Board 3: Risk Management in Helicopter Air Ambulance Operations Using PFMEA

Mr. Gustavo Sanchez, Purdue University

Gustavo is a PhD Candidate in the School of Aviation and Transportation Technology at Purdue University. He began his PhD study in Aviation Technology and Management at Purdue University in 2022. Gustavo earned a M.S in Aviation and Aerospace Management from Purdue University and a M.S. in Aeronautical Military Sciences from the Colombian Air Force University. He has experience as a helicopter pilot and his research interests include helicopter operations, advanced air mobility, and aviation safety.

Prof. Mary E. Johnson Ph.D., Purdue University

Mary E. Johnson is a Professor and Associate Head for Graduate Studies and Research in the School of Aviation and Transportation Technology (SATT) at Purdue University in West Lafayette, Indiana. She earned her BS, MS and PhD in Industrial Engineering from UTArlington

Mr. Shantanu Gupta, Purdue University

Shantanu Gupta is a PhD candidate in the School of Aviation and Transportation Technology at Purdue University with Dr. Mary E. Johnson. He earned his B.E in Mechanical Engineering from Visvesvaraya Technological University, India, M.S in Aviation and Aerospace Management and a Graduate Certificate in Applied Statistics from Purdue University, West Lafayette. Mr. Gupta worked with Dr. Johnson as research assistant on the PEGASAS Project 33 – Augmented Weather Information Project (AWIP) and Project 35 - Enhanced Hands-Minimized Weather Interfaces (EHMI) for pilots.

Process Failure Modes and Effects Analysis (PFMEA) in Helicopter Air Ambulance Operations

INTRODUCTION

Risk management is a cornerstone in aviation safety, especially in high-stakes operations like aeromedical services. The complex nature of aviation, characterized by dynamic environments and critical time constraints, requires robust safety protocols and well-trained personnel. The Process Failure Mode and Effects Analysis (PFMEA) is a fundamental tool for comprehensive risk management, widely implemented across various industries [1]. This paper illustrates how PFMEA may be taught in undergraduate and graduate aviation safety courses and how case studies may be used to illustrate the practical application of PFMEA.

In this paper, the practical application of PFMEA is demonstrated by conducting an in-depth analysis of helicopter air ambulance (HAA) accidents. This paper is structured in an aviation safety lecture format that begins by providing details, standards, and steps related to PFMEA and then uses an HAA accident from the National Transportation Safety Board's (NTSB) Case Analysis and Reporting Online [2] database to demonstrate the application of PFMEA. One component of such an aviation safety lecture would be a hands-on, applied project where the students will query the CAROL database to select an HAA accident, discuss the findings of NTSB accident investigation, and use the PFMEA framework as per the SAE AS13004™ [3] standard to identify risk factors and propose potential mitigation strategies. The significance of this study lies in its contribution to aviation safety education and demonstrating the application of PFMEA to aviation and engineering students using a real-world situation.

This paper aims to highlight the adaptability of PFMEA in addressing the multifaceted challenges of rotary-wing aeromedical transport, ultimately contributing to the advancement of safety protocols and operational efficiency of these operations. The subsequent sections discuss the theoretical foundations of Failure Mode and Effects Analysis (FMEA), types and standards of FMEA, application of PFMEA in analyzing rotary wing aeromedical transport operations, and an illustration of the effectiveness of PFMEA in risk mitigation using a real-world HAA accident.

FAILURES MODES AND EFFECTS ANALYSIS (FMEA) – BACKGROUND

Failure Mode and Effects Analysis (FMEA) is a methodical approach engineers and safety professionals use to identify, assess, and mitigate potential failure modes in a given process, product, or system [4][5]. FMEA is a widely used tool that evaluates potential process or product failures based on the probability of occurrence and the severity of their impact [6].

The FMEA process started in the U.S. armed forces and established the procedures to evaluate the reliability of military equipment [7]. Its primary aim is identifying and prioritizing product or service failures based on severity, occurrence probability, and detectability [8]. FMEA was created to help prevent problems and improve the quality and reliability of a system [9]. During the 1960s, the National Aeronautics and Space Administration (NASA) used FMEA in its quality and safety processes during the Apollo Program [10].

