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Failure mode and effects analysis applied to the maintenance and repair of anesthetic equipment in an austere medical environment

MICHAEL A. ROSEN[1,2], BENJAMIN H. LEE[2], JOHN B. SAMPSON[2], RAHUL KOKA[2], ADAORA M. CHIMA[2], ONYEBUCHI U. OGBUAGU[2], MEGAN K. MARX[2], THAIM B. KAMARA[3], MICHAEL KOROMA[4] AND ERIC V. JACKSON, JR[5]

[1]Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine, Baltimore, MD, USA, [2]Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA, [3]Department of Surgery, Connaught Hospital, College of Medicine and Allied Health Sciences, University of Sierra Leone, Freetown, Sierra Leone, [4]Department of Anesthesia, Ministry of Health and Sanitation, Freetown, Sierra Leone, and [5]Value Institute, Christiana Care, Wilmington, DE, USA

Address reprint requests to: Michael A. Rosen, Armstrong Institute for Patient Safety and Quality, 750 East Pratt Street, 15th Floor, Baltimore, MD 21224, USA. Tel: +1-407-620-1399; Fax: +1-407-620-1399; E-mail: mrosen44@jhmi.edu

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Abstract

Objective. Medical technology designed for Western settings frequently does not function adequately or as intended when placed in an austere clinical environment because of issues such as the instability of the electrical grid, environmental conditions, access to replacement parts, level of provider training and general absence of biomedical engineering support. The purpose of this study was to demonstrate the feasibility of applying failure mode and effects analysis as part of an implementation strategy for medical devices in austere medical settings.

Design. Observational case-study.

Setting/Participants/Intervention. We conducted failure mode and effects analysis sessions with 16 biomedical engineering technicians at two tertiary-care hospitals in Freetown, Sierra Leone. The sessions focused on maintenance and repair processes for the Universal Anaesthesia Machine. Participating biomedical engineers detailed local maintenance and repair processes and failure modes, including resource availability, communication challenges, use errors and physical access to the machine.

Main Outcome Measure(s). Qualitative descriptive themes in barriers perceived and solutions generated by biomedical engineers.

Results. Solutions generated involved redesigned work processes to increase the efficiency of identifying machine malfunctions, clinician engagement strategies, a formal plan for acquiring spare parts and plans for improving access to the machine. Follow-up interviews indicated solutions generated were implemented and perceived to be effective.

Conclusions. This study demonstrates the feasibility of using the failure mode and effects analysis approach to improve implementation of technology in austere medical environments.

Keywords: austere medical environments, failure mode and effects analysis, biomedical engineering, developing country, anesthesia machine, universal anesthesia machine

Introduction

Medical technology designed for developed countries fails to meet the needs of clinicians in resource-poor settings. Many medical devices designed for Western settings do not function adequately or as intended when placed in an austere clinical environment. Approximately 70–80% of medical devices fail under these challenging conditions [1]. The instability of the electrical grid, environmental conditions (e.g. heat, humidity and dust), access to replacement parts and consumables, level of provider training and general absence of biomedical engineering support in these settings contribute to many of these equipment failures [2–5]. The World Health Organization recently has focused on the need to bridge the gap in access to

technologies in developing countries [6], but little research has documented the demands on biomedical engineering capabilities or challenges faced in these settings.

In an effort to improve the safety and quality of perioperative medicine in Sierra Leone, the Sierra Leone Ministry of Health and Sanitation and the Johns Hopkins University Austere Anesthesia Health Outcomes Research Group agreed to work together on the Safe Anesthesia & Surgery in Sierra Leone Initiative in November of 2010. As part of this initiative, two Universal Anaesthesia Machines (UAMs; one for each of the major tertiary hospitals) were donated by their manufacturer (Gradian Health Systems, LLC), and the impact of these anesthesia machines on the safety and quality of perioperative medicine was assessed. The UAM was designed to meet the needs of the low-resource medical environment and to minimize dependence on biomedical engineering support. However, as all medical devices require maintenance and repair, Sierra Leonean biomedical engineering involvement in the installation, maintenance and repair of the anesthesia machines was identified as a key element to the safety and sustainability of these anesthesia machines.

Although examples exist at differing levels of sophistication [7], biomedical engineering programs are scarce in developing countries. Many low-resource countries lack individuals with expertise in clinical and biomedical engineering, access to replacement parts for medical equipment and sufficient infrastructure to ensure timely routine maintenance and repair. Consequently, equipment is often poorly maintained and therefore unreliable. These factors lead to potential hazards in the clinical environment and risks to patient safety. In 2012, Sierra Leone completed its first training course for biomedical engineers in >30 years. The training program was not sustainable during the country's prolonged conflict. This program will provide one of the fundamental building blocks for sustainable, higher-level medical care for Sierra Leoneans.

