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Failure mode and effects analysis applied to central venous catheter placement

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ABSTRACT

Despite diligent efforts, complications continue to occur during the placement of central venous catheters (CVCs). Healthcare Failure Mode and Effect Analysis has been promoted as a process improvement tool and this review describes the strategic application of Failure Mode and Effects Analysis (FMEA) to CVC placement. The objective is to demonstrate the utility of FMEA first as a tool for identifying quality or safety issues and second for guiding mitigation efforts.

INTRODUCTION

Central venous catheters (CVCs) are an essential component of modern healthcare. A prior prevalence study of six medical centres previously found that 29% of hospitalised patients had a central venous catheter[1] and the current number is likely higher. While these catheters provide clear benefits, the insertion procedure also includes immediate risks such as arterial puncture, pneumothorax, air embolism and retained guidewires, as well as delayed risks that include catheter-associated bloodstream infections (CLABSIs), non-functional catheters and venous thrombosis.[2–8] Efforts to improve the insertion procedure strive to preserve the benefits while reducing these risks. For example, maximum sterile barriers and checklists reduce CLABSIs,[9] ultrasound guidance lessens arterial punctures[8 10] and targeted training programmes cut down on retained guidewires.[11 12]

The exigency of Failure Mode and Effects Analysis (FMEA) stems from the persistent occurrence of complications despite implementing strategies specifically designed to address those risks.[13] FMEA is based on the premise that failures in any process can never be completely eliminated. Instead, the impact of those failures can be mitigated by revising the system to reduce the frequency of failure from any particular failure mode, improving the detection of the failure before it causes irrevocable harm and reducing the severity of failure when it inevitably occurs.[13]

Manufacturers have long used FMEA to improve the design and manufacture of medical devices. A recent comprehensive review lists multiple publications where FMEA has been applied to the blood transfusion process, medication use, radiation therapy, hospital management, information systems and other topics.[14] For central venous access, FMEA principles were employed when designing a training programme.[11] Nonetheless, searches of the literature failed to find any prior publications that applied FMEA to CVC placement in a rigorous step-by-step fashion. A detailed FMEA that catalogues the causal chains underlying complications along with the local factors influencing the frequency, detection and severity of the relevant failure modes should prove valuable during the design, implementation and assessment of improvement efforts.

BACKGROUND AND RATIONALE: OVERVIEW OF THE FMEA PROCESS

The first steps in FMEA are defining the scope of the analysis and assembling a team. The team is charged with breaking down the process into its individual steps and creating a detailed task analysis. For each step, the team then identifies the potential failure modes. When identifying failure modes, the team asks 'what could go wrong with this step?', 'what has gone wrong with this step in the past?' or 'what reservations do stakeholders harbor concerning this step?'.[13]

For each failure mode, the team then describes the potential effect of the failure along with the underlying cause for the failure. The potential effect is used to determine a severity score for each failure mode. The team also scores each failure mode according to the frequency of failure. Where possible, objective data is used to determine the frequency score. The team also scores each failure mode according to the current system's ability to detect the failure event.

In addition, the FMEA team reviews the safeguards, also known as control strategies, currently in place. These control strategies are typically designed to reduce the frequency, improve the early detection or minimise the severity of failure arising from each failure mode.

The team then multiplies the severity, frequency and detection scores to arrive at a Risk Priority Number (RPN) for each failure mode. Failure modes that lead to frequent events that not only have severe effects but also typically escape detection despite the control strategies already in place are identified by their higher RPNs. As new control strategies are implemented or existing control strategies are revised, the FMEA team then assesses the impact by tracking changes in the RPNs. Successful improvement projects lead to lower RPNs via control strategies that target the frequency, severity or detection of a particular failure mode.

The FMEA process acknowledges the contextual variance of RPNs between different operational environments according to the effectiveness of the local control strategies. For example, during central venous catheter placement, the operator attempts to centre the catheter tip relative to a target location such as the cavoatrial junction.[15 16] Variations in catheter tip position are expected and lead to creating tolerance bands around the desired target and the decision to reposition catheters when the tip falls outside the acceptable range.[17] However, for CVCs, different workgroups use various control strategies such as radiography, fluoroscopy, transoesophageal echocardiography,[18] electrocardiography[19] and combined electrocardiography-electromagnetic tracking systems[20] to assess catheter tip position.

