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RISKS IN THE IMPLEMENTATION AND USE OF SMART PUMPS IN A PEDIATRIC INTENSIVE CARE UNIT: APPLICATION OF THE FAILURE MODE AND EFFECTS ANALYSIS

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Objectives: The aim of this study was to identify risk points in the different stages of the smart infusion pump implementation process to prioritize improvement measures.
Methods: Failure modes and effects analysis (FMEA) in the pediatric intensive care unit (PICU) of a General and Teaching Hospital. A multidisciplinary team was comprised of two intensive care pediatricians, two clinical pharmacists and the PICU nurse manager. FMEA was carried out before implementing CareFusion infusion smart pumps and eighteen months after to identify risk points during three different stages of the implementation process: creating a drug library; using the technology during clinical practice and analyzing the data stored using Guardrails® CQI v4.1 Event Reporter software.
Results: Several actions for improvement were taken. These included carrying out periodical reviews of the drug library, developing support documents, and including a training profile in the system so that alarms set off by real programming errors could be distinguished from those caused by incorrect use of the system. Eighteen months after the implementation, these measures had helped to reduce the likelihood of each risk point occurring and increase the likelihood of their detection.
Conclusions: Carrying out an FMEA made it possible to detect risk points in the use of smart pumps, take action to improve the tool, and adapt it to the PICU. Providing user training and support tools and continuously monitoring results helped to improve the usefulness of the drug library, increased users' compliance with the drug library, and decreased the number of unnecessary alarms.

Keywords: FMEA, Smart pumps, Pediatric intensive care, Safety

As the hospital drug supply and administration system becomes more complex, there is a growing risk of medication errors at different stages involved (1;2). The development and implementation of new technologies have helped to reduce the number of medication errors occurring at all the stages of the process (3–7).

Errors that occur during the administration stage are the hardest to intercept (2), and technologies used during this phase are the quickest and cheapest to implement (8).

Smart infusion pumps can help to improve safety when administering intravenous drugs, where the flow rate needs to be closely monitored (8–10). A smart pump is a computerized version of a conventional pump with an added drug library. This library contains a list of drugs with details of their concentrations and maximum and minimum infusion rates. Using this information, hard and soft limits can be defined, both upper (UHL, USL) or lower (LHL, LSL), to prevent overdoses and underdoses, respectively. If a soft limit is exceeded as a result of a programming error, an alarm will sound to warn the user that the dosage or infusion rate may not be suitable for that patient. However, soft limits can be overridden and administration can continue. Hard limits, on the other hand, cannot be overridden, and if the alarm sounds because a hard limit is being exceeded then the user has to cancel the infusion or reprogram the pump (8). All information regarding infusion programming is stored in the pumps, and these data can later be analyzed and interpreted (11;12).

However, when new technologies are implemented they often introduce new risk points into the process, and these can lead to errors if they are not detected and intercepted in time. Failure modes and effects analysis (FMEA) can be used to prevent any new errors that may result from the implementation of new technologies. This technique aims to improve processes and is used to identify risk points in a product before and after it is introduced.

The authors thank all the staff at the Pediatric Intensive Care Unit for their collaboration and involvement in implementing this technology.

Table 1. Quantitative Variables Analyzed for Each of the Possible Errors and Values Assigned

Value assigned	Likelihood of occurrence (O)	Likelihood of detection (D)	Severity of outcome possibilities (S)
1	Remote: Probability of 1 in 10,000 No known occurrence	Very high: Probability of 9 out of 10 Error always detected	Slight annoyance: May affect the system
2	Low: Probability of 1 in 5,000 Possible, but no known data	High: Probability of 1 out of 10 Error likely to be detected	Moderate system problem: May affect the patient
3			
4			Major system problem: May affect the patient
5	Moderate: Probability of 1 in 200 Documented but infrequent	Moderate: Probability of 5 out of 10	
6			Minor injury
7	High: Probability of 1 in 100. Documented and frequent	Low: Probability of 2 out of 10	Major injury
8			Terminal injury or death
9	Very high: Probability of 1 in 20 Documented, almost certain	Remote: Probability of 0 out of 10 Detection not possible at any point	
10			

Potential errors or failure modes can be ranked according to the likelihood that they will occur and be detected, and the severity of any effects they may have on the patient (13). The FMEA method is currently used by a large number of institutions, healthcare-related and otherwise (14–16), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now uses it to identify what are known as sentinel events in each process (13).

