

Risk assessment of parenteral product preparation across secondary care acute trusts in the north of England

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- **OBJECTIVE** — To assess the extent of, and the risks posed by, the preparation of parenteral products in secondary care acute trusts in the north of England.
- **METHODS** — The frequency of preparation in near-patient clinical areas of a range of high risk parenteral products was assessed by ward-based pharmacy staff, using standard data collection forms. The total number of doses of parenteral products of all risk ratings prepared within all NHS pharmacy parenteral preparation units in the north of England was reviewed.
- **SUBJECTS AND SETTING** — Secondary care acute trusts covered by the Local Review Group (North). All near-patient clinical areas where parenteral products are prepared. All NHS pharmacy parenteral preparation units.
- **OUTCOME MEASURES** — Measurement of the extent of high risk parenteral product preparation being undertaken in near-patient clinical areas. Comparison with the total output of services provided by the pharmacy parenteral preparation units.
- **RESULTS** — A total of 1.2 million doses of high risk preparations were prepared in near-patient clinical areas per annum. The total number of products in all risk categories prepared in pharmacy parenteral preparation units was 2.3 million doses per annum.
- **CONCLUSIONS:** Improvements in patient safety may be gained by the optimisation of pharmacy manufacturing and preparation services. Optimising such services will need to be an ongoing, collaborative and multidisciplinary process.

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In 1976, the **Breckenridge report** noted the risks associated with the preparation of parenteral products in near-patient clinical areas.¹ Since then, many adverse incidents have occurred following errors in the preparation and administration of parenteral products.² The incidence of errors in ward-based intravenous drug preparation has been shown to be high and, although the consequences of most of these errors are minor, some errors will result in serious patient harm.³ The environment in wards in the locations where the preparation of parenteral products has been carried out has been shown to be of variable quality and to present a risk of product contamination.^{4,5} The recommendation of the Audit Commission in its report, “A spoonful of sugar,” was that parenteral products should be prepared under pharmacy control.

The identification and transfer to pharmacy control of the preparation of all high-risk parenteral products is therefore a key target for the NHS manufacturing and preparation service. Hence, the Modernisation of NHS Medicines Manufacturing and Preparation National Implementation Board commissioned a risk assessment project in June 2004.

The overall aim of this project was to gather data to enable broad, generalisable recommendations to be made to managers and staff at pharmacy parenteral preparation units about the number and types of products they should be preparing, based on the relative risk potential for each product. (Pharmacy parenteral preparation units include licensed manufacturing units, licensed centralised intravenous additive units and unlicensed aseptic dispensing units operating under a “Section 10” exemption.) The intention was to answer the following:

- What is the extent of preparation of high risk parenteral products in near-patient clinical areas in secondary care acute trusts in the north of England?
- How does this compare with output from pharmacy parenteral preparation units?
- What degree of overlap is there between the high-risk products prepared in near-patient clinical areas in trusts in the north of England?

The project was undertaken by the Local Review Group (north) (LRGN) and was hosted at Leeds Teaching Hospitals NHS Trust.

Method

All 51 secondary care acute trusts in the area covered by the LRGN were invited to participate in the data collection. Data collection was carried out in three phases.

Phase 1 The preparation of products in eight high risk product categories (listed in Table 1, p59) were evaluated in Phase 1.

Data were collected on the number of doses in each category prepared in near-patient areas. Data collection was performed by pharmacy staff as a series of three 24h “snapshots” during the course of their regular ward visits. Where near-patient clinical areas were not regularly visited (eg, theatre or X-ray departments), then special visits or liaison with staff working in these areas was arranged. During data collection, staff were asked to indicate the category of the product being prepared (eg, epidural) and, if possible, to identify the product itself (eg, diamorphine in bupivacaine).

Data collection documents and methods were piloted in two trusts — a medium sized non-teaching trust (Doncaster and Bassetlaw Hospitals NHS Trust) and a large, teaching trust (Leeds Teaching Hospitals NHS Trust). Data were collected from December 2004 to March 2005.

The resulting data were used to estimate annual use figures, taking into account participation rates and the relative activity of different trusts using data based on finished consultant episodes (FCEs). These annual estimates were checked by comparing them with computer-generated issue data.

