Texila International Journal | Open Access | Peer Reviewed

Journal: Texila International Journal of Medicine
https://doi.org/10.21522/TIJMD.2013.09.04.Art008

ISSN: 2520-3118
Volume 9 Issue 4, 2026

Enhancing Surgical Safety in a Newly Established Cardiothoracic Center Using Failure Modes and Effects Analysis for Improving Outcomes in East Africa

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Cite this article as: Juliet Ami Kwadzodeh, Mohammed Abdulkadir Mohammed, Sisay Bekele Woldemichael, Ragunath Ragunath. Enhancing Surgical Safety in a Newly Established Cardiothoracic Center Using Failure Modes and Effects Analysis for Improving Outcomes in East Africa. Texila Int J Med. 2026;9(4). **https://doi.org/10.21522/TIJMD.2013.09.04.Art008**

Received: 07.05.2026

Accepted: 21.10.2026

Published: 29.10.2026

Article Type: Original Research

Abstract *Surgical safety is a major patient safety priority, especially in high-risk specialties such as cardiothoracic surgery. Newly established centers in low-resource settings may face amplified risks from communication failures, inconsistent perioperative processes, equipment readiness gaps, delayed blood product availability, and delayed recognition of postoperative deterioration. This quality improvement study evaluated the use of Failure Modes and Effects Analysis (FMEA) to improve surgical safety in a newly established cardiothoracic and vascular center in East Africa. A prospective 12-month quality improvement study was conducted at Kalkaal Hospital Cardiothoracic and Vascular Center, Mogadishu, Somalia. A multidisciplinary team mapped the perioperative pathway, identified potential failure modes, scored risks using severity, occurrence, and detection ratings, calculated Risk Priority Numbers, and prioritized corrective interventions. Baseline and post-intervention indicators included surgical safety checklist compliance, equipment-related operative delays, structured handoff compliance, postoperative deterioration escalation time, ICU readmissions, and safety culture indicators. Twenty-one potential failure modes were identified. Five high-priority risks were selected for intervention: inadequate patient verification, delayed recognition of postoperative deterioration, equipment readiness failure, communication failure during handoff, and checklist noncompliance. Interventions included a cardiothoracic-adapted checklist, equipment readiness bundle, standardized handoff tool, ICU early warning escalation algorithm, daily safety huddles, and briefing/debriefing protocols. Checklist compliance improved from 72% to 96%, equipment delay events reduced from 10 to 6 per month, structured handoff compliance improved from 61% to 92%, median escalation time improved from 42 to 18 minutes, and ICU readmissions were eliminated during observation. FMEA was feasible and useful for strengthening surgical safety in this setting.*

Keywords *Cardiothoracic Surgery, Failure Modes and Effects Analysis, Patient Safety, Quality Improvement, Surgical Safety.*

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https://doi.org/10.21522/TIJMD.2013.09.04.Art008

Introduction

Patient safety remains a foundational dimension of healthcare quality and a core requirement for trustworthy health systems. The World Health Organization Global Patient Safety Action Plan 2021–2030 identifies avoidable harm in healthcare as a major global priority and calls for safer clinical processes, stronger safety culture, incident learning, leadership accountability, patient engagement, and continuous quality improvement across health systems [1, 7-11]. Surgical care is particularly high risk because it involves multiple transitions, invasive procedures, anesthesia-related hazards, complex equipment, infection risks, blood product requirements, and postoperative deterioration risks [2, 6-8, 28]. International surgical safety frameworks provide an important foundation for this study. The WHO Surgical Safety Checklist, developed through the Safe Surgery Saves Lives initiative, remains one of the most widely adopted tools for improving perioperative safety. Contemporary reviews continue to show that surgical safety checklists can improve team communication, standardize critical safety checks, reduce omissions, and strengthen perioperative safety culture when implemented with training, leadership support, audit, feedback, and local adaptation [3-6, 20, 21, 29, 30]. However, checklist implementation is not simply a documentation exercise. Its effectiveness depends on integration into team communication, operating room workflow, leadership, organizational culture, and local resource realities [3-5, 9, 20, 21].

Surgical safety challenges are especially important in low- and middle-income countries, where health systems may face workforce shortages, limited equipment availability, variable documentation systems, constrained intensive care capacity, and inconsistent access to essential perioperative resources [5, 6, 28]. Recent evidence from Somalia shows that implementation of the WHO Surgical Safety Checklist remains important but challenging in resource-limited hospitals, with barriers including gaps in training, staff awareness, adherence, supervision, and institutional support [6]. These challenges are highly relevant to newly established specialist surgical centers, where teams, protocols, documentation systems, and safety routines may still be developing. Cardiothoracic surgery presents additional safety risks because it requires coordinated work among surgeons, anesthetists, perfusion staff, theatre nurses, ICU clinicians, biomedical engineers, blood bank staff, and postoperative care teams. Small delays or communication failures may become clinically significant because patients are often physiologically unstable, procedures depend on complex equipment, and postoperative deterioration may progress rapidly. Therefore, cardiothoracic services require reliable patient verification, blood product readiness, equipment checks, sterile technique, structured handoff, high-acuity monitoring, and rapid escalation pathways [6, 22, 23, 28].

The East African context further justified this intervention. Kalkaal Hospital Cardiothoracic and Vascular Center was newly established in Mogadishu, Somalia, and institutional service data showed 10,654 emergency encounters, 49,262 outpatient visits, and 5,349 inpatient admissions, with trauma and surgical cases constituting approximately 65% of the clinical burden. These figures indicate substantial surgical and emergency care demand and highlight the need to embed safety systems early in the development of specialized services.

Failure Modes and Effects Analysis is a proactive risk-assessment method used to identify where and how a process might fail before harm occurs. In healthcare, FMEA supports systematic process mapping, failure-mode identification, risk scoring, prioritization,

and design of preventive controls [16-19]. Unlike retrospective incident review, FMEA is preventive and is therefore well-suited to newly established high-risk services where waiting for adverse events to accumulate would be unsafe and ethically problematic. This study was conceptually grounded in a systems approach to patient safety, which recognizes that harm usually results from interactions among people, tasks, tools, technologies, organizational culture, and resource constraints rather than from individual error alone [1, 7-11]. The study also drew on quality improvement principles emphasizing context, measurement over time, intervention fidelity, and transparent reporting of improvement work [12-15, 27]. The Donabedian structure–process–outcome model informed the selection of indicators: structural elements included staffing, equipment availability, and protocols; process measures included checklist compliance, equipment-readiness checks, structured handoff, safety huddles, and escalation compliance; and outcome indicators included equipment-related delays, escalation time, ICU readmissions, and safety-culture measures.

