

## Quality in Practice

# Engaging staff to improve quality and safety in an austere medical environment: a case–control study in two Sierra Leonean hospitals

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## Abstract

**Quality problem or issue:** Inadequate observance of basic processes in patient care such as patient monitoring and documentation practices are potential impediments to the timely diagnoses and management of patients. These gaps exist in low resource settings such as Sierra Leone and can be attributed to a myriad of factors such as workforce and technology deficiencies.

**Initial assessment:** In the study site, only 12.4% of four critical vital signs were documented in the pre-intervention period.

**Choice of solution:** Implement a failure mode and effects analysis (FMEA) to improve documentation of four patient vital signs: temperature, blood pressure, pulse rate and respiratory rate.

**Implementation:** FMEA was implemented among a subpopulation of health workers who are involved in monitoring and documenting patient vital signs. Pre- and post-FMEA monitoring and documentation practice were compared with a control site.

**Evaluation:** Participants identified a four-step process to monitoring and documenting vital signs, three categories of failure modes and four potential solutions. Based on 2100 patient days of documentation compliance data from 147 patients between July and November 2012, staff members at the study site were 1.79 times more likely to document all four patient vital signs in the post-implementation period (95% CI [1.35, 2.38]).

**Lessons learned:** FMEA is a feasible and effective strategy for improving quality and safety in an austere medical environment. Documentation compliance improved at the intervention facility. To evaluate the scalability and sustainability of this approach, programs targeting the development of these types of process improvement skills in local staff should be evaluated.

**Key words:** quality improvement, quality management, experimental research, general methodology, qualitative methods, organization science, health-care system, human factors, patient safety, practice variations, appropriate health care, developing countries, specific populations, hospital care, setting of care

Introduction

Background and rationale

Patients in developing countries face not only disparities in access [1–3] to health care but dramatic differences in the quality and safety of the care compared with those in developed countries [4–8]. Many factors contribute to the deficit in quality and safety including the lack of technology designed to function in low resource environments [9–11], differences in financial structures and supply chain management [12], and workforce issues and human resource practices [13, 14]. Cost-effective strategies to engage staff in quality improvement efforts are consistently identified as a critical gap [15]. In developed countries, effective safety and quality improvement strategies frequently (i) make use of frontline provider insights into work system strengths and vulnerabilities; (ii) leverage their expertise in the development of work process changes and (iii) build ownership of the problems and solutions to ensure that performance improves and implemented changes to work practices are sustained [16–18]. Low resource settings likely require similar approaches for engaging and empowering staff to address their own performance deficits. Indeed, reverse innovation suggests that solutions to care delivery challenges in low resource settings can inform practice in the developed world resources are increasingly constrained [19–21].

Objectives

This study aims to evaluate the feasibility and effectiveness of a systems-based methodology for engaging frontline staff in safety and quality improvement within an austere medical environment. This approach, failure mode and effects analysis (FMEA), originated in the aviation industry, but it has been widely applied in health care as a prospective risk analysis and mitigation process [22]. Recent research demonstrates the utility of FMEA when new technology is introduced into austere medical environments [23, 24], but its

empirical impact on quality of care has yet to be evaluated. To that end, we address two main goals relative to a basic process of care—monitoring and documentation of vitals. Specifically, we (i) qualitatively assess the feasibility of FMEA as a safety and quality improvement intervention in an austere environment and (ii) empirically evaluate the impact of FMEA on overall documentation compliance.

Methods

The Institutional Review Boards of the Johns Hopkins University School of Medicine and the Sierra Leone Ethics and Scientific Review Committee approved this study. Sites were part of a larger study assessing the impact of new anesthesia machines on patient outcomes. Through this study’s data collection efforts, it became clear that one of the study sites had very poor patient monitoring and documentation practices. In collaboration with facility leaders, the research team conducted FMEA as a quality improvement project selecting the lower performing facility as the case and the higher performing unit as the control facility.

Study design

This study used a concurrent case–control design. We collected measurements pre- and post-FMEA implementation in the surgical (pre- and post-operative) wards. As FMEA is an organizational intervention, facilities served as the case and control. The control facility received no intervention.

