Purchasing for safety - injectable medicines

Final programme report

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United Lincolnshire Hospitals Trust
Central Manchester and Manchester Children’s Trust (ICU/CCU)
Salford Royal Foundation Trust- Hope Hospital (ICU/CCU)

In collaboration with:
Atos Consulting
Engineering Design Centre - University of Cambridge.

(For a complete set of reports and outputs from the project, see the knowledge pack at www.pasa.nhs.uk/purchasingforsafety)
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Executive summary

Overview

Patient safety has been firmly established as a key priority for the NHS. Safety first (December 2006) built on previous publications, notably an Organisation with a memory (2000), and ‘Building a safer NHS for patients’ led to the establishment of the National Patient Safety Agency (NPSA). The principles of patient safety set out in these documents have since become pillars of the NHS quality and clinical governance agendas.

With patient safety rising up the government agenda and growing recognition of the role of procurement in addressing some of the issues, the All-party parliamentary group for patient safety was established in 2005. Its first meeting focused on patient safety in the procurement process, including the evaluation of medical technologies, the inclusion of patient safety issues as a pre-purchase criterion, the ability of users to make informed risk assessments when selecting, and the need for readily-available safety evidence and data to inform procurement decisions.

Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine. The NPSA received around 800 reports a month relating to injectable medicines between January 2005 and June 2006 (around 24 per cent of the total number of medication incidents). While most resulted in no or low harm, there were 25 incidents of death and 28 of serious harm reported in that period. To address this issue, the NPSA issued a series of patient safety alerts in March 2007 (www.npsa.nhs.uk).

One of the actions that Trusts are required to take under the alerts is to implement a purchasing for safety policy. In addition, many of the other actions can be delivered or supported by the procurement function, working with pharmacists and clinicians. The link between Procurement and safety solutions is established in the design-led approach endorsed by the DH and NPSA. This approach recognises that human beings would make fewer mistakes when products, services, processes, and environments are designed for safety. A ‘systems’ purchasing strategy indicates that design briefs and procurement decisions must be based on a detailed understanding of how staff and patients use – and sometimes misuse – products for safety solutions to be effective.

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 was 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, in this case in respect of injectable medicines. The overall objectives of the project were threefold:

- To demonstrate that ‘strategic’ purchasing can reduce clinical risk associated with the administration of injectable medicines.
- To learn lessons relating to the case of injectable medicines that will be of benefit to trusts and collaborative procurement hubs across the country.
- To develop an approach that could serve as a model for addressing wider governments policy issues through procurement.

The pilot objectives are closely aligned to the recommendations outlined in the Patient safety alerts. Various stakeholders in the network have been joined up to establish the purchasing for safety pilot programmes, and communications and joint collaborative work have been conducted with national agencies, societies and groups. The pilot programme
commenced in April 2007 to test the benefits and build an evidence base. Participating trusts were:

- Derby Hospitals Foundation Trust (focusing on theatres, imaging, maternity and oncology departments)
- United Lincolnshire Hospitals NHS Trust (focusing on oncology and haematology, critical care and coronary care departments)
- Central Manchester and Manchester Children’s Hospital NHS Trust
- Salford Royal NHS Foundation Trust
  (The latter two trusts combined to form a single pilot based around critical care)

The three pilots shared common objectives, commitment and enthusiasm to review their baseline medication management system, and prioritise risks and mitigation plans. However, they represented three different types and sizes of NHS Trusts with a variety of capabilities and project portfolios in the area of patient safety improvement. This further promotes the ability to transfer the findings to other Trusts, based on similar levels of maturity.

In three main phases of the programme, the pilots conducted:

- audit and baseline assessment for the products, processes and people involved in delivering medications management and procurement processes
- planning and implementation of selected workstreams, including trials where appropriate
- evaluation of the short-term benefits, as well as contributing to a tracking system for longer-term benefits.

In the baseline assessment phase, two main arms of research were conducted. The first arm focused on clinical risk assessment of the medications management process, and the second studied the procurement process in partnership with research conducted at the Engineering Design Centre/ University of Cambridge.

A risk assessment approach in the first arm resulted in prioritising risks and issues to be further addressed through purchasing for safety. The evidence and recommendations generated were further analysed to produce local and national projects in the form of a workstream structure. The purchasing for safety risk reduction strategies are presented in the diagram below.

*Figure 1: Purchasing for safety workstream structure*

![Diagram of Purchasing for Safety Workstream Structure](image-url)
The workstream approach enabled the evaluation of risk reduction strategies in a joint environment linking the clinical purchasing for safety team with purchasing, the industry and related national stakeholders.

Summary of recommendations

The workstreams conducted as part of the purchasing for safety pilot programme studied and evaluated the benefits and risks from applying the selected risk reduction strategies. A summary of the key workstreams’ rationales and recommendations is presented below.

1) Pre-prepared injectables: Purchasing ready-to-use and ready-to-administer injectables simplifies the medication administration process in the near patient areas and could dramatically reduce the chance of calculation and mixing errors. One of the ways it accomplishes this is by reducing the need for nurses to prepare IV solutions from available ward stock in near patient areas. The reduction of many of these risks can be made by controlling the process of preparation with a manufactured pre-prepared infusion. In two main pilots, this workstream established how risk can be reduced through the use of pre-prepared infusions, moving some of the risk from clinical areas to manufacturing units.

Many factors impact on whether a drug is suitable for manufacture in this way, including: drug licensing; shelf life; temperature controls; bulk of product and packaging for storage; cost; standardisation of solution strength; availability for manufacture; and demand for use in practice. A number of recommendations to local and national stakeholders were drawn from this workstream and are summarised below:

Local clinical team needs to consider the risk reduction benefits and time saving along with the cost implications for use of pre-prepared injectables in practice. It is recommended that they identify a shortlist of injectable drugs that could potentially be standardised to achieve similar benefits in practice in ICU and other parts of the Trust.

National, local and regional Purchasing can drive down costs where possible, as the increased acquisition cost of pre-prepared products to a single trust produces conflict between the risk/benefits and financial expenditure. Regular content management would also be required to ensure up-to-date unlicensed products’ databases.

Recommendations for the purchasing function indicated the need to work strategically with NHS Trusts to identify a national set of preferred solution strengths for drugs where pre-prepared presentations can reduce clinical risk. National purchasing then needs to work with industry and the NHS Manufacturing Units to ensure the appropriate range and scale of production, priced to provide a cost-effective alternative to existing and potential injectable drugs. Some ready-to-use preparations may be suitable for licensing.

2) Dose banding: Dose banding has been shown to be a viable purchasing for safety initiative for many standardised products. Aggregation to a regional level was achieved in this project, but a national approach and drive was advocated by some participants to lend consistency, maximise the benefits and deliver greatest value to the NHS. Standardisation would reduce the range of products, facilitate national procurement and persuade industry to apply for marketing authorisation. This approach was tested in chemotherapy drugs, although it may also be appropriate for some antibiotics. A regional purchasing specification has been produced as part of this workstream covering purchasing, logistics, quality and clinical risk management issues applying to the product, as well as packaging and labelling. Customer care issues, supply and performance monitoring were also considered important aspects.

3) Product information and labelling: In many cases product labelling and information has been found to fall short of the requirements of clinical practitioners and is recognised by the NPSA as a source of error and risk. The workstream at two pilots demonstrated that regulatory changes need to be made to provide practitioners with essential product information. Examples
were studied to build evidence of how this information should be presented to support safe injectable medicines practice (ie in a user-friendly, accessible way, for example using innovative label designs and clear technical information leaflets). Combining initiatives from the Royal College of Anaesthetists and NPSA would assist practitioners with product identification, selection and differentiation. These were seen to represent significant purchasing for safety and clinical risk management opportunities. It is recommended that this work is built on and taken forward nationally to ensure that all injectable medicines are supplied with adequate technical information to facilitate safe preparation and administration.

(4) **Devices management:** The workstream centred on the development of a business case and funding options for an equipment library, which is considered best practice for the optimum utilisation and management of medical devices. However, wider issues are the lack of national nomenclature for medical devices, a lack of understanding of the safety issues arising from the sheer variety of pumps in use in some trusts, and the extensive use of infusion pumps that are over ten years old. A push towards greater standardisation, and an identified cut-off point for obsolescence and replacement would reduce the risks associated with these issues.

(5) **Needle-free systems:** The workstream consisted of an evaluation of innovative, partially closed needle free systems. This assessment gave valuable feedback to inform clinical and purchasing decision makers of what an ideal system would look like. Such a 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. It was considered that health and safety and regulatory agencies could mandate use of needle-free systems for the preparation and administration of high risk drugs. National contracting by NHS Supply Chain would ensure cost and volume benefits to the NHS and industry.

(6) **Pump design:** Significant purchasing for safety benefits can be applied to medical devices. These included opportunities to develop a purchasing specification, as well as better utilisation of safety features built into ‘smart’ pumps. Results from this workstream showed that industry needs to do more to make these the default setting and ensure that pumps are user friendly and intuitive to operate. ‘Pump needs analysis’ software has the potential to support Trusts with standardisation of equipment, but further validation is required. Dose limiting software and analysis of end-user logs offer valuable tools to improve safe use of devices to administer injectable medicines. These features should be built into national guidance and purchasing specifications. In conjunction with this workstream, the Centre for Evidence based Purchasing is undertaking an evaluation of the various dose-limiting software systems available from providers and will produce a buyers’ guide in August 2008.

(7) **Barcoding:** Barcoding technology offers benefits for patient safety and asset management, bringing safe practice, efficiency and accountability to a range of healthcare processes. A strategic approach to purchasing and developing a solution that covers all applications (eg asset tracking, stock management, auto ID of patients and reconciliation of drugs) has shown to be the most cost effective solution for the NHS, and represents an important purchasing for safety opportunity. Whilst full connectivity may be some way off in practice, Trusts should be encouraged to make use of existing technology by implementing standalone solutions in the short term to demonstrate the benefits. Trusts should use DM+D to implement standard coding and should ensure that all relevant technology sourced in future is fully auto-ID enabled.

Key recommendations have been drawn in light of the evidence and workstream studies, and objectives agreed between local and national stakeholders who participated in joint active discussion. Recommendations highlight the role of local clinical staff, including the chief pharmacist, medical device manager, and clinical risk manager (as well as other clinicians) in establishing and developing purchasing for safety user-led approach. A strategic approach to purchasing in decision making and clinical engagement has also been explained in the form of recommendations to local/ regional and national purchasing. Furthermore, some changes in the way some products are regulated have been suggested, as well as a number of healthcare need-driven recommendations addressed to the industry.
Measuring the benefits

Significant benefits are expected from purchasing for safety initiatives to patients, staff, hospitals and trusts, as well as the procurement function and the NHS as a whole. In order to track these benefits, monitoring of performance would be required over a long term period. In the outset of this project, it was identified that the timescale would allow evaluation only of short and intermediate term benefits. However, the project developed a set of inputs, capabilities and processes requirements that would provide measures for establishing a purchasing for safety system, and therefore define a benefits and output tracking system for this purpose. The baseline criteria matrix and balanced scorecard present those as a balanced set of objectives and measures. The Balanced scorecard serves as a starting point to develop an appropriate process to measure the outcomes (clinical and financial) of the implemented objectives.

Outputs

Main outputs from this programme consist of research and risk assessment toolkits and questionnaires, sample documents (e.g., specifications), and detailed pilot and workstream outputs and reports, as well as project planning and management documentation. The programme outputs are available to trusts in the form of a knowledge pack at www.pasa.nhs.uk/purchasingforsafety. Valuable lessons have been learnt from this project, and a number of challenges exposed and handled. The expertise and valuable time of all project and pilot team members highly contributed to this programme and the lessons learnt.

Conclusion

In summary, a strategic and joint approach to purchasing for safety is required where efforts are coordinated between national (NHS PASA), regional and local purchasing, the NPSA, and the industry in response to managed clinical risk assessment evidence that is provided from local Trusts and the NHS. The project has shown the value of a multi-disciplinary ‘purchasing for safety’ team at trust level, working to common objectives. A comment from one of the pilot trusts: “We thought that the practice across the Trust was exemplary; the process has shown us not to rest on our laurels” shows that assumptions should not be made about current practice, and it is by allocating time and resource to assess the risks in current practice and address previous incidents that lessons can be learnt. Only then can further errors associated with the procurement and use of medications and devices in practice be managed and prevented.

With the government’s current emphasis on patient safety as a high priority for Trusts, there has never been a better time to address this agenda. This project has helped to position the procurement function to play a leading role by implementing purchasing solutions – locally, regionally and nationally – and there is a significant opportunity to build on the pilot work to support and deliver government policy on safety for the benefit of patients, staff and the NHS as a whole.
1. **Background**

1.1 The last few years have seen the issue of patient safety rise up the political agenda. Indeed, in 2004, an 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 National Patient Safety Agency (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 Medication errors remain a significant cause of medical error and, in 2004, the Chief Pharmaceutical Officer published recommendations to improve medication safety. This reinforced recommendations for the safe handling, preparation and administration of injectable medicines, with actions to improve labelling, information and training.

1.3 A retrospective record review for adverse events in British hospitals shows that ‘out of 8 million admissions to hospital in England each year, about 850,000 result in patient safety incidents which cost the NHS about £2 billion in extra hospital days.’ In other words, about 10 per cent of inpatient episodes in UK hospitals result in errors of some kind. Half of these errors are found to be preventable. Studies from the US have demonstrated that the added costs and financial burden associated with treating medication errors can be very high. According to evidence from the Joint Commission of American Hospitals in 2004, a study found that an estimated two per cent of admissions experienced a preventable Adverse Drug Event with an added cost per patient of $4,700. This could mean a cost of 2.8 million per year for a 700-bed teaching hospital.

1.4 Research studies have demonstrated that ‘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.

1.5 The All-Party Parliamentary Group for Patient Safety was established in 2005. Its first meeting focused on patient safety in the procurement process, including the evaluation of medical technologies, the inclusion of patient safety issues as a pre-purchase criterion, the ability of users to make informed risk assessments when buying and the need for readily-available safety evidence and data to inform procurement decisions.

1.6 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 was 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 was identified: *injectable medicines*.

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1 & 4 DH/Design Council; Design for Patient Safety: a system-wide design-led approach to tackling patient safety in the NHS
2 Building a safer NHS for Patients- Improving medication safety. London DH 2004
3 Prof Lucan Leape, Harvard School of Public Health, quoted in *Design for patient safety*, NPSA/Design Council, 2004
2. Introduction to injectable medicines and safety

2.1 Providing the right medication to the right patient at the right time first time is the positive outcome of an effective and safe medication management system, that is where healthcare providers prescribe, prepare, dispense, and administer medications to patients safely and appropriately. Yet, despite their unparalleled expertise and commitment to quality, errors and adverse incidents with medications have occurred, in some cases causing severe harm and significant financial burden to patients and healthcare providers.  

2.2 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.  

2.3 Evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine. The risks associated with using injectable medicines in clinical areas have been recognised for some time. In 2001, the Audit Commission found evidence that high risk injectables were often being prepared in clinical areas in English Hospitals. More recently, a risk assessment study of injectable medicine preparation in secondary care acute Trusts in the north of England found that high risk products, including cytotoxics were being prepared in clinical areas.  

2.4 The increasing number of new drugs and technologies introduced every year complicates medication use, as do the composite medical conditions requiring more complex treatment strategies. Risks associated with the preparation and administration of injectable medicines have been known for a long time and controls on their preparation in place since the 1970s when a working party, chaired by Sir Alistair Breckenridge, recommended that drugs should only be added to infusion fluids within a controlled pharmacy environment, and that pharmacists should advise on stability and compatibility issues, as well as training ward staff.  

2.5 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. A series of Patient Safety Alerts designed to mitigate these risks was published in March 2007.  

2.6 Medication incidents vary in the extent of harm they could cause to the patient. As reported in Safety in doses (2007), the majority of incidents (82.2%) resulted in no harm to patients. In a few cases, the reported medication error led to severe harm or death.  

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6 Source: Intravenous, Topical and Irrigation Fluids (report prepared for NPSG, October 2006)  
These included errors in the administration and prescribing of medicines. There are particular higher risk medicines that can be associated with severe harm, such as opioids, anticoagulants, anaesthetics, insulin, antibiotics, chemotherapy, anti-psychotics, epidurals and infusion fluids. In an ethnographic study of the incidence and severity of intravenous drugs in 10 wards of hospitals in the UK, over a six and ten day period, 249 errors were identified. At least one error occurred in 212 (49%) out of 430 intravenous doses. Three doses (1%) had potentially severe errors, 126 (29%) potential moderate errors and 83 (19%) potentially minor errors. Examples of how such errors occurred include when giving bolus doses or making up drugs that required multiple step preparation and complex calculation.

2.7 The frequency of occurrence of a particular error, as well as the extent of harm they can cause, are measures that can be used to assess and prioritise a particular risk for mitigation to be planned. Regular monitoring of these output and outcome measures can provide an indicator of the reduction of risk and medication error incidence.

2.8 Due to the repetitive nature of errors, that is an incident of misuse in one setting is likely to repeat itself in another; valuable information could be produced to help other organisations and individual providers to learn and prevent errors from occurring in their own organisations and practices. In spite of the differences and variability in type and nature of errors and individual practice, it is evident from the literature that the system changes necessary to prevent errors are similar. With so much evidence based information about error prevention at hand, a shift in the approach to handling patient and medication safety incidents should be considered; this indicates a shift from blaming and reacting to human error to effecting change through joint planning and team based implementation from the system as a whole.

2.9 The NPSA received around 800 reports a month relating to injectable medicines between January 2005 and June 2006 (around 24 per cent of the total number of medication incidents). Whilst most resulted in no or low harm, there were 25 incidents of death and 28 of serious harm reported in that period. Using data from NRLS, the NPSA has identified a number of system risks and recommendations that need to be made to promote the safety of injectable medicines.

2.10 To address this issue, the NPSA issued a series of patient safety alerts in March 2007:

- Promoting safer use of injectable medicines (Patient safety alert 20)
- Safer practice with epidural injections and infusions
- Actions that can make anticoagulant therapy safer
- Reducing the risk of hyponatraemia when administering intravenous infusions to children.

Other projects and guidance to enhance patient safety include the following:

- standardisation and centralisation of infusion devices to enhance safety
- design for safety (infusion devices and injectable medicines presentation).

2.11 The NPSA has recommended a number of actions for the NHS in reference to the Patient safety alert 20. One of these is to implement a purchasing for safety policy. In addition, many of the other actions can be delivered or supported by the procurement function, working with pharmacists and clinicians. The key actions are summarised below.

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Patient Safety Alert 20
Actions for the NHS and the independent sector

1. Undertake a risk assessment of injectable medicine procedures and products in all clinical areas to identify high risks, and develop an action plan to minimise them.
2. Ensure there are up-to-date protocols and procedures for prescribing, preparing and administering injectable medicines in all clinical areas.
3. Ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use.
4. Implement a ‘purchasing for safety’ policy to promote procurement of injectable medicines with inherent safety features.
5. Provide training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring injectable medicines.
6. As part of the annual medicines management audit programme, healthcare organisations should include an audit of medication practice with injectable medicines.

2.12 As purchasing is a critical step that introduces a major input to the clinical pathway and can contribute to each of the subsequent processes in medication management (i.e. selection, storage, preparation, labelling, administering and monitoring of injectable medicines and devices), this project addressed how a strategic (system-based) approach to purchasing can reduce the clinical risk associated with these subsequent steps. This included the product/ranges and features of products purchased and the purchasing process itself, as well as safety culture among staff and their performance.

3. Project objectives

3.1 With patient safety rising up the government agenda and growing recognition of the role of procurement in addressing some of the issues, Ministerial discussions were held. These resulted in a recommendation for NHS PASA to implement and fund pilot sites within the NHS to test Purchasing for Safety benefits in the area of injectable medicines.

3.2 The overall project objectives were threefold:

1. to demonstrate that strategic purchasing can reduce clinical risk associated with the administration of injectable medicines
2. to learn lessons relating to the case of injectable medicines that will be of benefit to trusts and collaborative procurement hubs across the country
3. to develop an approach that could serve as a model for addressing wider government policy issues through procurement.

The pilot objectives were closely aligned to the recommendations outlined in the Patient safety alerts published in March 2007, including (but not limited to) reduction of patient risk via the following means:

- colour, design and labelling of products
- standardisation of devices, medicines and sets, and supporting training and protocols
- centralisation of devices
- elimination/reduction of ‘open system’ medication in favour of pre-prepared products
- elimination of injectables requiring complex calculation and dilution
- double checking systems (e.g. bar-coding, electronic dose limiting software)
- provision of clear written information for clinical staff.
By addressing the above areas, we aimed to:

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

4. **Purchasing for safety framework and related concepts and stakeholders**

4.1 In a healthcare setting, where patient outcomes and safety are crucial to healthcare delivery, an informed purchasing decision that is based on evidence and feedback of benefit and safety is required. This user-led approach is built on informed risk assessment reviews performed by a multi-disciplinary team of clinicians and other disciplines in the clinical settings. This approach ensures that the conditions and risks associated with medication management and infusion delivery system are thoroughly identified, assessed and communicated back to purchasing.

4.2 This pathway differs from the conventional approach to any supply chain, as the user-led approach enables feedback and communication between users, purchasers and manufacturers to jointly develop specifications and safer products. Such an empowerment for the disciplines involved, emphasises the need to develop a coordinated approach to work jointly in planning and delivering purchasing for safety strategies. In reference to PhD Research from the Engineering Design Centre at the University of Cambridge\(^\text{12}\), the figure below has been adopted to present the conceptual framework for this project. The purchasing for safety conceptual framework illustrates purchasing and design for safety pathways.

*Figure 2: Purchasing for safety conceptual framework*\(^\text{11}\)

4.3 It is somewhat challenging directly to relate this figure to the contextual reality of the NHS. This is due to the fact that each box represents a rather complex and variable group of entities in the NHS - whether these entities represent Trusts and hospitals, healthcare,

purchasing professionals and patient needs, products and processes, or a variable spectrum of different levels of development in practice and maturity to undertake patient safety initiatives.

4.4 An example is presented below with the focus on the medications management process as the principal area to study the users part of the framework. Medication management systems include processes used to provide medication-related therapies to patients.

The figure below represents a near-patient process map.

*Figure 3: The medication process (IV)*

Processes essential to medications management systems include:

1. **Selection** of medications to be used in the hospital. Selection can follow a formulary or a non formulary based system, as decided by the purchasing committee and in alignment with the organisation’s strategy
2. **Procurement** of medications from outside sources and suppliers
3. **Storage** of medications to maintain supply. Storage could be in the pharmacy store, and other possible locations such as the emergency room or pharmacy stations
4. **Prescribing** and **ordering** the medication by the physician. Direction for preparing, dispensing or administration of the medication is given in the order
5. **Preparing** the formula. This includes the steps to compound and transform the prescribed medication to the appropriate dosage form for administration
6. **Dispensing**: providing the supply of medication for the patient
7. **Administration** of the ready medication to the patient’s body
8. **Monitoring** and evaluation of clinical measure and patient perceptions.
4.4 Despite the expertise of health care providers and quality assurance accreditation, errors in the systems of hospitals still occur. This has been the subject of root cause analysis and the following factors have been found to contribute to and exacerbate medication error.

