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Identification of Priorities for Medication Safety in Neonatal Intensive Care

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Abstract

Background: Although neonates are reported to be at greater risk of medication error than infants and older children, little is known about the causes and characteristics of error in this patient group. Failure mode and effects analysis (FMEA) is a technique used in industry to evaluate system safety and identify potential hazards in advance. The aim of this study was to identify and prioritise potential failures in the neonatal intensive care unit (NICU) medication use process through application of FMEA.

Methods: Using the FMEA framework and a systems-based approach, an eight-member multidisciplinary panel worked as a team to create a flow diagram of the neonatal unit medication use process. Then by brainstorming, the panel identified all potential failures, their causes and their effects at each step in the process. Each panel member independently rated failures based on occurrence, severity and likelihood of detection to allow calculation of a risk priority score (RPS).

Results: The panel identified 72 failures, with 193 associated causes and effects. Vulnerabilities were found to be distributed across the entire process, but multiple failures and associated causes were possible when prescribing the medication and when preparing the drug for administration. The top ranking issue was a perceived lack of awareness of medication safety issues (RPS score 273), due to a lack of medication safety training. The next highest ranking issues were found to occur at the administration stage. Common potential failures related to errors in the dose, timing of administration, infusion pump settings and route of administration. Perceived causes were multiple, but were largely associated with unsafe systems for medication preparation and storage in the unit, variable staff skill level and lack of computerised technology.

Conclusion: Interventions to decrease medication-related adverse events in the NICU should aim to increase staff awareness of medication safety issues and focus on medication administration processes.

Background

Medication safety is currently a major priority in healthcare.[1] Medication-related patient injury has been found to be a leading cause of adverse events in hospitalised patients,[2-4] often with serious sequelae[3,5] and huge economic implications.[6,7] The recently completed New Zealand Quality of Healthcare Study (NZQHS)[4] revealed that 12.9% of hospital admissions in New Zealand were associated with an adverse event, with similar rates reported for Australia (16.6%)[3] and the UK (10.8%)[6] in studies

using comparable methods. Approximately 15% of these adverse events were shown to be medication related, termed adverse drug events (ADEs).[4] Death or permanent disability resulted from 12.3% of ADEs, and the mean duration of hospital stay was 7.8 days. Almost half of these ADEs (43.9%) were deemed highly preventable.

Less is known about the epidemiology of ADEs in children, especially neonates. Estimates of rates of events vary substantially between studies, depending on the rigor with which events are identified, the outcome measures used and the setting in which the study takes place.

Newborn infants, particularly those requiring admission to a neonatal intensive care unit (NICU), pose unique challenges to the system for prescribing, dispensing, administering and monitoring medications compared with older children and adults.[8] This is largely because medication use in neonates has not been extensively researched, making treatment decisions more difficult.[9] Prescribing decisions must be made on an individual patient basis, as neonates are not an homogeneous group. They are born at different gestational ages and have continuously changing pharmacokinetic and pharmacodynamic parameters, which influences their ability to handle and tolerate medications. Not only is there little firm evidence upon which to guide decision making, but these changes must also be taken into account when prescribing medications for neonates. In addition, the range of licensed medications in appropriate dosage forms is limited, leading to complex dose calculations and dilutions prior to administration.[10,11] In a recent study by Kaushal et al.[12] the rates of medication error and ADEs in paediatric inpatients were found to be similar to those of a previous adult hospital study, but the rate of potential ADEs (defined as medication errors with a significant potential for injuring a patient) was about three times higher in neonates in the NICU compared with older children and adults. Further, higher rates of events in the NICU have been reported to coincide with a higher level of care.[13] Little is known about the characteristics of errors affecting this patient group, resulting in difficulty in targeting prevention strategies.

