

# A RISK ASSESSMENT OF THE PREPARATION OF PARENTERAL MEDICINES IN CLINICAL AREAS

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**OBJECTIVE** - To assess the risk involved in the preparation of parenteral medicines in non-pharmacy clinical areas.

**DESIGN** - Questionnaire and observation.

**SUBJECTS AND SETTING** - Clinical areas involved in parenteral medicines preparation at Perth Royal Infirmary.

**RESULTS** - Potential microbiological hazards, medication errors and potential hazards to staff were identified. Recommendations were based on these.

**CONCLUSION** - A number of hazards are present during the preparation of parenteral medicines in clinical areas at Perth Royal Infirmary. Since it is not feasible for all parenteral medicines to be prepared in the pharmacy, a number of simple control measures have been proposed to reduce the level of risk and to allow parenteral medicines to be prepared safely in clinical areas.

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In recent years there have been increasing concerns about the risks to health when receiving treatment and care.<sup>1</sup> Clinical governance is concerned with consistent improvement in the quality of clinical care across a whole organisation<sup>2</sup> and there is an increasing acceptance that the management of clinical risk is an important aspect of clinical governance.

Parenteral medicines are frequently used to treat patients admitted to hospital. The administration of poor quality parenteral medicines is associated with well-identified risks of mortality and morbidity.<sup>3,4</sup> Patients may be exposed to hazards that arise from deficiencies in systems of control employed to regulate the prescribing, preparation and administration of these medicines.

After the deaths of two children in a Manchester hospital as a result of contaminated parenteral nutrition solutions,<sup>5</sup> much attention was paid to standards of preparation, facilities and systems of control employed in hospital pharmacy aseptic units.<sup>6</sup> Most parenteral medicines, however, are prepared in uncontrolled clinical areas by nurses and doctors and this practice is not subjected to the same rigorous controls.

Many of the hazards associated with the use of parenteral medicines are related to personnel (eg, handwashing, staff training),<sup>7</sup> preparation environment and documentation. In order to reduce the risks associated with the preparation of parenteral medicines, factors influencing where medicines are prepared must be assessed.<sup>8</sup> These include:

- Complexity and risk of preparation error
- Potential for microbial growth in the finished product
- Health and safety aspects, eg, toxicity to the handler
- Chemical stability of the product and its shelf life
- Pharmaceutical considerations (eg, packaging system)
- Regulatory aspects
- Clinical issues

Having undertaken such an assessment, it should then be possible to determine the

best preparation location for different types of parenteral medicines.

Perth Royal Infirmary is a 380-bed district general hospital providing medical, surgical, orthopaedic, paediatric and critical care services to the population of Perth and Kinross. The pharmacy aseptic dispensary provides parenteral nutrition, cytotoxic chemotherapy, opioid syringes and patient controlled analgesia from a five-day, 9am to 5pm service. At the hospital, most parenteral medicines are therefore prepared in uncontrolled environments on wards, in theatres and in clinics.

The aim of this study was to identify risks associated with the preparation of parenteral medicines in clinical areas at the hospital and to make recommendations on reducing these risks to patients and staff.

## METHOD

A questionnaire was developed to determine the environmental conditions within each clinical area where parenteral medicines were prepared, the types of parenteral medicines prepared in the area and the training that had been provided to staff preparing the medicines. It was sent to all clinical areas involved in the preparation of parenteral medicines. (A copy of the questionnaire is available from the authors on request.)

A pharmacy technician, with experience in aseptic techniques and in training technical and nursing staff in the preparation of parenteral medicines, assessed current practice for the preparation of parenteral medicines in a number of clinical areas. To assist in this assessment, a standard checklist was developed based on published best practice<sup>9</sup> and the techniques and practices common to pharmacy aseptic preparation services.

