

Development and application of a risk assessment tool to improve the safety of patients receiving injectable medicines

By **A. M. Beaney**, MSc, MRPharmS, **A. Black**, MRPharmS, Dip PTQA, **C. R. Dobson**, MRPharmS, **S. Williamson**, BPharm, MRPharmS, **M. Robinson** MPharm

- **AIMS** — To enable the identification of products with the highest risks associated with their preparation in a clinical setting in a teaching hospital. To assess the transferability of the risk assessment tool to a district general hospital.
- **DESIGN** — Risks were identified. A risk-assessment tool was designed to calculate overall risk scores (ORSs). Scores were calculated for specific products in two hospitals.
- **SUBJECTS AND SETTING** — A range of wards in Freeman Hospital and North Tyneside District General Hospital.
- **OUTCOME MEASURES** — Development of the risk assessment tool and establishment of its transferability. Improvements to patient safety.
- **RESULTS** — ORSs were calculated for 4,005 items. Increased pharmacy input into nurse training, reinforcement of guidelines for the preparation of intravenous products and an attempt to transfer the preparation of items with the highest ORSs to the pharmacy department followed.
- **CONCLUSIONS** — High-risk products can be identified by using the tool developed. The tool is transferable between hospitals. Items with high ORSs should be provided as ready-to-administer products.

Alison Beaney is regional quality assurance specialist based at The Royal Victoria Infirmary, Newcastle upon Tyne, **Anne Black** is quality assurance pharmacist and **Clare Dobson** is a basic grade pharmacist at Freeman Hospital, Newcastle upon Tyne, and **Steve Williamson** is lead pharmacist for cancer services at Northumbria Healthcare Trust. **Mark Robinson** is a pre registration trainee at Sunderland Royal Infirmary and was a vocational pharmacy student at North Tyneside Hospital at the time the research was carried out. Correspondence to Anne Black, Pharmacy Department, Freeman Hospital, Newcastle upon Tyne NE7 7DN.

It has been recommended that all aseptic manipulations should be under pharmacy control.^{1,2} However, given the limitations of space and staffing in many busy hospitals, this is not achievable. For example, it has previously been found that 35 per cent of aseptic manipulations were carried out under pharmacy control, while 65 per cent continued to be performed at ward level.³

Over recent years, the Department of Health has emphasised the standards required for aseptic preparations undertaken in pharmacy departments.^{4,5} The book, "Quality assurance of aseptic preparation services", gives detailed current standards for aseptic preparation under these circumstances.⁶

There are no equivalent defined national standards for ward-based aseptic preparation, although the NHS Controls Assurance Standards for Medicines Management (which are currently in the process of being replaced) required trusts to undertake a risk assessment of intravenous products.⁷

Contamination, leading to infection, has been reported in the US with a propofol preparation,⁸ and in the UK with a container of saline for a patient with malaria.⁹ These incidents illustrate the need to adhere to aseptic techniques.

Previous work carried out at Freeman Hospital resulted in guidance about the preparation of injectable products being displayed on wards.¹⁰ While this undoubtedly helped to increase patient safety, it was recognised that other risk factors existed. In order to help address these, the following work was undertaken:

- Identifying the risk factors involved in the ward-based preparation of injectable products
- Developing a risk assessment tool that can be used to calculate an overall risk score (ORS) for the ward-based preparation of a particular injectable product in its preparative surroundings
- Using the tool to calculate the ORS for a range of products and situations at Freeman Hospital
- Investigating the transferability of the tool to another range of clinical settings at North Tyneside Hospital

- Comparing the results from the two hospital settings to identify common high-risk products and to validate the method

Methods

Identifying risk factors and developing an ORS formula A literature search was undertaken followed by a brainstorming exercise among pharmacy staff to identify risk factors. The identified risk factors were discussed with and, where appropriate, modified by senior nurses and infection control staff. A weighting was assigned to each of the risk factors and a formula was developed. Validation at this stage involved correlating the results achieved by using the formula with high-risk processes identified by senior ward nurses.

Calculating ORSs for products used at the Freeman Hospital Computer systems were analysed to determine which injectable products were issued to a representative sample of 30 wards and departments over a 12-month period. ORSs for each of these products, in the particular ward in which they were prepared, were calculated. The ORS for each product on each ward was confirmed by obtaining the opinion of senior nurses.

Following consultation with a trust statistician, it was decided to record the maximum ORS achieved for each product (rather than, say, the mean of the ORSs obtained) because this was deemed more appropriate when assessing risk.

