

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

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FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

Failure Modes and Effects Analysis, commonly referred to as **FMEA**, stands as a highly structured and systematic approach used primarily for proactive qualitative analysis. It is designed to identify potential failures within a system, process, or design before they occur, allowing mitigating actions to be prioritized and implemented. Fundamentally, FMEA involves listing the individual components or steps of a proposed system alongside any potential consequences that might arise from their failure, facilitating an objective audit that ultimately dictates the most prudent course of action moving forward. When rigorously applied, especially in complex environments such as healthcare or organizational psychology, FMEA shifts the focus from reactive problem-solving to anticipatory risk management, ensuring that safety and reliability are engineered into the system from its inception rather than merely patched onto existing flaws. This methodology moves beyond simple fault identification; it delves deeply into how and why a failure might manifest, examining the specific mechanisms of breakdown and their subsequent impact on overall system integrity and performance, making it an invaluable tool for enhancing resilience in human-centric operations.

The core principle governing **FMEA** is the detailed evaluation of component safety, where every element of a piece of equipment, a cognitive task, or an organizational process is scrutinized. Components are systematically listed against all potential failure modes, which are the specific ways in which a component or process step might fail to meet its intended function. Following this exhaustive listing, the analysis proceeds to evaluate the potential consequences of these failures--the "effects analysis"--before a comprehensive risk assessment is undertaken. This rigorous, step-by-step documentation ensures that no potential point of weakness is overlooked, demanding high discipline from the analyzing team. In the context of psychology, particularly human factors engineering, FMEA shifts its lens to analyze human-machine interactions, cognitive loads, decision-making processes, and communication breakdowns as potential failure points, treating these human elements as integral components of the overall system that require the same level of preventive analysis as mechanical parts.

While FMEA originated in traditional engineering fields, its utility has broadened significantly, becoming a crucial component of quality management systems across diverse sectors, including aviation, manufacturing, and notably, medicine and psychology. Its adaptability stems from its foundational premise: understanding the mechanisms of failure is the precursor to effective prevention. The methodology provides a formal framework for multidisciplinary teams to collaborate, pooling expertise regarding component function, operational environment, and potential human error pathways. This qualitative analytical technique is essential for anticipating latent conditions--system flaws that may lie dormant until combined with an active failure, such as a momentary human lapse--thereby contributing significantly to the construction of high-reliability environments where error tolerance is critically low.

Historical Context and Evolution

The genesis of **Failure Modes and Effects Analysis** can be traced back to the United States military, specifically during the 1940s, formalized under Military Procedure MIL-P-1629. This initial application was driven by the critical need to improve the reliability of weapons systems, ensuring that single component failures would not lead to catastrophic mission failure. The methodology emphasized a bottom-up approach, starting with individual components and analyzing how their failure would cascade through the system. This early military adoption established the foundational steps of failure identification, cause determination, and consequence assessment, setting the stage for its later widespread industrial application. The imperative for rigorous safety and reliability testing during the Cold War further cemented FMEA's status as a vital risk management tool within government and defense contracting sectors, refining the process into a repeatable, standard analytical procedure.

FMEA gained substantial civilian traction in the late 1960s with its adoption by the National Aeronautics and Space Administration (NASA) during the Apollo program. The necessity of flawless operation in space exploration highlighted the need for ultra-high reliability, pushing FMEA to become a cornerstone of spacecraft design and pre-flight checklist verification. NASA's adaptation introduced critical refinements, emphasizing the catastrophic potential of failures and necessitating redundancies for single points of failure. Following the success observed in aerospace, the methodology was integrated into the automotive industry in the 1970s and 1980s, where it became instrumental in reducing product recalls and improving consumer safety, standardized through industry groups like the Automotive Industry Action Group (AIAG). This industrial proliferation required further evolution, introducing the concept of the **Risk Priority Number (RPN)**, which allowed failure modes to be quantitatively ranked based on their severity, occurrence, and detectability, transforming FMEA from a purely qualitative listing method into a powerful quantitative prioritization tool.