To engage Sierra Leonean biomedical engineers in the implementation of the UAMs and ensure that their insights into local work system issues were included in initial and long-term strategies for sustained safe and effective use of the UAMs, we asked them to participate in a failure mode and effects analysis (FMEA). FMEA is a general approach to identifying and mitigating potential breakdowns in equipment and the broader work system. Originally adapted from applications in aviation, FMEA has been applied to a broad array of safety and quality issues in healthcare [8, 9]. Table 1 presents an overview of typical steps in the FMEA process and a description of how

Table 1 Overview of general FMEA steps (adapted from DeRosier *et al.* [8])

General FMEA step	Application in current project
Define the goals and form a team	The goal of the session was to identify any issues that may interfere with the maintenance and repair of the UAM and to develop strategies for mitigating those risks. The team was composed of Sierra Leonean biomedical engineers, a human factors professional, an anesthesiologist and two physicians with public health backgrounds.
Conduct a task analysis	The task analysis was performed as a part of the session. As the biomedical engineering departments were relatively new, maintenance and repair processes were still being formed for the hospitals.
Brainstorm potential failure modes	The group reviewed the processes outlined, and biomedical engineers 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 we've 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 biomedical engineers to think about solutions to the risks identified, whether or not they had direct control over the primary causal factors.
Assign effectiveness ratings	Formal feasibility and effectiveness ratings were not performed. Instead, the group focused on factors that were locally controllable and those that 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	Ongoing.

FMEA, failure mode and effects analysis; UAM, Universal Anaesthesia Machine.

this process was adapted to meet the constraints of the current project.

We report here the results of FMEA sessions conducted with 16 biomedical engineering technicians at two tertiary-care hospitals in Freetown, Sierra Leone. The sessions focused on maintenance and repair processes for the UAM. The purpose of this study was 2-fold: to demonstrate the feasibility of applying FMEA as part of an implementation strategy for medical devices in austere medical settings and to systematically advance the understanding of how biomedical engineering programs function in these settings.

Methods

This project was approved by Institutional Review Boards at both the Johns Hopkins University School of Medicine and the Sierra Leone Ministry of Health and Sanitation.

Participants and setting

Sixteen biomedical engineers from two tertiary-care government hospitals in Freetown, Sierra Leone, participated in two FMEA sessions of 90 min each. These sessions were facilitated by a human factors psychologist and an attending anesthesiologist from the Armstrong Institute of Patient Safety and Quality and the Johns Hopkins School of Medicine (Baltimore, MD, USA). The sessions were conducted at Princess Christian Maternity Hospital, a referral maternity hospital, where 5 biomedical engineers participated in one session, and Connaught Hospital, a referral and trauma hospital, where 11 biomedical engineers participated in one session. Three months before the FMEA sessions, the biomedical engineering participants attended training sessions for the UAM led by an expert biomedical engineer from Gradian Health Systems. At that time, they received an intensive and rigorous review of the anesthesia system and were taught routine maintenance, failure and fault recognition, and repair techniques.

Procedure

Each FMEA session lasted ∼90 min and proceeded as follows. Participants were welcomed and given a brief introduction to the session's purpose before they completed an informed consent form. A human factors psychologist (M.R.) provided a brief introduction to the FMEA process, an example of FMEA methodology applied to hospital patient monitoring in Sierra Leone, and corresponding handouts. The remainder of the session was a structured facilitated discussion between the biomedical engineers and members of the study team, including one human factors professional (M.R.), one anesthesiologist (J.S.) and two physicians with public health backgrounds (A.C. and O.O.). The discussion focused on three critical steps of the FMEA: defining local maintenance and repair processes, identifying barriers or failure modes in these processes and developing potential solutions for addressing the identified barriers.

Data collection and analysis

Sessions were audio recorded, and the session facilitators graphically mapped the group discussion for analysis and commentary. Photographs were taken of all visual artifacts (i.e. the process maps and lists of barriers and solutions) and stored on a laptop computer along with notes from the study team. Study team members integrated these data using thematic analysis. Specifically, similar ideas generated across different sessions were only represented once in the final results. There was a high degree of consistency in the processes, barriers and solutions identified by the different groups. Ideas originating in just one group are noted in the Results section. The biomedical engineering department was provided with a report of the session to help them implement the strategies developed. Additionally, the study team conducted semi-structured follow-up interviews with lead biomedical engineers at each site ∼6 months after FMEA sessions were conducted. The purpose of these interviews was to gather data about the degree to which solutions generated in the sessions were implemented and perceived to be effective.