Investigating the transferability of the tool The same method (except that 20 wards were used as a representative sample and issues over a six-month period were analysed) was followed by staff at the pharmacy department at North Tyneside Hospital, a district general hospital, in order to establish the transferability of the method. Common high-risk products were identified by analysing the maximum ORSs from the two sites.

Based on the experiences of staff at North Tyneside Hospital, a universal procedure for use of the tool was developed.

Results

Identifying risk factors and developing an ORS formula

A summary of the risk factors associated with the ward-based preparation of injectable products is set out in Panel 1. The risk assessment tool developed for calculating ORSs is shown in Panel 2 and a worked example of a calculation using the formula is shown in Panel 3. For all products, the senior nurse on the relevant ward agreed with the preparations

identified as highest risk using the risk assessment tool.

Freeman Hospital ORSs A total of 2,722 different products were issued to the representative sample of wards and departments over the 12-month period. The ORSs assigned to these products ranged from 1.4 to 65.3. Table 1 (p152) shows the 25 products assigned the highest maximum ORSs. Further details about the ORSs assigned at Freeman Hospital follow:

- 10 per cent of products (ie, 273) had maximum ORSs of 15 or above. These products comprised 46 different drugs
- Four products were given a maximum ORS of greater than or equal to 35
- The paediatric intensive care unit was identified as the ward or department where the highest number of products with ORSs in the top 25 were used

North Tyneside Hospital ORSs A total of 1,283 products were issued to the representative wards and departments over the six-month period. The ORSs assigned ranged from 1.4 to 54.0. Table 2 (p152) shows the 25 products assigned the highest maximum ORSs. Further details about the ORSs assigned at North Tyneside Hospital follow:

- 16 per cent of products (ie, 200) had maximum ORSs of 15 or above. These products comprised 58 different drugs
- Six products were given a maximum ORS of greater than or equal to 35

Panel 1: Identification and weighting of risk factors associated with the ward-based preparation of injectable products

| Code | Risk | Weighting |
|------|--|--------------------|
| A | ■ Number of aseptic manipulations | 1 per manipulation |
| B | ■ Calculations | 2 per calculation |
| C | ■ Use of part of vial or ampoule | 1 |
| D | ■ Background environment | |
| | Theatre | 0.5 |
| | Intensive treatment unit | 1 |
| | Ward | 1.5 |
| E | ■ Material hazardous to operator (eg, teratogenic) | 3 |
| F | ■ Material supports microbiological growth | 2 |
| G | ■ Route of administration | |
| | Intrathecal | 5 |
| | Epidural | 3 |
| | IV | 1 |
| | IM or SC | 0.8 |
| H | ■ Duration of administration | |
| | 7 day device | 3 |
| | 24h infusion | 2 |
| | Other infusion | 1.5 |
| | Slow IV | 1 |
| | IV, IM or SC bolus | 0.5 |
| I | ■ Unfamiliar process (defined as fewer than six ampoules or vials used in a 12-month period) | 2 |
| J | ■ Special needs patient (eg, neonate, fluid restricted, immunocompromised, patient with renal failure, intensive care patient) | 1.5 |
| K | ■ Dangerous practice (eg, pre-preparing unlabelled syringes in anticipation of being used) | 1.5 |

"IV" means intravenous, "IM" means intramuscular and "SC" means subcutaneous. The rationale for the risk factors chosen is as follows: The number of aseptic manipulations is directly linked to the risk of microbial contamination. This individual factor was seen as the most influential, and so was used as a multiplier. All other risks were considered to individually contribute to the overall risk, but not to be synergistic, and were therefore added together. Any calculation needed is prone to error. Some preparations require several complex calculations. Using part of a vial or ampoule is more prone to error than using a full container (in addition to any calculations involved), because of the possibility of incorrect measurement. The poorer the background environment, the more the risk of microbial contamination. With hazardous drugs, the risk to

the operator is a factor. Where contamination has occurred, using a microbiologically growth friendly medium, eg, parenteral nutrition is more likely to result in microbes replicating. The consequences of using contaminated products by some routes are more serious than by other routes.¹¹ The longer the duration of administration, the greater the risk of contamination occurring. Unfamiliarity with a product or the method of making it up can increase the likelihood of error. The consequences of contamination are more serious for certain patients (eg, neonates, or patients who are immunocompromised or are in an intensive care unit). Any dangerous practices used (eg, pre-preparing unlabelled syringes in anticipation of being used) increase the likelihood that an incorrect product will be administered to a patient.