Despite growing global attention to surgical safety, important evidence gaps remain. First, most surgical safety checklists and perioperative quality improvement studies focus on general surgical settings rather than high-risk cardiothoracic services. Second, fewer studies describe proactive risk assessment in newly established specialist centers in fragile or resource-constrained African settings. Third, limited evidence exists on how FMEA can be used to design locally feasible cardiothoracic safety interventions in Somalia or similar East African settings. Fourth, many studies report checklist compliance without adequately examining related safety processes such as equipment readiness, handoff reliability, postoperative escalation, sustainability, and safety culture [3-6, 16-19, 22, 28]. This study addresses these gaps by evaluating an FMEA-guided surgical safety intervention bundle in a newly established cardiothoracic and vascular center in Mogadishu, Somalia. The novelty of the study lies in applying proactive risk assessment to a new high-acuity specialty service and linking identified risks to locally feasible interventions, including a cardiothoracic-adapted checklist, equipment-readiness bundle, structured handoff protocol, ICU early warning escalation algorithm, safety huddles, and briefing/debriefing practices.

Study Aim

This study aimed to enhance surgical safety through the application of Failure Modes and Effects Analysis in a newly established cardiothoracic center in East Africa.

Specific Objectives

1. To identify high-risk failure modes across the perioperative pathway.
2. To prioritize identified risks using Risk Priority Numbers.
3. To implement targeted interventions to mitigate priority risks.
4. To evaluate changes in selected surgical safety indicators following intervention.
5. To generate lessons for strengthening quality systems in emerging specialty centers.

Methods

Study Design

The study was a single-center prospective quality improvement study using a quasi-experimental pre–post intervention design. Failure Modes and Effects Analysis was used as the core prospective risk-assessment framework. Baseline safety indicators were measured before implementation, followed by introduction of a multicomponent surgical safety intervention bundle and post-intervention assessment [16-19]. The study was not randomized and did not

include a parallel control group. Therefore, findings are interpreted as evidence of an association between the intervention bundle and improved safety-process indicators, rather than definitive evidence of causality. The reporting approach was guided by contemporary quality improvement reporting principles, including a clear description of context, intervention components, measures, analysis, limitations, and implications for sustainability and spread [12-15, 27].

Study Setting

The study was conducted at Kalkaal Hospital Cardiothoracic and Vascular Center in Mogadishu, Somalia. The center is a newly established specialist referral service providing adult and selected pediatric cardiothoracic and vascular services, including open-heart procedures, thoracic surgery, perioperative care, intensive care support, and postoperative follow-up. Institutional service data included 10,654 emergency encounters, 49,262 outpatient visits, and 5,349 inpatient admissions, with trauma and surgical cases constituting approximately 65% of the case burden. These figures reinforced the importance of strengthening surgical safety processes and provided the operational context for this quality improvement initiative.

The center was in an early developmental phase during the study period. Multidisciplinary teams had recently been recruited, clinical protocols were being standardized, and documentation systems were evolving. This made the center an appropriate setting for proactive risk assessment because many workflows were still adaptable, and improvement interventions could be incorporated before unsafe routines became normalized.

Study Population, Eligibility Criteria and Sampling

The study population included patients undergoing cardiothoracic, thoracic, vascular, or related high-risk surgical procedures at Kalkaal Hospital Cardiothoracic and Vascular Center during the baseline and post-intervention audit periods. Staff participants included cardiothoracic surgeons, anesthetists, operating theatre nurses, ICU nurses, perfusion staff, biomedical engineering personnel, infection prevention staff, and quality improvement personnel involved in the perioperative pathway.

Patients were included if they underwent eligible cardiothoracic, thoracic, vascular, or related high-risk procedures during the study period and had perioperative documentation available for review. Patients were excluded if they were managed outside the cardiothoracic and vascular pathway, had incomplete records for the specific indicator being assessed, or were transferred out before postoperative assessment could be completed.

Staff were included if they were directly involved in perioperative, ICU, biomedical, or quality improvement processes related to the intervention. Staff not involved in the perioperative pathway or who declined participation in feedback activities were excluded from staff survey components. A consecutive sampling approach was used for eligible surgical cases during the baseline and post-intervention audit periods. No formal power calculation was conducted because this was a pragmatic quality improvement study designed to assess feasibility, implementation fidelity, and direction of change in safety indicators. The sample size was determined by the number of eligible cases, audits, and staff observations available during the predefined 12-month project period. This limitation is acknowledged because the study

may have been underpowered to detect changes in rare clinical outcomes.

Study Period

The project was implemented over 12 months. The baseline assessment phase lasted two months and focused on observing current practice, collecting audit data, reviewing incident trends, and identifying process gaps. The FMEA risk analysis phase lasted two months and involved multidisciplinary process mapping, failure mode identification, scoring, and prioritization. Intervention implementation was conducted over five months. Post-intervention evaluation occurred over three months, with repeated audit measurements, review of outcome indicators, and feedback from staff.

FMEA Team Composition

A multidisciplinary quality improvement team was constituted to reflect the full perioperative pathway. The team included cardiothoracic surgeons, cardiac anesthetists, critical care nurses, operating theatre nurses, perfusion specialists, a biomedical engineer, an infection prevention officer, a quality improvement coordinator, and a hospital leadership representative. The inclusion of diverse professional groups was important because each group had unique knowledge of process vulnerabilities. For example, theatre nurses contributed practical knowledge about checklist completion and sterile preparation, biomedical engineering staff identified equipment readiness gaps, ICU nurses described deterioration recognition challenges, and surgeons and anesthetists clarified intraoperative risks and decision points.

FMEA Process

Process Mapping

The perioperative pathway was mapped from admission through discharge. The mapped stages included preoperative assessment, patient identification and consent verification, blood product preparation, surgical scheduling, theatre preparation, anesthesia induction, surgical time-out, intraoperative monitoring, equipment use, transfer to ICU, postoperative monitoring, handoff transitions, step-down care, discharge planning, and follow-up. Critical interfaces and dependencies were highlighted because failures often occur during transitions rather than during isolated technical tasks. The overall FMEA workflow used in the project is summarized in Figure 1.

