**Use of failure modes and effects analysis to mitigate potential risks prior to implementation of an intravenous compounding technology**

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**Purpose.** The purpose of this study was to identify potential failure points in a new chemotherapy preparation technology and to implement changes that prevent or minimize the consequences of those failures before they occur using the failure modes and effects analysis (FMEA) approach.

**Methods.** An FMEA was conducted by a team of medication safety pharmacists, oncology pharmacists and technicians, leadership from informatics, investigational drug, and medication safety services, and representatives from the technology vendor. Failure modes were scored using both Risk Priority Number (RPN) and Risk Hazard Index (RHI) scores.

**Results.** The chemotherapy preparation workflow was defined in a 41-step process with 16 failure modes. The RPN and RHI scores were identical for each failure mode because all failure modes were considered detectable. Five failure modes, all attributable to user error, were deemed to pose the highest risk. Mitigation strategies and system changes were identified for 2 failure modes, with subsequent system modifications resulting in reduced risk.

**Conclusion.** The FMEA was a useful tool for risk mitigation and workflow optimization prior to implementation of an intravenous compounding technology. The process of conducting this study served as a collaborative and proactive approach to reducing the potential for medication errors upon adoption of new technology into the chemotherapy preparation process.

**Keywords:** automation, chemotherapy, FMEA, healthcare failure modes and effects analysis, medication safety, pharmaceutical services, risk mitigation, sterile compounding

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Parenteral chemotherapeutic agents are considered high-risk medications, and errors in preparation may result in dire consequences. In one study, antineoplastic agents were cited as the second most common source of fatal medication errors.[1] The narrow therapeutic index and significant toxicities of these medications—and the vulnerability of patients receiving them—make preparation of precise doses critical. Incorrect dosages accounted for 38 of 141 errors identified in a study conducted in a large community hospital oncology ward.[2] The error rate for intravenous (IV) compounding without IV workflow technology in US hospital pharmacies has been reported as 9%, with incorrect doses accounting for the majority of errors.[3]

IV workflow management systems and IV robotics are the 2 types of automation technologies that are currently being used to reduce errors associated with compounding IV chemotherapy agents. These technologies utilize barcode scanning and image capture to ameliorate common sources of error associated with traditional IV compounding, such as incorrect drug or diluent selection and incorrect volumes withdrawn. Incorporation of gravimetric detection to the IV workflow system provides an additional safeguard compared to traditional volumetric verification processes such as the syringe pull-back method. The benefits of these IV workflow systems for improving the safety of IV preparation and reducing waste have been documented.[4] IV workflow systems utilizing gravimetric verification were shown to detect medication dosing errors in nearly 8% of prepared chemotherapy doses and prevent these errors from reaching patients.[5]

Changing pharmacy workflow can have unintended consequences, as staff could be unfamiliar with the potential risks for error with implementation of a new system. In order

to prevent risks associated with the adoption of a new IV workflow technology, proactive measures can be utilized to ensure that patients are not exposed to these foreseeable risks. The Institute for Healthcare Improvement's failure modes and effects analysis (FMEA) tool was used to identify steps in a new workflow, determine the potential for errors in those steps, and predict the likelihood of those errors to cause harm.[6] This tool has been validated previously, and the importance of risk management in the deployment of new medical technologies is known.[7,8] FMEAs have been previously conducted with a focus on smart infusion pumps, pediatric drug prescribing and administration, computerized order entry systems, and the prevention of controlled substance diversion.[9-12]

Furthermore, previous experience using the FMEA tool at our medical center prior to deployment of a chemotherapy IV robot yielded positive results. Therefore, prior to implementation of a new IV workflow system for manual admixture of hazardous medications,[a] an FMEA was conducted over a 13-month period in order to define the workflow for use, identify opportunities for error and their risk potential, and develop system and operational changes to mitigate risks.

**Methods**

The FMEA was performed between February 2018 and February 2019 by a team consisting of medication safety pharmacists; oncology pharmacists and technicians; members of the leaderships of the informatics, investigational drug, and medication safety services; and representatives from the technology vendor.

The objective of the initial phase of the analysis was to outline the process for using the technology. After each step of the process was defined, potential failures in the process

were identified. Each failure mode was then evaluated for severity based on clinical and operational impact, frequency, and detectability.

Failure modes were scored using both Risk Priority Number (RPN) and Risk Hazard Index (RHI) scores (Table 1).