Panel 2: Formula for producing an overall risk score (ORS)

$$\text{ORS} = \frac{A(B+C+D+E+F+G+H+I+J+K)}{2}$$

A to K are the codes set out in Panel 1

Panel 3: Worked example of an ORS calculation — IV erythromycin infusion for a child at a dose of 300mg four times a day

| Code | Score | Rationale |
|------|-------|---------------------------------|
| A | 5 | Five aseptic manipulations |
| B | 2 | One calculation |
| C | 1 | Part vial used |
| D | 1.5 | Ward background |
| E | 0 | Not hazardous to operator |
| F | 0 | Not growth-friendly |
| G | 1 | IV route |
| H | 1.5 | Short infusion |
| I | 0 | Familiar process |
| J | 0 | Not a special needs patient |
| K | 0 | No dangerous practices involved |

$$\text{ORS} = \frac{5(2 + 1 + 1.5 + 1 + 1.5)}{2}$$

$$= 17.5$$

"ORS" means overall risk score and "IV" means intravenous

Table 1: Overall risk scores (ORSs) for the 25 most high-risk products to prepare on a ward at Freeman Hospital

| Product | Maximum ORS (n=2-30) |
|-------------------------------|----------------------|
| Amphotericin (Fungizone) 50mg | 65.25 |
| Abciximab 2mg/ml | 40.50 |
| Alteplase 50mg | 37.50 |
| Liposomal amphotericin 50mg | 37.50 |
| Ganciclovir 500mg | 36.25 |
| Mycophenolate 500mg | 35.00 |
| Infliximab 100mg | 31.50 |
| Azathioprine 50mg | 31.25 |
| Streptokinase 250,000units | 27.50 |
| Aciclovir 250mg | 26.25 |
| Mannitol 20 per cent | 26.00 |
| Ceftazidime 1g | 25.00 |
| Ceftriaxone 1g | 25.00 |
| Ceftriaxone 2g | 25.00 |
| Disopyramide 10mg/ml | 25.00 |
| Epoprostenol 500microgram | 25.00 |
| Erythromycin 1g | 25.00 |
| Hydralazine 20mg | 25.00 |
| Aciclovir 500mg | 22.50 |
| Clarithromycin 500mg | 22.50 |
| Streptokinase 750,000units | 22.50 |
| Ceftazidime 2g | 20.00 |
| Ceftazidime 500mg | 20.00 |
| Methylprednisolone 125mg | 20.00 |
| Methylprednisolone 40mg | 20.00 |

All of the 25 most high-risk products identified were used as intravenous infusions

- The paediatric ward was identified as the ward or department where the highest number of products with ORS in the top 25 was used

Comparing results Seven products were common to the “top 25” of both hospitals. These were:

- Amphotericin (Fungizone) 50mg
- Epoprostenol 500microgram
- Alteplase 50mg
- Liposomal amphotericin 50mg
- Streptokinase 750,000units
- Aciclovir 250mg
- Ceftriaxone 1g

Figure 1 (p153) shows a comparison of the maximum ORSs of the 23 products that were evaluated at both Freeman and North Tyneside hospitals and were in the “top 25” of either hospital. (Products are presented in alphabetical order.)

Based on the experience of using the risk assessment tool in a setting different from that in which it was created, the universal procedure shown in Panel 4 (p153) was produced.

Table 2: Overall risk scores (ORSs) for the 25 most high-risk products to prepare on a ward at North Tyneside Hospital

| Product | Maximum ORS (n=1-20) |
|-------------------------------|----------------------|
| Amphotericin (Fungizone) 50mg | 54.00 |
| Acetylcysteine 2g/10ml | 51.75 |
| Vancomycin 500mg | 40.00 |
| Epoprostenol 500microgram | 38.00 |
| Liposomal amphotericin 50mg | 31.25 |
| Sodium fusidate 500mg | 31.25 |
| Teicoplanin 400mg | 31.25 |
| Disodium pamidronate 30mg | 27.50 |
| Erythromycin 1g | 27.50 |
| Methylprednisolone 1g | 27.50 |
| Streptokinase 750,000units | 26.25 |
| Aciclovir 250mg | 26.25 |
| Amoxicillin 500mg | 26.25 |
| Ampicillin 500mg | 26.25 |
| Cefotaxime 500mg | 25.00 |
| Ceftriaxone 1g | 25.00 |
| Cefuroxime 250mg | 25.00 |
| Vecuronium 10mg | 25.00 |
| Alteplase 50mg | 22.50 |
| Alfentanil 5mg/1ml | 22.50 |
| Meropenem 1g | 22.50 |
| Zoledronic acid 4mg | 20.00 |
| Diamorphine 30mg | 20.00 |
| Tazocin 4.5g | 20.00 |
| Tazocin 2.25g | 20.00 |

All of the 25 most high-risk products identified were used as intravenous infusions

Discussion

Identifying risk factors There is little published evidence about the risks associated with the preparation of injectable products on hospital wards. An observational study carried out to detect medication errors and identify risk during the administration of intravenous products found that almost half of the doses made up contained at least one mistake.¹² Most errors identified would only have caused short-term adverse effects, although a few (1 per cent) could have had serious consequences. The study noted that making up drugs that required multiple step preparation was particularly susceptible to error. This is consistent with the methodology used in this current paper, which puts the greatest emphasis on the preparation part of the process.