The integration of FMEA into fields like organizational behavior, medicine, and human factors psychology represents its latest evolutionary stage. While physical components are analyzed in engineering FMEA (Design FMEA or D-FMEA), process-oriented FMEA (P-FMEA) is particularly relevant to psychological domains. In healthcare, for instance, FMEA is used to analyze medication administration procedures or surgical protocols, viewing steps where human judgment or communication is required as critical components susceptible to failure. This application acknowledges that system failures often result not from equipment malfunction but from cognitive errors, communication gaps, or procedural deviations--all topics central to psychology. By mapping out the potential failure modes of human interaction and decision paths, FMEA provides a structured method for improving system design to better support human performance and reduce the likelihood of error, thereby directly influencing patient safety and organizational resilience.

Core Methodology: Identifying Failure Modes

The initiation of any **FMEA** study requires the precise definition of the system boundaries and the detailed mapping of the process or design under scrutiny. A failure mode is formally defined as the manner in which a component, subsystem, or process step could potentially fail to meet its functional requirement. Identifying these modes requires deep subject matter expertise and often relies on historical data, expert judgment, and brainstorming sessions to capture all plausible scenarios. In a human factors context, failure modes might include errors of omission (failing to perform a required step), errors of commission (performing a step incorrectly), sequencing errors (performing steps out of order), or timing errors (performing a step too early or too late). These human failure modes are often rooted in underlying psychological factors such as fatigue, distraction, high cognitive load, or confirmation bias, which must be carefully analyzed as potential causes.

The systematic identification process requires the FMEA team to ask critical "what if" questions for every component or step. For a technical component, this involves considering scenarios like "Does not turn on," "Leaks," or "Fails prematurely." For a psychological process, such as transferring critical patient information between shifts, the failure modes might be "Information incomplete," "Information misinterpreted," or "Information delivered to the wrong recipient." Each identified failure mode must be described in specific, technical terms that clearly articulate the exact nature of the failure, avoiding vague generalities. This specificity is crucial because the subsequent analysis of effects and causes depends entirely on the clarity of the identified mode. Furthermore, it is essential to consider both single failures and potential common-cause failures, where a single environmental condition or systemic flaw could induce multiple component failures simultaneously, significantly increasing overall risk.

Once the potential failure modes are listed, the next step involves detailing the local and systemic causes associated with each mode. The cause is the specific mechanism of failure, distinct from the mode itself. For instance, if the failure mode is "Incorrect dosage calculated," the potential causes might include "Operator fatigued," "Software interface confusing," or "Training inadequate." Psychologically, linking the mode (the observable error) back to the root cause (the psychological or environmental factor) is critical for effective intervention. Interventions targeting the mode (e.g., adding a checklist) are often less effective than interventions targeting the cause (e.g., regulating shift length to reduce fatigue). This process often employs tools like the "**Five Whys**" technique to drill down past superficial causes to identify the true systemic deficiencies that enable the human error, thereby ensuring that corrective actions address the fundamental vulnerability rather than just the symptom.

The Role of Effects Analysis and Severity Ranking

Following the identification of failure modes and their root causes, the **Effects Analysis** stage determines the consequences of each failure mode on the system, the customer, and, critically, on safety. The effect describes what actually happens if the failure mode occurs. This step transforms the abstract potentiality of failure into tangible outcomes, allowing for meaningful risk assessment. In engineering, the effects might relate to equipment damage or functional loss. In organizational and psychological contexts, the effects often involve performance degradation, mission abortion, financial loss, or, most critically, physical or emotional harm to personnel or clients. It is crucial during this stage to consider the worst credible outcome resulting from the failure mode, regardless of how frequently that mode might occur.

A critical component of the effects analysis is the assignment of a **Severity Ranking (S)**. Severity is typically measured on a scale (e.g., 1 to 10), where 1 represents no effect or minor inconvenience, and 10 represents catastrophic failure resulting in death, severe injury, or complete system collapse. The ranking criteria must be standardized and consistently applied across the entire FMEA study to maintain objectivity. When applying FMEA to human systems, establishing the severity scale requires careful consideration of ethical and regulatory standards. For example, in mental health care, a failure mode (e.g., "Misdiagnosis") might have effects ranging from minor delay in treatment (low severity) to irreversible psychological damage or suicide (high severity). The severity score is assigned based purely on the consequence of the failure, without regard for how likely that failure is to occur or how easily it might be detected. This separation ensures that highly dangerous failures, even if rare, receive the appropriate level of attention.

