce licensed, ready to use formulations of chemotherapy and other drugs for use in dose banding schemes.
- Manufacturers incorporate needle-free systems in ready to administer products.

19.2. Workstream 2 – Needle-free systems

- National practice standards to mandate needle-free systems for preparation and administration of cytotoxic chemotherapy and other high risk injectable medicines.
- Promote systems that works well from both a nursing and pharmacy perspective for drug preparation AND administration.
- Promote generic systems that are widely compatible with a range of infusion consumables and devices
- National contracting of needle-free systems to maximise cost and volume benefits
- Industry to undertake drug stability and microbiological sterility studies on needle-free devices to maximise expiry dates of pre-prepared products

19.3. Workstream 3 – Product information and labelling

- Replace patient information leaflet with product information sheet for use by clinical practitioners preparing and administering injectable medicines
- Present essential information as two sets - mandatory (red flag) and required
- Mandatory information to appear on box and ampoule / vial
- Use innovative ‘peelable’ multi-layer labels for containers, documentation etc
- Make use of RCoA critical care colour scheme to aid product identification; use design for differentiation of multiple strength products

19.4. Workstream 4 – Barcode design for safety

- Promote the use of barcoding for patient auto ID checking, medicine management and reconciliation and asset tracking.
- Industry to provide all licensed products with machine readable standard barcodes
- Integrate barcodes into e-prescribing, dispensing, labelling & administration systems
- Promote integration of barcode applications to reduce complexity, maximise compliance and cost effectiveness for NHS
- Consider the design of handheld devices to be used in near patient areas

19.5. Workstream 5 – Pump design for safety

- Develop national specification for design and procurement of infusion devices
- Dose limiting software ‘fail-safes’ to be standard within all new infusion devices
- User interfaces to be intuitive with entry via dose safety features (i.e. library)
- Tools for end user data download and analysis to be made available to Trusts
- Promote benefits of centralised equipment libraries for efficiency and access
- Generic ‘device needs analysis’ tools to be made available to support above
## 19.6. Recommendation summary

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## Appendix A - Pilot project plan & phase timings

### PASA Programme Board
- Programme Board Meetings
- Steering Group Meetings
- Derby Project Board Meetings
- Lincoln Project Board Meetings
- Manchester Project Board Meetings

### Derby Pilot

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### Delivery Phase
- Review prior experience with dose banding and identify key benefits and issues
- Undertake literature review of dose banding and extent of practice in UK
- Identify suitable products for dose banding together with rationale
- Develop specification to optimise formulation and presentation for safe banding
- Scope market for available licensed and specialist products from UK
- Work with Discourse to conduct cost / benefits analysis and procurement strategy
- Maintain progress plan and complete workstream report to present to Pilot Team
- Evaluate chemotherapy product exposed against against specification (if time)
### 2. Needle-Free Workstream

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#### Mobilisation & Selection Phase
- Select Workstream Lead
- Select Stakeholders
- Complete feasibility review - have resource - time available been taken into consideration?
- 1st Draft of Workstream Brief & Action Plan
- Plan and execute Mobilisation Meeting
- Engage stakeholders & reviewed 1st draft of workstream brief
- 2nd Draft of Workstream Brief & Action Plan
- Agree reporting and issue risk escalation methodologies
- Complete review of cost effectiveness
- Establish baseline measures

#### Delivery Phase
- Review current practice of techniques in local units and identify key issues
- Most industry representatives (Supplier & Teams)
- Establish accident rates from needle-stick injuries and other operator risks
- Agree quantitative and qualitative criteria for evaluation of these products
- Evaluate each product against existing practice & defined period
- Undertake benchmark analysis, identity strengths weaknesses of each product
- Develop rationale and business case for routine use of these products in NHS
- Maintain progress plan and complete workstream report to present to Pilot Team

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### Timeline

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NHS PASA Purchasing for Safety Pilot
Derby Hospitals NHS Foundation Trust
35 of 114
February 2008
### 3. Bar Coding Workstream

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#### Mobilization & Selection Phase
- Select Workstream Lead
- Select Stakeholders
- Complete feasibility review – have resource + time available been taken into consideration?
- 1st Draft of Workstream Brief & Action Plan
- Plan & execute Mobilisation Meeting
- Engage stakeholders & review 1st draft of workstream brief
- 2nd Draft of Workstream Brief & Action Plan
- Agreeing reporting and issue / risk escalation methodologies
- Complete review of cost effectiveness
- Establish baseline measures
- Complete review of cost effectiveness

#### Delivery Phase
- Undertake literature review of barcoding for safe medicines practice
- Identify benefits from barcoding for auto-identification & safe medicines practice
- Identify benefits for the whole ‘medicines use process’ for injectable medicines
- Gain approval of preferred option
- Identify staffs perception of requirements
- Develop business case to inform cost benefit analysis and practical application
- Identify potential barriers to implementation and options to overcome these
- Use findings to inform the implementation of barcoding
- Identify implications of national manufacturers / supply / design in relation to implementation
- Maintain progress plan and complete workstream report to present to Pilot Team

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### Delivery Phase

- Scope range of infusion pump technology available to support safer practice
- Review literature to identify benefits from 'guardian' type innovations
- Identify key benefits, issues and limitations of existing 'guardian' type systems
- Develop specification to address these and inform manufacturing requirements
- Leverage specification and checklist to inform purchasing for safety decisions
- Maintain progress plan and complete workstream report to present to Pilot Team

### Workstream Leads

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### 0. Final PHASE 2 Report

<table>
<thead>
<tr>
<th>Workstream Lead</th>
<th>Stakeholders</th>
<th>% achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tom Gray</td>
<td>QS, PF, MC, SP, AH</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>TG</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>TG</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>TG</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>QL</td>
<td>50%</td>
</tr>
</tbody>
</table>

- **Mobilisation & Selection Phase**
  - Obtain 1st draft versions of workstream reports
- **Produce 1st draft version of Final Phase 2 Report**
  - Forward 1st draft version to VPOA Project Manager for review
  - Produce 1st version of phase 2 report and issue to Project Board & Workstream Leads for consultation
  - Obtain sign-off from Pilot Sponsor of Phase 2 Report before submitting to PASA.
- **Final report for Phase 2 is issued to PASA.**
# Appendix B - Pilot risk register

## Issues - Guidelines

An issue is a problem or question affecting the progress programme **now**. The issue may be resolved or, in cases where the core team is not able to resolve the issue, the core team must maintain visibility and awareness of the issue.

<table>
<thead>
<tr>
<th>ID</th>
<th>Number assigned to issue using the following convention: Owner initials prefix followed by issue number in issue log e.g. JB/013</th>
</tr>
</thead>
</table>
| Issue Type | PEO: People and Skills  
ORG: Organisational  
FIN: Financial  
TEC: Technical (i.e. methodologies, procedures)  
REP: Reputational  
OTH: Other |
| Raised by | Name of the person raising the issue |
| Date Raised | Date first raised |
| Actions | Recommended/ proposed actions. |
| Due Date | Expected completion date for proposed mitigation actions |
| Status | Open - be clear about what action is required from others  
Closed - keep for 1 week and then shade grey to show completion  
Deferred - explain why and when to re-examine |
| RAG | Red: Typically indicates an issue that need to be escalated to the Consulting Management Team for information / action  
Amber: Typically indicates the an issue that need to be escalated to the Delivery Director for action  
Green: Typically indicates the an issue that can be managed within the engagement team |
| Owner | Person assigned to monitor and manage actions. |

**OWNER** : Tom Gray, Pilot Lead & Project Manager, Derby
<table>
<thead>
<tr>
<th>ID</th>
<th>Raised By</th>
<th>Date Raised</th>
<th>Issue Type</th>
<th>Issue Description</th>
<th>Impact</th>
<th>Actions</th>
<th>Curr. RAG</th>
<th>Prev. RAG</th>
<th>Due Date</th>
<th>Status</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tom Gray</td>
<td>03/10/07</td>
<td>PEO</td>
<td>Pilot Lead available time to Project</td>
<td>Delay to Pilot</td>
<td>Escalate issue to PASA Project Manager</td>
<td>18/10/07</td>
<td>Open</td>
<td>TG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Tom Gray</td>
<td>03/10/07</td>
<td>PEO</td>
<td>Departure of Pilot Sponsor in December 2007</td>
<td>Loss of governance and focus on pilot at a board level within the Trust.</td>
<td>Escalate issue to PASA Project Manager. Identify nominee for replacement Pilot Sponsor.</td>
<td>18/10/07</td>
<td>Closed</td>
<td>TG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Issue Types
- **PEO**  People and Skills
- **ORG**  Organisational (e.g. plans, sponsorship)
- **FIN**  Financial
- **TEC**  Technical (i.e. methodologies, procedures)
- **REP**  Reputational
- **OTH**  Other
<table>
<thead>
<tr>
<th><strong>Risks - Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A risk is any event that could impact on the programme and would have consequences on the capacity to deliver the agreed benefits if not managed appropriately.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ID</strong></th>
<th>Number assigned to risk using the following convention: Owner initials prefix followed by risk number in programme risk register i.e. JB/011</th>
</tr>
</thead>
</table>
| **Risk Category** | PEO: People and Skills  
ORG: Organisational (e.g. plans, sponsorship)  
FIN: Financial  
TEC: Technical (i.e. methodologies, procedures)  
REP: Reputational  
OTH: Other |
| **Raised By:** | Name of the person raising the risk at Programme level |
| **Risk Description** | Detailed description of the risk being raised |
| **Description of Impact** | Quantitative description of the impact on timings, benefits, cost and quality where applicable. |
| **I – Impact** | Rank potential impact between 1 - 9 |
| **L- Likelihood** | Rank likelihood between 1 - 9 |
| **Gross Risk Score (Pre-mitigation)** | The Gross Risk Score is calculated by multiplying the impact and likelihood scores together. |
| **Red** | Score of 67 - 100. Typically indicates a risk that needs escalation to CMT for information / action via monthly report. |
| **Amber** | Score of 34 - 66. Typically indicates a risk that needs to be managed by the Delivery Director |
| **Green** | Score of 1 to 33. Typically indicates the type of risk that can be managed within the engagement team |
| **Mitigation Actions:** | Description of actions to be taken to mitigate the risk |
| **Due Date** | Expected completion date for proposed mitigation actions |