FMEA procedure

Table 1 illustrates the steps of the FMEA process commonly applied in health care, as well as adaptations of these steps for this study. FMEA is a prospective risk analysis approach used to identify, define and mitigate existing and potential system errors or breakdowns [25].

Table 1 Overview of FMEA process

General FMEA step	Application in current project
Define the goals and form a team	The goal of the session was to identify any breakdowns in patient monitoring and documentation processes and to develop strategies for mitigating those risks. The team was composed of Sierra Leonean ward nurses and nurses in training, a human factors professional and two physicians with public health backgrounds.
Conduct a task analysis	The task analysis was performed as a part of the session.
Brainstorm potential failure modes	The group reviewed the processes outlined, and participants were prompted to identify failure modes by asking questions such as: What makes performing this step difficult or impossible? Why would things happen differently from what we have outlined here?
List potential effects of each failure mode	Consequences of failure modes were discussed, but many were immediately apparent to the entire team given the relatively simple processes identified.
Assign severity, occurrence and detectability ratings; derive risk index	Risks were rated qualitatively (e.g. does this happen frequently or infrequently?). A formal risk index was not calculated, because the intent was to target a relatively simple process and explore it in detail.
Prioritize the risks	Defining a relatively constrained process at the beginning allowed the group to address all of the risks identified in the session.
Brainstorm actions to eliminate risks	Session facilitators prompted participants to think about solutions to the risks identified, whether or not they had direct control over the primary causal factors.
Assign effectiveness ratings	Feasibility and effectiveness of proposed solutions are rated by participants on a three-point scale. Feasibility was rated with an emphasis on controllability (which factors that were locally controllable and which were under less direct control of local staff?).
Revise risk priorities	This step of a traditional FMEA was not carried out, because a formal risk index was not calculated initially.
Implement changes	The research team reported the results of the FMEA session as well as documentation compliance rates to the intervention facility’s leadership after the session was concluded.

General FMEA steps are adapted from DeRosier *et al.* [15].

It can be implemented as a part of continuous learning and improvement, as a means to generate design and system requirements or as a component of implementing a variety of system changes (e.g. changes in workflows, introduction of new devices [23, 24]).

We conducted the FMEA session in a conference room at the participants' facility. Each participant read and signed an informed consent form, and then listened to a short presentation, which covered the importance of global standards for patient monitoring and documentation [26], as well as an introduction to the purpose and process of FMEA. Following this overview, the group engaged in a structured, facilitated discussion focusing on three core objectives: (i) defining the steps of the monitoring and documentation process in their area; (ii) identifying and rating the frequency and criticality of failure modes in that process and (iii) generating strategies for addressing these failure modes and then rating the feasibility/controllability and efficacy of proposed solutions. A human factors professional with patient safety experience (M.R.) facilitated the 2-h session. Project team members (A.C., M.M.) reported results of the session and pre-implementation period documentation compliance rates to the intervention site leadership shortly after the session concluded.

### Setting

We collected data in two tertiary care government hospitals in Freetown, Sierra Leone. Princess Christian Maternity Hospital (PCMH) is a 145-bedded tertiary government hospital providing obstetric and gynecological care and located in the Eastern area of the Freetown metropolis. Connaught Hospital, also located in Freetown, is the largest tertiary care hospital in the country. It is a 275-bedded hospital and provides tertiary-level surgical (adult and pediatric) and medical services (except pediatric and maternal health related).

### Participants

Participants in the FMEA session included 11 ward nurses from 6 peri-operative wards at the intervention site hospital. Eight were trained nurses, two were nurses in training and one was a trained nurse in a designated leadership role. These nurses are responsible for the care of surgical patients receiving non-invasive management and being prepared for surgery or receiving post-operative management.

### Variables

This study draws from two data sources: qualitative data from the FMEA session, and monitoring and documentation compliance rates extracted from patient charts.

First, study team members (A.C., M.M.) took notes during the FMEA session and augmented those notes with information obtained from audio recordings of the session. Additionally, the group created visual diagrams of processes, lists of failure modes and potential solutions throughout the sessions. Participants rated the frequency, severity/criticality of failure modes, and the feasibility/controllability and efficacy of solutions on a three-point scale: low, moderate and high.