- In medication management, efforts to identify, prioritise, and minimise risk to the patient involve assessment and understanding of the process and the risk points involved, and a recognition of what will decrease the risks.\(^\text{13}\) Process study would also take into account the different scenarios that can potentially expose the current process to more errors, risk and delays.

- Both variability and variety can increase the potential for errors to occur. The transformation diagram in figure 4 overleaf identifies the different inputs and the variability included. The sources of variability related to each input challenge the process to ensure delivery of the performance objectives. Sources of both variation and variability are delineated in the figure.

**Figure 4: The transformation process**

<table>
<thead>
<tr>
<th>INPUTS</th>
<th>PROCESSES</th>
<th>OUTPUT</th>
</tr>
</thead>
</table>

1. **Products**  
(including drugs, devices and consumables)
- Availability
- Name and description
- Type (Brand / generic)
- Dose
- Dosage form
- Preparation technique
- Concentration and strength
- Presentation, labelling
- Level of information
- Dosing and calculation req.
- Infusion system compatibility
- Route of administration
- Price

2. **Patient**  
- Medical profile
- Demographics
- Diagnosis
- Status
- Matching patient
- Urgency of condition
- Drug hypersensitivity
- Medication record
- Nationality (cultural)
- Insurance scheme
- Financial situation

3. **Pharmacists**  
- Specialization
- Knowledge
- Role and Workload
- Communication skills
- Judgment and decision-making
- Safety culture

4. **Assistant Pharmacists**  
- Level of Training, skills, knowledge
- Communication skills
- Safety culture

5. **Nurses**  
- Handwriting, Communication skills, Knowledge  
- Wards ICU/ CCU/ Medical/ Surgery/ IVF
- Safety culture

6. **Clinicians and Consultants**  
- Specialty
- Level of Specialization
- Handwriting
- communication
- Availability
- Power & Level of interest
- Workload & availability
- Safety culture

---

**Medication management**

1. Procurement
2. Storage
3. Ordering and Transcribing
4. Preparation and Dispensing
5. Administration
6. Clinical Monitoring of effects.

- Right medication
- Right use & dose
- Right indication
- Right Patient
- Right time
- First time
5. Management literature review

System based causes of medication incidents in the NHS

Patient safety is now a high priority for the NHS; following a series of incidents and the publication of reports in this area, healthcare providers and researchers have begun to demonstrate a greater understanding of why medication errors occur.

5.1 According to the NPSA, in previous studies “the medical device was the major contributory cause in patients’ death in only around 20% of cases. In the other instances the other contributory factors were non device related.”14 A significant proportion of the remaining 80 per cent is attributed to human error or systems error. Human error is often implicated in medical mistakes. During the mid-1990s, Lucan Leape’s publication “Error in medicine” described the understanding and application of the science of human factors that could contribute greatly to patient safety.

5.2 Studies emerging from the Cognitive Technologies Laboratory at the University of Chicago look at defining complex system failure, error, safety, and resilience 15. They note that complex systems fail because of the combination of multiple small failures, each individually insufficient to cause an accident. These failures are latent in the system and their pattern changes over time. Reactions to failure focus on human error and result in the introduction of new rules that increase the complexity, thus introducing new forms of failure. Competing demands, dilemmas, conflicts and uncertainty are the central features of operations at the sharp end. Also, if there are technical and organisational conflicts, these overlap and interact.

5.3 They go on to state;

“Work system analysis methods, which are based on industrial and human factors engineering tools, have much to contribute toward patient safety, specifically because of their focus on systems. They offer principles and methods for analysing systems, which, if followed, should help health care administrators and clinicians properly analyse their units or facilities, and should lead to more robust patient safety interventions.”16

5.4 Based on the finding that ‘human beings make mistakes because the systems, tasks and processes they work in are poorly designed”17, 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.

The next section will review the literature on process design improvement and management.

Process and clinical risk management

5.5 As evidence in the JCAHO’s guide for medications management standards 4, root causes for medication errors are explained according to Process Management Literature. This

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16 Prof Lucan Leape, Harvard School of Public Health, quoted in Design for patient safety, NPSA/Design Council, 2004
section will provide an overview of the complexities involved with processes that can weaken the system and expose it to potential hazard.

5.6 Processes that are complex are more prone to error than those that have only a few steps. “Complex processes are at risk because of the variation and workarounds that commonly accompany them.” For example, processes with variable inputs are error prone. When one of several conditions or actions precedes the next step in a process, the risk of error increases. Complexity within a process is mostly easily identified when an attempt is made to break down the steps in the process by flowcharting. Processes that are complex usually involve poor systems and are more likely to expose a lack of consistent procedures or adherence to poor procedures, or lack of knowledge. Simplification has been proven to be the key to risk reduction where feasible in these cases. Building in checks and establishing clear standard operating procedures has also been shown to be helpful in reducing the risk of complex processes. Furthermore, there is clear evidence to show that standardising procedures decreases the risk of errors associated with the variations in how the process is followed.

5.7 Processes that are tightly coupled are also prone to error. That is, when a sequential step in the process starts immediately after the previous step or before the previous step is completed, it becomes almost impossible to stop the process if there is a failure in the early steps of the process.

5.8 As mentioned previously, some errors are the result of inattention. Human interventions are inherently error prone. When there is too much pressure or if a process is rushed, errors increase. If there is too much still time, errors also increase. Even if the workload is optimal, those performing a process can make errors due to distractions and interruptions or due to environmental factors, such as poor lighting or noisy working conditions.8

5.9 Evidence shows that when those involved in a process function as a team, reporting of near misses and potential errors increases. Members of a team are likely to point out potential risks and work together to improve the process. Where interaction occurs in a hierarchical way, with minimal communications mechanisms, errors are most likely to reach the patient.

5.10 Team work and regular feedback becomes more challenging as multiple disciplines are involved. For example, in order to base purchasing decisions on evidence of safety evaluations, purchasing and clinical disciplines need to be engaged. An informed purchasing decision is a strategic approach to viewing and practising purchasing and supply management. This is further evidenced in the strategic purchasing and supply academic and practical knowledge to date. A review summary is presented in the following section and in appendix A.

**Strategic purchasing and supply management**

5.11 The strategic significance of purchasing and supply practitioners has been widely acknowledged and evidenced in both literature and practice. The traditional emphasis on ‘optimising’ single transactions is being enhanced with the long-term view of procurement efficiency and effectiveness 18. Strategic roles, development stages and transition models have been developed to build a solid base of evidence on the effectiveness and need to develop and empower the role of purchasing and strategic supply to achieve outcomes in organisations. A literature review on the key models and tools developed by academics in management is at appendix A.

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Evidence based purchasing in multiple stakeholders open systems

5.12 It is rare to achieve the three objectives of effectiveness (quality), safety, and least cost together (Goldberg 2006). For instance, innovations in medical technologies could potentially offer high benefits, and even improved safety, but at the expense of increased cost or, in financial terms, risk. In avoiding uncertainty, purchasers might base their decisions on price, but this could lead to failure in achieving the benefit that will eventually save cost in the long term.

5.13 As a multi-disciplinary concept, evidence based approaches study the effectiveness of the intervention in question. In evidence-based purchasing this implies making decisions about effective, safe and affordable products and interventions. In healthcare, many stakeholders are involved in this decision, ranging from clinicians with a high level of discretion, to patients with increasing demands and expectations, finance directors and purchasers under pressures of cost reduction, and policy makers seeking better social health and equity.

5.14 When considering evidence based decision making in healthcare, it is important to understand who will make the decision and how many are the influencing parties. If these are various, it becomes crucial to manage the different perspectives in an open system.

5.15 Evidence-based purchasing is a new area of study of growing interest; evidence-based decision-making has been illustrated as a multi-step process of searching for evidence, appraising it and incorporating the best available evidence in the decision making process. A summary of literature review on evidence-based purchasing in multiple stakeholders open systems is provided in appendix A.

6. The NHS Purchasing context

6.1 This section examines the role and current situation of purchasing in the NHS in the light of both literature and practice. In particular, it identifies the different levels and types of purchasing activity for both pharmaceuticals and medical devices.

Levels of procurement in the NHS

6.2Procurement activity and interventions in the NHS occur at different levels, where purchasing decisions are made by a range of people and bodies:

- National (NHS PASA, NHS Supply Chain)
- Regional (Collaborative Procurement Hubs)
- Local (Foundation Trusts, non Foundation Trusts)
- Community (primary care and social care)
- Individual (Healthcare practitioners eg clinicians, technicians)

As this research is mainly focused on the study of injectable medicines and devices, the next section looks at the national picture in respect of the purchasing of pharmaceuticals.

21 Glasziou, P. and Haynes, B. (2005) The paths from Research to Improved Health Outcomes. Evidence Based Nursing. 8 (2) pp36-38
22 Gray 2001
23 Sackett, D.L et al. (1996) Evidence-Based Medicine: What it is and What it isn’t? BMJ 312 (7023), 13 January, 71-72
Sourcing pharmaceuticals for the NHS in England

6.3 NHS hospitals in England spend around £2.2 billion annually on pharmaceuticals, of which an estimated £1.7 billion is spent on branded pharmaceuticals. This section explains the current model for procuring pharmaceuticals and outlines the roles of national pharmacy groups, local pharmacy purchasing groups, collaborative procurement hubs and the NHS Purchasing and Supply Agency in managing procurement of pharmaceuticals in a coordinated and planned basis.

6.3.1 Objectives

The current national strategy for sourcing pharmaceuticals has been established and implemented since 2003. It serves to set out the basis on which those organisations involved with the procurement of both generic and branded pharmaceuticals in secondary care will work together to avoid the duplication of effort whilst achieving optimal value for the NHS as measured by:

- purchasing savings
- improved clinical outcomes
- reduced clinical risk
- reduced cost of provision.

6.3.2 Classification of pharmaceuticals

Pharmaceuticals (prescription only licensed medicinal products) can be classified as either:

- **generic medicines** – off-patent products that may be available from two or more suppliers. These products invariably lend themselves to large scale (national) contracting as awards relate to supplier selection (sourcing decisions are commercial ones)

- **patent protected (branded) medicines** - products that are single source (although products with similar (but not identical) therapeutic profiles may be available from two or more suppliers ). These medicines lend themselves to contracting by the localised purchasing groups/consortia as awards relate to product selection on a therapeutic basis (i.e. sourcing decisions are clinical ones) and contracting performance is dependent on clinical commitments agreed between pharmacists and prescribers.

A dynamic relationship exists between patent-protected and generic medicines with regular movement of products from branded to generic. Due to other complexities and variations, it has been realised that a national framework for purchasing pharmaceuticals needs to ensure that:

- the relationship between contracting for generic and branded products is managed on a fully coordinated and planned basis
- an understanding of the associated prescribing and pricing patterns is applied when designing NHS contracts
- the NHS manages and bridges between its clinical role of providing clinical (pharmaceutical knowledge) advice and its commercial role of purchasing medicines
- coordination is achieved to deliver a consistent national approach that is both transparent within the NHS and provides the industry with a coherent customer base
6.3.3 Existing pharmaceutical organisational networks and structures

NHS contracting arrangements for pharmaceuticals are currently delivered through a number of established organisational structures and networks. These are summarised in figure 5 and presented in detail with their roles and responsibilities in table B1 (Appendix B) in reference to the strategic framework to source pharmaceuticals for the NHS in England paper (October 2003).

The relationship between the local exploration of opportunities and the development of national strategies has been stated to be a dynamic one. For branded medicines opportunities may be identified at a local/regional level based on product knowledge, Pharmex data, and clinician attitude and then, as appropriate, developed and formalised at the national level, with local implementation reliant on clinical (prescriber) commitment and CPH support.

Figure 5: Existing pharmaceutical organisations networks and structure *

Strategies for improving Purchasing decisions

6.4 In the NHS in general, there are several problems or drawbacks that could set the agenda for ‘Purchasing for safety’ behind:

- decisions about outsourcing usually do not involve an assessment of risks and benefits
- purchasing decisions are often made by clinicians or budget holders with no evidence or coordinated strategy
- criteria for purchasing are subjective, price focused, and according to what the local trust can afford.

The main bodies that may have an opportunity to influence this situation are:

Collaborative Procurement Hubs (CPHs): Intended to ensure value for money and implement strategic procurement plans for those categories best sourced at regional level.
National Innovation Centre (NIC): As part of the NHS Institute for Innovation and Improvement (NHS Institute), and working together with Innovation Hubs, NIC aims to speed up the development and adoption of technological innovations that deliver the best results for the patient.

National Institute for Clinical Excellence (NICE): Provides technology appraisals on health equipment, clinical guidelines on managements of specific conditions, and clinical audit methods to support the other two.

Health Technology Assessment (HTA): HTA is funded by the Department of Health and managed by the National Coordinating Centre for Health Technology Assessment (NCCHTA) at the University of Southampton. HTA mainly assesses medical technology for clinical and cost effectiveness and focuses largely on invasive technologies that require clinical as well as economic evidence.

Adoption Hubs, Innovation Hubs, Training Hubs: Working together to help make better use of new technologies to increase ‘pull’ of innovative products, help overcome obstacles of innovators in entering the NHS, and develop training tools for the safe use of advanced medical technologies.

MediLink UK & Health Technologies Knowledge Transfer Network: National network of regionally-based independent programmes working for a common goal of raising the profile of the medical and healthcare sectors in the UK

National Patient Safety Agency: The NPSA leads and contributes to improved and safer patient care by informing, supporting and influencing healthcare organisations and individuals working in the health sector. Following the publication of Safety First, the NPSA is re-focusing its role around the collection and analysis of patient safety incidents via the National Reporting and Learning system (NRLS) and more rapid feedback to the NHS to identify risks and specify action to be taken. Over two million patient incidents have now been reported to the NRLS from the NHS.

Centre for Evidence-based Purchasing (CEP): Intended to “help and inform procurement decisions, and encourage the uptake of useful, safe, innovative products and procedures used in health and social care”. CEP outputs will guide purchasing decisions and help to speed adoption of new technologies throughout the NHS, and the organisation is undergoing major change to achieve this goal. In brief, the main objectives for the development of CEP are: first, the need to engage purchasing and supply practitioners in using evidence in the uptake of new technologies and shift decision making criteria from unsubstantiated opinions, or price and savings to more cost and clinical effectiveness measures; secondly, the limited state of medical device evaluation and scarce evidence on cost and clinical effectiveness indicated the need to reinvent the way medical devices are evaluated.

Pharmaceutical QA support for Purchasing for safety

6.5 The presence of QA support for procurement is required to meet the Core Standards for Acute Trusts in terms of safe procurement of medicines. It is also crucial in supporting the work arising from the recent NPSA Alert 20 (Safer use of injectable medicines). In some locations, there has been a shortage of resource; the need for a long term solution to the situation is urgently required has been emphasised during the course of this project. 25

6.6 QA support is fundamental to ensure patient safety and will include the following:

product specification approval, to ensure products are ordered correctly and checked correctly on receipt, prior to issue to the patient

- advice on, and approval of, service specifications for unlicensed medicines, homecare, over-labelling
- supplier audits
- risk assessments and the issue of guidance for use of medium or high risk products
- stability data collection and assessment, and information on stability of formulations
- assistance with contract management.

6.7 There are a number of areas to which QA support has an important input. These include:

- SCEP contracts, where the national MEPA scoring system is applied to all national contract lines. These risk assessments are carried out by Regional QA Services.
- central contracts. QA support is required to provide a risk assessment of samples, supplier audit, advice on suppliers and products, collation of QA reports and advice from other regions and national groups
- hub contracts: support is required for tenders eg for homecare services, contrast media and unlicensed medicines
- local trust contracts and purchasing of unlicensed medicines, tablet pre-packs and over-labelled medicines, homecare, as well as off-contract purchases (when the contracted supplier cannot supply).

Risk assessment in Purchasing

6.8 In 2001/2, two pharmacy purchasing groups started to develop a risk management approach to purchasing decisions, later collaborating with the NPSA. This initiative is presented as the start of a national, standardised approach to risk assessment, building on regional quality control systems that were mainly focused on product testing. It began in secondary care, with the intention that it could be rolled out in primary care as well.  

This led to a national concept of ‘Purchasing for Safety’, and is reflected on both the local and national levels, as follows:

Locally: hospital purchasing pharmacists evaluate purchasing decisions for safety, responsively with users as needed and within the approval of the DTC committee.

Nationally: Since 2003, NHS PASA has been working with NPSA, MHRA, suppliers and hospital pharmaceutical services and their quality controllers to reflect this new guidance through its contracting arrangements for the supply of pharmaceuticals to NHS hospitals in England.

Conclusion

6.9 Purchasing for safety is a form of evidence based purchasing practice, where purchasing decisions are based on clinical, economic as well as safety in use evidence. This evidence can be collated from a number of sources; these may include national agencies such as NICE, CEP and HTA, and also local knowledge as a result of risk assessment procedures and evaluation trials. Availability and access to such information by NHS Trusts, and purchasing decision makers is essential.

6.10 A joined up strategy for Purchasing for safety requires a joint collaborative approach between the various stakeholders involved in risk assessment, purchasing, evaluation and other organisations involved in the process. It is through developing communication mechanisms and feedback pathways that interaction between the right stakeholders can be facilitated and the purchasing for safety process can be effectively managed. This further highlights the question of how a strategic (system-based approach) to purchasing can reduce the clinical risk associated with these subsequent steps and multiple processes in practice.

6.11 The following section will present the methodology of the pilot programme.

7. Pilot programme: scope and methodology

Pilot trusts and project resources

7.1 The purchasing for safety pilot programme included three pilots across four NHS acute hospital Trusts. Having received Chief Executive support, the trusts applied to participate as pilot sites for the project supported by NHS PASA and focusing on agreed areas within the Trusts around injectable medicines. Pilot resources were committed to drive the purchasing for safety project in their Trusts and share their valuable expertise and time in line with the project’s objectives to study the clinical risk associated with the management and administration of injectable medicines. This allowed the practical demonstration of purchasing for safety as a means to impact on risk reduction.

The pilot Trusts were:

- Derby Hospitals Foundation Trust; Derby Hospitals is a progressive acute teaching hospital.
- United Lincolnshire Hospitals Trust; the Trust is a multi-site provider of acute hospital care for most of the county of Lincolnshire
- ICU/CCU department in Central Manchester and Manchester Children’s Trust (Manchester Royal Infirmary) and Salford Royal Hospitals Foundation Trust (Hope Hospital).

7.2 Trust resources reflected the multidisciplinary scope of this project. This local participation has also been linked to national stakeholders and representatives. The pilot teams included:

- Clinicians, nurses, pharmacists, consultants
- Clinical risk managers
- Medical device managers, medical engineering
- Purchasing; local, regional, national
- Specialist pharmacist groups
- Trust and NHS management
- IT management
- Industry; design and innovation, business development

*Roles covered also included:*

- Project sponsors representing Executive level and ensuring governance
- Project managers
- Project leads and change managers
National resources included Clinical and Procurement representative networks, societies and groups, including national category teams, academia, the Clinical Procurement Specialist Network; specialist consultants, as well as industry stakeholders and associations.

Scope

7.3 The pilot trusts focused on the following areas, and their respective processes and systems currently in place:

<table>
<thead>
<tr>
<th>Table 1: Clinical focus areas in the pilot programme</th>
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<tbody>
<tr>
<td>Pilot Trust</td>
</tr>
<tr>
<td>Derby Hospitals Foundation Trust</td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>United Lincolnshire Hospitals Trust</td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Central Manchester and Manchester</td>
</tr>
<tr>
<td>Childrens’ Trust &amp; Salford Royal Foundation Trust</td>
</tr>
</tbody>
</table>

7.4 In terms of process, the Trust’s pilot project encompassed purchasing and supply and storage, preparation and administration (including monitoring) of injectable medicines. Quality control also played an important role. Prescribing issues were not in scope.

Pilot processes included:

- IV medication and infusion management
- acceptable testing – undertaking risk assessments, analysis – looking at process and selection of equipment and drug products
- safe administration and risk reduction processes
- education and training of staff
- device management
- procurement.

7.5 In terms of product, all injectable medicines and the devices and consumables for their administration were in scope initially. The umbrella of injectable medicines is seen to include intraosseous, intravenous (push, infusion and combination) subcutaneous, intramuscular, epidural and intrathecal, intraarterial and intraocular administration. However, it was not possible to cover all products in this limited amount of time and resource availability for clinical staff; therefore phase one of this research focused on researching and assessing risk to produce evidence based selection and prioritisation of particular case studies and settings. Consideration was also given to the systems and processes that supported the products and services, such as packaging, labelling, use of colour and bar coding.

Project phases

7.6 The pilot programme consisted of three main phases: baseline assessment (audit phase), implementation of workstreams; and the evaluation and monitoring of findings and benefits.
7.7 The methods included in this research programme were literature review, multiple case studies, a workstream structure and participatory action research. Including multiple techniques controlled the quality and internal validity of the data collected within the context of each case study and each workstream. Data collection methods were face-to-face interviews, questionnaires, documentation and hard data analysis, focus groups, project board meetings and knowledge sharing seminar through participatory action research.

Preparation: building the knowledge base

7.8 During the planning phase and prior to the commencement of the pilots, desk research was conducted to place the project in its wider context, and to ensure that the project built on previous work. This included a comprehensive literature review - around patient safety and improved purchasing in general, and risks and errors in infusion/injectable therapy in particular. In collating this material, knowledge was built on the prior research and publications of the NPSA. In addition, meetings with stakeholders were used to identify the key issues and priorities to be addressed.

Phase 1 – audit and analysis of data to inform the pilot and provide a baseline

7.9 A thorough audit was conducted at each pilot site covering all products, practices and protocols associated with the administration of injectable medicines to identify the purchasing implications at each stage. The project methodology design included five main stages. These are demonstrated in figure 7 below.
7.10 In the baseline assessment phase, two main arms of research were conducted. The first arm focused on clinical risk assessment of the medications management process, and the second studied the procurement process in partnership with research conducted at the Engineering Design Centre/University of Cambridge.

7.11 A risk assessment approach in the first arm resulted in prioritising risks and issues to be further addressed through purchasing for safety. The evidence and recommendations generated were further analysed to produce local and national projects in the form of a workstream structure. The purchasing for safety risk reduction strategies are presented in the following structure:

**a. Clinical arm**
The first stage consisted of collation/analysis of existing safety-related hard data, including:

- review of adverse incidents, including near misses – type, number, frequency etc (at least last 12 months)
- results of risk assessment in near-patient areas.

Data collection and review was undertaken from key sources of reports, databases and assessment tools. These included the:

- National reporting and learning system incident data analysis
- Trust incident reports data
- Trust Pharmex data
- NPSA Risk assessment tools
- written protocols and procedures for the preparation and administration of injectable medicines.

These delivered the components of the risk assessment phase in a form of risk and issue register.

As part of issue investigation in the pilot Trusts, focus groups were conducted in major areas of specialty to establish key issues which each delivered an issue log for each pilot site.
Selected case studies were further analysed in detail via one-to-one interviews with key staff identified in each area, thus securing buy-in and consensus on priority areas. A web-based staff questionnaire was used to evaluate injectable medicines therapy by a large range of clinical staff of different disciplines and grades.