Applying FMEA to vascular access

Step 1: selecting and defining a specific vascular access procedure

Multiple factors led the FMEA team to select ultrasound-guided placement of a non-tunnelled, small bore (5-7Fr), multilumen catheter via the right internal jugular vein in a stable adult patient. This choice was justified by its ubiquity across a wide variety of providers and operational environments such as operating rooms, fluoroscopy suites, emergency departments and intensive care units. This suggested that a general task analysis and description of the resulting failure modes would have wide applicability even though the RPNs might vary between the different provider teams and operational environments.

It was necessary to select a particular catheter type, insertion site and technique since early versions of the task analysis demonstrated how variation complicated the analysis. For example, the specific steps and failure modes associated with placing a large bore (13-16Fr) multilumen haemodialysis catheter via the right common femoral vein in an unstable adult patient clearly differ from placing a 3Fr single lumen peripherally inserted central catheter via the left cephalic vein of a paediatric patient. Indeed, capturing the impact of the variations found during placement of various catheter types, access sites and insertion techniques will necessitate multiple FMEAs.

Early work also indicated the need to intentionally limit the scope of the FMEA. The pre-procedure steps such as determining the need for central venous access, selecting the appropriate vascular access device, choosing an insertion site and obtaining informed consent were deemed out of scope. Similarly, post-procedure steps, such as the protocols for using and eventually removing the catheter were excluded from this FMEA.

As a result, the decision was made to consider the steps that occur after completing the pre-procedure checklist ('time-out') and ending with the application of the sterile dressing. It was also decided to focus on the failure modes related to the processes required to safely place the catheter and largely ignore failure modes attributable to patient factors, supplies and equipment.

Step 2: preparing for FMEA

The operationalisation of FMEA required the creation of two FMEA teams. Distinct teams analysed central venous catheter placement in a fluoroscopy suite staffed by an interventional radiology (IR) team and an operating room (OR) staffed by a cardiac anaesthesiology team. The FMEA process was then reviewed with both teams, along with the project's scope. Both teams used a software package specifically designed for FMEA (XFMEA, Reliasoft, Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany), to organise their work and calculate the RPNs.

The IR team consisted of two attending physicians, a physician assistant, a diagnostic radiology resident and a technologist. This team reviewed and amended the task analysis along with the failure modes and effects. The IR team then focused on estimating the frequency and detection of failures in their operational environment.

For a second parallel team, an attending cardiac anaesthesiologist worked with an IR attending to review and amend the task analysis developed by the IR team. The steps, failure modes, effects and control strategies were revised to reflect the differences between the IR and cardiac OR environments as well as variations in personnel and equipment.

Step 3: hierarchical task analysis

The central venous catheter insertion procedure was divided into six segments and the steps within each segment were described (figure 1). Each team reviewed the detailed task analysis to confirm that it matched the steps in their operational environment since steps varied slightly between the two settings. For example, the sterile prep segment employed by the IR team included infiltrating the skin with a local anaesthetic. In contrast, cardiac anaesthesia's task analysis omitted this step since their patients were under a general anaesthetic during the procedure (see online supplemental materials for complete task analysis in both settings).