**OWNER :** Tom Gray, Pilot Lead & Project Manager, Derby
<table>
<thead>
<tr>
<th>ID</th>
<th>Date Raised</th>
<th>Raised By</th>
<th>Risk Cat</th>
<th>Risk Description</th>
<th>Description of Impact</th>
<th>Mitigation / contingency actions</th>
<th>RAG</th>
<th>Owner</th>
<th>L 1-9</th>
<th>L 1-9</th>
<th>Status</th>
<th>Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>03/10/07</td>
<td>TG</td>
<td>ORG</td>
<td>Aseptic Unit Staffing</td>
<td>Staff shortages means that Pilot Lead is having to provide clinical cover to the Aseptic Unit – thus minimising available time to the project</td>
<td>Share pilot lead responsibilities for workstreams with the Workstream Leads.</td>
<td>20</td>
<td>TG</td>
<td>5</td>
<td>4</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>2</td>
<td>03/10/07</td>
<td>TG</td>
<td>ORG</td>
<td>Internal – Trust</td>
<td>Internal changes to departmental management is having a consequence on the time available to the project by the Pilot Lead</td>
<td>Share pilot lead responsibilities for the workstreams with the Workstream Leads.</td>
<td>25</td>
<td>TG</td>
<td>5</td>
<td>5</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>3</td>
<td>03/10/07</td>
<td>TG</td>
<td>PEO</td>
<td>Annual Leave to key stakeholders and workstream leads</td>
<td>Delay and slippage to workstreams and overall to pilot study</td>
<td>Share responsibilities and identify suitable individuals to cover pilot activities</td>
<td>30</td>
<td>TG</td>
<td>6</td>
<td>5</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>4</td>
<td>03/10/07</td>
<td>TG</td>
<td>ORG</td>
<td>Christmas and Half Term Holidays</td>
<td>Lack of available resources to maintain activities to the pilot and workstreams, delay to workstream activities, overall slippage to pilot</td>
<td>Plan activities around key holiday dates and staffing availability.</td>
<td>25</td>
<td>TG</td>
<td>5</td>
<td>5</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>5</td>
<td>09/10/07</td>
<td>TG</td>
<td>PEO</td>
<td>Availability of workstream leads to pilot</td>
<td>Identified that some of the workstream leads proposed only work part-time to the Trust, and therefore their availability to lead and manage the workstreams may be impacted.</td>
<td>Ensure remaining stakeholders for the workstreams are able to commit to their own actions and activities, and to pre-manage workstream activities for around the days when the workstream leads are available.</td>
<td>28</td>
<td>TG</td>
<td>7</td>
<td>4</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>6</td>
<td>15/10/07</td>
<td>NB</td>
<td>ORG</td>
<td>Slow mobilisation of workstream meetings.</td>
<td>Slippage to the pilot</td>
<td>Concentrate on the mobilisation of Priority 1 Workstreams only and ensure meetings for these are booked ASAP.</td>
<td>35</td>
<td>TG / NB</td>
<td>7</td>
<td>5</td>
<td>CLOSED</td>
<td>18/10/07</td>
</tr>
<tr>
<td>7</td>
<td>21/11/07</td>
<td>MC</td>
<td>FIN</td>
<td>Withdrawal of funding by Baxter to support Design for Safety Workstream</td>
<td>Re-scoping of workstream or abandonment of workstream</td>
<td>Early notification of situation by workstream lead. Review alternative opportunities for workstream</td>
<td>40</td>
<td>MC</td>
<td>8</td>
<td>5</td>
<td>Closed</td>
<td>26/02/08</td>
</tr>
<tr>
<td>8</td>
<td>21/11/07</td>
<td>SP</td>
<td>ORG</td>
<td>Closure of Gynae Theatres 11th – 13th December</td>
<td>Impact on time available to workstreams and pilot by key stakeholders</td>
<td>Delegate activities to workstream stakeholders where possible.</td>
<td>25</td>
<td>NB</td>
<td>5</td>
<td>5</td>
<td>CLOSED</td>
<td>11/12/07</td>
</tr>
<tr>
<td>ID</td>
<td>Date Raised</td>
<td>Raised By</td>
<td>Risk Cat</td>
<td>Risk Description</td>
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<tr>
<td>9</td>
<td>18/01/08</td>
<td>TG</td>
<td>ORG</td>
<td>Tom’s involvement in Trust financial review of Medicines Management Workstream. Impact on time available to support PASA Pilot under question.</td>
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<td>Trust currently engaged with PWC in an 8/52 review of Trust financial position. Tom has been asked to support the Medicines Management Workstream review during an 8/52 period. This is anticipated to have significant conflicts against Tom’s available time to the PASA PIS Pilot.</td>
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<td></td>
<td><strong>Mitigation</strong> – need to ensure Workstream Leads are adequately supported to deliver workstream reports. Time efficiency planning required with Tom and Workstream Leads to look at available time and resources remaining within the scope of the PASA pilot.</td>
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<tr>
<td>10</td>
<td>18/01/08</td>
<td>SP</td>
<td>PEO</td>
<td>Detail and content of the Technical Information Workstream may not be to the “formal” requirements anticipated by PASA.</td>
<td></td>
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<td></td>
<td>Susanna concerned that the level of formal documentation captured within the workstream report may not be to the standard (or type) anticipated by PASA.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Mitigation</strong> – NB to work with SP and the workstream stakeholders to produce workstream report</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>11</td>
<td>18/01/08</td>
<td>NB</td>
<td>PRG</td>
<td>Delay to start of Needle Free Systems trial – and consequent impact on time available to complete workstream report and analysis.</td>
<td></td>
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<td></td>
<td>Due to delays in the involvement of Baxter and Teva supporting the trial – anticipated that 1st trialling of products will not commence until 28th Jan. Anticipate completion of trials mid February. Time remaining to complete evaluations and write up very tight.</td>
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<td></td>
<td><strong>Mitigation</strong> – discussed with TG and LQ at Project Board Meeting 18/01/08. Evaluation questionnaires to be implemented prior to 28th Jan. Activities to commence in the write up of the report prior to implementation, such that evaluation detail can be added as a final step.</td>
<td></td>
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</tr>
</tbody>
</table>
Appendix C – Governance chart

Purchasing for Safety Project
Derby Hospitals' Trust – Governance Structure

Trust Executive Board

Trust Pilot Sponsor
- Kathy Maclean – Medical Director

Trust Pilot Project Manager
- Nancy Bavin: Atos Consultant
- Assistant Director of Nursing
- Consultant Anaesthetist
- Clinical Risk Manager
- Nurse Clinical Facilitator
- Principle Pharmacist for procurement
- Trust Procurement Manager

Trust Pilot Facilitator
- Nancy Bavin: Atos Consultant

Trust Pilot Board Members
- Chief Technician
- Supplies Manager
- Lead Practitioner for Parenteral Therapies
- Medical Devices Committee
- Clinical Skills Co-ordinator
- Medical Devices Training Co-ordinator
- Infection Control
- Practice Development Nurse

Drugs and Therapeutics Committee

Trust Pilot Project Manager
- Tom Gray: Chief Pharmacist

Trust Pilot Board

PASA Project Sponsor
- Sam Forrest

PASA Project Manager
- Lara Qatami

Trust Pilot Board Members
- Assistant Director of Nursing
- Consultant Anaesthetist
- Clinical Risk Manager
- Nurse Clinical Facilitator
- Principle Pharmacist for procurement
- Trust Procurement Manager

Other Trust Pilot Members
(Infusion Systems Sub-Committee)
- Chief Technician
- Supplies Manager
- Lead Practitioner for Parenteral Therapies
- Clinical Skills Co-ordinator
- Medical Devices Training Co-ordinator
- Infection Control
- Practice Development Nurse

PASA Programme Board

Equipment Library Service
- Capital and Consumable purchasing
- Drugs and Therapeutics Committee
- Practice, therapy, development and discharge planning
- Medical Devices Committee
- Clinical Practice Development Group
- Patient Safety Group
- Risk Services

