

Patient Safety Improvement Projects and Failure Mode and Effects Analysis (FMEA) Policy – SAMPLE

3. Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
4. Prioritize the potential process breakdowns or failures.
5. Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
6. Redesign the process and/or underlying systems to minimize the risk of the effects on patients.
7. Test and implement the redesigned process.
8. Monitor the effectiveness of the redesigned process.²

III. PROCEDURE:

A. Identification

1. The [*insert name of facility's quality committee*] may initiate a patient safety improvement project at any time in response to the following:
 - a. The improvement priorities of the organization
 - b. Findings from internal root cause analyses
 - c. Recommendations received from the [*insert name(s) of applicable committee(s), e.g., medical executive committee, patient safety committee, other*]
 - d. Safety alerts issued by external groups, such as The Joint Commission, the U.S. Food and Drug Administration (FDA), and the Institute for Safe Medication Practices (ISMP)
 - e. National patient safety improvement goals established by external groups, such as The Joint Commission, The Leapfrog Group, and the Agency for Healthcare Research and Quality (AHRQ)
 - f. Literature sources and knowledge-based information on patient safety improvement
2. Improvement projects are resource-intensive; therefore, the [*insert name of facility's quality committee*] will consider many factors before initiating a patient safety improvement project. Questions to be considered include, but are not limited to, the following:
 - a. Does the issue represent a high-priority for improvement for the organization?
 - b. Does the issue represent a substantial risk to patient safety?
 - c. If the concern is not addressed, is there a high probability that a sentinel or critical event will occur?
 - d. Will the organization receive substantial negative publicity or loss of accreditation if the concern is not addressed?
 - e. Will failure to conduct an improvement project result in deterioration of staff member or physician morale and/or loss of trust in the leadership's commitment to patient safety?
3. When the decision is made to initiate a patient safety improvement project, the [*insert name of facility's quality committee*] shall carry out these steps:
 - a. Establish a statement of objectives (e.g., what is intended to occur as a result of the project).
 - b. Establish the team of people responsible for completing the project.
 - i. The team shall be comprised of physicians and staff members personally involved in the system and process to be improved. Recommendations for team members may be solicited from other medical staff committees, hospital departments, and the administration. Ideally, the team includes four to seven individuals who are "subject matter experts" and who have different levels and types of knowledge about the system and process to be improved. Consider including team members with no experience with the activity, product or process, as this provides a different perspective. The team should be composed of eight to 12 members.
 - ii. A chairman or co-chair position is named.
 - iii. The team may report directly to the [*insert name of facility's quality committee*] or be formed as a task group reporting to another medical staff or hospital committee.

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- iv. A team facilitator, knowledgeable in proactive risk assessment techniques or performance improvement methods, will be named to support the project team activities.
- c. Establish a deadline for project completion.

Note: All investigation and monitoring documents shall be handled and maintained as professional/quality review documents and shall contain citations to applicable professional/quality review statute(s) that afford(s) confidentiality.

B. Patient Safety Improvement Project

1. At the first meeting of the team, the project objectives defined by the *[insert name of facility's quality committee]* are presented and discussed. The scope of the project is defined and a project timeline is established.
2. If the team is conducting an FMEA, the steps listed below will be completed by the team:
 - a. Organize information about the process or sub-process under study using a top-down flowchart to illustrate each step.
 - b. Conduct a hazard analysis.
 - i. Identify failure modes for each step and for the hand-offs between steps.
 - ii. Identify the areas of greatest concern by determining the criticality of each failure. This is done by:
 1. Determining the potential effect of each failure mode
 2. Ranking the severity of the failure effect, the frequency/probability of each failure, and the detectability of each failure
 - c. Identify the root cause(s) for the areas of greatest concern (also known as critical failures).
 - d. Recommend risk reduction strategies and actions that are necessary to eliminate critical failures, reduce the likelihood of critical failures, and/or mitigate the effects of critical failures. When developing strategies and actions, the team will consider relevant recommendations for process improvements found in safety-related, knowledge-based literature sources and other information.
 - e. If no action is recommended for a failure identified as critical, the rationale for this decision must be documented.
3. If the team is not conducting an FMEA, the process improvement model described in the hospital's performance improvement plan will be used.
4. When the project team has recommended risk reduction strategies and/or actions designed to achieve project objectives, a summary of the project along with the recommendations is submitted to the *[insert name of facility's quality committee]* for review and approval. At a minimum, the report will include the following details:
 - a. A summary of the project activities
 - b. Recommended risk reduction strategies and/or actions (including responsible person/department and suggested timeline for completion) and rationale for each recommendation
 - c. Measures that will be used to evaluate the effectiveness of risk reduction strategies and/or actions
5. At the final team meeting, the report of the patient safety improvement project is approved. The report should represent a consensus of all the project team members. Team members unable to attend the final meeting are required to approve the report prior to it being forwarded to the *[insert name of facility's quality committee]*.
6. The number of meetings required to complete a patient safety improvement project will vary according to the issues involved, the scope of the project, and the urgency of the situation. It is not necessary to hold a specific number of project team meetings; however, all of the steps detailed above must be completed before the patient safety improvement project is ready for presentation to the *[insert name of facility's quality committee]*.