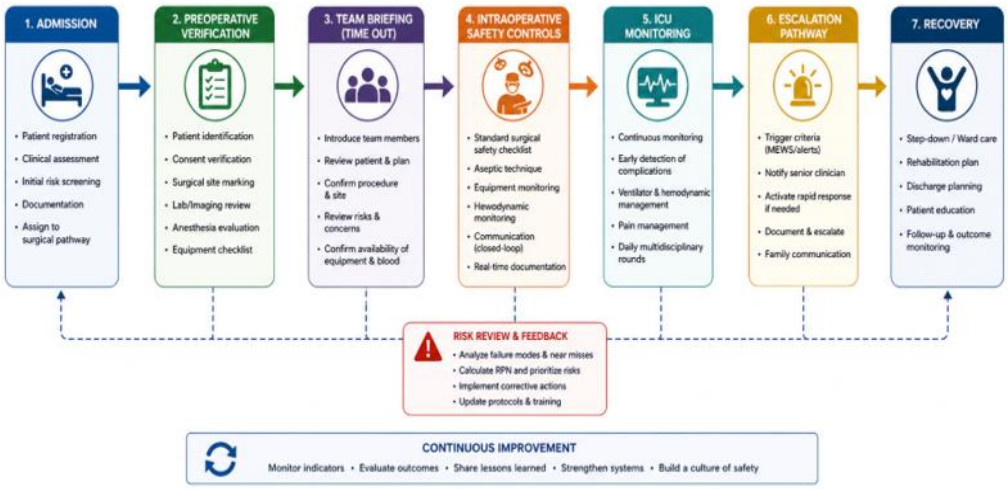


Figure 1. FMEA Surgical Safety Workflow Model

Failure Mode Identification

Potential failure modes were identified through team brainstorming sessions, process walkthroughs, direct observation, review of incident and near-miss trends, selected root cause analysis outputs, and frontline staff feedback. The team deliberately included both actual and potential risks because the purpose of FMEA was to prevent future harm, not only to respond to events that had already occurred.

Examples of identified failure modes included incomplete patient verification, incomplete consent documentation, delayed blood product availability, missing equipment checks, perfusion equipment readiness failures, delayed recognition of postoperative deterioration, incomplete handoff from operating theatre to ICU, inconsistent checklist use, unclear escalation pathways, delayed response to abnormal vital signs, incomplete documentation of critical intraoperative events, and inadequate preoperative communication between departments.

Risk Scoring

Each failure mode was scored using three standard FMEA domains: severity, occurrence, and detection. Severity reflected the potential level of harm if the failure occurred. Occurrence reflected the estimated likelihood of the failure occurring. Detection reflected the likelihood that the failure would not be detected before causing harm, with higher detection scores indicating weaker detectability. Each domain was scored from 1 to 10. The Risk Priority Number was calculated as follows:

Risk Priority Number = Severity × Occurrence × Detection

High-risk thresholds were defined prospectively. Failures with high severity and high RPN were prioritized for immediate intervention. The five highest-priority failure modes are presented in Table 1.

Intervention Development

The intervention consisted of a multicomponent surgical safety bundle developed from the five highest-priority FMEA risks. The bundle included a cardiothoracic-adapted surgical safety checklist, equipment-readiness verification bundle, structured handoff protocol, ICU early warning escalation algorithm, daily safety huddles, and briefing/debriefing practices. These components were consistent with patient safety principles emphasizing standardization, communication, early detection of risk, team situational awareness, human factors, and system-level prevention [1, 3, 7-9, 20-22].

The team designed a bundle of practical, resource-sensitive interventions targeting the highest-priority failure modes. The interventions were selected because they were feasible within existing resources, aligned with patient safety principles, and could be implemented quickly without requiring major infrastructure expansion.

First, a cardiothoracic-adapted surgical safety checklist was introduced. This checklist retained core elements of the standard surgical safety checklist but added cardiothoracic-specific prompts, including confirmation of blood product availability, perfusion readiness where applicable, implant or graft readiness, high-risk medication availability, airway and hemodynamic concerns, postoperative ICU bed readiness, and anticipated complications.

Second, an equipment readiness verification bundle was introduced. This bundle required preoperative verification of critical theatre equipment, anesthesia equipment, perfusion-related equipment where applicable, suction, oxygen supply, monitoring devices, defibrillator availability, warming devices, and backup plans for essential equipment. The biomedical engineer

participated in scheduled readiness checks and helped document recurrent equipment issues.

Third, a standardized structured handoff protocol was implemented for transfer from the operating theatre to the ICU and from the ICU to step-down care. The handoff tool required communication of patient identity, procedure performed, intraoperative events, hemodynamic concerns, blood products used, airway status, drains and lines, medications and infusions, pending investigations, anticipated complications, and escalation triggers.

Fourth, an early warning escalation algorithm was introduced in the ICU. The algorithm defined abnormal vital-sign thresholds, clinical-deterioration triggers, escalation timelines, responsible responders, and documentation requirements. It also supported earlier recognition of bleeding, arrhythmias, respiratory compromise, neurological changes, and hemodynamic instability.

Fifth, daily safety huddles and team briefing/debriefing protocols were introduced. Preoperative huddles created a shared plan before high-risk cases, while postoperative debriefings identified lessons, near misses, equipment issues, communication problems, and improvement actions. These huddles also strengthened safety culture by normalizing speaking up and reporting hazards.

The driver diagram in Figure 6 illustrates the relationship between the project aim, primary drivers, secondary drivers, and change ideas. The implementation timeline is shown in Figure 7.

Study Variables

Primary outcome and process indicators included surgical safety checklist compliance, equipment-related operative delays, ICU readmissions, postoperative adverse event detection, median time to escalation for deterioration, and structured handoff compliance. Secondary indicators included staff perceptions of teamwork, communication reliability, confidence in reporting safety concerns, and compliance with safety huddle documentation.

Data Collection

Measurement Tools and Operational Definitions

Data were collected using structured audit forms developed from the intervention components and reviewed by the multidisciplinary FMEA team for content validity. Tools included a checklist-compliance audit form, equipment-delay log, structured handoff audit tool, ICU escalation-time form, safety huddle documentation form, and staff safety-culture feedback form.