Trust Pilot

Trust Pilot Sponsor
- Sam Forrest

PASA Project Sponsor
- Lara Qatami

Trust Pilot Board

PASA Programme Board
## Appendix D – Communications plan

<table>
<thead>
<tr>
<th>Document</th>
<th>Pilot Project Board</th>
<th>Pilot Project Team</th>
<th>Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust PID</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Governance Structure</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Risk Register</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Project Action Plan</td>
<td>X</td>
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<tr>
<td>Communications Plan</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bar Coding Workstream Brief</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Dose Bundling Workstream Brief</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Needle Free Systems Workstream</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Technical Information / Labelling Workstream Brief</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Design for Safety Infusion Pumps Workstream Brief</td>
<td>X</td>
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<tr>
<td>Training Workstream Brief</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Stakeholder Plan</td>
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<td>Project Board Agenda</td>
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<td>X</td>
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</tr>
<tr>
<td>Project Board Minutes</td>
<td>X</td>
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<tr>
<td>Trust Weekly Report</td>
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<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Note: 'X' indicates involvement.*
# Appendix E – Executive Summary

## Purchasing for Safety Injectable Medicines Project – Derby Hospitals Pilot

### Objective

Derby Hospitals Foundation NHS Trust has applied for, and been accepted as, one of the pilot sites for the PASA managed “Purchasing for Safety – Injectable Medicines” Project. The project is designed to address the issues around purchasing for safety, and to demonstrate that procurement can play a vital role, not just in supporting but also in delivering a key government policy.

### Background

The last few years have seen the issue of patient safety rise up the political agenda. Consequently, the Department of Health has endorsed a designated approach to patient safety, and has recognised the interdependence between design and procurement. Whilst the procurement function has contributed to a number of initiatives, there has, to date, been no systematic, joined-up approach to purchasing for safety. This PASA led project aims to address this issue.

### Scope

The Derby pilot has selected to focus on the following workstreams:

- **Dose Banding of Chemotherapy**
- **Needle Free systems for delivery of chemotherapy**
- **Technical Information: start into leaflet, and its presentation on labelling and packaging**
- **Design for Safety in infusion pumps**
- **Evaluate business case for Barcoding identification**

### Deliverables

- Derby Project Initiation Document
- High Level Plan – Key Phases & Dates
- Communications Plan
- Governance Structure
- Data collection questionnaire, for interviews/meetings
- Findings & Recommendations – to support planning of Phase 2 (Implementation)

### Dependencies

Appropriate stakeholders are used throughout the interview and data collection / capture phase.

- Pilot Trust is supportive on implementing guidance and project findings.
- Chief Executives approval is obtained.

### Key Activities

- Identification & set up of Pilot Project Board & Project Team
- Identification & agreement of key stakeholders
- Delivery of Manchester Project Initiation Document
- Delivery of High Level Plan – with key phasing & dates
- Structure of weekly pilot review meeting
- Structure of monthly pilot project board meetings
- Delivery of Governance Chart, Risk Register & Communications Plan
- Establish and mobilise five workstreams.
- Conduct focus meetings & prepare action plans
- Conduct evaluation of investigation.
- Capture & analyse findings
- Produce summary of findings & recommendations
- Deliver Business Case Studies
- Preparation for Phase 3 - Implementation

### Resources

- **Pilot Sponsor – Kathy Mclean**
- **Pilot Lead – Tom Gray**
- **Pilot Project Team & Stakeholders**
- **Pilot Facilitator – Nancy Bavin (Atos Consulting)**

### Benefits

There are significant benefits which the Trusts can reasonably expect to realise with their participation in this project. This include (but are not limited to):

- Avoid increased LOS or requirements for care that may occur as a direct result of adverse patient safety incidents.
- Reduce the cost of litigation.
- Improve Trust reputation for patient safety.
- Enhance sales, which will release further funding for patient care.
- Standardisation and rationalisation of policies and procedures with respect to injectable medicines.
- Identification of training needs for staff and the opportunity to develop ongoing guidance.

---

NHS PASA Purchasing for Safety Pilot
Derby Hospitals NHS Foundation Trust

February 2008
## Appendix F – Stakeholder map

<table>
<thead>
<tr>
<th>Workstream</th>
<th>Workstream Lead</th>
<th>Role</th>
<th>Trust</th>
<th>Workstream Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bar Coding</td>
<td>Gill Ogden</td>
<td>Risk Manager</td>
<td>Derby</td>
<td>Heather Swanston&lt;br&gt;Michelle Harris&lt;br&gt;Tom Gray&lt;br&gt;Gwen Rees&lt;br&gt;Sarah Girdlestone&lt;br&gt;Teresa Purdy&lt;br&gt;Karen Jeppson&lt;br&gt;Rebecca Perkins&lt;br&gt;Tim Harrison&lt;br&gt;Emma Harris&lt;br&gt;Dwain Mclean&lt;br&gt;EPR Development &amp; IM&amp;T</td>
</tr>
<tr>
<td>Dose Banding</td>
<td>Peter Fox</td>
<td>Principal Pharmacist - Purchasing</td>
<td>Derby</td>
<td>Colin Ward&lt;br&gt;Tom Gray&lt;br&gt;Tracy Hickman&lt;br&gt;Tom Gray&lt;br&gt;Anueraa Gulderia&lt;br&gt;Anaesthetic&lt;br&gt;Chief Pharmacist&lt;br&gt;Directorate Lead Pharmacist&lt;br&gt;Directorate Lead Pharmacist&lt;br&gt;Directorate Lead Pharmacist</td>
</tr>
<tr>
<td>Technical Information</td>
<td>Susanna Piggott</td>
<td>Anaesthetist</td>
<td>Derby</td>
<td>Felix Underwood&lt;br&gt;Anueraa Gulderia&lt;br&gt;Tom Gray&lt;br&gt;Stuart Parks&lt;br&gt;Anne Ford&lt;br&gt;Val Garner&lt;br&gt;Naz Sudhan&lt;br&gt;Miriam Klein&lt;br&gt;David Cousins&lt;br&gt;Anaesthetist&lt;br&gt;Anaesthetist&lt;br&gt;Chief Pharmacist&lt;br&gt;Theatre Nurse&lt;br&gt;ODS &amp; Practice Educator&lt;br&gt;Anaesthetist&lt;br&gt;PharmD (New York)&lt;br&gt;NPSA&lt;br&gt;NPSA</td>
</tr>
<tr>
<td>Design for Safety - Infusion Pumps</td>
<td>Mark Cannell</td>
<td>Derby</td>
<td>Thomas Spicer</td>
<td>Baxter Reps&lt;br&gt;Nursing Reps</td>
</tr>
</tbody>
</table>
| Needle Free Systems     | Amanda Hewitt   | Chemotherapy Pharmacist | Derby   | Tom Gray<br>Colin Ward<br>Peter Fox<br>Emma Dyson<br>Debra Fisher<br>Daniel Green<br>Chief Pharmacist<br>Principal Pharmacist - Purchasing<br>Pharmacy Technician<br>Baxter Representatives<br>Teva Representatives | Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby<br>Derby

NHS PASA Purchasing for Safety Pilot  
Derby Hospitals NHS Foundation Trust
Appendix G – Mini-questionnaire analysis

A general questionnaire on injectable medicines practice was developed by NHS PASA with input from pilot Trusts, seeking information from a wide range of clinical practitioners of different professions and grades. To maximise feedback the questionnaire was developed as an online survey hosted by Exodus market research.

The information collected represents a wide range of views on the risk and quality of injectable medicines practice in the Trust and provides context for the work streams that are being taken forward in phase 2 of the pilot.

Section One: Background information

321 participants accessed the on-line survey, with 232 completing the questionnaire – this represents approximately 5% of the clinical workforce. This is a disappointing return, due in part to technical difficulties and the short time scales for completion. 62% of questionnaires were completed by nurses and midwives, 12.5% by pharmacists and approximately 6.5% by doctors. 10.5% of respondents worked in Critical Care (ITU and Theatres), 8.5% in maternity services, 4.5% in Imaging and 3.5% in Oncology – pilot focus areas; 70% of respondents did not specify there area of work.

Over 75% of respondents indicated that they were involved in preparing and 73% in administering injectable medicines, although the definition was not clear. This is surprising given that simple extrapolation of pharmacy issue data suggests that only 38% of injectable medicines are reconstituted at ward level (12% using syringe and needles, and 26% using the closed Baxter ‘Minibag plus’ system. As expected a smaller number of respondents (pharmacy) were directly involved in procuring medicines.

Section Two A: Medical equipment

86% of respondents indicated that they used syringes to prepare and administer injectable medicines, with 65% using syringe pumps. 67% of respondents indicated that they administer bolus injections – again surprising given the availability of ready to administer infusions in this Trust. 41% of respondents used gravity to administer infusions (this correlates with issue data that suggests 40% of infusion therapy involves plain intravenous fluids). 58% use ‘Minibag plus’ and 66% a volumetric infusion pump. Given that pumps are considered to reduce risks associated with infusion therapy this is an encouraging result. Over 40% of respondents utilise central or long lines to administer injectable medicines, and given the prevalence of healthcare acquired infections, such as MRSA, this is an important focus for a Trust wide implementation of ‘aseptic no touch’ technique.