A wide range of FMEA standards and guidelines are available that provide a comprehensive understanding of the scope and general procedures to follow when conducting FMEA in particular situations. These include but are not limited to:

1. **MIL-STD-1629A**. The military standard offers comprehensive guidelines for conducting the FMEA on military systems, encompassing equipment, software, and hardware [11].
2. **ISO 26262.** Developed for the automotive industry, aiming to provide guidelines for functional safety management and risk identification [12].
3. **SAE AS13004™.** Developed by SAE International, provides guidelines for performing FMEAs on aerospace systems. It includes pre-analysis procedures and explanations regarding its applications for process design and safety, along with detailed guidance on documenting process improvement [3].

TYPES OF FMEA

There are types of FMEA that are specialized to the needs of specific industries or applications, e.g. systems, manufacturing, and process improvement. More information on a few applications include:

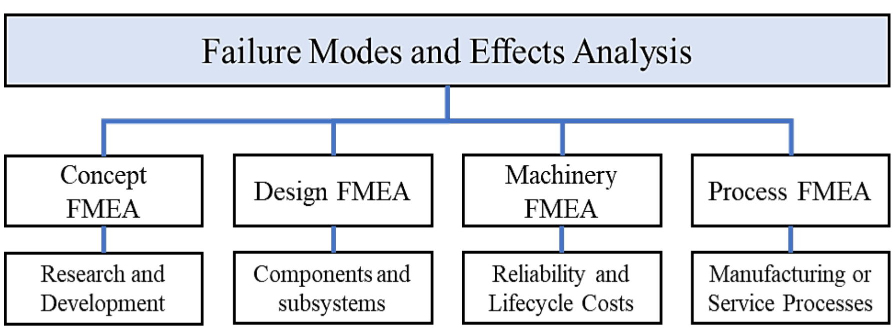
Concept FMEA (CFMEA): Applied during the conceptual design phase of product development to identify and evaluate potential failures and risks. The general steps followed are similar to traditional FMEA but include elements suitable for the initial phases of the new concept, eliminating risk by identifying potential failure modes.

Design FMEA (DFMEA): This type of FMEA aims to identify and prevent design failures that reduce safety levels and reliability before producing a new product or executing a process. The DFMEA identifies the potential failure modes while designing the concept to improve the product, explore alternatives, and develop a framework for designing new products.

Machinery FMEA(MFMEA) Evaluates machinery reliability. Based on the results of this analysis, maintenance personnel can take action to prevent failures and minimize both planned and unplanned downtime. This type of FMEA can include implementing automated fail-safe shutdown techniques that reduce the risk of equipment damage or product defects.

Process FMEA (PFMEA): Determines the conditions where the product or service does not satisfy the customer's requirements. The PFMEA evaluates productivity, maintainability, costs, and quality to propose alternatives to eliminate weaknesses within the system [13]. Figure 1 provides a summary of the different types of FMEAs.

Figure 1. Types of FMEA.



Once the students have selected an accident, they will present a summary of the NTSB accident investigation report, analyze the accident using PFMEA as per the SAE AS13004™ [3] standard, and present findings in a PFMEA table. To that end, the following sections highlight the PFMEA steps, an analysis of the HAA process, and an illustration of PFMEA using an HAA accident.

