Errors associated with the preparation of aseptic products in UK hospital pharmacies: lessons from the national aseptic error reporting scheme

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ABSTRACT

Background Pharmacy aseptic units prepare and supply injectables to minimise risks. The UK National Aseptic Error Reporting Scheme has been collecting data on pharmacy compounding errors, including near-misses, since 2003.

Objectives The cumulative reports from January 2004 to December 2007, inclusive, were analysed.

Methods The different variables of product types, error types, staff making and detecting errors, stage errors detected, perceived contributory factors, and potential or actual outcomes were presented by cross-tabulation of data.

Results A total of 4691 reports were submitted against an estimated 958 532 items made, returning 0.49% as the overall error rate. Most of the errors were detected before reaching patients, with only 24 detected during or after administration. The highest number of reports related to adult cytotoxic preparations (40%) and the most frequently recorded error was a labelling error (34.2%). Errors were mostly detected at first check in assembly area (46.6%). Individual staff error contributed most (78.1%) to overall errors, while errors with paediatric parenteral nutrition appeared to be blamed on low staff levels more than other products were. The majority of errors (68.6%) had no potential patient outcomes attached, while it appeared that paediatric cytotoxic products and paediatric parenteral nutrition were associated with greater levels of perceived patient harm.

Conclusions The majority of reports were related to near-misses, and this study highlights scope for examining current arrangements for checking and releasing products, certainly for paediatric cytotoxic and paediatric parenteral nutrition preparations within aseptic units, but in the context of resource and capacity constraints.

INTRODUCTION

Errors associated with the prescribing, preparation and administration of injectable medicines in secondary care has attracted much attention with studies indicating that errors with injectables occur at a higher rate than with other forms of medicines.[1–6] According to the UK's National Patient Safety Agency (NPSA) recommendations for making injectable medicines safer, some high-risk injectables namely all cytotoxic and total parenteral nutrition (TPN) products and all additions to TPN must be compounded in the pharmacy to minimise risks associated with their preparation.[7] This particular policy is not new to the UK where pharmacy departments have been involved in the preparation and supply of intravenous injections since the Breckenridge Report.[8] Nowadays, as well as cytotoxic products and TPNs, some hospital aseptic units offer a central intravenous additive service (CIVAS) for the preparation of antibiotic, analgesic and other injections and infusions.[9]

The aseptic preparation of medicines in the UK may be carried out in units holding a Manufacturers Specials Licence from the Medicines and Healthcare Products Regulatory Agency (MHRA) or in unlicensed units under Section 10 exemption from the licensing requirements of the Medicines Act provided a number of conditions are met, and there is an acceptable level of quality assurance (QA) together with regular external audit.[10] The development and implementation of technical policy on pharmaceutical QA issues and the coordination of the monitoring of quality in relation to medicinal products prepared in and purchased by hospitals in the UK are carried out by the NHS Pharmaceutical Quality Assurance Committee (NHSPQAC) against accepted standards.[10] No area of practice is without risk, and pharmacy aseptic services have not been without error.[11] For example, there was a serious incident in the UK in 1994 where the administration of contaminated TPN resulted in the death of two infants, but in general there is very little in the academic literature about errors in pharmacy-controlled aseptic preparation units. The National Aseptic Error Reporting Scheme (NAERS) has been collecting data on pharmacy compounding errors via regional pharmacy QA specialists in the UK and returning quarterly summary reports since August 2003.[12] The NPSA defines a patient safety incident as any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care, with prevented patient safety incidents being defined as 'near misses.'[13] The NAERS database is unique because it collects data on all patient safety incidents including in-process errors that do not reach the patient (near-misses).[12] In fact, the vast majority of the NAERS errors are near misses and have been detected before the product leaves the pharmacy, so they are classed as prevented patient safety incidents.

