

Quality Improvement and Patient Safety in Orthopaedic Surgery

Julie Balch Samora
Kevin G. Shea
Editors

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Julie Balch Samora
Department of Orthopedics
Nationwide Children's Hospital
Columbus, OH, USA

Kevin G. Shea
Department of Orthopedics
Stanford University
Stanford, CA, USA

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Preface

When the Institute of Medicine published *To Err is Human* in 2000, it served as a “wakeup call” for healthcare in the United States, demonstrating a safety problem with patient morbidity and mortality directly attributable to medical errors. The pursuit of safety is a multidisciplinary enterprise, and systems approaches are critical to improving quality of care. Providers, hospitals, and organizations that continuously improve clinical care are devoted to excellence. Efficacy, efficiency, appropriateness of care, availability, timeliness, effectiveness, continuity of services, safety, and respect are all aspects of quality care that must be promoted at the highest level. We work in highly complex environments that include significant risk; we must remain ever vigilant to improve the systems in which we work to provide the best care for patients and families.

Regardless of our role in healthcare, we all have the opportunity to be change agents, promoting continuous improvement. This book is designed for trainees, advanced practice providers, and orthopedic surgeons who desire to make improvements in quality and safety of care for their musculoskeletal patients. We encourage and challenge you to be ambassadors for continuous healthcare improvement, and to do so in a supportive and respectful manner. We commit to our colleagues and to our patients to strive for the highest levels of quality care, supporting each other as we hold ourselves accountable to continuously improve. We seek to create an environment of “supportive accountability.”

The origin of this book is stemmed from the creation of several patient safety and quality improvement didactics for the American Academy of Orthopaedic Surgeons. Recognizing their value, we decided to craft a textbook originating from these initial presentations. We brought together several authors who are experts in various areas of patient safety and quality improvement to provide an overview of the critical issues in healthcare. From basic quality improvement principles to surgical site infection prevention to opioid stewardship to physician well-being, we hope that these chapters will serve as a nice reference moving forward. Leadership will remain critical to craft a culture of safety and continuous improvement, and each of us can be leaders in this arena. We hope you find the contributions of these esteemed authors valuable as you strive toward the highest quality care, minimizing harm and improving outcomes.

Columbus, OH
Stanford, CA

Julie Balch Samora
Kevin G. Shea

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Contributors

Ayesha Abdeen, MD, FAAOS, FRCS(C) Department of Orthopaedic Surgery, Boston Medical Center, Boston, MA, USA

Brielle Antonelli, BS, PA-S Department of Orthopaedic Surgery, Brigham and Women's Hospital, Boston, MA, USA

Peter F. Armstrong, MD, FRCSC, FAOA, FACS, FAAP OrthoPediatrics Corp, Warsaw, IN, USA

Jessica L. Block University at Buffalo, State University of New York, Buffalo, NY, USA

Janice M. Bonsu, MD MPH Department of Orthopaedics, The Ohio State University Wexner Medical Center, Columbus, OH, USA

K. Keely Boyle University at Buffalo, State University of New York, Buffalo, NY, USA

Kevin J. Bozic Department of Surgery and Perioperative Care, Dell Medical School at the University of Texas at Austin, Austin, TX, USA

Gregory A. Brown, MD, PhD CHI St. Alexius Health, Williston Orthopedic Clinic, Williston, ND, USA

Dwight Burney, MD Retired from Clinical Practice, Presbyterian Medical Center in Albuquerque, Los Ranchos de Albuquerque, NM, USA

Eli M. Cahan, MD, MS Department of Pediatric Orthopaedics, Stanford University, Stanford, CA, USA
New York University School of Medicine, New York, NY, USA

Michelle S. Caird, MD Department of Pediatric Orthopedics, C.S Mott Children's Hospital, University of Michigan Medical Center, Ann Arbor, MI, USA

Antonia F. Chen, MD, MBA Department of Orthopaedic Surgery, Brigham and Women's Hospital, Boston, MA, USA

Melissa A. Christino, MD Department of Orthopedic Surgery, Boston Children's Hospital, Harvard Medical School, Boston, MA, USA

Joseph P. DeAngelis, MD Beth Israel Deaconess Medical Center, Boston, MA, USA

Jaime Rice Denning Orthopaedic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA

Anna Farrell Department of Orthopaedics, The Ohio State University Wexner Medical Center, Columbus, OH, USA

Steven L. Frick, MD Department of Orthopaedic Surgery, Stanford University School of Medicine, Center for Academic Medicine, Palo Alto, CA, USA

Janene Fuerch Byers Center for Biodesign, Stanford University, Stanford, CA, USA

Michael J. Goldberg, MD The Schwartz Center for Compassionate Healthcare, Boston, MA, USA

Mitchell T. Gray, MD Indiana University School of Medicine, Indianapolis, IN, USA

Andrew Grose Hospital for Special Surgery, Sleepy Hollow, NY, USA

Stephanie Holmes Department of Orthopaedic Surgery, University of Utah School of Medicine, Salt Lake City, UT, USA

Serena S. Hu Department of Orthopaedic Surgery, Stanford University School of Medicine, Center for Academic Medicine, Palo Alto, CA, USA

Kerwyn Jones Akron Children's Hospital, Akron, OH, USA

Ajay Kanakamedala, MD Department of Orthopedic Surgery, NYU Grossman School of Medicine—NYU Langone Orthopedic Hospital, New York, NY, USA

Karl Koenig Division of Orthopaedic Surgery, Department of Surgery and Perioperative Care, Dell Medical School, Austin, TX, USA

Benjamin J. Kopp Division of Orthopaedic Surgery, Department of Surgery and Perioperative Care, Dell Medical School, Austin, TX, USA

Eric Krohn Department of Pediatric Orthopedics, C.S. Mott Children's Hospital, University of Michigan Medical Center, Ann Arbor, MI, USA

Donald H. Lee Department of Orthopaedic Surgery, Vanderbilt University Medical Center, Nashville, TN, USA

Philipp Leucht Department of Orthopedic Surgery, NYU Grossman School of Medicine—NYU Langone Orthopedic Hospital, New York, NY, USA

Jacqueline Li Department of Orthopaedics, Faculty of Medicine, University of British Columbia, Vancouver, BC, Canada

James S. Lin Department of Orthopaedics, The Ohio State University, Columbus, OH, USA

Bob Lokken St. Luke's Health System, Boise, ID, USA

Eric C. Makhni Wayne State University School of Medicine, Henry Ford Health System, Detroit, MI, USA

Michelle C. Marks, PT, MA Setting Scoliosis Straight, San Diego, CA, USA

Jed I. Maslow, MD, MSc Department of Orthopaedic Surgery, Vanderbilt University Medical Center, Nashville, TN, USA

James J. McCarthy, MD, MHCM Orthopaedic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA

Kelly H. McFarlane Stanford Health Care, Stanford, CA, USA

Devan Mehta, MD Department of Orthopedic Surgery, NYU Grossman School of Medicine—NYU Langone Orthopedic Hospital, New York, NY, USA

Daniel J. Miller, MD Gillette Children's, St. Paul, MN, USA

Justin P. Moo Young, MD Department of Orthopaedic Surgery, Vanderbilt University Medical Center, Nashville, TN, USA

Meredith G. Moore, MD Department of Surgery and Perioperative Care, Dell Medical School at the University of Texas at Austin, Austin, TX, USA

Peggy L. Naas, MD, MBA Retired, Department of Orthopaedic Surgery, Abbott-Northwestern Hospital, Allina Health, Minneapolis, MN, USA

Ron Navarro, MD Kaiser Permanente, Pasadena, CA, USA

David Nelson, MD Greenbrae Surgery Center, Greenbrae California, Greenbrae, CA, USA

Peter O. Newton, MD Rady Children's Specialist of San Diego, San Diego, CA, USA

Joshua M. Pahys Shriners Hospitals for Children, Tampa, FL, USA

Mit Patel Wayne State University School of Medicine, Detroit, MI, USA

Mathew Pate Orthopaedic Surgery Residency Program, Spectrum Health—Michigan State University, Grand Rapids, MI, USA

Althea Anne Perez Department of Orthopaedics, University of Cincinnati, Cincinnati, OH, USA

Juliana Perl Byers Center for Biodesign, Stanford University, Stanford, CA, USA

Michael S. Pinzur, MD Orthopaedic Surgery and Rehabilitation, Loyola University Health System, Maywood, IL, USA

Carmen Quatman, MD, PhD Department of Orthopaedic Surgery, Ohio State University Wexner Medical Center, Columbus, OH, USA

Asheen Rama, MD Division of Pediatric Anesthesia, Department of Anesthesiology, Perioperative, and Pain Medicine, Stanford University School of Medicine, Stanford, CA, USA

David Ring, MD, PhD Dell Medical School, Austin, TX, USA

Karl C. Roberts West Michigan Orthopaedics, Grand Rapids, MI, USA
Orthopaedic Surgery Residency Program, Spectrum Health—Michigan State University, Grand Rapids, MI, USA

Julie Balch Samora, MD, PhD Department of Orthopedics, Nationwide Children's Hospital, Columbus, OH, USA

Will Shaffer AAOS, Washington, DC, USA

Kevin G. Shea, MD Department of Orthopedics, Stanford University, Stanford, CA, USA

Bryan Snyder Orthopaedic Surgery, Harvard Medical School, Cerebral Palsy Center, Boston Children's Hospital, Boston, MA, USA

Vishwas R. Talwalkar, MD Department of Orthopedic Surgery and Pediatrics, Shriners Hospital for Children Medical Center, University of Kentucky, Lexington, KY, USA

James K. Wall, MD, MSE Biodesign, Stanford University, Stanford, CA, USA

Stuart Weinstein, MD University of Iowa, Iowa City, IA, USA

Jennifer M. Weiss, MD Department of Orthopedic Surgery, Kaiser Permanente, Los Angeles, CA, USA



Quality Improvement Principles and Models

1

James S. Lin and Julie Balch Samora

Quality Improvement Principles

In 2001, the Institute of Medicine defined six domains of healthcare quality: safe (avoidance of harm from care); timely (reduce wait times and delays); effective (using evidence to guide care); efficient (avoid waste of time and resources); equitable (employ consistent quality of care across diverse patients); and patient-centered (include patient preferences, needs, and value into all decision-making) [1]. Since then, many quality improvement endeavors have been developed from these domains. More recently, the Institute for Healthcare Improvement (IHI) has also emphasized this last domain, embracing a patient-centered concept of quality improvement organization [2, 3].

Quality Improvement Models

There are many models that can be employed in quality improvement endeavors. Different models may have processes that overlap, and healthcare institutions may use a combination of models in their efforts to improve the system.

J. S. Lin (✉)

Department of Orthopaedics, The Ohio State University, Columbus, OH, USA

e-mail: james.lin@osumc.edu

J. B. Samora

Department of Orthopedics, Nationwide Children's Hospital, Columbus, OH, USA

e-mail: julie.samora@nationwidechildrens.org

Model for Improvement/Institute for Healthcare Improvement (IHI)

The Institute for Healthcare Improvement (IHI) was founded to improve health care by redesigning the system to prevent errors, waste, delay in care, and unsustainable costs. The model for improvement, developed by the associates in process improvement, provides a framework comprised of three questions [4, 5]:

1. What are we trying to accomplish? (Aim)
2. How will we know that a change is an improvement? (Measure)
3. What change can we make that will result in improvement? (Intervention)

Establishing a time-specific and measurable goal sets the stage for efforts of improvement. An organization may employ an aim statement to establish the specific objectives for improvement. This statement should answer: What (or from what to what)? For whom? By when? How much, and For How Long? A SMART (Specific, Measurable Achievable, Realistic, and Timeline) aim is a helpful way to remember the items that should be included in a complete aim statement [6]. An example of an aim statement is as follows:

1. What?—Improve patient-reported pain control from current baseline to “good” or “excellent.”
2. For whom?—Patients undergoing distal radius fracture reductions in the emergency department.
3. By when?—December 2022
4. How much?—by 50%
5. Sustain for at least 6 months

The aim statement would be as follows: By December 2022, we will improve the proportion of patients undergoing distal radius fracture reductions in the emergency department who report good or excellent pain control by 50% and sustain for at least 6 months.

Measures are critical in determining if a change equates to improvement [7]. In the above example, the patient-reported variable serves as an outcome measure. There are several different categories of measures that should be considered. Three measures commonly employed in quality improvement are (1) outcome measures, (2) process measures, and (3) balancing measures [8].

Outcome measures are the intended result. They convey the most direct information on how a system affects a patient or other stakeholder. Examples include Disabilities of the Arm, Shoulder, and Hand (DASH) scores for patients undergoing reverse total shoulder arthroplasty; surgical site infections per 1000 posterior cervical spine fusions; the number of days between injury, and diagnosis of scaphoid fractures. Process measures occur at the system level and represent the uptake of an intervention such as a new protocol. They can help to assess if a quality improvement endeavor is on track to accomplish its intended aim. While the outcome

measure represents the expected result deriving from various improvement interventions, a process measure is often more directly in the control of the improvement team and more readily observed. Examples of process measures include: (1) percentage of patients who underwent narcotic education before undergoing elective shoulder arthroplasty; (2) frequency of pre-prep alcohol neck scrub used before cervical spine surgery; and (3) average daily appointment openings in a hand surgery clinic. It is essential to quantify process measures and outcomes measures. Without such quantification, it will be impossible to determine if the interventions (process measures) are linked to the outcome measure (intended result). Lastly, balancing measures are employed to ensure that improvement in one part of the system does not perturb another part of the system. For example, an accelerated mobilization program that has the goal of reducing hospital length of stay following total knee arthroplasties should ensure readmission rates which are not increasing.

Critical to the IHI model are four critical safety behaviors [9]:

1. Use of and compliance with safety protocols. Protocols only work if everyone follows them. Examples include surgical time-outs and operating room checklists. For instance, the World Health Organization (WHO) Surgical Safety Checklist has been shown to reduce mortality and complications in many health-care systems around the world [10]. These protocols maximize the safety of patients undergoing surgery, but they are only effective if they are consistently performed.
2. Speaking up. Concerns should be identified and reported with current protocols and conditions. Near misses and errors present valuable learning opportunities, but only if an individual recognizes and shares them. The institution should promote a just culture of mutual respect, where team members are encouraged to speak up. A climate of improved safety and teamwork has been associated with decreased patient harm and severity-adjusted mortality [11].
3. Listening. Listening to others' concerns—including those of the patient—is critical to quality patient-centered care. The Joint Commission estimates that 80% of serious safety events are due to miscommunication among healthcare providers [12]. Speaking up and listening are behaviors critical to effective communication.
4. Self-care. Healthcare provider wellness is important for patient safety. Suboptimal health can result in suboptimal attention and care for patients. Reducing stress and burnout of providers will improve patient safety [13].

Root Cause and Common Cause Analysis

Root cause analysis is commonly employed in healthcare and quality improvement to analyze adverse events. The objective is to identify underlying system and individual issues that predispose to errors [14]. In addition, common cause analysis consolidates causes from multiple events to identify any common causes for those events [15]. Models to perform analyses include the 5 Whys method, cause & effect or fishbone diagram, and pareto charts.

5 Whys Methodology

The 5 Whys Methodology is a simple tool to assess root causes. It aims to determine the cause-and-effect relationships between various underlying factors that lead to the identified problem in question [16]. For example, consider the issue of too many unplanned overnight admissions for single level lumbar microdiscectomies.

1. Why? Late end times for scheduled afternoon cases.
2. Why? Morning cases are running late.
3. Why? Long room turnover times.
4. Why? Waiting for the re-sterilized microsurgical discectomy tube trays.
5. Why? Limited number of available trays for procedure in hospital (root cause).

Although the 5 Whys approach can be useful to identify contributors to an adverse event or a near miss, the methodology is limited as often, errors are not due to one simple issue. Errors are often the result of multiple factors, and this method is not necessarily able to distinguish between casual factors (secondary or tertiary drivers of an event) and root causes (a primary driver or fundamental cause of the event).

Pareto Charts

The Pareto Principle—or 80-20 rule—asserts that a minority of factors contribute to the majority of the effect [17]. Specifically, it contends that 80% of the effects are due to 20% of factors for many events, so focusing efforts on these few vital contributors is more likely to have a meaningful impact. Pareto charts (see Fig. 1.1) are

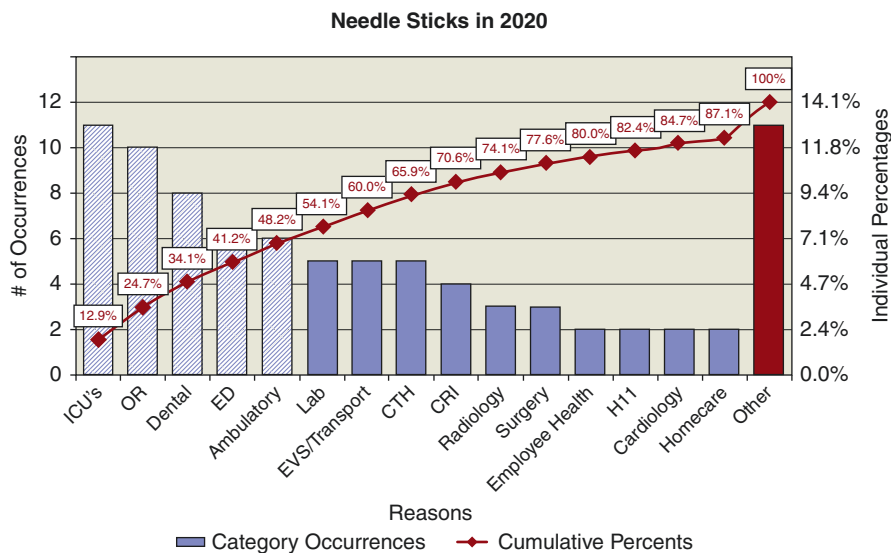


Fig. 1.1 Example of a Pareto chart depicting the cumulative number of needle sticks over 1 year and location where they occurred

a graphical representation of these contributing factors. They typically rank factors from highest to lowest prevalence, illustrating each as a bar along the X-axis. The percent contribution is displayed on the Y-axis, and the cumulative contribution as a point-to-point line graph is superimposed onto the bar graph [18]. In the needle stick example, focus (e.g., biggest effect for effort put forth by the team) should be within the ICU and OR areas (highest number of occurrences on the left of the X-axis), not in cardiology or homecare (lowest number of occurrences on the right of the X-axis).

Cause and Effect (Fishbone) Diagram

Fishbone diagrams, or cause and effect/Ishikawa diagrams, may be used to identify the root causes of an identified problem [19]. The diagram is organized with the “head” being the specific problem or outcome requiring improvement (Fig. 1.2). The large “bones” of the diagram stem from a spine pointing toward the head, and they represent the primary categories of inputs of every process. Detailed causes under each major category comprise the smaller “bones.” Common categories of inputs include the 5 “M’s,” [materials, methods, manpower, machinery (equipment), and mother nature (environment)]. In healthcare, common categories include the 4 “P’s,” [people, policies, procedures, and plant (technology)] [20]. These models can offer a valuable tool to organize efforts and generate improvement ideas.

Plan, Do, Study, Act (PDSA) Cycle

PDSA cycles are methods to test interventions on a small scale [21]. These cycles are iterations in which a change is trialed, and the results are analyzed. In the Plan stage, the team should be formed; the goal should be defined; and pertinent variables requiring measurement should be established. The process will be mapped,

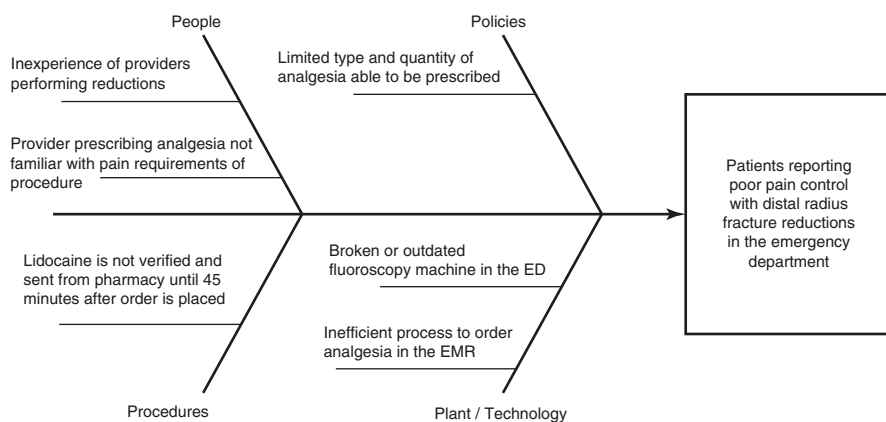


Fig. 1.2 Example of a fishbone diagram with the identified problem in the box as the head of the diagram

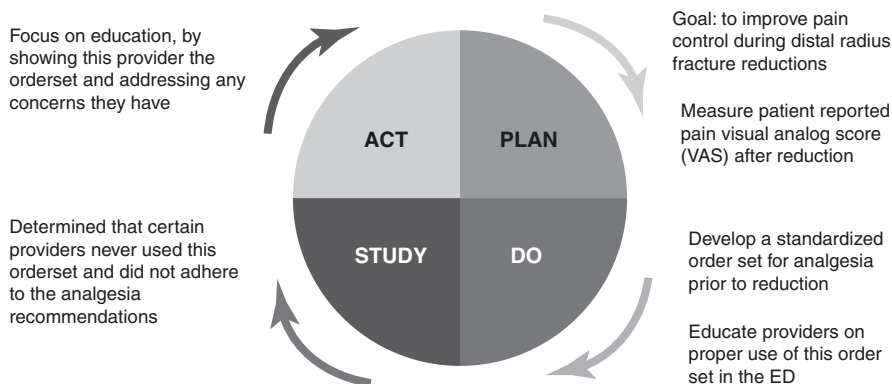


Fig. 1.3 Example of a PDSA cycle

and baseline data should be collected. In the Do stage, the team may develop solutions and implement a pilot intervention. In the Study stage, results from the pilot intervention are analyzed. Goals and plans are modified accordingly. Finally, the updated plan is implemented in the Act stage [22] (Fig. 1.3).

The findings from one cycle are employed in the next cycle, as a decision is made to either embrace, modify, or abandon the change. Therefore, PDSA cycles with negative results are just as important as successful ones, as they serve to reveal incorrect assumptions and bring additional variables into consideration.

Key Driver Diagrams

The Key Driver Diagram (KDD) is a tool that some organizations use to organize a quality improvement project (Fig. 1.4). The diagram is a visual representation of the relationship between (1) the aim of the QI effort; (2) the primary key drivers that directly contribute to achieving that aim; and (3) the interventions or secondary drivers that affect the primary drivers [7]. The KDD serves as a central tool (road-map) for the multidisciplinary team to remain organized and focused on their efforts to achieve the project's outcome. A well-organized KDD can often prevent project scope creep. An example of a KDD is depicted below.

Six Sigma and DMAIC

Originally developed by Motorola and General Electric for quality improvement endeavors, Six Sigma is a set of tools that organizations use to improve system processes by focusing on eliminating defects, reducing variability, and waste [23]. The principal methodology employed by Six Sigma projects is DMAIC—which is an acronym for the five phases that comprise the process [24].

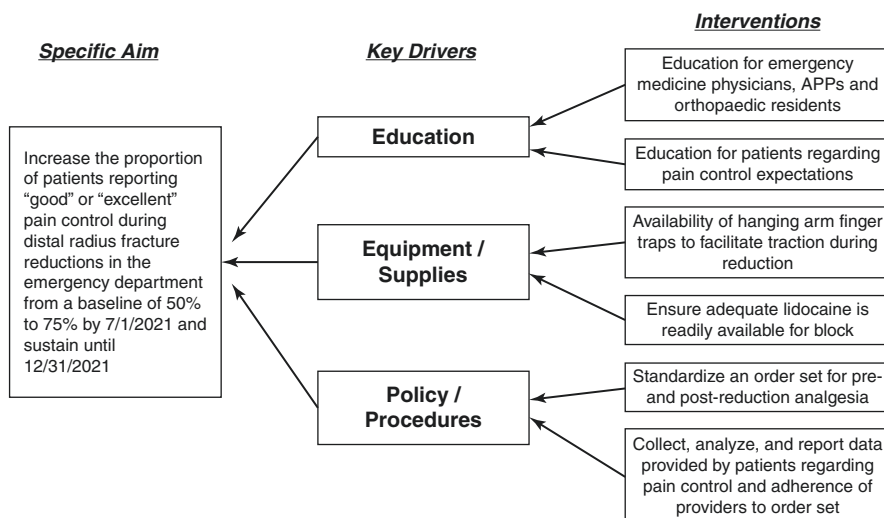


Fig. 1.4 Example key driver diagram on an effort to improve pain control of patients undergoing distal radius fracture reductions in the ED

1. Define the problem, opportunity, goals, improvement intervention, and the roles and processes.
2. Measure the process performance. Baseline processes and data should be captured.
3. Analyze the process and determine the problem's root causes and process variability.
4. Improve system performance by addressing the problem's root causes, eliminating system waste, and streamlining the process.
5. Control the improved process and sustain results.

An example of the DMAIC methodology employed at a children's orthopedic center may be the following: Define problem—the length of stay of patients undergoing posterior spinal fusion for adolescent idiopathic scoliosis at that institution exceeds the national average. Measure—baseline data is captured, including length of stay and post-operative practices. Analyze—root cause analysis is performed, finding that patient-controlled analgesia (PCA) pain pumps are a rate limiting step to discharge. Improve—the surgical team collaborates with the pain team to modify their processes and emphasize multimodal analgesia techniques to more quickly wean from the PCA. Control—team education is provided with the goal to sustain the new process.

Lean Management

Lean is another framework originally employed by the manufacturing industry that organizations can use to improve system processes [25]. It focuses on optimizing efficiency by eliminating waste, which can be energy, time, or materials. The principles of lean management include:

1. Identifying what customers value (rather than what the organization perceives as valuable).
2. Identify the steps that produce the value and unnecessary steps that do not.
3. Prioritize the steps that provide that value.
4. Allow the customer's needs guide what is produced.
5. Continue to improve the system by eliminating areas of waste as they are identified.

Lean management and Six Sigma are complementary approaches often employed in healthcare quality improvement efforts. Specifically, they are valuable when standardization and process efficiency are critical for the quality intervention [19]. An example of the Lean methods employed in spine surgery is exhibited by the Seattle Spine Team approach. In their work, key service providers collectively defined the value to perform the most effective complex spine surgery while minimizing cost and complications [26, 27]. They created a value stream map that detailed the steps during an admission of a complex spine surgery case. Each specific area was studied to identify waste. They created a future state map to identify the ideal value stream. The steps were then standardized. When the future state is codified, it becomes the new current state and a new iteration for improvement can be made [25].

Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)

TeamSTEPPS is an instructional framework developed by the Department of Defense (DoD) and Agency for Healthcare Research and Quality (AHRQ) to improve teamwork in healthcare [28]. This framework is comprised of four trainable skills, which include:

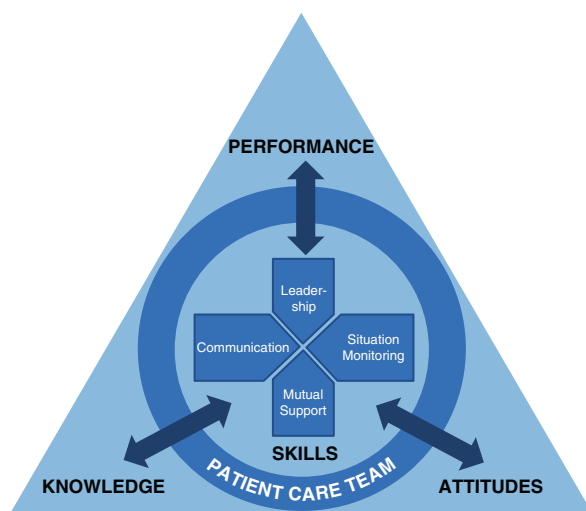
1. Leadership—an effective leader communicates clear objectives, values team member input, empowers team members to actively participate, and resolve conflicts.
2. Situation Monitoring—the process of continuously assessing the situation, specifically with regard to patient status, team members, environment, and progress towards the goal.

3. **Mutual Support**—team members should be able to anticipate and support each others' needs by having knowledge about the responsibilities of their peers. The team culture should be conducive to mutual support, where assistance is readily sought and offered.
4. **Communication**—the team should have a process that enables effective exchange of important information between team members. One strategy for effective communication during team handoffs is the SBAR method, and acronym for situation, background, assessment, and recommendations. An example of the SBAR method is:
 - (a) **Situation**: “Dr. Smith, I am sending John Doe to you for urgent evaluation for his right knee.”
 - (b) **Background**: “He is a 30 year old male with history of polysubstance abuse who has had two days of atraumatic right knee pain and swelling. He was positive for COVID-19 one month ago but has since recovered.”
 - (c) **Assessment**: “I am concerned for septic arthritis of his knee joint.”
 - (d) **Recommendation**: “I recommend an urgent knee aspiration, and I am making him NPO for possible surgery.”

Proficiency in these four central skills is then said to result in the outcomes of performance, knowledge, and attitudes of a team. The TeamSTEPPS instructional framework is depicted in Fig. 1.5.

There are a number of programs, organizations, and models that are dedicated to improving quality in medicine. Improvement in healthcare organizations is a dynamic goal, and it requires a multifaceted approach that involves effective leadership, attention to processes, a culture of safety and support, and continuous efforts to succeed.

Fig. 1.5 TeamSTEPPS instructional framework



Conclusion

Quality improvement must be a pillar of patient care. There are multiple quality improvement principles and models that orthopedic surgeons and their teams can use to provide the highest level of care. Surgeons can choose among various tools to help achieve the aims of improving quality care for their patients.

As surgeons, committing to improving the care we provide is essential. It is time to think less about “what currently is” and focusing more on establishing “what should be” and using improvement science to get there [29].

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Concepts of Patient Safety

2

David Nelson

Introduction

As the preceding chapter has demonstrated, the concepts have been developed for many years in other disciplines, and only recently have been applied to surgery. Most of us have not been trained in these issues, and it is hoped that this chapter will help you get started in your personal quest for patient safety.

The aviation industry started in 1903 with the first flight by the Wright brothers. It was extremely hazardous; in 1912, eight of fourteen Air Force pilots died in crashes. Only 63 years later, aviation was amazingly safe. In 1979, the key concepts of aviation safety were being established, and they were incorporated into commercial flight rules by 1982. This rapid adoption of safety concepts is why aviation is a leader in safety, with less than one fatality per 100,000 flight hours. Compare this to 44,000–98,000 deaths per year due to medical error *in hospitals alone*, making medical errors the third leading cause of death in the US, and the need to apply modern safety concept to medicine is clear.

The key finding was that airplane crashes are not caused by airplanes that crash, that is, defective airplanes. Based on a study of airline accidents from 1968 to 1976 and 7000 reports of near accidents, John Lauber in 1979 discovered that aviation accidents were caused by human error almost all of the time. The study of human abilities and limitations in order to design systems, organizations, jobs, machines, tools, and consumer products for safe, efficient, and comfortable human use is called human factors. This discipline was used over the following decades in fields beyond aviation, including nuclear reactors, and industrial manufacturing, and has led to dramatic decreases in safety events (accidents and near accidents). What is even more remarkable is that the science of human factors, 50 years after it was

D. Nelson (✉)

Greenbrae Surgery Center, Greenbrae California, Greenbrae, CA, USA

e-mail: nelsondl@pacbell.net

applied to aviation and after it was widely shown to improve safety in many fields, the science has barely begun to be applied to surgery. Not only were we *not taught* the concepts in our residency, but many of our mentors taught us the *opposite* behaviors.

The rest of this chapter will provide an overview of some of the safety concepts that have been developed by the science of human factors that apply to surgery.

Teamwork

The primary finding from Lauber's 1979 aviation study, and one of the fundamental conclusions from human factors research, is that teamwork (also called Crew Resource Management in aviation) is a key in any activity that has large teams working with high technology, especially where mistakes can harm or kill people. Teamwork does not occur intuitively to most surgeons. They are trained to think that there is one captain of the ship, the surgeon, and everyone's job in the room is to support the surgeon. While this at first reading may seem correct, research has shown that success and safety are more likely if everyone is a member of a team with a common goal. The surgeon is the leader of the team. They need to communicate the game plan to the team. Everyone supports the mission (a successful surgery), not just the team leader. The team functions best when there are maximally open lines of communication and people are not isolated in their own silos. "You do your job and I will do mine" changes into doing one's own job with the mission in mind. Everyone on the team must be aware of the entire team's activities, facilitating the contribution of other team members, pitching in where needed, and speaking up when mistakes or omissions are noted. The teamwork approach also recognizes the "authority gradient" in the room, and the surgeon needs to actively solicit even the lowest on the gradient to understand that they not only have the right to speak up if they feel that the surgeon might be making a mistake, but that they have an obligation to speak up. The team is functioning well if the lowest on the gradient feels comfortable speaking up to the highest, is wrong, and still gets praised for helping the team avoid a possible error. A corollary of the team concept is that if something goes wrong, it is generally not an *individual* error, it is a *team* error.

We all have known surgeons who perform according to the model that the surgeon is at the top of the hierarchy, who will tell everyone what to do with the absolute power and tone of voice of a dictator. What the dictator does not understand is that the functioning of the team in the room goes down with every demeaning command, and that the lowest on the hierarchy will never speak up even when they are aware of a problem or safety issue.

Communication

Team function depends on communication, as any fan of team sports knows. Good communication is what allows each member to know what all the other members are doing and thinking. Not only does bad communication result in breakdown in team function but has been identified as a component of almost every adverse event in a study of hospital errors. A medical malpractice carrier examined 23,658 malpractice cases from 2009 to 2013. They identified over 7000 cases where communication failures harmed patients. A review of reports to the Joint Commission revealed that miscommunication was present in 70% of sentinel events.

Black Box Thinking

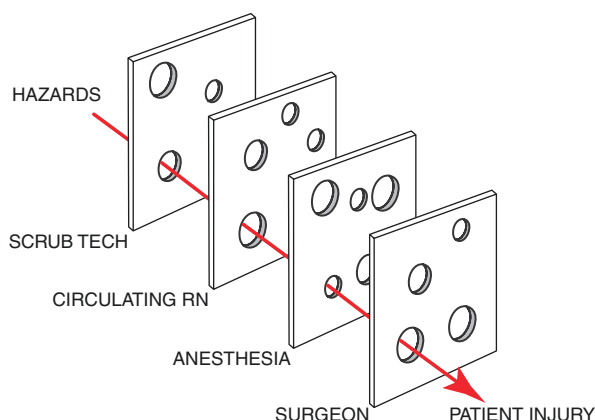
Aviation has developed a concept called *Black Box Thinking*, which is quite consistent with the human factors engineering analysis of the nature of errors. The concept is very applicable to the operating room. Mistakes are rarely failures due to bad individuals or bad intentions. They are rarely due to a single error. Fatal errors happen when highly trained and up-to-date medical professionals are going about their daily business, with diligence and concern, but are overworked, are making complex medical decisions under pressure, and working within systems that were not designed to prevent error. Most errors are due to a constellation of issues.

Each error, therefore, is not a time for the industry-standard approach of name, blame, and shame. This approach generally fails to understand the nature of errors in complex systems, and rarely prevents the error from recurring. If the error is complex, the analysis needs to be complex, and all the data must be gathered before any judgments are made. The first thing airline investigators do is look for the “black box” (actually two metal boxes painted international orange, so they are easier to find), which records a plethora of data from the aircraft as well as from the personnel on board. The purpose of the investigation is not to punish “bad individual” or the single error, but to find the complex interplay of factors at multiple levels of human and system issues, in particular, that led to the accident. If properly investigated, understood, and then promulgated, future accidents can be prevented. Knowing that full disclosure of the truth is essential to preventing future accidents, airline personnel will not be punished if they report violations of protocol with 48 h. Compare this to the standard practice at most hospitals, errors are done by bad people doing bad things and they must be punished. An investigation of the incident is done, conclusions are drawn, people are punished or fired, and the institution’s contribution is minimized. Finally, the writeup is buried deeply lest plaintiff lawyers get wind of it, and no one ever learns from the error, and it gets repeated on a regular basis. Black box thinking takes the opposite approach; errors in complex systems

are rarely due to single causes or bad individuals, but merit complete evaluation of personal, institutional, and particular contributions, then distributed to the institution or profession as a learning tool. The corollary to black box thinking is that every near miss is a free lesson, and near misses need to be analyzed just as fully as errors that result in patient harm, or the next near miss may not be a miss.

Multiple Layers of Defense

James Reason, an emeritus professor of psychology who studied human factors in accidents, observed that fallibility is part of the human condition; everyone makes errors. Since we cannot change the human condition, if we are to decrease errors, we need to change the conditions under which people work. One change is to design systems incorporating the insight that there always will be errors and structure the system so that there are multiple layers of defense designed to catch the errors before they effect the mission of the organization. Reason proposed the Swiss Cheese Model to illustrate his thesis. Modified for the operating room, the system would look like this:



Swiss Cheese Model

In the model, each person on the team is a slice of Swiss cheese, in which every hole represents an error or hazard to the patient. The propagation of an error will only proceed to patient injury if each member of the team makes (or fails to catch) the same error. In the operating room, each person on the team is a line of defense against error. They are responsible for knowing the name of the patient and the surgery to be performed, what their part in the procedure is, and what other parts of the team would be doing and should be aware of other factors which might be relevant (e.g., the X-ray machine broke yesterday, what to do if the drapes catch fire, who in central supply knows the location of all of the orthopedic supplies, etc.). Each person is charged with executing the procedure in such a way as achieving the mission of the team and catching any error that is within their sphere to catch.

Putting It All Together

Each of us on the team, including the surgeon, the nurse, the surgical tech, the transport tech, has an obligation to the patient for a safe hospital experience. Do not depend on your hospital administration to be responsible for your being a safe surgeon. The surgeon cannot delegate this to the administration or the charge nurse or the patient safety coordinator; it is your responsibility. Develop a program to lead in a positive way, not a dictatorial way. Strive to create a unified team in the OR by arriving on time, knowing the names of your teammates and greeting them, letting them know what the procedure is, expecting them to step up to the challenge and be a line of defense against errors. Remember to be liberal in praise in public and criticize in private, but only in a constructive way. It is not easy to be a team leader and expect to have to work on your own personal style. You will not always make the right moves. Learn from your mistakes but keep building the team. Do not expect the patient to know the correct side, site, or procedure; create your own checklist and bring it with you to the bedside so that no one can lead you astray. No one knows the patient or the procedure better than you do, so own the timeout. Insist on the surgeon leading the timeout with the active participation of every member of the team. When you take the timeout seriously, the team will too. Specifically, address each member of the team, especially the members at the low end of the authority gradient, and teach them that they not only have the right to speak up for safety, but that is their job. Praise team members when they correct you, even if they are wrong: "Thank you for speaking up, however I verified with the patient in the holding area that that allergy written on their armband is incorrect. But I appreciate you paying attention to that detail, I might have not known that. Thanks!"

You did not learn orthopedics in a day, and learning to be a leader may in some ways be harder. But the achievement of improved patient safety will be a great accomplishment alongside your orthopedic skills.

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TeamSTEPPS: Strategies and Tools to Enhance Performance and Patient Safety

3

Andrew Grose and Dwight Burney

Background

All work in healthcare occurs in a complex, joint cognitive system, a setting where work is accomplished between humans working with each other and machines, (e.g., computers, anesthesia machines, fluoroscopy, etc.) [1]. Working in such systems requires interface between not just the machines and humans, but also between humans themselves. As the machinery in other fields such as nuclear power, space exploration, and aircraft flight operations became more reliable over the past 50 years, it became obvious that human–human interactions we had previously taken for granted were now extremely important for performance. This was initially conceptualized in a manner that considered human performance as potentially defective and in need of correction. It wasn't that humans had become worse at anything, but simply that other aspects of the system became fine-tuned and extremely reliable, and perhaps more importantly, extremely complex. This evolving complexity and reliability reinforced the notion of “human error” as a failure mode and stimulated a fair amount of research on limiting and mitigating against human error [2]. Subsequent research in safety science has suggested that rather than consider human performance as a potential defect in the process, it is probably more useful to

“The most difficult subjects can be explained to the most slow-witted man if he has not formed any idea of them already; but the simplest thing cannot be made clear to the most intelligent man if he is firmly persuaded that he knows already, without a shadow of a doubt, what is laid before him.”
Leo Tolstoy, *The Kingdom of God is Within You*, 1894.

A. Grose (✉)
Hospital for Special Surgery, Sleepy Hollow, NY, USA
e-mail: grosea@hss.edu

D. Burney
Retired from Clinical Practice, Presbyterian Medical Center in Albuquerque, Los Ranchos de Albuquerque, NM, USA

consider human performance as a vital catalyst for appropriate system adaptation. It is this adaptation that creates resilience and a robust system capable of maintaining reliable performance in a constantly changing world. One of the dominant features of the modern health care system is the great extent to which humans are used in precisely this manner—i.e., as the grease that keeps the wheels moving on the production line of patient care. We keep those wheels moving often by acting as an essential buffering agent, continuously mitigating against system failure. Large harm events—e.g., wrong site surgeries—are considered catastrophic failures, but the more valid question to ask is how do we get it right so much of the time? And what skills could we employ that would help us get better at what we already do very well? Fortunately, there exists decades of literature defining not only what those skills are, but also the theoretical basis behind them. Those skills revolve around the domains of information transfer and resource allocation. The bulk of what TeamSTEPPS deals with its information transfer, but it cannot be overstated that this largely serves the second domain of appropriate resource allocation.

Since information is distributed throughout the system, information sharing must be managed appropriately for efficient system function. While this can seem obvious, it is remarkable how commonly we as humans fail at simple communication. To better understand the importance of predictability, consider a monitor such as the pulse oximeter. As a function within the joint cognitive system this monitor has information, and we need it. System designers have programmed it to beep with each beat and for the pitch to change as saturation increases and decreases. This control is extremely tight, i.e., we do not permit any deviation from that form of information delivery and it is stable from setting to setting. This tight control is essential for us to adequately interpret information. Imagine, for example, if each pulse oximeter was permitted to change how it conveyed the information it had? Or each fluoroscopy machine? If each item was permitted to transmit information however it wanted, we would spend extra effort trying to make sense of what the device was trying to say. This cognitive load would prevent us from doing the work we consider important. Interacting with people is no different, and yet we assume that our lives have prepared us for adequate function in such complex systems. We do succeed in conveying information just well enough a great deal of the time. Unfortunately, however, ample empirical evidence exists that we also fail at an unacceptable rate. It is clear that without specific training, we lack adequate skills enabling us to do what humans do best: anticipate, recognize, and respond to situations that develop. All of the TeamSTEPPS tools should be considered just that: tools we use—like the instruments on the back table in a surgery—to permit adequate anticipation, recognition, and response from the entire system. The foundation for these tools rests in activity theory and theories of performance adaptation.

Activity theory is a theoretical model for how humans engage in work (or play for that matter) [3]. Consider a basketball game: Every game has a goal (score more points than your opponent), rules (dribbling, out of bounds, limiting contact), tools (ball, backboard, teammates), and roles (center, guard, and coach) that help us organize play. Goals, Rules, Tools, and Roles are the fundamental concepts in activity theory. Each player needs to understand those issues to perform well. Just like the

design of the pulse oximeter, the rules we work under mandate certain performance expectations in terms of how we relay information and investigate or perform tasks. Most of these are so second nature to us we don't think about them much—akin to driving to work and not really paying attention; they just happen intuitively. Activity theory has a significant limitation, however, in that it doesn't really account for unexpected events, and those are critically important to us. Learning tools that cannot be adapted for various situations, or that don't contribute to our ability to adapt on the fly, can't really serve our work in the real world. In order to function in the real world, we need to be able to pivot and shift gears as we progress in our work. We conceptualize that as Threat Management and Task Adaptation (TM&TA) [4]. TM&TA divides events into two categories: threats, and tasks adapted to local context. Issues beyond our control we call threats. All work must be organized such that threats are managed appropriately for successful completion. Task adaptations are the constant ongoing modifications of what we do in response to how events are unfolding in front of us. Those adaptations are the changes we make in resource allocation—whether that is capital resources, manual effort, or cognitive resources—that seem appropriate based on our understanding of the situation.

Using these two models, we can organize all our work. In short, we know we need a plan, a way to perform our tasks (involving rules, both technical and non-technical) and the tools we use must facilitate anticipation, recognition, and appropriate response to situations as they unfold. These actions—anticipation, recognition, and response—are considered the work any team does in real life to make sure work is accomplished [5]. TeamSTEPPS should therefore be considered a toolbox, from which we choose tools as we need to successfully *anticipate, recognize, and respond*. To make this more concrete, we will consider specific TeamSTEPPS tools as they are used in the domains of PLANNING, EXECUTION, and REVIEWING & MODIFYING our work.

Planning

All of our work requires planning, some of which is relatively static and may be somewhat standardized. This is where threats are managed through *anticipation*. Many of these issues are taken for granted, such as room set up and skin prep for a total knee replacement. Regardless, there is almost always benefit in a face-to-face meeting among relevant team players prior to beginning work. We call this meeting a *Briefing*. Just like the basketball game, a good briefing has several basic components:

- Who is playing on our team?
- What is the game? (Trigger finger? ORIF Acetabulum?) What are the critical steps?
- Essential responsibilities?
- What potential problems could occur? What are our contingency plans for those?
- What questions or concerns does anybody have?

Finally, it is our very strong recommendation that the leader (in this case the surgeon) reminds everyone at the end of the expectation that safety concerns will be brought to his/her attention immediately. A good template for this statement is: “If anyone has a safety concern at any time, I expect you to bring it to my attention immediately.”

It is probably important to briefly consider checklists. TeamSTEPPS tools are NOT checklists, but checklists can be EXTREMELY effective adjuncts to ensure we employ such tools effectively. Consider, for example, the preoperative TimeOut and the Surgical Safety Checklist. Though the TimeOut portion is used as a Briefing in most centers, it probably isn’t a good time/place for the type of briefing listed above. The TimeOut should check that issues discussed in the Briefing are now in place (e.g., “yes, we did get the blood in the OR as requested” or “cefazolin was given at XX”). Most importantly, however, the WHO researchers noted that the Surgical Safety Checklist, of which the Time Out is the second component, was intended as only a template to be modified for local use [6]. The checklist is a separate tool, used as a prompt to guide us through both very routine events (to ensure we have not overlooked something routine) and also in extremely rare events (because we could never be expected to remember or possibly have not even encountered such an event before). The important point to remember is that checklists are NOT TeamSTEPPS. TeamSTEPPS are behavioral skills people employ. Checklists are memory aids.

Execution

Execution is where the rubber meets the road and work gets done. It is both perhaps the most important area for effective teamwork and the hardest to practice and do well. The broad concerns are as follows:

- Are we getting work done as planned?
- Is anyone’s workload overwhelming? This can be tricky to pick up on, because most often the cognitive workload is the problem for an individual, rather than a physical workload problem.
- Are we progressing as expected?

From a teamwork perspective, the skills are **monitoring the situation** (cross-checking work accomplished, assessing individual stress levels, and assessing the environment for risk), **offering assistance** when necessary, and using **standardized communication**. In a high functioning team, a lot of this activity can happen without any talking whatsoever, and that’s great. But when you need to communicate verbally, the best method is to have standardized patterns of speech. Two simple elements are **CALLOUT** of important information (e.g., announcing incision at the start of a case, or that cementing or reaming is about to occur in a femoral canal), & **READBACK** of critical information to verify it was understood. There are many types of standardization in terms of passing complex information (e.g., some of you

may have heard of or use I-PASS), but we will use the tool SBAR as prototype [7]. These names are mnemonics for the tools; SBAR stands for Situation, Background, Assessment, & Recommendation. SBAR comes from the nuclear submarine world. SBAR guides the sender in both bringing the important information to the table and also in organizing it. The organization aids the receiver because it sets up expectations and assists with sense-making. It is important to understand that the sender has a great deal of freedom within this framework to compile whatever information they see fit. This flexibility can be crucial in threat management and task adaptation.

Review and Modify

This takes us to Review & Modify, which are skills every team must have to succeed a high percentage of the time. Team members must have the ability to ask clarifying questions as the situation develops. They must also be able to bring important issues to the team leader. Just as with the components of execution, these efforts often go unnoticed and work hums along fine. Unfortunately, the perception of how easy it is for people to question or bring issues to the leader is notoriously misunderstood by the person at the top. **Leaders (in this case surgeons) tend to consider the team much higher functioning in this capacity than anyone else in the room.** This discrepancy has important ramifications on our ability to get work done. Remember that our distributed cognition requires important information to be processed through the system and arrive at the leader in a timely and useful manner. Any obstruction to that flow degrades our ability to accomplish our task. As leaders we have a responsibility to keep channels open between staff and each other and especially between all staff and us. One aspect of this is promoting psychological safety, which is essential for people to perform well in general, as well as to create the environment where team members can transmit important concerns up a hierarchical gradient. Intangible methods for this revolve around simply getting to know people as people rather than as objects present to do work for you. Even in the best of circumstances, however, any team member can become preoccupied with and aspect of work they deem critical while others can see a different and potentially dangerous problem develop. At such times, it is crucial to be able to move information in a way that regroups the whole team around solving a new problem. TeamSTEPPS considers the “CUS Statement” to be an essential tool for relaying critical information in this scenario. CUS stands for CONCERNED/ UNCOMFORTABLE/SAFETY ISSUE.

A CUS statement is a four-part tool that starts with calling the person by name, stating that there is a concern, *briefly* stating the problem, and proposing a solution using “We”, or “Let’s”. Note that this starts with a personal concern presented directly to another team member (potentially the leader). The information is presented as that person’s concern. My team members know that when they say “Andrew, I have a concern” I will stop whatever I’m doing like Pavlov’s dog because I recognize they have a critical concern. This is essential because in our Joint cognitive system, they may well be aware of critical dangers I cannot see from my

vantage point. After the problem is stated, the solution is proposed as a group activity using, We or Let's to return to a team-based solution. Practicing the CUS statement is essential for your team, because saving it for a critical moment may be too late.

Finally, we have to mention two team regrouping mechanisms. The first is the Huddle, which is a rapid and impromptu team meeting to consider new important information. The Huddle works very much like an SBAR and Briefing combined:

- What is the new situational development?
- What is the recommended solution & why? (If there is time, this question is best used as an open discussion among relevant team members. In an emergency, it may be a simple direction from the team/situational leader.)
- What are our new tasks/roles?
- What questions/concerns does anyone have about moving forward?

Again, we can't emphasize enough that this template is left purposely simple, but following it is extremely helpful.

Last, but certainly not least, is the DEBRIEF. Though this is the last thing your team may do in an event, it is probably the most crucial. Simply stated, if you don't regularly debrief, you can't reliably get better. Debriefing has three questions: "What did we do well?" (to make sure we keep it for next time), "What do we want to do differently next time?"—and here is the crucial component—"How will we make that happen?" The final question is critical because though many issues can be sorted out at the individual level, sometimes change will require system support, and the system needs your debriefing to learn about these issues. Your team's ability to debrief well should be considered a good indicator of how high functioning you are in the other domains, as it requires high degrees of psychological safety, a willingness to speak up, and, perhaps most important, a commitment to learning and improving. The perceptive and thoughtful surgeon will probably notice that team members can be very reluctant to discuss process issues during debriefing and will often completely avoid discussing any behavior up the hierarchy.

It is often the case that an institution or surgeon may add to the debrief and include items relevant to post-operative care. This is fine and can often be helpful in transitioning care to the next step. The essential items, however, are the three questions:

- What did we do well?
- What would we like to do differently next time?
- How will we make that happen?

Conclusion

No matter which safety methodology you follow, whether it be High Reliability Theory, Reason's Swiss Cheese Model, or Resilience Engineering/Safety II, the ability to succeed seems to revolve around **anticipation** of threats/opportunities, **recognition** of current state through situation monitoring, **responding** with adequate mobilization of resources, and **learning** from each opportunity. TeamSTEPPS tools are simply facilitators of each of those events. We should be applying them not because we hope to be safe—truly the lowest common denominator in patient care—but because we want to perform at the highest level we can. For the surgeon, recognized as leader of the surgical team, learning and practicing these “nontechnical” skills is critical for improving the team's performance and avoiding harm to the patient. We strongly encourage everyone to participate in formal training in these tools, and to work with some form of simulation or coaching to ensure both comfort and adequate skill level in performance.

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Shifting from Volume to Value

4

Meredith G. Moore and Kevin J. Bozic

To transition from health care delivery revolving around volume and intensity of services to care delivery centered on value, one must maintain proper headings on this journey: the ship's bearings should be set on the "north star" of maximizing patient-centered health outcomes achieved per health care dollar expended, consistent with Porter and Teisberg's trailblazing definition of value-based care [1]. With active prioritization of this guiding principle when setting up or delivering care, the trajectory of the mission will align with the ultimate goal of providing value to patients. Many cite access, cost, or quality issues as the source of malady in the U.S. health care system; the true disconnect is in accountability for providing value to patients just as any company would be expected to do for its shareholders. The numerator of the value equation, outcomes, should be reported by the patient where possible, since the patient is the ultimate authority on his or her condition and functional goals. The denominator, cost of care, is minimized (i.e., cost containment achieved) by improving health outcomes (e.g., prevention, treatment earlier in the disease course, faster recovery). Minimizing cost maximizes value, as does optimizing outcomes, and these actions in combination have maximal upward effect on value.

Historically, profit-seeking motivations have driven utilization. There is long-standing precedent for a value-agnostic approach to caring for patients. With health care rather than health as the point of emphasis, our system trends toward ballooning service charges and tests ordered. These line items may have little to no beneficial impact on the patient's health status. This turgid system permits fragmented delivery and fractured underlying payment structures. From all angles—patient, provider, and payor—there are disruptors skewing the value equation by driving up the cost of care denominator. Payors traditionally contend that the practice of

M. G. Moore · K. J. Bozic (✉)

Department of Surgery and Perioperative Care, Dell Medical School at the University of Texas at Austin, Austin, TX, USA

e-mail: Meredith.Moore@austin.utexas.edu; kevin.bozic@austin.utexas.edu

medicine should be protected from market forces, consumer pushback, and expectations of transparency. With the rise of medical malpractice suits, defensive medicine took hold among providers to safeguard against litigation. Furthermore, technological advances have engendered sophisticated diagnostic and treatment capabilities dependent on expensive machinery. Novel, “cutting-edge” health care technology commands higher profit margins tantalizing to hospital systems. Hospitals are easily engaged in a “medical arms race” of unnecessary spending including construction of high-tech facilities not at all based on a regional or population-based need. Moral hazard results from the separation between patient and payor, where patients are protected against the consequences of excessive medical spending by their health plan. Without personal financial investment (i.e., “skin in the game”) in the context of the health insurance buffer and often being left in the dark about anticipated expenditures and outcome deliverables, patients do not have full information to act according to true preferences when it comes to receiving healthcare. These factors came together to create a system quite disconnected from the concept of creating value for patients.

This overutilization landscape presents the challenge of designing a care delivery strategy that offers concrete and improving value to patients. To do this requires refined measurement tools in order to characterize both the numerator [outcomes] and denominator [costs] of the value equation. Incentives must be realigned with those interventions and care activities effectuating a direct impact on patient health. A fee-for-service mechanism of reimbursement incentivizes the provider to drive up volume and intensity of services, regardless of their relative utility. Metrics must change with patient preferences and the tenets of evidence-based medicine. Care delivery models require logical reorganization such that they facilitate value-centric practices. This should involve downstreaming, which is the practice of providing care in settings that are less resource-intensive, by clinicians working at the top of their licenses [2]. For instance, an orthopedic surgeon should not offer an elective operation to a person whose musculoskeletal condition is exacerbated by untreated anxiety or depression, and likewise an orthopedic surgeon need not provide an indicated behavioral health intervention when a non-MD provider is better suited to this task. Orthopedists must work within multidisciplinary teams to deliver the right services for the individual patient and to ensure that the right person is delivering these services. Value-added to the patient should always justify the resource cost. Cost-shifting alone is not the answer.

Pressure to reduce cost certainly can result in perverse incentives. All health care stakeholders should consider that the single most powerful lever for reducing cost is *improving health*. A healthier patient enjoys a higher quality of life, while simultaneously bearing less burden on the health care system. The underlying principle here is that health is inherently less costly than disease. This win-win situation is at the heart of value creation. Creating health comes first, and from this foundation over time the cost reductions will come. If health is not improved, no value is created.

Fundamentally, in order to be an attainable goal, both a mile marker and an endpoint, value must be measured. Value generation lies in caring for a patient's

medical condition over the full cycle of care. It is not isolated to a hospital, a practice, a site, a specialty, or an intervention. A full cycle of care spans from initial symptoms to diagnosis to resolution of symptoms. Outcomes come into play at any point in this cycle. They are defined as the full set of health results that matter for the patient’s condition. Costs are the total expenditure for care addressing the patient’s particular condition over this full care cycle; in tracking them, actual cost expenditures should be tallied, and methods such as time-driven activity-based costing provide the most accurate figures.

Outcomes may refer to a wide variety of concepts, and clarification of which outcomes are most relevant to value creation is of utmost priority. In orthopedics, patients may have many care goals, with return to function and reduction of pain usually central to these goals. Patient-reported outcome measures (PROMs) empower clinicians to make evidence-based, patient-centered decisions. They are generated quite simply: patients, as the most credible source of information about their health status, respond to questionnaires regarding aspects of their perception of their health such as level of pain or degree of function. These responses are then scored, and scores can be indexed to those of other patients and practices. By transforming qualitative patient disease experiences (i.e., symptoms and physical limitations) into quantitative representations of the previously subjective data, PROMs elevate the patient perspective into useful, quantifiable clinical information. With PROMs, we can evaluate the value of various interventions with metrics more relevant than mortality or readmission rate. A paradigmatic value-based healthcare system must integrate patient perspective, and PROMs are a meaningful way for a clinician to achieve this, as they allow for comparison over time, among providers, across patients, and between populations. For instance, the status of the joint drives treatment in osteoarthritis, and this is best gleaned not from radiographs alone that may be discordant with patient symptoms but directly from the patient. Acronyms relevant to patient-reported outcomes must be delineated for proper understanding (Table 4.1).

In orthopedics, much progress has been achieved in recent years on defining standardized measures. Outcome measures may be broad, such as quality of life scales like the 36-Item Short Form Health Survey (SF-36) and Patient-Reported

Table 4.1 Patient-reported outcome terminology and acronyms explained. (Derived from National Quality Forum’s *Patient-Reported Outcomes Environmental Scan* report, page 4) [3]

Terminology	Acronym	Description	Example
Patient-reported outcome	PRO	Data reported directly by the patient	Symptom of depression, e.g., anhedonia
Patient-reported outcome measure	PROM	Tool, instrument, or single-item questionnaire	Patient health Questionnaire-9 (PHQ-9) standardized 9-item tool to screen for depression
Patient-reported outcome performance measure	PROM-PM	Performance indicator based on PROM data aggregated for an accountable healthcare entity	% of patients with diagnosis of major depression or dysthymia and initial PHQ-9 score > 9 with a 6-month follow-up PHQ-9 score < 5

Outcomes Measurement Information System (PROMIS) Global. Outcomes measures can also be more granular with condition-specific measures such as the Disability of Shoulder, Arm and Hand questionnaire (DASH) or the Hip Disability and Osteoarthritis Outcome Score (HOOS) for hip pathology in potential total hip arthroplasty patients. Yet even these more condition-specific measures do not stand alone, and only consensus will allow us to forge ahead as orthopedic providers accountable for bettering musculoskeletal health as a contributor to overall patient well-being. Building consensus across practices regarding most useful outcome measures will enable standardization and systematic tracking. Value-based systems should focus on tracking one general wellness indicator PROM, and one condition-specific PROM in order to characterize the evolving state of the patient's primary musculoskeletal complaint in the context of their overall health status.

The other pertinent point about outcome measurement as a mechanism of shifting emphasis from volume to value is that outcomes should be measured in real time. In a research capacity, PROMs allow for comparisons of treatment effectiveness. When PROs are the subject of research, a reporting delay is permissible and will not obstruct the utility of the results, yet when employed in daily clinical practice they need to be available and easily visible to the orthopedic provider at the point of care. This allows for the patient-derived metrics to be clinical decision-drivers rather than retrospective markers. For example, pre-operative PROs have been shown to predict meaningful improvement in function after total knee or total hip arthroplasty [4] and can therefore inform the treatment course when available in advance of a potential joint reconstruction. Technology certainly helps in this respect, as cloud-based electronic platforms allow for tablet-based patient data entry and concurrent (i.e., real time) data access by their practitioner. Technological advances supporting outcome collection also enable a higher capture rate than that achieved with pen and paper, facilitating more complete implementation.

Integration of PROMs will follow a tri-phase model over time. In the first phase of integration, PROMs become a part of clinical workflow and become enmeshed in the clinical culture—in fact, cultural change may form the most formidable barrier to implementation. In the second phase, population-level usage (i.e., orthopedic providers across subspecialties and geographies) begin to utilize PROMs and the ubiquity of these measures promotes shared decision-making by allowing for standardization with score thresholds signifying clinical meaning/interpretation. An example of this would be pre-operative KOOS JR score thresholds as a predictor of whether or not the patient is likely to achieve clinically KOOS JR score thresholds for predicting whether a patient is likely to meaningful functional improvement after total knee arthroplasty [5]. Phase three then supports accountability for shared outcomes based on PROMs.

