Using failure mode and effects analysis to improve the safety of neonatal parenteral nutrition

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Purpose. Failure mode and effects analysis (FMEA) was used to identify potential errors and to enable the implementation of measures to improve the safety of neonatal parenteral nutrition (PN).

Methods. FMEA was used to analyze the preparation and dispensing of neonatal PN from the perspective of the pharmacy service in a general hospital. A process diagram was drafted, illustrating the different phases of the neonatal PN process. Next, the failures that could occur in each of these phases were compiled and cataloged, and a questionnaire was developed in which respondents were asked to rate the following aspects of each error: incidence, detectability, and severity. The highest scoring failures were considered high risk and identified as priority areas for improvements to be made.

Results. The evaluation process detected a total of 82 possible failures. Among the phases with the highest number of possible errors were transcription of the medical order, formulation of the PN, and preparation of material for the formulation. After the classification of these 82 possible failures and of their relative importance, a checklist was developed to achieve greater control in the error-detection process. FMEA demonstrated that use of the checklist reduced the level of risk and improved the detectability of errors.

Conclusion. FMEA was useful for detecting medication errors in the PN preparation process and enabling corrective measures to be taken. A checklist was developed to reduce errors in the most critical aspects of the process.

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Preparing parenteral nutrition (PN) is a complex combination of high-risk activities. It is a critical process due to the complexity of the formulations and because the multidisciplinary nature of nutritional therapy makes it particularly susceptible to errors. When PN-related errors reach patients, a large percentage of patients are injured; thus, PN is considered a high-risk medication.[1]

In the 1990s, an observational study found that 9% of i.v. mixtures were improperly formulated, with PN mixtures exhibiting the highest error rate (37% for manual preparation and 22% for automated preparation).[2] Other studies have found that PN is one of the treatments most often associated with medicine-related problems.[3,4] The neonatal population is particularly vulnerable, and small errors can have severe consequences in these patients. The reported rate of medication errors for the pediatric population is three times higher than for adults.[5]

Two methods are used to manage the risks associated with critical processes: reactive (measures are taken after the occurrence of the adverse event to prevent it from happening again) and proactive (processes are analyzed a priori to prevent the adverse event from occurring in the first place). One of the most popular proactive methods is failure mode and effects analysis (FMEA), introduced in 1940 for use in the U.S. armed forces. It was further developed in the 1960s with the space program, and in the 1990s it was introduced into the hospital environment.[6]

According to the Joint Commission, FMEA is a systematic analysis technique, performed prospectively by a team, to prevent the appearance of problems associated with a proc-

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ess before they occur.[7] Since 2001, the Joint Commission has required each accredited hospital to perform at least one proactive risk assessment annually. Since the mid-1990s, the Institute for Safe Medication Practices (ISMP) has recommended the use of FMEA to prevent medication errors.[8] Among other practices aimed at preventing PN-related errors, ISMP-Spain recommends that FMEA be performed whenever any element of PN preparation is to be modified.[9] Only one study has been conducted that focused solely on PN.[10] In that study, conducted in a pediatric population, FMEA results were compared before and after improving a PN prescription and production program. No specific studies analyzing the manual preparation and dispensing processes have been performed in the neonatal population.

The purpose of this study was to conduct a prospective, systematic analysis of the various stages in which PN for neonates is prepared, applying FMEA to identify possible errors and enable the implementation of measures to prevent their occurrence.

Methods

The study was conducted in a general hospital with 350 beds. We analyzed the preparation and dispensing of PN for neonates from the perspective of the pharmacy service; aspects such as indications for use, administration, or monitoring were not analyzed. FMEA was performed in accordance with the processes described in the appendix.[11] A team of seven pharmacists with experience in FMEA was established, one of whom, an expert in safety analysis methodology, acted as the facilitator. A process diagram was drafted, illustrating the different phases of the neonatal PN process (Figure 1). Next, the failures that could occur in each of these phases were compiled and cataloged, and a questionnaire was developed in which respondents were asked to rate the following aspects of each error: incidence (probability of the event occurring), detectability (probabilities of the event not being detected and of it reaching the patient), and severity (effect of the error on the patient). This rating scale is displayed in Table 1. The numeric score that quantified these three items was used to calculate the risk priority index (RPI) (incidence × detectability × severity). The RPI is a numeric assessment of risk assigned to a process, or steps in a process, as part of FMEA. The final score obtained was the mean of the individual RPI values. The highest scoring failures were considered high risk and identified as priority areas in which improvements should be made.

