How Regulators Assess and Accredit Safety and Quality in Surgical Services

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"The spectacles of experience; through them you will see clearly a second time."

—Henrik Ibsen

Background

Systems Thinking and Surgical Safety

With an estimated annual 234 million surgeries performed worldwide, surgery has become an inherent part of health care [1], corresponding to one operation for every 25 people alive [2]. Performing surgical procedures is risky [3]. For example, in industrialized countries, major complications are estimated to occur in 3–16 % inpatient surgical procedures. It is estimated that 0.4–0.8 % of these major complications result in permanent disability or death [2].

Despite research and global safety initiatives over the past decade demonstrating that surgical complications can be preventable, reports suggest that adverse events continue to occur at alarming rates [4]. In an attempt to mitigate risk, there is an increased global recognition on the need to develop standards, requirements, and recommendations within surgical centers. The World Health Organization (WHO) launched the Safe Surgery Saves Lives campaign in January 2007 to improve consistency of surgical care and adherence to safety practices. The Surgical Safety Checklist was created through an international consultative process. The checklist is a 2-min tool, much like the checklist a pilot uses before takeoff, and is designed to help operating room staff improve teamwork and ensure the consistent use of safety processes [5]. In the U.S., as an example, national regulatory groups have been established to focus on integrating and advocating a quality standard for health care. These regulatory groups include for example DNV GL, Joint Commission on Accreditation of Health Care Organizations, the National Quality Forum, the Agency for Healthcare Research and Quality, the National Committee on Quality Assurance, and the Leapfrog Group [2, 6]. More recently in 2014, the Surgical Never Events Taskforce developed a

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series of recommendations for new standards and systems to further develop and improve the safety of surgery in UK hospitals [7].

Quality of Care in Surgery Settings

The ideal way to ensure quality of care is to have internal quality assurance processes within each individual setting, and to have an external means of measuring quality of care across settings, for similar procedures. If each provider is vigilant in benchmarking/tracking quality indicators and is engaged in continuous efforts to improve patient outcomes, patient health and safety will be better protected [8]. State licensing, federal certification, and accreditation standards all require some level of internal quality assurance.

However, from an external perspective, quality of care is most often measured through determining compliance with minimum state, federal, or accreditation standards. Compliance is determined through periodic surveys or complaint investigations. Data on compliance trends is collected by the state and federal government and accreditation organizations, but there is very little data or analysis that is routinely made available to the public about the quality of care in surgery settings. Further, the data collected by external entities varies greatly in its rigor and requirements, and quality comparisons across all setting categories for the same procedures are not possible at the current time.

Other mechanisms for measuring quality may include research studies or quality indicators. However, there have been very few published studies, articles, or analysis about the quality of care in surgery and especially outpatient settings readily available to the public. A growing public concern relates to the question of how increased volumes of specific procedures can minimize negative patient outcomes. This is consistent with other studies and practices for other types of surgical procedures. Indeed, some state and federal standards require minimum numbers of procedure as a condition of qualifying to perform those procedures.

While each of these methods of measuring quality of care has benefits, they are often under the oversight authority of different agencies or organizations (both public and private). The available information maintained or collected by these agencies differs greatly. Therefore, it is difficult to reach overall conclusions about the relative quality of care provided across all categories of outpatient and inpatient surgical settings, for general surgery or for subspeciality procedures.

Comparison of Current Assurance Schemes in Surgical Safety: National and International

Many clinicians and hospital administrators wonder how regulators assess safety and quality in surgical services. Accreditation is a process of review that health care organizations participate in to demonstrate their ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. The health care organization or ambulatory surgery center pays a fee to the accreditation organization (AO) for the costs related to oversight of the setting.

A quality assurance scheme of surgical services can be in the form of a mechanism to ensure that the end-users are going through a safe and the least risky journey within the health care organization, pursuing an outcome acceptable by certain standards (http://www.asianhhm.com/surgical-speciality/quality-assurance). To date, there are very few assurance schemes targeting surgical safety. In Table 45.1, we document examples of assurance schemes related to surgical safety. These examples show that surgical assurance schemes are still patchy and vary highly from one practice to another, and from one country to another. The examples are categorized into the following types [9]: (1) national or international, (2) Statutory regulation and institutional licensing, (3) or voluntary system (e.g., peer review and health care accreditation).

The advantage of statutory regulations and institutional licensing as forms of assurance schemes is their visibility in that they mandate health care providers to change the way surgery is organized and practiced. For example, the surgical checklists introduced by the World Health Organization (WHO), which were designed and implemented throughout the globe to help reduce surgical mortality and complications, have been

Table 45.1 Overview of international regulatory and quality assurance schemes

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 7151:1988	1988		Surgical instruments—Non-cutting, articulated instruments—General requirements and test methods
Internationally	Voluntary system		ISO	ISO 7153-1:1991	1991	Contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and specific instruments for orthopedic surgery. It takes into account steel grades and chemical compositions	Surgical instruments—Metallic materials—Part 1: Stainless steel
Internationally	Voluntary system		ISO	ISO/DIS 7153-1	Under development	Standardization in the field of surgical instruments such as forceps, scissors, scalpels and retractors	Surgical instruments—Materials—Part 1: Metals
Internationally	Voluntary system		ISO	ISO 7153-1:1991/ Amd 1:1999	1999		
Internationally	Voluntary system		ISO	ISO 7740:1985	1985	Lays down the dimensions of two sizes of fitting features for detacheable scalpel blades and the handles with which they are used. It secures a good fitting and interchangeability of detachable blades for scalpels manufactured in different countries or by different manufacturers. The transitional period for a gradual adaption of the fitting dimensions specified in this standard should end with the year 1990	Instruments for surgery—Scalpels with detachable blades—Fitting dimensions

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Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 7741:1986	1986	This standard deals with materials, heat treatment and hardness of component parts, corrosion resistance, workmanship and cutting ability of scissors and shears used in the surgery and defines the test methods	Instruments for surgery—Scissors and shears—General requirements and test methods
Internationally	Voluntary system		ISO	ISO 13402:1995	1995	Describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure	Surgical and dental hand instruments—Determination of resistance against autoclaving, corrosion and thermal exposure
Internationally	Voluntary system		ISO	ISO 8828:2014	2014	ISO 8828:2014 specifies the recommended procedures for handling orthopedic implants, hereafter referred to as implants, from receipt at the hospital until they are implanted or discarded. This guidance applies to implants (such as currently used metal, ceramic, or polymeric implants) and also to acrylic resin and other bone cements. This guidance does not apply to the implant manufacturer. However, it contains references to the stocking of implants that can be useful for manufacturers and especially for third-party suppliers	Orthopedic implants

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 12891-1:2015	2015	ISO 12891-1:2015 specifies the method to be followed for the retrieval and handling of surgical implants and associated tissues and fluids. In particular, it specifies the essential steps to be followed for the safe and proper obtaining of the clinical history, pre-explantation checks and examinations, collection, labelling, cleaning, decontamination, documentation, packing and shipping. It also provides guidance on infection control. *Note* National or other regulations, which can be more stringent, can apply. ISO 12891-1:2015 does not apply in cases of explantation where there is no intention to collect retrieval data. However, many clauses give useful information which can apply in these cases also. ISO 12891-1:2015 specifies the method to be followed for the retrieval and handling of surgical implants and associated tissues and fluids. In particular, it specifies the essential steps to be followed for the safe and proper obtaining of the clinical history, pre-explantation checks and examinations, collection, labelling, cleaning, decontamination, documentation, packing and shipping. It also provides guidance on infection control. *Note* National or other regulations, which can be more stringent, can apply. ISO 12891-1:2015 does not apply in cases of explantation where there is no intention to collect retrieval data. However, many clauses give useful information which can apply in these cases also	Retrieval and analysis of surgical implants—part 1: retrieval and handling

