

Overcoming cost-related and other barriers to implementing risk-reduction strategies for injectable therapies

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- **OBJECTIVE** — To identify risk reduction measures in relation to injectable therapy, to propose and implement patient safety improvements and to estimate the costs associated with them. To identify barriers which might hinder the implementation of a “purchasing for safety” initiative.
- **SUBJECTS AND SETTINGS** — Clinical areas at Freeman Hospital, Newcastle upon Tyne, including general intensive treatment unit (ITU), cardiology ITU and a surgical ward.
- **OUTCOME MEASURES** — Identifying costs associated with injectable medicines prepared in clinical areas. A pathway to the development of a robust approval process for procurement of medicines with inherent safety features in preference to those without.
- **METHODS** — Higher risk items made in clinical areas were identified. Risk reduction measures were implemented and evaluated.
- **RESULTS** — A variety of risk reduction measures were implemented, including provision of ready-to-use and ready-to-administer products, dose calculating tools and protocols for complex methods remaining in clinical areas.
- **CONCLUSIONS** — Risks can be reduced for injectable medicines prepared in clinical areas. Risk reduction measures have costs associated with them. Even though barriers to implementation of these measures are frequently raised, it is possible to make safety improvements in a budget conscious trust.

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It has long been advocated that the preparation of injectable medicines should, wherever possible, be performed in a pharmacy.^{1,2} However, it has more recently been accepted that, with the level of activity in clinical areas, it is unlikely that pharmacy departments will ever have the capacity to produce more than a proportion of injections used in wards and theatres.³

With a view to targeting pharmacy resources towards preparations that pose greater risks for patients, risk assessment has become an important part of a pharmacy manager's toolkit. Work initially undertaken at Freeman Hospital resulted in the concept that a tool can be successfully used to rank injectable medicines prepared in clinical areas in terms of their overall risk.³

Using the premise that clinical pharmacists are in the best position to take the lead in risk assessing the preparation and administration of injectable medicines, the National Patient Safety Agency has recently published an alert that requires health care organisations to risk assess their practices and procedures associated with injectable therapy.⁴ The alert suggests that risk assessment should be a joint exercise with pharmacy and clinical area staff and it provides a risk management tool to assist with the process.

Previous studies have produced lists of higher risk preparations^{5,5} which have provided a useful baseline for organisations targeting future risk assessments and have demonstrated that the implementation of various measures can reduce the risks associated with injectable medicines.

The NPSA tool, and its predecessors, facilitates the identification of higher risk preparations that should be targeted by pharmacy aseptics, procurement and/or clinical pharmacy staff when implementing risk reduction measures.

However, to date, little published work has looked at the costs associated with implementing risk reduction measures. With a view to developing previous research at Freeman Hospital (a hospital typical of many others across Britain in that it has no centralised intravenous additive service [CIVAS]), this small study was undertaken to try to understand the costs associated and the issues from the perspectives of pharmacy and nursing staff and clinical area managers.

Method

Phase 1: baseline risk assessment A baseline risk assessment of the preparation of injectable products (previously identified as higher risk) in three clinical areas (cardiology intensive treatment unit [ITU], general ITU and surgical ward) was performed.

This was carried out using an evolved version of a published risk assessment tool.³ Clinical pharmacists visited wards and departments at drug administration times for one month and observed nurses preparing injectable medicines. In addition to the presence of risk factors, a record was made of the drugs, diluents and consumables used and the time taken by nursing staff to prepare the injectable product.

Pharmacy financial data was then used to calculate drug costs (including associated diluents, etc). Nursing time costs were based on the time actually taken to prepare products, adjusted using professional judgement where the procedures observed to be used were not ideal, according to recommended safe practice.^{6,7,8} The salary of a mid-grade nursing practitioner was used in the cost calculation.

For each higher risk drug product prepared during phase 1, a technical evaluation was sought with regard to the possibility of batch preparation, preparation at a CIVAS unit or the purchase of ready-to-use or ready-to-administer presentations. Potential costs of these options were evaluated.

Based on the outcome of the technical evaluation, pharmacy staff targeted seven preparations to consider further in phase 2.

Phase 2: implementing risk-reduction measures Meetings were held with the relevant directorate managers and nursing managers (modern matrons) to discuss which risk reduction measures should be implemented on a trial basis and to aid communication during phase 2.

As a result, five products with inherent safety features were purchased, after approval from the local drug and therapeutics committee (DTC). For two products, dose calculating tools and protocols for complex preparation were produced by clinical pharmacy staff and introduced. Training was provided to nursing staff, where applicable.

The observation and cost calculation methods used in phase 1 were then repeated for the new preparation, for a period of three months.