Results

The evaluation process detected a total of 82 possible faults distributed over the various phases of the process (Figure 1). Among the phases with the highest number of possible errors were transcription of the medical order (22 failures), preparation of the PN (18 failures), and preparation of material to compound PN (13 failures).

The RPI values obtained (Table 2) ranged from 11 to 479. The failure producing the highest RPI was misidentification of medical order with data for another patient, associated with the medical prescription phase. Failures with high RPI values occurred in the following phases: prescription (error in the calculation of the components), transcription (confusion between insulin and heparin, sound-alike errors, confusion between heparin concentrations of 5% and 1%, and exceeding the maximum rate of administration), preparation of material for the formulation (look-alike failures [e.g., confusing disodium glycerophosphate vials with trace elements vials, confusing vials of potassium acetate with sodium acetate, and confusing heparin concentrations of 1% and 5%]), formulation of PN by the pharmacist (misreading of the quantities to be added, confusing vials of sodium acetate with potassium acetate [look-alike error]), and nurse review when the PN is received (formulation report review by nursing staff outside of pharmacists' working hours, which meant that a pharmacist would be unable to correct any error detected).

After the classification of these 82 possible failures and their relative importance, a checklist was drafted to achieve greater control in the error-detection process (Figure 2). The questionnaire was divided into two parts. The first part verified that the prescription was correct and validated the patient identification data, the contributions of components (checking the dose limits with the neonatology unit), the route of administration, the osmolarity, and the presence or absence of heparin. The second part of the questionnaire tested whether the drugs prescribed exactly matched those specified on the formulation report in order to check the transcription to the computer application. The checklist was designed to be completed in less than five minutes. A second evaluation was then carried out, following the FMEA methodology, according to which the checklist approach reduced the level of risk and improved the detectability of errors. Thus, the mean RPI values before and after the implementation of the process were 137 and 48, respectively.

Discussion

FMEA is increasingly being used as a means of assessing processes and improving their safety. It has been applied to improve safety in drug distribution systems,[12] prevent errors of formulation in chemotherapy in general[13] and especially for pediatric patients,[14] and improve the safety of i.v. medication administration to hospitalized patients.[15-17] Processes classified as high risk for the patient,

Table 1.
Criteria for Failure Mode and Effects Analysis Scoring

Criterion	Point Value	Description
Incidence		
Remote	1–2	Occurrence unlikely (may occur once in a period exceeding 5 yr)
Infrequent	3–4	Occurrence possible (may occur once during a period of 2–5 yr)
Occasional	5–8	Occurrence likely (may occur several times in 1–2 yr)
Frequent	9–10	Occurrence probable, immediately or in a short period of time (may occur several times in a year)
Detectability		
Low	9–10	Detection unlikely at the moment of occurrence
Moderate	7–8	Detection possible at the moment of occurrence
Occasional	5–6	Likely to be detected at the moment of occurrence
High	1–4	Almost always detected immediately
Severity		
Low	1–2	No injuries, no increase in duration of hospital stay, no need to raise the level of clinical care
Moderate	3–4	Increase in duration of hospital stay or in the level of clinical care for 1 or 2 patients
High	5–8	Permanent loss of function (sensorial, motor, physiological or intellectual), need for surgical intervention, increase in duration of hospital stay or in the level of clinical care for 3 or more patients
Catastrophic	9–10	Death or major loss of function (sensorial, motor, physiological or intellectual), such as suicide, rape, hemolytic transfusion reaction, surgery performed on the wrong patient, theft of a child

Figure 1. Phases of the neonatal parenteral nutrition (PN) process. The number of possible failures associated with each phase appears in parentheses.

