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Application of Failure Mode, Effect and Criticality Analysis (FMECA) to Improve Safety in Cancer Chemotherapy Prescription and Administration Processes

James O'Leary[1]*, Aisling Dunne[1], Sean O'Brien[2]

[1] Department of Pharmacy Practice and Patient Safety, School of Pharmacy, Trinity College Dublin, Dublin, Ireland.
[2] Department of Oncology Pharmacy and Risk Management, School of Pharmacy, University College Cork, Cork, Ireland.

***E-mail** ✉ james.oleary@tcd.ie

Abstract

The administration of oncological medications represents a high-risk medical procedure where clinical errors can result in fatal patient outcomes. Failure Mode, Effects and Criticality Analysis (FMECA) is a well-established methodology for identifying and preventing latent systemic risks, and its efficacy has been demonstrated across diverse sectors, including healthcare delivery. The objective of this investigation was to identify potential vulnerabilities in the prescription and administration phases of oncology treatments to facilitate the implementation of targeted preventive interventions. This investigation utilized a prospective FMECA methodology. A working group of public health resident physicians from the University of Padua analyzed the clinical chemotherapy workflow. This analysis was conducted in collaboration with an interdisciplinary panel from the Veneto Institute of Oncology (a designated comprehensive cancer center) alongside two regional provincial hospitals. A process map was constructed to delineate 9 distinct phases of the chemotherapy continuum, spanning from the initial formulation of the treatment plan to final drug administration, to identify all potential failure modes. Criticality scores were determined by evaluating severity, frequency, and detection probability using modified versions of validated, previously published assessment scales. Corresponding clinical safety strategies were subsequently formulated and synthesized. The analysis revealed 22 distinct failure modes distributed across the sequential stages of the oncological care process, with 7 specific failure modes categorized as high risk. Every phase within the chemotherapy delivery workflow was determined to be potentially vulnerable, and at least one corrective intervention was developed for each identified high-risk failure mode. To mitigate root causes or enhance the detection probability of these failures, a comprehensive set of 10 systemic recommendations was formulated. FMECA serves as an effective, proactive tool for uncovering latent vulnerabilities in high-risk clinical processes. Practical safety strategies were successfully established for every high-risk failure mode identified during the analysis.

Keywords: Patient safety, Proactive management, Chemotherapy administration, Cancer treatment

Introduction

The rising incidence and preventability of medication errors make them a critical concern in healthcare. These clinical mistakes can yield fatal outcomes for a variety of reasons, ranging from acute drug toxicity to therapeutic inefficacy [1, 2].

According to the European Medicines Agency, a medication error is an inadvertent failure within the pharmaceutical treatment continuum that causes, or has the potential to cause, patient harm. Errors during the prescription, dispensing, storage, preparation, and administration of therapeutics are the most frequent preventable causes of adverse events in clinical practice, imposing a substantial burden on public health systems [3].

Data from the National Academy of Medicine (formerly the IOM) in the United States indicated that medication-related errors are responsible for the mortality of 1 out of

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every 131 outpatients and 1 out of every 854 hospitalized inpatients [4].

Given the severe impact of these errors, multiple domestic and international bodies have issued clinical guidelines to prevent or mitigate their consequences on patient populations, spanning the sequential stages of the therapeutic workflow [5-8].

To mitigate clinical risks, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) mandates that healthcare institutions implement proactive risk management strategies. These activities aim to detect vulnerabilities in medication prescription and administration workflows, anticipate their potential consequences, and implement systemic changes to minimize the risk of patient injury [9, 10].

One prominent strategy implemented for this purpose is the failure mode and effects analysis (FMEA) [11].

As a proactive risk evaluation tool, FMEA is used to detect latent vulnerabilities in intricate, high-risk operational processes, enabling the formulation of corrective interventions before adverse events occur. Furthermore, FMEA is increasingly used to prospectively evaluate and optimize safety protocols across complex medical pathways, including pharmaceutical administration and blood transfusions [12].

The Institute for Safe Medication Practices has advocated the use of FMEA to avert medication errors since the mid-1990s [13].