The point of preparing intravenous injections within hospital pharmacy units is to minimise risks associated with their preparation in clinical areas and improve the quality of the final product.[14] While any health professional can potentially commit an error or violate a procedure at some point in their practice, the past decade has seen a shift in focus away from scrutinising the individual,

Table 1 Numbers of errors recorded according to types of error involved for each category of product

Product type	Error type										
	Transcription	Calculation	Drug	Dose/strength	Diluent	Final vol.	Label	Expiry	Container	Other	Total
Cytotoxic adult	211 (10.3%)	70 (3.4%)	49 (2.4%)	94 (4.6%)	126 (6.2%)	110 (5.4%)	826 (40.4%)	188 (9.2%)	50 (2.4%)	323 (15.8%)	2047
Cytotoxic paediatric	11 (8.5%)	4 (3.1%)	1 (0.8%)	10 (7.8%)	4 (3.1%)	3 (2.3%)	57 (44.2%)	13 (10.1%)	1 (0.8%)	25 (19.4%)	129
Parenteral nutrition—adult	93 (13.1%)	63 (8.9%)	86 (12.1%)	59 (8.3%)	8 (1.1%)	23 (3.2%)	220 (30.9%)	11 (1.5%)	7 (1%)	141 (19.8%)	711
Parenteral nutrition—paediatric	35 (19%)	18 (9.8%)	23 (12.5%)	12 (6.5%)	4 (2.2%)	17 (9.2%)	21 (11.4%)	7 (3.8%)	6 (3.3%)	41 (22.3%)	184
Other intravenous additive	140 (10.8%)	90 (6.9%)	29 (2.2%)	57 (4.4%)	54 (4.2%)	141 (10.9%)	417 (32.1%)	102 (7.9%)	39 (3%)	229 (17.6%)	1298
Other prefilled syringes	35 (11.1%)	10 (3.2%)	15 (4.8%)	12 (3.8%)	8 (2.5%)	15 (4.8%)	83 (26.4%)	25 (8%)	3 (1%)	108 (34.4%)	314
Other	20 (9.1%)	11 (5%)	7 (3.2%)	11 (5%)	10 (4.5%)	10 (4.5%)	46 (20.9%)	17 (7.7%)	8 (3.6%)	80 (36.4%)	220
Data missing	2 (4.4%)	4.0 (8.9%)	0	1 (2.2%)	1 (2.2%)	3 (6.7%)	20 (44.4%)	8 (17.8%)	0	6 (13.3%)	45
Total	547 (11.1%)	270 (5.5%)	210 (4.2%)	256 (5.2%)	215 (4.3%)	322 (6.5%)	1690 (34.2%)	371 (7.5%)	114 (2.3%)	953 (19.3%)	4948

towards rectifying the systems and general practices that lead to unsafe events.[15] Understanding the context in which compounding errors occur thus becomes an important part of the QA process towards the enhancement of safety.

While recent UK patient safety initiatives are aimed at improving the safety of injectable medicines in clinical areas,[7] the current study reports on safety within pharmacy production units. The cumulative error reports relating to the preparation of aseptic products in UK hospital pharmacies as collected by NAERS from January 2004 to December 2007, inclusive, were analysed. The present paper summarised the compounding errors reported to NAERS to include product categories, types of errors, the staff involved in making and detecting the errors, the stage at which errors were detected, perceived contributory factors, and potential or actual outcomes. Our aim was to investigate the NAERS reports in order to provide an understanding of the errors being made and reported to the database.

METHODS

The collection of data by NAERS has been described elsewhere[12] and is detailed in Appendix 1 (web-only material) with the reporting categories detailed in Appendix 2 (web-only material). A total of 43 hospital pharmacies participate fully or partially in the Scheme. For the purpose of the current analysis, the cumulative data for the period January 2004 to December 2007 were collated onto one spreadsheet and exported to the software package SPSS (SPSS, Chicago, Illinois). The different variables were presented by cross-tabulation of the data. The study dealt with anonymised data and was approved by the Kingston University, Faculty of Science Research Ethics Committee.

RESULTS

There were a total of 4691 lines of data (reports) for the period January 2004 to December 2007, inclusive. An estimated 958 532 items were made during the same period; thus, 0.49% of items made were associated with at least one error. Most of the reports related to the adult cytotoxic product (40%), followed by other intravenous additives (27%), adult parenteral nutrition (15%), other prefilled syringes (7%), paediatric parenteral nutrition (4%) and paediatric cytotoxic preparations (2%) with 5% recorded as other product and 1% not recorded. Only 24 of the errors in the current study were detected during or after administration to the patient, so the majority of the reports related to near-misses.