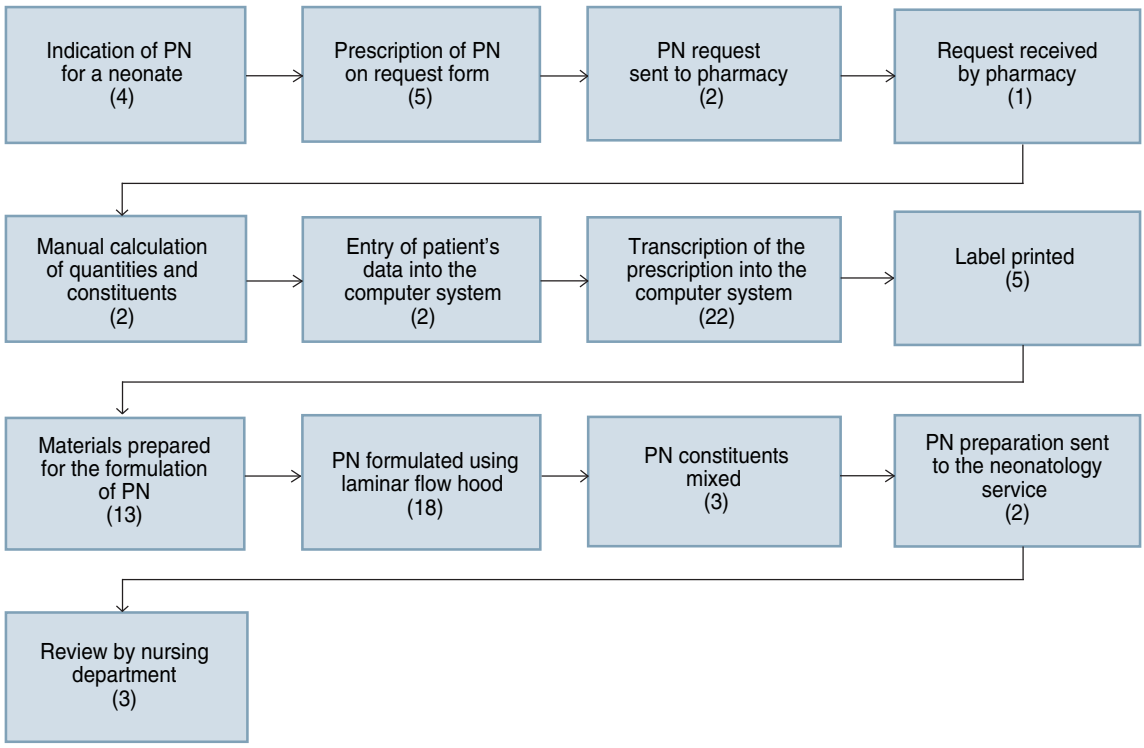

Table 2.
Possible Failures at Each Stage of the Process and the Corresponding RPI[a]

Stage and Possible Failure	RPI
Indication of neonatal PN	
Confusion of item or value in the analysis result	234
Confusion of analysis result	167
Confusion of patient identity	134
Appropriateness of the indication	68
Prescription of neonatal PN	
Misidentification of patient data on the medical order	479
Miscalculation of the PN constituents	312
Poor handwriting creating confusion	221
Patient not identified or incompletely identified	186
Failure to prescribe a necessary constituent of PN	77
Convey request to pharmacy	
Request not sent to pharmacy or lost	60
Request sent late (outside pharmacy working time)	39
Receive request at pharmacy	
Prescription not deposited at the specific reception point	38
Manual calculation of the total components, according to the weight stipulated	
Calculation error	187
Confusion between one item and another	69
Entry of patient's data into the computer system	
Patient identification number selected/entered erroneously	145
Date selected/entered erroneously	88
Transcription	
Confusing insulin and heparin	278
Confusing heparin concentrations (5% and 1%)	269
Exceeding stipulated administration rate	256
Adding excessive heparin (unstable physical–chemical mixture)	194
Using inorganic calcium salts, exceeding the solubility product	138
Error in calculating per kg body weight with respect to total value	122
Confusing rapid insulin with isophane insulin or others	117
Provoking an imbalance in other electrolytes when matching chlorides to the prescription	117
Using inorganic phosphorus salts, exceeding the solubility product	106
Confusion between g of nitrogen and g of amino acids	103
Excessive osmolality for the route of administration	96
Nonselection or erroneous selection of the route of administration	79
Failure to take into account the lipid supply of fat-soluble vitamins	68
Adding water rather than diluting other constituents	66
Computer procedure not validated (requires pharmaceutical validation of computer calculations, of the formulation report, and of the label)	54
Exceeding the maximum limit for fat-soluble vitamins	54
Failure to add zinc on overlooking its presence on the prescription form	54
Exceeding the maximum limit for water-soluble vitamins	52
Not completing to the total volume with water	52
Omitting to add the purge volume	43
Calculating the dose/kg of zinc when its dose is always standard	34
Stating double rather than single purge volume	23