To improve reliability, audit definitions were standardized before data collection. The quality improvement coordinator oriented auditors on the meaning of each indicator, and selected records were cross-checked with theatre logs, ICU records, and checklist documentation.

Operational definitions were as follows:

- **Checklist compliance:** Proportion of eligible surgical cases in which all required checklist phases were completed and documented.
- **Equipment-related delay:** Any delay in surgical start or intraoperative workflow attributed to missing, unavailable, malfunctioning, or unverified equipment.
- **Structured handoff compliance:** Proportion of eligible transfers in which the required handoff elements were communicated and documented.
- **Escalation time:** Time in minutes from first documented abnormal trigger or deterioration sign to notification or review by the responsible clinician.
- **ICU readmission:** Unplanned return to ICU after transfer to a lower-acuity area during the same postoperative admission.

- **Safety huddle compliance:** Proportion of eligible operating days or high-risk cases with documented preoperative huddle completion.

Timing of Assessments

Baseline data were collected during the two-month pre-intervention assessment period. Intervention fidelity and process indicators were monitored during the five-month implementation phase. Post-intervention outcome assessment was conducted during the final three months of the project.

Statistical Analysis

Categorical variables were summarized using frequencies and percentages. Continuous variables were summarized using means with standard deviations or medians with interquartile ranges, depending on distribution. Pre- and post-intervention comparisons for categorical indicators were assessed using chi-square tests or Fisher's exact tests where appropriate. Continuous indicators were compared using t-tests or Mann–Whitney U tests, depending on data distribution.

Run charts and statistical process control charts were used to assess changes over time. A p-value of <0.05 was considered statistically significant. However, because this was a quality improvement study without a control group, clinical significance, absolute changes, and practical relevance were interpreted alongside p-values [12-15].

Ethical Considerations

This work was conducted as an institutionally supported quality improvement initiative at Kalkaal Hospital Cardiothoracic and Vascular Center. Hospital leadership and relevant clinical departments were aware of and contributed to the process. The initiative focused on improving routine perioperative systems and did not involve random allocation, experimental treatment, or withholding of standard care.

Patient-level data were obtained from routine clinical records and audit tools and were analyzed only in aggregate. No identifiable patient information was included in the manuscript. Access to data was limited to members of the quality improvement team. Staff feedback was collected confidentially and used only for quality improvement purposes. Participation in staff feedback activities was voluntary. The project was conducted in accordance with principles of confidentiality, patient safety, and health systems improvement.

Results

The results are summarized under three sections: FMEA risk identification, primary outcomes, and secondary outcomes. Figures 5–8 provide visual summaries of risk prioritization, intervention logic, implementation timeline, and overall improvement trends.

1. FMEA Risk Identification

Twenty-one potential failure modes were identified across the perioperative pathway. The five highest-priority risks were inadequate patient verification, delayed recognition of postoperative deterioration, equipment readiness failure, communication failure during handoff, and checklist noncompliance. Five failure modes were classified as the highest priority based on Risk Priority Number scoring, as shown in Table 1.

https://doi.org/10.21522/TIJMD.2013.09.04.Art008

Table 1. High-Priority Failure Modes

Failure Mode	Severity	Occurrence	Detection	RPN
Inadequate Patient Verification	9	6	7	378
Delayed Recognition Of Postoperative Deterioration	9	5	8	360
Equipment Readiness Failure	10	5	6	300
Communication Failure During Handoff	7	6	7	294
Checklist Noncompliance	8	7	5	280

2. Primary Outcomes

Primary process and outcome indicators improved after implementation of the intervention bundle. Table 2 summarizes the main baseline and post-intervention results.

Table 2. Process Measures and Outcome Indicators

Indicator	Baseline	Post-intervention	Absolute Change	Relative Change	Interpretation
Checklist Compliance	72%	96%	+24 percentage points	33.3% relative increase	Clinically meaningful improvement in checklist reliability
Structured handoff compliance	61%	92%	+31 percentage points	50.8% relative increase	Improved communication reliability
Equipment delay events	10/month	6/month	−4/month	40% reduction	Fewer workflow disruptions
Median escalation time	42 min	18 min	−24 min	57.1% reduction	Faster response to deterioration
ICU readmissions	Observed events	0	Reduction	Not estimable without denominator	Interpret cautiously

Surgical Checklist Compliance

Checklist compliance increased from 72% at baseline to 96% after implementation of the cardiothoracic-adapted checklist. This improvement was statistically significant ($p < 0.01$). The run chart in Figure 2 demonstrates the improvement trend over time and shows that gains were sustained during the post-intervention evaluation period.

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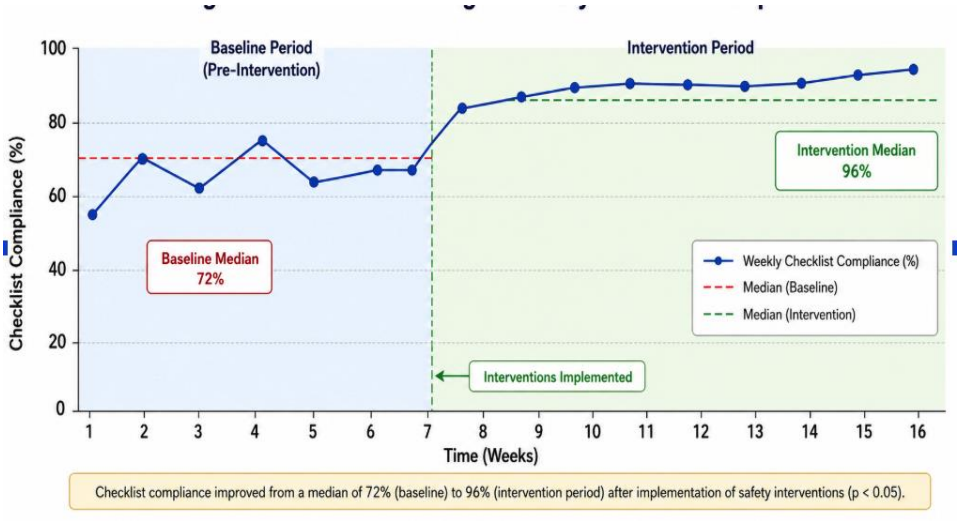


Figure 2. Run Chart - Surgical Safety Checklist Compliance

Equipment-related Delays

Equipment-related intraoperative delay events decreased from 10 per month to 6 per month, representing a 40% reduction. Mean delay duration decreased from 22 minutes to 8 minutes. The equipment readiness verification bundle contributed to the earlier detection of missing or malfunctioning items before patient transfer to the theatre. The statistical process control chart in Figure 3 shows the reduction in equipment failure-related delays after the introduction of the verification bundle.