Second, we collected four variables from patients' charts that demonstrate compliance with patient monitoring and documentation: temperature, blood pressure, pulse and respiration rate. Research coordinators (A.C., M.M.) visited each unit in each facility on alternate days, reviewed the patient charts for all admitted patients since the last review and documented whether or not there was at least one measurement of each of the four patient vital signs for each patient hospital day. We aggregated these four separate measures of documentation compliance into a dichotomous overall documentation compliance measure for each patient day. Overall documentation compliance

was assigned a value of 'one' when all four measures were present, and 'zero' when at least one vital sign was missing from the patient record for a given day. To truly impact patient care, vitals should be documented at frequencies greater than once per day. However, practices in participating facilities were far from standards and a metric of documenting vitals at least once per day provided a meaningful improvement target.

### Study size

We collected data in two hospitals comprising a total of 18 wards (six in the control site and 12 in the intervention site).

### Statistical methods

We use logistic regression to examine differences in overall documentation compliance rates per patient day for pre- and post-implementation time periods at both the intervention and control hospitals. Specifically, we use a stepwise approach where Model 1 regresses facility (intervention, control) onto overall documentation compliance; Model 2 adds time period (pre- and post-implementation) and Model 3 adds an interaction term for facility and time period. A significant interaction between facility and time period, as well as an odds ratio of documentation compliance significantly  $<1$  when comparing the post- to pre-implementation periods at the intervention site, will be taken as evidence of the efficacy of the FMEA intervention.

## Results

### Qualitative data

We summarize results below for the process mapping, failure mode identification and solution generation.

#### Process description for monitoring and recoding patient vitals

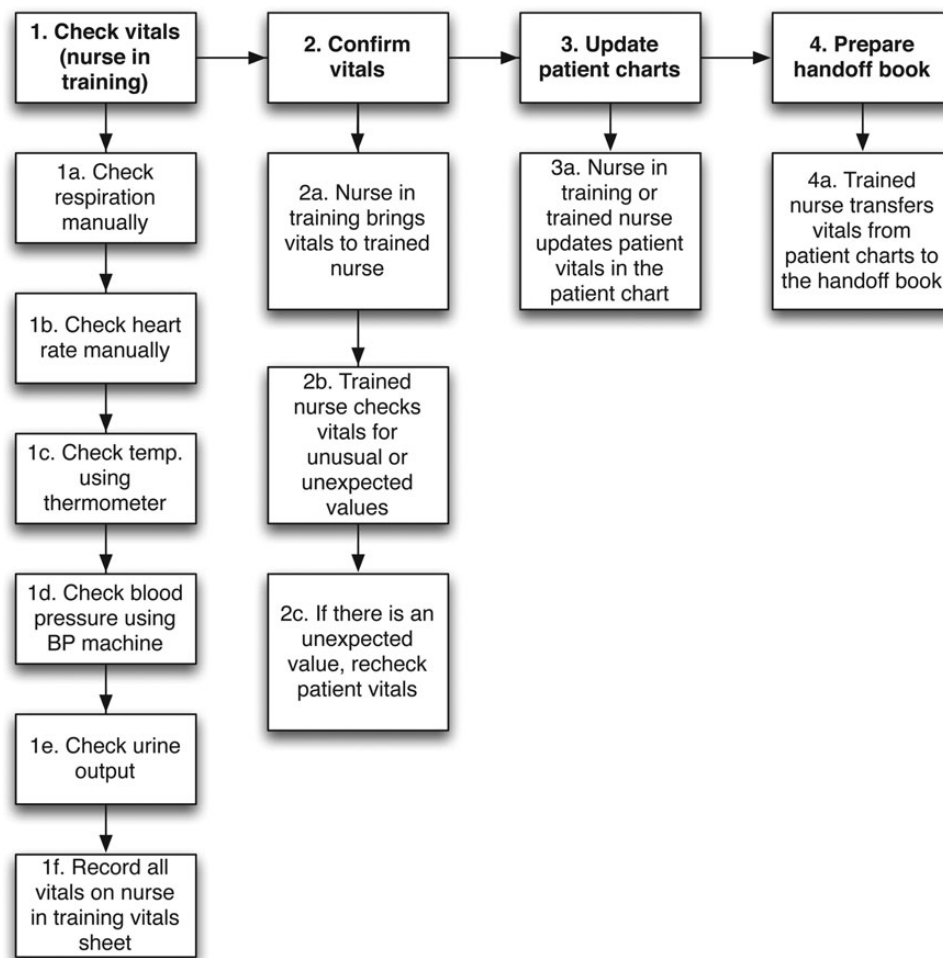
Figure 1 illustrates four main steps identified by participants in their patient monitoring and documentation processes. First, nurses in training check vitals for all patients on the wards and record this information on a single sheet of paper, which they present to a trained nurse. Second, the trained nurses confirm that the vitals were taken appropriately (i.e. the values do not fall outside of an expected range) and repeat measurement of any unusual vital signs. Third, either the trained nurse or nurse in training transcribes the patient data from the single sheet of paper to each patient's medical ward record. Fourth, at the end of the shift, nurses transcribe vitals from each patient's medical record into a handoff log—a summary of all patients on the ward used to communicate between nursing shifts.

