Dose banding

1 Summary:

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 batch manufacturing and purchasing for safety initiatives.

The workstream was identified from issues raised by the Chemotherapy focus group in phase 1 of the project. A small multi-professional group was formed to work collaboratively with the East Midlands Re:Source Procurement Hub to identify criteria for dose banding, develop a procurement specification (for the formulation, presentation, labelling and packaging) to tender against the pharmaceutical market.

2 Background:

2.1 Aim and key benefits

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 ready to administer chemotherapy products.

In order to minimize the number of products required and realize 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 harmonized 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

2.2 Workstream summary (see Appendix A)

3 Objectives:

- Review prior experience with dose banding and identify key benefits and issues
- Undertake literature review of dose banding and extent of practice in UK
- Identify suitable products for dose banding together with rationale
- Develop specification to optimise formulation and presentation for safe handling
- Scope market for available licensed and ‘specials’ products from UK
- Work with Re:Source to conduct cost : benefit analysis and procurement strategy
- Maintain progress plan and complete workstream report to present to Pilot Team
- Evaluate chemotherapy product procured against agreed specification (if time)

Methods and measures

3.1 Workstream design

This workstream was designed to work together with the Re:Source procurement hub which was working with NHS Trusts in the East Midlands to prepare a specification for, and let a contract to provide, a range of ready to use chemotherapy drugs for use in dose banding schemes.

3.2 Evaluation(s)

3.2.1 The concept

The dose banding concept has already been evaluated by Trusts and implemented in a number of cancer centres in the UK. While there is a common principal, there is local variation in its application in practice.

3.2.2 The specification

The detail of the specification will be checked by the members of the Re:Source Sourcing Group in conjunction with Trust Pharmacy staff, Cancer network staff and Quality Control Pharmacists
3.2.3 Tenders

Tenders will be evaluated and contracts awarded using standard PASA evaluation techniques which comply with current regulations. Supplier scoring systems will be agreed by the members of the Sourcing Group.

4 Workstream outputs

4.1 Literature review

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

Derby-Burton Cancer Network – Proposal for Dose Banding

4.2 Focus groups

Re:Source Procurement Hub Sourcing Group Minutes (Appendix D)

4.3 Draft specification

See Appendix B

4.4 Evaluations

Audit of Dose Banded Cyclophosphamide at Derby Hospitals (Appendix C)

5 Discussion

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.

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.

It is hoped that the specification developed by the Re:Source NHS Collaborative Procurement Hub for the East Midlands Hospitals can be used elsewhere to given a consistent approach to the sourcing of these products.
It is also hoped that, by working collectively, Hubs and Cancer Networks can bring some degree of standardisation to the range of products required.

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

6 Recommendations

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

7 Acknowledgements

We are grateful for the input of Procurement specialists at the Re:Source NHS Collaborative Procurement Hub and the Pharmacists from the East Midlands who contributed to the development of the specification.

8 References

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

Derby-Burton Cancer Network – Proposal for Dose Banding
Workstream 1: Appendix A – Dose banding

Purpose:

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 suit batch manufacturing and purchasing for safety initiatives.

Aim:

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

Objectives:

1. Review prior experience with dose banding and identify key benefits and issues
2. Undertake literature review of dose banding and extent of practice in UK
3. Identify suitable products for dose banding together with rationale
4. Develop specification to optimise formulation and presentation for safe handling
5. Scope market for available licensed and ‘specials’ products from UK
6. Work with Re:Source to conduct cost : benefit analysis and procurement strategy
7. Maintain progress plan and complete workstream report to present to Pilot Team
8. Evaluate chemotherapy product procured against agreed specification (if time)

Stakeholders:

Lead: Peter Fox, Principal Pharmacist, Procurement
Team: Colin Ward, Directorate Lead Pharmacist – Cancer Services
       Tracy Hickman, Sourcing Manager, Resource
       Members of Re:Source Sourcing Group

Milestones:

Oct 2007 Set up work stream, identify stakeholders, agree brief and action plan
Nov 2007 Objectives 1-3; progress report for Pilot Board (20/11/07)
Dec 2007 Objectives 4-6; meet Re:Source and agree collaborative approach
Jan 2008 Objectives 7-8; present report to Pilot Board; Evaluation (if time)

Measures:

- Input measures  risk:benefit analysis, capacity
- Output measures  cost:benefit analysis, capacity
## Workstream 1: Dose banding