Comparing results Differences in the products identified as each site’s “top 25” high-risk products are to be expected. This is because different products will be in use at a tertiary specialist centre (Freeman Hospital), as compared with a district general hospital

(North Tyneside Hospital). Where products were common to both hospitals, the differences in ORSs can be explained by factors such as:

- Local variation in environments
- Use of different dose ranges in trusts with separate formularies
- Differences in types of patients in which products were used
- Differences in the familiarity of staff with the product

Despite this, drugs which are likely to be high-risk across the NHS have been identified. However, it is not possible to produce a definitive list of high-risk items. The research suggests that risk assessments should be carried out locally by following a defined universal procedure (see Panel 4).

Managing risk The product which gave the highest ORS at both sites was amphotericin (Fungizone) 50mg intravenous infusion. This is because of the complex dosing, preparation and administration schedules involved. Although it would be reasonable to conclude that this product

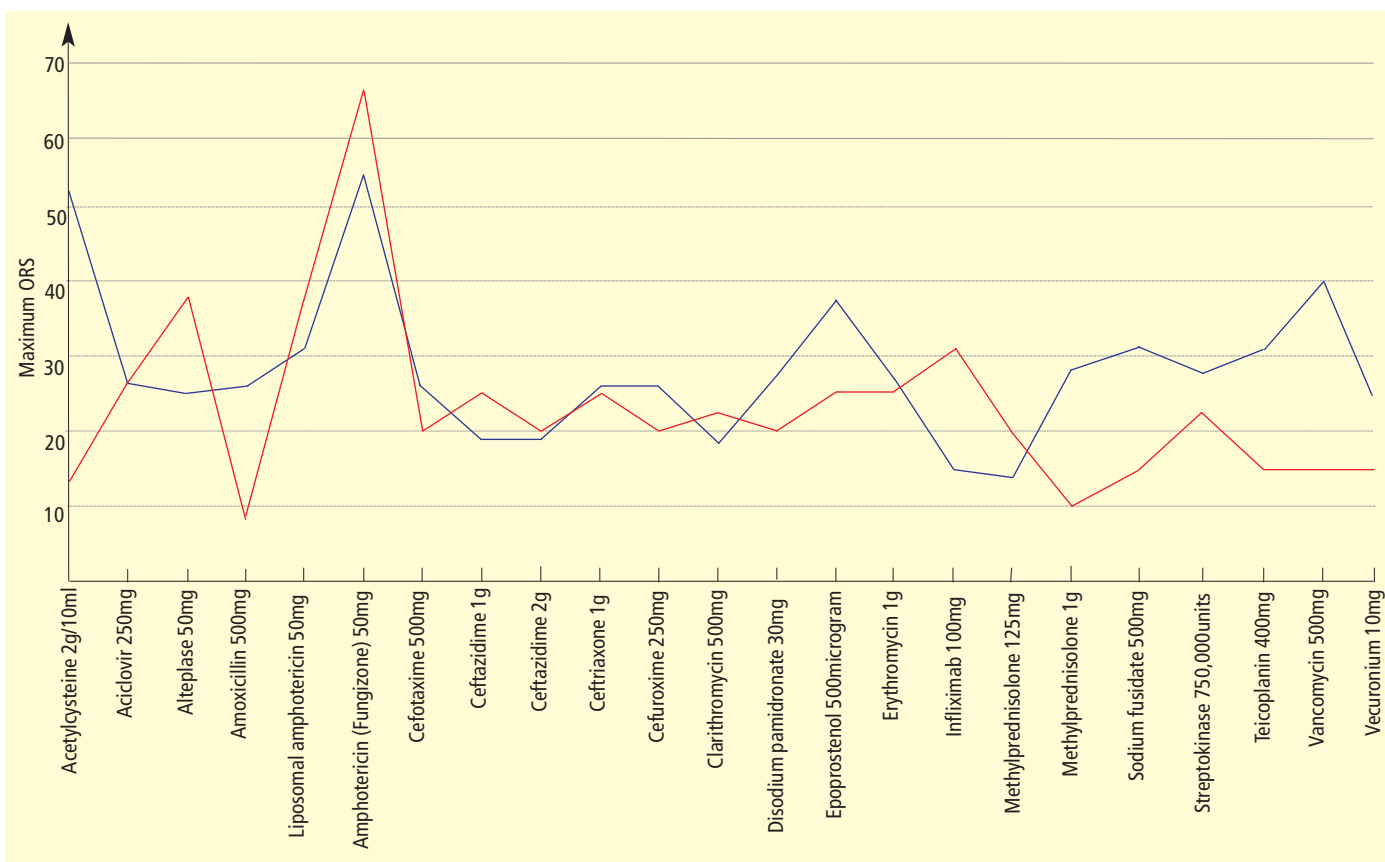


Figure 1: A comparison of the maximum ORSs of the 23 products that were evaluated at both Freeman and North Tyneside Hospitals and were in the "top 25" at either site. The red line represents the maximum ORS for the product achieved at the Freeman Hospital and the blue line represents the maximum ORS for the product achieved at the North Tyneside Hospital. "ORS" means overall risk score. All 23 products were used as intravenous infusions.

Panel 4: Procedure developed for using the risk assessment tool

1. List all injectable drugs issued to each location for a specific period (eg, six months)
2. Interview a senior member of nursing staff from each location to establish the exact method of administration of any unfamiliar drugs and to give a nursing perspective on the preparations perceived to carry high risks
3. Individually assess each preparation process against the risk factors. Enter the resulting scores into the risk assessment tool spreadsheet and calculate the ORS
4. To ensure consistency of results and transferability of data, make the following assumptions when totalling the number of manipulations and calculations:

- Do not include administering the product to patients as a manipulation
- Do not include making up a standard dose (eg, ceftazidime 1g) as a calculation
- Assess each product for standard or variable doses. For example, furosemide may be given as a standard dose of 20mg (20mg/2ml vial), in which case a full vial is used. Only one manipulation is required to draw up the dose and no calculation is necessary. However, if a variable dose of 30mg is given, two vials are required, which gives double the number of manipulations. A calculation is also introduced, and a part vial is used. This increases the risk score
- Give the highest risk possible for each product (ie, use multiple vials or possible non-standard dose options)
- Do not include prefilled syringes — there are no manipulations and so the formula is not designed to cover these