A prior editorial noted that despite the significant volume of oncological research conducted annually and the widespread recognition of clinical safety, relatively few temporal and financial resources have been dedicated to the quality and safety of oncological care, including efforts to reduce medication errors [14].

An escalating demand for oncological care, coupled with the inherent complexity of malignant diseases and their therapeutic regimens, has collided with a contracting healthcare workforce, resulting in a crisis in oncology care delivery. Consequently, the management and treatment of oncology patients have progressively transitioned toward outpatient services, resulting in decreased hospital admissions and shorter inpatient stays [15, 16].

Presently, the majority of oncological therapies are administered within ambulatory or outpatient settings [17].

Oncological treatment represents a high-risk medical practice and stands as the second most frequent context for fatal medication errors within the United States [18]. This vulnerability has similarly been documented within the Italian healthcare system, where antineoplastic and immunomodulating therapeutics constitute the second most common pharmacological category involved in fatal adverse drug reactions [19, 20].

The intricate nature of chemotherapeutic regimens, coupled with the narrow therapeutic index of many oncological agents, renders this treatment continuum highly vulnerable to critical errors. Furthermore, contemporary cancer therapies have become increasingly prolonged, requiring coordination among diverse healthcare professionals, clinical settings, and medical specialties, thereby inherently increasing the risk of error. In this regard, an analysis by the United States Pharmacopeia (USP) of oncology-related errors from 1998 to 2003 found that 25% resulted from improper dosing or quantity, 20.4% from prescriber errors, 18.6% from omissions, and 12.5% from incorrect timing. Less frequent errors included unauthorized medication delivery, faulty drug preparation, extra dosing, incorrect administration techniques, wrong patient identification, wrong route of administration, or inappropriate dosage forms [21].

The significance of this clinical challenge has achieved widespread recognition; in Italy, for example, the Ministry of Health has responded by publishing targeted institutional guidelines governing the prescription and administration of oncological therapies [22].

Within this demanding clinical environment, the application of Failure Modes and Effects and Criticality Analysis (FMECA) represents a highly valuable approach for evaluating these workflows and enhancing patient safety. The objective of this study was to conduct a prospective, systematic evaluation of the sequential phases of chemotherapy prescription and administration, using the FMECA framework to identify potential errors and facilitate the implementation of preventive safety interventions.

Materials and Methods

The FMECA methodology was deployed within the oncological medication prescription and administration workflow to expose latent errors across the various stages of the clinical continuum and to establish priorities for subsequent corrective interventions. This evaluation was

executed between April and June 2022, focusing specifically on the processes governing the prescription and delivery of cancer therapies within ambulatory clinics operated by the Veneto Institute of Oncology-IRCCS (IOV-IRCCS). The Organization of European Cancer Institutes formally accredits this comprehensive cancer center and functions as a regional epicenter for the diagnosis and management of oncological conditions. The study also encompassed the medical oncology units of two distinct provincial hospitals located within the Veneto region of Italy: the Ospedale dell'Angelo in Mestre (Venice) and the Ospedale "San Bortolo" in Vicenza.

Following an orientation meeting conducted with an expert panel to outline the principles and operational parameters of FMECA, the prescription and administration of oncological regimens was selected as the target high-risk process for systematic evaluation. The interdisciplinary working group comprised public health resident physicians from the University of Padua, assigned to various healthcare administrative sectors within the Veneto region, collaborating with public health specialists, clinical risk managers, and specialized oncology nurses active in the outpatient clinics of the participating healthcare facilities.

The complete FMECA framework comprised six sequential procedures, which are detailed in **Table 1**.

Table 1. General stages for executing a failure mode, effect and criticality analysis.

Step	Description
1	Select a process for analysis
2	Assemble a multidisciplinary team
3	Diagram the process, including all individual steps
4	Determine a risk priority value for each step in the process
5	Identify a target area for improvement based on the calculated risk priority
6	Apply interventions and collect outcome measurements

To conceptualize and evaluate the clinical workflows and constituent subprocesses, a process map was formulated to visually delineate the sequential operations required for prescribing and administering oncological therapies (**Figure 1**).