#### Failure modes identified

Table 2 details the four types of failure modes identified by participants along with the mode's frequency and criticality ratings. The first three involve collecting data and the fourth involves recording data.

First, a combination of inadequate or improperly trained staffing and lack of role definitions adversely influences all monitoring and documentation process steps. Nurses in training typically collect patient vitals (Step 1), but not all units have nurses in training. Trained nurses viewed the collection of patient vital signs solely as the responsibility of nurses in training; therefore, in their absence, patient vital signs were not collected reliably.

Second, key equipment failures (i.e. blood pressure machine, thermometers) prohibited the collection of certain vital signs.



**Figure 1** Ward monitoring process as defined by staff in Sierra Leone.

Third, technical skill deficits with nurses in training prevent completion or accurate patient monitoring. For example, patients with irregular heartbeats, a relatively infrequent problem, but one with potentially critical implications, were the most likely to have errors or omissions in their documented vitals. Yet accurate monitoring and documentation most impacted the quality of their care.

Fourth, appropriately collected vital signs may be omitted from the patient's medical record at two points. Trained nurses may fail to transfer vitals into the patient charts from the single sheet of paper for various reasons. The chart may be perceived as a physicians' tool that has little value for nurses. Trained nurses have competing priorities, significant workload and must manage staffing shortages. Additionally, trained nurses may skip directly to Step 4 of the process—entering vitals directly into the handoff book without first entering them into the patient charts.

The handoff book should summarize all nursing-related patient information on the ward, and nurses refer to it frequently. According to the current process, patient vital signs should be transcribed from the individual charts to the handoff book so that there is both a permanent record for each patient as well as a user friendly resource for nurses to refer to during their shift and at shift changes. However, as trained nurses do not typically use the patient charts in their work processes, entering vitals here can be easily omitted.

### Solutions generated

Table 3 details solutions generated and feasibility and effectiveness ratings for the priority failure modes. Participants generated two core strategies to address issues of staffing, role definitions and performance expectations (failure modes occurring in Steps 1, 3 and 4). They proposed that the matron of the hospital issue a memo, which would establish a policy that set expectations for staff regarding the value of patient monitoring and documentation. Staff believed this would be highly effective, because the matron is a strong authority figure and staff members have been responsive to memos from the hospital matron for other issues in the past. This was rated as highly feasible and something within the control of local hospital staff.

Additionally, participants developed an explicit delegation process whereby a single trained nurse would be responsible for recording patient vitals into patient charts and the handoff book. This role would rotate among the trained nurses daily to avoid overburdening any one nurse. This solution was also rated as highly effective and highly feasible, and within the control of local staff.

To address skill deficits, primarily for nurses in training (failure modes in Steps 1c and d), the group agreed that additional skill tutorials for nurses in training were needed, but that this solution would only be moderately effective and moderately feasible because of the difficulty in scheduling training, as well as the frequent turnover in nurses in training rotating through the wards.