Data were also collected on the number of adult and paediatric parenteral nutrition products prepared at pharmacy parenteral preparation units. Actual data were collected from batch production records. Adjustments for missing data were made, based on participation rates and FCEs.

Phase 2 The preparation in near-patient clinical areas of 48 “high” or “high/medium” risk products, which are not part

of any of the high risk product categories studied in Phase 1, was evaluated in Phase 2. The products (listed in Panel 1) were selected with reference to previous published^{5,6} and unpublished risk assessment work carried out in a total of six trusts, including teaching and non-teaching hospitals. These drugs were chosen not only because they have been assessed to be of high or high/medium risk but also because they are widely used in clinical practice. Two study days, attended by chief pharmacists and aseptic managers from a variety of trusts, were held during the development of the lists to ensure wide consultation.

Following a pilot at Doncaster and Bassetlaw Hospitals NHS Trust, data were collected from March to July 2005. Actual data were collected and annual estimates were made in the same way as for Phase 1.

Phase 3 In Phase 3, the total output of pharmacy parenteral preparation units was evaluated. Data relating to the preparation of (a) non-parenteral nutrition adult products and (b) non-parenteral nutrition paediatric products were collected using batch and preparation records from March to July 2005. Adjustments for missing data were made, based on participation rates and FCEs.

Data handling An Access database was developed by the pharmacy information technology department at Leeds Teaching Hospitals NHS Trust. Data from the three phases were added to the database and analysed. A series of reports was developed in order to facilitate analysis.

Results

Participation The participation rate varied between each data collection phase — the highest was 82 per cent in Phase 1 and the lowest was 69 per cent in Phase 3.

Product preparation in near-patient areas A summary of the number of products in each of the eight high-risk drug categories (Phase 1) and the 48 named high and medium/high risk drugs (Phase 2) prepared in near-patient areas is set out in Table 1.

Information about the numbers and types of specific (a) epidural products (b) intrathecal products and (c) potassium-containing solutions prepared in near-patient areas is given in Tables 2 (p60), 3 (p61) and 4 (p62–3).

The following additional information should be noted:

- For cytotoxic products, the “Mito-in” reconstitution and administration device⁷ (ie, mitomycin bladder irrigation) accounted for about 64 per cent of products prepared in near-patient areas.
- The other cytotoxic products prepared were: 5-fluorouracil intravitreal injection, methotrexate, intra-articular injection, methotrexate intramuscular injection (for ectopic pregnancy), methotrexate intravenous injection (for ectopic pregnancy) and cyclophosphamide intravenous injection (for vasculitis).
- Preparation of adult parenteral nutrition bags in near-patient areas mainly

Panel 1: High or high/medium risk products studied in Phase 2

Drug name	Presentation
Abciximab	Syringe
Acetylcysteine	Infusion bag
Aciclovir	Infusion bag
Adrenaline	Syringe
Alfentanil	Syringe
Alteplase	Infusion bag
Aminophylline	Infusion bag
Amiodarone	Infusion bag
Amphotericin (Fungizone)	Infusion bag
Amphotericin (AmBisome)	Infusion bag
Azathioprine	Infusion bag
BCG	Instillation device
Ceftazidime	Infusion bag
Ciclosporin	Infusion bag
Clarithromycin	Infusion bag
Clonidine	Syringe
Co-trimoxazole	Infusion bag
Desferrioxamine	Infusion device
Disopyramide	Infusion bag
Dobutamine	Syringe
Dopamine	Syringe
Dopexamine	Syringe
Epoprostenol	Infusion bag
Erythromycin	Infusion bag
Ganciclovir	Infusion bag
Gentamicin (once daily doses)	Infusion bag
Glycerol trinitrate	Syringe
Hydralazine	Syringe
Iloprost	Syringe
Infliximab	Infusion bag
Insulin (soluble)	Syringe
Iron dextran	Infusion bag
Lymphoglobulin (equine antilymphocyte globulin)	Infusion bag
Magnesium sulphate	Infusion bag
Methylprednisolone	Infusion bag
Morphine sulphate	Syringe
Mycophenolate	Infusion bag
Noradrenaline	Syringe
Pamidronate	Infusion bag
Phenytoin	Syringe
Remifentanyl	Syringe
Sodium fusidate	Infusion bag
Sodium nitroprusside	Infusion bag
Streptokinase	Infusion bag
Teicoplanin	Infusion bag
Thymoglobulin (rabbit antithymocyte globulin)	Infusion bag
Vancomycin	Infusion bag
Vecuronium	Syringe

