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Original Article

# The frequency and importance of reported errors related to parenteral nutrition in a regional paediatric centre☆

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SUMMARY

*Aim:* To determine the frequency and significance of reported errors related to parenteral nutrition (PN) in a regional paediatric centre.
*Methods:* In our children's centre, it is policy that "any unexpected event with an actual or potential detrimental effect on a patient is formally reported on an incident report (IR1) form" by staff. We therefore reviewed all IR1 forms related to PN between January'06 and June'09. The errors were categorised according to where in the PN process they occurred. Harm scores (severity of the error in relation to patient safety) were based on the framework of the American 'National Coordinating Council for Medication Error Reporting and Prevention' (NCC MERP).
*Results:* Over 18,588 PN days, 46 errors were identified, giving an error frequency of 0.24%. Of these, 5 (11%) occurred during the prescription process, 9 (20%) during the transcription process, 11 (24%) during dispensing, 7 (15%) during delivery of PN to the ward and 14 (30%) during the administration process. No errors were reported during the preparation/compounding process. 43 (94%) errors did not result in patient harm, while 3 (6%) errors resulted in temporary harm.
*Conclusions:* Reported PN related errors resulting in harm appear to be rare. Most occur during dispensing and administration suggesting that more robust checking procedures are required during these phases. The widespread reporting of non harmful errors indicates that staff have an appropriately low threshold for completing IR1 forms; these represent a valuable audit tool for improving patient safety.


## 1. Introduction

Parenteral nutrition (PN) is widely used for infants and children with intestinal failure from a variety of underlying conditions or in preterm newborns with gastrointestinal immaturity.[1,2] Deficiencies in the care of patients receiving PN, including inadequate documentation, poor monitoring and avoidable complications, have recently been highlighted in a report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD).[3] The UK National Aseptic Error Reporting Scheme (NAERS) stated that errors with paediatric aseptic preparations including PN appeared to be associated with greater levels of perceived patient harm.[4] Providing safe and effective PN to children is a complex process requiring the formulation of stable, sterile solutions containing a wide variety of ingredients. These have to meet the needs of diverse individual patients, ranging from extremely premature 450 g newborns to 100 kg adolescents with a vast array of associated complicating medical conditions. Guidelines have been published in an attempt to standardise the approach to PN for different age groups[5] and to emphasise safe practice. As with any process in medical care, there is the potential for harmful errors to occur, although there is little available information in the literature regarding the frequency and significance of these errors in children. In our hospital it is a requirement that "any unexpected event with an actual or potential detrimental effect on a patient is formally reported on an incident report (IR1) form" including any related directly to PN. We therefore decided to review all such reports in order to determine the nature, frequency and significance of errors.

*Abbreviations:* PN, Parenteral nutrition; IR1, Incident form.

☆ NCC MERP – National Coordinating Council for Medication Error Reporting and Prevention Conference presentation: Poster at RCPCH meeting at Warwick 2010 and ESPGHAN meeting at Istanbul 2010, oral presentation at BAPEN 2010.

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## 2. Methods

Our centre provides secondary general and tertiary specialist paediatric services, including a comprehensive range of specialities for a catchment population of around four million. All PN prescribing is done by an experienced pharmacist with reference to standard protocols[5] and working as part of a multidisciplinary nutritional support team.[6] The amino acid solutions used are "Vamin 18EF" and "Vaminolact"(Fresenius Kabi); the amino acid/glucose solutions are collectively referred to in the text as 'Vamin'.

We retrospectively reviewed an electronic database collated by the risk management team that details all the medication errors reported on IR1 forms based on the clinical area reporting them, e.g. paediatric medicine, paediatric surgery, paediatric intensive care, neonatology, pharmacy aseptics and on call pharmacy, etc. All IR1 forms related to PN between January'06 and June'09 were retrieved from this database and scrutinised in order to determine the frequency and nature of the reported errors. The total PN days were based on all the paediatric and neonatal patients given PN in the hospital during the study period and this information was collected from a database maintained by the pharmacy aseptic unit prospectively.

The reported PN errors were then categorised according to where in the PN process (from prescribing to intravenous delivery) they occurred. We divided this into six stages (Fig. 1) as follows:

1. 'Prescription': the composition of PN as decided and written down by the PN prescriber in consultation with relevant clinical teams.

