

# Outcomes of the risk reduction implementation project

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This article describes a project to implement strategies to reduce the risk associated with the preparation of parenteral products in clinical areas. It follows a risk assessment of NHS trusts in the north of England



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In 2005, a risk assessment of parenteral product preparation across secondary care acute trusts in the north of England was successfully completed.<sup>1</sup> The National Implementation Board for modernisation of NHS medicines manufacturing and preparation then commissioned a follow-on implementation project, which was hosted at Leeds Teaching Hospitals NHS Trust and conducted within the 51 acute secondary care hospital trusts in the north of England.

The project had three principal aims:

- To support chief pharmacists in acute trusts in the north of England in the implementation of risk reduction strategies and to address local risks relating to parenteral products
- To agree, through clinical scrutiny, a range of standard parenteral products suitable for preparation by pharmacy manufacturing units (PMUs)

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- To achieve risk reduction in specific areas (relating to cytotoxic dose banding, potassium-containing solutions, cardioplegia solutions, eye injections or irrigations, paediatric infusions and epidurals or intrathecal) identified by the risk assessment project

This article sets out the outcomes of the implementation project.

## Supporting chief pharmacists

To support chief pharmacists in the development and application of local action plans a series of educational events were held across the north of England from October 2005 to June 2006. During these events the risk assessment project results were fed back to the trusts to enable good practice to be shared.

Progress within trusts was monitored by a questionnaire. Two thirds of the trusts that responded indicated that they have been successful in dealing with local risk issues. Approximately half of the responding trusts identified one or more high risk preparation activity that was unknown to pharmacy

management before being highlighted by the risk assessment project. These activities most commonly involved processes being undertaken in theatres — areas which traditionally receive a relatively low level of clinical pharmacy support. It is recommended that all trusts review arrangements for the provision of parenteral products in theatres. The National Patient Safety Agency alerts issued earlier this year provide a suitable framework for assessment.<sup>2</sup>

The questionnaire results also showed that aseptic services in many trusts are regularly operating at or above 80 per cent of their capacity. This may be a barrier to the transfer of preparation activities from clinical areas. Local pharmacy aseptic units need to review their current product range and, if necessary, transfer the preparation of some higher use items to centralised services in the PMUs.

### Risk assessment project

The risk assessment project described in this article was published in the February issue of *Hospital Pharmacist* (2007;14:58–64).

## Panel 1: Standard parenteral products suitable for preparation in pharmacy manufacturing units

Drug and route	Concentration	Units prepared in clinical areas (pa)
Acetylcysteine IV (i)	3–15g in 100–1,000ml	15,814
Aciclovir IV (i)	200–800mg in 100–250ml	18,617
Adrenaline IV (s)	4mg, 5mg, 8mg in 50ml	22,905
Alfentanil IV (s)	25mg in 50ml	26,777
Aminophylline IV (i)	250mg, 500mg, 1,000mg in up to 1,000ml	33,318
Amiodarone IV (i)	300mg, 600mg, 900mg in 250–500ml	23,509
Ceftazidime IV (i)	1g, 2g, 3g in 100ml	79,551
Clarithromycin IV (i) <sup>i</sup>	500mg in 250ml	101,776
Clonidine IV (s)	150µg, 300µg in 50ml	10,095
Dobutamine IV (s)	250mg in 50ml	13,746
Dopamine IV (s)	200mg in 50ml	8,537
Dopexamine IV (s)	50mg, 200mg in 50ml	1,977
Epoprostenol IV (i)	500µg in 50ml	2,022
Erythromycin IV (i)	500mg, 1,000mg in 250ml	14,448
Gentamicin IV (i) (once daily doses)	120–640mg in 40–80mg steps in 100ml	32,393
Insulin soluble IV (s)	50 units in 50ml	51,450
Magnesium sulphate IV (i)	8mmol, 16mmol, 24mmol in 250–500ml	30,354
Methylprednisolone IV (i)	500mg in 100ml, 1,000mg in 250ml	12,910
Morphine sulphate IV (s)	50mg, 100mg in 50ml	52,453
Noradrenaline IV (s)	4mg, 8mg, 16mg in 50ml, 32mg in 250ml	57,956
Pamidronate IV (i)	30mg, 60mg, 90mg in 250–500ml	10,239
Phenytoin IV (s)	1,000mg, 1,500mg in 100ml	6,891
Remifentanil IV (s)	2.5mg, 5mg in 50ml	11,313
Streptokinase IV (i)	1.5million units in 100–250ml	2,228
Teicoplanin IV (i)	200mg, 400mg in 100ml	56,149
Vancomycin IV (i)	500mg, 1,000mg in 250ml	46,480
Vecuronium IV (s)	5mg, 10mg, 20mg in 50ml	8,351

Also included in the list, as recommended by the Royal College of Anaesthetists Special Working Group, are:

