

DETERMINING THE RATES AND TYPES OF ERRORS IN PHARMACY-MANAGED ASEPTIC PREPARATION UNITS

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- **OBJECTIVE** - To determine the types and rates of errors in pharmacy-managed aseptic preparation units.
- **DESIGN** - Manual recording of errors at aseptic units. Data collated and, for the national scheme, reported back.
- **SUBJECTS AND SETTING** - Eight aseptic units (pilot study) and aseptic units throughout the United Kingdom (national reporting scheme).
- **RESULTS AND CONCLUSIONS** - Error rates were generally low, but certain specific and recurring errors were identified.

Risks associated with the ward-based preparation of aseptic products have been recognised for a long time. For example, Breckenridge recommended as far back as 1976 that injectable products should be prepared under the control of pharmacy.¹ The uptake of this advice has been limited, but more recent guidance has reinforced that this principle should still be pursued.²

However, pharmacy aseptic services themselves have not been without errors. In particular, a serious incident in the United Kingdom in 1994, where the administration of contaminated total parenteral nutrition solutions resulted in the death of two infants, led to a wide-ranging review of many aspects of hospital pharmacy aseptic services. Following the incident, specific guidance on the standards to be applied to aseptic dispensing activities within the National Health Service was issued by the Department of Health.³ In addition, all unlicensed aseptic preparation services were made subject to a regular external audit, co-ordinated by members of the NHS Pharmaceutical Quality Assurance Committee (PQAC), with units holding "specials" licences being subject to regular inspection by the Medicines and Healthcare products Regulatory Agency. The PQAC also published detailed guidance of the standards to be met in unlicensed pharmacy-managed aseptic facilities.⁴

Despite the attention paid to regulating pharmacy aseptic services, few studies have been carried out to determine the error rates in pharmacy-controlled aseptic preparation units. Some small-scale studies, such as that carried out in the then South Thames region, have looked at the types and causes of error, and useful learning points were gained from these.

It was therefore decided to undertake a pilot study to record and evaluate the type and frequency of errors occurring within aseptic processing activities, with the aim of identifying areas of weakness in the procedures, materials, equipment and control systems typically used in preparing products in an aseptic unit. It is important to note that this study was designed to look at errors occurring in processes within aseptic preparation units. Most errors will be detected by

normal checks incorporated into the production process, and so do not indicate that a patient received a defective or incorrect product. The pilot study was then to be rolled out at other units to launch a national error reporting scheme.

METHODS

Pilot study Staff at eight pharmacy aseptic units recorded details of errors at the time they were detected within the unit. The information was then collated monthly at each site, transcribed to a blank Excel spreadsheet and sent electronically to the scheme co-ordinator. The sample units, staff from which had volunteered to take part, represented a mixture of sizes of units, some of which were licensed and others unlicensed. The definition of error used is shown in Panel 1. Participants were asked to classify each error according to the following criteria:

- Licensed status of aseptic unit
- Type of product being produced
- Error type
- Person who detected the error
- The stage in the production process at which the error was detected
- Person who made the error
- Contributory factors
- Severity of outcome (if the product containing the error had been administered to a patient) or potential outcome (if the error was detected before administration)

Participants were also asked for any brief, relevant comments. Regarding

Panel 1: Definition of error used in the pilot study

"Any occurrence that takes place at any stage of the product preparation process, up to and including storage and distribution, which has the potential to impact on the quality of the product in such a manner that it places the patient receiving the product at risk."

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Panel 2: Summary of the classification of severity used in the national reporting scheme

- None — an error which could have no effect on a patient
- Minor — an error which, if left undetected, could cause non-permanent harm
- Moderate — an error which, if left undetected, could cause semi-permanent harm
- Major — an error which, if left undetected, could cause major permanent harm
- Catastrophic — an error which, if left undetected, could cause death

The classification is a summary of that set out in the National Patient Safety Agency document, "Doing less harm"⁵

contributory factors, more than one factor could be included. Regarding severity, unit managers were asked to estimate whether the severity of the outcome or potential outcome was "none", "minor", "moderate" or "severe". Definitions of the severity categories were not provided at the pilot stage.

The study was run jointly between members of PQAC and the Pharmaceutical Aseptic Services Committee (formerly the National CIVAS Group).

National reporting scheme. Following feedback from participants on the pilot study, several of the reporting categories were clarified to ensure a more accurate classification of results. In particular, the classification of severity was changed to that used in the National Patient Safety Agency "Doing less harm" document⁵, with definitions provided (see Panel 2).

The error reporting arrangements were essentially the same as for the pilot study, except that:

- Staff at all aseptic units in the United Kingdom were invited to submit data
- Responses were co-ordinated regionally by members of PQAC, before being sent to the national controller.

National report summaries are produced every three months. The data is reported back to participants. Specific issues (such as problems attributed to "look alike" packages) are reported back to companies as appropriate.