Novel payment schemes provide a scaffold on which to build a value-based system. Bundled payments for a group of providers over a full episode of care incentivize value creation—importantly, transcending payment for each compartmentalized service (i.e., fee-for-service). Most payment model innovations in orthopedics, and medicine in general, have revolved around procedure-based bundling, e.g., Bundled-Payments for Care Improvement (BPCI) and BPCI Advanced. Yet condition-based

bundling, while not prevalent today, aligns incentives upstream by incentivizing optimal management of the condition rather than efficient performance of the procedure [6]. Performance risk entails providers accepting financial risk for the health outcomes they achieve per health care dollar expended, as opposed to actuarial risk, which entails accepting financial risk for the prevalence of disease in a community. Performance risk emerges as an integral element of an optimized, value-based system.

In summary, the current U.S. health care system and fee for service payment model promotes overutilization and is stifled by fragmentation. Musculoskeletal care delivery calibrated to maximize value requires active prioritization of improving health outcomes. With the use of deliberate downstreaming, condition-based bundling, multidisciplinary teams, and consistent measurement of standardized patient-centered outcomes, a successful transition to health care payment and delivery models that incentivize greater value is achievable.

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Quality Improvement: Using Care Pathways in EMR

5

Karl C. Roberts and Mathew Pate

Introduction

Clinical medicine has been slowly evolving from delivering experience-based care to a new paradigm incorporating increased utilization of evidence-based medicine (EBM) to guide clinical decision-making. The concept of EBM has been championed since the nineteenth century, with increasing support in the medical community over time, reflected in the widespread interest and creation of clinical practice guidelines (CPGs) in the last 20 years.

The Institute of Medicine began developing methods for CPGs in the 1990s, with the formation of the Agency for Health Care Policy and Research (AHCPR) which later became known as the Agency for Healthcare Research and Quality (AHRQ). Desire for CPG development was birthed largely due to rapidly escalating healthcare costs, widespread variability of care, and frequent utility of futile treatments [1, 2]. Today the concept of applying evidence to establish recommended clinical treatment guidelines and to identify best practice is widespread, with international organizations such as the Cochrane Library, Britain's National Institute for Health and Care Excellence (NICE), and the AHRQ leading the way. Medical specialty societies have become increasingly involved in the creation of evidence-based protocols and guidelines for their members.

EBM is defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The aim of EBM

K. C. Roberts (✉)

West Michigan Orthopaedics, Grand Rapids, MI, USA

Orthopaedic Surgery Residency Program, Spectrum Health—Michigan State University, Grand Rapids, MI, USA

M. Pate

Orthopaedic Surgery Residency Program, Spectrum Health—Michigan State University, Grand Rapids, MI, USA

is to integrate the experience of the clinician, the values of the patient, and the best available scientific information to guide decision-making about clinical management” [3]. The overriding goal of EBM is to decrease variability in care, encourage the adoption of best clinical practice, and improve patient outcomes, decrease unnecessary care, and improve value in healthcare.

CPGs have become the vehicle for the implementation of EBM. This process, however, is not always an easy task and presents many obstacles which occur either at the design, implementation, or evaluation phase [4]. Dependable and effective implementation strategies to encourage adoption of CPGs are vital. Common barriers include a lack of awareness of the clinical guidelines among physicians in the healthcare system, and a lack of physician buy-in making compliance poor [1, 3–5]. One barrier to physician buy in is that CPGs have been criticized as being too prescriptive and lacking in impact with limited recommendations due to insufficient evidence [3]. Physicians may be skeptical of CPGs as they are seen as a threat to physician judgment and autonomy by removing the expertise of the physician in the decision process. Facilitators of CPG implementation include clinical and management staff involvement in the CPG, cultivating awareness of the CPG among physicians, incorporation of CPGs into the electronic health record, and frequent re-examination of recommendations with updates to the CPG as necessary to ensure recommendations remain up to date [4–7].

Another reason of skepticism from clinicians is the valid concern that CPGs could be used to make coverage decisions from insurers or arbitrarily used to drive down the cost of care or decrease utilization of care. This is not the intent of CPGs. The goal of CPGs is to incorporate best existing evidence with the experience and judgment of the physician in the context of the unique clinical characteristics and values of the patient, to arrive at the best care and limit the utilization of unproven treatments [1, 2]. At times, evidence may lead to increased utilization of a procedure or diagnostic test and could even increase the cost of care with the end result being offset by better patient outcomes and fewer adverse events [8]. Though there may be situations in which these pathways lead to the utilization of a more expensive diagnostic test or procedure, there is an abundance of literature that elucidates the overall lower cost for the patient and the healthcare system [1, 8–12]. For example, it has been well documented that complications and mortality rate are elevated for hip fracture patients with delayed surgery (defined as surgery >24–48 h from injury) [11–13]. Though it may cost a hospital system more resources to ensure that all indicated patients receive an operation within that timeline, the increased cost upfront is recovered in the savings from lower perioperative complications and decreased length of stay in the hospital.

The skepticism of physicians can lead to a lag between best evidence and incorporation into practice [4]. This is magnified by the challenge of individual physicians trying to stay up to date with review and appraisal of new evidence due to the explosion of research publications. Open access journals and pay to publish journals without robust peer review make assessing the quality of any given study challenging and often the most accessible evidence does not reflect the best evidence. Many

physicians do not have the time or resources to appraise a study properly. Identifying possible confounding variables, methodological flaws, or conflict of interest that could make the conclusions suspect is critical before acknowledging the impact and validity of a scientific study to guide clinical practice. This highlights the importance of a thorough literature search with appraisal of quality of evidence to ensure the best evidence is used to formulate recommendations [4, 5, 14].

The greatest challenge to utilization of evidence may be that many CPGs are incomplete as evidence is often lacking such that recommendations may not exist regarding the entire scope of clinical care for a condition within a CPG [4]. This challenge can be overcome by using CPGs as a guide along with expert opinion where evidence is lacking to develop comprehensive care pathways or appropriate use criteria (AUC) for specific clinical scenarios. These care pathways can be further modified by considering the resources of any given institution, but the overriding influence is on increasing the utilization of evidence-based care whenever possible. As further evidence arises, these CPGs, AUCs, and care pathways should be revised and edited accordingly.

Whereas the goal of CPGs has been to improve adoption and utilization of evidence-based best practice, the same benefit has been proposed for the rapid adoption of the electronic medical record (EMR). The EMR provides accurate and up-to-date patient information, improves communication, reduces medical errors through electronic safeguards and alerts, and allows standardization to decrease variability in care, thus providing safer, more efficient, and higher quality care.

Using evidence-based CPGs to create a care pathway incorporated into an EMR solves many of the aforementioned problems and barriers to adopting EBM [4–6, 14, 15]. EMRs provide the unique opportunity to operationalize a clinical care pathway created from best evidence to increase adoption and compliance by physicians in order to improve patient care and outcomes. By creating care pathways within an EMR, the transition from evidence to adoption can be expedited and variability can be minimized.

The implementation of CPGs has resulted in improved care and efficacy [7], increased efficiency [14], and decreased healthcare costs and resource utilization in physicians with defined care pathways [8–11, 16]. As physicians and health care systems are increasingly challenged by the transition from a volume-based system to a value-based system, CPGs play a pivotal role in the ability to apply EBM to clinical practice. In a study of 6090 total hip arthroplasties within a high volume health care system that implemented the use of a CPG for preoperative, operative, and postoperative phases of care, patients had shorter length of stay in the hospital and an average individual cost savings of \$2533. This study suggests that widespread implementation of CPGs in the setting of total hip arthroplasty could lead to an annual savings of \$1.2 billion in healthcare dollars in the United States [11].

Creation and implementation of evidence-based care pathways into the EMR are a great opportunity for quality improvement and have the potential to improve value in all areas of musculoskeletal health.

How to Create a Care Pathway within an EMR

- Identify condition and define episode of care.
- Identify relevant clinical practice guidelines and evidence that will be used as the foundation to guide treatment.
- Establish a multidisciplinary team to create a pathway understanding the goal is for the evidence to guide the process.
- Create an aspirational care map based on evidence and modify accordingly to compensate for the resources of the institution, using expert opinion to fill in the gaps where evidence is lacking.
- Work with information technology specialists familiar with the hospital EMR to create the pathway and set-up guide-rails encouraging compliance, triggering alerts and using best practice advisories or hard stops within the pathway to ensure adherence to best practice.
- Identify areas where institutional support is lacking and address any deficiencies or barriers prior to implementation of the care pathway.
- Work with quality specialists to define metrics to follow and performance measures to assess compliance and key outcomes measures within the pathway.
- The care pathway is the first step in the quality improvement process, and education among providers, monitoring of compliance to ensure consistent adoption and utilization, and assessing performance measures and outcomes allows for a real-time cycle of quality improvement.

It is critical to have a multi-specialty team of physicians and care givers across the continuum of care for a specific condition when creating a care pathway. Physician champions from each area of care can drive the process and encourage buy-in across hospital departments (orthopedic surgery, anesthesia, hospitalists, emergency medicine physicians, physical and occupational therapists, and others). Commitment of the hospital to the process to provide adequate institutional resources and necessary funding is paramount. Quality improvement specialists and EMR IT specialists are essential to create and implement the care pathway within the EMR and facilitate continuous quality improvement following implementation. The resources required by an institution are highest during creation and implementation of a care pathway, and once operationalized it will result in a more efficient cycle of normal quality improvement efforts.

There Are 4 Stages to Development of a Care Pathway

Stage One: Creation of Care Map

A multidisciplinary team should be created to identify the evidence and create an aspirational care pathway using consensus expert opinion to fill in gaps where evidence is lacking. A pathway map for an episode of care should be created to identify the decision points and best practices from admission to discharge. Performance measures and metrics to track for quality improvement should be identified at the

outset of the project. Critical hard stops and best practice advisories should be implemented into the pathway to ensure compliance and guide evidence-based care. Frequent meetings are required during this stage with specific timelines to drive the care pathway forward.

Stage Two: Creation of Care Pathway into the EMR

Once an aspirational care map has been created, it is important to assess the resources of the institution to determine if barriers to implementation exist. Identification of barriers can help direct institutional resources to improve care where there may be deficits or particular limitations of the institution. Once the care map and institutional resources have been aligned, the EMR and IT specialists begin programming the care pathway in to the EMR. This is best accomplished in a test environment as it takes multiple builds and trials to ensure that the pathway is running as intended with appropriate hard stops, best practice advisories, and data collection. Fewer meetings of the multidisciplinary team are required during this stage, but meetings should still occur to assess progress, validate the build, and ensure the process is moving forward according to the timeline.

Stage Three: Implementation and Compliance

Once the care pathway has been created and tested within the EMR, it is critical that an educational campaign is performed prior to implementation to raise awareness and encourage physician buy-in. Physician champions should present the care pathway and rationale to all providers involved in the episode of care, and strategic multimedia resources highlighting the pathway should be placed around physician workstations. Presentations at multiple department and section meetings across the continuum of care help to engage all providers who may be using the pathway, such as emergency medicine physicians, hospitalists, and advanced practice providers or residents. Once the pathway goes live, early monitoring for compliance with rapid feedback is essential to encourage appropriate utilization and adoption. It is important to monitor compliance and give continuing feedback until routine utilization is achieved. The implementation stage is the most challenging since this is where change in physician behavior to minimize variation of practice occurs. Feedback is given in real-time, with expected accountability for all members of the team.

Stage Four: Quality Improvement

Once implementation has been achieved, the pathway goes into operational mode and the cadence of meetings and the structure of the team goes back to normal quality improvement efforts. If designed well, the built in outcome and performance measures will be able to be monitored in real time without lag and fewer resources will be required for data abstraction as this should be automated into the EMR. Meetings at this stage focus on quality improvement with identified performance measures and benchmarking of results for comparative assessment. Obstacles in the pathway are identified, and focused efforts are made on system improvement to address these

issues. Within a year of implementation, process improvement shifts should have been realized and efforts shift to sustaining the quality improvement and redefining the pathway as evidence evolves.

Case Example

Hip fractures are a common injury, and the prevalence is expected to increase over time as the population ages and life expectancy increases. It is estimated that there could be over six million hip fractures annually worldwide by 2050 [17]. This represents a significant healthcare burden with associated morbidity, mortality, and loss of independence experienced by patients and significant cost to the healthcare system for care. As the episode of care for an elderly patient >65 years old with a low energy hip fracture is well defined, and there are existing evidence-based CPGs, it is well suited to the creation of a care pathway within an EMR.

Patients were captured on presentation to the emergency room once diagnosed with a low energy hip fracture, and the pathway was intended to guide treatment from presentation through hospitalization and often surgical intervention culminating in discharge from the hospital.

The AAOS CPG on the Management of Hip Fractures in the Elderly [17, 18] was created by a multidisciplinary work group following established methodology and published in 2015 representing a 3 year process reviewing more than 17,000 research articles to arrive at 28 recommendations spanning the episode of care from diagnosis to treatment. The recommendations in this guideline were used to create a care pathway along with performance measures and best practice advisories within our hospital EMR. The electronic care pathway was created by a multidisciplinary team involving hospital quality specialists, nursing clinical specialists, information technology and EMR staff, physicians representing co-management across the spectrum of care (Emergency Medicine, Orthopedics, Internal Medicine, and Anesthesia) as well as in collaboration with physical therapists and care management professionals.

Over the course of a year, the care pathway was created in the EMR after creation of a care map based on the AAOS CPG. Best practice advisories were used for VTE prophylaxis, and standard work was created for osteoporosis diagnosis and management, surgical decision-making incorporating the AAOS AUC, and discharge communication and checklists. Institutional changes included using fascia-iliac blocks and multimodal analgesia on admission to avoid narcotics and delirium, routine co-management of patients with hospitalists, elimination of Buck's traction, surgery within 24 h of admission, routine use of tranexamic acid, institution of a transfusion protocol to minimize transfusion, early mobility post-operatively within 24 h, elimination of foley catheters, and standard recommendations for osteoporosis management, discharge planning and follow-up. Prior to operationalizing the pathway, deficient institutional resources were noted in the ability to timely administer fascia-iliac blocks (FIAB) for preoperative multimodal analgesia to avoid narcotics and delirium, and the institution committed resources to train the ER physicians to

administer blocks when anesthesiologists were not available. Three critical performance measures early on were utilization of FAIB, surgery within 24 h of admission, and mobilization of patients within 24 h of surgery. A significant obstacle to implementation was that some physicians would choose not to use the care pathway and would fall back to older order sets which allowed non-compliance with the pathway and occurred either due to lack of awareness or due to using orders that had been intentionally removed from the pathway such as bucks traction, parenteral narcotics, tramadol or foley catheters. Early efforts following implementation were focused on tracking utilization and enrollment of patients in the care pathway which would ensure proper order sets were used. Physician and advance practitioner education was provided to ensure accountability and to drive compliance. Within 6 months, utilization of the pathway had improved allowing efforts to shift toward quality improvement. Once the pathway was operationalized, it allowed QI efforts to focus on dashboards with real-time data without lag which creates a much more responsive real-time cycle of quality improvement compared to previous lagging metrics.

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Pre-op Optimization Checklists

6

K. Keely Boyle, Jessica L. Block, and Michael S. Pinzur

Introduction

Orthopedic surgeries currently comprise a substantial proportion of the inpatient and outpatient surgeries performed in hospitals as well as outpatient surgery centers throughout the United States, especially orthopedic reconstructive surgeries [1, 2]. Many individuals that undergo non-urgent orthopedic surgery have multiple medical comorbidities that increase the risk for perioperative complications. An increasing proportion of the population is either morbidly obese or diabetic, challenging our ability to improve our outcomes and continue to enhance patient function and quality of life.

Many orthopedic surgical solutions are being offered to an ever-aging patient population with an increasing number of medical comorbidities. It has long been accepted that those patients with complex medical comorbidities are more likely to develop perioperative complications and unfavorable outcomes following surgery. One of the major tenants of the patient safety movement is the use of well-thought-out decision-making algorithms to avoid errors or omissions that predispose patients to develop complications.

Hospitalist-Orthopedic co-management programs were initially developed to decrease the risk of perioperative mortality and morbidity in geriatric patients with hip and femur fractures [3]. Lessons learned from treating this geriatric population with similar medical comorbidities led to the identification of specific risk factors that predicted an increased risk of postoperative death, medical complications, and

K. K. Boyle · J. L. Block

University at Buffalo, State University of New York, Buffalo, NY, USA

e-mail: kkboyle@buffalo.edu; jblock2@buffalo.edu

M. S. Pinzur (✉)

Orthopaedic Surgery and Rehabilitation, Loyola University Health System,
Maywood, IL, USA

e-mail: Mpinzu1@lumc.edu

overall poor clinical outcomes. We all accept the notion that sick patients are more likely to develop complications and achieve poorer outcomes as compared to healthy patients without substantial medical comorbidities. Our working hypothesis is that by making sick patients less sick, they will have fewer perioperative complications and achieve improved clinical outcomes.

The first step in the development of this new patient care pathway is medical optimization of modifiable risk factors prior to undertaking non-urgent orthopedic surgery. Best practice would suggest that we [1] identify key risk factors or medical conditions that could negatively impact patients during the perioperative period [2], optimize any modifiable medical comorbidities (Fig. 6.1), and [3] create seamless handoffs during the phases of care “hand-offs” (Fig. 6.2), when most medical errors occur. We will focus on a checklist methodology to optimize patients for non-urgent orthopedic surgery [4].

Fig. 6.1 The pre-operative checklist

THE PRE-OPERATIVE CHECKLIST	
Modifiable Risk Factors	
☐	Smoking
☐	Morbid Obesity (BMI >40)
☐	Glycemic Control (Hgb A1C <8%)
☐	Anemia
☐	Hypertension
☐	Anemia
☐	Nutrition
Non-Modifiable Risk Factors	
☐	Cardiac <i>clearance</i>
☐	Organ-specific Medical co-morbidity
☐	Metabolic Syndrome
☐	Opioid use / tolerance
☐	Osteoporosis
☐	Sleep Apnea
☐	Bladder Function
☐	Depression
☐	Frailty
Surgical Considerations	
☐	VTE prophylaxis
☐	Skin preparation
☐	Prophylactic antibiotics

Fig. 6.2 Top handoffs in orthopedic surgery

THE DIG FIVE HANDOFFS IN ELECTIVE ORTHOPAEDIC SURGERY
• Entering the pre-operative area from home.
• Entering the Operating Room and the induction of anesthesia.
• The Recovery Room process.
• Leaving the Recovery Room and admission to the hospital.
• Discharge from the hospital to home or a skilled care facility.

Medical Comorbidities: Modifiable Risk Factors

We arbitrarily divide medical comorbidities into those that are modifiable and those that are not modifiable. Coronary artery disease can be optimized, but not eliminated in affected patients. The same can be said for renal failure or other selected organ system function. Focus should be placed on modifiable disease factors and optimization prior to performing non-urgent orthopedic procedures.

Our arthroplasty colleagues have taught us that there are several risk factors that can be modified and improved, prior to performing reconstructive surgery. Objective improvement of these risk factors decreases complication rates and improves overall clinical outcomes [4, 5].

Smoking

Every tissue in the human body is affected by smoking and nicotine use, including the musculoskeletal system. Smoking increases a person's risk for orthopedic injuries and diseases such as fractures and osteoporosis. Smoking reduces blood supply to bones, slows production of bone-forming cells, and decreases the body's ability to absorb calcium from the diet. Smoking is an independent risk factor for complications after surgery including pulmonary function, infection, wound healing, and cardiovascular events [6–8]. Smoking increases a patient's risk for pulmonary complications by six-fold after receiving general anesthesia. Smoking causes microvascular constriction, which compromises the ability of the body to deliver essential oxygen to tissues leading to wound healing problems. Some organizations advocate testing their patients on the day of surgery for evidence of smoking with the cotinine blood test.

Morbid Obesity

Obesity predisposes patients to developing perioperative complications and can contribute to poorer outcomes as compared with non-obese patients [9]. The accepted threshold for reconstructive procedures is a body mass index (BMI) < 40. It has been demonstrated that patients with BMI > 40 are more likely to experience worse clinical outcomes, a higher rate of hospital readmission, and experience major medical complications after surgery [9–11], including:

- Infection
- Poor wound healing
- Difficulty breathing
- Blood clots/pulmonary embolism
- Readmission within 30 days of surgery

Many surgeons now use a BMI of 40 as a target. Each organization needs to make a decision on whether these modifiable risk factors should identify a “hard” or “soft” stop. Best practice involves the provision of programs and care pathways to address these issues, rather than simply denying care. Patients with a BMI > 40 are asked to achieve weight reduction with a goal set between the surgeon and patient and receive nutritional counseling or other weight loss options in the elective surgical setting. Some surgeons have proposed written contracts between themselves and their patients for achieving attainable weight loss goals. The patient may also be offered a referral to bariatric surgeon colleagues for an evaluation and discussion of alternative weight loss options [12].

Diabetes and Glycemic Control

Adequately controlling blood glucose levels perioperatively for diabetic patients minimizes the risk of pneumonia, need for a transfusion, delayed discharge from the hospital, and infection [13]. Patients with diabetes have high blood glucose levels at baseline, and these glucose levels will increase further postoperatively with the stress of surgery. This rise in blood glucose after surgery impairs the ability of leukocytes to fight infection. Having adequate control of blood glucose levels before surgery will help to reduce a patient’s risk for infection and readmission to the hospital after surgery.

Diabetic control should be optimized prior to non-urgent procedures to ensure the best possible clinical outcomes. Hemoglobin A1c (HbA1c) has been demonstrated to be an excellent measure of diabetes management. While an optimal HbA1c target of $\leq 6\%$, the current upper limit of acceptable diabetic control is a HbA1c of 8%. Most guidelines advise a HbA1c below 8.0% for elective orthopedic surgery as a safe target [14]. Some institutions may opt for lower preoperative values due to the known complications associated with patients with higher HbA1c levels and blood glucose levels. It has been shown that it may take many patients over 6 months to attain the target HbA1c and for others this goal may not be feasible.

Another important aspect of diabetic management is immediate postoperative glucose control with a target <180 mg/dL. Recent evidence has demonstrated correlations between preoperative HbA1C and inpatient postoperative blood glucose levels with associated risk of infection. A preoperative HbA1c of >8.0gm/dL demonstrated consistently elevated blood glucose levels postoperatively well above 200 mg/dL, with a dramatically increased infection risk compared to those patients with a preoperative HbA1c below 6.6%.

Hypertension

The threshold for a “soft” stop is a diastolic blood pressure > 110 mm Hg. Depending on the magnitude of hypertension, this modifiable risk factor can be corrected by a

return to the patient's primary care physician or, if minimally above the desired threshold, can have hypertension medications adjusted by the hospitalist at the pre-operative hospitalist-anesthesiologist clinic visit.

Anemia

Anemia is defined in females as hemoglobin <12 g/dL and/or hematocrit <36 g/dL; and in males as hemoglobin <13 g/dL, hematocrit <39 g/dL. Correcting anemia decreases the risk for postoperative cardiovascular complications. Identifying the reason why patients are anemic will drive their therapy options. Anemia of chronic disease can occur when patients have a long-standing history of certain diseases. In patients with anemia of chronic disease, considerations of accepting a hemoglobin and hematocrit that is slightly lower than the threshold values previously described are a reasonable approach. It is still recommended to try and optimize those patients with anemia of chronic disease after obtaining laboratory values [15, 16]. For patients with known iron-deficiency anemia, preoperative IV iron treatment has been shown to potentially increase hemoglobin, although there is not necessarily evidence to support IV iron decreasing the need for blood transfusions or short-term clinical outcomes [17].

Nutrition

Healthy eating, exercise, proper supplementation, avoiding harmful products/ substances, and managing chronic diseases can all help to improve and sustain good nutritional status. When we think of malnourishment, the images that tend to come to our mind are very thin or even very sick people. Interestingly, studies have shown that a high percentage of patients with a BMI > 30 are malnourished [18]. Patients that have been identified as obese and malnourished have a significantly higher complication rate, including:

- Infection
- Hematoma formation
- Renal complications
- Cardiac complications

Nutritional status can be assessed by measuring laboratory values from the blood (e.g., vitamin D, albumin, iron, zinc). Deficiencies in one or more of these values can contribute to medical issues. For example, low levels of zinc have been associated with depression, excess stress, and anxiety. Low vitamin D levels are known to contribute to reduce calcium absorption, bone loss, decrease muscle strength, and increase falls. This is important for maintenance of bone health after surgery and to help treat osteoporosis and prevent fractures [18–20].

Medical Comorbidities: Non-Modifiable Risk Factors

The next step in the process is optimization of medical comorbidities, most commonly cardiac-related. Patients receiving ongoing care with a medical specialist are often advised to have an updated visit with their primary care physician as well as any specialist (i.e., cardiologist, pulmonologist, rheumatologist, dentist, neurologist, pain management specialist) to optimize their medical conditions. Many office-based primary care physicians are not familiar of the perioperative stresses placed on the modern patient undergoing orthopedic procedures. For those not practicing in an institution that has a centralized preoperative program established, it is our responsibility to create relationships with the physicians that help us to optimize our patients. We need to engage the community in our care pathways and improving outcomes.

Metabolic Syndrome

Metabolic syndrome is a combination of health problems including abdominal obesity, high blood pressure, abnormal amount of lipids (triglycerides, cholesterol), and type II diabetes. There has been a reported link for decades between patients with metabolic syndrome and chronic diseases (heart disease, arthritis, kidney disease, mental health issues) as well as early death. Recently, it has been demonstrated that metabolic syndrome is an independent risk factor for postoperative complications including wound complications and readmission to the hospital after surgery for patients undergoing total knee or total hip replacement [21].

Hypothyroidism

Hypothyroidism can cause many different symptoms, including weight gain or difficulty losing weight, depression, and excessive tiredness. It is important for patients to be evaluated by their primary care doctor prior to elective surgery who have a family history of thyroid problems or have symptoms consistent with a thyroid condition. Thyroid function and optimization by the medical services should also be considered when indicated if a patient is admitted to the hospital and undergoing more urgent orthopedic surgery.

Inflammatory Conditions

Some patients with inflammatory conditions, autoimmune conditions, or other medical conditions may be taking or have been taking glucocorticoids for a long time. It is important to be aware of these patients and the amount of glucocorticoids they are taking. It is likely that an important feedback-response pathway in the body is suppressed. During times of stress, such as surgery, the adrenal glands may not respond

appropriately [22, 23]. The surgeon should discuss this with the anesthesiologist and postoperative care team to ensure the patient is receiving the recommended dosing of perioperative steroids.

Opioid Use/Tolerance

Patients who are using preoperative opioids for management of chronic pain have been associated with poorer outcomes after surgery [24]. Patients who are taking opioids preoperatively usually require higher doses of opioids to control postoperative pain [25]. The brain becomes accustomed to the opioids depending on many factors, but dosing amount and duration are known to influence the need for higher levels of opioids after surgery if not decreased preoperatively. Patients that are on chronic opioids need to be aware of potential pain management difficulties following surgery. In some cases, patients become tolerant of opioids, and it becomes very difficult to manage postoperative pain and other medication modalities should be considered. A discussion with their pain medication provider and requested written plan is advised. Many organizations as well as states have instituted new regulations for prescribing opioids, including all electronic prescribing and preoperative identification of those patients utilizing opioids.

Osteoporosis/Fragility

Osteoporosis is a common condition that occurs in both men and women. About 54 million Americans have osteoporosis and low bone mass. Studies show that 1 in 2 women and about 1 in 4 men age 50 and older will break a bone due to osteoporosis [26]. Osteoporosis or osteopenia causes bones to become less dense and weak, which can predispose to fractures. The FRAX tool (Fig. 6.3) is available to use to evaluate a patient’s 10-year fracture risk (hip, spine, forearm, and shoulder). There are many health conditions, medications, and certain procedures that increase our chances of developing osteoporosis.

Please see the following website to find out more: www.nof.org/patients/what-is-osteoporosis/.

Fig. 6.3 FRAX criteria

FRAX Criteria
Postmenopausal women over age 50
Men over age 60
Patients who have sustained a fragility fracture
People with low bone density (osteopenia)
Patients with known endocrine disorders

Obstructive Sleep Apnea and CPAP Use

Obstructive sleep apnea has been shown to increase risk of perioperative complications, especially pulmonary (lung) complications [27]. There are two main types of sleep apnea, obstructive and central sleep apnea. Obstructive is the most common type of sleep apnea and occurs at nighttime usually when people are sleeping and trying to breathe. Obstructive sleep apnea does not allow for normal air movement in and out of the lungs because there is repeated collapse (blockage) of the airway when the throat muscles relax during sleep. OSA causes repeated awakenings and disrupts sleep. Disrupted sleep can cause many symptoms including those listed below. OSA can also worsen other chronic health conditions such as high blood pressure, coronary artery disease, congestive heart failure, heart rate problems (arrhythmias), depression, anxiety, and difficulty controlling blood sugar.

Many people do not know that they have sleep apnea and often, different people have different symptoms. If patients or their loved ones notice these signs when sleeping, they should see their primary care doctor for more testing:

- Snoring
- Daytime sleepiness
- Pauses in breathing
- Difficulties with memory and concentration
- Changes in mood or irritability
- Frequent urination at night
- Morning headaches and dry mouth

Bladder Function

It is important to recognize our patients who have a medical history involving urinary retention (difficulty urinating) or frequent urination. Conditions that can predispose to urinary difficulties include benign prostate hypertrophy (BPH), prostate cancer, radiation, or history of urologic surgery. These patients are predisposed to postoperative urinary retention (POUR). This is usually due to many reasons, but most commonly can be a result of anesthesia, opioid use, and not ambulating as the patient normally would. It is important to identify those patients who are on medications for urination prior to surgery, and to ensure that they can be maintained on those medications throughout the perioperative period.

Depression

Depression is a very difficult condition to manage and when not recognized or treated properly, can lead to complications around a patient's surgery [28]. There have been many reported complications associated with patients who experience depression including prolonged use of opioids, increased postoperative pain,

increased use of healthcare resources, and worse patient-reported outcomes. It is important that patients with depression are identified and managed properly by their primary care physicians and specialized providers prior to and after surgery when possible. Stressful situations, including surgery, can challenge anyone's mental health, and it is very important that good coping strategies and appropriate support are in place. For the surgeon, recognizing depression and being able to refer their patient to seek appropriate help is important not only to help improve outcomes, but for maintaining the doctor–patient relationship.

Frailty

Physical frailty is a medical syndrome with multiple causes and contributing factors that are characterized by diminished strength, endurance, and reduced physiologic function that increases an individual's vulnerability for developing increased dependency and/or death [29]. Physical frailty can potentially be prevented or treated with specific modalities, such as exercise, protein-calorie supplementation, vitamin D, and reduction of polypharmacy.

Surgical Considerations

Risk for Venous Thromboembolism

Does this patient have one of the known risk factors for the development of a post-operative thromboembolic event?

- History of a deep venous thrombosis or pulmonary embolus
- Hypercoagulable state
- History of cancer
- History or presence of atrial fibrillation or cardiac arrhythmia
- Morbid obesity

Is this patient on an anticoagulant? Will they be required to stop their medication and / or bridge with a different medication? What is the most reasonable option for VTE prophylaxis in this patient? All of these issues should be addressed either before, or at, the preoperative medical optimization evaluation [30, 31].

Antibiotic Prophylaxis

Most patients will require some form of antibiotic prophylaxis. This will usually be a first-generation cephalosporin [32]. The dose should be weight adjusted. What is the evidence-based alternative in antibiotic-allergic patients? A policy should be developed to accommodate for the use of vancomycin and gentamycin as well as

other surgery specific antibiotics. Remember that 1 g of vancomycin cannot be infused faster than a rate of 1 g per hour and should be fully administered 30 minutes prior to incision. A consideration should be made to start the infusion in the holding area.

Methicillin-Resistant *Staphylococcus Aureus*

Who should be screened for MRSA? Or should all patients be decolonized preoperatively? There is data to suggest that there is a benefit to prophylactically decolonizing all patients with povidone-iodine nasal swabs undergoing reconstructive orthopedic procedures [33].

The Hospitalist-Anesthesiologist Preoperative Visit

Best practice organizations now employ the hospitalist-orthopedic co-management patient care model. It is now appreciated that the greatest number of errors occur during a handoff. The use of preoperative checklists and a careful preoperative evaluation by both the anesthesiologist and hospitalist supports accomplishing seamless handoffs during the perioperative period. Many institutions have a care model in which the hospitalist that sees the patient preoperatively also follows the patient postoperatively during the admission or outpatient setting. This type of model allows for continuity of care and decreases the chances of error.

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Suggested Reading

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Surgical Site Infection Risk Reduction

7

Brielle Antonelli and Antonia F. Chen

Introduction

Surgical site infections (SSI) are a tremendous burden to the patient, surgeon, and healthcare system. Even though surgeons and hospitals follow prevention protocols and sterile surgical techniques, the rate of SSI can range from 0.7% in low-risk patients to 7.9% for high-risk patients [1, 2], with mortality of infected arthroplasty patients reaching 19.5% over 5 years [3]. SSIs have three classifications: superficial, deep, and organ/space based on the Centers for Disease Control and Prevention [4] (Table 7.1). Besides the serious morbidity and mortality associated with SSI, the financial burden is also substantial [5].

Preoperative Risk Factors

Methicillin Sensitive *Staphylococcus Aureus* (MSSA)/Methicillin Resistant *Staphylococcus Aureus* (MRSA)

The incidence of MRSA is increasing and leads to 29.5% of SSIs [6]. MRSA was the cause of SSI in 40% of primary hemiarthroplasty, 39% in revision hemiarthroplasty, 23% in primary total hip arthroplasty (THA), and 21% in revision THA cases [6]. Preoperative nasal carriage of *S. aureus* is a significant independent risk factor for orthopedic SSI [7].

Screening often occurs in the preadmission visit (Fig. 7.1). MSSA positive patients are administered cefazolin preoperatively, while MRSA positive patients are given vancomycin and cefazolin, preoperatively. Decolonization following

B. Antonelli · A. F. Chen (✉)

Department of Orthopaedic Surgery, Brigham and Women's Hospital, Boston, MA, USA
e-mail: bjantonelli@bwh.harvard.edu; afchen@bwh.harvard.edu

Table 7.1 Classifications for surgical site infections from the centers for disease control and prevention [4]

Surgical site infection classification	Criterion
Superficial	Occurs within 30 days of surgery AND affects surgical incision and surrounding superficial tissues ONLY AND at least 1 of the following: (a) Purulent incisional drainage (b) Infectious organisms have been recognized from an aseptic incisional specimen or subcutaneous tissue culture (c) Surgical incision being opened by surgeon or physician AND at least one sign or symptom: Localized pain/tenderness, swelling, erythema, or heat
Deep incisional	Occurs within 30–90 days from surgery AND Affects deep fascial tissue of the surgical incision AND at least 1 of the following: (a) Purulent incisional drainage (b) Dehiscence of incision or opening or aspiration by surgeon or physician AND infectious organisms have been recognized from an aseptic incisional specimen or subcutaneous tissue culture AND at least one sign or symptom: Fever ($>38^{\circ}\text{C}$), or localized pain/tenderness (c) Presence of abscess or evidence of deep infection identified on gross anatomical or histopathologic exam, or radiographic test
Organ space	Occurs within 30–90 days from surgery AND Affects body parts found deeper than fascial/muscle layers involved in or opened during surgery AND at least one of the following: (a) Purulent drainage from a drain placed into the respective organ/space (b) Infectious organisms have been recognized from an aseptic incisional specimen or subcutaneous tissue culture (c) Presence of abscess or evidence of deep infection identified on gross anatomical or histopathologic exam, or radiographic test AND at least one of the principles are met for a certain organ/space infection [4]

nasal mupirocin application and antiseptic body washes can decrease MRSA-related SSIs from 2.3% to 0.3% [8]. The use of mupirocin in *S. aureus* carriers has also been deemed cost-effective with minimal adverse effects [9, 10]. The success of this preoperative decolonization protocol was predicted to save one hospital \$230,000 [11].

Obesity

Obesity is defined as a body mass index (BMI) greater than or equal to 30 kg/m^2 [12]. Obese orthopedic surgery patients have double the risk of developing a SSI [13]. In elective orthopedic procedures such as primary total joint arthroplasty

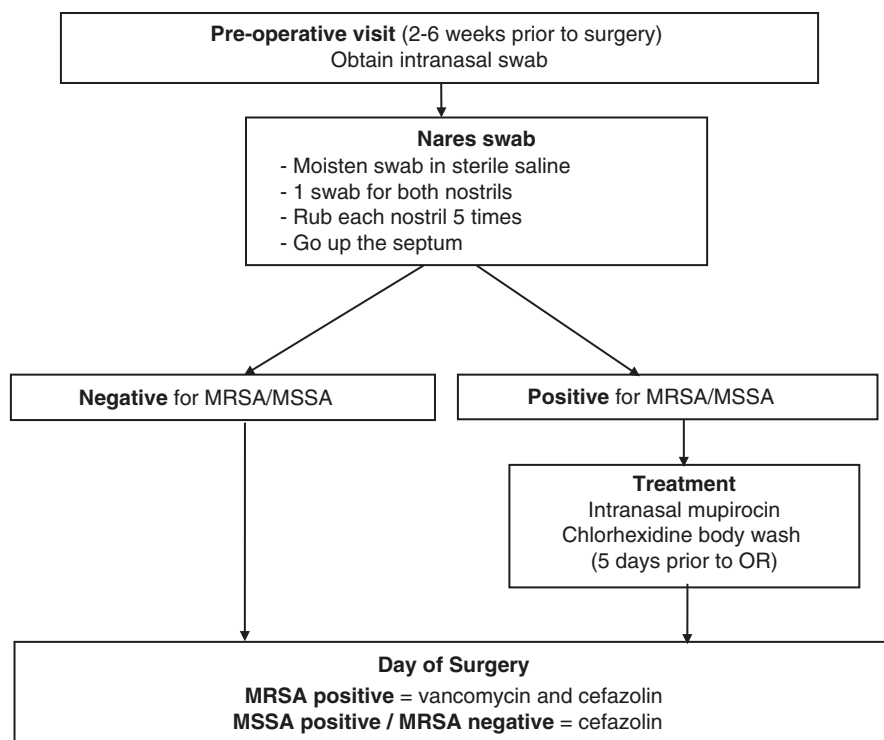


Fig. 7.1 Preoperative screening and patient management MRSA/MSSA colonization prior to orthopedic surgery

(TJA), the requisite BMI pre-procedure cut-off is often 40 kg/m² [14], with some surgeons using a more stringent cut-off of 35 kg/m². Operative time increases by 1 min for every extra 1 kg/m² in body mass [15], which increases infection risk.

The increased SSI rates associated with obesity are linked to the amount of adipose tissue that has higher bacterial counts [16] altering wound healing [17–22]. Morbidly obese total knee arthroplasty (TKA) patients have increased wound healing complications of 22% compared to 2% for those with a normal BMI [23].

Preoperative obesity screening should be implemented at least 6 weeks preoperatively to give obese patients adequate time to safely lose weight before surgery. These patients should have glucose levels, nutritional laboratory tests, and blood counts evaluated, as well as cardiac and renal function assessments [24]. Patient education regarding the extent of complications associated with obesity should be provided. Patients may be referred to a nutritionist and/or specialists for weight loss management.

Diabetes Mellitus and Hyperglycemia

Orthopedic surgery patients with blood sugar abnormalities have an increased risk for postoperative infections and complications. Since the surgical process affects the body's response to blood sugar with increased insulin resistance and altered eating patterns before and after surgery [25], diabetic and hyperglycemic patients are vulnerable to adverse surgical outcomes.

Diabetes Mellitus

Pooled data for TJA and spinal surgery patients with diabetes in the U.S. displayed a significantly higher risk for SSI development when adjusted for hyperglycemia and BMI [25]. The odds ratio (OR) for development of an SSI was 2.8 [26] for orthopedic surgery patients with a preoperative serum glucose level of >125 mg/dL or a postoperative level of >200 mg/dL [27]. Foot and ankle surgical patients with diabetes display a 10- and 6-fold increased risk of SSI compared to non-diabetic patients [28]. Diabetic patients undergoing lumbar procedures had a fourfold increased risk for SSI development compared to non-diabetic patients [29]. Diabetic patients undergoing cervical spine procedures have higher rates of SSI [30]. Diabetic orthopedic trauma patients have up to a 25% SSI rate with glucose >220 mg/dL [31].

Hyperglycemia

Hyperglycemia increases infection rates due to its impact on the immune system and healing process. Hyperglycemia is defined as fasting blood glucose >125 mg/dL and >180 mg/dL 2 h postprandial [32]. Patients with stress-induced hyperglycemia (>200 mg/dL) undergoing open fracture surgery were at a significantly higher risk for developing an SSI at 30 days [33]. Arthroplasty patients who had hyperglycemic levels (>140 mg/dL) the morning after surgery had a threefold increased risk of developing a periprosthetic infection (PJI) [17]. Orthopedic trauma patients with more than two blood glucose levels >200 mg/dL had a 170% higher SSI risk compared to patients with blood glucose levels below that threshold [33]. Primary TKA patients with perioperative glucose levels >6.9 mmol/L displayed a fourfold increase of developing PJI compared to patients with normal glucose levels of <6.1 mmol/L [18]. Patients should have fasting blood sugar levels checked on the day of surgery to allow for intervention.

Diabetes Screening

Glucose should be measured at preoperative screening, and levels should be <200 mg/dL. HbA1c measures the percentage of glycosylated hemoglobin, which provides a measure of glucose control over 3 months. The guidelines for acceptable HbA1c target values in patients for surgery are often <8–9% (68–75 mmol/mol) [19], while the American Association for Hip and Knee Surgeons (AAHKS) recommends a HbA1c level <7.7% to reduce PJI risk [20, 21]. Depending on a patient's preoperative levels, surgeons will most likely suggest strict glycemic monitoring

and control programs to help patients drop their levels within the normal range; however, this can take some patients up to 6 months [19, 22]. Fructosamine is glycosylated albumin, which provides a measure of glucose control over 2–3 weeks. One study demonstrated fructosamine levels ≥ 292 $\mu\text{mol/L}$ significantly increased the risk of PJI (OR 6.2), reoperation (OR 3.4), and readmission (OR 3.4) [34].

Glucose challenge tests (plasma or capillary glucose, GCTpl and GCTcap, respectively) and random plasma or capillary glucose (RPG or RCG, respectively) can be evaluated preoperatively [35]. GCTpl is the least expensive screening tool with effective screening results in high-risk populations [36].

Implementation of glucose monitoring and patient management to improve glycemic control preoperatively includes integrative care from multiple specialties. There have been successful outcomes with tight intraoperative glycemic control and the use of a basal bolus regime of insulin that can reduce rates of wound infection, bacterial counts, and acute respiratory and renal failure [37]. Hyperglycemia and diabetes can also be treated with insulin after surgery but using a sliding scale with insulin correction is not recommended in all patients as it may cause further complications [25].

Rheumatoid Arthritis

Rheumatoid disease raises orthopedic infection rates by 3.7%, which also increases with greater disease chronicity and the use of immune modulators [38]. This inflammatory disease impacts immune system function and can adversely affect wound healing. Prescription medications often given to rheumatoid patients, including immunosuppressive steroids and disease-modifying anti-rheumatic drugs, also contribute to increased SSI risk [38]. Therefore, preoperative clinic visits should include education and guidance for modified medication regimens leading up to surgery (Table 7.1) [39].

Anemia

Anemia is defined as hemoglobin levels <13 g/dL in men and <12 g/dL in women [40]. Anemia is detected in as many as 35% of elective orthopedic surgery patients [41], which can lead to increased length of stay, infection, and mortality [42, 43]. Patients with low preoperative hemoglobin are more vulnerable to SSI development due to the increased probability of blood transfusions along with the use of anticoagulation medications [44]. Preoperative anemia screening includes complete blood count, iron, vitamin B₁₂, and folic acid levels to determine the causes such as malnutrition, iron deficiency, chronic renal insufficiency, or chronic inflammatory disease [45]. Depending upon the blood test, appropriate intervention can successfully optimize patients (Fig. 7.2) [46].

For those with low iron, oral iron supplements (325 mg TID) or intravenous iron (1000 mg), vitamin B₁₂ (1 mg), and/or folic acid (5 mg) [47] taken 3–5 weeks

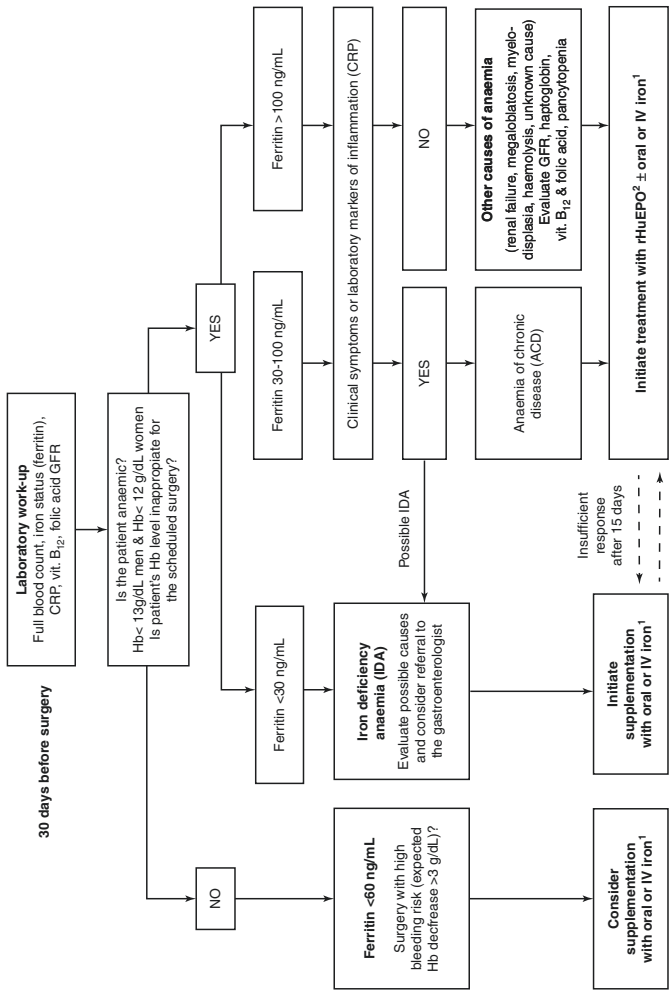


Fig. 7.2 “Consensus algorithm for pre-operative haemoglobin optimisation from the Spanish Best Practice in Peri-operative Anaemia Optimisation Panel from SEDAR (Sociedad Española de Anestesiología y reanimación)”.¹ If time available for Hb optimization prior to surgery is short, there is intolerance to oral iron, functional iron deficiency, or a poor response to rHuEPO, IV iron should be administered.² rHuEPO administration may be an off-label use for some operations, thus requiring a careful risk to benefit evaluation. Explanatory notes: *the reduction of 1 g/dL in Hb concentration is equivalent to 150 mg iron loss. Thus, considering that 1 ng/mL ferritin is equivalent to 8 mg of stored iron, for an expected Hb decrease of 3–4 g/dL a minimum of 60 ng/mL ferritin is needed to recover from postoperative anemia. *Hb* hemoglobin, *CRP* C-reactive protein, *GFR* glomerular filtration rate, *IV* intravenous, *rHuEPO* recombinant human erythropoietin. In: Bisbe E., et al. “Peri-operative treatment of anaemia in major orthopaedic surgery: a practical approach from Spain.” Blood Transfus 2017; 15: 396–306. ©SIMTIPRO Srl. Permission granted to Brielle J. Antonelli for publication in a Springer Book. No other use permitted

preoperatively can help improve iron levels before surgery. If oral iron cannot be tolerated, such as in elderly patients on other medications, intravenous iron can be administered, which is faster acting, safe, and has minimal side effects but is more expensive and less accessible [46]. Iron levels can be replenished within 2–3 weeks, and hemoglobin levels can increase by 1–3 g/dL after 1 month [48, 49]. Intravenous iron sucrose treatment has been beneficial in hip fracture patients who required less need for postoperative transfusions compared to patients without treatment [50]. Other intravenous iron formulations with cost-effective benefits have been effective in high doses including ferric carboxymaltose, low molecular weight iron dextran, sodium ferric gluconate, or iron isomaltoside 1000 [46, 48].

Preoperative erythropoietin can help stimulate epoetin alpha, a natural glycoprotein produced by renal pericapillary cells in reaction to reduced oxygen tension [51]. Epogen acts on bone marrow to stimulate red blood cell (RBC) differentiation and maturation, thereby increasing total RBC mass in anemic patients [51]. Its use has resulted in decreased need for transfusions and consequently less PJI in THA and TKA patients [52]. However, there are serious side effects, such as cardiovascular problems, thromboembolic events, stroke, mortality, and tumor growth, which have led to a black box warning [53]. It is also expensive and can cost \$3500 for a 15-day treatment course [51].

Malnutrition

Another independent risk factor predisposing orthopedic surgery patients to SSI is malnutrition [54]. As many as 50% of orthopedic surgery patients are malnourished and are often not identified or treated preoperatively, potentially leading to further complications [55]. Malnourishment can cause suppressed immune responses, apathy, cardiac and renal complications [56], sarcopenia, hematoma formation [57], and impaired wound healing [58]. Malnourished patients have higher readmission rates, 308.9% higher hospital costs [59], and a 3 days longer LOS compared to properly nourished patients [57, 60].

Nutrition markers can be checked with routine preoperative blood tests at least 2 weeks preoperatively to identify at-risk patients and determine abnormal metabolic markers. Malnutrition is often defined as albumin <3.5 g/dL, prealbumin <18 mg/dL, total protein <6.0 g/dL, total lymphocyte count (TLC) <1500 cells/mm³, iron <45 µg/dL, serum transferrin <200 mg/dL, and 25-hydroxyvitamin D (25OHD) <30 ng/mL [61]. Levels of albumin <3.5 g/dL have been directly linked to increased postoperative infection rates in patients undergoing spinal fusion [62] and in THA patients who showed increased morbidity and 30-day mortality rates by 5.94-fold [63]. Orthopedic surgery patients with preoperative albumin <3.5 g/dL had a 2.5-greater risk for developing postoperative SSI [54, 64–66]. Patients with low albumin or protein can be given low sugar nutritional supplements twice a day for at least 14 days preoperatively or referred to a nutritionist. Low transferrin levels are independently correlated to increased surgical infection [67] and predict delayed wound healing in THA patients [68]. Low preoperative TLC is controversial, with

some studies stating no association with infection [69, 70], while others have shown they increase deep infection and excessive wound drainage [71, 72].

Other significant markers are low iron, vitamin D, and total protein levels. Iron is needed for hemoglobin production, and decreased iron levels with reduced protein counts inhibit wound repair and overall healing [73]. Vitamin D is important for bone and muscle health, calcium regulation, and control of immune responses [74]. Preoperative 25OHD <30 ng/mL in primary TJA patients correlates with PJI and aseptic joint loosening [75]. Low levels have been linked to sepsis and increased pathogenicity, leading to organ system complications, severe associated infection, and mortality in hospitalized patients [76]. Insufficient vitamin D levels can be increased with 6 weeks of oral supplementation [77] and can potentially reduce poor postoperative outcomes [78].

Skin antigen testing, arm circumference, and triceps skin fold metrics correlate with malnutrition [70]. Spinal surgery and TJA patients who were screened for malnutrition using integrated anthropometric metrics while using standardized nutritional measurement tools, such as the Rainey-MacDonald nutritional index and the Mini Nutritional Assessment, displayed predictive results indicative of malnutrition [61].

Tobacco Use

In 2017, 14% of American adults still reported cigarette smoking [79], even though the prevalence is decreasing [80]. The prevalence of smokers among the population is high for those undergoing spinal surgery [81] and TJA [82]. Preoperative screening should assess patient smoking history and use the physician quality reporting system, which has been successful using physician-reported quality measures for Medicare to reduce SSI risk [83]. The health complications associated with tobacco chemicals include bone healing interference, with reduced bone cell metabolic activity mostly attributable to nicotine [84], along with inhibited collagen synthesis and vasoconstriction [85], wound hypoxia [86, 87], and weakened immune responses directly leading to SSI.

For THA patients who smoked preoperatively, deep SSI developed in 1.5% of patients with an overall increased 2.71-fold risk of postoperative infection [88]. This increased risk was also noted in TKA [89] and spinal fusion patients who smoked preoperatively [90], where smoking attributed to 10.4% development of SSI [91]. Smokers undergoing orthopedic surgery have increased risk of wound complications such as hematomas, wound discharge, and incision site dehiscence [92]. The frequency and length of time a patient smoked are influential when assessing patients' infection and complication risk [93].

These serious complications can be avoided with abstinence from smoking or smoking cessation programs at least 4–8 weeks preoperatively to allow the body's physiological responses to normalize and reverse some of the damage from tobacco consumption [94–96]. The longer the cessation period, the greater the reduction in

postoperative complications [97]. Elective orthopedic surgery patients following a 4 weeks program reduced their postoperative complication rate by 34% [93]. These patients displayed improved tissue oxygenation, inflammatory responses, and bone metabolism after smoking cessation for 4 weeks [95]. The most effective smoking cessation therapy programs have included a combination of weekly counseling sessions with a trained smoking cessation therapy nurse and nicotine replacement therapy at least 4 weeks preoperatively [98]. Other nicotine replacement therapies include prescription medications such as bupropion SR (Zyban) or varenicline tartrate (Chantix), or over-the-counter products such as nasal sprays, nicotine patches, gum, and inhalers [83].

Alcohol Consumption

Alcohol abuse is defined as consuming five or more standard drinks per day [99]. Preoperative alcohol intake predisposes patients to increased morbidity and mortality [100]. Patients undergoing TJA who abused alcohol have increased immediate postoperative complications such as stroke, surgical infections, blood clots, delirium, pneumonia, arrhythmia, gastrointestinal bleeding, and shock [100]. Alcohol consumption has been identified as an independent risk factor for surgical and overall medical complications, longer LOS, and behavioral issues in TJA patients [101]. Furthermore, high alcohol consumption (>168–252 g/week) was linked to higher TJA PJI incidence at 1 year postoperatively compared to patients who abstained from alcohol or were low- to moderate drinkers (>0–168 g/week). Patients undergoing spinal fusion who abused alcohol have increased postoperative complications and longer hospitalizations with higher medical costs [102].

It is important to preoperatively screen every patient for a detailed alcohol history and quantify their usage and frequency, keeping in mind that self-reported consumption levels are often underestimated. Screening measures currently used to identify at-risk patients include Alcohol Use Disorders Identification Test (AUDIT-C) [100] and Complications Evaluation Questionnaire (CEQ) [103]. Programs incorporating preoperative screening and counseling for patients have been cost-effective with medical savings around \$1755 per quality adjusted life year [104].

Excessive and high alcohol consumers should have preoperative abstinence addressed [105]. With alcohol cessation, organ dysfunction can be reversed over time and hemostasis can improve within 4–8 weeks of alcohol abstinence [99]. After 3–4 weeks of cessation, wound healing capability is restored with significantly reduced postoperative morbidity and LOS [101]. Cardiac and immune function can normalize within 1–2 months of cessation, and excessive stress responses may be minimized after 3 months. This intervention should be multi-disciplinary and include counseling sessions, motivational health dialogue [99], pharmacological and psychological mediation, relapse prophylaxis with frequent follow-up, and possibly medications for withdrawal or alcohol substitution [106].

Depression and Anxiety

Anxiety and depression often coexist and are both risk factors for orthopedic surgery SSI and complications due to the impact on the body's immune response [107]. It is another independent risk factor for the development of PJI and postoperative morbidity in TKA patients [108]. Orthopedic polytrauma patients with depression and anxiety had significantly higher chances for developing an infection (OR 3.0) [109]. Spinal surgery patients who expressed preoperative depression also display significant postoperative complications and adverse effects [110].

The most common screening tools for depression and anxiety are the Patient Health Questionnaire-2 and 9 [107]. The suggested screening tool specifically for spinal surgery patients is the Zung depression questionnaire, which stratifies patients for lumbar surgery depending on their risk level [110]. Preoperative screening and identification of the stage of depression are important because many patients may also develop depression after surgery. The development of postoperative depression is especially high in orthopedic surgery compared to other surgical specialties and can occur as soon as 2 days after surgery [111]. Preoperative evaluation and screening protocols can be conducted in clinics and should integrate advice and treatment from a psychologist or psychiatrist while specifically going over realistic patient expectations. Providers and counselors need to be patient with treatment and intervention outcomes since many approaches for depression can fail or take a long time to produce positive results [107]. Common treatment involves cognitive behavioral therapy, psychotherapy, medications, counseling from clinical specialists, and in extreme cases, electroconvulsive therapy [112].

Cardiovascular Disease

Adverse cardiovascular function contributes to impaired wound healing and infection, while medications to treat cardiovascular disease can also significantly increase infection risk [113]. Direct independent risk factors for increased SSI after orthopedic surgery include acute myocardial infarction [114, 115], coronary heart disease [116], congestive heart failure [114, 117], and hypertension [114, 118]. TJA patients with atrial fibrillation have an increased need for blood transfusions, prolonged LOS, and higher PJI and readmission rates [113]. Patients with cardiovascular disease undergoing spinal surgery with instrumentation also have increased SSI rates [119].

Patients with cardiovascular disease are often on anticoagulation regimens with heparin, warfarin, or high-dose aspirin, which are direct independent risk factors for infection [120]. Warfarin therapy can increase bleeding during TJA since normalized international normalized ratio (INR) levels are often kept between 2.0 and 3.0 [121]. This therapy can interfere with wound healing and can lead to wound complications, such as hematoma, excessive wound drainage, and bleeding, which can further predispose patients to SSI [120].

Preoperative laboratory tests for INR levels can be a significant predictor for postoperative infection. Higher preoperative INR levels have been associated with deep SSI in TJA patients [17]. INR levels >1.5 among TJA aseptic revision patients were 2-times more likely to develop a surgical infection [120]. Therefore, it is recommended preoperative screening includes INR levels. These patients should also stop anticoagulation medications preoperatively to decrease their risk of bleeding, wound complications, and SSI.

Renal Failure and Dialysis

Dialysis and immunosuppressants often given to patients with renal pathology have adverse effects on the immune system and healing processes [122]. Renal disease and associated complications have been linked to increased postoperative morbidity and mortality with higher infection rates due to the mechanism of the disease, varied metabolic function, and perioperative complications [123].

A study on THA dialysis patients reported a mortality rate of 5.8%, early complication rate of 58%, and a deep infection rate of 13% [124]. TKA dialysis patients display similar adverse results with an 8.0% risk for late infection and 3.7% early revision rate [125]. Dialysis may be associated with a fourfold higher rate of infection compared to patients not on dialysis [125]. Patients undergoing lumbar spinal fusion with end-stage renal disease have a 1.6-fold increased risk of developing a major postoperative medical problem, including elevated infection rates and increased need for blood transfusions linked to higher 90-day and 1-year mortality rates [126].

Prior to surgery, preoperative serum creatine level should be measured to be <1.3 mg/dl [127]. A creatinine clearance formula predicts clearance in patients taking BMI and age into consideration while measuring their 24-h creatinine excretion [128]. Other preoperative laboratory levels that should be obtained in these patients include hemoglobin and potassium, since dialysis patients are often anemic or hyperkalemic. Preoperative hemoglobin should be corrected to at least 10 g/dL and potassium to <5 mEq/L [129].

Medication regimens and dialysis schedules are important to review since they may need preoperative alteration to optimize these patients. Preoperative consultation with a nephrologist is recommended to reduce postoperative infection risk after altered dialysis regimens [125]. Consultation with multiple providers helps to preoperatively correct and monitor fluid management, antibiotics, urea, glucose, and electrolyte levels in these patients who often display imbalances [130].

Conclusion

A reduction in SSI is achievable when providers and healthcare institutions prioritize this goal and work as a collaborative multi-disciplinary team to improve patient outcomes.

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Reduction of Wrong Site Surgery

8

Justin P. Moo Young, Jed I. Maslow, and Donald H. Lee

Introduction

In 1999, the Institute of Medicine released a report identifying medical errors as a key contributor to hospital deaths. Since then, significant funding and research has focused on the understanding and prevention of these errors [1, 2]. Despite subsequent attention, it is estimated that 251,454 deaths per year are still related to medical errors, making it the third leading cause of death in the United States behind heart disease and cancer [3, 4]. Under the umbrella of medical errors possible in surgery or invasive procedures, wrong site surgery (WSS) is classified as a preventable “never-event” that carries severe consequences to both patient and provider [3].

The comprehensive term “WSS” includes surgery performed on the wrong site, on the wrong side, on the wrong patient, with the wrong implant, or with the wrong procedure. Originally endorsed in 2002 and updated in 2011, the National Quality Forum categorized unambiguous and preventable adverse events, or Serious Reportable Events (SRE), into one of seven domains. These domains included surgical or invasive procedures, of which WSS was one major component [5]. By understanding the burden of WSS, identifying who is at risk, and determining the measures available to prevent these events, surgeons are able to both prioritize a culture of patient safety and minimize complications in their practice.

