

# A RISK ASSESSMENT OF THE WARD-BASED PREPARATION OF PARENTERAL MEDICINES

By A. M. BEANEY, MSc, MRPHARMS, and J. GOODE, BSc, MRPHARMS

- **OBJECTIVES** - To determine the number of parenteral products made up on wards. To assess the contamination risk involved with making up the products by carrying out environmental monitoring and analysing preparation techniques.
- **DESIGN** - Questionnaire and observation. Environmental monitoring using contact plates, settle plates and air sampling.
- **SUBJECTS AND SETTING** - A range of wards at Freeman Hospital, Newcastle-upon-Tyne (excluding theatres).
- **RESULTS** - Potential contamination risks involving environmental conditions and preparation technique were highlighted. Recommendations based on these were made.
- **CONCLUSION** - The environmental conditions, staff training and techniques varied greatly.

This work was presented as a poster at the European Association of Hospital Pharmacists meeting in Vienna 2002, having won the 2001 Antigen award of the Guild of Healthcare Pharmacists.

Ms Beaney is regional quality assurance specialist and Ms Goode was a preregistration trainee at the time the study was carried out, at the Freeman Hospital, Newcastle-upon-Tyne. Correspondence to Ms Beaney at Pharmacy Department, Freeman Hospital, Newcastle-upon-Tyne NE7 7DN (e-mail [alisonm.beaney@nuth.northy.nhs.uk](mailto:alisonm.beaney@nuth.northy.nhs.uk)).

As long ago as 1976, it was realised that the best way to reduce the risk of parenteral medicines being contaminated was for all aseptic manipulations to be carried out under pharmacy control.<sup>1</sup> In many busy hospitals, however, this is just not possible given the limitations of space and staffing resources in pharmacy aseptic units, and so many parenteral medicines are made up on wards.<sup>2</sup>

While there are standards and external audits in place for the aseptic preparation of products undertaken in pharmacies,<sup>3,4,5,6</sup> there are no equivalent defined national standards for ward-based aseptic preparation, although the Committee for Proprietary Medicinal Products recognised the need to limit the time between preparation and administration to minimise the risk of microbial contamination.<sup>7</sup>

The need to adhere to strict aseptic techniques to prevent contamination and possible infection was highlighted by incidents such as the contamination of a container of saline with blood from a malaria patient,<sup>8</sup> and the contamination of propofol in the United States.<sup>9</sup>

The aim of this study was to identify the contamination risks associated with preparing parenteral medicines on wards, both in terms of the environment in which they are made up, and the preparation techniques used. Recommendations would then be made on reducing the risks.

## METHOD

**Phase 1** A questionnaire was developed to determine the type of products prepared on wards, how often the products were made up, how much time was spent making them up, and how much ward-based aseptic preparation was carried out within normal pharmacy opening hours. The questionnaire also addressed some of the issues associated with contamination, such as whether any policies on aseptic manipulations were in use on the ward (and whether the ward had a copy of the policy) and the level of training

required before staff were permitted to carry out aseptic manipulations. The questionnaire was sent to all 32 wards (but not theatres) at the Freeman Hospital, Newcastle-upon-Tyne. Each ward was asked to choose a typical day to base their responses on, or give average results for a typical day.

**Phase 2** A detailed plan of the layout of each of 11 wards was made, indicating the exact location where parenteral medicines are prepared. Based on the plan, the environmental conditions in the locations where aseptic manipulations were carried out were monitored by one of the authors using settle plates (90mm diameter, containing casein soya bean digest agar with 1% glucose) contact plates (55mm diameter, containing tryptic soya agar with inactivators) and active air sampling. The air sampling was carried out, taking 100L samples, results being multiplied by a factor of 10 to convert to cfu (colony forming units)/m<sup>3</sup> to allow comparison with EU grades. The laminar flow cabinet in the pharmacy aseptic suite, used for preparation of parenteral nutrition products, and a custom-made glovebox with filtered air (used on Ward 2 to prepare BCG bladder instillations) were also monitored to provide a comparison. Conditions in both of these locations would be expected to achieve EU "Grade A" standard. The monitoring was performed on one occasion in each ward during the time a member of staff carried out an aseptic manipulation. Where necessary, results were extrapolated to allow comparison with EU grades.