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National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 12891-2:2014		ISO 12891-2:2014 specifies methods for the analysis of retrieved surgical implants. ISO 12891-2:2014 describes the analysis of retrieved metallic, polymeric and ceramic implants. The analysis is divided into three stages which are increasingly destructive. ISO 12891-2:2014 can also be applied to other materials, e.g. animal tissue implants. ISO 12891-2:2014 can be applied in accordance with national regulations or legal requirements regarding the handling and analysis of retrieved implants and tissues and associated biological material	Retrieval and analysis of surgical implants—part 2: analysis of retrieved surgical implants
Internationally	Voluntary system		ISO	ISO/TR 14283:2004		ISO/TR 14283 provides fundamental principles for the design and manufacture of active or non-active implants in order to achieve the intended purpose	Active or non-active implants
Internationally	Voluntary system		ISO	ISO/CD TR 14283	Under development		Implants for surgery
Internationally	Voluntary system		ISO	ISO 14607:2007	2007	ISO 14607:2007 specifies particular requirements for mammary implants for clinical practice. With regard to safety, ISO 14607:2007 specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer	Non-active surgical implants—mammary implants
Internationally	Voluntary system		ISO	ISO/WD 14607	Under development		Non-active surgical implants—mammary implants

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO 14630:2012	2012	ISO 14630:2012 specifies general requirements for non-active surgical implants. ISO 14630:2012 is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue. With regard to safety, ISO 14630:2012 specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements	Non-active surgical implants
Internationally	Voluntary system		ISO	ISO 16054:2000	2000	Minimum data sets for surgical implants	Implants for surgery
Internationally	Voluntary system		ISO	ISO 16061:2015	2015	ISO 16061:2015 specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment. This International Standard also applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves. With regard to safety, this International Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the manufacturer. This International Standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants, and ophthalmic implants	Instrumentation for use in association with non-active surgical implants

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National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
Internationally	Voluntary system		ISO	ISO/WD 17327	Under development		Non-active surgical implants—implant coating
Internationally	Voluntary system		ISO	ISO/CD 19227	Under development		Cleaning of orthopedic implants—general requirements
Internationally	Voluntary system		ISO	ISO 10282:2014	2014	ISO 10282:2014 specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves. It covers gloves with smooth surfaces and gloves with textured surfaces over part or the whole glove. ISO 10282:2014 is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling, packaging, and storage procedures are outside the scope of ISO 10282:2014	Single-use sterile rubber surgical gloves
Internationally	Voluntary system		ISO	ISO 10334:1994	1994	Specifies the dimensions and mechanical properties and gives test methods. The mechanical properties specified are tensile strength, elongation, and resistance to damage in bending and in torsion. Surface finish is not covered	Implants for surgery—malleable wires for use as sutures and other surgical applications

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	The UK	Association of Breast Surgery (ABS) at BASO	Quality assurance guidelines for surgeons in breast cancer screening	1992 (first publication), updated in 1996, 2003, 2009	The guidelines are addressed principally to surgeons working in the screening program for breast cancer, who will use the guidelines in a personal capacity to audit their own activity	Breast cancer screening program
National	Voluntary system	Australia	Queensland Health, Governmental organization	VLAD system		VLAD charts provide an effective, easily visualized display of surgical performance and can be applied to pediatric cardiac surgery. Early detection of change, whether improvement or deterioration, is important for ongoing quality assurance within a cardiac surgery program	
National	Voluntary system	The UK		Quality assurance program (QAP)		The implementation of a QAP improved quality of care in terms of consistency of patient selection and outcomes of surgery during a period of major reorganization of cancer services in London. The QAP framework presented could be adopted by other organizations providing complex surgical care across a large network of referring hospitals	
International	Voluntary system		WHO	Surgical safety checklists:		The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anesthesia (“sign in”), before the incision of the skin (“time out”) and before the patient leaves the operating room (“sign out”). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation	

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National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	USA	Accreditation Association for Ambulatory Health Care (AAAHC)	Handbook for small office-based surgery practices			
National	Statutory regulation and institutional licensing	The UK	Care Quality Commission (CQC)			CQC inspection is based on the following questions: (1) are services safe, (2) are services effective, (3) are services caring, (4) are services responsive to people's needs, (5) are servies well-led	In general clinics but include surgical practices
International	Voluntary system	EU	European Union	European guidelines for quality assurance in breast cancer screening and diagnosis			
National	Voluntary system	USA	American College of Surgeon	American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®)		Various surgical quality assurance programs within surgery, using four key principles required to measurably improve quality of care and increase value: (1) Standards, (2) Right Infrastructure, (3) Rigorous data, (4) Verification	Various surgical services e.g. National Accreditation Program for Breast Centers (NAPBC), Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBASAQIP)

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	UK	The Association for Periope-rative Practice (AfPP)			Guidance on a number of perioperative issues e.g. best practice for safe handling of surgical sharps, PCC perioperative support worker, safer surgery checklist, etc.	Perioperative
National	Voluntary system	UK	The Royal College of Surgeons of England			Develop a range of guidance aimed to provide a robust framework for promoting good practice in surgery, professional development and effective delivery of surgical services e.g. guidance for individual surgeons and for the surgical team on professinalism and good practice, guidance on day-to-day working practices that facilitate and promote the delivery of effective services, and guidance and tools on appraisals and revalidation	
National	Voluntary system	UK	The Royal College of Surgeons of Edinburgh (RCSEd)			RCSEd develops a range of guidance aimed to provide a robust framework for promoting good practice in surgery, professional development and effective delivery of surgical services	
National	Statutory regulation and institutional licensing	Canada	Accreditation Canada			Accreditation Canada's sector and service-based standards help organizations assess quality at the point of service delivery. They are based upon five key elements of service excellence: clinical leadership, people, process, information, and performance. These standards contain the following sections: Investing in surgical care services. Engaging prepared and proactive staff. Providing safe and appropriate services. Maintaining accessible and efficient clinical information systems. Monitoring quality and achieving positive outcomes	

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National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Statutory regulation and institutional licensing	France	The Haute Autorité de santé (HAS)—or French National Authority for Health			Provides practice guidelines in general that also include surgery services	
International	Voluntary system	EU	*The European Union of Medical Specialists* (Union Européenne des Médecins Spécialistes—UEMS)			*The main activities of the EUMS can be summarized in four headings*: Surgical training Standard of the Certificate of Completion of Specialist Training (CCST) Continuing Medical Education in Surgery (Continuing Professional Development) Surgical Quality Control	
National	Statutory regulation and institutional licensing	USA	Centers for medicare and medicaid services (CMS)			*Include conditions of participation for hospitals with surgical services, for example*: (1) If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. (2) Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC	