All products are intravenous, except BCG (Bacillus Calmette-Guérin), which is intravesicular, and desferrioxamine, which is subcutaneous

Table 1: Summary of product preparation in near-patient clinical areas

Data collection phase	Product category (Phase 1) or product type	Number of doses prepared in near-patient areas (actual data)	Number of doses prepared in near-patient areas (estimated data)
Phase 1	Cytotoxics	1,192	
Phase 1	Adult parenteral nutrition feeds	3,615	
Phase 1	Paediatric parenteral nutrition feeds	537	
Phase 1	Intrathecal/epidural preparations	61,892	
Phase 1	Potassium-containing solutions	108,197	
Phase 1	Intraocular injections	15,136	
Phase 1	Eye drops/eye irrigations	20,380	
Phase 1	Cardioplegia solutions	2,933	
	Subtotal	213,882	235,270
Phase 2	The 48 “high” or “medium” risk drugs listed in Panel 2	813,160	992,055
	Total		1,227,325

Only doses described as “intraocular”, “intracameral” or “intravitreal” were included in the intraocular product category — doses described as “periocular” (eg, given by subconjunctival injection) were excluded.

consisted of the addition of vitamins and trace elements to pre-made bags.

- For intraocular injections, cefuroxime intracameral injection, in either sodium chloride 0.9 per cent or balanced salt solution, accounted for about 86 per cent of products prepared in near-patient areas.
- Most of the preparation of eye drops in near-patient areas involved the use of kits assembled and supplied by pharmacy staff. For eye irrigations, the most common preparations involved additions to balanced salt solution.

Product preparation in pharmacy parenteral preparation units The total number of products prepared in pharmacy parenteral preparation units in the north of England was 2,269,000 units per annum. Parenteral nutrition output (Phase 1) was 129,000; adult non-parenteral nutrition products (Phase 3) was 1,854,561; and paediatric non-parenteral nutrition products (Phase 3) was 285,610.

Discussion

It is clear that high risk products are still being prepared in near-patient clinical areas at hospitals in the north of England. The extent of such preparation varies between product categories and types, as well as between trusts.

Relatively few parenteral nutrition feeds are prepared in near-patient clinical areas. However, that any are prepared in this way is of concern, because these products usually contain lipid emulsion and are infused over extended periods (typically 24h) at room temperature, making them particularly susceptible to microbial growth.⁸

Other high-risk products being prepared in near-patient areas that ideally should not be include cefuroxime intracameral injection (in either sodium chloride 0.9 per cent or balanced salt solution). This requires two dilution stages and seven manipulations, giving it an overall risk score of 33 (a high score) using the Newcastle Risk Assessment Tool.⁶

Table 2: Examples of epidural products prepared in near-patient clinical areas in trusts in the north of England

Product	Number prepared (per annum)
Alfentanil 2.5mg in 0.1% bupivacaine 250ml	513
Bupivacaine 0.25%	135
Bupivacaine 0.5%	20
Bupivacaine 0.125%	300
Bupivacaine 0.5% heavy	1,300
Clonidine 1.5 microgram/ml in bupivacaine 0.125%	40
Clonidine 150–300 micrograms in bupivacaine 0.08% 500ml	5
Clonidine 150–300 micrograms in bupivacaine 0.125% 250ml	5
Clonidine 1 microgram/ml in levobupivacaine 0.125%	104
Diamorphine 3mg in 3ml	200
Diamorphine 50mg in bupivacaine 0.1% 500ml	280
Diamorphine in bupivacaine miscellaneous	150
Diamorphine in bupivacaine	45
Diamorphine 5mg in bupivacaine 0.1% 400ml	500
Diamorphine 5–10mg in bupivacaine 0.08% 500ml	1,400
Diamorphine 30mg in bupivacaine 0.1% 500ml	83
Diamorphine 20mg in bupivacaine 0.1% 500ml	447
Diamorphine 20mg in bupivacaine 0.1% 250ml	30
Diamorphine 10mg in bupivacaine 0.1% 250ml	130
Diamorphine 15mg in bupivacaine 0.1%	83
Diamorphine in ropivacaine	5
Diamorphine or fentanyl in lidocaine	7
Fentanyl 100 microgram in 2ml	1,500
Fentanyl 0.8 microgram/ml in bupivacaine 0.1%	30
Fentanyl 1,000 micrograms in bupivacaine 0.1% 250ml	15
Fentanyl 2 microgram/ml in bupivacaine 0.1%	265
Fentanyl 2 microgram/ml in bupivacaine 0.1% 100ml	1,464
Fentanyl 2 microgram/ml in bupivacaine 0.1% 10–20ml bolus	308
Fentanyl 2 microgram/ml in bupivacaine 0.15% 250ml	680
Fentanyl 50 microgram in bupivacaine 0.125% 20ml	480
Fentanyl in bupivacaine	256
Fentanyl in lidocaine	200
Levobupivacaine 0.25% 5–10ml	1,500
Levobupivacaine 0.5% 3ml	1,500
Methylprednisolone 80mg in levobupivacaine 0.5% 10ml	250
Morphine/adrenaline/bupivacaine 0.25% mixtures	40
Pethidine 100mg in 50ml sodium chloride 0.9%	20
Steroid unspecified	7
Triamcinolone 40mg in bupivacaine 0.125% 20ml	150
Triamcinolone 40mg in lidocaine 1% 20ml	30
Total	14,477