The RPN is the numeric product of the failure mode severity, frequency, and detectability scores. Clinical severity was scored between 1 (no harm) and 4 (death or major loss of function); production severity was scored between 1 (downtime of less than 30 minutes) and 4 (downtime greater than 4 hours). Frequency scores were between 1 (remote; likely to occur once every year at most) and 4 (frequent; likely to occur daily). Failure modes were considered as either detectable (score of 1) or undetectable (score of 4). RPN values were calculated for each failure mode using the following equation: RPN = CS × OS × F × D, where CS indicates clinical severity; OS, operational severity; F, frequency; and D, detectability. The minimum RPN score for a mode was 1, while a maximum score was 256. The RPN prioritizes the failure modes in order to guide the allocation of resources to address the highest-priority failures; higher RPN values indicate higher risk and priority.

The RHI assigns each failure mode to a risk category based upon severity and frequency. RHI values were calculated for each failure mode using the following equation: RHI = CS × OS × F. The minimum RHI score for a mode was 1, while a maximum score was 64. Higher RHI values signify severe failures that occur frequently and are considered a greater risk (ie, high risk).

After the modes were scored using both RPN and RHI, the modes considered high risk were addressed. In the analysis, modes were considered high risk if the RPN or RHI score was 9 or higher. Interventions were identified for the high-risk modes. The RPN and RHI scores were recalculated based on the prospective impact of the intervention.

**Results**

The vendor provided 2 product demonstrations and developed a video recording of the IV compounding technology in use. The ability to consult the recording and the expertise of the staff members who were familiar with the vendor's chemotherapy compounding robot, which has similar features, were critical in developing the 41-step workflow process. After the expected workflow was defined, each step was examined for error potential. A total of 16 failure modes were identified. Each mode was scored using both RPN and RHI scores (Table 2), and those deemed the highest-risk modes were highlighted. In the exercise, the RPN and RHI scores were identical for each failure mode because all modes were considered detectable (score of 1).

Each of the 5 highest-risk modes (those with RPN and RHI scores of 9) were further assessed. The ability to advance through the product preparation process is prohibited by the system design in 3 of the 5 modes. Because a staff member encounters a hard stop and cannot proceed, actions were not identified for these 3 modes. For the 2 remaining failure modes, mitigation strategies and system changes were identified. The system modification requests included a change to less ambiguous terminology within the software, as well as implementation of a photo preview option for the technician after photographs of the final product and ingredients are taken. Both modifications were submitted to the vendor and completed prior to implementation of the technology and resulted in lower RPN and RHI scores (6 for both). A site-specific procedural change consisted of a policy statement that technicians must alert the pharmacist of any dose discrepancies of ±5% of the ordered dose.

**Discussion**

Potential risks associated with the implementation of IV compounding technology were reduced after conducting a systematic FMEA. Inclusion of medication safety experts, a front-line technician, local and departmental pharmacy leadership members, and vendor representatives provided rich discussion, varied perspectives on approach, and creativity in system redesign. While others have coordinated with vendors during the analysis process, members of this project are unaware of a healthcare FMEA team that has included vendor representatives as part of the multidisciplinary group.[9] The addition of vendor contacts proved to be beneficial for 2 primary reasons. First, while a product demonstration was conducted and recorded on-site, hands-on experience with the technology was limited, making it challenging to define the dispensing process. Additionally, at the time, the technology had narrow use in the United States; therefore, limited current users could be consulted. Inclusion of vendor representatives in the analysis also allowed them to better understand the potential failure modes and communicate the FMEA team's concerns to their leadership team. As a result, the vendor proactively responded by making 2 software changes prior to implementation of the technology at the site.

RPN is the most frequently used measure for FMEA quantification outside of healthcare. From civil engineering to agriculture, RPN calculations are the standard calculation for ranking the risks of failures in systems to be implemented.[13,14] RHI was an additional metric used in the study to prioritize the most severe and probable failures independent of the ability to detect the failures. The National Center for Patient Safety (NCPS) advocates for use of a hazard score rather than an RPN when using its Healthcare Failure Mode and Effect Analysis (HFMEA) tool.[15] After the analysis was completed, all identified failures were deemed detectable, making the RHI value equal to the RPN value

and superfluous to the prioritization of risk. In future applications of FMEA, it may be beneficial to use levels of detectability to assist in the risk prioritization beyond that of binary (detectable or not detectable) classifications used in the analysis described here.