Summary action plan and progress report

<table>
<thead>
<tr>
<th>Ref</th>
<th>Issue</th>
<th>Action(s)</th>
<th>Date started</th>
<th>Date due</th>
<th>Lead</th>
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<tr>
<td>1</td>
<td>Workstream setup</td>
<td>Agree Workstream team, brief, action plan and maintain progress report for monthly Pilot Boards</td>
<td>Oct 2007</td>
<td>Ongoing</td>
<td>Peter Fox</td>
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<td>3</td>
<td>Literature and practice review</td>
<td>Undertake a review of literature and UK practice related to dose banding to inform analysis</td>
<td>Oct 2007</td>
<td>Dec 2007</td>
<td>Colin Ward and Workstream team</td>
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<td>4</td>
<td>Quality Assurance input</td>
<td>To seek input from regional / national QA groups</td>
<td>Nov 2007</td>
<td>Dec 2007</td>
<td>Lara Quatami</td>
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<td>5</td>
<td>Specification</td>
<td>To agree specification for dose banded products across region</td>
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<td>Feb 2008</td>
<td>Peter Fox and Tracy Hickman (Re:Source)</td>
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<td>6</td>
<td>Local Evaluation</td>
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<td>Feb 2008</td>
<td>Feb 2008</td>
<td>Colin Ward</td>
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<td>7</td>
<td>Procurement contract</td>
<td>Hub to develop OJEC advert for provision of dose banded products against agreed specification</td>
<td>Feb 2008</td>
<td>May 2008</td>
<td>Tracy Hickman</td>
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<td>8</td>
<td>Final report</td>
<td>Write up work stream in report template provided and report back to Pilot Board 13.2.08</td>
<td>Dec 2007</td>
<td>Feb 2008</td>
<td>Peter Fox and Workstream team</td>
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### Workstream 1: dose banding

**Monthly progress report:**
- ☐ Oct 2007
- ☐ Nov 2007
- ☐ Dec 2007
- X Feb 2008

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<th>Progress</th>
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<td>Agree Workstream team, brief, action plan and maintain progress report for monthly Pilot Boards</td>
<td>Oct 2007</td>
<td>G</td>
<td>Nov 2007</td>
<td>Monthly progress report to Pilot Board meetings First meeting of Re:Source Project group 6.11.07 Minutes to follow</td>
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<td>4</td>
<td>Need for QC input into specifications identified</td>
<td>Nov 2007</td>
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<td></td>
<td>No support available within timescale. Hub will attempt to award contract without QC input</td>
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<td>Draft specification to be prepared following review of Royal Devon &amp; Exeter Trust’s document</td>
<td>Nov 2007</td>
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<td>Jan 2008</td>
<td>Draft specification circulated to Re:Source group members for comment. Will be passed to PASA project on completion Re:Source group meeting scheduled for 30.1.08</td>
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<td>6</td>
<td>Local evaluation of dose banded product</td>
<td>Feb 2008</td>
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<td>Oct 2007</td>
<td>Evaluation of Cyclophosphamide Dose Banding Attached in Appendix C</td>
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<td>7</td>
<td>Procurement contract for dose banded products</td>
<td>Feb 2008</td>
<td>A</td>
<td>Feb 2008</td>
<td>OJEC advert placed award of contract subject to EU guidance timetable</td>
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<tr>
<td>8</td>
<td>Final workstream report</td>
<td>Feb 2008</td>
<td>G</td>
<td>Feb 2008</td>
<td>Draft of Final report Complete</td>
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</tbody>
</table>

Key: **Blue** - fully implemented; **Green** - good progress / on target; **Amber** - some progress / issues; **Red** - No progress / major issues

**Issues for escalation:**

<table>
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<th>Ref</th>
<th>Issue</th>
<th>Options</th>
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</thead>
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<tr>
<td></td>
<td>Practice different in most Trusts</td>
<td>Can this be standardized? Does it need to be as the contract will be for a service not a product?</td>
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<tr>
<td></td>
<td>Lack of QC Pharmacist support on Re:Source Group Input required for review of product specifications, shelf life etc</td>
<td>Award to be made without QC support – see minutes of Sourcing Group 30.1.08</td>
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</tbody>
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Phase 2 workstream brief – **Appendix A**  
Dose Banding Progress Report  
Updated 12.2.08
Workstream 1: Dose banding  
Appendix B – Final specification:

Specification

Contract for the provision of a service to supply ready to administer chemotherapy products for the member Trusts of Re:Source NHS Collaborative Procurement Hub.