Data relate only to instances where it was possible to identify the product (and not just the product category) being prepared and totals are therefore not the same as in Table 1.

Table 3: Examples of intrathecal preparations prepared in near-patient clinical areas at trusts in the north of England

Product	Number prepared (per annum)
Baclofen various doses	84
Bupivacaine 0.5%	1,670
Diamorphine 0.5–3mg in water for injections	520
Diamorphine 400 micrograms in 0.4ml	800
Diamorphine 5mg in water for injections 5ml	150
Diamorphine 300–500 micrograms in bupivacaine 0.5% plain or heavy	694
Diamorphine 300 micrograms in bupivacaine 0.5% up to 4ml	886
Diamorphine 5mg/ml in bupivacaine 0.5%	390
Diamorphine 300 micrograms in bupivacaine heavy 0.5% up to 4ml	3,603
Fentanyl 25–30 micrograms in bupivacaine 0.5% plain or heavy	200
Fentanyl 25 micrograms in bupivacaine 0.5% up to 4ml	425
Fentanyl 25–100 micrograms in bupivacaine heavy 0.5%	23
Fentanyl 25 micrograms in levobupivacaine	175
Levobupivacaine 0.25% 5–10ml	1,500
Midazolam 2mg in glucose 5% to 3ml	150
Morphine 360mg	10
Morphine preservative free 10mg in 10ml sodium chloride 0.9%	50
Triamcinolone 40mg in lidocaine 2% 5ml	30
Triamcinolone in lidocaine miscellaneous doses	30
Vancomycin intraventricular	1
Total	11,391

Intrathecal chemotherapy injections are not included. Data relate only to instances where it was possible to identify the product (and not just the product category) being prepared and totals are therefore not the same as in Table 1.

For potassium-containing solutions, guidelines from the National Patient Safety Agency (NPSA) state that “commercially prepared ready to use diluted solutions should be used wherever possible” and “where there is a requirement for potassium solution in a dilution which is not available commercially . . . the solution should be prepared in the hospital pharmacy wherever possible”.⁹ Particular problems are encountered with the preparation of potassium phosphate solutions in near-patient areas, because two different strengths of the concentrated solution from which dilutions are made are available.¹⁰

That an average of 2,639 (based on the data from the 41 trusts that participated in

Phase 1) doses per trust per annum are being prepared in near-patient areas is of concern. Only one trust (Royal Liverpool and Broadgreen University Hospitals NHS Trust) has stopped the use of concentrated potassium-containing solutions in near-patient clinical areas completely.¹¹

It should be noted that, for cytotoxics, a risk assessment carried out by Quality Control North West concluded that provided the Mito-in device (cytotoxic) is used in accordance with its licence, its preparation in near-patient clinical areas is associated with a medium (rather than a high) level of risk (personal communication). Preparation of this product in a pharmacy unit or department is therefore desirable, but not essential.

Use of this device is increasing because of the clinical need to administer the drug close to the time of surgery,¹² making it difficult for pharmacy staff to provide the product in a ready-to-use format.

