The American Journal of Surgery 221 (2021) 598–601

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Original Research Article

Applying international organization for standards 9001 to create an effective surgical quality committee

Douglas P. Slakey*, James S. George, Edwin Anderson, Donna Willeumier, Kelly Guglielmi

Department of Surgery, CMC, Advocate Aurora Health, Chicago IL, 60611, United States

ARTICLE INFO

Article history:
Received 7 July 2020
Received in revised form
23 October 2020
Accepted 5 November 2020

Keywords:
Patient safety
Surgical quality
ISO9001
Surgical site infection
Quality management system

ABSTRACT

Background: Efforts to improve surgical safety are limited by several factors and no consensus exists regarding the most effective way to improve surgical quality. The use of ISO 9001 quality standards within healthcare is recognized but has not been widely applied for improving surgical outcomes.
Methods: A surgical quality committee was created using ISO 9001:2015 standards. Quality objectives were assessed to understand how any suggested changes will be impacted due to risks and opportunities inherent in the system.
Results: The initial quality focus was on surgical site infections in 5 services. Change in surgical infection ratio from 2018 to 2019 showed significant improvement: coronary bypass 1.288 vs. 0.901; Colon 1.359 vs. 0.589; Hysterectomy 2.119 vs. 1.022; Knee 1.391 vs. 0.306; Hip 0 vs. 0.302.
Conclusions: This is one of the first studies using ISO 9001 to improve surgical quality. The results indicate both acceptance and success of applying continual improvement strategies.
© 2020 Elsevier Inc. All rights reserved.

Introduction

Providing high quality, safe, reliable, and cost-effective care is essential because of the inherent risk and potential impact of adverse surgical outcomes.[1] Establishing and maintaining a culture of quality and safety is embraced throughout healthcare organizations, yet strategies that effectively and consistently achieve this remain elusive. Traditional approaches to surgical quality are embodied in department-specific morbidity and mortality conferences and operating room committees.[2,3] These efforts at improving safety are limited by the siloed nature of individual departments and lack of involvement by the diverse team of people who impact the care of the surgical patient. Healthcare agencies and regulatory bodies have proposed and utilized a variety of regulations and standards to encourage the establishment of a vigorous culture of safety, yet no consensus exists regarding the most effective way to improve surgical quality.[2]

Outside healthcare, many industries derive their quality management systems from standards established by the International Organization for Standardization (ISO®). ISO traces its origins to 1946 and is recognized as a leader in establishing international standards for safety and quality.[4] The use of ISO quality standards (ISO 9001) within healthcare is recognized but has not been widely applied in the United States as a methodology for improving surgical outcomes.[5,6] To improve surgical quality within our hospital we developed a new, multidisciplinary committee – the Surgical Services Quality Outcomes Committee (SSQOC) - using ISO 9001:2015 quality management system (QMS) standards.[7] Key elements of the ISO 9001:2015 QMS standards are listed in Table 1. In this paper, we discuss how the committee was designed and created and highlight early results in reducing surgical site infections.

Methods - design and establishment of the SSQOC

The foundational concept that led to the design of the SSQOC was the belief that surgical services are, by definition, complex systems. The features of complex systems (distinguishable subsystems, the interaction of human beings with technology, a variable natural environment, the need for informational connections between parts of the system, and power gradients) are inherent to surgery.

The SSQOC has a formal charter that was approved by hospital leadership and board. The primary responsibilities of the committee are to evaluate specific quality measures, to initiate system-

* Corresponding author. Surgical Services CMC, Aurora Health 600 N Lake Shore Drive, 2901 Chicago, IL, 60611, United States.
E-mail address: douglas.slakey@aah.org (D.P. Slakey).

https://doi.org/10.1016/j.amjsurg.2020.11.014
0002-9610/© 2020 Elsevier Inc. All rights reserved.

Table 1
Quality management system.