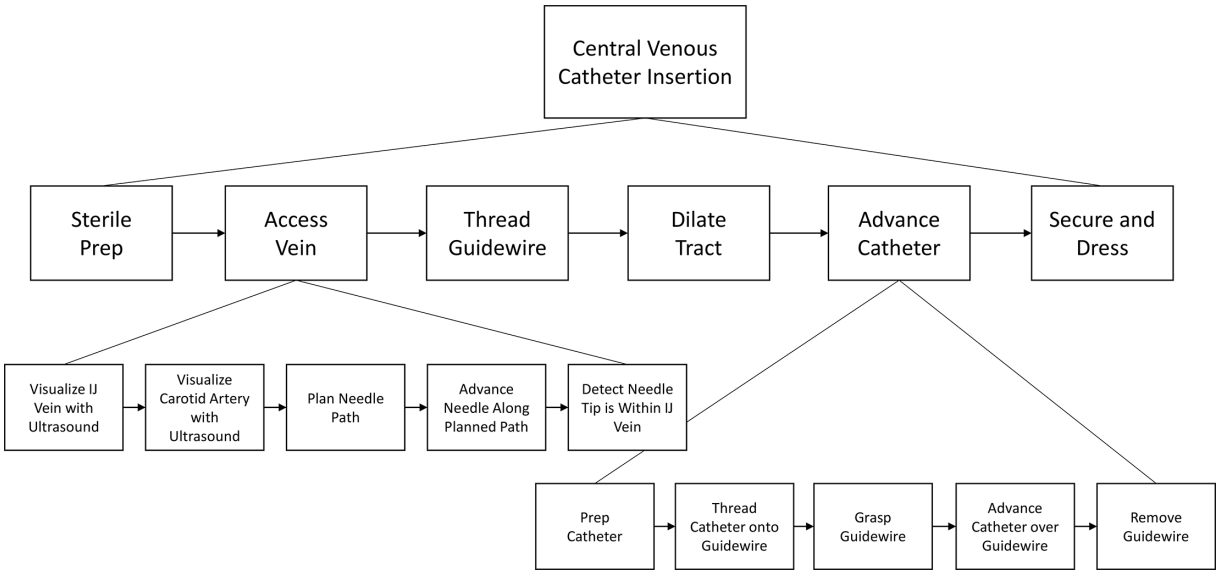

Figure 1 Hierarchical task analysis: the six segments are shown along with individual tasks within two segments. As detailed in online supplemental materials, each task includes multiple subtasks.

Step 4: list failure modes for each step

The teams then listed the failure modes for each step along with their potential causes, effects and existing controls. Figure 2 shows a portion of the resulting FMEA. Even though central venous catheter placement is commonly regarded as a 'short, simple procedure', the team catalogued more than 70 different failure modes. The complete catalogue is included in (online supplemental files 1; 2). Despite this long list of failure modes, the two FMEA teams acknowledge that their accountings