The output of the effects analysis provides the necessary input for prioritizing mitigation efforts. Failures identified as having severe consequences (high S score) immediately flag the need for attention, even before considering other risk factors. If a failure mode carries a Severity of 9 or 10, organizations often establish mandatory requirements for design changes or procedural modifications that eliminate the mode entirely or provide failsafe mechanisms. This rigorous focus on minimizing severe harm aligns perfectly with core ethical principles in psychology and human factors, emphasizing that the primary goal of system design must be to protect the well-being of the human operator and the end-user. The analysis ensures that resources are not disproportionately spent addressing low-impact, high-frequency failures while ignoring high-impact, low-frequency catastrophic risks.

Adapting FMEA for Human Factors and Cognitive Systems

While traditionally focused on hardware, the application of **FMEA** in Human Factors and Cognitive Systems (HFC FMEA) addresses the complexity inherent in human performance within engineered environments. Unlike mechanical components, human operators are adaptive, variable, and

susceptible to psychological states such as stress, fatigue, and distraction, which must be modeled as potential failure precursors. HFC FMEA demands a shift from analyzing passive component deterioration to analyzing dynamic human-system interfaces, procedural compliance, team coordination, and decision-making under uncertainty. For example, a failure mode like "Incorrect data entry" is analyzed not only by its immediate cause (a momentary lapse) but by the systemic factors that enabled the lapse, such as poorly designed user interfaces, excessive task load, or lack of standardized operating procedures, all of which fall under the purview of cognitive psychology.

In this adaptation, the traditional concept of a "component" is expanded to include critical steps in a process, communication links, cognitive tasks, and organizational structure elements. The failure modes identified often relate directly to recognized human error classifications.

Slip: An execution failure where the intention was correct but the action performed was wrong (e.g., pressing the wrong button).

Lapse: A memory failure (e.g., forgetting to perform a step in a sequence).

Mistake: A planning failure where the intention itself was incorrect due to poor rule application or faulty knowledge (e.g., misdiagnosing a situation).

Violation: A deliberate deviation from a safe operating procedure.

By classifying human failure modes in this manner, intervention strategies can be tailored more effectively. For slips and lapses, solutions often involve system design changes (forcing functions, improved visibility, reducing cognitive load). For mistakes and violations, solutions focus more on training, procedural clarity, and organizational culture improvements. HFC FMEA thus serves as a powerful diagnostic tool, helping system designers and organizational leaders understand where and how human cognition is most likely to break down, allowing them to design systems that are robust and forgiving of inevitable human error.

Calculating Risk Priority Number (RPN) in Psychological Contexts

The quantification of risk within **FMEA** is achieved through the calculation of the **Risk Priority Number (RPN)**, which is the product of three independent rating factors: Severity (S), Occurrence (O), and Detection (D). The formula is expressed as: $RPN = S \times O \times D$. Each factor is typically rated on a scale of 1 to 10, meaning the RPN score can range from 1 (lowest risk) to 1000 (highest risk). This numerical score provides an objective basis for ranking failure modes, ensuring that organizational resources are allocated to address the highest risks first. Failure modes with high RPNs require mandatory corrective actions before the system or process can be implemented or continued.

In psychological and process FMEA, defining the Occurrence (O) and Detection (D) scales requires specific interpretation. **Occurrence (O)** measures the frequency or likelihood that the specific cause of the failure mode will occur. This often relies on historical incident data, expert estimations, or simulations. For human errors, a high occurrence score might be assigned to a task known to be highly susceptible to human factors, such as tasks performed under time pressure, low light conditions, or high distraction levels, based on established human performance data. **Detection (D)** measures the likelihood that the failure mode, should it occur, will be detected by the system or the operator before it results in the severe effect. A low detection score (high D number, indicating poor detectability) is assigned if there are no checks, alarms, or redundancies in place to catch the error, making the system highly vulnerable.

For cognitive systems, detection challenges are often paramount. If a medical professional makes a calculation error while prescribing medication (failure mode), and the system provides no warning and no independent check is mandated (high D score), the RPN will be significantly higher than if the system automatically flagged out-of-range doses (low D score). The RPN calculation forces the FMEA team to systematically evaluate three distinct dimensions of risk. By focusing on reducing the RPN, corrective actions can target any of the three factors: reducing the Severity (S) through system redundancy, reducing the Occurrence (O) through improved training or workload management, or reducing the Detection score (D) by implementing better error-proofing mechanisms and quality checks. The resulting prioritization list drives efficient risk mitigation efforts across the organization.