Apart from the Mito-in device, all preparation of cytotoxics in near-patient areas occurred in departments other than oncology or haematology. On one hand, this is encouraging, because cytotoxics are no longer being prepared in haematology and oncology departments, meaning that production in near-patient areas is minimal. On the other hand, it is worrying, because staff working in other departments are perhaps less likely to have the knowledge and skills required to handle cytotoxics safely and to ensure that the drugs are provided in a suitable presentation.

Variety of products prepared in near-patient areas There is a wide variation between trusts in the types of products being prepared in near-patient areas. For example, only five of the 40 different types of epidural product were prepared in more than one trust (diamorphine in bupivacaine, diamorphine 20mg in bupivacaine 0.1% 500ml, diamorphine 10mg in bupivacaine 0.1% 500ml, fentanyl 2 microgram/ml in bupivacaine 0.1% 100ml and fentanyl 2 microgram/ml in bupivacaine 0.1%). Four different clonidine and local anaesthetic mixtures and 32 different opiate and local anaesthetic solutions were reported.

For intrathecal preparations, there seems to be a greater degree of uniformity of formulation — diamorphine 300 micrograms in bupivacaine heavy 0.5 per cent was used by five trusts, with minor variations (for example, plain bupivacaine with diamorphine) being used by another four trusts.

The number of different intravenous solutions of potassium chloride reported in use was 53 and this does not include unspecified “miscellaneous” doses. As for all the high risk category products, clinical review is needed to determine the need for such a diverse range of preparations and to assess the potential for minimising risk by standardising practice where possible. In particular,

Table 4: Examples of potassium-containing solutions prepared in near-patient clinical areas at trusts in the north of England (continued on p63)

Product	Presentation	Number prepared (per annum)
Intravenous potassium chloride-containing solutions		
Potassium chloride 100mmol in sodium chloride 0.9% 1,000ml	Bag	5
Potassium chloride 10mmol in glucose 10%/sodium chloride 0.18% 500ml	Bag	5
Potassium chloride 10mmol in glucose 2.5 %/sodium chloride 0.45% 500ml	Bag	2
Potassium chloride 10mmol in sodium chloride 0.45% 500ml	Bag	5
Potassium chloride 120mmol in sodium chloride 0.9% 1,000ml	Bag	3
Potassium chloride 120mmol in sodium chloride 0.9% 250ml	Bag	1,000
Potassium chloride 13mmol in glucose 5% 500ml	Bag	30
Potassium chloride 20–40mmol in sodium chloride 0.9%	Bag	290
Potassium chloride 20–40mmol in glucose 5%/sodium chloride 0.45%	Bag	52
Potassium chloride 20–40mmol in glucose 10% 500ml	Bag	2
Potassium chloride 20–40mmol in glucose 5%/sodium chloride 0.45% 500ml	Bag	400
Potassium chloride 20–40mmol in glucose 10%/sodium chloride 0.18% 500ml	Bag	100
Potassium chloride 20–40mmol in glucose 5%/sodium chloride 0.45% 1,000ml	Bag	300
Potassium chloride 20–40mmol in Hartmann's 1,000ml	Bag	200
Potassium chloride 20–40mmol in sodium chloride 0.9% 500ml	Bag	30
Potassium chloride 20–60mmol in glucose 5% 500ml	Bag	7
Potassium chloride 20mmol in glucose 20% 500ml	Bag	88
Potassium chloride 20mmol in sodium chloride 0.9%	Bag	20
Potassium chloride 20mmol in glucose 10% 1,000ml	Bag	1
Potassium chloride 20mmol in glucose 4%/sodium chloride 0.18% 1,000ml	Bag	43
Potassium chloride 20mmol in glucose 4%/sodium chloride 0.18% 500ml	Bag	3
Potassium chloride 20mmol in sodium chloride 0.45% 500ml	Bag	5
Potassium chloride 20mmol in sodium chloride 0.9% 100ml	Bag	12
Potassium chloride 30mmol in glucose 4%/sodium chloride 0.18% 500ml	Bag	146
Potassium chloride 40mmol in sodium chloride 0.9% 50ml	Bag	20
Potassium chloride 40mmol in glucose 5% 1,000ml	Bag	104
Potassium chloride 40mmol in glucose 5% 100ml	Bag	30
Potassium chloride 40mmol in sodium chloride 0.9% 250ml	Bag	3
Potassium chloride 40mmol in sodium chloride 0.9% 100ml	Bag	1,052
Potassium chloride 60mmol in dextrose saline 1,000ml	Bag	250
Potassium chloride 60mmol in sodium chloride 0.9% 1,000ml	Bag	18
Potassium chloride 60mmol in 50ml	Bag	13
Potassium chloride 80mmol in sodium chloride 0.9% 1,000ml	Bag	20
Potassium chloride 80mmol in Hartmann's 1,000ml	Bag	134
Potassium chloride 80mmol in sodium chloride 0.9% 500ml	Bag	16
Potassium chloride miscellaneous doses	Bag	1,353
Potassium chloride 100mmol in 50ml	Syringe	2,334
Potassium chloride 10–20mmol in glucose 5%	Syringe	540
Potassium chloride 10mmol	Syringe	1,100
Potassium chloride 10mmol in 50ml sodium chloride 0.9%	Syringe	17
Potassium chloride 20mmol in 10ml	Syringe	4,500
Potassium chloride 20mmol in 20ml sodium chloride 0.9%	Syringe	219
Potassium chloride 20mmol in 40ml	Syringe	657
Potassium chloride 20mmol in sodium chloride 0.9%	Syringe	377
Potassium chloride 20–40mmol in 10–20ml sodium chloride 0.9%	Syringe	82
Potassium chloride 40mmol in sodium chloride 0.9% 40ml	Syringe	1,024
Potassium chloride 40mmol in sodium chloride 0.9% 50ml	Syringe	180
Potassium chloride 40mmol in sodium chloride 0.9%	Syringe	2,500
Potassium chloride 50mmol in 50ml	Syringe	1,800
Potassium chloride 60mmol in 30ml	Syringe	1,100
Potassium chloride 60mmol in 50ml	Syringe	103
Potassium chloride 60mmol in 60ml	Syringe	8,088
Potassium chloride 80mmol in 50ml	Syringe	7
Potassium chloride miscellaneous doses	Syringe	1,800
	Total	32,190
Intravenous potassium and phosphate-containing solutions		
Potassium acid phosphate 20mmol in sodium chloride 0.9% 100ml	Bag	300
Potassium acid phosphate 9mmol in glucose 5% /sodium chloride 0.45% 500ml	Bag	100
Potassium acid phosphate solutions miscellaneous	Bag	602

