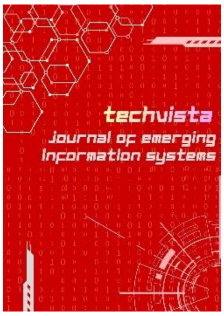

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Implementation of Six Sigma and FMEA in Improving Production Efficiency and Quality in the Manufacturing Industry

Utari Hadrawi[1]

[1]Faculty of Engineering, Islamic University of Makassar (UIM)

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Abstract

This study focuses on the development and implementation of a Hospital Management Information System (HMIS) aimed at optimizing web and mobile-based patient services. The research explores how the integration of advanced digital technologies enhances patient satisfaction, reduces service times, and minimizes administrative errors. Employing a quasi-experimental design, the study compared the performance of an experimental group utilizing the HMIS with a control group using traditional systems. Results indicate significant improvements in all key areas, highlighting the effectiveness of HMIS in improving healthcare service quality. This study contributes to the growing body of research supporting the adoption of digital solutions in healthcare management.

Introduction

In an increasingly globalized and highly competitive industrial environment, product quality has become a decisive factor influencing organizational sustainability and market competitiveness. Manufacturing firms are no longer assessed solely on their production capacity but also on their ability to consistently deliver products that meet stringent quality standards while minimizing defects and operational inefficiencies. Quality failures not only increase production costs through waste and rework but also undermine customer trust and corporate reputation. Consequently, quality management has emerged as a strategic priority for manufacturing organizations seeking to achieve operational excellence and long-term competitiveness (Marković, 2008; Alam et al., 2024; Chiarini et al., 2021).

The importance of quality control is particularly evident in industries characterized by continuous production processes, where even minor deviations can propagate across large production volumes and result in substantial defect accumulation. Effective quality control systems enable organizations to detect deviations early, identify root causes, and implement corrective actions in a timely manner. Sugiharto et al. (2023) emphasize that systematic control

[1] Corresponding Author: Utari Hadrawi, Address: Jl. Perintis Kemerdekaan No.KM.9, RW.No.29, Tamalanrea Indah, Kec. Tamalanrea, Kota Makassar, Sulawesi Selatan 90245

and supervision mechanisms are essential to ensure that production activities remain aligned with predefined standards and organizational objectives. In this context, quality control serves not merely as a technical function but as an integrated managerial approach aimed at ensuring consistency, reliability, and customer satisfaction (Paulin, 2022; Ranjith Kumar et al., 2022; Tambare et al., 2021).

Despite its recognized importance, many manufacturing firms continue to face persistent quality-related challenges, including high defect rates, process variability, and inefficiencies in identifying the underlying causes of production failures. Traditional quality inspection methods often focus on detecting defects after production rather than preventing them from occurring in the first place (Broday, 2022; Zheng et al., 2021; Saberironaghi et al., 2023). Such reactive approaches are increasingly inadequate in competitive markets that demand high precision, cost efficiency, and rapid responsiveness. As a result, organizations are compelled to adopt more systematic, data-driven methodologies that emphasize defect prevention, process optimization, and continuous improvement.

One of the most widely adopted methodologies in modern quality management is Six Sigma. Six Sigma is a structured, data-driven approach that aims to reduce process variation and defects to a level of no more than 3.4 defects per million opportunities (DPMO), corresponding to a quality level of 99.99966 percent. The methodology follows the DMAIC framework Define, Measure, Analyze, Improve, and Control which provides a systematic roadmap for problem identification, root cause analysis, and sustainable process improvement (Usman, 2021; Pérez-Balboa et a., 2024; Al-Rifai, 2024). By integrating statistical analysis with managerial decision-making, Six Sigma enables organizations to improve process capability and enhance customer satisfaction.

While Six Sigma offers a comprehensive framework for quality improvement, its effectiveness can be further enhanced through the integration of complementary analytical tools. One such tool is Failure Mode and Effect Analysis (FMEA), which focuses on identifying potential failure modes within a process, assessing their severity, occurrence, and detectability, and prioritizing corrective actions based on calculated risk levels. Bayu Hernanda and Winursito (2024) argue that FMEA plays a critical role in preventive quality management by enabling organizations to anticipate failures before they materialize. When integrated with Six Sigma, FMEA strengthens the analytical rigor of the Improve phase by ensuring that corrective actions are targeted toward the most critical risk factors.