Further actions were not identified for 3 of the high-risk modes identified because the user could not proceed with preparation if these failures occurred. The use of forcing functions that do not allow progression to the next steps is a high-leverage strategy for reducing errors. It is also an expected element of IV workflow management systems to increase IV accuracy according to the THRIV coalition, a group endorsed by the Institute for Safe Medication Practices.[16]

An important limitation of the FMEA to consider is the focus on process optimization. The FMEA described here exclusively focused on risks at the user level because the clinical severity and frequency associated with user error were high despite a high rate of error detection by the technology. Software or mechanical failures were not further explored because preparation using the equipment could not proceed if these failures occurred. However, there may be utility in further analyzing the unintended consequences of these failures, such as the need to revert to manual preparation of products, and proactively planning for technology downtimes. Another key limitation of the FMEA was the subjective nature of the risk severity and frequency scoring scale. Notably, the large size of the group participating in the FMEA and the varied backgrounds of participants may have reduced the impact of potential biases.

One important decision point when defining the expected workflow involved the review of the image capture by the verifying pharmacist. The technology utilizes both image capture and gravimetric analysis to determine the accuracy of the dose prepared. During preparation, the technician may proceed with injection of the medication dose prior to

review of the syringe image by the pharmacist. When the technology is used in this way, gravimetric analysis functions as the primary method to determine dose accuracy, with electronic image capture enabling additional confirmation. The team weighed the potential for delays in product preparation while awaiting pharmacist verification of the electronic image with the ability to intercept dosage errors prior to product injection. It was determined that employing image capture as a historical record of the preparation that can be consulted if concerns in preparation exist rather than as a mechanism for real-time verification was an appropriate use of the technology.

An unintended consequence of the decision to use image capture as a secondary source of dose confirmation was recognized after implementation of the technology in one of the health system's affiliated infusion centers. Prior to use of the technology, the pharmacist was required to visually inspect the syringe volume prior to injection of the medication into the final product container. It was expected that staff would resume the practice of a visual review of the syringe contents prior to injection if a technology failure occurred and manual preparation was required; however, staff implemented the syringe pull-back method to determine dose accuracy. We suspect that staff felt comfortable with the syringe pull-back approach because the technology workflow allowed for visual inspection of the syringe contents after, rather than during, product preparation.

While there are a number of different IV workflow management systems, the FMEA approach described in this article is applicable to any institution that identifies this technology as the most suitable for its infusion preparation process. In cases of institutions utilizing different IV workflow systems in chemotherapy preparation, the described FMEA method may serve as a template for risk stratification and mitigation prior to implementation.

## Conclusion

An FMEA conducted prior to implementation of an IV compounding technology is a useful tool to address future workflow issues and identify potential failure modes within the dispensing process. Inclusion of vendor representatives in the analysis is recommended, particularly when analyzing workflows where there is limited experience with the technology. A collaborative approach may also allow for system changes to reduce risks prior to product implementation. The project described here can serve as a template for others conducting FMEA of a new technology.

## Disclosures

The authors have declared no potential conflicts of interest.

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**Key Points**

- Parenteral chemotherapeutic agents are considered high-risk medications, and errors in preparation may result in fatal consequences.
- Intravenous workflow technology presents an opportunity to reduce risks associated with the parenteral chemotherapy preparation process.
- Healthcare failure modes and effects analysis is a useful tool to ensure safety and efficiency prior to adoption of a new intravenous workflow technology.

**Table 1.** Risk Priority Number and Risk Hazard Index Scoring Rubric

| | | Points Assigned |
|---|---|---|
| **Severity Scoring** | | |
| **Clinical (employee or patient)** | **Production** | |
| No harm | Downtime of <30 minutes | 1 |
| Temporary harm; intervention and/or increased monitoring | Downtime of 30 minutes to <2 hours | 2 |
| Significant and/or long-term harm | Downtime of 2-4 hours | 3 |
| Death or major loss of function | Downtime of >4 hours | 4 |
| **Frequency Scoring** | | |
| Remote; likely to occur once every year at most | | 1 |
| Uncommon; likely to occur once a month | | 2 |
| Occasional; likely to occur once a week | | 3 |
| Frequent; likely to occur daily | | 4 |
| **Detectability Scoring** | | |
| Detectable | | 1 |
| Undetectable | | 4 |

