Original Article

Systems-based Quality Improvement as a tool to implement the Surgical Safety Checklist in Rwanda

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ABSTRACT

Objective: Effective strategies for implementation of the World Health Organization's Surgical Safety Checklist (SSCL) are not well characterized in resource-limited settings. Our objective was to utilize a systems-based quality improvement (QI) approach to initially implement a single, high-priority item from the SSCL.
Setting: Butaro Hospital, a rural district hospital in northern Rwanda.
Methods: A surgical service QI team was formed and trained with support of local leadership and expatriate staff trained in QI methodology. The team identified perioperative antibiotic administration as the first SSCL area for improvement. Baseline performance was measured by sampled chart review of Cesarean sections. Using systems-based QI methods and the Model for Improvement, a protocol for choice and timing of perioperative antibiotics was identified as the necessary intervention, developed, and then implemented. The impact on performance and spread of QI was measured.
Results: At baseline, only 5.2% of Cesarean section patients received both correct choice and timing of a prophylactic antibiotic agent. After development of the protocol, appropriate choice and timing of antibiotic was observed in 61.7% of cases ($p < 0.001$). This initial QI initiative stimulated additional projects to implement other components of the SSCL and to improve quality of surgical and anesthetic care.
Conclusions: Implementing one component of the SSCL using QI methodology focused on stakeholder engagement, measurement, and team-based development of iterative systems of improvements facilitated a cultural change at Butaro Hospital. Training and support in QI methods can create an environment in which the SSCL and other efforts for quality in surgical and anesthetic care can be more readily implemented.

Keywords: Antibiotic Prophylaxis - Checklist - Surgical Procedures - Quality of Health Care - Developing Countries

INTRODUCTION

In 2007, the World Health Organization launched a campaign to improve the quality of surgical care worldwide [1]. A key component of this effort was the Surgical Safety Checklist (SSCL). The SSCL is a 19-item checklist centered on select operating room events that occur prior to the induction of anesthesia, incision of the skin, and patient exit from the operating room [2, 3]. In initial studies, use of the SSCL was demonstrated to reduce morbidity and mortality in high-, middle- and low-income settings, on average reducing the rate of surgical complications by 36% [3]. While successful adoption of the SSCL is associated with improved teamwork and communication [4], and cultures of teamwork have been demonstrated to improve patient outcomes [5, 6], the exact mechanism of improvement in surgical outcomes after SSCL implementation is unknown [3].
In practice, the impact of the SSCL on patient outcomes is variable and contingent on the effectiveness of its implementation [7]. Investigations in high-income countries have linked successful SSCL implementation to the ability of leaders to demonstrate both why and how the checklist should be used [8]. Active leadership combined with engagement of surgical teams through discussion, training and piloting, in conjunction with a number of key activities including cross-disciplinary communication, coaching, and ongoing feedback are important factors associated with successful SSCL implementation [8]. In middle income countries, more formalized strategies consisting of intensive training of local implementation teams followed by gradual roll-out and support with additional resources for perioperative monitoring have also been linked to effective SSCL implementation [9]. Many of these processes overlap with quality improvement (QI) methodology, an approach that has been successful in improving healthcare quality in even the most resource-limited settings [10-14].
While the SSCL typically is implemented as a whole, this can be overwhelming for settings where concepts of QI have not been introduced. We utilized the Model for Improvement, a traditional QI methodology of small cycles of change [15], to initiate implementation of the SSCL in a district hospital in rural Rwanda. We began with a single element of the SSCL to introduce the concepts of QI, including stakeholder and leadership engagement, measurement and team-based development of iterative systems improvements through the Plan-Do-Study-Act cycles.
The goal of this quality improvement project was to build capacity for the spread of quality in our district hospital surgical department and for adoption of other SSCL components over time. We describe the results of this approach to improvement as a potential method to implementing the SSCL while building a broader culture and capacity for quality health care.

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METHODS

Setting

Butaro Hospital is a 150-bed district hospital based in Burera, a rural district in northern Rwanda. In 2007, the non-governmental organization Partners In Health in partnership with the Rwandan Ministry of Health began strengthening the health system in Burera District. With the opening of a new hospital in 2011, including two operating theaters and a 24-bed surgical ward, a multidisciplinary effort to increase surgical services and improve the quality of surgical care delivered became an area of focus.