Types of error according to product type

There was provision for more than one type of error to be recorded for any one product; consequently, a total of 4948 errors were recorded for the 4691 lines of data (see table 1). The most frequently recorded error was a labelling error (34.2%) followed by transcription errors (11.1%), incorrect expiry (7.5%), final volume errors (6.5%), calculation errors (5.5%), incorrect dose/strength (5.2%), incorrect diluent/infusion fluid (4.3%), incorrect drug (4.2%), and incorrect containers (2.3%) with 19.3% of errors recorded as 'other.' While different types of error were recorded for all the product categories, certain error types were reported more with some preparations (see table 1).

Personnel involved in detecting and making the errors

There was provision, where appropriate, for the involvement of more than one person in any one error to be recorded; consequently, a total of 5527 people were reported to have contributed

Table 2 Numbers of personnel involved in detecting and making the reported errors

Error made by	Error detected by									
	Pharmacist	Technician	ATO	Student technician	Pre Reg	Nurse	Doctor	Patient	Other	Missing	Total
Pharmacist	305 (36.3%)	210 (25.0%)	62 (7.4%)	7 (0.8%)	1 (0.1%)	150 (17.8%)	11 (1.3%)	7 (0.8%)	38 (4.5%)	50 (5.9%)	841
Technician	1378 (48.7%)	1154 (40.8%)	97 (3.4%)	12 (0.4%)	7 (0.2%)	111 (3.9%)	5 (0.2%)	9 (0.3%)	47 (1.7%)	9 (0.3%)	2829
ATO	590 (41.9%)	626 (44.4%)	125 (8.9%)	6 (0.4%)	5 (0.4%)	33 (2.3%)	1 (0.1%)	1 (0.1%)	21 (1.5%)	1 (0.1%)	1409
Student technician	82 (49.4%)	70 (42.2%)	9 (5.4%)	3 (1.8%)	0	2 (1.2%)	0	0	0	0	166
Pre Reg	80 (63.0%)	40 (31.5%)	3 (2.4%)	0	2 (1.6%)	1 (0.8%)	0	1 (0.8%)	0	0	127
Nurse	3 (25.0%)	2 (16.7%)	0	0	1 (8.3%)	1 (8.3%)	1 (8.3%)	0	0	4 (33.3%)	12
Doctor	5 (45.5%)	5 (45.5%)	0	0	0	1 (9.1%)	0	0	0	0	11
Patient	1 (50.0%)	1 (50.0%)	0	0	0	0	0	0	0	0	2
Other	8 (14.3%)	31 (55.4%)	12 (21.4%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	0	0	0	2 (3.6%)	56
Missing	50 (67.6%)	9 (12.2%)	1 (1.4%)	0	0	4 (5.4%)	0	0	2 (2.7%)	8 (10.8%)	74
Total	2502 (45.3%)	2148 (38.9%)	309 (5.6%)	29 (0.5%)	17 (0.3%)	304 (5.5%)	18 (0.3%)	18 (0.3%)	108 (2.0%)	74 (1.3%)	5527

Table 3 Stage at which errors were detected for each product type

Product type	Stage at which error detected									
	First check in assembly area	Operator check in preparation area	During labelling	Final check prior to release	At release stage	In clinical area prior to administration	In clinical area during or after administration	Other	Not recorded	Total
Cytotoxic adult	1045 (55.9%)	109 (5.8%)	47 (2.5%)	451 (24.1%)	65 (3.5%)	108 (5.8%)	7 (0.4%)	31 (1.7%)	5 (0.3%)	1868
Cytotoxic paediatric	27 (24.3%)	11 (9.9%)	5 (4.5%)	41 (36.9%)	6 (5.4%)	16 (14.4%)	1 (0.9%)	4 (3.6%)	0	111
Parenteral nutrition—adult	383 (56.2%)	56 (8.2%)	30 (4.4%)	99 (14.5%)	43 (6.3%)	22 (3.2%)	4 (0.6%)	43 (6.3%)	1 (0.1%)	681
Parenteral nutrition—paediatric	74 (41.3%)	21 (11.7%)	0	47 (26.3%)	16 (8.9%)	7 (3.9%)	3 (1.7%)	11 (6.1%)	0	179
Other intravenous additive	504 (39.3%)	179 (14.0%)	128 (10.0%)	262 (20.5%)	110 (8.6%)	35 (2.7%)	6 (0.5%)	56 (4.4%)	1 (0.1%)	1281
Other prefilled syringes	60 (19.4%)	24 (7.7%)	4 (1.3%)	76 (24.5%)	78 (25.2%)	9 (2.9%)	1 (0.3%)	58 (18.7%)	0	310
Other	68 (31.3%)	33 (15.2%)	7 (3.2%)	35 (16.1%)	40 (18.4%)	3 (1.4%)	2 (0.9%)	26 (12%)	3 (1.4%)	217
Not recorded	24 (54.5%)	3 (6.8%)	3 (6.8%)	8 (18.2%)	2 (4.5%)	2 (4.5%)	0	0	2 (4.5%)	44
Total	2185 (46.6%)	436 (9.3%)	224 (4.8%)	1019 (21.7%)	360 (7.7%)	202 (4.3%)	24 (0.5%)	229 (4.9%)	12 (0.3%)	4691