Previous empirical studies have demonstrated the effectiveness of Six Sigma and FMEA, both individually and in combination, across various industrial contexts. Han et al. (2008) reported significant improvements in process performance and defect reduction following Six Sigma implementation in construction operations. Similarly, ElMekkawy et al. (2006) found that defect analysis using structured quality tools contributed to measurable gains in productivity and product consistency. These studies collectively suggest that systematic quality management approaches can deliver substantial operational benefits when properly implemented.

However, despite the growing body of literature on Six Sigma and FMEA, several gaps remain. First, many studies focus on either Six Sigma or FMEA in isolation, offering limited insight into their synergistic application within a unified quality improvement framework. Second, empirical evidence from manufacturing sectors in developing economies, particularly in Indonesia, remains relatively scarce. Given the unique operational challenges faced by manufacturing firms in emerging markets such as variability in raw material quality, equipment limitations, and workforce skill disparities there is a need for context-specific studies that examine how these methodologies perform in real-world industrial settings.

Moreover, existing studies often emphasize short-term improvements without sufficiently addressing the sustainability of quality gains over time. Continuous production environments require not only initial defect reduction but also robust control mechanisms to ensure that improvements are maintained. The Control phase of Six Sigma, when reinforced by preventive tools such as FMEA, has the potential to institutionalize quality improvements and prevent regression to previous performance levels. Nevertheless, empirical investigations that explicitly examine post-improvement performance metrics, such as changes in sigma levels and DPMO, remain limited.

Against this backdrop, the present study seeks to address these gaps by examining the implementation of Six Sigma integrated with Failure Mode and Effect Analysis in a manufacturing company producing paint canisters. The study focuses on identifying critical quality issues, analyzing root causes of defects, prioritizing risk factors, and evaluating the effectiveness of corrective actions through measurable performance indicators. By employing secondary production data and applying the DMAIC framework, this research provides a comprehensive assessment of quality improvement outcomes before and after intervention.

The objectives of this study are threefold. First, it aims to evaluate the baseline quality performance of the production process using Six Sigma metrics, including DPMO and sigma levels. Second, it seeks to identify and prioritize key failure modes through FMEA to support targeted improvement initiatives. Third, it assesses the extent to which the integrated application of Six Sigma and FMEA contributes to sustainable improvements in product quality and process efficiency. The novelty of this study lies in its integrated analytical approach and its empirical focus on a continuous manufacturing process within the Indonesian industrial context. By bridging methodological rigor with practical relevance, this research contributes to both the theoretical advancement of quality management literature and the practical implementation of data-driven quality improvement strategies in manufacturing industries.

Methods

This study employed a quantitative and applied research design aimed at improving product quality through the integrated implementation of the Six Sigma methodology and Failure Mode and Effect Analysis within a continuous manufacturing environment. Six Sigma was selected as the primary framework due to its effectiveness in reducing process variation and defects through data driven analysis, while FMEA was incorporated to strengthen preventive risk identification and prioritization, as recommended in quality management literature (Usman, 2021; Bayu Hernanda & Winursito, 2024). The research was conducted in a manufacturing company producing metal paint canisters, where quality defects directly affect operational efficiency and customer satisfaction. The continuous nature of the production process justified the adoption of structured and preventive quality improvement approaches.

The methodological process followed the Six Sigma DMAIC framework. In the Define phase, quality problems were identified based on historical production records indicating defect levels above acceptable standards, and Critical to Quality characteristics were established in alignment with customer requirements (Marković, 2008). During the Measure phase, secondary production data were collected to calculate Defects Per Million Opportunities and sigma levels as indicators of baseline process capability. The Analyze phase involved statistical analysis of defect data, supported by Pareto analysis to identify dominant defect types. At this stage, Failure Mode and Effect Analysis was conducted to systematically identify potential failure modes, evaluate their severity, occurrence, and detectability, and calculate Risk Priority

Numbers to prioritize improvement actions, consistent with the approach suggested by ElMekkawy et al. (2006).