Table 45.1 (continued)

National/ international	Statutory regulations and Institutional licensing/ voluntary system	Country, if national	Regulators/ organizations providing the requirements	Keywords	Year of publication (between 2000 and 2015)	Brief description of assurance schemes	Focus of assurance
National	Voluntary system	USA	Joint Commission (JC)			Include standards on Surgical Site Infection (SSI)	Hospital acquired infections
National	Voluntary system	USA	Joint Commission (JC)			Include Surgical Care Improvement Project (SCIP)	National quality partnership of organizations interested in improving surgical care by significantly reducing surgical complications
National	Voluntary system	USA	Joint Commission (JC)			*Office-based surgery accreditation*	Smaller surgical practices
International	Voluntary system		Joint Commission International (JCI)			None found specific related to surgical services	
International	Voluntary system		Accreditation Canada International			None found specific related to surgical services	
National	Voluntary system	Canada	Accreditation Canada			Accreditation Canada's sector and service-based standards are based upon five key elements of service excellence: clinical leadership, people, process, information, and performance	
National	Voluntary system	Canada	Royal College of Physicians and Surgeons of Canada			Among their core functions is to accredit medical education under two broad categories: (1) the residency programs sponsored by Canada's 17 medical schools, (2) and the learning activities pursued by physicians who engage in continuing professional development	Residency programs and learning activities pursued by physicians for professional development

part of many national regulations in the USA and Australia [10, 11]. Since 2012, the US Centers for Medicare & Medicaid Services (CMS) requires ambulatory surgery centers (ASC) to conduct quality reporting that includes the use of surgery checklists for all, not only Medicare, patients [12, 13].

Within voluntary schemes, it is worth noting that non-governmental, private sector regulators are rapidly gaining their influence in the way that surgery is practiced, billed and supervised [6]. For example, the Leapfrog Group [13] has become one of the most powerful forces in the private regulatory sector and provides excellent evidence on the impact of this sector on surgical care. Furthermore, specialty colleges or board and professional licensing bodies are key players in developing assurance schemes based on consensus into more uniform, regulated schemes. For example, there is a global trend in developing and implementing a scheme for physicians' continuous professional development such as schemes to maintain physicians' competence [14]. In Australia, as an example, the Royal Australasian College of Surgeons requires surgeons to maintain their skills, knowledge and competence by self-directed learning, teaching, researching, publishing scientific articles, and attending educational gatherings such as scientific meetings, workshops, and seminars. In most of western countries, surgeons must retain records to verify their competence and professional development [14].

The specialty colleges or boards can also potentially be the champions in closing the gap in the areas in need of regulations such as robotic surgery. Technology advancements in surgery are growing rapidly, for example, the scale and spread of 3-D organ and prosthetic printing. This growth creates an urgent need for assurance schemes to ensure the quality and safety of patients not being harmed from the technology. Currently, there are no standards, nationally or internationally, for assuring patients are not harmed during the use of robotic surgery. However, there is a growing consensus in this field, such as a consensus document produced by The Society of American Gastrointestinal and Endoscopic Surgeons [15, 16]. This consensus document provides guidance to surgeons wishing to perform robotic surgery to fulfill specific training prior to performing it.

Most surgical assurance schemes have a focus mainly on prescriptive, rather than performance-based frameworks. Whereas health care practitioners need assurance schemes that are performance-based to help them put systems thinking into practice. This is crucial to ensure that end-users receive the necessary treatment with the desired outcome. There remains an evidence gap forcing regulators to be ever vigilant about the safety and reliability of surgical services [9].

Outpatient/Ambulatory Surgery

National and international professional associations have published information about the quality of care provided in outpatient settings for their own specialties, there have been very few published studies, articles, or analyses about the overall quality of care in outpatient surgery settings. In addition, there is little information about the relative quality and safety of specific outpatient surgical procedures across the range of settings in which these surgeries are performed.

Quality of care is most often measured by internal facility quality assurance processes, and by information collected by oversight agencies through determining compliance with minimum state, federal, or accreditation standards. Data may be collected by the state and federal government, accreditation organizations, and internal facility quality assurance processes, but this data is not analyzed in such a way as to reach a determination about the quality of care, nor is this information readily available to the public.

In order to protect public health and safety, and to provide more information about health care being provided in outpatient surgery settings, a fresh look at the oversight, transparency, and quality of care across all settings is warranted. Some of the opportunities will require additional analysis and stakeholder involvement to develop and will take more time than others.

Future Challenges in the Assessment and Regulation of Surgical Safety and Quality

The Surgical Never Events Taskforce standards provide an overarching framework with high level descriptions of what should constitute standard practice for peri-operative procedures that can be developed locally to create standardized practices within organizations [7]. For surgical centers that are required to meet specific standards or requirements that promote quality assurance and improve the processes by which their services are held accountable to the public, accreditation and/or regulation models provide the means of ensuring the correct environment for clinical practice has developed into a form of public regulation [17]. In brief, the regulatory model is driven by the government in which standards are set and the inspection of health care organizations within these standards produce verification for continued operation, often a condition for receiving public funding. Accreditation is often characterized by a model driven by self-regulation or voluntary participation, where the compliance of standards are both defined and assessed by an independent body [18]. This external validation of standards in safe practices can provide the patient and relevant stakeholders with information about surgical center's commitment and progress toward quality improvement and safety, with benchmarking performance against other accredited facilities. An organization's motivation for accreditation can stem from a number of different areas, all of which are subject to the model adopted. As a result, these local standards and their oversight are highly dictated by local country specific policies.

Developing and Applying Surgical Standards

The growing interest in the development and application of standards for surgical centers is due to the presumption that accreditation may provide surgical centers the advantage of improving outcomes of surgical practices. However, given the only recent growth of regulation and accreditation in surgical centers, there is little research to empirically support this claim. Recently two studies were published that examined the impact of accreditation in bariatric and ambulatory surgical centers [19, 20]. The outcomes of bariatric surgery performed compared between those done at accredited versus non-accredited centers using a nationally representative database evaluated a total of 277,068 bariatric operations performed within a 3-year period. Results of the study indicated that accreditation in bariatric surgery was associated with more than a threefold reduction in risk-adjusted in-hospital mortality [19]. The results, however, were not as favorable toward accreditation in a study that examined the impact of accreditation in ambulatory surgical centers (ASC) suggesting no systematic differences in the quality of care between ASCs that were accredited or and those that were not accredited. This aligns with the most comprehensive meta-analysis of accreditation and certification studies and which demonstrated little to no evidence supporting any lasting positive outcomes of these efforts given the way accreditation is presently conducted [21].