J. P. Moo Young (✉) · J. I. Maslow · D. H. Lee
Department of Orthopaedic Surgery, Vanderbilt University Medical Center,
Nashville, TN, USA
e-mail: Justin.p.moo.young@vumc.org; Jed.i.maslow@vumc.org; Donald.h.lee@vumc.org

Scope of the Problem

Although every medical profession and surgical specialty are affected by wrong site surgery, the difficulty in understanding the prevalence of WSS and identifying interventions to minimize these events is, in part, due to a lack of standardized reporting. Twenty-seven states as well as the District of Columbia have authorized reporting systems in an effort to decrease wrong site surgery, however large variations exist between these systems [6]. Several specialties may also overlap in the surgeries they perform, complicating standardization in reporting. For example, orthopedic, plastic, and general surgeons may all perform hand surgery, while neurosurgeons and orthopedic surgeons may both perform spine surgery.

Despite this known error in reporting, a systematic review of surgical “never-events” estimated the prevalence of WSS at approximately 1 event per 100,000 surgeries [3]. The Joint Commission, which maintains one of the largest databases for reporting, has shown that WSS has remained relatively stable over the last few years—83, 110, 83 WSS events in 2017–2019, respectively [7]. This data exists despite the fact that reporting is mainly voluntary and advertised as significantly smaller than the actual prevalence. Other databases estimate anywhere from 683 to 34,000 annual WSS in the United States [8].

Rates of WSS vary by specialty, and those with the highest rates of WSS involve symmetrical anatomy such as pelvic, urinary, genital, and dental structures as well as the chest, breast, eyes, and extremities [9, 10]. Ophthalmology reports one of the highest rates of WSS since 2006, estimated at 1.8 events per 10,000 procedures. Anesthesiology is another notable specialty with 1.28–3.63 WSS per 10,000 regional blocks and 2.66 WSS per 10,000 pain procedures, as nerve blocks and other invasive pre-operative procedures pose yet more opportunities for wrong procedures or sites [9, 11–14].

Historically, orthopedic surgery has been one of the most common surgical specialties for WSS events [9, 11, 15–17]. On average, reports estimate a rate of 1.2 WSS per 10,000 orthopedic cases, and physician surveys project a career risk of 8–25% for WSS in orthopedic surgery [3, 9, 11, 18]. Within orthopedic surgery, certain subspecialties carry a higher risk for WSS than others. For example, sports medicine surgeons surveyed all knee surgeons and reported that 8.3% of respondents had experienced at least 1 WSS in their career [19]. Also, 13% of foot and ankle, 21% of hand, and 50% of spine surgeons have reportedly experienced at least 1 WSS in their career [20]. The increased rates in hand and spine surgery (1 in 27,686 cases and 1 in 3110 cases, respectively) are, in part, associated with increased symmetry, as WSS in spine surgery includes the wrong level and in hand surgery includes the wrong phalanx or digit [18, 21, 22]. More recent longitudinal data has shown that other specialties more consistently affected by WSS include dentistry and neurosurgery [10].

Timeline

In the late 1900s, a large culture shift in healthcare manifested after several key policy and practice changes regarding medical errors were instituted. Traditionally, medicine had been practiced within a culture of private professionalism, where good physicians were considered to be those who did not make mistakes. However, as the scope and impact of medical errors became more transparent, several adjustments were made. In 1988, the London Medical Defence Union became the first organization to publish safeguards for WSS prevention, and in 1997, the Canadian Orthopaedic Association implemented a site-marking initiative. Shortly afterwards, the American Academy of Orthopaedic Surgeons (AAOS) President, Dr. James D. Heckman, appointed the first task force on WSS to study the problem in the United States. Popularizing the “Sign Your Site” campaign, the AAOS augmented awareness of WSS around the same time that the first Joint Commission Sentinel Event Alert was issued on the topic (Fig. 8.1). By 2000, 78% of AAOS members surveyed were aware of the program, most agreeing that it would be beneficial in reducing WSS [18].

A major turning point in healthcare’s culture occurred in 1999 after the Institute of Medicine released the report, “To Err is Human,” which estimated that medical errors resulted in between 44,000 and 98,000 deaths annually [1]. This shifted private professionalism to a culture valuing safety and transparency. Beginning in 2001, states began instituting their own policy changes; New York required site signing and verification while Florida enforced financial penalties for WSS events. These changes continued to affect orthopedic surgery as the Joint Commission on Accreditation and Healthcare Organizations issued a second Sentinel Event Alert, revealing that 41% of reported events were either orthopedic or podiatric in origin. As a result, after the Joint Commission WSS Summit in 2004, a universal protocol was launched. This protocol received public endorsement in 2006 by the National Quality Forum, resulting in system-wide checklists and patient safety awareness [18, 23].

Financial and Legal Ramifications

WSS is rare but costly. Though it comprises only 2% of all orthopedic surgery claims, its likelihood of financial compensation to the plaintiff is extremely high. For example, in the United States, approximately 30% of non-WSS orthopedic claims resulted in court award to the plaintiff while an astonishing 84% of WSS orthopedic claims resulted in payment. In the United States, the average payment in 2013 was \$156,281 for WSS claims [24]. There are similar findings from litigation studies in England and Wales, which showed that orthopedic surgery was



Fig. 8.1 Popularized by the AAOS “Sign Your Site” campaign, physicians now mark their operative site, decreasing the likelihood of wrong site surgery

highest in rates of WSS and that WSS claims were the most successful litigation (89% payment) with a mean cost of £43,596 [25]. Other data from England showed that the total cost for WSS claims from 2005 to 2006 was approximately £1,098,975 [15].

Cost to providers extends beyond the courtroom. Certain states impose fines to both hospital and provider in the event of WSS. The Florida Code 15 mandatory reporting system may fine hospitals and physicians individually and require physician community service. If deemed egregious, a WSS may even result in the suspension or revocation of a practitioner's medical license. In an AAOS Bulletin titled "No defense for wrong-site surgery," David Levy described WSS as a breach of standard of care and a form of "battery" [26]. Several individuals may be affected by WSS. The "first victim," referring to the patient, may be harmed in WSS, but there exists a "second victim," referring to the offending provider, who may also suffer behavioral, cognitive, or emotional reactions resulting in positive or negative consequences. Recently, emphasis has been placed on providing support for the "second victim" after WSS [27].

Patient and Family Considerations

Both patients and their families may experience adverse effects from WSS. Therefore, considerations must be made on how to disclose the event and how to manage the clinical problems that may follow. In most scenarios, admission of the mistake after all relevant information is gathered is considered a priority. Open communication is frequently initiated by the surgeon offering the apology. Numerous states have adopted legislation which protects apologizing physicians from having these statements used against them in litigation. Though apologies may not protect physicians from legal action, it may improve the physician–patient relationship with heightened trust and a more positive emotional response [28, 29].

Multiple barriers obstruct effective communication and disclosure of an error. Surgeon-related factors include concern for legal action, fear, loss of reputation, denial, or apprehension. Patients or family have varying degrees of prior medical knowledge and, due to the recent WSS, may be confrontational, making communication difficult. A two-armed approach to addressing medical errors was proposed by Johnson et al. [30, 31]. One arm addresses the patient and family by expressing empathy, the consequences of the error, a proposed treatment plan, and that treatment plan's implementation. The second arm addresses the system-related error via open communication with relevant organizations, proposal of a system change, and subsequent implementation of that change.

Causes of Wrong Site Surgery

Analyses of WSS events have led to greater understandings of why they occur and how to prevent them. The cause of WSS is thought to be either a single breakdown in care or, more often, a multifactorial disconnect from several defects in a process or system. The Center for Transforming Healthcare identified 29 main causes of WSS categorized by phase of care. These include errors in the scheduling, pre-operative holding, intra-operative, and organizational culture phases of care, such as

booking errors, site-marking errors, distractions, lack of a safe culture, and time-out errors [32].

An alternative method of identifying causes of WSS is to categorize by type of error, including communication errors, individual errors, or system errors. According to a root cause analysis of 672 cases, communication errors, defined as misinformation communicated among staff, misperception among staff, withheld information that should have been available to operating room staff, or failure to speak up among staff, are a cause of up to 21% of WSS cases [3]. Individual error, on the other hand, is an example of a single breakdown in care, while system errors include possessing but not following safety procedures such as a time-out, following inadequate safety procedures such as not visibly marking the surgical site, or completely lacking a safety protocol [23].

These three aforementioned sources of error can be altered by patient or surgeon factors, increasing or decreasing the risk of subsequent WSS. For example, in spine surgery or superficial soft tissue procedures, anatomical considerations such as morbid obesity, multiple similar appearing lesions, transitional anatomy, or congenital deformity can make identifying the correct site more difficult [33]. Patients may also wrongly participate in the process by responding to the incorrect name or errantly marking their own surgical site. A study by Bergal et al. showed that only 68.2% of patients were compliant with marking their own surgical site with a “YES” when instructed [34].

The surgical environment as well has factors that increase the risk for WSS. Examples include emergency cases, pressure to start or complete cases within a certain time frame, interruptions, and unfamiliar equipment. Additionally, the risk of WSS increases when surgeons become fatigued, perform multiple procedures during one episode of care, or involve multiple surgeons in one case [33, 35]. There remains debate regarding the correlation between WSS and increasing surgeon age or caseload volume; surgeons and partners must consider their ability to perform surgery as age and practice volume increase [21, 22].

Techniques for Preventing Wrong Site Surgery

All levels of healthcare delivery offer opportunities to prevent WSS. For example, individual techniques may be standardized. These include preoperative briefing, verification of the scheduled procedure using the history, physical examination and imaging, verification of the scheduled procedure by two health care staff members, and the marking of the actual incision rather than simply initialing the operative site or side [36]. With regard to spine surgery, pre-incision fluoroscopy or fixed bony markers, such as screws, wires, and angiography coils, can and should be used to identify the correct spinal level prior to incision (Figs. 8.2 and 8.3) [33]. Previous lumbar spine surgery studies have estimated that approximately 5–15% of patients would be subject to wrong-level exposure, and potentially wrong-level surgery, without the use of routine localizing radiography [37, 38]. Postoperative debriefing

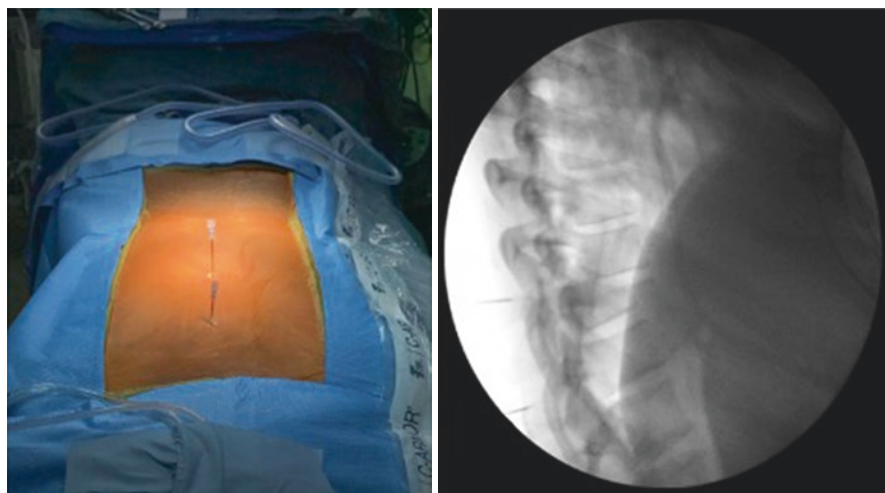


Fig. 8.2 Pre-incision fluoroscopy, alongside radiographic markers such as spinal needles, provides surgeons the opportunity to identify the correct operative site before proceeding. Here, a spine surgeon utilizes two spinal needles to identify a thoracic fracture-dislocation prior to incision. A clinical photograph (left) and its associated fluoroscopic image (right) are provided for comparison

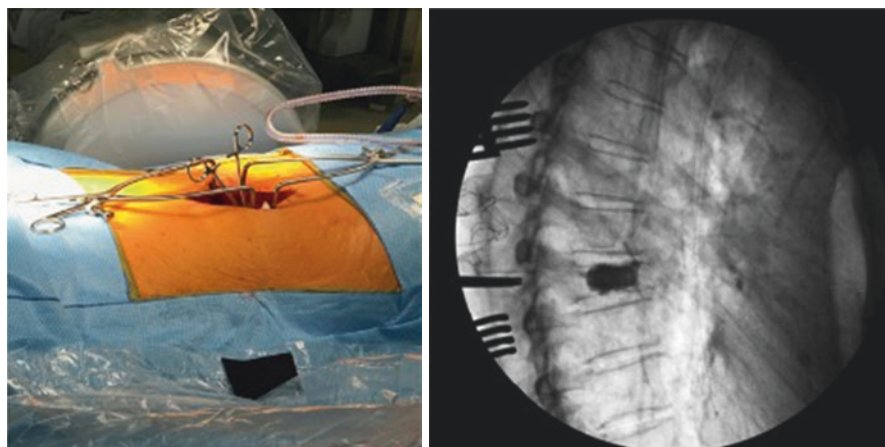


Fig. 8.3 Fixed bony markers can and should be utilized alongside localizing radiography to ensure that the correct spinal level is being addressed. A clinical photograph (left) and its associated fluoroscopic image (right) show that a prior T8 kyphoplasty, confirmed using Kocher forceps on its spinous process, was used to verify the proper spinal level

may further promote a culture of safety and serve to correct or identify unsafe behaviors that may contribute to future WSS.

Other interventions to prevent WSS can occur in healthcare systems at the global, national, and hospital level. On the global and national level, the Universal Protocol

and the World Health Organization (WHO) Safe Surgery Checklist embody efforts to standardize the surgical process [39, 40]. The core requirements of the preoperative process include verifying the patient, marking the surgical site, and performing a time-out prior to starting the procedure. Other national organizations have adapted these protocols to address their individual needs, such as the Veterans Affairs Correct Surgery Directive [41]. With national societies recognizing their role in encouraging patient safety, the AAOS has acknowledged the evidence-based TeamSTEPPS program, an initiative designed to educate healthcare providers and improve patient safety and communication [42].

On the hospital level, preoperative processes have been further customized. Preoperative briefings, while commonplace in most hospitals, can vary in the amount or type of detail discussed. Numerous hospitals have implemented extended time-outs that include a briefing on the procedure, technical details, special equipment or implants, anesthesia input, and other special considerations. Other groups have experimented with requiring patient participation in preoperative surgical site marking. In addition to the Bergal et al. study previously mentioned, in which less than 70% of patients were compliant with preoperative site-marking instructions, DiGiovanni et al. experienced even fewer compliant patients (59%) and more incorrect participation, ranging from no site marking to incorrect site marking.

Both authors concluded that patients often still take, and may prefer, a passive role in their care [34, 43]. Still, encouraging active patient participation preoperatively may be an opportunity to further reduce WSS risk. Other preoperative tools have included use of an anatomic marking form to be completed and verified by the patient in clinic and delivered to the preoperative staff on the day of surgery. Using this protocol, only one event in 4.5 years has been reported, though 7% of patients were dissatisfied with the process [44]. Other tactics include addressing language barriers. Targeting an at-risk patient population, hospitals can make interpreters easily available for non-English speaking patients to limit miscommunication [45]. Still, other research has studied the efficacy of nursing staff performing the preoperative surgical site marking rather than surgeons. The authors reported that surgical site marking was done correctly in all 353 patients and no WSS occurred during the study period, possibly offering a safe alternative for surgeon site marking [46].

Event reporting as well as morbidity and mortality conferences are important in promoting a culture of patient safety. Institutions should consider providing simple near-miss and event reporting avenues to encourage and streamline the process. Easier reporting allows for more frequent root cause analysis and a better understanding of the actual burden of WSS within particular healthcare systems. Staff training programs, including multi-year programs, safety-specific courses, and organized near-miss analyses with post-error provider education, can reduce errors that lead to WSS. One study found that after individualized provider education, a significant reduction in inappropriate time-out procedures or incorrect case bookings that were considered near-miss WSS events occurred [47].

Conclusion

Wrong site surgery is a devastating occurrence to both patient and provider. Ultimately, prevention starts with the first patient encounter and continues through successful completion of the surgical procedure. The responsibility for safe surgical execution should be shared by the patient, family, pre-operative staff, intra-operative staff and surgeon. While the surgeon may be key to WSS prevention, consideration at all levels of healthcare delivery is essential.

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Learning from Mistakes

9

Peggy L. Naas

The Word “Mistake”

Just hearing the word “mistake” can make the hair stand up on the back of surgeons’ necks. We remember mistakes we have made, seen, or read about. We remember very tough Morbidity and Mortality (M&M) conferences in the past when, as chief residents presenting cases, our actions and the actions of our attendings, junior residents, and medical students were attacked with curt words.

Synonyms can include errors, adverse events, “when things go wrong,” “unanticipated outcomes,” “mishap,” “surgical misadventure,” “everything going south,” “we see this.” Each term has different meanings to various individuals, who may define them and use them differently.

There remains anxiety surrounding mistakes, reflecting a potential barrier to actually learning from those mistakes.

Definition

Mistakes can be defined broadly, including

any preventable adverse effect of care whether or not it is evident or harmful to a patient.

A narrower definition is:

An act or omission that has serious or potentially serious consequences for a patient and that would have been judged wrong by knowledgeable peers at the time it occurred [1].

P. L. Naas (✉)

Retired, Department of Orthopaedic Surgery, Abbott-Northwestern Hospital, Allina Health, Minneapolis, MN, USA

Either of these definitions are not without dispute. What medical science has thought “preventable” has changed over time.

It was thought that Ventilator-Associated Pneumonias (VAPs) were not preventable until a bundle of interventions showed the rate could be greatly reduced and even be brought to zero. After this information was known and published, failure to implement such a bundle would then be classified as a mistake [2].

James defines preventable adverse events as “all unexpected and harmful experiences that a patient encounters as a result of being in the care of a medical professional or system because high quality, evidence based medical care was not delivered...” [3].

These mistakes or errors include errors of commission, omission, communication, context, and incorrect diagnoses. These types of errors may vary in their ability to be detected or seen. They may also vary in stimulating learning and system changes to prevent them from occurring again.

Good Surgeons Make Mistakes

The Institute of Medicine (IOM) in *To Err is Human: Building a Safer Health System* took the position that humans make mistakes [4]. Because we, as surgeons, are human, it follows that we will make mistakes. Making mistakes unfortunately is not unexpected and is not evidence that we are flawed as doctors.

But part of the surgeon and caregiver emotional reaction to “mistakes” is that to make a mistake is a threat to our very identity of being a good doctor. Excellence becomes confused with perfection. Mistakes demonstrate our lack of perfection, our “unrealistic and pervasive expectation of perfection [5].”

We perceive that a mistake reflects our failure to “do no harm.”

Mistakes elicit feelings of guilt, shame, “loss of sense of self,” and loss of our “entire persona” of being a surgeon and physician [6].

Trying to “integrate... imperfection and forgiveness” is a significant struggle for physicians who have made mistakes [7]. Our reaction to mistakes is also colored by fear of legal consequences, fear of the medical malpractice process, outcome, and consequences. This fear, guilt, and shame can be a barrier to our willingness to see, admit, and learn from mistakes.

System Defenses to Protect Patients from Mistakes While We Learn and Improve

James Reason has encouraged the perspective that errors are not made primarily because the people are morally deficient and so people should not be shamed and blamed. The majority of errors are from slips and lapses, not from knowledge gaps. Because humans are fallible, they need to be surrounded by systems with multiple layers of defenses to control the consequences of human errors [8].

A colleague uses the phrase “not thinking clearly or clearly not thinking” about cognitive errors and slips [9]. Justin Morgenstern offers an excellent list with entertaining examples of our many cognitive biases [10].

Opportunities to Learn

“Everybody makes mistakes, but the challenge is to make only original mistakes.”

Augustus A. White III, MD, PhD [11].

“Learn from the mistakes of others, you can’t live long enough to make them all yourself.”

Attributed to: Eleanor Roosevelt, Mark Twain, Groucho Marx, US Navy Admiral Hyman G. Rickover, Oliver Wendell Holmes, Warren Buffett [12].

If we’re going to make mistakes, how do we:

- Identify them?
- Learn from them?
- Prevent them?
- Create systems where when we make mistakes, we prevent mistakes from causing harm to our patient(s)?

Individual Learning

We can learn through self-reflection and having enough humility to perceive when we made an error. Much can be gained through honest review about what has happened in our own practice and through observation of the practices of others [1].

We can learn much from narratives offered by “exemplar” physicians who have managed “post traumatic growth” after having made a serious mistake. A study found that 61 physician “exemplars” achieved both personal and professional growth after making serious mistakes. Of these 61 physician errors, the outcome for the patient was death in 43% (26/61). Lawsuits were filed in 21% of cases (13/61). These physicians’ process may provide a positive road map for us individually and for our organizations [7].

We have the opportunity to measure our own practices, preparing for credentialing, board exams, and for some methods of recertification. Literature reviews in peer reviewed journals provide metrics against which we can measure our own work.

By prospectively studying the expected results, outcomes, and complications from procedures we perform, or the most common errors in patients with certain diagnoses we see in our practice, we can individually prepare to see and prevent mistakes and errors.

We can participate in registries and measure our outcomes and patient reported outcomes compared to others’ results [13]. (Also see Chaps. 10 and 12 in this book).

The American Academy of Orthopaedic Surgeons (AAOS) and others produce tools for practice comparisons we pursue as individuals:

clinical practice guidelines [14], appropriate use criteria, clinical performance measures, patient-reported outcomes, and measures [15]. (Also see Chaps. 11 and 12 in this book).

Most of us learned little about critical topics in safety science.

Excellent books with which to start our education could include:

Black Box Thinking, Why Most People Never Learn from Their Mistakes: But Some Do by Matthew Syed, Portfolio/Penguin; 2015

This text offers many great examples that challenge us to investigate our failures to improve systems to deliver care in the face of medical complexities and imperfections. It also emphasizes that individuals and organizations should recognize that open acknowledgment and investigation of mistakes may be one of the most rapid, efficient ways to reduce mistakes and patient harm; creating a culture that pursues mistakes may create the safest care environment.

The Checklist Manifesto, How to Get Things Right by Atul Gawande, Metropolitan Books, Henry Holt and Company, LLC, 2009

The history, development, research, and use of the saving power of checklists. (also see Chap. 6 in this book). The human brain is quite good at creative, adaptive thinking, but it performs inconsistently when required to do repetitive tasks. The human brain does not follow a series of command lines like a computer, and our brains may miss important steps. Integration of safety checklists into processes increases the likelihood of following all critical safety steps throughout the process.

How Doctors Think by Jerome Groopman, First Mariner Books, 2008

Dr. Groopman's book is particularly helpful in seeing that cognitive common errors (confirmation bias, anchoring, availability, affective error) in medicine are traps into which we can fall. Three constructive questions to rescue us (and our patients) from those traps.

Zero Harm, How to Achieve Patient and Workforce Safety in Healthcare, Craig Clapper, James Merlino, Carole Stockmeier, Editors, Press Ganey Associates, Inc., 2019

Excellent principles of safety science, high reliability organizations and how they function, safety leadership.

Group Learning

“Surgery is a team sport.” Anonymous.

“Teamwork makes the dream work.” Anonymous.

Learning together offers the opportunity to learn from the mistakes of others, dive more deeply into understanding an event, pool different perspectives on causation, and develop a shared model to explore solutions. Best of all, it can counter the isolation of having made a mistake and never having the opportunity to discuss it with others.

Organizational Learning

Learning from mistakes and creation and testing of possible solutions are not just for individuals or groups. Organizations have to learn so protections can be improved, resources can be deployed appropriately, environmental risks can be addressed, risks and learnings can be communicated, and a positive culture can be created to help prevent mistakes [16].

In the commentary of the Wu et al. article “Do House Officers Learn from Their Mistakes?” published 12 years after the original paper, Hastie and Paice suggest the key question now is not about the house staff. Rather the right question is if health care organizations learn from the “mistakes that its systems allow to happen, and whether the system can be changed for the benefit of patients and those members of staff working within the organisation” [17].

Both organizational error prevention and error management strategies are critical for organizations to detect error, avoid injurious effects of error, and learn to prevent future error while creating favorable opportunities for that learning [18].

Informal Learning

Learning opportunities can arise out of a circumstance, a mistake during a case, something that occurs in an institution while we happen to be rotating there, or something in our practice done by ourselves or one of our partners. These learning opportunities are left to chance. They may or may not occur, may or may not occur while we are present, or even hear about. Ideally a chance mistake will not be repeated, so learning in this circumstance is episodic and unpredictable.

However, watching others grapple with mistakes and disclosure of those errors is an important source of informal learning [19]. Hopefully, the role modeling reflects positive coping and best practice disclosure behaviors and not “do as I say, not as I do.”

Formal Learning

Other opportunities can be purposeful, longitudinal, and didactic planned learning. These formal learning opportunities tend to be structured for sequential and progressive learning. These opportunities may be scheduled routinely on a repeating basis and part of our practice calendar and the life of our organizations [16].

Some Organizational Learning Opportunities to Be Leveraged

- Simulation, learning through practice
- Video and virtual reality learning
- Morbidity and mortality conferences (see Chap. 29)
- Incident reporting systems, detecting mistakes and harm
- Chart and case reviews
- Patient claims and complaints
- Prospective risk analyses

Simulation

Simulation is very powerful and a great way to experientially learn from mistakes in a blame free, harm free practice. It is an example of participatory error management training. Responding in simulated clinical scenarios with problem solving, decision making, technical interventions, and making mistakes in a setting where consequences can be explored can reduce occurrences of errors in real life [20].

Both technical skills as well as team functioning can be tested along with the physical space, equipment, and resource access. By experiencing simulated errors in a supportive environment, we will be better able to take action and to cope when mistakes are experienced in real life. Any of us who have been able to immerse ourselves in a simulated scenario whether in a laptop flight simulator application or operating room emergency simulation can attest to that emotional engagement and “psychological fidelity.” It is not only an opportunity for learning from technical mistakes but also to experience leadership and team dynamics both during the simulation and in the debrief after [21]. (Also see Chap. 21 in this book).

Video and Virtual Reality Learning

Just as video and audio review after a simulation shows participants insights into their skills, actions, and group dynamics, so does video of actual cases. Varying surgical technical skills as rated by peers from laparoscopic video have been associated with surgical outcomes [22].

This has also been seen in peer review of video from laparoscopic right hemicolectomy [23].

Video review and feedback from a pool of raters have been used as a source for technical skill improvement for practicing surgeons [24].

Video and audio of the operating room during laparoscopic cases were reviewed and transcribed identifying safety threats (in equipment, organization, physician environment) as well as “support for resilience” of the system such as clinicians’ calm behaviors and depth in intraoperative resources [25].

Just as black boxes record all cockpit conversations as well as all operational information on commercial aircraft, a recent peer reviewed publication has reported on a commercially available OR Black Box (Surgical Safety Technologies, Inc., Toronto, ON, Canada). This technology has been used to identify “fly on the wall,” very detailed intraoperative events, errors, and distractions affecting patient safety.

De-identified reports are provided monthly to the health system and reviewed by a multi-specialty and multi-professional team. This technology has the potential to bring “black box thinking” directly to surgery settings revealing both technical and non-technical team and room dynamics [26].

In the U.S., it was first installed in Northwell Health’s Long Island Jewish Medical Center in N.Y. As of September 2020, this technology is being trialed in five operating rooms at UT Southwestern’s William J. Clements Jr. University Hospital and in several other health systems [27].

Virtual reality training has also been used to train laparoscopic technical skills [28] as well as orthopedic arthroscopic, hip and knee arthroplasty, and femoral nailing skills to reduce errors and patient harm. These are technologies to allow surgeons no harm, no blame, no shame learning opportunities, as well as bringing sophisticated risk and mistake practices to light as surgeons and operating teams perform in actual cases.

Incident Reporting Systems—Detecting Mistakes and Harm That Does Occur

Almost every organization has one of various incident reporting systems (IRS), and individuals can participate either in reporting incidents or reviewing incidents reported. This allows participation in common cause and root cause analyses [29].

IRS certainly can focus attention and necessary resources in the learning available from those reported incidents. Frontline staff and surgeons can both engage. It does require a safe culture in order to report, as well as willingness to improve. A

very powerful tool is to send feedback to those people who report incidents so they understand reporting was valued, what was learned, and what might change [16].

Agency for Healthcare Reporting and Quality (AHRQ) has created common formats for reporting and legal protection for such reporting through Patient Safety Organizations [30].

In England and Wales, the National Reporting and Learning System (NRLS) is a voluntary and largest incident reporting system in the world for the National Health System (NHS). The largest number of reported surgical patient incidents were in trauma and orthopedics [31].

Chart and Case Reviews

Almost all of us one time or another have performed case reviews, either as part of research, for publication, or for peer review in our leadership roles. Which charts we actually have the opportunity to review will affect the value added. Organizations select local triggers for review as well as using a national trigger tool. A trigger such as need for blood transfusion might then reveal a technical mistake resulting in unexpected blood loss. Or it can illuminate improvements such as unused cross-matched blood consistently going to waste which might suggest a re-examination of routine orders [32].

Patient Claims and Complaints

Much can be learned from patient claims and complaints. These represent a limited look at the range, frequency, and totality of mistakes and harm, yet provide a valuable viewpoint and statistical analysis. When claims are filed, they command attention, and significant resources can be brought to bear by an organization in response to patient complaints and claims.

In orthopedics, intraoperative errors are those most likely to lead to litigation [33].

To a surgeon, claims can be very emotionally fraught and this can be a barrier in learning from any mistakes. Medical associations as well as medical malpractice organizations are beginning to provide preparation and support for healthcare professionals and patients and families responding to events of harm [34].

Patient complaints can be very helpful to understand communication and behavior flaws in ourselves or our peers, as well as diagnostic mistakes which also elicit patient complaints [35].

Prospective Risk Analyses

Prospective risk analyses can be performed when a new procedure or a new technology is going to be adopted. This is the prospective analysis of published, known experience, or mistakes of other adopters. The discussion includes the most likely

risks of the procedure, equipment, or technology. There are several specific techniques including an IHI resource, prospective risk assessments: Failure Modes and Effects Analysis (FMEA). This is the opportunity to actually be preventive, rather than looking at mistakes retrospectively. It allows for the training and preparation of the team and organization before attempting the procedure or technology. Simulation could potentially be deployed to avoid mistakes and harm [36].

Orthopedic Surgeons as Leaders

Orthopedic surgeons have practice, departmental, hospital, educational leadership, and executive roles. We lead surgical and care teams, and many are educators for trainees and staff.

As leaders, we have the opportunity and responsibility to personally model, as well as mentor, successful positive learning from mistakes. We can lead not only through our behaviors as we learn from our own mistakes, but also by demonstrating our focus on the safety of our patients. We can lead with safety as we fulfill our many roles. To build supportive processes so others can recover and grow personally and professionally after having made mistakes creates an organizational culture with multiple benefits [7].

In Conclusion

Because we are human, we will make mistakes. Our goal is to practice within a system of defenses, so no harm reaches our patients while we learn from those mistakes and create additional safety nets.

We can learn from our own mistakes and also from the mistakes of others. We can learn both as individuals and in groups. These discoveries can increase actual and prospective safety for our patients.

There are many formal and informal learning opportunities within our practice lives. We can improve and productively leverage these opportunities to learn from mistakes.

Through active participation within incident reporting systems, chart and case reviews, review of patient claims and complaints, and prospective risk analyses, we can see and learn from mistakes. Direct experiential learning through simulations, video observation, virtual reality, and black box and other analytics is particularly powerful. These educational modalities can provide safe spaces for not only learning technical skills but also for practicing team communication and dynamics.

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Use of Registries and Prospective Cohorts to Improve Care

10

Joshua M. Pahys, Michelle C. Marks, and Peter O. Newton

Randomized clinical trials (RCTs) are considered the gold standard for research to evaluate the efficacy of treatments. However, designing and implementing RCTs for surgical procedures can be significantly challenging [1, 2]. Considerable obstacles to performing RCTs include: patient selection, patient reluctance to randomization, difficulties to blinding, surgeon preferences, cost, high proportion of loss to follow-up, and patient crossover [3]. To combat these challenges, researchers have developed prospective observational cohort studies to reflect routine practices, many of which have produced results that rival the validity of RCTs [3–6].

Registries can be used to critically evaluate varying treatment for similar conditions and associated outcomes across a wider patient base. Subgroups can be potentially identified within a similar condition/population (e.g., low back pain, adult spinal deformity, knee osteoarthritis) to stratify patient risk and possibly better predict poor vs. successful outcomes. Lastly, registries may be able to provide intermittent feedback of treatment outcomes, which has itself been suggested to increase awareness and improve quality of care [1, 3].

With recent healthcare reforms in the United States, optimization of independent clinical and patient-reported outcome measures has received increased attention. Various efforts have been developed to promote performance improvement initiatives in order to identify validated metrics to improve objective performance [7, 8].

Multicenter data collection yields sufficient data volume for quick evaluation of outcomes and treatment, while collaboration among institutions allows for

J. M. Pahys
Shriners Hospitals for Children, Tampa, FL, USA
e-mail: jpahys@shrinenet.org

M. C. Marks
Setting Scoliosis Straight, San Diego, CA, USA
e-mail: mmarks@ssshg.org

P. O. Newton (✉)
Rady Children's Specialist of San Diego, San Diego, CA, USA

assessment of variability in practice [9]. By utilizing performance improvement initiatives across healthcare systems, and thereby recognizing variations in surgical management and subsequent outcomes, Best Practice Guidelines (BPGs) may be established to effectively promote standardization of operative and postoperative protocols. Comparative analysis of an individual surgeon's outcomes in a dashboard reporting format provides a mechanism for the development of BPGs, which may be implemented to improve areas of patient care. Advancements in automation of data collection as well as integration with the electronic medical record allow for real-time performance assessment on a weekly or daily basis, thus promoting continuous self-guided improvements in medical management [10].

Numerous registries and prospective cohorts have been implemented across a variety of disciplines within orthopedics in an effort to improve care, patient outcomes, and surgeon performance. Registries exist within a single institution, state, country, or international collaboration. This chapter will review some of the subspecialty registries and cohort studies to highlight the power of this work as well as its future directions.

Joint Replacement

The most widely recognized orthopedic registry began in 1975 with the Swedish Knee Arthroplasty Register followed by the Swedish Hip Arthroplasty Register in 1979 [11]. The Swedish Hip Arthroplasty Register reported a three-fold reduction of severe complications over a 20 year period on 86,207 total hip arthroplasties after uniform implementation of the register across the country [12]. Many countries have followed with a goal to provide implant-specific revision risk data that is typically published on an annual basis. The USA has a range of registries from institutional to state and national collaborations. The Mayo clinic has the most established institutional arthroplasty registry [13]. Kaiser Permanente [14] and the Michigan Arthroplasty Registry Collaborative Quality Initiative [15] (MARCQI) are examples of successful regional and state sponsored registries. The American Joint Replacement Registry (AJRR) was established in 2010 with a goal to be the comprehensive arthroplasty registry for the USA with over 400 participating institutions [16].

Arthroplasty registries provide vast numbers of patients to dramatically increase statistical power to detect rare events that may be undetected in smaller RCTs or databases from a single institution. Similarly, it is argued that RCTs are more often performed in high volume centers by high volume surgeons. Thus, outcomes of these studies, while less biased, may be skewed away from broader community practices and a more generalized patient population—these studies may not be generalizable to the general population of both surgeons and patients, limiting their relevance and the value of widespread adoption/implementation [17]. Lastly, registries may potentially provide less biased information when it comes to conflicts of interest. Labek et al. found that lower revision rates were

published by authors with financial conflicts compared to national registries utilizing the same implants [18].

The power and importance of arthroplasty registries were highlighted with post-market surveillance of metal-on-metal hip resurfacing implants that were identified to have high revision rates by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) [19]. This finding was confirmed by National Joint Replacement Registries in the United Kingdom (NJR) and the New Zealand Registry [20]. These collaborative findings resulted in the voluntary recall of this product from the market [21]. The existence of these large registries is credited with identifying this implant failure as large numbers of patients are required to elucidate complications that may only occur a handful of times within a single institution which may be potentially overlooked [17]. Further, existing registries such as Kaiser Total Joint Replacement Registry (TJRR) utilized the information from these studies to more efficiently identify and notify potential patients at risk for metal-on-metal implant failure [22].

The Kaiser TJRR has published several large volume studies from its prospectively collected registry. Namba et al. reported on the risk factors of deep surgical site infections (SSI) in 56,216 total knee arthroplasties [23]. Such a large registry was necessary to better evaluate patients with postoperative infections as the incidence of SSI was relatively low at 0.72% ($n = 404/56,216$). The authors reported statistically higher rates of postoperative infections in patients who were obese, diabetic, and those with osteonecrosis or posttraumatic arthritis. The authors demonstrated a reduction in SSI with several modifiable surgical factors including the use of antibiotic irrigation and a 9% decrease risk of infection per 15-min increment reduction of operative time. Similarly, the performance of a quadriceps release exposure and antibiotic laden cement both led to higher SSI rates [23]. These findings enabled surgeons to identify and optimize at-risk patients and potentially modify their current practice to reduce SSI rates.

In 2012, several Michigan hospital systems and a large insurance provider formed a voluntary statewide total joint arthroplasty registry: the Michigan Arthroplasty Registry Collaborative Quality Initiative. The MARCQI has been able to collect data on 95% of elective joint arthroplasty surgeries performed within the state to minimize any selection bias [24]. Evaluation of the registry noted wide variations in transfusion practices after total joint arthroplasty (TJA) [25]. These noticeable discrepancies created a quality initiative among the sites to raise awareness of the American Association of Blood Banks' (AABB) transfusion guidelines (e.g., postoperative transfusion should only be considered if hemoglobin is 8 g/dL or less in an asymptomatic patient) [26]. Data were evaluated on 1872 TJA cases before and after educational material on AABB transfusion guidelines was reviewed by each institution [25, 26]. The authors reported a reduction in postoperative transfusions from 16% to 3%, and an 80% reduction of TJA patients transfused with a hemoglobin <8 g/dL. The mean length of stay was 1.5 days shorter for nontransfused patients. The number of readmissions and patient morbidity remained unchanged between the two groups [25]. In this study, the MARCQI registry was

able to identify outliers from current transfusion guidelines. With the simple distribution of educational material regarding current transfusion protocols recommended by the AABB, the transfusion rates for TJA patients across an entire state were substantially lowered in a matter of 6 months without an increase in patient complications [25, 26].

Trauma

The National Trauma Data Bank (NTDB) is a trauma registry established in 1997. The NTDB is maintained by the American College of Surgeons and seeks to capture all injury victims alive on arrival with a hospital admission. The registry contains over five million cases from >900 US trauma centers [24].

Belmont et al. evaluated 44,419 hip fractures in the NTDB to identify risk factors for in-hospital mortality [27]. Dialysis, cardiac disease, and an elevated injury severity score (ISS) were significant predictors of mortality, while obesity, diabetes, and a procedure delay of greater than 2 days influenced complications. This information helped institutions recognize at-risk patients, but also highlighted the need for timely surgical intervention to reduce patient mortality.

Cantu et al. also utilized the NTDB to evaluate the factors associated with in-hospital mortality in 7540 patients with femur fractures [28]. The NTDB data provided ISS scores as well as time to surgery, both of which had significant impacts on patient mortality in this cohort. The overall in-hospital mortality rate was 1.4% in the study. Mortality rates were increased nearly five times if surgery was delayed beyond 48 h compared to within 12 h of arrival. Interestingly, severely injured patients (ISS > 26) had higher mortality rates if surgery was performed under 12 h vs. between 13 and 24 h from arrival. This information substantiated previous lower powered studies on the timing of femur fracture treatment. However, it also highlighted that a brief delay (13–24 h) in surgery may be beneficial in the severely injured patient to promote better resuscitation [28]. These two studies highlight the benefits of large registries to evaluate adverse events that may have a less than 1–2% incidence. These studies have shaped treatment recommendations that would be much more challenging and time consuming with RCTs and/or single center studies [24].

Sports Medicine

The Multicenter Orthopaedics Outcome Network (MOON) was established between seven sites in 2002 to prospectively determine variables at the time of injury that would best predict short- and long-term outcomes of anterior cruciate ligament (ACL) reconstruction [29]. The MOON database not only recorded surgical outcomes, but also focused on patient-reported outcome measures (PROM) using validated outcome instruments and activity rating scales to objectively measure patient

function. Spindler et al. reported on the outcomes and function of 1592 patients 10 years after unilateral ACL reconstruction [30]. Patient outcome scores improved at 2 years postoperative and were maintained at 10-year follow-up. However, activity level scores declined over time. The authors found lower postoperative outcome scores for patients with higher body mass index (BMI), smokers, patients needing a lateral meniscectomy, and those with grade 3–4 articular cartilage pathology. These findings have helped to shape patient counseling and expectations as well as evaluate for any possible modifiable patient risk factors prior to surgery.

The Multicenter ACL Revision Study (MARS) Cohort was developed to evaluate treatment and outcomes of revision ACL reconstruction after multiple studies exhibited poor outcomes with the procedure [31]. The MARS cohort prospectively collected data on 1205 patients who underwent a revision ACL reconstruction at one of 52 centers (both private and academic) across the US. Wright et al. published the final results of the MARS Cohort in 2014 [32]. The authors demonstrated that the use of an autograft resulted in significantly better PROM and a nearly three-fold decrease in graft re-rupture rates. Utilizing the prospective MARS cohort, the authors were able to publish the first study to identify the optimal graft choice for revision ACL reconstruction.

Spine

The Harms Study Group (HSG) is a collaborative group of surgeons who participate in a prospective, multicenter research study evaluating the surgical outcomes of adolescent idiopathic scoliosis (AIS) patients that was initiated in 1995. An infrastructure was established to standardize data collection methods, employ central radiographic measuring, and perform central data quality assurance. Since 1995, over 6000 AIS patients have been prospectively enrolled with operative data, radiographs, and PROMs all collected in a centralized database with a minimum of 2–20 years of postoperative follow-up [33]. Regular in-person meetings with HSG surgeons helped identify potential shortcomings with the existing King classification system for AIS and prompted the creation of the Lenke Classification of AIS, which is one of the most cited works in spinal deformity to date [34]. Since that time, the HSG has produced studies to help guide level selection [35, 36], as well as develop consensus based guidelines for the reduction of intraoperative blood loss [37] and length of hospital stay [38] after AIS surgery. Lonner et al. summarized the evolution of AIS surgery over a 20-year period in the HSG [39]. The authors reported significant decrease in blood loss, operative times, length of stay, and complication rates as well as improvements in PROMs.

The HSG also sought to improve individual surgeon performance through the creation of dashboard reporting. Quality dashboards are mechanisms to consolidate and analyze outcomes data, which can then be converted to feedback to guide performance improvements [40, 41]. Dashboards can be utilized to help manage process measures and improve outcomes to enhance clinical performance and patient

care. They have been used as successful management tools in the treatment of various specific diseases and conditions in clinical settings [10, 42–44]. The University of California Los Angeles quality dashboard project implemented in the Department of Neurosurgery was recently published, and describes attempts to prioritize quality and safety, patient satisfaction, and efficiency, with aims to develop a real-time daily or weekly feedback mechanism that allows for continuous performance improvement [10].

Dashboard reporting was evaluated over an 8-year period for HSG surgeons. Surgeons were able to exercise self-guided practice improvement measures, and improvements in outcomes were demonstrated. This dashboard reporting initiative illuminated the large variance in existing care standards and served as a catalyst for the development and implementation of best practice guidelines. Employing open forum-based discussions and evaluation of real performance data enabled the development of two BPGs for perioperative care and minimization of blood loss in AIS treatment [37, 38]. Most of the HSG surgeons adopted both BPGs, and continued improvement was observed over the second half of the 8-year dashboard reporting period (Figs. 10.1, 10.2, and 10.3).

However, other factors may account for the observed improvements. The Hawthorne effect, coined by George Elton Mayo, an Australian born psychologist, researcher, and organizational theorist, was based on the research he conducted in

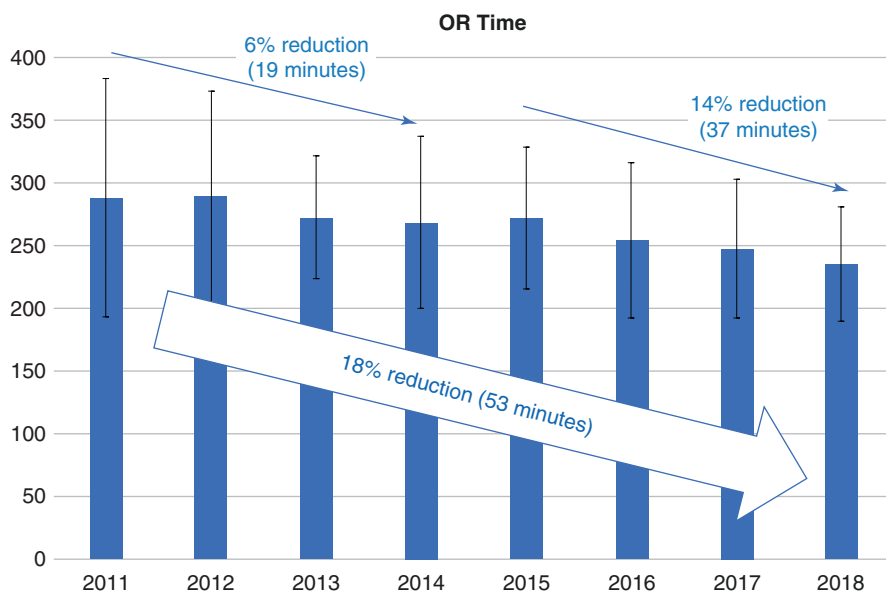


Fig. 10.1 Average reduction in OR time demonstrated across an 8-year period for nine surgeons participating in dashboard reporting with the Harms Study Group (HSG) for posterior spinal fusion (PSF) in adolescent idiopathic scoliosis (AIS). Best practice guidelines implemented by surgeons in the study group underwent two iterations in 2013 and 2016

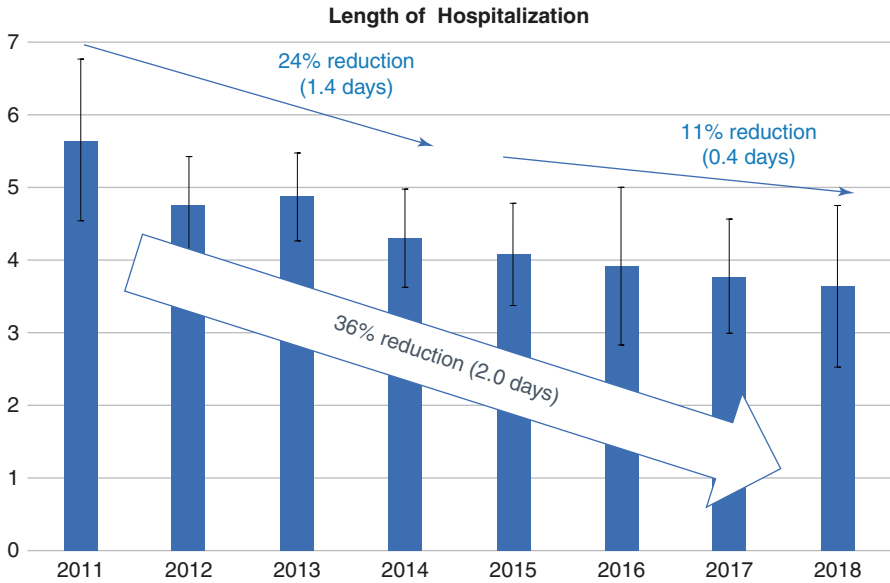


Fig. 10.2 Average reduction in length of hospitalization demonstrated across an 8-year period for nine surgeons participating in the HSG dashboard reporting

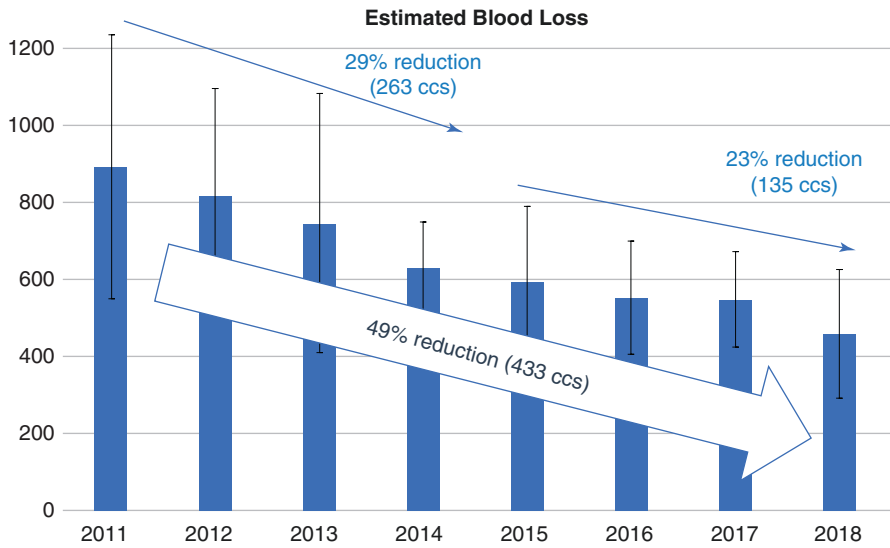


Fig. 10.3 Average reduction in estimated blood loss demonstrated across an eight-year period for nine surgeons participating in the HSG dashboard reporting

the late 1920s and early 1930s searching for methods of improving productivity. His studies were conducted in the Hawthorne plant at the Western Electric Manufacturing Company, where he recognized that “behavior during the course of an experiment can be altered by a subject’s awareness of participating in an experiment.” The Hawthorne effect is well documented across disciplines [45–47], with specific implications for the field of medicine, and this is readily evident from disparities in clinical practice versus clinical trials [48]. Variability in clinician performance because of the Hawthorne effect is apparent, and in some cases, increased transparency serves as a useful tool for sustaining and improving care compliance [49].

The HSG also expanded its collaborative efforts into cerebral palsy (CP) and neuromuscular scoliosis, prospectively evaluating the outcomes of over 600 patients. Samdani et al. demonstrated a higher complication rate in CP patients with larger curves requiring staged procedures [50]. The authors recommended earlier surgical intervention in the CP population and found a decrease in complication rates with single day surgery performed on major curves $<70^\circ$. Jain et al. produced a subclassification of the Gross Motor Function Classification System (GMFCS) level 5 patients to identify, risk stratify, and optimize CP patients with more extensive comorbidities who are at higher risk for significant complications [51]. The HSG has also published findings demonstrating the positive effects on patient and caretaker outcomes after PSF in CP patients [52]. The multicenter cooperative effort allowed for extensive study on a complex patient population to help guide treatment practices and improve patient outcomes.

Not all cohorts must contain large numbers of patients to produce viable results and improve outcomes. The Seattle Spine Team Approach was developed after a multidisciplinary approach to the evaluation and management of adult spinal deformity patients was enacted at a single institution [53, 54]. The authors implemented a dual surgeon approach, had patients presented and cleared by a live multidisciplinary preoperative conference, and implemented an intraoperative protocol for coagulopathy management. These changes coupled with increased transparency resulted in a 12-fold decrease in return to surgery in the first 3 months after surgery and a three-fold decrease in severe complications. These positive changes highlight the evolution and development of best practice guidelines that can occur at the level of a single institution but have a broader effect on the orthopedic community [55].

The Future of Registry and Prospective Cohorts

The International Spine Study Groups (ISSG) and European Spine Study Group (ESSG) are two multicenter, international prospective cohorts of adult spinal deformity (ASD) surgery patients. ASD patients have a much higher level of heterogeneity of clinical presentation and treatment options compared to the typical AIS patient, which can present considerable challenges in the evaluation of treatments and patient outcomes [55]. ASD classification systems have been historically focused on radiographic parameters and PROMs, but recent studies suggest there are many more relevant patient factors that were being

overlooked [56–58]. The ISSG/ESSG sought to utilize machine learning and predictive analytics to evaluate hundreds of data points per patient that would be impractical for individuals to perform manually [59–63]. Oh et al. utilized predictive computer models for improving ASD patient selection practices. The authors demonstrated the ability to predict which ASD patients would achieve significant quality of life improvements 2 years after surgery with 86% accuracy [64]. Ames et al. [55] utilized artificial intelligence-based hierarchical clustering of patient types and various interventions on 1612 ASD patients. The study sought to identify data patterns and classification clusters to construct a “risk-benefit grid” for each patient. The authors reported the “Artificial Intelligence-based ASD Classification” could not only improve outcome and complication prediction, but also educate surgeons on which treatment patterns would yield optimal improvements with the lowest risk tailored to each individual patient. These predictive models can help drive interventions for high-risk individuals, which in turn has been shown to reduce emergency room and specialist visits [65].

Conclusion

Observational prospective cohort multicenter studies and registries have positively impacted orthopedic care over the past few decades. Expanding beyond research reporting and into quality improvement initiatives, registry data can inform a surgeon’s individual performance and highlight areas for improvement and enhanced patient outcomes. It has also been shown that the cost of amassing quality clinical registry data is less than that of randomized controlled trials, albeit not without challenges. The overall infrastructure cost which encompasses expensive human capital required for data acquisition, quality assurance, radiographic assessment, IRB approval, and data use agreements has posed a barrier for universal adoption among health care systems [33]. Advancements in technology are providing mechanisms for more efficient registry data capture directly from the electronic health record and data analysis using artificial intelligence. These innovations in data acquisition and analysis will undoubtedly continue to expand the influential role of prospective observational research in orthopedics.

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Clinical Practice Guidelines and Appropriate Use Criteria to Guide Care

11

Gregory A. Brown and Antonia F. Chen

Introduction

Gordon Guyatt coined the term “evidence-based medicine” in an editorial in 1991 [1]. Guyatt’s mentor, David Sackett, defined evidence-based medicine (EBM) in the following manner:

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidenced based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care [2].

As there is no way to standardize “individual clinical expertise,” EBM has focused on “the best available external clinical evidence from systematic research.” In order to determine the best evidence, levels of evidence have been developed to grade evidence. In orthopedic surgery, five levels of evidence in four different categories (Therapeutic Studies, Prognostic Studies, Diagnostic Studies, and Economic and Decision Analyses) have been defined [3].

The vast majority of work in EBM has been focused on therapeutic effectiveness. Level I therapeutic evidence consists of high-quality (low risk of bias) randomized controlled trials (RCTs). In order to provide individuals with the best available external clinical evidence from systematic reviews, the American Academy of Orthopaedic Surgeons (AAOS) formalized the systematic review process under the

G. A. Brown

CHI St. Alexius Health, Williston Orthopedic Clinic, Williston, ND, USA

A. F. Chen (✉)

Department of Orthopaedic Surgery, Brigham and Women’s Hospital, Boston, MA, USA

e-mail: afchen@bwh.harvard.edu

Evidence-Based Quality and Value (EBQV) Committee. Evidence-based clinical practice guideline (CPG) working groups use Level I therapeutic evidence (RCTs) to make recommendations for nonoperative, operative, and post-operative treatments. When there is insufficient Level I evidence to make recommendations, appropriate use criteria (AUC) working groups can provide criteria for treatment options.

Evidence-Based Quality and Value Committee

The AAOS began its efforts in EBM with the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS). MODEMS intended to provide tools for generating high-quality evidence for musculoskeletal conditions/treatments and developed questionnaires for multiple patient/anatomical subgroups including upper extremity, pediatrics, spine, and lower limb [4]. These questionnaires were patient-reported outcome measures (PROMs). In addition to developing and validating the PROMs, MODEMS included normative data. MODEMS PROMs were intended to standardize outcome evidence to be used in future guidelines and recommendations. Ultimately, MODEMS efforts led to the development and validation of the Disabilities of the Arm, Shoulder and Hand (DASH) upper extremity PROM and the health-related quality of life (HRQL) SF-36 (version 1) PROM [5]. However, of the 2419 hip and knee records, only 150 patients had baseline, first post-operative and second post-operative complete data [5]. Given the difficulty of collecting follow-up patient data, MODEMS was abandoned. With the lessons learned from MODEMS, the American Joint Replacement Registry (AJRR) was founded. AJRR collects procedural data (Level I), patient comorbidities and complications data (Level II), and patient-reported outcomes data joint/disease-specific PROMs and health-related quality of life (HRQL) PROMs (Level III). Radiographic data have been proposed as level IV data but have not yet been implemented. Note that levels of data are different from the levels of evidence. In 2016, AAOS approved the Quality Outcomes Data (QOD) work group list of recommended PROMs found in Table 11.1 [6, 7].

The organizational structure that ultimately led to the EBQV Committee is noted in Fig. 11.1. The EBQV Committee was created in 2013 when the Evidence-Based Practice Committee, Appropriate Use Criteria Committee, and the Guidelines and Technology Oversight Committee merged into a single committee. The introduction of high-value healthcare resulted in the formation of the Performance Measures Committee (PMC) in 2014. In 2018, the PMC was incorporated into EBQV to coordinate CPG and performance measure (PM) development into a single evidence collection, review, and grading process. The first two CPGs were approved in May 2007: *Diagnosis of Carpal Tunnel Syndrome* and *Prevention of Symptomatic Pulmonary Embolism in Patients undergoing Total Hip and Knee Arthroplasty*.

In addition to the organizational development of EBM within AAOS, the CPG development process has improved over time. In 2013, several changes were implemented: [1] recommendation stems were changed from “We recommend” to

Table 11.1 AAOS quality outcomes data work group recommended PROMs

Category	Patient-reported outcome measurement (PROM)
General quality of life	Veterans RAND 12
	PROMIS (PROMIS 10 or CAT)
Treatment outcome	Single Assessment Numeric Evaluation (SANE)
Foot and ankle	Foot and Ankle Ability Measure (FAAM)
	Foot and Ankle Disability Index (FADI)
Knee (anterior cruciate ligament)	International Knee Documentation Committee (IKDC) Subjective Knee Form (Pedi-IKDC)
	Marx Activity Rating Scale
Knee (osteoarthritis)	Knee Injury and Osteoarthritis Outcome Score (KOOS)
	Knee Injury and Osteoarthritis Outcome Score Jr. (KOOS Jr.)
Hip (osteoarthritis)	Hip Disability and Osteoarthritis Outcomes Survey (HOOS)
	Hip Disability and Osteoarthritis Outcomes Survey Jr. (HOOS Jr.)
Shoulder	American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)
	Oxford Shoulder Score (OSS)
Shoulder (instability)	American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)
	Western Ontario Shoulder Instability Index (WOSI)
Elbow	Disabilities of the Arm, Shoulder, and Hand Score (DASH)
	Quick-DASH
Wrist	Disabilities of the Arm, Shoulder, and Hand Score (DASH)
	Quick-DASH
Hand	Disabilities of the Arm, Shoulder, and Hand Score (DASH)
	Quick-DASH
Spine	Oswestry Disability Index (ODI)
	Neck Disability Index (NDI)

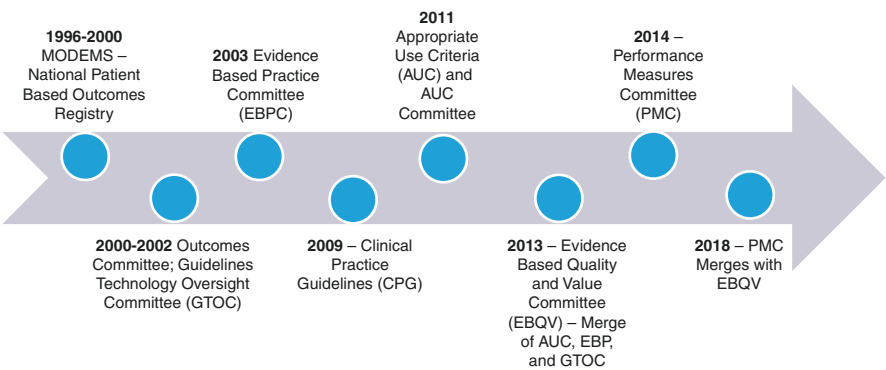


Fig. 11.1 Timeline of American Academy of Orthopaedic Surgeons (AAOS) evidence-based medicine committees resulting in the Evidence-Based Quality & Value Committee in 2013

“Strong/Moderate/Limited evidence supports”; PICO questions (an acronym for Patient/Population, Intervention, Comparison, and Outcome discussed below) were initially used; and “Inconclusive” recommendations were removed from the CPG recommendations. To allow for all AAOS fellows to provide suggested topics for

new/revised CPGs, the Key Informant (KI) role was created in April 2018. In April 2019, the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) Evidence-to-Decision Framework for CPGs was incorporated into the AAOS process.