to the 4691 error reports (see table 2). Technicians were the most likely personnel to be associated with making an error (51.2%), followed by ATOs (25.5%) and pharmacists (15.2%). The involvement of other personnel stood at less than 7% in total. Pharmacists were most likely to detect errors (45.3%) compared with technicians (38.9%) and ATOs (5.6%).

Stages at which errors were detected for product type and error type

The stages at which errors were detected for each product type were examined (see table 3). Figure 1 is a flow chart showing the drug use process from production to administration and illustrates the opportunities for error detection as seven distinct stages. Errors were mostly detected at first check in assembly area (46.6%), followed by final check prior to release (21.7%), operator check in preparation area (9.3%), at release stage (7.7%), during labelling (4.8%), in clinical area prior to administration (4.3%), and in clinical area during or after administration (0.5%) with 4.9% recorded as 'other' and 0.3% instances of non-recording. Errors with some products were detected to a larger extent than average at certain stages in the process. All types of error were detected at the various stages in the process (see table 4).

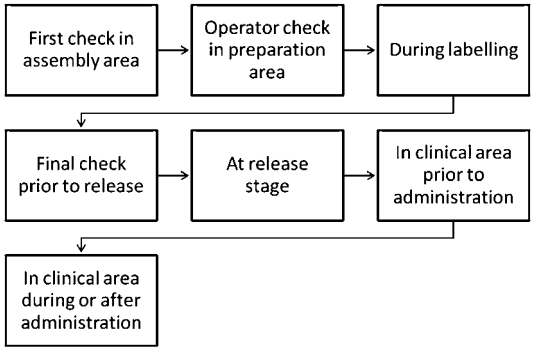

Figure 1 Flow chart of the drug use process from production to administration illustrating the seven stages for error detection.

Factors perceived to have contributed to errors

The factors (5522) perceived to have contributed to errors with each product type were examined (see table 5). The highest rated factor (78.1%) was that of individual staff error followed by distraction/interruption (4.3%), inadequate training (3.7%), workload above planned capacity (3.2%), staffing level below establishment (3.1%), inadequate computer system (2%), process design (1.7%), poor storage/distribution (0.8%), facility/equipment error (0.8%), poor segregation (0.6%) and poor quality of starting materials used (0.4%) with 1.4% not recorded.

Potential impact of error

When potential outcomes of the errors as potential for impact on the patient were examined, it was found that the majority