As part of the implementation phase, the audit findings were further analysed and reviewed to identify which risks and issues represent national projects versus local initiatives for implementation. This led to the establishment of the Purchasing for safety workstream structure, and recommendations for improvement.

b. Procurement and device management arm
As part of the Devices management and procurement arm of this research, and in collaboration with PhD Research from the Engineering Design Centre at the University of Cambridge, focus groups and interviews with key staff (clinical, pharmacy, device managers, EDME and purchasing) were conducted to identify responsibilities, clinical protocols/safety controls and potential barriers, and to explore issues such as usage, storage and management of equipment, training and competency assessments, reasons for level of product variety, purchasing approaches, decision-making and overall safety culture. A summary paper of the outputs to date from EDC research can be found in the knowledge pack (www.pasa.nhs.uk/purchasingforsafety).

Findings from the baseline assessment were compiled in the form of:
   a. Purchasing for safety baseline criteria matrix
   b. risk register for the key risks and issues identified as a result of process risk assessment
   c. workstream structure for the prioritised risk reduction strategies to be evaluated in the context of the pilot Trust.

Particular selection and evaluation criteria were used to analyse the issues and prioritise actions. The risks were analysed according to specific criteria, which included for both risks and the risk reduction strategy: impact, frequency, proximity, and risk assessment. The risk reduction strategies evaluation criteria included: national congruence/alignment to NPSA alerts, products of choice, expected benefits, clinical risk, challenges in implementation/feasibility and the strategic fit with Trusts’ initiatives.

Recommendations and specific risk reduction actions and measures were established for each pilot as part of an implementation plan. Risk reduction strategies were categorised in a workstream structure, (as shown in figure 8):

**Figure 8: Purchasing for safety workstream structure**

<table>
<thead>
<tr>
<th>System optimisation/re-design</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Devices</strong></td>
</tr>
<tr>
<td>- Product range and management: Centralisation/equipment</td>
</tr>
<tr>
<td>- Design &amp; innovation:</td>
</tr>
<tr>
<td>- designs for safety</td>
</tr>
<tr>
<td>- needle-free/closed systems</td>
</tr>
<tr>
<td>- Training &amp; information:</td>
</tr>
<tr>
<td>- devices training</td>
</tr>
<tr>
<td><strong>Administration to patient</strong></td>
</tr>
<tr>
<td>- Protocols for administration: safer use of Gentamicin</td>
</tr>
<tr>
<td>- Use of technology:</td>
</tr>
<tr>
<td>- bar-coding</td>
</tr>
<tr>
<td>- dose-limiting software</td>
</tr>
<tr>
<td><strong>Medicines</strong></td>
</tr>
<tr>
<td>- Product rationalisation:</td>
</tr>
<tr>
<td>- pre-prepared injectables</td>
</tr>
<tr>
<td>- dose-banding</td>
</tr>
<tr>
<td>- Technical information:</td>
</tr>
<tr>
<td>- technical information leaflets &amp; labelling</td>
</tr>
</tbody>
</table>

System view of treatment pathway and support systems (joining up of patient & product interactions, communication & handover points etc)
Phase 2 – implementation and trialling

7.12 The implementation phase addressed 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, they were further categorised to present what could be achieved in the short, medium and long terms.

7.13 It is important to stress that ‘quick fixes’ were not the main solutions being sought; rather, we aimed to encourage system-based improvements that are sustainable. It was always recognised that the long-term and some of the medium-term solutions would be delivered after the end of the pilot term; however, the pilot was designed to set the trust on a pathway for change and a follow-up evaluation at least 12 months after the conclusion of the pilots will be needed to measure the full benefits.

7.14 In particular workstreams, product trials were carried out during phase 2, in conjunction with the relevant stakeholders.

7.15 The workstream methodology for this phase allowed observation and evaluation of the approach and communication between clinical users and purchasing as well as interaction with the industry. This enabled the capturing of requirements and recommendations for stakeholders and healthcare agencies across the health care supply chain.

7.16 An example project methodology design for one of the pilots for Phase 2 is outlined in figure 9 below.

Figure 9 - phase 2 methodology
Phase 3 - evaluation

7.17 Following the conclusion of phase 2, evaluation was carried out to:

- determine how far the project had met the objectives overall (project process questionnaire)
- identify system-based improvements and assess benefits to date
- assess the outputs of the workstream trials
- measure any reduction in clinical risk/adverse incidents (as far as possible in timeframe of pilots)
- measure attitudes/perceptions of changes and the change process amongst key staff.

7.18 A key research output developed as a tool for performance management and evaluation was the Balanced scorecard (see section 9). An example draft for the Purchasing for safety balanced scorecard has been prepared by NHS PASA and ATOS Consulting. This may be further developed to be utilised as part of the follow-up with Trusts in order to capture longer term benefits. The output has been reviewed by the Programme Board, in addition to feedback obtained from pilot leads.

Knowledge sharing

Cross-pilot seminar

7.21 At the end of the pilot programme, a seminar was held bringing all participants who had developed and implemented ‘purchasing for safety’ principles and practice across the three pilots together with key national stakeholders to enable learning and sharing of ideas and experience. Outputs from the day have been reflected in the recommendations and in the planning for the next steps needed to build on the ‘purchasing for safety’ work.

Knowledge pack

7.22 A knowledge pack is available via PASA’s website (www.pasa.nhs.uk/purchasingforsafety). It represents the key learning and outputs (eg toolkits, sample documents and reports) from the year-long project, as well as being the repository for wider materials and resources. The knowledge pack will serve as a practical purchasing-orientated resource for NHS professionals involved in the procurement, preparation and administration of injectable medicines.
8. Summary of findings

This part presents findings from the research activities undertaken at the pilot Trusts and across the Purchasing for safety project as a whole. These include a summary of the outputs from the baseline assessments relating to the safety culture, product ranges, incident analysis, focus groups, risk assessments (particularly high risk injectable products) and case studies. More detailed outputs from phase 1 can be found in the individual phase 1 pilot reports.

A summary of the main risks identified across the pilots is followed by the purchasing for safety workstream structure with the key risk reduction strategies and purchasing for safety solutions arising from the recommendations.

Key outputs from workstreams undertaken in the implementation phase are presented along with the challenges in implementation and the recommendations for improvement for the Trust and national stakeholders. Detailed workstream and pilot evaluation results can be found in individual workstream reports.

Phase 1 - Baseline criteria for Purchasing for safety

8.1 As evidenced in the literature and previous publications on patient safety, the systems and design-led approach to reducing medication errors have been adopted as the study and analysis approach. This has been illustrated in the Purchasing for safety framework.

8.2 As part of phase 1, a comprehensive assessment of the key factors and inputs to medications management was established and researched. In spite of the multiple variables that can complicate the medications management process, table 2 below shows clearly the common systems analysis framework; if assessed carefully, taking into consideration all factors, inputs, and processes, this can be used by the Trust team to highlight the risk areas involved in the process, to enable further assessment and prioritisation for mitigation plans.

Baseline assessment

8.3 Baseline assessment for some of the relevant areas was performed in the Trusts, utilising several toolkits and questionnaires that have been prepared as part of the research in this project in collaboration with pilot teams, specialists, partners and stakeholders. Published toolkits by the NPSA were also utilised to identify high risk medicines and the MaPsAF tool was used to assess safety culture.

8.4 Differences in baseline existed between the different pilots, such as safety culture maturity, level of standardisation and centralisation of infusion pumps, integrated risk assessment processes, and key risks and issues that required management and mitigation.
<table>
<thead>
<tr>
<th>Discipline-Components of Purchasing for safety framework</th>
<th>Priority focus areas (maturity matrix, balanced scorecard)</th>
<th>Scope (phase one, two, or three) + recommendations</th>
<th>Toolkits and databases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users – Trust</td>
<td>• Safety culture</td>
<td>Product range and management (concentrations &amp; products)/ rationalisation and dose banding</td>
<td>PHARMEX Pharmacy and medical devices databases</td>
</tr>
<tr>
<td></td>
<td>• Resources for improving patient safety</td>
<td>Preparation: near patient, pharmacy, quiet and sterile areas, licensed aseptic units, source from NHS manufacturing units, or commercially available</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical governance</td>
<td>Technical information and colour labelling Staff information leaflets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Integrated risk management (process and product)</td>
<td>Administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reporting incidents and learning</td>
<td>Technology solutions barcoding/auto-identification and dose limiting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Injectable medicines management (product and practice)</td>
<td></td>
<td>NPSA risk assessment tool Pro-file Database (specials)</td>
</tr>
<tr>
<td>Users and materials management – Trust</td>
<td>• Device management (product and practice)</td>
<td>Product range &amp; management Sufficiency and utilisation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Defined list of approved infusion devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical devices policy or set of guidelines covering the purchasing process: does it recommend standardisation, centralisation or provide guidance on device replacement?</td>
<td></td>
</tr>
<tr>
<td>Users- Clinical setting</td>
<td>• Infusion delivery system</td>
<td>Usability and Design for safety Connectivity Compatibility Technical information</td>
<td></td>
</tr>
<tr>
<td>Users- Information &amp; communication</td>
<td>• Evidence and information management</td>
<td>Scope of the programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Communication, alignment and internal management</td>
<td></td>
<td>Questionnaire Mapsaf culture assessment tool</td>
</tr>
<tr>
<td></td>
<td>• Evaluation and feedback systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Skills and competences of clinical staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Training and practice development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>User- Purchasing interface</td>
<td>• Clinical engagement</td>
<td>RECOMMENDATIONS Further research</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Regular feedback on risk assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pre-purchase evaluation (eg usability)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Evidence &amp; specifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Organised communication and management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement</td>
<td>• Culture</td>
<td>Further research</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approach to purchasing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Procurement process</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Performance and supply management</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• Communication and alignment with local, regional and national purchasing function
• Applying risk assessment principles
• Skills and competences

Supplier management
• Relationship type
• Evidence & specifications
• Regular performance audit
• Evaluation

Further research

Detailed findings on some of the assessed areas in the pilots are presented in the individual pilot reports.

Key risks and issues

8.5 Baseline assessment of some of the key areas has revealed the following risk areas.

Table 3: Key risks and recommendations from phase 1

<table>
<thead>
<tr>
<th>Medications management stages</th>
<th>Risks and issues</th>
<th>Preliminary recommendations (phase 1) requirements and learning</th>
</tr>
</thead>
</table>
| Procurement and selection     | • Selection of wrong medicine  
• Unavailability of device or injectable medicine  
• Fragmentation of decision making  
• Competing drivers for purchasing decisions  
• Lack of available QA and QC services  
• Lack of evidence on risk assessment and cost effectiveness | • Commercial availability of dose banding for cytotoxic chemotherapy and other appropriate products against clear product specification  
• Ready to administer products injectable medicines and contrast media, as appropriate (stability, volume etc)  
• Safety issues core to purchasing decisions in commercial Procurement Hubs  
• Centralisation and rationalisation of devices  
• Joint development ventures with industry  
• Promote evaluation trials and synthesise and implement evidence of safety and cost effectiveness (e.g business cases, specifications..etc)  
• Locally: Off contract product evaluation and communication / alert process  
• Locally: Standardisation of consumables and devices if not already implemented |
| Ordering and transcribing     | • Calculation errors  
• Incomplete and/or ambiguous prescriptions which do not include important information, eg details of the diluent, final volume to be administered, final concentration or intended rate of administration. | • Refer to NPSA safer practice standards.  

Preparation
• Inaccurate solution strength  
• Drug diluents compatibility  
• Sharps injury  
• Complex calculations  
• Calculation errors  
• Unsafe handling , poor aseptic technique leading to introduction of contaminants of injection thus infection to patient or risk and hazard to staff  
• 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  
• Stop use of ‘open bowl’ techniques (e.g contrast media)  
• Dose banding for chemotherapy and other dispensed medicines where appropriate and no commercially available product |

27 NPSA, Promoting safer use of medicines, Patient safety alert- 20, www.npsa.nhs.uk
| Labelling and information | • Inadequate and unclear labelling information  
• Lack of information about injectable medicines available to healthcare professionals at the point of use | • 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)  
• Refer to NHS Injectable Medicines Guide & ensure protocols reflect principles (with focus on administration)  
**NATIONAL**  
• Discuss with MHRA a change in labelling guidelines to clearly display essential information on packaging (i.e. prioritise over license / licensee information)  
• Support and input to the NHS Injectable Medicines Guide as regards commercial availability and purchasing for safety recommendations |
| Checking | • Failure to follow patient identification procedures leading to administration to the wrong patient.  
• Failure to follow administration checking procedures leading to wrong route administration | • 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 |
| Administration | • Calculation errors  
• infusion device use and administration errors; over-infusion, under-infusion, extravasation | • Medical devices should be designed with safety at forefront; current safety options are too often buried under layers of menus instead of being offered as default primary choices  
• 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 stan  
• Early development and adoption of barcode reconciliation for medicines  
• Full implementation of drug library / guardian software limits in infusion pumps  
• Evaluate dose-limiting software |
| Monitoring – Gentamicin protocols | • Confusion over regimen being used  
• Monitoring requirements  
• Dose calculations  
• Responsibilities of staff involved  
• Variance in practice between trusts impacting on rotating training & doctor’s understanding | |
| Training | Variable level of training and skills among staff. | • 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 |
| Infusion device management | • Insufficient number of devices  
• Complex to use  
• Huge range | • Effective implementation and management of standardisation and centralisation of infusion devices projects |
Case studies

8.6 Assessment of the risks led to prioritising a number of case studies. Background and details on the rationale and selection of those case studies can be found in appendix C.

Table 4: Case studies – phase one

<table>
<thead>
<tr>
<th>Pilot Trust</th>
<th>Clinical setting</th>
<th>Issues and case studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Derby</td>
<td>Case Study A – Theatres and Imaging</td>
<td>Presentation and storage of injectable medicines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowledge decay in training</td>
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<tr>
<td></td>
<td></td>
<td>Second checking of injectable medicines</td>
</tr>
<tr>
<td>Derby</td>
<td>Case Study B – Chemotherapy</td>
<td>Dose banding for chemotherapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bolus injection versus infusion</td>
</tr>
<tr>
<td>Derby</td>
<td>Case Study C – Maternity</td>
<td>Standardisation of Syntocinon products</td>
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<tr>
<td></td>
<td></td>
<td>Use of extension lines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poor labelling and product information</td>
</tr>
<tr>
<td>ULHT</td>
<td>ICU</td>
<td>Pre-prepared injectables</td>
</tr>
<tr>
<td></td>
<td>Chemotherapy</td>
<td>Dose banding</td>
</tr>
<tr>
<td></td>
<td>Theatre</td>
<td>Gentamicin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Staff information leaflets</td>
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<tr>
<td>CMMC, SRFT</td>
<td>Critical care</td>
<td>Critical care- preprepared injectables</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Colour labelling</td>
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<tr>
<td></td>
<td></td>
<td>Training, Barcoding</td>
</tr>
</tbody>
</table>

Procurement focus groups: issues to inform Purchasing for Safety maturity tool

8.7 Workshops and interviews conducted by EDC Research as part of this project have highlighted a number of issues. The following figure illustrates the main areas and requirements for enabling purchasing for safety within procurement.

Figure 10: Procurement requirements for Purchasing for safety

- More national guidance
- Local data history on previous purchases
- Experience shared across Trusts
- Life-cycle costing discipline
- Internal management
- Communication improvements
- Feedback systems
- Ease of use
- User experience
- Servicing & maintenance implications
- Training requirements

8.8 As can be seen in figure 10, requirements have been categorised into three main sections: baseline requirements, improvement of the procurement process, and some evaluation criteria.

8.9 The baseline requirements came as no surprise, as they incorporate many of the findings made by the NPSA in their previous study. However, the issues around the procurement process are still to be improved. Two pilot trusts so far have displayed many of the boxes to be ticked for their baseline requirements, but interviews have shown that neither internal procedures, nor attitudes towards them necessarily reflect these requirements. Further work is planned by EDC in modelling these procedures through mapping, and also eliciting softer cultural issues which may be presenting barriers.

8.10 Each trust also expressed a desire to have some evaluation criteria by which to measure their improvements – either through data available through national bodies, or shared experiences from other Trusts.

Phase 2

8.11 After undergoing analysis and prioritisation, mitigation actions and suggestions for change were recommended. These were developed into workstreams to be further evaluated for benefit and risk in clinical settings. The workstream approach provided the setting where interaction with purchasers, manufacturers, and other national stakeholders was facilitated. The programme office at NHS PASA coordinated this interaction and enabled communication and feedback between local and national stakeholders.

8.12 The workstreams demonstrated in this structure show the link and role that purchasing can play in minimising and mitigating risks and error arising in the medications and medical devices management. A summary of each workstream, with its rationale, objective, methods for implementation and evaluation results, as well as feasibility and challenges in implementation is presented in this section.

*Figure 11: Purchasing for safety workstream structure*

<table>
<thead>
<tr>
<th>System optimisation/re-design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices</td>
</tr>
<tr>
<td>Administration to patient</td>
</tr>
<tr>
<td>Medicines</td>
</tr>
</tbody>
</table>

**System view of treatment pathway and support systems**
(joining up of patient & product interactions, communication & handover points etc)
Purchasing for safety – injectable medicines: summary of workstreams

8.13 A number of strategies were selected and designed to reduce the risk associated with injectable medicines, devices use and management. Long-term technological solutions were also studied as part of the workstreams, and formed an important strategic solution, manifested in barcoding and auto-identification technologies. Other risk reduction strategies proving feasible and achievable in the intermediate term include process simplification interventions, product and process standardisation, and ensuring adequate and clear technical information is available for staff alongside clear product presentation and differentiation (packaging and labelling). Innovation in design for safety, including the availability and ease of use of smart software in pumps, is another important strategy involving joint development and feedback with manufacturers and purchasing.

8.13 Workstreams selected in each pilot are shown in the following table

<table>
<thead>
<tr>
<th>Table 5: workstreams selected per pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot 1: Derby</td>
</tr>
<tr>
<td>Pilot 2: Lincoln</td>
</tr>
<tr>
<td>Pilot 3 CMMC</td>
</tr>
<tr>
<td><strong>Rationalisation- Drugs</strong></td>
</tr>
<tr>
<td>Dose Banding</td>
</tr>
<tr>
<td>Pre-filled Syringes</td>
</tr>
<tr>
<td>Pre-filled Syringes</td>
</tr>
<tr>
<td><strong>Standardisation and Centralisation- Devices</strong></td>
</tr>
<tr>
<td>Equipment library</td>
</tr>
<tr>
<td><strong>Design and innovation</strong></td>
</tr>
<tr>
<td>Dose limiting software</td>
</tr>
<tr>
<td>Needle Free systems</td>
</tr>
<tr>
<td><strong>Technical information and labelling</strong></td>
</tr>
<tr>
<td>Phenylephrine</td>
</tr>
<tr>
<td>Bupivucaine</td>
</tr>
<tr>
<td>Gentamicin</td>
</tr>
<tr>
<td>Amiodarone</td>
</tr>
<tr>
<td>Epoprostenol</td>
</tr>
<tr>
<td>Noradrenaline</td>
</tr>
<tr>
<td><strong>Training – infusion devices</strong></td>
</tr>
<tr>
<td>Training</td>
</tr>
<tr>
<td><strong>Technology- Barcoding</strong></td>
</tr>
<tr>
<td>Barcoding</td>
</tr>
<tr>
<td>Barcoding</td>
</tr>
</tbody>
</table>

8.15 Some examples of the workstreams studied as part of this programme are summarised in this section. The content has been adapted from the original workstream reports.

**Pre-prepared injectables - introduction**

Purchasing ready to use and ready to administer injectables simplifies the medication administration process in near patient areas and could dramatically reduce the chance of calculation and mixing errors. One of the ways it accomplishes this is by reducing the need for nurses to prepare IV solutions from available ward stock in near patient areas.

Potential error and risks from the preparation of drug infusions have been identified as an output of the first phase of assessment at both United Lincolnshire Hospitals (ULHT) and the ICU/CCU department at Manchester Royal Infirmary and Hope Hospital pilot. The process of preparing drug infusions has been shown to carry the following potential risks:

- inaccurate solution strength
- introduction of contaminants
- drug diluents compatibility
- sharps injury
- complex calculations

Many of these risks can be reduced by controlling the process of preparation with a manufactured pre-prepared infusion. Each of the pilots decided to undertake a workstream to establish the impact on safe use of high risk injectable medicines through the purchase and use of pre-prepared injectable medicines.

This workstream further established how risk can be reduced through the use of pre-prepared infusions in particular settings, moving some of the risk from clinical areas to manufacturing units. The following overview focuses on the activities undertaken at ULHT pilot. Further details on the Manchester workstream pilot are available in the knowledge pack.
Safer practice through the use of pre-prepared injectables
United Lincolnshire Hospitals Trust (ULHT)

Background
ULHT has no manufacturing unit, but does have aseptic units which provide a service which is typically for chemotherapy drug preparation. This is limited to drugs with expiry dates of up to 1 week for individual patients. The additional measures to achieve manufacturing status require significant investment, with the need for a purpose built facility, with quality control systems and analysis certificates.

Phase one of this research studied drug preparation hazards; a summary of the background, problem statement, proposed changes and potential benefit can be found in appendix C

Workstream team and methodology
The workstream lead and project lead worked together to initiate a process to determine the practice in place in areas that frequently use injectable medicines. Obvious areas were Oncology and Haematology, and Intensive Care Units (ICU). Oncology and Haematology were found to have the most significant risk drugs; typically chemotherapy drugs were well controlled through the aseptic suite service, with some pre-prepared products already in use. ICT had the high usage, but had comparatively few pre-prepared products.

Workstream activities included the following:
- Short-listing high risk injectables that were currently being prepared in near patient areas,
- Testing and implementing a trial to assess the risks and potential benefits in enhancing patient safety and reducing medication errors and related incidents.

Additionally, the pilot studied ways of assessing the economic impact and cost-effectiveness of purchasing and using the drug in a pre-prepared form.

Evaluation methods
It was planned to pilot the use of the drug for a 2 week time frame, across both Lincoln ICUs. A longer pilot was not possible, with the initial order set-up being further complicated by the controlled drug ordering system.

Stakeholders were included in the selection of potential products to consider for a pilot and the ordering processes that are required. The stakeholders were purchasing and other pharmacists and nursing leads.

Product selection
Product selection was determined by several factors:

Stability – of the drug as a solution ready for use. Short acting insulin is a commonly used infusion and was excluded as not being stable for longer than 24 hours, due to its interaction with the plastic syringes it is prepared in.

Standardisation – Agreement on standardised solution strengths would be needed across the ICUs in the pilot areas. Drugs such as noradrenaline and adrenaline are constituted in different ways by each of the ICUs, one creating a solution strength that was standard for all patients, the other creating a weight related dosing for individual patients. Both of these process differed from the most commonly used solution strength nationally.

Demand – A product that is rarely used would be a poor choice in any time limited evaluation.

Availability – based on drugs that were already being manufactured in either NHS manufacturing units or by the drug companies. Some commercial drug companies indicated an intent to introduce product lines, but these systems were at the development stage. One company was able to demonstrate prototype connector devices for their short infusion 100ml diluents bags, but not systems that were in production. An NHS manufacturing unit did provide sufficient response to enquiries to enable a shortlist to be considered.