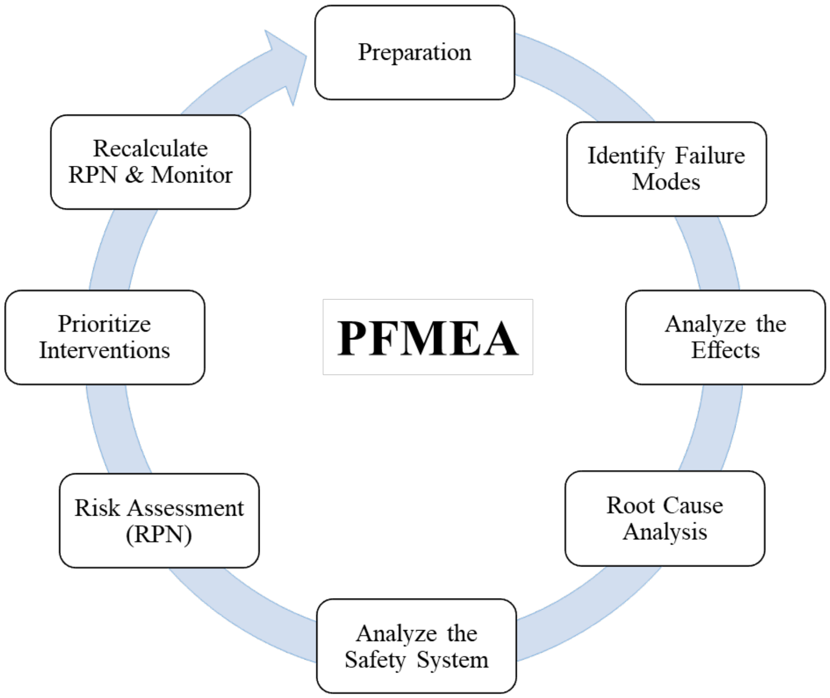
PFMEA - STEPS

The *Failure Modes* highlight the incorrect operation and how the failure occurs within the process. The *Effects* include the implications or consequences that the failure has on the designed function. During the PFMEA, the likelihood of occurrence (O), the severity of the event (S), and the detectability (D) of the failure before its materialization are ranked from 1 to 10 to calculate the Risk Priority Number (RPN = Severity x Occurrence x Detection). The following list summarizes the significant steps during the application of PFMEA on HAA accidents and provides an overview of how it may be applied in the aviation safety course capstone:

1. **Preparation:** This initial step defines the specific process, system, or product to be analyzed. This step narrows down the topic and outlines the boundaries, objectives, and goals of the FMEA study. During the preparation step, the students would receive training regarding the PFMEA methodology, identify the elements, and visualize the process of a typical HAA operation. The process flow diagram allows the students to identify steps and stakeholders during the service cycle.
2. **Identify Failure Modes:** This step identifies all potential failure modes within the outlined scope. During this part of the process, the students will analyze all feasible scenarios, considering all possibilities from the most frequent to the rarest occurrences, and analyze the accidents during HAA operations using the CAROL database.
3. **Analyze the Effects:** After identifying the possible failure modes, the students will identify and assess the effects of each failure. This analysis determines the impact on the system (severity), process, and stakeholders. Understanding the effects of failure modes will help the students prioritize the failures that require immediate attention based on severity or if the process needs to be redesigned to reduce the likelihood of failure.
4. **Root Cause Analysis:** Identifying the causes of each failure mode involves determining the specific event that could have led to the potential failure. The root cause analysis helps in understanding how these failures might occur, establishing the foundation for the next steps of the PFMEA. There may be more than one cause associated with one failure mode; students must analyze each failure to identify their root cause(s).
5. **Analyze Safety System:** In this step, an initial assessment of the safety barriers or measures, in terms of technology, regulations, and training, is conducted to understand the severity, occurrence, and detectability of the failures within the system.
6. **Risk Assessment:** The Risk Priority Number (RPN) is a decision-making tool that aids safety managers in prioritizing the most critical failure modes. Balancing safety vs production is a subjective task. However, the RPN quantitatively measures the risk, removing subjectivity from the equation. The students must evaluate all risks during the risk assessment, regardless of their RPN values.
7. **Prioritize interventions:** Based on the available resources and the RPN, the students will formulate specific actions or strategies to mitigate the probability of occurrence and detectability of the risks, using technological tools, training programs, and implementing regulations. These actions aim to improve the current safety barriers in place or implement new safety barriers to reduce the likelihood or severity of failures.
8. **Recalculate RPN and Monitor Performance:** After introducing safety barriers regarding technology, regulations, and training into the system, safety personnel and managers must monitor the safety performance of their operations and evaluate the effectiveness of the safety measures established by the company.

Each step in the PFMEA process is designed to contribute to a comprehensive understanding of potential failures, their causes, and their effects. Figure 2 describes the PFMEA process. This process design enables proactive risk management and the development of effective mitigation strategies to prevent or minimize the likelihood of system failures and their associated effects.