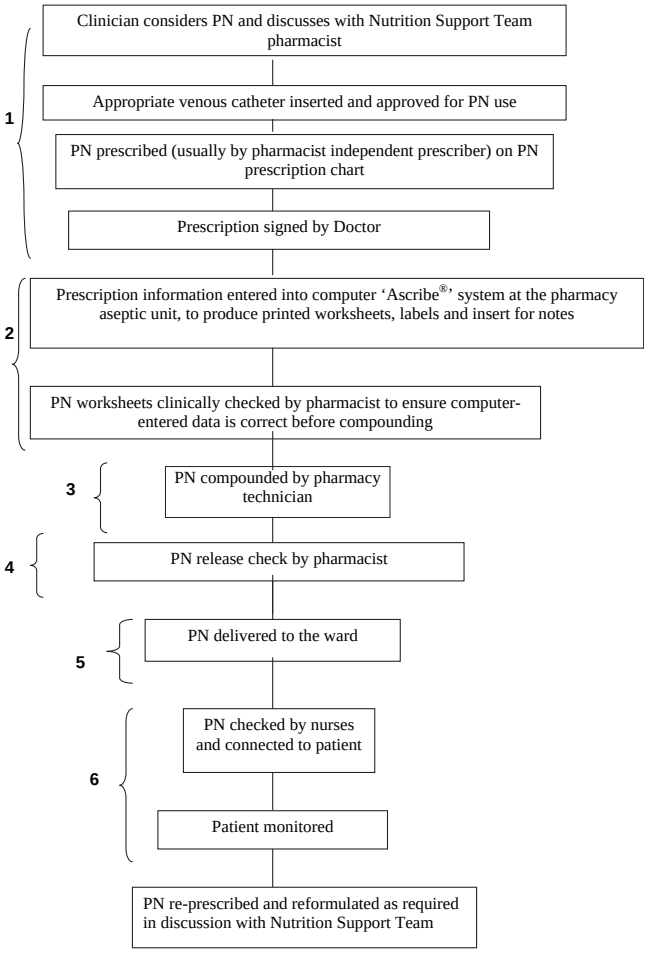



**Fig. 1.** Pathway illustrating the six stages of the PN process at Leeds Teaching Hospitals.

2. 'Transcription': the process whereby the prescription is converted to a printed work sheet for pharmacy (using the prescribing software called 'Ascribe®'; Ascribe Ltd is a healthcare company that delivers clinical IT systems including modules for pharmacy and PN); this also includes production of a printed copy of the prescription that is sent to the ward for insertion in the patient's notes, the labels for the PN bags, and the work sheet ('recipe' sheet) for the pharmacy technicians to read from when compounding the PN.
3. 'Preparation/compounding': the process during which the Pharmacy Aseptic Unit prepares the PN solution. This requires the mixing of a wide range of ingredients, both macro-solutions (amino acids, glucose, electrolytes and water) and micro-solutions (vitamins and trace elements).
4. 'Dispensing': the final checking procedures, performed by the pharmacist, where the printed paperwork is checked against the original prescription and any deviations annotated on the original prescription. The aqueous bag and lipid bag/syringe are visually examined for particulate matter or creaming, weighed as a safety check to make sure they are within the predicted limits (+or −5%), and all source containers (i.e. ampoules, syringes, vials) re-checked to ensure that the correct ingredients have been used at the right volumes. The final part of dispensing is for the labels to be placed on the aqueous bag and lipid bag/syringe respectively.
5. 'Delivery': this is where the finished product (comprising PN fluids, original prescription, and documentation for filing in the patient notes) is taken from pharmacy to the ward.
6. .'Administration': this happens at the bedside, where nursing staff examine the product and check the documentation against the original PN prescription before the PN is infused into the patient. Nursing staff also check that the route of administration is suitable and that the rates are correctly read from the bag/syringe labels before the infusion pumps are set. After this, there is ongoing clinical and biochemical monitoring of the patient and the PN is then reformulated following discussion with the nutrition support team (Paediatric gastroenterologist, specialist nurse, dietician and pharmacist)

The significance of an error was determined by assigning a 'harm score' (severity of the error in relation to patient safety) based on the framework of the American 'National Coordinating Council for Medication Error Reporting and Prevention' (NCC MERP).[7] Within the NCC MERP index there are four groups for categorising medication errors (Table 1).