Risk reduction modelling – The level of risk that was assessed for the use of the drug compared to the pre-prepared product benefits. Potassium chloride is an example where risk is minimised already through pre-prepared solutions of intravenous infusion fluids at various strengths and where used as a continuous infusion, the solution was not diluted further. This meant that no calculation benefits or diluents were needing to be removed from that process. Potassium chloride use was not a standardised process when that was factored in.

29 Pre-prepared injectables workstream report - United Lincolnshire Hospitals Trust, March 2008
Storage – Enough space for storage could be a limiting factor in practice. Pre-prepared products, by virtue of the fact that they are ready to use, are bulkier than vials or ampoules. When considering some drugs, the dosage range could vary significantly, necessitating more stock being carried. Gentamicin was considered in this context, but would require 7 different strengths and availability was an issue. The need for temperature controlled storage also needed to be considered for short or longer term use.

Shelf life – all drugs are limited in their shelf life through expiry dates. An understanding of the shelf life was required to ensure that the turnover rate was sufficient to avoid unnecessary waste.

Compatibility of product to Trust infusion devices and pumps – The compatibility would ideally not be a barrier to use in the standard approaches used in the trust. A potential barrier would be to have to recalibrate equipment for the purpose of a short pilot.

Licensing – Consideration of licensing rules. The burden of risk is placed on the Trust when using unlicensed products. When using the NHS manufacturing units, certificates of product quality control checks provided significant assurances, thus making the use acceptable with the risk benefits anticipated.

Products of choice
Based on these factors, morphine sulphate 1mg/ml in a 50 ml syringe was selected for trial. Specifically:
- It was a standardised approach across both ICUs
- It did feature as a drug involved in injectable medicine incident reports in the Trust, although not in the ICU environment.
- Demand was sufficient to ensure turnover could be achieved in the timescale of the pilot use and also with in the limits of expiry dates (3 months).
- It was availability through an existing NHS manufacturing supplier of other products to the Trust.
- Risk reduction benefits were anticipated (scored as a moderate risk using NPSA assessment tool)

Outputs and results
The pilot of 50 ml pre-filled morphine syringes in intensive care demonstrated risk reduction benefits and timesaving for the staff involved. The evaluation provided a unanimously held belief that this was a safer practice. Results of the evaluation trials are detailed in the workstream report.

The workstream recommendations are:

Local clinical
- Consider the risk reduction benefits and time saving with the cost implications for continued use in practice.
- Consider other drugs that could be standardised to achieve similar benefits in practice in ICU and other parts of the Trust.

Purchasing/PASA
- Drive down costs where possible, as acquisition costs produce conflict between the risk benefits and financial expenditure.
- Provision of an accessible and up to date manufacturers list for any pre-prepared injectable products, which would make the search much simpler for all acute organisations.
- Work with NHS Trusts to provide a national set of preferred solution strengths for drugs which could be pre-prepared.

Quality Control and Assurance
- Develop and approve a risk assessment tool to assess safety in purchasing specials; this includes technical information and design, labelling and packaging of the pre-filled syringe.

Industry
- Enable larger range and scale of production, priced to provide a cost effective alternative to existing and potential injectable drugs.

Conclusion
The objectives of reducing risk and improving patient safety for certain high risk medicines appear to be achievable if the funding of a wider roll out is justified and implemented. Further exploration of opportunities to apply risk reduction or safety improvements in practice with using pre-prepared products should be considered. Standardisation will play a key part in any change that is made and an emerging data collection about this approach, particularly in intensive care units, may reveal a need to develop a regional approach for some products. A handful of products may benefit from a national approach, based on an NHS-wide consensus on standardised solution strengths and working with industry and the regulators towards licensing where possible.

30 A recent EU ruling could clear the way for commercial companies to publish details of their Specials
**Dose-banding - introduction**

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

NHS Trusts have insufficient capacity for the aseptic production of chemotherapy drugs to meet their expanding needs; therefore external suppliers are required to supplement the current service through the provision of a high quality, cost effective service to supply read-to-administer chemotherapy products.

In order to minimise the number of products required and realise other benefits a “dose banding” scheme is proposed. Dose banding is defined as “a system whereby, through agreement between prescribers and pharmacists, doses of intravenous cytotoxic drugs calculated on an individual basis that are within defined ranges or bands are rounded up or down to predetermined standard doses”.

The key benefits are:

- reduction in patient waiting times through improved pharmacy workflows
- increased pharmacy capacity
- reduction of medicine waste by avoiding incomplete use of vials when preparing individual doses and the ability to re-assign syringes if administration is cancelled.

If dose banding across cancer networks can be harmonised then:

- there will be consistency of dose banding for medical staff who may work on more than one site
- consensus on the nomograms will reduce the range of products required and this may result in reduced prices.

For further information see:

- Scottish Cancer Pharmacy Group – Guidelines for dose banding of cancer chemotherapy. June 2005
- Derby-Burton Cancer Network - Proposal for Dose Banding
### Dose banding for chemotherapy injectables

**Derby Hospitals Foundation Trust Experience and summary of workstream report.**

<table>
<thead>
<tr>
<th>Background</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase one of this research studied the case for chemotherapy preparation and administration hazards; a summary of background, problem statement, proposed changes and potential benefit is presented in appendix C.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aims and objectives</th>
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</thead>
<tbody>
<tr>
<td>This work stream aimed 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.</td>
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<table>
<thead>
<tr>
<th>Outputs (detailed in workstream report)</th>
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<tbody>
<tr>
<td><strong>Literature review</strong></td>
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<tr>
<td><strong>Focus groups</strong></td>
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<tr>
<td><strong>Draft specification</strong></td>
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<td><strong>Evaluations</strong></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Observations and recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose banding has been shown to be an effective approach to managing demand on units preparing chemotherapy drugs without any reduction in the quality of patient care.</td>
</tr>
<tr>
<td>Many units have implemented dose banding schemes and sourced products from licensed special manufacturing units. There are differences in the way dose banding has been implemented resulting in a wide range of products being used.</td>
</tr>
<tr>
<td>It is recommended that the specification developed by the Re:Source NHS Collaborative Procurement Hub for the East Midlands Hospitals is widely shared, and can be used elsewhere to given a consistent approach to the sourcing of these products</td>
</tr>
<tr>
<td>By working collectively, Hubs and Cancer Networks can bring some degree of standardisation to the range of products required.</td>
</tr>
<tr>
<td>Standardisation may bring about reductions in production costs at specials manufacturing units and, as demand becomes clearer, may convince the pharmaceutical industry to market licensed ready-to-use products.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose banding is a viable purchasing for safety initiative for many standardised products and should be done at least at a regional level. A national approach or co-ordination would maximise the benefits, lend consistency and deliver greatest value to the NHS. Standardisation will reduce the range of products, facilitate national procurement and persuade industry to apply for marketing authorisation. A purchasing specification needs to address purchasing, logistics, quality and clinical risk management issues applying to the product, packaging and labelling. Customer care issues, supply and performance monitoring were also considered important aspects.</td>
</tr>
</tbody>
</table>

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33 Dose Banding workstream report - Derby Hospitals Foundation Trust, March 2008

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Safer practice through clear and adequate product information and labelling

(Summary of Derby Hospitals Trust and CMMC/SRFT pilots’ experience adapted from the workstream reports.)

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 readily available on the product primary and secondary containers.

The workstream was identified from issues raised by the Theatres and Imaging focus group in Derby pilot and ICU/CCU in Manchester/Salford pilots as part of phase 1 of the project. A small multi-professional group was formed to identify and evaluate essential information, optimise designs to reduce selection, preparation and administration errors and evaluate these with end users. The following will mainly focus on the aims, methods and findings from the workstream conducted at Derby Hospitals. Further details can be found in workstream reports.

Aims and objectives of the workstream

- To identify possibilities for improvements in product labelling and information, which could enhance safety of injectable medicines within theatre environment.
- To produce label and information sheets for local use within Trust.
- To recommend new presentation of products i.e. box and ampoule label package inserts to make essential safety information high profile.
- Key benefit - create safety standard for purchaser.

To achieve the objectives, pilot activities were summarised as follows:

- Review issues with technical information for a range of injectable medicines
- Identify information sources for theatre practitioners and rate accessibility
- Recommend layout and content of technical information for package insert
- Identify essential label information for safe preparation and administration
- Design labels to present information and aid selection using RCOA scheme
- Evaluate label designs for ease of selection, use and other end user benefits

Workstream team and methodology

A multidisciplinary group representing the professions involved in administration of injectable medicines in theatre was formed. The group included nursing staff, operating department practitioners, anaesthetists and pharmacists. Surgeons were not included because, while they may administer drugs, they are not usually involved in the preparation, this task being performed by the scrub nurse.

The team was led by a Consultant Anaesthetist, and consisted of theatre nurses, anaesthetist, professional development, critical care and chief Pharmacist in Derby city general hospital. Focus groups were held in the Pharmacy seminar room and product evaluations were conducted in the operating theatre suites.

Incident reports were collated and reviewed by the workstream lead

New box labels, drug information inserts and a “Kardex” style drug monograph were drafted and reviewed by members of the focus group. These were printed in house and evaluated over a one week period in the operating theatres.

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34 Product information and labelling workstream report- Derby Hospitals Foundation Trust, March 2008
**Products of choice**

Two products were chosen for evaluation. These had been identified in phase 1 as high risk injectable medications:

a) Phenylephrine is supplied in a dose 1000 times greater than that required for clinical use and requires complex dilution before use.

b) Bupivacaine is supplied in multiple strengths; accidental IV injection has very high mortality rate

**Outputs and results**

**Focus groups**
- Perceived shortcomings of current product information identified, for boxes, ampoules/vials and information sheet
- Ideals for the content and display of product information were produced for drug boxes, ampoules and information leaflets.
- Two data sets for product information were produced; absolute (mandatory) and relative (required) data
- The role of colour, for example as used in the RCoA scheme, was considered. Overall the group thought that judicious use of colour enhances safety and correct product identification.
- A multilayered peel off ampoule label was demonstrated by Miriam Klein. Has potential use as label for syringe, or as drug administration record. Also could allow essential safety information to be attached to each and every ampoule in box.

**Evaluation questionnaires**
- A total of 25 questionnaires were returned 9 for phenylephrine and 16 for bupivacaine.
- A large amount of information was contained in the free text responses.
- Detailed evaluation can be found in workstream report.

Overall, results indicated that:
- Colour is considered a useful aid to product identification.
- Most medical staff did not use the current information leaflets because of familiarity and frequent use of the drugs being evaluated.
- Responses regarding the layout and organisation of the information sheets and Kardex were positive.
- The new design bupivacaine box was easy to identify; the new design phenylephrine box was not.

**Recommendations**
- Replace patient information leaflet with product information sheet for use by practitioners preparing and administering injection.
- Present information as two sets mandatory (red flag) and required.
- Mandatory to appear on box and ampoule/vial.
- Make use of RCoA colour scheme to aid product identification.

**Summary and conclusion**

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

In summary, changes in product labelling and packaging and in the content and format of product information proposed by the workstream should not be technically difficult to implement. They have the potential to reduce medication error by aiding swift identification of the correct drug in the work place. Speed of selection and identification is of critical importance in theatre/anaesthesia environment where delay in administration of a drug may lead to significant morbidity.

The financial consequences of a medication error if it results in serious morbidity may be very high (defence costs, claims). There is therefore a cost benefit to introducing any measure which increases medication safety. To have real impact in reducing medication error, the proposed changes would need to be implemented uniformly and universally throughout UK.

There is an opportunity for NHS PASA to drive national implementation via the contracting process.
**Safer practice with Gentamicin**

*(Summary of United Lincolnshire Hospitals experience adapted from the workstream report.)*

**Introduction**

The problems of poor labelling and the lack of access to technical information with the use of injectable medicines increases risk. The risks are associated with preparation, administration and monitoring. Error in these areas provides an increased risk that can expose patients to avoidable harm.

Gentamicin is a highly effective drug for treating many infections but carries with it some risk. The most significant risks are renal damage and hearing loss. Renal damage could result in long term renal failure and ultimately death. Deafness can result in varying degrees from tinnitus to total hearing loss. An example of a Summary Product Characteristics document can be found in Appendix A of the workstream report.

Bearing these risks in mind, the prescribing, administration and monitoring processes all carry potential serious consequences for patients if an error was made. Not all drugs carry this level of risk and so there is a need to take extra care in prescribing, administration and monitoring to ensure optimal and safe treatment.

**Aims and objectives of the workstream**

To investigate and demonstrate that purchasing medicines that include technical information about prescribing, preparation and administration will reduce the clinical risk. The desired benefits were:

- reduced risk when making calculations of creatinine clearance
- reduced risk when making dose calculations
- reduced risk of failing to monitor levels effectively
- reduced risk of overdosing or sub-therapeutic dosing
- standardised approach across the Trust and in conjunction with the microbiology service used.

**Workstream team and methodology**

A team consisting of the Principal Pharmacist, Clinical Risk Manager, Principal Pharmacist (Risk), information pharmacists, microbiologist specialists, and Procurement Pharmacists worked jointly to assess the risks, study and develop solutions.

**Evaluation(s)**

Phase 1 interviews and focus groups identified that there were risks to patient safety. These issues were based around the following points:

- confusion over the regimen being used
- monitoring requirements
- dose calculations
- responsibilities of staff involved
- variance in practice between trusts impacting on rotating training doctor’s understanding

Using the NPSA risk assessment tool, the risk level was assessed as moderate; however, the issues of monitoring requirements, variance in practice and confusion about regimen are not included and therefore a higher level of risk exists.

Using an adaptation of a Failure Mode Event Analysis tool, risks were identified that take into account patient safety and also the systematic approach in place to recognise error and intervene to mitigate against harm. This assessment can be seen in the workstream report. One of the additional benefits of this tool is the ability to re-assess the risk when actions are completed and so demonstrate the risk reduction measures as well.

The solutions that have been developed aim to provide a set of tools to reduce risk and improve safer practice.

**Problem 1 – Correct dosage**

Underdosing - if too little is prescribed the treatment may be “sub-therapeutic”

Overdosing – if too much is prescribed, it could lead to patient harm, causing renal damage or hearing impairment, potentially leading to long term damage and even death.

**Solution development**

The solution needed to ensure that the right dose is prescribed. For Gentamicin there are two important parameters: the patient’s renal function and the patient’s ideal body weight. Current guidelines do not include the latter.
Actions required
  • A dose calculation tool that will ensure the patients renal status and eliminate those patients who are not appropriate for a once daily dosing regime.
  • Revision of the dose calculation in the guideline and tables to enable staff to use the principle of dose banding with ideal body weight calculations.
  • Development of an intranet based calculator that will eliminate the need for a manual calculation and potential errors that could occur.

Problem 2 – Dosing frequency
Too frequent – could overdose the patient
Too infrequent – could provide sub therapeutic treatment, leading to prolonged illness and/or a poor outcome

Solution development
The ideal solution would explicitly guide the team in the right prescribing and administration frequency. The current prescription chart was designed for regular doses at a set time and frequency. The daily dosing regime can include 24, 36 or 48 hour intervals, depending on the results of the monitoring that is required.

The solution of using a sticker provides prompts, details the prescribing standards and also supports administration monitoring accuracy. The following sticker design was created by the workstream lead, in consultation with microbiologists and pharmacists. It has been approved for use by the Trust’s Drug and Therapeutic Committee. An important consequence of this design is that no more than three doses can be given before a review is made.

Problem 3 – Appropriate monitoring of Gentamicin levels
Unless the regime is appropriately monitored there may be sub therapeutic treatment or overdosage, the latter potentially causing renal or auditory damage.

Solution development
The existing tool for monitoring the results of the Gentamicin level is the Hartford Gentamicin Nomogram. This tool is reliable and has been used with effect. The problem centres on the accurate documentation of sampling times in relation to administration and the 6-14 hour window for checking the sample. That information needed to be captured on the microbiology blood test request form. To capture the detail, the sticker solution above is a method of creating prompts for collecting timings and may prompt the blood sampling required.

The interpretation of the results could also be strengthened using a web based calculator tool. The calculator tool will be able to identify the dosage interval required and the frequency of monitoring. It will also trigger the toxic range to alert the staff member to stop the treatment, seek advice and access an urgent medical review.

Actions required
  • As Problem 2
  • Incorporate into the web based tools identified in Problem 1.
  • Implement training package, for dissemination into each team.
  • Implementation plan for the introduction of the revised antibiotic guidelines.
Additional actions
Revision of the antibiotic guideline which incorporates the dosing and monitoring methods. (Shared
document with North Lincolnshire and Goole NHS Foundation Trust. Current version is shown in appendix D
of the workstream report. This is required in any case due to the review frequency of the policy.

Measures
- Incident and intervention rate regarding Gentamicin.
- Questionnaires during the pilot phase.
- Feedback from users

These will be used to evaluate the trial following approval of the new Antibiotic Policy.

Long term measures/benefits can be monitored using a balanced scorecard approach (workstream report)

Outputs and results
- Gentamicin prescription sticker was designed, printed and approved for use.
- The Antibiotic Policy was revised, in line with the need to comply with North Lincolnshire and Goole NHS
  Foundation Trust’s requirements. The policy does not include any mention of the sticker system or web
  based calculator. The policy was to be submitted for approval to the Drugs and Therapeutic Committee
  following the close of the pilot programme (the previous meeting having been cancelled).
- The development work for the calculator tool was commissioned during the pilot, and would subsequently
  be tested/piloted.

Recommendations/lessons learned
(Fuller recommendations can be made following the trial and evaluation.).

Local clinical
Changing practice for a Trust wide risk area and joint working with another Trust can prolong the process in
obtaining agreement on clinical standards. Sufficient time therefore needs to be given to complete all the
necessary governance arrangements, although other organisations may not have this challenge. United
Lincolnshire Hospitals NHS Trust has a service level agreement with Path Links which is managed by North
Lincolnshire and Goole NHS Foundation Trust. In essence, the Microbiology service is provided by another
organisation, who are part of a larger network.

Purchasing – all levels
Injectable medicines purchase should take into account the provision of tools that enable safer practice, i.e.
safety solutions and the quality of information provided with the drug.

National purchasing
- Encourage standardisation of information provision.
- Develop a system for current practice standards to be available and accessible for all NHS
  organisations.
- Standardise prescription charts, at least to the acute sector, so that solutions can be considered for all
  NHS organisations.

Industry
- Provide safety solutions as part of the product design for all products, even if they are old or common-
  place in practice.
- Use risk assessment tools such as Failure Mode Event Analysis to reduce the risks in practice for all
  injectable medicines.
- Provide accessible tools for complex calculations, e.g. for weight, body mass or surface area.

Conclusion
Full conclusions can only be drawn following a trial of the new solutions and in the light of subsequent
permanent changes in practice. The Trust intends to continue the work that has started and to implement the
solutions to improve safety with the use of Gentamicin. Further information on the outputs will be available
in due course.
Devices management

A baseline of the situation on standardisation and centralisation of infusion pumps at the four Trusts has been established. The different stages reached by the Trusts are summarised in table 6 along with action plans pursued as part of the purchasing for safety project. In learning from experiences where standardisation and centralisation have been achieved, key risks, challenges and how they were overcome was studied. These relate to the time, the training arrangements and the willingness and ability of clinical staff to undergo training, management of the resources and volume of equipment that the equipment library will produce, as well as the difficulty faced in implementing a replacement programme. A thorough critical evaluation, applying several strategies for training, selecting manufacturers who provide open ended access to training for all products across the specialist groups of users, undergoing risk assessment, better planning and long term management of equipment library are among the key lessons attained from some pilots’ experiences. The study of the business case for the formation and funding of an equipment library as part of the workstreams at ULHT follows.

<table>
<thead>
<tr>
<th>TRUST</th>
<th>Stage</th>
<th>Action plan as part of the purchasing for safety project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Derby</td>
<td>Standardised- centralised in equipment library</td>
<td>More specialised to focus on design for safety- mainly device library software, safety features</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment of pumps needs assessment software.</td>
</tr>
<tr>
<td>ULHT</td>
<td>Initial standardisation in each hospital - the need to study equipment library in Lincoln</td>
<td>Study centralisation of devices and case for equipment library at Lincoln County Hospital</td>
</tr>
<tr>
<td>Manchester</td>
<td>Standardised as part of PPI - currently in implementation phase, replacement and training</td>
<td>Training for devices use in Critical care-workstream-</td>
</tr>
<tr>
<td>Salford</td>
<td>Implemented standardisation</td>
<td>Assessment of benefits of standardisation</td>
</tr>
<tr>
<td></td>
<td>Study the need for an equipment library</td>
<td></td>
</tr>
</tbody>
</table>

Table 6: Pilot Trusts baseline situation and action plan in device management
Centralisation of Infusion devices - equipment library
United Lincolnshire Hospitals Trust (ULHT)

Summary
Optimal management of a trust’s infusion devices is important in ensuring appropriate selection and availability of equipment for patient treatment. Medical Equipment Libraries are viewed as best practice in medical equipment management. The absence of an MEL at Lincoln County Hospital created delays in patient treatment in 2004 and there is evidence to suggest that the position has not improved. The overall aim was to ensure that all of the trust’s main sites have access to a medical equipment library and to replace infusion equipment at one site in particular. The workstream undertook an option appraisal for centralising medical equipment and developed a business case for the selected option(s).

Background
In 2004, there was agreement in principle to establish MELs, following partnership work with consultants from KPMG, but funding did not follow. At that time, an audit was undertaken to check whether there was any disadvantage to patients through lack of access to a volumetric infusion device. The results of the audit were as follows:
- Average delay in receiving therapy - 1.8 hours.
- Worst case 8 hours or substitute sub-optimal gravimetric infusions.
- Nursing time lost through chasing access to pumps estimated at 4wte.
- No standardisation of volumetric pumps.
- In contrast to other hospitals, staff could not find equipment ‘hidden’ in cupboards.

As-is position
- Standardisation in pumps achieved
- 30% growth (statistically significant) in giving set usage over last 16 months at Pilgrim and Lincoln. Louth growth 100% (statistically significant). Grantham has had a slight decline in usage, but not statistically significant.
- Known problems of ongoing shortages at Lincoln and at Pilgrim. The MEL at Pilgrim runs out of pumps to issue consistently.
- Incident report through lack of availability of pumps (Datix ID 39729).
- Request from Hospital @ Night team to establish an equipment library.

Aims and objectives
1. Establish current status:
   - Incident data
   - Resources and their distribution of equipment throughout the Trust
   - Variance from standardisation
   - Risk to patient safety
2. Develop areas for improvement through meetings and survey/questionnaires
3. Develop business case, with safety and cost benefit analysis
4. Provide a process map for assessing needs and developing a business case.

Appraisal
Two actions were seen as equal joint first priorities
- Establish a medical equipment library at Lincoln County Hospital.
- Refresh the medical equipment library at Pilgrim Hospital, Boston.

A secondary aim was to establish an MEL at Grantham Hospital if space could be found.