OBJECTIVE

The aim of this study was to carry out a FMEA on the risk points in the use of smart infusion pumps in a pediatric intensive care unit (PICU) before and after the devices are implemented to identify possible actions for improvement and to assess the effects that those improvements could have on the risk points detected.

MATERIALS AND METHODS

This study was carried out by a multidisciplinary team made up of two intensive care pediatricians, two clinical pharmacists, and the PICU nurse manager. The research team analyzed and identified any possible risks at different stages of the process, both in January 2010, before the technology was fully implemented, and in June 2011, a year and a half after its implementation.

According to the FMEA method, the following qualitative variables were identified for each risk point or failure mode (13;17): (i) Failure causes, *(ii)* Failure effects, (iii) Opportunities to improve and recommendations to minimize the likelihood of occurrence.

Quantitative variables were also analyzed for each of the possible errors (see Table 1), and the values assigned to each failure mode were reached by team consensus through periodical meetings before and after the technology was fully implemented in the unit.

Finally, the consensus values were then multiplied (O × D × S), and the products could be used to prioritize possible improvements according to their scores. The risk points with the highest scores would be a higher priority, and improvements should be made to decrease the likelihood of them occurring and the severity of their possible consequences. The implementation of the new technology suggested migration from CareFusion conventional systems, both volumetric and syringe pumps, to CareFusion's Alaris Guardrails® with safety software.

The team used the Guardrails® CQI v4.1 Event Reporter software to carry out a systematic review of the data stored in the pumps to gain a descriptive sense of what problems occurred and used the pumps' event log data for a quantitative analysis of user response to dosing alerts and programming errors that were averted.

This processing program gives the user information regarding nursing staff compliance with the drug library (percentage of drug library use), number of alarms triggered (ratio number of alerts/number of infusions started through the drug library),

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clinical meaning of alarms triggered, drugs involved and users' response to those alarms in terms of infusion reprogramming or cancellation (percentage of reprogramming infusion after a related-soft limit alert).

Audits of pumps enabled the team to gather all this information and determine the final score of each failure mode identified, because every item analyzed is directly associated with the causes and effects described.

RESULTS

Table 2 shows the risk points identified by the team in the three stages of the process: (i) creating the drug library, (ii) using the smart pumps in clinical practice, and (iii) stored data analysis.

Also shown are the scores that the team gave to each risk point in the system during the preliminary stages of implementing the technology and after it had been implemented, respectively. Cells are shaded to highlight risk points with higher scores where priority improvements need to be made.

Early Stages of Implementation

During the first month after implementation, a 17,725 infusion pump audit found the drug library was used in 84 percent of medication infusions, the ratio "number of alerts/number of infusions started through the drug library" was 1.74 percent and the percentage of reprogramming infusion after a related-soft limit alert was 16 percent. All these parameters gave an idea of the percentage of use of the drug library and the amount and type of unnecessary alarms that may lead to alarm fatigue.

According to these data, the priority risk points in the early stages of the process, when the *drug library was being drawn up*, are errors caused when defining limits and by a failure to adapt limits to the unit's clinical practice.

The risk points with the highest score in the *use of the drug library* during clinical practice were: slow upload and update of data on the systems; incorrect profile or standard concentration of the drug selected by nursing staff; failure to comply with protocols in place; failure to confirm the dosage or infusion rate after an UHL alarm; and reprogramming the infusion without using the safety software.

Finally, according to the scores given, the priority risk points during the *data analysis process* were: slow download speed; and the risk of failing to distinguish between alarms caused by real programming errors and those used for training purposes or caused by incorrect use of the system.

Eighteen Months after Implementation

The team suggested a series of improvements that could be made to minimize the risks detected in each stage of the process. These actions were taken, and 18 months after the smart pump technology was introduced in the PICU, it was found that most of the risk points identified had practically disappeared.

A 624,252 infusion audit revealed the drug library was used in 92 percent of medication infusion, the ratio "number of alerts/number of infusions started through the drug library" dropped to 0.4 percent, and the percentage of reprogramming infusion after a related-soft limit alert increased to 30 percent.