Risk to patients

In response to the question ‘which medical devices introduce the greatest risk’, the answer is all devices and methods pose a potential risk to patients. There was an overwhelming view that bolus administration can be done quickly but often with inadequate checks and uncontrolled rate. Infusion therapy using pumps adds complexity, and equipment is not always intuitive or user-friendly, although allows controlled rate of infusion and reduces risk of air emboli and other complications of gravity infusions, which require greater surveillance. Central access cannulae were considered an infection risk by many, and the Trust has recently adopted ‘aseptic no touch technique’ policy and procedures to minimise infection risks.

Concerns were expressed as to errors arising from ‘setting up’ and use of infusion devices, due to lack of training, competency and ability to tamper with pump settings on some devices.

Risks to staff

Risks to staff were highlighted through needle-stick injuries and preparation of injectable medicines at ward level (e.g. opening glass ampoules), as well as contamination / inoculation during cannulation procedures. Plastic ampoules of diluents (e.g. water for injections) are used across the
Trust, replacing glass wherever possible. Needle free systems should be adopted more widely for parenteral therapy.

**Design issues and changes**
Availability of pre-filled syringes and infusions of medicines with long shelf life and plastic packaging were considered important. 84% of respondents identified that high risk medicines should be standardised and prepared in pharmacy. [The Trust currently provides about 20% of injectable medicines as ready to use pre-filled products with expiry dates up to 28 days where appropriate. The vast majority of high risk medicines, including cytotoxic chemotherapy and parenteral nutrition are already prepared in pharmacy].

65% of respondents believe that unlicensed products should be prepared in NHS manufacturing or commercial units. [Repackaging of any injectable medicine transfers liability to the Trust and makes the product technically ‘unlicensed’. Pharmacy holds an MHRA approved special manufacturers ‘specials’ license to allow batch production of pre-filled injectable medicine products to rigorous standards of good manufacturing practice. Other ready to administer injections are dispensed for individual patients from pharmacy ‘satellite’ facilities that receive regular quality assurance and inspection, thus minimising the risk to patients].

Dose rounding / banding was identified as an effective method of increasing safety by 58% of respondents, and use of colour to differentiate between products and doses by 90% of respondents [coloured stickers are applied to high risk products prepared by pharmacy e.g. epidural and cytotoxic products and to differentiate between products (e.g. pre-filled syringes of heparin and insulin). The Royal College of Anaesthetists critical care labelling scheme (using colour and design to differentiate between therapeutic ‘families’ of injectable medicines, is adopted in critical care areas].

A large number of responses were received regards design and functionality of infusion devices – including ease of use (simple interface, portability, better battery life, instruction cards) safety (drug library, dose calculation and limits), security (tamper-proof, lockable keypad/settings) and new technologies (reconciliation of prescription and patient, tracking and administration record etc), as well as better staff training, standardisation and availability of devices. [Issues of standardisation and availability have been largely addressed through the equipment libraries on each site, but there is scope to improve user interface, safety and security features].

Use of dose limiting software is considered an effective risk reduction measure by 78% of respondents and use of dosage conversions charts by 80% [these are adopted for certain products e.g. anticoagulants, aminoglycosides etc. Dose limiting software is available in some medical devices, although not always fully utilised and electronic prescribing and administration of medicines is still at a development stage within the Trust, which hopes to pilot this in late 2008].

Clean and quiet areas for the preparation of injectable medicines are considered important by 83% of respondents, but the majority recognised that these are rarely available outside dedicated pharmacy aseptic preparation facilities (94%).

**Section Two B: Injectable medicines**

**Injectable medicine products**
The most commonly prepared injectable medicines in clinical areas included antibiotics, analgesics, and anti-emetics. Reference was made to Insulin, Glyceryl Trinitrate, Morphine and other products that are routinely prepared by the Pharmacy, which indicates some confusion with the definition of ‘preparation’. [The majority of routinely used antibiotics are either prepared as ready to administer infusions (e.g. erythromycin, ceftazidime) by pharmacy, or are prepared using the Baxter Minibag plus™ system in ward areas, although stat dose of antibiotics are routinely prepared in clinical areas e.g. gentamicin for catheterisation, pre-/peri-operative antibiotics].

Products that were considered complex to prepare or administer, in terms of dosages, volume and rates, included variable dose products (heparin, insulin, GTN), doses/rates calculated by weight
(e.g. inotropes and neonatal doses), where multiple vials were required or small dose from a single vial (e.g. paediatric doses) and complex preparations (e.g. phenylephrine dilutions). In addition preparation that required reconstitution (e.g. benzyl penicillin) or dose adjustment according to levels (e.g. gentamicin) was considered problematic.

**Injectable medicines practices**
29% of respondents considered that pharmacy-prepared injectable medicines took too long to arrive with 56% considering this to be sometimes the case. However, 72% of respondents considered that they lacked time for preparation and administration of injectable medicines at ward level.

86% of respondents confirmed that pharmacy prepare cytotoxic chemotherapy medicines, with 10% prepared by nurses and 7% by doctors. Again this is surprising in that preparation of all cytotoxic medicines is undertaken in specialised pharmacy facilities apart from intravesicular Mitomycin-C bladder irrigations which are prepared and administered by trained nurses in Urology using the Mitoin™ (Physion) administration device.

Prescribed dosages were usually considered clear, although 8% of respondents identified usually having difficulty calculating doses, with the majority (60%) sometimes finding doses difficult to calculate – this reflects a learning need within the Trust. Coupled with a high level of interruptions during injectable medicines preparation and administration (43% usually interrupted and 47% sometimes interrupted), and the complexity of injectable medicines (multiple strengths, volumes and administration rates) this represents a high risk for medication errors to occur.

33% of respondents considered that training in injectable medicines preparation and administration was adequate; however, 23% of respondents considered that training was inadequate with 43% considering this to sometimes be the case. 24% of respondents were concerned at the lack of information or conversion charts for injectable medicines therapy, with 48% considering this to sometimes be the case.

10% of respondents described multiple use of vials in their injectable medicines practice, although 60% did not use multiple vials. [Preparation involving multiple vials is considered complex and should be conducted within pharmacy facilities]. Use of multiple dose vials is also limited to pharmacy aseptic manufacturing and critical care (e.g. pre-operative sessional use in theatre), to minimise the risk of cross contamination of patients.

**Device related issues**
Unavailability of infusion devices was considered a common problem by 18%, with 57% sometimes experiencing difficulties and 26% rarely or never experiencing problems – this may reflect the availability of an equipment library which has recently been established at DRI site, following success at DCGH. 49% of respondents have experienced equipment malfunction from time to time, and 40% device configuration or device contamination problems; the establishment of managed equipment libraries on each site will reduce this.

Other issues that can be related to the use of infusion devices included extravasation (considered uncommon but occurring occasionally 53%), over-infusion (31%), and under-infusion (35%).

25% of respondents considered that infusion device training was inadequate, this may, in part, reflect the view of medical staff responding to the survey (13%) who currently receive little or no training. 37% of respondents indicated that there is a lack of guidance about which device to use for a specific procedure; this may be due to a lack of knowledge (51%) or a lack of up-to-date written protocols (40%), which are not always followed (55%). Concerns were also expressed about manufacturer’s instructions being unclear (53%) and not always followed (62%).
Section Two C: safety culture

The majority of respondents (89%) considered the Trust to have a positive safety reporting culture, with 90% feeling that staff were encouraged to learn from mistakes, although only 25% reported regularly receiving feedback on incidents and near-misses that they reported; 30% reported receiving occasional feedback, but 45% little or no feedback. The majority (65%) considered that the current IR1 form was suitable for recording medication errors related to injectable medicines.

Types of errors
Respondents indicated that errors due to injectable medicines being accurately reported varied widely:

- wrong patient 81%
- wrong medicine 74%
- wrong route 69%
- wrong formulation 61%
- administered to allergic patients 61%
- wrong dose, route or frequency 50%
- omitted medicines 17%

There was mixed compliance with aseptic no touch technique, with only 25% indicating that this was accurately reported. Further training is currently underway to promote aseptic techniques.

Key decision makers
Pharmacy was identified as being responsible for decisions to purchase injectable medicines by only 68% of respondents, although 30% indicated that they did not know who was responsible for procurement decisions. Drugs and Therapeutics Committee were considered to only be involved in these decisions in 56% of cases, again with a large proportion unaware. Regional pharmacy purchasing consortia were only considered to be involved in purchasing decisions by 35% of respondents. The procurement manager was only considered to be involved by 34% of purchasing decisions and the regional commercial procurement hub by 20% of respondents.

Anaesthetists were considered decision makers by 40% and other doctors by 45% of respondents; senior clinicians were considered influential by 50% but junior doctors by only 10%. The Medical Devices Committee was considered influential by 54% of respondents and involved in decisions to purchase medical equipment by 49%

This reflects a rather poor understanding of the strategic and operational processes and groups involved in medicines and equipment procurement in the Trust, and represents an important learning opportunity.

Conclusions
The questionnaire represents a wide diversity of opinion from different staff groups around many aspects of safe practice with injectable medicines. It is evident that there is a lack of awareness around the strategic and operational processes for managing injectable medicines in the trust, and despite a positive safety culture, a lack of feedback.