- Include drug infusion bags (eg, for metronidazole, ciprofloxacin). Add one manipulation for attaching the giving set
- Do not include any diluents used (eg, sodium chloride or glucose)
- Assign one calculation to infusions for determining the infusion rate
- Do not assign a calculation for adding a standard diluent volume (eg, reconstituting a powder)
- Do not assign a calculation for determining a mg/kg dose (ie, assume that the actual dose to be given is always written on the inpatient treatment chart)

should be prepared in a pharmacy department, it may not be possible to do this because, for example, resources allocated to the pharmacy budget might not be adequate to cover this activity. In the case of the Freeman and North Tyneside hospitals, bids have now been made for funds to transfer the preparation of this and other high-risk items to pharmacy facilities. Another possibility is to transfer the production of high-risk items to CIVA (central intravenous additive) units, as long as stability data for the product confirm that this is appropriate. A potential candidate for this is erythromycin infusion, which had a maximum ORS in the "top 25" at both of the hospitals studied.

Purchasing pre-filled syringes could be another option. Although more expensive than formulations that require preparation, these reduce risk and could therefore represent a good medicines management investment in the long term. Where such ready-to-administer products are not available, there is a case for persuading the pharmaceutical industry to produce them. It might also be appropriate for provision to be made such that regulatory authorities consider the need for having ready-to-administer formulations when licensing medicines.

Where none of the options set out above is viable, better training of nursing staff, with pharmacy involvement, can help

reduce risk. For example, good practice is now reinforced at Freeman Hospital by a “clinical skills intravenous study day”. This emphasises “no touch” and other manipulation techniques, and includes a pharmacist speaking about the risks of contamination and a pharmacy technician giving a practical demonstration of intravenous product preparation. At North Tyneside Hospital, specific guidelines for the preparation and administration of all the intravenous products used in the trust have been introduced, and a new “intravenous preparation skills” training package for nursing staff is being developed.

Conclusion

The risk assessment tool developed at Freeman Hospital can be used to identify high risk products in a range of clinical settings. The universal procedure for use of the tool must, however, be carefully adhered to in order to give a consistent approach to the calculation of ORSs.

There is a case for transferring the preparation of the products with the highest ORSs to pharmacy departments. Risks for items that continue to be prepared in clinical areas should be minimised by having pharmacy staff provide appropriate training to nursing staff and give advice on reconstitution practices.

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