Surgical and anesthetic care is provided primarily by Ministry of Health (MOH) employed general practitioners and nurse anesthetists, respectively, with the support of visiting teams of expatriate surgeons and anesthesiologists. Similar to other East African district hospitals, the vast majority (72%) of major surgical procedures provided at Butaro Hospital are Cesarean sections for emergency obstetric care [16].

Study Design

The study, conducted from September 2011 to May 2012, was a descriptive evaluation of the effect of a QI capacity building effort on improvements in performance in a single SSCL item and subsequent spread to implementing other QI efforts. The study timeline is presented in Figure 1.

Systems-Based Quality Improvement

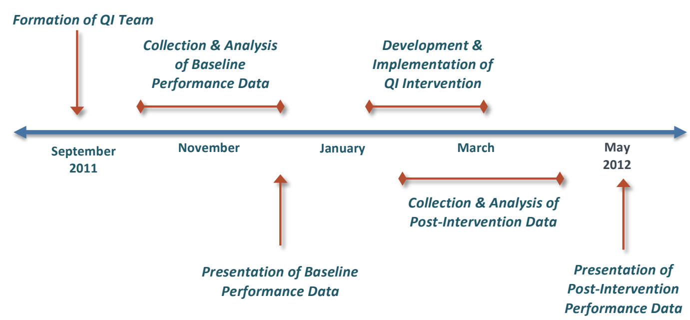
The Butaro Hospital surgical QI initiative began with the formation of a multidisciplinary surgical QI team under the leadership of the hospital director, who not only approved the formation of the team but also attending meetings and contributed his clinical and systems-based knowledge. Broad engagement was sought through a survey of individuals from operating theatre, surgical ward, and pharmacy department staff. All interested parties were invited to participate. The final surgical service QI team (18 members) included the Rwandan general practitioners working in the surgery and maternity departments, nurse anesthetists, the head of midwifery, nurses from the surgical and maternity wards, and a pharmacist. Expatriate research fellows trained in QI methodology supported team meetings and provided real-time training and coaching in QI methods needed to develop and implement the work.

After review of the SSCL components, brainstorming potential existing gaps in performance, and existing studies that prove perioperative antibiotics are an important intervention to reduce surgical site infections (SSIs) [17-25], the QI team chose the administration of prophylactic perioperative antibiotics from the many possible SSCL items as the initial checklist component for improvement. To ensure proper choice and timing of prophylactic antibiotics, the SSCL includes the administration of perioperative antibiotics in the operating room within 1 hour prior to incision.

Baseline performance for perioperative antibiotic administration was measured (see below) and results presented to the QI team. Cause and effect analysis recognized a number of possible causes for poor performance, including no existing protocols in place for prophylaxis before Cesarean section. Therefore, a subset of the surgery QI team developed and implemented a targeted intervention to improve perioperative antibiotic use, specifically the introduction of a hospital-wide perioperative antibiotic protocol for Cesarean sections.

The impact of implementing the selected SSCL item was measured by repeat performance measurement of perioperative antibiotic use and identifying evidence of spread to other areas for improvement from review of the QI team meeting minutes and observation of changes in practice and culture after the QI initiative.

Figure 1: Study timeline. The Butaro Hospital surgical quality improvement initiative began with the formation of a QI team. Baseline performance data on perioperative antibiotic administration was then collected and presented, leading to the development and implementation of a QI intervention. Performance data on perioperative antibiotic administration after the development of the intervention began was compared to the pre-intervention performance data.



Antibiotic Administration Performance Measurement Population

Women 18 years of age or older sequentially undergoing Cesarean section between May 1 2011 to January 28, 2012 (baseline), and January 31, 2012 to April 31, 2012 (post-intervention) were included in performance measurement.

Data Sources

Routinely collected data from surgical and anesthesia operating theatre logs, surgical operative notes, hospital ward logs and registries, and inpatient medical records was utilized.

Performance Measures

Three indicators were selected by the QI team: administration of a single antibiotic agent in the operating room, administration within 1 hour of incision and both correct agent and timing. Data on these indicators were collected using a customized collection form. To understand factors associated with higher or lower performance, data extracted included a number of potential confounders including: indication for Cesarean section (emergent or elective); presence of expatriate surgeon, expatriate anesthesiologist, or member of QI team during the operation; administration of pre-operative antibiotics; after hours operation ("late case" was defined as done between

1800 and 0800 hours); type and timing and duration of preoperative antibiotic(s); perioperative fever, and factors which increase wound classification to contaminated from the standard clean-contaminated for Cesarean sections.