However, no improvements were made to the data update and download process after the initial stages of the study. Improvements here can only be made by the manufacturer, not by healthcare personnel.

DISCUSSION

When new technologies are introduced, they bring new risk factors along with them, opening the door to new errors on top of the ones that the intervention aimed to avoid in the first place. It is, therefore, advisable to carry out an FMEA before introducing the new system.

Although some authors questioned whether or not this method was reliable (18;19), several organizations, such as the Institute for Healthcare Improvement (IHI), have published the results obtained by different healthcare bodies after FMEAs were carried out in various departments and at different stages of the drug supply and administration process. One FMEA found that one of the highest-ranking risk points in a neonatal intensive care unit was at the intravenous drug administration stage (20). It is, therefore, exceedingly important to ensure that all safety measures are effective to reduce the risk of administration errors.

The IHI has published the results of an FMEA on the use of smart infusion pumps. The two most important risk points identified were the lack of available pumps due to limited resources, and users' perception of the system as not very intuitive. These factors may lead users to program intravenous infusions without using the safety software, and this will increase the risk of failure (17).

Wetterneck et al. published the results of an FMEA carried out in a North American hospital before the implementation of smart infusion pump technology (21). The risk points identified included entering the wrong patient weight, selecting the wrong profile, and programming infusions not included in the drug library. In all cases, the team suggested that staff should be trained to program infusions using smart pumps. This would increase staff awareness of the possible repercussions that not using the safety software or ignoring the system's infusion alerts could have on the patient.

In the present study, three main stages in the implementation of smart infusion pump technology were defined. In each stage, the team identified several risk points that could lead to failures in the system. These risk points ranged from incorrect interpretation of results leading to an under- or overestimation of the impact the technology could have on the unit, to the programming of infusions without the safety software, with the usual risk of error.

During the *early stages of the implementation* process, the highest-rated risk points during the *drug library creation* stage

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Table 2. Risk Point Ratings *before and after* the Technology Was Introduced

PROCESS 1: Designing the drug library											
FAILURE	CAUSES	EFFECTS	O (BI)	D (BI)	S (BI)	O × D × S (BI)	O (AI)	D (AI)	S (AI)	O × D × S (AI)	ACTIONS REQUIRED
Drug used not included	One-off need	Drug programmed not included in the library Risk of error	6	1	4	24	2	1	3	6	Periodical reviews Assess new drugs for possible inclusion
Included drug used infrequently	Not administered with pump	Lots of lines, not very intuitive, not used as much	7	4	1	28	6	4	1	24	Periodical reviews Remove unnecessary lines
Incorrect limits set	Data entered manually Few units available	Complicated calculations, not very intuitive, unnecessary alarms, and error risk	6	3	4	72	1	3	4	12	Double check data entered Periodical reviews
Very strict limits	Not suitable for clinical practice	Unnecessary alarms and risk of administration error	8	2	4	64	3	2	2	12	Periodical reviews Allow margin to round up or down
Very broad limits	Not suitable for clinical practice	Risk of administration error	2	8	5	80	1	8	5	40	Periodical reviews
Drug included in the wrong profile	Data entered manually	Unnecessary alarms and error risk	2	2	3	12	1	2	2	4	Double check List of drugs and profiles
PROCESS 2: Using pumps with drug libraries											
FAILURE	CAUSES	EFFECTS	O (BI)	D (BI)	S (BI)	O × D × S (BI)	O (AI)	D (AI)	S (AI)	O × D × S (AI)	ACTIONS REQUIRED
Pumps not available on the unit	Not enough pumps or pumps not updated with latest version of the library	Infusion programmed without the drug library and risk of error	1	1	4	4	1	1	4	4	Contact manufacturer, schedule updates in advance, staff collaboration, identify pumps that have not been updated, radio frequency systems
Slow data upload/update	Using systems without WiFi or few port multipliers	Delays Incomplete process	9	7	3	189	9	7	3	189	Use smart towers, port multipliers or WiFi antennas
Incorrect profile selected	Users' lack of knowledge. Distraction, overload work, stress	Unnecessary alarms and risk of administration error	6	7	4	168	2	7	4	56	Training Provide list of drugs and profiles
Incorrect drug (D) or concentration (C) selected	Lack of training Unintuitive library Distraction, overload work, stress	Unnecessary alarms and risk of administration error	D 2 C 6	D 7 C 7	D 5 C 4	D 70 C 168	D 1 C 2	D 7 C 7	D 5 C 4	D 35 C 56	Training Periodical reviews to update the library
Incorrect weight entered	Lack of training Incorrect weight confirmed by default/old data used Distraction, overload work, stress	Unnecessary alarms and risk of administration error	6	3	3	54	4	3	3	36	Training