Table 4 (continued from p62): Examples of potassium-containing solutions prepared in near-patient clinical areas at trusts in the north of England

Product	Presentation	Number prepared (per annum)
Intravenous potassium and phosphate-containing solutions (contd)		
Potassium acid phosphate 40mmol in sodium chloride 0.9% 60ml	Syringe	600
Potassium phosphate 8.71% in water for injections 20ml	Syringe	600
Potassium phosphate 40mmol in 50ml	Syringe	2
Potassium acid phosphate 10mmol in 10ml	Syringe	120
	Total	2,324
Potassium solutions used in haemofiltration or dialysis fluids		
Potassium chloride 10–80mmol in haemofiltration fluid	Bag	546
Potassium chloride 20mmol in Haemosol dialysis fluid 3 litres	Bag	1,218
Potassium chloride 20mmol in Aqualact 5 litres	Bag	2,885
Potassium chloride 25mmol in lactate-free haemofiltration fluid	Bag	521
Potassium chloride 40mmol in haemofiltration fluid	Bag	1,456
Potassium chloride 4mmol per litre in peritoneal dialysis solution	Bag	73
Potassium chloride miscellaneous doses in haemofiltration fluid	Bag	2,500
	Total	9,199

Data relate only to instances where it was possible to identify the product (and not just the product category) being prepared and totals are therefore not the same as in Table 1.

it is important for all pharmacy staff to follow clinical governance principles and liaise with prescribers to ensure that high risk drugs or routes of administration are only used when there are no suitable, lower risk, alternatives. Wherever possible licensed products should be used. Before supplying or prescribing a “special” or extemporaneously dispensed product pharmacists should satisfy themselves that there is a real clinical need.