Results

Process description

Local biomedical engineering staff identified both preventative maintenance and repair processes that were relevant to the UAM. First, three preventative maintenance schedules were outlined. The department was implementing a daily equipment rounding process in which technicians visited each unit of the hospital to inspect and inquire about any malfunctioning devices. Additionally, biomedical engineering staff was developing 6-month and yearly maintenance processes for all devices in the hospitals, but initial ideas for a routine maintenance process for the UAM are outlined in Fig. 1. The plan included detailed inspections about every 6 months, and replacement of specific parts yearly. The repair process typically was initiated by a clinician's verbal report to a biomedical engineering representative that triggered an on-site visit. The biomedical engineer would then assess the nature of the problem (i.e. equipment failure or lack of staff training) and determine whether the device needed to be removed from clinical use for repair in the biomedical engineering department or could be repaired locally by a technician.

Failure modes identified

As detailed in Table 2, the participating biomedical engineers identified a number of critical barriers to effective maintenance and repair of the UAM. As would be expected in this type of setting, the highest perceived barrier was access to spare parts, including air filters and oxygen sensors, as well as lack of availability of proper repair tools. Currently, each department had access to only one set of repair tools for multiple technicians.

Communication between biomedical engineers and clinical staff was also identified as a frequent and critical failure mode. This failure manifested in two primary ways. First, as the

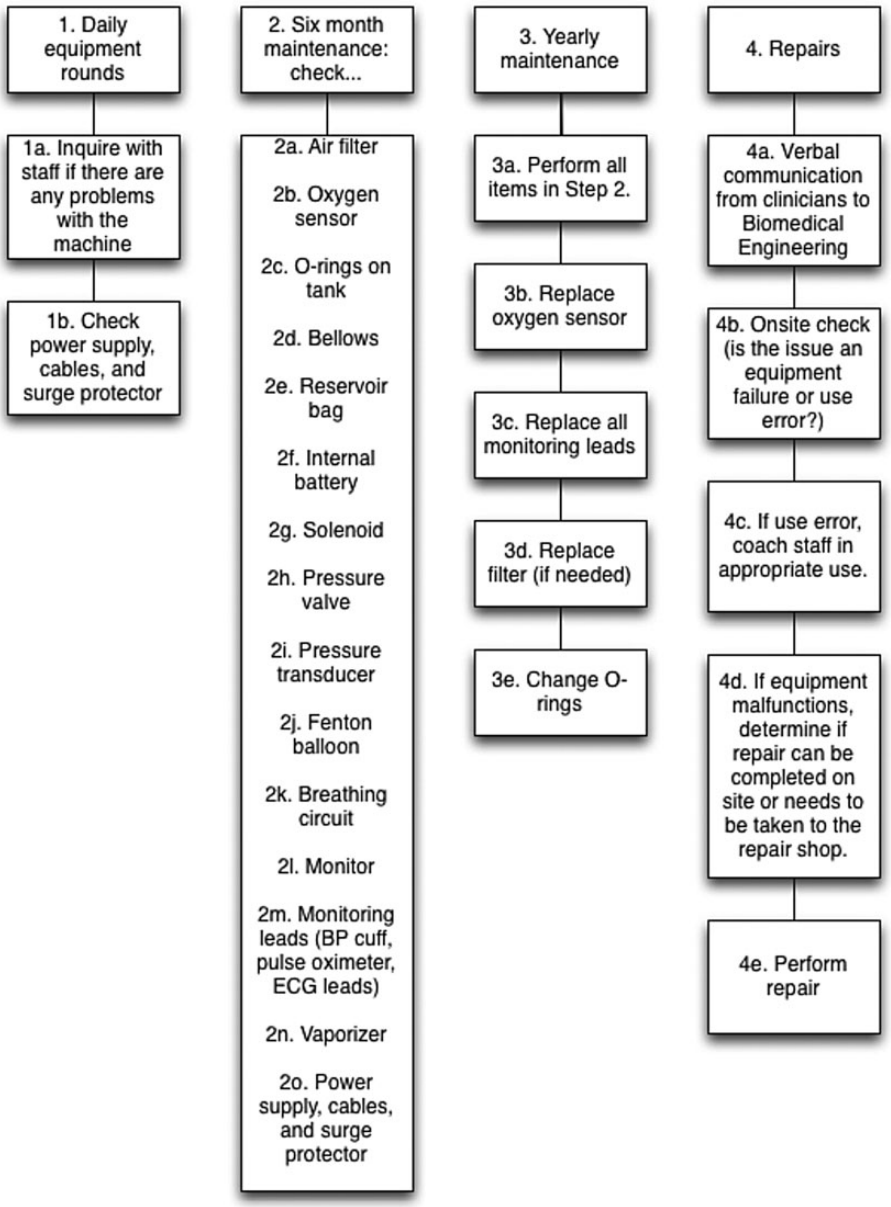

Figure 1 Maintenance and repair processes for the Universal Anaesthesia Machine.

