AI Agent-Based Support for Failure Mode and Effects Analysis (FMEA)
ASHP Artificial Intelligence Case Studies

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Case Study Type: Patient Safety

Tool Type: Clinician or Internal-Facing, Internally Developed

Case Overview:
Failure Mode and Effects Analysis (FMEA) is a proactive risk assessment method used to identify, prioritize, and mitigate high-risk failure points within a process. While valuable, traditional FMEA facilitation can be resource intensive, requiring facilitators to simultaneously guide multidisciplinary discussion, document failure modes, maintain the scoring grid, and ensure consistent application of severity, occurrence, and detection ratings. This initiative evaluated an AI-enabled FMEA support agent designed to reduce facilitator burden by converting meeting discussions and transcripts into structured draft grid content, highlighting documentation gaps, and supporting consistency in scoring. By shifting routine grid completion and reconciliation outside of live team meetings, the tool allows meeting time to focus on meaningful discussion of process risks, safeguards, and mitigation strategies. AI-generated content is not used autonomously; facilitators and subject matter experts review, validate, and revise all outputs before incorporation into the final FMEA. This human-in-the-loop approach preserves team judgment while improving efficiency, documentation, completeness, and scoring reliability.

Tool and Project Details:
"Emmy", an AI-based agent, was developed to support structured FMEA facilitation, reducing the documentation and scoring burden traditionally carried by the facilitator. The AI agent was trained to translate meeting discussion and transcripts into draft grid content, allowing live sessions to focus on multidisciplinary discussion of process risks, safeguards, and mitigation strategies rather than line-by-line grid completion. The AI agent supports the following activities:

- Meeting documentation and artifacts: Generation of team charters, meeting transcripts, team and executive-ready meeting notes, FMEA grid updates, reducing administrative burden.
- Scoring validation: Cross-checks team discussion against grid entries after every session to flag gaps or misalignments that need team review.
- Transcript-to-grid quality assurance: Identifies failure modes discussed verbally during meetings but not yet documented in the FMEA grid, and brings them back for team confirmation.
- Analytical support: Generation of Risk Priority Number (RPN) summaries, pareto charts, and risk prioritization grids to identify the “vital few” risks quickly.

Key Elements of Success:
Key elements of success centered on the pharmacy department’s ability to develop, iterate, and implement an AI-based agent within an active FMEA project rather than treating the work as a standalone AI technology use case. Pharmacy medication safety/quality team members translated real facilitation needs into defined agent standards and instructions, tested prompts against actual meeting outputs, refined the agent based on

facilitator and subject-matter-expert feedback, and embedded the tool into the existing FMEA workflow with clear human review expectations. Multidisciplinary collaboration with pharmacy operations, medication safety, quality, nursing, and operational leaders ensured the agent supported practical workflow needs while preserving team judgment. The initiative was developed with oversight from the Brown Health AI Center of Excellence and AI governance structure, which provided a system-level framework for responsible AI use, appropriate approvals, risk review, and alignment with organizational expectations. This governance infrastructure was a key enabler of success, allowing the pharmacy team to innovate quickly while maintaining accountability, consistency, and confidence in use of AI within a real medication safety project.

Impact on Outcomes:
The AI assistant reduced facilitator burden by shifting routine documentation, draft grid completion, and transcript reconciliation outside of live team discussion. This allowed facilitators to focus on guiding conversation during meetings, clarifying the processes and risks, and ensuring scoring reflected team consensus rather than managing the mechanics of FMEA grid entry in real time. Transcript-to-grid quality assurance helped identify verbally discussed failure modes or safeguards that may otherwise have been omitted. Scoring validation improved alignment between team discussion and assigned severity, occurrence, and detection ratings, supporting a more consistent and transparent approach to risk prioritization. Overall, the process became more efficient, less administratively burdensome, and better aligned with the purpose of FMEA: using multidisciplinary discussion to identify failure points, evaluate existing safeguards, and select mitigation strategies.

Role of the Pharmacy and Pharmacists:
Pharmacy and medication safety leaders designed and implemented the AI agent assisted workflow and served as primary facilitators throughout the FMEA process. Pharmacists helped define requirements, develop prompts, validate outputs, and ensure recommendations aligned with medication safety principles. Pharmacy collaborated with multidisciplinary stakeholders to review AI-generated content, maintain process integrity, and support adoption. No specialized AI certifications were required; however, facilitators received training on prompt development, human review expectations, scoring validation, and appropriate use of AI-generated outputs to support discussion without allowing the tool to replace team judgment.

Budget & Resource Allocation:
This initiative was developed using existing organizational AI resources and staff with expertise in FMEA facilitation. No additional software purchases or external consulting services were required. The primary investment involved facilitator time dedicated to AI-agent workflow design, prompt testing, and validation. Return on investment was demonstrated through reduced administrative burden, improved documentation quality, and increased efficiency during FMEA completion. Leveraging existing technology enabled rapid implementation while minimizing financial impact.

Lessons Learned:
Early concerns focused on ensuring AI outputs were accurate, complete, consistently scored, and appropriately governed. These challenges were addressed by establishing a human-in-the-loop review process where facilitators validated all outputs before including in the FMEA grid or actions taken. A key lesson was that scoring should remain driven by team discussion and subject matter expertise, with AI used afterward to support documentation completeness, identify gaps, and check scoring consistency. The most important success factors were leadership support for access to AI tools, interdisciplinary collaboration, and

a shared understanding that AI functions as a decision-support tool rather than a replacement for human judgment. By reducing the mechanics of grid completion and scoring review, the AI-based agent helped demystify FMEA for participants and supported improved trust, adoption, and consistency throughout implementation.

Future Goals & Ongoing Monitoring:
Future efforts will explore the expansion of AI agent support across additional safety and quality workflows, including root cause analysis, gap analysis, and white paper document generation. Ongoing monitoring will assess documentation quality, facilitator satisfaction, process efficiency, adoption rates, scoring consistency, reduction in live meeting time spent on grid entry, and the frequency of transcript-to-grid reconciliation findings. Human review requirements will remain in place to ensure scoring, risk prioritization, and final content reflects team judgment and subject matter expertise. Findings are being shared through national and local professional presentations and educational forums to support broader discussion regarding practical and responsible AI use in healthcare quality and patient safety initiatives.

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