Although a hospital-wide voluntary incident reporting system was in place at the time of this study it was vastly underutilised, with only 13 neonatal medication-related incidents reported over the preceding 2 years. Because of this well recognised limitation of voluntary reporting systems and the reactive nature of any resulting quality improvement efforts, a systematic, proactive approach to medication safety has been advocated by the UK National Health Service.[1] One such technique used in industry to evaluate system safety is failure mode and effects analysis (FMEA).[14-16] It originated in the 1960s in the aerospace industry but has since been adapted and used by various industries – including aviation, automobile, manufacturing and, more recently, the healthcare industry – as a quality improvement tool to improve safety. FMEA examines the individual components of a system or process, identifies potential errors and gauges what the possible effects will be, before events take place.[14]

There appears to be no published work to date investigating the application of FMEA to the NICU medication use process. Given the complexity of medication use in NICUs and the potential for serious consequences of even small errors in this vulnerable patient group, proactive efforts that may reduce medication error should be investigated. It was therefore hypothesised in the present study that the application of FMEA to the entire NICU medication use process would be useful in identifying high-risk processes where systems improvements are most needed.

Aim

The aim of our study was to identify and prioritise potential failures in the NICU medication use process.

Methods

Study Setting

This study was undertaken in a 16-bed, tertiary level NICU based in Dunedin Hospital, Dunedin, New Zealand, over a 12-week period (January–March 2003). There are approximately 250 admissions to the Dunedin unit each year, with an average length of stay of 20 days. In the NICU, prescriptions are handwritten by the medical staff and the majority of medications are administered to

Table I. Healthcare failure mode and effects analysis (FMEA) steps

1. Select a process to evaluate with FMEA
2. Recruit a multidisciplinary team
3. Describe the process in a flow diagram
4. Determine potential failure modes, causes and effects
5. Conduct risk priority analysis
6. Develop and implement actions and outcome measures

patients directly from ward stock via what is termed an 'imprest' system. This system is where each ward or unit in the hospital holds a small store of approved imprest medications, which are usually those commonly used in that particular ward. Imprest stock items vary between wards. In the neonatal unit, many of these imprest items are commercially available adult formulations requiring dilution at ward level, prior to administration. Nursing staff review the medication order, select the medication from the imprest stock then prepare the medication for administration. Clinical pharmacy services include a daily visit to the unit by the ward pharmacist to review medication charts, participation in the weekly multidisciplinary team meeting (where complex cases are discussed), and the provision of drug information as requested.

Steps Involved in the Study

The traditional FMEA process (as shown in table I)[14,15] was used as the basis for this study. An eight-member panel was established that included management representatives (one organisational level, two neonatal unit, one pharmacy) and front-line clinical staff representatives (two medical, one nursing, one pharmacy). A series of nine meetings of the panel were held throughout the study. A flow diagram of the current NICU medication process was first developed by two of the panel members by observing procedures and by requesting input from those staff members involved in each specific part of the process; it was subsequently agreed upon by the team.

Each step in the medication use process was considered to:

1. identify all possible failures, (environment-related, equipment problems, human errors or any other faults in the system). Failures were considered under the four main categories:
   - organisation (organisational structure, policy and safety culture; organisational resources and constraints; staffing levels, skill mix, workload and training; national regulations and policy);
   - environment (work environment, e.g. noise levels, lighting and layout);
   - technology (availability, accessibility, maintenance and design features of all computers, printers, telephones, facsimiles and medication-related equipment); and
   - personnel factors (staff knowledge base and skills, motivation, teamwork and communication).
2. list the root causes that could generate each failure;
3. determine the possible effects of each failure.

Once the basic failures, causes and effects were established, the relative importance of each to the overall system was rated. For all of the steps in the process, all potential failures were organised into an FMEA matrix table. Using pre-established 10-point ranking scales,[14] panel members independently rated each failure for:

- likelihood of occurrence (O) – estimate of the probability of the failure actually occurring;
- severity (S) – estimate of severity of failure effect on patient outcomes should the failure actually occur;
- likelihood of detection (D) – estimate of the probability of the failure going undetected and reaching the patient without correction.