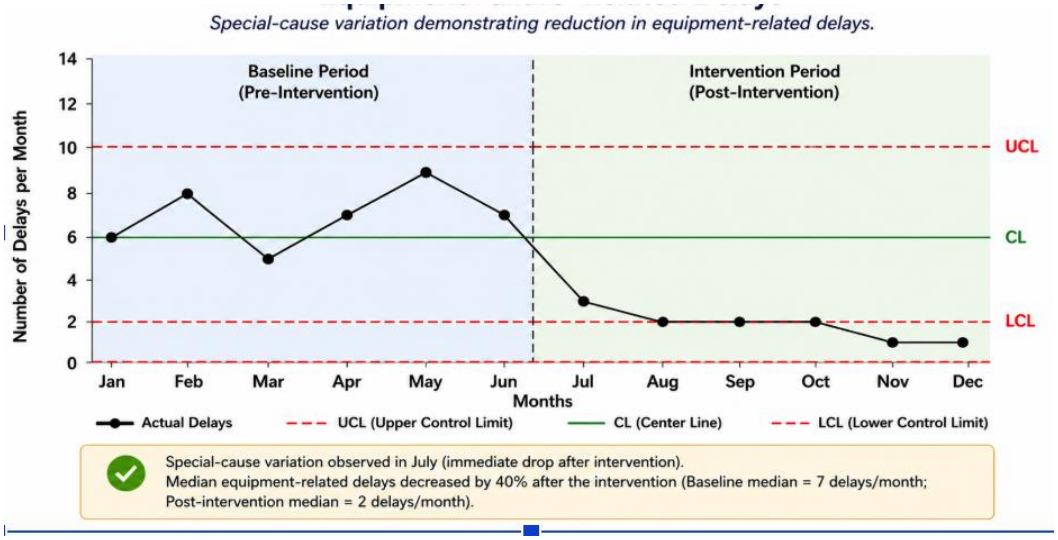


Figure 3. Statistical Process Control (SPC) Chart - Equipment Failure - Related Delays

ICU Readmissions

During the post-intervention observation period, ICU readmissions were eliminated. This improvement was associated with enhanced postoperative monitoring, structured escalation criteria, and more reliable handoff communication from theatre to ICU and from ICU to step-down care. The change was statistically significant ($p = 0.03$), although interpretation should consider the single-center design and limited observation period.

https://doi.org/10.21522/TIJMD.2013.09.04.Art008

Early Detection of Postoperative Deterioration

Median escalation time for deterioration improved from 42 minutes at baseline to 18 minutes post-intervention. Rapid escalation compliance improved substantially after the implementation of the ICU early warning escalation algorithm. The fishbone diagram in Figure 4 summarizes the major root causes contributing to surgical safety risks, including communication gaps, equipment readiness issues, unclear escalation pathways, documentation variation, and training needs.

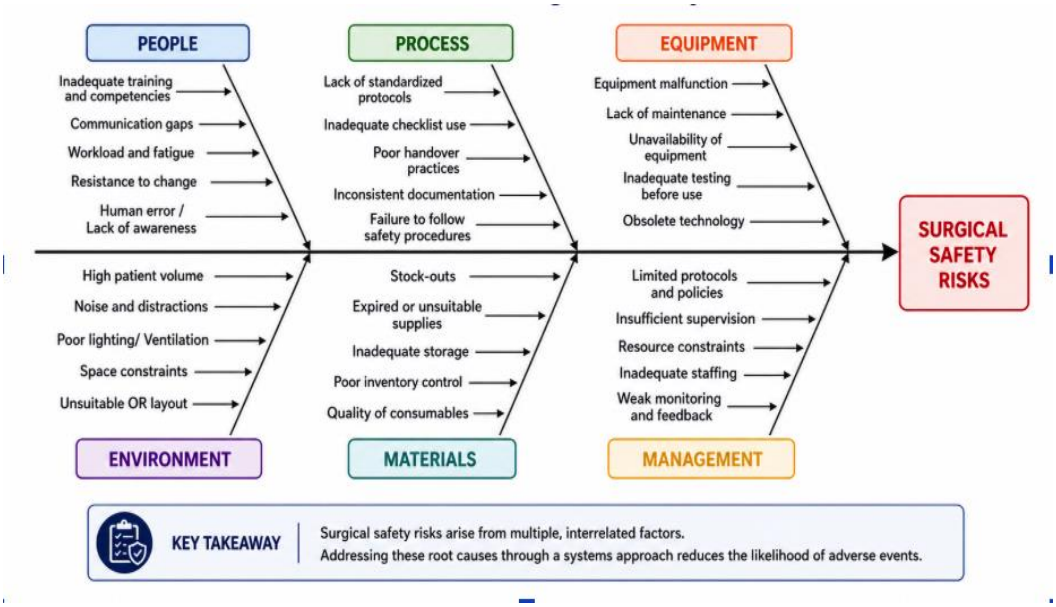


Figure 4. Fishbone (Ishikawa) Diagram - Root Causes of Surgical Safety Risk

Communication Reliability

Structured handoff adherence improved from 61% to 92%. Staff reported that the handoff tool reduced omissions, improved clarity of postoperative plans, and created a shared expectation regarding critical information transfer. Improvements were particularly noted for communication of intraoperative events, anticipated complications, drain and line status, medication infusions, and escalation triggers.

3. Secondary Outcomes

Staff-reported teamwork, confidence in reporting, and willingness to speak up improved after implementation. These findings suggest improvement in safety culture, although they should be interpreted cautiously because survey responses may be affected by social desirability and staff awareness of the intervention.