Continued on next page

Table 2 (*continued*)

Stage and Possible Failure	RPI
Print label	
Printing the label for another patient	111
Printing the label for another day	72
Printing the formulation report for another patient	70
Printing the formulation report for another day	39
Not printing the formulation report	11
Prepare materials for formulation	
Confusing sodium acetate with potassium acetate	307
Confusing vials of disodium glycerophosphate with trace elements	294
Confusing heparin 1% with heparin 5%	252
Confusing vials of sodium chloride with potassium chloride or sodium phosphate	244
Confusing heparin with insulin	196
Confusing the concentration of glucose to be used	168
Confusing sterile water-for-injection vials with other containers	168
Confusing sterile water-for-injection vials with other mini plastic containers	159
Diluting water-soluble vitamins with the wrong diluent	99
Not having sufficient laboratory materials available	81
Confusing vials of fat-soluble vitamins for children with those for adults	72
Omitting a constituent from the mixture	54
Using an inappropriate size of PN bag	34
Formulate PN in laminar flow hood	
Confusing sodium acetate with potassium acetate	311
Erroneous reading of the quantities to be added	296
Confusing heparin 1% with heparin 5%	242
Confusing vials of sodium chloride with potassium chloride or sodium phosphate	240
Confusing disodium glycerophosphate with trace elements	213
Confusing heparin with insulin	196
Confusing the concentration of glucose to be used	189
Confusing sterile water-for-injection vials with other containers	186
Confusing sterile water-for-injection vials with other mini plastic containers	152
Ignorance or nonapplication of aseptic technique	148
Failure to use filters when working with glass vials	148
Failure to check for particles in suspension before adding lipids	148
Diluting water-soluble vitamins with the wrong diluent	109
Inadequate or insufficient purging of air	95
Confusing fat-soluble vitamins for children with those for adults	84
Failure to respect the order of addition of constituents	81
Failure to seal the PN bag correctly	57
The use of syringes of inappropriate size	47
Final preparation	
Incorrect external labeling of the PN bag	167
Incorrect labeling of the PN bag on completion	164
Failure to protect from the light	21
Storage and dispatch	
Storage at room temperature	76
Dispatch by pneumatic tube	48
Review by nursing staff	
Review carried out outside pharmacy working time	255
Failure by nursing staff to check the formulation or label report against the medical report	163
Use of PN after 24 hr	126

[a]The risk priority index (RPI) is calculated as follows: incidence × detectability × severity. The final score obtained was the mean of individual RPI values. The highest scoring failures were considered high risk and identified as priority areas in which improvements should be made. PN = parenteral nutrition.

Figure 2. Neonatal parenteral nutrition (PN) checklist.

PHARMACY AND NUTRITION AREA

NEONATAL PARENTERAL NUTRITION CHECKLIST

1st Part---Medical Prescription Review

Patient's name: ……..... Clinical History Number .....