Table 4 Stage at which errors were detected for each error type

Error type	Stage at which error detected									
	First check in assembly area	Operator check in preparation area	During labelling	Final check prior to release	At release stage	In clinical area prior to administration	In clinical area during or after administration	Other	Missing	Total
Transcription	345 (63.1%)	24 (4.4%)	10 (1.8%)	80 (14.6%)	42 (7.7%)	21 (3.8%)	4 (0.7%)	20 (3.7%)	1 (0.2%)	547
Calculation	166 (61.5%)	33 (12.2%)	10 (3.7%)	35 (13.0%)	10 (3.7%)	4 (1.5%)	1 (0.4%)	11 (4.1%)	0	270
Drug	140 (66.7%)	29 (13.8%)	2 (1.0%)	27 (12.9%)	6 (2.9%)	1 (0.5%)	1 (0.5%)	4 (1.9%)	0	210
Dose/strength	114 (44.5%)	32 (12.5%)	8 (3.1%)	52 (20.3%)	24 (9.4%)	14 (5.5%)	3 (1.2%)	9 (3.5%)	0	256
Diluent	106 (49.3%)	61 (28.4%)	7 (3.3%)	32 (14.9%)	3 (1.4%)	0	0	5 (2.3%)	1 (0.5%)	215
Final volume	38 (11.8%)	40 (12.4%)	8 (25.8%)	116 (36.0%)	20 (6.2%)	9 (2.8%)	1 (0.3%)	14 (4.3%)	1 (0.3%)	322
Label	920 (54.4%)	34 (2%)	59 (3.5%)	435 (25.7%)	100 (5.9%)	106 (6.3%)	3 (0.2%)	31 (1.8%)	2 (0.1%)	1690
Expiry	201 (54.2%)	3 (0.8%)	16 (4.3%)	86 (23.2%)	17 (4.6%)	29 (7.8%)	4 (1.1%)	15 (4.0%)	0	371
Container	49 (43%)	33 (28.9%)	1 (0.9%)	17 (14.9%)	4 (3.5%)	4 (3.5%)	0	5 (4.4%)	1 (0.9%)	114
Other	246 (25.8%)	166 (17.4%)	39 (4.1%)	187 (19.6%)	143 (15.0%)	29 (3.0%)	7 (0.7%)	129 (13.5%)	7 (0.7%)	953
Total	2325 (47%)	455 (9.2%)	235 (4.7%)	1067 (21.6%)	369 (7.5%)	217 (4.4%)	24 (0.5%)	243 (4.9%)	13 (0.3%)	4948

Table 5 Factors perceived to have contributed to errors with each product type

Product type	Perceived contributory factors											Total
	Staff error	Inadequate training	Facility/ equipment error	Poor quality of starting materials used	Inadequate computer system	Process design	Poor storage/ distribution	Staffing level below establishment	Workload above planned capacity	Poor segregation	Distraction/ interruption	Not recorded	
Cytotoxic adult	1745 (80.7%)	75 (3.5%)	23 (1.1%)	13 (0.6%)	55 (2.5%)	47 (2.2%)	10 (0.5%)	51 (2.4%)	40 (1.9%)	17 (0.8%)	58 (2.7%)	29 (1.3%)	2163
Cytotoxic paediatric	98 (64.9%)	4 (2.7%)	2 (1.3%)	2 (1.3%)	13 (8.6%)	2 (1.3%)	0	5 (3.3%)	6 (4%)	1 (0.7%)	15 (9.9%)	3 (2%)	151
Parenteral nutrition—adult	621 (77.6%)	15 (1.9%)	2 (0.3%)	1 (0.1%)	13 (1.6%)	5 (0.6%)	11 (1.4%)	35 (4.4%)	55 (6.9%)	4 (0.5%)	27 (3.4%)	11 (1.4%)	800
Parenteral nutrition—paediatric	155 (68.3%)	7 (3.1%)	5 (2.2%)	3 (1.3%)	7 (3.1%)	6 (2.6%)	1 (0.4%)	13 (5.7%)	12 (5.3%)	2 (0.9%)	14 (6.2%)	2 (0.9%)	227
Other intravenous additive	1161 (80.1%)	61 (4.2%)	10 (0.7%)	3 (0.2%)	19 (1.3%)	24 (1.7%)	14 (1%)	46 (3.2%)	55 (3.8%)	1 (0.1%)	34 (2.4%)	21 (1.5%)	1449
Other prefilled syringes	288 (71.1%)	25 (6.2%)	0	0	3 (0.7%)	4 (1%)	3 (0.7%)	17 (4.2%)	5 (1.2%)	3 (0.7%)	52 (12.8%)	5 (1.2%)	405
Other	201 (78.2%)	12 (4.7%)	2 (0.8%)	0	0	8 (3.1%)	2 (0.8%)	3 (1.2%)	3 (1.2%)	5 (2%)	19 (7.4%)	2 (0.8%)	257
Not recorded	42 (60%)	4 (5.7%)	0	0	0	0	1 (1.4%)	1 (1.4%)	0	0	20 (28.6%)	2 (2.9%)	70
Total	4311 (78.1%)	203 (3.7%)	44 (0.8%)	22 (0.4%)	110 (2%)	96 (1.7%)	42 (0.8%)	171 (3.1%)	176 (3.2%)	33 (0.6%)	239 (4.3%)	75 (1.4%)	5522

(68.6%) were reported to have no potential outcomes associated with them, 18.4% a minor outcome, 3.9% a moderate outcome, 2.6% major and 0.1% (four reports) a potentially catastrophic outcome—the latter were all near-misses identified before reaching clinical areas (see table 6). The potential outcome was not recorded in 6.4% of the reports.