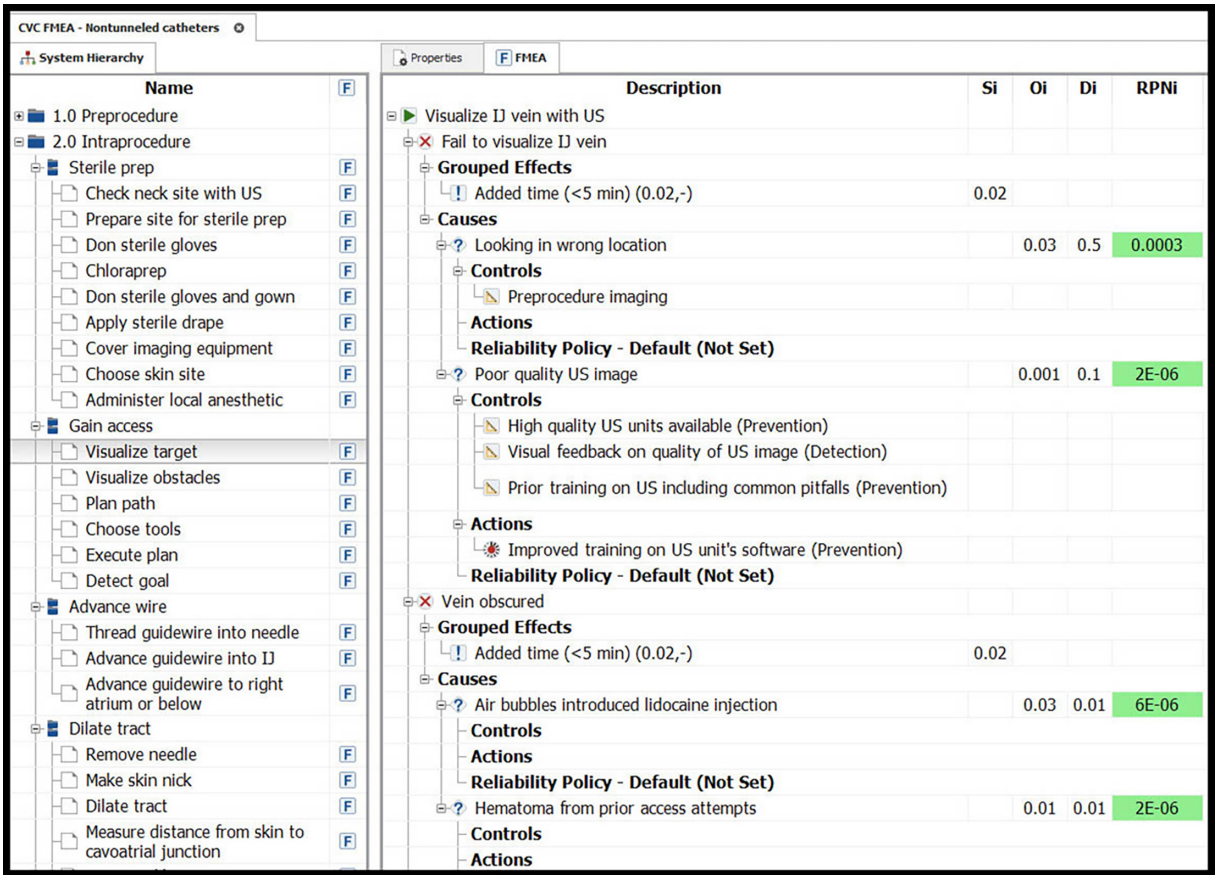

Figure 2 Screenshot from the Failure Mode and Effects Analysis (FMEA) software that illustrates how information regarding each failure mode was captured and organised. Columns labelled 'Si', 'Oi' and 'Di' contain the severity, frequency and detection scores, respectively. The column labelled 'RPNi' contains the Risk Priority Number.

Table 1 Rubrics used to score the severity, frequency and detection for each failure mode

(a) Severity scoring rubric	
Severity score	Estimated cost ($)
0.02	<30
0.06	31–100
0.2	101–300
0.6	301–1000
2	1001–3000
6	3001–10 000
20	10 001–30 000
60	30 001–100 000
200	>100 000
(b) Frequency scoring rubric	
Occurrence score	Estimated frequency
0.001	Occurs less than once a year
0.003	Occurs about once a year
0.01	Occurs about once per quarter
0.03	Occurs about once per month
0.1	Occurs about once per week
0.3	Occurs multiple times per week
1	Occurs about once per day
2	Occurs multiple times per day
(c) Detection scoring rubric	
Detection score	Estimated frequency
0.01	Almost always detected
0.1	Nearly always detected
0.25	Easy to detect
0.5	50/50 chance of detection
0.75	Hard to detect
0.9	Nearly always escapes detection
0.99	Almost always escapes detection

of failure modes, causes, effects and controls are incomplete. Rather, this work is intended to serve as a starting point where the catalogue can be expanded as previously unknown failure modes are discovered and new control strategies are developed.

Step 5: estimating the severity of failure

Severity is often scored using a 1–10 scale number that reflects the most serious effect for a given failure mode. Given the broad range of adverse events associated with medical procedures, it was previously suggested to use the direct costs attributable to these adverse events to calculate severity scores.[21] This cost and probability-based set of scoring schemes (table 1) mirrors that described by von Ahsen.[22] In addition, Rhee and Ishii contend that 'cost is a universal language that can be easily understood in terms of severity among engineers and others'.[23] Switching from ordinal numbers to estimated costs and probabilities also addressed a prior criticism of FMEA.[24]

The severity scoring rubric was constructed with a logarithmic scale to best capture the marked cost differences between minor and major events. The effect of failures that caused pain and/or lost time was estimated to be much smaller than the severity scores of other failure modes. The costs of CLABSIs have been previously estimated[25] and when using 2024 dollars, map to a severity score of 60. Based on the reported cost of carotid artery injuries,[26] inadvertent catheter placements into the carotid artery also led to a severity score of 60. The cost of retained guidewires was estimated at between $3 and 10K but could be substantially higher based on its classification as a sentinel event and denial of payment for associated charges during that hospitalisation. Severity scores were linked to the effects. Since the effects of any particular failure mode did not change when switching settings, the same severity scores were used for the IR and OR teams. In contrast, Shebl *et al* allowed two different FMEA teams that were both studying the same process to independently assign severity scores using ordinals and this likely contributed to the variability they observed.[27]

Step 6: estimating frequency and early detection of failures

Ideally, the FMEA teams would use objective data regarding the frequency of each failure mode and the ability of existing control strategies to detect those failures. Instead, the FMEA teams used their experience in training residents when creating their frequency and early detection estimates. The IR FMEA team based their estimates on the performance of a second-year radiology resident (PGY3). The cardiac anaesthesiologist based the performance of residents 6–18 months into their anaesthesiology residency (PGY2-3).