biomedical engineering department was a relatively new entity, a formal, written reporting system was not in place, and breakdowns in verbal communication caused delays in repairs and missing reports. Second, biomedical engineering reported a hesitancy of clinical staff to report malfunctioning equipment. They reported multiple instances of staff failure to report malfunctioning equipment even when asked directly about its status. The engineers' interpretation was that clinicians feared that they would be blamed for the failure or malfunction of the machine/device or held personally accountable for the cost of repairs or replacement.

Two additional themes emerged. First, engineering access to the UAM was limited because of its high rate of use in surgical cases. Biomedical technicians did not have ready access to the attire required (scrubs) to enter the operating theater. Second, biomedical engineers perceived that a high frequency of use errors caused equipment damage (e.g. improper handling of different types of sensor leads, including pulse oximetry) and compounded their challenge of scarce replacement parts.

Solutions generated

Participants developed a diverse set of potential solutions to the failure modes identified. These are detailed in Table 3 and are grouped into four main categories. First, the engineers proposed several 'redesigned work processes to increase the efficiency of identifying machine malfunctions'. The planned daily rounding process was expanded to enable biomedical engineering staff to ask questions more proactively and perform several critical maintenance tasks (oxygen sensor calibration

Table 2 Failure modes identified by Sierra Leonean biomedical engineers

Relevant process steps (see Fig. 1)	Failure modes identified
2a–o, 3a–e, 4e	Resource availability • Lack of spare parts • Lack of repair tools
1a, 4a	Communication • Untimely and hesitant reporting of broken equipment because of organizational culture (clinicians believe if they report a broken device, they will be blamed for it or held responsible for its repair/replacement cost) • Verbal reporting of equipment malfunctions (miscommunication, forgotten communication)
2a–o, 3a	Use errors • Inappropriate use of equipment because clinicians were not properly trained in its use (equipment is working, but staff are not using it appropriately) • Failure of nurse anesthetist to perform daily maintenance (cleaning the machine and oxygen sensor check)
1a–b, 2a–o, 3a–e, 4b	Lack of physical access to the machine • The machine was not always available for inspection because it was being used for patients • Biomedical technicians did not have scrubs to wear in the operating room area

Table 3 Solutions generated by Sierra Leonean biomedical engineers

Failure modes identified	Solutions generated
Resource availability	Processes for acquiring spare parts • Implement a new ordering process for spare parts to ensure that orders are placed when a spare part is used, not when spare is broken • Develop a formal inventory of which parts can be sourced locally and identify specific vendors for these parts
Communication	Work process redesign for identifying malfunctions • Expand daily rounds to include more assertive questioning, a calibration check to assess oxygen sensor functioning and a pressure check on the breathing circuit—performed by the biomedical engineers as a double check on nurse anesthetists' daily maintenance and machine checks • Implement a written service request and an anonymous reporting system for equipment failures
Use errors	Clinician engagement strategies • User training wherein biomedical engineers will demonstrate effective use of equipment, specifically use of sensor leads, that promotes longevity of the equipment • Develop a tiered response to lack of nurse anesthetist maintenance wherein nurse anesthetists will first coach on maintenance practices and then report to the anesthesiology department if clinicians are chronically failing to maintain the machines (e.g. cleaning)
Lack of physical access to the machine	Strategies for improving access to the operating theatres • Obtain and maintain a reserved set of operating room scrubs for biomedical engineers • Develop and maintain a point of contact in the anesthesia department who can arrange the timing of biomedical engineering visits to the operating rooms

and breathing circuit pressure check) as a double check to daily clinician maintenance. Biomedical engineering participants believed that this redundancy would address staff failure to communicate system breakdowns and maintain the engineers' familiarity with the machine. Additionally, biomedical engineering staff proposed a written process for service requests to eliminate information loss and delays through the current verbal system.

Second, two ideas were generated to address the 'spare parts accessibility issue'. First, finding parts locally within Sierra Leone is a challenge, but the UAM came with spare parts for most components. The biomedical engineers decided to

implement checks to ensure that new parts were ordered as soon as spares were used, rather than waiting until the spares needed replacing, to minimize downtime of the machine. Second, several parts, most notably the air filter for the oxygen concentrator, were designed in a way to make replacements easily accessible. Automotive air filters can be used in the machine, and the biomedical engineers decided to develop a process for ensuring they have a local supply for as many device parts as possible.