DISCUSSION

This is the first study to report on the cumulative errors detected and reported by pharmacy compounding units in the UK to include the categories of product involved, types of error, the stage at which errors were detected, perceived contributory factors, and potential or actual outcomes. Only 24 of the errors in the current study were detected during or after administration to the patient, so the majority of the reports relate to near-misses. The estimated overall compounding error rate of 0.49% compared well with 0.45% reported in a study using similar methodology[16] but not with an observational study that found a mean error rate of 9%[17] for intravenous compounding in the pharmacy. Measuring error rates is notoriously challenging, and incident reporting can underestimate the true rate of error,[18] which could explain the difference noted above. Nonetheless, these figures are in sharp contrast to an often-quoted observational study that found that 49% of intravenous doses prepared in clinical areas contained at least one mistake[1] and another that found that 43%, 99% and 20% of doses prepared in UK, German and French hospital wards, respectively, contained a labelling error.[3]

Our primary aim was to develop a better understanding of factors associated with the errors that had been detected and reported to NAERS. A total of 40% of errors related to adult cytotoxic preparations, which could simply relate to high quantities of these products being made by pharmacy compounding units. However, this type of product involves largely the preparation of patient-specific doses according to body surface area and as such the handling of variable data, which could present more scope for errors and partly explain the pattern of error types found. The preparation of individualised chemotherapy doses involves several steps, and that could also add to the problems observed. The findings might also lend credence to the argument for the dose-banding of adult cytotoxic preparations where standard doses can be provided using a selection of prefilled infusions or syringes,[19] further streamlining the production process. The findings certainly highlight a need for uniform and robust final checks to ensure that when they occur, errors with cytotoxic product do not leave compounding units.

By examining the cross-tabulated data, it appeared that staffing level being below establishment and workload above planned capacity were thought to have impacted on errors with parenteral nutrition products more than with other products. The preparation of parenteral nutrition is complex, and even where standardised multicompartment bags are used, compounding will still involve the addition of a number of extra components such as vitamins, trace elements and electrolytes according to patient needs. Also, it is the authors' experience that many units prepare parenteral nutrition in the last work session of the day, which could contribute to the observed errors. Our findings are in the context of an underlying resource and capacity issue, where there are known recruitment and capacity problems within pharmacy technical services in the UK.[20–26] This presents a particular challenge because while studies indicate that a large percentage of high-risk compounding still takes place in clinical areas,[27] these will need to be transferred to specialised pharmacy units.

Table 6 Reported potential outcomes according to product type

	Potential outcome						
Product type	**Catastrophic**	**Major**	**Moderate**	**Minor**	**None**	**Not recorded**	**Total**
Cytotoxic adult	1 (0.1%)	49 (2.6%)	53 (2.8%)	249 (13.3%)	1339 (71.7%)	177 (9.5%)	1868
Cytotoxic paediatric	0	2 (1.8%)	6 (5.4%)	34 (30.6%)	63 (56.8%)	6 (5.4%)	111
Parenteral nutrition—adult	0	15 (2.2%)	32 (4.7%)	137 (20.1%)	496 (72.8%)	1 (0.1%)	681
Parenteral nutrition—paediatric	1 (0.6%)	21 (11.7%)	18 (10.1%)	47 (26.3%)	88 (49.2%)	4 (2.2%)	179
Other intravenous additive	0	22 (1.7%)	49 (3.8%)	309 (24.1%)	814 (63.5%)	87 (6.8%)	1281
Other prefilled syringes	2 (0.6%)	7 (2.3%)	22 (7.1%)	48 (15.5%)	218 (70.3%)	13 (4.2%)	310
Other	0	6 (2.8%)	5 (2.3%)	34 (15.7%)	164 (75.6%)	8 (3.7%)	217
Not recorded	0	0	0	6 (13.6%)	36 (81.8%)	2 (4.5%)	44
Total	4 (0.1%)	122 (2.6%)	185 (3.9%)	864 (18.4%)	3218 (68.6%)	298 (6.4%)	4691

By examining the cross-tabulated data it also appeared that errors with paediatric parenteral nutrition were associated with minor, moderate and major outcomes more than other products were. This perhaps reflects the complexity of the process of compounding paediatric parenteral nutrition and the typical number of ingredients used.[28] It also appeared that errors with paediatric parenteral nutrition were detected in clinical areas during or after administration more than other products were, which highlights again the need for robust final check and release procedures to stop these errors from leaving the production area. The same applies to errors with paediatric cytotoxic products that appeared to be detected at later stages in the process, such as at final check prior to release and in clinical areas prior to administration more than other products were. The checks are especially important in the context of staff shortages.