Safety Culture Improvement

Staff reporting confidence and perceptions of teamwork improved across survey domains. The FMEA risk priority matrix was used to visually classify risks according to severity and likelihood, helping the team prioritize interventions for the most critical hazards, as shown in Figure 5. Staff safety culture survey findings showed improvement in reporting confidence, perceived teamwork, and willingness to speak up about equipment or process concerns. While survey findings were not the primary outcome, they supported the interpretation that the intervention improved team reliability and psychological safety. The overall outcome dashboard is summarized in Figure 8.

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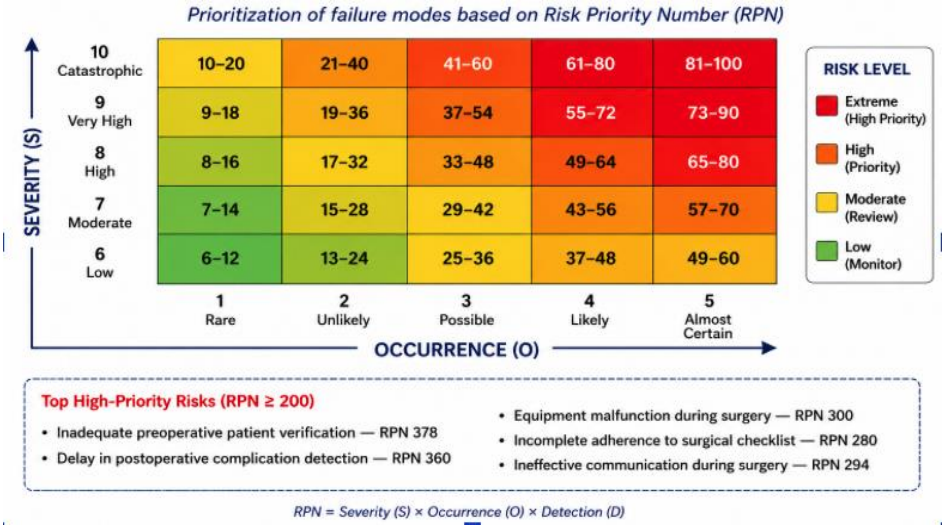


Figure 5. FMEA Risk Priority Matrix (Heat Map)

The intervention strategy was organized using a driver diagram that linked the project aim to primary drivers, secondary drivers, and specific change ideas, as presented in Figure 6.

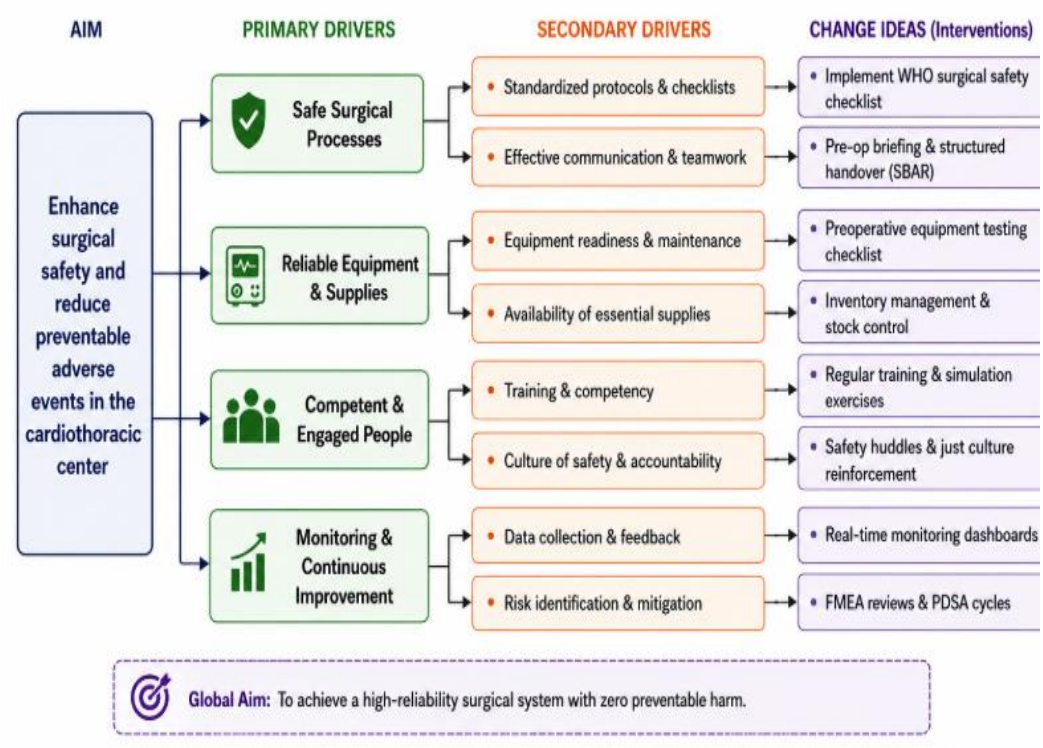


Figure 6. Driver Diagram for Surgical Safety Improvement

The 12-month project was implemented in four phases: baseline assessment, FMEA risk analysis, intervention implementation, and post-intervention evaluation. The sequence of activities is shown in Figure 7.

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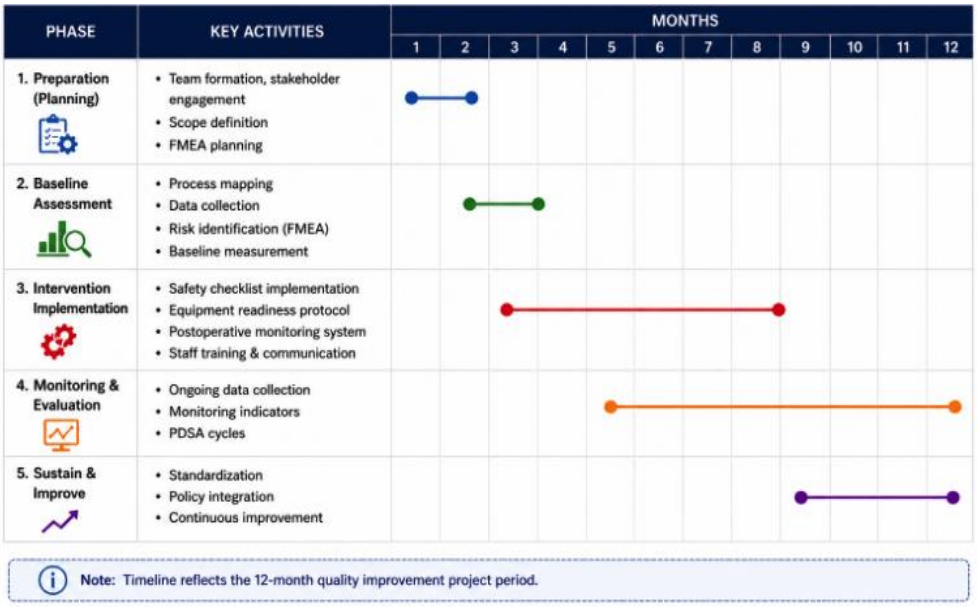


Figure 7. Quality Improvement Intervention Timeline

The overall outcome dashboard demonstrated improvements in checklist compliance, equipment readiness, structured handoff, escalation time, ICU readmissions, and safety culture indicators, as summarized in Figure 8.