## 3. Results

Over 18,588 PN days, 46 errors were reported on IR1s, giving an error frequency of 0.24%.Of these, 5 (11%) occurred during prescription, 9 (20%) during transcription, 11 (24%) during dispensing, 7 (15%) during delivery and 14 (30%) during administration or monitoring (Table 2). No errors were reported from the preparation/compounding process which is stringently quality controlled in the pharmacy aseptic unit. Fig. 2 shows the severity of errors based on the NCC MERP index classification. Fourteen were category B, i.e. circumstances or events that have the capacity to cause error, but the error did not reach the patient, while 32 errors reached the patient (category C, D and E). Of the total errors, 43/46 (94%) did not result in patient harm (categories B, C, D), while 3/46 (6%) resulted in temporary harm (category E) (Table 3). The 3 errors that resulted in temporary harm included one transcription error where potassium prescribed as 1.5 mmol/kg/day was incorrectly transcribed as 15 mmol/kg/day in a ventilated preterm infant. This error was picked up on a routine blood gas analysis which demonstrated rising potassium levels, prompting checking and

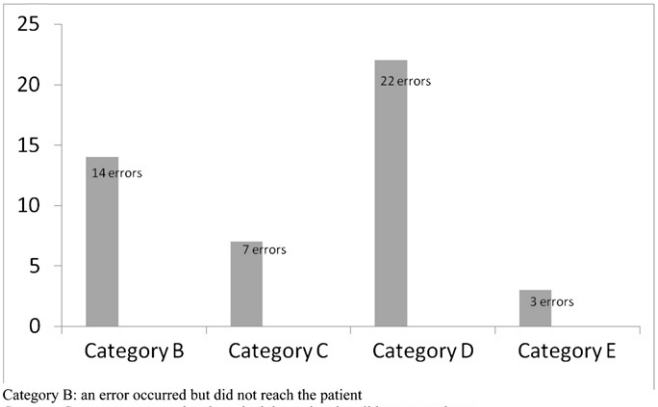
**Table 1**
Categorising medication errors based on NCC MERP index.

| Category | Category details | Group |
|---|---|---|
| A | | No error |
| B | An error occurred but did not reach the patient | Error, no harm |
| C | An error occurred and reached the patient but did not cause harm | |
| D | An error occurred and reached the patient; monitoring was then required to confirm that there was no harm to the patient, and/or intervention required to preclude harm | |
| E | An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention | Error, harm |
| F | An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation | |
| G | An error occurred that may have contributed to or resulted in permanent patient harm | |
| H | An error occurred that required intervention[a] necessary to sustain life | |
| I | An error occurred that may have contributed to or resulted in patients's death | Error, death |

[a] An 'intervention' includes changes in therapy or active medical/surgical treatment, while an 'intervention necessary to sustain life' includes cardiovascular and respiratory support (e.g. CPR, intubation etc).

**Table 2**
Examples of errors classified according to where they occurred in the PN process.

| PN process step | Errors *n* (%) | Examples of errors |
|---|---|---|
| Prescription | 5 (11%) | Incorrect calculation of PN volume by prescriber<br>Wrongly prescribed 100 ml/kg instead of 100% maintenance<br>PN prescribed for 14 h, discontinued at 10 h as chart unclear<br>Correct PN given to correct patient but not signed by doctor<br>Glucose concentration error in prescribing |
| Transcription | 9 (20%) | Different patient ID on PN prescription<br>Surname incorrectly spelt<br>Incorrect infusion rates and date of birth on PN bag<br>No expiry date on Vamin bag<br>Difference in glucose concentration<br>Inadequate lipid in lipid bag (×2)<br>Incorrect potassium concentration<br>PN made with 30% rather than 20% Intralipid |
| Preparation | No errors reported | |
| Dispensing | 11 (24%) | Vamin rate transcribed for lipid rate and vice versa on PN bag<br>Mislabelling of Vamin and lipid bags (×6)<br>Bag of lipid/PN leaking (×2)<br>PN prescription for insertion in patient's notes did not accompany bag (×2) |
| Delivery | 7 (15%) | PN did not reach ward and could not be located (×7) |
| Administration | 14 (30%) | Extravasation of PN from central venous catheter<br>PN bag expired as bags used out of sequence (×2)<br>PN bags used out of date sequence (×2)<br>Central PN (glucose concentration > 12.5%) given via peripheral line<br>PN bag pierced while 'spiking' with giving set<br>Incorrect rates of Vamin/lipid administered (×7) |




Category B: an error occurred but did not reach the patient
Category C: an error occurred and reached the patient but did not cause harm
Category D: an error occurred that reached the patient, and required monitoring to confirm that it resulted in no harm and/or required intervention to preclude harm
Category E: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

**Fig. 2.** Categorisation of PN errors based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).[7]

discontinuation of PN. This baby required active management of hyperkalaemia and this incident was investigated as a serious untoward incident. The other 2 errors were administration errors, one where the Vamin rate was incorrectly set resulting in a rapid infusion of Vamin causing fluid overload and hyperglycemia requiring treatment with a single diuretic dose and insulin and the other was PN extravasation which was managed by the unit guidelines. No errors resulted in prolongation of hospital stay, intervention immediately necessary to sustain life, or caused permanent harm or death.