Re:Source NHS Collaborative Procurement Hub is a new NHS purchasing organisation representing the majority of NHS Trusts within the East Midlands region. Further information can be found at www.resource-cph.nhs.uk.

1. **Duration of contract**

   1.1 Unless terminated under the terms of any succeeding clause, the contract shall run for a period of 24 months with an option to extend for a further two 12 month periods. Re:Source reserves the right to terminate by giving not less than 6 months notice in writing. Suppliers may terminate the contract by giving not less than 6 months notice in writing.

   1.2 The contract will commence on xx and shall continue until xx. The contract will have an option to extend for a further two 12 month periods.

2. **Participating customers**

   2.1 This tender is being issued on behalf of the following Trusts (and includes the requirements of Trusts to whom they are currently providing a service). The named Trusts have all participated in the consultation process and have committed to ensure a successful outcome to this tender:

   - United Lincolnshire Hospitals
   - Northampton General Hospital
   - Kettering General Hospital
   - Derby Foundation Hospitals
   - Sherwood Forest Hospitals
   - University Hospitals of Leicester
   - Nottingham University Hospitals

   2.2 Any NHS Trusts which subsequently join Re:Source will have the right to join this contracting arrangement at any point during the life of the contract.
3. **Introduction**

3.1 This specification details the requirements for the provision of a service to supply ready to administer chemotherapy products for use in participating Trusts.

3.2 Participating Trusts within the East Midlands currently have insufficient capacity for the aseptic production of chemotherapy drugs to meet their expanding needs, therefore a supplier(s) are sought to supplement the current service through the provision of a high quality, cost effective service to supply ready to administer chemotherapy products.

3.3 The aim of this tender is to provide a significant improvement in the supply of ready to administer chemotherapy products, and specifically to achieve

- Optimisation of the formulation, presentation and labelling of products to improve safe handling and reduce risks to patients and staff. (This tender forms part of the ‘Purchasing for Safety – Injectable Medicines’ project which is being led by the NHS Purchasing and Supply Agency; therefore there is a particular emphasis on improving safety in the supply, handling and administration of these products)
- Reduced stock inventory
- Regular, managed deliveries of agreed volumes
- Transparent on-cost per unit

3.5 Re:Source, acting on behalf of participating Trusts, reserves the right to award to more than one supplier to achieve the aims of this tender.

4. **Products (including packaging and labelling)**

4.1 A list of the chemotherapy products and an indicative number of units required by the participating Trusts is provided in Appendix 2. The stated numbers of units are based on current usage and expected growth. However they may be subject to change during the life of the contract.

4.2 If an MHRA (Medicines and Healthcare products Regulatory Agency) or EMEA (European Medicines Agency) licensed product becomes available to replace any of the listed products during the life of the contract, the participating Trusts reserve the right to purchase that product in place of the unlicensed product.

4.3 Ready to administer chemotherapy should be manufactured using medicinal components available through NHS Purchasing and Supply Agency (NHS PASA) contracts wherever possible. If NHS PaSA contracts are not accessible, suppliers must indicate their sourcing policy and the costs of medicinal components to be used.
Components without a UK Marketing Authorisation will not be accepted by the participating Trusts.

4.4 Where non-NHS PaSA contract lines are used, suppliers may be requested to provide samples of the components for testing/approval by a Quality Assurance Pharmacist acting on behalf of the participating Trusts. If any components are identified as being unsuitable by the Quality Assurance Pharmacist then they must not be used to manufacture final products for supply within this contract. All component samples for testing/approval will be provided free of charge and will be non-returnable. Samples should only be provided where specifically requested.

4.5 All products must be supplied with a minimum of two thirds of the available shelf life remaining unless otherwise agreed by the ordering Trust. An acceptable shelf life for products that have a short shelf on manufacture (e.g. one month or less) must be agreed with an individual Trust as two thirds may be insufficient.

4.6 Suppliers may be required to provide samples of final products for testing/approval by a Quality Assurance Pharmacist. Suppliers will be notified separately of samples required. All samples for testing/approval will be provided free of charge and will be non-returnable. Samples should only be provided where specifically requested.

4.7 Suppliers are required to describe how they would maintain continuity of supply during periods of unavailability of NHS PaSA contracted medicines or alternative medicine agreed at the start of the contract. No substitution of any component is acceptable unless expressly agreed by the ordering Trust.