Clinical Practice Guidelines

A complete description of the AAOS CPG methodology can be found on the AAOS website [8]. The current CPG process is initiated when the EBQV Committee selects a new topic or determines that new evidence can support a full update of an existing CPG. A work group is formed with AAOS members, specialty societies, primary care providers, physical therapists, and other appropriate medical/surgical specialties. Two co-chairs are selected, one representing AAOS and the other representing the appropriate subspecialty society. An oversight chair is appointed by the EBQV Committee. All work group members are vetted for possible financial conflicts of interest (FCOIs) to avoid bias in the working group. In addition to self-reported conflicts of interest, websites reporting data from the Sunshine Act (<https://www.cms.gov/OpenPayments> and <https://projects.propublica.org/docdollars/>) are reviewed to determine if any unreported FCOIs are listed. In spite of public reporting of FCOIs through the Centers for Medicare and Medicaid Services (CMS) Open Payments website and ProPublica's "Dollars for Docs" website, FCOIs continue to be an issue with medical professional societies [9]. Individuals with FCOIs may serve as key informants and provide the working group with topics and/or questions to be considered by the CPG working group.

The process for developing, approving, and publishing/releasing a CPG is presented in Fig. 11.2. The working group has two formal meetings to develop the CPG. The initial meeting determines the PICO questions and inclusion/exclusion criteria. After the initial meeting, AAOS staff perform a comprehensive literature review, abstracts and analyze the evidence, and summarize the evidence. At the final meeting, the working group reviews the evidence and writes recommendations for each PICO question. A rationale for each recommendation is drafted by an individual work group member based on the group discussion for that recommendation. The rationales are reviewed by the work group members before the draft CPG is distributed for peer review.

The recommendations in the CPG are framed by PICO questions. PICO is an acronym for Patient/Population, Intervention, Comparison, and Outcome. The details of each "letter" are as follows:

- **Patient or Population:** Describe the most important characteristics of the patient. (e.g., age, disease/condition, gender).
- **Intervention; Prognostic Factor; Exposure:** Describe the main intervention. (e.g., drug or other treatment, diagnostic/screening test).
- **Comparison (if appropriate):** Describe the main alternative being considered. (e.g., placebo, standard therapy, no treatment, the gold standard).

Clinical Practice Guideline Process Flowchart

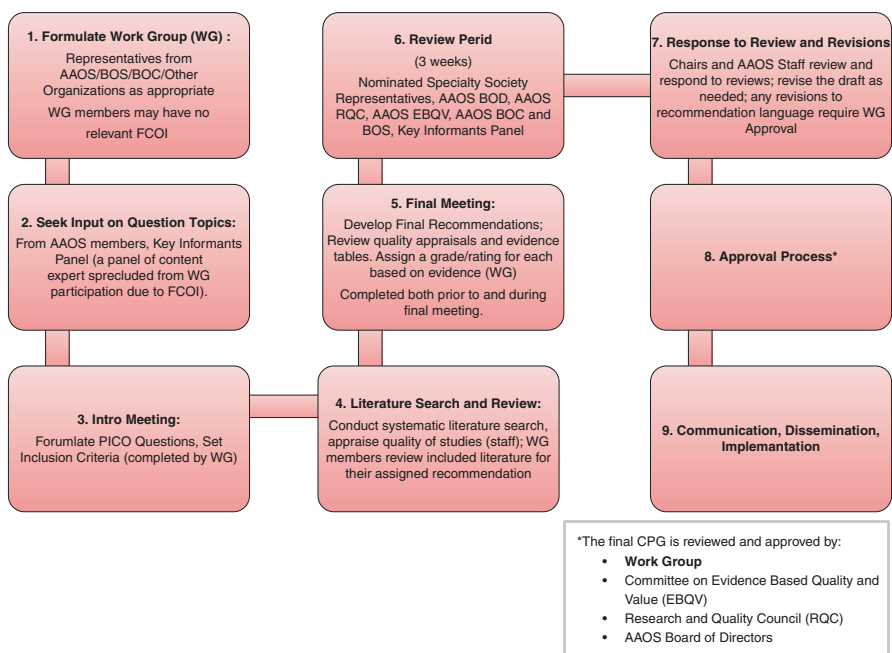


Fig. 11.2 Clinical Practice Guideline process. AAOS American Academy of Orthopaedic Surgeons, BOC AAOS Board of Councils, BOD AAOS Board of Directors, BOS AAOS Board of Specialty Societies, CORQ AAOS Council on Research and Quality, EBQV Evidence-Based Quality and Value, FCOI Financial conflicts of interest, PICO Patient/Population, Intervention, Comparison, and Outcome

- **Outcome:** Describe what you're trying to accomplish, measure, improve, or affect. (e.g., reduced mortality or morbidity, improved functional outcomes, accurate and timely diagnosis).

These parameters provide further clarity in defining inclusion criteria for the literature review and evaluating the evidence. Standard inclusion and exclusion criteria for a CPG literature search are as follows:

Work Group Defined Criteria

1. Study must be of an *<enter disease topic of interest>* injury or prevention thereof.
2. Study must be published in or after *<work group selects date, not to precede 1966>* for surgical treatment, rehabilitation, bracing, prevention, and magnetic resonance imaging (MRI).
3. Study must be published in or after *<work group selects date, not to precede 1966>* for X-rays and nonoperative treatment.

4. Study must be published in or after <work group selects date, not to precede 1966> for all others non specified.
5. Study should have 30 <work group may choose to increase the sample size if justified> or more patients per group.
6. For surgical treatment, a minimum of N days/months/year (refer to PICO questions for detailed follow-up duration).
7. For nonoperative treatment, a minimum of N days/months/year (refer to PICO questions for detailed follow-up duration).
8. For prevention studies, a minimum of N days/months/year (refer to PICO questions for detailed follow-up duration).

Standard Criteria for all CPGs

- Articles must be a full article report of a clinical study.
- Retrospective non-comparative case series, medical records review, meeting abstracts, meta-analyses, systematic reviews, historical articles, editorials, letters, and commentaries are **excluded**. Bibliographies of meta-analyses and systematic reviews will be examined to ensure inclusion of all relevant literature.
- Confounded studies (i.e., studies that give patients the treatment of interest AND another treatment) are **excluded**.
- Case series studies that have non-consecutive enrollment of patients are **excluded**.
- Controlled trials in which patients were not stochastically assigned to groups AND in which there was either a difference in patient characteristics or outcomes at baseline AND where the authors did not statistically adjust for these differences when analyzing the results are **excluded**.
- All studies evaluated as “very low quality” will be **excluded**.
- Composite measures or outcomes are **excluded**, even if they are patient-oriented.
- Study must appear in a peer-reviewed publication.
- For any included study that uses “paper-and-pencil” outcome measures (e.g., SF-36), only those outcome measures that have been validated will be included.
- For any given follow-up time point in any included study, there must be $\geq 50\%$ patient follow-up (if the follow-up is $>50\%$ but $<80\%$, the study quality will be downgraded by one Level).
- Study must be of humans.
- Study must be published in English.
- Study results must be quantitatively presented.
- Study must not be an in vitro study.
- Study must not be a biomechanical study.
- Study must not have been performed on cadavers.
- We will only evaluate surrogate outcomes when no patient-oriented outcomes are available.

After the initial meeting, AAOS staff including research librarians, analysts, and biostatisticians perform a systematic literature review of appropriate medical literature databases utilizing the PICO questions and inclusion/exclusion criteria. All relevant abstracts are reviewed. Full articles of all abstracts that appear to meet the PICO questions and inclusion/exclusion criteria are pulled. Articles that meet the PICO questions and inclusion/exclusion criteria are abstracted, evidence quality is graded, and data tables are constructed for each PICO question, subpopulation, intervention, comparison, and outcome. When multiple studies with comparable outcome measures are available, meta-analyses are performed.

RCTs are evaluated using the GRADE methodology [10]. The RCTs are graded based on random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective reporting, and other biases.

Once the RCTs have been graded, the quality is assigned based on the number of flaws on the study: high-quality (1 flaw), moderate-quality (2–3 flaws), low-quality (4–5 flaws), and very low-quality (≥ 6 flaws). Observational studies evaluating treatment effects start as low-quality studies and can be upgraded to moderate-quality if certain criteria are met [8].

At the second (final) work group meeting, the work group reviews the evidence for each PICO question. Based on the evidence for different populations/subgroups, number of interventions, number of comparators, and outcomes, each PICO question may generate one or more recommendations. The Strength of Evidence (SoE) for each recommendation is determined by the work group based on the guidelines in Table 11.2. Evidence may be upgraded for a strong treatment effect or downgraded for heterogeneity of outcomes between studies. Effectiveness of treatments are assessed based on minimally clinically important differences (MCIDs). A treatment effect must meet the MCID to be clinically significant. Treatments may reach statistical significance ($p < 0.05$) compared to placebo/control. However, if the

Table 11.2 Strength of evidence guidance

Strength	Overall Strength of Evidence	Description of Evidence Quality	Strength Visual
Strong	Strong	Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.	
Moderate	Moderate	Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention.	
Limited	Low Strength Evidence or Conflicting Evidence	Evidence from one or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	
Consensus*	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion. Consensus statements are published separate from recommendations with evidence.	

Table 11.3 Recommendation “stems” based on the strength of evidence

Guideline language	Strength of recommendation
Strong evidence supports that the practitioner should/should not do X, because...	Strong
Moderate evidence supports that the practitioner could/could not do X, because...	Moderate
Limited evidence supports that the practitioner might/might not do X, because...	Limited
In the absence of reliable evidence, it is the opinion of this guideline work group that...	Consensus

treatment effect size does not meet the MCID, the treatment is not considered clinically effective. The recommendations are drafted based on the strength of the evidence and recommendation “stems” listed in Table 11.3. A rationale for each recommendation is included in the final document based on discussion notes from the final meeting.

Once the draft CPG is compiled, it is sent for peer review to appropriate subspecialty societies, AAOS Board of Directors, the Council of Research and Quality (CORQ), EBQV Committee, Board of Councilors (BOC), Board of Specialty Societies (BOS), and key informants. The work group Chairs and EBQV staff review all peer review comments. Any recommendation reviews require work group approval. The final CPG is reviewed and approved by the CPG work group, EBQV, CORQ, and the AAOS Board of Directors (BOD).

Appropriate Use Criteria

AUCs are tools helped to determine the *appropriateness* of select orthopedic procedures. An “appropriate” procedure is one for which the expected health benefits exceed the expected negative consequences by a sufficiently wide margin. AUCs are derivative products of CPGs or systematic reviews. AUCs differ from CPGs, since CPGs are created to inform clinicians *if* a procedure should be done based on the best available evidence. On the other hand, AUCs are created to inform clinicians *which patients* should receive certain procedures. This involves using *clinician expertise* and *experience*, in conjunction with *relevant evidence*, to rate the appropriateness of various treatments for a heterogeneous set of hypothetical, but clinically realistic, patient scenarios. AUCs can use Level II-V evidence while CPGs must be based on Level I evidence.

AUCs are developed in two stages. The first stage is to work with the writing panel to develop materials that are guided, but not entirely driven, by evidence. The writing group creates three sections that define the scope of the AUC. The group develops an “**assumptions list**,” that assumes certain variables are in place before consulting a specific AUC. For example, it can be assumed that patient history has been reviewed and physical examination has been conducted prior to referencing the specified AUC. The group then develops “**patient factors/scenarios**,” which is a list of patient indications to classify patients in terms of the variables that

clinicians take into account when deciding whether to recommend a particular procedure. Finally, the writing group derives a “**treatment list**” and provides a list of common treatments for a specific disease being addressed in the AUC.

The parameters for patient factors/scenarios should be: (1) **comprehensive**—they should cover a wide range of patients, (2) **mutually exclusive**—there should be no overlap between patient scenarios/indications, (3) **homogenous**—the final ratings should result in equal application within each of the patient scenarios, and (4) **manageable**—the number of total voting items (i.e., # of patient scenarios x # of treatments) should be practical for the voting panel. The target number of total voting items should range between 2000 and 6000. This means that not all patient indications and treatments can be assessed in one AUC.

The second stage is the voting panel, which should combine clinical experience, expertise, and relevant evidence in the form of CPG recommendations. This is a multidisciplinary panel and no relevant FCOIs are allowed. The voting panel members rate the appropriateness of select treatments based on patient factors/scenarios via two rounds of voting to determine which procedures/interventions are appropriate for specific patient profiles. This voting panel then rates treatments on a 9-point scale, with 1–3 being “rarely appropriate,” 4–6 being “may be appropriate,” and 7–9 being “appropriate.” After the first round of ratings, the individuals meet in-person to discuss areas of disagreement and re-vote using the modified Delphi method. No attempts are made at gaining consensus.

Incorporating Clinical Practice Guidelines into Clinical Practice

Incorporating CPGs into individuals’ clinical practice allows orthopedic surgeons to improve the value of the care they deliver by focusing on evidence-based best practices. By standardizing care, best practices and care pathways can be utilized to minimize length of stay (LOS), adverse events, and poor outcomes, which all significantly impact the total cost of care and usually results in cost outliers. *Management of Hip Fractures in the Elderly* [11] provides an opportunity to see the impact of implementing CPGs.

PREOPERATIVE REGIONAL ANALGESIA—*Strong evidence supports regional analgesia to improve preoperative pain control in patients with hip fracture.*

A previous study by Zywił et al. [12] found that approximately 50% of elderly patients who underwent fragility hip fracture surgery developed perioperative delirium, which delayed discharge to skilled nursing facilities and increased LOS with associated significant increase in incremental episode of care costs. By implementing preoperative regional anesthesia, specifically fascia iliaca nerve blocks, the need for opioid pain medications can be reduced and fewer patients may develop delirium.

SURGICAL TIMING—*Moderate evidence supports that hip fracture surgery within 48 h of admission is associated with better outcomes.*

Delaying surgery has a significant impact on mortality [13, 14] and reduces the likelihood that the patient will return to independent living [15]. Delays to the operating room (OR) can be caused by (1) delays in medical evaluation/clearance for surgery, (2) unnecessary work-up, (3) anti-coagulation reversals, or (4) delirium.

Table 11.4 Shorter time to the operating room (OR) results in reduced length of stay (LOS) for patients with hip fractures [16]. Time to OR and LOS are listed as mean (standard deviation)

	Number (%)	Time to OR (h)	LOS (h)
No delay	290 (74.4%)	11.9 (8.0)	120.4 (61.9)
Warfarin	35 (9.0)	40.3 (17.3)	159.4 (62.2)
Clopidogrel	9 (2.3%)	101.3 (38.6)	183.7 (63.9)
Medical problem	49 (12.6%)	51.0 (39.7)	196.0 (173.6)
No OR time	7 (1.8%)	31.7 (10.0)	114.1 (23.8)

Hip fracture care pathways can mitigate each of these causes by standardizing care so that (1) the hospitalist/internist sees the patient in the emergency room and not the next morning, (2) unnecessary cardiac work-up are avoided and anesthesia can treat the patient as though the work-up was positive, (3) standardized warfarin reversal protocols and tranexamic acid use can reduce anti-coagulation delays, and (4) fascia iliaca regional blocks can reduce the need for opioid pain medication to avoid delirium. Reducing time to OR reduces LOS as noted in Table 11.4 [16].

If reducing time to OR is beneficial, isn't decreasing the time to the OR to 24 h better? Reducing time to the OR to less than 24 h was proposed as a performance measure. However, the evidence does not support a significant improvement in outcomes by reducing the time to the OR from 48 to 24 h. Sobolev et al. reviewed 139,119 medically stable patients with hip fractures in Canada from 2004 to 2012. The authors correlated time to OR with mortality (Fig. 11.3). Time to OR of 24–48 h (inpatient day 2) had a slightly lower mortality rate than 0–24 h (day of admission), but this number was not statistically significant [17].

CEMENTED FEMORAL STEMS—*Moderate evidence supports the preferential use of cemented femoral stems in patients undergoing arthroplasty for femoral neck fractures.*

Revision surgery after hip fracture surgery is costly, especially when revising for periprosthetic fracture. Hevesi et al. determined that the hospitalization costs for fracture (median, \$25,672) were significantly higher compared to the costs for revision due to dislocation/instability (\$17,911; $p < 0.001$) and wear/loosening (\$20,228; $p < 0.001$), even when controlling for patient comorbidities ($p < 0.001$) [18]. Intra-operative and early perioperative periprosthetic fractures are more common after performing total hip arthroplasty using uncemented femoral stems compared to cemented femoral stems, as Abdel et al reported that the 30 day periprosthetic fracture relative risk was ten times higher for uncemented femoral stems compared to cemented femoral stems [19]. Tanzer et al. evaluated the three best cemented and uncemented femoral stems in the Australian National Joint Replacement Registry and found a periprosthetic fracture hazard ratio (HR) equal to 9.14 ($p < 0.001$) favoring cemented femoral stems [20]. Both of these studies were primarily

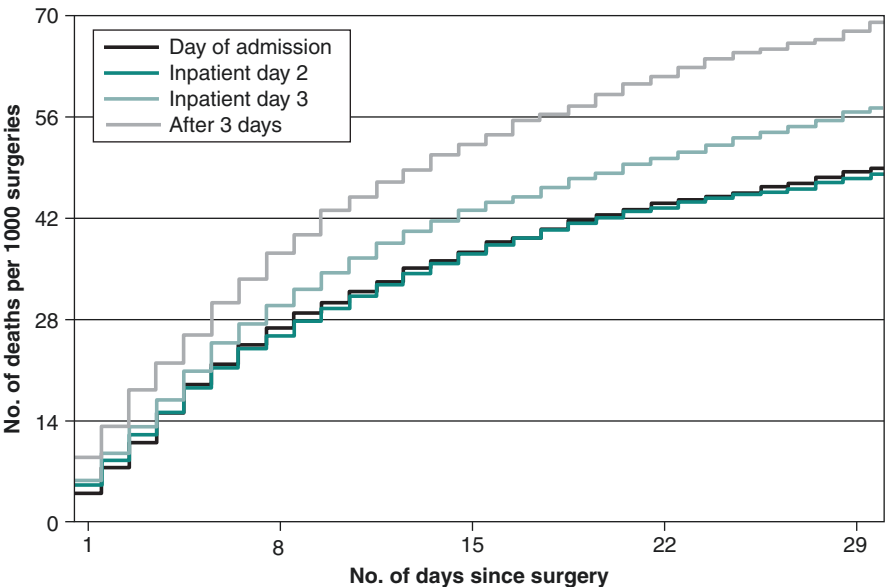


Fig. 11.3 Time to operating room and mortality correlations for 139,119 Canadian hip fracture patients [17]

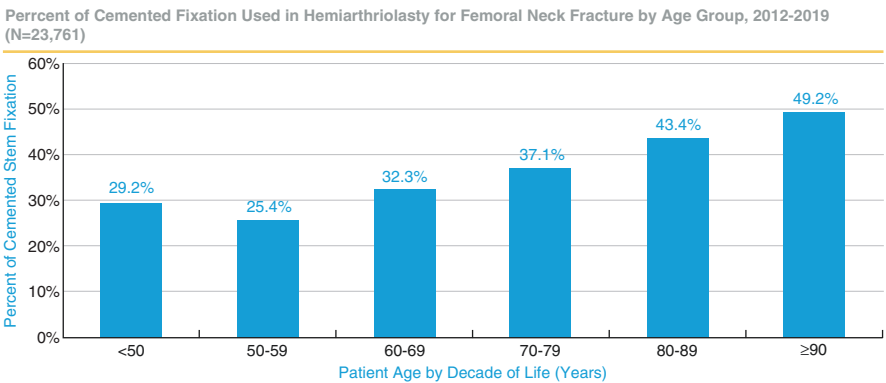


Fig. 11.4 Percentage of patients receiving cemented femoral stem fixation for femoral neck fractures in the United States between 2012 and 2019 [21]. (Figure taken from the American Joint Replacement Registry (AJRR) Annual Report 2020)

evaluating elective total hip arthroplasty patients so the impact of using uncemented femoral stems in osteoporotic patients can only be magnified.

American orthopedic surgeons who treat hip fractures have been slow to adopt the recommendation to use cemented femoral stems in hip fracture arthroplasty, as noted in the American Joint Replacement Registry (AJRR) Annual Report 2020 [21]. Even in patients whose age was greater than or equal to 90 years, only 49.2% of patients received cemented femoral fixation (Fig. 11.4). Possible reasons for the

low recommendation adoption rate include failure to recognize the problem of periprosthetic fractures since they are relatively rare events and discomfort with cementing techniques. The situation may be analogous to elective induction of labor prior to 39 weeks gestation. Individual obstetricians did not see the consequences of early term deliveries and instead met pregnant women's expectations for early deliveries. Multiple studies have demonstrated increased adverse long-term infant outcomes for neonates delivered prior to 39 weeks gestation compared with neonates delivered at 39 weeks gestation [22]. The American College of Obstetricians and Gynecologists (ACOG) responded with specific guidance to avoid early term deliveries and educate ACOG members of the risks of pre-term delivery [22]. CPGs can serve as educational tools to inform physicians and improve patient outcomes, and if physicians do not change their femoral fixation, performance measures may be imposed to change behavior.

Future Work

The CPG process continues to evolve. One of the fundamental problems is generating sufficient high-quality evidence. Although RCTs eliminate bias, RCTs have at least three inherent flaws: (1) inclusion and exclusion criteria resulting in study populations that are often not generalizable to many patient subgroups, (2) RCTs do not have adequate statistical power to compare rare outcomes such as infection or revision surgery, and (3) RCTs are powered for the primary outcome and rarely have sufficient statistical power to conduct subgroup analyses.

Perhaps the most notable example of the first problem relates to risk factors for venous thromboembolic (VTE) events after total joint arthroplasty (TJA). All known RCTs regarding VTE prophylaxis after TJA exclude patients with previous VTE events or other VTE high-risk factors. Consequently, the *American Society of Hematology 2019 guidelines for management of venous thromboembolism: Prevention of venous thromboembolism in surgical hospitalized patients* made no mention of risk factors when prescribing VTE prophylaxis pharmacologic agents after TJA [23]. By excluding this subgroup of patients from RCTs, by definition, there is no high-quality evidence of VTE risk factors after TJA for patients with previous VTE.

For the second point, finding differences in rare outcomes requires large numbers of patients for adequate statistical power. Therefore, registries with prospective data collection have more statistical power than RCTs. An example of a type II error, or finding no difference when a difference exists, can be found in the *Surgical Management of Osteoarthritis of the Knee* [24] CPG. One recommendation stated, "Strong evidence supports no difference in outcomes or complications between posterior stabilized and posterior cruciate retaining arthroplasty designs." However, the most recent AAOS AJRR Annual Report shows a higher revision rate for posterior-stabilized (PS) total knee arthroplasty (TKA) compared to cruciate-retaining (CR) designs (Fig. 11.5) [21]. This difference in revision rates for PS versus CR designs is confirmed out to 13 years with data from the Australian

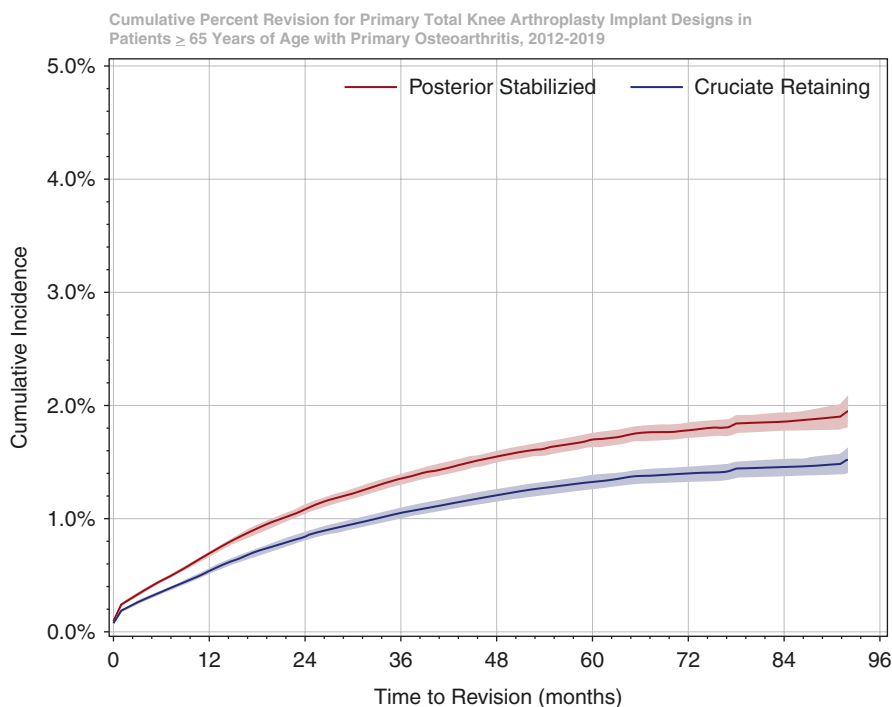


Fig. 11.5 Total knee replacement revision rates comparing posterior-stabilized and cruciate-retaining designs in the United States between 2012 and 2019 [21]. (Figure taken from the American Joint Replacement Registry (AJRR) Annual Report 2020)

National Joint Replacement Registry [25]. The all cause revision rate for PS TKAs was higher than for CR TKA designs ($HR = 1.45$, $p < 0.001$) and for loosening or osteolysis ($HR = 1.93$, $p < 0.001$) [25].

The GRADE method automatically assigns an observational study as low quality. However, Concato et al. suggest that “[t]he results of well-designed observational studies (with either a cohort or a case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic.” [26] EBM/GRADE needs to develop a means for assessing bias in well-design prospective, observational outcome studies (registries) as high-quality studies, particularly for rare and/or long-term outcomes. Due to cost alone, it is unlikely a RCT will ever provide long-term outcomes.

When comparing rare outcomes such as periprosthetic joint infection, explicit power analyses need to be performed. Even though multiple high-quality RCTs may assess rare outcomes, that does not mean that a meta-analysis has sufficient statistical power to find a difference when a difference exists. Another example from the *Surgical Management of Osteoarthritis of the Knee* [24] CPG evaluating antibiotic bone cement states that “Limited evidence does not support the routine use of antibiotics in the cement for primary TKA.” The number of subjects ($n_1 = n_2$) needed

for adequate statistical power to find a difference when a difference exists can be calculated using the equation for binary outcomes (e.g., infection, no infection) [27]:

$$n_1 = n_2 = \left[\left(2p_m q_m \right)^{1/2} z_{1-\alpha/2} + \left(p_1 q_1 + p_2 q_2 \right)^{1/2} z_{1-\beta} \right]^2 / \Delta^2$$

where

$$\begin{aligned} p_1, p_2 &= \text{sample probabilities} \\ q_1, q_2 &= 1 - p_1, 1 - p_2 \\ p_m &= (p_1 + p_2) / 2 \\ q_m &= 1 - p_m \\ \Delta &= \text{difference} = p_2 - p_1 \end{aligned}$$

Using Kleppel’s meta-analysis results [28] as estimates of the infection probabilities,

$$\begin{aligned} p_{\text{ALBC}} &= 0.0116 \\ p_{\text{non-ALBC}} &= 0.0182 \\ n_1 = n_2 &= 5282 \end{aligned}$$

Since the antibiotic-loaded bone cement (ALBC) and non-ALBC subgroups each had less than 2000 patients, the meta-analyses do not have sufficient statistical power to find a difference in infection rates. Therefore, the evidence technically does not support the recommendation regarding ALBC. All meta-analyses on this subject (Table 11.5) actually demonstrate a lower infection rate with ALBC but have insufficient power to find a statistical difference. Separate power analyses are needed independent of RCT grading to determine if the evidence is “Inconclusive.”

RCTs have the underlying assumption that a single treatment option is best for all patient subgroups included in the trial, unless the trial is statistically powered for subgroup analyses. It is rare for orthopedic RCTs to have subgroup analyses. An example of this third problem with RCTs is found in the *Management of Hip Fractures in the Elderly* [11]. “Moderate evidence does not support routine use of preoperative traction for patients with a hip fracture.” However, the analysis of the

Table 11.5 Recent findings of meta-analyses regarding effectiveness of antibiotic-loaded bone cement (ALBC) for total knee arthroplasty (TKA) [28–30]

		Number of		ALBC			Non-ALBC		Needed
		Included	Number of	Number of	Infection Rate	Number of	Number of	Infection Rate	Subjects per
Author	Year	Trials	Infections	TKAs	Rate	Infections	TKAs	Rate	Subgroup
Wang	2013	2	20	1661	1.20%	25	1627	1.54%	18,327
Zhou	2015	5	46	3461	1.33%	60	3176	1.89%	7620
Kleppel	2017	9	23	1979	1.16%	35	1924	1.82%	5282

evidence combines femoral neck fractures (intracapsular hip fractures) with intertrochanteric hip fractures (extracapsular hip fractures). Intracapsular hip fractures have intracapsular bleeding, and the intracapsular pressure causes pain. This is similar to pediatric septic hip arthritis where patients prefer to flex their hip to reduce intracapsular pressure and pain. Similarly, patients with intracapsular hip fractures would prefer to have their hips flexed and traction would extend the hip joint, increase the intracapsular pressure, and increase their pain. Intertrochanteric hip fractures do not have an intracapsular hematoma, but typically have more fracture shortening, muscle spasm, and pain from muscle spasms. Approximately, 50% of hip fractures are intracapsular fractures and 50% are extracapsular fractures. If traction worsens intracapsular pain and improves extracapsular pain, the net benefit for all hip fractures would be zero, but the benefit for extracapsular hip fractures would not be identified without an appropriate subgroup analysis. The hypothesis that different hip fractures respond differently to the same treatment is supported by a recent prospective observational study on fascia iliaca blocks [31]. The authors found that femoral neck fractures benefited most from preoperative fascia iliaca blocks and both femoral neck and intertrochanteric fractures benefited from postoperative fascia iliaca blocks.

Conclusions

The CPG and AUC processes and products have evolved and improved since their inception. The first step in improving any process is being aware of potential and/or real issues. Awareness of the above issues will allow AAOS to deliver better CPGs. However, the CPGs are only as good as the evidence. RCTs need to be conducted to fill evidence gaps noted in CPGs. New study designs need to be incorporated into RCT and observational trials. Problems with study design cannot be addressed with post hoc analysis. Observational study designs are much better than RCTs for assessing prognostic factors, subgroup analyses, rare events, and long-term outcomes. AAOS hopes to leverage their existing and new registries to conduct observational outcome studies and develop better prognostic evidence. This will require thoughtful foresight when determining each registry's data elements.

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Joseph P. DeAngelis

In the pursuit of quality improvement, healthcare institutions and providers rely on instruments and metrics to assess and advance high-value healthcare. A performance measure (PM) is a quantitative metric of structures, processes, and outcomes, which yield information about critical aspects of clinical care and their effect on patients. The primary purpose of a performance measure is to identify opportunities to improve patient care and outcomes.

When considering the role of performance measures in the healthcare ecosystem, it is important to recognize that they are scientifically valid measures of performance, based on the best evidence available. Ideally, they focus on topics of high impact that are important for the care of orthopedic patients. Importance can be defined by many factors, including prevalence, disease severity, and/or impact on functional status, variation in care, total societal cost of care, etc.

The intent of a PM is to identify and address a gap in performance where there is known variation in clinical behavior or the outcomes of interest. To be effective, performance measures should incorporate input from a broad cohort of stakeholders and should emphasize feasibility in application. Importantly, the collection of supporting data for measurement should not place undue burden on clinicians, patients, or families.

The book was inadvertently published with unnecessary/incorrect article notes. This has been removed from the chapter.

J. P. DeAngelis (✉)
Beth Israel Deaconess Medical Center, Boston, MA, USA

In the transition from fee-for-service to value-based healthcare, the utility of a performance measure is increased when broadly adopted. For this reason, incorporation of performance measures into value-based programs is emphasized. In the current environment, whenever possible, an effective PM can be included in Centers for Medicare & Medicaid Services (CMS) payment programs.

For individual orthopedic surgeons, there are many benefits to the implementation of performance measures. At its most basic, measuring performance can provide a point of reference to compare your practice to your peers. As a baseline, performance measures can tell you how well you are doing currently and may reveal areas for improvement. As a broader assessment of the healthcare system, many performance measures direct quality improvement because they encompass all of the work related to care delivery and address the health of individuals and populations. This approach is dynamic as measures influence assessment, direct interventions, and provide feedback to providers. Performance measures are both systematic and ongoing.

Clinical performance measures should be patient-centered and outcome-oriented, whenever possible. Structuring them with this focus maximizes the significance of the measurement process for an entire healthcare system and directs resources efficiently because they should be implemented to address a performance gap. In identifying a deficiency, a performance measure creates an opportunity for improvement. While there is concern that these instruments can be used to penalize, this possibility may result from any comparison and is not unique nor is it intrinsic to a performance measure. Recognizing the broader applicability of these comprehensive measures, performance measures can be used to monitor and improve care, report a result for a merit-based incentive program for CMS, and to validate an outcome in a certification program.

In the American Academy of Orthopaedic Surgeons (AAOS) quality cycle, systematic reviews are used to survey the literature and generate clinical practice guidelines (CPGs). When the existing evidence is limited, appropriate use criteria (AUCs) are developed. However, when the available literature provides evidence that is strong, a performance measure can be developed. This requirement limits the number of PMs, because strong evidence is limited in the orthopedic literature.

In considering performance measures, it is helpful to think of them in four different domains: Structural, Process, Outcome, and Patient Experience.

Structural

Structural performance measures assess the healthcare infrastructure. They describe the characteristics of a care setting, including facilities, personnel, and/or policy. An example of a structural PM would be the percentage of physicians in a practice who have systems in place that track and follow patients with a high number of falls.

Process

Alternatively, a process PM quantifies the steps in a plan of care that should be followed to provide the best-possible care. This approach determines if the services rendered to patients are consistent with the standard of routine clinical care. An example of this type of PM would be achieved by calculating the percentage of women who are between 50 and 85 years old, who sustained a fracture and then underwent bone mineral density testing or received a prescription for a drug to treat osteoporosis.

Outcome

An outcome performance measure assesses a patient's health as a result of the care they received. An example of this type of PM can be found in the percentage of surgical site infections within 30 days following the surgical procedure. There is a strong movement from both CMS and the private payers toward the development of outcome measures. Many of the existing tools are process measures that, on their own, do not directly improve care.

Patient Experience

A performance measure can also be developed to assess the patient experience. In this case, these PMs provide feedback on the patients' experience of care and offer guidance on how it may be improved.

Having considered these types of PMs, process performance measures are the most frequently used and often the easiest to develop. While outcome PMs are frequently used, they often depend on the retrieval of claims data for the insurer. This additional step in the execution of an outcome PM makes their implementation and adoption more difficult. Risk adjustment for patient conditions, co-morbidities can be major limitations of using retrieval claims for PMs.

When considering all of the possible ways to develop a performance measure, there are many different data sources that help inform their creation. Coding data can be pulled from medical records, insurance claims, and administrative systems. They can also be extracted from registries and from a paper-based chart. Given all of the various potential sources of information, each presents its own complexities and limitations. A review of a paper-based (physical) chart requires the manpower to actually review the chart, read the notes, extract unstructured data, and convert it into structured data. Once done, this type of data may reflect a specific patient's experience, but it is time consuming, labor intensive, and prone to errors of reviewer interpretation and data handling. Conversely, it is easy to extract claims data because it is coded data. In its raw form, digital data are easy to assess, quickly processed, and widely available. The extracted information can form conclusions based on

large populations easily, but this type of information is limited by the accuracy of the codes used and the process of data entry. As a result, the conclusions reached may be inaccurate, incomplete, or they may not reflect the patient's experience.

The structure of a performance measure informs its intent. Intrinsic to the development process of a performance measure is the specification of each element. This step includes each detail and algorithm as informed by clinical and technical knowledge. There are seven key components within a measure specification, depending upon the nature of the measure:

Measure Title, describes the measure's focus and target population;

Measure Description, provides a brief narrative of the intent of the measure and its impact on a patient;

Numerator, specifies the clinical action central to the measurement;

Denominator, specifies the target population and duration of interest;

Exclusions, include the factors that remove a patient from consideration based on the best-available clinical evidence;

Exceptions, conditions that remove a patient, procedure, or unit of measurement from the denominator, only if the numerator criteria are not met; and

Data Sources, identifies the source(s) of information to be utilized for the measure implementation.

(Of note, the numerator should include the inclusion criteria, such as diagnosis, age ranges, and other positive selection factors.)

The process of developing a performance measure follows several guiding principles. It begins with the creation of PICO questions.

PICO questions are a structured framework that are used to clearly define the concepts, or variables, that form a specific research question.

Population/Problem/Patient—What is the problem to be addressed? What are the characteristics of the patient population, or disease of interest?

(The dependent variable)

Intervention—What is the relevant treatment or exposure? What action or change would affect the patient/problem/population?

(The independent variable)

Comparison—What is the alternative to the intervention?

(The "control group")

Outcome—What are the relevant effects?

What is measured to show what the intervention has accomplished or improved?

This series of questions is then used to develop the clinical practice guidelines, which prepare the potential performance measures and create the evidence-based foundation that is required for performance measure development.

After assessing a systematic review, and developing the CPG, an assembled workgroup will need to determine if there is strong or moderate evidence to support a performance measure. If so, it will create the necessary architecture for measure development. Once the specifications are complete, the measure must be tested.

Validity testing ensures that a performance measure accurately assesses the components as intended and that the results are consistent with the evidence. Reliability testing measures the repeatability, or precision, of the measurement. Feasibility testing is qualitative and renders an assessment of the availability of the data required for the measure's execution, as well as the ease and cost of obtaining that data.

In essence, performance measures require a delicate balance. A measure should be high impact, addressing an important topic, and be usable. At the same time, the performance measure should address an evidence-based gap in care. Lastly, an ideal measure should be feasible and scientifically acceptable. Naturally, the challenge is to find the “sweet-spot” and include all of these elements.

It is easy to create a measure that is evidence based and that people adhere to 99.9% of the time. However, this combination does not make a very good performance measure because it offers little room for improvement. There is no gap to close. Obviously, the challenge is to find an issue that has a strong evidential support, but poor clinical adherence. In this deficit, a performance measure can be used to improve patient care.

As discussed in the preceding chapter, CPGs provide the evidentiary support for a performance measure. If the CPG is grounded in good evidence, it is likely that a derivative performance measure will lead to improved patient care and patient outcomes. For this reason, performance measures are only based on strong, or moderately strong, recommendations from a CPG. If the evidence is insufficient, then a performance measure is excluded from development.

With the ongoing development of registries and prospective cohorts, the opportunity for quality improvement has dramatically increased. Registries provide a novel perspective on orthopedic care. They create an aggregation of data that forms the intersection of structure, process, clinical outcomes, and patient experience—the four domains of performance measures. While participation in a registry, like the American Joint Replacement Registry (AJRR) or the Shoulder and Elbow Registry (SER) registry, allows surgeons to compare their clinical performance with current trends and historical data, these dataframes represent a tremendous opportunity for performance measurement. Additionally, because a Qualified Clinical Data Registry (QCDR), like AJRR or SER, can submit performance measure scores to CMS on a clinicians' behalf, these programs can fulfill MIPS reporting requirements.

In looking to the future of performance measurement, it is likely that registries and prospective cohorts will play a central role in their development, testing, and validation. The pathway to performance measure development follows discrete steps that are easily executed once there is a well-developed registry.

The first step is to identify a concept to measure and begin specification. Once a measure has been created, it needs to be tested. If the required data are not available, it is possible to identify ways to pilot the data collection. Once the data are collected, the presence of performance gap needs to be confirmed by calculating the overall performance rate and assessing the variability. When appropriate, the performance measure will then require validity and reliability testing to confirm that it captures the intended clinic outcome or action, and that it differentiates between good and bad clinical care.

If the instrument completes this process, it will be presented for public comment before it is approved for use. An established performance measure can be disseminated and used widely for as long as it continues to address a gap in clinical performance. Ironically, as part of the ongoing maintenance of a performance measure, it is likely that a successful measure will become obsolete over time. By highlighting an opportunity for improved patient care that is evidence based, but not consistently implemented, a performance measure should close the gap by eliminating variability and, in doing so, cease to be necessary.

Suggested Reading

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Interpreting and Implementing Evidence for Quality Research

13

Eli M. Cahan and Kevin G. Shea

Interpreting Evidence

In late 1999, the Institute of Medicine released its landmark report, *To Err is Human* [1]. The report documented the frequency and magnitude of medical error—preventable harm caused by provider decision-making—in the United States. While the original report estimated 98,000 preventable deaths caused annually from medical error, subsequent analyses have estimated that the figure may be substantially higher [2].

Much of this medical error was deemed to result from provider variation from best practices and as a result, the report accelerated the movement toward evidence-based medicine (EBM) [3]. Evidence-based medicine prioritizes the “conscientious, explicit, and judicious use of current best evidence” to guide care [1, 4].

But what if current evidence is composed of “subjectively selected, arbitrarily summarised [*sic*], laundered, and biased conclusions of indeterminate validity or completeness” [5]? What, then, constitutes “the evidence in evidence-based medicine” [6]?

Building the pedagogy of modern medicine on tenuous research may constitute a shaky foundation [7]. In 1994, Altman declared poor medical research—conducted by “researchers who use the wrong techniques (either willfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions”—a “scandal” [8].

E. M. Cahan

Department of Pediatric Orthopaedics, Stanford University, Stanford, CA, USA

New York University School of Medicine, New York, NY, USA

e-mail: emcahan@stanford.edu

K. G. Shea (✉)

Department of Orthopedics, Stanford University, Stanford, CA, USA

e-mail: kgshea@stanford.edu

Indeed, analyses conducted since this whistleblowing has illuminated the so-called reproducibility crisis [9]. Up to 85% of the evidence base is false [10]. Conclusions are more likely to be false than true [11]. Tens of billions of dollars in research funding are wasted annually, including an estimated \$28 billion in the United States alone in 2015 [10, 12]. The minority of this is due to fraud (~2%) [13]. Rather, the overwhelming majority is due to more occult forces on the macro and micro levels of research conduct.

“Macro” Influences on Research Integrity

On the macro level (the research ecosystem as a whole), incentives are misaligned with production of quality, instead favoring quantity [14]. At the investigator level, length of curriculum vitae, impact factors, and H-scores are the primary criteria for tenure [15]. At the institutional level, grant funding is the key indicator of prolific, enterprising academic departments; “grantsmanship”—the confident narration of *conclusions*, rather than *findings*—too often predominates over stewardship of quality science [16]. At the level of private and public funders, demonstration of internal *efficacy* rather than external *effectiveness* is frequently the primary objective [17, 18]. Moreover, innovation and novelty tend to be compensated over reliability [7, 19].

These tendencies produce false-positive findings that do not translation into therapies that are *effective* at the bedside or *relevant* to patients [20, 21] or conceal true negatives. Half of completed studies are unpublished (including over one-third of RCTs), contributing to an estimated \$240 billion of funding wasted [22, 23].

The elevation and emphasis on positive studies, including of false positives, and the lack of focus on negative outcome studies, including concealment of false negatives can be more precisely discussed in terms of sensationalism and distortion versus inaccessibility (Fig. 13.1) [24].

Fig. 13.1 “Macro” level forces on integrity of the scientific ecosystem

		Intent	
		Overt	Occult
Findings	Positive	Sensational • Positive publication bias • Time-lag bias • Novelty lust	Distorted • Citation bias • Spin phenomenon
	Negative	Intentionally Inaccessible • File-Drawer effect	Unintentionally Inaccessible • Grey Literature • Language Barrier

Sensationalism

Sensationalism in the literature results from the preference for novelty and statistical significance [7]. In some fields, positive findings approach 100% of the published literature [25]. Positive findings are nearly five-fold more likely to be published than negative findings [26]. To the extent pioneering findings are particularly treasured for their potential to publish in high-impact journals, the higher rewards come with higher risks of fallacy; retraction rates are positively correlated with journal impact factor [27].

Distortion

Distortion refers to the fact that the scientific literature is recursive; fewer than 1% of all publishing scientists contribute to 42% of all papers, including 87% of those with high-impact (>1000 citations) [28]. Moreover, “spin”—defined as “biased presentation, intended to ensure that audiences view matters favourably [*sic*]”—skews the evidence base toward confirmation of preconceived hypotheses [29]. Studies have demonstrated evidence of spin in up to 63% of RCTs with statistically insignificant results [30], 84% of non-randomized clinical trials, and 86% of observational studies [29].

The spin phenomenon has downstream implications, as distortion propagates through the literature. They are implicated in “higher levels” of evidence: one-third of Cochrane meta-analyses include trials with high suspicion of reporting bias [31]. Indeed, some 20% of meta-analyses become non-significant after adjustment for biased studies incorporated, with a 26% reduction in average treatment effects found [31].

Inaccessibility

Inaccessible literature has been referred to as the scientific universe’s “dark matter” [32], the origins of which may be intentional or unintentional. Intentional inaccessibility results from the withholding, or “locking away,” of non-significant studies—a phenomenon known as the “file-drawer” effect [33, 34]. Quantification of the “mass” of the file-drawer problem has been difficult but may account for nearly one-third of studies in certain disciplines [35]. Adverse events often go undetailed: in one review of matched published and unpublished RCTs, 95% of unpublished studies contained information on adverse events, while only 46% of published studies did [36].

Unintentional inaccessibility results from failure of broad dissemination of study findings, often via the so-called grey literature that is unavailable through typical channels such as PubMed [33, 37]. Upon inclusion of outcomes found in grey literature, 46% of meta-analyses demonstrated reduced effect sizes, with reductions of 20% on average [38].

“Micro” Influences on Research Integrity

At the micro level (individual researchers themselves), a seminal *Lancet* series on value and waste in research identified 5 stages of study susceptible to compromise by decisions of researchers: prioritization, design, conduct, interpretation, and implementation/dissemination (Fig. 13.2) [39].

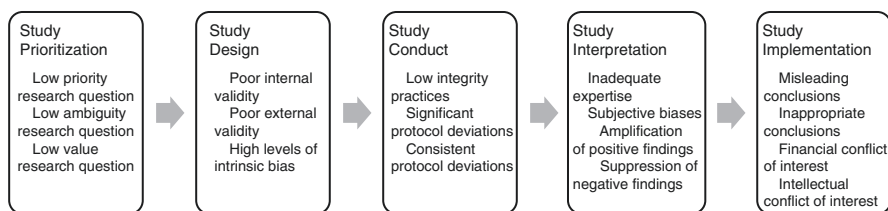


Fig. 13.2 “Micro” level forces on integrity of the scientific process. (Adapted from [39])

Study Prioritization

The first stage addresses study prioritization [40]. In order to confer value, research activity must be tethered to insufficiently answered questions of clinical relevance [17]. Creation of value and prevention of waste at the stage of study prioritization necessitate that: (i) studies address questions with residual uncertainties; (ii) studies are non-redundant (iii); studies yield informational value greater than their financial and labor costs; and (iv) studies address questions relevant to providers and/or patients [41].

Too often, these conditions are not fulfilled: upon initiation of new systematic reviews, fewer than half were aware of preexisting reviews in the literature [42]. One-fifth of RCTs made no reference to preexisting reviews upon initiation; and of the ones that did, only 54% utilized preexisting information to influence study plan [43]. Meanwhile, even as “value of information” analyses can model the costs versus benefits of studies by quantifying the financial value of clinical “certainty,” few studies weight these rigorously [44–48]. Finally, ambiguities addressed by studies favor statistical *significance* over clinical *relevance*: only 3% of research trials address non-drug treatments, whereas the majority consider pharmaceutical treatments that are ranked low-priority by patients and providers [49, 50].

The consequences of a mismatched research agenda are fourfold: (i) perpetuation of use of ineffective treatments; (ii) non-use of potentially effective treatments; (iii) restriction of treatment arsenal to interventions with (potentially biased) documented evidence; and (iv) non-adherence resulting from promotion of treatments misaligned with patient desires [51]. All four imply morbidity and mortality.

Study Design

The second stage addresses study design [20]. Up to 28% of preclinical research waste is derived from design lapses (Fig. 13.3) [52]. More than four in five studies had some degree of methodological bias that compromise internal and/or external validity [53].

Bias arises primarily from three design domains: effect-to-bias ratio and power (effecting internal validity), versus heterogeneity (effecting external validity) [19]. First, effect-to-bias ratio (colloquially the “signal-to-noise” ratio) considers the magnitude of effects compared to intrinsic biases conferred by study design

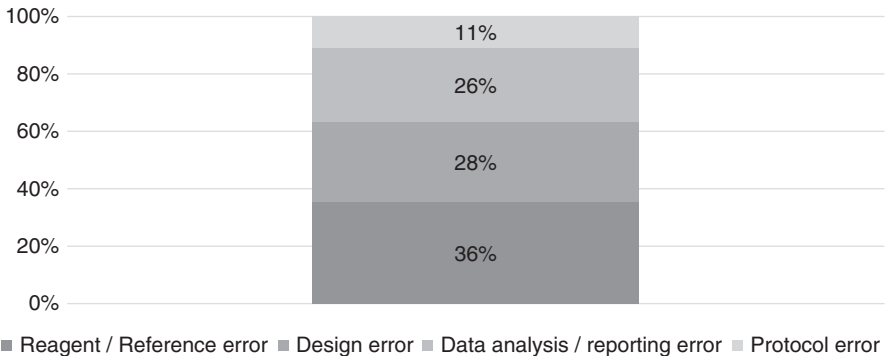


Fig. 13.3 Sources of irreproducibility waste in preclinical studies. (Adapted from [52])

(impacting Type 1 error). For example, studies in fields like genomics yield minimal effect sizes that are often indistinct from design biases [19]. Second, power analyses are critical for avoidance of false negatives (Type 2 error); yet, most subsequent studies on a given topic are underpowered to resolve the uncertainties of their precursors [54]. Third, heterogeneity enhances the generalizability (external validity) of a study. While standardization reduces within-experiment variation (increasing experimental sensitivity), it hinders extrapolation beyond experimentally controlled conditions (generalizability) [55].

Study Conduct

The third stage considers study conduct [19, 56]. In preclinical research, up to 47% of research waste was derived from lapses in study conduct including contaminated or faulty reagents, heterogenous reagent characteristics between experiments and/or laboratories, inconsistent or inadequate laboratory practices, and unclear or inaccessible process protocols (Fig. 13.3) [52]. In clinical research, lack of decision-making transparency may be even more prevalent, as elements of RCTs (such as eligibility criteria, randomization techniques, allocation concealment, and subgroup analysis) vary up to 100% from protocols [57]. Higher researcher degrees of freedom become especially problematic when such changes in the research plan are neither documented nor accounted for in data analyses [57, 58]. Across a wealth of other clinical study types (surveys, qualitative studies, observational studies, diagnostic studies, and predictive modeling), items essential to reproducibility are likewise omitted at high rates (Table 13.1) [59].

The consequences of poor process control exist not only at the non-replicability of a given study. If faulty processes are adopted by subsequent studies, then viral spread of the pathology ensues. Termed by Ioannidis the *vibration of effects*, the “cumulative detrimental impact” of process flaws “may be multiplicative” [60].

Table 13.1 Examples of inadequate reporting in clinical research other than RCTs and systematic reviews. (Adapted from [59])

Study type	Research reporting guideline	% studies <i>excluding</i> items from research reporting guideline (or otherwise relevant, if none)
Diagnostic studies	STARD	• Estimates of reproducibility: 100% • Estimates of diagnostic accuracy between subgroups: 90% • Distribution of severity of disease or comorbidity: 89% • # Eligible patients not participating: 14% • Blinding of test readers: 84% • Management of indeterminate or outlier results: 83%
Observational studies	STROBE	• Details of selection: 90% • Confounders: 49%
Clinical prediction research	REMARK	• Sample size: 83% • Reporting of missing data: 38% • Methods for handling missing data: 54% • Reporting of adjusted results of model: 80%
Qualitative research	SRQR	• Provision of survey itself: 65–92% • Provision of survey after contacting authors: 46% • Description of development process: 83% • Description of sample representativeness: 89% • Reporting of sample size calculation: 94%
Survey research	N/A	• Description of study context: 73% • Description of sampling method: 63% • Method of data collection: 60% • Method of analysis: 57%

Data Interpretation

The fourth stage refers to data interpretation [19, 59]. Errors in analysis and reporting of data, which may be intentional or unintentional, accounted for 25% of research waste (Fig. 13.3) [52]. The root causes for unintentional data interpretation error committed by researchers may be divided into two categories: technical deficiency and psychological tendency.

Technically, most research is done by investigators who are primarily clinicians without adequate support from those with robust quantitative training [61]. According to one survey, fewer than one-fifth of clinician-investigators expressed self-efficacy for conducting a variety of quantitative statistical analyses; in lieu of independent quantitative capabilities, 60% of clinician-investigators deemed statistical methodologic support “indispensable” [62].

Relating to psychological tendencies, interpretation of data by researchers is often subjective [63]. The “affection” of researchers for their hypotheses can lead to idiosyncratic framing of data interpretation in favor of preexisting beliefs [64, 65]. According to one analysis, 25% of study conclusions were unsupported by statistical evidence [66]. Numerous biases can amplify positive results, whether by

Table 13.2 Biases impacting data interpretation in relationship to research hypothesis

Type of bias	Mechanism of bias
<i>Positive</i>	<i>Amplification of findings</i>
Confirmation bias	Selection and overweighting of supportive evidence
Orientation bias	Hypothesis shapes methods in a recursive manner
Wish bias	Distortion of subjective data due to “wishful thinking”
Optimism bias	Overstatement of pre-test probability
Plausibility bias	Overvaluation of mechanistic and/or pathophysiologic “plausibility”
<i>Negative</i>	<i>Suppression of findings</i>
Rescue bias	Discount contrary data as “outliers” or as “negligible”
Auxiliary hypothesis bias	Ad hoc modification of methods to rationalize contrary findings

approach to data processing, or by ultimate conclusion (Table 13.2) [67]; effects found in such studies are often inflated [68, 69]. Conversely, other biases describe the suppression of negative results (Table 13.2); in these cases, reasons may be found to declare findings “negligible” or “outliers” [67, 68].

Implementing Evidence

The final stage considers study dissemination and implementation [59]. As articulated by Glasziou and colleagues, “research publication can both communicate and miscommunicate”; they enumerate four key problems in research communication: missing, misleading, inconsistent, and misstated or misarticulated information [59].

The consequences of these four issues are far-reaching: successful publication does not presuppose successful generalization. In data made available by the pharmaceutical companies Amgen and Bayer, up to 89% of preclinical candidate molecules could not be validated [70, 71]. For molecules progressing beyond the bench, fewer than one-fifth succeeded in Phase II clinical trials in 2010 [72]. The top 10 selling prescription drugs in 2015 had a clinical response rate of less than 20% [73].

The Evidentiary Base in Clinical Research

Clinical research faces additional risks of compromise compared to biomedical research, due to factors including financial conflicts. Between 1994 and 2012, industry funding supporting biomedical research grew 26% (now accounting for 60% of total US research funding), while government funding shrank 13%; the proportion devoted to clinical research grew to 40% [74]. Concurrently, funding by private disease advocacy organizations (DAOs)—many of which are supported by industry—has increased 70% [74]. Compared with biomedical trials, clinical trials

were 138% more likely to have been privately funded, whereas they were 48% less likely to mention funding sources [75].

Moreover, any degree of “positive experience” with industry makes a significant impact on implicit attitudes toward study products [76]. Clinical trials funded by industry are 34–70% more likely to report positive findings than non-industry studies [77, 78].

Blemishes in individual studies diffuse upon uptake into clinical practice guidelines (CPGs). This form of impurity—compromise of CPGs directly influencing patient care—has been termed an “intellectual conflict of interest (COIs)” [79]. Up to 87% of CPG committees include members with industry COIs [79]. Additionally, 63% of organizations themselves disseminating CPGs are directly funded by industry [80]. Finally, 20% of organizations writing CPGs have no formal COI reporting procedures, and CPGs published by this cohort are 10% more likely to recommend for, and 24% less likely to recommend against, industry patented products [80].

Implications of Poor-Quality Research

The enormity of challenges in research have adverse consequences at both the individual and systemic level [81].

Informed consent (essential to “patient-centered medicine”) and non-maleficence (avoidance of harm) are pillars of ethical study on humans dating back to the Nuremberg trials [81]. However, research lapses conflating risk-benefit ratios violate this tenet: 86% of meta-analyses do not include full data on primary harm outcomes [82]. Further, individuals enrolled in redundant trials (due to incomplete literature review, nonspecific hypotheses, poor methodology, or underpowering) are exposed to unnecessary risks; both individuals receiving the intervention in cases of non-efficacy (with potential for avoidable adverse events), and those receiving the control in cases of efficacy (with potential for lost therapeutic benefit) [83].

This magnitude of morbidity suffered by patients in this manner has been isolated across multiple conditions: thrombolytic drugs demonstrated conclusive efficacy for myocardial infarction for over a decade before acceptance as standard of care [84, 85]; tranexamic acid illustrated significant resolution of surgical bleeding over a decade before its routine entry to clinical practice [86]; and up to 50,000 infants died from failure to implement evidence in prevention of sudden infant death syndrome available half a century earlier [87]. Analogously, failure in dissemination leads to direct effects on *future* patients: for example, the estimated 150,000 adults suffering myocardial infarctions after treatment with rofecoxib or the millions of children receiving vitamin A with deworming therapy (after evidence of their toxicity and inefficacy had been noted, but not published) [22].

At the systemic level, beneficence (the exhortation to “do good”) and justice (the mandate to do so equitably) form the final two principles in biomedical ethics. The capability of flawed research to squander systemic resources impacts the ability of

the medical community at large to adhere to these principles in terms of lost funds, manpower, and time. Weak studies waste research investment [88]; deplete “front-end” and the “back-end” staffing (while also diverting study patients) [89]; and exhaust minutes and months on cognitive and/or practical inefficiencies. This time scarcity is particularly acute for those most dependent on the fruits of research, such as patients with cancers or rare diseases [88].

Stewarding Evidence-Based Research

Reinforcement of high-quality clinical research must occur from the bottom-up. However, academic institutions are often resistant to change, decrying what may appear as “bureaucratic” measures for quality assurance [15]. Institutions also often identify “structural” factors out of their control as the cause of research lapses [15].

Yet, academic institutions employ an increasingly large share of influence on the nature, and direction, of research. 76% of investigators with an uninterrupted, continuous research presence are housed within academic centers [28]. A shift toward the expectation of rigor in bedside study is necessary: clinical departments within academic institutions are optimally placed to effect this manner of change, with ready access to the “micro” features of study. At the same time, they grasp strong influence over the “macro” incentives held by investigators [90].

Administering and rewarding high standards for research practice catalyze a virtuous cycle. Informed by clinical research frameworks, recommendations at each research stage offer new strategic tools coupled with existing research practice guidelines to foster achievement of these high standards [41, 49, 55, 90–108](Table 13.3). The formation of Departmental Review Boards (DRBs) can also formalize the commitment to research excellence by utilizing objective criteria prioritize studies and enforce best practices.

Strong methods decrease the amount of adjustment required to compensate for poor data. The probability of publication for studies with strong methods is higher, and published studies with heightened generalizability are likewise more impactful in the secondary literature [104, 109].

A unifying term for the recommendations above is *evidence-based research* (EBR). To the extent evidence-based medicine is tethered to research data for clinical decision-making, veracity symbolized by EBR should no longer be considered a perk solely associated with rigorously academic institutions.

Rather, an approach to research production by clinical departments—and to research consumption by clinical providers—guided by EBR is a necessity for the well-being of patients, capable of improving patient outcomes while conserving scarce human and financial resources. In other words, it is a prerequisite for high-quality patient care in an evidence-based and data-driven era.