	YES	NO	NA
I. PARENTERAL NUTRITION (PN) IDENTIFICATION			
1. Does the birth date in the prescription agree with patient's age on the label?			
2. Does today patient's weight agree with the previous day patient's weight?			
3. Is patient's weight between 0 and 4 kg?			
II. MACRONUTRIENTS AND VOLUME			
4. Is caloric amount provided between 90 and 140 kcal/kg?			
5. Macronutrients:			
1. Are lipid amounts provided between 0 and 4 g/kg?			
2. Is glucose amount provided between 4 and 19 g/kg?			
3. Are amino acid amounts provided between 0.5 and 4 g/kg?			
6. Is volume between 100 and 200 mL/kg?			
III. ELECTROLYTES			
7. Electrolytes:			
1. Is sodium between 2 and 4 meq/kg?			
2. Is potassium between 2 and 4 meq/kg?			
3. Is chloride between 2 and 3 meq/kg?			
4. Is calcium between 2 and 5 meq/kg?			
5. Is phosphate between 1.1 and 2 mmol/kg?			
6. Is magnesium between 0.12 and 0.5 meq/kg?			
IV. VITAMINS AND OLIGOELEMENTS			
8. Vitamins:			
1. Is Vitalipid content 4 mL/kg (maximum 10 mL)?			
2. Is Soluvit content 1.5 mL/kg (maximum 3.7 mL)?			
9. Oligoelements:			
1. Is Peditrace content 1 mL/kg?			
2. Is Oligo Zinc content 0.2 mL?			
V. OTHERS			
10. 1. Is osmolarity higher than 650 mOsm/L?			
2. In that case, is PN going to be administered through a central venous access?			
VI. DRUGS IN PN			
11. 1. Is heparin prescribed in PN?			
2. If heparin is prescribed, is the dose 0.5 IU per mL of PN?			
12. Is insulin prescribed in PN?*			

NA = not applicable. *Insulin must not be prescribed in PN according to local protocol.

If one of the answers is "NO," please contact the doctor.

Signed: Date:

Figure 2 (*continued*)

2nd Part---Transcription and Preparation Review

PARENTERAL NUTRITION TRANSCRIPTION REVIEW	YES	NO	NA
I. PN IDENTIFICATION			
1. Is patient's name in medical order (MO) the same as in pharmacy preparation sheet (PPS)?			
2. Is patient's weight in MO the same as in PPS?			
3. Is the date in MO the same as in PPS?			
4. Has PN a 30-mL purge volume?			
II. MACRONUTRIENTS AND VOLUME			
5. Macronutrients:			
1. Is lipid content (g/kg) in MO the same as in PPS?			
2. Is glucose content (g/kg) in MO the same as in PPS?			
3. Is amino acid content (g/kg) in MO the same as in PPS?			
6. Is total volume in MO the same as in PPS?			
III. ELECTROLYTES			
7. Electrolytes:			
1. Is sodium content (meq/kg) in MO the same as in PPS?			
2. Is potassium content (meq/kg) in MO the same as in PPS?			
3. Is chloride content (meq/kg) in MO the same as in PPS?			
4. Is calcium content (meq/kg) in MO the same as in PPS?			
5. Is phosphate content (meq/kg) in MO the same as in PPS?			
6. Is magnesium content (meq/kg) in MO the same as in PPS?			
IV. VITAMINS AND OLIGOELEMENTS			
8. Vitamins:			
1. Is Vitalipid content (mL) in MO the same as in PPS?			
2. Is Soluvit content (mL) in MO the same as in PPS?			
9. Oligoelements:			
1. Are Peditrace content (mL) in MO the same as in PPS?			
2. Are Oligo Zinc content (mL) in MO the same as in PPS?			
V. OTHERS			
10. Is venous access in MO the same as in PPS?			
VI. DRUGS IN PN			
11. If heparin has been prescribed, is the prescribed dose in MO the same as in PPS?			

NA = not applicable.

If one of the answers is "NO," please repeat medical order transcription.

PARENTERAL NUTRITION PREPARATION REVIEW	YES	NO	NA
11. Have material and products been prepared by a pharmacy technician and double-checked by a pharmacist?			
12. Have all medications been used?			
13. Is PN light protected?			

Every answer must be "YES."

Signed: Date:

such as transfusions[18] and other activities carried out in hospital emergency areas, have also been evaluated using FMEA.[19,20]

One of the limitations of FMEA is its subjectivity, as different medical professionals working under the same conditions can reach different conclusions, as shown by Shebl et al.[21] To minimize this problem, explicit criteria have been stipulated to assess the frequency, severity, and detectability of failures.[22,23] However, it is important to note that an RPI score that designates a failure is not the most important factor, as the main goal is to classify the risk by phases and to determine orders of magnitude among possible failures.