- Bupivacaine epidural infusion (0.1 per cent and 0.125 per cent)
- Fentanyl in bupivacaine epidural infusion (fentanyl 2µg/ml in bupivacaine 0.1 per cent and 0.125 per cent)
- Midazolam (IV syringe)

Diamorphine 300µg in bupivacaine heavy 0.5 per cent 4ml (intrathecal injection) is included as it is so commonly used, and cefuroxime (intracameral injection), following data about its usage.<sup>1</sup>

Key: i = infusion bag s = syringe

### List of products

A list was compiled of commonly used high risk products for adult patients, which were clinically appropriate and technically suitable for preparation in PMUs. To do this, a consultation process was undertaken with PMU managers and staff at Quality Control North West, with clinical input being provided by groups such as the Royal College of Anaesthetists (RCA) and the Intensive Care Society, a multidisciplinary group aiming for the standardisation of infusions used in intensive care units.

The final recommended list comprises 32 drugs, including two epidural infusions, one

intrathecal injection and one intraocular injection (see Panel 1).

To identify preferred epidural and intrathecal solutions advice was sought from the RCA. The RCA Specials Working Group draft list of recommended drugs was included in the recommended list for this project. In addition, the intrathecal injection diamorphine 300µg in bupivacaine heavy 0.1 per cent 4ml, as used in obstetric practice, was also included in the final list as it was the most commonly used intrathecal injection identified in the risk assessment project (3,603 units prepared in clinical areas per annum).

## Panel 2: Paediatric products suitable for preparation in pharmacy manufacturing units

Drug	Concentration*	Doses prepared in pharmacy (pa)	Doses prepared in clinical areas (pa)
Benzylpenicillin IV	100mg/ml, 150mg/ml	13,026	6,084
Cefotaxime IV	50mg/ml, 100mg/ml, 200mg/ml, 250mg/ml	34,200	1,200
Ceftazidime IV	40mg/ml, 100mg/ml, 200mg/ml	21,527	861
Cefuroxime IV	25mg/ml, 50mg/ml, 100mg/ml, 125mg/ml	25,551	
Ceftriaxone IV			ND
Flucloxacillin IV	10–50mg/ml, 50mg/ml	14,087	452
Insulin IV			
Meropenem IV	10–50mg/ml, 50mg/ml, 100mg/ml	17,402	ND
Tazocin IV	225mg/ml	14,412	ND
Vancomycin IV	5mg/ml, 10mg/ml, 50mg/ml	12,349	400
Dobutamine IV	1.2–4.8mg/ml, 50mg/50ml	18,502	556
Dopamine IV	1.2–4.8mg/ml, 30mg/50ml	757	1,080
Heparin IV	0.5u/ml, 1u/ml, 5u/ml, 10u/ml	6,374	1,460
Potassium chloride IV		14	1,704
Potassium phosphate IV		ND	1,095

Following discussions with the multidisciplinary expert group, the following epidural solutions were also included:

- Levobupivacaine 0.125 per cent
- Fentanyl 2µg/ml in levobupivacaine 0.125 per cent
- Clonidine 1µg/ml in levobupivacaine 0.125 per cent

\*Concentrations listed were found to be used by between one and seven trusts

Key: ND = no usage data (these products were added to the list by the discussion group)

### Specific areas

To reduce risk in the use of paediatric infusions, a multidisciplinary expert group met to consider the findings of the risk assessment project. For paediatric products, a list of 18 preferred products suitable for preparation in PMUs was compiled, which includes three epidurals and 15 intravenous solutions (see Panel 2). A mechanism for ongoing review of the product range and for communicating the needs of paediatric clinical services to PMUs was also proposed. It was noted that future developments in the use of “smart-pump” technology<sup>3</sup> and the more widespread use of standard concentration infusion solutions with the infusion rate varied to achieve the correct dose will increase the demand for these products. More agreement within and between trusts

about the type of dose calculations used and the presentation of solutions will increase patient safety during transfer to and from specialist units.

### Conclusion

One of the four “pillars” of modernisation of hospital manufacturing services process is clinical governance.<sup>4</sup> The risk assessment of parenteral products project and this implementation project set out to assist with the identification of products which form part of the clinical governance agenda for hospital trusts and PMUs in the north of England. Participating trusts have identified local risks and are working towards achieving risk reduction. A similar process will now need to be undertaken by all trusts in England and Wales following the NPSA alerts issued in March.

These projects and their findings will provide information that can be used to initiate and guide local agendas. A key part of reducing the number of high risk products prepared in clinical areas will be to ensure local aseptic services have a risk focus and that back up PMU services are available. The development and launch of the Pro-File database<sup>5</sup> has made access to the modernised manufacturing services more efficient and will help all trusts in the delivery of their own local risk reduction strategy and response to the NPSA alerts.

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