**Table 2** Failure modes identified

Step	Failure mode	Ratings	
		Frequency	Criticality
Step 1: Check vitals	<i>Staffing/role definitions and expectations</i> (applies to all substeps) • No nurse in training available on the unit; trained nurses are either too busy or do not see monitoring and documentation as a part of their role	Moderate	High
Step 1a: Check respiration manually	<i>Technical skill deficiency</i> • Nurse in training cannot check vitals appropriately	Low	Moderate
Step 1b: Check heart rate manually	<i>Technical skill deficiency</i> • Nurse in training cannot check vitals appropriately	Moderate	Moderate
Step 1c: Check temperature using thermometer	<i>Technical skill deficiency</i> • Nurse in training cannot check vitals appropriately	Low	Moderate
	<i>Equipment failure</i> • Thermometer is not available	Moderate	High
Step 1d: Check blood pressure using a blood pressure machine	<i>Technical skill deficiency</i> • Nurse in training cannot check vitals appropriately	Moderate	Moderate
	<i>Equipment failure</i> • Blood pressure machine is not available	High	High
Step 1e: Check urine output (if needed)	<i>Technical skill deficiency</i> • Nurse in training cannot check vitals appropriately	Moderate	Moderate
Step 1f: Record all vitals on nurse in training vitals sheet	<i>Omission</i> • Nurse in training fails to document vitals in patient chart due to staffing, workload, role definition or performance expectations	High	High
Step 2: Confirm vitals			
Step 2a: Nurse in training brings vitals to trained nurse	<i>Workload and task prioritization</i> • Trained nurse fails to record vitals in the handoff book	High	Moderate
Step 2b: Trained nurse checks vitals for unusual or unexpected values	<i>Workload and task prioritization</i> • Trained nurse fails to record vitals in the handoff book	Low	High
Step 2c: If there is an unexpected value, trained nurse and nurse in training recheck patient vitals	<i>Technical skill deficit/misinterpretation of vitals</i> • Trained nurse does not interpret vitals appropriately due to either a skill deficit or because vitals are being viewed for one time period only, not as trends over time	Low	High
Step 3: Update patient charts	<i>Workload and task prioritization</i> • Trained nurse fails to record vitals in the handoff book	High	High
	<i>Ambiguous roles</i> • Variability in who transfers vitals from the vitals sheet to the patient chart (trained nurse or nurse in training) can lead to no one entering data	High	Moderate
Step 4: Prepare handoff book	<i>Workload and task prioritization</i> • Trained nurse fails to record vitals in the handoff book	High	Moderate

To address shortages in required equipment and supplies needed to obtain patient vital signs (Steps 1c and d), staff proposed advocating to external entities for specific needs (i.e. blood pressure machines, thermometers) and rated this solution as highly effective, but with low feasibility or control by local staff.

### Outcome data

From 5th June to 5th September 2012, we collected monitoring compliance data for 228 patients, representing a total of 2100 patient days. The baseline data collection period consisted of the 9 days preceding the FMEA session (4th July) and post-intervention data collection continued for 63 days after the session. Data were collected from 147

patients at the intervention site (65 from the pre- and 82 from the post-implementation periods), and 81 at the control site (30 from the pre- and 51 from the post-implementation periods). Hospital length of stay ranged from 1 to 30 days across sites and time periods.

### Primary results

We present the primary logistic regression results conducted with SPSS version 21 in Table 4. Three models are presented, each with the dependent variable of overall documentation compliance.

Model 1 includes the independent variable of facility ('zero' for the control facility and 'one' for intervention facility). This model was significant, as determined by the model  $\chi^2$  statistic of 366.94

**Table 3** Solutions proposed for identified failure modes

Failure modes	Solutions	Ratings	
		Feasibility/ Controllability	Effectiveness
Staffing, ambiguous roles, performance expectations, omissions	Policy: Memo from hospital matron reinforcing the importance of patient monitoring and recording, establishing adherence to monitoring and documentation standards as a priority for the organization.	High	High <sup>a</sup>
Steps 1, 3 and 4	Role clarification/work process: Explicit delegation of patient monitoring task each day among the nursing staff. Responsibilities would include checking patient charts to ensure that all necessary data have been entered and following up to correct any omissions. The role should rotate every day to ensure it does not overburden any one provider.	High	High
Technical skill deficit Steps 1a–e	Training: More tutorials for nurses in training on obtaining and recording vitals.	Moderate	Moderate
Equipment failure Steps 1c and d	Advocate: Request external support (NGOs, medical missions) for key supplies and equipment needed to adhere to monitoring standards.	Low	High
	Advocate: Request specific types of equipment that are more durable.	Low	High

<sup>a</sup>This solution was rated as highly effective if it were to be a repeated semi-annual reinforcement of policy.