What should be in the Library?
For Pilgrim & Lincoln approximate numbers of the following medical devices within each should be included.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Number</th>
<th>Cost/Unit</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG Monitors</td>
<td>20</td>
<td>£1000</td>
<td>£20000</td>
</tr>
<tr>
<td>Syringe Pumps</td>
<td>20</td>
<td>£1750</td>
<td>£35000</td>
</tr>
<tr>
<td>Syringe Drivers</td>
<td>30</td>
<td>£900</td>
<td>£27000</td>
</tr>
<tr>
<td>Volumetric Pumps</td>
<td>60</td>
<td>£2000</td>
<td>£120000</td>
</tr>
</tbody>
</table>

Items linked to library as service exchange unit whilst other equipment in for repair / servicing
- NIBP 4 £1750 £7000
- Defibrillators 2 £6000 £12000
- Suction Units 3 £750 £2250
- Tympanic Thermometers 4 £300 £1200
- Pulse Oximeters 4 £1000 £4000

Total £228,450

### Capital costs to implement

<table>
<thead>
<tr>
<th>Site</th>
<th>Space Available Now</th>
<th>Cost Work Required</th>
<th>Equipment Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilgrim</td>
<td>Yes</td>
<td>£3000</td>
<td>£50,000*</td>
</tr>
<tr>
<td>Lincoln</td>
<td>Yes</td>
<td>£20000</td>
<td>£120,000**</td>
</tr>
<tr>
<td>Grantham</td>
<td>No</td>
<td>£20000</td>
<td>£0***</td>
</tr>
</tbody>
</table>

**Notes**

* In the first instance £53,000 was deemed enough to refresh the library at Pilgrim Hospital; thereafter it depended on what financial structure was established to continuously update the equipment. The primary spend would be on volumetric infusion pumps.

** For Lincoln, the initial spend would be to establish a library with 50 volumetric pumps and a handful of other devices, and develop the library from this basic starting point. A possible location had already been established.

**** For Grantham, the target was to pull in existing equipment into the library, although no location had been found.

### Funding options

**Option 1**
Approach MDG for funding. A bid for £150,000 was made in November 2007. The bid failed in principle, although £35000 was agreed for infusion pumps and AEDs (10 volumetric infusion pumps and 5 defibrillators). The primary concern was the number of ‘revenue’ (+£5k) items within the bid.

**Option 2**
Approach Executive Board for funding (both capital and revenue. Capital would be needed to establish library at Lincoln (elevics, equipment racks, network connection, computer, new wall/door way, move phones etc) and to update library at Pilgrim (update equipment racks, put in network connection, computer). Revenue would include increased budget for parts.

To properly man facilities on three sites, the minimum requirement was for 2wte at B3 Safety Inspection Technician level, sharing the workload across the service to meet demand. Initially, 1.5wte for the Pilgrim and Lincoln sites were requested.

**Option 3**
Seek funding from EB for library set-up charges and recover revenue through rental charges for new equipment. A challenge was to decide whether to charge for all items even those donated, or just those bought to establish the library. Also, what should the rental charge be?

### Outputs
The workstream identified and increased demand for infusion devices. This has not been matched with the availability of devices, causing some delays and disruption in clinical practice. Previous steps taken to standardise infusion pumps were demonstrated to be in place with a slight improvement in the overall stock of pumps in use as a consequence. This is outweighed by the increased activity and subsequent demands (30% growth in 3 years) resulting in the need for investment.

### Conclusion
Medical Equipment Libraries are viewed as best practice in medical equipment management. The absence of an MEL at Lincoln County Hospital created delays in patient treatment in 2004 and there is evidence to suggest that the position is no better now.

The difficulty in justifying the spend on an MEL on a cost basis is that the saving is primarily achieved by utilising nurses time better, treating patients more efficiently and reducing the length of stay. It would simply be one of a series of measures aimed at reducing the patient stay and therefore difficult to see cause and effect.

However, there is no evidence that any hospital has closed down an MEL because it didn’t work. Set up sensibly and with adequate resources, they represent an excellent way of optimising the use of key ‘infrastructure’ items of medical equipment, whilst ensuring that the equipment is kept ‘fit for purpose’.

The MEL at Pilgrim Hospital has become a victim of its own success - having been built up from items at the end of their normal life, it has served to keep them going rather than replace them. There has not been a replacement programme for MEL equipment.
Needle free systems

Summary of Derby Hospitals' experience

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

Aims and benefits
One of the main issues identified from Phase 1 was the potential for needle stick injuries whilst aseptically preparing cytotoxic products. The aim of this 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. The workstream evaluated the Teva ‘Tevadaptor™’ and Baxter ‘Chemo-Aide™’ products within specialist pharmacy aseptic dispensing services using qualitative and quantitative techniques to rate ease of use, time saving, staff safety etc and to make national recommendations for safe aseptic dispensing practice.

Key benefits include:
- Operators (eliminates the risk of needle stick injuries).
- Ease of use (less manipulations required).
- Safer administration (decreases the risk of spillage)
- Reduced risk of cytotoxic exposure for both preparation and administration.
- Reduced preparation time

Methodology

Workstream design
The needle-free pilot was taken forward by a multidisciplinary team of pharmacists, nurses and pharmacy technicians. Evaluation took place on the chemotherapy day case unit at the Derbyshire Royal Infirmary, as the area with the highest demand for aseptically prepared cytotoxic products.

Measures and evaluation
The two needle-free devices selected for the pilot were the ‘Chemo-Aide™’ marketed by Baxter and the ‘Tevadaptor™’ marketed by Teva. Both had the benefit of being needle-free for both preparation and administration purposes. The devices were piloted separately, for one week each.

Measures
Quantitative measures included preparation timings, incident rates and cost of consumables. Qualitative measures included an assessment questionnaire for both pharmacy and nursing staff discussing advantages/disadvantages of each product and current practice.

Outputs and results

Focus groups
Discussions took place with Baxter and Teva on separate occasions in order to view the needle-free system and demonstrate its use, raise any issues concerning preparation or administration with needle-free systems, discuss pricing of the needle-free system and train staff in the use of the system for preparation or administration.

Discussions also took place with risk services to review any in-house Incident reports relating to cytotoxic needle stick injuries or any other risk to operators.

Evaluation(s)
The first evaluation was devised to review local practice for preparation. Six local hospital aseptic units were sent questionnaires; four replied. The findings were as follows:
- All units used needles for manipulations
- Two units used chemotherapy mini spikes/dispensing pins where appropriate
- Mini-spikes/dispensing pins were the only needle-free devices used for manipulations
- Advantages for using Mini-spikes/dispensing pins included reduction in number of manipulations involving needles, therefore decreasing risk of needle stick injuries
- Cost was deemed the biggest disadvantage of using a needle-free device
- In the past 12 months, three units had two cytotoxic needle stick injuries whilst one unit did not have any
In the past 12 months, two units had two cytotoxic spillages within the isolator whilst two units did not have any. Compared to the number of items prepared locally, needle stick injuries happened less than 0.5% of the time.

A questionnaire was used at the end of the two week pilot period to retrieve qualitative data, for both the ‘Tevadaptor™’ and ‘ChemoAide™’ from a pharmacy preparation and a nursing administration perspective.

**Pharmacy evaluation**

*Current practice evaluation*
- Needles were most advantageous for use with cytotoxic preparation due to their ease of use.
- The factor most influential on use of needles for cytotoxic reconstitution was size.
- The highest risk associated with use of needles was needle stick injuries
- Other advantages for use of needles stated by operators included adequately packaged and can be used with any vial or infusion bag.

*‘ChemoAide™ evaluation*
- Operators found quite easy to use
- Cytotoxic spillage was deemed to be the highest risk; also cross contamination
- The most advantageous factor was ease of use
- The least advantageous factor was cost
- No incidents occurred during pilot

*‘Tevadaptor™ evaluation*
- Operators found very easy to use
- Contamination of environment and disposal were deemed the highest risk
- The most advantageous factor, compared to current practice, was how safe the device was to use.
- The least advantageous factor was cost
- No incidents occurred during the pilot

**Nursing evaluation**

*Current practice*
- Needles only used for pre-meds when the set has no ‘clear link™’ (integral needle-free) device.
- Needles were deemed most advantageous for use due to low cost.
- The least advantageous factor was the risk of needle stick injury

*‘ChemoAide™ evaluation*
- Nursing staff found quite difficult to use
- Contamination of the nurse was deemed the highest risk
- The most advantageous factor, compared to current practice, was how safe the device was to use
- The two least advantageous factors were cost and complexity of use.
- Three incidents occurred during the pilot

*‘Tevadaptor™ evaluation*
- Nursing staff found very easy to use
- Nursing staff felt there was little to no risk during administration
- The most advantageous factors, compared to current practice, were safety and ease of use
- The least advantageous factor, compared to current practice, was cost.
- No incidents occurred during the pilot

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

**Conclusion**
The overall aims of the work stream were met, despite the short time frame. In order to take this pilot forward, more in-depth evaluations could be done nationally to collate information about cytotoxic needle stick and spillage incidents throughout the UK to help support the use of needle-free devices. More research is also required from the pharmaceutical industry who supply such devices, with regard to the stability and sterility of products when needle-free devices are in situ. As more data becomes available, like NIOSH, this is likely to lend support to national recommendations from regulators such as HSE.
Design for safety- infusion pumps

Summary of Derby Hospitals experience

Introduction
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 be 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 may not be intuitive to use.

Background
Successful standardisation of volumetric infusion technology over a 1100(plus) bed Acute Trust had been completed in Derby, and the introduction of dose limiting software in mains powered syringe drivers had been achieved; evaluation of the effective use of the Trust’s inventory of volumetric infusers would precede a drive to implement the similar software additions to these latter pumps. Numbers of these could be evaluated from the working logs of the Pumps and compared to the PNA tool to measure confidence in its recommendations.
Phase one indicated significant potential for risk management within the administration of medication. The statistics identified this as the area of most incidents, and with the most harm to patients. Any positive impact into these systems would greatly benefit patient care. It is suggested that dose limiting software could prevent some of the prescription and programming errors that occur (Death by Decimal point, etc)

Rationale
The workstream was identified from issues raised by the focus groups in phase 1 of the project. The workstream focused on learning from errors recorded in the user logs of Trust Baxter Colleague™ pumps, evaluating the impact of drug library and software limits on error reduction and developing a specification for manufacturers and procurement managers to optimise the user interface and key features for ‘purchasing for safety’ decisions.

A full and in depth comparative review of the functions of Medication Error Reduction software is available from the MHRA, titled “MHRA 04097 (2004): Dose limiting software for infusion devices: Drug’ Lib, Guardian, Guardrails, Pharmguard”. Where this document excels is in its practical evaluation of the 2004 market place of these infusion device based dose limiting software systems.

Also identified within the work groups was the unavailability of Pumps at the patient interface when needed. This hazard had been very well managed by the introduction of Equipment Libraries on both sites – but an assessment of the number of pumps required was based more upon reaction and ‘clairvoyance’ than planning and science. A “Pump Needs Assessment” (PNA) would help inform the purchasers of their requirements.

Aims and objectives
To identify a real need to implement the dose limiting software, and identify deficits in current practices within the delivery of volumetric infusions within the Trust from downloads of key logs on the pump units. Identify if the current stock of volumetric pumps were being effectively utilised, and to test against these figures a new PNA tool.

To achieve the aims, activities of the workstream included:
- Scoping range of infusion pump technology available to support safer practice
- Review literature to identify benefits from ‘dose limiting’ type innovations
- Collating and evaluating user logs from pumps to report findings and key themes
- Identifying key benefits, issues and limitations of existing ‘dose limiting’ type systems
- Developing specification to address these and inform manufacturing requirements
- Developing specification and checklist to inform ‘purchasing for safety’ decisions
- Critique Pump Needs Assessment Tool.

Workstream team
This workstream was led by medical devices lead at Derby Hospitals, supported by the cooperation of Equipment Library staff, clinical staff, and staff from Baxter Healthcare Ltd who downloaded thousands of hours of data and then provided the analysis to deadline.

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Evaluation

Methodology
All pumps accessible within the Trust had their data and service logs downloaded at least once in a three-week window. Access to pumps within a small number of areas was denied due to physical moves within the Trust. All accessible wards/departments were approached to complete snap-shot data via verbal questionnaire, collated in spreadsheet form.

Measures
The data was obtained by downloading each pump via its RS232 communications port; downloaded onto Laptops via the manufacturer’s proprietary download software. Equipment library stock was used to allow swapping of pumps, as download process is only accessible whilst not delivering an infusion. Records of department and serial number were also recorded to add further scope to the analysis.

The Pump Needs Assessment is an Excel application produced by the Pump manufacturer. A representative of the company visiting each ward within the trust, and then interviewing available staff for the information performed this assessment. A number of areas were unable to provide the data due to a variety of reasons.

Outputs and results
Data analysis: Clinical Informatics (see Appendix C of workstream report)
Please note the following is a summary of the main points from the Clinical Informatics Report, not an evaluation of the report and its contents; this is covered in the discussion and conclusions section below.

• **Battery management**
  Derby City General experienced an average of 15% of batteries having one or more deep discharges. Derbyshire Royal Infirmary experienced a similar % of battery discharges, averaging around 20%. It would be a good opportunity to review practice on those departments that have a high % of battery discharges. The Battery Health report indicated an overall average of 3% of the time pumping on battery for both hospitals.

• **Asset utilisation**
  The data indicates that the average utilisation rate was 60% for both hospital sites. However, it also illustrates the fluctuation in usage of the infusion pumps, with utilisation rates of 89% for Derbyshire Royal Infirmary and 76% for Derby City General, within the observation time frames.

• **COLLEAGUE GUARDIAN utilisation**
  The use of the dose mode feature in starting an infusion averaged around 16% to 17% in relation to the rate volume method. It is suggested that the use of the dose mode feature be reviewed and opportunities explored to implement the COLLEAGUE GUARDIAN feature as this potentially represents increased patient safety benefits.

Data analysis: Pump needs assessment (see Appendix D of workstream report)
Please note the following is a summary of the Pump Needs Assessment, not an evaluation of the report and its contents; this is covered in the discussion and conclusions section below.

• The number of pumps counted upon ward/clinical areas were fewer than the number predicted as required using the “requirement” tool. Recommended increase in pump numbers by 116 channels – to meet projected clinical need, plus further 10 on “recommendation”.

Discussion of findings can be found in detail in the workstream report.

Recommendations
• Discuss the issues with the manufacturer of these systems, and possibly re evaluate some time later.
• Implement Dose Limiting Software on volumetric infusors, evaluate impact of introduction of software to syringe drivers.
• There are significant purchasing for safety benefits that can be applied to medical devices and opportunities to develop a purchasing specification, as well as better utilisation of safety features built into ‘smart’ pumps.
• Industry needs to do more to make these the default setting, user friendly and intuitive. ‘Pump needs analysis’ software has potential to support Trusts with standardisation of equipment, but further validation is needed.
Dose limiting software and analysis of end-user logs offer valuable tools to improve safe use of devices to administer injectable medicines. These features should be built into national guidance and purchasing specifications.

Conclusions
The conclusions are presented against each of the original objectives.

- **Scope range of infusion pump technology available to support safer practice**
  
  *Much is available on the market currently; the prerequisites for the effective use of this technology should not be forgotten; time and effort is needed to standardise on drug concentrations to allow these technologies to work.*

- **Review literature to identify benefits from ‘dose limiting’ type innovations**
  
  *The above holds true again; the benefits are not clearly identified in any paper, more hinted at, but if utilised as part of a serious and determined approach to deliver infusions safer, this technology will help.*

- **Collate and evaluate user logs from pumps to report findings and key themes**
  
  *The Clinical Informatics output has shown issues clearly and in a manner easy to engage others.*

- **Identify key benefits, issues and limitations of existing ‘dose limiting’ type systems**
  
  *Theoretical benefits are the reduction of medication errors involving infusions through these systems, but these are not a panacea, as the whole system (from dispensing to administration) has potential pitfalls throughout. The interface on the pumps does not default to the safety function; rather the user must negotiate a number of menu screens to choose to use the safer mode. Medication formularies must be standardised across a hospital or Trust to allow the development of the dosing libraries within the pumps. Updates to these libraries are difficult to manage without wireless technology to support it.*

- **Develop specification to address these and inform manufacturing requirements**
  
  *Simply put, it must be easy to do the right thing, and conversely difficult to do wrong. The safety features on a pump need to be organised so an establishment, in which the standardisation of concentrations has been successful, may choose to prioritise dose limiting within the pumps, making the user employ the system as default.*

- **Develop specification and checklist to inform ‘purchasing for safety’ decisions**
  
  *It is apparent that the introduction of this technology to a Trust or hospital has to be performed with a number of prerequisites. The outlay in the capital may only constitute a fraction of the investment. A significant dedication of time and effort of sufficiently empowered staff is necessary to introduce a standardised list of drugs, so that this list can be successfully applied to a dose limited drug library on the smart pumps.*

- **Critique Pump Needs Assessment Tool.**
  
  *The PNA was an interesting item; its development is timely as many Trusts try to balance ever more constrained capital spending against the increasing tide of advanced techniques of treatment and an increasingly litigious environment. This is a welcome tool, but needs further work to make it sensitive to NHS establishments and non-American working practices.*
Technological solutions and connectivity in the medications and device management process

Barcoding - introduction

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 workstream prepared a case to study and evaluate the use of barcodes for the reconciliation, identification (of patients and products) and safe administration of injectable medicine at two pilots. Technology limitations and delays to implementation of electronic prescribing and medicines administration limited the opportunity for any hands-on work in this workstream.

Advantages/feasibility and challenges in implementation were studied as part of the barcoding and auto-identification workstreams at both Manchester Royal Infirmary, and Derby Hospitals Foundation Trust. (See workstream reports for details.)
Barcoding workstream – Central Manchester and Manchester Children’s Trust (CMMC)

The workstream was identified from issues raised by the focus groups in phase 1 of the project. It studied the case to support the use of barcodes for the reconciliation, identification (of patients and products) and safe administration of injectable medicines.

**Background**
Analysis of incident reports during 2006 – 2007 at CMMC showed that 480 administration errors were reported, accounting for 42.9% of the total errors. There were a total of 53 reports of wrong drug / wrong patient administration errors. A further analysis of over 12,000 incidents from critical care departments from a total of 151 trusts over a 6 month period showed that 61% of the total was related to administration.

Following a network wide study of preparation and administration errors on Critical Care units in Greater Manchester, there was an unacceptably high incidence of failure to check the identity of patients prior to the administration of intravenous therapy, with this not happening at all in one of the units studied. Barcoding technology was identified from the project board as one of five workstreams which may have the potential to eliminate wrong drug/wrong patient errors. It was further postulated that electronic recording of administration by means of a barcoding system may provide more comprehensive information as to the true incidence of errors in administration.

Feedback from interviews with stakeholders (nursing staff, medical staff, pharmacy staff), and from parties connected to the pilot project, indicated an interest in the use of barcoding technology, but with caveats about the practicalities involved. A major weakness of the business case was the lack of hands-on experience of such a system.

**Design**
- The workstream design was to create a business case for the implementation of barcoding for the administration of injectable medicines. There was no opportunity within the project to trial any aspects of barcoding mainly due technology limitations.
- A literature search was undertaken to identify potential benefits and disadvantages of barcoding.
- Co-incidentally, contact was made with Cardinal Health, and meetings arranged to discuss the feasibility of sourcing pre-filled injectables with barcodes and the use of barcoding – syringe driver interface technology.
- Process mapping of current practice in the preparation and administration of injectable medicines was undertaken. This was then repeated for the potential use of barcoding systems in this activity.
- A multidisciplinary workshop (with pharmacy, IT, nursing and medical staff invited from across the two sites) was arranged to examine the process of barcoding.

Outputs from the workshop were applied to the medicines process including procurement, dispensing, prescribing, administration and monitoring.

The setting of study was the administration of injectable drugs within critical care across the two sites.

Stakeholders in this workstream were identified as:
- Nursing staff from the two units directly involved in the administration of injectables.
- Clerical staff – who would be involved in the production of bar codes for patients
- Pharmacy staff including antibiotic pharmacist, risk pharmacist, critical care pharmacists, purchasing pharmacy staff, pharmacy IT manager.
- Medical staff, including Clinical Director.
- Critical care IT staff.

**Findings**
- Current problems with injectable medicines were reviewed in the group. These included incorrect labelling, or no labelling at all, checking inconsistencies, similar looking products, interruption during preparation and checking, and taking over care of a patient from a previous shift.
- The current drug administration process was mapped highlighting the areas where a drug identification step was involved. These steps are open to interpretation error, and may be improved by the use of barcoding technology.

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38 Barcoding and auto-identification systems at the point of Administration- Central Manchester and Manchester Children- ICU/CCU. Workstream report- March 2008
Advantages of implementing a barcoding system were described, and measures identified. These were:

1. Improved audit trail – the use of a bar-coding system may improve the accuracy of error detection rates, and thus provide essential information about common errors, hence can guide improvements to eliminate errors. The current system of critical incident reporting will only identify a small proportion of errors actually occurring. The electronic capture of drug administration information could also make auditing the use of drugs much easier.
2. Staff time – may be improved, although much depends on the ease of use of the hardware.
3. Improved policy compliance – variations in practice between health care professionals may be reduced with the use of drug specific protocols built in to the drug administration devices.
4. Staff confidence – may be improved with the use of potentially dangerous drugs if there is a feeling that there is always a fail-safe check before the drug is administered to the patient.
5. Financial benefits – reduced errors may well lead to reduced litigation costs and hence reduced insurance premiums. Improved public confidence in the organisation may follow.
6. Patient flow – may improve with reduced length of stay as a consequence of reduced number of incidents of patient harm.
7. Stock control – may improve resulting in reduced costs with overstocking and an improved ordering system.

Barriers and disadvantages were discussed. These were listed as:

1. Cost of implementation. There would be a considerable capital investment required for the hardware involved, as well as a significant time investment.
2. Staff time – unless a proper pilot of the system was undertaken, it would be impossible to determine whether a barcoding system would save staff time in the administration process.
3. Training – would have to be given to all existing staff and a continuing program set up for new starters.
4. Unknown errors – the use of a barcoding system may give rise to errors not anticipated with the current process.
5. Equipment failure is a real possibility, if not a probability.
6. Information contained in pharmaceutical manufacturers barcodes may be inconsistent across products. This may lead to in-house barcoding with attendant resource difficulties.
7. Staff over-rides may occur, negating the whole safety aspect of the system. Similarly, lost or forgotten staff identification barcodes may be swapped between staff.

Cost/benefits were discussed. These were listed as:

1. Reduced litigation costs
2. Reduced length of stay costs
3. Increased patient flow (payment by results)
4. Increased revenue through patient choice
5. Reduced infection rates, hence less chance of fines.
6. Reduced waste
7. Reduced stock holding
8. HMSR incentives

Discussion and conclusion
There was considerable theoretical support for the wider use of barcoding on discussion with stakeholders throughout phases 1 and 2. Inconsistencies in checking patient’s identity was a clear concern from a previous network audit looking at the preparation and administration of injectables which may be solved by the use of bar-code recognition identification of injectables, patients and staff. Potential risks and benefits were outlined for the use of barcoding, with the biggest obstacles being the financial cost of implementing such a system, and ensuring that the infrastructure was in place to support the technology. Without knowledge of how these systems work in practice, it is difficult to assess properly the vagaries of such a system. Standards need to be set for the information required in bar-codes on injectable medicines, be they original containers of pharmaceuticals, or pre-filled syringes.

Use of bar-coding systems can significantly reduce administration errors of injectables. Bar-coding systems may increase awareness and recording of administration errors, and thus focus resources on reducing this burden.