Table 13.3 High-quality research practices at each stage in the study process

Stage	Quality criteria	Risk criteria	Tools	Mechanism	Guideline
Prioritization	(a) Systematic review? (b) Relevant to PI's interests? (c) Causes alteration of MGMT? (d) Disease/DALY burden (e) Future grant potential? (f) Future center-for-excellence potential?	(a) Completion likelihood (b) Redundancy (c) Irrelevant to clinicians? (d) Irrelevant to patients? (e) Resources (labor, infrastructure, funding) required	(1) Value of information (2) Involvement of librarians (3) Involvement of patients/patient advocates	(1) Calculate net present value at cost of capital (2) Thorough literature review informing redundancy and methods (3) Discovery of patient-side priorities	GRADE
Design	(a) Literature review (b) Design appropriateness (c) Power calculation (d) Pilot conducted? (e) Measurability of metrics? (f) Hypothesis clarity (g) Multi-institutional (h) Multi-departmental	(a) Effect-bias ratio (b) Effects on vulnerable populations? (c) Conflicts of interest: Outcome (d) Conflicts of interest: Financial	(1) Involvement of statisticians (2) Involvement of methodologists (3) Core outcome sets (4) Futility evaluation	(1) Power estimation and protocol refinement (2) Feasibility/pilot studies and question-appropriate design thinking (3) Ensure adequate, directly comparable information solicitation (4) Consider comparator and effect-to-bias ratio, regarding provability of primary endpoint	STARD, INVEST
Conduct	(a) Integration in clinic workflow (b) Enrollment pool adequacy (c) Enrollment rate adequacy (d) Requires follow-up by provider? (e) Requires follow-up by patient?	(a) Adverse event risk (b) Severe AE (SAE) risk (c) Dropout risk (d) Non-adherence risk (e) Protocol complexity (f) Metric bias susceptibility (g) Metric variability (h) Improvisation potential (i) Vibration of effects potential	(1) Trial registration reports (2) Protocol deviation (3) Central data feed (4) Progress reports (5) Blockchain integration	(1) Maintain accountability to protocol throughout study course (2) Document presence and details of variation from protocol (3) Data spot-checking and monitoring to ensure (i) internal validity (ii) salience to study question (4) Audit study progress on a routine basis (5) Consider future use, to facilitate transparency	STROBE, SPIRIT

Interpretation	(a) Publication potential (b) Secondary citability: Outcomes (c) Secondary citability: Audience breadth (d) Clear target journal(s) (e) Clear target audience(s) (f) Topic “heat”	(a) Ambiguity in discussion or conclusions (b) Backlash potential (c) Extent of “spin”	(1) Appointment of data referees (2) Involvement of design colleagues (3) Primary objective preregistration (4) Quantitative storytelling	(1) Use statistical scorekeeping to ensure integrity of interpretation (2) Improve data representation (3) Avoid “fishing” through data via post-hoc hypothesis formation (4) Resolve ambiguities in conclusions for concrete “key point” articulation	CONSORT
Generalization	(a) Overall generalizability (b) Risk-benefit ratio: Objective (morbidity/mortality) (c) Risk-benefit ratio: Subjective (symptoms/satisfaction) (d) Is the intervention scalable? (e) Is the intervention actionable? (f) Sample heterogeneity present? (g) Outcome directness (h) Comparator usefulness	(a) Exclusion criteria narrowness (b) Barriers to implementation: Cost-effectiveness (c) Barriers to implementation: Expertise (d) Barriers to implementation: Labor (e) Barriers to implementation: Infrastructure	(1) Clinical adoption estimation (2) Feasibility-Fidelity analysis (3) Introduction of standardized heterogeneity	(1) Attempt quantification at potential impact of findings to ensure clinical relevance adoption (2) Consider ability to replicate intervention protocol in vivo vs. requirement of modification (that may compromise effects) (3) Improve representativeness in order to increase generalizability	INQUIRE

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Devan Mehta, Ajay Kanakamedala, and Philipp Leucht

Introduction

The advents of anesthesia and antisepsis in the late nineteenth century allowed for lengthier and more complicated interventions, permitting surgeons to discover the immense benefits of using exogenous materials to treat fractures. In 1877, British Surgeon Joseph Lister employed silver wire to fix a transverse patella fracture [1]. In 1886, Carl Hansmann of Germany was the first to report plate osteosynthesis [2]. This formative time in surgical experimentation paved the way for decades of successful implant design and implementation. Today, modern orthopedic surgery would not exist without implants to stabilize fractures, augment bony healing, correct deformity, or even completely replace joint biology.

Along with the evolution of orthopedic implants, modern orthopedics has seen an explosion of the use of biologic therapies to improve musculoskeletal regeneration in a variety of orthopedic applications. An impressive variety of biologics is already implemented commonly in the form of various graft options, bone substitutes, cell-based therapies, and recombinant human growth factors. In the United States alone, over 500,000 bone grafting procedures are performed yearly, with this number easily more than doubling on a global scale [3–5]. As increased research funding is allocated to the development of such biologic therapies, the use of biologics in orthopedic surgery will become more prevalent [6].

There is no doubt that over the last few years, the adoption of certain implants and biologics has far outpaced the scientific evidence that actually supports their

Devan Mehta and Ajay Kanakamedala contributed equally with all other contributors.

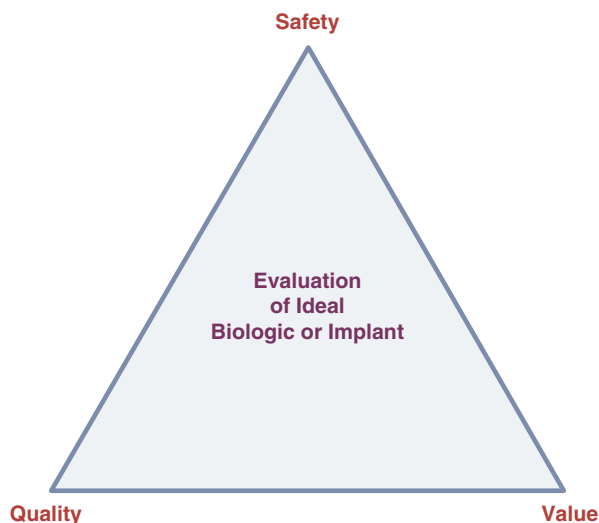
D. Mehta · A. Kanakamedala · P. Leucht (✉)

Department of Orthopedic Surgery, NYU Grossman School of Medicine—NYU Langone Orthopedic Hospital, New York, NY, USA

e-mail: Devan.Mehta@nyulangone.org; Ajay.Kanakamedala@nyulangone.org;

Philipp.Leucht@nyulangone.org

Fig. 14.1 Three vital points of assessment of biologic or implant



use. This tendency is likely due to the relatively high prevalence and debility associated with orthopedic conditions, the lack of satisfactory commonplace treatment options, and the widespread direct-to-consumer marketing of treatments that fall outside of conventional regulation [7]. As the population ages and our scientific knowledge continues to develop, orthopedic biologics and implants will continue to advance, allowing orthopedic surgeons to provide the most cutting-edge care for patients. However, this inevitable growth in technology means that the responsibility of patient safety will increasingly fall on the surgeon. In bioethical terms, patient safety can be broken broadly into two associated concepts: beneficence and non-maleficence [8]. Beneficence means that an intervention should be provided with the intent of doing good for the patient, after weighing the appropriate risks and benefits [9]. Non-maleficence means that a procedure should not harm the patient or others in society [10]. Orthopedic surgeons need to maximize these ideals of beneficence and non-maleficence by methodical critical evaluation of biologics, implants, and their uses. A complete evaluation of these augments involves the assessment of three categories: quality, safety, and value (Fig. 14.1).

Quality

A technology can be considered of high quality if it reasonably solves an existing problem or improves upon the shortcomings of a previous solution. For example, in joint arthroplasty, several studies have shown that highly cross-linked polyethylene liners are far more durable and wear-resistant when compared to conventional polyethylene [11–13]. In addition, the use of highly cross-linked liners significantly reduced rates of revision surgery for total hip and knee arthroplasty [13, 14]. Highly cross-linked polyethylene technology is of a definitively higher quality than

conventional polyethylene. A thorough assessment of quality for an implant or biologic involves an evaluation of the product's mechanism of function, method of implementation, and ultimate patient benefit.

Mechanism

When critically assessing a biologic or implant for quality, it is important to understand its function at the most theoretical level and how its use can be of benefit in practical circumstances. For instance, it is known at a clinical level that bone marrow-aspirate concentrate (BMAC) promotes bony union when utilized in patients with delayed union or non-union after fracture surgery [15]. However, in order to appreciate the full benefit of this biologic, a surgeon must understand that BMAC allows for a local, concentrated delivery of skeletal progenitor cells and potent growth factors which have osteogenic and osteoinductive properties [16]. Without this deeper knowledge, a surgeon may be compelled to utilize BMAC for a hypertrophic non-union, which would fail to address the patient's underlying issue of excessive motion at the fracture site rather than a lack of biology.

To further assess quality after understanding the mechanism of action of a biologic or implant, it is important to compare its basic function with that of available alternatives. This allows the surgeon to critically decide whether or not it fundamentally approaches a problem differently. In the 1950s, the dynamic hip screw (DHS) was invented to treat intertrochanteric (IT) hip fractures [17]. In 1988, the cephalomedullary nail (CMN) was invented [18, 19]. The CMN could also successfully stabilize IT hip fractures, but unlike the DHS, its use did not require a stable fracture pattern or a thick intact lateral femoral cortex [19]. This example shows how differing mechanisms of biologics or implants can solve the same problem and that surgeons should consider these differences when assessing quality.

Intended Indications and Actual Use

After understanding the function and basic biology of a biologic or implant, a surgeon must evaluate the device's potential uses, which can be divided into two categories: approved uses and off-label uses. When the Food and Drug Administration (FDA) approves a device for a certain application, that means it has conducted careful investigation into its risks and benefits for that use only. Off-label use, or physician-directed use, means that although a biologic or a device is approved for one specific circumstance, it can be used for another application that has not been studied as extensively or rigorously [20]. When using a product off-label, the surgeon, not the manufacturer, assumes all liability. Platelet-rich plasma (PRP) is a prime example of a biologic with multiple uses. It is FDA approved as a material to mix with bone graft to make it easier to handle or to keep wounds moist [6]. However, as surgeons begin to understand the underlying mechanism of PRP through basic science and smaller scale trials, the majority of uses have become

off-label [21]. These include injections for accelerating tendinous and ligamentous healing and alleviating the symptoms of osteoarthritis [6].

If surgeons do elect to use a product for an indication that is not approved, its use must always be within the authorized practice of medicine and in the best interest of the patient. In such cases, surgeons must assume the professional and ethical responsibility to be well informed about the product, to base its use on scientific rationale and sound medical evidence, and to maintain awareness of the product's use and effects. The existing fund of knowledge about available biologics and implants is always growing, so it is vital for surgeons to be familiar with current literature. In addition, surgeons intending to use a product off-label should make it a priority to appropriately counsel their patients about the benefits and risks of the proposed treatment, and of the alternative treatments that might be available [20].

Efficacy

Efficacy is the ability of an implant or biologic to produce its desired or intended result. For example, it has been shown that BMAC injected percutaneously in cases of delayed or non-union after open reduction and internal fixation resulted in clinical and radiologic union in 95% of cases [22]. Without delving deeply into patient conditions and study designs, one can reasonably conclude that BMAC is efficacious for treating delayed unions and non-unions.

Although a solution may seem mechanistically sound in a given application, actual efficacy outcomes can fall short of expectations. One such example is that of bone morphogenetic protein 7 (BMP-7). BMPs are cytokines that have been shown to promote osteogenesis and aid in spine fusion [23]. In the late 1990s and early 2000s, several animal models showed significantly increased rates of successful fusion when BMP-7 was utilized [24, 25]. These early studies paved the way for conditional FDA approval for rhBMP-7 in 2004 for posterior lumbar fusions. However, when a large, prospective randomized controlled trial was performed, the data showed that patients treated with rhBMP-7 actually had significantly less bone formation when compared to autograft alone [26]. This led to the ultimate FDA rejection of rhBMP-7 [27]. The initial optimism and ultimate failure of this biologic in the clinical setting highlight the necessity of a culture of continuous scrutiny and improvement. Apart from basic science and biomechanics research, well-designed randomized controlled trials with long-term follow-up of patients are the best measures of device efficacy and patient safety. If an inefficacious product is used, the procedure itself can be considered as a patient harm event.

Safety

According to the FDA, an implant or biologic can be considered safe if it can be determined, based on scientific evidence, that the probable benefits to health from the use of the device for its intended use outweigh any probable risks [28]. The goal

is to maximize beneficence and minimize maleficence and patient harm. However, for the practicing surgeon, an assurance of safety from the FDA is not enough. In addition to weighing the risks against benefits of use, safety conscious providers who intend to implement devices should reflect on personal ability and limitations, develop patient-centered plans, and continually promote new outcomes data.

Assessing Risks and Benefits

A complete safety evaluation for a biologic or implant starts with an analysis of the risks and the benefits. Risks can be defined as the likelihood of certain adverse events arising which may include, but are not limited to, infection, device failure, damage to local tissues, need for device removal, allergic reaction, and disability. In order to fully develop a risk profile, these complications must be stratified according to probability of occurrence in specific patient populations. For example, when utilizing a musculoskeletal allograft, the risk of transmission of HIV is reported to be 1 out of 1.6 million cases, while the risk of bacterial infection is significantly greater with rates of 0.5–10% reported in the literature [29–31]. However, diabetes and smoking are correlated with increased infection rates [32]. Therefore, when stratifying infection risk for musculoskeletal allograft use, a diabetic smoker is at a higher risk of bacterial infection than a young, healthy patient, and both patient populations are at low risk of HIV transmission.

Benefits can be defined as the many reasons that the use of a biologic or implant can improve a patient's health and lifestyle. Benefits can be divided into obvious medical benefits and personal patient-centered benefits. Obvious medical benefits include reasons such as limb preservation, improvement of extremity function, alleviation of pain, prevention of future interventions, or treatment of infection. Personal patient-centered benefits are less quantifiable and relate to a patient's specific social circumstances. These include patient perceived improvements in traits such as happiness, confidence, and acceptance. For instance, a teenage girl with severe spinal deformity who undergoes instrumented fusion benefits from the implants medically because they improve her spinal alignment, but also emotionally because she gains confidence and feels she "fits in" better with her peer group.

Surgeon Self-Reflection

Once the risks and benefits of biologic or implant use have been fully evaluated, the next step in safety comes from self-reflection by the surgeon. If a surgeon understands how to conceptually utilize a device, the subsequent question he or she should ask is: Am I comfortable to safely and effectively use this in my patients for a given indication? Surgeons should be comfortable assessing their own strengths and limitations and be prepared to ask for help if needed. Expansion of this topic is outside the scope of this chapter, but a true analysis of safety would be incomplete without mentioning the importance of self-evaluation.

Developing a Patient-Centered Plan

After a surgeon has concluded that the benefits of using a biologic or implant outweigh the risks and that he or she can safely use the device, a patient specific plan must be formulated. This plan should address the following vital points in a sequential manner: preparation, utilization, follow-up, and surveillance.

First is preparation. This involves making sure that the patient is optimized for treatment and that the biologic or implant is optimized for the patient. If the surgeon needs to obtain specific clearances, tests, or imaging studies, this needs to be implemented early in the preparation process. In most cases, the surgeon will also need to communicate with the device manufacturer or distributor to ensure that the proper equipment will be present during the actual procedure.

Second is planning for utilization, which not only entails understanding exactly how the device will be administered in a specific patient, but also anticipates how to compensate for any unexpected complications. It outlines precisely when and how the device will be used and also determines exactly who will be involved in the procedure.

Third is planning for patient follow-up. After a biologic or implant has been utilized, a surgeon needs to decide, based on the mechanism of the device used, how often the patient needs to be seen initially and evaluated. For example, if a patient is being treated with a ring external fixator for distraction osteogenesis, then the patient will require strut adjustments and needs to be seen frequently [33]. On the contrary, if a patient receives a PRP injection in the clinic for chronic knee osteoarthritis, then it would be acceptable to evaluate the patient only a few times a year after an early follow-up. During these follow-up evaluations, the surgeon should also be aware of the possible complications associated with the device or biologic and know how to treat them.

Fourth is surveillance. This is extremely important for patient safety, especially in the context of biologic use. This means deciding how long to follow a patient, after the patient has maximally benefitted from the biologic or implant, in order to monitor for adverse events or device failure. Surveillance is also dependent upon the type of implant or biologic used. A patient with a successful total shoulder arthroplasty would benefit from annual or biennial evaluations and radiographs to assess for implant integrity. However, a patient who received a BMAC injection for osteoarthritis would be less likely to need any long-term surveillance.

Evaluating Outcomes and Promoting a Culture of Scrutiny

In order to evaluate safety and safely utilize biologics and implants, orthopedic surgeons must continuously be up to date with the literature. Safety is the most commonly determined by patient outcomes data from large randomized controlled trials which are peer-reviewed and published. Even if a technology may initially seem

safe when used in patients, long-term investigation may prove otherwise. The metal on metal (MoM) hip arthroplasty is a prime example of how long-term investigation uncovered the underlying dangers of a MoM articulation. MoM hips were introduced in the late 1990s with the aim of improving outcomes in young patients with hip arthritis. However, these devices experienced high short-term failure due to metallosis and implant failure due to osteolysis. Eventually, these findings were confirmed in large trial and database studies and the FDA began recalling MoM implants in 2010 [34].

As a result, when it comes to continually improving implants and biologic safety, orthopedic surgeons should continue to promote a culture of long-term scrutiny. There must be sustained research pertaining to the physical and chemical characteristics of these devices from a basic science and biomechanical level. The use of identified individual implants and biologics should be tracked in large databases that are available for study. The orthopedic community must use appropriate, standardized, and validated technologies for detecting and defining outcomes. In addition, there should be a push toward ensuring good, sound, experimental design for future studies [35]. These considerations will lead to more effective safety evaluation of the technologies orthopedic surgeons use to treat patients.

Value

The third category to assess when evaluating biologics and implants is value. In healthcare, value can be defined as the health outcomes achieved per dollar spent. In many cases, value is an important consideration because medical practice and research does not take place in a cost-agnostic vacuum [36]. The decisions of the surgeon to use a certain biologic or implant can have financial implications for the patient, the overall system, or both. A lengthy discussion is outside the scope of this chapter, but it is important to recognize that when it comes to safety evaluation and research, institutions are fiscally incentivized to study technologies of high value or to improve the perceived value of promising innovations.

Conclusion

As the field of orthopedic surgery continues to evolve, increasingly more technological advances in biologics and implants will be introduced, allowing for modern and improved patient care. Therefore, a complete evaluation of device quality, safety, and value is vital to ensure that a surgeon is providing the most patient safety centered care. The deeper understanding of these technologies allows for clear and effective communication with patients who ultimately bear the positive and negative consequences of these biologics and implants.

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The Cyclical Process of Medical Device Realization: Development, Implementation, and Quality Control

15

Peter F. Armstrong and Bryan Snyder

Orthopedic surgeons have the incredible responsibility and privilege of caring for patients, both young and old, afflicted with a myriad of musculoskeletal (MSK) diseases and skeletal deformities acquired congenitally, developmentally, and/or traumatically. Implants, devices, and instruments that are used to treat these afflictions should improve MSK function safely and effectively.

The cyclical process required to realize a medical device from conceptualization to engineering design, through implementation, manufacture, quality control, and preventing/mitigating failures will be outlined (Fig. 15.1). This paradigm is highly complex with multiple permutations and combinations beyond the scope of this chapter; however, we present an overview of the fundamentals.

The orthopedic device industry is held accountable to comply with both national and international rules and regulations designed to ensure safe, high-quality devices for use (Fig. 15.2). The lifecycle of a device is based on ensuring patient safety, with mandatory quality assessments and controls implemented at all phases of device development based on a risk management paradigm in which the types and severities of patient risk are defined throughout the product lifecycle.

P. F. Armstrong (✉)
OrthoPediatrics Corp, Warsaw, IN, USA
e-mail: parmstrong@orthopediatrics.com

B. Snyder
Orthopaedic Surgery, Harvard Medical School, Cerebral Palsy Center, Boston Children's Hospital, Boston, MA, USA
e-mail: brian.snyder@childrens.harvard.edu

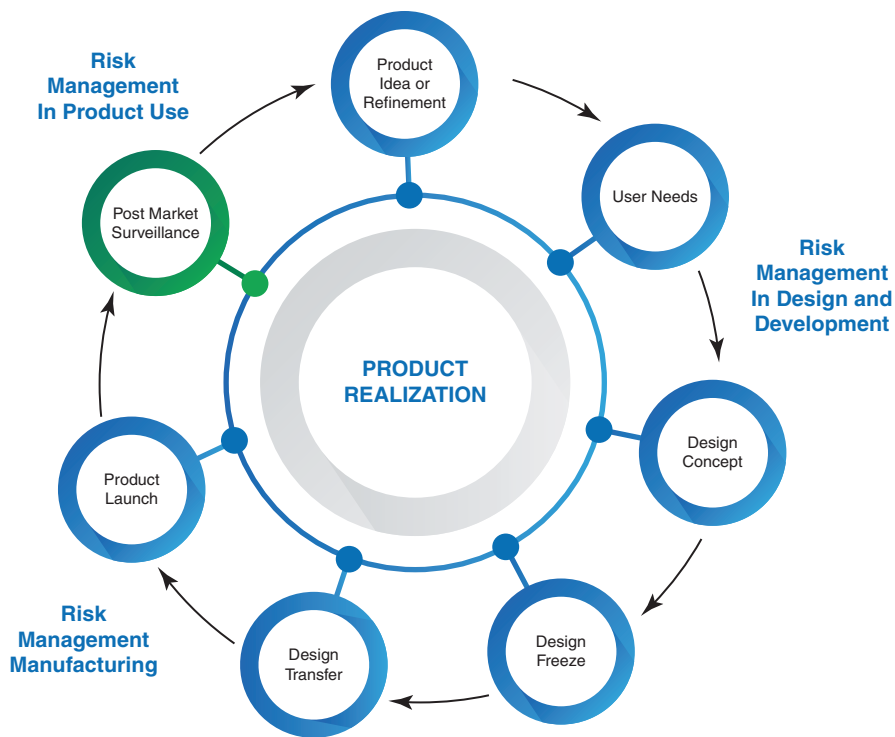


Fig. 15.1 Product realization: a cyclical process

United States Code of Federal Regulations

Title 21 – Food and Drugs

Part 803 Medical Device Reporting

Part 820 – Quality System Regulation

Manufacturers must implement a quality system

Internationally

Medical Device Single Audit Program (MDSAP)

European Union Medical Device Regulation (EUMDR)

International Organization for Standardization

ISO 13485:2016-Medical devices -- Quality management systems -- Requirements for regulatory purposes

References ISO 14971:2019 – Application of Risk Management to Medical Devices

Fig. 15.2 Key regulations and standards governing the medical device industry

Design/Development

Paradigm for Evaluation

The engineering team specifies inputs requisite to the design concept and desired characteristics to meet user needs, with a focus on function and performance. Objective outputs that validate fulfillment of these requirements are identified.

- **Indication:** *What is the clinical problem being addressed? Who is the intended patient population?* Identify unique considerations in the intended patient population such as children and the elderly including pathoanatomy, pathophysiology, and duration of use. Multiple sizes of a device may be required to accommodate children and adults over a wide range of heights and weights, which can change over time with growth. Performance goals change with age that reflect evolving physical activity demands in the same patient over time. Devices may need to serve dual functions for an indeterminate number of years without failing, including obtaining and maintaining correction of MSK deformity, while predictably modulating skeletal growth or accommodating changes in the functional performance of the axial and/or appendicular skeleton. In the elderly, poor bone quality and associated medical co-morbidities can affect surgical technique, stability of device implantation, risk of wound complications (infection, wound healing), and effectiveness of treatment.
- **Mechanism:** *What is the design concept? What are intended benefits and associated risks?* Elucidate the scientific and engineering principles that support the device being safe and effective in treating a specific MSK problem. Design variables such as the material properties and structural geometry of the device are controlled by manufacturer, but the pathoanatomy, integrity of the implant–tissue interface (bone, cartilage, tendon, ligament, and/or muscle), and applied loading “dose” (mode, magnitude, and number of cycles) are “controlled” by the patient. In particular, bone “quality” critically affects implant stability.
- **Outcomes:** *Does the device perform its intended function? Is the new device better (efficacy), safer (fewer complications), faster, and/or cheaper than current devices?* A logical hierarchical sequence of validation experiments that prove both the safety and efficacy of the device must be executed, starting with simplified bench top simulations, evolving to ex-vivo cadaver models that emulate the pathoanatomy being treated. For de novo devices and applications, in-vivo animal models that mimic the pathophysiology being addressed may be required to evaluate both intended (efficacy) vs. unintended side effects (safety). Success and failure criteria must unambiguously be specified a priori in preclinical experiments and clinical follow-up studies using objective clinician and patient-reported outcomes as well as comparative effectiveness metrics relative to current devices and treatments.

Implementation

Precise engineering documents are generated for manufacturing the device as well as stipulating critical attributes related to its implementation and use including labeling (indications), surgical technique, and packaging. An initial assessment is performed using internal and external sources to identify risks related to producing the device, severity, and estimated occurrence rates.

Identifying Risk

- *External Sources:* A thorough review of the literature is conducted to identify if there is a published record of hazards associated with the use of similar devices. The Manufacturer and User Facility Device Experience (MAUDE) database is interrogated to reveal adverse event medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters (health care professionals, patients, and consumers) with the use of similar devices.
- *Internal Sources:* Examine post-market surveillance data collected from the use of similar products and previous versions of the product to identify defects and/or difficulties associated with precedents.
- *Design Failure Mode & Effect Analysis (DFMEA):* Analyze hazards and failure modes introduced by a new or modified design, ranking the danger/severity of potential flaws. Risks are addressed hierarchically: flaws in design, implementation, manufacturing, product use. The etiology of high probability malfunctions is investigated; tests to confirm suspected mechanisms of failure carried out and identified defects corrected. Through Risk Priority Number (RPN), the DFMEA chronicles improvements by comparing the RPN before and after implemented changes in the design, manufacture, or use of a device. (Quality One International <https://quality-one.com/dfmea/>).

Design Validation

Prototypes are made using technologies such as 3D printing to physically model various iterations of the device so that the design team and users can evaluate form, function, and fulfillment of requisite inputs. The best candidate versions of the device are manufactured for inspection and mechanical testing to validate that the device satisfies all specified inputs and outputs, including user requirements and those mandated by regulatory bodies. Importantly, provocative mechanical testing of the device subjected to extreme working conditions is conducted to confirm safety and prevent unforeseen failure.

Design Review

At planned intervals, the design is reviewed to ensure that development activities are completed according to plan and that the device meets user requirements. Simulations using sawbones, cadavers, and in vivo animal labs are performed so that users can provide feedback to the design team on how the product performed in real time.

Design Transfer

After completion of all reviews validating attainment of stipulated inputs and outputs (efficacy) and investigation of hazards and failure modes (safety), the design is transferred to the manufacturer.

Manufacturing

A manufacturing process control plan (MPC) is generated, and a process failure mode effects analysis (PFMEA) is instituted to estimate the risk that the manufacturing process will create a product that does not meet user and/or regulatory specifications. Based on the PFMEA, the MPC incorporates all the inspections and product testing required to achieve in-process quality control through all phases of manufacturing. In a product portfolio, there can be hundreds of part numbers with thousands of product attributes. Risk estimation is used to separate low risk attributes (e.g., mallet handle) from high-risk attributes (e.g., screw to plate interface). The PFMEA determines the extent and veracity of inspections and process validations throughout the stages of the manufacturing procedure. *Installation qualification* confirms that manufacturing equipment was correctly installed and that established maintenance/calibration schedules were followed. *Operational Qualification* institutes the range of settings used in producing the device. Some processes cannot be verified thru visual inspection without damaging the product (e.g., sterilization, welding, and packaging), thus destructive testing is required to substantiate product quality. Certifying tests must be performed using a sufficient sample size to confirm with high probability that the device meets all quality control conditions mandated by regulators.

Regulatory Approval

Prior to marketing the device, regulatory approvals must be obtained (Table 15.1). The US and the EU are two of the most demanding regulatory environments. FDA regulation of devices was motivated by patient safety concerns (The Medical Device Regulation Act or Medical Device Amendments of 1976). Novel devices that have no predicate (i.e., device used before 1976) are automatically classified as class III, i.e., high-risk devices that require stringent safety and efficacy data for FDA approval unless proven to be substantially equivalent to a similar device with an established record of safety and efficacy for the labeled indication (510 k). Class III devices require premarket authorization (PMA), which necessitates an investigational new device (IND) application and the performance of safety and clinical effectiveness trials that compare the new (or repurposed) device to the current standard of care and/or natural history of the untreated disease entity. These prospective clinical trials can cost millions of dollars and require years to complete. In the EU, an entity called a notified body (company that regulates device approval and grants Conformité Européenne mark allowing a device to be marketed in EU countries)

Table 15.1 FDA approval pathways

Premarket notification (510(k)/PMN)	Expedited process allowing a device to enter the market within 90 days of application if it is similar to an approved device
Premarket approval (PMA)	Truly novel devices—No similar product exists on the market. Device may pose a significant risk to the patient. Requires rigorous pre-approval evaluation <i>Traditional PMA</i> —Submit package showing safety and efficacy <i>Modular PMA</i> —Submit parts of PMA package as they become available <i>Streamlined PMA</i> —Use previous reviews of similar products approved by FDA to assess device when submitting PMA <i>Product development process</i> —FDA works with device company to assure that ex vivo testing protocols and in vivo IDE trials address FDA requirements and/or specific concerns. FDA highlights steps necessary for product approval; final approval is contingent upon completion of these steps
Humanitarian device exemption (HDE)	Conditions with an incidence of <4000 patients/year. Must demonstrate <i>probable</i> clinical benefit
Investigational device exemption (IDE)	For novel or off-label use of devices deemed to pose significant risk. Requires IRB approval for patient use

contracts with device companies to review technical documentation generated during the design, development, and manufacturing of the device to determine whether associated risks have been sufficiently mitigated and EUMDR¹ requirements met. The notified body within the approving country determines these specific requirements. Class IIb (most orthopedic devices) and class III require submission to notified body. Submissions include clinical and preclinical evidence supporting device safety and efficacy that includes review of clinical studies typically nonrandomized single-arm case series with historic control subjects.

Establishing Safety: *Is the proposed device safe to use in a healthy person? Is the proposed device safe to use in population affected by malady of intended application?* Requires rigorous testing of device. Bench tests conducted according to standardized test protocols (ASTM or ISO) to evaluate device performance in controlled systems and/or environments biomimetic to clinical applications. Ex vivo cadaver studies and in vivo animal models MUST represent the pathoanatomy and pathophysiology being treated to reflect how the device will function in vivo. For example, discontinuities and abrupt changes in geometry or material stiffness induce localized stress peaks in the structure that predispose fatigue failure and mechanical couplings are prone to crevice corrosion. Analyses should include material, chemical, and mechanical properties (stiffness, strength, viscoelasticity, wear, and fatigue), biocompatibility (toxicity), electromagnetic compatibility, sterility, and shelf life stability. For new innovative devices (e.g., hybrid products that

¹As of the date of this writing, the Medical Device Directive (MDD) remains as the governing regulation in the EU. However, it is expected that the new regulation (EUMDR) will go into effect in May 2021, thereby replacing the MDD.

combine biologics or drug delivery systems with conventional implants), standardized test protocols and established performance criteria may not exist.

Establishing Efficacy: *Substantiate claims and indications for use.* Necessitates specification of defined objective performance criteria for each device a priori for preclinical and clinical evaluations. Analyses predicated on establishing objective clinical outcomes that define success/failure of these devices to *predictably* alter disease trajectory over specified time interval to achieve desired clinical effect: reducing pain, correcting skeletal deformity, improving function and/or QOL (patient + family/caregivers). Besides in vivo animal models of disease, clinical studies are often required to assess risk vs. benefit (Fig. 15.3). Most clinical outcome studies for orthopedic devices are retrospective (level 3 evidence or below). Multi-center, multi-practitioner study groups compensate for lack of power related to small patient cohorts with variable consistency. Combining Level 3 + 4 studies and performing meta-analysis improves “power” but cannot control for bias and poor experimental design of aggregated studies with inconsistent inclusion/exclusion criteria, duration patient follow-up, and non-uniform assessment of clinical, radiographic, and patient specific outcome parameters. Since randomized control studies are expensive, time consuming, and with many patients refusing “randomization” to placebo control group, there is increasing reliance on historical controls, using published natural history studies of untreated disease as endpoints to show

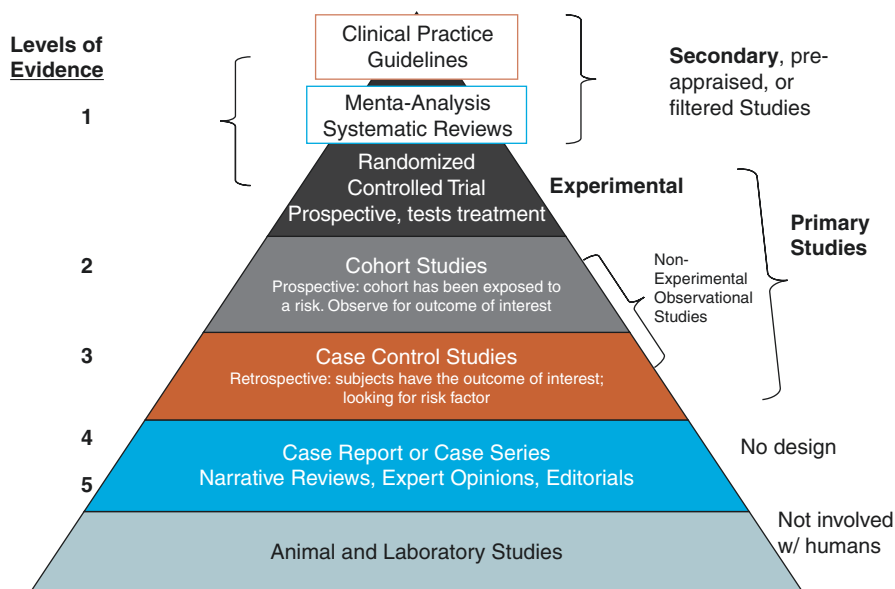


Fig. 15.3 Hierarchy of Study Types and Levels of Clinical Evidence. Levels of evidence are arranged in a ranking system used in evidence-based practices to describe the strength of the results measured in a clinical trial or research study. The design of the study and the endpoints measured affect the strength of the evidence. 2016 Modified Evidence Pyramid. SUNY Downstate Medical Center, Medical Research Library at Brooklyn

effectiveness. Recently, the FDA has supported the use of Real World Data and Real Word Evidence as a robust, cost efficient means to evaluate device safety and efficacy. Clinical data collected during routine care of patients can be leveraged to demonstrate reasonable assurance of safety and effectiveness in de novo request, HDE and premarket approval application, as long as patient selection maximizes representation of affected population, minimizes bias and data elements (including complications), and are collected in a standardized manner. Part of CDRH's strategic priorities is the enhanced role of patients' perspective in the regulatory process.

“Off Label” Use: *Application that deviates from approved use described on product label.* FDA does not regulate practice of medicine. Physicians may use medical products by any means they believe to be in the best interest of their patients, as long as the *presumed therapeutic benefits outweigh the risks*. The AMA policy on “off label” use is “*based on sound scientific evidence and sound scientific opinion.*” However, there are few studies that establish the safety and efficacy of the “*physician directed*” use of a product. Most studies are retrospective case series (level 4 studies) plagued by small numbers of patients, and inconsistent surgical technique, device application, and clinical follow-up. For small “niche” markets, device manufacturers are reluctant to perform expensive safety and efficacy studies to evaluate new applications for devices previously approved for unrelated indications. Liability escalates when using a device for an off-label indication, with physicians assuming the risk. Insurance coverage for off-label device use is not assured and is often denied by insurance carriers. Currently, there is no direct pathway to evaluate *physician directed* use of an existing device for a new application. An IDE is required to conduct prospective controlled studies to evaluate the new “off-label” use of a medical device and IRBs will NOT allow human studies to be conducted that uses a device for an “off-label” indication.

Post-Market Surveillance

Monitor Manufacturing Process for Conformance

- Audit—Proactive
 - Non-conformance
 - Corrective and preventive action (CAPA)

Post-market Surveillance—Reactive and proactive

- Surveys, Post-market clinical follow-up, MAUDE, complaints

After the product is manufactured and launched for use, the FDA mandates post-market surveillance to continually evaluate product performance. Device manufacturers are mandated to report product flaws; post-market surveillance data inform the Corrective Action/Preventive Action (CAPA) process. However, since this reporting system is voluntary for healthcare providers and consumers, adverse events are substantially underreported.

When a Device “Fails”

A 1986 General Accounting Office study showed that hospitals reported <1% of problems with medical devices; the more serious the problem, the less likely it was to be reported. In response to this finding, the following provisions were enacted:

1. The Safe Medical Devices Act of 1990 imposed significant new reporting requirements on the medical device industry and users of medical devices.
2. The final Medical Device Reporting (MDR) rule was published in December 11, 1995. (Federal Register).

Reporting

Device Company

When a device company receives a complaint, it must be carefully reviewed to determine if a *reportable* adverse event occurred. Very strict reporting timelines apply. All this information must be transparent to FDA and the public. Events that must be reported to the FDA:

1. Deaths, serious injuries, and malfunctions (within 30 days of becoming aware).
2. Event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to public health (within 5 days of becoming aware).

Device companies also have the option of utilizing the Voluntary Malfunction Summary Report Program where device malfunctions are reported in summary form on a quarterly basis in MDRs. Separate summary reports are required for each unique combination of brand name, device model, and problem code.

User Facility

Hospitals and surgical care centers must report a suspected medical device-related death to both the FDA and the manufacturer. Serious medical device-related injuries must also be reported to the manufacturer. While these facilities are not required to report a device malfunction, the FDA encourages health care professionals, patients, caregivers, and consumers to submit voluntary reports of significant adverse events or product problems to MedWatch (Form FDA 3500).

Complaint Investigation

Once the determination has been made that an event is reportable, investigation of the root cause for the device “failure” is pursued. It is critically important that the company have all relevant information necessary to conduct a thorough forensic analysis:

- Patient Details
 - (a) Age
 - (b) Weight

- (c) Underlying condition
- (d) Compliance with health care provider instructions
- Surgery Details
 - (a) Technique
 - (b) Size of implant
 - (c) X-rays
 - At time of insertion
 - When failure identified
 - Following revision
 - (d) Direct discussion with surgeon (Company Chief Medical Officer)
- Product Details
 - (a) Catalog number
 - (b) Lot number
 - (c) If possible, return of implant

The root cause of device failures can be many, but generally fall into the following categories:

1. Design
2. Manufacture
3. Incorrect use (Surgeon error)
 - (a) Failed to follow manufacturer's endorsed surgical technique
 - (b) Damage to the device at time of implant
 - (c) Wrong product size, etc.
4. Failure at tissue-implant interface
 - (a) Mechanics: failure to establish sufficient mechanical stability of construct coupled to bone or target tissues necessary to facilitate biological processes for healing
 - (b) Biology: failure as a consequence of metabolic bone disease (osteomalacia, osteoporosis, etc.), poor vascularity (smoking, diabetes), infection, neoplasm (benign and malignant)
5. Patient non-compliance
6. Accident
7. Unknown

It is the company's primary responsibility to determine whether there is anything in the design (category 1) and/or manufacture (category 2) of the device that contributed to its "failure." This analysis includes a thorough review of the design and manufacturing documentation to establish that all engineering specifications were met at all phases of production. When the issue is a broken implant, the returned device is analyzed by a metallurgist to critically determine material (i.e., fatigue, crevice corrosion) and/or structural factors (i.e., inappropriate mechanical coupling) that may have contributed to its failure. These analyses may necessitate further mechanical testing to ensure that the device can withstand the applied loads and

biological milieu in which it must function for a particular clinical situation. If it is determined that the root cause requires more intensive investigation to define and correct a design or manufacturing flaw, a Corrective and Preventive Actions (CAPA) is opened, the purpose of which is to collect sufficient information for a detailed forensic analysis. After investigating the product and detecting specific problems, a remedial action plan is initiated to mitigate the problems and prevent recurrence. The CAPA subsystem is fundamental to quality assurance, communicating to responsible individuals essential to effectively dealing with product malfunctions by providing relevant information for management review, verifying/validating corrective actions, and documenting remedial activities to prevent recurrence of a device failure. If it is ascertained that there was an error in manufacturing, it is critical to establish how many lots the manufacturing error impacted. To the best of its ability, the company must identify the location of each of the defective devices and whether the device was implanted. A Health Hazard Evaluation (HHE) is performed to determine the risk of continued use of the device by patients. If it is resolved that there is a significant risk, a field action of a limited recall of affected lots is initiated, and the recalled (non-implanted) devices replaced with non-defective devices. If the root cause is a design flaw that affects all identical devices manufactured to that point in time, an HHE is conducted to define the risk of continued use of the product and to conclude whether a field action, including a recall, is appropriate to reduce continued exposure to patients.

Category 3 issues can be addressed by improving opportunities for surgeon education. While the company has no control over categories 4–7, anticipated patient-related problems may be mitigated by optimizing biology to facilitate tissue healing by advocating supplementary treatment with appropriate pharmaceuticals and optimizing mechanics by providing surgeons with an array of implants sizes, shapes, and anchors to improve the structural stability of constructs.

Conclusion

All stakeholders, patients, physicians, researchers, and device manufacturers must be active in realizing the cyclical process required to develop a medical device from conceptualization to engineering design, through implementation, manufacture, and quality control. The safe and ethical practice of medicine requires that physicians and surgeons foster meaningful relationships with the device industry and the FDA to establish appropriate guidelines for the development and evaluation of innovative devices that satisfy the needs of underserved patient populations, particularly children, and to disseminate information regarding the safety and efficacy of products currently in use and in further need of development to ameliorate musculoskeletal pathology. Physicians and surgeons need to balance their moral obligation to provide patients the best possible treatments with respect for FDA regulations and guidelines to ensure patient safety.

Suggested Reading

CE Marking. https://ec.europa.eu/growth/single-market/ce-marking_en

Code of Federal Regulations Title 21. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

Corrective and Preventive Actions. <https://www.fda.gov/corrective-and-preventive-actions-cap>

ISO 13485—Medical devices—ISO. <https://www.iso.org/iso-13485-medical-devices>

ISO 13485:2016—Medical Devices Quality Management Systems. <https://www.iso.org/standard/59752.html>

ISO 14971:2019—Application of Risk Management to Medical Devices. <https://www.iso.org/standard/72704.html>

MAUDE—Manufacturer & User Facility Device Experience. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Medical Device Reporting (MDR): How to Report Medical Device Problems. <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>

Medical Device Reporting for User Facilities. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-user-facilities>

Medical Device Single Audit Program (MDSAP) | FDA. <https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap>

Overview of Device Regulations. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>

The European Medical Device Regulation of 2017. <https://www.eumdr.com>



Karl Koenig and Benjamin J. Kopp

Introduction

Case Example: A 34-year-old patient presents to clinic with a displaced, minimally comminuted bimalleolar ankle fracture and is scheduled for surgery the following day. The surgeon considers her options for potential implants. A pre-contoured locking plate for the lateral malleolus? Perhaps, but she decides intraoperatively that the patient's bone quality will allow adequate fixation with a non-locking plate. For the medial malleolus, she elects to use two non-cannulated screws. Despite these seemingly minor decisions, her selected construct resulted in charges which were about \$1000, or 70% less than if she had utilized a pre-contoured locking plate and cannulated screws [1]. The financial impact of decisions like these can have a dramatic impact on healthcare expenditures over time and illuminate the dramatic impact that orthopedic surgeons can have on the costs of care.

Annual healthcare spending in the United States has reached over \$3 trillion and continues to rise [2]. Although large portions of the budget originate from administrative burden and inefficiencies of the system, choices about musculoskeletal care have an enormous impact. Decisions about operative indications, implant selection, and effectively avoiding costly complications occur on a daily basis and can be a large driver of healthcare spending. It is important for surgeons to understand and appreciate this impact in order to maximize the value of their care.

K. Koenig (✉) · B. J. Kopp

Division of Orthopaedic Surgery, Department of Surgery and Perioperative Care, Dell Medical School, Austin, TX, USA

e-mail: karl.koenig@austin.utexas.edu; bjkopp@ascension.org

Cost

The definition and measurement of cost in healthcare are complicated by the additional stakeholders and pricing opacity between hospitals, payers, and equipment/technology suppliers. For healthcare providers, costs are usually considered to be the expenses incurred to provide healthcare service. For payers and patients, it is the amount they must pay to the provider, or from the patient perspective, it is the combined out of pocket costs to provider and payer [3]. For the purpose of this chapter, cost will primarily be discussed from the perspective of the provider as this is more reflective of the actual cost to provide services to the patient.

In any conversation about cost in healthcare, it is important to distinguish between costs and charges. Whereas costs are the actual expenses incurred to provide a healthcare service, the charge is the amount that the provider asks from payers and patients in exchange for the service. Reimbursement is then defined as the amount a patient or payer negotiates as payment for the service, which is usually much less than the charge. Although there is a presumed direct relationship between higher costs and higher charges, it is important to note that charges for a service may be significantly higher than the actual cost for multiple reasons. Some providers may charge more for services in order to help offset the cost of providing charity care, community outreach, or other services which are poorly reimbursed. Providers may also charge more in order to yield higher reimbursement rates from deeply discounted contracts with some patients and payers. This practice widens the divide between charges and the actual cost of providing services. These mechanisms to obtain higher reimbursement rates from commercial payors are often justified by hospitals and providers by the need to offset losses from uninsured patients, or those covered under government contracts such as Medicare or Medicaid which often reimburse at rates below the actual cost of care.

Another reason that providers may charge more than the cost of the service stems from a lack of thorough understanding of the actual costs of the service they provide, and therefore must rely on estimates and historical reimbursements for similar services. This method is utilized under the assumption that reimbursement rates reflect the intensity of the service provided and indirect costs for services are distributed evenly among services, which is very unlikely to be the case [4]. Indirect costs are those which are not directly and completely attributable to the specific service being evaluated but are necessary for the completion of a service. These include items such as building maintenance, reusable medical equipment, and staff whose work involves multiple services.

In order to better understand the actual cost of a service, one method which has emerged is time-driven activity-based costing, or TDABC. On its surface, it is a relatively simple concept, requiring only the quantity of time and cost per unit of time for each input to provide a service throughout the entire episode of care [5]. First, the medical condition and treatment episode is defined. Then a process map is created which documents the locations and time of each resource involved along with direct costs of treatment. Equipment costs are calculated by dividing annual operating costs, maintenance, and depreciation by the number of minutes it is available for use. Employee costs are calculated using the total annual compensation

divided by the number of minutes they are available for clinical care. These cost calculations are then combined with thorough observations of time spent at each point in the process to produce a total cost for the service. The final process map exposes high cost steps, underutilized capacity, and rate limiting steps which can be adjusted to increase efficiency and decrease total costs. This method has been utilized effectively to decrease costs throughout the treatment of pediatric patients with distal radius fractures [6] and adults undergoing total joint arthroplasty [4].

Even for seemingly straight-forward direct costs such as commonly used orthopedic implants, there remains room for improvement with regard to price transparency and cost reduction. For example, a 2018 study investigated the perception of cost for orthopedic trauma implants and compared it to nationally published cost data [7]. Among 76 residents and 51 attendings, implant costs for 13 common procedures were underestimated by over \$800. Despite underestimating costs, the majority of respondents were aware of literature supporting superior outcomes of one implant or another and expressed a willingness to change to a less expensive implant when superiority had not been demonstrated in the literature. This establishes the importance of price transparency within hospitals and surgery centers, and the need for individual surgeons to continue to advocate for pricing information. Efforts should also be made on an institutional level to create infrastructure to provide cost information which is readily available at the time a decision is made in order to facilitate more informed value judgments.

Costs, however, should not be considered in isolation when making treatment decisions. As discussed in a previous chapter regarding value in healthcare, the expected outcomes must also be taken into account. Because patients are unique and present with a variety of pathologies, the least expensive option is not always going to provide the highest value, and therefore there is an expected amount of variation in treatment costs across patient populations.

Variation

Case Example: Two shoulder surgeons are discussing techniques and equipment they use for isolated rotator cuff repair and decide to compare implant costs on some of their recent cases. They find that surgeon A has had a mean cost per case of nearly \$2800, while surgeon B has a cost per case of less than \$1000 despite working within the same hospital system. When looking into specific items used, they find that the cost of individual suture anchors ranged from \$75 to \$1775, identifying this as a driver of variation and an opportunity for cost savings.

While this may seem far-fetched, it is something we see every day in hospitals all around the nation. This variation reflects a 2016 study within a single healthcare system [8], which found similarly high levels of cost variation for primary ACL reconstruction [9]. Researchers in other subspecialties have also found wide variation in costs for peri-articular fractures [10] and spine surgeries [11].

Warranted vs. unwarranted. It is important to recognize and acknowledge that a portion of this variation in cost could be appropriately accounted for by a specific patient's needs compared to others, commonly referred to as *warranted* clinical

variation. *Unwarranted variation*, on the other hand, is defined as variation that cannot be explained by the specific condition or preference of the patient and can only be explained by performance of the health system [12]. This can be much more challenging to distinguish on a large scale. Multiple conceptual models are being investigated for identifying unwarranted clinical variation at scale, but it is often more practical to apply these principles at the level of treatment for specific conditions where outliers and opportunities for cost reduction can be more readily identified.

Physician Behavior

The key to lowering musculoskeletal healthcare costs arising from unwarranted variation is to empower surgeons with the information needed to make decisions based on both cost and effectiveness. When surgeons are equipped with sufficient data, pricing information, and appropriately aligned incentives, behaviors can be shifted in a manner which does not appear Draconian and allows the surgeon to continue to use appropriate clinical judgment when treating individual patients.

One way to influence behavior is the introduction of professional guidelines, which are created by surgeons and based on objective clinical data. In orthopedics, the most well-known examples are the Clinical Practice Guidelines, or CPGs created by the American Academy of Orthopedic Surgeons which are available for a variety of common conditions. These CPGs have been shown to have a significant impact on the use of some low-value treatments such as hyaluronic acid injections for knee arthritis [13]. These guidelines, however, are only as strong as the evidence that supports them and often leave room for interpretation when supporting evidence is inconclusive.

Physician behavior regarding value decisions also appears to be influenced by volume, with higher volume surgeons for specific cases trending towards less variation and lower costs. This has been observed across surgeries in multiple subspecialties including ACL reconstruction, proximal humerus fractures, and lower extremity arthroplasty [9, 14, 15]. Although many factors could potentially contribute to this correlation, it was found that implant costs, length of stay, and discharge destination were important factors. It is possible that the increased volume leads to more knowledge and awareness of costs associated with these decisions and facilitate high-value care.

Cost Reduction Strategies

Transparency. The largest barrier to reducing spending tends to be the lack of price transparency. Due to the layers of complexity within implant supply chains, determining the true cost of implants can be incredibly challenging. Part of this lack of transparency is secondary to the private nature of contract negotiations between hospitals and suppliers but can also be attributed to “hidden costs” such as the high

cost of disposable instruments used with certain implants or imaging/guidance systems. When price information is readily available, however, surgeons have been shown to reliably move toward lower-cost constructs. In a randomized controlled survey of 226 surgeons, it was found that availability of pricing information for upper extremity implants reduced costs by 9% [16]. Similarly, a study at a single institution created a guide to implant costs for seven commonly used constructs in orthopedic trauma. Each available vendor was classified as green (preferred vendor), yellow (midrange), or red (used for patient-specific requirements). The chart was then posted in operating rooms, and surgeons were instructed to use their discretion when making implant choices. This intervention resulted in a 20% decrease in costs for the selected implants without limiting implant choice or implementing administrative policies [17].

Matrix pricing. One way to simplify implant costs at the administrative level is the use of matrix pricing, also known as index pricing at some institutions. In a matrix pricing system, an institution establishes a single price for a standard construct such as an intramedullary nail or those used in arthroplasty. This allows the surgeon freedom of choice among the vendors who agree to this uniform price but obviates the need for more nuanced price transparency since the price is the same for each construct regardless of the vendor. It also allows multiple vendors access to the facility if they are willing to match their competitors' prices without the need for myriad individual negotiations and discussions about which implant is "better" when there is minimal clinical evidence to either support or refute the claims. Matrix pricing implementation at a single institution was shown to contribute to cost reduction of 37% for hip hemiarthroplasty and 49% reduction in costs for intramedullary nails in the first year of implementation [18]. Despite the potential benefits of matrix pricing, however, it requires a high level of coordination between administration and the surgeons practicing at an institution. The introduction of price thresholds can also diminish the number of companies willing to provide implants and can limit surgeon choice, which may create issues with implementation at some institutions.

Unblinded Cost Data. Another powerful driver of physician behavior is availability of unblinded financial impact data (with comparisons to peers) within an institution. The availability of this information empowers individual surgeons to hold themselves accountable for their financial footprint and provides opportunities to identify variance and share best practices throughout an organization. One example is the use of a Surgeon Value Scorecard. This method was implemented for surgeons performing lower extremity arthroplasty at a single hospital with encouraging results [19]. In this study, surgeons put together a list of metrics to be tracked including patient demographics, length of stay, discharge disposition, patient experience, finances, and operational factors. After 8 months of regular reporting of these metrics, mean total costs for arthroplasty procedures decreased by 8.7%, including a 17.1% decrease in direct variable costs. These cost savings were a product of the visibility of high-cost areas and practices, along with the identification of surgeons with lower costs and equivalent outcomes who could share best practices.

Bundled Payments. The results of Winegar and colleagues, however, may be confounded by the participants' enrollment in the Bundled Payment for Care Improvement or BPCI program, which seeks to drive physician behavior by offering financial incentives to surgeons for lowering costs of care. Such bundled payment initiatives are a type of alternative payment model, or APM, which seek to provide an alternative to the fee-for-service payment system in an effort to incentivize high-value care. In a typical procedure-based bundle, a price is set for a defined perioperative episode and any cost savings is then partially distributed to each of the major participants who contributed to the savings. Such programs have demonstrated effectiveness in widespread application for total joint arthroplasty. A 2019 study comparing 280,000 patients treated in a bundled payment system to 377,000 treated prior to its implementation found a 3.1% decrease in total costs with no change in complication rates. This idea can be expanded upon with condition-based bundles, which are based on the entire care cycle for a given diagnosis up to and including surgical care, as opposed to separating out the surgical episode. A condition-based bundle helps to incentivize high-value care throughout the entire treatment course and can effectively compensate surgeons as well as other multidisciplinary team members collaborating and choosing high-value non-operative interventions.

Summary

As healthcare costs continue to rise, it is important for orthopedic surgeons to understand and recognize their ability to drive spending. This begins with a basic understanding of cost accounting and tools such as TDABC, which can be used to identify opportunities for lowering costs while maintaining or improving outcomes. Through these efforts, unnecessary variation in costs can be reduced in order to provide higher value care. When coupled with individual surgeon awareness, broader organizational efforts can help to promote high-value behaviors. The availability of information regarding implant costs, treatment guidelines from trusted organizations, and unblinded peer data have been shown to be effective at driving behaviors. On the administrative side, competitive pricing systems and various forms of shared savings models have also been shown to be effective. Orthopedic surgeons must remain active and informed as we are best positioned to continue to lead these efforts while ensuring that safe and effective patient care remains the highest priority.

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Development of Care Maps for Complex Conditions

17

Stephanie Holmes and Jacqueline Li

Introduction

Care pathways in health care originated as a concept in the mid-1980s in Boston, when the New England Medical Center began efforts to codify patient care delivery. From there, care pathway use has spread to healthcare systems all over the world. The influence of care pathways on health care delivery is expected to increase, particularly in the United States. Many of the original care pathways were in the field of oncology, but their use is being widely adapted to other areas of medicine [1]. This chapter will focus on the development of care pathways for complex conditions. We will describe a care pathway and what its goals are and will follow with an example [2] of how to design a care pathway, how to implement it, and then how to evaluate it. The chapter will conclude with an overview of some of the important issues which arise during the development of care pathways.

A care pathway is a method of managing care based on evidence and clinical practice guidelines for a specific disease state in a defined patient population [1, 3]. The goals of a care pathway need to be defined at the outset of its development and can include improvements in patient outcomes and quality of care, more efficient resource utilization (i.e., decreasing costs), and reducing variation in treatment [1]. A care pathway can accomplish more than one of these goals, but it is important to establish the goals of the pathway from the beginning.

S. Holmes (✉)

Department of Orthopaedic Surgery, University of Utah School of Medicine,
Salt Lake City, UT, USA
e-mail: Stephanie.Holmes@hsc.utah.edu

J. Li

Department of Orthopaedics, Faculty of Medicine, University of British Columbia,
Vancouver, BC, Canada
e-mail: jacqueline.li@bcchr.ca

Designing a Care Pathway (See Table 17.1)

The design phase is arguably the most important step of care pathway utilization. The first step in pathway development is to *identify the therapeutic problem*. Problems which lend themselves well to pathway development generally fall into at least one of the following categories: high cost, high prevalence, therapeutic heterogeneity, and societal importance [1]. An example of a high-cost problem is that of hip fractures, which cost \$5.96 billion dollars per year in the United States [4]. Diseases with high prevalence include diabetes, osteoarthritis, and hypertension. Low back pain is a disease with therapeutic heterogeneity or wide variation in treatment. A care pathway targeting evaluation and management of low back pain would have as its goal standardizing treatment and thus normalizing outcomes and resource utilization. Lastly, a condition which is important to society whether due to its prevalence, morbidity, or perceived variation in treatment is a good candidate for a care pathway, such as oncology care.

After the target therapeutic problem or disease is identified, we then need to *define the population of patients* who will be candidates for the pathway. In a hip fracture pathway, which was designed and implemented at a level 1 trauma center [2], all patients older than 55 with a hip fracture were included, unless they were involved in a high-energy trauma or had multiple fractures. In general, a pathway is designed for a patient population which is treated in a specific location, so either at

Table 17.1 Designing a care pathway

Identify therapeutic problem
• High cost
• High prevalence
• Therapeutic heterogeneity
• Societal concern
Identify patient population
• Specific condition
• Constrained location
Decide on sources of evidence
• Clinical practice guidelines/appropriate use criteria
• Literature based on efficacy/safety
• Literature based on cost
Choose outcomes to be measured
• Performance metrics
• Compliance
• Variance
Identify stakeholders who will design pathway
• Providers
• Patients
• RN care coordinators
Identify who will administrate pathway
• Providers
• Hospital administrators
• Case managers
• Pathway vendors

a single facility, as in the hip fracture example where all patients were treated at a single level 1 trauma center, or at multiple facilities within a single healthcare system or within a defined geographic location.

There is currently a lack of standardization and policy for best practices for the development of care pathways [1] and thus there is considerable variation in how care pathways are developed and implemented. One of the most notable areas of variation is in the *sources of evidence* used to develop pathways [1]. In the absence of established guidelines for selecting the best-quality evidence when designing a pathway, it becomes important to decide at the outset what criteria will be used to evaluate the quality of evidence used in the design process. In general, clinical practice guidelines (CPG) and appropriate use criteria (AUC) are considered good sources of evidence for care pathway development [1]. The Institute of Medicine updated its definition of CPG in 2011 and described the necessary characteristics of a trustworthy CPG [5]. Due to its rigorous methodology, transparency, and evidence-based design, a trustworthy CPG is the preferred source of evidence for a care pathway. Peer-reviewed literature which addresses efficacy and safety is also valuable [3]. In the hip fracture pathway example, which was designed to decrease the number of patients who received hip fracture surgery after 48 h, the pathway developers used studies which showed that patients with hip fractures who received earlier surgery had a lower risk of morbidity and mortality. If one of the goals of the pathway is to decrease resource utilization, then the designers will need to use literature which is based on cost analysis. In short, it is vital that in the early stages of pathway design, the development team defines how they are going to evaluate the quality of the evidence they will use. If poor studies or information sources are used, the pathway will likely not accomplish its goal.

Another component of pathway design is identification of the *outcomes* to be measured. Outcomes can refer to two different concepts in pathway design: *performance metrics* (i.e., what is being measured by the pathway), and outcomes which *evaluate utilization* of the pathway [1]. In the hip fracture pathway example, the performance metrics measured by the pathway included time to surgery, complications, hospital costs, and several other data points. The outcomes which evaluate utilization of the pathway itself generally fall into two categories: *compliance and variance*. Compliance refers to both enrollment of patients with the target condition as well as to keeping patients on the pathway. Variance means deviation from the pathway, usually when enrolled patients are treated in a way that was not described by the pathway, e.g., a cancer patient received chemotherapeutic agent X instead of agent Y. All care pathways will be affected by variance, and one of the measures of a robust, well-designed pathway is how it allows variance to be used to modify or improve the pathway itself [6]. An important consideration during pathway design is how the outcomes of pathway utilization will affect providers. Will compliance (i.e., enrollment of patients and maintaining them on the pathway) be used as a performance measure for the providers, potentially affecting their reimbursement? [1].

The stakeholders who will be involved in the design and implementation of the pathway should be identified at the outset. In some systems, there is a strong culture

of dedication to quality improvement, but in other systems, some stakeholders may need additional incentive to participate in care pathway design. In the hip fracture pathway example, stakeholders included patients, orthopedic surgeons, emergency room physicians, anesthesiologists, hospitalists, the lean manager, and the RN care coordinator. After identifying the therapeutic problem and the goals of the pathway, the design team should also define the barriers to the desired outcome. The design team described prolonged time to consult hospitalists, prolonged time to cardiology clearance, poor physician-to-physician communication, and elevated INR as barriers to timely surgical management of patients with hip fractures, and they addressed each of these as they developed their pathway.

The next key component of pathway design is *administration*. Members of the team which will manage a pathway generally include providers, hospital administrators, case managers, and sometimes even pathway vendors [3]. The hip fracture pathway used a lean manager and an RN care coordinator. Lean managers in health-care are generally administrators who hold an advanced degree in business administration or hospital management. In the hip fracture care pathway, benchmark sessions were held *before* implementation to determine which outcomes to measure, including patient focus groups, and Kaizen meetings with all members of the pathway team were conducted to modify and improve the pathway during implementation. Kaizen is a term which originated in the business arena, and means gradual, constant improvement by doing small things better and achieving increasingly higher standards. It involves all levels of participants, from front line employees to CEOs [7]. It is also critical to secure the support of the health care system within which the care pathway will operate, and this can sometimes be a challenge for pathway design teams.

Care pathway design has been adapted for use in developing countries. One example is a care pathway designed to help providers with screening and management of developmental dysplasia of the hip (DDH) in pediatric patients. In many countries around the world, DDH is often not diagnosed until walking-age. Late diagnosis of DDH often requires more invasive surgical treatment and can result in long-term disability. These care pathways aim to reduce the prevalence of walking-age DDH by providing healthcare providers with an algorithmic guide for DDH screening and management. Developed care pathways are context-specific, taking into account a country's local needs and diversity of practice settings.