**Table 4** Change in overall documentation compliance at the study sites pre- and post-FMEA implementation

	Model 1			Model 2			Model 3		
	Odds ratio	95% CI for odds ratio		Odds ratio	95% CI for odds ratio		Odds ratio	95% CI for odds ratio	
		Lower	Upper		Lower	Upper		Lower	Upper
Constant	1.57	–	–	1.78	–	–	5.15	–	–
Facility	0.130	0.105	0.162	0.128	0.103	0.159	0.028	0.018	0.043
Time period				0.823	0.665	1.02	0.180	0.118	0.277
Facility × Time							9.944	5.954	16.609
Block $\chi^2$ [df]		366.94 [1]			3.18 [1]			87.70 [1]	

For the facility variable, the referent case is the control site (0 = control; 1 = intervention); for the time period variable, pre-implementation is the referent category (0 = pre-implementation; 1 = post-implementation); the dependent variable is overall documentation compliance per patient day which is equal to one when all of the four vital signs (temperature, blood pressure, pulse rate and respiratory rate) were present in a patient's chart for a given day.

(df = 1). The odds ratio for the facility variable indicated that patients at the intervention facility were 0.130 times less likely to have overall documentation compliance than patients at the control facility (95% CI [0.105, 0.162]).

Model 2 added the time period variable ('zero' for the pre-FMEA and 'one' for post-FMEA). The block  $\chi^2$  statistic was significant (3.18, df = 1).

Model 3 added an interaction term for facility and time period. The block  $\chi^2$  statistic was significant (87.70, df = 1), as was the coefficient for the interaction term (Wald  $\chi^2$  = 77.022). The Model 3  $\chi^2$  statistic (457.81, df = 3) indicate good model fit and superiority over Models 1 and 2.

To further explain the interaction between the facility and time, Table 5 details logistic regression results for overall documentation compliance in the pre- and post-implementation periods for each facility independently. At the intervention site, staff members were 1.79 times more likely to document all four patient vitals after FMEA implementation than before (95% CI [1.35, 2.38]). However, staff members were 0.180 times less likely to document all four patient vitals in the post-implementation time period for patients at the control facility (95% CI [0.118, 0.277]).

**Table 5** Overall documentation compliance

	Intervention	Control
Pre-implementation	81/651 (12.4%)	170/203 (83.7%)
Post-implementation	181/891 (20.3%)	171/355 (48.2%)
Change	7.9%	–35.5%
Odds ratio	1.79*	0.180*
95% CI for odds ratio	[1.35, 2.38]	[0.118, 0.277]

Number of patient days with all four vitals documented/number of patient days (percentage of patient days with all four vitals documented).

\* $P < 0.001$ .

### Other analyses

Table 6 provides *post hoc* logistic regression analyses of pre- and post-implementation changes in documentation compliance for each individual vital sign at the treatment and control facilities. The odds that staff would document a patient's vital signs increased significantly for all four vital signs at the intervention facility (temperature OR = 2.16; blood pressure OR = 1.75; pulse rate OR = 2.15; respiratory rate



**Table 6** Changes in individual vital sign documentation compliance at intervention and control sites

	Temperature		Blood pressure		Pulse rate		Respiratory rate	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Pre-implementation	145/651 (22.3%)	183/203 (90.1%)	114/651 (17.5%)	172/203 (84.7%)	173/651 (26.6%)	184/203 (90.6%)	168/651 (25.8%)	184/203 (90.6%)
Post-implementation	341/891 (38.3%)	285/355 (80.3%)	241/891 (27.0%)	171/355 (48.2%)	390/891 (43.8%)	283/355 (79.7%)	384/891 (43.1%)	283/355 (79.7%)
Change	16%	−9.8%	9.5%	−36.5%	17.2%	−10.9%	17.3%	−10.9%
Odds ratio	2.16**	0.445*	1.75**	0.167**	2.15**	0.406*	2.18**	0.406*
95% CI for odds ratio	[1.72, 2.72]	[0.262, 0.756]	[1.36, 2.24]	[0.108, 0.259]	[1.73, 2.68]	[0.237, 0.695]	[1.75, 2.71]	[0.237, 0.695]

Number of patient days with vital documented/number of patient days (percentage of patient days with all vital documented).