FMEA Application in High-Reliability Organizations (HROs)

High-Reliability Organizations (HROs), such as nuclear power plants, air traffic control centers, and specialized surgical teams, operate in environments where the potential for error is constant but the requirement for flawless performance is absolute. **FMEA** is a foundational tool in HRO philosophy, supporting the organizational commitment to **preoccupation with failure** and **sensitivity to operations**. For HROs, FMEA is not a one-time analysis but an ongoing, iterative process used to continuously refine procedures and identify emerging risks. The formal structure of FMEA supports the HRO principle of non-punitive reporting, encouraging staff to identify and report near misses and latent failures without fear of blame, thereby increasing the accuracy and depth of the failure mode data available for analysis.

In the context of HROs, FMEA is often coupled with other human error analysis methods, such as the Human Error Assessment and Reduction Technique (HEART) or Systematic Human Error Reduction and Prediction Approach (SHERPA), to provide a comprehensive view of human vulnerability. The FMEA framework provides the necessary structure to translate abstract concepts of organizational safety culture into concrete, measurable risk reduction strategies. For instance, FMEA can be used to analyze the communication protocols during critical transitions (e.g., shift

handovers in a control room), treating the process steps--such as confirming readbacks or documenting status--as components susceptible to failure modes like "Mishearing instruction" or "Ambiguous reporting." The high severity ranking assigned to these communication failures necessitates the implementation of strict, standardized communication tools like SBAR (Situation, Background, Assessment, Recommendation), which act as corrective actions to reduce the occurrence of the failure modes.

The success of FMEA in HRO environments lies in its ability to drive systemic change rather than simply addressing individual competence. When FMEA reveals a high RPN related to human error, the solution is rarely to retrain the individual; instead, the focus shifts to redesigning the environment, procedures, or technology to make it impossible or extremely difficult for the error to occur. This perspective aligns with James Reason's Swiss Cheese Model of accident causation, where FMEA acts to identify and close the "holes" (latent conditions and active failures) in the system's defensive layers. By systematically analyzing the potential effects of failure before they materialize, HROs maintain high vigilance and minimize drift toward failure, sustaining reliability despite operating under extreme complexity and pressure.

Limitations and Future Directions of FMEA in Psychology

Despite its robustness, **FMEA** possesses inherent limitations, particularly when applied to highly dynamic psychological systems. One major challenge is the inherent difficulty in accurately estimating the **Occurrence (O)** and **Detection (D)** rates for human errors. Unlike mechanical parts, human performance lacks deterministic reliability curves; factors like stress, team dynamics, fatigue cycles, and emotional state introduce high variability that is difficult to quantify precisely on a simple 1-to-10 scale. If the occurrence rate is misestimated due to reliance on biased expert opinion or incomplete historical data, the resulting RPN may inaccurately prioritize risks, leading to misallocation of crucial organizational resources. Furthermore, the analysis is often static, analyzing a system at a specific point in time, and may fail to account for complex interactions between multiple concurrent failures or the emergent behavior of complex systems, where the whole is greater than the sum of its failing parts.

Another significant limitation arises from the methodology's focus on identifying single points of failure. Traditional FMEA is less effective at analyzing complex, interdependent systems where system failure arises from the synergistic interaction of multiple, minor, non-catastrophic failures--a scenario common in organizational accidents. While some extensions, like Failure Modes, Effects, and Criticality Analysis (FMECA), attempt to address this by introducing criticality rankings, FMEA fundamentally struggles with modeling complex organizational phenomena like cultural deficiencies, poor leadership, or chronic understaffing, which act as pervasive causes across multiple failure modes rather than localized component failures. This necessitates integrating FMEA findings with broader organizational safety climate assessments to gain a holistic view of

systemic vulnerability.

Future directions for FMEA in psychology involve integrating it more tightly with advanced simulation and probabilistic risk assessment (PRA) techniques. Utilizing computational modeling of cognitive processes (e.g., cognitive architectures) can help generate more realistic estimates for occurrence rates of specific cognitive failures under varying workload conditions. Furthermore, the development of specialized software tools tailored for Process FMEA in human factors is crucial, allowing for better visualization of failure pathways and the effective linkage of root psychological causes to procedural effects. This evolution aims to transform FMEA from a powerful descriptive and prioritizing tool into a more accurate predictive instrument, enhancing its utility in proactively designing resilient systems that anticipate and accommodate the full spectrum of human variability and error.

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