Component	Example
1. Customer Focus	Understand customer expectations
2. Leadership Involvement	Set direct and goals, strategy
3. Engagement of People	Broad-based participation
4. Process-Based Approach	Align resources with anticipated results
5. Rigorous and Transparent Use of Data	Share data to drained and understand improvement outcomes
6. Continual improvement	Results are not the finish line; the goal is to continue to improve
7. Evidence-Based Decision-Making	Use of data to direct and evaluate decisions and strategy
8. Relationship Management	Optimize value for all involved; mutual benefit

wide improvements, and to promote standardization (reliability) that improves patient outcomes. Each surgical department quality improvement committee refers adverse outcome concerns that extend beyond those that are clearly attributable to an individual to the SSQOC. In addition, the SSQOC is responsible for assessing global measures of surgical quality, such as surgical site infection rates and readmission rates. Finally, the committee is charged with the responsibility of implementing and monitoring the performance of the novel surgical services using quality management protocols.

The committee specifically follows ISO 9001:2015 Quality Management System methodology for facilitating change management. Quality objectives, termed key result areas (KRAs), are assessed comprehensively to understand how any suggested changes will be impacted by risks and opportunities inherent in the system. Evaluation of quality initiatives includes the organizational context to ensure identification and incorporation of internal and external operational considerations and to ensure the involvement of all interested parties (stakeholders). An appreciation of organizational culture underpins all efforts to communicate and educate regarding quality changes within the organization. In addition, regular monitoring of outcome data and transparency in reporting is mandatory. Documentation and reporting are important components of QMS, consequently the SSQOC reports up to the hospital quality management oversight committee, the board, and the system.

This committee is designed to promote broad participation inclusive of the wide range of people who impact surgical patient care. The structure of the SSQOC is such that multidisciplinary work groups are assigned quality topics. The groups perform in-depth analysis of patient, environmental and system factors that impact patient care and then develop comprehensive processes and procedures to implement as quality improvement projects along with outcome measures to follow. This QMS process is described as a continual quality process consisting of four integral components Plan-Do-Check-Act (PDCA) (Fig. 1).

Results in reducing surgical site infections

In the first six months following its formation, the SSQOC focused on, introduced, and executed substantial changes in spine, total joint, gynecologic, and colorectal surgery. The primary outcome measure chosen for analysis was surgical site infection (SSI). Baseline data was established using the Standardized Infection Ratio (SIR), derived from the National Healthcare Safety Network (NHSN). The SIR adjusts for various facility and/or patient-level factors that contribute to risk within each facility. A logistic regression model was used for each surgical site infection risk adjustment. A resulting SIR greater than 1.0 indicates that more infections were observed than predicted. Conversely, an SIR less than 1.0 indicates fewer were observed than predicted. Secondary outcomes included relevant process measures such as appropriate pre-operative antibiotic and timeliness of administration, and skin preparation.

Multidisciplinary working groups consisting of interested parties/stakeholders (one for each focus service) were formed to assess the data and identify potential areas for improvement. A success factor in the formation of work groups was to limit those most closely associated with the focus area. For example, colorectal surgeons were assigned to the total joint work group and vice versa. The objective was to reduce explicit and unconscious bias.[8] The work groups were provided a standard template for analysis of processes and systems that were deemed relevant to SSI. Work groups met bi-weekly to discuss findings and develop suggestions for process improvement initiatives. The framework used for presenting process improvement strategies to the SSQOC is depicted in Table 2.

Not unexpectedly, there was significant overlap in findings and improvement strategies identified by the workgroups. Broadly, the improvement strategies fell into 6 categories: recognition and standardized approach to higher-risk patients, uniform application of enhanced recovery protocols, reducing flow disruptions in the operating room, reducing variability in skin preparation and dressings, ensuring prophylactic antibiotic use was clinically relevant, and ensuring accurate documentation.

Some findings were surprising. For example, it was identified that in some orthopedic cases, although prophylactic antibiotics were given “within the approved time” prior to incision, it was in fact not unusual that the intravenous dose occurred after the tourniquet was inflated and therefore tissue concentration at the surgical site was not clinically adequate. Simply relying on routine performance metrics did not identify this. Another unexpected finding was that colorectal patients seen at different clinic locations were being given different instructions regarding pre-operative bowel preparation despite the surgeons being the same. It was also identified that patients were not being given consistent instructions or were unable to obtain supplies for skin cleansing prior to surgery. These were among areas where process changes were made and reinforced using ISO 9001 QMS standards. As a result of findings indicating an opportunity for improvement, a surgical pre-optimization clinic was created.