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C. Actions and Follow-Up

1. The *[insert name of facility's quality committee]* is responsible for evaluating the thoroughness and credibility of patient safety improvement projects and the merits of the recommended risk reduction strategies and/or actions.
 - a. The thoroughness and credibility are evaluated by considering the following questions:
 - i. Did the project have multidisciplinary participation and obtain input from those closest to the processes and systems under review?
 - ii. Did the team follow a logical and systematic process to arrive at recommended risk reduction strategies and/or action plans?
 - iii. If an FMEA was done, did it include all the elements required by The Joint Commission and this procedure?
 - b. The merit of the risk reduction recommendations is evaluated by considering the following questions:
 - i. Will the risk reduction strategies and/or actions recommended by the team achieve the project objectives?
 - ii. Can the recommendations be implemented within a reasonable time, considering available financial and human resources?
 - iii. Are the people/departments responsible for implementing the recommendations clearly identified and are the timelines for completion reasonable yet aggressive?
 - iv. Will the measures of effectiveness adequately evaluate the success of risk reduction strategies and/or actions?
2. The *[insert name of facility's quality committee]* approval of the patient safety improvement project report acknowledges its approval of the recommendations, as well as the thoroughness and credibility of the project.
3. If the *[insert name of facility's quality committee]* does not approve the report, the project team will reconvene to address the questions or concerns of the committee and make necessary changes. Upon completion of its charge, the team will present a new report to the *[insert name of facility's quality committee]* for review and approval.
4. Implementation of the risk reduction strategies and/or actions will begin immediately following *[insert name of facility's quality committee]* approval of the project report. All risk reduction strategies and/or actions will be pilot tested prior to full implementation. The project team is reconvened to determine how the recommendations will be tested. Test methods for redesigned processes include, but are not limited to, the following:
 - a. Conduct another FMEA of the new (redesigned) process.
 - b. Conduct a critical analysis of the worst-case scenario under the new process. For example, if the new process is dependent on computer tracking, has a manual system been established and proven to serve as an adequate back-up if the computer fails?
 - c. Pilot test the new process and evaluate each step for accuracy, staff member compliance, and ease of approach.Examples of test methods for other recommended changes (e.g., staff training, new equipment):
 - a. Pilot testing and gathering input from those involved
 - b. Evaluating effects of training
 - c. Obtaining feedback from people using new equipmentIf the recommended action involves the redesign of a sub-process, the project team will evaluate the effect of the new sub-process on other steps before implementing changes.
5. A summary report of all approved patient safety improvement projects will be incorporated into the performance improvement reports that are presented to the *[insert name of appropriate oversight committee, e.g., medical executive committee]* and the governing body. A summary report of all approved patient safety improvement projects, including details of the action plans, implementation timeline and measures of effectiveness, will be presented to the *[insert name of appropriate oversight committee, e.g., patient safety committee]*.

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6. The *[name of appropriate oversight committee, e.g., patient safety committee]* will receive regular reports on the progress of risk reduction strategies and/or actions and measures of the effectiveness of actions for each patient safety improvement project that is conducted. The facilitator of the project team is responsible for providing this report to the *[insert name of appropriate oversight committee, e.g., patient safety committee]*.
 - a. The *[insert name of appropriate oversight committee, e.g., patient safety committee]* will monitor pilot testing and implementation of the actions to ensure adherence to the timeline outlined by the project team.
 - b. If the pilot tests of the actions do not achieve desired results, the project team will reconvene to discuss and recommend revisions to the initial recommendations. Any revisions to the initial recommendations will need the approval of the *[insert name of facility's quality committee]*, following the same process as the initial project approval.
 - c. The *[insert name of appropriate oversight committee, e.g., patient safety committee]* will monitor the effectiveness of actions until the membership of the committee is reasonably assured that the actions achieved desired results (monitoring will continue for at least six months following full implementation of the recommendations).
 - d. If it becomes apparent that the recommended actions are not being implemented as planned or if the measures of action effectiveness reveal that a problem still exists and the *[insert name of appropriate oversight committee, e.g., patient safety committee]* cannot resolve the issue, the matter will be referred to the *[insert name of facility's quality committee]* for action.
7. The *[insert name of appropriate oversight committee, e.g., patient safety committee]* will periodically share general information relating to the improvement of patient safety that is derived from improvement projects with managers, staff, and medical staff members.

References

1. The Joint Commission, *Accreditation Requirements – Hospital Program*, LD.04.04.05, Element of Performance 10, The Joint Commission, Joint Commission Resources, Oakbrook Terrace, IL, Effective July 1, 2016.
2. Ibid, "Proactive Risk Assessment," Leadership Accreditation Requirements.

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