The risk priority score (RPS) for each panel member was determined for each failure by calculating the product of the three factors: $O \times S \times D$. The data were found to be skewed in distribution, so the median of the RPSs recorded by the eight panel members was selected as the more appropriate measure of central tendency and used to obtain an overall RPS for each failure. Those processes with the highest scores are those considered by the team to be the highest risk and where process improvements are most needed.

Results

The flow diagram of the current medication use process developed and agreed by the panel – which included all steps involved from decision to treat

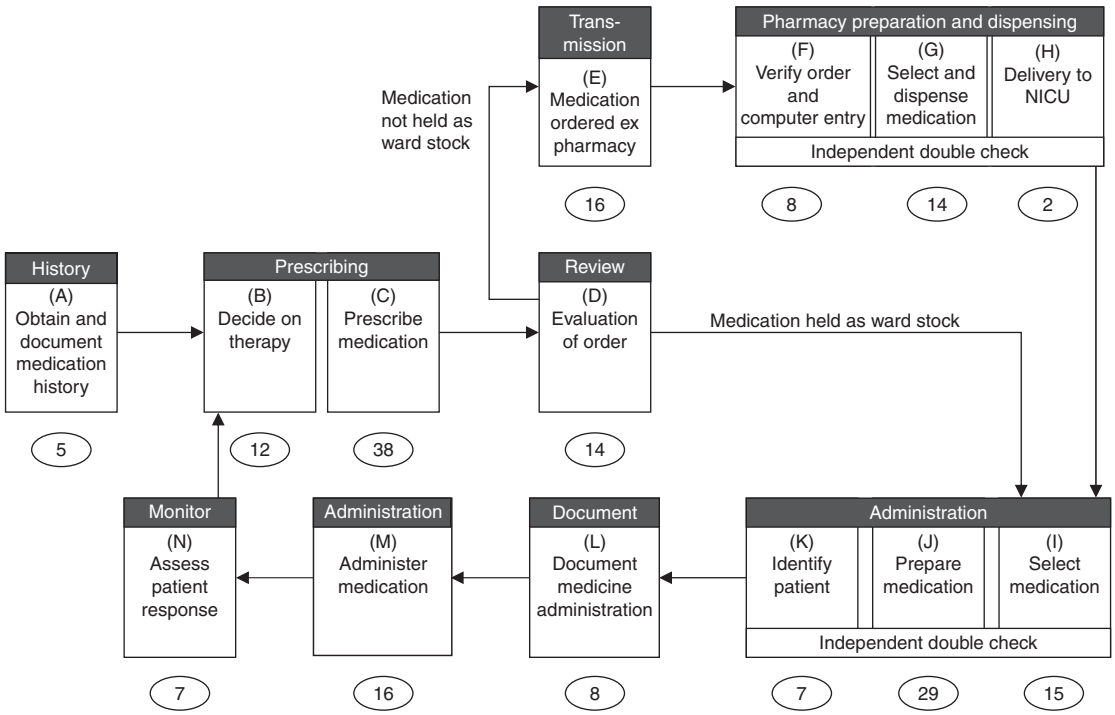

Fig. 1. Flow diagram of neonatal intensive care unit (NICU) medication use process. Numbers indicate the frequency of potential failures identified at each step in the process.

and prescribing, through to pharmacy or nurse preparation of the medication and administration of the medication to the patient – is shown in figure 1.

Over the entire medication use process, the panel identified a total of 72 potential failures with 193 associated causes and effects. Two of the causes and effects were found to relate to the entire medication use process, leaving 191 that were stage specific and are shown in figure 1. The frequency of potential failures in each step of the medication use process is provided. By way of example, for the process step M 'administer medication', the potential failures and associated causes and effects identified by the panel and organised by system are shown in table II.

Vulnerabilities were found to be distributed across the entire process, but multiple failures and associated causes were possible when prescribing medication and when preparing the medication for administration. When considered by system, the majority of failures could be attributed to organisational factors (83), followed by personnel (47), technology (38) and environmental issues (25).