Six months following the creation of the SSQOC, based on work group and committee efforts, a significant reduction in risk-adjusted SSI rates were noted (Table 3). Follow-up of process measures revealed sustained improvement in all secondary outcomes focus areas.

Discussion

The International Organization for Standardization is an international, multidisciplinary panel which determines specifications and standards adopted worldwide. The origin of the ISO can be

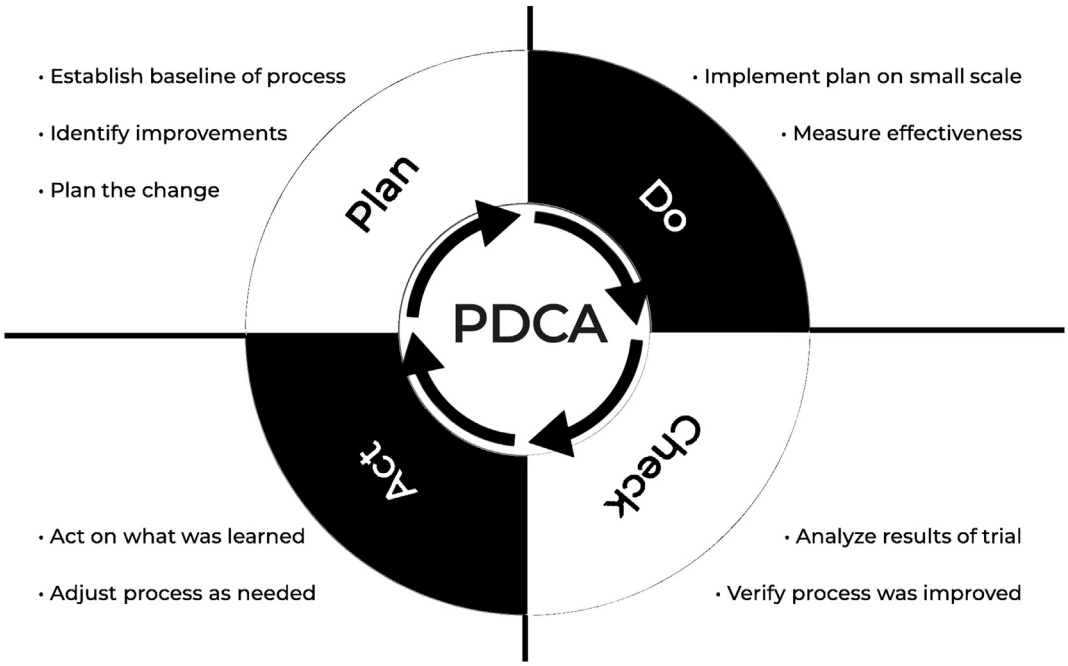

Fig. 1. Plan - Do - Act – Check.

Table 2
Risk-based thinking.

- Determine the risks that may impact the organization's ability to meet objectives
- Plan and take actions to address risks and opportunities
- Define and manage processes to identify and address the risks in organizational operations
- Determine which risks need to be monitored, measured, analyzed, and evaluated
- Enable continual improvement by responding to the changes in risk and opportunities
- External Provision – Manage Third-Party Risks

traced back to 1946 when delegates from twenty-five countries met in Geneva, Switzerland, to find solutions to the issue of international standardization.[9]

While ISO standards have been in use since 1951, the organization initially covered a limited number of industries. Gradually the application of ISO standards evolved from providing recommendations on organizational challenges to becoming a consultative entity.[5] In addition to increasing the number and breadth of standards, the ISO began to include quality measures for the industries covered by ISO standards. Today, the ISO is the largest organization that develops international standards of practice, with approximately 23,217 standards and members from 164 countries.[4]

ISO quality standards applicable to the healthcare sector were first published in the 1990's as ISO 9001(10). ISO 9001:2015 is a family of standards used to regulate and certify both the quality of services and the quality management systems of organizations to promote uniformity and best practices in each field. These standards help organizations of all types to provide products and services that meet the customers' needs by providing guidelines for their operations. Importantly, ISO 9001 emphasizes *continual* improvements in quality of goods and services.