Table 2. Continued

Programming bolus doses, intermittent infusions and continuous infusions without specifying the mode of administration in the library	Lack of training Unintuitive library	Unnecessary alarms and risk of administration error	5	3	3	45	2	3	3	18	Training Provide administration guidelines as support documents
Failure to comply with protocols regarding standard concentrations and administration times in intermittent infusions	Lack of training	Unnecessary alarms and risk of administration error	6	7	5	210	2	7	5	70	Training Provide administration guidelines as support documents
Programming a higher/lower dosage to administer in a proportionally longer/shorter time	No programs analyse dosage and administration time separately	Risk of administration error	2	8	5	80	1	8	5	40	Training and provision of administration guidelines Systems that analyse dosages and administration times separately for intermittent infusions
Ignoring a soft limit without confirming the dosage or speed	Alarm fatigue	Risk of administration error	6	8	2	96	2	8	2	32	Training Review and edit limits
Dosage/speed not confirmed after a hard limit alarm and infusion reprogrammed not in accordance with the library	Alarm fatigue Lack of awareness of risk of error	Risk of administration error	8	4	4	128	2	4	4	32	Training Thorough review of limits and adaptation to clinical practice

PROCESS 3: Analyzing saved data after smart pumps have been used

FAILURE	CAUSES	EFFECTS	O (BI)	D (BI)	S (BI)	O × D × S (BI)	O (AI)	D (AI)	S (AI)	O × D × S (AI)	ACTIONS REQUIRED
Pumps required for data download cannot be found	Pumps shared between different units	Incomplete download and data missing	1	1	4	4	1	1	4	4	Schedule the download in advance, staff collaboration, radio frequency system
Slow download speed	Using systems without WiFi or few port multipliers	Delays	9	7	3	189	9	7	3	189	Use smart towers, port multipliers or WiFi antennas
Failure to distinguish between alarms caused by real programming errors, those used for training purposes and those caused by incorrect use of the system	Incorrect programming for training purposes Failure to comply with protocols	Overestimation of the impact of the technology	9	7	1	63	2	6	1	12	Thorough review of alarms detected

O, likelihood of occurrence; D, likelihood of detection; S, severity of outcome possibilities; BI, before the technology was fully introduced; AI, after the technology was fully introduced.

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were related to limits setting. These failures can lead to an increased risk of programming errors, because users decide not to use the safety software because of "alarm fatigue" (22), or because they have entered overly broad limits, either by mistake or because they have failed to adapt the limits to the unit's real clinical practice.

Eighteen months after implementation, the risk of these errors had decreased thanks to the periodical data reviews and the lower number of drugs to be included and changes to make.

The likelihood of having to manually input a drug not included in the library was moderate in the initial stage before implementation, but had been reduced once the smart technology had been in use for a year and a half. Periodical reviews and day-to-day use made it possible to identify drugs likely to be administered intravenously using a smart pump in the PICU, so the final version of the drug library should now include all the drugs required. This means that there should be no need to program an infusion of a drug not included in the library.

The likelihood of finding drugs in the library that are not actually used in the PICU was high before the implementation process began, but moderate a year and a half later. Some drugs do not need to be administered using infusion pumps, and although a lot of these have been removed from the library there are still lots on the system that are barely used or not used at all. The latest version of the drug library no longer includes them (23).

The likelihood of a drug being mistakenly included in another profile decreased from low to remote after the implementation period. This is thanks to periodical reviews, good communication with the nursing staff (who flag any discrepancies), and the updating of lists made available in the PICU showing the profile under which each drug is included.

The highest-ranking risk points identified during the *smart pump usage stage* were consistent with those of Wetterneck et al. (21).