Sample size

We chose a sample size to estimate baseline performance within +/-10% at a 95% confidence level and 80% power, assuming 50% performance in the correct agent and timing measure. Based on these calculations, we planned to review the first 194 women sampled who underwent C-section starting in May 2011. This number was able to be decreased after the initial 31 reviews when it became apparent that the rate of correct perioperative antibiotic administration was so low that a much smaller sample size was needed to obtain a reasonable estimate of the baseline rate and therefore data collection was stopped after the newly revised sample size (63 charts) had been reviewed.
A minimum post-intervention sample size of 67 study participants was calculated in order to detect a 20% increase in single agent perioperative antibiotic use, with a statistical power of 80% and alpha value of 0.05.

Statistical Analysis

Descriptive statistics were used to calculate performance rates with confidence intervals in the selected areas for improvement. Rates before and after the QI intervention were compared using the $\chi 2$ test and Fisher's exact test as appropriate. The analysis comparing performance rates pre- and post- the QI intervention was repeated coding missing values as failures. Independent variables were examined using bivariate analysis for their association with improvement in the selected performance measures. A p value <0.05 was considered significant. All analyses were conducted using STATA version 12.1 (Stata Corporation, College Station, Texas, USA).

Human Subjects Protection

Medical records and other sources of routinely collected clinical data were reviewed and no patient identifiers were entered into the database. No direct patient interactions occurred. Both the Partners Human Research Committee in Boston and the Rwanda National Ethics Committee approved the study.

RESULTS

Cesarean Sections at Butaro Hospital

Patient characteristics from the pre and post-QI period are described in Table 1. No significant differences were seen between the two groups. Most cases were emergent cases, and all were classified as clean-contaminated wounds.

Overall 12.7% of patients in the pre-QI and 11.1% in the post-QI group had clinical risk factors for infection (e.g. an open wound, pre-existing infection such as pneumonia or UTI). No patients had documented perioperative evidence of gynecologic infection at the time of Cesarean section.

Characteristics	Pre *n* = 63	Post *n* = 90	*p* Value
Age (mean (SD))	27.3 (6.1)	27.7 (5.6)	0.67
Emergent cases	96.7%	100%	0.16
Clinical risk factors for wound infection*	12.7%	11.1%	0.14

* open wound (n = 2), prolonged rupture of membranes (n = 1), premature rupture of membranes (n = 1), pre-existing infection (n = 16)

Baseline Performance

At baseline almost all patients (n = 58, 92.1%) undergoing Cesarean section were receiving multiple antibiotic agents in the operating theater. In addition, the majority (n = 48, 82.8%) of these patients received these agents late, either at or after incision. Therefore, at baseline only 5.2% of cases had both correct choice and timing of the prophylactic antibiotic agent.

QI Process

Presentation of baseline performance rates was followed by several QI team-based brainstorming sessions to conduct a root-case analysis for the performance gaps.
The team identified the absence of an agreed upon hospital protocol for prophylactic antibiotic administration in Cesarean sections as a primary cause for gaps in the selected performance measures and prioritized its implementation for the initial improvement cycle. Another potential reasons for failure to administer antibiotics perioperatively was a lack of knowledge regarding the efficacy of perioperative antibiotics in prevention of surgical site infections. In our hospital, availability of antibiotics was specifically cited as not being a barrier to improved performance. After review of international and national guidelines as well as input from specialists in obstetrics and gynecology, general surgery, and anesthesia, a smaller multidisciplinary team of eight hospital and expatriate staff reached a consensus on a protocol that reflected national and international standards (single-agent, single-dose perioperative antibiotic administration in Cesarean sections for women without other indications for antibiotics) (Figure 2).

Several other areas for improvement emerged from these brainstorming sessions, including: the need in general for clinical guidelines and protocols appropriate for resource-constrained settings such as a Rwandan district hospital; gaps in communication among team members as volume and types of surgery increase at Butaro Hospital; concerns about current processes and staff capacity to ensure safe operations; sterile processing of instruments, and post-operative wound care.