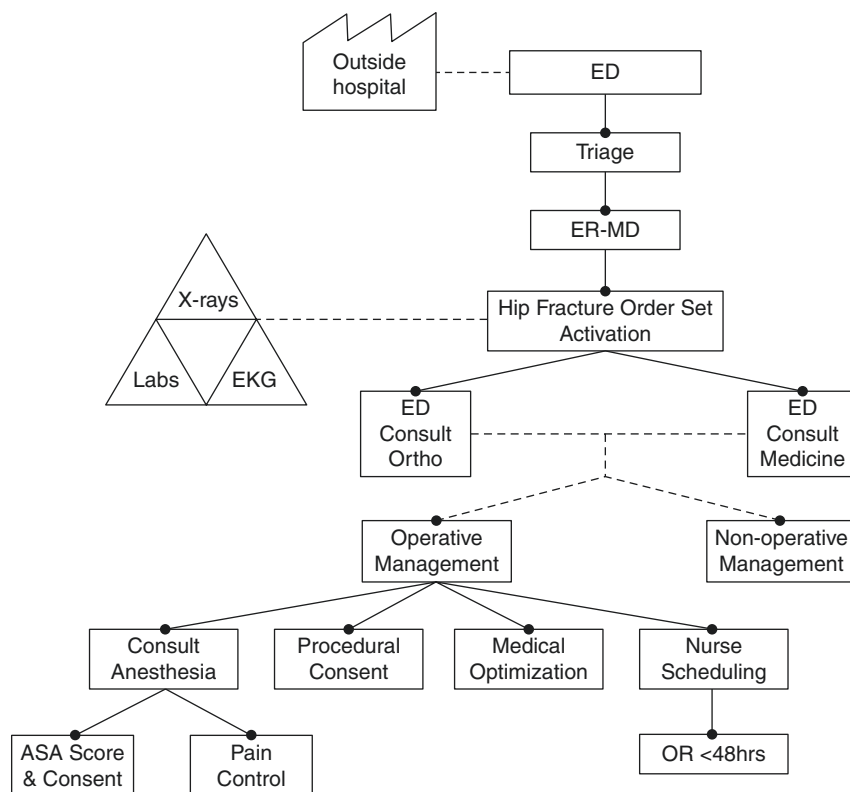
A feasible, multi-phase process has been designed to assist developing countries with the development of their own care pathways. In phase 1, partnerships are formed with relevant organizations within the country of interest. A working group is assembled, with emphasis placed on the recruitment of leaders and stakeholders representing each participating organization in order to increase project buy-in. All working group members are sensitized to the current literature on DDH screening and management during a virtual, informal literature review process that takes place over an approximately 3-month time span. Concurrent with the literature review, surveys are administered to the various specialty groups in order to evaluate local practice patterns, needs, and access to resources/expertise prior to care pathway development.

Upon completion of the literature review, the group is familiarized on the Delphi process during an initial meeting hosted by an external facilitator. All existing care pathways are reviewed, then the Delphi (phase 2) is initiated. The Delphi approach is a commonly used technique that facilitates structured group communication in order to obtain a convergence of opinion on a particular topic [8, 9]. The modified Delphi approach used to develop care pathways consists of a preliminary survey followed by a series of iterative Delphi surveys interspersed between virtual meetings. Delphi surveys consist of a series of statements covering important components of DDH screening and management. After a Delphi survey is administered to the working group, the collected responses are analyzed for a predetermined threshold of agreement. A virtual group meeting held after each round of survey provides the facilitator with an opportunity to present the results and obtain feedback on statements lacking in agreement through group discussion. The group input is summarized, the statements are refined as necessary, then the survey is redistributed to respondents of the previous Delphi round, thus beginning the subsequent round. The Delphi process concludes when either the predetermined consensus threshold or maximum number of iterations is reached.

The outcome of the Delphi process is a comprehensive list of consensus statements which are used during the final phase (phase 3) to develop the algorithm and formulate the guidelines. The assembled writing panel, consisting of a sub-group of nominated working group members, is then presented with the drafted materials and provide multiple rounds of feedback before the care pathway is finalized.

Components of a Care Pathway (See Fig. 17.2)

The components of a care pathway include policy/procedure guidelines, which will ideally cover the issue of variance and how to respond to it. Another component is the protocol, which should include a timeline, a list goals to accomplish before moving to the next step, and a list of events to be measured. The protocol from the hip fracture care pathway defined events to be measured as: time to surgery, duration of surgery, detection of complications, hospital cost, transfusion rate, 30-day readmission rate, and in-hospital mortality rate. The protocol should also allow for documentation of variance from a task. Finally, most care pathways will include standardized order sets; increasingly, standardized order sets are felt to be one of the most critical components of successful care pathways [6]. A white paper from the University of Kentucky gives a comprehensive overview of efficient order set design and management, and describes four essential steps: (1) establishing a functioning governing body and a structure for order set management that is tied to key organizational objectives; (2) planning/tracking the workflow of order set maintenance; (3) developing and applying a style guide that focuses on consistency and ease of use; and (4) implementing methods to encourage and streamline clinician involvement [10]. Within this type of order set development framework, the order sets that form the backbone of a care pathway may be efficiently designed and, when necessary, modified in response to variance noted during pathway utilization.



Value stream map of the integrated care pathway. ASA = American Society of Anesthesiologists, ED = emergency department, EKG = electrocardiogram, ER-MD = emergency department physician

Fig. 17.1 Value stream map of the integrated stream pathway. (From Sayeed et al., 2018. Used with permission)

In Fig. 17.1, which is a flow chart from the hip fracture pathway example, the authors illustrate the concept of “continuous flow,” which means that progression from one process to the next is not possible unless all components of the previous process are completed.

Implementation of a Care Pathway (See Fig. 17.2)

Another factor to be addressed during pathway design is the logistics of implementation. The organizational structure of the team should be defined, and how communication will occur should be structured [1]. There should be a strong focus on

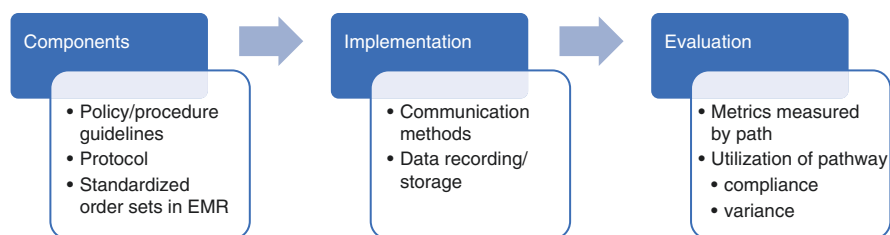


Fig 17.2 Evaluation of a care pathway

efficiency and respect for members' time. The hip fracture care pathway team used a combination of emails, seminars, conference calls, and scheduled meetings with the care team members. Designers must also decide how to record and store data, which is generally a combination of the existing electronic medical record and one or more adjacent databases. HIPAA-compliant methods to communicate to patients should be established, and generally involve a combination of web portals and secure email [1].

Evaluation of a Care Pathway (See Fig. 17.2)

Evaluation of a care pathway really means answering the question “Is it working?” or “Is it doing what we wanted it to do?” Evaluation should occur not just at the end of the timeframe defined by the protocol, but also at set points during the implementation of the pathway. This allows for flexibility and the chance to improve the pathway based on variance. The participants in pathway evaluation include providers, administrators, case managers, information technology specialists, statisticians, and the research team. In terms of evaluating the utilization of the pathway itself, compliance is the most commonly used metric—i.e., are people enrolling in the pathway and staying on it? Compliance is used most frequently for evaluation in large part because as the use of pathways has increased, it has become apparent that it is often difficult to measure and track outcomes and improvements in quality of care [1]. During interim evaluation settings, attention should also be paid to identifying the options which exist for modifying the pathway based on measurements obtained during evaluation—in other words, does the pathway have enough flexibility for variance to be used to improve it [6, 11].

Important Considerations for Pathway Design

There are several important points which need to be weighed when designing a care pathway. The first is to make sure there is *transparency* in the methodology [1]. For example, was the therapeutic target chosen based on improving care or reducing cost? Both can be goals of a care pathway, but it is essential to declare the goals up

front. Pathway designers should aim for similar transparency during evaluation and selection of the sources of evidence which will be used. Secondly, in the era of more patient-centered health care, some thought should be given to patient awareness [1, 12]. The development team in the hip fracture pathway example included patient focus groups when they were trying to identify the barriers to timely surgical management of hip fractures. Questions to answer in this context include: Will patients be made aware of the details of the pathway, and of what their options will be if they disagree with some component of the management the pathway entails? Will patients be informed if providers are subject to pathway-related incentives? Will patients be allowed to opt of the pathway and still receive their desired care? This last consideration becomes important particularly for pathways involving cancer drugs. A third consideration is one which was touched on earlier in this chapter: how can the designers reduce variance while still allowing flexibility in decision making on the part of the providers? This has a significant effect on physician compliance with a pathway and may also affect patients' willingness to enroll and stay on the pathway. A rigid pathway which has myriad rules and little room for modification will likely result in unwilling patients and frustrated providers.

A related concern is physician resistance. Factors which have been shown to have an effect on physicians' willingness to participate in pathways include administrative burden, lack of ability to make decisions and use their clinical judgment, disappointment with the frequent failure of pathways to demonstrate improvements in quality of care and patient-centered outcomes [1]. Physicians have expressed frustration when pathway compliance is used as a performance measure during their evaluations, particularly when deviation then results in negative financial repercussions [1]. Finally, it is important to remember that analysis of the impact of a pathway on outcomes and quality of care is often far harder to perform than analysis of compliance and the impact of a pathway on resource utilization [1].

Care pathways are used to improve the management of defined groups of patients, generally involve a multidisciplinary team, and formulate care from evidence-based guidelines and sources. They may aim for improved outcome measures or decreased resource utilization, but most pathways involve both goals. Pathway design should be transparent and methodical and involve input from multiple sources; it is often overseen by dedicated personnel such as care coordinators and pathway managers. Pathways should allow for variance, flexibility, and ideally for variance to be used to modify and improve the pathway when needed. Designers should consider the issues of transparency, patient awareness, and the effect of implementation on providers. Care pathways have the potential to significantly improve the care of many different types of patients in various areas of medicine, and thoughtful pathway design will maximize that capability.

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Communication Strategies to Minimize Harm and Improve Care in Orthopedic Surgery

18

Daniel J. Miller, Mit Patel, and Eric C. Makhni

The art of communication is the language of leadership.—James Humes

Introduction

As social beings, humans communicate with each other every day. This communication may be verbal or non-verbal. Although many believe that they are effective communicators, this is not the case within healthcare [1]. Orthopedic surgeons are routinely rated as some of the least empathic and worst communicators of all medical disciplines [2]. The end result of poor communication is a decrease in the quality, safety, and value of care provided. There has been an increased focus on communication in recent literature, and numerous techniques have been identified to improve and facilitate communication both between healthcare team members and with patients and their families. This chapter will review the importance of communication for orthopedic surgeons, the adverse effects of poor communication, and practical tips for improving communication.

D. J. Miller
Gillette Children's, St. Paul, MN, USA

M. Patel
Wayne State University School of Medicine, Detroit, MI, USA
e-mail: mitpatel@wayne.edu

E. C. Makhni (✉)
Wayne State University School of Medicine, Henry Ford Health System, Detroit, MI, USA
e-mail: emakhni1@hfhs.org

Why Communication Matters

Medical errors are a leading cause of death, harm, and disability, and in many instances are avoidable [3]. In the increasingly complex arena of modern healthcare, adverse events are rarely the result of a singular technical mistake and/or procedural error [1]. Rather, most errors or patient-safety events are the net result of contributing factors from multiple dimensions. Analysis of sentinel events in patient safety by the Joint Commission on the Accreditation of Healthcare Organizations (The Joint Commission) reveals that breakdowns in communication and/or teamwork are major contributing factors to adverse outcomes [4].

Furthermore, breakdowns in communication and/or teamwork have been specifically implicated in analyses of adverse surgical events related to orthopedics including: wrong site surgery [5], retained surgical instruments or sponges [6], and inadvertent disease transmission through transplantation [7, 8]. Observational studies within ORs found that approximately 31% of all communications could be categorized as a failure related to timing, information, or audience [9].

The importance of clear and effective communication is amplified at academic institutions where attending physicians work with trainees. The National Surgical Quality Improvement Program (NSQIP) demonstrated that risk-adjusted postoperative morbidity is correlated with levels of communication with attending physicians and trainees [10]. Furthermore, a study of 146 errors in management of surgical patients at three teaching hospitals found that 43% of cases were associated with breakdowns in communication among personnel [11].

Many adverse events or breakdowns in care can have medicolegal ramifications [8]. An analysis of 258 closed malpractice claims involving patient harm related to errors in surgical care implicated breakdowns in communication in 24% of cases [12]. A separate analysis of malpractice claims involving trainees revealed an even higher incidence (70%) of breakdowns in teamwork or communication [13].

Orthopedic providers should aim to improve means of communication in order to enhance patient safety. While orthopedic surgeons spend a great deal of time developing technical skills (e.g., interpretation of medical imaging, anatomic knowledge, surgical finesse), development of non-technical skills (e.g., interpersonal, cognitive, and personal resource abilities) may be just as important to providing high quality care [3]. While orthopedic surgeons readily understand the increased risk associated with patient factors such as obesity or smoking, poor surgeon interpersonal skills may play an analogous role toward errors and poor outcomes [14, 15].

From a practical and quality of life standpoint, improving teamwork and communication has been shown to increase the efficiency of surgical cases and OR utilization [8]. Effective communication among colleagues is protective against burnout [16]. Improving communication skills has the potential benefit of enhancing the lives of orthopedic surgeons in addition to the patients they serve.

Defining Communication

The single biggest problem in communication is the illusion that it has taken place.—
George Bernard Shaw

Communication can be defined as the clear, accurate, and timely handoff of information between members of the healthcare team and/or the patient. Poor communication may be erroneous, incomplete, inappropriate, poorly timed, or completely absent [17]. The end result is substandard care with potential adverse effects on the patient and/or medical system.

Many healthcare providers have a poor understanding of the importance of communication and/or their own communication deficiencies [17]. Perhaps this is due to lack of training as only approximately 20% of physicians receive formal instruction on how to communicate effectively [1].

Orthopedic surgery is among the top five medical specialties in terms of risk of malpractice claims [18]. A significant proportion of malpractice claims are the result of poor-quality communication between providers and patients [1, 19]. A deeper analysis of malpractice claims within orthopedic surgery highlights the critical role of the preoperative discussion, as many instances of malpractice are related to the lack or absence of a truly informed consent prior to surgery [19, 20]. To mitigate this risk, surgeons should pay extra attention to ensuring that patients have a reasonable understanding of the risks, benefits, alternatives, and expected postoperative course. Encouraging the patient to ask questions and providing written educational materials can help.

Formal team-building programs such as Crew resource Management (CRM) or Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) have been used, resulting in decreased observed errors and adverse outcomes [4, 21] (see Chap. 3).

Communication in the Perioperative Setting

Effective leadership plays a critical role in ensuring a culture of safety within medicine. Surgeons as the metaphorical “captain of the proverbial ship” have a unique opportunity to set the tone of the operating room with their presence, demeanor, and actions. A commitment to patient safety and well-being permits a culture of safety to permeate the OR.

Psychological safety is the belief that one will not be chastised, punished, and/or embarrassed for sharing their views, ideas, or beliefs. Psychological safety is particularly critical in rapidly evolving and/or complex systems that require significant collaboration such as healthcare [17]. Creating an environment of psychological safety encourages all members of the healthcare team, particularly those in

“subordinate positions” to speak up if they have concerns [22]. Unfortunately, many nurses are reticent to highlight potential mistakes or errors made by physicians [17]. Cultural values may confuse the act of challenging a “superior” with poor manners and/or disrespect [23].

Surgeons should reinforce any feedback when it is provided and thank colleagues openly for their input. Dismissing safety concerns as “silly” or “stupid” is destructive to a culture of universal mutual respect. Intimidating, abusive, and/or disrespectful behavior should be corrected by a patient safety officer in a timely manner. In addition to contributing to medical errors, abusive and/or derogatory behavior may decrease patient satisfaction, increase the cost of care, and may influence employees to leave the field medicine [17].

The traditional hierarchy or authority gradient between physicians, nurses, and other OR staff must be overcome in order to maintain a safe and collegial working environment [4]. One way to facilitate this is communicating on a first-name basis in-lieu of using formal titles (i.e., “Dan” instead of “Dr. Miller”). Certainly, one should avoid general references to persons by title (e.g., “Hey Anesthesia”) if at all possible. Ensuring that each member of the OR team knows the names and roles of other personnel in the OR can be facilitated during a pre-operative ‘huddle’ or during the time-out as recommended by the World Health Organization (WHO).” Additional means of reinforcing a “flat hierarchy” include sharing plans of action, soliciting for advice from other team members, and asking individuals directly if they have any safety concerns. Using open-ended questions (e.g., “What safety concerns do you have?”) as opposed to closed-ended questions (e.g., “Are there any safety concerns?”) can be fruitful in this regard. A flat hierarchy is also important because it shifts focus from perceptions of individual importance to the collective importance of a team achieving a successful outcome [15] (see Table 18.1).

Perhaps the largest hurdle for organizations to overcome with respect to teamwork and psychological safety is embracing cultural change towards these approaches. Medicine has a long-standing history of hierarchy based on the autonomy, expertise, and infallibility of physicians. Although physicians are the natural leaders for implementing cultural change in an institution, few have formal leadership training [17].

In the aviation industry, the critical periods of take-off and landing are recognized as high-stakes time periods where teamwork and attention have to be at their

Table 18.1 Tips for effective communication in the OR

• Reinforce a culture of safety in the operating room with your behavior
• Be on a first-name basis with your team
• Make eye contact when speaking with team members (if able)
• Set a positive tone for the room with your body language, affect, and tone
• Be forthright with your team regarding your plan of action and any concerns you may have
• Encourage everyone in the room to speak up with any safety concerns (and reinforce this behavior when it occurs)
• Commit to structure language tools such as a time-out and a postoperative debrief
• Use open-ended questions as opposed to closed-ended questions when able (e.g., “what safety concerns does everyone have? As opposed to does anyone have any safety concerns?”)

best. To facilitate this, a “sterile cockpit” is implemented whereby only flight-related information is exchanged on the flight deck and between/to air traffic control during these critical moments [15]. Applying a “sterile cockpit” policy to critical periods in the operating room (e.g., during cementing in a total joint arthroplasty or during acute correction of a spinal deformity) can help minimize distraction and maintain situational awareness [24]. It is important to recognize and respect this for all members of the healthcare team, not just the surgeon. For example, the anesthesia team needs heightened attention during the periods of intubation/extubation, whereas the nursing team requires complete attention during a final count of sutures and sponges during wound closure. Although these periods are relatively “low stress” for the surgeon [15], they must respect the process for their colleagues.

Standardized Communication Tools

Structured language tools are an effective means of avoiding breakdowns in communication both in the inpatient and perioperative settings. Two of the more commonly used tools are CUS and SBAR.

CUS

A standardized graded assertiveness policy can help team members communicate their concerns in an organized manner [15]. The CUS mnemonic was originally created by United Airlines as an empowering way for team members to overcome apprehension for voicing concerns in a vertical hierarchy of power. C, U, and S stand for “I’m concerned, I’m uncomfortable, this is unsafe, or I’m scared” and are meant to be used in an escalating fashion with safety concerns by any member of a team [4]. This tool is particularly relevant to the operating room where team members may have a tendency of timid or deferential language toward physicians or surgeons.

SBAR

The SBAR tool was originally developed by the US Navy to improve fidelity of communication in nuclear submarines. It has since been extrapolated to a variety of civilian applications including healthcare. SBAR stands for situation, background, assessment, and recommendation. This framework provides a terse and systematic means for communicating high-stakes information with a clear articulation of action items. The framework is meant to minimize misinterpretation related to variations in communication styles and is readily applied in the healthcare environment with particular use during hand-offs between care providers [4].

Briefings

Briefings are standardized habits that seek to facilitate communication to pro-actively identify potential safety hazards and/or inefficiencies in care [8]. Although briefings are an effective tool for communication, they are insufficient on their own without mindful implementation and a commitment to safety [8]. Introducing briefings into a medical care community takes time and requires thoughtful and continuous effort in order to achieve acceptance and “buy in” toward this practice [22]. Regular formal training is important to reinforce the utility and benefit of these practices. Empowering physician and nurse “champions” of briefings or standardized communication tools can help facilitate their assimilation into routine clinical operations [22]. Perhaps the most valuable way to encourage these behaviors is to share data with clinical staff on improvements in clinical outcomes related to their incorporation [22].

A preoperative briefing (Table 18.2) is an effective tool that surgeons can use to increase the efficiency, safety, happiness, and level of communication in the OR [25]. The preoperative brief is best performed with all members of the OR team (e.g., surgeon, anesthesia, circulating nurse, scrub technician, and any other relevant parties). This should be performed prior to the patient’s arrival in the operating room as care members will be actively focused on their tasks by that point.

Intraoperative Briefings and Checklists

In 2006, the WHO published “Guidelines for Safe Surgery” which contained a surgical safety checklist involving three phases of case (before induction of anesthesia, before skin incision, and before patient leaves the OR) [26]. The effectiveness of this pathway toward preventing morbidity and mortality in global surgical care has been indisputable [21, 27–29]. Furthermore, use of the WHO checklist has been associated with improvement in perceptions of teamwork and safety among OR team members [30].

Table 18.2 Important items to consider discussing in a preoperative huddle

• Any relevant medical comorbidities and/or pre-existing conditions (e.g., con
• Plan for positioning and operating room table
• Confirmation of appropriate equipment, implants, and/or allografts
• Confirmation of room setup including planned positioning for OR table, scrub table, and image intensifier (if needed)
• Anesthetic considerations such as at the need for muscle relaxation/paralysis
• Need for monitoring equipment such as an arterial line and/or urinary catheter
• Need for intraoperative medications such as irrigation, topical antibiotics, or local anesthetics
• Need for blood products
• Estimated length of procedure and expected blood loss
• Need for postoperative casting, splinting, or durable medical equipment
• Plan for postoperative disposition
• Indication or contraindications for postoperative medications such as ketorolac or dexamethasone
• Any specific safety related concerns

Pre-Induction Pause

A formal pause and checklist are recommended by the WHO prior to induction of anesthesia. This safety check-point confirms the patient identity, site marking, anesthesia equipment, patient allergies, airway risk, and expected blood loss. Although the surgeon does not have an active role in this process (and in fact, may not be physically present for this process), the surgeon should respect the importance of this step and avoid any noise or chatter that may distract the team from their work.

Pre-Incision Pause

A preoperative time-out or surgical pause is critical to prevent morbidity and mortality associated with surgical care. As opposed to the pre-induction pause, which may only involve the nursing and anesthesia team, the pre-incision pause should involve all team members who are participating in a patient’s surgical care (e.g., nurses, anesthesia staff, surgeons, scrub technicians, radiology technologist, neuro-physiologist, device representative, etc.). Care teams must maintain certain key elements of the pre-incision time out as mandated by the WHO Surgical Safety Checklist (e.g., site confirmation, prophylactic antibiotics, etc.) while adding or modifying these elements to fit institutional preferences and/or surgery specific elements (e.g., for a spinal deformity case, confirmation of baseline neuromonitoring data prior to surgical incision).

Postoperative Briefing

A debriefing procedure improves documentation of care provided in the OR and streamlines the coordination of postoperative care [17]. A formal debrief also promotes a process of continual quality improvement by asking team members to consider what went well, what could have gone better, and what could be done better in the future (see Table 18.3).

Table 18.3 Important items to consider discussing in a debrief huddle

• Procedure(s) performed
• Confirmation of estimated blood loss, fluid resuscitation, urinary output, and blood products
• Confirmation of medications given
• Confirmation of wound class
• Confirmation of correct sponge and needle counts
• Confirmation of intraoperative specimens and disposition
• Planned disposition of the patient
• Plan for postoperative pain management (e.g., need for patient-controlled analgesia)

Communication with Patients

In addition to working with other members of the healthcare team, effective communication with patients and their families is critical. Physician–patient communication has the highest impact on patient satisfaction with medical care [31]. Given the increasing emphasis on satisfaction as a metric and driver to volume, surgeons should seek avenues to improve their communication skills.

Surgeons with more a dominant/ patriarchal approach and lower concern/anxiety in their voice have been found to have increased rates of malpractice claims [32]. Shared decision-making entails a thoughtful dialogue between providers, patients, and any invested caregivers or loved ones regarding the risks, benefits, and alternatives of treatment options. These options should be thoughtfully considered and weighed related to the patient's goals, values, cultural background, and potential barriers [33]. Patient-based care models focus on the thoughtful coordination of care while placing emphasis on the emotional health and support of patients and their care givers. Patient-based care models incorporate the multidimensional biopsychosocial aspects of care in addition to the unique preferences, goals, and wishes of patients [33]. Information should be modified to suit a patient's health literacy and may be augmented with infographics or formal decision aids [33]. Shared decision-making has been shown to improve patients' knowledge with respect to risk and outcomes for medical procedures and is associated with higher perceptions of health care interactions [34, 35]. Shared decision-making is particularly important for elective procedures and in instances where there is no clear-cut superior treatment based on existing evidence.

Elywn et al. described a simple, three step model for incorporating shared decision-making practices when communicating with patients [36]. These steps include team talk, option talk, and decision talk. "Team talk" is the notion that everyone (physician, patient, family) is working together to help decide the best possible option for the patient. "Option talk" outlines all of the possible treatment options (including observation) and the salient risks and benefits of each. It is important that the provider allows adequate time for questions related to each of these options. "Decision talk" focuses on helping the patient come to their best choice for treatment moving forward. It is important to recognize that in most cases, choices related to treatment are not urgent and can be deferred to allow time for further contemplation or research.

Prior to entering a room, the surgeon should knock and allow for a brief pause to ensure that the patient doesn't have any objection to a person entering (e.g., if they are still changing clothes).

Physician body language when interacting with patients and their families is critical. Whenever possible, surgeons should aim to be at the same level as the people they are communicating with. Typically this involves sitting down to meet patients who may be in a clinic chair or hospital bed [37]. Maintaining eye contact is important to convey a sense of focus and attention on the provider's behalf. To that end, providers should avoid checking their phone, watch, or pager during a patient interaction. If or when a mobile device or pager does go off, it is important

for physicians to acknowledge this disturbance, apologize for it, and to maintain focus on the patient interaction. If a provider does have to unexpectedly step away (e.g., to answer a page while on call), the urgency of the communication should be relayed to the patient. Maintaining an open posture with the body and legs is more inviting and welcoming compared to having the arms crossed or closed which connotes a more confrontational tone. Other non-verbal behaviors that have been associated with patient satisfaction include leaning forward, nodding, gesturing, assuming a closer interpersonal distance, and facial expressions [38, 39]. When communicating, providers should be cognizant of their language and word choice. Certain commonly used terms in orthopedic surgery have a more negative emotional impact vs others (e.g., pain has a more negative connotation over ache; rupture has a more negative impact over tear) [40].

Qualitative studies have demonstrated that patients often place a high emphasis on being listened to and that this desire/need is not often prioritized by surgeons [2, 41]. Surgeons should aim to begin encounter with open-ended questions that encourage patients to express their background, symptoms, and concerns without judgment or undue time pressure. Listening without interrupting is important to ensure that patients feel heard and to maximize satisfaction. Surgeons should also make an effort to get to know a patient as a person, as this has been shown to increase patient satisfaction [42]. A natural and thoughtful manner of achieving this is through the social history with questions such as “What do you do for fun?” or “What brings you joy?” Perceived empathy is another measure that is commonly correlated with patient-reported physician satisfaction scores. Perhaps the most critical aspect of physician communication linked to overall perceived rating is related to the physician showing respect to the patient [43].

The mnemonic AIDET®, which stands for Acknowledge, Introduce, Duration, Explanation, Thank you, can be used to remember key elements of effective communication. It was developed by the Studer Group and has been promoted and successfully utilized in a variety of different industry settings including healthcare, food services, and hospitality [44]. “Acknowledge” includes warmly greeting the patient and any other individuals who are in the room with them. The provider should make eye contact with each individual and inquire as to what their relationship is with the patient. Providers are encouraged to ask patients their preferences for how they would like to be referred to (whether it be their first name or a nickname) and their preferred use of pronouns. “Introduce” includes communicating the full name and title of the provider and their role in easy-to-understand terms (e.g., joint replacement specialist instead of arthroplasty surgeon). The provider should also introduce other members of the healthcare team (e.g., medical trainees, advanced practice practitioners, or nurses) and explain their role. “Duration” includes giving reasonable timeline for the current encounter and for the treatment course. This may include estimations regarding longevity of disability or symptoms (including time off of work), timeliness of further testing and/or additional treatment (such as surgery), and expectations regarding timing of future follow-up or communications. In general, it is better to err on the longer side when estimating these durations to increase patient satisfaction. “Explanation” includes a detailed

description regarding next steps of action and providing appropriate resources to allow patients and their caregivers to contact with any questions. Providers should ask for verbal confirmation of the critical information provided in order to ensure comprehension. Asking open-ended questions such as “What other questions do you have?” or “IS there anything else I can help you with today?” help ensure that patients are fully satisfied with their care. Wherever possible, written or published materials such as educational packets, websites, and visit summaries should be provided to patients to ensure knowledge retention. “Thank you” emphasizes the importance of gratitude on the behalf of the medical care team. Recognize that patients and their families typically have many choices for where and how to seek their medical care. Providers are encouraged to thank both the patient and their loved ones for actively engaging in the healthcare experience [44, 45]. After the medical encounters have concluded, follow-up phone calls or communications from a care team can serve to improve patient satisfaction, improve adherence with treatment recommendations, and reduce risk of readmission [45–47].

Telemedicine represents a new avenue for provider–patient communication (see Chap. 30). Although there are technical limitations with respect to the physical examination and immediacy of diagnostic testing (e.g., radiographs, lab tests, etc.), information exchange and relationship building seem to be similar between telemedicine encounters and in-person visits [48]. Telemedicine encounters have the advantage of reducing travel burden and time off of work on the behalf of the patient [49]. Telemedicine postoperative interactions following total joint arthroplasty have been shown to reduce unscheduled clinic visit while improving patient satisfaction and clinical outcomes [50]. Telemedicine has also been found to be effective for physiotherapy related to total joint arthroplasty [51], shoulder arthroplasty [52], and back pain [53]. Given the novel nature of telemedicine as a tool, further research is needed to refine best practices related to this medium.

Conclusion

Effective communication is critical to ensure the quality, safety, and value of care, and is a critical driver of patient satisfaction. Orthopedic surgeons should be well versed in the available tools to facilitate communication, both in and out of the OR. Surgeons should commit to improving these soft skills in addition to technical skills to prevent adverse events and maximize outcomes.

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Integration of Physician Management into Supply Chain Optimization

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Kelly H. McFarlane, James K. Wall, and Kevin G. Shea

Evolution of Supply Chain from the Basement to the Boardroom

A supply chain is a system of organizations, people, activities, information, and resources involved in the procurement and movement of a product or service from source to consumption (from the supplier to the consumer). Simply, it is the sequence of processes involved in the production and distribution of a commodity. Supply chains exist for every product, and many come from regions all over the world. Supply chain is how you get what you need to care for patients, instruments, medication, dressings, DME, surgical supplies, implants, etc. Supply chain departments need to evolve and innovate to meet the demands of value-based care, and they need clinician support and integration to do so.

Whereas traditionally supply chain was focused on pricing, data analytics, and materials management, it is increasingly focused on value, automation, and utilization of advanced forecasting and modeling. Historically, there has been a low investment in this space; however, the recent focus on value-based care has highlighted the opportunity supply chain optimization present to unlock value in a health system.

The old model involves supply chain management making decisions on products and vendors and implementing those decisions in the hospital. While the intent may

K. H. McFarlane
Stanford Health Care, Stanford, CA, USA
e-mail: kmcf@stanford.edu

J. K. Wall
Biodesign, Stanford University, Stanford, CA, USA
e-mail: JWall@stanfordchildrens.org

K. G. Shea (✉)
Department of Orthopedics, Stanford University, Stanford, CA, USA
e-mail: kgshea@stanford.edu

include what is best for patients, without significant clinician involvement, the focus is largely on cost savings, as the decision-makers are removed from the day-to-day impact on patient care. Clinicians, with expert insights into impact and outcomes of decisions, can and should be involved in this decision-making process.

A new model of supply chain engages clinicians as experts, to facilitate better decisions about product selection, value, and cost. Overtime, this clinician integration into supply chain has expanded the focus to include standardization and utilization of products. The ultimate goal is for the focus to include value-based care and population health management. In the new model, supply chain management proposes products and contracts, facilitates decision-making, and implements supply chain decisions with close involvement from clinicians who provide input and feedback on products and services from a patient-care lens. Both groups work in collaboration along with operations, bringing multiple perspectives that all center around value-based care.¹

Goals of a Physician and The Value Proposition

When we talk about value-based care, the equation for a physician is simple: Value = Quality, with quality being directly linked to patient outcomes. However, as we have seen in the broader discussions of healthcare at the government and society levels, $\text{Value} = (\text{Quality} + \text{Service}) / \text{Cost}$. In addition to outcomes and quality metrics, the system has a responsibility to consider the cost to patients, the healthcare system, and our society as a whole. Cost control has often been seen as a direct conflict with the physician's sole focus on patient care. In reality, physicians are in the best position to provide input on cost savings that keep high-quality patient care as the central focus.

The value proposition can be broken into the components of the equation: quality, service, and cost. In supply chain, quality has several domains; one aspect of quality refers to a product's reliability; supply chain management focuses on identifying and tracking MBOs, recalls, and defects. Supply chain management also considers data integrity via item file management and is responsible for all levels of inventory management. Clinicians have a role to play in identifying quality, including which products work best for patients, offer the best outcomes, and do so at the lowest cost? This focus will help clinicians and supply chain management work together to maximize value.

Service adds in the layer of customer satisfaction, and this is two-fold: patient satisfaction and clinician satisfaction. Good service is built on the reliability of the right product at the right time for the right patient.

Cost is the most easily measured. Supply chain management focuses on achieving the lowest prices possible with reasonably low variation. Best-in-practice supply chain management utilizes data to develop benchmarks for competitive pricing and negotiates to meet these benchmarks and achieve lower costs. However, cost-cutting is clearly not the answer in and of itself. Higher costs can sometimes generate better value. Quality, service, and cost are parts of a three-legged stool—all three

are necessary to consider when working toward higher value. Ultimately, the value achieved by supply chain management is realized when the clinician has access to the tools and products they need to provide high-quality care for their patients at a cost that is reasonable for the system.

Standardization—What It Is and What It Is Not

What Is It

The goal of standardization is to reduce variation in health care that does not contribute to higher quality, better outcomes, and lower cost. If there is no clear benefit to variation in a care process or supply chain item, removal of this variation can lower cost and reduce complexity. Decreasing complexity in complex, highly matrixed organizations can reduce risk.

The defect rate in healthcare products is close to 1 in 10, as estimated by the Institute for Healthcare Improvement. Most industries do not accept a defect rate greater than 1 in 1000. Airlines, for example, measure error at the level of 1 in 1000,000.² How do these other industries achieve such dramatically lower error rates? This is done in many ways, including standardization of processes and use of checklists.

Standardization has already happened in many areas of clinical practice. For example, recommendation for pre-op antibiotic administration has been standardized to within 1 h of surgery. The Safe Surgery Checklist is an example of a standardized process utilizing a checklist that has been implemented in clinical practice. It has prevented countless errors since it was first published and widely adopted in national and international health care systems. It makes sense for standardization of supplies to be implemented as well when the variation in supply chain does not add value and is not associated with improved outcomes.

Opportunities

Currently in orthopedics, there is excessive product variation. Oftentimes, a health system will have upwards of 10–15 vendors for commonly used orthopedic implants, surgical tools used for spine care, joint arthroplasty, and trauma care. Excessive product variation provides surgeon choice but is also associated with a variety of negative outcomes for the system and potentially for patients. Too many choices do not necessarily improve surgical outcomes, and excessive choice adds to complexity, cost, and risk in many settings. When it comes to supply chain management, excessive variation leads to reduced leverage in contract negotiation and therefore higher costs. Service from suppliers may be decreased as well if their individual contracts are smaller. The administrative burden of managing the variation is significant; there is increased complexity and cost when it comes to sourcing, ordering, delivering, and storing products, which requires additional supply chain labor.

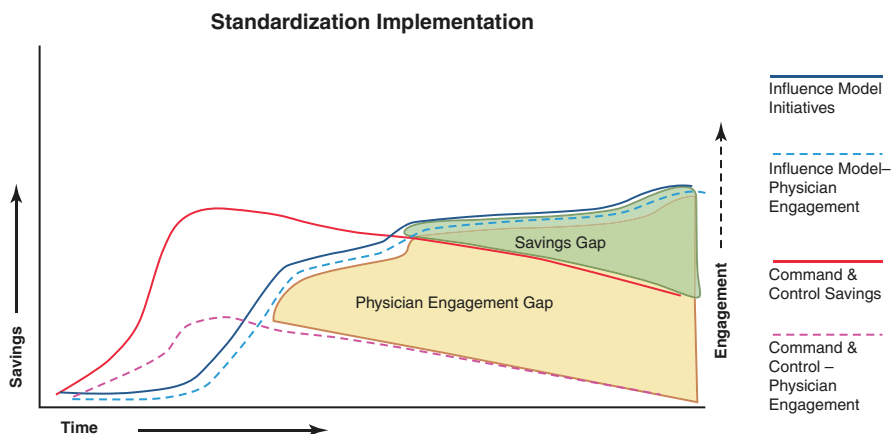
There is often excess stored inventory, higher rates of expiration of products, and more complex sterilization processes—all requiring additional management and introducing further complexity and variation into clinical practice.

An opportunity exists to move toward supply standardization, which may counteract many of the complexities listed above. It can reduce costs—both hard costs of supplies and labor costs. It can improve quality of care and increase value, focusing on supplies that are most reliable and highest quality. Ultimately, standardization allows more time and resources to be focused on patient care and service, rather than supply chain management.

Missteps

While there is an opportunity to increase standardization, complete reliance on a single product or vendor can have negative effects on a health system. There must be a balance between standardization, flexibility, and market dynamics that may support contracting with several vendors in some domains. If a single product is placed on backorder or discontinued, the hospital should have other options readily available. If one company has a major disruption in supply chain, this may impact a health system ;thus, in some surgical domains, several vendors may be justified to support and maintain quality and provide some redundancy for supplies.

If standardization and consolidation are undertaken by supply chain management alone, they may unknowingly cut out a product that surgeons found to be of highest quality or needed because it came in certain sizes or configurations that are essential for taking care of a spectrum of patients with different needs. This is why communication and integration of surgeons into the supply chain management process are crucial. While supply chain management may be able to move faster on their own, there is a risk that these decisions may negatively impact clinical care as well as erode the trust and relationship with clinicians.



Case Studies

The Case for Savings Via Supply Chain Management

It is important to secure the economic future of our hospitals and health systems in order to achieve our mission of caring for patients. If a hospital needs to increase profits by \$32 million, there are a few different ways to do so. In the simplest terms, a hospital can increase revenue or decrease expenses. Increasing profit by \$32 million is not as simple as increasing revenue by \$32 million because increased revenue is generated by increasing expenses. If the profit margin is 10%, we must effectively increase revenues by \$320 million. The other option is to decrease expenses, which can be done by decreasing labor costs or decreasing supply costs. To reduce the labor costs by \$32 million, a hospital must eliminate a significant number of jobs, which may mean letting as many as 400 employees go. Can the hospital afford to lose that many staff and still provide the highest quality care? How do you decide who to let go? Another option is to decrease expenses via supply costs. By consolidating inventory management and reducing third party spend on suppliers by 15%, the hospital can achieve \$32 million in savings without any layoffs.

Which of these three options seem most advantageous for health care systems?

How Not to Save Costs on Implants

A Nursing Supply Chain Director approaches a surgeon and states with enthusiasm, "Great news, we just got a great price on clavicle fracture plates and now we have this one vendor for all clavicle fractures!" The surgeon, typically supportive of this kind of work, responds with exasperation, "That brand works well for about 50% of clavicle fractures, which is great, but they don't make a plate for anterior plating distal $\frac{1}{3}$ clavicle fractures, or for smaller patients." The interaction leaves the Director wishing she had this input from the surgeon previously, and the surgeon feels the same way.

A simple answer to this problem lies in proactive communication: If supply chain management can ask the high-volume trauma surgeons about clavicle plates in a timely manner before the decision needs to be made, everyone wins. Surgeons feel invited to communicate their needs and preferences, and supply chain management can make decisions and negotiate cost savings with the advantage of full information from the experts.

Standardization: "How Many Different ACL Grafts Do We Need?"

In 2015, an institution with 15 sports medicine surgeons had contracts with 6 different ACL allograft companies. This was due to a variety of reasons including surgeon preference and expectations. An inventory check found 7 expired grafts in the freezer, ranging in cost from \$2500-3000 each. The complexity of the allograft

supplies and variation in use led to a need to keep a higher level of inventory which is associated with higher costs and a higher likelihood of expiration. The sports medicine surgeons and supply chain management came together and asked a fundamental question, “Are 6 different allograft companies necessary?” Together they moved toward reducing the number of vendors, and by 2016 had contracts with only two different ACL allograft companies that could provide grafts that satisfied the surgeon’s needs. This provided increased value via fewer expired products, less allocated inventory space, and a reduction in price per graft, savings that could be passed on to the patient. The reduced complexity also saved on the costs of inventory management and staff time.

Fast forward to 2019, when the surgeons determined they needed another graft option based upon new research. A new problem was posed to the surgeons and supply chain management team, “How do we add another graft option while maintaining value, minimizing costs, and acting in the best interest of our patients?” Based on their previous experience, they started the process with three questions for the surgeons:

1. Is there good evidence to justify the addition of supplies and complexity to our inventory?
2. Is there consensus among the clinicians regarding this need?
3. Does this new item replace a current stocked item, and should we replace it?

As a Member to a Chair: Value Analysis Committee

A Value Analysis Committee is a central organizational forum centered on partnership and collaboration. It is a central committee for control of the supply chain optimization process, and it is both value-added and process-driven. Equally important is what it is not: a Value Analysis Committee is not dictating medicine, it is not adding cumbersome bureaucracy, and it should not be strictly a products review committee.

There are stages of effectiveness and added value that a Value Analysis Committee can achieve, and this usually takes time. At the beginning, the focus of a committee should be tactical: “How do we develop a structure that allows us to effectively address supply costs and reduce inventory complexity when possible?” Oftentimes, it is helpful to start with new product introductions and benchmarking supply costs to gain an understanding of current state and where the biggest opportunities may lie. The next stage of development includes creating value for the organization—critical items are identified and visible, there is movement toward standardization, an examination of spend and utilization, and a critical focus on optimization and obsolescence.

Advanced Value Analysis Committees are able to provide cost and utilization trending. By this stage, there is ideally a dashboard to track progress. The committee can focus on negotiation with vendors, standardization, and consolidation. There is typically a fair amount of vendor/supplier relations work, along with utilization

management work at the procedural level. Fully clinically integrated committees are the gold standard—they are able to directly link value to their own work within the supply chain. Ideally the supply costs and value are aligned across the organization, and there is an interdisciplinary partnership focused on balancing quality and costs, along with risk sharing when it comes to achieving value. There are also consistently tracked metrics.

Your Role as a Stakeholder and Partner

As a stakeholder and clinical partner, you bring incredible value in your ability to link clinical practice to the supply chain. You act as a representative of the medical staff to supply chain leadership, and as such should work to understand the procurement process within your organization. Your role involves engaging with fellow clinicians as a champion of supply chain, sharing the core values and impact of the work, along with current or new initiatives, all ultimately focused on the patients' best interests. You should meet early and often with colleagues and communicate, communicate, communicate! The supply chain process can be complex. Don't be afraid to engage your supply chain colleagues in the education process, both for yourself and for your colleagues. At the same time, bring your clinical expertise to the table. Be willing to challenge the old way of thinking and think outside the box.

Your role is to act as a representative of the medical staff in meetings and correspond with supply chain management. You serve as a link between clinical practice and supply chain decisions, and you are the expert when it comes to the impact on patient care. You need to learn and understand the procurement process within your organization in order to effectively engage in innovating and improving it. Be prepared to ask questions. In addition, you have the opportunity to act as a champion of supply chain. You can communicate the value supply chain management that can provide to your colleagues and gain cultural buy-in. Your success will be determined by your ability to communicate, communicate, communicate—with both your surgeon colleagues and supply chain partners.

The role of supply chain management is to lead and facilitate procurement decisions with significant engagement and input from you as the clinical partner. They should be relied on to support and advise you during the learning process, while also being actively engaged in learning from your expertise in clinical care. Ultimately, they are also responsible for creating transparency and clearly communicating at every step along the way.

There will be challenges. There are many priorities competing for your time as an orthopedic surgeon. There will be gaps in your knowledge and gaps in the accessible data. You may hit roadblocks when it comes to educating and influencing your colleagues on the importance of this work. However, supply chain optimization is important work that ultimately helps unlock value for your patients. You will stretch yourself and your own goals, learning how to work with other departments in the hospital and gaining greater understanding and control over the system of which you are a part.

Takeaways

Engage: Get involved! Your support is crucial to the success of the supply chain initiatives discussed in this chapter.

Align and Partner: Communicate, engage, and understand clinical and operations requirements when it comes to supply chain. Share clinical knowledge and gain knowledge on procurement and supply chain. Be a partner in this process.

Balance: Balance patient care requirements with supply chain involvement, and data integrity and robust processes with results. Do not expect perfection from the start. Focus on moving in the right direction.

Focus on the Ultimate Goal: Think about the intersection of clinical and financial goals at every opportunity—ultimately, it's all about value and putting the patient first.

Evolve: Embrace the growth and learning journey. This is an iterative process. Have fun.

If you want to go fast, go alone. If you want to go far, go together.—African proverb

Suggested Reading

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Organizational Response to Error

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Jaime Rice Denning and James J. McCarthy

When organizations focus on response to “error,” they often mean “harm,” but there are really two different responses. Therefore, it is important to start with a couple important definitions: ERROR is an act of commission (doing something wrong such as ordering a medication for a patient who is allergic to that medication) or omission (failing to do the right thing such as failing to order Lovenox or other VTE prophylaxis for a joint replacement patient despite evidence supporting the benefit of doing so) that leads to an undesirable outcome or significant potential for such an outcome [1]. Harm is physical or mental damage or injury that causes someone or something to be hurt, broken, or made less valuable or successful [2].

Response to ERROR is really a PROACTIVE process and includes establishing behaviors of high reliability organizations—this includes adopting a just culture within the organization and diligent *monitoring* for errors, *meetings*, or huddles for identification and prevention of errors, and *mentoring* or coaching all members of an organization to place emphasis on quality improvement. Response to HARM is primarily REACTIVE but requires a strong surveillance system to identify harm and a programmed response with the authority to enact and maintain a meaningful response.

We will start with an overview of the origins of organizational response to error and then will focus in on organizational response to error in healthcare and orthopaedic surgery. Other industries outside of healthcare have led the way in response to error. Aviation, train transportation, and nuclear power are examples of other industries that have established highly reliable and safe industries. There are a few more important definitions here. “Reliability” is the probability that a system, structure, process, or person will successfully perform the intended function. A definition of Highly Reliable Organizations (HROs) comes from Weick & Sutcliffe, *Managing the Unexpected*. HROs are “organizations which operate under very trying

J. R. Denning (✉) · J. J. McCarthy

Orthopaedic Surgery, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH, USA

e-mail: jaime.denning@cchmc.org; james.mccarthy@cchmc.org

conditions all the time and yet manage to have fewer than expected accidents” [3]. The emphasis for these HROs, including healthcare, that operate in complex, high-hazard zones for extended periods without catastrophic failures is the adoption of high reliability science. When U.S. nuclear power plants adopted high reliability practices, the significant events per plant dropped from 0.9 to 0.02 over 24 years. When the Navy adopted high reliability practices, the number of aircraft destroyed (and associated fatalities) dropped from 776 in 1954 to 13 in 2014 [4]. The few of the specific practices the Navy introduced were angled decks on aircraft carriers, institution of the Naval Aviation Maintenance Program, Squadron Safety Program, System Safety Aircraft Design, creating Safety climate/culture [4].

The specific programs and practices of the Navy are not necessarily directly applicable to healthcare and orthopedics, but general high reliability practices are relevant. These high reliability practices are best described by Weick and Sutcliffe as 5 behaviors of HROs:

1. *Preoccupation with failure.* Even small errors are regarded as a symptom that something is wrong with the system. People in HROs spend extra time identifying activities they don’t want to go wrong.
2. *Deference to expertise.* (Not necessarily deference to the “highest ranking official”) This simply means that the authority to make decisions migrates to the person with the most experience regarding the problem at hand regardless of their rank or title. “People often ‘mistake general expertise for situational knowledge’. Years and years of experience do not mean that the experienced so-called expert has all the necessary information to manage the current situation” [3].
3. *Commitment to resilience.* Having the ability to adapt when the unexpected occurs; the ability to detect, contain, and recover from errors before they cause more serious problems.
4. *Sensitivity to operations.* Ability to concentrate on a task while having a sense of the big picture—paying attention to what’s happening on the front line.
5. *Reluctance to simplify:* Do not take shortcuts. Take steps to question assumptions or “the way things have always been done” to create a more complete picture of ongoing operations [3].

Organizational response to error in healthcare/orthopedic surgery relies on monitoring, meeting, and mentoring with an emphasis on continuous quality improvement and a culture of safety. The essential components of continuous quality improvement are based upon the teaching of C. Edward Deming. His “Model for Improvement” asks 3 questions: What are we trying to accomplish? How will we know that a change is an improvement? And what changes can we make that will result in improvement? [5, 6]. A culture of safety is a product of many things within an organization. According to the Health and Safety Commission: a POSITIVE safety culture is characterized by communications based on trust, shared perceptions of the importance of safety, and confidence in preventive measures to prevent errors [1].

The first step in response/prevention of errors is monitoring for errors because “you do not find what you are not looking for.” At the divisional level, we start our orthopedic surgery faculty meetings with a safety report and enlist everyone to participate. The placement of the safety report at the beginning of the faculty meeting indicates that it is the number one priority, and discussion of safety will not get forgotten or pushed past the end of the meeting by other business. At the division level, we have a Safety Chair who is the known point-person for any concerns, errors, or events. Some specific examples of safety issues that get discussed at a typical faculty meeting are orthopedic technicians volunteer concerns, and suggestions about avoiding casting errors in clinic (marking the site to be casted, unclear orders, etc.), residents inform us if a standardized tote for doing joint aspirations is missing in the emergency department or if there are delays in reductions or problems with the portable fluoroscopy machine. In addition to mitigating issues in real time, other orthopedic partners let us know if there are concerns about sterility breeches in the operating room so that these things can be recorded, tracked, and acted upon.

At the hospital level, monitoring occurs via methods such as dashboards. Boards must ensure that metrics that meaningfully assess organizational safety and a culture of safety are in place and systematically reviewed, analyzed, and the results acted upon. (A dashboard that no one ever sees or that no one acts upon to improve would not be an adequate response to error). Our organization transparently shares information and metrics around harm events and action plans for improvement across our organization. This information is shared via email and Centerlink (employee intranet homepage). The Patient and Employee Safety dashboards are right on the front page of Centerlink, safety articles are featured, and detailed information about OSHA recordable injuries/illnesses, bloodborne pathogen exposure, serious safety events, and hospital acquired conditions over the past 7 days and fiscal year to date are visible. Also at a hospital level, a small group of surgeons and administrators meet monthly with operating room (OR) staff and data personnel to go over dashboards for venous thromboembolism (VTE), blood transfusion over a certain threshold, and other measures to see if there are any trends within these dashboards, and then speak with the involved surgeon or team if necessary to find out what could be done to improve.

This next important step in an orthopedic or healthcare response to error is having meaningful meetings. This includes meetings dedicated to discussion of errors such as the traditional Morbidity and Mortality (M&M) conference and “shorter” meetings like huddles and debriefs. It has become important to have physician-specific training to facilitate moving away from punitive M&M Rounds toward a more effective, modern approach to patient safety and adverse events. This could include training around Just Culture, Psychological Safety, Adverse Event Reporting, Disclosure, Brief/Debriefing, and Patient Safety Huddles. Reflection offers the opportunity to learn from experience and allows for checks on the status of learning systems and Just Culture. The absence of physician focused training has led to the persistence of individual-focused one-off episodes of learning (e.g., M&Ms) rather than system-based learning. To use examples from our institution,

we have required “huddles” (may be via brief telephone conversation) at the start of each operating room day between the surgeon and OR nursing and anesthesia teams; these huddles may be initiated by the surgeon or the circulating OR nurse and include positioning details, reviewing special equipment, or any areas of anticipated concern. The occurrence of these huddles is tracked by OR schedulers, recorded in a safety dashboard, and acted upon if they are not occurring. For complex hip and spine cases, there is a weekly debrief including surgeons, trainees, ambulatory, and inpatient nursing and advanced practitioners that run through a thorough checklist for each surgical patient for the week to make sure preoperative, intraoperative, and postoperative orders and needs are anticipated and that portions of complex care that can be standardized are consistently standardized (such as surgical site infection prevention, education for patients and families, and postoperative order sets).

Across all of the surgical services in our institution, we recently revamped and improved our QI tracking system. Case documentation and discussion took place in various formats throughout the divisions, and information was entered in standalone databases which had little data query capability, making it cumbersome to see trends. We developed a queryable, centralized QI database to standardize collection and reporting of M&M cases with the use of this data to drive QI initiatives. The architecture of the database was developed within the context of utilization of data to initiate and track QI projects in addition to standardization of data entry across divisions. Nine surgical divisions started to utilize the centralized, electronic QI database in the fall of 2017, resulting in 14-fold increase in the number of M&M cases documented, compared to the same period in 2016. The standardization of the system allowed for recognition of near misses, cases that need further investigation or quality improvement projects and those that need to be discussed at leadership level for multi-system evaluation. The system can query trends and monitor ongoing QI work. Next steps to further improve the system include exporting potential M&M cases from the electronic medical record into the database to capture additional cases that might be otherwise missed by self-reporting alone and spreading the QI database to non-surgical divisions.

The third and final “M” of response to error is Mentoring. Hospital or health system leadership (starting with the CEO) must embed a vision for total patient and employee safety within the organization and establish safety as a core value. To accomplish this, they must:

- Possess a thorough understanding of the principles and behaviors of a just culture and be committed to teaching and modeling them.
- Demonstrate the principles of trust, showing respect, and promoting inclusion.
- Establish safety-mindfulness for all clinicians and the workforce and model these behaviors and actions including transparency, effective teamwork, active communication, civility, and direct and timely feedback.
- Include accountability for safety as part of the leadership development strategy for the organization.
- Identify physicians, nurses, and other clinical leaders as safety champions to spread the safety culture throughout the organization.

Safety culture has been discussed at length, so now discussion will shift to Just Culture as it relates to operational response to error. Dr. Lucian Leape, a Harvard Public Health Professor and leader of the modern patient safety movement, stated (in testimony to Congress regarding patient safety) that “the single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes” [7]. Just culture requires a change in focus from errors and outcomes to system design and management of employee behavioral choices. Just culture is a culture that recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes that many individual or “active” errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts “no blame” as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (such as falsifying a record or performing professional duties while intoxicated). Harkening back to the Mentorship/Leadership tenet of “response to error,” Leaders promote a just learning culture which sees patient safety as problems with the system that should be learned from organizationally.

Leaders must possess a thorough understanding of the principles and behaviors of a just culture and be committed to teaching and modeling them. Human error is and always will be a reality. In a just culture framework, the focus is on addressing systems issues that contribute to errors and harm. While clinicians and the workforce are held accountable for actively disregarding protocols and procedures, the reporting of errors, lapses, near misses, and adverse events is encouraged. The workforce is supported when systems break down and errors occur. In a true just culture, all workforce members, both clinical and non-clinical, are empowered and unafraid to voice concerns about threats to patient and workforce safety.

There are three main types of behaviors and each should be met with a different type of response in a Just Culture organization [8].

- Human error is “an inadvertent slip or lapse.” Since human error is expected, systems should be designed to guide people toward doing the right thing (and easily avoid doing the wrong thing). In a just culture, the person making this type of error should be supported and the system should be evaluated and improved to prevent the same error from occurring.
- At-risk behavior is “consciously choosing an action without realizing the level of risk of an unintended outcome.” In a just culture, the person making this type of error should be counseled as to why the behavior is risky and system improvements should be made if necessary.
- Reckless behavior is “choosing an action with knowledge and conscious disregard of the risk of harm.” In a just culture, the person making this type of behavior should receive disciplinary action.

In summary of organizational response to error, this is a proactive process of creating a Safety Culture through Monitoring, Meeting, and Mentoring with a focus on quality improvement, high reliability science, and a Just Culture.

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Using Simulation to Decrease Patient Harm

21

Asheen Rama

How does one define simulation? Whether it be a game of chess used to teach war strategies or a highly realistic fight cockpit experience for an instrument only landing, the word invokes imagery of an imagined experience in which reality is suspended and experiential learning takes place. The Oxford English Dictionary defines simulation as the “technique of imitating the behavior of some situation or process (whether economic, military, mechanical, etc.) by means of a suitably analogous situation or apparatus, especially for the purpose of study or personnel training [1].” Over the second half the twentieth century, simulation has come to play a prominent role in healthcare systems as a tool to reduce patient harm [2]. But what exactly is “patient harm?” “Patient harm” can be contextualized as adverse events, which refer to harm from medical care rather than underlying disease. These adverse events can be further subcategorized as preventable, ameliorable, or due to negligence and are often the topics of morbidity and mortality rounds and patient safety committees across various medical and surgical subspecialties [3]. Orthopedic surgeons are well aware of the unanticipated events, the near misses, and medical crises associated with the perioperative environment. Whether it be cardiac arrest, uncontrolled hemorrhage, or wrong limb surgery, the list of potential adverse events is numerous and underlies the need to train perioperative teams for low frequency, high-stakes scenarios and performs as a high reliability organization (HRO). Simulation has the potential to prophylactically prepare the operative team to be able to address such events. To deepen and further understand how simulation can be used to reduce patient harm, this chapter will provide an overview of the history, various types, and examples of healthcare simulation with particular focus on interdisciplinary team-based perioperative simulation.

A. Rama (✉)

Division of Pediatric Anesthesia, Department of Anesthesiology, Perioperative, and Pain Medicine, Stanford University School of Medicine, Stanford, CA, USA

e-mail: asheen21@stanford.edu

The use of simulation as an educational tool in the modern healthcare system originates from three major movements in the late twentieth century related to early task-trainer models for resuscitation training, more sophisticated manikin simulators mimicking aspects of human physiology, and reforms in medical education [2]. Changes in the training landscape including work hour restrictions, shorter, more streamlined paths for training, and the recognition of information overload at the expense of clinical and communication skills led to the inclusion of simulation technologies into undergraduate medical education [2]. In addition, societal and political pressures were simultaneously driving changes in healthcare [2]. In 1999, with increased public and government awareness following an Institute of Medicine publication entitled, “To Err is Human,” the country was astounded by the large number of deaths, ~98,000 per year, attributed to medical errors [4]. Congressional hearings with various government agencies, professional groups, accreditation organizations, and insurers would lead to the formation of a structured path forward to prevent such harm. Hospital accreditation through the Joint Commission now focused on new safety standards and executive and clinical leaders were pressured to create and foster a healthcare environment where safety is a top priority [5]. Through an amalgamation of technology, educational reforms, as well as societal and governmental pressures, simulation emerged as a vital tool to train healthcare students and teams by providing experiential learning without harm to the patient.

Many principles behind building a culture of safety in healthcare come from high reliability organizations including the military, aviation industry, the National Aeronautics and Space Administration, and nuclear power plants [6]. These HROs must function at a high level to avoid catastrophes. By practicing and preparing for adverse events, hospital personnel can similarly hone skills. A pioneer in the field of medical simulation, anesthesiologist David Gaba at Stanford University was inspired by the aviation industry’s core teamwork behavior training and crew resource management training, and developed simulation-based Anesthesia Crisis Resource Management (ACRM) in the 1980s [7]. Anesthesiologists worldwide would eventually adopt this training and focus not only on the technical aspects of patient care, but also the complex nature of teamwork and behaviors needed during medical crises. The ACRM principles included communication, resource utilization, and leadership [7]. Adverse events such as cardiac arrest can be simulated and healthcare teams can be assessed on teamwork and coordination of their efforts [7]. Simulation instructors will often work with simulation technicians to create, design, and conduct scenarios with the aid of mannequins. Audio and video tools for recording are often used for post scenario debriefing and feedback. Specially trained and experienced physicians often serve as facilitators and instructors to focus on key learning objectives which vary from knowledge, procedures, and judgments in addition to ACRM principles. Simulation debriefing methodology often draws from adult learning theory to enhance the educational experience and optimally engage participants [8]. Various programs train healthcare educators on optimal simulation facilitation and debriefing techniques, including Stanford University’s Center for

Immersive Learning, TeamSTEPPS from the Agency of Healthcare Research and Quality, and Harvard University's Center for Medical Simulation.