4.8 Suppliers must specify if and when they can include barcodes which need to conform to the GS1 standard. Therefore organisations need to be members of (if non NHS) or contact the NHS helpdesk of GS1uk – www.gs1uk.org to facilitate the use of these codes and have software capable of producing high definition barcodes in black ink.

4.9 Suppliers are required to indicate how they plan to manage price variations of active ingredients in line with market conditions to ensure that the Trusts continue to receive value for money (e.g. where generic products become available following patent expiry of a branded medicine).

4.10 All products supplied under this contract must be labelled in accordance with all relevant statutory requirements as a minimum and labelling should be in line with current best practice guidance, i.e. NPSA guidance on the labelling of injectable medicines. Label design and detail will be subject to approval by the participating Trusts, prior to commencement of the contract.
4.11 Secondary packaging is required for all chemotherapy products. Suppliers must ensure that both the product and secondary packaging are labelled.

4.12 All products supplied must be compatible with needle-free systems.

4.13 There may be a requirement for suppliers to provide products with a needle-free system in situ. This option must be available and Trusts will clearly specify where this is a required.

4.14 Trusts may request specific presentations to ensure compatibility with infusion systems in place within their individual Trust.

4.15 Where a pre-filled syringe is specified as the required presentation, the syringe provided must be:

- Polypropylene
- Luer-lok
- Graduated in millilitres

4.16 Where a bag is specified as the required presentation, the bag must be:

- Flexible
- Latex-free

5. **Ordering and delivery**

5.1 Orders will be placed separately by the individual Trusts and payment for goods will be made directly by them.

5.2 Suppliers will need to supply products to the locations as listed in Appendix 1 and specify a standard lead time to enable Trusts to manage their ordering cycles.

5.3 Deliveries may be required 52 weeks of the year, including weeks containing bank holidays. Where delivery charges apply they must be stated in the pricing schedule, with the exception of additional deliveries due to errors or short deliveries by the supplier (which will be free of charge to the participating Trusts).

5.4 Orders should be delivered within normal working hours.

5.5 Suppliers will undertake to maintain all pharmaceuticals at the correct storage temperature for the time they are in the supplier’s care – including maintaining the cold chain where appropriate. Suppliers will be required to provide evidence that the appropriate temperatures have been maintained and that all systems have been validated.
5.6 Suppliers must contact the Trust concerned within 24 hours of receipt of the order if they are unable to supply products within an agreed lead time. They must also provide an explanation of why they are unable to meet the agreed lead time and an alternative delivery date at this time.

5.7 Suppliers will be responsible for ensuring security of delivery to the appropriate delivery point.

5.8 Suppliers should describe how they plan to manage the supply of ready to administer chemotherapy during times of unexpected high and low demand, to aid in inventory management in participating Trusts, e.g.

- Capacity management to manufacture at short notice.

5.9 Suppliers are required to detail any contingency arrangements and disaster plans that they have in place to ensure a continuing service to the Trusts.

5.10 Suppliers are required to state their maximum capacity for aseptically prepared products, their current output and detail any plans to expand this capacity.

6. Packaging (transit)

6.1 All products should be packaged in such a way as to give them adequate protection from damage during transit, e.g. in a semi-rigid container. Participating Trusts reserve the right to return/reject goods, which, upon inspection after delivery, are found to be in an unusable/unacceptable condition.

6.2 The weight of a package should ideally be no more than 10kg, but must not exceed 15kg. Where possible the weight of the package should be indicated on the outside of the container.

6.3 Suppliers are responsible for ensuring that items are packed in a way that does not put the person unpacking products at risk from exposure to cytotoxic products, e.g.

- Adequate labelling on the outer packaging to highlight that the contents are cytotoxic
- Ensuring that products are not packed directly beneath the seal tape where they may be subject to knife damage
- Secondary packaging on all products to capture contents in the event of leakage
- Any other reasonable precautions

6.4 Where different products, i.e. different drugs, strengths, pack sizes and presentations are supplied in the same container, suppliers must ensure that the products are clearly segregated and identifiable.
7. **Quality**

7.1 Suppliers must have a quality control system in place that is acceptable to the participating Trusts. Details of quality control systems must be provided.

7.2 Suppliers are required to describe their batch testing processes and indicate whether this will affect lead times.

7.3 Suppliers are required to provide a Certificate of Conformity for every batch of every product supplied with the respective products at the point of delivery.

7.4 Suppliers are required to provide a formal statement of stability for each product. This statement should include appropriate references and have been independently reviewed.

7.5 A statement that the finished product complies with the relevant general monograph and any appropriate individual monograph of the BP should be made available upon request.