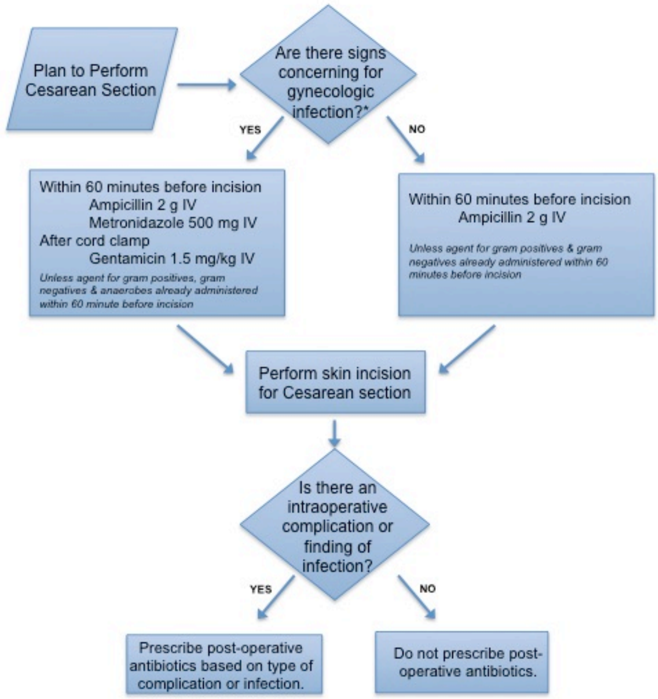


Figure 2: Butaro hospital Perioperative Administration of Antibiotics for Cesarean Sections Protocol.

Implementation of Protocol

Around the time of protocol implementation, the Medical Director of Butaro Hospital was becoming more actively engaged in championing quality improvement to improve clinical care across departments. With his leadership, members of the multidisciplinary QI team introduced the protocol to all clinical and ancillary staff at Butaro Hospital. The introduction of the protocol included presentation of hospital baseline performance rates for prophylactic antibiotic use, review of national and international standards, and a summary of the team's rationale for an agreed upon protocol. The details of the protocol were then reviewed and discussed intensively in the already scheduled daily morning report for all hospital staff. Consensus was reached in a stepwise fashion with the protocol formally adopted as the new hospital policy for prophylactic antibiotic use in Cesarean sections. The protocol was then circulated to all interested parties and posted in visible areas in the surgical wards and operating theaters of the hospital.

Post-QI Intervention Analysis

Significant improvements in the appropriate choice and timing of perioperative antibiotics were observed after the QI intervention at Butaro Hospital (Table 2). Adherence to both correct choice and timing improved to 61.7% ($p < 0.001$). No difference in results was seen when missing outcomes were reclassified as failures to adhere to the protocol. None of the factors studied in bivariate analysis including presence of an expatriate care provider or member of the QI team were associated with differences in rates of adherence to appropriate antibiotic administration in the post-QI period.

Table 2: Pre- and post-intervention performance rates (95% confidence interval) with perioperative antibiotic administration protocol for women undergoing Cesarean section.

Area for Improvement	Pre-Intervention *n = 63**	Post-Intervention *n = 90***	*p* Value
Administration of a single prophylactic antibiotic	n = 59 7.9% (2.6 - 17.6%)	n = 86 86.0% (76.9 - 92.6%)	< 0.001
Appropriate timing (≤1 hr prior to incision)	n = 63 17.2% (8.6 - 29.4%)	n = 83 71.1% (60.1 - 80.5%)	< 0.001
Appropriate prophylactic antibiotic agent & timing	5.2% (1.1 - 17.6%)	61.7% (50.3 - 72.3%)	< 0.001

*Missing data for antibiotic type (n=4)
**missing data for antibiotic type (n=4) and timing (n= 7)

Spread of QI
Spread of this culture of QI was observed with additional QI projects initiated in the months following the first project. A number of these addressed the other gaps identified during the analysis of the existing system for prophylactic antibiotic use while others focused on expansion of SSCL implementation. These projects have included introduction of intraoperative material counts (i.e. sponges, instruments); prevention of oxygen stock out; improvements in surgical kit preparation and sterilization methods by visiting referral hospitals in the capital city for further training; and training in postoperative wound care and surveillance for postoperative infections including the appropriate use (i.e. reductions in use) of postoperative antibiotics in the postpartum ward. On follow up in February 2013, the Butaro Hospital surgical and anesthesia staff were observed to be continuing monitoring oxygen supplies and requested additional training in kit preparation and sterilization. A program to monitor the number of days spent in hospital post-procedure was also initiated after the QI initiative, as a first step to better understand outcomes for patients.