Third, the engineers developed 'clinician engagement' strategies to minimize the impact of improper use on machine functioning. The plan included formal training sessions on proper use of devices (e.g. how to hold monitoring leads to minimize damage) and a coaching and reinforcement strategy for clinician maintenance duties (e.g. cleaning the machine between cases).

Fourth, strategies for 'improving biomedical engineering access to the operating theatre' included reserving operating room attire (scrubs) for technician use and developing a point-of-contact in the nurse anesthetist department to coordinate scheduling for machine maintenance and repair.

Follow-up interviews

The study team conducted follow-up interviews with lead biomedical engineers at each site. These interviews qualitatively assessed the degree to which solutions generated by participants were implemented and effective. For 'resource availability' solutions, biomedical engineers did not require spare parts yet, but had proactively established lines of communication with manufacturers. For 'communication' solutions, engineers have implemented a formal written reporting and error-logging system as well as more focused and proactive questioning of staff on equipment failures. Staff felt both strategies were effective and an improvement on past processes. For 'clinician engagement' solutions, one site reported the use of continuing ongoing education of clinicians on machine use and maintenance. The second site no longer perceived a need to do this but felt that biomedical engineering staff were listened to when a need did arise that involve biomedical engineering expertise related to the UAM. For access solutions, both sites reported effectively securing operative theater attire. Additionally, one site reported having established dedicated time slots for maintenance, so biomedical engineering and clinical staff all knew when maintenance would occur.

Discussion

The inadequacy of current medical devices designed for austere environments greatly limits the safety and quality of care provided in these settings. Both care providers and patients will benefit from improved access to fully functioning medical equipment. Unfortunately, there is a lack of detailed information about the true demands these austere environments place on medical equipment and the professionals who use and maintain it. Studies that systematically document such challenges contribute to the knowledge base needed to inform the development and implementation of devices that will meet the true needs of patients and providers alike.

One study in one setting will not solve the problem. However, we hope that this study demonstrates the feasibility of the FMEA approach and its utility for aiding the adoption of technologies. The FMEA approach enables local providers to become stakeholders in the creation and implementation of processes for maintenance and repair and contributes to a broader understanding of the pressures biomedical engineering professionals face in austere environments. If future implementation projects in developing countries pursue this or a similar systematic approach of documenting the barriers faced by local professionals, a comprehensive picture of 'ground truth' in austere environments can emerge.

As demonstrated in this study, FMEA shows promise as a valuable strategy for device implementation in austere environments in two key ways: it improves local processes that impact the long-term effectiveness of the device and serves as a cross-check for technical knowledge delivered to biomedical engineers in other modes (e.g. previous orientation sessions). First, the biomedical engineers identified many deficiencies in their current work practices that, if corrected, likely will improve longevity of the UAM and other medical devices under their care. Better device malfunction reporting systems, spare part acquisition plans, access to the device and clinician engagement strategies likely will increase the long-term impact of the UAM and build the capacity of the biomedical engineering department to manage other devices. Second, the FMEA was a valuable opportunity to gauge an understanding of previous training and to reinforce salient points. For example, the biomedical engineers initially perceived the availability of air filters as one of the most challenging barriers to maintenance. However, the UAM was designed to use an automotive air filter in the oxygen concentrator because automotive parts are more easily accessible than medical device parts in resource-poor environments. This information was covered in the initial training, but none of the technicians recalled it immediately. Once they were reminded, the technicians no longer perceived air filter availability as an issue.

By using the FMEA process and engaging key biomedical engineering experts, local biomedical engineering staff and session facilitators conducted a systematic review of the processes for routine maintenance, servicing and repair of faulty equipment. Session participants identified threats to safe use (and patient safety) and developed strategies for mitigating risks/hazards. Because the FMEA process is highly structured and general, the lessons learned in these sessions can be used in other areas of the hospital and the process itself can be replicated when other devices are introduced into service. Results of follow-up interviews conducted ~6 months after conducting FMEA sessions indicated that the sessions did have an impact on local implementation of the UAM machine. Solutions generated in the FMEA sessions were implemented in many cases and perceived to be effective.

Conclusion

This article provides a case study that documents the utility and feasibility of FMEA as a structured approach to engaging local staff in identifying and solving socio-technical systems-related

issues that can limit the impact of medical devices in austere environments. Future studies that use such approaches can create the knowledge base necessary for developing solutions to the problems faced by patients, providers and other staff in these challenging settings.

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