In light of the limited evidence comparing the safety and outcomes of accredited and non-accredited surgical centers, a very important contribution to accreditation is the process of assessment and regulation that allows for organizations to understand the range of risks that are present, their ability to control them, the probability of occurrence and its potential impact—Fig. 45.1. If risks are properly assessed and managed then it stands to reason that, with appropriate controls in place, the safety and quality of surgical outcomes can be increased. As surgical centers are moving towards a greater emphasis on establishing standards and requirements that mitigate and potentially eliminate risks to the patient, accreditation systems have the potential to address the reliability of this process. Fortes and colleagues [22] describe the development of accreditation as a tool "to evaluate the risks that occurred in the hospital environment, with the objective of protecting the professional that worked at these units." These good intentions, however, come with various challenges for accreditation surveyors related to implementing approaches that

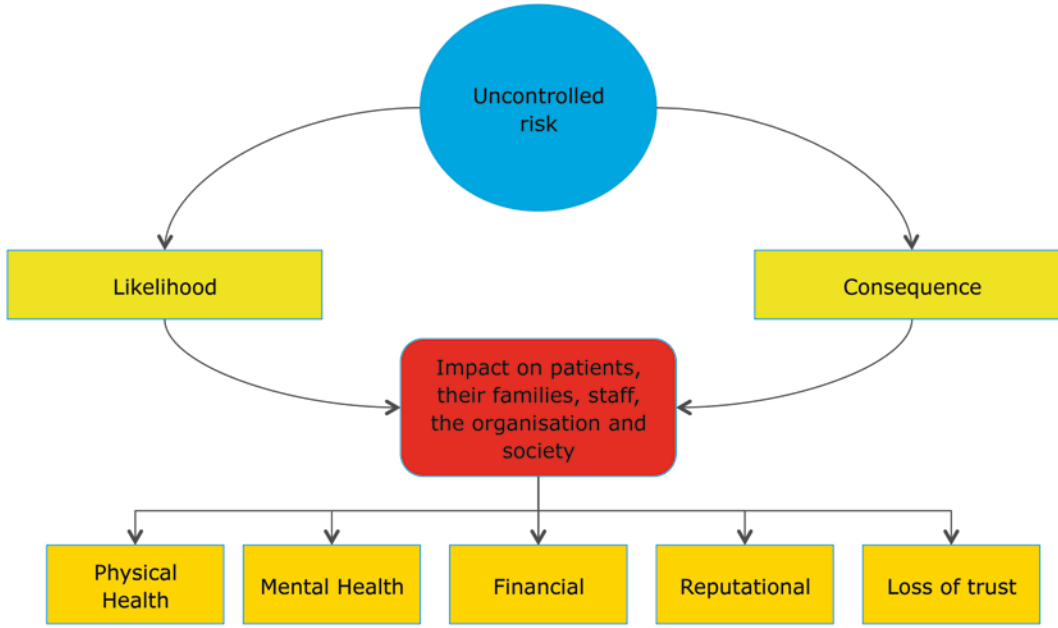

Fig. 45.1 Enterprise Risk Management approach and its impacts on patients, families, providers, managers and society

accurately assure that the surgery center policies and procedures designed to aid clinical practice are reflected in safe patient outcomes and are internalized by the providers doing the surgery.

Specifically, the activities related to the assessment of surgical safety centers, which are often characterized as having dynamic and complex infrastructures, can be a daunting process for external accreditors. This is especially the case when properly identifying the unique risks specific to the center being assessed. This is mostly due to a process that is dependent on the willingness of the organization to report and disclose past, current, and anticipatory errors. Unfortunately, the culture of fear of punishment and litigation leads hospital personnel to avoid disclosing or to shading this information [23]. As a result, in order to gain an accurate understanding of the center's adherence and performance to mitigating risk, the assessor must rely on a deep knowledge of the domain, have the skills to tactfully navigate the political challenges, using nimble risk management approaches and tools. Assessors must additionally use their time and resources wisely to provide a wider assessment of the factors that may be relevant to surgical safety outcomes in capturing all the salient features of surgical operation [24]. Vincent et al. [24] suggests including factors such as equipment design and use, communication, team coordination, human factors affecting individual performance, and the working environment [25, 26]. Others who have conducted and analyzed over 100 surgical RCA point to the need to better understand what the employees and staff feel is important and relevant to the investigation [27]. The broad competencies expected by assessors can be difficult to achieve and presents a challenge in both recruiting and training surveyors, and in providing an objective evaluation by third party agencies.

Building Safety Through Accreditation and Risk-Thinking: Responsibility and Accountability

Researchers are identifying strategies in auditing that ensure risks are being accurately assessed. For a successful adaptation strategy, this demands a more dynamic approach that focuses on the

system as a whole by including all levels of the organization from top leadership to workers at the coal face [28]. Yet for decades, auditing and safety improvements have been driven by the retrospective review of incident reports, errors, and violations. The problem with these approaches is that they mean a negative event has already occurred. A more proactive approach is to assess the likelihood and consequence of something going wrong within a process and the system in which it takes place and to put in place controls to prevent or mitigate the negative event [29]. Such a risk-based approach underpins the nature of accreditation.

Designated individuals should be responsible for the clinical and financial outcome of patient pathways and accountable to senior management. All information should be distilled as it flows upwards, to keep leaders informed but not overwhelmed with data, with appropriate levels of detail for each audience. In some of the best examples, quality and safety are built into the strategic goals and become a central part of all board meetings, supported by robust internal audits to verify the established high standards of governance, as with financial audits, are consistently applied [30].

Optimizing and Standardizing Clinical and Organizational Processes

Doctors have typically been deeply resistant to standardization, believing that every patient is unique. However, such an individual-by-individual approach actually increases the likelihood of errors. Leading providers have achieved dramatic results by implementing standard guidelines and operating procedures, increasing patient survival rates and cutting the cost of care significantly. The path to standardization can, however, be slow and painful, with staff at all levels reluctant to change behavior, resulting in a frustrating lack of compliance. Clinical leaders must be relentlessly vigilant in checking and double-checking adherence to protocol, making those on the front line directly accountable and stressing that guideline adherence is not a loss of professional autonomy, merely a replacement of pure *individual* autonomy by more *collective* autonomy [31]. Results should be fed back to the pathway owners, whose task is to continuously improve the performance and thus the quality of care. Information technology (IT) plays a vital role in measuring outcomes and improving processes. However, some of the most impressive breakthroughs have occurred in organizations where the IT infrastructure was still unsophisticated, so technological limitations are no reason for inactivity [32].

A Culture Devoted to Quality and Reliability

Health care can be thought of as hypercomplex, involving interacting processes, systems and people (Table 45.2). Risk based approaches offer a way to tackle the way in which people and socio-environmental factors interact. Risk thinking encompasses cyclical, continuous and dynamic processes of assessing hazards and selecting, implementing and evaluating controls to reduce the potential of those hazards from becoming harm [33]. It offers a means to create safer, high quality care by addressing in structured, scientific ways human, technical and organizational issues, i.e. the nexus of factors and circumstances where preventable harm most often arises [8]. In doing so, it supports the spread and sustainability of good practice, by enabling people to understand their local context; the nature of any innovation; and its planned cause and effect (including foreseeable positives and negatives).

Learning from other high risk sectors supports this [34]. Responding to major disasters such as Flixborough and Piper Alpha [35], other sectors have made great strides in improving safety at a system level by using risk based approaches [36]. They have been able to think ahead about what the obstacles and hazards might be; how those obstacles and hazards might prevent improvements or become harmful outcomes; and how systems can then best be designed to prevent or mitigate unintended results [34].