DISCUSSION

QI is increasingly recognized as an important tool for improving health outcomes and strengthening health care systems in the developing world [26]. While use of the SSCL has demonstrated a significant reduction in mortality and other postoperative complications, strategies for its effective implementation in resource-limited settings are not well characterized. Within our context, a rural district hospital in Rwanda with limited human and material resources, it was clear that simultaneously implementing all components of the SSCL de novo was likely to be met with failure. Therefore, we utilized an alternate approach focused on implementing a single component of the SSCL embedded within a systems-based QI initiative to introduce the concept of change and serve as a launching pad for full implementation of the SSCL.
We anticipated barriers in achieving consensus on which SSCL area to improve first, determining what types of interventions would be feasible in our environment, and acceptance of the identified intervention by the hospital staff. The formation of a multidisciplinary team supported by QI training emerged as a critically needed tool necessary to overcome these barriers. Training and ongoing support in QI methods cultivated a sense of teamwork and empowerment among the surgical staff

that facilitated a change in behavior and culture. This team-based transformation led to easy agreement upon an intervention to improve the administration of perioperative antibiotics in Cesarean sections. Also critically important to facilitating uptake was presentation of the newly developed protocol by the surgical and anesthesia providers to the entire hospital staff. This led to consensus amongst the many disciplines involved in perioperative antibiotic administration. Overall, this QI initiative resulted in significant improvements in the timing and choice of prophylactic perioperative antibiotic administration.

This initiative resulted in the spread of QI to other areas of perioperative care. Specifically, measurement of perioperative antibiotic administration also stimulated efforts to reduce the administration of unnecessary post-operative antibiotics. Interval review of baseline performance data by the QI team revealed a high rate of postoperative antibiotic prescription. In a subset analysis prior to the QI intervention, 100% of patients (n = 10) received broad-spectrum postoperative antibiotics. However, only 10% of these patients had any documented clinical risk factors for wound infection and none had any documented gynecologic infections. Data from other resource constrained areas suggests that the postpartum infections requiring antibiotics only occur at a rate of ~ 10% [27], suggesting the high rate of postoperative antibiotic administration was not warranted in our setting. Following the QI initiative, the rate of patients receiving postoperative significantly decreased to ~40% of patients (n = 90, p value < 0.001).

This study has several limitations. As with any chart review, the data are dependent on the completeness and accuracy of routine clinical documentation and so improvement may reflect change in documentation rather than change in practice. However observation by a number of the co-authors (GNM, BWT, RR) have also qualitatively validated the measured improvement in practice. Further, this study was designed to measure processes (i.e. appropriate administration of perioperative antibiotics) rather than outcomes (e.g. rate of SSIs), and so the long-term impact on patient's clinical outcomes was not ascertained in our work. Next, following implementation of the protocol, we still found antibiotics were administered after incision in 30% of cases. Further investigation is required to determine reasons for continued non-adherence to the established protocol, whether due to individual resistance to change or whether there are unidentified underlying system gaps. Finally, we only followed the impact of the QI initiative over a relatively short period of time. We have observed an major ongoing barrier to the persistence of effect of the QI initiative in resource-constrained settings is the high staff turn over in rurally located hospitals and may expect this to influence quality at our hospital as well. Formal review at 1-year following the start of the QI initiative is currently in progress. Another project will be required to measure the effect of having implemented one SSCL component as part of a systems-based QI initiative on the ease and efficacy of full implementation of the SSCL at our hospital.

CONCLUSION

Our experience suggests that training and support in QI methods can create an environment in which improvements in surgical and anesthetic care can be implemented in a resource-limited setting. By investing in training, coaching, and focusing on stakeholder engagement followed by measurement and team-based development of iterative systems of improvements, the hospital was able to successfully implement one component of the SSCL, a vital first step to facilitating the cultural change needed for the longer-term improvement in practices for safe surgical and anesthetic care. Work is still needed to understand the next steps in achieving higher rates of adherence to QI interventions, particularly in such environments where a high rate of human resource turnover is common. Ultimately our characterization of the processes needed to build a culture of quality suggests that team-building through QI can facilitate implementation of the SSCL and extend to other aspects of patient care as the culture of quality grows.

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COMPETING INTERESTS
None.

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