Staff correctly identify opportunities to improve the safety of injectable medicines therapy, which is at times complex, time consuming and inadequately resourced within clinical areas.

The questionnaire highlights a number of areas for improvement – in training, choice and use of equipment, responsiveness of pharmacy services, and feedback following medication incidents and near-misses.
Recommendations for Phase 2 workstreams

A number of the themes identified in the mini-questionnaire are being carried forward to workstreams identified in Phase 2 of the ‘purchasing for safety’ pilot. Staff views and recommendations support:

1. Dose banding and greater availability of standardised ready to administer injectable products. Whilst these are widely available for many products there is scope to extend the range further, and a need for aseptic dispensing when manufacturing is not considered economically viable. Facilities for aseptic preparation at ward level are woeful and whilst some staff indicated that pharmacy could be unresponsive at times, most staff identified the lack of time they had for safe medicines preparation at ward level.

Procurement of suitable ready to use injectable medicine products was considered a high priority by respondents although there was confusion as to who was responsible for this and the systems and processes supporting purchasing decisions – these will be addressed through phase 2 of the pilot.

2. Needle free systems are considered an important method of safeguarding staff from inoculation accidents, and whilst widely adopted for administration of high risk medicines (e.g. chemotherapy) in many areas of the Trust, these are not currently utilised in the preparation of such high risk products. Use of plastic single-dose ampoules are welcomed and widely used in the Trust.

3. Information and labelling were both identified as areas where improvements could be made, both in terms of product packaging and identification, but also technical information and instructions for preparation and administration.

4. Barcodes were not specifically identified although recognition of the use of SMART technologies for positive patient identification and reconciliation of product with patient were both highlighted as important risk reduction measures.

5. The questionnaire contains a wide range of recommendations for the safe and effective use of medical devices – from availability of clean, calibrated devices to recommendations for enhancements to user interfaces, security and functionality. The infusion device workstream will address many of these issues and concerns.

6. Training also featured throughout the questionnaire with a need to improve this – making this more accessible, available to a wider range of staff and improving information to assist with the choice and use of medical devices used in injectable medicines administration.

Acknowledgements

The Project Board are grateful to all staff who took the time to complete this on-line questionnaire and for their helpful observations that will be taken into consideration in phase 2 of the pilot and in particular the design and objectives of the workstreams.
Appendix Hi – Evaluation of Needle-free systems (Pharmacy)

Assessment of safety of needle free systems - pharmacy research

Report of the research findings

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March 2008
1 Assessment of safety of needle free systems - Pharmacy

1.1 Current practice using needles

1.1.1 Ease of use

- Respondents were asked to rate a list of factors that may influence the ‘ease of use’ of needles for cytotoxic reconstitution with regards to which would be most influential. Complexity of use was seen to be most influential, with shape and size coming in second. Disposal after use was seen to be the least influential by all respondents.

1.1.2 Risks
• Rating the risks associated with the current use of needles, respondents felt that needle stick injury carried the highest risk. Spillage and contamination of the operator were jointly next highest, and disposal was seen to be the lowest risk.

![Chart showing the number of respondents aware of risks associated with needle use.](chart)

• None of the respondents were aware of any other risks associated with the current use of needles that had not been listed in the previous question.

1.1.3 Advantages

![Bar chart showing mean scores of advantages.](chart)

• The speed of using needles for cytotoxic reconstitution was seen to be its biggest advantage by respondents. The price was seen to be least advantageous.

• One respondent commented further on the advantages of using needles:

  "Can be used with any sized vial or bags without difficulty."
• Half of the respondents questioned said they are aware of other possible advantages of using needles for cytotoxic reconstitution.

Comments on other advantages
Can be used with any sized vial or bags without difficulty. Most are packaged quite easily and easily accessible.

1.1.4 Disadvantages

• When asked to rate disadvantages associated with using needles for cytotoxic reconstitution, the time taken was seen to be the most disadvantageous. This was followed by complex technique. The cost of the consumables was found to be least disadvantageous by respondents.
Two of the respondents questioned stated that they are aware of other possible disadvantages of using needles for cytotoxic reconstitution.

Comments on other disadvantages
Aerosol from needle.
Cross contamination.

1.2 Chemoaide device

1.2.1 Ease of use

All of the respondents who answered this question found the Chemoaide needle free system quite easy to use.
- Two thirds of respondents stated that using the Chemoaide system it takes between 1 and 5 minutes to reconstitute cytotoxic drugs. One respondent stated that it takes them longer than this.

1.2.2 Risks

- When asked to rate risks associated with the use of the Chemoaide system for cytotoxic reconstitution, spillage was seen as the highest risk. Needle stick injury was thought to be the lowest risk, followed closely by disposal.

- One respondent commented further on the risks associated with the use of Chemoaide:
  
  “Spillage due to force required to twist/push on to leurlock.”
Three quarters of respondents were not aware of any unlisted risks associated with the use of Chemoaide for the preparation of cytotoxic chemotherapy. One respondent said that they were aware of other risks.

The respondent who stated there were other risks was asked to specify what they were:

“Cross contamination, exposed syringes/liquids, as not always a closed system.”

### 1.2.3 Advantages

The highest rated advantage of the Chemoaide system is that it is easy to use. This came out significantly higher than the other advantages listed. The price was seen by respondents to be least advantageous.
• Only one respondent stated that they were aware of other advantages to the Chemoaide system that were not listed in the previous question.

• One respondent who stated there are no other risks that they are aware of commented further: “Not really any different from current practice.”

1.2.4 Disadvantages

• The cost of consumables was seen as most disadvantageous to the use of Chemoaide for cytotoxic reconstitution by the majority of respondents. Needle stick injury and complex technique were seen as equally least advantageous.

• One respondent commented on the disadvantages of using Chemoaide: “Can still be spiked with dispensing pin.”
The majority of respondents are not aware of any other disadvantages associated with the use of Chemoaide for the preparation of cytotoxic chemotherapy. One respondent stated that they are aware of another disadvantage.

The respondent who stated the existence of other disadvantages was asked to specify further:

“Need to use more syringes to reconstitute a number of vials rather than one as it pushes the solution back when adding to vials with powder to reconstitute.”

**1.2.5 Problems**

All of the respondents who answered this question stated that problems had occurred during the use of the Chemoaide device.

<table>
<thead>
<tr>
<th>Comments on problems occurring during the use of Chemoaide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need to use more syringes to reconstitute a number of vials rather than one as it pushes the solution back when adding to vials with powder to recon. Also occasionally leakage of solution in vial adaptor when drawing up. Sometimes hard to twist syringe to connector on bag. It takes a bit of force - twisting and connecting.</td>
</tr>
</tbody>
</table>
None of the respondents answered that incidents had occurred during the use of the Chemoaide device that resulted in an IR1 form being completed.

One respondent commented further:

“Only used a couple of times.”

**1.2.6 Value for money**

Of the respondents who answered this question, there was an equal split between whether or not the Chemoaide device offers value for money for the trust.

The respondent who was of the opinion that it was good value for money made the following observation:

“It is cheap”
1.3 Tevadaptor device

1.3.1 Ease of use

- Three quarters of respondents found the Tevadaptor needle free system very easy to use. The remaining respondent stated that they found it quite easy to use.

- Two thirds of respondents stated that it takes them between one and five minutes to reconstitute cytotoxic drugs using the Tevadaptor device. One respondent replied that it takes them longer than this.

**Comments on time taken to reconstitute cytotoxic drugs**

Time dependant on individual product.

n/a, only trialled outside rooms.
1.3.2 Risks

- When asked to rate the risks associated with the use of the Tevadaptor system for cytotoxic reconstitution, contamination of operator and contamination of environment were seen as the highest risks. Needle stick injury was seen as the lowest risk by all respondents.

- One respondent replied that they are aware of other risks associated with the use of Tevadaptor for the preparation of cytotoxic chemotherapy. The remaining respondents are not aware of any other risks.

- The respondent who was aware of other risks specified as follows:

  “Droplets of drug are sometimes on the vial and syringe adaptors when disconnected.”
1.3.3 Advantages

- The safety of the Tevadaptor system in cytotoxic reconstitution was seen as the most advantageous aspect. This was quite closely followed by ease of use, while the price was seen to be the least advantageous.

- Three quarters of respondents are not aware of any other advantages of using Tevadaptor for cytotoxic reconstitution. One respondent is aware of unlisted advantages:
  
  "It is easy to draw up and add to bag."
1.3.4 Disadvantages

The most disadvantageous aspect of using Tevadaptor for cytotoxic reconstitution was seen to be the time taken, followed by the cost of consumables. Needle stick injury was stated as the least disadvantageous by all respondents.

Half the respondents stated that they are aware of other disadvantages of using Tevadaptor for cytotoxic reconstitution.

Comments on other possible disadvantages
Creates a lot of waste - you lose some overage as can't get everything out of vials, certain items we can't use it for. packaging creates paper particles and too bumpy to wipe properly.
No syringe transfer device (i.e. frog!!).
1.3.5 Problems

- Half the respondents stated that problems had occurred during the use of the Tevadaptor device.

**Comments on problems occurring during the use of the Tevadaptor device**

Only with the fluorouracil vials occasionally and some saline vials with extra large rubber septum.