Table 45.2 Dimensions and attributes of the hyper complex nature of health care

Dimensions	Attributes
Vulnerability and involvement of "end user"	• Unwell, fearful, impaired communication • Variable knowledge—information asymmetry and vulnerability to quackery and fraudulent information • End user is also a component but non-standardized (genetics, social circumstances, choices = life course) • Most processing is "off plant"
Leadership and culture	• High degree of professional autonomy and power • Silo working with emphasis on specialization • Ambiguous and ambivalent relationship to management • Poor history of safety education and culture—implicit rather than explicit
Highly politicized	• Constant wholesale change • Evolution rather than system design • Conflicting goals • Regulatory tensions—centralism vs. localism • Ideological toy • Almost daily media coverage
Activity patterns	• Large numbers • Difficult to impossible to shut down • Lots of predictability but episodes of uncertainty (new diseases, major incidents)—not just emergencies but immediate sustained changing needs
Technical/competence	• Differentiated workforce with varying education and competence—from no post-compulsory education to post-doctoral • Research to practice gap—information overload and varying competence in critique and application • Tendency towards pseudo-invention and pseudo-understanding • Guidance/guideline multiplicity and (in)coherency • Diversity of providers and equipment—lack of standardization and evolutionary introduction/adoption
Geography	• System orbiting and overlap in patient pathways • Patient movement within and across systems and organizations (primary, secondary, tertiary health care; social care; voluntary sector) • Regulation behind the curve—often different for primary, secondary, tertiary health care; social care; voluntary sector—reflected by being "under" different government departments

Accreditation provides a framework for organizations to put risk thinking into practice and address the hypercomplexity of health care. It is a program of activity in which trained external peer reviewers evaluate an organization's compliance with preestablished standards [37, 38], that can be applied to specific areas (such as managing infection risk or wrong site surgery [39]) or across an organization's services. The iterative processes build on risk thinking by helping an organization to drive best practices in risk management (Table 45.3).

Table 45.3 Iterative best practices in risk management

Step 1:	Map processes (including how processes connect within and between organizations)
Step 2:	Identify and assess risks to human, technological and organizational safety and performance
Step 3:	Establish prevention and mitigation controls to deliver safe and reliable results
Step 4:	Continuously monitor to evaluate the efficacy of those controls

The risk thinking inherent in accreditation supports wider models of improvement, such as the Baldrige Model [13]—Fig. 45.2. By supporting organizations to identify, prioritize, and manage risks accreditation tackles the key dimensions of quality.

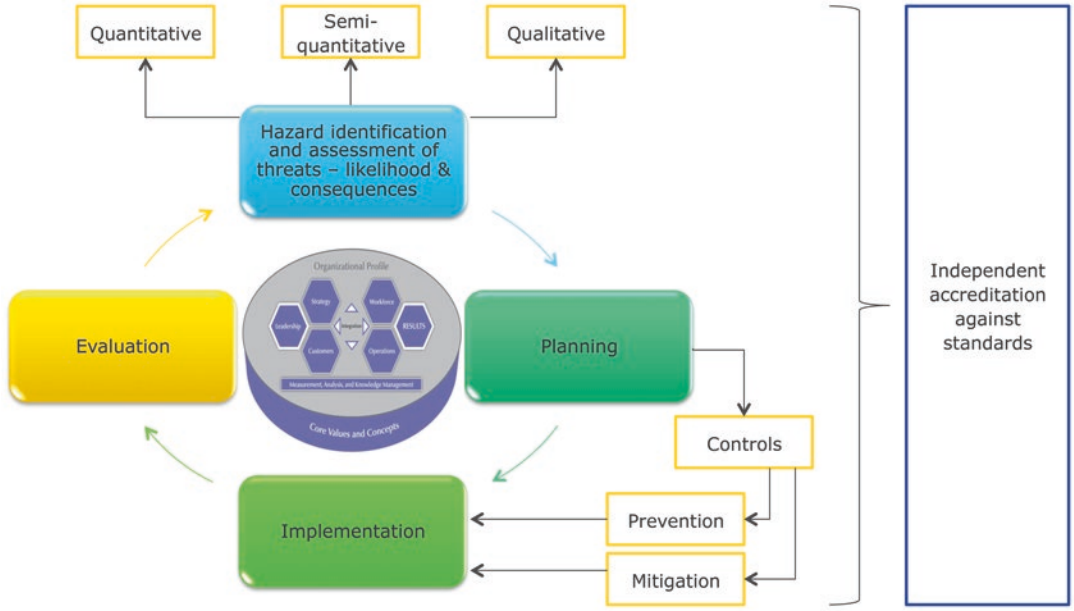

Fig. 45.2 Risk-based thinking underpinning accreditation and other quality improvement models, such as the Malcolm Baldrige National Quality Award

Wrong-Site Surgery: A Dynamic Risk Management Model

One way to bring accreditation to life is to use an example of how the risk thinking that underpins it can be applied to practice. The problem of wrong-site surgery is a useful illustration. Wrong-site surgery includes operations performed on the wrong side or site of the body, the wrong procedure performed, and surgery performed on the wrong patient [40]. Wrong-site surgery is classified as a never-event [13] because it is both preventable and can be devastating for patients and professionals alike.

Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse (WSPE) events, although rare, are more common than health care providers and patients appreciate [41]. Wrong-site surgery is associated with failures in communication (70 percent), procedural noncompliance (64 percent), and leadership (46 percent) [42]. Other system and process causes are listed in Table 45.4. Risk factors associated with wrong-site surgery are emergency cases, multiple surgeons, multiple procedures, obesity, deformities, time pressures, and unusual equipment or setup, and room changes. Prevention of WSPEs requires new and innovative technologies, reporting of case occurrence, and learning from successful safety initiatives (such as in transfusion medicine and other high-risk nonmedical industries), while reducing the shame associated with these events.

Organizations that want to deliver highly reliable and patient centered outcomes based around the model in Fig. 45.3 can assure regulators and accreditors that they are managing their risks, constantly vigilant at what could go wrong, assessing the likelihood and consequences, and developing robust yet proportional controls at each stage of the surgical patient pathway [44].

Learning from Experience: The Accreditation Process and How to Ensure Effective Implementation

Accreditation programs vary extensively as do the organizations that carry out accreditation visits. There is however one constant across all accreditation programs and that is the need for organizations to undertake a deep and authentic

Table 45.4 Causes of wrong-site surgery [43]

System factors	Process factors
• Lack of institutional controls/formal system to verify the correct site of surgery • Lack of a checklist to make sure every check was performed • Exclusion of certain surgical team members • Reliance solely on the surgeon for determining the correct surgical site • Unusual time pressures (e.g., unplanned emergencies or large volume of procedures) • Pressures to reduce preoperative preparation time • Procedures requiring unusual equipment or patient positioning • Team competency and credentialing • Lack of complete information • Organizational culture • Orientation and training • Staffing • Environmental safety/security • Continuum of care • Patient characteristics, such as obesity or unusual anatomy, that require alterations in the usual positioning of the patient	• Inadequate patient assessment • Inadequate care planning • Inadequate medical record review • Miscommunication among members of the surgical team and the patient • More than one surgeon involved in the procedure • Multiple procedures on multiple parts of a patient performed during a single operation • Failure to include the patient and family or significant others when identifying the correct site • Failure to mark or clearly mark the correct operation site • Incomplete or inaccurate communication among members of the surgical team • Noncompliance with procedures • Failure to recheck patient information before starting the operation