In the Improve phase, corrective actions were designed and implemented based on the identified root causes and high risk failure modes, focusing on process adjustments and quality control enhancements. Post improvement production data were then collected using the same measurement procedures to assess changes in DPMO and sigma levels, ensuring methodological consistency. The Control phase emphasized the sustainability of improvements through standardization of revised procedures and continuous quality monitoring using statistical process control tools. The overall research framework and performance comparisons before and after improvement are presented in Figure 1. The use of established Six Sigma metrics and standardized FMEA procedures ensured methodological validity and reliability, providing a robust basis for evaluating quality improvement outcomes in the manufacturing process.

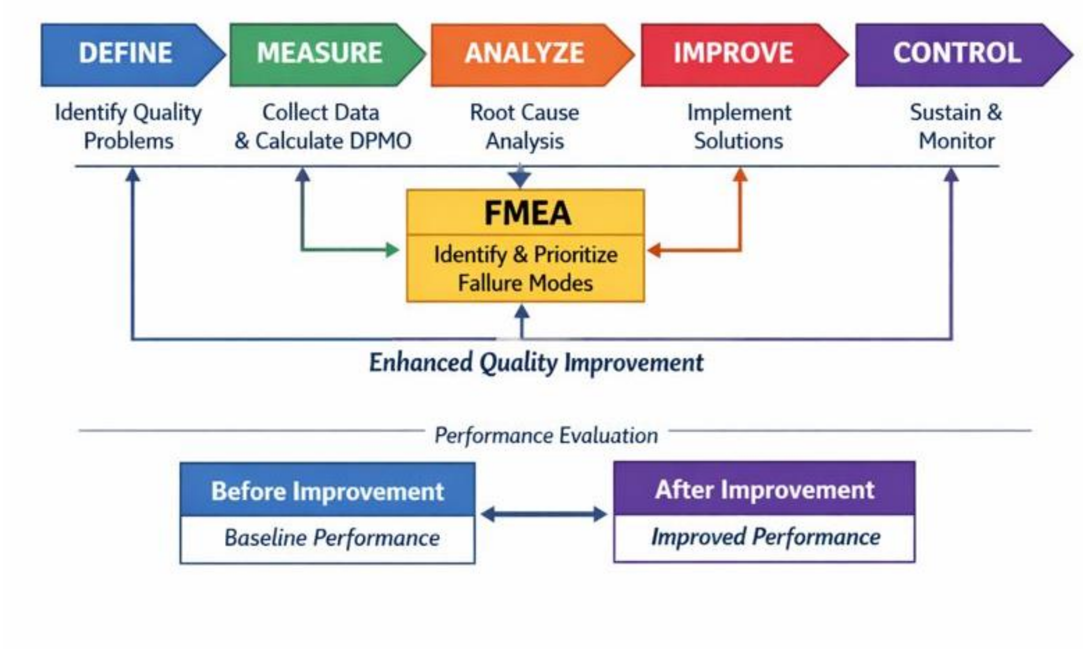

Figure 1. Research Framework Integrated Six Sigma and FMEA

Results and Discussion

Overview of Defect Data During the Observation Period

The analysis was conducted using secondary production data collected during June and July 2024. Over the two-month observation period, a total of 220,000 paint canisters were produced. From this output, 5,700 defective units were identified, indicating the presence of quality deviations that required systematic investigation. The initial defect profile provides a baseline for evaluating the effectiveness of the Six Sigma and FMEA implementation in subsequent stages.

Table 1. Summary of Production Defects (June–July 2024)

Month	Total Units Produced	Total Defects	DPU
June	100,000	2,500	0.025
July	120,000	3,200	0.0267

The DPU (Defects Per Unit) for both June and July indicates that approximately 2.5% to 2.7% of the products are defective. This rate suggests that a significant portion of the production process is yielding suboptimal outcomes, which may affect overall product quality and customer satisfaction (Arsyad, 2022). By establishing this baseline, the organization has a clearer understanding of the current state of defects, serving as a starting point for improvement efforts through the DMAIC (Define, Measure, Analyze, Improve, and Control) process. Through the implementation of Six Sigma techniques, the aim is to systematically reduce these defects by addressing root causes, improving process efficiency, and ensuring that production standards are consistently met. This foundational data highlights the necessity for continuous monitoring and adjustment to achieve higher quality standards and reduce variability in the production process.