While the environmental monitoring was being carried out one of the authors, who was trained in aseptic techniques, made detailed observations on pre-manipulation practices, aseptic manipulation techniques, labelling, documentation and checking procedures were made. A record of whether the product was administered immediately was also made. The Freeman Hospital's operator validation broth test was also undertaken on a typical ward by a validated pharmacy operator.

**Phase 3** Based on the results obtained in phases 1 and 2, recommendations to reduce the risk of contamination were made.

## RESULTS

**Phase 1** Of the 32 wards who were sent questionnaires, 22 returned them completed (69 per cent response rate). Preparations each day varied from none to more than 10 (see Table 1), totalling 247 aseptic manipulations a day for the hospital as a whole.

Given that the average number of aseptic manipulations carried out daily in the pharmacy is 77, this means that approximately 25 per cent of aseptic preparation is carried out in the pharmacy, and 75 per cent is carried out on the wards.

The most common type of manipulation was reconstitution of antibiotics. Other manipulations included additions to infusions and, out of pharmacy hours, some wards made up ganciclovir, which is treated by the Freeman Hospital as a cytotoxic. The time estimated for performing each aseptic manipulation varied from less than 5 minutes to more than 20 minutes, the average being 7.3 minutes per item. Approximately 50 per cent of respondents indicated that most of the aseptic manipulations were undertaken when the pharmacy was open.

Of the wards that responded to the questionnaire, 50 per cent said that they had a policy for aseptic preparation. However none was able to supply a copy — three wards sent a copy of their nurse training document instead. None of the respondents mentioned the Freeman Hospitals “Hospitals and community policy on medicines 1993” or the “Hospital intravenous drug administration policy 1999” that cover certain aspects of aseptic preparation, although not in much detail.

Regarding training, 59 per cent of wards mentioned that nurses on their wards attended the intravenous study day run by the trust. Thirty-six per cent of wards mentioned the hospital’s competency assessment policy whereby authority to carry out aseptic preparation depends on the staff member carrying out aseptic manipulation correctly on six occasions and answering questions, as assessed by a senior nurse.

**Phase 2** The results of settle plates and contact plates are shown in Table 2, and air sampling in Table 3 (p308). The observations made during ward visits are summarised in Panel 1 (p308). The operator broth test showed contamination with *Staphylococcus* in seven out of the 20 containers.

**Phase 3** Recommendations made as a result of phases 1 and 2 were:

- To develop guidelines for aseptic preparation and to display a laminated copy of the guidelines on wards

**Table 1: Number of daily aseptic manipulations on**

Number of manipulations	Number of wards
none	1
1–4	3
5–9	6
10 or more	12

- To advise on the most suitable location for aseptic manipulation, where more than one location in a ward was in use
- To increase the level of pharmacy input into nurse training.

## DISCUSSION

The monitoring carried out using contact plates, settle plates and air sampling showed that the environment in the wards in the locations where aseptic manipulations are carried out was extremely variable. For airborne contamination, the variation is largely unavoidable, due to the nature of access and ventilation. The failure of the validation test in the ward situation by an experienced pharmacy operator is further evidence of the potential risk of contamination of products when prepared in this uncontrolled environment.

Surface contamination (as monitored by contact plates) can be controlled to a certain extent by, for example, properly cleaning the benches on which medicines are to be prepared. That this was not always carried out,

along with the fact that none of the wards were able to supply a copy of their policy for aseptic preparation, is worrying. But the guidelines developed and displayed in wards, which give simple instructions on aseptic technique and prompt staff to clean surfaces and wear gloves, should improve the situation.

Better staff training should also help reduce the risk of contamination during the preparation of parenteral products. The trust’s “intravenous study day” was a potentially useful means of training, but in reality, there was little reference to aseptic technique and a long waiting list for attendance. In its place, the new “clinical skills intravenous study day” has more emphasis on aseptic technique, and includes a presentation on reducing contamination during the preparation of IV medicines given by a pharmacist, and a practical demonstration given by a pharmacy technician. Similarly, there were previously no written guidelines for the competency assessment policy, and so bad practice was potentially allowed to perpetuate. It is hoped that the written guidelines on display and pharmacy staff input into training will prevent this.