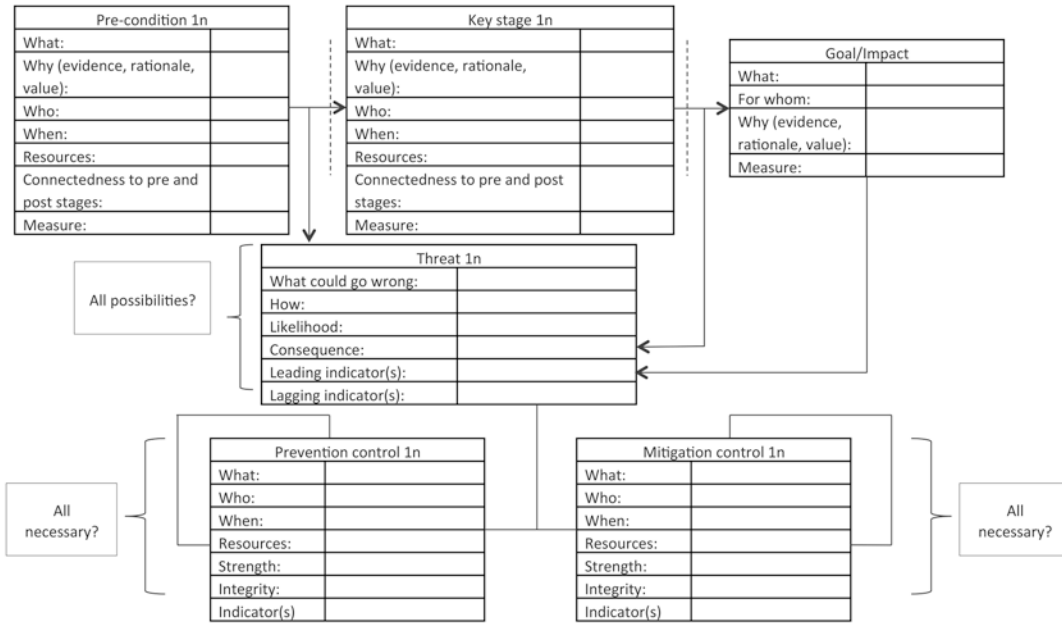

Fig. 45.3 Risk-based process mapping

reflection process to learn from their experiences. By undergoing accreditation, organizations have multiple opportunities to learn from experience and influence positive change; the challenge is identifying these learning opportunities and ensuring their effective implementation.

Accreditation is not and should never be a one-off process that organizations only engage with in the run up to and during the actual accreditation visit. The evidence shows that these types of accreditation approaches rarely if ever lead to lasting change in quality, outcomes or value [21]. Accreditation must be viewed as a continual learning process taking place at every level of the organization and supported by the accreditation journey. All accreditation programs have two key stages: preparation and accreditation. The first covers the key actions that an organization should undertake before an accreditation visit—Table 45.5.

The second stage, the accreditation process itself, varies from program to program, and normally includes the requirement for an on-site visit. This will be followed by either an accreditation award or the need to implement improvement actions prior to accreditation being awarded. Organizations that achieve accredited status may then be required to undergo periodic visits prior to a full re-accreditation visit. The nature and timing of these visits again varies extensively between programs but all will require a full re-accreditation visit 2, 3 or even 4 years after the initial visit.

A good accreditation program will not require an organization to develop systems that are not already required by law, professional guidelines, etc. They serve rather as a framework within which organizations can guide, co-ordinate and implement their quality and safety improvement activities. Unfortunately, in the years between initial and re-accreditation visits, many organizations focus on other priorities and let their attention drift from the accreditation requirements. By drifting from the accreditation program organizations also find that their quality and safety improvement activities also drift and have highly variable outcomes.

Table 45.5 Actions to undertake prior to an accreditation visit

Key actions:
• Understanding the accreditation program and standards/requirements;
• Establishing governance arrangements for the accreditation;
• Pulling together and briefing a team;
• Identifying what help is available from the accreditation body;
• Conducting a self-assessment;
• Producing an action plan with clear roles and responsibilities;
• Implementing the action plan and reviewing progress.

So how do organizations ensure continual buy-in to an accreditation program and use it as an on-going performance improvement tool?

There are several key factors to be considered:

1. *Selection of the right accreditation program* is crucial. Accrediting organizations must have a clear remit and that must be understood by the organization being accredited. The accreditation program itself should include a requirement for self-assessment and on-site visits. The length of these visits should be proportional to the size of the organization to allow adequate time to understand the organization's processes. The accreditation program must be cyclical and must be used to drive *continuous improvement* and therefore the structure and content of any program should drive this.
2. Accreditation programs *must allow for improvement action* to be taken when a problem is identified. There is much merit in having an improvement process to enable organizations with identified problems the opportunity to put into place improvement actions. The process should not end with the production of the action plan but must involve review of plan implementation and follow up by the accreditation agency. Reports on accreditation outcomes must be shared with staff and the organizations so that they have a clear action plan to work from.
3. The team sent to audit an organization must have experience and deep domain knowledge the organization's field. They needs to understand how clinical teams work, how to assess

and capture optimal team performance designed around surgical microsystem system properties [45, 46]. This will help to ensure understanding of the organization and buy-in from those that they are auditing. The provision of support in the form of education and guidance is essential for organizations going through accreditation. Accreditation programs need to be conceptual with guidance on practical implementation.

4. Senior managers must however ensure that the mark of success of any accreditation program is not merely the achievement of an award, but the *learning and improvement opportunities associated with accreditation*. The way in which senior managers engage with clinicians and hospital staff and promote the accreditation program will have a direct effect on the program and quality improvement. Without senior management buy in and support it is unlikely that staff will wholly commit to, and engage with the process and opportunities for improvement may be lost [47]. Senior managers who react positively to the accreditation process and proactively respond to improvement recommendations will demonstrate to staff that accreditation can be used as a learning opportunity rather than as a "stick to beat" the organization [48].
5. *Authentic communication* within organizations and the establishment of multidisciplinary teams, in which clinicians actively participate, are also essential. Clinicians may be reluctant to participate in accreditation programs if the lack of transparency and their lack of awareness of what the program is trying to achieve or if they have little or no input to the preparation process [49]. Gaining their input to resultant quality improvement activities will therefore be challenging. Nominating clinical leads, developing communication plans and sharing knowledge within teams will all help with learning.
6. Finally, it is vital that organizations *set realistic expectations*. Accreditation milestones and deliverables should be established at the outset and actively discussed and agreed upon. These should not impose unrealistic expectations on staff and should allow time for improvement actions. Any improvement work should be based on standard quality improvement methodology such as "Plan, Do, Study, Act" to ensure that improvement actions are embedded within the organization [50].

Does Accreditation and Certification Make a Difference?

Accreditation and certification have been proposed as interventions to support patient safety and high quality health care. Guidelines recommend accreditation but are cautious about the evidence, judged as inconclusive. The push for accreditation continues despite sparse evidence to support its efficiency or effectiveness. Greenfield and Braithwaite identified the effects of accreditation on promoting change and professional development, indicating that the effects were probably due to accreditation and certification, but lacking firm evidence [51]. A systematic review by Nicklin et al. [52] found several positive benefits of accreditation; however, the study lacked rigor to support their conclusions. Shaw et al. [53] found evidence for positive effects between accreditation, certification and clinical leadership, systems for patient safety and clinical review, but was fell short of endorsing accreditation, and concluded with recommending further analysis to explore the association of accreditation and certification with clinical outcomes. Furthermore, Ho et al. [54] have demonstrated an unintended negative impact on the learning environment of medical students and trainees, including decreased clinical learning opportunities, increased non-clinical workload, and violation of professional integrity in preparation and during accreditation and certification.