Exposure of cytotoxic solution in syringe adaptor.

- None of the respondents had encountered problems during the use of the Tevadaptor device that resulted in an IR1 form being completed.
1.3.6 Value for money

![Bar chart showing 2 respondents who think Tevadaptor offers value for money for the trust]

- Both of the respondents who answered this question felt that the Tevadaptor device offers value for money for the trust.

**Comments on whether Tevadaptor offers value for money**

More safe.
Quick and easy to use.

1.4 Other comments

- One respondent commented further on the questionnaire:
  
  “A syringe - to syringe adaptor would be useful.”
Assessment of safety of needle free systems - nursing research

Report of the research findings

Written by:

March 2008
1 Assessment of safety of needle free systems - Pharmacy

1.1 Current practice using needles

1.1.1 Use of needles

- Nearly six in ten of the respondents stated that they do currently use needles to administer chemotherapy.

**Comments on whether needles are currently used**
With SBVD only.
Paclitaxol giving set low absorption.
Paclitaxol - low absorption sets pre-meds.

1.1.2 Risks
• Rating the risks associated with the current use of needles, respondents felt that needle stick injury carries the highest risk. Contamination of the nurse was next highest, and harm to patient was seen to be the lowest risk.

![Bar chart showing number of respondents aware of other risks associated with needle use for cytotoxic chemotherapy]

• None of the respondents are aware of any other risks associated with the current use of needles that had not been listed in the previous question.

1.1.3 Advantages

![Bar chart showing mean scores for advantages of using needles for reconstitution]

• The ease of using needles for cytotoxic reconstitution was seen to be its biggest advantage by respondents. The safety was seen to be least advantageous.
None of the respondents who answered this question are aware of any other possible advantages of using needles for reconstitution.

### 1.1.4 Disadvantages

When asked to rate disadvantages associated with using needles for cytotoxic reconstitution, needle stick injury was seen to be the most disadvantageous. This was followed by complex technique. The cost of the consumables was seen to be least disadvantageous by respondents.
None of the respondents are aware of any other possible disadvantages of using needles for reconstitution.

1.2 Chemoaide device

1.2.1 Ease of use

Nearly six in ten respondents found the Chemoaide device to be at least quite difficult to use. Two respondents stated that it was very easy to use.

One respondent commented further on the ease of use of the Chemoaide system:

“Short giving sets. Priming giving sets.”
• All respondents stated that using the Chemoaide system it takes between 1 and 5 minutes to reconstitute cytotoxic drugs.

• The respondent who did not give a time expanded this by saying:
  "Dependant on bag/syringe volume."

### 1.2.2 Risks

When asked to rate risks associated with the use of the Chemoaide system for cytotoxic reconstitution, contamination of nurse was seen as the highest risk. This was followed closely by contamination of the environment. Needle stick injury was thought to be the lowest risk, followed by disposal.

• One respondent commented further on the risks associated with the use of Chemoaide:
  "Bolus administration same method used - risk of spillage for nurse he same. Infusion connector flimsy, risk of breaking when connecting."
• Six in ten of the respondents stated that there are other risks associated with the use of Chemoaide.

Comments on other risks
Giving sets not long enough, risk of pulling out extravasations - + joining sections snaps when joining to chemo bag.
Giving sets too short - the connector broke when screwed into place.
When attaching to chemo back, the connection broke twice.
Unable to see which is dripping (chemo or saline) at quick glance.

1.2.3 Advantages

• The highest rated advantage of the Chemoaide system is that it is safe. The price was seen by respondents to be least advantageous.
The complex technique was seen as most disadvantageous to the use of Chemoaide for cytotoxic reconstitution by the majority of respondents. Needle stick was seen as the least disadvantageous.

None of the respondents are aware of any other advantages of using Chemoaide for preparation of cytotoxic chemotherapy.

1.2.4 Disadvantages
Two thirds of respondents stated that they are aware of other disadvantages of using Chemoaide for the preparation of cytotoxic chemotherapy.

**Comments on other disadvantages of using Chemoaide**

- Poor quality sets.
- Felt to be poor quality i.e. snapped connectors.
- They fell apart or broke on several occasions.
- Twice whilst trialling the attachment cracked leaving nurses and patients exposed to chemo.

### 1.2.5 Problems

All but one of the respondents stated that problems had occurred during the use of the Chemoaide device.

**Comments on problems occurring during the use of the Chemoaide device**

- Cracking of screw fixture.
- Didn't like the 3 clamps - forget to unclamp them.
- They fell apart or broke on several occasions.
- Three sets crumbled when attached to bags of chemo; the lines are not long enough.
- Need to be careful connecting infusions.
- Twice the attachment cracked leaving nurses and patients exposed to chemo.
Five respondents replied that incidents had occurred during the use of the Chemoaide device which required an IR1 form to be completed.

Comments on incidents requiring an IR1 form

Cracking of the connector, short set pulled.
They fell apart or broke on several occasions.
Three sets broke.
Connection broke - no spillage.

1.2.6 Value for money

None of the respondents felt that the Chemoaide device offered value for money for the trust.

Comments on value for money of Chemoaide

It felt 'cheap'.
Because they are not safe.
I don't know the cost.
Difficult to use.
1.3 Tevadaptor device

1.3.1 Ease of use

- All respondents found the Tevadaptor needle free system at least quite easy to use. More than eight in ten stated that it was very easy to use.

- One respondent replied that they had not yet used this system.

- All respondents who answered this question stated that it takes them between one and five minutes to reconstitute cytotoxic drugs using the Tevadaptor device.

**Comments on time taken to reconstitute cytotoxic drugs**
Dependant on chemo.
Depends on what chemo you are giving.
1.3.2 Risks

When asked to rate the risks associated with the use of the Tevadaptor system for cytotoxic reconstitution, the respondents who replied stated that each of the listed risks was lowest. They expanded on their answers:

Comments on risks associated with the use of the Tevadaptor system

There are no risks that I can see!
Low risk of contamination or needle stick injury.
No risk of contamination or needle stick injury or harm to patient.

No respondents are aware of any other risks associated with the use of Tevadaptor for the preparation of cytotoxic chemotherapy.
1.3.3 Advantages

- The safety of the Tevadaptor system in cytotoxic reconstitution was seen as the most advantageous aspect. This was quite closely followed by ease of use, while the price was seen to be the least advantageous.

- All respondents replied that they are unaware of any other possible advantages of using Tevadaptor for cytotoxic reconstitution.
### 1.3.4 Disadvantages

#### Rating of Disadvantages Associated with the Use of the Tevadaptor System for Cytotoxic Reconstitution

<table>
<thead>
<tr>
<th>Category</th>
<th>Mean Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of consumables (base: 5)</td>
<td>1.8</td>
</tr>
<tr>
<td>Needle stick injury (base: 4)</td>
<td>2.75</td>
</tr>
<tr>
<td>Time taken (base: 4)</td>
<td>3.5</td>
</tr>
<tr>
<td>Complex technique (base: 4)</td>
<td>4</td>
</tr>
</tbody>
</table>

**Mean scores (1 = most disadvantageous, 4 = least disadvantageous)**

- The most disadvantageous aspect of using Tevadaptor for cytotoxic reconstitution was seen to be the cost of consumables. The complex technique was rated as the least advantageous by all respondents.

#### Are You Aware of Any Other Possible Disadvantages of Using Tevadaptor for Cytotoxic Reconstitution?

<table>
<thead>
<tr>
<th>Number of Respondents (base: 5)</th>
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<tbody>
<tr>
<td>5</td>
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</table>

- None of the respondents stated that they are aware of other disadvantages of using Tevadaptor for cytotoxic reconstitution.
1.3.5 Problems

None of the respondents reported any problems during the use of the Tevadaptor device.

None of the respondents encountered problems during the use of the Tevadaptor device that resulted in an IR1 form being completed.
1.3.6 Value for money

- All of the respondents who answered this question felt that the Tevadaptor device offers value for money for the trust.

Comments on whether Tevadaptor offers value for money
Safe for nurse and patient - very good.
I don't know the cost.
Can't put a price on safety of staff and patients.

1.4 Overall perceptions
1.4.1 Rating of devices

- The Tevadaptor device was rated as the best overall device by all respondents. The Chemoaide device was rated quite low, with the current needle administration (where applicable) being rated as having the lowest overall benefits by the respondent who uses it.

- Respondents were asked to give the single highest benefit of the devices which they favoured.
<table>
<thead>
<tr>
<th>Device</th>
<th>Single Overall Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>current needle free</td>
<td>No change to current practice.</td>
</tr>
<tr>
<td>administration</td>
<td></td>
</tr>
<tr>
<td>Chemoaide device</td>
<td>Giving bonuses for the nurse.</td>
</tr>
<tr>
<td>Chemoaide device</td>
<td>Needle free.</td>
</tr>
<tr>
<td>Tevadaptor</td>
<td>Safety in all areas.</td>
</tr>
</tbody>
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Appendix Hiii – Evaluation of Bupivacaine Labelling and Information

Assessment of Bupivacaine drug presentation and information research

Report of the research findings

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March 2008
1 The respondent’s work area or unit

1.1 Trust respondent belongs to

- 11 out of 16 of the respondents stated that they belong to Derby Hospitals NHS Trust. Three respondents belong to South Derbyshire, with the remaining two being split between DCGH and Surgical Services.