Step 7: calculate the RPNs

The RPNs are calculated by multiplying the scores for severity, frequency and detection. As shown in figure 2, many of the failures caused by different failure modes had RPNs less than 1. However, the failure modes that led to breaks in sterile technique, arterial puncture and retained guidewires were substantially higher (table 2).

Step 8: review existing control strategies for high-priority failure modes and propose changes

As an example, table 2 compares three failure modes. Both FMEA teams identified insufficient time for the chlorhexidine/alcohol solution to dry as one of their highest-priority failure modes. While training was listed as a control strategy, the teams tacitly acknowledged that education is often an unreliable strategy, especially when confronting production pressure in their operational environments. Given this issue, one might consider an additional control strategy where the sequence of steps is changed so that the operator performs other tasks while the chlorhexidine/alcohol solution dries. This strategy can be incorporated into the packaging of supplies used

Table 2 Comparison of Failure Mode and Effects Analysis attributes for three failure modes shared between two different workgroups

Step	Description	Failure mode	Cause	Effect	Severity	Setting	Frequency	Detection	RPN	Existing control	Possible additional control
2.1.03	Prep site with chlorhexidine+alcohol solution	Insufficient drying time	Flawed belief on time required coupled with time pressure	Early CLABSI	60	IR	2	0.99	118.8	Training on sterile prep	Training with a sequence that builds in time
						OR	2	0.99	118.8		
2.1.06	Unfurl drape	Contaminate drape	Flawed method for draping	Early CLABSI	60	IR	0.3	0.9	16.2	Training on technique for spreading drape	Staff in the room calling out when they witness a break in technique
						OR	0.01	0.5	0.3		
2.2.06	Detect that the needle tip is within the IJ vein	Continue to advance the needle despite the tip being in the vein	Lack of feedback	Carotid artery puncture	2	IR	0	0.5	0.003	Ultrasound visualisation of the needle's tip	Training on ultrasound visualisation of needle tip
						OR	1	0.9	1.8	Aspirate while advancing the needle	

The results illustrate how Risk Priority Numbers (RPNs) can vary substantially between workgroups due to prior implementation of different control strategies.
CLABSI, catheter-associated bloodstream infection; IR, interventional radiology; OR, operating room.

for CVC placement.[28] For example, the chlorhexidine/alcohol applicator can be packaged in the outermost layer of a bedside kit. The next layer can include the sterile gown and the inner layer includes the drape and catheter kit. Such layering of supplies 'nudges' the operator[29] to follow a sequence which includes time for the chlorhexidine/alcohol solution to dry while the operator dons gown and gloves before draping the patient.

In the cardiac OR, contaminating the drape during its unfurling was judged to be less frequent and more readily detected than in the IR fluoroscopy suite (table 2). Potential explanations include more effective training, more stringent oversight by OR personnel and/or a culture where breaks in sterile technique are more reliably called out.

Conversely, in the IR fluoroscopy suite, carotid artery puncture caused by failure to track the needle tip with ultrasound was considered less frequent and more readily detected than in the cardiac OR. The most likely explanation is the difference in how ultrasound is used in those two settings. As shown in figure 3A–C, the IR team advances the needle within the plane of the ultrasound beam. As a result, the needle tip is identified as the end of an echogenic line. The ultrasound image from this 'in-plane' method also readily conveys both the course of the needle relative to the target and the distance remaining between the needle tip and the target. The benefits of this lateral approach come with a cost since it increases the probability in the next step that the guidewire might travel cranially towards the skull base rather than caudally towards the right atrium. However, the IR team routinely uses fluoroscopy to monitor guidewire advancement and thus readily detects the occurrence of this failure mode.