A recent extensive meta-analysis literature review [21] uncovered three systematic reviews and one randomized controlled trial. The lone study assessed the effects of accreditation on hospital outcomes and reported inconsistent results from one controlled study, the randomized trial from South Africa from 2003. The study [55], however, is weak scientifically, and does not address morbidity or patient safety

measures well enough to support any conclusions across a wide range of safety systems examined.

The methodological challenges of measuring the effects of accreditation/certification are increased by the complexity of the hospital organizations and their heterogeneous components. Lessons can be learned from non-controlled studies such as cross-sectional studies [56]. Comparison between accredited and non-accredited hospitals yields important information about potential differences between these hospitals, but cannot provide information about the observed variations, and whether the results are transferable to other settings.

The review by Brubakk et al. [21] provides a comprehensive overview of the effects of accreditation and/or certification of hospitals on quality and patient safety outcomes and concludes that due to scant evidence, no conclusions could be reached to support its effectiveness. Accreditation programs require substantial financial and labor investments, and distract health care teams from their primary clinical goals. Accordingly further research about the clinical impact of these programs is needed, and it is important to weigh the transactional opportunity and financial costs of accreditation against other financial investments in quality improvement interventions.

Before planning further studies to evaluate impact of accreditation and certification efforts, a more thorough and nuanced analysis of the available evidence about which components of accreditation/certification seem to be most effective in enabling patient centered, high quality and safer outcomes should be performed [57]. These conclusions need to be considered given the impact of how accreditation is managed and executed, and the varied political, financial and organizational macro- and meso-health care constraints [58].

How Best to Prepare for Accreditation Visit?

Accreditation typically occurs over a 3-year cycle—Fig. 45.4. During the accreditation assessment, assessors are looking for evidence of effective risk assessment and controls. Where these are absent or inadequate the assessors will identify them as non-conformities to enable the organization to take corrective actions prior to reassessment. It should not be seen as a one-off event or as an end in itself. Rather it is a continuous process that provides a structure for organizations to manage their risks, improve the quality of their services and to realize the benefits outlined in Table 45.6. A health care organization can prepare for an accreditation visit be following the steps in Table 45.7. Ideally and learning from other high risk domains, healthcare accreditation will be a continuous process of assessment and learning akin to high reliable nuclear power, aviation and maritime industries [36, 59].

Conclusions

Accreditation continues to grow internationally despite inconclusive evidence to support its effectiveness. The surgical space, by nature, is a high-risk hypercomplex environment where hazards lurk around every corner and for every patient. Health care institutions continue to face challenges in providing safe patient care in increasingly complex and demanding technical, organizational, and regulatory environments. Real, sustainable change comes from the organizations and hardworking staff that deliver care to patients. It is odd that something so important and personal as health care does not have widely acknowledged or adopted "industry standards" of inspection, reporting, and improvement.

Both high reliability theory and systems theory provide conceptual and practical frameworks for supporting accreditation driven approaches towards delivering safe and reliable care. Although many ambiguities and conflicts arise from the implementation of these theoretic constructs, they should guide the development of work processes and stimulate innovation in designing ways to provide safe and effective care within health care systems. Organizing surgical care around the pursuit of safety and reliability as an overarching priority is a professional obligation for all members of the health care team. This goal can be accomplished by organizing around and shaping a culture focused on reliable performance but requires substantial investments in human capital.

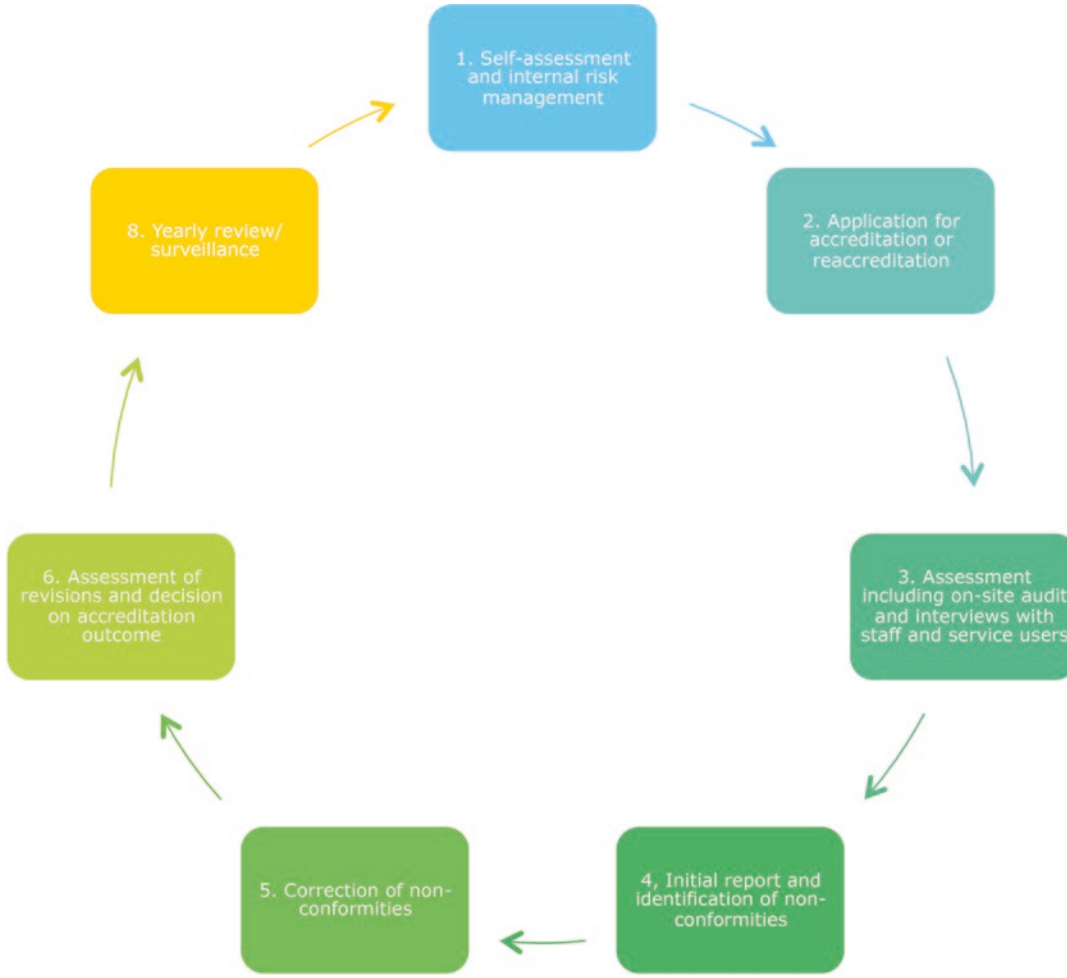

Fig. 45.4 Virtuous and continuous accreditation cycle

Table 45.6 The benefits of accreditation for an organization

Positive impact	Evidence
Improved organization and coordination	?????
More systematic management practice	????
Improved professional practice and compliance with expected standards of care	???
Compliance with QI mechanisms and achievement of other quality indicators	?
Perception amongst health professionals	?