Figure 2. PFMEA Steps.



AN AVIATION SAFETY COURSE – CAPSTONE PROJECT RELATED TO FMEA

This paper aims to demonstrate how FMEA (specifically, PFMEA) may be taught in an aviation safety course at the undergraduate and/or graduate level. and how the application of PFMEA in analyzing HAA operations and accidents may be demonstrated to students. Therefore, within the scope of the prospective aviation safety course, this paper uses the Process Failure Modes and Effects Analysis (PFMEA) as per the SAE AS13004™ [3] standard to identify the risks associated with HAA operations to demonstrate the PFMEA methodology with a real-world situation. Once the students have strengthened their theoretical background in PFMEA and have seen an application of the analysis, they will participate in a capstone project to conduct an in-depth analysis of an HAA accident using PFMEA. During this capstone project, the students will query the NTSB - CAROL database [2] and select one HAA accident in the U.S. using the following criteria:

1. Aircraft Category is *Helicopter.*
2. Air Medical is *True.*
3. Event Type is *Accident.*
4. Event Date is *on or after 01/01/2019*
5. Event Date is *on or before 12/31/2022*
6. Country is *The United States*

HELICOPTER AIR AMBULANCE PROCESS

The HAA process is summarized here based on information in the FAA AC 135-14B [14]. The HAA transportation process starts with a request for aeromedical transport from an Emergency Medical Services (EMS) agency or hospital. The HAA dispatch centers that receive these requests assess the urgency of each situation along with an analysis of the patient's health condition. Once the transportation mission is approved, the pilot at the selected HAA base starts detailed mission planning according to the company's Standard Operating Procedures (SOPs). If the weather conditions at departure, enroute, and destination are above the Visual Flight Rules (VFR) minimums for FAR Part 135 operations and are receiving approval from the Operation Control Center, the pilot prepares the aircraft to pick up the patient.

Aircrews perform the preflight procedures and safety briefings with the medical personnel for the aeromedical transport. The safety briefing includes emergency procedures, communications, and contingencies that may arise during the patient's transport. After takeoff, the aircrews communicate with the OCC to update the weather conditions and receive additional information regarding the patient's condition. After landing at the heliport or site of the emergency, the medical personnel evaluate and stabilize the patient for transport. They transfer the patient onto a specialized stretcher or medical litter designed for helicopter transport.

Throughout the flight, the medical team continuously monitors the patient and communicates with the receiving facility to provide updates on the patient's condition. Upon reaching the destination, the medical team transfers the patient to the receiving medical facility's staff. After that, the aircrew returns to the base to complete the forms and records and prepare the aircraft for the next flight. These activities include refueling procedures, maintenance checks, and inspections. Table 2 summarizes the process during a typical rotary-wing aeromedical transport.

HELICOPTER AIR AMBULANCE – ACCIDENT

As an illustration of the practical application of PFMEA for accident prevention, an HAA accident due to Controlled Flight into Terrain (CFIT) was analyzed. Table 3 shows a part of the example that may be used to demonstrate the application of PFMEA methodology in HAA accident analysis and prevention. Once the students have a theoretical understanding of FMEA, steps, and standards regarding PFMEA and have seen an example of using PFMEA to analyze an HAA accident, they will approach their capstone project by querying the CAROL database and selecting an accident. Then, the students would present a summary of the findings in the NTSB final accident investigation report, including:

1. Factual information
    a. History of flight
    b. Personnel information
    c. Weather information
    d. Organization information
2. Probable causes
3. Findings
4. Recommendations

After the presentation, the students and the instructor would discuss the probable causes of the HAA accidents as found in the NTSB reports. Then, the students will rigorously identify potential failure modes (e.g., inadequate mission planning, missed maintenance inspection), effects (e.g., flying in marginal weather conditions, fuel starvation), and causes (e.g., fatigue, lack of training) related to their selected HAA accident. Finally, the students will propose mitigation strategies and safety barriers to prevent HAA accidents. Table 3 illustrates the example results of the PFMEA on HAA accidents due to CFIT and provides example mitigation strategies or recommended actions to prevent CFIT-related HAA accidents.