## 4. Discussion

Our study demonstrates that reported PN related errors resulting in harm appear to be rare. Most occur during dispensing and administration suggesting that more robust checking procedures are required during these phases. The literature contains little information regarding error rates during PN. A prospective observational study involving both adult and paediatric patients reported an error rate of 1.6%.[8] The UK NAERS, reported an error rate of 0.49% for aseptic preparations including adult and paediatric PN.[4] The initial rate of PN prescribing errors in a neonatal intensive care unit was 14.5%, reducing to 6.8% following introduction of an interactive computerised PN worksheet.[9] The lower error rates found in our study may be because our PN prescribing is pharmacist led; this arrangement not only speeds up the process but is likely to increase safety.[10] Any errors in the preparation/compounding stage identified during standard operating checks by the pharmacist are reported via an internal reporting system (not on IR1 forms) and corrective action taken before dispensing can occur. Although such errors are not identified by our methodology, since by definition they are confined to pharmacy, none represent a risk to patients. Standard operating procedures, quality control measures[11] and the use of an automated compounding device[12] are among the mechanisms for reducing the risk of preparation error. Although our methodology raises the question of whether IR1 reporting identifies all PN process errors involving patient risk, it is clear that staff do have a low threshold for reporting 'minor' errors, suggesting that under reporting of important errors is unlikely. Serious untoward incidents that do result in harm are commonly known about by the clinical teams and investigated as a clinical governance issue; as a nutrition team we were not able to identify any of these that did not also have an IR1 report. We are therefore confident that our study

**Table 3**
PN errors resulting in patient harm.

| Number | Error | Type of error | Consequence/Intervention/Outcome |
|---|---|---|---|
| 1 | Potassium prescribed as 1.5 mmol/kg/day transcribed as 15 mmol/kg/day in a preterm infant | Transcription | Rising potassium identified on routine blood gas analysis, prompting checking and discontinuation of PN; active management of hyperkalaemia required |
| 2 | Extravasation of PN in a newborn | Administration | Localised swelling and redness of the skin; PN discontinued and venous catheter removed; infant managed as per in-house extravasation guidelines |
| 3 | Vamin given too rapidly due to pump infusion rates being set incorrectly | Administration | Fluid overload and hyperglycaemia; insulin infusion and one dose of diuretic required |

gives an accurate picture of PN related errors in our particular hospital setting.

It is concerning that there were two incidents that could have caused death if undetected (Table 3), but the overall error rate is very much lower than in general for medication errors which have a similar potential to cause patient harm.[13] Further improvements in safety might come from the development of electronic prescribing transferring the bedside prescription directly to the compounder or prescribing directly into the pharmacy compounding software and setting up 'alerts' for parameters exceeding the defined ranges in the software, as this would prevent transcription errors. There is an increasing role for 'standardised' PN bags alongside individually 'tailored' feeds,[14] but while commercially produced standard feeds will be end product tested and quality assured, this is not likely to have a great impact on safety issues overall.[11]

Error reporting is considered fundamental to the broad goal of error reduction, thereby improving patient safety.[15] Incident reporting forms (standard within NHS hospitals) represent a useful resource for quality audit and improving patient safety. The main limitation can be underreporting and not having systems in place for analysing, sharing and acting upon data collected. In our clinical practice, IR1's are reviewed at ward based clinical governance meetings and the information about drug prescribing errors is circulated thus, raising awareness and helping to introduce safeguarding mechanisms. This study is an example of how IR1 forms have been used to perform an audit of service quality and to bring about changes in prescribing that should improve patient safety.

Most of the errors in our study occurred in the administration, dispensing and transcription stages of PN and as a consequence, these findings have lead to a number of modifications to our practice. Prescription forms have been redesigned to include details of acceptable electrolyte ranges, prompting the prescriber to question intakes that fall outside these limits. Lipid labels are now stamped in red to reduce mislabelling of Vamin and lipid containers. More pharmacists and pharmacy technicians have been trained to use the relevant compounding PN computer software "Ascribe®" which would help reduce transcription errors. There is also ongoing staff education and training aimed at reducing administration errors. We would encourage similar audits in other units providing PN for children.

## Statement of authorship

PN carried out data analysis and interpretation, participated in study design and drafted the manuscript. DH carried out data collection and participated in study design, data analysis and interpretation and helped to draft the manuscript. JP conceived the study, and participated in its design and coordination and helped draft the manuscript. All authors read and approved the final manuscript.

## Ethical approval

As this was an audit of routinely collected data, review by the research ethics committee was not sought.

## Conflict of interest

There were no conflicts of interest with the submitted work.

## Acknowledgements

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