7.6 Trusts reserve the right to carry out an inspection of the suppliers’ premises, methods, documentation and quality control systems prior to the implementation of this contract.

7.7 For the period of the contract the supplier will ensure that they hold suitable MHRA licensed approval for the supply of aseptically prepared, ready to use chemotherapy products. A copy of this license must be provided. Suppliers are required to notify participating Trusts of any changes in their license status within a maximum of 5 working days.

7.8 Suppliers must detail their procedures to ensure that counterfeit medicines do not enter the supply chain.

7.9 Suppliers must advise Trusts if they have supplied products to the Trusts which are subject to an MHRA Drug Alert or Recall. This notification must be communicated to the Trusts immediately on receipt of the Alert and includes all medicines and devices.
7.10 Suppliers must be able to provide a full audit trail for all products supplied on request by the Trusts, within 24 hours of the request.

7.11 Suppliers are required to submit a completed specification sheet for each product that they supply (Appendix 3) for approval by the participating Trusts with their offer.

7.12 Suppliers are required to submit a sample of each of the following products with their offer. The purpose is to examine the presentation only and therefore samples must not contain the active ingredient and should be clearly marked ‘sample’

1. Carboplatin 400mg in 500ml Glucose 5% (bag)
2. Cyclophosphamide 900mg in 45ml (pre-filled syringe)
3. Fluorouracil 3600mg in 115ml (Folfusor SV 2.5)
4. Fluorouracil 2119mg in 89ml (Paragon)
5. Vincristine 2mg in 20ml (pre-filled syringe)
6. Methotrexate 2.5mg on 0.1ml (pre-filled syringe)

8. Customer care

8.1 The supplier will provide details of a liaison officer as a reference point for all routine queries.

8.2 The supplier will provide details of a liaison officer as a reference point for all technical queries.

8.3 The supplier will provide details of the person responsible for managing the contract, who should be sufficiently senior within the organisation to be able to take action as necessary.

9. Estimated quantities

9.1 Any usage requirements detailed are based on past usage and forecast growth, therefore Re:Source cannot be held responsible for any increase/decrease in demand for the listed products.
10. **Supplier performance and monitoring**

10.1 The contract will be subject to review on a regular basis with Re:Source and representatives from participating Trusts to determine if standards of service and quality are being adhered to and to review pricing. The timing of reviews will be agreed on award of the contract.

10.2 Service levels will be measured against an agreed set of performance indicators (Appendix 4). If performance does not meet the agreed service levels a period of 3 months will be given to allow for improvement. If improvement has not been achieved, notice will be given to terminate the contract and the service re-tendered.

11. **Additions to product range**

11.1 Future additions to the product range may be agreed between Re:Source and the supplier(s) during the course of the contract. Any such additions will only be incorporated once Re:Source and the participating Trusts are satisfied that any additional product fully meets all aspects of the contract.

12. **Invoicing and credits**

12.1 Separate invoices shall be raised for each delivery. The invoices will, where possible, detail the items in the sequence shown on the relating order.

12.2 Suppliers must send invoices to the correct invoicing address as advised by the individual Trust.

12.3 Consolidated invoices on a weekly or monthly basis may be preferred and this facility must be available to all participating Trusts on request. Electronic invoicing must be available by suitable means via the NHS Messaging Service

12.4 Suppliers will issue any credits within 5 working days following the resolution of problems.
13. **Sustainability**

13.1 Suppliers are required to provide a copy of their organisation’s environmental policy with their offer. Suppliers should detail how their organisation is addressing environmental and sustainability issues in relation to this contract.

13.2 Suppliers are required to indicate how they will manage their stocks so as to meet the needs of this contract, while minimising the amount of waste product.

14. **Returns policy**

14.1 Suppliers are required to provide details of their goods returns policy, which will comply with the current standards for Good Distribution Practice as a minimum.