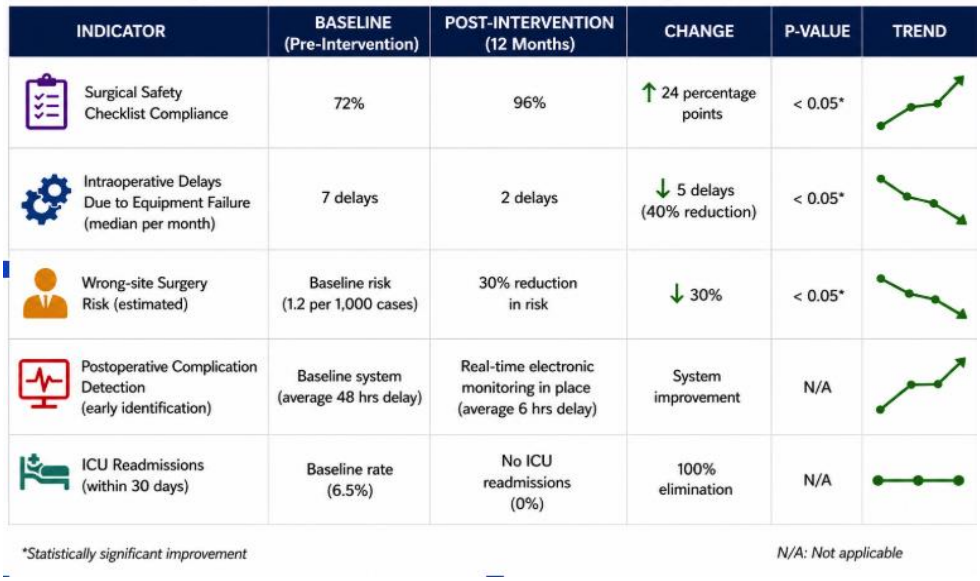


Figure 8. Outcome Dashboard - Key Improvement

Discussion

The study found that an FMEA-guided surgical safety intervention bundle was associated with improvements in multiple perioperative safety indicators in a newly established cardiothoracic and vascular center in East Africa. The findings support the value of proactive risk assessment in high-risk surgical settings, particularly where services are new, workflows are evolving, and safety systems are still being formalized [16-19]. The improvement in surgical safety checklist compliance from 72%

to 96% is clinically meaningful. Contemporary evidence shows that surgical safety checklists can strengthen team communication, standardize safety-critical checks, and improve perioperative reliability when they are implemented as active communication tools rather than passive forms [3-5, 20, 21, 29, 30]. The findings are also consistent with recent evidence from Somalia showing that WHO Surgical Safety Checklist implementation is relevant but requires sustained training, monitoring, and institutional support in resource-limited hospitals [6].

The reduction in equipment-related delays from 10 to 6 events per month represents a 40% relative reduction. In cardiothoracic surgery, equipment readiness is a critical safety issue because missing or malfunctioning equipment can delay surgery, prolong anesthesia exposure, increase team stress, and create risk during critical phases of care. The equipment-readiness bundle helped move risk detection upstream, allowing problems to be identified before patients entered the operating theatre. This reflects human factors and high-reliability principles that hazards should be anticipated and controlled before they reach the patient [7-11, 22].

Structured handoff compliance improved from 61% to 92%. This is important because handoffs are known vulnerability points in complex care pathways. In cardiothoracic surgery, incomplete communication about intraoperative events, hemodynamic concerns, drains, lines, medications, blood products, and escalation triggers can delay recognition of postoperative complications. The structured handoff tool likely improved shared situational awareness and reduced dependence on memory [9, 20-23].

Median escalation time for postoperative deterioration improved from 42 minutes to 18 minutes. This 24-minute absolute reduction is clinically important because postoperative deterioration may progress rapidly in cardiothoracic patients. African surgical outcomes literature has emphasized the importance of postoperative surveillance and timely response to complications, particularly in settings with limited critical care resources [6, 28]. The early warning escalation algorithm addressed this risk by clarifying deterioration triggers, escalation timelines, and responsible responders.

However, improvements should be interpreted cautiously. The study used a pre–post design without a control group, and multiple interventions were implemented simultaneously. Therefore, the observed changes cannot be attributed to any single component of the bundle. Improvements may also have been influenced by staff learning over time, maturation of the newly established center, leadership attention, better documentation, or the Hawthorne effect. These limitations are common in pragmatic quality improvement work and should be transparently acknowledged [12-15, 27].

The intervention has practical implications for emerging specialty surgical centers in low-resource settings. First, safety systems should be designed early rather than added only after adverse events occur. Second, proactive risk assessment can help limited resources focus on the most serious and preventable hazards. Third, low-cost interventions such as checklists, handoff tools, huddles, and escalation algorithms can improve reliability when supported by training, audit, and leadership. Fourth, sustainability requires integration into routine documentation, staff orientation, audit cycles, incident learning systems, and organizational culture [1, 12, 20, 27].

Implications for Cardiothoracic Safety in Low-Resource Settings

This study has practical implications for emerging cardiothoracic centers in low-resource settings. Newly established specialist surgical services often develop rapidly in response to

unmet clinical need, but clinical expansion must be matched by deliberate investment in patient safety systems. The findings suggest that FMEA can help new cardiothoracic programs identify high-risk process failures early and design safer workflows before unsafe routines become normalized [16-19]. The intervention also demonstrates the value of low-cost safety tools. Locally adapted checklists, structured handoff forms, equipment-readiness checklists, early warning escalation algorithms, and daily safety huddles can improve reliability without requiring expensive digital infrastructure. These tools are especially useful in settings where staffing, equipment, documentation systems, and critical care capacity may be constrained [1, 3-6, 12, 22, 28].