\* $P < 0.01$ .

\*\* $P < 0.001$ .

OR = 2.18) and decreased at the control facility (temperature OR = 0.445; blood pressure OR = 0.167; pulse rate OR = 0.406; respiratory rate OR = 0.406).

## Discussion

### Key results

In line with calls for an increased emphasis on implementation research [27], this study demonstrates the feasibility and efficacy of FMEA as a tool to engage local health-care staff in identifying weaknesses and improving their work processes in an austere medical environment. FMEA participants identified vulnerabilities in their current work practices, generated solutions and, ultimately, improved the quality of the care that they provided to patients. Documentation compliance rates improved from pre- to post-implementation by 16 to 17% for temperature, pulse and respiration rate, and 9.5% for blood pressure at the intervention facility.

### Limitations

The intervention and control sites in this study differed in overall documentation compliance in the pre-intervention phase, with the control site performing at much higher levels initially. This suggests that work practices in austere environments are highly variable, even between health facilities located within the same city and overseen by the same parastatal. Additionally, the significant decrease in overall documentation compliance observed at the control facility appears to be driven by blood pressure documentation compliance, which was reduced by 36.5% compared with compliance reductions between 9.8 and 10.9% for the other vital signs. As detailed in the FMEA sessions at the intervention facility, documenting blood pressure requires a blood pressure machine, which was frequently absent and difficult to replace. Work processes highly dependent on factors outside the control of local staff, such as missing or malfunctioning medical equipment, may be difficult to target with interventions focusing on frontline provider engagement alone [28].

An additional factor that may have impacted decrease in compliance at the control site involves the 6-month rotation schedule for nurses in training where they are moved to different wards. This occurred in June, shortly after our intervention. It is possible that this rotation produces a cyclical dip in quality and safety analogous to that observed with new cohorts of residents. The FMEA interventions around role clarity and monitoring could have helped to protect against this decline in the treatment facility while the control site nurses were dealing with a less structured work environment.

Due to resource constraints, we did not conduct a formal implementation evaluation to determine the extent to which each unit implemented FMEA interventions. The products of the FMEA session were discussed at a stakeholder meeting including hospital and nursing leadership. However, interviews with nursing supervisors did indicate that role assignments were made, and that senior nurses did begin reviewing the documentation of junior nurses and nurses in training.

### Interpretation

Overall, results suggest that FMEA can be an effective tool for improving quality of care processes in low resource settings. *Post hoc* analyses of changes in documentation compliance rates of the four individual vital signs suggests that the FMEA process can capture the insights of local staff into the greatest opportunities to improve. Specifically, blood pressure documentation compliance rates were the least impacted by FMEA at the intervention site (~9% improvement, compared with 16 to 17% for other vitals). The main failure mode for blood pressure was access to the blood pressure machine—a failure mode rated as highly frequent and critical. Additionally, solutions to this equipment failure were rated to have low controllability by local staff. This appears to have been borne out in the data, and therefore, local staff members seem very capable of identifying work processes, which are or are not within their power to change. Greater involvement of executive leaders in earlier phases of FMEA may help overcome resource-related failure modes, as leadership involvement is related to quality performance [29].

### Generalizability

The cost of interventions can limit spread and sustainment of safety and quality improvement efforts, particularly in low resource settings. This study did not include a formal cost-effectiveness analysis, but completing the intervention required no capital investments and only minimal time for staff involvement. However, external experts conducted the FMEA session. A next step in advancing this approach as a scalable method of safety and quality improvement in low resource settings could be the development of training programs targeting FMEA skills for local staff.

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