The risk priority scores calculated in this study ranged from 273 down to 33. Details of the top 30 RPSs are shown in table III. The highest ranking issue was a general lack of medication safety training perceived due to a lack of awareness of medicine safety issues. This point was raised by one of the panel members during the brainstorming sessions and was subsequently rated the top ranking issue by the team. The majority of the remaining top 30 RPSs were found to relate to the medication administration stage and, particularly, the preparation and administration processes. For example, incorrect dose administration was found to be a common potential failure with medication administration, but had multiple system-wide causes. These included staff being unfamiliar with neonatal equipment (personnel), lack of information available about very specialised equipment (technology), poor workflow in the unit (environmental), lack of accountability for checking (organisational), pump design faults (technology), and out of date or missing medication protocols (organisational). Lowest rankings were related to

Table II. Failures, causes and effects categorised by system for process step 'M' ('administer medication') in figure 1

System	Potential failure category	Causes	Effects
Organisation			
Lack of accountability	Dose Flow rate	Alarm overrides Action taken not recorded	Overdose – death, transfer to higher level of care, increased length of stay, ADRs Underdose – delay or poor control of condition, unwanted effects
Drug and equipment protocols and guidelines	Dose	Lack of drug and equipment protocols Missing protocols Out of date protocols Lack of drug incompatibility information Misinterpretation of information	Overdose – death, transfer to higher level of care, increased length of stay, ADRs Underdose – delay or poor control of condition, unwanted effects
	Timing	Unclear protocols Lack of protocol for management of missed or vomited doses	Medications administered too soon or too late leading to overdose or underdose
Medications prescribed in multiple places	Timing	Medications administered in main operating theatre or on transports not taken into account	Duplicate doses administered
Handwritten plan for schedule of medication administration	Timing	Transcription error Wrong date on administration sheet	Missed doses Incorrect timing Poor control of condition
Use of IV syringe for oral doses	Route	Syringes for IV and oral doses look the same	ADR
Environment			
Workflow	Dose	Inaccessible information at place of administration	Overdose, underdose
Workload	Timing	Interruptions, forget, busy	Doses delayed, duplicated or omitted
Multiple medication access	Route	Similar looking lines, lines not labelled or incorrectly labelled Lines labelled for drug not access type Look-alike medications, e.g. milk, lipid	ADR Extravasations
Technology			
Use of inline filtration, specialised lines and equipment	Dose	Drug trapped in filter Lack of information about drug use via filters Manufacturer faults – break in lines due to bad-fitting connectors, faulty filters Three-way tap wrong way	Overdose, underdose Delays in management of condition
	Timing	Dead space of equipment issues	Delay in drug administration, poor control of condition
	Route	Wrong connections are allowed – design fault	ADR

Continued next page

Table II. Contd

System	Potential failure category	Causes	Effects
Pump design fault	Flow rate	Pump not protected from free flow Mechanical failure Power failure Pump not delivering amount it says	Overdose, underdose
Personnel			
Training, experience, education	Dose Flow rate	New staff Unfamiliar with neonatal equipment, e.g. rapid flush of drug, delay in drug delivery as not aware of dead space issues Failure to check protocols Syringe not in pump correctly Failure to double-check at bedside Override alarm without correcting problem, e.g. failure to recognise kinked tubing, blocked filter	Overdose, underdose, ADRs, incorrect timing of drug delivery

ADR = adverse drug reaction; **IV** = intravenous.

equipment malfunctions and cultural influences of parents in drug therapy decisions.

From these high-risk processes, the panel selected a mix of ongoing performance measures and immediate actions as top priorities for the next 12-month period (table IV).

Discussion

In the present study, a large number of potential failures and associated causes were identified and were found to be distributed throughout the NICU medication use process. Multiple failures were found to be associated with prescribing medication and preparation of the medication for administration. The highest ranking issue was a perceived lack of awareness of medication safety across the organisation. The next highest ranking issues, and therefore highest risk procedures (perceived more likely to result in patient harm), were found to occur in the administration stage. Common potential failures related to errors in the dose, timing of administration, infusion pump settings and route of administration. Causes were multiple, but were largely associated with organisational factors relating to an unsafe work environment for medication preparation and storage in the unit, variable staff skill level and lack of computerised technology.