1.2 Job title of respondent

- Just under a quarter of respondents replied saying they are theatre practitioners, and a further quarter stated that they are consultant anaesthetists. Three respondents stated that they are ODPs.
2 Assessment of new Bupivacaine drug presentation and information

2.1 The existing drug box design

2.1.1 How often the drug is used

- More than four in ten respondents use the drug Bupivacaine daily, and just fewer than four in ten use it 2 or three times a week. Less than 20% of respondents use it weekly or less frequently.

2.1.2 How easy is it to distinguish between different drug strengths?

- 95% of respondents found it very or quite easy to distinguish between different strengths of the drug Bupivacaine. Only one respondent found that it was not that easy.

**Comments on distinguishing between drug strengths**

I think 0.5 should stay as on present boxes and should not be 0.50 - it's confusing. Read the label.
2.1.3 How useful is the information displayed on the existing drug box?

![Bar chart showing the usefulness of the information on the existing drug box]

- The vast majority of respondents (80%) find the existing drug box information quite useful. Only one respondent stated that it was not that useful.

There was only one comment made on the information on the existing drug box for Bupivacaine:

"Not for intravenous should be more prominent."

2.1.4 Are there any aspects of the current box design that are particularly useful or helpful?

![Bar chart showing the responses to the usefulness of the current box design]

- Just under half of the respondents stated that there were aspects of the current box design for Bupivacaine that were particularly useful or helpful.

**Comments on current box design**

Clear, easy to reach.
0.5% and 0.25% in large lettering and different colours clearly marked.
Different colour for 0.5% and 0.25%.
Warning sign - not for intravenous injection.
Different colours for different strengths of Bupivacaine.
The strength inside the lip.
Not for intravenous injection should be more prominent.
2.2 The new (proposed) drug box design

2.2.1 Frequency of drawing up the drug

2.2.2 Relative agreement with statements about new drug box

- Just fewer than six in ten respondents stated that they draw up Bupivacaine at least two or three times a week. Over a quarter of respondents (28%) draw up the drug less than weekly.
• The statements respondents were most likely to agree with were “it is easy to distinguish between different strengths of drug” and “the packaging makes it easy to identify the drug in a new workplace”. With 1 = strongly agree and 2 = agree, there was a sense of agreement with all statements.

Comments on statements
The writing is more spread out on the old box which makes it clearer and easier to read than the new box where the writing is very close together. I found no problems with the strength markings on the original box, plus always check the strength before giving. The old box and packaging are easy to distinguish between the two strengths. What is on the box does not make it any safer to draw up if the ampoules inside the box are not different. It is not any easier to distinguish between strengths. No different in effect from current packaging.

2.2.3 Features of the packaging that makes it prone to errors

are there any features of the packaging which makes it prone to administrative errors

<table>
<thead>
<tr>
<th></th>
<th>number of respondents (base: 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>no</td>
<td>13</td>
</tr>
<tr>
<td>yes</td>
<td>2</td>
</tr>
</tbody>
</table>

• Only two respondents felt that there were features of the presentation and packaging of the drug Bupivacaine which make it prone to administrative errors.

Comments on the presentation and packaging
Not if read properly. Currently the sterile outer packaging displays the strength of drug but the packets are very similar. Not the packaging - user error. Box marked 0.5% at a quick glance can be mistaken for 50%.
2.2.4 Additional safety information needed

- 85% of respondents felt that the existing information was sufficient to ensure the safe use and drawing up of Bupivacaine. Two respondents felt that additional safety information was needed.

**Comments on additional safety information required**

Use by date.
Maybe identify it is a local anaesthetic.
User error.
Identify type of drug i.e. Bupivacaine for local anaesthetic.

2.2.5 Specific changes in the new box design

- Half of the respondents felt that there were specific changes in the new box design which were effective in improving safety.

**Comments on changes which improve safety**

Not if you are familiar with the drug.
Strength of drug very clearly marked more than once.
The inner lid with strength displayed is good.
Warning - not for intravenous injections.
Clearly marked and more colourful.
Grey for LA - better than when LAs come in same box as saline.
The prominent warning re: avoid intravenous.
Easier to identify strengths.
Colouring of different strengths 0.25 and 0.5.

- The vast majority of respondents felt that there were no specific changes in the new box design which were actively ineffective in improving safety.

- The one respondent who felt that the new box design did have elements which were ineffective in improving patient safety was asked to specify. He commented:
  
  "All of it."

2.2.6 Preferred packaging

- More than half of the respondents stated that they prefer the new box design. Three in ten have no preference, and only two respondents prefer the old design.
2.3 The existing drug information leaflet

2.3.1 Use of the existing leaflet

- More than six in ten respondents stated that they do not currently refer to the drug information leaflet for Bupivacaine.

**Comments on whether existing drug information leaflet is used**

- I know the drug.
- Do not administer drug, only draw up for the surgeon or prepare on request of anaesthetist.
- Not in my remit.
- Familiar with it.
- I am experienced in the usage of the drug.
- I would not be using the drug if I was not aware of the information on the leaflet. I would consult an anaesthetic text.
- Simpler.
- I use it too often.

**Reasons for referring to the existing drug information leaflet**

- If asked for drug info from doctor or student, drug allergies.
- I read them all before I use them.
- Mainly referred to when teaching students.

**Details of the type of information used on the existing leaflet**

- If asked for drug info from doctor or student, drug allergies.
- Uses, side effects etc.
- To explain the types of drugs I use.
2.3.2 Is the existing leaflet helpful?

- Of the four respondents who answered this question, there was an even split between whether or not they found it helpful to their role.

**Comments on whether existing leaflet is helpful**

- Clear and easy to read.
- Not enough detail.
- Directed to patients but most often used by a doctor, so more medical information.

2.3.3 Other sources of information

- Respondents were most likely to go to the BNF for more information, with three in ten respondents giving this as an option. One fifth of respondents said that they would ask the trust pharmacists, while a further fifth said all the information they could need is provided on the leaflet.

- Two respondents stated that they would consult a source not listed, and they both cited this source as the Anaesthetist's text book.
2.3.4 Other information required.

- The majority of respondents did not think that there was any information inadequately covered on the current leaflet.

**Comments**

The patient information leaflet is useful but a medical information leaflet would be useful providing contraindications, side effects etc. I think that if you are using this drug you should be aware of the information already. A more medical based slant on the information contained on the leaflet.

2.4 The new drug information leaflet

2.4.1 The new leaflet allows the drug to be used safely

- Nearly eight in ten respondents agree or strongly agree that the new leaflet allowed the drug Bupivacaine to be used safely. Only one respondent strongly disagreed with this statement.
Comments on the new information leaflet
Obviously need to be trained in administration. The leaflet can't cover this. The information in the leaflet is not sufficient in itself if the user has not been adequately trained to use the drug. Clear and concise. It is trying to be a poor pharmacy text book. As an ODP I find the indications, contraindications etc better than the current information sheets available but have heard a number of doctors express concerns of some of the information accurately.

2.4.2 Information not in the new leaflet

- All but one of the respondents felt that there was not any information about the drug Bupivacain that was not in the new leaflet. The respondent who said that there was did not specify what information they had to look elsewhere for.

2.4.3 Statements about the new leaflet
• The statement most strongly agreed with was “information was provided in a clear and organised manner”, but none of the statements have a mean of more than 2 which means that they were all at least agreed with.

Comments on statements about the new leaflet
There are factual areas on the leaflet as it stands currently. The colour today on the info leaflet of concentration does not tally with the box and the yellow is illegible. I disagree with the toxic dose of 2mg/1kg.

2.5 The proposed Kardex

2.5.1 Statements about the proposed Kardex

<table>
<thead>
<tr>
<th>mean agreement with statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>information was provided in a clear and organised manner (base: 13)</td>
</tr>
<tr>
<td>I found the layout of the bupivacaine kardex helpful (base: 13)</td>
</tr>
<tr>
<td>the order of the information suited me in my role (base: 13)</td>
</tr>
</tbody>
</table>

• All statements had a mean score of around 2, which means that on average respondents agree with them. “The order of the information suited me in my role” was slightly less likely to be agreed with.

Comments on statements about the Kardex
Colour of drug on Kardex should correspond to colour of drug on box. Yellow text is difficult to read. No mention of peororal parenthesis as an indicator or early toxicity. 2mg toxic dose or maximum recommended dose?
### 2.5.2 Preferred method of ‘look-up’

![Bar chart showing preferred method of look-up]

- Nearly six in ten respondents stated that they would use the proposed Kardex as a primary source of information. Only three respondents replied that they would not want to do this.

**Comments**

But I would recommend it to a trainee.

I would be more likely to consult an anaesthetic text or online, since I would be likely (in my role) to have a more in depth response.

### 2.6 Further information

#### 2.6.1 Any other information missing from the packaging or drug information leaflet?

![Bar chart showing missing information]

- Only one respondent felt that there was specific information missing from the packaging or drug information leaflet for the drug Bupivacaine. When asked to specify, they commented:

  "Identify on the box that this is a local anaesthetic."