Furthermore, experience from the Derby pilot concluded that barcoding technology offers benefits for patient safety and asset management, bringing safe practice, efficiency and accountability to a range of healthcare processes. Initial conclusions indicated that a strategic approach to purchasing and developing a solution that covers all applications (e.g. asset tracking, stock management, auto ID of patients and reconciliation of drugs) is likely to be the most cost-effective solution for the NHS, and represents an important purchasing for safety opportunity.
9. Benefits and benefits tracking

9.1 Expected benefits from implementing and delivering the purchasing for safety have been identified and elaborated as part of this research. Potential benefits to staff, Trusts, patients, procurement, industry and the NHS have been demonstrated. There is much that can be done at Trust level to realise these benefits, although national implementation in certain areas (such as pre-prepared injectables and technical information) would be required in order to maximise benefits across the health care system. These are summarised below.

Benefits for patients

9.2 Patients receiving IV therapy could expect a safer experience of healthcare, arising directly from the adoption of certain risk reduction strategies outlined in this report. This should improve public confidence and result in a targeted and measurable reduction in the incidence and consequences of error in the administration of injectable medicines.

Benefits for healthcare professionals

9.3 Healthcare professionals would benefit from:

- a standardised range of devices and medicines that are easier to understand and use and so minimise the risk of human error
- adoption of systems for the better management and utilisation of equipment
- improved support through clear and adequate technical information for the preparation and administration of injectable medicines
- reduced risk of needle-stick injuries through adoption of needle-free systems.

Benefits for the procurement community

9.4 Driving safety through procurement raises the profile of procurement, not only within the pilot sites and the Hubs, but also in the wider NHS. Specifically, this project has demonstrated the potential for procurement to deliver government policy, increasing credibility and reputation of the profession at all levels.

Benefits for the healthcare industry

9.5 The healthcare industry supplying this market can benefit from the opportunity to add value to their product offerings and to differentiate their products based on safety considerations. In particular, the project has highlighted the importance of a structured feedback loop between users, purchasers and manufacturers to ensure ‘design for safety’ as well as usability is built in at an early stage and when making incremental product improvements. The outputs and initiatives of the project allows more effective new product development, in the line with standardised requirements. Opportunities to trial and/or submit for evaluation new or innovative products have been created during the pilot phase and could potentially help drive adoption of innovation within the wider NHS.

Benefits for the NHS

9.6 Although not possible to quantify in a small scale pilot, it is clear that a concerted action by the NHS will lead to a significant reduction in the burden of medical accidents/adverse incidents relating to injectable medicines therapy. This, in turn, will:

a) avoid increased lengths of stay or requirements for care that may occur as a direct result of adverse patient safety incidents. Although difficult to quantify accurately in relation to injectable medicines alone, patient safety incidents cost the NHS an
estimated £2 billion\textsuperscript{39} a year in extra bed days, excluding those relating to healthcare associated infection

\begin{itemize}
\item b) reduce the cost of litigation. The total annual cost to the NHS of settling clinical negligence claims rose sevenfold between 1995 and 2000. £579.3 million was paid out in connection with clinical negligence claims in 2006-07\textsuperscript{40}. In 2005-06, the comparable figure was £560.3 million. Whilst it is not known what proportion of this relates to the administration of injectable medicines, it is clear that the scope for savings is considerable.
\end{itemize}

**Benefits tracking**

9.7 At the outset of the project, it was recognised that timescales available for the pilot programme were challenging and that it takes time to achieve real change and to reap substantive and sustainable benefits in terms of reduced clinical risk to patients and staff. NHS PASA and the pilot trusts recognised that this pilot programme represents the beginning, rather than the end, of a continuous improvement process.

9.8 In the short term, each workstream was evaluated immediately post pilot to assess the experience, determine users’ views and attitudes and capture lessons; however, longer-term benefits and outcomes (for example, a measurable reduction in frequency and/or severity of patient safety incidents) will only become apparent with the adoption of evidence-based purchasing for safety policies in the months following the conclusion of the project and associated trials.

10.9 A mechanism that would enable both the trusts and NHS PASA to monitor progress and measure longer-term benefits is therefore required and a generic tool has been developed for local adaptation and use.

9.10 The main purpose of the Balanced Scorecard tool is to develop an appropriate process to measure the outcomes (clinical and financial) of the implemented objectives. This may also provide a means by which trusts can demonstrate to commissioners their approach to patient safety.

9.11 According to Kaplan and Norton\textsuperscript{41}, the Balanced Scorecard captures the critical value-creating activities performed by skilled, motivated organisational participants. It acknowledges the difficulties associated with attempting to measure economic profits in periods as short as a year, and values other measures such as product innovation, design, staff skills and customer loyalty, that, if well managed through effective and efficient processes and governance, can deliver better clinical and financial outcomes.

9.12 In Purchasing for safety, inputs and capabilities are required as baseline measures and would need monitoring and management. The processes in the Trust including clinical governance, risk management and procurement need to be established and developed to process the inputs to best effect. This is manifested in the implementation and monitoring of updated protocols and policies, and high performance communication mechanisms.

9.13 A generic version of the tool is available and can be adapted to fit local circumstances and priorities.

9.14 The following set of structures present the main components of the Balanced Scorecard, developed and tailored to the purchasing for safety project activities. These are summarised as:

\begin{itemize}
\item Source: Building a safer NHS for patients
\item Source: NHS Litigation Authority website. Figure includes both damages paid to patients and the legal costs borne by the NHS
\end{itemize}
1. Capability
2. Processes and policies
3. Benefits: economic, clinical, performance of resources
4. Patient outcomes

**Figure 12: Balanced scorecard structures**

### A. Balanced scorecard

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Patient Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usability</td>
<td>Clinical effectiveness</td>
</tr>
<tr>
<td>Convenience</td>
<td>Patient safety</td>
</tr>
<tr>
<td>Performance</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td>Resources/Staff</td>
<td></td>
</tr>
<tr>
<td>Efficiency</td>
<td></td>
</tr>
<tr>
<td>Market</td>
<td></td>
</tr>
</tbody>
</table>

### Processes and Policies

<table>
<thead>
<tr>
<th>Processes and Policies</th>
<th>Capability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variety</td>
<td>Evidence</td>
</tr>
<tr>
<td>Connectivity</td>
<td>Capacity</td>
</tr>
<tr>
<td>Risk</td>
<td>Design</td>
</tr>
<tr>
<td>Clinical Governance</td>
<td>Compatibility</td>
</tr>
<tr>
<td>Communications</td>
<td>Resources</td>
</tr>
<tr>
<td></td>
<td>Culture</td>
</tr>
</tbody>
</table>

### B. Capability

<table>
<thead>
<tr>
<th>Capability</th>
<th>Measure</th>
<th>Target</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Product QA</td>
<td>Does it exist?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evidence used to develop performance specifications.</td>
<td>Does specification exist?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer delivers required outputs (including training)</td>
<td>Does it indicate outputs?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Does product meet requirements?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PNA assessment tool</td>
<td>What is needed to operate effectively?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product audit</td>
<td>What is available to operate effectively?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evaluation of performance</td>
<td>Does product perform as required?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Joint development</td>
<td>Is there feedback on performance and capability and at what frequency?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delivery mechanism is compatible</td>
<td>Is system fit for purpose?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Engineering capable to make safety decisions</td>
<td>Is clinical engineering trained?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Engineering input to procurement decisions</td>
<td>Is there any involvement?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training Policy</td>
<td>Does it exist?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Competency based staff training</td>
<td>Is training available?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Safety conscious culture</td>
<td>Is training delivered?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Does it exist for clinical staff?</td>
<td></td>
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<td></td>
<td></td>
<td>Does it exist for procurement?</td>
<td></td>
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</tbody>
</table>
C. Process

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variation</td>
<td>Policy on product standards</td>
<td>Does it exist?</td>
</tr>
<tr>
<td></td>
<td>Equipment specification standards in procurement</td>
<td>Is it implemented?&lt;sup&gt;1&lt;/sup&gt;&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Fixed dosage/conc. for specific preparations</td>
<td>Does equipment deliver policy?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Does dose banding exist?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is 'prefilled' used?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is 'pre-prepared' used?</td>
</tr>
<tr>
<td>Connectivity</td>
<td>e-Prescribing</td>
<td>Is it implemented?</td>
</tr>
<tr>
<td></td>
<td>Auto dispensing</td>
<td>Does it exist?</td>
</tr>
<tr>
<td></td>
<td>Bar coding &amp; auto ID</td>
<td>Does it exist?</td>
</tr>
<tr>
<td>Risk</td>
<td>Assessment process with governance committee and resources</td>
<td>Is it in place for Pharma?&lt;sup&gt;3&lt;/sup&gt;&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is it in place for Devices?&lt;sup&gt;3&lt;/sup&gt;&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Frequency of review</td>
</tr>
<tr>
<td>Clinical Governance</td>
<td>Incident reports</td>
<td>Is it used to inform procurement?&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is it used to inform training?&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What reports go to MHRA?</td>
</tr>
<tr>
<td>Communications</td>
<td>Purchasing framework in place</td>
<td>Is it in place for Pharma?&lt;sup&gt;5&lt;/sup&gt;&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Open structured contact across stakeholders</td>
<td>Is it in place for Devices?&lt;sup&gt;5&lt;/sup&gt;&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Does it exist?</td>
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<td></td>
<td></td>
<td>Who is involved?</td>
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</table>

D. Benefits

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usability</td>
<td>Ease of use</td>
<td>Staff feedback</td>
</tr>
<tr>
<td></td>
<td>Reduction in injuries</td>
<td>Accident record log</td>
</tr>
<tr>
<td>Convenience</td>
<td>Improved clinical activity performance</td>
<td>Staff feedback</td>
</tr>
<tr>
<td>Performance</td>
<td>Improved product capability</td>
<td>Reliability and maintenance reports</td>
</tr>
<tr>
<td>Cost</td>
<td>Whole life cost improvement</td>
<td>Business case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits tracking</td>
</tr>
<tr>
<td>Resources</td>
<td>Improved staff outputs</td>
<td>Staff feedback</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Increased patient throughput</td>
<td>Staff feedback</td>
</tr>
<tr>
<td>Market</td>
<td>Increased product availability</td>
<td>Market research</td>
</tr>
</tbody>
</table>

E. Patient Outcomes

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Effectiveness</td>
<td>Quality of Life Measures</td>
<td>QUALY Feedback</td>
</tr>
<tr>
<td>Patient Safety</td>
<td>Reduced litigation</td>
<td>NHS LA returns</td>
</tr>
<tr>
<td></td>
<td>Reduced complaints</td>
<td>Patient feedback</td>
</tr>
<tr>
<td></td>
<td>Reduced incidents and near misses</td>
<td>NPSA returns</td>
</tr>
</tbody>
</table>
10. **Recommendations**

10.1 Recommendations for establishing and developing purchasing for safety have been addressed to the stakeholders and multiple disciplines involved. These are presented in this section with reference to particular workstreams when specific recommendations are made.

10.2 An overview of the purchasing for safety stakeholders and disciplines is illustrated in figure 13 below

*Figure 13: Purchasing for safety disciplines*

**Purchasing for Safety Stakeholders**

- **Regulatory bodies:** MHRA, NICE
- **NHS and responsible healthcare organisations:** NPSA, Royal colleges
- **Manufacturers:** Industry, NHS manufacturing units
- **Purchasing:** Local/Regional, National
- **Evaluation:** NICE, CEP, HTA, QA, QC, Industry
- **TRUST Purchasing for safety team**

**Summary of recommendations**

*Medications management (Trust) purchasing for safety team*

10.3 The complexities associated with prescribing, preparing and administering injectable medicines means that there are greater potential risks for patients than for other routes of administration. The NPSA produced a list of guidelines addressing each stage of the medications management process to the multiple professions involved.

10.4 To deliver a purchasing for safety approach a number of key actions have been concluded as an output from this project. The approach taken in this project demonstrated the value of a multidisciplinary 'purchasing for safety team', with clear agreement on roles and responsibilities between the chief pharmacist, clinical risk manager, senior practitioners and staff, as well as the interface with Purchasing. Details of those developed and employed for this project are available in the knowledge pack. Key actions are summarised below.

- Identify the incidents, errors, risks, and potential hazard embedded in injectable medicines, infusion devices and related processes
- Map processes and identify risks and complexities
- Review protocols and processes associated with the medications process
- Prioritise clinical settings and issues for attention
- Conduct risk assessment for near-patient areas and identify injectable medicines scoring the highest risk and hazard potential
Chief pharmacist and senior practitioner should conduct risk assessment for all injectable medicines to determine the safest presentation and location for storage and preparation.

- Identify which medicines are amenable to a purchasing for safety solution
- Develop risk reduction strategies and establish focused projects or workstreams to address
- Agree with workstream team members their roles and responsibilities
- Identify benefits and clinical risks (checklist) and liaise with Purchasing to build a cost structure
- Conduct planning, workshops and training for the implementation of each workstream
- Engage with staff to encourage provision of regular and adequate feedback on injectable medicines errors and risks in use
- Assess safety culture among the various disciplines in the Trust.
- In managing product range and volume as well as safety in use, device managers need to:
  - undertake risk assessment and usability evaluations with staff
  - review incidents related to devices
  - assess baseline volume and variety of devices
  - conduct pump needs assessment
  - plan and ensure management of equipment library.

Trust Purchasing team

10.5 A ‘strategic’ approach to purchasing has been studied in literature and practice. Baseline assessment of the procurement process as well as the workstream approach enabled studying any gaps in current practice and led to a number of recommendations as follows.

- Purchasing practitioners need to develop skills and processes for clinical engagement through working across functions in using clinical risk assessment to inform purchasing decisions and protocols
- Collaborate in joint approaches that aim to standardise practice, an important example being the implementation of DM+D descriptors along with NHS PASA and suppliers.
- When procuring new technologies, ensure all equipment is fully auto-ID enabled (future proof).

10.6 Local and regional Purchasing can also play an important role in delivering purchasing for safety upon driving and undertaking the following actions:
- develop purchasing specifications in response to specific risk reduction strategies
- study financial viability and cost effectiveness of purchasing for safety solutions
- address purchasing, logistics, quality control, clinical risk management and other safety considerations in product labelling and packaging
- source and secure availability for appropriate pre-prepared injectables and dose banded chemotherapy drugs – after gaining agreement from clinicians on accepted concentrations for rationalisation.

National Purchasing

10.7 Purchasing for safety workstreams also emphasised the need for national purchasing action. Specific points are listed below.

Dose banding: national lead by NHS PASA to implement or co-ordinate purchasing of dose banded (standardised) product, to maximise benefits and deliver greatest value for NHS.
Barcoding and auto-identification systems: a strategic approach to purchasing auto-identification systems, planning for and developing a solution that covers all applications (eg asset tracking, stock management, auto ID of patients and reconciliation of drugs).

Design for safety: develop purchasing specifications and national guidance for better utilisation of safety features built into ‘smart’ pumps.

Needle free systems: national contracting would ensure cost and volume leverage and benefits to both NHS and industry.

Technical information: national action should be designed to:
• work towards the inclusion of appropriate technical information in all licensed injectable products, using the contracting process as the driver
• ensure essential technical information for use is available as an essential safety feature when adjudicating contracts
• consider making public products/companies that were non-compliant
• coordinate message to industry: the NHS wants to buy products where information matches the NHS’ use of the product (currently, does not match practice)
• discuss changing SPC with suppliers where necessary
• as new products are introduced, review opportunity to change dosage instructions and SPC
• consider need for longer term contracts to allow opportunity to work with supplier and achieve continuity in packaging (but balance against need for competition).

Pre-filled syringes - develop national solutions by:
• liaising with industry to discuss a balanced and collaborative means to match patient needs to market availability.
• identifying orphan formulations wanted by the NHS and analysing product usage trends eg Potassium Chloride.
• creating dialogue around therapeutic standardisation
• aggregating demand for rationalised range of products and creating consensus
• segmenting the above list and working with industry and regulators toward licensing for one or two preparations
• collaborating with QA and other colleagues to define a structured process for procuring pre-prepared injectables.

NHS and healthcare organisations

10.8 NHS PASA and NPSA should jointly disseminate guidance and a step approach to purchasing for safety to enhance clinical engagement. Trusts require access to central/standard technical information. Currently, the only such resource is the ‘Hammersmith’ injectables guide. The following should be considered:
• national promotion of guide.
• easy web access (currently only available by paid subscription)
• easy-to-refer-to format/guide for nurses and doctors
• ability to add local policies, protocols and practices on use of particular drugs.

The following recommendations are aimed at the NHS as whole, although many of the actions would need co-ordination from the centre:
• study (survey and evaluate) the standardisation of high risk injectables
• develop a consensus and plan for dose banded, standardised concentrations in NHS Trusts (cancer network, hospital pharmacists, and Intensive care societies)
• provide unified voice as to what is needed for safe injection systems
• agree standards for labelling and required information on leaflets, labels and packs
• support from Trusts to allow manufacturers to deliver evidence to support change
• combining existing initiatives will assist practitioners with product identification, selection and differentiation
• pump needs analysis software has potential to support Trusts with standardisation of equipment.
• dose limiting software and analysis of end user logs offer valuable tools to improve safer use of devices to administer injectable medicines.

Regulators

10.9 Regulatory bodies (principally MHRA) need to consider the following:
• **Needle free systems**: mandate the use of needle free systems for the preparation and administration of high risk drugs
• **Product and technical information**: 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 (eg using innovative label design, clear technical information leaflets to support safe injectable medicines practice).

Evaluation

10.10 The key recommendation is that NHS PASA, NPSA and the National QA Committee should draft a joint statement to define good QA practice in supporting purchasing for safety. This would also serve to:
• emphasise that QA is critical for ensuring confidence in unlicensed products
• clarify/re-state requirement for QC involvement in buying new, especially unlicensed products
• help support funding case for better/more equitable QA services to ensure access to expertise across the country.

10.11 In addition, evaluation agencies need to disseminate information and evidence on available for cost effectiveness studies.

Industry

10.12 It is recommended that manufacturers consider their ability to:
• provide stability data to Trusts
• provide evidence to support changes in approach to improve safety eg design solutions for labels and products
• work with healthcare delivery staff to understand requirements and deliver improvements
• ensure compatibility of products/consumables and systems
• supply pre-filled syringes with usable information for practitioner
• co-operate with national purchasing to change SPC where necessary
• incorporate safety features in standard labelling (as discussed at PfS workshop and workstream outputs)
• develop standard information sheets that promote user knowledge and understanding to deliver improved patient safety.

10.13 For **needle free systems**, the ideal system was considered to be:
• entirely closed (including containment of drug vapours)
• 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.

10.14 The **design for safety** workstream found that industry needs to do more to make the default setting user friendly and intuitive, and that further work was needed to make the pumps need analysis tool tested more sensitive to the NHS environment and non-American working practices.
11. Learning from the project process

11.1 Lessons have been learnt from the purchasing for safety project including from the planning and execution. These were recorded and managed on daily basis in the form of a risk register at each site. In addition, direct feedback was obtained from key stakeholders immediately post pilot via completion of a comprehensive process evaluation questionnaire. Feedback is summarised below.

Success criteria

11.2 Important factors in making the project a success were enthusiasm and commitment to change and the presence of good communication with the local purchasing team. The establishment of a purchasing for safety project team and committee at the Trust was seen as an important factor. This function may already be present in the Trust in the form of a risk reduction working group/project team tackling prioritised actions identified by integrated governance committees. Leadership, project management and facilitation were believed to be crucial in delivering the project.

11.3 Other key success criteria for the purchasing for safety project included assessment of baseline assessment, support form senior management and support and involvement from executive level. The trust teams believed practice of project management skills and methods were key to planning and delivering the project. Additionally, there was a high need to access national databases and online information through the various selection and evaluation processes.

11.4 Further factors were good communication with regional and national teams, commitment and flexibility from suppliers, expertise in the regulatory aspects of labelling and content of products, the need to have QC and QA pharmacists on board, local funding to support outcome decisions, support from the consultant team and time allocation from identified resources. Maintaining momentum from phase 2 into phase 3 was seen as important success in achieving the expected benefits.

Rating elements and workstreams of the project

11.5 Respondents were asked to rate a number of elements of the project; all of these came out with a mean score indicating some improvement was felt. The most improvement was indicated to be equally the help received from the NHS PASA project manager and the support provided by the pilot facilitator. As for elements of the workstreams in building purchasing for safety, higher rating was given to evaluating the benefits and risks of implementing the workstream and contributing to improvement in patient safety through reducing risk of medication error. Respondents believed there was benefit from establishing and analysing the baseline situation in the Trust, increasing staff awareness of patient safety and medication errors, and enhancing safety culture within the Trust.

Barriers faced and the way they were overcome

11.6 Inadequate time available for the project whilst carrying on with day-to-day work was the most quoted barrier, with all respondents indicating this to be the case. This was overcome by extensive use of personal time, hard work, enthusiasm and commitment from all members of the workstream. Prioritisation of activities also helped. Difficulties in funding some of the product evaluation trials also caused some delay. In some cases, discussions with manufacturers helped in overcoming the funding issue.

11.7 Lack of support from senior management and poor communication with the purchasing manager were seen as the least likely to be a barrier.
Biggest lesson leant from the purchasing for safety project

11.8 Respondents were asked to list what they felt was the biggest lesson learned from the process. Their comments provided valuable feedback and learning, some of which are listed below.

- The complexity of medication issues from purchasing to administration
- "We thought that the practice across the Trust was exemplary, the process has shown us not to rest on our laurels." This shows that assumptions could not be made about current practice, even though 'best practice' had been implemented previously.
- The high need of a QA pharmacist to be involved in the procurement process.
- Resources of time and financial investment are required to make any significant changes in clinical practice.

12. Conclusion

12.1 The Purchasing for safety project and pilot programme found that a strategic and multi-disciplinary approach to purchasing is required to enable a joint approach between the multiple stakeholders and decision makers. A strategic (systems) approach emphasises the need to assess the risks associated with the medication management stages, and to use this evidence to inform purchasing decisions. Safe design would then be specified for injectable products and devices as well as the processes involved with the medications and device management stages including procurement policy and practice. Close collaboration between Purchasing and clinicians is crucial for success.

12.2 The project has highlighted a set of risk reduction strategies where procurement solutions can positively impact on patient safety. While the full impact can only be quantified over time following a permanent change of practice by the trust(s) concerned, a wealth of evidence has been gathered to support local, regional and national action.

12.3 In addressing the central issue of how strategic purchasing can reduce clinical risk associated with the administration of injectable medicines, baseline requirements for purchasing for safety were established as part of the pilot programme in reference to evidence in literature and practice. These included the need for

a) a safety culture to be present among both clinical and procurement personnel, with regular reporting and learning from incidents
b) a dedicated team including the multiple disciplines involved in medications and device management processes
c) Clinical Governance and executive level support
d) integrated risk management for process and product
e) injectable medicines and devices management of volume and variety
f) training protocols and procedures for staff
g) evidence-based decision making and clinical engagement in purchasing decisions
h) evaluation mechanisms and databases, in addition to information management systems
i) communication mechanisms and internal management
j) skills and competences of clinical staff as well as purchasing personnel.