Directorate and nursing managers were contacted half way through phase 2 to check that they were content with progress.

Phase 3: evaluation of risk reduction measures

At the end of phase 2, the measures were evaluated by the directorate and nursing managers. The opinion of nursing staff in the three clinical areas was also sought, by way of an interview-based survey.

As a result of the opinion of some directorate managers that it was not appropriate to include nursing time costs (see discussion for further details), costings were recalculated.

Results

Phase 1 The preparation of 88 different higher-risk products was assessed. Of these, 37 were initially identified as being potential candidates on which to trial risk reduction measures, with technical assessments results prompting pharmacists to focus on seven products. The costs associated with preparing these seven products by the methods traditionally used at the hospital are included in Table 1.

Phase 2 Following discussions with directorate managers and modern matrons, it was decided to implement and evaluate risk reduction measures for seven preparations. These were:

- Glyceryl trinitrate 50mg in 50ml, diluted in glucose 5% (syringe)
- Heparin 5,000 units in 1,000ml, diluted in sodium chloride 0.9%, (infusion bag)
- Fentanyl 2.5mg in 50ml (syringe)
- Pamidronate disodium 60mg in 250ml, diluted in glucose 5% (infusion bag)
- Cefuroxime 750mg and metronidazole 500mg, in 100ml (infusion bag)
- Iloprost 100micrograms in 50ml, diluted in sodium chloride 0.9% (syringe)
- Naloxone 16.1mg in 500ml, diluted in glucose 5% (infusion bag)

Ready-to-administer preparations of heparin, fentanyl and pamidronate disodium were purchased, as was a ready-to-use vial of glyceryl trinitrate and a closed system device for mixing antibiotics.

The costs associated with the preparation of the seven products with risk reduction methods in place are set out in Table 1, together with a comparison of the costs previously associated with their preparation.

Phase 3 Table 2 (p200) shows the costs associated with preparing the risk-reduced products with nursing time costs removed.

Table 3 (p200) shows the decision taken by directorate managers with respect to permanently implementing the risk reduction measures after completion of phase 2 (see discussion for reasons).

Discussion

The inclusion of costing information has brought a different perspective to the risk reduction work published to date. It seems logical and reasonable to ascertain the total preparation cost in the way shown, including nursing time. However, in high dependency clinical areas (eg, ITU), standards dictate that strict ratios of nursing staff to patients must be adhered to.⁹ Resource is carefully managed at directorate level to ensure that the required staffing levels are maintained using the minimum operational staff. As a result, it was strongly felt that, for example, releasing 20 minutes of nursing time through the introduction of a ready-to-administer medicine, does not provide a tangible saving as the nursing staff have to remain in the clinical area with the patient. Therefore, it was necessary to re-evaluate the costings removing any benefits attributed to staff time savings (see Table 2).

Information about the decisions made for the seven products is given below.

Glyceryl trinitrate It was agreed by nurses and managers that the licensed ready-to-use preparation of glyceryl trinitrate was more convenient and safer than preparing the

drug from multiple ampoules (drug and diluent). The cost increase per dose could be offset by the cost of the diluent, which was not needed in the ready-to-use preparation.

Heparin The licensed ready-to-administer preparation of heparin was popular with nursing staff. The drug cost increase per bag could, in fact, be more than offset by a reduction in the associated consumables cost. In addition, the nursing time cost was considered to be relevant because a second nurse was previously required to assist in priming the line. The product has been subsequently placed on permanent stock in both trial areas.

Fentanyl The aseptically prepared (in a licensed manufacturing unit) ready-to-administer, prefilled syringe (PFS) preparation of fentanyl was popular with nursing staff. They appreciated not having to make up this widely used product repeatedly — during the trial period, 500 prefilled syringes were used by the general ITU. The associated increase in drug expenditure meant that, despite staff outcry, time saving and risk reduction benefits, the decision was taken to revert to preparing the drug in clinical areas.

One directorate manager intervened before phase 2 to remove her clinical area from the study for this preparation (despite the DTC approval) because of the likely impact on drug budget. On the basis of the results, she felt vindicated in her decision.

It was noted that a 30ml PFS would have been a better product to have bought, since the most usual rate of administration is 1ml/hour. This option was discussed with the production unit and could have been provided. However, the cost would still have been an insurmountable problem for the clinical areas studied.