Most potential errors were found to occur at the stages of medication prescribing and preparation of medication for administration, suggesting that these parts of the process are the most complex and involve a greater number of steps than other stages. This finding is consistent with previous studies, but whether it is the prescribing or the administration stage that is more prone to errors depends largely on the method of error detection or definition of error used. In the neonatal and paediatric intensive care setting, errors occurring at the administration stage have previously been found to be the most common.[13,17] However, in one of these studies,[17] a low rate of prescribing errors was found because, by definition, those errors that were detected before administration were not included. Administration errors were found to be infrequent in the study by Kaushal et al.,[12] where errors were mainly attributed to the stage of drug ordering. However, a limitation of this study, as acknowledged by the authors, is that the error detection method used chart review

Table III. 'Top 30' risk priority scores (RPSs) stratified according to the process stage

Process	Potential failure category	System	Cause	RPS
General stage				
Across all stages	Lack of medication safety training	O	Lack of awareness of medicine safety issues	273
Administration stage				
Administer medication	Dose	P	Variable level of experience - unfamiliar with neonatal equipment	265
Administer medication	Dose	T	Specialised equipment, lack of information available	252
Prepare medication	Dilution/concentration	E	Lack of environment free of stressors	249
Administer medication	Dose	E	Workflow – poor design and cramped unit	247.5
Prepare medication	Potential for nonsterile product use	E	Lack of environment free of stressors	245
Administer medication	Timing	P	Variable level of experience, failure to check protocols	245
Administer medication	Route	O	Similar looking and multiple lines, labelled for drug not access type	245
Select medication	Strength of correct medication	E	Unsafe storage, lack of neonatal dose forms, lethal doses on ward	240
Prepare medication	Muddle medicines for one patient	E	Lack of environment free of stressors	240
Prepare medication	Potential for nonsterile product use	P	Lack of training, education, inexperience in sterile techniques	240
Administer medication	Dose	O	Lack of accountability	240
Administer medication	Route	T	Equipment design fault, wrong connections allowed	238
Administer medication	Timing	T	Specialised equipment, lack of information, dead space issues	232
Select medication	Incorrect drug	T	Handwritten prescriptions, unclear, use of abbreviations	231.5
Prepare medication	Inadequate check of medicine or pump	E	Lack of environment free of stressors	228
Prepare medication	Potential for nonsterile product use	O	Use of floor stock, bypass Aseptic Production Unit	227.5
Administer medication	Dose	T	Pump design fault – not protected from free flow, mechanical failure	227.5
Administer medication	Time	O	Nurse handwritten plan for schedule of medication administration	227.5
Administer medication	Route	O	Use of Intravenous syringes for oral doses	227.5
Administer medication	Time	E	Lack of environment free of stressors	226
Identify patient	Incorrect patient	O	No name band, only one form of patient identification to check	225
Administer medication	Time	O	Duplicate medication chartings	225
Administer medication	Dose	O	NICU drug protocols, out of date, missing etc	224
Prepare medication	Failure to check medicine or pump	E	Lack of environment free of stressors	215.5
Prepare medication	Inadequate check of medicine or pump	O	Only check medication not pump, no written check procedure	212.5
Prepare medication	Rate	P	Variable calculation skills	212.5
Monitoring stage				
Assess patient response	Incorrect data	P	Variable level of experience, levels at wrong times	242
Assess patient response	Incorrect data	T	Transcription of laboratory data required	218
Assess patient response	Inaccurate assessment	O	Manual system of test ordering, tests at wrong times	217.5

E = environment; **NICU** = neonatal intensive care unit ; **O** = organisation; **P** = personnel; **T** = technology.