Identification of Critical to Quality (CTQ) Characteristics

The Define and Measure stages of the DMAIC framework identified six Critical to Quality (CTQ) characteristics relevant to paint canister production. These CTQs represent measurable attributes directly affecting product conformity and customer requirements. Using these CTQs, the total number of defect opportunities was calculated by multiplying total units produced by the number of CTQs.

Table 2. CTQ Metrics and Initial Sigma Level

Metric	Value
Total Units Produced	220,000
Total Defects	5,700
Total Opportunities	1,320,000
DPO	0.00432
DPMO	4,320
Sigma Level	4.08

The initial sigma level of 4.08 indicates that the production process is currently performing below the Six Sigma benchmark of 6 sigma, which represents a near-perfect process with extremely low defect rates (3.4 DPMO). While 4.08 is a solid level, indicating better-than-average industry standards, it still highlights that there is room for improvement. Achieving a sigma level closer to 6 would significantly reduce defects, enhance process capability, and ensure higher customer satisfaction. By focusing on reducing variations and addressing root causes through the DMAIC methodology, the organization can strive towards higher process performance and better quality outcomes, ultimately moving closer to the Six Sigma ideal. This incremental improvement not only benefits operational efficiency but also strengthens the company’s competitive advantage in the market (Muharam, 2017).

Root Cause Identification Using Fishbone Analysis

To systematically identify potential sources of defects, a cause-and-effect (fishbone) analysis was conducted during the Analyze stage. The analysis categorized potential causes into five main dimensions: machinery, material, method, environment, and manpower.

Table 3. Fishbone Analysis Results

Category	Identified Root Causes
Machinery	Wear and degradation of injection molding machines
Material	Inconsistent raw material quality
Method	Irregular IML robot labeling process
Environment	High humidity in production area
Manpower	Operator skill and training gaps

The highest Risk Priority Number (RPN) is associated with material contamination, which has an RPN of 216, followed closely by uneven labeling with an RPN of 210. These findings highlight the most critical areas that need immediate attention to reduce defects and improve product quality. Material contamination poses a significant risk as it can lead to defects affecting the structural integrity, appearance, and functionality of the final product. Similarly, uneven labeling can result in misidentification or inconsistencies in product presentation, impacting customer perception and satisfaction. Addressing these issues through targeted corrective actions, such as enhancing quality control measures for material inputs and refining labeling processes, will help minimize these defects (Qamar et al., 2024). Implementing robust inspection protocols, ensuring consistent training for operators, and leveraging Six Sigma tools like FMEA will further mitigate risks and drive continuous improvement in the production process.

Failure Mode and Effect Analysis (FMEA) Results

Following root cause identification, FMEA was employed to prioritize risks associated with specific failure modes. Severity (S), Occurrence (O), and Detection (D) scores were assigned to each failure mode, and the Risk Priority Number (RPN) was calculated.

Table 4. FMEA Risk Assessment Results

Failure Mode	S	O	D	RPN
Uneven labeling	7	6	5	210
Incorrect molding dimensions	8	5	4	160
Material contamination	9	4	6	216

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Improvement Actions Implemented

Based on the FMEA prioritization, several improvement actions were implemented during the Improve stage of the DMAIC cycle. These actions targeted the highest-risk failure modes and were designed to reduce defect occurrence and process variability.

Table 5. Improvement Actions and Targeted Issues

Improvement Action	Target Issue
Preventive maintenance scheduling	Machine wear
Supplier quality audits	Material variability
Operator training programs	Labeling inconsistency

Regular maintenance schedules are crucial for addressing machine wear and tear (Pranata & Setyawan, 2022). Over time, equipment used in continuous production processes can degrade, leading to increased defect rates and inconsistent product quality. By implementing scheduled maintenance, such as inspections, calibration, and necessary repairs, downtime can be minimized, ensuring that machines operate efficiently. According to Bloch & Geitner (2012) this proactive approach helps maintain the precision and reliability of manufacturing equipment, reducing defects caused by mechanical failure or irregular performance. Supplier quality control checks focus on improving material variability, which directly impacts product consistency. Variations in raw materials can lead to defects such as dimensional inaccuracies, surface imperfections, or material inconsistencies. Through rigorous supplier assessments, including regular testing and audits, the organization ensures that incoming materials meet predefined quality standards. This reduces the likelihood of defects associated with poor material quality, thus enhancing the overall product reliability and customer satisfaction (Agus & Shukri, 2012).