In 1996, the American Legion Hospital in Crowley, Louisiana, was the first healthcare organization to adopt ISO 9001(10). Since then, nearly 500 hospitals and healthcare organizations throughout the United States have applied for ISO certification under the rigorous ISO 9001:2015 criteria and standards. Within the United States DNV GL has incorporated ISO 9001 process standards into hospital accreditation. [10,11] Due to the extensive auditing and procedural adjustments necessary to obtain ISO certification, organizations must first perform internal checks to evaluate their current QMS and acknowledge gaps that may exist.

The application of ISO 9001 to surgical services is uncommon. However, a limited number of studies have demonstrated significantly improve patient outcomes.[5,6] The application of ISO 9001 standards in our surgical quality improvement process has improved outcomes in SSI rates. The SSQOC created an environment fostering engagement and empowerment of a wide variety of stakeholders thereby increasing commitment and enthusiasm for quality improvement related change. Increased transparency of outcomes data has heightened awareness of the need to improve

Table 3
Surgical site infection.

2018					2019			
Infection	Type Infections	Expected	SIR	#Procedures	Infections	Expected	SIR	#Procedures
CABG	6	4.657	1.288	448	4	4.44	0.901	406
COLO	16	11.775	1359	420	7	11.878	0.589	428
HYST	6	2.832	2.119	352	3	2.934	1.022	362
KPRO	4	2.876	1.391	732	1	3.267	0.306	843
HPRO	0	1.025	0	127	1	3.307	0.302	382

Abbreviations: CABG Coronary artery bypass graft; COLO Colon resection; HYST Hysterectomy; KPRO Total knee replacement; HPRO Hip replacement.

and the benefits of following the QMS (improved patient outcomes and improved reliability of systems).

Although the use of ISO 9001:2015 guidelines in surgical practice has potential advantages, its implementation is not without certain challenges [12]. The perceived diversity of the U.S. healthcare system combined with long held traditions such as department focused quality committees has led to skepticism concerning the feasibility of broadly applying ISO 9001 standards. Among issues that may arise when implementing ISO 9001 quality standards is their inherent rigidity. Although standards are intended to specify procedures to be followed when providing care to patients, they cannot account for every possible scenario and thus must be adaptive while still maintaining the integrity of their intended purpose. ISO 9001 does recognize this challenge but requires knowledgeable and committed leadership to facilitate appropriate implementation of the continual quality improvement strategy. The inherent flexibility within ISO 9001 is embodied in the fact that while requirements define what is ultimately required, they do not necessarily dictate how to meet the requirement, allowing the organization to determine exactly how it achieves QMS standardization.

One advantage of ISO 9001 QMS is that it does not replace other quality improvement tools (for example Lean or Six Sigma). ISO 9001 standards apply to identification of problems, guidelines for the organizational structure to address quality, and an emphasis on continual quality improvement. ISO 9001 specifically leaves decisions about the tools used to accomplish the standards to the user.[11]

For a quality management team (like the SSQOC) to be successful, members must understand the roles and responsibilities of the various professionals and stakeholders who effect outcomes, and those affected by process changes. Incorporating and engaging all affected parties and the system that supports, or fails to support, them are critical to understanding any proposed quality standards and processes changes. One of the key purposes of the ISO QMS is to act in a preventive manner. This is distinct from traditional, often reactive, quality methods that focus on policy refinement and enforcement as opposed to continual quality improvement designed to prevent rather than respond to adverse events. In this regard, the primary function of the SSQOC is preventative rather than responsive to adverse events.

Implementation of the SSQOC included the need for effective leadership. Leaders play a critical role in directing the efforts of surgical providers and other stakeholders towards the achievement of a common goal. Furthermore, leaders are a necessary entity in change management, because they mobilize support for proposed changes and monitor the activities of team members to ensure that the improvements are effectively and efficiently implemented. The leaders of surgical quality management teams must be conversant with surgical operations to address any issues that may arise.