In all the phases of the process, the one in which most failures occurred was that of the pharmacist's transcription of the medical order into the computer, probably because this requires a large number of calculations, proper selection of constituents, and assessment of their compatibility in the i.v. bag. The preparation of materials for and the formulation of PN, steps that are closely related, are also considered risky due to the complexity of the mixtures, both in the variety of components to be used and in the different and sometimes miniscule volumes to be added.

In the phase of the pediatrician's prescription, the highest RPI calculated was for confusion of the medical order with the data for another patient. This error could result in the administration of PN to a child who does not need it or its omission to one who does, or in the case of twins, assigning the necessities of one twin to the other. This error is considered very serious, and its high RPI value is the result of its low detectability. In the case of neonates, validation of patient identification is conducive to risk, because many children are still unnamed at the time of prescription. Moreover, in the case of twin births, the surnames are identical and can induce confusion; the date of birth is the same for various patients admitted to the unit, and clinical history numbers are correlated and therefore very similar. To ensure accurate patient identification, the checklist included, in addition to the patient's name and clinical history number, an item to verify that the date of birth (from the pharmacy service) coincided with the age in days indicated by the prescribing physician and that the patient's weight was consistent with that recorded the day before.

A noteworthy finding was the high number of look-alike and sound-alike errors. There may have been an error concerning drugs or PN components because they sounded similar (e.g., insulin, heparin) or were visually similar (such as the vials of sodium glycerophosphate and trace elements) or because the same units of measure were used (e.g., confusing g/kg of nitrogen with g/kg of amino acids). This type of error is common in daily clinical practice, and many organizations, such as ISMP and the Joint Commission, have published recommendations to minimize this risk.[24-26] The phases in which the request is delivered to the pharmacy, its receipt there, the data-entry process, the printing of the label or the formulation report, drug storage, and drug delivery to the neonatology department are all associated with low RPI values.

These data are consistent with those of previous studies evaluating the risks associated with PN.[27,28] A prospective study of the frequency and severity of errors made in the prescription, transcription, preparation, and administration of PN found, as did our analysis, that the most frequent errors occur during transcription (39% of all errors).[27] Another study also highlighted this activity as the main source of error.[28] The introduction of electronic prescribing has resulted in a notable reduction in the rate of errors related to PN in the neonatal unit.

According to FMEA results, use of the checklist was effective in reducing RPI values at our hospital. This tool helps in the systematic review of the phases in which the process may fail, and helps to detect errors before they reach the patient. Furthermore, its use can ensure that these criteria are implemented in the same way by all staff involved and makes it possible to record failure events for future analysis and thus improve the whole process. Its ease of implementation and the very brief time required to complete the checklist make its application feasible in a health care setting.

Conclusion

FMEA was useful for detecting medication errors in the PN preparation process and enabling corrective measures to be taken. A checklist was developed to reduce errors in the most critical aspects of the process.

References

1. Cohen MR, Smetzer JL, Tuohy NR et al. High-alert medications: safeguarding against errors. In: Cohen MR, ed. Medication errors. Washington, DC: American Pharmacists Association; 2007:317-411.
2. 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.
3. Cerulli J, Malone M. Assessment of drug related problems in clinical nutrition patients. *J Parenter Enteral Nutr.* 1999; 23:218-21.
4. Heyland DK, Montalvo M, MacDonald S et al. Total parenteral nutrition in the surgical patient: a meta-analysis. *Can J Surg.* 2001; 44:102-11.
5. Kaushal R, Bates DW, Landrigan C et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA.* 2001; 285:2114-20.
6. DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effects analysis: the VA National Center for Patient Safety's proactive risk analysis system. *Jt Comm J Qual Improv.* 2002; 28:248-67.
7. Joint Commission. Medical errors, sentinel events, and accreditation. A report to the Association of Anesthesia Programs Directors, October 28, 2000. www.saaahq.org/meetingpapers/2000/croteau.ppt (accessed 2014 Mar 20).
8. Redfern E, Brown R, Vincent CA. Improving communication in the emer-