#### 2.6.2 Further comments

- Only one respondent made any further comments:

  "Why do we need to change? Most problems are user error."
Appendix Hiv – Evaluation of Phenylephrine Labelling and Information

Assessment of new Phenylephrine drug presentation and information research

Report of the research findings

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March 2008
1 The respondent’s work area or unit

1.1 Trust respondent belongs to

- 7 out of 9 of the respondents stated that they belong to the Derby Hospitals NHS Trust. The remaining two are split between DCGH and South Derbyshire.

1.2 Job title of respondent

- There is no one job title that respondents are more likely to state that they hold. Two out of the eight respondents replied that they are theatre practitioners.
2 Assessment of new Phenylephrine drug presentation and information

2.1 The existing drug box design

2.1.1 How often the drug is used

- Only two respondents use the drug Phenylephrine daily, and two thirds use it 2 or three times a week. One respondent only uses the drug weekly.

2.1.2 How easy is it to distinguish between different drug strengths?

- 75% of respondents found it quite easy to distinguish between different drug strengths. One respondent said that this was not at all easy.

**Comments on distinguishing between drug strengths**

Not applicable - only one strength available.

Wasn't aware more than one concentration was available in our trust.

It is manufactured as either 10mg/ml or 100mcg/ml.

Didn't realise there were two available strengths.
2.1.3 How useful is the information displayed on the existing drug box?

- The majority of respondents (75%) find the existing drug box information quite useful. Only two respondents stated that it was not that useful.

Comments on the information on the existing drug box
- Never read the information on the drug box.
- It tells you what it is.

2.1.4 Are there any aspects of the current box design that are particularly useful or helpful?

- Two thirds of the respondents stated that there are aspects of the current box design for Phenylephrine that are particularly useful or helpful.

Comments on current box design
- Striking colour helps me find it quickly as long as supplier is not changed.
- Colour.
- Easy to read name of drug and concentration.
- Colour signs with drug name and concentration.
- Colour of box - bright red and red/blue line.
- Colours are clearly identifiable.
2.2 The new (proposed) drug box design

2.2.1 Frequency of drawing up the drug

- Three quarters of respondents stated that they draw up Phenylephrine at least two or three times a week. The remaining two respondents draw up the drug less than weekly.

2.2.2 Relative agreement with statements about new drug box
The statements respondents were most likely to agree with were "cautionary information and warning specific to the drug are clearly visible" and "the information provided on the box is easy to read and understand". With a mean score of 3.1, "It is easy to distinguish between different strengths of the drug" was not agreed with by respondents.

**Comments on statements**

Information on dose may help.
The fact that all vasupressons are now pink, e.g. ephedrine, adrenaline and phenylephrine may make them confusing.
No information on drug boxes can compensate for dilutional (human) error.

---

**2.2.3 Features of the packaging that makes it prone to errors**

| are there any features of the packaging which makes it prone to administrative errors |
|--------------------------------|----------------|
| no                          | yes           |
| number of respondents (base: 9) |               |
| 5                           | 4             |

Over half of the respondents feel that there are features of the presentation and packaging of the drug Phenylephrine which make it prone to administrative errors.

**Comments on the presentation and packaging**

'Correct dose' is not 'one ampoule' as with many other drugs. Writing is tiny. Not presented in the dilution we would use for IV administration.
2 concentrations are manufactured.
Colour similar to ephedrine/adrenaline.
This formation requires dilution - a major source of potential error.
2.2.4 Additional safety information needed

![Bar chart showing the number of respondents for additional safety information needed.]

- Just fewer than eight out of ten respondents feel that the existing information is sufficient to ensure the safe use and drawing up of Phenylephrine. Two respondents feel that additional safety information is needed.

**Comments on additional safety information required**
- Perhaps the manufacturer should be stated.
- Also, the expiry date on the outside of the box.
- How to dilute the drug.

2.2.5 Specific changes in the new box design

![Bar chart showing the number of respondents for specific changes in the new box design.]

- Two thirds of respondents felt that there were specific changes in the new box design which were effective in improving safety.

**Comments on changes which improve safety**
- Bigger writing.
- Lilac colour as in syringe label.
- Enlarge warning "must be diluted before use".
- Insert on flap of box.
- Different colour.
- More information on outer package that's written clearer and in larger lettering than the old box. The label inside the lid of the box.
- Must be diluted label.
• Over four in ten respondents felt that there were no specific changes in the new box design which were actively ineffective in improving safety.

**Comments on changes which are ineffective in improving safety**

Colour pale, keep deep red to be seen from a distance.
Name of drug could be in a larger font, not quite as clear as on existing box.
New colour and smaller writing with Phenylephrine sign.
Colouring.

**2.2.6 Preferred packaging**

• More than half of the respondents stated that they prefer the new box design. One respondent has no preference but a third of respondents prefer the old box design.

**Comments on preferred packaging**

But keep the more significant colour.
Useful to have safety information and storage information clearly visible.
Both clearly state the drug concentration (10mg/ml).
More information on box and clearer to read. Label inside the lid of the box. Clear instructions on how to be diluted.
2.3 The existing drug information leaflet

2.3.1 Use of the existing leaflet

- Nearly nine in ten respondents stated that they do not currently refer to the drug information leaflet for Phenylephrine.

**Comments on whether existing drug information leaflet is used**
- Familiar with dose already.
- I already know about this drug.
- Had no reason to.
- Familiar with day to day use - no need to refer to leaflet for information.
- Familiar with drug.
- I am aware of the pharmacodynamics and kinetics of Phenylephrine.
- I am using it regularly so I know what I am doing.
- If I needed to - I'm not an anaesthetist, so I wouldn't be administering the drug.
- I use the drug frequently, and I know about its uses and side effects already.

**Reasons for referring to the existing drug information leaflet**
- If I needed to provide information for the anaesthetist.

2.3.2 Is the existing leaflet helpful?
• Of the two respondents who answered this question, there was an even split between whether or not they found the existing leaflet helpful to their role.

**Comments on whether existing leaflet is helpful**
The information is present, but it is not easy to read (small).

### 2.3.3 Other sources of information

![Bar chart showing sources of information](image)

- Respondents were most likely to go to the BNF for more information, with more than a third of respondents giving this as an option. A quarter of respondents said that they would ask a colleague, while a further fifth said they would go to the trust pharmacist.

- One respondent stated that they would consult a source not listed, and they cited this source as the Anaesthetic pharmacology texts.

### 2.3.4 Other information required.

![Bar chart showing information needed](image)

- Is there any information that you think is missing or inadequately covered on the current leaflet?

- 5 respondents said "no"
- 2 respondents said "yes"
• The majority of respondents did not think that there was any information inadequately covered on the current leaflet.

Comments
Details regarding dilution to prepare drug for clinical use.

2.4 The new drug information leaflet

2.4.1 The new leaflet allows the drug to be used safely

![Bar chart showing the distribution of respondents' agreement on the adequacy of the new leaflet.]

- Nearly nine in ten respondents agree or strongly agree that the new leaflet allows the drug Phenylephrine to be used safely. Only one respondent stated that they disagree with this statement.

Comments on the new information leaflet
Prefer to put 1ml Phenylephrine in 100ml bag of saline. The leaflet directs you to have 2 syringes - one of which is 10x stronger than the other. One day, somebody will mix them p. Infusion instructions - suggest translate dose into ml/l as well. Don’t like phrase normal concentration for clinical use - several concentrations are in clinical use.

2.4.2 Information not in the new leaflet

![Bar chart showing the distribution of respondents' responses to the question about missing information.]

- There was any information about the drug that you needed to look for elsewhere.
• All but one of the respondents feel that there was not any information about the drug Phenylephrine that is not in the new leaflet.
• The respondent who felt that there was information they had to look for elsewhere was asked to specify what information this was:
  “The infusion rate is stated but no drug concentration - this could be misleading”

2.4.3 Statements about the new leaflet

The statement most strongly agreed with was “The order of the information suited me in my role”, but none of the statements has a mean of more than 1.8 which means that respondents agree or strongly agree with them all.

Comments on statements about the new leaflet
Info about dilution.
There is duplication of information regarding dilution.

2.5 The proposed Kardex

2.5.1 Statements about the proposed Kardex

• The statement most strongly agreed with was “information was provided in a clear and organised manner”, but none of the statements has a mean of more than 2 which means that they were all at least agreed with.

**Comments on statements about the Kardex**
Practical application would be better ‘before’ i.e. to the left of pharmacology information. Interaction with MA01 and contraindications should be separate.

### 2.5.2 Preferred method of ‘look-up’

![Bar chart showing preference for using the proposed Kardex as a primary source of look up information.](image)

• Three quarters of respondents stated that they would use the proposed Kardex as a primary source of information. Only two respondents replied that they would not want to do this.

### 2.6 Further information

#### 2.6.1 Any other information missing from the packaging or drug information leaflet?

![Bar chart showing responses to the question of whether any other specific information is missing from the packaging or drug information leaflet.](image)

• None of the respondents felt that there was any other information missing from the packaging or drug information leaflet.

#### 2.6.2 Further comments

• Only one respondent made any further comments:

  “If Phenylephrine labels are included in the box, it will be more helpful.”