In the case of SSQOC, the committee elected the chief of surgical services as its chairperson and the executive director of surgical services as the vice-chairperson. These two individuals have extensive knowledge and experience in surgical practice and the operations of healthcare organizations; hence, they have been able to create an environment in which effective quality plans and process changes can be implemented using the ISO 9001 framework.

A notable challenge the SSQOC faced was the need to design an effective strategy for motivating surgeons and surgical teams to follow new recommendations and standardized processes outlined by the quality management team. Overcoming this challenge requires an appreciation of perspectives, sharing of meaningful data, evidence-based decision making, and leadership commitment to facilitating change by engaging and empowering those on the front lines of patient care.

Another challenge faced but he SSQOC was time commitment. Leadership, and budgets, must acknowledge the importance of adequate allocation of resources (primarily human capital). Our success was facilitated by an institutional commitment to “zero harm”. The SSQOC has a dedicated quality specialist RN and data analytic support as well as adequate clinical leadership availability.

Conclusion

This experience of applying ISO 9001:2015 continual improvement methods to surgical quality improvement demonstrates both feasibility and success. Application of QMS following ISO 9001 structure can be an effective methodology to help improve surgical outcomes.

Financial disclosure

The authors have no relevant conflicts of interest. This study was conducted without any outside funding.

Summary

A surgical quality committee was created using International Organization for Standards (ISO) 9001:2015 standards. Using ISO 9001 continual quality improvement and change management techniques significant improvement in surgical site infection rates were observed.

References

1. Porter, Michael E., and Thomas H. Lee. "The strategy that will fix health care." Harv Bus Rev 91, no. 10 (October 2013): 50–70.
2. Reines HD, Trickey AW, Donovan J. Morbidity and mortality conference is not sufficient for surgical quality control: processes and outcomes of a successful attending Physician Peer Review committee. *Am J Surg*. 2017;214(5):780–785. https://doi.org/10.1016/j.amjsurg.2017.04.008.
3. Marder RJ. *Effective Peer Review: The Complete Guide to Physician Performance Improvement*. third ed. Danvers, MA: HCPro, Inc; 2013.
4. ISO. The ISO story. https://www.iso.org/the-iso-story.html; 2019. Accessed 18 June 2020.
5. Beholz S, Konertz W. Improvement in cost-effectiveness and customer satisfaction by a quality management system according to EN ISO 9001:2000. *Interact Cardiovasc Thorac Surg*. 2005;4:569–573.
6. Beholz S, Koch C, Konertz W. Quality management system of a university cardiac surgery department according to DIN EN ISO 9001 : 2000. *Thorac Cardiovasc Surg*. 2003;51(3):167–173. https://doi.org/10.1055/s-2003-40312.
7. van den Heuvel J, Koning L, Bogers AJ, Berg M, van Dijen ME. An ISO 9001 quality management system in a hospital: bureaucracy or just benefits? *Int J Health Care Qual Assur Inc Leadersh Health Serv*. 2005;18(4-5):361–369. https://doi.org/10.1108/09526860510612216.
8. Santry HP, Wren SM. The role of unconscious bias in surgical safety and outcomes. *Surg Clin North Am*. 2012;92(1):137–151. https://doi.org/10.1016/j.suc.2011.11.006.
9. ISO. ISO 9000 family-quality management. https://www.iso.org/iso-9001-quality-management.html; 2019 [Accessed 18 June 2020.
10. Kolka JW. ISO 9001 and Health Care: easier, faster and better than other accreditation programs. Available at: http://asq.org/quality-progress/1999/08/standards-outlook/iso-9001-and-healthcare.html; 2019. Accessed 18 June 2020.
11. Lovett JM, Burney RG. *Using ISO 9001 in Healthcare*. second ed. Milwaukee, WI: ASQ Quality Press; 2014.
12. Al-Najjar SM, Jawad MK. ISO 9001 implementation barriers and misconceptions: an empirical study. *Int J Bus Adm*. 2011;2(3). https://doi.org/10.5430/ijba.v2n3p118.