Table IV. Agreed priorities for the next 12 months to minimise high-risk potential failures

Task	Description
Immediate actions	
Medication safety training	Key aspects of medication error prevention as they relate to neonates to be incorporated into new staff orientation programmes (nursing, medical and pharmacy). In progress for neonatal nursing staff and for fifth-year medical students
Use of oral syringes	Source of supply and cost implications for the use of oral syringes for all oral doses currently being investigated by management
Safe storage of medications	To rearrange medication storage on the unit to reflect safe medication practices Project underway to identify look-alike and sound-alike products Potentially dangerous medications to be removed from ward stock, or to look distinctive
Ongoing performance measures to be established for:	
Wrong time administration	Monthly audit of medication charts, target 80% correct time administration
	'Wrong time' has been defined as greater than 1 hour of prescribing for 'stat' (once only medications) and for 'regular' medications, where dose not given prior to the next scheduled dose
Labelling of lines	Monthly audit of all lines – to be labelled with access type and fluid/medication being administered, target 90% correct labels
Handwritten prescriptions	Monthly audit of prescribing against prescribing guidelines, target 90%

and voluntary reporting, and was better at detecting prescribing errors. Hence, many administration errors may have been missed.

An important finding of the present study with regard to medication process stages is that errors associated with the administration stage were judged to have the highest risk of occurrence and be more likely to result in patient harm. Errors that occur later in the process are the least likely to be detected and intercepted prior to reaching the patient,[18] whereas failures that occur earlier in the process are more likely to result in process disruptions (e.g. delays or additional work) rather than patient harm.[19]

We found that incorrect dose, time, infusion pump settings and route of administration were the most common types of potential administration errors. This is consistent with the findings of prospective studies of medication incidents in paediatric inpatients,[12] neonatal and paediatric intensive care admissions[17] and in a level III NICU,[13] where incorrect dose, timing and rate of drug administration were common types of error. The potential for dose errors in the NICU due largely to decimal point misplacement in medication calculations has also been highlighted.[20]

Fundamental to improving medication safety is a clear understanding of the nature and causes of medication errors so that the most effective prevention strategies can be implemented. Misinterpretation of unclear or incomplete prescriptions, dosage miscalculations and use of imprest stock are some of the factors reported to contribute to nursing medication administration errors.[21] Descriptive data relating to the mechanisms of medication error and the successful application of prevention strategies appears to be lacking in the NICU setting. Both prescription and administration error rates in a paediatric nephrology ward of a French hospital were found to decrease with the use of computerised prescribing plus a unit dose dispensing system as compared with handwritten prescriptions and use of imprest stock.[22] Suggested strategies for preventing potentially harmful medication errors in paediatric inpatients in an American hospital include computerised physician order entry (CPOE) with clinical decision support systems (CDSS), ward-based clinical pharmacists monitoring each stage of the medication use process and improved communication among practitioners.[23] However, because such strategies have been found to be effective elsewhere does not automatically mean they will be universally successful.

The impact of any prevention strategy very much depends on the process of medication use and the nature of serious or commonly experienced errors. In the present study, the associated causes of error were found to be multifactorial, suggesting that a combination of strategies will be required to improve medication safety. Common themes identified were unsafe work environment for medication preparation and storage in the unit, variable staff skill level and lack of computerised technology. Use of unit dose dispensing – where medications are pre-

pared in the pharmacy and delivered to the NICU in ready-to-use individual patient doses – would probably have the most impact in error reduction. However, unless restricted to a small group of high-risk medications, this would be very resource-intensive from the pharmacy viewpoint. Other options that would be expected to reduce the potential for error include greater pharmacist involvement in the medication administration processes at ward level, redesign of the unit to allow safe storage of medication and creation of a dedicated medication preparation area less susceptible to distractions and interruptions. An electronic prescribing system integrated with pharmacy, laboratory and radiology systems would target the potential failures associated with the prescribing process.