Observations were carried out in eight clinical areas considered to provide a range of different patient groups. The following areas were chosen:

- Theatres
- Coronary care unit
- High dependency unit

- Intensive therapy unit
- Medical admissions ward
- Medicine and haematology ward
- Paediatric ward
- Care of the elderly ward

## RESULTS

Analysis of the results from 58 completed questionnaires (67 per cent) highlighted the following hazards (the number of incidences of each hazard is shown in parenthesis):

- Staff used a sink draining surface (3) and a wooden worktop (4) to prepare parenteral medicines
- Hazards in the immediate vicinity to preparation areas were listed as sink (48), drain (16), general waste bin (47), external air vent (15) and window (11)
- There was no formal training for medical staff in the preparation of parenteral medicines

During the observation of eight staff preparing parenteral medicines, several hazards were noted (Panel 1).

## DISCUSSION

Considerable literature and guidance is available relating to the preparation of parenteral medicines under controlled pharmacy conditions.<sup>6,9,10</sup> There is, however, a lack of evidence-based guidance available for the preparation of such medicines in clinical areas, outside the control of pharmacy. At Perth Royal Infirmary, as in many other hospitals, most parenteral medicines are prepared in clinical areas before administration to the patient. This current study, in addition to other recent work,<sup>11</sup> highlights that preparation of parenteral medicines in clinical areas carries a significant risk to the patient and to staff preparing the medicines. Although there is no evidence to show that the hazards identified in this current study have led to sepsis, medication errors or harm to staff, the risk of events occurring is highlighted and therefore cannot be ignored.

It is proposed that these risks may be managed by implementing a range of relatively simple control measures. These would include ensuring the capability of staff, providing a suitable preparation environment and implementing systems of work that include a risk assessment process for individual products.

It is not necessary or desirable for all parenteral medicines to be provided from a pharmacy controlled aseptic service, since many products can be made in patient care areas with acceptable levels of risk. A recent report has advocated that the practice of preparing aseptic preparations on hospital wards should be stopped.<sup>12</sup> This development would not be feasible with the current

### Panel 1: Number of potential hazards identified when eight staff members were observed preparing parenteral medicines

#### Potential microbiological hazards

● No handwashing	1
● Incorrect swabbing technique	1
● Vial punctured immediately after swabbing	1
● Air drawn from the room into a syringe	1
● Lack of "no touch technique"	2
● Sink used to dispose of excess drug in the syringe during preparation	1
● Glass ampoules opened with a paper towel	1
● Preparation undertaken on a non-sterile cardboard tray	1
● Antibiotic syringe placed uncapped on a cardboard tray after preparation and carried through the ward to the patient	1

#### Potential for medication errors

● Staff interrupted during preparation	2
● No check of the medication chart by a colleague	1
● Drug or diluent not checked	2
● Calculations not checked	6
● Dose measured inaccurately	5
● No check that drug was dissolved before drawing back into a syringe	1
● Syringe not labelled	6
● Syringe labelled, but no patient name	1

#### Potential hazards to staff

● Spillage during the preparation, including antibiotic preparations	4
● Sharps risk from empty ampoules taped to syringes to identify the contents	1

level of demand for aseptically prepared medicines (in 1997, 65 per cent of aseptic medicines prepared in NHS trusts were prepared on wards<sup>13</sup>) and the lack of capacity in aseptic dispensing departments within the NHS. Such a development may also place undesirable barriers in the way of patient-centred care. When a medicine is presented in a form that requires no further manipulation and there are no health and safety risks to staff preparing the medicine, then preparation can safely be undertaken in patient care areas by suitably trained staff, thus ensuring the patient receives the medicine at the required time. The risk management approach as set out in this paper is supported by a recent Clinical Resource and Audit Group publication.<sup>14</sup> Centralised Intravenous Additive Services (CIVAS) have traditionally focused on the preparation of high volume, low risk products such as intravenous antibiotics. The challenge for pharmacists providing specialist aseptic services is to minimise high risk activities on wards by providing high risk parenteral medicines and parenteral medicines for high risk patients from a controlled aseptic service.<sup>15</sup>

## RECOMMENDATIONS

The following recommendations are based on the results of the risk assessment undertaken and peer review of the findings. They are similar to the findings of other studies carried out locally and nationally.<sup>11,15</sup>

### Preparation environment

*Standards should be agreed for the preparation environment for parenteral medicines in clinical areas* There is wide variation in the environmental conditions available for the preparation of parenteral medicines within clinical areas in our hospital. Standards should be developed to give guidance on a suitable preparation location and environment. This does not imply that all clinical areas require controlled environmental conditions such as in a pharmacy aseptic unit, but that designated areas that are easily cleaned and free from clutter are used for the preparation of parenteral medicines.