Training programs for operators aim to eliminate inconsistent practices. Inadequate training can lead to human errors such as improper handling, misalignment during assembly, or incorrect application of processes. By providing comprehensive training sessions and ongoing support, operators become more proficient in performing their tasks with higher accuracy. Consistent and well-trained operators contribute to reducing defects, enhancing process efficiency, and maintaining a high standard of product quality across the production line. Table 6. Post-Improvement Sigma Level.

Post-Improvement Performance Measurement

After implementing the improvement measures, production performance was re-evaluated using the same CTQ metrics. The post-improvement results indicate a substantial reduction in defects, with total defective units decreasing to 2,200.

Table 6. Post-Improvement Sigma Performance

Metric	Value
Total Units Produced	220,000
Total Defects	2,200
Total Opportunities	1,320,000
DPO	0.00167
DPMO	1,670
Sigma Level	5.07

After implementing the corrective measures, the post-improvement sigma level increased to 5.07, signifying a substantial enhancement in process performance. This improvement reflects the effectiveness of the Six Sigma approach in reducing defects and optimizing the production process (Han et al., 2008). Previously, the DPMO was 4,320, meaning there were 4,320 defects per million opportunities. With the implementation of targeted improvements, the DPMO decreased to 1,670, representing a 61% reduction in defects. This significant reduction underscores the success of the DMAIC framework in addressing root causes, streamlining operations, and ensuring that quality standards are met consistently. As a result, the production process is now more reliable and efficient, contributing to greater customer satisfaction and competitive advantage (Maulina, 2023).

The findings of this study reinforce the strategic relevance of integrating Six Sigma and Failure Mode and Effect Analysis as complementary quality management approaches in manufacturing environments. Rather than focusing on numerical improvements alone, the results demonstrate how structured problem identification and risk prioritization contribute to more resilient production systems. This aligns with previous studies suggesting that Six Sigma effectiveness depends not merely on defect reduction outcomes but on its capacity to institutionalize systematic decision-making processes (Antony et al., 2019).

The application of FMEA played a critical role in translating process data into actionable improvement priorities. By systematically ranking failure modes based on risk exposure, the organization was able to allocate resources more efficiently toward high-impact issues. This supports the argument advanced by Stamatis (2003) that FMEA enhances managerial focus by shifting attention from reactive quality control to proactive risk mitigation. In this context, quality improvement emerges as a preventive rather than corrective endeavor.

From an operational perspective, the study highlights the importance of aligning technical interventions with human and organizational factors. Improvements in machine maintenance and material control were effective because they were complemented by operator training and process standardization. This finding resonates with socio-technical system theory, which emphasizes that sustainable quality improvement requires coherence between technology, people, and procedures (Trist, 1981). Theoretically, this study contributes to quality management literature by demonstrating that process capability enhancement is not an isolated technical achievement but the outcome of integrated analytical frameworks. Practically, the findings suggest that manufacturing firms seeking continuous improvement should prioritize structured risk assessment tools alongside statistical quality methods to sustain long-term performance stability.

Conclusion

the implementation of Six Sigma and Failure Mode and Effect Analysis (FMEA) has proven to be highly effective in enhancing the quality control of paint canisters. The study achieved a significant improvement in sigma levels, reducing defects substantially, and aligning the production process with industry best practices. By addressing root causes through systematic analysis and continuous monitoring, the results demonstrate a clear path toward achieving higher quality standards. The integration of Six Sigma and FMEA ensures that potential risks are proactively managed, fostering a culture of continuous improvement. Going forward, maintaining and further enhancing these gains will require ongoing commitment to process optimization, advanced analytics, and the adoption of innovative technologies to sustain and elevate quality performance.

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