gency department. *Emerg Med.* 2009; 26:658-61.
9. ISMP España. Recomendaciones para la prevención de errores de medicación: prevención de errores relacionados con la nutrición parenteral. www.ismp-espana.org/ficheros/Bolet%25C3%25ADn%2027%20Junio%202008.pdf (accessed 2013 Mar 9).
10. Bonnabry P, Cingria L, Sadeghipour F et al. Use of a systematic risk analysis method to improve safety in the production of pediatric parenteral nutrition solutions. *Qual Saf Health Care.* 2005; 14:93-8.
11. Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. *Clin Chim Acta.* 2009; 404:75-8.
12. McNally KM, Page MA, Sunderland VB. Failure-mode and effects analysis in improving a drug distribution system. *Am J Health-Syst Pharm.* 1997; 54:171-7.
13. Sheridan-Leos N, Schulmeister L, Hartranft S. Failure mode and effect analysis: a technique to prevent chemotherapy errors. *Clin J Oncol Nurs.* 2006; 10:393-8.
14. Robinson DL, Heigham M, Clark J. Using failure mode and effects analysis for safe administration of chemotherapy to hospitalized children with cancer. *Jt Comm J Qual Patient Saf.* 2006; 32:161-6.
15. Wetterneck TB, Skibinski KA, Roberts TL et al. Using failure mode and effects analysis to plan implementation of smart i.v. pump technology. *Am J Health-Syst Pharm.* 2006; 63:1528-38.
16. Adachi W, Lodelce AE. Use of failure mode and effects analysis in improving the safety of i.v. drug administration. *Am J Health-Syst Pharm.* 2005; 62:917-20.
17. Apkon M, Leonard J, Probst L et al. Design of a safer approach to intravenous drug infusion: failure mode effects analysis. *Qual Saf Health Care.* 2004; 13:265-71.
18. Burgmeier J. Failure mode and effect analysis: an application in reducing risk in blood transfusion. *Jt Comm J Qual Improv.* 2002; 28:331-9.
19. Redfern E, Brown R, Vincent CA. Identifying vulnerabilities in communication in the emergency department. *Emerg Med.* 2009; 26:653-7.
20. Redfern E, Brown R, Vincent CA. Improving communication in the emergency department. *Emerg Med.* 2009; 26:658-61.
21. Shebl NA, Franklin BD, Barber N. Is failure mode and effect analysis reliable? *J Patient Saf.* 2009; 5:86-94.
22. WHO. Marco conceptual de la clasificación internacional para la seguridad del paciente. www.who.int/patientsafety/implementation/icps/icps_full_report_es.pdf (accessed 2013 Mar 9).
23. Otero MJ, Codina C, Tamés MJ et al. Errores de medicación: estandarización de la terminología y clasificación. *Farm Hosp.* 2003; 27:137-49.
24. Institute for Safe Medication Practices. FDA and ISMP lists of look-alike drug names with recommended tall man letters. www.ismp.org/tools/tallmanletters.pdf (accessed 2013 Mar 9).
25. ISMP España. Prevención de errores por confusión en los nombres de los medicamentos. www.ismp-espana.org/estaticos/view/63 (accessed 2013 Mar 9).
26. Joint Commission. Sentinel event alert: look-alike, sound-alike drug names. www.jointcommission.org/assets/1/18/SEA_19.pdf (accessed 2013 Mar 9).
27. Sacks GS, Rough S, Kudsk KA. Frequency and severity of harm of medication errors related to the parenteral nutrition process in a large university teaching hospital. *Pharmacotherapy.* 2009; 29:966-74.
28. Lehmann CU, Conner KG, Cox JM. Preventing provider errors: online total parenteral nutrition calculator. *Pediatrics.* 2004; 113:748-53.

Appendix—Steps involved in failure mode and effects analysis

Step 1. Select the high-risk process.
Step 2. Select the team of experts.
Step 3. Describe the process using a chart or flow diagram.
Step 4. Perform the risk analysis.
   a. Identify the failures that may occur at each stage of the process.
   b. Analyze the possible causes and effects of these failures.
   c. Analyze the risk of each of these failures: severity, probability, and detectability before harm is caused to the patient.
Step 5. Take action to reduce or eliminate the possibility of failures, prioritizing those with higher risk priority index values.