15. **Contract implementation/change management**

15.1 Suppliers are required to describe the arrangements and timetable they propose to fully service this contract. This should include an implementation plan and assistance in switching suppliers.
### Appendix 1 – Delivery locations

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<thead>
<tr>
<th>Member Trust Name</th>
<th>Delivery Location(s)</th>
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<tr>
<td>Derby Hospitals NHS Foundation Trust</td>
<td>(1) Pharmacy Store, Derbyshire Royal Infirmary, London Road, Derby, DE1 2QY&lt;br&gt;(2) Pharmacy Store, Level 1, Kings Treatment Centre, Derby City General Hospital, Uttoxeter Road Derby, DE22 3NE</td>
</tr>
<tr>
<td>Nottingham University Hospitals NHS Trust</td>
<td>(3) Pharmacy Stores, Nottingham University Hospitals NHS Trust, City Hospital Campus, Hucknall Road, Nottingham, NG5 1PB&lt;br&gt;(4) Pharmacy Stores, Queens Medical Centre, Nottingham University Hospitals NHS Trust, Derby Road, Nottingham, NG7 2UH</td>
</tr>
<tr>
<td>Sherwood Forest Hospitals NHS Foundation Trust</td>
<td>(5) Pharmacy Department, King’s Mill Hospital, Mansfield Road, Sutton-In-Ashfield, Nottinghamshire, NG17 4JL</td>
</tr>
<tr>
<td>University Hospitals of Leicester NHS Trust</td>
<td>(6) Leicester Royal Infirmary, Pharmacy Stores, Gate 9, Havelock Street, Leicester, LE1 5WW&lt;br&gt;(7) Leicester General Hospital, Pharmacy Stores, Gwendolen Road, Leicester, LE5 4PW&lt;br&gt;(8) Glenfield Hospital, Pharmacy Stores, Groby Road, Leicester, LE3 9QP</td>
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</tbody>
</table>
| United Lincolnshire Hospitals NHS Trust | (9) Pharmacy, Lincoln County Hospital, Greetwell Road, Lincoln, Lincs, LN2 5QY.  
| Kettering Hospital | (11) Pharmacy Department, Kettering General Hospital, Rothwell Road, Kettering, Northants, NN16 8UZ  
| Northampton General Hospital | (12) Pharmacy Stores, Northampton General Hospital, Cliftonville, Northampton, Northants, NN1 5BD |
Workstream 1: Dose Banding
Appendix C - Detailed *Evaluation* findings:

Audit of commercial dose banded Cyclophosphamide PFS v aseptically dispensed individually dosed Cyclophosphamide.

Introduction:

The chemotherapy day unit at the Derbyshire Royal infirmary is amongst one of the busiest units within the hospital. The satellite pharmacy is based on the day unit and is dedicated to providing both a cytotoxic CIVA service and oral medication dispensing service.

Reduced waiting times have been targeted in accordance with the NHS cancer plan. This has caused more pressure on the day unit staff to treat as many patients as possible thus creating added pressure on the pharmacy team to manufacture and deliver chemotherapy on time.

Dose banded, commercially sourced chemotherapy was one option chosen to help relieve some of the pressure on both nursing and pharmacy staff to allow the increased workload to be handled efficiently and safely.

Audit:

Cyclophosphamide was the drug chosen for the dose banding pilot due to fact it was the most time costly drug to prepare aseptically. Commercial stock was sourced and dispensed in accordance with local dispensing procedures. To evaluate if dispensing time was being saved, times were recorded over a two week period -

- Dispensing a regimen aseptically (including Cyclophosphamide).
- Dispensing a regimen aseptically (excluding Cyclophosphamide) and dispensing dose banded commercially sourced Cyclophosphamide

Results:

The graph below shows the average time to dispense each chemotherapy regimen using aseptically dispensed Cyclophosphamide (pre dose banding) and commercially sourced dose banded Cyclophosphamide (post dose banding).
The table below shows the average time taken to dispense a Cyclophosphamide containing regimen pre and post dose banding and the average time saved.

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Dispensing time Pre dose banding (minutes)</th>
<th>Dispensing time Post dose banding (minutes)</th>
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<tr>
<td>RCHOP</td>
<td>35</td>
<td>19.5</td>
<td>15.5</td>
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The overall average time taken to dispense a Cyclophosphamide containing regimen pre and post dose banding are shown below.
By implementing a dose banding pilot, on average, the time taken to dispense a chemotherapy regimen containing Cyclophosphamide has been reduced from 29.5 minutes to 15 minutes which equates to a saving of 14.5 minutes per regimen.

Conclusion:

The dose banding pilot has proven to be effective on meaningfully reducing dispensing time.

The time gained has helped the satellite respond quicker to inpatient chemotherapy requests. With the demand of delivering chemotherapy to the clinic environment, inpatient chemotherapy was always left to the latter part of the day but now it can be implemented and delivered safely within our daily time constraints.

Advances have been made in oral chemotherapy, allowing patients to be treated at home, reducing IV administration incidents and freeing administration time. However this involves additional workload for the cancer team. Time saved by implementing dose banded commercially available Cyclophosphamide will allow the team to safely deliver the increased demand for oral chemotherapy.