Hazards associated with poor checking, documentation and labelling procedures, which could potentially lead to medication errors, were also identified. Ideally, a United Kingdom code of intravenous administration practice should be established to ensure uniform standards. In the meantime, a second nurse check was included in the guidelines.

The high number of aseptic manipulations carried out at ward level (75 per cent, as opposed to 65 per cent in the “North West study”<sup>2</sup>) is probably a reflection of the absence of a CIVA service at the Freeman Hospital.

**Table 2: Environmental conditions at various locations, measured using contact plates and settle plates**

Location	Contact plates (cfu/55mm plate)	Settle plates (cfu/90mm plate/4h)
Pharmacy aseptic unit	0 (A)	0 (A)
Ward 2 (glovebox)	0 (A)	0 (A)
Ward 4x	200b (U)	16b (C)
Ward 4y	300b (U)	96b + 64m (U)
Ward 6x	7b + 1m (C)	48b (C)
Ward 6y	15b (C)	14b (C)
Ward 16x	6b + 1m (C)	48b (C)
Ward 16y	1b (B)	32b (C)
Ward 23x		29b (C)
Ward 23y		29b + 10m (C)
Ward 26	16b (C)	80b (D)
Ward 27	12b (C)	0 (A)

Where more than one location on the ward was monitored, the results are indicated as “x” and “y”. The EU equivalent grades<sup>6</sup> for the particular type of monitoring are shown (in parenthesis) for comparison. “U” means unclassified, “b” is bacteria and “m” is mould, and “cfu” is colony forming unit

**Table 3: Environmental conditions at various locations, measured using air sampling**

Location	Count (cfu/m <sup>3</sup> )	
Pharmacy aseptic unit	<1	(A)
Ward 2 (glovebox)	<1	(A)
Ward 4	160	(D)
Ward 6x	230	(U)
Ward 6y	40	(C)
Ward 8	90	(C)
Ward 10	60	(C)
Ward 11	50	(C)
Ward 12x	100	(C)
Ward 12y	20	(C)
Ward 18	30	(C)
Ward 20x	60	(C)
Ward 20y	10	(B)
Ward 23	40	(C)
Ward 26	120	(D)
Ward 27	130	(D)

Where more than one location on the ward was monitored, the results are indicated as "x" and "y". The EU equivalent grades<sup>6</sup> for the particular type of monitoring are shown (in parenthesis) for comparison. "U" means unclassified and "cfu" is colony forming unit

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Despite the lack of a CIVA service, there is some scope for transferring high-risk products to pharmacy. Other means of reducing contamination risk include purchasing items from licensed CIVAS units in other hospitals or from pharmaceutical companies. In a risk management conscious trust, this type of purchasing decision may be seen as a good medicines management investment. It might also be a good idea to lobby the pharmaceutical industry to respond to the need for ready-to-administer presentations.

## CONCLUSIONS

Standards of environment, training and practice are variable at ward level. However, increasing pressure on pharmacy means that a significant proportion of aseptic manipulations will continue to be carried out beyond pharmacy control. This does not mean that pharmacy staff should not be involved – risks should be assessed by pharmacy staff, and advice given on their reduction. Other means of reducing risks, such as establishing guidelines, buying in certain products or transferring the preparation of high-risk products to pharmacy, should also be considered. Indeed, further work has been carried out on the development of a risk assessment tool which has won the 2003 Baxter Award of the Guild of Healthcare Pharmacists.

**ACKNOWLEDGEMENTS** Thanks to Allison Sykes, Control of Infection, at Freeman Hospital Newcastle-on-Tyne and the staff of the NHS Pharmaceutical Quality Control Laboratory at Stockton.

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## Panel 1: Percentage incidence of potential risks observed when staff members prepared parenteral medicines on 11 wards

### Potential contamination risk

No handwashing	33
Preparation area not cleaned	83
Gloves not worn	83
Procedures not present on ward	100
Preparation not given immediately	0

### Potential medication risk

No check of the medication chart by a colleague	17
Correct documentation not present on ward	100