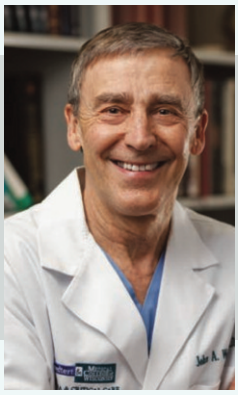
Volume 5
Issue 1
April 2021
ISSN:5101195-3

# KOSOVA JOURNAL OF SURGERY




www.koscs.org

# A Primer on Surgical Quality and Patient Safety



**JOHN A. WEIGELT, DVM, MD, FACS**
*Professor of Surgery*
*University of South Dakota*
*Sanford School of Medicine*
*Email: John.Weigelt@usd.edu*

Surgical quality and patient safety activities are imbedded in the performance improvement movement which began in the 1950's. William E. Deming observed an approach in Japan and brought principles back to Ford Motor Company in 1981; he coined the term system of profound knowledge. Key elements of this system were an appreciation of the system's workings, an understanding of variation, acceptance of the limits of knowledge, and the interaction between actions and human nature. The emphasis stressed that inspecting for quality should stop and instead the system should built to quality. The actions involved supporting a plan; doing; checking; and acting (PDCA).[1]

This PDCA cycle focused on proper planning first. The plan was implemented and the checking ensured that the plan was working as expected. If not, the action needed was to fix the plan until the desired result was consistently reached. The excuse that "our problems are different" was not accepted.

Avedis Donabedian introduced these same principles to medicine in his book *An Introduction to Quality Assurance in Health Care* published in 2003.[2] He defined three components of performance improvement: Structure, Process, and Outcome. Structure was the environment of our healthcare system. Process described the activities to accomplish care. Outcome was the result of our structure and processes. Donabedian also introduced the term Continuous Performance Improvement (CPI), which is what the PDCA cycle promotes.[3]

CPI is the backbone of surgical quality and patient safety. The approach has evolved as does any important idea. This discussion will present our current state and show how quality and patient safety are linked.

**Guiding Principles for Quality and Patient Safety**

While initial quality efforts focused on the structure and especially the processes, the activities fell short of providing meaningful outcomes. Most outcomes were coarse. An example of this is mortality that was easy to identify but implementing interventions that directly affected mortality rates was difficult. The con-founders were many and separating cause and effect to achieve change in the PDCA cycle proved difficult. Evidence-based medicine (EBM) helped move quality activities to focus on outcomes.

**Evidence Based Medicine (EBM)**

Using EBM applies scientific principles to medical practice. EBM is the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients.

This term is traced to Eddy in 1990.[4] Most recently, EBM ranks the quality of evidence and balances its risks and benefits.[5] This leads to a classification system for EBM (Table 1). The first classification is regarding how the evidence is developed. While a randomized controlled trial is the gold standard, we know medical information often falls short of that goal. Thus, we must understand and interpret the evidence differently at each level.

**Table 1**

| Category | Description |
|---|---|
| **Level I** | Randomized controlled trial |
| **Level II-1** | Well-designed controlled trials no randomization |
| **Level II-2** | Well-designed cohort/case control analytic studies; More than one center or group |
| **Level II-3** | Multiple time series with or without the intervention |
| **Level III** | Opinions clinical experience, descriptive studies, reports of expert committees |

We also must interpret the evidence in terms of risk benefit to the patient and to medical resources. Coupled with the level of evidence, EBM has a risk benefit classification **(Table 2).**

| Category | Description |
|---|---|
| **Level A** | Good scientific evidence. Benefits outweigh potential risks. |
| **Level B** | At least fair scientific evidence. Benefits outweigh potential risks. |
| **Level C** | At least fair scientific evidence. Benefits, but balance with risks are too close for making general recommendations. |
| **Level D** | At least fair scientific evidence. Risks outweigh potential benefits. |
| **Level I** | Scientific evidence is lacking, conflicting. Risk versus benefit cannot be assessed. |

As we examine this classification system, patient safety enters the discussion. The goal would be to choose scientifically sound treatments that provide benefits with low risk. While that is a goal, it is often not possible or ignored. In an attempt to focus our quality and safety efforts, the Institute of Medicine developed a set of aims in 2001.[6] These IOM aims were called STEEEP. Each letter stood for a specific objective associated with quality and safety.