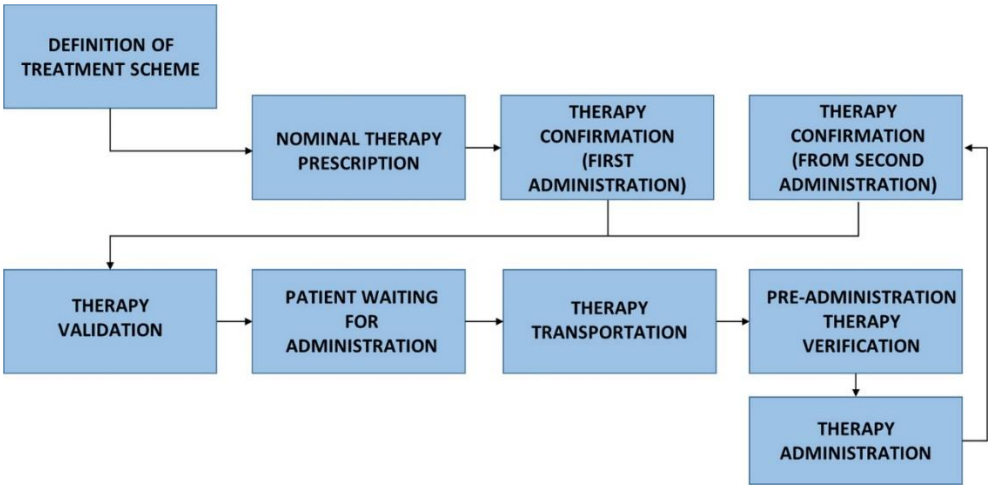

Figure 1. Sequential stages of the medication delivery continuum.

Potential vulnerabilities within each subprocess were uncovered through structured brainstorming sessions, drawing on the professional experiences of the participating practitioners and a meticulous review of the institutional operating protocols governing the comprehensive workflow in these clinical units.

The systematic investigation of the process permitted the identification and classification of failure modes and systemic vulnerabilities based upon three core

dimensions: frequency of occurrence (the probability that a specific failure will manifest); detectability (the likelihood that an error will be intercepted before reaching the patient); and severity (the clinical impact of the failure on patient outcomes). **Table 2** outlines the multi-point evaluation framework deployed in this research, which was modified from assessment metrics validated in prior literature [23, 24].

Three designated members of the analysis team independently assigned scores for the frequency of occurrence, detectability, and severity of each hypothetical failure mode.

Table 2. Assessment metrics for frequency of occurrence, detectability, and severity

Category	Operational definition/Criteria	Rating
Likelihood of failure	Annually	1
	Monthly	2
	Weekly	3
	Daily	4
	Multiple times per day	5
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Probability of detection	Almost certain (≥ 90% chance of discovery)	1
	Highly probable (≥ 75% chance of discovery)	2
	Moderately likely (≥ 50% chance of discovery)	3
	Low probability (≥ 25% chance of discovery)	4
	Unlikely (≥ 10% chance of discovery)	5
	Extremely rare to impossible (0–9% chance of discovery)	6
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Impact severity	Minor disruption: potential minor impact on the oncology delivery system	1
	Mid-level technical issue: potential to impact the patient	2
	Critical technical breakdown: potential to impact the patient	3
	Low-level physical harm or injury	**4**
	Severe physical harm or injury	**5**
	Fatal outcome or patient death	**6**

The risk priority number (RPN) was subsequently computed to provide a quantitative risk assessment for each failure mode. This index was derived by multiplying the individual ordinal scores assigned to the three evaluative criteria:

$$\text{RPN} = \text{severity} \times \text{occurrence} \times \text{detectability} \quad (1)$$

The median values of the computed RPNs for the detected failure modes were utilized to establish the definitive risk scores, with the accompanying RPN ranges also presented. Within the FMECA architecture, the RPN serves as a quantitative surrogate metric for the risk profile of a complete process or an isolated operational step, thereby reflecting its overall criticality. This metric highlights the specific workflow elements most likely to induce clinically severe adverse events. The maximum attainable RPN value is 180. For this study, an RPN > 20 was defined a priori as indicative of a high-risk failure mode. This threshold represents a conventional cut-off value at the 75th percentile and was used to prioritize intervention efforts. However, it is acknowledged that all identified vulnerabilities warrant mitigation with varying degrees of urgency.