In contrast, the cardiac anaesthesia team advances the needle along a course that is orthogonal to the ultrasound beam (figure 3D). As a result, the needle is reduced to an echogenic point and the operator must pan the ultrasound transducer to discern the location of the needle's tip, the course of the needle relative to the target and the distance between the target and needle tip. Complicating matters further, the low internal pressure of the internal jugular vein means that the force required to advance the needle through the vessel wall often causes the near and far walls of the vein to coapt (figure 3E). Failure to recognise this failure mode and relying primarily on aspiration of blood to detect when the needle tip enters the vein can cause the operator to puncture both walls of the vein and continue needle advancement until the tip enters the carotid artery (figure 3F). The advantages and disadvantages of the different ultrasound imaging planes and their linked failure modes have been described previously.[30–35]

These comparisons demonstrate how the calculated RPNs account for the differences in local processes and operational environments. These comparisons also begin to illustrate the impact of different control strategies, and the potential benefits of sharing knowledge gained from reporting and investigating adverse events.

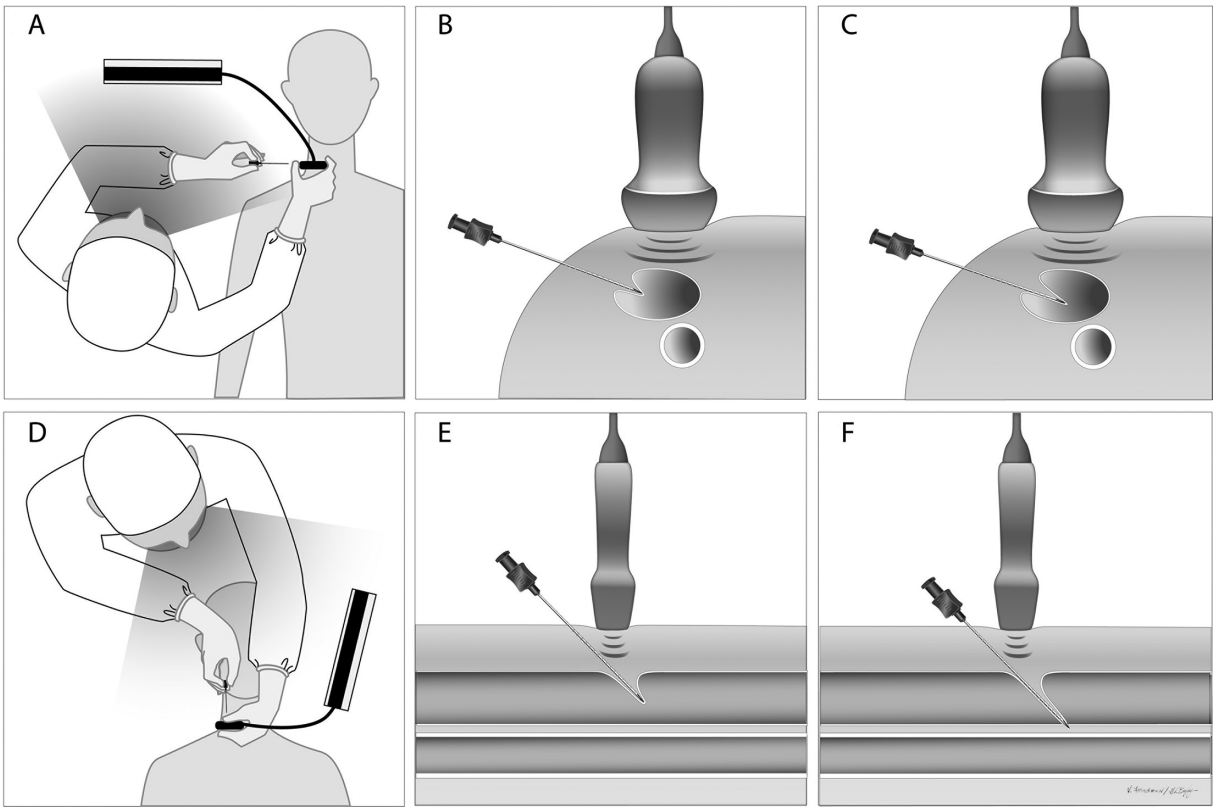

Figure 3 (A–C) Practices used in interventional radiology's operational environment. (D–F) Practices in the cardiac operating room's operational environment. In each case, the operator's field of view includes the ultrasound screen as well as the patient's right neck (panels A and D). The middle panels (B and E) depict the imaging plane of the ultrasound transducer. The right-sided panels (C and F) illustrate how the vein can begin to collapse due to pressure exerted by the needle's tip.