*The current environment in clinical areas should be assessed and upgraded as necessary* The environment used for preparation should be assessed in each clinical area against the agreed standards and any actions required to bring areas up to the agreed standard should be taken.

### Training

*All staff involved in the preparation of parenteral medicines should receive formal training* In Tayside, medical staff receive little or no formal training in the preparation of parenteral medicines. Since the development of IV trained nurses, medical staff are required to prepare parenteral medicines less often. This lack of expertise and practice increases the likelihood of poor technique. All staff required to prepare parenteral medicines should be given formal, competency-based training.

Regular training updates should be available for all staff involved in the preparation of parenteral medicines. An update or refresher course would reinforce initial training and prevent the development of poor technique. This is good practice and should be part of continuing professional development for all staff involved in aseptic preparation.

#### Checklist

A checklist should be posted next to preparation areas. Many members of staff prepare parenteral medicines on an infrequent basis, often with limited time available. A checklist posted over the preparation area with the main points on aseptic technique and the checks required during preparation would be a simple and effective reminder.

#### Documentation

Documentation for preparation and checking should be agreed. There is currently no documentation of the preparation or checking details in clinical areas. A simple system should be agreed to allow the documentation of essential information, including the identity of staff preparing and checking parenteral medicines and the time of preparation.

A ward reference manual providing advice on the preparation and administration of parenteral medicines should be available and reviewed regularly. The current "Preparation and administration of intravenous medicines" manual available in clinical areas needs to be updated to include these recommendations and to include good practice statements and checklists. The manual and supporting reference materials for preparation of parenteral medicines should be available electronically and should be regularly reviewed and up-dated.

#### Preparation of parenteral medicines

A multidisciplinary team should assess the options for preparation of parenteral medicines. Pharmacy staff should review the range of parenteral medicines prepared in the aseptic dispensary to take into account high-risk products and products for high-risk patients. Products available in ready-to-use form should be used where possible.

Where parenteral medicines are not available in a ready-to-use form and are not provided via a pharmacy aseptic service, a multidisciplinary team should undertake a risk assessment to determine the optimal location for the preparation of parenteral medicines for high-risk patients.

#### Audit

A regular audit of clinical areas used for the preparation of parenteral medicines should be implemented. An audit tool based on the agreed standards for the preparation of parenteral medicines in clinical areas should be developed. An audit should be carried out on a regular basis, to confirm compliance with

the agreed standards or highlight any potential risks requiring corrective action. Results from the audit cycle should be communicated through clinical audit meetings.

#### Management/implementation

A multidisciplinary steering group should be formed to take forward the actions required to improve the safety of parenteral medicines prepared in clinical areas. A multidisciplinary group has been formed for NHS Tayside with a remit given by the area drug and therapeutics committee and the area control of infection committee. The group has nominated membership from medicine, nursing, pharmacy, infection control and clinical governance. The group is charged with reviewing current practice, establishing control systems and monitoring practice standards.

#### CONCLUSION

This work has shown that currently, a number of hazards are present during the preparation of parenteral medicines in clinical areas in Perth Royal Infirmary, resulting in risks to patients from medication errors and microbial contamination.

Given that it is neither desirable nor feasible for all parenteral medicines to be prepared within pharmacy, a number of simple control measures have been proposed to reduce the level of risk and allow parenteral medicines to be prepared safely in clinical areas.

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#### Exercises in clinical accuracy checking

The exercises in clinical accuracy checking series has been suspended pending the appointment of a new editor for *Hospital Pharmacist*.

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