**Safe:** avoiding injuries to patients caused by the care that is intended to help them.

**Timely:** reducing waits, and sometimes harmful delays, for both those who receive and those who give care.

**Effective:** providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.

**Efficient:** avoiding waste, including waste of equipment, supplies, ideas, and energy.

**Equitable:** providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

**Patient-centered:** providing care that is respectful of and responsive to individual preferences, needs, and values, and ensuring patient values guide all clinical decisions.

Clinical examples of STEEEP aims are easily identified. Some examples are below.

Safety – Using a time out in the operating room.

Timely – Keeping our clinic schedule on time is an attempt to reduce waits for patients.

Effectiveness – Using perioperative antibiotics correctly.

Efficiency – Trying to avoid physician induced demand.

Equity – Fairness in the distribution of our care.

Patient centered – Explaining all options for care completely.

As quality interventions evolved, reporting outcomes became possible. One outcome recognized by the IOM was clinical efficiency. Clinical efficiency are interventions producing the greatest healthcare benefit for the lowest cost. Clinical efficiency uses 4 terms: under use and waste; appropriate use; overuse and waste; and harm, misuse, and waste. Each of these can be defined and identified in medicine today.

Under use and waste – This occurs when needed services are not provided resulting in avoidable outcomes occurring which consume more medical resources. The excess resource consumption represents waste. Lack of appropriate vaccinations is one example.

Appropriate use –The care we provide is appropriate and based on data supporting the benefit at the right cost. This is where we would like to use our medical resources.

Overuse and waste – When medical care or services provide little or no benefit, there is overuse and waste of resources. This is where physician induced demand occurs. A procedure is used with very little benefit simply because a physician can provide the procedure.

Harm, misuse and waste – Finally, we have the application of medical resources that do not have benefits and might even cause harm. The recent suggestion that hydroxycholoroquine could be used to treat COVID pulmonary disease is a possible example.[7]

Application of EBM and clinical efficiency takes the quality activities within medicine beyond measuring process compliance. While process metrics are still needed, our focus must be on outcomes that directly influence patient safety.

**"Never Events" or Serious Reportable Adverse Events (SRE)**

Another attempt in 2001 focused on outcomes and safety. The term "Never Event" was introduced by Ken Kizer, MD and the National Quality Forum (NQF).[8] These events were egregious medical errors that should never occur. An example is wrong site surgery. The initial list of never events was hyperbolic and over-time revisions have made the list more appropriate. The name has actually changed as well with never events being changed in favor of Serious Reportable Events or SREs. An SRE represents adverse events that are unambiguous and usually preventable with proper interventions and quality checks. These events are clearly identifiable, measurable, and result in death or significant disability. SREs are designed to help the healthcare field assess, measure, and report performance in providing safe care. Currently, the list includes 29 serious reportable events grouped into seven categories.

These categories include 1. surgical or procedural events; 2. product or device events; 3. patient protection events; 4. care management events; 5. environmental events; 6. radiologic events; and 7. criminal events. The list from the NQF is below.[8]

**Surgical Events**

Surgery or other invasive procedure performed on the wrong body part

Surgery or other invasive procedure performed on the wrong patient

Wrong surgical or other invasive procedure performed on a patient

Unintended retention of a foreign object in a patient after surgery or other procedure

Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists Class I patient

**Product or Device Events**

Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting

Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended

Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting

**Patient Protection Events**

Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person

Patient death or serious disability associated with patient elopement (disappearance)

Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility

**Care Management Events**

Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

Patient death or serious injury associated with unsafe administration of blood products

Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting

Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy

Artificial insemination with the wrong donor sperm or wrong egg

Patient death or serious injury associated with a fall while being cared for in a health care setting

Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility

Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen

Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

**Environmental events**

Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a health care setting

Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances

Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting

Patient death or serious injury associated with the use of restraints or bedrails while being cared for in a health care setting

**Radiologic Events**

Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area

**Criminal Events**

Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider

Abduction of a patient/resident of any age

Sexual abuse/assault on a patient within or on the grounds of a health care setting

Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

**Public Reporting**

Transparency in medical care regarding quality of safety requires public reporting. Organizations in the United States provide public reporting of medical processes and outcome metrics. Reported metrics include SREs, but other metrics also appear. A number of national organizations including www.leapfroggroup.org, www.healthgrades.com, and www.medicare.gov/care-compare/ report numerous metrics including SREs. The reporting is at the hospital and provider level. The Medicare site reports hospital and provider outcomes for care provided to Medicare beneficiaries. The state of Minnesota was one of the first states to legislate public reporting of SREs. This occurred in 2003. They now produce an annual report. (www.health.state.mn.us/facilities/patientsafety/adverseevents/docs/2019ahereport.pdf )

All facilities must do a root cause analysis (RCA) when a SRE occurs.[9,10] An RCA is really the check part of a PDCA cycle and usually results in an action to correct the adverse outcome. In 2018, the most common SRE was the lack of appropriate rules, policies, and procedures followed closely by communication errors. These two are the most common year after year.

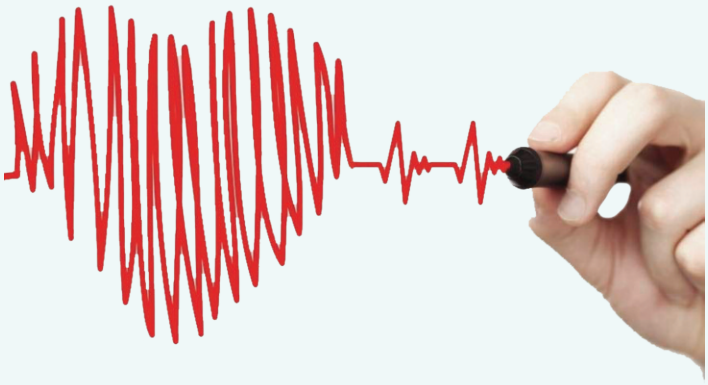
When a specific approach for a root cause analysis is accepted, the process asks three questions. What is the problem? Why did it happen? How can it be prevented in the future? Along with these three questions are three problem solving steps that harken back to the PDCA cycle of Dombedian. The first step is to accurately define the problem. The group responsible for the RCA must agree on what the problem is before any solution can be achieved. The second step is the analysis of the data surrounding the event. Numerous tools are available for this step. The third step is to suggest solutions that will prevent future occurrences. The Joint Commission and National Patient Safety Foundation have specific information explaining the RCA process.

The other development concerning SREs and public reporting are the implications surrounding care reimbursement. In the United States, the Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that additional costs are associated with many preventable errors, including those considered

"Never Events." Since February 2009, CMS has not paid for any costs associated with wrong-site surgeries.

**How to Start a Surgical Quality and Safety Program**

A review of the literature is the first step. The American College of Surgeons (ACS) is a good place to start. The ACS has recognized quality and safety from its inception. The most recent effort was culminated in the *Optimal Resources for Surgical Quality and Safety* published in 2017.[11] This document is a handbook regarding surgical quality and safety. It addresses the underpinnings of quality and safety, addresses specific surgical activities, and addresses how quality efforts are organized.



Most hospitals will have some organizational structure for quality and safety. Quality and safety activities often exist within a separate department or are spread over many departments. Some key questions will need answers. What is the purpose or goal of the quality department? What metrics are evaluated? Are there routine data collections? Is the focus on process measures for quality? Are there safety data collected? Are routine reports provided to stakeholders? How does the department interact with the surgical disciplines? Is there a surgical champion?

If quality and safety data are being collected and reported, you have a great start. Often surgical quality and safety is ignored while emphasis is placed on diabetes, cardiovascular disease, and other medical conditions. This is why a surgical champion is needed. It is imperative that balance be achieved between medical and surgical metrics allowing providers and patients to see a complete picture of quality activities within the institution.

Where to begin is always a question. As you explore surgical measures, you will always find low hanging fruit. These areas should be your initial focus. Looking at perioperative antibiotic use, appropriate preoperative test use, and SSI rates in high risk procedures are all good starting points. As you begin, proper data collection with validity and reliability is imperative. Reporting of data should be transparent. Your surgical colleagues will accept findings that have such rigor, but reject poorly collected or reported data.

Whether or not you proceed with public reporting or reporting to your patients will depend on many issues. A major one will be the buy-in you establish with your data among your colleagues. Most beginning programs have to work to gain peer trust, but once obtained, positive feedback is the result.