Greenfield D, Braithwaite J. Health sector accreditation research: a systematic review. Int J Qual Health Care. 2008;20(3):172–83

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Greenfield D, et al. (2012) The standard of healthcare accreditation standards: a review of empirical research underpinning their development and impact. BMC Health Serv Res. 2012;12:329

Table 45.7 Steps to prepare for an accreditation visit

1. Form team	(a) Designate responsibilities for ensuring that preparatory work is addressed and that all staff within the organization understand and own the accreditation process
2. Review previous survey results where they exist	(a) Ensure previous requirements/non-conformities have been addressed and action plans implemented
3. Complete a self-assessment within units and across the organization	(a) Survey or interview key stakeholders (leadership/management staff, clinicians, support and ancillary staff, patients and carers, representatives from organizations that connect along care pathways) (b) Observe practice—use tracer methodologies to follow patients along pathways and processes to identify if appropriate controls are in place and working (Fig. 46.3)
4. Identify areas for improvement	(a) Based on the self assessment identify and share strengths and weaknesses (b) In DNV GL's Standards, areas for improvement are categorized as: 1. Non-conformities Category 1 (Major): i. An absence of one or more required system elements or a situation which raises significant doubt that the services will meet specified requirements ii. A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to a requirement of the standard iii. A category 2 non-conformity that is persistent (or not corrected as agreed by the hospital) shall be up-graded to category 1 iv. A situation that on the basis of available objective evidence may directly lead to unacceptable risk of patient harm or does not meet minimum standards of care 2. Non-conformities Category 2 (Minor): i. The hospital has a lapse of either discipline or control during the implementation of system/procedural requirements but which does not indicate a system breakdown or raise doubt that services will meet requirements 3. Observations: i. An observation is not a non-conformity, but something that could lead to a non-conformity if allowed to continue uncorrected 4. Opportunities for improvement: i. An opportunity for improvement relates to areas and/or processes of the hospital which may meet the minimum requirements for accreditation but which could be improved to reach best practice
5. Develop action plans to address areas for improvement	(a) Engage stakeholders for each area of improvement and create a specific, measurable, achievable, relevant and time-bounded action plan that should address: 1. What needs to be changed 2. Why 3. How it will be changed (the steps to be taken) 4. Who will be responsible 5. When the change should be completed 6. The measures that will be used to show that the change has been implemented, is having the desired effect (or not) and that the change can be sustained over time
6. Implement action plans to deliver necessary improvements	(a) Use the Plan, Do, Study, Act cycle of improvement to implement, revise and sustain change

(continued)

Table 45.7 (continued)

7. Prepare for the site visit by the accreditation audit team	(a) Keep in mind that the value of accreditation is in helping your organization to improve by providing an independent, structured, constructively critical review of your pathways and processes. It will only deliver this value if you and the staff within your organization are committed to accreditation as a learning opportunity and are honest with the accrediting body as to your strengths and weaknesses. To this end, organizations should have in place mechanisms to ensure that staff and service users are able to share openly their experiences of what works and what does not. (b) The emphasis of the accreditation visit will be on observing practice in real-time—how patients are treated and processes put into practice. To support this, the auditors will need access to supporting documentation that shows how the hospital is organized, how care is delivered and how care ought to be delivered according to the hospital's own polices and procedures. You should typically expect to provide the audit team with: 1. Organizational charts for the organization as a whole and broken down by service areas 2. A map showing the locations of patient care and treatment and other services 3. A list of current in-patients with room number, age, diagnosis, attending physician, primary nurse, admission date and any other significant information 4. Patient census for the last 12 months including patient acuity/case mix 5. Current surgical schedule where applicable 6. Most recent accreditation and/or ISO certification where applicable 7. Bylaws of the Governing Body 8. Minutes of the Government Body 9. Medical staffing bylaws, rules and regulations 10. Minutes of the Medical Executive Committee 11. Organizational plan for patient care/scope of service for each department and patient care unit 12. Terms of reference for the Quality Oversight/Management Review Committee 13. Minutes of the Quality Oversight/Management Review Committee—including performance improvement data for the last 12 months, complaints data for the last 12 months (showing complaints received and response), incident data for the last 12 months (showing incidents reported and response), root cause analysis for the last 12 months 14. Minutes from Environment of Care/Safety Committee 15. Risk management policy and procedures 16. Risk assessment—organizational wide and unit specific as applicable including risk management plan 17. Management plans for the physical environment and annual evaluations 18. List of contracted services, companies and individuals—surveyors will select a sample for review 19. List of other organizations with whom you share care for patients (including organizations that refer patients and accept patients on discharge)—surveyors will select a sample to contact for feedback 20. Nursing service plan of administrative authority/delineation of responsibilities for delivery of patient care 21. Infection Control Plan with risk assessment/hazard vulnerability analysis 22. List of employees including name, title, unit, and hire date 23. Skill mix of staff 24. List of current patients who have had restraint (chemical or physical) or seclusion used during hospitalization 25. List of patients discharged with the past 6 months who had restraint (chemical or physical) or seclusion used violent or self-destructive behavior during their hospitalization 26. Policies and Procedures, typically including but not necessarily limited to: i. Autopsies ii. Blood and Blood Product Administration iii. History and Physical Examination iv. Informed Consent v. Medication Security vi. Moderate Sedation

8. Site visit by audit team	vii. Patient Assessment (Nursing, respiratory, nutritional services, etc.) viii. Pain Management ix. Patient Care Planning/Interdisciplinary Treatment Plan x. Patient Grievance xi. Procedural Verification Process (Practices ensuring the correct patient, site & procedure) xii. Restraint or Seclusion xiii. Verbal/Telephone Orders (a) The audit team will focus on reviewing how care and other processes are delivered in real-time. To do this, you will need to: 1. Receive the audit team and show them around the premises 2. Provide the audit team with a dedicated room that they can use for the duration of their visit 3. Present a summary of your services and be prepared to answer questions on recent, current and foreseen threats to quality 4. Provide the audit team with access to the resources outlined in step 7 as well as access to patient records to enable them to use the tracer methodology in following patients through their care pathways 5. Provide the audit team with access to staff and, through clinical staff, access to patients and their families to interview and follow 6. Provide the audit team with access to telephone numbers and contact details so that they can follow-up with contractors, partner organizations and former patients and their families
9. After the site visit	(a) Review the audit report, which will outline the findings including whether or not the organization has reached the necessary standard for accreditation or if corrective actions are needed before additional assessment (b) Where a corrective action plan is needed your organization will typically have 30 days from receipt of the audit report to submit their action plan to the accrediting body for review (c) The corrective action plan should address: 1. Each of the specific unmet elements in turn 2. A full explanation of the actions take to address the unmet elements 3. When the actions were completed 4. The impact of the actions including how they will be maintained 5. Measurement criteria and methods that are in place to monitor the elements (d) Moving forward, your organization should use the standards you are assessed against as a way to make risk management and quality improvement a continuous process. The standards reflect best practice in health care quality and patient safety and should be part of every employees day to day work—incorporated into their unit and personal objectives

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