Perhaps nowhere in the healthcare setting it is more vital to practice team-based training than the operating room due to the "high-stakes" environment. The clinical arch of the surgical patient requires the coordination of a perioperative team comprised of nurses, surgical technicians, anesthesiology care teams, and surgical teams. Patients present with medical comorbidities and various types of pathophysiology. Nurses are gatekeepers ensuring various safety measures, anesthesiologists maintain normal physiologic parameters in the face of noxious surgical stimuli using clinical pharmacology, and surgeons manipulate complex anatomy to restore structure and function. Whereas the professional diversities of this group perform well during normal daily patient care, unanticipated challenges can lead to breakdown and suboptimal patient care. Medical crises faced by these teams are high risk, low frequency events for which the optimal response to mitigate poor outcomes requires team-based interdisciplinary training. One study found that the overall incidence of cardiopulmonary resuscitation (CPR) in surgical patients was approximately 1 in 200 [9]. The rare nature of this event alone underlies the importance of team-based simulation training. Simulation has been studied in numerous ways and shown to benefit healthcare teams. Breaking down the hierarchies of the past, participants have reported feeling more empowered to speak up [10]. Fewer medication dosing errors [11], more accurate management and recognition of medical conditions [12], less reliance on memory for tasks and promoting use of cognitive aids [13], and discovery of system-based deficiencies as a quality improvement tool [14] are just a few examples on how simulation leads to promoting a strong patient safety culture [15].

Several types of simulation are common in the healthcare setting. Each has their own unique features for providing educational experiences to healthcare teams. Perhaps the simplest form of simulation is the familiar problem-based learning scenarios (PBLs) such as those presented during oral board examinations. PBLs require examiners and learners to have a shared mental model and work through scenarios to test knowledge and judgment. Additional examples of low-fidelity simulations include the use of inexpensive mannequin torsos which are used by the American Heart Association for practicing high quality chest compressions. Healthcare personnel practice chest compressions to learn appropriate rate, depth, and recoil as well as the appropriate placement of defibrillation pads. Full size adult and pediatric mannequins have pushed the boundaries of realism and not only look authentic, but also feel and sound human. Such mobile mannequins can be controlled to change various physiologic and anatomical features while appearing realistic and can range from newborns to elderly patients.

In order to provide a high-fidelity simulation experience, educators can create scenarios in simulation labs which are freestanding facilities dedicated to providing immersive learning experiences. These facilities such as Harvard University Center for Medical Simulation or the Stanford University Center of Immersive and Simulation Based Learning are resource rich centers staffed by professional faculty

members where teams of healthcare individuals can participate in experiential learning. Scenarios can be specially tailored to the learning needs of the participants at their level of experience and specific to their specialty. Using sophisticated mannequins, various healthcare environments can be simulated including outpatient clinic settings, operating rooms, and inpatient units. While the quality of immersion or realism has a significant role to play, increasing level of sophistication and realism come at a cost. Conducting experiential learning with hospital employees requires the staff to take time off from clinical duties which can strain busy clinical schedules [16]. In addition, the cost of start up for simulation centers can come at enormous costs ranging from \$200,000 to \$1.6 million [17].

Another commonly used modality is in situ simulation. In situ simulation occurs in the actual clinical environment and similar to simulation labs, educators and simulation technicians can provide high-fidelity mannequins along with audio-video equipment for recording and post simulation video playback debriefing. This type of simulation offers advantages including timeliness and less disruption to staffing constraints demanded by busy clinical schedules [18]. The simulations are often shorter and tailored to specific scenarios in the actual care unit such as the intensive care unit, operating room, or inpatient ward. Unlike simulation labs, in situ simulation offers the ability to test a team's performance in their actual work environment and often utilize mobile simulation carts. In situ simulation allows educators to assess team readiness for handling medical crises with their resources and under normal workflow processes [18].

In addition to simulation labs and in situ simulation, immersive technologies provide innovative ways to supplement simulation-based education. Head mounted displays for virtual reality (VR) and augmented reality (AR) simulations provide realistic, cost effective, standardized clinical training scenarios. For example, VR simulations can supplement traditional cadaver-based simulations used to flatten the learning curve for the acquisition of arthroscopy skills and provide unique, standardized experiences [19]. VR has been a vital teaching tool in several industries including aviation, where it has been credited to reduce human error-related airline crashes by 50% [20]. Additional examples of VR being used to train healthcare professionals in complex procedures such as cardiac lead extractions [21], advanced life support resuscitation training [22], as well as non-technical skills including communication have been reported [23]. In addition to standardized assessment, VR may reduce set-up time and costs. For instance, typical preparation and take-down times of in situ simulations can be up to an hour and require multiple personnel [18]. This increased efficiency translates to additional time for patient care and learning during the valuable debrief.

While resource rich labs and VR have unique advantages as simulation modalities, it is worthwhile to explore an example of an in situ simulation which offers in house team training and opportunities for process improvement. The following will serve as an example of an in situ medical crisis simulation. After identifying key learners including anesthesiology and orthopedic surgery residents and attendings, nurses, technicians, and code blue intensive care unit response teams, a simulation educator along with a simulation technician creates a scenario in an operating room

in which the team must work together during a crisis. After a brief introduction to the manikin, vital signs, and environment, actors often referred to as “confederates” assume the role of perioperative staff. A confederate anesthesiology attending performs a regional nerve block after a simulated time out. During the peripheral nerve block, the simulation technician alters the vitals to display an arrhythmia and cardiac arrest. The simulation participants are thrust into a medical crisis and must assume team roles. Table 21.1 illustrates the educational objectives that may be used during the debrief of this scenario.

In an ideal performance, the participants function as a well-oiled machine having a shared mental model of identified leadership, effective closed loop communication, and activation of the call for help system. All the while, a simulation instructor guides the scenario down a pathway depending on the team’s response such as appropriate code drug dose administration, defibrillation, and airway management and hemodynamic support. The exercise is recorded for later debriefing which can use video playback. After the simulation, participants are engaged in a formal debriefing process which incorporates adult learning theory to optimize recall, retention, and participant engagement. Table 21.2 illustrates additional examples of perioperative simulations with accompanying learning objectives.

In conclusion, simulation in healthcare is a powerful educational tool which allows perioperative healthcare teams to practice in immersive scenarios and translate that experience to optimal performance in real-life situations, from routine surgical procedures such as fracture reductions and arthroscopy to medical crisis. Perioperative scenarios often reflect high stakes, low frequency events that require a team to rapidly come together with a shared mental model. Within the last several decades, various forms of simulation and technologies have been developed as a response to the needs of healthcare organizations and healthcare educational training. Simulation will continue to serve a role in healthcare organizations to reduce patient harm.

Table 21.1 Educational objectives during debrief session

Participant	Educational goals of simulation
Nursing	• Timely recognition of escalation and care and activating code blue response system • Bringing in the crash cart • Placing defibrillator pads on patient
Anesthesiologist	• Assuming team leader role • Closed loop communication • Managing local anesthetic systemic toxicity • Airway and hemodynamic support
Surgeon and surgical tech	• Assisting in high quality chest compressions, rate, depth, adequate recoil • Placing backboard under patient • Helping with additional intravenous access
Pharmacist	• Closed loop communication • Appropriately stating and providing code epinephrine doses
Available help arriving	• Non-technical skills such as situational awareness • Using cognitive aids when appropriate

Table 21.2 Additional examples of scenarios and learning objectives

Examples of in situ perioperative simulations	Examples of learning objectives
Fat emboli syndrome (FES)	• Advanced cardiopulmonary life support • Pathophysiology and risk of FES
Local anesthetic systemic toxicity (LAST)	• Medical management of LAST • Use of cognitive aids • Intralipid administration
Perioperative fire	• Skin prepping • Fire triad • Fire extinguisher locations and protocols
Malignant hyperthermia (MH)	• MH cart • Dantrolene administration • Medical crisis management
Cannot intubate cannot ventilate scenario	• Difficult airway algorithm • Emergency airway management • Supraglottic airways
Medical crisis and communication	• Non-technical skills • Leadership, communication, situational awareness • ACRM principles
Code blue in the magnetic resonance imaging scanner	• Contrast allergies • Protocols for removing patient and resuscitating outside the scanner
Patient death	• Breaking bad news • Discussing end of life care

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Safe and Effective Alleviation of Pain and Optimal Opioid Stewardship

22

Kerwyn Jones and David Ring

Introduction

Opioid overdose deaths in the United States increased 350% between 2001 and 2016 [1]. This corresponded with increased opioid prescriptions, including a record 259 million opioid prescriptions in 2012 [2]. Furthermore, 38% of nonmedical opioid users report that they received their opioids from a family member or friend that had a prescription [3, 4]. Many people that develop opioid use disorder start taking opioids as part of their medical care. The duration of opioids prescribed is correlated with future risk of nonmedical use of prescription opioids (NМУPO) [5, 6].

The number of opioid prescriptions is trending downward since 2012 but is still three times higher today than it was in 1999 [7]. The record number of opioid prescriptions in the United States is greater than all other nations with documented trends [8]. Americans are prescribed twice as much opioids per capita as people in Australia, 6 times more than in France [9]. Prescription of opioid medication has caused substantial harm and merits great care. There is evidence that people with iatrogenic opioid use disorder are turning increasingly to illicit heroin and fentanyl. There are also signs that the unsafe prescribing practices adopted in the US and Canada over the last three decades are starting to take hold in Europe, China, and other parts of the world [10]. To some degree, clinicians have lost the public's trust, resulting in legislative action to set legal maximums for opioid prescriptions and requirements for education on safe and effective alleviation of pain [11].

K. Jones (✉)
Akron Children's Hospital, Akron, OH, USA
e-mail: kjones@chmca.org

D. Ring
Dell Medical School, Austin, TX, USA
e-mail: David.Ring@austin.utexas.edu

Pain Alleviation Based on Evidence in the Biopsychosocial Paradigm

In the biomedical model of human illness, all symptoms correspond with and are completely accounted for by pathophysiology. The biopsychosocial model of human illness posits that symptom intensity varies according to the thoughts, emotions, and circumstances in which the pathophysiology is experienced, interpreted, and acted on. The word disease can be used to refer to the objectively measurable pathophysiology and the word illness to the subjective state of being unwell. The notable variation in illness for a given disease and pain for a given nociception point us to a range of health opportunities that are not routinely considered [10].

Nociception is the physiology of actual or potential tissue damage. It is objectively measurable pathophysiology (disease). The revised definition of *pain* from the International Association for the Study of Pain is “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” [12]. In other words, pain is the unpleasant thoughts and emotions that can accompany nociception.

Among people that are recovering from injury, pain that is more intense than expected for a given pathology and point of recovery is associated with greater misconceptions and distress in relation to nociception [13–15]. Similar relationships are consistently noted for atraumatic pathology including highly prevalent pathology of the aging human body such as arthritis and tendinopathy [16]. Often the distress is related to life roles and financial security (social health) [17, 18]. Collectively, these lines of evidence suggest that there is a notable risk of misdiagnosis of social and mental health opportunities and mistreatment of misconceptions and distress with opioid medications [10].

What this mounting evidence points to is that, for humans, getting comfortable is largely a matter of reorienting common misinterpretations of symptoms and alleviating associated stress and distress. A focus solely on pharmaceutical and physical techniques may leave these important aspects of comfort and health unaddressed and has the potential to expose people to iatrogenic, psychological, and financial harm.

Medications play a specific and limited role. That role can be strategized so that discussions about medications are not personal to a specific clinician. The strategies can facilitate accurate diagnosis and prompt treatment of all aspects of the illness, including the mental and social (comprehensive care). The optimal use of opioids is the smallest dose for the shortest time possible.

Pain Alleviation after Planned/Discretionary Surgery

A person chooses discretionary orthopedic surgery when they are having difficulty accommodating pathology, and the potential for benefit from surgery seems to outweigh the potential for harm. It is the responsibility of the orthopedic surgeon to

ensure this choice is not based on common misconceptions about symptoms [16, 19]. Misconceptions are nearly universal due to the human mind's protective stance, particularly with respect to pain [19, 20]. It is an evolutionary advantage to prepare for the worst. Clinicians can anticipate misconceptions, address them with compassion, and gently reorient them over time. Motivational interviewing and other tactics offer useful communication strategies [21]. Musculoskeletal specialists may be the only clinician and team member with sufficient expertise to discern helpful and accurate interpretation of symptoms from unhelpful and less accurate interpretation of symptoms [22].

Specialists may also be best qualified to discern elements of distress and stress in a person's thoughts, emotions, and behaviors in response to symptoms. There are verbal and non-verbal signs of misinterpretation and distress that surgeons can be attentive to and prepared to address [23, 24]. For instance, a laborer in their 50s who depends on their body for their livelihood is going to have a different regard for symptoms than people in other life situations. Orthopedic surgeons can coordinate care with the patient's larger team, letting the primary care doctor and others know when potential mental and social health opportunities are identified. It is important to work as a team.

Teamwork can be facilitated by development of strategies for patient readiness, mental and social health priorities *prior to discretionary surgery*, and a limited role for opioids. One strategy can be to wean people completely off opioids prior to discretionary surgery. This can be equated to having people stop smoking, lose weight, or improve their hemoglobin A1C levels prior to discretionary surgery. Often those health priorities do as much or more for a person than surgery can accomplish.

Strategies for communication and coordination are also important. Make it easy for the musculoskeletal specialist who identifies misinterpretation of symptoms and important levels of stress or distress to help communicate that to the patient and the team in a compassionate, collegial manner that nurtures the patient–specialist relationship [25].

Pain After Unplanned Surgery

People that have urgent or emergent surgery for infection or fracture are not able to ready themselves for pain alleviation. Such events are unsettling, and clinicians can anticipate misconceptions, worry, despair, and insecurity. Indeed, people with injury and infection are more likely than the average person to be engaging in risky activities associated with mental and social health opportunities such as substance misuse and premonitory worry and despair.

These issues can be addressed proactively. A recent AAOS CPG recommends routine screening for mental and social health opportunities [17]. Most hospitals have psychiatry, psychology, social work, and case management expertise to help with recovery. Care strategies can incorporate these resources.

Pain that is more intense or longer duration than expected for a given injury or pathology can trigger a search for compartment syndrome, infection, or inadequate fixation. When those are unlikely (and most of the time they are), the patient–clinician relationship should be emphasized, identifying common misinterpretation of symptoms, notable levels of worry and despair, and making sure a person has adequate social support and security. Great strides have been made initiating buprenorphine treatment for people admitted with adverse events related to opioid use disorder, making them less likely to relapse, and more likely to engage in treatment [25]. This applies to people who have urgent surgery. Attention to mental and social health is an important part of their overall recovery.

Strategies for Safe and Effective Postoperative Pain Management

Safe and effective alleviation of postoperative pain management begins with tasks, strategies, and interventions (Table 22.1). The most effective strategies require sharing of roles via a collaborative team. Physician participation and support for the initiative, good data and analytics assistance, and hospital leadership support are also key components. Members of the team should include surgeons, nursing leadership, anesthesia, pharmacy, pain management providers (when available), informatics, quality support, and preferably a patient advocate that can bring to the forefront the patient’s perspective. Surgeons are the driving force for their patients as they are the providers that bring the patients to the perioperative realm as well as the provider ultimately responsible for postoperative pain management after the patient returns home. Members of the anesthesia, pharmacy, and pain management team offer expertise for the appropriate choice of opioid medications, dosing, and frequency of use. They also provide expertise on alternative pain alleviation medications. Informatics team members are valuable for their ability to configure the electronic medical record to enable high reliability of compliance with the guidelines, pathways, and education tools developed. A member of the patient advocate team is invaluable for their “outside in” view of the proposed processes that will affect them as patients. This is especially helpful for their input regarding

Table 22.1 Suggested Tools for Safe and Effective Alleviation of Pain and Optimal Opioid Stewardship

- Practice-wide strategy for safe and effective alleviation of pain. This is a powerful tool for depersonalizing discussions with patients and moving away from opioids
- Pilot projects with early adopters to nurture culture change. Order sets with lower defaults and respecting the consensus maximums for strength and number of pills, and duration of opioid treatment
- Electronic order sets can measure clinician behavior relative to their peers and can be used for engagement and motivation
- In academic centers: Provide resident and fellow trainees with clear strategies for safe and effective alleviation of pain. Motivate attending specialists to approach safe and effective alleviation of pain as an important part of their teaching and mentoring

development of patient educational materials such as appropriate assessment of pain at home, techniques to manage that pain, and proper disposal of unused narcotics.

Opioids

Opioids are habit forming. In addition, their physiologic effect of suppressing respiration makes them inherently risky. Thus, a strategy of prescribing as little as possible for the shortest possible duration is prudent [26]. The CDC Guideline for Prescribing Opioids for Chronic Pain recommends clinicians to prescribe the lowest effective opioid dosage, and the same holds true for the pain of injury or surgery [27]. Surgeons should be aware of the Morphine Equivalent Dose (MED) for medications prescribed and they should aim for the weakest opioid in the smallest number for the shortest time possible, always within the maximums set by their practice-wide strategy.

Several groups have publicized strategies for safe and effective alleviation of pain and optimal opioid stewardship. One example is the AAOS Pain Alleviation Toolkit [27]. Each practice can use these strategies as a starting point for their own approach. The specifics of the strategy are probably not as important as simply having one in place as a tool clinicians and patients can use to keep safe and comfortable. These are not policies which can get patients and specialists in trouble but rather are strategies and tools that patient and specialists use for safe and effective alleviation of pain and optimal opioid stewardship.

Non-opioid Medications

Commonly prescribed, low risk, low-cost non-opioid medications include ibuprofen and acetaminophen. Used alone, these medications yield good postoperative analgesia [28]. Since the medications have different actions, and different potential harms, they can be used together, alternating ibuprofen and acetaminophen [29]. Furthermore, concerns about the increased potential for bleeding and bone healing after intraoperative or preoperative use of ibuprofen seem overstated [30].

Pregabalin and gabapentin are antiepileptic medications that may influence pain. Their use in the management of pain has had mixed results [31]. There is some potential for misuse of gabapentinoids. More evidence is needed regarding the potential benefits and potential harms of these medications.

Physical Interventions

Low cost, low-risk physical interventions such as ice, heat, wrapping, and immobilization can be helpful. Environmental factors may affect the patient's perceived level of pain and may function as a distractor as well. Examples of methods that can

be utilized by almost all patients are aromatherapy and music. Although the evidence may not be as strong, aromatherapy, and locally applied oils may positively influence daily pain associated with osteoarthritis [32]. Music may function primarily as a distraction for pain alleviation. In general, distraction therapy can be very effective with children. Methods include utilization of videos, gaming systems, music, playing with toys, and even virtual reality [33]. Meditation may reduce pain via psychological, neurological, and physiological mechanisms that help modulate painful stimuli [34]. Cognitive behavioral therapy has been studied primarily in persistent pain with varying but somewhat promising results for both adults and children [35].

Proper Disposal of Unused Opioids

Unused opioids are at risk for inappropriate use or diversion. Proper disposal of unused opioids will eliminate the temptation for members of the household and visitors. Disposal of medications in wastewater leads to presence of those medications in public water supply [36]. Appropriate solutions include pharmacy-based medication take-back programs, Detera Drug Deactivation System pouches, and Drug Enforcement Administration or local law enforcement drug drop boxes. Patient education regarding proper disposal increases the likelihood of proper disposal.

Conclusions

Missed diagnosis and mistreatment of misinterpretation of symptoms, stress, and distress with opioids are a quality and safety priority. The evidence that people in other parts of the world achieve effective pain alleviation using few opioids reminds us that opioid stewardship efforts have low potential for harm associated with undertreatment of pain. On the contrary, it can be argued that setting limits on opioids makes us more thoughtful about the evidence regarding effective pain alleviation in the biopsychosocial model. The goal will remain safe and effective alleviation of pain.

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Diversity and Cultural Competence to Enhance Quality and Safety

23

Julie Balch Samora and Ron Navarro

Diversity has been described as a range of human differences, including but not limited to race, ethnicity, gender, gender identity, sexual orientation, age, social class, physical ability or attributes, religious or ethical values system, national origin, and political beliefs [1]. There have been studies in various fields that have demonstrated the vast benefits of diversity, including financial advantages, reduced absenteeism, improved productivity, enhanced communication and exchange of innovative ideas, and decreased turnover [2–5]. Furthermore, heterogeneous groups have been shown to outperform homogenous groups in problem-solving [3].

In the context of healthcare and racial diversity, health policy experts, medical educators, and clinicians recognize the need to diversify the healthcare workforce in order to reduce health disparities and improve the overall health of the population [6]. Augustus White contended in 2002 that “increasing diversity enriches not only our patients, but also our profession and our nation [7].” Individuals of different racial and ethnic backgrounds differ in their perceptions and interpretations of symptoms, beliefs about appropriate treatments, reactions to pain and suffering, and understanding of the healer and patient relationship [8]. Patients who are managed by a physician who is “similar” to them are more likely to be satisfied with their treatment, communicate more effectively, follow recommendations, and have better health outcomes [9–13]. Having diverse providers and providers with culturally competent abilities will improve care for patients.

“Underrepresented in medicine (URM) means that those racial and ethnic populations are underrepresented in the medical profession relative to their numbers in the general population,” as defined by the Association of American Medical Colleges

J. B. Samora

Department of Orthopedics, Nationwide Children’s Hospital, Columbus, OH, USA

e-mail: julie.samora@nationwidechildrens.org

R. Navarro (✉)

Kaiser Permanente, Pasadena, CA, USA

e-mail: Ronald.A.Navarro@kp.org

(AAMC) [14]. The early AAMC definition of underrepresented minority (URM) includes Blacks, Mexican Americans, Native Americans (American Indians, Alaska natives, and Native Hawaiians), and mainland Puerto Rican. The Institute of Medicine described the need for more racial diversity among healthcare professionals as it would lead to improved access to care for minorities, permit better communication with patients, and greater patient-centered care around health care decision-making [15].

Minority groups currently comprise over 30% of the United States population [16]. The need for diversity in healthcare has taken on new importance [17]. Estimates by the Pew Research Center show that by 2065, no racial or ethnic group will be in the majority in America [18]. A medical anthropology study has shown that individuals of different racial and ethnic backgrounds have different understanding of the healer and patient relationship which can affect their treatment and outcomes [19, 5]. African-American male patients were significantly more likely to undergo preventative screening tests and agree to the flu shot if they were offered by black male physicians rather than white male physicians [20]. Chen and others [21] showed that African-American and Latino patients who perceived racism in the healthcare system physicians of their own race.

While the ideal of “colorblind” care or care that is rendered without regard to race is preferred, without more healthcare professional racial diversity, this may be more difficult to realize. The most recent Orthopaedic Practice in the United States survey (response rate 26%) by the American Academy of Orthopaedic Surgeons in 2016 revealed 6.7% Asian, 1.5% African-American, 1.7% Hispanic, and 0.4% American Indians/Alaskan Native self-identified racial percentages of non-Caucasian orthopedic surgeons [22]. These figures compare with the 2010 United States census which showed 4.8% Asian, 12.6% African-American, 16.3% Hispanic, 0.9% American Indians/Alaskan Native, and 0.2% Native Hawaiians/Pacific Islander self-identified racial percentages of population [23–26].

Okike et al. [27] evaluated racial and ethnic diversity in orthopedic surgery residency programs. They found that total minority representation in orthopedics averaged 20.2% during the most recent years studied (2001–2008), including 11.7% for Asians, 4.0% for African-Americans, 3.8% for Hispanics, 0.4% for American Indians/Alaskan Natives, and 0.3% for Native Hawaiians/Pacific Islanders. Orthopedic surgery was significantly less diverse than all of the other residencies examined during this time period. It is critical to entice diverse trainees into the field, as the percentage of minority medical students who plan to practice in underserved areas is four times that of other medical students [28–31].

A plethora of orthopedic research has focused on whether disparity in care exists based on race [32], if racial variation influences pre- and intra-operative findings in patients undergoing surgery [33], and whether race is independently associated with outcomes [34]. Interestingly there is new thinking around race research studies that emphasize limiting the overarching conclusions of effects of race [35, 36]. The thinking is that race may capture a lifelong social experience and so residual

confounding around the effect of race cannot be eliminated after statistical control for weak proxy measures such as education level or financial status [35, 36].

Culturally competent care or care that is routinely delivered in a way that meets the social, cultural, and linguistic needs of patients remains aspirational at this time. Nonetheless, there is a need for cultural competence education for health professionals. Horvat et al. [37] found that patient-related outcomes improved after care were provided by professionals with culturally and linguistically diverse backgrounds. Nivet and Berlin [38] contend that cultivation of a workforce with the perspectives, aptitudes, and skills needed to fuel community-responsive health-care institutions is essential.

A tactical way to begin to build in culturally competent care is to implement patient-physician language concordance where both patient and physician speak the same language [39]. In California, a recent senate bill passed that mandates all California health plans provide language assistance services to patients with limited English proficiency. Parker et al. [40] confirmed significant improvements in glyce-mic control among limited English proficiency Latino patients with diabetes who switched from language-discordant to language-concordant primary care providers. Interestingly, McLaughlin et al. [41] found that health system interventions can build trust. These authors studied African migrant patients' trust in Chinese physicians and found that the trust evolved beyond the immediate patient-physician interaction.

High level leaders envision diversity as an organizational asset that provides a dissenting opinion and may help to avoid group think. This can lead to more robust decision-making which is better implemented with more rapid adoption and more effective to the end goal [42]. Blanding [43] expressed how immigrants can be a driver of innovation and entrepreneurship. Jon Gordon who is a noted expert in leadership emphasizes a dependable work ethic ("Show up and do the work" is a phrase he uses) in garnering respect as a team member [44]. Merit comes from displaying competency. This is a way that minorities can be seen as having earned coveted positions via the work and not quotas.

The ability to recruit and train minority orthopedic surgeons beyond the current percentages may not occur soon. Predominately Caucasian surgeons must learn to better interact with minority patients. Caucasian surgeons in leadership positions must also learn to better mentor racially diverse students and learn to promote racial diversity in hiring. Culture and leadership also remain critical. Peek et al. [45] report survey results that suggest the most successful strategy found to influence the diversity of faculty at medical institutions was institutional leadership creating a climate "where diversity is high among priorities, in allocating resources to implement policies and practices regarding diversity [46, 47]."

Jimenez-Almonte et al. [48] found a correlation between making diversity and institutional goal through professional platforms and increased minority representation. Gebhardt [49] has suggested that active mentoring and access to role models are crucial factors that influence minorities' interest in orthopedic surgery. One study found that an ethnically diverse program and targeted minority recruitment

efforts were important factors for minority applicants considering a residency program [50]. Another study revealed that medical students who completed an orthopedic summer internship program as part of a target pipeline curriculum for underrepresented minorities were more likely to apply to orthopedic surgery residency [51].

With diversity as a priority, we can create and maintain a workforce in orthopedic surgery that understands the unique needs of diverse patients but also that better reflects the U.S. population in order to reduce healthcare disparities, improve the overall health of our population, and enrich the field of orthopedics as a whole.

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Michelle S. Caird and Eric Krohn

Science of Radiation Health

The risks of exposure to ionizing radiation have been known for over a century, and the orthopedic surgeon should have a basic knowledge of the science of radiation and its health risks [1]. Ionizing radiation is a form of high energy electromagnetic radiation that includes ultraviolet (UV) light, plain radiographs, and gamma radiation. This radiation has enough energy to cause an atom to become “charged” or ionized and thus can break chemical bonds. This can cause damage to biologic tissues, and these effects can be divided into deterministic or stochastic effects. Deterministic effects have a cause-and-effect relationship and represent direct tissue damage, which includes skin erythema, hair loss, cataracts as well as instant death if doses are high enough. Stochastic effects are related to the cumulative damage to DNA resulting in errors that can lead to teratogenesis or carcinogenesis. These effects are much more difficult to predict and are dependent on multiple variables such as genetics, duration of cumulative exposure, area exposed, and age. While deterministic effects have a threshold dose before effects are seen, stochastic effects can only be discussed in relation to risk increase as cumulative dose increases [1, 2].

To understand current guidelines in radiation safety, a basic knowledge of the units of measure for radiation is necessary. The actual physical dose of ionizing radiation is defined by the unit Gray (Gy), with $1 \text{ Gy} = 1 \text{ J/kg}$. Since certain forms of ionizing radiation are known to be more biologically harmful than others (such as alpha compared to gamma), an equivalent dose unit is necessary, given in the unit Sievert (Sv). For example, 1Gy of alpha radiation is 20 Sv, whereas 1Gy of gamma radiation is 1 Sv. The International Commission on Radiological Protection (ICRP) has set maximal dose limits per year as 20 mSv for the body and lens of the eye,

M. S. Caird (✉) · E. Krohn

Department of Pediatric Orthopedics, C.S Mott Children’s Hospital, University of Michigan Medical Center, Ann Arbor, MI, USA

e-mail: sugiyama@med.umich.edu; kreric@med.umich.edu

Table 24.1 ICRP maximal dose limits

Tissue exposed	Occupational limit
Entire body	20 mSv/year, averaged over 5 year period
Lens of the eye	20 mSv
Thyroid	150 mSv
Skin	500 mSv (averages dose of 1 cm ² of most highly exposed skin)
Feet and hands	500 mSv

150 mSv for the thyroid, and 500 mSv for the skin, feet, and hands [2]. The average background radiation dose a person receives due to cosmic rays and natural isotopes is about 3 mSv/year (Table 24.1).

How does this translate into dosages for patients and medical personnel? In the field of medicine, there are multiple sources of exposure to ionizing radiation. Medical isotopes, fluoroscopy, plain radiography, and CT scans are all possible sources [2, 3]. A single chest X-ray results in a dose of about 0.01 mSv while a chest CT can deliver a dose of about 8 mSv. That chest CT delivers ~20 mGy to the breast. Current understanding is that the cancer risk due to radiation exposures is higher with a dose of >100 mGy to a certain organ system [2]. Medical exposure to ionizing radiation is a health risk that must be safely minimized.

The Risk of Exposure

Exposure to ionizing radiation has been a known health risk since soon after the implementation of its use [1]. Increases in knowledge, safety training, and better equipment have decreased the risk of injury to patients, surgeons, and staff, but have not eliminated it. Deterministic effects are rare in orthopedic surgery as the threshold dose is rarely achieved to produce these effects. However, hair loss has been reported in interventional cardiologists in areas not protected by the lead apron [4]. There are also case reports of radiation-induced cataract development in interventional cardiologists and radiologists [5]. A survey of Scoliosis Research Society members showed a 30% incidence in cataracts as well [6]. Moreover, it has been demonstrated that arthritis develops in a rat model with exposure to ionizing radiation [7]. Considering most protective garments cover the vital organs, gonads, thyroid, and eyes, there is a real risk for the orthopedic surgeon whose upper and lower extremities are poorly protected during surgery. It is also known that there is increased direct exposure to a surgeon's hands in certain procedures [8].

An important complication of radiation exposure to consider is the development of cancers. While ICRP maximum dosages are well below the threshold believed to be needed to produce any deterministic effect, it is difficult to establish the threshold dose where a significant risk of stochastic effects begins. An increased risk of cancer development in orthopedic personnel has been shown. A 13% incidence of thyroid cancer was seen in the survey of Scoliosis Research Society members, showing they are at increased risk for the development of thyroid cancers when compared to the

general population [6]. Increased cancer risk has also been shown among orthopedic surgeons in a small study of one Italian orthopedic hospital [9].

Not only surgeons and staff face risks of exposure to ionizing radiation, patients are also at risk. Children are particularly susceptible to the stochastic effects of radiation due to their high metabolic rate and the significant lifespan after exposure. Exposure to ionizing radiation for radiation therapy has been linked to osteochondroma formation in children and has been reported to cause lower extremity deformity requiring correction [10]. A large multicenter study on CT scans on children showed that a radiation-induced solid cancer was expected for every 300–760 abdomen and pelvis CTs and for every 270–800 spine CTs. Considering more than four million CT scans are performed per year on children in the US, this led to an estimation of 4870 future solid cancers attributable to CT scans on children in the US alone [11]. While diagnostic and intraoperative imaging is essential in modern medicine, the risks of exposing patients to ionizing radiation cannot be ignored.

Reducing the Exposure

The ALARA Principle

X-ray imaging, fluoroscopy, and CT scans are essential tools in orthopedic surgery. Still, there are many areas where the reduction of exposure to ionizing radiation can be undertaken. The focus should be placed on making exposure to ionizing radiation “as low as reasonably achievable” or ALARA. It is a wide-ranging concept that demands constant consideration in the diagnostic, pre-operative, operative, and post-operative use of ionizing radiation and measures used to protect all parties involved [12, 13].

While ALARA does incorporate the mantra of personal radiation protection in the form of time, distance, and shielding (Fig. 24.1), it also goes far beyond that. With this principle in mind, the utility of every individual test involving ionizing radiation should be considered by the ordering provider. Stewardship of diagnostic

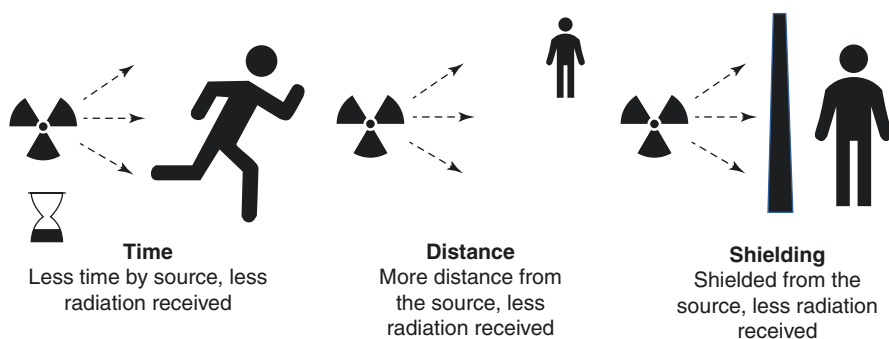


Fig. 24.1 The time, distance, and shielding principle

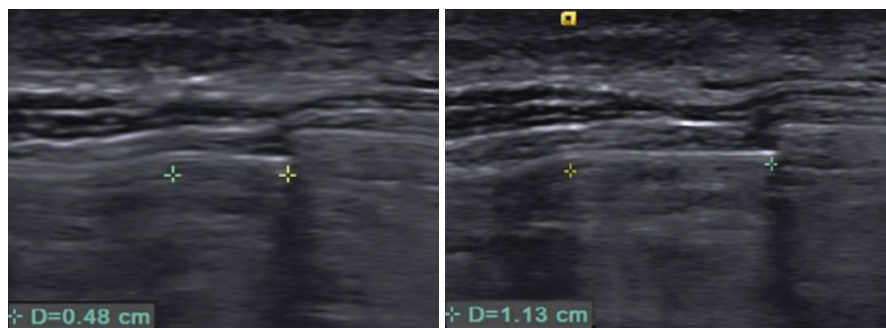


Fig. 24.2 Ultrasound before and after lengthening of a magnetically controlled growing rod implant showing 6.5 mm of lengthening achieved

imaging is an important concept in reducing radiation exposure. Any available options without ionizing radiation should be considered. If ionizing radiation must be used, care should be taken to communicate the requested images as specifically as possible to the technologist with regard to the anatomic area and positioning to reduce unnecessary or repeated exposure.

Alternative Imaging

Other imaging modalities such as MRI or ultrasound may be useful and do not expose the patient to ionizing radiation. While MRI is an excellent tool, it is expensive and time-consuming to perform. It does not provide bony detail at the level of CT, but methods are improving. Ultrasound is less expensive and an appropriate alternative to ionizing radiation in some cases. The use of ultrasound in the diagnosis and reduction of pediatric forearm fractures has been studied and is a viable alternative to X-ray imaging with no difference in pain experienced by the patients [14–16]. Additionally, ultrasound has started to replace plain radiography in the lengthening of magnetically controlled growing rod implants (Fig. 24.2) for use in early-onset scoliosis [17, 18]. Technological advancements with the use of ionizing radiation are also at the forefront of radiation safety. The EOS system (Biospace, Paris, France) uses a high sensitivity xenon particle detector developed by G. Charpak that reduces the X-ray dose by 80–90% when compared to plain radiography and can be used in scoliosis patients and to study lower extremity alignment [19].

Operating Room

In the orthopedic operating room, intraoperative fluoroscopy using a c-arm machine is a major source of exposure to ionizing radiation. Exposure to the orthopedist, staff, and patient comes in two forms, direct and scatter. In a direct exposure, the

X-ray beam exposes the body part being imaged and may expose the surgeon's or assistants' hands if they are directly in the X-ray beam. Scatter radiation is that which reflects off a surface to other parts of the room. While the patient's exposure is primarily direct, the surgeon and staff exposure is mainly from scatter radiation. Scatter levels decrease proportionally to the inverse of the distance squared from the X-ray tube. Doubling the distance between the source and the person results in one-fourth of the scatter radiation reaching the person [13, 20].

Certain modifications to the c-arm machine can reduce the overall dose per image. Intermittent fluoroscopy should be used with a 3-sec burst with a "long off" interval. Also, pulse mode decreases the radiation dose by 70%. When possible, the image should be collimated to reduce the beam area. This also increases the contrast of the image. These methods can decrease dosage to the surgeons, staff, and patients. Bang et al. showed that an AI-enabled fluoroscopy system that uses ultrafast collimation significantly reduces radiation exposure to patients and scatter effect to endoscopy personnel [21].

Whenever possible, the c-arm machine should be positioned with the source below the patient and the receiver above them to reduce the amount of scatter radiation to the room. With image capture and memory storage, previous images can be brought up to avoid repeat imaging. Exposure alarms can be set to warn the surgeon and operator of the amount of exposure received [22]. Finally, it should be noted that while the mini c-arm machine produces less ionizing radiation than its larger counterpart [23], surgeons work much closer to it and should remain careful with its use [20].

Communication between the surgical staff and radiology technician is another area where exposure can be decreased. When operating the c-arm, the terms used by the surgeon to direct the technologist currently have no standardization. There is wide variability and overlap in the terminology used for movements of the c-arm machine. The introduction of clear, unambiguous terminology has been shown to reduce the time and the exposure to obtain the desired image [24]. All personnel who have exposure to ionizing radiation should wear dosimeters according to guidelines so that exposure can be monitored and interventions can be undertaken if high dosages are noted.

Education

Educating residents, staff, and surgeons on dose reduction techniques may be one of the most powerful ways to reduce exposure. No current educational standards exist for the teaching of radiation safety within orthopedic surgery residency programs, and there is a concern for a lack of knowledge among orthopedic trainees regarding radiation safety [25]. At one institution, implementation of an intervention program for training residents in the reduction of ionizing radiation showed decreased overall dosages for not only the residents but also the attending surgeons [26]. Surgeon experience was also found to be an important factor as the presence of a senior surgeon resulted in a 40% decrease in the amount of radiation in the intervention

and control group. Shah et al. showed that implementation of a competency check-off in diagnostic fluoroscopy for radiology residents was associated with a decrease in cumulative radiation dose [27].

Physical Barriers

One of the best ways to protect against radiation exposure is physical barriers. While this can be as simple as a lead wall which has the benefit of protecting the entire body, this is not feasible for most orthopedic procedures. Thyroid shields, lead aprons, and leaded glasses should be worn by all personnel who are exposed to ionizing radiation. Even so, a recent survey of orthopedic surgeons found that only 64.6% always wear a lead apron when being exposed to radiation. This number drops to 30.8% with use of thyroid shields and 3.1% for leaded glasses [28].

Lead aprons and thyroid shields should have a lead equivalency thickness of 0.5 mm and leaded goggles at a level of 0.15 mm. A thickness of 0.25 mm reduces 90% of scatter radiation while a thickness of 0.5 mm reduces 99% of scatter, but at twice the weight [20, 22]. While the 99% protection level is desired, recent literature has shown concern for the ergonomic injury risk posed by heavy lead aprons [29]. Novel garments made with bismuth oxide and other nonlead radiation blocking materials have shown equivalent protection to lead garments and have the benefits of being more flexible and lightweight. One study found that thyroid shields made of a novel material were 27% lighter than their lead equivalents [30, 31]. Hopefully, further developments in this field will lead to more ergonomically advantageous personal protective equipment.

Shielding of patients during diagnostic imaging, however, has recently fallen out of favor. The American Association of Physicists in Medicine has published a position statement against routine shielding of the gonads and fetus during diagnostic imaging. This is due to it providing negligible or no benefit to patient's health and it may also affect the quality of the exam [32].

Conclusion

Exposure to ionizing radiation in modern medicine and specifically orthopedic surgery is a risk of the occupation that cannot be ignored or avoided. Surgeons and staff must work to reduce the exposures of themselves and their patients with all the tools available to them. Understanding the risks and following the ALARA principle are paramount to limiting exposure. Judicious use of imaging and incorporation of novel techniques like ultrasound will reduce the use of ionizing radiation. Education and cooperation between surgeons and radiology technicians can minimize exposure to ionizing radiation. Orthopedic surgeons must take the lead on reducing exposure, not only for patient and staff health, but also for their own.

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Melissa A. Christino, Vishwas R. Talwalkar,
Michael J. Goldberg, and Jennifer M. Weiss

Introduction

Issues related to physician well-being and burnout have increasingly become recognized as institutional priorities in recent years, particularly with heightened media attention regarding global public health crises and the COVID-19 pandemic. Multiple studies have shown that at any one time, a significant percentage of physicians are burnt out, which has collateral effects on professional satisfaction, patient care, and economic costs to the United States (US) healthcare system [1–4]. Physician and clinician burnout has been extensively studied, particularly with regard to patient safety and quality of care, and as such, most of this chapter is dedicated to discussing ways to mitigate burnout and enhance professional fulfillment. The term “wellness” has become a catchment phrase for many of these issues in the medical literature, however given its broad connotations, also distracts from the critical issues that affect clinician well-being, which is a more appropriate term. It is important to appreciate that there are multiple stressors that physicians endure in the current healthcare environment in their quest to provide selfless, quality care to those in need.

M. A. Christino (✉)

Department of Orthopedic Surgery, Boston Children’s Hospital, Harvard Medical School,
Boston, MA, USA

e-mail: Melissa.Christino@childrens.harvard.edu

V. R. Talwalkar

Department of Orthopedic Surgery and Pediatrics, Shriners Hospital for Children Medical
Center, University of Kentucky, Lexington, KY, USA

e-mail: vtalwalkar@shrinenet.org

M. J. Goldberg

The Schwartz Center for Compassionate Healthcare, Boston, MA, USA

e-mail: mgoldberg@theschwartzcenter.org

J. M. Weiss

Department of Orthopedic Surgery, Kaiser Permanente, Los Angeles, CA, USA

Burnout. Burnout is defined as emotional exhaustion, feelings of detachment and cynicism, and having a sense of low personal accomplishment and efficiency, and is typically the result of a prolonged response to occupational and personal stressors [5]. Physician burnout has been deemed a healthcare crisis [6–8] and has significant effects on the healthcare system. Burnout affects not only physicians, but also other healthcare professionals as well. Most of the literature in this chapter refers to physician burnout but these concepts can be extrapolated to all healthcare workers.

Moral Injury. The concept of “burnout” can be off-putting to many physicians, as the connotation suggests a failure of personal resilience or resourcefulness. However, systems limitations and competing demands often lead physicians down a path of frustration, stress, and ultimately decreased productivity, engagement, and emotional distress. Moral injury, initially described as a military term for soldiers returning from war, is the result of what Dean et al. described as “the challenge of simultaneously knowing what care patients need but being unable to provide it due to constraints that are beyond our control” [9]. The healthcare system in the US does not consistently support physicians in compassionate and autonomous patient care. This conflict can lead to “burnout.” This concept is gaining traction in the literature among physicians and will likely be studied more in the context of healthcare in the future.

Second Victim Syndrome. Second victim syndrome is an important concept that is a common experience for clinicians that can lead to significant distress. It refers to the psychological or emotional trauma that a clinician experiences as the direct result of an adverse patient outcome [10]. Generally, the first victim is the patient who has experienced an error or suboptimal outcome, and the “second victim” is the physician or clinician and the personal manifestation of that event for them. Clinicians often blame themselves after such events, feel distraught, lose confidence, and experience a deep sense of failure [11]. These feelings can fester and cause emotional disturbance, burnout, serious mental health conditions, substance abuse issues, and even suicide. Malpractice lawsuits, for example, cause considerable sustained stress for physicians. A cross-sectional survey of the American College of Surgeons showed that burnout, depression, and recent thoughts of suicide were associated with having had a recent malpractice lawsuit [12]. Consequences of second victim syndrome can be severe and long-lasting and literature advocates for both peer and institutional systems to help support physicians psychologically, enhance resilience, and maintain stamina for continued quality care.

COVID. The COVID-19 pandemic has brought about unprecedented changes to the US healthcare system. While the importance of physician well-being was increasing, this pandemic catapulted its significance and exposed the mental toll that providers experience in the high stakes arena of healthcare. Nightly news stories showed the faces of exhausted clinicians, and the public mobilized to support healthcare workers like never before. In some of the worst days in modern medicine, physicians and other healthcare workers tirelessly persisted and sacrificed their personal safety to care for others. This has not come without an emotional and personal cost. Frontline workers reported high rates of depression, anxiety, insomnia, and psychological distress, and those dealing directly with COVID patients had higher rates [13–16]. Burnout, fatigue, symptoms of post-traumatic stress disorder, and physician suicide have also been significant concerns [17–19]. Isolation, fear

for personal safety and inadequate personal protective equipment, transmission of disease to family members, decreased patient volumes, financial instability, lack of wellness resources and support, and family life stressors have been identified as additional drivers of distress during the pandemic [20–22]. Institutions across the country have scrambled to provide emotional support and mental health programs for physicians and other healthcare providers to sustain and care for their workforce [23]. The full magnitude of this pandemic's emotional effects on healthcare workers will likely not be revealed for some time [24].

Prevalence of Physician Burnout

Physician burnout is prevalent among attending physicians and trainees, with doctors experiencing higher burnout rates compared to the general working population [1, 2, 25]. Studies estimate burnout rates in US healthcare workers to be between 35 and 54% [26]. Women report higher rates of burnout compared to men, and residents and fellows have been shown to be at particular risk for burnout across specialties [26–29].

Surgeons are also at high risk. A 2008 study of 7905 surgeons found a 40% burnout rate, with 30% of surgeon respondents experiencing symptoms of depression, and only 36% reporting that their work schedule allowed adequate work-life balance [30]. A follow-up analysis found that 6.3% of surgeons reported suicidal ideation in the 12 months preceding the survey. This rate was higher than the rate of suicidal ideation in the general population and was strongly associated with symptoms of depression and burnout [31]. Only 26% of those with suicidal ideation sought psychiatric help. Suicide rates are also high among orthopedic surgeons. Pamela Wible reported on 33 orthopedic suicides in a 2018 analysis [32]. Since that time, the authors are aware of at least 2 more.

While orthopedic surgery is regarded as a highly sought after and competitive specialty, orthopedic surgeons are not immune to the systemic pattern of burnout among physicians across the country. In fact, a recent systematic review suggested that burnout rates among orthopedic surgeons may vary across institutions, but are not substantially different than reported burnout rates in other specialties [33]. Recent evidence also suggests that surgeons who experience microaggressions, bullying, and harassment in the workplace experience burnout at higher rates [29].

In a study of 7288 physicians, orthopedic surgeons were in the top quartile for burnout when physicians were stratified by specialty [1]. Sargent reported a burnout rate of 28% among orthopedic faculty and a 56% burnout rate among residents, and this was despite the fact that 93% of participants in both groups would choose orthopedics again with fairly high rates of overall job satisfaction [34]. A recent membership survey of the Pediatric Orthopaedic Society of North America found that 38% of respondents reported personal burnout and 46% reported team burnout [35]. More than three quarters of current or acting orthopedic department chairs reported moderate or high levels of emotional exhaustion, which correlated with a lack of personal-professional life balance [36].

Trainees are at particular risk for burnout demonstrating some of the highest rates of burnout in the literature. A recent study of 661 orthopedic surgery residents

found a burnout rate of 52%. This study also demonstrated 13% of trainees screened positive for depression, 61% met criteria for hazardous alcohol use, and 7% reported recreational drug use [37]. Factors that were significantly associated with components of burnout included being early in training, having unmanageable work volume, feeling unsupported, and being unable to maintain out of work commitments such as exercise or attending health maintenance appointments. Burnout has also been recently linked to lower performance on the Orthopedic In-Training Examination (OITE); residents in earlier years of training demonstrated higher scores of emotional exhaustion and depersonalization [38]. The results from these studies are concerning. Programs must educate their trainees about work-related stress and strive to improve modifiable risk factors that may improve resident experience and performance.

Burnout not only affects the individual physician and their patients, but it can have far reaching consequences in one's personal and professional life (Fig. 25.1). A study of orthopedic spouses found that decreased marital satisfaction was associated with partner irritability and fatigue [39].

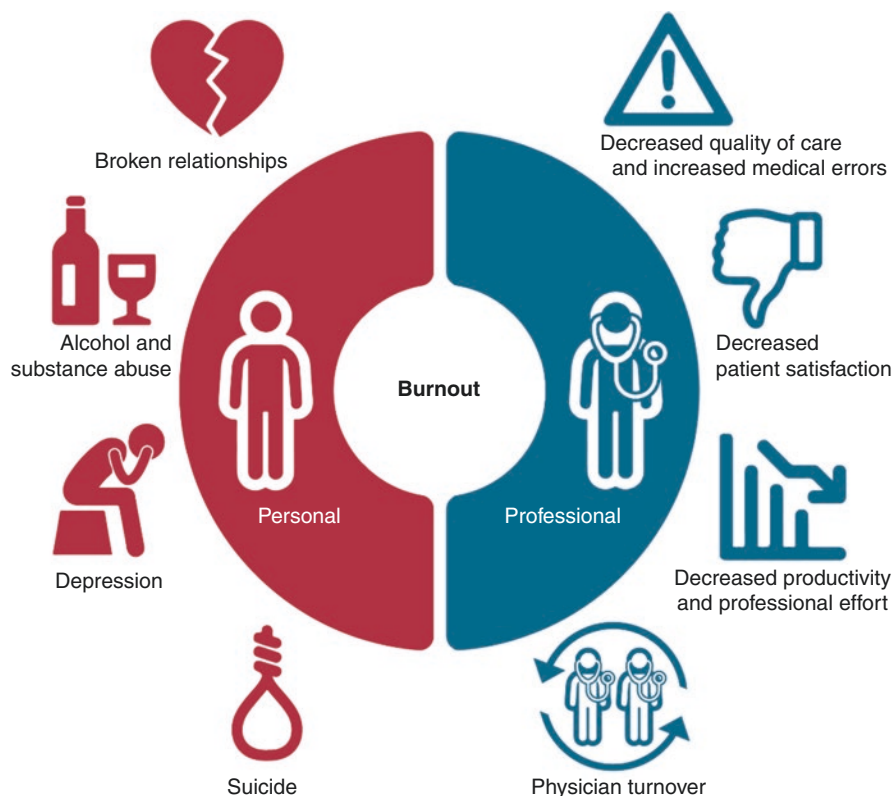


Fig. 25.1 Personal and professional consequences of physician burnout [59]. Figure adapted from: Shanafelt TD, Noseworthy JH. Executive Leadership and Physician Well-being: Nine Organizational Strategies to Promote Engagement and Reduce Burnout. *Mayo Clin Proc.* 2017;92(1):129–46. <https://doi.org/10.1016/j.mayocp.2016.10.004>

Implications for Patient Safety and Quality Care

Consequences of physician burnout can be significant, negatively affecting delivery of high-quality care, and leading to increased patient safety concerns. Multiple studies have shown increased self-reported medical errors to be associated with physician burnout [40–43]. Medical errors can result in substantial patient morbidity, mortality, cost, and resource expenditure [44].

A study of intensive care physicians and nurses showed that burnout was associated with clinician-rated patient safety concerns; this study also demonstrated that emotional exhaustion predicted patient mortality [45]. Internal medical residents were found to have high rates of burnout (76%) and this correlated with greater suboptimal patient care behaviors [46]. The Minimizing Error, Maximizing Outcomes (MEMO) Study of primary care physicians found that stressed, burned out, and dissatisfied physicians reported greater likelihoods of reporting medical errors or compromised patient care [47].

A cross-sectional study of 7905 surgeons found that burnout and depression were independent predictors of reporting a medical error. Every one point increase on the depersonalization and emotional exhaustion burnout domains was associated with an elevated risk of reporting a medical error within the last 3 months (11% and 5% increased risk, respectively) [40].

Disruptive behavior has also been associated with burnout. In a study of Chinese orthopedic surgeons, intraoperative irritability or losing one's temper in the OR was significantly correlated with burnout and emotional exhaustion as measured by the Maslach Burnout Inventory [48]. The consequences of disruptive physician behavior can be far reaching. It inhibits effective communication, erodes the team dynamic and collaborative efforts, and compromises patient and provider safety [49].

Patient satisfaction and experience are also affected by burnout. In a study of 178 matched patient-physician dyads, relationships between burnout dimensions and patient outcomes were analyzed [3]. Physician depersonalization as well as patient-perceived depersonalization was positively associated with recovery time and negatively associated with patient satisfaction. In addition, patients who experienced more empathetic and compassionate care from physicians were shown to have higher experience and outcome scores [50]. Compassion can be cultivated and learned, thereby improving outcomes; however, time constraints, lack of autonomy, and burdensome documentation requirements can negatively affect and hinder provider compassion [50, 51].

The fundamental physician–patient relationship is an important form of engagement that can mitigate burnout. When patients are referred to as “customers, clients, or members,” the climate of healthcare shifts to that of a consumer driven interaction [52]. When physicians are referred to as “providers,” respect is difficult to maintain [53]. Protecting the sanctity of the physician–patient relationship is critical to promoting meaningful work among physicians and providing optimal care to patients.

The “Triple Aim” is a popular concept that has guided health system performance and includes three dimensions: improving health of the population,

enhancing patient care, and reducing costs [54]. More recently, some authors contend that this model should be expanded to include a fourth aim of care team well-being, maintaining that optimal care of patients requires care of the provider [55]. Furthermore, they argue that healthcare team well-being is a prerequisite for the traditional Triple Aim performance dimensions.

The Cost Case to Promote Clinician Well-Being

Clinician burnout affects the bottom line of hospitals and organizations. In addition to the already significant human toll of burnout's downstream effects, financial implications are significant, and these include costs related to staff turnover, lower productivity, and medico-legal liability for lower quality care. Recent studies have examined the cost case for investing in physician well-being [4, 56, 57]. By highlighting the direct financial effects on institutions, increased awareness and acknowledgement of these issues may help to drive policy and institutional change.

Costs related to physician turnover are substantial, and include direct costs of recruitment and onboarding, as well as indirect costs related to the lost revenue of a physician who is leaving and startup costs of a new physician. Burned out physicians have been found to be more likely to leave their jobs compared to those without burnout [56]. Total costs related to replacing a single physician range from \$500,000 to \$1,000,000 [57]. While these estimates include many of the direct and indirect costs of turnover, they often do not take into consideration more intangible costs of turnover, such as negative impacts on patient access, lost patient care revenue, and the collateral effects on other physicians who become overburdened with the increased workload if another physician leaves or reduces their work hours.

A recent cost-consequence analysis of a hypothetical model of US physicians estimated the cost to the US healthcare system of physician burnout [4]. The costs related to physician turnover and reduced clinical hours alone cost the US Healthcare system approximately \$4.6 billion per year and individual organizations approximately \$7600 per employed physician each year. These estimates were conservative and did not include indirect costs that were more difficult to quantify, such as lost patient care revenue, lower reimbursements due to low organizational patient satisfaction scores, medical errors, or malpractice lawsuits. This study strongly argued for organizational investment in initiatives to reduce burnout and enhance physician well-being as a cost-saving measure. Not only is there value from an ethical and patient safety standpoint to support and encourage physician well-being, there is evidence of significant financial incentive from an organizational perspective.

Organizational Strategies to Promote Physician Well-Being

In the fall of 2019, the National Academy of Medicine released a 300-page consensus entitled, *Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being* [26]. This report highlights the profound and systemic

consequences of clinician burnout and calls upon leaders of health care organizations, government, and industry to prioritize initiatives to improve clinician well-being for the benefit of clinicians, patients, and the nation. A systems-based model examined the effects of the healthcare environment, work system factors, and front-line care delivery as experienced and filtered through the individual clinician (Fig. 25.2). Evidence-based recommendations included multi-level suggestions focused on improving clinical work and learning environments, implementing work systems changes that enhance well-being, and minimizing burnout and enhancing professional well-being.

Investment in individual and organizational strategies has been shown to reduce physician burnout [57–60]. Shanafelt notes that “most institutions operate under the erroneous framework that burnout and professional satisfaction are solely the responsibility of the physician... (but) there is a strong business case for organizations to invest in efforts to reduce physician burnout and promote engagement” [59]. The call for system changes to improve the environment in which the physician functions are driven by data and supported by national organizations [6, 26, 61, 62]. No matter how adaptable, dedicated, and inspired a physician is, personal resilience strategies will ultimately fail if the healthcare system does not also support physicians to engage in efficient and meaningful work.

Enhancing professional satisfaction is one way to mitigate the effects of burnout. In fact, studies have shown that higher levels of professional satisfaction are associated with decreased burnout rates. In a study of 465 physicians, higher rates of burnout were found in those who spent less than 20% of their professional time on

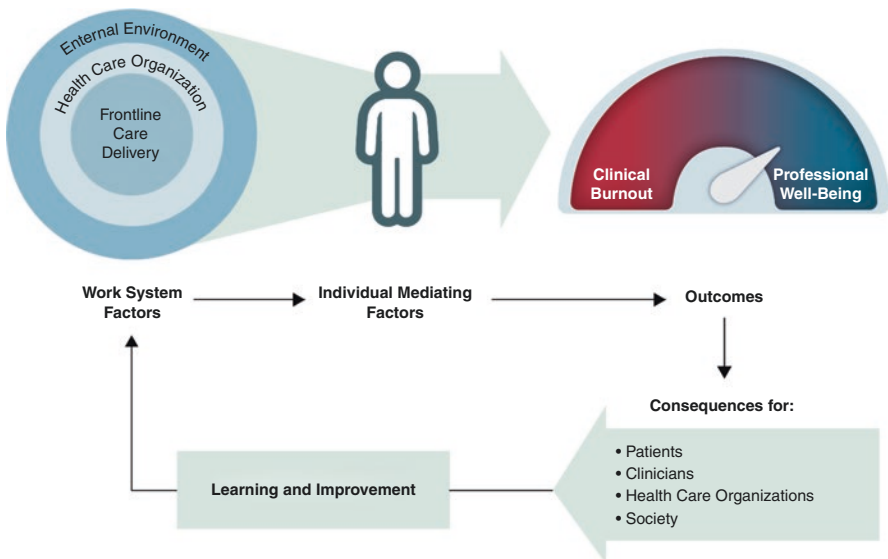


Fig. 25.2 National Academy of Medicine systems model of clinician burnout [26]. Figure adapted from: National Academies of Sciences, Engineering, and Medicine. Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being. Washington, D.C.2019

their clinical passions [63]. The Stanford model of professional fulfillment strives to improve physician-well-being and engagement through espousing a culture of well-ness, improving workplace efficiency, and enhancing personal resilience strategies [64]. A multi-institutional consensus review utilized this framework to make concrete recommendations for healthcare organizations about how to work towards reducing burnout and enhancing professional satisfaction (Fig. 25.3) [65]. Fundamental to their recommendations was creating a culture of well-being through leadership development initiatives, teamwork and collegiality, appreciation, equity and inclusion, decreasing inefficiency of practice, establishing a leadership supported and funded wellness program, and providing organizational support for individual physician resilience and self-care.