12.4 In deriving Purchasing for safety risk reduction strategies, a number of strategies were selected and designed, aimed at reducing the risk associated with injectable medicines, devices use and management. Long-term technological solutions arose as an important
strategy, requiring the collaboration of all stakeholders in the purchasing for safety landscape; this has been manifested, for example, in barcoding and auto-identification technologies. On the other hand, other risk reduction strategies proving feasible and achievable in the intermediate term include process simplification interventions, product and process standardisation, ensuring adequate and clear technical information is available for staff, in addition to product presentation and differentiation (packaging and labelling). Innovation in design for safety including the availability and ease of use of smart software in pumps is another important strategy involving joint development and feedback with manufacturers and purchasing.

12.5 Key recommendations for a purchasing for safety framework have been drawn in light of the evidence and workstream studies, and objectives agreed between local and national stakeholders who participated in joint active discussion. These have been further discussed by the Steering Group, which proposed the convening of sub-group(s) to take forward key national actions.

12.6 Recommendations highlight the role of local clinical staff, including the chief pharmacist, medical devices manager and clinical risk manager, as well as other clinical stakeholders, in establishing and developing a purchasing for safety user-led approach. A strategic approach to purchasing in decision making and clinical engagement has also been explained in the form of recommendations to local/regional and national purchasing. Furthermore, changes in the way some products are regulated have been suggested, as well as a number of healthcare need-driven recommendations addressed to the industry.

12.7 In sharing lessons about purchasing for safety with other NHS Trusts, a knowledge pack is available via NHS PASA’s website at www.pasa.nhs.uk/purchasingforsafety. It represents the key learning and outputs (eg toolkits and reports) from the year-long project. The knowledge pack will serve as a practical purchasing-orientated resource for NHS professionals involved in the procurement, preparation and administration of injectable medicines.

12.8 In summary, a strategic and joint approach to purchasing for safety is required where efforts are coordinated between national, regional and local purchasing, the NPSA, and the industry in response to systematic and managed clinical risk assessment evidence that is provided from local Trusts and the NHS. Comments like “We thought that the practice across the Trust was exemplary; the process has shown us not to rest on our laurels” show that assumptions should not be made about current practice, and it is by allocating time and resource to assess the risks in current practice and address previous incidents that lessons can be learnt. With the government’s current emphasis on patient safety as a high priority for Trusts, there has never been a better time to address this agenda. This project has helped to position the procurement function to play a leading role by implementing purchasing solutions – locally, regionally and nationally – and there is a significant opportunity to build on the pilot work to support and deliver government policy on safety for the benefit of patients, staff and the NHS as a whole.
References

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Hinrichs, S. 2008 Capturing requirements for safer procurement processes; Focus on infusionsystems in NHS Trusts. (Work in progress). Engineering Design Centre/ University of Cambridge.

Scottish Cancer Pharmacy Group – Guidelines for dose banding of cancer chemotherapy. June 2005

Derby-Burton Cancer Network – Proposal for Dose Banding

Appendix A

Strategic purchasing and supply management literature

A.1 Strategic Purchasing and Supply

The strategic significance of purchasing and supply practitioners has been widely acknowledged and evidenced in both literature and practice. The traditional emphasis on ‘optimizing’ single transactions is being enhanced with the long-term view of procurement efficiency and effectiveness. Strategic roles, development stages and transition models have been developed to build a solid base of evidence on the effectiveness and need to develop and empower the role of purchasing and strategic supply to achieve outcomes in organisations. These are summarised in light of the literature in this appendix.

Two major strategic roles of purchasing practice are identified in literature: rationalization and development. Rationalization indicates making decisions of “what needs to be purchased” and finding effective ways for dealing with a huge number of transactions. Thus, demanding cooperation with internal functions as well as external suppliers. On the other hand, the development role indicates supplier involvement, as suppliers become an important source of technical development.

Reck and Long (1988) provide a four stage development model or positioning tool that can be used as a detailed benchmarking mechanism for firms to position themselves in order to make changes (Cousins in Hines et al. 2000) in purchasing to evolve into a strategic function. Table A -1 below lists “The Four Stages of Purchasing development”.

Table A -1 : "The four stages of purchasing development" (Source: Adapted from Reck and Long 1988)

| Stage 1 | In the passive stage, purchasing normally begins as a reaction to requests from the other departments. Many of the purchasing legitimate activities are handled by other functions outside purchasing. |
| Stage 2 | In the independent stage, purchasing departments spend considerable time attempting to professionalize the purchasing function by introducing such things as computerised information systems, formalised supplier programs, and communication links with technical function. |
| Stage 3 | In the supportive stage, top management views purchasing departments as essential business functions. Purchasing is expected to support and strengthen the firm’s competitive advantage by providing timely information to all departments in the firm about potential changes in the price and availability of materials, which may impact the firm’s strategic goals. |
| Stage 4 | In the integrative stage, the firm’s competitive success rests significantly on the capabilities of the purchasing department’s personnel. Purchasing role within the firm changes from facilitator to functional peer. This development process must be implemented and guided by management over a period of time. |

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Models on purchasing strategies

In understanding how the purchasing activities need to be changed, and how resources can be distributed most effectively, the transition model shows the movement from a purchasing focus on Flat Pricing at one extreme, towards evidence based and Network and Relationship Management at the other extreme.

Figure A-1: Transition model (Source: Hines et al. 2000)

The Transition Model

Five distinct phases are identified. These are ‘flat pricing’, ‘total cost focus’, ‘supply side management’, ‘strategic sourcing’, and ‘network and relationship management’. Each stage is differentiated based on a set of characteristics consisting of nine purchasing assessment factors, such as key objectives, key issues, or performance measures. These are illustrated in table A-2 below.

Table A-2 Characteristics of purchasing and supply strategies (Source: Hines et al. 2000)

<table>
<thead>
<tr>
<th>Stages of Excellence</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
<th>Stage 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approach</td>
<td>Flat Pricing</td>
<td>Total Cost Focus</td>
<td>Supply-side Management</td>
<td>Strategic Sourcing</td>
<td>Network &amp; relationship management</td>
</tr>
<tr>
<td>Description</td>
<td>Adversarial Tactical Focus on Price Transactional</td>
<td>Focus on Total Cost Distant Relationship with suppliers</td>
<td>Focus on Supply service package Develop closer Relationships with suppliers</td>
<td>Cooperative Strategic focus on supply commitment to sing/few suppliers</td>
<td>Focus on supply demand and mutual development Total commitment</td>
</tr>
<tr>
<td>Key Objectives</td>
<td>Contain Price</td>
<td>Contain cost over total product life</td>
<td>To gain from suppliers their specialist expertise and skills</td>
<td>Work jointly with suppliers to increase value in supply chain</td>
<td>Improve total understanding Mutual network Development Total commitment</td>
</tr>
<tr>
<td>Supply mechanism</td>
<td>Volume leverage</td>
<td>Cost leverage</td>
<td>Total service Benchmarking supplier development</td>
<td>Leverage through cooperation</td>
<td>Network leverage</td>
</tr>
<tr>
<td>Supply Structure</td>
<td>Multi Supply Multi relationship</td>
<td>Multi supply multi relationship</td>
<td>Fewer suppliers</td>
<td>Single/ few key suppliers</td>
<td>Network of key single suppliers</td>
</tr>
<tr>
<td>Strategic Approach</td>
<td>Tactical</td>
<td>Tactical</td>
<td>Moving from tactical to strategic</td>
<td>Strategic</td>
<td>Strategic</td>
</tr>
<tr>
<td>Why Fails</td>
<td>Focus on Price not on cost</td>
<td>Focus on quality not on service</td>
<td>Resistance or failure to share relevant information with</td>
<td>Focus on cooperation not involvement</td>
<td>Too expensive Need high level of trust/dependency</td>
</tr>
</tbody>
</table>
Table A-3: Implementation stages for the transition model, adapted from Value Stream Management 2000, p.198

<table>
<thead>
<tr>
<th>Stage</th>
<th>Purpose</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Assessment</td>
<td>The purchasing organisation should benchmark where it currently sees itself against the characteristics and criteria listed within the model</td>
</tr>
<tr>
<td>2</td>
<td>Strategy Development</td>
<td>Purchasing should consider where it wants to be and examine the gaps in its approach vis-à-vis what the model is telling them. They should then develop a strategy to take the function forward.</td>
</tr>
<tr>
<td>3</td>
<td>Benchmarking</td>
<td>The stage is to use the model to review current progress and see how the function is developing</td>
</tr>
</tbody>
</table>

It is rare to achieve the three objectives of effectiveness (quality), safety, and least cost together (Goldberg 2006). For instance, innovations in medical technologies could potentially offer high benefits, and even improved safety, but that on behalf of cost, or in financial terms, risk. In avoiding uncertainty, purchasers might base their decisions on price, but this might lead to failure in achieving the benefit that will eventually save cost on the long term (e.g. Gaade and Haakinson 2003, Kraljic 1983).

1.2 Evidence-based Purchasing

Evidence-based purchasing is a new area of study of growing interest; consequently, academic literature on evidence-based purchasing is not extensive. Evidence-based decision-making has been illustrated as a multi-step process of searching for evidence, appraising it and incorporating the best available evidence in the decision making process (e.g. Pfeffer

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47 Glasziou, P. and Haynes, B. (2005) The paths from Research to Improved Health Outcomes. Evidence Based Nursing. 8 (2) pp36-38
& Sutton 2006, Glasziou & Haynes 2005, Gray 2001, Sackett et al. 1996, Shaxon 2005). It is also clarified that Evidence-based approaches are part of a larger multi-faceted process. This includes the production of evidence through research, disseminating the results into databases and guidelines, the implementation of evidence-based decision making through education and management of change, and finally monitoring and managing performance (eg Belsey and Snell 2003).

Gray (2001) also summarises the strategies that a purchaser must follow in the management of the introduction of innovation, as follows: innovations that do more good than harm, and are affordable, should be introduced at a defined standard of quality; whereas, innovations that do more harm than good but have already entered the service, should be stopped and no longer offered. The same applies for such innovations that have not entered the service yet. This is usually related to the lack of evidence from good quality research that an intervention is effective.

Gray (2001) explains the role purchasers can play in promoting trials for those innovations where the effect is unknown and need to be investigated during trials. Purchasers also need to plan the introduction of those innovations that require training and infrastructure, which would imply slowing their introduction.

1.3 Multiple stakeholders

When considering Evidence based decision making in healthcare, it is important to understand who will make this decisions and how many are the influencing parties. If these are various, it becomes crucial to manage the different perspectives in an open system. This will be briefly viewed in this section by reviewing relevant organisational theory research.

As a multi-disciplinary concept, evidence based approaches study the effectiveness of the intervention in question. In evidence-based purchasing this implies making decisions about effective, safe and affordable products and interventions. In healthcare, many stakeholders are involved in this decision, ranging from clinicians with high level of discretion, to patients with increasing demands and expectations, finance directors and purchasers under pressures of cost reduction, and policy makers seeking better social health and equity.

In developing a deeper understanding of decisions implementation in multi-stakeholder environments, contingency approaches literature bonding, informational and control approaches. A bonding approach involves the potential users in defining the important features of the decision as a means to enhance the probability of their acceptance. This implies having little power. On the other hand, informational approaches would aim to create a link between experts and potential adopters by using knowledge and rational argumentation in attaining persuasion and promoting adoption, which indicates a medium level of power.

49 Sackett, D.L et al. (1996) Evidence-Based Medicine: What it is and What it isn’t? BMJ 312 (7023), 13 January, 71-72)
## Existing pharmaceutical organisational networks and structures

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Description</th>
<th>Role</th>
<th>Responsibilities</th>
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</table>
| **NPSG**     | Operating at the national level, NPSG advises the Chief Operating Officer of NHS PASA on matters relating to the procurement and supply of pharmaceuticals to the NHS. It consists of two pharmacists (either chief pharmacists or technical or procurement specialists) from each of the six national purchasing groups along with PCT representatives, a Quality Controller and observers from the DH and the Home Countries. | To oversee delivery of national strategies relating to pharmaceuticals, as agreed with the Commercial Directorate and in consultation with CPHs | - to be the accountability focus in the relationship between the Chief Executive of NHS PASA, collaborative procurement hubs/confederations and representatives of hospital pharmacists in delivering the national strategy agreed with the DH Commercial Directorate  
- to review its terms of reference - and that of PMSG - to take into account the interests of the Commercial Directorate, NHS PASA, representative pharmacy purchasing groups and CPHs - the latter being drawn from procurement leads as opposed to pharmacists |
| **PMSG**     | PMSG is an operational sub group of NPSG. It consists of pharmacy procurement specialists and NHS PASA category managers. Amongst other roles PMSG brings together a national overview of commercial and pharmaceutical expertise to assist NHS PASA coordinate pharmacy purchasing group activity and to advise the pharmacy purchasing groups on the most appropriate award decisions, so as to achieve maximum benefit for the NHS whilst avoiding and managing any introduction of risk to supply. | To devise and implement the delivery of a national pharmaceutical strategy agreed with the NHS and CD | - to bring together, at the national level, the required expertise - both pharmaceutical (specialist procurement pharmacists), some of whom may also be representatives of CPHs/confederations, together with commercial (NHS PASA) representatives - to deliver the agreed national strategy  
- to be accountable to NPSG (and hence, in terms of reporting performance, to the DH)  
- to link with pharmacy purchasing groups and CPHs towards delivery of national strategies  
- to review the availability of dedicated specialist pharmacist support to pharmacy purchasing groups and local health economies (NB this is the subject of a separate proposal)  
- to identify and develop strategic opportunities for the procurement of branded medicines in consultation with the appropriate stakeholders  
- to advise all collaborative procurement hubs and pharmacy purchasing groups of these strategies  
- to measure performance of their implementation, across the NHS, using Pharmex data |
| CPHs and confederations | To ensure all commercial spend of member trusts is strategically sourced and provides best value for patients | - to develop workplans in conjunction with national strategies  
- to drive volume/commitment opportunities within NHS PASA contracts  
- to work with the pharmacy purchasing groups to develop an appropriate sourcing work plan for pharmaceutical products; identifying and exploiting cost reduction opportunities whilst not adversely impacting clinical outcomes or increasing clinical or supply chain risk  
- to work with PMSG and PASA to identify those opportunities that can be best leveraged at a national level  
- to work with their pharmacy purchasing groups to drive uptake of any ensuing framework contracts, whether established by themselves or PASA  
- to consider funding for pharmaceutical procurement specialists and their boards’ access to pharmaceutical input |
| Pharmacy purchasing groups | Each NHS trust is represented on a purchasing group by a pharmacist or technician. Representing the interests of the trusts’ budget holders, clinicians and relationships with PCTs, these pharmacists meet locally and regularly on a group basis to align procurement standards and approaches, and exploit the purchasing power of their collective trusts. The resulting business is either aggregated at a regional level (for branded products) through 14 geographically based pharmacy purchasing groups, or at a national level (for generic and near patent expiry products) through the 6 SCEP award groups. | To identify pharmaceutical needs at a local/regional level and support the CPHs/confederations to ensure that these needs are met effectively by the external market | - pharmacy purchasing groups to work with CPHs (and confederations) in order to deliver local commitment to national strategies  
- to work with CPHs/confederations to develop appropriate pharmaceutical sourcing plans, and in particular to identify and define the clinical requirements for pharmaceutical products on behalf of the relevant trusts  
- to work with CPHs and confederation category / purchasing managers to standardise products and minimise costs where this does not adversely affect clinical outcomes or risk  
- to support CPHs and confederations in driving the uptake of the pharmaceutical contracts (whether established by the CPHs or PASA) and produce the associated compliance reports  
- to review the geographic boundaries and number of purchasing groups to ensure that there is consistency in their size and that they are able to work effectively with local clinicians and CPHs/confederations  
- to contribute to the strategic development of contracting opportunities for branded medicines through PMSG and CPHs/confederations |
| **PASA** | The pharmacy purchasing groups are supported by a dedicated PASA buyer (category specialist) and Quality Assurance and Technical Pharmacists. Business identified by the groups is competitively tendered on their behalf by NHS PASA. Following adjudication of tenders by the group, reflecting the interests of its constituent trusts, their clinicians and budget holders, NHS PASA also awards and manages the resulting contracts on behalf of the groups. | To undertake the sourcing and commercial negotiations of pharmaceutical contracts on behalf of the NHS | - to monitor performance relative to that of other pharmacy purchasing groups using Pharmex data | - to work with CPHs, confederations and PMSG to identify and agree those pharmaceuticals that are most effectively sourced at a national level | - to effectively source and establish framework contracts on behalf of the NHS | - to support CPHs and confederations in driving the uptake of the national framework contracts |
| **Hospital pharmacists** | On a day-to-day basis, hospital pharmacists combine clinical and technical roles. On the one hand, they provide prescribing advice to clinicians and deliver clinical services, while on the other they are responsible for the availability, when required, of medicines of suitable quality through the management, on a day-to-day basis, of purchasing and dispensing activities. Their activities include support for the management of clinical directorate prescribing budgets, input into Drugs and Therapeutic Committees, the maintenance of hospital formularies and delivery of the associated disciplines within trusts that accompany these roles (e.g. Patient Safety and Clinical Governance). Hospital pharmacists support their role through access to shared services and specialist expertise - including those for Medicines Information, Quality Assurance and Control, Education and Training and Technical Services. | | |
| **Specialist procurement pharmacists** | To ensure that there are sufficient qualified pharmacists within the NHS | | - to review the availability of dedicated resources across England to ensure the provision of high quality, expert professional and technical advice and support for PMSG, procurement groups, CPHs / Confederations and their associated local health economies | - to seek funding to support the establishment of new posts either through existing Specialist Pharmacy Services agreements with local economies, procurement confederations or collaborative procurement hubs |
# Case study selection at Derby Hospitals Foundation Trust pilot

<table>
<thead>
<tr>
<th>Focus Groups</th>
<th>Supporting Data Analysis</th>
<th>Case Study</th>
<th>Potential Benefits</th>
<th>Target</th>
</tr>
</thead>
</table>
| **Appendix C- Case studies**

## Case study selection at Derby Hospitals Foundation Trust pilot

<table>
<thead>
<tr>
<th>Name</th>
<th>Location</th>
<th>Topics (Problem)</th>
<th>Pilot Trust Data</th>
<th>Case Study</th>
</tr>
</thead>
</table>
| **Chemistry** | Derby City Hospital | Does standing (Chemistry) | Workload data from chemotherapy pharmacy showing high staff turnover. Much work has been done to manage the workload and provide adequate training in preparation in advance and use of PPE. Process of documentation from incident and internal pharmacy audit reports that high risk of errors in the handling of vincristine and vinblastine. Process has been developed in DHT with good effect. | Increasing demand for chemotherapy drug handling training. 
- Introduction of a new training program for new staff. 
- Improvement of documentation processes. | Clinical Staff in Pharmacy, ODPs, Pharmacists, and medication administration nurses. |

| **Chemistry** | Derby City Hospital | dare administration (Chemistry) | Incident reports relating to incorrect type and dose of vincristine and vinblastine. 
- Improving medication administration practices in the chemotherapy ward. | 
- Introduction of a new training program for new staff. | Clinical Staff in Pharmacy, ODPs, Pharmacists, and medication administration nurses. |

| **Chemistry** | Derby City Hospital | Needle free systems for administration | Evidence of reduced skin puncture injury with needle free systems in other chemotherapy units and in pilot studies. 
- Improved safety for staff and patients. 
- Reduced risk of infection and cross-infection. | 
- Reduced risk of infection and cross-infection. | Clinical Staff in Pharmacy, ODPs, Pharmacists, and medication administration nurses. |

| **Theatre** | Derby City Hospital | Preparation of injections prior to list | Evidence of reduced skin puncture injury with needle free systems in other chemotherapy units and in pilot studies. 
- Improved safety for staff and patients. 
- Reduced risk of infection and cross-infection. | 
- Reduced risk of infection and cross-infection. | Clinical Staff in Pharmacy, ODPs, Pharmacists, and medication administration nurses. |

| **Theatre** | Derby City Hospital | Knowledge decay in skills and competency | Evidence of reduced skin puncture injury with needle free systems in other chemotherapy units and in pilot studies. 
- Improved safety for staff and patients. 
- Reduced risk of infection and cross-infection. | 
- Reduced risk of infection and cross-infection. | Clinical Staff in Pharmacy, ODPs, Pharmacists, and medication administration nurses. |
### Case Study A – Theatres and imaging

- Presentation and storage of injectable medicines
- Knowledge decay in training
- Second checking of injectable medicines

#### Pilot Site:
Derby Hospitals NHS Foundation Trust

#### 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 most other areas within the Trust, due to restricted access and lack of daily clinical pharmacy services. Medicine checking tends to be unidisciplinary and documentation is limited.

Medication error reporting rates are lower than expected in the Trust, and there are literature reports of unsafe processes e.g., open bowl techniques, multi-vial use etc.

#### Area: Theatres and Imaging, represented by General and Obstetric Theatres and X-Ray

#### Proposed Changes:
1. Imaging – contrast media in different volumes, differentiated by colour. Separate through storage in appropriate imaging areas.
   - Use of commercial labelled pre-filled syringes or preparation of contrast prior to use, to eliminate open bowl use
   - Theatres – separate emergency / routine drugs, use original packaging, maximise use of pre-prepared injections / infusions
2. Replace ageing equipment / standardise consumables / checks
3. Introduce second checking for all preparation and administration of injectable medicines in theatre and imaging areas.
   - Separate injectable medicines preparation and administration (i.e., different staff member prepares and checks / administers)
   - Restrict access to injectable medicines to ensure second check e.g., nurse / CDP / Radiographer prepares / supplies injectable drug to medical staff rather than allowing unrestricted access.

#### Statement of Problem (Issue):
1. Presentation of Injectable Medicines (storage, packaging, labelling, selection etc)
   - Imaging – similarity between products / use of labels. Use of sterile bowls to draw up from (only differentiated by viscosity)
   - Theatres – similar packaging, storage of ‘free ampoules’ in labelled drawers, poor labelling, bigger storage area
2. Knowledge Decay – maintaining competency
   - Imaging – Ageing equipment, breakdown, loss of knowledge
   - Theatres – lack of parental checklist to document checks, training not consistent across disciplines
3. Checking of injectable medicine – not always double check at preparation and administration

#### Potential Benefit:
1. Imaging – reduce risk of open bowl contamination and selection / injection errors using labelled pre-filled syringes.
   - Opportunity to standardise injector equipment and consumables required – reducing costs / training
   - Theatres – minimise risk of selection errors. Emergency drugs available (ready to administer) from specific storage areas
2. Standardised equipment, maintained to maximise availability and minimise additional training burden
3. Maximise second checking by appropriate discipline (utilising knowledge, skills and experience)
   - Separates preparation and checking activity to increase chance of detecting medication error
   - Ensure parental checklist always used to prompt and document checks (of injection site, equipment and treatment)
## Case Study B – Chemotherapy

- Dose banding for chemotherapy
- Bolus injection versus infusion

### Pilot Site:
Derby Hospitals NHS Foundation Trust

### Area:
Cytotoxic chemotherapy preparation and treatment area (chemotherapy suite)

### 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 (under / over dose) and to staff (exposure due to mishandling, spillage). There are many controls in place for safe preparation & administration of cytotoxic chemotherapy and a proactive risk management culture.