Table 2. PFMEA - HAA Operations, Process Flow (Form Adapted from SAE AS13004™ [3])

Process Number:	**FO-001**	**Prepared by: AT 690**	
Process Name:	**Air Medical Transport**	**Date:**	**12/1/2023**

Operation	**Step**	**Administration** ●	**Planning** ■	**Transport** ⬇	**Load** ★	**Deliver** ▲	**Prepare** ◎	**Operation Description**	**Control Methods**
EMS Request	1	●						Receive request at Operations Control Center (OCC) from healthcare provider	Transportation Protocol established by the Air Medical Operators.
Dispatch	2		■					Plan Base, Aircraft, Crew Selection. Weather analysis, and Transportation Requirements	Company SOP's. Dispatch software
Preflight	3		■					Prepare the aircraft for the mission. Fuel check. Crew check.	Checklist. Recurrent training. Supervision program
Takeoff	4			⬇				Depart from the Base to pick up the patient	ATC regulations. Local hazard analysis
Landing	5			⬇				Arrive at the hospital/landing zone to pick up the patient	ATC regulations. Local hazard analysis
Patient	6				★			Receive the patient from medical personnel	Transportation Protocol established by the Air Medical Operators.
Takeoff	7			⬇				Depart from hospital/landing zone to the receiving hospital	ATC regulations. Local hazard analysis
Landing	8			⬇				Land at the hospital to transfer the patient	ATC regulations. Local hazard analysis
Patient	9					▲		Deliver patient to the medical personnel at the receiving hospital	Transportation Protocol established by the air medical operators.
Takeoff	10			⬇				Depart from the hospital toward the Base	ATC regulations. Local hazard analysis
Landing	11			⬇				Arrive at the Base station	ATC regulations. Local hazard analysis
Postflight	12						◎	Refuel and service helicopter	Checklist. Recurrent training. Supervision program
Forms	13						◎	Prepare administrative records and forms	Company SOP's

Table 3. PFMEA – Helicopter Air Ambulance, Accident Analysis (Form Adapted from SAE AS13004™ [3]) – For Illustration Only

Helicopter Air Ambulance Operations				Key Contact / Phone		Safety Manager				Date (Orig): 12/1/2023	Date (Rev)		6/1/2023			
Process Number			FO-1	Flight Operations						**Customer Approval Date:** 11/1/2023						
Operation	**Step**	**Potential Failure Mode**	**Potential Effect(s) of Failure**	**Severity**	**Potential Cause(s) of Failure**	**Current Process**				**Recommended Action**	**Action Results**					
						Prevention & Detection Controls	**Occurrence**	**Detection**	**RPN**		**Responsible**	**Severity**	**Occurrence**	**Detection**	**RPN**	
Dispatch	2	Inadequate mission planning	Flying in marginal weather conditions	8	▪ Fatigue ▪ Lack of training ▪ Pressure	OCC Supervisor OCC Recurrent Training Dispatch Software	5	7	280	Automate weather-related services for pilots. Automate SRM procedures	Operations Control Center	8	5	3	120	
Preflight	3	Inadequate mission planning	Fuel Starvation	8	▪ Fatigue ▪ Lack of training ▪ Pressure	Preflight Risk Assessment Pilots' recurrent training Dispatcher Protocol	6	6	288	Dispatch software and preflight risk assessment	Fight Operations	8	3	6	144	
Preflight	3	Missed Maintenance Inspection	Aircraft Unairworthy	10	Improper use of maintenance checklists	Company SOP's Recurrent Training RCM Program	7	6	420	Maintenance manager per Base	Maintenance	10	3	3	90	
Preflight	4	Inadequate Risk Analysis	Unintended flight in Instrument Meteorological Conditions (U-IMC)	10	Controlled Flight into Terrain (CFIT)	Company SOP's Flight Simulators HTAWS	7	7	490	Automated Risk Management Software	Operations Control Center	10	6	3	180	

CONCLUSION

Integrating PFMEA into aviation safety education, using case studies and real-life scenarios from the NTSB's CAROL database, may be used to provide students with a robust foundation in risk management. This approach may prepare them for the complexities of modern aviation operations while instilling elements of a culture of safety, critical thinking, and continuous improvement.