The working group scrutinized the criticality of each discrete failure mode to determine whether the associated risk fell within acceptable parameters or necessitated systemic optimization. Failure modes with the highest quantitative scores were designated as high-risk, making them the primary focus areas requiring immediate deployment of targeted safety strategies.

Results and Discussion

The systematic evaluation identified 22 potential vulnerabilities distributed across the sequential stages of the therapeutic prescription and administration workflow (**Figure 1**), with 7 distinct failure modes categorized as high-risk. The specific operational stages exhibiting the highest frequency of potential errors were “Confirming

therapy (from second administration onwards)" (2) and "Checking therapy before administration" (2).

The calculated RPNs (**Table 3**) ranged from 6 to 30. The most critical vulnerabilities, characterized by the highest quantitative RPN scores, were situated within the "Validating therapy" and "Checking therapy before administration" stages. Illustrative examples of these high-scoring failure modes included "Error in validating previously prescribed and confirmed therapy", "Error in identifying the right patient", and "Error in identifying the therapy to administer to the patient".

Table 3. Potential failure modes within the therapeutic prescription and administration workflow, organized by risk priority number within each stage alongside cumulative criticality metrics

Process phases and potential failure modes	RPN values (Medians and Ranges)
1. Protocol and treatment plan configuration	**26**
· Inaccuracies or omissions when inputting standard treatment templates	10 (5–10)
· Omission or delays in revising established treatment protocols	8 (4–10)
· Neglecting to inform clinical staff regarding revised or newly available treatment templates	8 (4–10)
2. Standard medical prescription	**64**
· Omission of premedications customized to patient-specific profiles (e.g., historical allergies)	24 (12–36)
· Missing or inaccurate prescription of necessary supportive care (e.g., antiemetics, gastric protectors)	16 (16–20)
· Clerical or documentation errors made by the clinician on mandatory paperwork	12 (10–20)
· Overlooking mandatory pre-treatment blood test results before ordering therapy	8 (2–8)
· Inability to issue prescriptions due to software or electronic health record (EHR) outages	4 (4–4)
3. Initial cycle treatment verification	**12**
· Flawed or missing review of lab work and diagnostic tests required before the first dose	12 (10–12)
4. Subsequent cycle treatment verification (Cycles 2+)	**40**
· Flawed or missing review of lab work and diagnostic tests required before continuing therapy	20 (10–32)
· Inadequate tracking of chemotherapy toxicities, resulting in missed dose adjustments or omitted supportive care	20 (20–42)
5. Clinical validation of therapy	**30**
· Oversight or error during the validation of previously ordered and verified protocols	30 (10–32)
6. Pre-administration patient waiting period	**28**
· Excessive congestion and overcapacity within patient waiting zones	16 (2–24)
· Patient experiencing syncope (fainting) while waiting	12 (10–18)
7. Medication logistics and transport	**30**
· Compromise or physical damage to prepared clinical doses during transit	30 (10–40)
8. Pre-infusion bedside verification	**60**
· Failure to correctly verify and match the patient's identity	30 (10–40)
· Failure to correctly cross-check and match the medication order to the patient	30 (10–50)
9. Clinical administration of therapy	**46**
· Untimely delays in starting the medication infusion	16 (10–24)
· Tissue injury resulting from chemotherapy extravasation (drug leaking into surrounding tissue)	10 (8–16)
· Adverse events triggered by a failure to follow designated infusion rates or schedules	8 (8–10)
· Adverse events caused by an incorrect infusion bag sequence or omitting required concurrent therapies	6 (6–9)
· Delayed intervention or failure to respond to infusion pump alerts or patient call lights	6 (6–6)

The cumulative criticality values calculated for each sequential stage were 26 for the "Defining treatment plan" phase, 64 for the "Nominal therapy prescription" phase, 12 for the "Confirming therapy (First administration)" phase, 40 for the "Confirming therapy (from second administration onwards)" phase, 30 for the

"Validating therapy" phase, 28 for the "Patient waiting for treatment to be administered" phase, 30 for the "Transportation of drugs" phase, 60 for the "Checking therapy before administration" phase, and 46 for the "Administering therapy" phase.