Moreover, the role of clinical pharmacy staff in the risk assessment of product preparation in near-patient clinical areas looks set to increase in the future. The results of this risk-assessment project have been shared with the NPSA which is set to issue a bulletin on injectable medicines later this year. This is likely to require trusts to risk-assess the preparation of all parenteral products used and to control all procedures that are found to be of high risk. Clinical and technical pharmacy staff will have a role working with nursing and medical colleagues in the implementation of the requirements of the patient safety alert.

Modernisation of pharmacy preparation services All pharmacy aseptic units are now required to have capacity plans for pharmacy parenteral preparation services. To supply all the high risk products currently prepared in near-patient clinical areas in a ready-to-use form from a pharmacy service, an overall increase in NHS manufacturing and preparation capacity of approximately 50 per cent would be required. Modernisation of the NHS manufacturing and preparation services, along four central pillars (see Panel 2), will not be able to provide all of this increased capacity.¹³ Instead, there

are several factors which may help to make capacity available within existing facilities. These include:

- Establishing collaborations with neighbouring units. Examples of this have been developed in the north west of England.^{14,15} Preparation in centralised licensed units allows for larger batch sizes and longer shelf-lives, therefore enabling a greater number of products to be prepared in advance.
- Increased use of dose banding and preparation in advance in cancer services. This development would potentially have the greatest impact on increasing efficiency within the existing service.
- Improving the communication of product availability. This helps to increase the uptake of the centrally prepared products. It is to be noted that there are currently instances where ready-to-use products are being prepared in one or more licensed units but some trusts continue to prepare them in near-patient clinical areas. This

is particularly the case for some epidurals and potassium-containing solutions. The establishment of the National NHS Specials Database (Pro-File)¹⁶ is a key step in the future development of an improved collaborative approach to product provision.

- Reducing demand by persuading trusts to use alternative routes of administration for products — for example, IV to oral antibiotic “switching”. Scope for this in some trusts is shown in the “A Spoonful of Sugar” report. At some trusts, just 20 per cent of the overall spend on antibiotics is on orally administered products whereas in other trusts this figure is as high as 40 per cent. Moreover, it should be noted that only some antibiotics are in high or high/medium risk product preparation categories. Where capacity is currently limited, consideration should be given to transferring the preparation of lower risk antibiotic products out of pharmacy control.

Panel 2: The four central pillars of the NHS manufacturing and preparation service modernisation

- Clinical governance — to apply the principles of clinical governance to the prescribing, manufacture, supply and administration of unlicensed medicines
- Capital investment — to maintain and modernise the current NHS manufacturing capacity
- National co-ordination — to create a cohesive national service with robust communication networks that is responsive to changing patient needs
- Working with industry partners — to agree good practice principles in partnership

The completion of this project provides all participating trusts with an opportunity to review their own aseptic service provision and procurement procedures and also to review the numbers of high risk products prepared in near-patient areas within the trust that may need to be subject to increased control.

A further implementation project has been funded by the National Implementation Board to support trust chief pharmacists in this task. Work will also be undertaken to address the various issues this project identified in each drug category. Links to current work of various clinical and technical groups will be established with the aim of developing lists of desired products.

We believe that this project, although conducted in trusts in the north of England on behalf of the Local Review Group (north), has generated data which are generalisable to the National Pharmacy Manufacturing and Preparation Service as a whole.

Limitations Not all trusts in the project area provided data, and so it was necessary to produce annual estimates which, while based on sound principles, might not accurately represent the actual extent of product preparation in near-patient areas. In addition, only a “snapshot” of preparation on

three days was analysed and, although there is nothing to suggest that any of these days were unusual in terms of the extent of preparation, it is possible that different results would have been obtained had different days been chosen.

The list of 48 high and high/medium risk drugs was carefully chosen to suit trusts in the project area as a whole. Individual trusts may have chosen other preparations, more appropriate to their needs, particularly those treating a high percentage of specialist patients (eg, cardiac and haematology patients).

Conclusions

Many trusts have taken part in the risk assessment process as part of this project and have found high risk areas of practice within their organisations which need to be addressed locally. Some trusts have already drawn up action plans in response to their findings. It is recommended that all trusts and pharmacy services review their own practice and ensure that parenteral preparation services are increasingly focused on the reduction of risk to the patient.

A combination of local and collaborative initiatives, with a multidisciplinary approach at both levels will be needed to produce an overall reduction in risk.

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There is a diary page with reunions, branch meetings, courses and health events (www.pjonline.com/diary).

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