The PFS supplied were a line already in production for use within the trust. This raised a difficult, as yet unsolved, dilemma of why patients in one clinical area might be treated with an inherently safer product than those in other areas. Whether the devolution of drug budgets to individual directorates is necessarily a good thing when considering

Table 1: Cost comparisons for risk assessed preparations

Drug(s)	Costs (£) associated with preparation of drug(s) originally used (per dose)				Costs (£) associated with preparation of drug after risk-reduction measures implemented (per dose)				Cost (£) difference (per dose)
	Drug cost	Consumables cost	Nursing time cost	Total	Drug cost	Consumables cost	Nursing time cost	Total	
Glyceryl trinitrate	3.35	2.63	4.26	10.24	3.64	1.46	2.13	7.23	- 3.01
Heparin	0.42	1.89	3.20	5.51	1.60	0.60	2.13	4.33	- 1.18
Fentanyl	1.20	1.46	6.39	9.05	4.76	1.09	4.26	10.11	+ 1.06
Pamidronate disodium	46.54	1.20	4.26	52.00	90.00	0.60	2.13	92.73	+40.73
Cefuroxime and metronidazole	1.08	0.81	4.26	6.15	1.60	0.60	2.13	4.33	- 1.82
Iloprost	93.88	1.91	4.26	100.05	93.88	1.91	4.26	100.05	0.00
Naloxone	152.93	1.71	12.78	167.42	152.93	1.71	12.78	167.42	0.00

Table 2: Cost difference of preparations, with nursing costs excluded

Drug(s)	Cost difference per dose (£)
Glyceryl trinitrate	-0.88
Heparin	-0.11
Fentanyl	3.19
Pamidronate disodium	42.86
Cefuroxime and metronidazole	0.31
Iloprost	0.00
Naloxone	0.00

the patient safety arena is a question for further consideration.

Pamidronate disodium 60mg in 500ml infusion The pamidronate disodium preparation was commissioned as an unlicensed “special” from a commercial manufacturing unit and given an expiry of eight weeks. The drug is rarely used in the wards/departments studied, and its unfamiliar nature to nursing staff was a factor in the local risk assessment.

The need for this preparation arose twice during phase 2. However, on both occasions, the ready-to-administer preparation was not used, because the drug had been prescribed as a smaller volume. Hence, although pharmacy staff made nursing staff aware of the availability of the preparations specially procured for the study, they went out of date and were not used. This highlighted the difficulty in buying stock of short-dated high-cost preparations. It also emphasised the vital importance of ensuring that the specification for the special procured is exactly in line with the requirements of the specialty. The decision was taken not to continue to purchase this preparation after phase 2. However, a procedure was written for the complex unfamiliar preparation method which reduced the risks associated with future preparation in the clinical area.

Cefuroxime 750mg in metronidazole 500mg infusion The delivery system bought consisted of a metronidazole infusion, which can be docked with a vial of cefuroxime, creating a licensed infusion combination that removes the need for aseptic manipulations. Nursing staff were trained in using the device and were impressed by the time saved, as well as by the patient safety improvements. Time saving was seen as relevant, being particularly helpful at night when qualified staff numbers were reduced. (It should be noted that the staff-to-patient ratios referred to earlier are not required on a general surgical ward). This contributed to managers deciding to keep the preparation.

Iloprost and naloxone Factors that increase the preparation risk of injectable medicines include complex calculations and complex preparation methods.⁴ Therefore, the introduction of dose calculating tools and the provision of worked examples in a chart format and preparation protocols will reduce the risk potential. These also fulfil the NPSA requirement for availability of the correct technical information at the point of use.⁴

With the availability of these tools for iloprost and naloxone, the preparation process had fewer risk factors involved and did, therefore, demonstrate a risk reduction. In addition, the clinicians’ satisfaction with the documents provided was high. Other than the clinical pharmacists’ time to prepare such materials, the method is cost neutral and was felt to be a significant risk reduction factor in the clinical area.

By performing the risk assessment process, even for these relatively few products, some tangible risk reduction benefits have been realised. However, the opportunity for maximum risk reduction has not been taken up in all cases. The main barriers to the implementation of patient safety initiatives can be identified as:

- Cost
- Patient safety with injectables not being a high enough priority
- Communication

Cost Financial considerations are an important element of any directorate manager’s decision-making process. In some of the examples shown, there was an increased cost associated with buying a safer presentation. Price is a difficult barrier to overcome in a cost conscious trust, and it is therefore important that NHS organisations have a “purchasing for safety” policy that enables the benefits of inherently safer products to be recognised as relevant costs and their procurement to be realised to the benefit of patients. Ideally, the pharmaceutical industry should take up the patient safety agenda and only offer their products in ready-to-use or ready-to-administer devices at realistic prices.