During the early stages of the implementation process, a lack of training for nursing staff leads to errors when the drug is selected on screen. This can lead, in turn, to further administration errors and other mistakes. For example, staff may fail to realize that, if an infusion is not prepared in accordance with the unit's standard concentrations and drug library protocols but is still programmed using the safety software, it will lead to discrepancies in the system and new potential errors. For instance, users sometimes prepared different drug concentrations to the standard ones established in the drug library, but started the infusion through the drug library. This led to discrepancies in infusion volume that generated alarms not necessarily associated with a real error.

Training sessions and the production of support documents such as administration guidelines and compatibility tables (24) helped to minimize the risk of errors at this stage and decrease the number of unnecessary alarms. This meant that, *a year and a half later*, any alarms that did sound were taken more seriously. According to the decrease of the ratio "number of alerts/number of infusions started through the drug library" and the increase of the percentage of reprogramming infusion after a related-soft limit alert, before and after the implementation phase, the team was able to diminish the amount of unnecessary alarms and, therefore, the risk of alarm fatigue, with the improvement of the quality of the drug library design.

Like Wetterneck et al. (21), the study team found that there was a risk of entering an incorrect patient weight. Because patients in the PICU have very different physical characteristics, the systems generally have a weight range of between 1 kg and 100 kg. This means that 1 kg appears by default, and it is not possible to enter a weight of over 100 kg. Entering the wrong weight could lead to unnecessary alarms or an increased margin of error, and this increases the risk of administration errors. The introduction of training sessions and making users aware of this problem meant that the likelihood of this failure was reduced a year and a half after implementation.

With regard to the data upload process, this can only be improved if CareFusion makes improvements to the system's connectivity. The ranking for this was the same both before and after the implementation process. Similarly, the option of developing systems that analyze administration times and dosages separately, without having to set a speed for intermittent infusions (23), can only be provided by the manufacturers, and it was not possible to improve this after the implementation process.

Wetterneck et al. (21) identified other aspects of the hardware that could be improved. For example, capital letters could be used to help users differentiate between similar drug names, and soft and hard limits could be allowed for each medication in the drug library.

None of these suggestions were made in this study. The version used already included the option of using capital letters. Although lower hard limits were not allowed by the system, they were not believed to be essential. In fact, given the wide range of different patients in the PICU and the different physiological systems affected, setting lower dosing limits would be complicated. The limits would always be soft limits so that they could be overridden and administration could continue if deemed necessary.

Unlike in other organizations (13), the availability of the pumps was not a problem in the hospital studied here. However, it is important to take into account that the data update process is slow and can sometimes take several days. This means that, although pumps are always available in the PICU, some of them might not have the latest version of the drug library installed.

Finally, incorporating a training profile solved the problem of differentiating between alarms caused by real programming errors and those used for training purposes, one of the failure modes identified in the FMEA during the *smart pump data analysis process.* However, like the upload process, the download is slow and CareFusion needs to speed up this process. It was impossible to improve this during the implementation process.

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Most of these risk points identified in the first FMEA lead to unnecessary alarms that might detract nurses from using the technology with the subsequent increased probability of a programming error reaching a patient (25). The data presented in the results section showed both the compliance and the number of infusions reprogrammed after a soft limit alarm increased, whereas the number of unnecessary alerts decreased, after 18 months of implementation. This is consistent with the values assigned by the team to each risk point after the implementation of the improvement measures. Carrying out an FMEA in the PICU made it possible to optimize the smart pump implementation process, identifying any possible risk points and taking action to intercept them.

Some authors question the usefulness of the AMFE method for prioritizing interventions aimed at improving patient safety (18;26), while others say that its inherent subjectivity means that it should not be the only method used (27). However, the method relies on a teamwork system involving various healthcare professionals, and FMEA may still be a valuable tool for the detailed analysis of each process and early detection of potential failures (28;29).

CONCLUSIONS

Carrying out an FMEA made it possible to detect risk points in the use of smart pump technology, take action to improve the way in which the tool is used, and adapt it to the characteristics of the PICU.

Providing user training, support tools, and continuously monitoring results helped to improve the usefulness of the drug library, increase users' compliance with the drug library, and decrease the number of unnecessary alarms and are key to ensuring that the technology is used effectively and with lower risk.

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CONFLICTS OF INTEREST

The authors report no conflicts of interest.

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