RESULTS

Pilot study A total of 357 error reports were received from data submitted on a total of 190,000 products. This represents an error rate of 0.19 per cent. Data setting out the error types and contributory factors are shown in Tables 1 and 2. Regarding the potential severity of the outcome of errors, 49 per cent were classified as "none", 35 per cent as "minor", 12 per cent as "moderate",

and 4 per cent as "serious". Data for errors with a potentially severe or moderate outcome was further broken down so that specific and recurring errors could be identified. These were identified as:

- Selection of incorrect strength of cytotoxic preparation where several strengths are commonly in use

- Incorrect cephalosporin used, or finished product labelled with incorrect cephalosporin product name
- Cytotoxic doses supplied on wrong day of regimen
- Selection of incorrect intravenous infusion fluid

The number of products that actually left a pharmacy department with an error in them was seven and the number of products that left a pharmacy department with an error in them and were administered to patients was one. All of the errors in products that left a pharmacy department (whether or not the product was then administered) were classified as having no or minor consequences.

National reporting scheme In the first nine months of the national scheme, a total of 1,697 error reports were received from the data submitted on a total of 155,000 doses. This represents an error rate within processes of 1.09 per cent.

Data setting out the error types and contributory factors are shown in Tables 3 and 4.

Table 1: Types of error recorded during the pilot study (n = 357)

Error type	Number of errors
Incorrect transcription	39 (11)
Calculation error	25 (7)
Incorrect drug used	11 (3)
Incorrect dose used	36 (10)
Incorrect diluent or fluid used	14 (4)
Made up to incorrect final volume	36 (10)
Labelling error	122 (34)
Incorrect expiry date added to final product	28 (8)
Inadequate closure	3 (1)
Particles found in product	0 (0)
Other	43 (12)

Figures in parentheses represent the percentage occurrence of that particular type of error, compared with all error types

Table 2: Contributory factors recorded during the pilot study (n= 357)

Contributory factors	Number of errors
Staff error	224 (51)
Inadequate training	9 (2)
Inadequate facility or equipment	5 (1)
Process failure	4 (1)
Labelling (wrong details on label for final product)	139 (32)
Mislabelling (wrong label put on final product)	8 (2)
Storage or distribution	0 (0)
Inadequate staff levels	4 (1)
Excessive workload	45 (10)

Figures in parentheses indicate the percentage occurrence of that particular contributory factor, compared with all contributory factors. More than one contributory factor could be recorded against each error reported

Table 3: Types of error recorded during the national reporting scheme (n = 1,697)

Error type	Number of errors
Incorrect transcription	291 (17)
Calculation error	35 (2)
Incorrect drug used	52 (3)
Incorrect dose or strength used	52 (3)
Incorrect diluent or infusion fluid used	35 (2)
Made up to incorrect final volume	34 (3)
Labelling error	631 (37)
Incorrect expiry date added to final product	137 (8)
Incorrect containers (eg, infusor bag) used	53 (3)
Particulates found in product	222 (13)
Other	154 (9)

Figures in parentheses indicate the percentage occurrence of that particular type of error, compared with all error types

Of these errors, the potential outcome was classified as minor for 17 per cent, moderate for 3.4 per cent, major for 1.6 per cent and catastrophic for 1 per cent.

The number of products that left a pharmacy department containing an error was 31 and the number of products that left a pharmacy department containing an error and were then administered to a patient was three. One of the errors in products that left a pharmacy department was classified as moderate. The remainder were classified as having no or minor consequences.

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DISCUSSION

There are some notable differences between the data submitted to the national reporting scheme and those gathered during the pilot study, especially concerning the percentage error rates reported. More aseptic units have contributed to the national scheme than the pilot study, and so it is possible that there are significant differences between units in either the error rate or the error reporting rates. Current work is looking at possible reasons for these differences.

Discrepancies aside, the data are useful in highlighting potentially vulnerable areas of the aseptic preparation processes currently in use and identifying valuable learning points. Participants can also use it to compare their own data with the national figures. The overall error rates for both the pilot study and the national error reporting scheme are considerably lower than those found in studies of the ward-based preparation of aseptic products. For example, a recent study reported an error rate of 13 per cent in the preparation of intravenous doses in a ward environment.⁶ Even if the further work mentioned above shows that some units are under-reporting errors, it is unlikely that the overall error rate will rise to the extent that it will be comparable to that found in ward-based preparation.

Moreover, the authors of the ward-based study highlighted a lack of current evidence to show that the centralised preparation of aseptic products under pharmacy control improved service quality.⁶ It is hoped that the participation of more aseptic units and the continued collection of data will allow a clear and ongoing demonstration of the risk reductions that can be achieved by centralisation of the preparation of intravenous doses in well managed, pharmacy-controlled units.

REFERENCES

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Table 4: Contributory factors recorded during the national reporting scheme (n = 1,697)

Contributory factors	Number of errors
Staff error	1,241 (62)
Inadequate training	40 (2)
Facility or equipment error	21 (1)
Poor quality of starting materials used	10 (1)
Inadequate computer system	99 (5)
Poor process design	23 (1)
Poor storage or distribution of final product	289 (14)
Staff level below designated levels for the establishment	21 (1)
Workload above planned capacity	43 (2)
Poor segregation of ingredients	21 (1)
Staff distracted or interrupted	198 (10)

Figures in parentheses represent the percentage occurrence of that particular type of contributory factor, compared with all contributory factors. More than one contributory factor could be recorded against each error reported