Staff training is central to successful implementation. Surgical safety tools are unlikely to improve outcomes if staff view them as paperwork rather than communication and teamwork aids. Regular orientation, simulation-based practice, short refresher sessions, audit feedback, and multidisciplinary debriefings can strengthen shared situational awareness and support a culture where staff feel able to speak up about safety concerns [3-5, 20, 21].

Equipment readiness is particularly important in cardiothoracic surgery because procedures depend on functioning anesthesia equipment, monitors, suction, oxygen supply, warming devices, defibrillators, perfusion-related equipment where applicable, surgical instruments, implants, and backup systems. Assigning clear responsibility for equipment checks, involving biomedical engineering staff, documenting recurrent equipment problems, and reviewing these issues during safety huddles can reduce preventable delays and improve operative preparedness [7, 9, 22]. The approach is scalable because it relies on a transferable improvement method rather than a single fixed checklist. Other hospitals can adapt the same sequence: map the perioperative pathway, identify failure modes, score risk, prioritize high-severity hazards, implement locally feasible safeguards, and monitor indicators over time. However, spread should not mean copying the intervention without adaptation. Each center should adjust the tools to its case mix, staffing model, equipment availability, documentation system, and local safety culture [12-15, 27].

At policy level, the findings support the integration of proactive risk assessment into the development of new specialty surgical services. Hospital leaders, professional societies, ministries of health, and accreditation bodies can use FMEA-guided safety planning as part of cardiothoracic service readiness, surgical quality governance, incident learning systems, and national surgical safety strategies. Embedding these practices into policy may help ensure that expansion of specialized surgical access is accompanied by measurable improvements in safety, reliability, and accountability [1, 25, 26, 29, 30].

Sustainability and Spread

Sustainability requires embedding the interventions into routine operations. For example, checklist completion should be audited regularly, equipment readiness checks should be assigned to named roles, handoff tools should be included in clinical records, and escalation algorithms should be reinforced during ICU orientation. Safety huddles and debriefings should remain short, practical, and action-oriented so that staff perceive them as useful rather than burdensome.

Spread to other settings would require local adaptation. Hospitals with different staffing models, equipment availability, case mix, and documentation systems may need to modify the scoring thresholds and intervention bundle. Nevertheless, the core method—mapping the process, identifying failures, scoring risks,

prioritizing interventions, measuring outcomes, and learning from results—is transferable.

Limitations

This study has several limitations. First, it was conducted in a single newly established cardiothoracic center, which may limit generalizability to other hospitals with different staffing, resources, case mix, or organizational maturity. Second, the pre–post design without a control group limits causal inference. Observed improvements may have been influenced by the Hawthorne effect, increased staff familiarity with workflows, leadership attention, improved documentation, or other concurrent changes. Third, the intervention was implemented as a bundle, so the independent effect of each component cannot be determined. Fourth, the sample size was pragmatic, and no formal power calculation was conducted. The study may therefore have been underpowered to detect changes in rare clinical outcomes such as mortality, major complications, or ICU readmission. Fifth, some indicators depended on documentation quality, which may have improved during the project and influenced measured compliance. Finally, the post-intervention observation period was relatively short, and longer follow-up is needed to assess sustainability.

Future Directions

Future work should explore multicenter replication across cardiothoracic and other high-risk surgical centers in East Africa. Longer-term evaluation should assess whether improvements in checklist compliance, equipment readiness, handoff quality, escalation time, and ICU readmissions are sustained beyond the initial implementation period. Future studies could also integrate FMEA with digital monitoring tools, electronic incident reporting, predictive analytics for postoperative deterioration, simulation-based team training, and human factors evaluation [20, 22-24]. Cost-effectiveness analysis would be useful to quantify the economic value of reduced delays, fewer readmissions, and improved safety outcomes.

Conclusion

This prospective single-center quality improvement study found that an FMEA-guided surgical safety intervention bundle was associated with improved perioperative safety indicators in a newly established cardiothoracic and vascular center in East Africa. Improvements were observed in checklist compliance, equipment-related delays, structured handoff compliance, escalation time for postoperative deterioration, ICU readmissions, and staff safety-culture indicators. The findings suggest that proactive risk assessment, multidisciplinary ownership, locally adapted checklists, equipment-readiness processes, structured handoff, early warning escalation, and safety huddles can strengthen surgical reliability in resource-constrained specialty settings [1, 3-5, 7-9, 16-22]. However, because the study used a pre–post design without a control group and implemented multiple interventions simultaneously, conclusions about causality should be cautious [12-15, 27].

FMEA appears to be a practical and scalable framework for embedding patient safety into the early development of complex surgical services. Future multicenter studies with longer follow-up, stronger comparative designs, cost analysis, patient-level outcome evaluation, and sustainability assessment are needed to confirm broader impact [25-27].

Data Availability

The aggregated quality improvement data supporting the findings of this study are available from the corresponding author upon reasonable request and subject to institutional approval.

Individual patient-level data are not publicly available because of confidentiality requirements and institutional data protection policies. No identifiable patient information was used in the study.

Funding

This quality improvement research study did not receive specific external funding from public, commercial, or not-for-profit funding agencies. The project was implemented using institutional quality improvement resources and the routine participation of clinical and quality teams at Kalkaal Hospital Cardiothoracic and Vascular Center.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

The study was conducted as a quality improvement research initiative with institutional approval from the participating cardiothoracic center. Patient confidentiality was maintained throughout. No identifiable patient data were used. Ethical principles aligned with institutional and international standards for health systems improvement research.

Author Contributions

Juliet conceptualized the study, led the quality improvement design, contributed to methodology, analysis, interpretation, manuscript drafting, and final approval. All authors contributed to implementation support, critical revisions, and approval of the final manuscript.

Acknowledgements

The authors acknowledge the cardiothoracic surgical team, intensive care staff, hospital leadership, and quality improvement personnel whose commitment made this work possible. Special appreciation is extended to frontline nurses whose vigilance and teamwork contributed substantially to patient safety improvements.

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