Patient safety with injectables not being a high enough priority The study showed that directorate managers’ main focus was on cost and achieving financial balance. As a consequence, they did not appear to give safety a high enough priority and to embrace the risk reduction benefits that could be gained by using higher cost products. Initiatives such as the recent publication from the NPSA should help to raise risk reduction as a priority. It is also clearly important to ensure that clinical practitioners can see the benefits of using safer products and translate these to managers.

Communication In this study, we learnt that ensuring the involvement of all managers is vital. Operational staff must also be fully informed and, where necessary, trained in the use of any new preparations.

With hindsight, it was felt that if there had been more direct contact with clinical directors (rather than indirectly through directorate and nursing managers) some outcomes might have been different.

Pharmacy staff are also key to ensuring successful implementation of risk-reduction measures, with dispensary and stores staff fielding any inappropriate requests and clinical staff reinforcing the practice at ward level.

We believe that this study has shown that, in order to introduce a new preparation on the basis of reduced risk, it is necessary to adhere to the following steps:

- Identify the potential patient safety benefits of the change and any changes required to accommodate the change (eg. storage capacity)
- Identify the cost of the change
- Communicate at all levels and engage appropriate leaders and stakeholders
- Approach budget holders to ensure their “buy-in” to the initiative
- Instigate the relevant organisational approval process (often DTC)
- Purchase the product according to local procurement procedure (including quality assurance assessment if required for unlicensed medicines)

Table 3: Decisions of clinical area managers as to whether to permanently implement risk reduction measures

Drug(s)	Cardiology ITU	General ITU	Surgical ward
Glyceryl trinitrate	Implemented	Implemented	N/A
Heparin	Implemented	Implemented	N/A
Fentanyl	Not implemented	Not implemented	N/A
Pamidronate disodium	N/A	N/A	Not implemented
Cefuroxime and metronidazole	N/A	N/A	Implemented
Iloprost	N/A	N/A	Implemented
Naloxone	N/A	N/A	Implemented

- Implement the change, employing robust change management techniques to ensure that the change is successfully embedded
- Monitor the impact of the change
- Audit to ensure that the change is maintained and re-assess risk to ensure that further risks have not been introduced

The product authorisation process described could be refined if a pathway was developed within the organisation to provide a link to purchasing systems, thereby enabling the incorporation of the “purchasing for safety” process. To this end, a two-stage approval process could apply as follows:

- Stage one: traditional organisational drug approval, on the basis of clinical effectiveness and cost.
- Stage two: “purchasing for safety” approval, with respect to drug presentation on the basis of safety in use.

Such a two-stage process would enable transparency for drug manufacturers, emphasising that patients will receive the most appropriate therapy and that it is important to deliver medicines in a presentation suitable for safe administration.

Conclusion

Risk assessment is time consuming but valuable. To target high risk medicines and go through this process, as advocated by the NPSA Patient Safety Alert, will be resource intensive for a large trust. For this initiative to be worthwhile, the decision making body, often the DTC, must be amenable to purchasing decisions on the basis of patient safety as well as clinical efficacy. An organisational policy from trusts, along with realistic pricing policies and safety strategies from the pharmaceutical industry, would enable this agenda to move forward, to the mutual benefit of patients, staff and hospital management.

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References

1. Breckenridge. Report of the working party on the addition of drugs to intravenous fluids (HC(76)9) Breckenridge report. London: Department of Health; 1976.
2. Audit Commission. A spoonful of sugar: recipes for risk reduction. London: The Commission; 2001.
3. Beaney AM, Black A, Dobson CR, Williamson S Robinson M. Development and application of a risk assessment tool to improve safety of patients receiving injectable medicines. *Hospital Pharmacist* 2005;12:150–4.
4. National Patient Safety Agency. Promoting safer use of Injectable Medicines. London: The Agency; March 2007.
5. Hardy L, Mellor L. Risk assessment of parenteral product preparation across secondary care acute Trusts in the north of England. *Hospital Pharmacist* 2007;14:58–64.
6. van Zanten ARH, Engelfriet PM, van Dillen K, van veen M, Nuijten MJC, Polderman KH. Importance of non-drug costs of intravenous antibiotic therapy. *Critical Care* 2003;7: R184–90.
7. Low J, Macintyre J, McIver L, Lannigan N, on behalf of the Association of Scottish Trust Chief Pharmacists. The development of a capacity planning model for pharmaceutical services to cancer patients. *Pharmaceutical Journal* 2003;270:239–40.
8. Ryan DM, Daniels SE, Somani SM. Personnel costs and preparation time in a centralised intravenous admixture program. *American Journal of Hospital Pharmacy* 1986;43:1222–5.
9. Department of Health. Quality critical care: beyond comprehensive critical care. London: The Department; 2005.