Errors with other prefilled syringes appeared to be judged as having moderate potential outcome for the patient more than other products were and were also mostly detected at release stage (25.2%). This is perhaps to be expected because the supply of prefilled syringes is more akin to a dispensing operation where the final check is essentially the main part of the checking process. Errors with other prefilled syringes appeared to be attributed to inadequate training, and distractions and interruptions more than other products were, and this is worth considering for those who manage pharmacy aseptic units. The majority of all errors were reported to have been made by technicians most likely because technicians are involved in preparing products more than any other staff. The majority of all errors were reported to have been detected by pharmacists, and again this reflects the standard pattern of work in pharmacy departments, where technicians have overall responsibility for the preparation of work and pharmacists for the final check.

Strengths and weaknesses of the study

Since the majority of the reports related to near-misses, the data should be seen in the context of errors that were picked up and reported to NAERS rather than errors that had reached the patient. The NAERS reporting system is well publicised within the participating hospital production units and is now an established Scheme in its fifth year of operation; nonetheless, the main weakness of this study is the fact that it relies on detection and self-reporting of errors by staff working within these units. In addition, although the cross-tabulation of data implies certain patterns of association, where high numbers were reported in any one category, this may simply be a virtue of low reporting with the other categories of data. The authors acknowledge there would be variability between staff, even in the same unit, in the number of reports detected and submitted to the Scheme. These factors perhaps explain the difference between the rates of error reported in this study and those found in an observational study. There could also be variability in the qualitative judgements made—for example, when assessing criteria such as the potential impact of a near miss. The categories of data analysed relate to an initial reporting template which was piloted and distributed for use at the outset of the Scheme. The Scheme may need to be updated to take account of areas where the category 'other' was overused. Also, because the majority of the reports submitted to NAERS relate to near-misses, the data could be a reflection of the existence of effective error detection and reporting processes, rather than highlighting real problem areas that in fact escape detection and reporting. Effective checking and screening procedures allied to a reporting system can potentially maximise patient safety. Importantly, because the Scheme does not collect information on items made per product type, the frequency of errors found within each product category cannot be contextualised any further. Nonetheless, as it stands, this study makes a valuable contribution to the QA of pharmacy production units by highlighting possible relationship between the various categories of errors, as summarised below.

Implications

Our study shows that where pharmacy compounding errors are detected and reported, these relate mainly to adult cytotoxic preparations, which may relate to high volumes being produced or may be the result of the variety of processes involved in the compounding these products. The majority of the errors were near-misses, but errors with paediatric parenteral nutrition preparations, although small in number, appeared to be detected and reported as accidents that had reached the patient more than other products were. Errors with all paediatric preparations also appeared to be associated with the greater levels of perceived patient harm. The findings could be seen as a starting-point from which better error detection and reporting systems can be developed and further monitored in due course. The areas of weakness identified by this study can be used to introduce additional and perhaps more robust checks within individual aseptic units and contribute more globally to the programme of QA conducted by NHSPQAC, but any changes will need to take place with due consideration of existing resource and capacity issues within NHS aseptic units.

CONCLUSIONS

While the majority of the reports related to near-misses, our study highlights the possibility of certain relationships that can be used to improve the reporting, analysis and management of pharmacy compounding errors in the future. Certainly, there is scope for examining current arrangements for the checking and

release of paediatric products, which appeared to be detected in clinical wards areas more than other products were and also appeared to be linked to a greater potential for patient harm, but any changes would need to take place in the context of resource and capacity constraints.