The other aspect of a good quality and safety program is to collaborate with others who are interested in improving their care. Once again, the *Optimal Resources for Surgical Quality and Safety* can help. Quality collaboratives are a way to bring different organizations and programs together. The collaboration helps share data on patients as well as offer an opportunity for surgeons to share ideas and outcomes related to their clinical care. Numerous types of collaboratives have arisen including surgical collaboratives. An entire chapter in *Optimal Resources for Surgical Quality and Safety* is dedicated to surgical collaboratives.

A successful surgical quality collaborative requires 1) leadership; 2) a shared vision; 3) funding; 4) an existing infrastructure to support organizational requirements; 5) a performance assessment system; and 6) a process to report results. Some caveats for each area.

Leadership – A surgical champion with experience in quality improvement activities is imperative. Leadership must be able to engender trust among potential members.

Vision – This should be a shared vision among potential members of the collaborative. Stakeholders include surgeons, other healthcare professionals, administrators, hospital organizations, funding organizations, and performance measurement organizations.

Structure – Numerous options exist including a Chapter of the American College of Surgeons, a hospital system, or a university. The key element is the ability to provide a supportive environment for members of the collaborative.

Funding –A budget commensurate with proposed activities is necessary. A logical source is membership

dues. Other external sources are tapped as the benefits of the collaborative become recognized.

Performance assessment system – A system to collect data is imperative. Existing registries, specific disease specific systems, or homegrown data collection systems are all possible. The ACS has been developing registries to measure quality and safety for years. Specific programs started with Cancer and Trauma. The American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®) allows hospitals to monitor surgical patients and report outcomes. These data can be compared to similar institutions to assess the clinical care. It is risk adjusted and provides a 30-day follow-up. These data have been used to develop a Surgical Risk Calculator.[12]

Reporting results - A reporting system for the data is also necessary.

**Summary**

Patient safety and quality needs must be imbedded into our daily practice and not become an afterthought. Systems exist to fashion a safe environment for our patients. These systems are not new, but do require a dedication to basic principles associated with optimal patient care. Understanding these principles and applying them to our surgical practices is imperative. Such actions will help us provide appropriate surgical care to our patients.

## REFERENCES

1. Moen RD, Norman CL. Circling Back. Quality Progress. Nov 2010; 43 (11): 22-28.

2. Donabedian A, Bashshur R. An Introduction to Quality Assurance in Health Care. Oxford University Press; 2003.

3. Donabedian, A. Explorations in Quality Assessment and Monitoring Vol. 1. The Definition of Quality and Approaches to Its Assessment. Ann Arbor, MI: Health Administration Press; 1980.

4. Eddy DM. Practice policies: Where do they come from? JAMA. 1990;263:1265–72.

5. Sackett DL, Rosenberg WM, Gray JA, et al. Evidence based medicine: What it is and what it isn't. BMJ. 1996;312:71–2.

6. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academies Press (US); 2001. PMID: 25057539.

7. Geleris J, Sun Y, Platt J, et al. Observational Study of Hydroxychloroquine in Hospitalized Patients with Covid-19. N Engl J Med. June 18, 2020; 382:2411-2418. DOI: 10.1056/NEJMoa2012410

8. Kizer KW, Stegun MB. Serious Reportable Adverse Events in Health Care. www.ahrq.gov/downloads/pub/advances/vol4/Kizer2.pdf. Accessed September 2020.

9. Root Cause Analysis in Health Care: Tools and Techniques. 5th ed. Oakbrook Terrace, IL: Joint Commission Resources; 2015

10. National Patient Safety Foundation. RCA2 Improving Root Cause Analyses and Actions to Prevent Harm. Boston, MA: National Patient Safety Foundation; 2015.

11. Hoyt DB, Ko CY, Jones RS, et al. Optimal Resources for Surgical Quality and Safety. Chicago, IL: American College of Surgeons; 2017.

12. Hornor MA, Ma M, Zhou L, et al. Enhancing the American College of Surgeons NSQIP Surgical Risk Calculator to Predict Geriatric Outcomes. J Am Coll Surg. 2020 Jan;230(1):88-100.e1. doi: 10.1016/j.jamcollsurg.2019.09.017. Epub 2019 Oct 28. PMID: 31672676.