**Table 2.** Failure Modes Identified in IV Workflow Technology[a]

| | | | | Severity | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode** | **Process Step** | **Cause** | **Effect** | **Clinical** | **Production** | **Frequency** | **Detectability** | **RPN** | **RHI** |
| Interface problems | EMR system transmits order to IV workflow server | Software or hardware failure | Revert to manual preparation | 1 | 22 | 11 | 11 | 22 | 22 |
| Barcode unreadable and/or barcode scanner inoperable | "Import Preparation" window appears and system-generated barcode on medication label scanned | Equipment failure | Unreadable barcode requires manual generation of new label; inoperable scanner requires reassignment to device with working scanner | 1 | 2 | 1 | 1 | 2 | 2 |
| Wrong medication or | Imported information | User error | Error will be identified; | 2 | 1 | 3 | 1 | 6 | 6 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| vial size selected | verified; drug group and vial size to be used in preparation selected via drop-down menu and confirmed | | technician must cancel preparation and then preparation must be reconfirmed | | | | | | |
| Label malfunction | Once preparation is confirmed, first label printed | Equipment failure | Preparation reassigned to device with working printer; manual intervention to unjam labels or add labels if labels are depleted | 1 | 1 | 1 | 1 | 1 | 1 |
| Wrong components selected[a] | Components needed to compound preparation gathered | User error | Error will be identified; technician must obtain correct components | 3 | 1 | 3 | 1 | 9 | 9 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Wrong preparation selected | Preparation to be compounded selected | User error | If wrong preparation selected, error will be identified in subsequent steps | 1 | 1 | 3 | 1 | 3 | 3 |
| Wrong barcode scanned[a] | "Component Barcode" (manufacturer barcode) of the final container scanned | User error | System would detect error in barcode; technician may not proceed | 3 | 1 | 3 | 1 | 9 | 9 |
| Product components misaligned or not visualized by camera | Components to be used in preparation aligned in view of camera; photo taken | User error | Pharmacist will not be able to view what was used in preparation | 1 | 1 | 2 | 1 | 2 | 2 |
| Scale not calibrated | Scale alignment confirmed, ensuring that air bubble on level indicator is properly centered | Equipment failure | Technician would be required to align scale until bubble centered | 2 | 1 | 2 | 1 | 4 | 4 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Incorrect final container placed on scale | Final container placed on scale, weighed, and removed | User error | System would alert that container not as expected (weight incorrect) | 2 | 1 | 3 | 1 | 6 | 6 |
| Incorrect barcode scanned and/or item not scanned[a] | Barcode of vial being used for preparation is scanned | User error | System will not allow user to proceed with compounding until correct item scanned | 3 | 1 | 3 | 1 | 9 | 9 |
| Dose withdrawn incorrect[a] | System determines if injected amount is appropriate | User error | If dose less than acceptable range, system prompts user to withdraw amount needed to reach correct dose (cannot proceed otherwise)<br><br>If dose more than acceptable range, system automatically fails preparation and it cannot be | 3 | 1 | 3 | 1 | 9 | 9 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | used for the patient; if product is within acceptable range, technician can “Accept,” “Reject,” or “Continue” | | | | | | |
| Label does not print or printer malfunction | Product label printed | Software or equipment failure | Troubleshoot printer, redirect label printing, or use Epic label | 1 | 2 | 2 | 1 | 4 | 4 |
| Incorrect label affixed | Final container removed from scale; final label attached to container | User error | Label will not match product ingredients and/or dose | 3 | 1 | 1 | 1 | 3 | 3 |
| Error not detected visually[a] | Pharmacist verifies preparation by checking patient information, drug, diluent, photo, and video | User error | Incorrect product dispensed | 3 | 1 | 3 | 1 | 9 | 9 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Pharmacist does not select “DUE” | After confirmation, pharmacist selects “DUE” on system manager and bags final container | User error | No issue with compounding preparation, as preparation would already be completed at this point; pharmacist would not have checked preparation details before releasing to patient | 1 | 2 | 3 | 1 | 6 | 6 |

Abbreviations: DUE, drug use evaluation; EMR, electronic medical record; IV, intravenous; RHI, Risk Hazard Index; RPN, Risk Priority Number.

[a]Highest-risk mode, as determined by RPN and RHI scores of 9.