This pilot has also involved a change in nursing practice. Although this has not been formally evaluated, anecdotally, the feedback has been positive.

Future developments:

This pilot has demonstrated the time savings to be made with dose banded commercially available products and supports further usage and expansion (e.g. 5-Fluorouracil, Oxaliplatin, Rituximab, Epirubicin).
Workstream 1: Dose banding
Appendix D – Sourcing group minutes

Sourcing Group – Unlicensed Specials, Chemotherapy Dose-Banding Minutes
6th November 2007

Present:

Tracy Hickman, Sourcing Manager, Re:Source procurement Hub (chair)
Jane Page, University Hospitals of Leicester
Ruth Wilne, United Lincolnshire Hospitals
Peter Fox, Derby Hospitals
Alan Sayers, Sherwood Forest Hospitals
Christine Clarke, University Hospitals of Leicester
David Lovett, University Hospitals of Leicester
Adrian Fairbrother, Northampton General Hospital

In attendance:

Liessa Newnham, Business Development Manager, re:source
Tracey Duggan, Category Assistant, re:source
Andrew Wilson, Purchasing Manager, re:source
Lorraine Sheriff, Data Analyst, re:source

Apologies:

Scott Hillery, Kettering General Hospital
Colin Ward, Derby Hospitals
Sarah Pacey, Nottingham University Hospitals

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<tr>
<th>Discussion Ref</th>
<th>Discussion</th>
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<tbody>
<tr>
<td>1</td>
<td>Welcome, Introductions &amp; Apologies</td>
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<tr>
<td></td>
<td>TH welcomed the group. Introductions were made and apologies noted.</td>
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<tr>
<td>2</td>
<td>Project Definition and Scope</td>
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<td></td>
<td>The group discussed the scope of the project and agreed that this tender exercise should cover chemotherapy products only. Other medicines may be considered at a later date, depending on the learning from the chemotherapy project</td>
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<td>3</td>
<td>Purchasing for Safety, Injectable Medicines Project</td>
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<td></td>
<td>PF and RW gave an update on the progress of the project at Derby Hospitals and United Lincolnshire Hospitals. PF explained how the unlicensed medicines tender links into the project. The group agreed that the main focus of the project should be on quality and safety.</td>
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<td>4</td>
<td>Dose Banding</td>
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Methodologies

The group highlighted that the systems were different for each trust; however the national group were looking to produce a toolkit.

It was highlighted that the Scottish Consortium had recently completed a similar project; however the volume did not seem to make any difference to the banding.

Thames Valley had also been out to tender and savings had been achieved. TH to investigate their approach.

TH queried if it was possible for the sourcing group to decide the way the East Midlands dose band. It was agreed that this would require wider clinical consultation and should not be within the remit of the Sourcing Group.

Range of Products

The group agreed to email TH with a list of products and doses, in addition to any plans to expand usage. CC to provide information for Northampton, Kettering and Leicester.

Specification Development

The group went through the sample specification and made amendments. TH to update and email to the group for confirmation.

The group agreed that the following were also important to the region and needed to be included in the specification:

- Turnaround times
- Delivery
- Liability – chase back to the originator
- Stability data – to be independently review
- Reporting or errors
- Packaging
- Labelling
- Copy of licence

A discussion took place regarding the QC of the products and the lack of QA pharmacist support within the East Midlands region. TH to discuss with PaSA under the purchasing for safety projects.

The group continued looking at the scope of the project and whether the tender would specify geographical areas or if suppliers would need to be product specific. It was agreed that the group would not specify in the tender and that it would be the suppliers who would need to make suggestions.

TH highlighted to the group that she had previously been approached by Baxter who wanted to set up a compounding unit in the East Midlands, preferably Leicester. The group agreed that this would be something to look at in the future but would concentrate on the current usage for the moment.
CC also highlighted that Clinovia had also shown interest in setting up a unit in the region to actually give the chemo to patients.

DL to fax through any previous sample specifications to 0115 979 5362.

**Baseline Data**

TH noted that the data could be retrieved from Pharmex but would need to be validated by participating Trusts.

The group highlighted that they all had pricing agreements in place but no contract, apart from United Lincolnshire Hospitals who were working from an expired contract.