To address the failure modes classified as potentially high-risk, at least one targeted risk-mitigation strategy was formulated to either decrease their occurrence rate or enhance their probability of detection. This analytical process yielded the 10 distinct institutional interventions outlined in **Table 4**.

Table 4. Interventions recommended to optimize the oncology prescription and administration workflow

Process phase	Recommended safety actions
Standard medical prescription	· Implement active patient identity verification by asking them to verbally state their full name, height, weight, and the specific medication they are receiving. · Integrate automated system flags that trigger whenever an administration route deviates from standard protocols, or when a therapy specifically requires a Central Venous Catheter (CVC). · Mandate a clinical pharmacist review of the dosage and delivery route for any non-standard treatment plans before formal therapy validation.
Treatment verification (Cycles 2+)	· Embed automated system alerts that trigger if out-of-range or abnormal laboratory results are entered into the patient record. · Utilize forcing functions (such as mandatory digital checkboxes) to verify that all protocol-specific lab work has been completed. · Require a mandatory assessment step (via digital checkboxes) documenting the presence or absence of toxicities from the prior cycle. · Configure automated system flags to alert providers if necessary supportive care or premedications are missing, and implement a structured therapy confirmation checklist.
Medication logistics and transport	· Enforce strict transport protocols: medications must be sealed within a closed, leakproof plastic bag and placed inside a rigid, impact-resistant, leakproof secondary container. If administration is delayed, drugs must be maintained at room temperature or refrigerated as specified to prevent degradation.
Clinical validation of therapy	· Deploy automated system alerts that immediately flag any variances or deviations from the designated protocol outlined in the treatment plan.
Pre-infusion bedside verification	· Utilize electronic barcode scanning to cross-check and match the labels on the infusion bags against the active medical record (ensuring exact alignment between what was prescribed and what was prepared).

Every discrete stage of the oncological chemotherapy pathway presents latent vulnerabilities. The FMECA conducted in this investigation identified over 20 distinct failure modes distributed across the operational continuum, with approximately one-third categorized as high risk. For each high-risk vulnerability, at least one targeted intervention was formulated to limit these errors or optimize their detection, culminating in a total of 10 systemic recommendations.

Consistent with the established literature [25], our findings demonstrate that the "nominal therapy prescription" stage represents the greatest risk zone due to multiple potential error pathways. Consequently, safety management frameworks in this phase have developed specialized tools to reduce the occurrence and increase the detectability of these diverse errors, ultimately lowering their associated RPNs. For example, a computerized physician order entry (CPOE) system—a technology that improves medication administration safety—was implemented across the hospitals participating in this investigation. The utilization of CPOE eliminates operational errors stemming from illegible handwriting or manual transcription inaccuracies [26]. Furthermore, this digital architecture incorporates functionalities such as automated drug dosage verification and real-time alerts for dangerous pharmacological interactions, thereby further mitigating the potential for error [27].

Nevertheless, the systematic evaluation identified additional latent vulnerabilities within the "nominal therapy prescription" phase. The most critical failure mode involved the "Failure to prescribe premedication tailored to the type of patient (e.g., allergy history)", an omission that could precipitate acute anaphylaxis during therapeutic administration. This observation aligns with published literature, which has previously demonstrated that allergic responses and adverse drug reactions constitute a major origin of medication-related adverse

events [28]. These specific errors were found to be closely linked with an "Incorrect/incomplete evaluation of results of blood tests and/or other tests required for the established treatment plan" as well as an "Incomplete evaluation of toxicities encountered following administration of chemotherapy, failure to modify treatment dosage, or failure to administer ancillary/supportive therapy (steroids, antiemetics, PPIs, etc.)". Within this framework, integrating clinical decision support systems directly into the CPOE infrastructure can raise institutional safety thresholds by providing practitioners with pre-established default dosage and delivery route parameters during the prescribing stage [29]. Such integrated systems can also provide advanced pharmacological safety mechanisms, including automated checks for drug-allergy or drug-drug cross-reactivity, automated reminders for necessary laboratory monitoring, and tailored prescriptive recommendations that match patient-specific clinical variables [30, 31].