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REFERENCES

1. **Taxis K,** Barber N. Ethnographic study of incidence and severity of intravenous medicine errors. *BMJ* 2003;**326**:684—7.
2. **Taxis K,** Barber N. Causes of intravenous medication errors: an ethnographic study. *Qual Saf Health Care* 2003;**12**:343—7.
3. **Cousins DH,** Sabatier B, Begue D, *et al*. Medication errors in intravenous medicine preparation and administration: a multicentre audit in the UK, Germany and France. *Qual Saf Health Care* 2005;**14**:190—5.
4. **Wirtz V,** Taxis K, Barber ND. An observational study of intravenous medication errors in the United Kingdom and in Germany. *Pharm World Sci* 2003;**25**:104—11.
5. **O'Hare MCB,** Gallagher T, Shields MD. Errors in the administration of intravenous drugs. *BMJ* 1995;**10**:1536—7.
6. **Hartley GM,** Dhillon S. An observational study of the prescribing and administration of intravenous drugs in a general hospital. *Int J Pharm Pract* 1998;**6**:38—45.
7. **National Patient Safety Agency**. Patient safety alert number 20, promoting safer use of injectable medicines. National Patient Safety Agency: 2007. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812.
8. **Breckenridge A.** *Report of the working party on the addition of drugs to intravenous infusion fluids [HC(76)9] [Breckenridge report]*. London: Department of Health and Social Security, 1976.
9. **Allwood MC.** Practical guides. I: central intravenous additive services. *J Clin Pharm Ther* 1994;**19**:137—45.
10. **Beaney AM.** *Quality assurance of aseptic preparation services*. 4th edn. London: Pharmaceutical Press, 2005
11. **Gandy RJ,** Beaumont IM, Lee G, *et al*. Risk management and the aseptic preparation of medicines. *European Hospital Pharmacy* 1998;**4**,114—19.
12. **Bateman R.** Determining the rates and types of errors in pharmacy-managed aseptic preparation units. *Hosp Pharm* 2003;**10**:496—8.
13. **National Patient Safety Agency.** What is a patient safety incident. http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident/ (accessed 12 December 2009).
14. **Hospital Pharmacists Group.** Aseptic preparation: pharmacy's responsibility in managing risk. *Pharm J* 2002;**268**:193.
15. **Stump LS.** Re-engineering the medication error-reporting process: removing the blame and improving the system. *Am J Health Syst Pharm* 2000;**57**:S10—17.
16. **Limat S,** Drouhin JP, Demesmay K, *et al*. Incidence and risk factors of preparation errors in a centralized cytotoxic preparation unit. *Pharm World Sci* 2001;**23**:102—6.
17. **Flynn EA,** Pearson RE, Barker KN. Observational study of accuracy in compounding i.v. admixtures at five hospitals. *Am J Health Syst Pharm* 1997;**54**:904—12.
18. **Brown C,** Hofer T, Johal A, *et al*. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Qual Saf Health Care* 2008;**17**:170—7.
19. **Plumridge RJ,** Sewell GJ. Dose-banding of cytotoxic drugs: a new concept in cancer chemotherapy. *Am J Health Syst Pharm* 2001;**58**:1760—4
20. **Department of health.** Modernising the NHS hospital medicines manufacturing service, 2003. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4003015. (accessed 28 May 2009).
21. **Gandy RJ,** Beaumont IM. Evaluating the impact of major investment in aseptic preparation on capacity and collaboration. *Hosp Pharm* 2006;**13**:221—5.
22. **Gandy RJ,** Beckford JLW, Booth MD. Secondary care coalface: the challenge of capacity management in aseptic preparation. *Pharmacy Management* 2006;**22**.
23. **Gandy RJ,** Beaumont IM. Analysing aseptic preparation—workload measurement and capacity planning. *Hosp Pharm* 2003;**10**:328—37.
24. **Gandy RJ,** Beaumont IM. Analysing aseptic preparation—survey design and data assessment. *Hosp Pharm* 2003;**10**:338—47.
25. **Dixon R,** Forsey P, Morrison L. NHS technical specialists—strengthening the career path. *Hosp Pharm* 2007;**14**:337.
26. **NHS Pharmacy Education and Development Committee.** National hospital pharmacy staffing survey 2006. http://www.nhspedc.nhs.uk/pdf/Survey2006.pdf.
27. **Hardy L,** Mellor L. Risk assessment of parenteral product preparation across secondary care acute trusts in the north of England. *Hosp Pharm* 2007;**14**:58—64.
28. **Sobotka L**, ed. *Basics in clinical nutrition*. 3rd edn. Prague: Galen, 2004.