### 5. Any Other Business

Nothing to report

### 6. Date and Time of Next Meeting

Tbc

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<tr>
<th>5</th>
<th>Any Other Business</th>
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<td>Nothing to report</td>
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<th>6</th>
<th>Date and Time of Next Meeting</th>
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Phase 2 workstream Findings – **Appendix D**

Dose Banding

Feb 2008
Sourcing Group – Unlicensed Specials, Chemotherapy Dose-Banding Minutes  

30th January 2008

Present:

Tracy Hickman, Sourcing Manager, re:source procurement Hub (chair)  
Jane Page, University Hospitals of Leicester  
Peter Fox, Derby Hospitals  
David Lovett, University Hospitals of Leicester  
Scott Hillery, Kettering General Hospital  
Jill Theobald, Sherwood Forest Hospitals

In attendance:

Andrew Wilson, Purchasing Manager, re:source

Apologies:

Colin Ward, Derby Hospitals  
Sarah Pacey, Nottingham University Hospitals  
Christine Clarke, University Hospitals of Leicester  
Adrian Fairbrother, Northampton General Hospital  
Alan Sayers, Sherwood Forest Hospitals  
Rena Chauhan, Nottingham University Hospitals  
Ruth Wilne, United Lincolnshire Hospitals

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<tr>
<td></td>
<td>TH welcomed the group. Introductions were made and apologies noted.</td>
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<td>2</td>
<td>Baseline</td>
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|                | TH explained that baseline information from Pharmex had been issued to each Trust for validation. A number of responses had been received. PF provided information for Derby at the meeting. Validation of Sherwood Forest Hospitals data is still outstanding. JT/AS to provide validation. | JT/AS  
|                | The group reviewed the product list (Appendix 2). TH to confirm diluent for Cyclophosphamide – 100ml bags for relevant Trust | TH  
|                | Possible future additions to product range to be amended to include Irinotecan. | TH  
|                | Methotrexate pre-filled syringes to be amended to exclude all licensed preparations. | TH  
|                | TH to check Pharmex data against information provided by CC on Leicester, Northampton and Kettering usage. | TH  
|                | Baseline figures to be revised based on validated data. | TH  

Phase 2 workstream Findings – Appendix D  
Dose Banding  
Feb 2008
The group discussed the current suppliers and other suppliers in the market. It was suggested that NHS production units should be made aware of the tender through Tim Root. AW to ensure all suppliers are aware of the tender.

## 3 Tender Specification

TH circulated a compilation of the comments received from the group regarding the tender specification and the group discussed each point in turn. TH to amend the specification accordingly. (see below for amended version).

The group discussed timescales for the project. AW to add contract start date to the specification once a timetable for the tender has been established and a procurement process has been decided upon (e.g. open, restricted, etc). AW to confirm project timescales with the group.

The group questioned liability. AW to check Terms and Conditions and report back to the group.

AW circulated a document with Key Performance indicators for discussion. (see below for agreed indicators)

## 4 Tender Evaluation Criteria

The group discussed the criteria on which the tender should be evaluated. TH highlighted that offers can only be evaluated against elements included in the specification.

The agreed criteria were:

- Commercial (Total cost) – 40%
- Technical (Ability to meet specification) – 60%

## 5 Savings methodology

The group agreed that savings should be calculated as follows:

**Forecast/Opportunity Delivered**

(Current Price – New Price) x Existing Volumes

**Benefits Tracked**

(Current Price – New Price) x Actual Volumes (to be obtained through**
<table>
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<tr>
<th>6</th>
<th><strong>QA Pharmacist Requirements</strong></th>
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<tr>
<td>TH informed the group that the Purchasing for Safety Project Board had been contacted regarding the provision of QA Pharmacist support for the project, but that no support was available through this route.</td>
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<tr>
<td>The group agreed that the tender should be issued without input from a QA Pharmacist to avoid further delay to the project.</td>
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<td>JP has prepared a paper detailing QA Pharmacist requirements which has been forwarded to Richard Bateman for discussion at the next National QA Pharmacists Group meeting. JP to feedback to the group at the next meeting.</td>
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<td>JP</td>
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<th>7</th>
<th><strong>Any Other Business</strong></th>
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<tr>
<td>AW confirmed that the advert for the tender should be issued within two weeks of the meeting. AW to inform the group members once the advert has been issued.</td>
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<td>AW to develop pricing schedule for tender, which is to include an additional column for needle-free systems</td>
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<td>AW</td>
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<th>8</th>
<th><strong>Date and Time of Next Meeting</strong></th>
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<tr>
<td>To be confirmed</td>
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<td>AW</td>
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