DISCUSSION

FMEA provides insights into the inherent complexity of even a basic medical procedure such as central venous catheter placement. The task analysis revealed more than 40 individual steps with more than 70 different failure modes. As expected, the two different workgroups exhibited minor differences in the overall process. Comparing the FMEA data for the two teams also highlighted how differences in control strategies alter the RPNs for specific failure modes.

The results also suggest a possible interaction between detection and frequency for key failure modes. Specifically, improved detection strategies such as team members watching for breaks in sterile technique and calling them out when they inevitably occur create a feedback loop where operators learn to monitor their own performance and adjust their technique to reduce the frequency of such errors. In the same fashion, learning to vary the ultrasound imaging plane to more reliably detect a needle that is off course or that pressure from the needle tip has collapsed the vein, might lower the frequency of failed passes or carotid artery punctures.

Another key aspect of FMEA is that it creates a platform for sharing knowledge across different workgroups. Task analysis can identify common steps, where different workgroups will face the same failure modes. While healthcare's siloed natures tend to undermine the dissemination of knowledge, cataloguing failure modes along with the resulting severity, frequency and detection scores together with existing control strategies provides opportunities for these different teams to learn vicariously.[36 37]

This report has multiple limitations. First was the lack of empirical data regarding the frequency and detection of various failures caused by the different failure modes. Since the RPNs are based on estimates, it will be more difficult to assess whether changes in control strategies are effective. Second was the limited scope of the project with data from only two teams and the decision to focus only on a narrowly defined procedure. Additional FMEA iterations will be needed to build a larger catalogue that includes data from other teams, other vascular access devices and working environments (table 3). Still, this catalogue of steps, failure modes, control strategies and RPNs can serve as a starting point for other teams looking to better understand and improve their local processes.

Finally, the value of FMEA has been questioned, particularly the reliability and validity of the RPNs.[24 27 38 39] The mathematical concerns associated with using ordinal numbers can be avoided by using potential costs when calculating RPNs. Still, the values used to calculate RPNs were estimates rather than actual measurements of performance in the different operational environments. As such, the reliability and validity of the RPNs from these

Table 3 Opportunities for additional Failure Mode and Effects Analyses

Teams	Critical care, emergency medicine, surgery, vascular access
Procedures	Devices: PICCs, large bore central venous catheters, tunnelled catheters, implanted devices Sites: peripheral, subclavian or femoral veins[5 45] Patients: paediatric (neonates vs teenagers), adult
Settings	Bedside: ICU versus non-ICU, emergency room Available equipment: ultrasound, fluoroscopy, ECG
Phases of care	Pre-procedure Post-procedure Catheter removal

ICU, intensive care unit; PICC, peripherally inserted central catheter.

two FMEAs can be debated. Despite these concerns, Shebl *et al* contend that FMEA has clear value in three settings.[38]

First, the FMEA catalogue of failure modes helps trainees since their list of known failure modes is often incomplete. Error training[10 40 41] as well as studying collections of known failure modes, facilitates early detection. In addition, learning proven recovery strategies from those failure modes leads to improved performance.[42]

Second, FMEA has value when introducing new processes or tools. Predicting failure modes and their consequences is analogous to a 'premortem' exercise.[43 44] In a premortem exercise, a team uses their knowledge of a system's weaknesses to predict how a planned task or project might fail.

Third, FMEA can be helpful when comparing different systems of care or processes. Comparing the different steps along with their failure modes and accompanying control strategies can provide insights into the advantages and disadvantages of each approach. In this report, FMEA showed clear differences in how ultrasound is used to help guide a needle towards the internal jugular vein.

In summary, FMEA is a well-established but imperfect tool. As detailed in this review, FMEA provides valuable insights into how an invasive procedure such as central venous catheter placement might be improved.

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