Capacity is an ongoing problem with growing demand – much has been done to address this through scheduling, use of oral treatment, etc. Dose banding offers capacity benefits / commercial availability.

Venomous chemotherapy is always given by slow bolus administration. There may be benefits in administering most injectable medicines by bolus to ensure close monitoring and better patient communication.

### Proposed Changes:
1. Introduce dose banding for further products (based on usage, stability, presentation, etc). Estimate 25% of total products.
   - Trial for in-house pharmacy dispensed products
   - Trial for external manufactured special / commercial products
   - Promote standardisation of dosing algorithm
   - Agree dose bands for each product and exclusion criteria
   - Agree specification for standard presentation of each product
2. Bolus administration for all chemotherapy where appropriate
   - Bolus administration for simple, low risk injectable medicines
   - Develop training, professional accountability for administration
   - Clear procedure for management of intermittent infusions
   - Evaluate bolus preparation versus intermittent infusion in clinical area to assess time, resource, risk, benefit for staff and patients.

### Statement of Problem (Issue):
1. **Dose banding** to increase capacity for chemotherapy
   - Not suitable for all products (physio-chemical stability)
   - Limited shelf-life (pre-filled syringes are not ‘final containers’)
   - Lack of clinical evidence to support dose standardisation
   - Poor labelling and presentation of individual dose banding product
2. **Bolus administration** versus intermittent infusions
   - Lack of patient communication / monitoring for adverse effects
   - Lack of accountability by nursing staff for administration
   - Increased preparation and administration time required
   - Not universally supported by all interventionalists
   - No benefits on training / checking requirements

### Potential Benefit:
1. Increased capacity for dispensing chemotherapy
   - Reduced preparation and dispensing time (up to 50%)
   - Reduced dose selection errors
   - Identify products that can be commercially purchased
   - Standardisation of dose calculation (BSA) and banding
   - Standardisation of product preparation and presentation
2. Better accountability, monitoring and patient care
   - Better differentiation from simple low risk injections
   - Better management of infusion therapy (e.g., line, patency, etc.)
   - Facilitate study will highlight resource requirements and allow benefits analysis for patient care and ward staff resource
Case Study C – Maternity

- Standardisation of Syntocinon products
- Use of Extension lines
- Poor labelling and product information

Pilot Site:
Derby Hospitals NHS Foundation Trust

Area: Maternity Services

Background:
Maternity Services are low 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. Syntocinon 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 Syntocinon products
   - Lack of standardisation nationally and locally use of different strengths of Syntocinon pose a risk to patient safety
   - Lack of stability data to support pharmacy preparation / storage
   - Ward / Theatre preparation and storage - ? Labels/checks/errors
2. Extension lines / multiple connectors
   - ‘Dead space’ in extension lines could result in ‘bolus’ of drug and incompatibility if drugs mix in set.
   - Large volume/high flow rate in emergency increases dead space
3. Poor labelling and information
   - Inappropriate use of brand name on commercial products
   - Quality of information – small writing, unclear, inaccessible
   - Errors converting from concentration in ‘units’ to ‘milli per hour’

Proposed Changes:
1. Review national guidelines and rationalise strengths
   - Consider standard concentration and adjust dose by rate
   - Consider availability of pre-made special or commercial product
   - Consider pharmacy preparation of other injectable medicines
   - Consider standardised labelling by indication / administration
2. Review rationale for use of extension lines / connectors
   - Manufacturer to redesign extension set to reduce ‘dead space’
   - Consider alternative large bore set with reduced ‘dead space’
3. Standardised labelling of key information for administration
   - 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
   - Potential for single concentration, ready to use pre-filled product
   - Reduced risk of errors from mixing up similar looking syringes
   - Reduced cost through block NHS purchase agreement
   - National clinical guidelines for maternity services
2. Reduce administration complexity and line selection errors
   - Reduced risk from inappropriate bolus of drug in ‘dead space’
   - Cost effective procurement and standardised training in Trust
3. Essential information for safe and effective use of product
   - Less risk of confusion, error and delay to treatment
   - Better availability of technical information for preparation
   - Clear information for safe administration of product
### Case Study Selection at United Lincolnshire Hospitals Trust Pilot

#### Focus Groups

<table>
<thead>
<tr>
<th>Name</th>
<th>Location</th>
<th>Topics Raised (Problem)</th>
<th>Supporting Data Analysis</th>
<th>Case Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oncology / Haematology</strong></td>
<td>ULHT</td>
<td>Dose Banding (Chemo)</td>
<td>Evidence from Incidents and internal pharmacy error reports that high workload leading to some errors in preparation and administration.</td>
<td><strong>Case Study?</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose banding has been adopted although inconsistently and with variable approaches. Issues and need for standardised products and approach are being highlighted through the cancer network.</td>
<td><strong>YES</strong></td>
</tr>
<tr>
<td><strong>ICU CCU Onc/Hae m</strong></td>
<td>ULHT</td>
<td>Gentamicin</td>
<td>Problems in the use of Gentamicin has been identified in the recent NPSA Safety alerts. This has been highlighted in special groups of patients (i.e. children). NPSA recommendations also highlight.</td>
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<td></td>
<td></td>
<td></td>
<td>Challenges faced with the current regimes and variation of preparation of Gentamicin leading to a risk of errors in prescribing, calculation, preparation and administration.</td>
<td><strong>YES</strong></td>
</tr>
<tr>
<td><strong>ICU CCU Onc/Hae m</strong></td>
<td>ULHT</td>
<td>Pre-prepared injectables</td>
<td>Evidence from Incidents reports that near patient and ward preparation of some injectable medicines imposes risk of medication errors. Furthermore, high workload in the pharmacy leads to some errors in preparation and administration of injectables.</td>
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<td></td>
<td>NPSA recommendations highlight the need to provide ready-to-administer and ready-to-use injectable products of standard strength as a strategy to minimise the risk when preparing and administering injectable medicines that present complexity in dosing and calculation.</td>
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</tbody>
</table>

#### Problem Statement

- Increasing demand for chemotherapy is placing unresourced burden on chemotherapy services, leading to risk of errors in prescribing, preparation and administration.
- Challenges faced with the current regimes and variation of preparation of Gentamicin leading to a risk of errors in prescribing, calculation, preparation and administration.
- Complex calculation and dosing of some injectable medicines, in near patient areas, as well as overload on pharmacy leading to increase in risk of errors associated with the prescription, preparation and administration of injectable medicines.

#### Proposed Action Plan

- Take topic forward to Case Study. Individuals for structured interview identified as:
  - Oncology Pharmacist Lincoln
  - Oncology Pharmacist Boston
  - Consultant Oncologist Lincoln
  - Consultant Haematologist Lincoln
  - Questions for structured interview to be developed.

- Take topic forward to case study: Individuals for structured interviews identified as:
  - Pharmacist Louth
  - Microbiologist Grantham
  - ICU Nursing Boston
  - Gen Ward Nursing Lincoln
  - Oncology Nursing Boston

#### Potential Benefits

- Increased capacity
- Reduced risk from complex calculations
- Reduced risk from complex preparation
- Simplified preparation of cytotoxic drugs
- Standardisation of treatment dosing
- Standardisation of education and training

#### Target

- Clinical Staff
- Nursing Staff
- Pharmacists

- YES

#### Case Study

- Yes
| ICU CCU Onc/Hae m | ULHT | Staff Information Leaflet | Product information often does not provide sufficient or accessible information on preparation and administration of injectable medicines. This has been identified as crucial to ensure correct reconstitution of injectable medicines. | Lack of effective technical information has been highlighted by NPSA in Alert 20 - injectable medicines. NPSA recommendations highlight the need to ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use. | Poor labelling and poor availability and access to technical information increases risks in prescribing, preparing and administering injectable medicines and leads to errors. | Take topic forward to a case study, Individuals identified for interviews are: Pharmacy & Procurement ICU Nursing ICU Pharmacist ICU ICU Pharmacist | Better information for prescribing e.g. dose and route Better technical information for preparation of injections Clearer information for correct administration of injections Critical information for monitoring clinical / adverse effects | Clinical Staff Nursing Staff Pharmacists Procurement | Yes |
Case Study: Dose Banding

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<thead>
<tr>
<th>Pilot Trust:</th>
<th>Area:</th>
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</thead>
<tbody>
<tr>
<td>United Lincolnshire Hospitals NHS Trust</td>
<td>Oncology / Haematology</td>
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</tbody>
</table>

**Background:**
Increasing demand for chemotherapy is placing unresourced burden on chemotherapy services, with the potential to lead to risk of errors in prescribing, preparation and administration.

**Proposed Changes:**
The Trust already use a dose banding variable of 5% for a range of drugs that are prescribed in relation to surface area (calculated through parameters of weight and height). As this exists, the opportunity remaining would be to review the range variables and consider if the most common doses can be prepared in advance or in time with efficient workload planning, leaving less urgency in the preparation cycle. This must be considered in context with the shelf life and risk of wastage.

**Statement of Problem (Issue):**
Dose banding can improve efficiency and cost effective use of some chemotherapy drugs. The principle is to make small adjustments to either use an incremental range of doses or round up or down within narrow margins from a precise dose. For example 104mg of drug which is contained in a 50mg vial, could be rounded down to 100mg and use only 2 vials rather than 3.

**Potential Benefit:**
- Increased capacity
- Reduced risk from complex calculations
- Reduced risk from complex preparation
- Simplified preparation of cytotoxic drugs
- Standardisation of treatment dosing
- Standardisation of education and training
## Case Study: Pre-prepared Products

<table>
<thead>
<tr>
<th>Pilot Trust:</th>
<th>Area:</th>
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<tbody>
<tr>
<td>United Lincolnshire Hospitals NHS Trust</td>
<td>All (CCU, ICU, Oncology &amp; Haematology)</td>
</tr>
</tbody>
</table>

### Background:
Drug preparation hazards include dose calculations, reconstitution contamination, distractions and sharps injuries. The controls that exist rely on human actions, supported by training, information resources and experience. External provision of the drugs in ready to administer state will remove many of the risks identified above.

### Proposed Changes:
Look for opportunities to purchase pre-prepared items that are ready to administer. Cost benefit and safety benefit analysis of both high risk calculations and the time consuming preparation requirement, along with availability, shelf life and storage implications. Specific drugs include Aggrastat, clarithromycin, teicoplanin, erythromycin, ambisone, noradrenaline, adrenaline and fentanyl.

### Statement of Problem (Issue):
Complex calculation and dosing of some injectable medicines, in near patient areas, as well as overload on pharmacy leading to a potential increase in risk of errors associated with the prescription, preparation and administration of injectable medicines. In addition to this some drugs require considerable preparation due to the reconstitution or dilution process, which can also impact on effective use of time.

### Potential Benefit:
- Increased capacity
- Reduced risk from complex calculations
- Reduced risk from complex preparation
- Simplified preparation of cytotoxic drugs
- Standardisation of treatment dosing
- Standardisation of education and training
### Case Study: Gentamicin

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<thead>
<tr>
<th><strong>Pilot Trust:</strong></th>
<th><strong>Area:</strong></th>
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<tbody>
<tr>
<td>United Lincolnshire Hospitals NHS Trust</td>
<td>All (CCU, ICU, Oncology &amp; Haematology)</td>
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</tbody>
</table>

**Background:**
Gentamicin is a powerful antibiotic and carries risk of renal damage and deafness if the patient has too high a concentration. This needs management through blood testing for levels at regular intervals. 4 methods are used in the Trust:
- Daily doses (7mg/kg) following a nomogram
- Divided doses (twice or three times a day, often for patients with renal impairment)
- Divided low dose (as above but for endocarditis)
- One off prophylactic use to coincide with an invasive intervention

**Proposed Changes:**
The Trust has guidelines that can be improved to capture the various methods used.

- The favoured daily dose regimen is not covered by a manufacturing licence, but is commonly used in NHS trusts, so reference sources such as the BNF show primary use as a divided dose.
- Development of a prescribing and monitoring system using stickers on drug charts.

**Statement of Problem (Issue):**
Protocol and Monitoring process for Gentamicin is complicated and confused by the variety of regimes used. Potential for error and therefore risk to incorrect dosing is significant.

**Potential Benefit:**
- Reduced risk from complex calculations
- Reduced risk from complex preparation
- Simplified preparation of cytotoxic drugs
- Standardisation of treatment dosing
- Standardisation of education and training
## Case Study: PILS v Staff Information Leaflets

**Pilot Trust:**  
United Lincolnshire Hospitals NHS Trust

**Area:**  
All (CCU, ICU, Oncology & Haematology)

### Background:

Manufacturers are required to provide patient information leaflets for all drugs. The PILs do not contain information about reconstitution and administration as a rule. This information is usually available in a Summary of Product Characteristics (SPC) document, which pharmacy staff can access or is on the internet [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk). Some information is available in other ways, through the UCLH Injectable Medicines Administration Guide, BNF and trust intranet, but no one solution covers everything.

### Proposed Changes:

Recommend that PASA pursue a national solution and provide a Staff information leaflet for all injectable medicines and a review system to ensure information remains current.

Consider how the design of the leaflet can highlight key characteristics that clinical staff need to use the drugs safely, in a summary table in a standard format.

### Statement of Problem (Issue):

Poor labelling and poor availability and access to technical information increases risks in prescribing, preparing and administering injectable medicines and leads to errors.

### Potential Benefit:

- Better information for prescribing e.g. dose and route
- Better technical information for preparation of injections
- Clearer information for correct administration of injections
- Critical information for monitoring clinical / adverse effects
## Appendix D

### Recommendations and objectives – multiple disciplines/ workstreams- Purchasing for safety project

<table>
<thead>
<tr>
<th><strong>Function</strong></th>
<th><strong>Trust Purchasing for safety approach (General)</strong></th>
<th><strong>Rationalisation &amp; standardisation (pharmaceuticals)</strong></th>
<th><strong>Centralisation &amp; decision making</strong></th>
<th><strong>Information and labelling</strong></th>
<th><strong>Design and innovation</strong></th>
<th><strong>Technology (bar coding &amp; auto-ID)</strong></th>
<th><strong>Informed purchasing decisions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchasing</td>
<td>Local and Regional</td>
<td>Assess how mature the Trust is in conducting a purchasing for safety (PFS) approach</td>
<td>Search and secure for availability and sources for pre-prepared and dose banded injectables in resonance to agreed concentrations with clinicians.</td>
<td>Assess the purchasing decision making process in the Trust, drivers at baseline, and develop objectives and action plans towards centralisation and reform to purchasing decision making.</td>
<td>Ensure essential technical information for use is available as an essential safety feature in assessing products upon contracting</td>
<td>Search and secure availability sources for products (PFS&lt; DS) (after clinical agreement on prep.)</td>
<td>Participate in identifying purchasing specifications and feasibility of applying barcoding and auto-identification technologies in practice and with suppliers.</td>
</tr>
<tr>
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<td>Assess any obstacles that might form barriers to PFS practice</td>
<td>Develop clinical engagement; work across functions, and improve communication skills with the right people</td>
<td>Develop Purchasing specifications</td>
<td></td>
<td></td>
<td>Develop clinical engagement (work across functions, and communicate with the right people)</td>
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<tr>
<td></td>
<td>Liaise with pharmacy team to develop cost analysis and financial viability studies.</td>
<td>Address purchasing, logistics, Quality Control, clinical risk management in product labelling and packaging</td>
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<td></td>
<td></td>
<td>Develop Purchasing specifications</td>
<td>Promote and drive evidence based purchasing by ensuring the right capabilities and processes are available</td>
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<td>Collaborate in implementing DM+D descriptions with PASA and suppliers</td>
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<td>Collaborate and discuss with industry on a balanced means to match patient and staff needs to product design</td>
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<tr>
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<td></td>
<td>Collaborate and discuss with industry on a balanced means to match patient needs to market availability</td>
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<th>Informed purchasing decisions</th>
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</thead>
<tbody>
<tr>
<td>National Purchasing groups</td>
<td>Provide national focus and drive implementation of standard descriptors (eg using DM+D descriptions and GS1 coding) to drive bar-coding and supply chain efficiency statement – all software to adopt DM+D</td>
<td>Identify orphan formulations wanted by the NHS and analyse product usage trends eg KCl</td>
<td>Co-ordinate message to industry: the NHS wants to buy products where information matches the NHS’ use of the product (currently, does not match practice). (PASA)</td>
<td>Develop purchasing specifications and national guidance for better utilisation of safety features built into ‘smart’ pumps</td>
<td>Needle free systems: National contracting by NHS PASA would ensure cost and volume leverage and benefits to both NHS and industry</td>
<td>A strategic approach to purchasing and developing a solution that covers all applications (e.g. asset tracking, stock management, auto ID of patients and reconciliation of drugs) *</td>
<td>Promote and drive evidence based purchasing by ensuring the right capabilities and processes are available</td>
</tr>
<tr>
<td></td>
<td>NHS PASA to develop a system to manage availability and market trends (commercial intelligence link to innovation) and develop communication channels with industry</td>
<td>Create dialogue regarding therapeutic standardisation</td>
<td>Ensure essential technical information for use is available as an essential safety feature in assessing products upon contracting</td>
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<td></td>
<td>NHS PASA and NPSA to disseminate guidance and a step approach similar to purchasing for safety to enhance clinical engagement</td>
<td>Aggregate demand for a rationalised range of products and create consensus (80/20 principle). What would you accept? (PASA to inform and consult with NHS manufacturing units)</td>
<td>Challenge suppliers to change the SPC where necessary. As new products are introduced, review opportunity to change dosage instructions and SPC</td>
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<td></td>
<td>Contracting: Seek more imaginative relationships/contracting basis with suppliers eg purchasing organisation (PASA?) develops/ holds the licence for a supplier to manufacture against in a long-term partnership</td>
<td>NHS PASA to update and manage content for a database for available products and preparations</td>
<td>Inclusion of appropriate technical info in all licensed injectable products is an achievable objective. (Easier for Specials – not covered by MHRA.) -Consider need for longer-term contracts to allow opportunity to work with supplier and achieve continuity in packaging (but balance against need for competition etc)</td>
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<td>And/or advertise for a licensed product requirement with 2-year time horizon to pull new products through</td>
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<td>NPSA</td>
<td>NHS PASA and NPSA to disseminate guidance and a step approach similar to purchasing for safety to enhance clinical engagement</td>
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<td>Trusts require access to central/standard technical information. With existing ‘Hammersmith’ Guide, need to consider: • National promotion of guide • Easy web access (currently only by paid subscription) • Easy-to-refer-to format/guide for nurses and doctors • Ability to add local policies, protocols &amp; practices around how particular drugs are used</td>
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<td>NHS/NPSA?</td>
<td>Support from trusts to allow manufacturers to deliver evidence to support change. Unified voice as to what is needed for safe injection systems</td>
<td>Engagement in agreeing standards across trusts based on what is acceptable not just what each trust wants. Agree dose banding to allow licensing of pre-filled syringes Support from trusts to allow manufacturers to deliver evidence to support change</td>
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<td>NHS to agree standards for labelling and information</td>
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<td>Risk assessment</td>
<td>Identify the incidents, errors, risks, and potential hazard embedded in injectable medicines, infusion devices and related processes.</td>
<td>Agree on accepted concentrations and work collaboratively towards standardising practice</td>
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<td>Map processes and identify risks and complexities</td>
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<td>Review protocols and processes associated with Medications process</td>
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<td>Prioritise clinical settings, cases, and workstreams</td>
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<td>Conduct risk assessment and identify injectable medicines score the highest risk and hazard potential</td>
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<td>Identify which is amenable to a purchasing for safety solution</td>
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<td>Assign workstream teams and leads</td>
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<td>Identify benefits and clinical risks (checklist)</td>
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<td>And liaise with purchasing to undergo a cost structure.</td>
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<td>Conduct planning, workshops and training for the implementation of each workstream</td>
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<td>Staff engagement and assessment of safety culture</td>
<td>Engage staff to provide regular and adequate feedback on injectable medicines errors and risks in use</td>
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<td></td>
<td>Assess safety culture</td>
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<td>Nurses</td>
<td>Provide adequate feedback on errors</td>
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<td>Pharmacists</td>
<td>Liaise with device managers on consumables requirements</td>
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<td>EBME Medical device managers</td>
<td>Conduct needs assessment and assess product range and volume</td>
<td>Standardise procedures for purchasing devices</td>
<td>Standardise procedures for purchasing devices</td>
<td>Correct cost code necessary for when device delivered to trust (delivery box clearly identified as medical device for correct pathway)</td>
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<td>Standardise practice in terms of types of information requested to build in software</td>
<td>Consider quarantine for training (min. % of staff trained before releasing new product)</td>
<td>Coordinate procedure centrally through body (e.g. infusion systems committee, medical device committee) or individual (medical device coordinator)</td>
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<td>Liaise with necessary stakeholders – front end users, purchasing/supplies department, medical equipment library (if available)</td>
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<td>Devices management</td>
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<td>Consult global databases (eg. ECRI, BIME, CEP)</td>
<td>Conduct trials on new standardised potential purchases (devices)</td>
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<td>Conduct ‘show and tell’ day to short list available products, invite front end users to assess products (devices).</td>
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<td>QC/QA PASA, PMSG Pharmacist groups</td>
<td>Joint statement from relevant bodies defining good QA practice in purchasing for safety</td>
<td><strong>QA is critical for ensuring confidence in unlicensed products</strong> Clarify/re-state requirement for QC involvement in buying new, especially unlicensed products Support funding case for QC services &amp; provide access to expertise</td>
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<td>CEP/ BIME</td>
<td>Evaluation agencies to disseminate information and evidence available for cost effectiveness studies</td>
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<td>NICE</td>
<td>Evaluation agencies to manage and disseminate information and evidence available for cost effectiveness studies</td>
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<td>Industry</td>
<td>Provide stability data to trusts</td>
<td>Supply pre-filled syringes with usable information for practitioner.</td>
<td>Cooperate with National purchasing to change the SPC where necessary</td>
<td>Evidence to support changes in approach to improve safety e.g. design solutions for labels and products.</td>
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<td>Evidence to support changes in approach to improve safety e.g. design solutions for labels and products.</td>
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<td>Work with care delivery staff to understand requirements and deliver improvements.</td>
<td>Compatibility of products and systems</td>
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<td>NHS Manufacturing units</td>
<td>Pro-File database content management and regular updating</td>
<td>Trusts need the ability/infrastructure to communicate with each other to facilitate the sourcing of unlicensed product</td>
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Regulators | Function | Trust Purchasing for safety approach (General) | Rationalisation & standardisation (pharmaceuticals) | Centralisation & decision making | Information and labelling | Design and innovation | Technology (bar coding & auto-ID) | Informed purchasing decisions
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MHRA | | 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 (eg using innovative label design, clear technical information leaflets to support safe injectable medicines practice) | | | | Mandate the use of needle free systems for the preparation and administration of high risk drugs | |
| | | Challenge suppliers to change the SPC where necessary. | | | | | |
| | | As new products are introduced, review opportunity to change dosage instructions and SPC | | | | | |

The key objective is to develop a pro-active approach to assessing need and minimising risk. Since multiple stakeholders and agencies are involved representing multiple disciplines, a coordinated and planned approach in communications and role identification is required.

And a joint approach to Purchasing for safety between:
1. National agencies: NPSA, NHS PASA, NICE
2. Local Trusts