Analyzing helicopter ambulance accidents in a capstone project as part of an aviation safety course may provide realistic scenarios to students who may have no first-hand knowledge of these HAA operations. Using the PFMEA methodology provides a structured approach widely used in industry and has been codified into approved standards. Using standards for PFMEA process steps, structure of forms, and vocabulary may prepare the students for industry, academia, or agency risk management roles. Real-life examples to spark student interest may increase student engagement in the hands-on exercises.

Courses in aviation safety, whether taught in engineering or in technology programs, should include hands-on exercises where students apply PFMEA or other standard risk-management tools to real-world case studies, preferably from the NTSB's CAROL database. An aviation safety course with a capstone project to apply PFMEA to conduct accident analysis will provide students with insights into real-world applications of risk assessment for improving aviation safety.

LIST OF REFERENCES

[1] C. S. Carlson, *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes using Failure Mode and Effects Analysis*, 1st ed., vol. 2. WILEY, 2012. doi: 10.1002/9781118312575.

[2] National Transportation Safety Board [NTSB], “Case Analysis and Reporting on Line (CAROL) Database.,” 2024. https://data.ntsb.gov/carol-main-public/query-builder (accessed Jan. 15, 2024).

[3] *AS13004: Process Failure Mode and Effects Analysis (PFMEA) and Control Plans,* SAE International, 2017.

[4] Stamatis, “Failure Mode and Effect Analysis (FMEA),” in *Six Sigma and Beyond*, 1st ed., vol. 6, CRC Press, 2002, pp. 275–338.

[5] H. Liu, *Improved FMEA Methods for Proactive Healthcare Risk Analysis*, 1st ed. Springer Singapore Pte. Limited, 2019. doi: 10.1007/978-981-13-6366-5.

[6] A. Von Ahsen, L. Petruschke, and N. Frick, “Sustainability Failure Mode and Effects Analysis – A systematic literature review,” *Journal of Cleaner Production*, vol. 363, p. 132413, Aug. 2022, doi: 10.1016/j.jclepro.2022.132413.

[7] I. Nicolin and B. A. Nicolin, “Failure Mode and Effect Analysis for a military nose landing gear project,” *INCAS Buletin*, vol. 13, no. 4, pp. 205–212, Nov. 2021, doi: 10.13111/2066-8201.2021.13.4.17.

[8] S. M. Sulaman, A. Beer, M. Felderer, and M. Höst, “Comparison of the FMEA and STPA safety analysis methods–a case study,” *Software Quality Journal*, vol. 27, no. 1, pp. 349–387, Dec. 2017, doi: 10.1007/s11219-017-9396-0.

[9] M. P. Stephens, *Productivity and Reliability-Based Maintenance Management*, 2nd ed. Purdue University Press, 2022. doi: 10.2307/j.ctv1zrzs0z.

[10] V. Jumbad, J. J. Salunke, and M. A. Satpute, “FMEA Methodology for Quality Improvement in Sheet Metal Industry,” *International Journal of Engineering Research and Technology*, vol. V5, no. 01, Jan. 2016, doi: 10.17577/ijertv5is010123.

[11] *MIL-STD 1629A Handbook for Reliability Procedures for Performing a Failure Mode, Effect and Criticality Analysis,* United States Department of Defense, 1980.

[12] *ISO 26262-5, Road vehicles — Functional safety,* International Organization for Standardization, 2018.

[13] D. C. De Aguiar, V. A. P. Salomon, and C. H. P. Mello, “An ISO 9001 based approach for the implementation of process FMEA in the Brazilian automotive industry,” *International Journal of Quality & Reliability Management*, vol. 32, no. 6, pp. 589–602, Jun. 2015, doi: 10.1108/ijqrm-09-2013-0150.

[14] Federal Aviation Authority [FAA], “Advisory Circular: Helicopter Air Ambulance Operations,” U.S. Department of Transportation, AC No. 135-14B, March 26, 2015.