In our evaluation, the "Checking therapy before administration" stage emerged as the second-most-critical phase within the therapeutic continuum. Two prospective failure modes native to this stage—specifically, an "Error in identifying the right patient" and an "Error in identifying the therapy to administer to the patient"—are thoroughly documented in prior literature and emerged as highly relevant in our analysis as well [32-34]. Indeed, patient misidentification remains a fundamental challenge within patient safety, and its complete eradication would represent a significant advancement in healthcare quality. Among the countermeasures deployed within the environments evaluated here, the verbal verification of patient identity by requesting their full name and date of birth represents an essential, foundational corrective action. Alternate strategies detailed in the literature include cross-checking via barcode verification and scanning systems to match individual patients with their designated therapies. However, the definitive utility of these systems in outpatient settings remains a subject of ongoing academic debate.

Although the present evaluation did not document critical failures during the active "therapy administration" phase, this stage is characterized by a substantial number of latent vulnerabilities, making it the third most critical phase overall. This finding is consistent with published studies indicating that the active administration stage is among the most error-prone phases of the medication continuum [35]. In this regard, the technology-enabled delivery of therapeutics via smart infusion pumps is a primary mechanism for reducing errors during this phase of chemotherapy administration. This technology has become standard institutional practice for the delivery of high-alert fluids (such as those containing cytotoxic agents). It has been shown to prevent 5% of errors during intravenous chemotherapy administration [36, 37]. Compared to manual fluid administration, smart infusion pumps offer the benefit of tightly regulated delivery, enabling fluids to be administered in exceptionally small volumes or at highly precise, pre-programmed rates and intervals.

Our analysis further demonstrated that the "Transportation of drugs" phase requires careful administrative oversight due to the critical risk of physical damage to prepared solutions during transit from the central pharmacy to the ambulatory clinic. Indeed, fulfilling the core clinical objective of delivering the therapeutic agent to "the right place at the right time for the right person" requires a secure, dependable transport method to enhance the traceability and reliability of the pharmaceutical logistics chain [38]. International clinical practice guidelines mandate that medications be transported out of the pharmacy within sealed, leakproof plastic enclosures and carried in rigid, shock-resistant, leakproof secondary containers composed of materials that facilitate straightforward cleaning and decontamination. Furthermore, if the medications are not intended for immediate clinical administration, they must be stored at room temperature or refrigerated to prevent chemical degradation that could compromise their therapeutic efficacy or safety [39, 40].

As highlighted in previous research, the risk of transmission of airborne pathogens (such as SARS-CoV-2) due to prolonged patient stays in potentially congested environments, such as ambulatory waiting areas, warrants distinct clinical consideration [23]. While the exact probability and clinical severity of this particular failure mode are difficult to quantify, it remains a necessary target for mitigation due to the severe potential outcomes of such infections in vulnerable patient populations, particularly those experiencing therapy-induced neutropenia (a severe drop in white blood cells). There remains an insufficient body of empirical research and formal reporting on specialized care protocols for oncology outpatients during infectious disease outbreaks. Presently, regular hand hygiene, physical distancing, the mandatory utilization of medical masks, and—where

clinically indicated—routine screening protocols represent the baseline standard practices that all outpatient oncology units should systematically enforce to prepare for prospective pandemic events [41].

The FMECA framework is subject to several inherent limitations, the primary one being the unavoidable subjectivity involved in selecting specific failure modes and calculating their corresponding criticality indices. To minimize this potential bias within the current study, explicit, standardized rubrics were constructed to evaluate the frequency, detectability, and severity of the projected failure modes, and the entire working group collectively debated each vulnerability.

Additionally, it must be recognized that while the failure modes evaluated here may apply to external institutions, the inherent heterogeneity of healthcare delivery systems and variations in structural characteristics (such as the integration of information technology architectures) render any definition of RPNs highly context-specific. Consequently, conducting structured interviews with healthcare personnel operating across different countries would be highly beneficial for generating a more universally generalizable model.

Conclusion

In conclusion, the empirical findings of this study demonstrate that FMECA serves as a valuable methodology for optimizing the quality of healthcare delivery and minimizing errors in patient management. It proved highly effective in delineating actionable areas for systemic improvement within the prescription and administration pathways of oncological drug therapies.

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