The highest ranking issue was a perceived lack of awareness of medication safety across the organisation due to a lack of medication safety training, which the panel believed should be incorporated into the orientation package for new staff. Given the multidisciplinary nature of medication errors, training of all healthcare professionals in aspects of medication safety has been recommended.[17,24,25] Inexperienced medical and nursing staff, and poor training are important risk factors for recurrent medication errors.[25,26] Higher rates of prescription errors have been reported to occur when new and junior doctors join the team,[25,27,28] yet doctors seldom receive practical training on how to prescribe safely.[25] Reported errors involving doctors appeared to decrease after training was provided by a senior paediatric pharmacist,[29] although this was open to confounding factors in an uncontrolled longitudinal study.

There appears to be only one other published study describing the application of FMEA to an entire medication use process,[14] which was at an acute care hospital in the US. In that study the traditional FMEA process was followed and a total of 26 potential causes of error were identified. The top-rated failures identified were similar to our findings and related to unsafe storage of medications at ward level, mistakes in dose calculations and infusion flow rates, and not checking patient identity before administration. Hence, these issues are not unique to the NICU medication process.

The information obtained from the FMEA process has helped guide the selection of medication safety priorities for the next 12-month period and will serve as a basis for comparison of RPSs of any redesigned processes that may be instituted in the future. Other benefits were gained from undertaking this study. First, development of the flow diagram highlighted that an independent double-check was not being extended to the bedside. Inadequate checking of the infusion pump settings and completion of medication administration documentation prior to the medication being given to the patient were two problems identified. Extension of the independent double-check process has now been implemented. Second, when setting priorities for action, it became evident that not only were immediate actions required, but the establishment of simple ongoing performance measures are also required if future trends are to be monitored. The other benefit not anticipated at the outset of the present study was that the FMEA process encouraged teamwork, more open discussion about errors and promoted a systems-based approach to thinking about the possible causes of error.

To aid identification of potential failures, a systems-based approach was used in the present study. Vincent et al.[30] advocate a systematic approach to error management and have developed a framework for analysing risk and safety in clinical medicine to examine all the various influences on clinical practice. Such an approach is not part of the traditional FMEA method, but in this study appeared to provide a more ordered and efficient approach to identification of potential failures and their causes compared with the traditional FMEA method used by Williams and Talley.[14] In addition, by consideration of causes of error intrinsic to the current systems, the present study has highlighted that decisions and procedures put in place at the organisational level are important contributors to potential errors. As advocated by others,[31] strategies to prevent medication errors in healthcare need to follow the lead from industry and focus on changes to systems rather than changing the individual to achieve medication safety.

It has been argued that FMEA and other priority analysis techniques limit risk management to events with serious outcomes or potentially serious out-

comes, so interventions are limited to a small range of problems.[32] Whilst this viewpoint is acknowledged, it can also be argued that addressing these high-risk procedures will also provide solutions for less significant failures. Further, such serious events occur only rarely and may take decades to be identified if reliance is solely on voluntary incident reporting procedures. The advantage of the present study is that intervention strategies need not be limited to just severe events, they can also be targeted by stage, unit process, potential failure or system category. Another criticism of FMEA is that because priorities are assessed by a panel, if the panel inappropriately assesses the risk associated with a particular system or process, then the organisation may allocate considerable resources correcting a perceived rather than an actual recurrent or serious event.[33] It is therefore vital to select a multidisciplinary panel which represents managerial, clinical, quality and risk management expertise. Inclusion of a lay-person on our panel (a person who had no personal knowledge of the process) would have provided an impartial and valuable viewpoint. FMEA is often considered to be resource intensive.[19] The process requires a number of meetings of already busy management and clinical staff, plus additional time by the facilitator to co-ordinate and lead these meetings and collate information. In the present study, effective use of time was achieved by holding meetings only when the combined opinion of the panel was necessary, circulating information prior to meetings, and keeping meetings focused and brief.

Conclusions

Proactive risk assessment based on FMEA aided identification of high-risk procedures in the NICU medication use process. Interventions to decrease medication-related adverse events in the NICU should address lack of staff awareness of medication safety issues and focus on medication administration processes.

Acknowledgements

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