Shanafelt et al. argued that “engagement is the positive antithesis of burnout,” and identified seven drivers of burnout and engagement that organizations have a responsibility to help address: workload, efficiency, control over work, work-life integration, individual/organizational alignment, social support/sense of commu-nity, and meaningfulness of work (Fig. 25.4) [59]. They described their experience

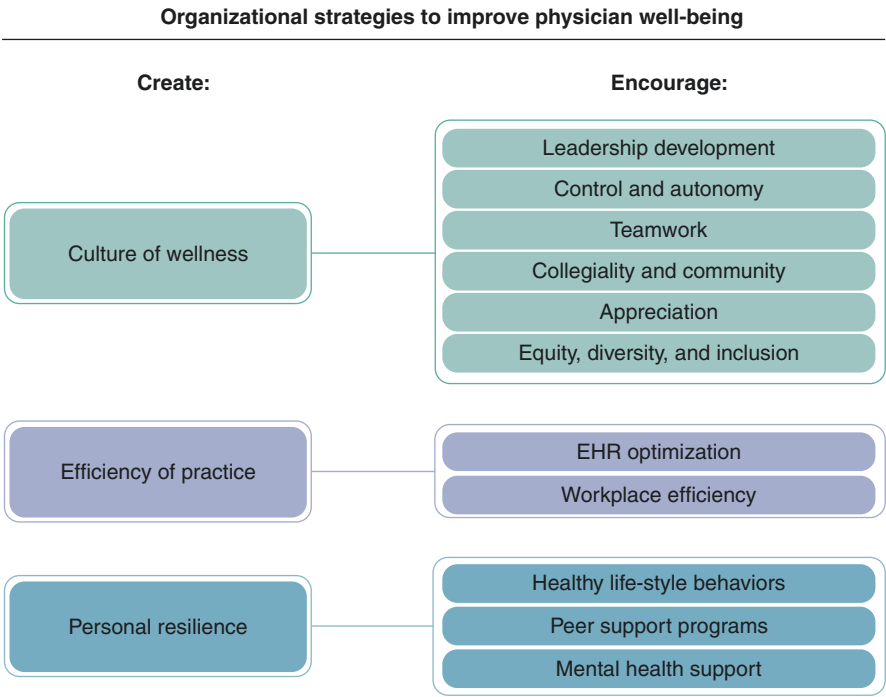


Fig. 25.3 Consensus organizational strategies to improve physician well-being [65]. Authors advocated for working towards Stanford model wellness domains by encouraging specific evidence-based strategies. Abbreviations: EHR, electronic health record. Figure adapted from: Olson K, Marchalik D, Farley H, Dean SM, Lawrence EC, Hamidi MS, et al. Organizational strategies to reduce physician burnout and improve professional fulfillment. *Curr Probl Pediatr Adolesc Health Care*. 2019;49(12):100664. <https://doi.org/10.1016/j.cppeds.2019.100664>



Fig. 25.4 Drivers of physician burnout and engagement [59]. Figure adapted from: Shanafelt TD, Noseworthy JH. Executive Leadership and Physician Well-being: Nine Organizational Strategies to Promote Engagement and Reduce Burnout. *Mayo Clin Proc.* 2017;92(1):129–46. <https://doi.org/10.1016/j.mayocp.2016.10.004>

at the Mayo Clinic, where leadership intentionally and comprehensively prioritized promoting physician engagement and successfully reduced burnout rates among their staff in a multi-year effort that is ongoing. Organizational strategies and initiatives focused on acknowledging and assessing the problem of burnout. They had strong committed leadership, implemented targeted interventions to affect change, cultivated community, promoted flexibility and work-life integration, and provided resources for self-care and personal resilience.

Culture change in an organization can be difficult and takes time. A large private orthopedic practice in North Carolina described their experience of intentionally prioritizing and creating a culture of wellness within their department over a 4 year period while measuring physician satisfaction [66]. Interventions included a formalized mentor program, class dinners, leadership education, and partnering with Vanderbilt University’s Patient Advocacy Reporting System (PARS) to utilize a data-driven program to increase professionalism and identify at-risk physicians. Physician engagement and resilience improved rising above Press Ganey national averages for these domains. The authors attribute the success of this process to strong support and commitment from the leadership, and the creation of a distinct leadership position within the department with the support, authority, and funding to lead physician well-being efforts.

Greater awareness of the dangers and consequences of physician burnout have started to turn the tides towards a movement of prioritizing and protecting physician well-being. The added stress of the COVID-19 pandemic on clinicians and healthcare workers has further catapulted the importance of clinician well-being across healthcare institutions and among the general public. National consensus recommendations identify key strategies to mitigate burnout, including leadership prioritization, physician involvement and engagement, targeted institutional interventions, promoting a culture of wellness, assessing and monitoring burnout and professional

well-being in frontline clinicians, and investing in research in this space [26, 57, 59, 65]. Organizational and systems approaches are absolutely essential to optimally support physicians in their work and to drive culture change towards embracing both patient and care-giver well-being as a strategy to ultimately maximize performance, satisfaction, and outcomes in healthcare.

Conclusions

In 2021, the shift in approach to well-being among physicians and clinicians is clear. Resilience is an important muscle, and our profession has long ago maximized the strength of our resilience. Language is important, and moral injury is the term that best describes the canary in the coalmine of healthcare. The toxicity of the coalmine must be addressed by systems improvement, deepening and respecting physician/clinician patient relationships, and re-elevating the autonomy and drive of individual clinicians to do what is correct for their patients. This is not only the right thing to do, but the organizational investment in supporting clinician well-being is a profitable endeavor that can improve patient care and outcomes.

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Advocacy to Promote Quality Musculoskeletal Care

26

Stuart Weinstein and Will Shaffer

Advocacy must be viewed in the context of the American healthcare system which has continued to be under considerable scrutiny. All Americans, including members of Congress, want to have access to high quality healthcare at a reasonable cost. In the US, healthcare costs continue to rise with America spending almost 20% of GDP on healthcare, almost twice as much as the next developed nation without having commensurate top tier outcomes. Our delivery system is fragmented, and the quality of care Americans receive is quite variable. Furthermore, many Americans are either uninsured or underinsured which hinders their access to care.

Advocacy requires a basic understanding of who pays for healthcare coverage in America and Congress' role. The US employer-based health care coverage system dates to World War II when the War Labor Board instituted wage and price controls but exempted fringe benefits (e.g., healthcare) which were tax deductible. Hence while most countries of the world evolved to government sponsored insurance, the United States adopted the employer-based health care coverage system. The federal government became involved in healthcare in 1965 with the birth of Medicare and Medicaid. Medicare is for Americans aged 65 and older who have worked and paid into the system; it also provides health insurance to younger people with disabilities. Medicaid is a state-federal program for families and individuals with low income and limited resources. In 2018, approximately one-third of all Americans were on a government insurance program. With our aging population, about 10,000 Americans go on to Medicare daily. Any changes to Medicare or Medicaid coverage decisions by either Congress or the regulatory agencies (HSS) are often mirrored by the private insurers.

S. Weinstein (✉)
University of Iowa, Iowa City, IA, USA
e-mail: stuart-weinstein@uiowa.edu

W. Shaffer
AAOS, Washington, DC, USA
e-mail: shaffer@aaos.org

In the American political system, laws are made by the Legislative Branch of government which consists of 435 members of the House of Representatives and 100 senators. Laws may be introduced by any member in either chamber. With respect to healthcare legislation, each chamber has *committees of jurisdiction* (House–Ways and Means and Energy and Commerce; Senate Finance and HELP committees being the most important) which develop and assess legislation. In the House, a simple majority of 218 out of the 435 members is required to pass a bill. In the Senate, 51 votes are required to pass legislation. However, the Senate has a unique procedural rule, requiring 60 out of 100 votes to stop debate and call for the vote. Once the bill passes either chamber, a companion bill must pass the other chamber at which time it goes to the House-Senate conference committee which produces the final language to the bill, which then must be passed by each chamber before it is sent to the President for his/her signature (Fig. 26.1). In our system, the party in the majority in either chamber has considerable influence over the outcome of legislation.

Laws passed by the Congress are generally written using broad language. It is then up to the federal agencies with the assistance of the White House Office of Management and Budget with public comments to produce regulations that specify how the law is to be interpreted. While thousands of bills may be introduced each congressional session, only about 5% will even pass a single legislative chamber, with only 2–3% ever becoming law.

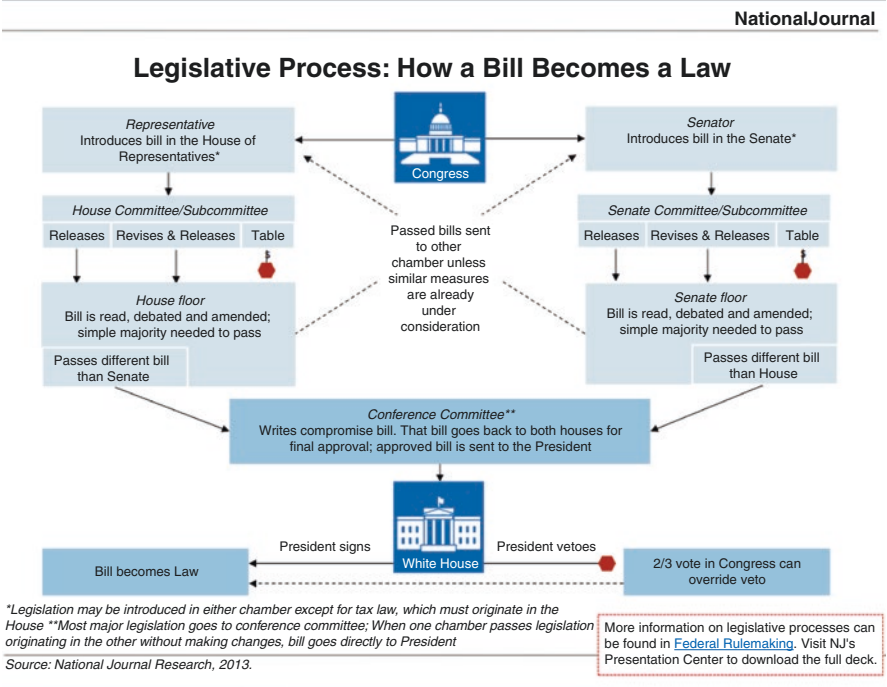


Fig. 26.1 Legislative process: how a bill becomes a law

AAOS and Advocacy

The AAOS established the Washington DC office in 1979 with a primary focus on musculoskeletal research funding issues. As members became more interested in advocacy and as the federal government had greater influence on healthcare decisions, the American Association of Orthopedic Surgeons, a 501 C6 organization, was founded, which allowed it to play a greater role in advocacy at the federal and state level. In 1999, the Association established the political action committee (AAOS PAC now known as OrthoPAC) to advance the legislative agenda of the AAOS and interested subspecialty groups. The AAOS office of government relations (OGR) provides members with a full-time staff on Capitol Hill to promote a proactive presence on the “Hill” on legislative and regulatory issues. The OGR also helps promote and represent the viewpoints of the orthopedic community before federal and state legislative, regulatory, and executive agencies. The OGR also helps members prepare testimony before congressional committees or federal agencies. Importantly, they also provide very important state advocacy services and appropriate comment on proposed federal regulations.

The OrthoPAC is critical to the AAOS advocacy efforts. A PAC is a committee organized for the purpose of raising and spending money to elect candidates for office. The OrthoPAC is a pragmatic political action committee, not an ideological one. The PAC advocates on multiple issues and supports candidates from all parties who support *Musculoskeletal issues*. *Our issues* are those legislative and regulatory issues prioritized by the OGR, The Council on Advocacy, and the AAOS Board each election cycle. These are the “marching orders” for all AAOS advocacy efforts. Having a vibrant, well-funded PAC allows the AAOS and individual members to have increased *access* to members of Congress. This access leads to enhanced *opportunities* to express our opinion on various issues. We can tell members of Congress what we are for and what we are against and why. We can tell them how a particular legislation or regulation hurts or helps our patients, or how it helps or hinders their access to our care, how it affects healthcare costs, and finally how it affects the quality of care we are able to deliver. Most importantly, a robust PAC allows for the development of important *relationships* with members of congress. It allows us to build meaningful trusted relationships with members to keep the lines of communication open on the issues of the day. It also affords us the opportunity to show how we are working as an organization to be part of the healthcare solution to bring “value” to the care we provide. It gives us the opportunity to highlight the initiatives of the AAOS including clinical practice guidelines, appropriate use criteria, registries, and performance measures, all aimed at improving the quality and safety of orthopedic care. A strong quality and safety program is a fundamental pillar of advocacy: the more robust our quality data, the greater the strength and credibility of our advocacy message.

Finally, with respect to the advocacy process, it is important for AAOS members to realize that advocacy success requires patience and persistence, as most major laws take many years to be enacted or repealed. For example, the ACA took 6 years to enact while repealing the flawed sustainable growth rate (SGR) took 15 years of

sustained advocacy efforts. The successful push to allow team physicians to care for their teams across state lines took 5 years of Federal and State advocacy to come to fruition.

Each state government will have its own parallel structure with the executive (governor) and the legislature and state regulatory agencies with similar processes. State advocacy efforts cannot be minimized as such issues as medical licensure and scope of practice are often decided at the state level.

Regulations and Agencies

Advocacy at the Federal Department and Agency level is quite different from congressional advocacy. The agencies interpret the broad laws that congress enacts. The regulations that result from this interpretation of law are guided by public, policy experts and the regulated business' input during public comment periods. AAOS' philosophy for agency engagement rests with the expert scientific knowledge of our members and leaders. The agency personnel are generally highly educated, with advanced degrees (e.g., MD, PhD, JD, and MPH). The advocate must remember that the agency personnel are as highly trained and knowledgeable as the advocate. AAOS relies on science and quality evidence basing on their arguments. Contact with the agency personnel must be frequent and consistent.

The AAOS OGR interfaces with these Federal Departments and their component agencies:

- Health and Human Services (<https://www.hhs.gov/about/agencies/orgchart/index.html>)
- VA (<https://www.hhs.gov/about/agencies/orgchart/index.html>)
- DOD (<https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency>)
- DOJ (<https://www.justice.gov/civil/consumer-protection-branch/opioid>)
- DEA (<https://www.dea.gov>)
- Office of Management and Budget (<https://www.whitehouse.gov/omb/>)
- Congressional Accountability Office (<https://www.gao.gov>)

Within each of these federal departments and agencies, OGR has personal relations with government regulatory managers. The process is itself highly regulated by rules developed by each agency for their rulemaking. Rulemaking is the formal process by which the law is going to be applied to the affected industry, consumers, and practitioners. A proposed rule must be published and open for public comment for up to 90 days. All public comments are reviewed and accepted or rejected in the writing of the Final Rule.

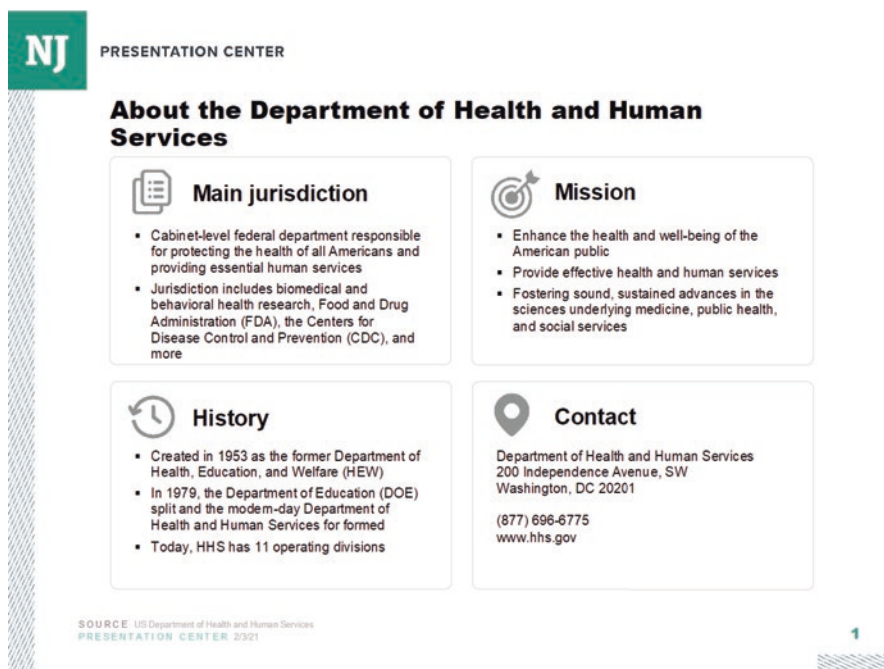
The rule-making process is cyclical such as the annual rules produced by CMS for the Inpatient Prospective Payment System (IPPS) or the Outpatient Prospective Payment System (OPPS). Similar annual rules affect Nursing Homes, Hospitals, Durable medical equipment and Pharmacies. All annual rules are monitored by OGR for any impact on Orthopaedic Surgeons and Musculoskeletal Care.

There are also episodic rules arising from hot button issues such as the opioid crisis which generated rules from all the above federal department and agencies. For this reason, the Federal register is monitored by OGR staff daily. It is common for the rule-making process to go on for years. An good example of this is the Complex Joint Replacement Center for Medicare Medicaid Improvement (CMMI) demonstrations.

During the public comment period, OGR prepares comments gathered from AAOS members and prepares the comment letter for the AAOS' President. The letter will contain the AAOS principles, leadership knowledge, concerns, and recommendations to help the agencies to come to rationale and effective rules in applying the law. The approval process for an AAOS comment letter includes the AAOS council and committee chairs prior to final presidential line approval.

Little known by the general public, deregulation has a lawful basis and requires careful rulemaking and the same comment period as regulation. As such, the last 4 years OGR experienced an era of more regulatory activity in the guise of deregulation.

Federal Departments are a cabinet level umbrella organization managing many agencies. HHS (Fig. 26.2) is the most frequent department that OGR engages. Many of the agencies that govern medicine are housed within HHS (see HHS org chart Fig. 26.3) such as CMS (Figs. 26.4, 26.5, and 26.6), FDA (Figs. 26.7, 26.8, and 26.9), and NIH.



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About the Department of Health and Human Services



Main jurisdiction

- Cabinet-level federal department responsible for protecting the health of all Americans and providing essential human services
- Jurisdiction includes biomedical and behavioral health research, Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and more



Mission

- Enhance the health and well-being of the American public
- Provide effective health and human services
- Fostering sound, sustained advances in the sciences underlying medicine, public health, and social services



History

- Created in 1953 as the former Department of Health, Education, and Welfare (HEW)
- In 1979, the Department of Education (DOE) split and the modern-day Department of Health and Human Services for formed
- Today, HHS has 11 operating divisions



Contact

Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

(877) 696-6775
www.hhs.gov

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Fig. 26.2 About the department of health and human services

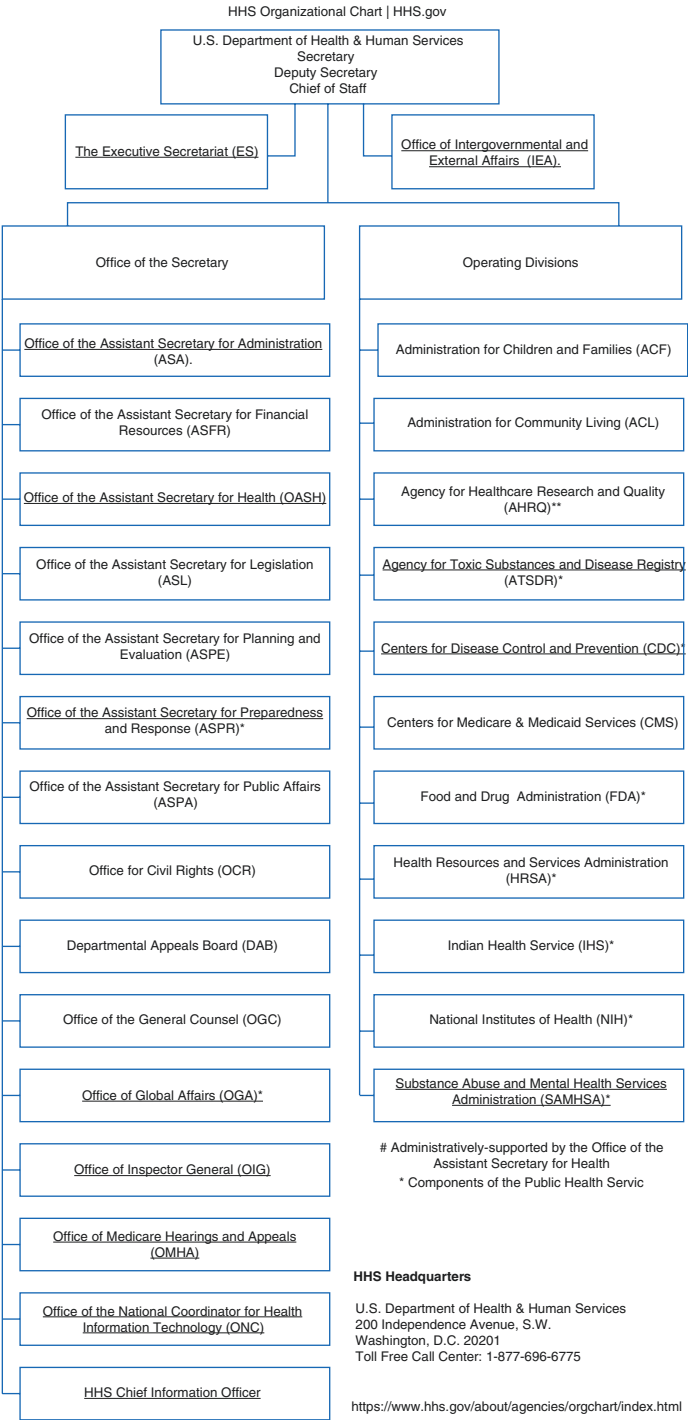


Fig. 26.3 HHS Organizational Chart | [HHS.gov. https://www.hhs.gov/about/agencies/orgchart/index.html](https://www.hhs.gov/about/agencies/orgchart/index.html)

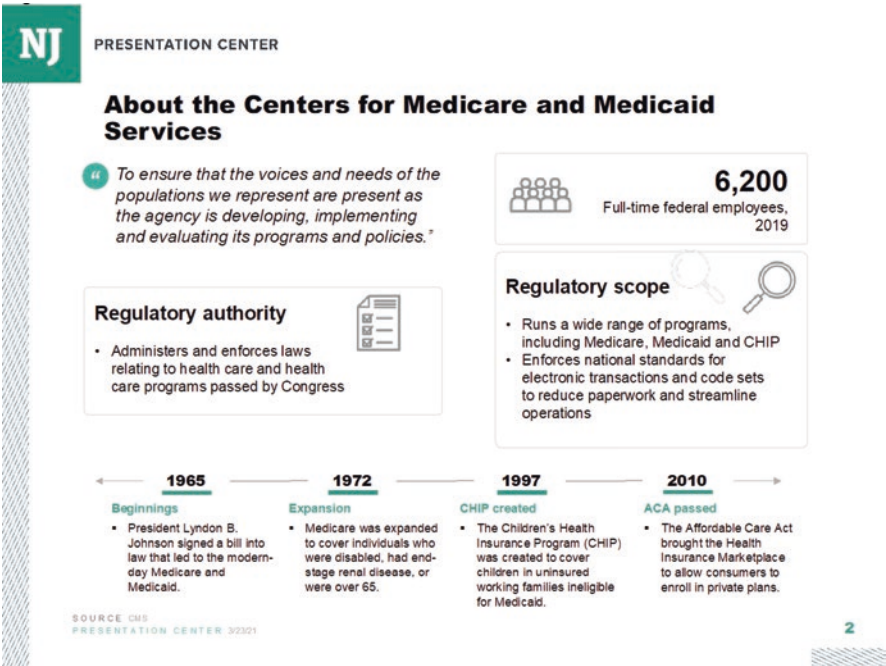


Fig. 26.4 About the centers for medicare and medicaid services

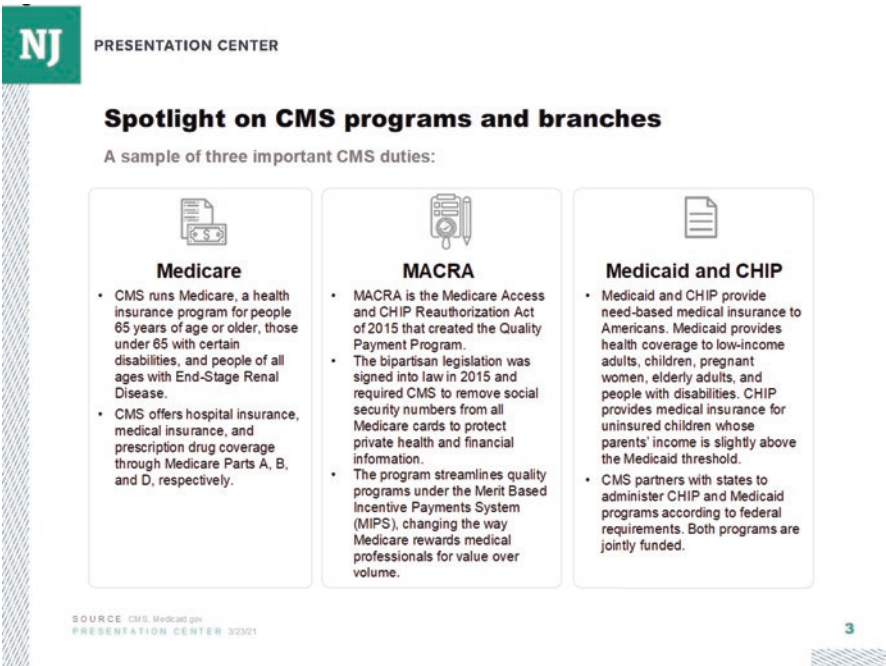
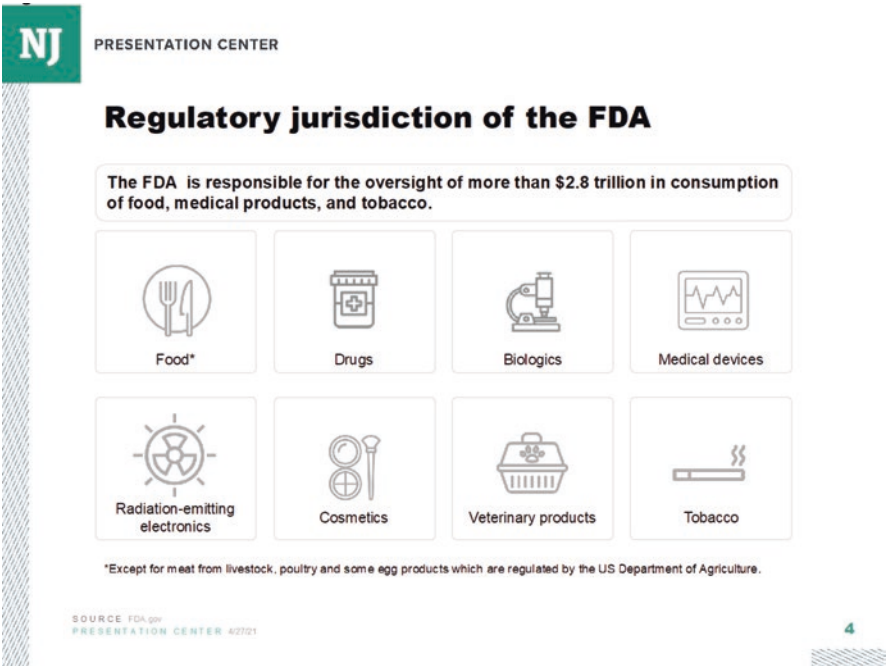


Fig. 26.5 Spotlight on CMS programs and branches



Specific Agencies Issues

OGR advocates most frequently The Centers for Medicare and Medicaid services and the Federal Drug Administration (Fig. 26.4).

Advisory Committees and Task Forces

Federal agencies depend on contractors and volunteer physician advisors for guidance in the regulatory process. Examples of Federal contractors include AMA and NQF. AAOS solicits active members (liaison officers) to serve on these governmental work groups through the Committee Appointment Process (CAP) and the Accelerated Committee Appointment Process (ACAP). These liaison officers are matched to the committees of jurisdiction. The liaison officer can serve as a resource to AAOS committees, and the committees can help advise the liaison officer when specific questions arise (Table 26.1).

Table 26.1 Organizational liaison positions funded by AAOS in 2018

Accreditation Council for Graduate Medical Education (ACGME) Residency Review Committee for Orthopaedic Surgery (2)
AMA House of Delegates - Orthopaedic Section Council – Delegate (5)
AMA House of Delegates - Orthopaedic Section Council -Alternate Delegate (4)
AMA-convened Task Force to Reduce Opioid Abuse (2)
American College of Radiology (ACR) - Appropriateness Criteria Expert Panel on Musculoskeletal Imaging (2)
American College of Radiology (ACR) - Appropriateness Criteria Expert Panel on Musculoskeletal and Neurological Imaging (2)
American College of Radiology (ACR) - Appropriateness Criteria Expert Panel on Pediatric Imaging
American College of Surgeons (ACS) - Board of Governors (2)
American Geriatric Society (AGS) - Geriatrics for Specialists Initiative (2)
AMPAC Board of Directors
Blue Cross Blue Shield Assoc (BCBSA) Expert Panel – Spine (3)
CMS Beneficiary Engagement and Incentives: Direct Decision Support (DDS) Model
CMS Pain Management/Throughput Measure Expert Group (2)
CMS TEP - Development of Inpatient Outcome Measures for the Merit-based Incentive Payment System (MIPS)
Joint Commission ADOPT Guidance Project
MACRA Episode-Based Cost Measures Clinical Subcommittee (2)
National Bone Health Alliance
National Obesity Collaborative Care Summit
National Quality Forum (NQF) Musculoskeletal Standing Committee (Co-Chair)
National Quality Forum (NQF) Surgical Standing Committee
NQF NQF Opioid Stewardship Action Team (2)
Pain Management Best Practices Inter-Agency Task Force
PCORI Physician Specialty Society Roundtable
PCPFoundation Board of Directors
Physician Consortium for Performance Improvement (PCPI) - Primary Representative
Physician Consortium for Performance Improvement (PCPI) - Quality Improvement Advisory Committee (QIAC)
Surgical Quality Alliance
Team Physician Consensus Conference 2018 (2)
United States Pharmacopeia (USP) Opioid Roundtable (2)

In summary, advocacy goes beyond the political process and touches on Capitol Hill. The regulations that flow from the law can be molded by effective engagement with the agencies. Indeed, most tangible advocacy “wins” have come through the interface with the regulators.



The Role of the Board in Driving Performance Improvement

27

Bob Lokken and Kevin G. Shea

Introduction

By way of introduction, I have spent abundant time reporting to and serving on boards, including as chair. I spent nearly 20 years as a CEO in the technology sector. Two of the boards I served are healthcare organizations: St. Luke's Health System of Boise, Idaho, and St. Alphonsus Regional Health System (a division of Trinity Health) also in Boise, Idaho. I currently serve as Chairman of the Board for St Luke's Health System. I would note, with some pride, that these health systems are currently recognized as IBM Watson Health 2020 Top 15 health systems in the US. I do not claim any credit for their achievements. This specific recognition dually weights both *quality performance* and the *rate of performance improvement*.

It is critical for board members to ask questions in order to drive performance improvement. This chapter will delve into the types of questions that are most useful to ask, and where a board's time is best spent. In addition to the three types of questions that are vitally important to PI work, I will add a fourth role for the board, *mentoring*, that can highly impact the outcomes and success of performance improvement work.

Are We Discussing Quality or Value Improvement? Or Something Else?

I am going to use Performance Improvement (PI) in this chapter to mean the organization's efforts to improve its performance in the strategic domain of current focus. That may be improvements in quality, or in value, or in another strategic

B. Lokken
St. Luke's Health System, Boise, ID, USA

K. G. Shea (✉)
Department of Orthopedics, Stanford University, Stanford, CA, USA
e-mail: kgshea@stanford.edu

domain. For the purposes of the board's role and the insights offered in this chapter, the concepts are relatively universal. I also use "PI" to mean organizational performance, not individual performance as in that of a specific physician. Hospital boards do have a role in credentialing and such matters dealing with individual doctors, but that is not the focus of this chapter.

Quality as a Fiduciary Responsibility of the Board

Statutory compliance to minimal quality standards is strikingly different than performance improvement. The two should not be confused. Compliance work may involve such activities as credentialing physicians and passing compliance audits. Improvement efforts are different because of their aspirational and optimizing nature. Compliance to satisfy a regulatory body is not the same as raising the bar of standards for the organization in service to patients and their families. Board training on quality too often focuses on the legalistic fiduciary role of the board. This chapter will instead focus on the board's role in supporting the performance improvement process.

Why Is the Board Important in PI Efforts?

PI is complex and challenging, and rarely if ever occurs via happenstance or casual efforts. The odds of success improve dramatically when the "organization" is aligned behind the effort, with everyone pulling in the same direction and supporting one another. At the top of the organization, with its fiduciary responsibilities, lies the board of directors or board of trustees. The alignment of the board is critical to the success of any effort required to make material, systemic, and enduring improvements. A board can also derail PI efforts. There may be confusion about what specifically the role of the board is. The board is not an operational entity and board members may lack clinical background. An example of two PI efforts will illustrate the critical role of the board in PI.

A Tale of Two Organizations' Performance Improvement Efforts

Over the last decade, I was in position to closely observe two different organizations launch and pursue systemic PI efforts. While both organizations set big goals and pursued them for more than a decade, the outcomes achieved were starkly different. One organization made steady, significant improvements; so much so they are now ranked as one of the top performing organizations in their industry. The second organization has yet to make any statistically significant improvement from their original baseline measure.

Both organizations have capable people who care deeply for the constituents they serve. And both organizations faced significant challenges with the change management efforts required to make needed improvements. However, two things were very different. First was how the boards of each organization engaged with and handled oversight of the improvement work. The second difference was how the organizations internally dealt with the barriers and challenges they both inevitably encountered when they made changes intended to make progress toward their improvement goals.

Both boards started with all the metrics and data they could gather, set ambitious goals, and established an annual review of progress. The board of the successful organization was more focused, more engaged in efforts and results, and incorporated an accountability review cadence into every meeting of the board. This contrasted with the board that ultimately failed. The failed board had dozens of metrics and benchmarks in their reports, in effect defocusing discussions. They rarely, if ever, talked about progress or reviewed the metrics outside of the annual review meeting. Instead, their meetings were packed with pedantic, administrative details, but with little or no discussion on the results (or lack thereof) that the PI efforts were yielding. Accountability was limited to an annual review meeting during which lack of progress was discussed, bemoaned, and dismissed. There were many complaints of how difficult and challenging the efforts had been this year, and how next year would certainly “be better.”

The second difference between the two organizations was how they dealt with change management internally—specifically barriers, resistance, and challenges to changes needed to drive improvement. The successful organization dealt with resistance and barriers by viewing them as natural and even expected. Resistance was simply something to be overcome, even if multiple approaches were required. The failed organization treated nearly every barrier as a full stop crisis and abandoned all efforts as a result. The strategic intent of both organizations never wavered. But one organization expected resistance and altered tactics until the change effort yielded results, while the failed organization abandoned efforts or diluted them to “not upset anyone,” and never achieved the desired outcomes.

The key insight here is not the differences in these two efforts. Rather it is that the first, the board engagement pattern, was in fact facilitating success. It is no surprise to anyone that improvement efforts in any organization face barriers and challenges. But what seemed to be lost on many was how the teams responded to these challenges would ultimately determine success or failure. And how the board engages is critical to how the organization itself responds.

The Importance of the Board's Role

Change is hard, and striving for improvement is challenging. Success in PI lies not in avoiding challenges and resistance, but rather in how the organization reacts and overcomes them. The board can, and should, play a vital role in helping the

organization stay focused, centered, resilient, and unrelenting by encouraging the PI teams to overcome barriers. Conversely, the board can create distraction and through its actions or inactions send a clear message about what is important—pedantic administrative activities or strategic results.

Nothing is an absolute guarantee of success. But an effective fully engaged board is critical to increasing the odds of success of any PI effort. The rest of this chapter will explore the specifics of how a board can be effective in partnering with the operational leadership and PI teams to help drive success. The four key roles of the board include: (1) setting and maintaining focus, (2) continually being passionate and outspoken about what is best for patients and their families, (3) establishing a positive, proactive, and encouraging cadence of accountability, and (4) mentoring leadership teams when the board has outside expertise to help with the journey.

Four Key Roles for Boards to Support PI

Staying Anchored on True North

All organizations inevitably “tilt” toward self-service over time; this may not be a deliberate choice, so much so as the result of gravitational pull. As this happens, teams begin to lose sight of and begin to drift away from a focus on the needs of their constituents. In healthcare, constituents are the patients and their families. Internally, teams need to stay on guard so that this natural tendency does not take hold. The number one responsibility of the board is to be a constant, outspoken, and passionate voice for patients and their families—the “true north” of all performance improvement work.

There are two ways that tilting away from true north creeps into an organization. The first is that the details, complexity, and technical nature of workflows and processes can become all-consuming to the team. This is the level of focus needed to “get it right” in healthcare. But the consequence of become overly absorbed in detail is that decisions begin to drift and eventually lose sight of those they are intended to serve. The second way teams wander from true north happens when they begin to overweight the perceived needs and desires of the staff (e.g., physicians, nurses, administrators, etc.). This is understandable as they are the ones doing the work. But if it swings too far out of balance, the risk is that staff-centric decisions may not be in the best interests of patients and their families.

The board has a unique perspective when it comes to patient and family care, as typically the board is made up of people outside the organization and outside of healthcare. As such, they are less likely to get mired in technical detail. The board tends to be free of some of the biases that naturally befall the teams doing the work, and this allows them to keep an outside perspective on behalf of patients and their families. Boards should be passionate and outspoken advocates for this true north orientation. The best way this manifests itself is by board members asking probing questions of staff about what is best for patients and how internal needs may or may not be compromising the true mission of healthcare.

Some examples of the types of questions board members should be asking include:

1. These priorities/programs/changes feel like they are designed to accommodate staff. Where do the patients' needs fit in, and what is the impact on their families?
2. During discussions in board and/or board committee meetings, if medical matters become too complex to follow, ask for a deeper explanation in lay-terms.
3. Make sure the focus remains on outcomes that matter to patients. Question and probe to ensure PI outcomes are clear and patient-centric.
4. When negative patient outcomes are reported to the board, challenge staff to figure out ways to reduce or eliminate these negative patient outcomes in the future.
5. To stay oriented to true north, the patient/family perspective is critical. Ask what the system is doing to collect regular Patient Reported Outcome Measures (PROMS), for both general health measures and for disease-specific measures.
6. Is the system reporting PROS/PROMS to clinicians, along with the costs for providing specific care? Movement to reimbursement bundles is inevitable. Giving providers a "blank check" for care is going to disappear. And for certain conditions, the payment modality will go into care bundles, so care bundles will expand. This will force financial risk on the system/providers to produce better outcomes at lower costs.
7. Financial toxicity is a threat to our communities and individuals—some patients will avoid necessary care due to high costs. How is the system addressing affordability issues to improve overall community health?

Start Focused, Stay Focused

Defining the focus of PI work is the job of the operations, staff, and leadership of the organization. That said, given the dynamics of focusing an organization and the battles that are likely to ensue, the board can and should play a vital role in ensuring the organization starts focused and stays focused.

The discussion of focus for the board begins with a grounding in how important focus is to the success of any PI effort. PI work requires that new patterns of behavior and practices be adopted. Making these changes is difficult on the team and makes the work different than well entrenched practices. As a result, PI work takes extra time and effort. We all understand time is a finite resource; therefore, focusing on the critical few things is an absolute prerequisite for success.

Leaders must understand and internalize the importance of focus. In the acclaimed book, *"4DX—The Four Disciplines of Execution,"* the authors reference a study conducted on multiple teams, both large and small, and organizations of all types. The study revealed some eye-opening results with respect to focus. Teams that had 1–3 strategic goals during a given timeframe typically achieved 100% of their goals. Teams that had 4–6 strategic goals achieved 50% of their goals. And lastly, teams that began with 7 or more goals typically achieved none of their goals.

If focus is so crucial, why is it so rare? The reason is simple: focus is hard. To focus means saying “no” to more things than you say “yes” to. There are always many more worthy things to be accomplished than there is bandwidth to accomplish them. Different team members are passionate about their own favorite items on the list. This means to focus requires a team to say no to good and maybe even great ideas, but also to say no to someone’s “baby.”

This is especially hard for people closest to the situation. The closer you are to a situation and to the people and the work, the harder saying no becomes. (Note: one approach is to replace “no” with “not now” or “yes later”—this can take some of the sting out of reducing the number of goals).

This is where the role of the board in PI comes into crystal clear focus. First, the board should continually ask questions about focus, and remind leadership at the beginning of the planning year about the laws of focus. Do you want to be an organization that sets clear and focused goals, achieves them every year, and moves forward? Or do you want to be one of those ineffective organizations that has dozens of metrics and goals, but year in, year out, achieves none of them? That is the value of the tale of two organizations described earlier.

Next, the board should structure all agendas and the allotment of time during meetings such that the focus items (the critical few) are forefront and dominate the meeting. The board, through its actions and use of time, sends the critical message that they a) care about focus and results, and b) the focus items will not be set aside, slip away, or get shortchanged. Lastly, the board should not become part of the problem itself. Boards can fall into the trap of demanding the latest and most modern issue get immediate attention; thereby defocusing and distracting from the difficult work of PI.

Specific suggestions for board members committed to PI:

- Challenge leadership to a critical few goals and narrow focus.
- If there are still too many goals, suggest some efforts be staged and sequenced, such that a few goals are first accomplished, then the next set becomes a priority.
- Do not let hot topics of the moment overwhelm discussions. If something is truly urgent and direction shifting, then reprioritize and refocus. The original items can be put on hold if need be.
- Anchor the agenda on a few priorities and stay on track. Do not let the board be a source of distraction.
- If progress is not reported at every meeting, ask why. If progress is not being accomplished, ask why. If the team requires more focus and/or needs additional resources, make sure they get what they need.

Commit to a Reliable and Supportive Cadence of Accountability

PI work is hard. If there is no accountability, there will be no improvement, period. If there were no consequences for inaction, and if there were no support for needed action, then why would anyone bother with such difficult work? How would you

manage to get a team of people to align and put in the hard work and sacrifice? How would you sustain that alignment and hard work long enough to see the payoff? Bottom line—no accountability means no improvement.

An accountability system is a “must have” for PI work. But not all accountability systems are equally effective, and some are downright counterproductive. Most people associate the term accountability with the punitive assigning of blame and then punishment. Punitive types are not effective at driving PI or the type of culture within which most people want to work.

The type of accountability system I am espousing is supportive and effective at producing results. This is not a year end (after the fact) critical examination, but rather a predictable cadence designed to help the teams stay focused and ensure they have the resources they need, and barriers removed, that are impeding progress. This type of accountability system is most effective in PI work because it proactively engages, supports, and helps the teams achieve their goals. It has clear roles and expectations of both those doing the work, leading the work, and overseeing the efforts. The book *4DX* describes such a system and is summarized in Table 27.1.

It is foundational to expect that obstacles and barriers will arise, and the team must have a plan for dealing with such resistance. Some of the barriers are within the team itself, and the team should be able to figure out a way to deal with these issues. Often the barriers that arise will be outside the scope of the team’s ability to handle, and this is the role of leadership. Sometimes it has more resources, sometimes it is removing outside barriers coming from competing priorities or other

Table 27.1 Roles and responsibilities in an effective accountability system

Phase of execution	Roles	
	Leadership	Staff/team
Start	Organize the team; set clear expectations on processes; ensure clear, measurable, and focused goals are set for the team	Participate in setting focus areas and goals
Middle	Conduct a cadence of regular check-in meetings. Use the meetings to maintain focus of the team; start with results, and then dig into activities as needed; rapidly identify barriers and support the team by removing barriers and securing resources that the team needs to be successful. Recognize efforts and results; seek alternatives when solutions are revealed to be non-optimal	Communicate, attitude, and effort—it has been said that the only things that a team member has completely under his/her control are the attitude and effort he/she brings to the table. In addition to this, team members must communicate regularly with the other team members and leadership about what is working and what needs to be changed. Barriers need to be identified and communicated ASAP, such that team members and leadership have a chance to respond, adapt, and overcome
End	Conduct a review meeting that is focused on lessons learned, recognizes and rewards efforts and successes	Attend and engage in the review meeting. Help generate ideas for further improvements and changes that should be considered

departments within the organization. The cadence meetings are designed to both maintain the focus of the teams, and to surface barriers that are getting in the way, and to get the right person to deal with the matter.

The teams work together to drive the target results and improvements, with the full understanding that barriers will arise, and that dealing with them in a timely manner makes the difference between success and failure.

The Board's Role in the Accountability System

The board is the highest echelon of accountability in the organization. So, it is obvious that the board has an important role as well. The board should set the tone for the organization's focus and persistence. Here are some sample tactics a board might use.

- Ensure PI goals are focused, clear and measurable—at the start of the year. You can only hold people accountable for things that were agreed upon up front.
- Make sure the board maintains focus with senior leadership by putting annual goal review and progress reports first or early in every agenda. There should be no confusion about what the board considers most important.
- Do not simply schedule progress reports early in the agenda but allot sufficient time to spend on the 1–3 most important goals of the organization. You cannot say this is most important, and then spend 90% of the meeting time on other matters.
- Ask questions about progress. Stay focused on results, and through your questions, set clear expectations that barriers are likely to occur, and so are adjustments to effectively address them.
- Activities and results are different—stay focused on results and outcomes. Let the team focus on activities and adjusting tactics as needed.
- The resources needed for these efforts are the domain of the leadership team and should be well understood and committed at the outset. But occasionally, the board might need to approve additional capital.
- Support the team. Making changes rarely makes one the most popular person in the room. If leadership does not have the full support of the board—progress will eventually derail. So regularly communicate support for the PI team.

Mentoring

Board members are typically community leaders who are accomplished in their own domains—often not healthcare. However, board members' knowledge, expertise, and experiences can be leveraged by the leaders who are overseeing the PI work. When this is the case, individual members of the board can add value by coaching and/or mentoring the PI leadership.

I am currently chairing a board which maintains skills, experiences, and competency grid for all of the board members. Its primary purpose is for board recruiting and development, to ensure the board has a broad range of backgrounds and expertise to draw from governing the organization. Leadership, change management, contracting, safety, reliable organizations, technology, and other areas of expertise are on the list to ensure the board has both depth and breadth in many areas. A secondary use of this information could be to help PI leadership to find potential board members who can serve as coaches/mentors for the PI leaders. This is a “win-win” for both the team leaders and for the board members, as it provides additional expertise to the leadership team and deepens the engagement of the board members in the organization’s journey and challenges.

Summary

Asking questions, especially valuable questions at the right time, is critical to supporting PI work. Questions are most valuable when they help the teams stay centered on the true north of patients and their families; help the teams stay focused, rather than being a source of distraction; and when they are part of an effective and supportive accountability system, used to drive results. Using these imperatives as a framework, board members’ questions begin to add value and become an instinctual rhythm with the senior leadership team.

PI teams should see board members as partners in the organization’s improvement efforts. Leadership can use board authority and visibility to gain and embed team alignment and effort. And when appropriate, that partnership can be extended into a coaching or mentoring relationship.

This chapter described a tale of two organizations’ major PI efforts, with one success and one failure. Hopefully, the concepts in this chapter will help both PI leadership and board members obtain improved clarity on how the board can support and accelerate the PI work of the organization. Often, success or failure depends on this partnership.



Juliana Perl, James K. Wall, and Janene Fuerch

Introduction

The development and adoption of innovative products and services in the healthcare industry are subject to a complex landscape of multiple stakeholders and a strong regulatory environment. In order to attain successful adoption of an innovation, a company generally needs to provide a solution to user needs, protect intellectual property, complete clinical and regulatory requirements, create a sustainable business model, and connect with users. Ultimate adoption of an innovative technology or service by the healthcare system is most often judged based on the value it delivers.

This chapter explores innovation and value creation in the US healthcare system. In light of the slow but steady shift from fee-for-service to value-based care plans, we look to define value through the lenses of patients, physicians, hospital systems, insurers, and government. A simplified way to define value is the relationship of quality to cost. However, there is not yet broad consensus on a single, detailed definition within the healthcare industry. Furthermore, the contributing factors to value (such as quality and cost) are often prioritized differently among the various stakeholders. The information in this chapter will provide a better understanding of the key decision makers for new product adoption, the factors they use for evaluation, and the framework for the overall evaluation of how these factors influence the process of innovation.

J. Perl · J. K. Wall (✉) · J. Fuerch

Byers Center for Biodesign, Stanford University, Stanford, CA, USA

e-mail: jperl4@stanford.edu; jkwall@stanford.edu; jfuerch@stanford.edu

Defining Value

As healthcare costs continue to escalate in the US and around the world, there is a resounding emphasis on providing care of high value. But what exactly is value?

Value in healthcare is typically defined as the ratio of quality to cost. In practice, it is a term used to evaluate how a product or service benefits patients and practitioners in comparison to the monetary cost incurred by a system.¹

Value = Quality/Cost

While there is broad consensus on this generalized conceptual definition, healthcare stakeholders have a vast collection of nuanced differences in the definition, measurement, and evaluation of value. Such nuances exist in the analysis of both quality and cost, as well as through the inclusion of additional factors of value. Quality can include treatment efficacy, effectiveness, safety, and outcomes. Positive contributors to the quality numerator in the value equation can also include service, customer satisfaction, and engagement. Meanwhile, cost most often pertains to economic costs but can vary in the evaluated time frame and inclusion criteria. Sometimes costs can take the form of expended time and mental/emotional strain, such as additional documentation burden, inefficient patient flow, or disrupted workflows.

Many institutions take an expanded view of value as quality, engagement, and service in relation to cost.

Quality is meant to maximize the safety and effectiveness of care. Traditionally, attempts to maximize effectiveness rely on evidence-based outcomes. Providers are meant to treat patients with the method deemed most efficacious by quantitative research studies. A more modern approach emphasizes the role of the patient in value determination. Quality care is not simply a blanket treatment recommendation for an indication, but it is personalized to the outcomes prioritized by patients. A personalized approach to define quality also means that measurement would rely on a patient's desired outcome, rather than a predetermined standard. Some healthcare systems have used patient satisfaction as a leading measurement tool of care quality, referred to as Patient Reported Outcome Measurements (PROMs). Overall, a provider's focus on developing the optimal care for an individual is representative of the magnification effect of *engagement* on quality and value.

While these components of individualized patient focus and shared decision-making are recognized as the core of value-based care, there are still nuanced differences in the views among stakeholders.² Payers tend to have a stronger focus on specific, pre-identified, and measurable clinical outcomes/PROMs. Good outcomes,

¹Teisberg, E., Wallace, S., & O'Hara, S. (2020). Defining and Implementing Value-Based Health Care: A Strategic Framework. *Acad Med*, 95(5), 682–685.

²Marzorati, C., & Pravettoni, G. (2017). Value as the key concept in the health care system: how it has influenced medical practice and clinical decision-making processes. *J Multidiscip Healthc*, 10, 101–106.

as measured and defined by payers, allow payers to limit future spending on expensive alternative or repeated treatments.³ Health systems also develop their own series of data-driven value measurements to optimize resource allocations, and can include complication rates, readmissions, and other factors that indicate care is delivered efficiently without extra expense.⁴ From a population health perspective, there is a lack of consensus on whether to measure quality in the form of broader population health indicators or a collection of social determinants and outcomes.⁵

Measurements of quality are essential to fully understand care improvements, but can place large burdens on physicians, patients, healthcare systems, and payers. In 2016, Casalino et al. report on this burden in the “US Physician Practices Spend More Than \$15.4 Billion Annually To Report Quality Measures.”⁶ The study focused on the number of hours that physicians across four common specialties, including orthopedics, dedicate to quality measurement reporting. Few physicians believed the reported outcomes actually correlated to the quality of care their patients received. This disconnect between physicians and value managers adds additional costs to the system.

Service represents the ease of access to care. The inclusion of access in the value framework expands the scope from a single patient experience and moves it to the population-based level. How does a system get the best outcomes, at the lowest cost, to the most people? If the decision to incorporate a new product or service allows for more people to receive care at a reasonable price, then value is being created within the healthcare ecosystem.

Cost continues to be the main barrier in maximizing healthcare value. Analysts aim to associate a monetary value to care improvements and weigh it against the actual expected financial requirements. The financial burden includes the direct cost of the new technology, as well as a series of indirect costs of adoption, which could include training requirements, support personnel, supply chain demands, and device accessories. Some novel or complex devices require extensive periods of training. Staff must be compensated for that time and facility space may come at a cost. A reusable device also requires personnel, equipment, and supplies to sterilize, while a disposable device increases the cost of medical waste. Costs could also be incurred for maintenance, repair, or in some cases, licensing.

³Rihn, J. A., Currier, B. L., Phillips, F. M., Glassman, S. D., & Albert, T. J. (2013). Defining the value of spine care. *J Am Acad Orthop Surg*, 21(7), 419–426.

⁴Amanatullah, D. F., McQuillan, T., & Kamal, R. N. (2019). Quality Measures in Total Hip and Total Knee Arthroplasty. *J Am Acad Orthop Surg*, 27(6), 219–226.

⁵Schapira, M. M., Williams, M., Balch, A., Baron, R. J., Barrett, P., Beveridge, R., ... Hubbard, R. A. (2020). Seeking Consensus on the Terminology of Value-Based Transformation Through use of a Delphi Process. *Popul Health Manag*, 23(3), 243–255.

⁶Casalino, L. P., Gans, D., Weber, R., Cea, M., Tuchovsky, A., Bishop, T. F., ... Evenson, T. B. (2016). US Physician Practices Spend More Than \$15.4 Billion Annually To Report Quality Measures. *Health Aff (Millwood)*, 35(3), 401–406.

The cost of the technology must also be analyzed alongside the potential for reimbursement, desire from self-pay patients, and other sources of revenue that could offset costs. Different healthcare systems and medical specialties have varying standards for the margins they prefer to collect in order to consider adoption. Favorable reimbursement that addresses the accumulated indirect costs leaves administrators with a more positive outlook. Additionally, technology with mass appeal to some patient populations, such as surgical robots, has the potential to attract new patients and therefore increase revenue.

Various stakeholders also lack consensus on what to prioritize in cost evaluations.⁷

- Patients care about their out-of-pocket costs.
- Providers care about costs related to their specific patient segments and demographics.
- Hospitals and health care systems need to account for their served populations and provided treatments.
- Payers must look broadly at the costs of all beneficiaries, and public payers must consider all national healthcare spending.

With separate but intertwining stakeholders, each trying to optimize costs within their own area, it is challenging to pursue optimal healthcare savings for all.

Weighting Value

Once the components of value evaluation are defined and established, the relative importance of each component must still be determined. This is made complicated by the fact that prioritizations can differ across stakeholders. A study asked patients, physicians, and employers what was most important to them when choosing healthcare services, thus evaluating the weight, or level of priority, of the different parts of the value equation⁸ The options consisted of quality, cost, and patient experience. They found that each stakeholder group had very different priorities, with

Table 28.1 represents the share of patients, physicians, and employers that ranked a specific element of value as the single most important in choosing healthcare services.

Patients focusing on quality and cost, physicians focusing on quality, and employers focusing on patient experience and cost. This discrepancy in priorities emphasizes the difficulty of optimizing healthcare value. Is it most important to

⁷Gupta, R. (2019). Health Care Value: Relationships Between Population Health, Patient Experience, and Costs of Care. *Prim Care*, 46(4), 603–622.

⁸Health, U. o. U. (2017). *The State of Value in U.S. Health Care*. Retrieved from <https://uofuhealth.utah.edu/value/>

Table 28.1 Share of patients, physicians, and employers that ranked a specific element of value as the single most important in choosing healthcare services

Most important factor in choosing services, by stakeholder	Quality (%)	Cost (%)	Patient experience (%)
Patients	62	26	12
Physicians	88	5	7
Employers	20	37	43

improve quality, experience, or cost? For whom are we maximizing value? Conflicting goals and incentives make it difficult for healthcare systems and policy makers to select from various models of value-based care.

Value-Based Reimbursement

The US healthcare system has seen a slow shift over the past decade from fee-for-service to value-based care. Fee-for-service is a traditional payment model that ties a specific price to a treatment, procedure, or other component of care. While straightforward, this method can incentivize higher spending. A provider can increase profits by doing and spending more, regardless of the actual benefit to the patient or the quality of care. Value-based care instead focuses on quality, not quantity, and delivering the best possible health outcomes. This encompasses many new care delivery and reimbursement models being deployed, such as accountable care organizations, hospital-based purchasing programs, pay for performance, full risk insurance models, and bundled payments.

Bundled payments are particularly relevant for orthopedic procedures, including total joint replacements. Originally proposed in the Affordable Care Act of 2010, a bundled payment consists of a one-time payment that is meant to cover both the services provided for a patient undergoing a procedure as well as any follow-up care for 30, 60, or 90 days. Providers and the healthcare delivery system keep what they do not spend and are therefore incentivized to keep their costs as low as possible and prevent complications.

The Affordable Care Act also established the Center for Medicare and Medicaid Innovation (CMI).⁹ CMI was tasked with testing ways to reduce expenses while improving care within the social insurance programs. The group developed 89 different payment and service delivery models between 2011 and 2020.

Hospital Value Committees

Hospital systems and payers, which facilitate the vast majority of purchasing decisions in the healthcare system, tend to be most concerned with these health economics equations. Historically, individual providers held immense decision-making

⁹Center for Medicare and Medicaid Innovation Established, § 42 U.S.C. 1315a (2010).

power. Today, however, especially in hospital systems and independent ambulatory surgery centers, purchasing decisions frequently must flow through a value committee (e.g., value analysis committees, value analysis teams, technology assessment committees). These committees aim to achieve greater value by either increasing quality for a justifiable cost, or by maintaining quality and lowering costs.

A surgeon's desire to use the newest, biomaterial implant that comes at twice the current cost may not be justifiable in improved outcomes, quality of life, patient satisfaction, or other factors of increased value. On the other hand, decreases in cost cannot come at the expense of decreased quality. A less expensive implant with a shorter lifespan may not be acceptable. In making these decisions, value committees rely more and more on high-quality evidence, making it incumbent for innovation technologies to demonstrate value with high-quality data.

Hospital value committees perform clinical and economic analyses that align with the institution's definition of value in order to determine if a system-wide adoption of a product or service would increase the system's value. Committee members span across categories of personnel, often including physicians, nurses, administrators, liability specialists, supply chain specialists, and purchasing agents. In a hospital setting, a physician often referred to as the "physician champion" will submit a new product or technology to the committee. The committee will review the proposal, and an initial trial of the product can take several months. Once feedback is received, workflow and outcomes are analyzed, and relevant purchasing contracts are considered, the committee will decide whether or not to allow future purchase and use of the product. Online data and analytic solutions for supply chain management have strengthened the ability of value committees to judge new product requests by delivering product performance, regulatory and clinical information as well as offering insight into competitive alternatives.

Payer Value Committees

Payers perform a similar value analysis to decide if a specific product or service should receive reimbursement. The product or service company often leads the reimbursement process. They advise physicians on what codes to submit for reimbursement and convince payers to accept those codes. The analysis by payers includes strict requirements for clinical evidence. They analyze the current treatment paradigm for relevant indication and determine if the new element of treatment will increase or decrease costs over the entire course of a patient's care journey and across the payer's network. While improved outcomes generally lead to lower costs over time, payers also analyze proposals that increase costs but significantly improve quality of life measurements.

There is often a high bar for outcome evidence, which typically requires multiple randomized controlled trials with significant outcome benefits. The specific evidence required by these committees differs across payers, and the same proposal may lead to different coverage decisions from different payers. Since each payer has

its own approval process and varying levels of required information, it is important for innovators to consider where to focus their resources. Differences between payers include their likelihood to be early adopters of particularly novel technology, the demographics of their covered lives, and the intensity of their review processes.¹⁰

CMS is often the first payer to cover a new product, which can come in the form of a National Coverage Decision (NCD) or a Local Coverage Determination (LCD).¹¹ NCDs are typically reserved for breakthrough technologies expected to significantly improve patient health or for technologies expected to have significant budgetary impacts. These decisions are high stakes, as they are binding and usually not reversed. After a complete coverage decision request is submitted by the innovator, CMS is mandated to complete its NCD evaluation within six months (or nine months if an external Technology Assessment is needed). LCDs are made by one of the 12 Medicare Administrative Contractors (MACs) and the carrier advisory committee made up of physicians. Decisions by LCDs can be revised with the proposal of any meaningful, new evidence.

Private payers frequently follow the guidance of CMS coverage decisions, though they also complete their own analysis. These analysis committees often include physicians, plan administrators, economists, and statisticians and tend to examine broader factors compared to CMS. For example, a coverage decision by UnitedHealthcare on total artificial disc replacement for the spine (effective on November 1, 2020)¹² references applicable coding, clinical evidence, literature reviews, positions of professional societies, FDA approval decisions, CMS coverage decisions, and UK guidance from the National Institute for Health and Care Excellence. Private payers also consider the precedent set by their competitors.

The foundation of coverage decisions is also becoming increasingly data driven. Real world evidence consisting of data derived outside of controlled or academic settings is becoming more meaningful. Hospitals, independent delivery networks, payers, and other institutions are attempting to collect and evaluate as much information as possible on sourcing and outcomes. This creates a larger need for well-structured information technology (IT) systems and electronic health records (EHR). Research by Harvard University Professor Michael Porter helped identify integrated IT platforms as one of the key pillars for establishing value-based care^{13,14} In 2011, CMS started offering financial incentives, now known as Promoting Interoperability Programs, for the reporting of electronic clinical quality measures.

¹⁰Yock, P. G. (2015). *Biodesign: the process of innovating medical technologies* (Second edition ed.). Cambridge; New York: Cambridge University Press.

¹¹Medicare Coverage Determination Process. *Centers for Medicare & Medicaid Services*. Retrieved from <https://www.cms.gov/Medicare/Coverage/DeterminationProcess>

¹²UnitedHealthcare. (2020). Total Artificial Disc Replacement for the Spine – Commercial Medical Policy.

¹³Porter, M. E. (2009). A strategy for health care reform--toward a value-based system. *N Engl J Med*, 361(2), 109–112.

¹⁴Feeley, T. W., Landman, Z., & Porter, M. E. (2020). The Agenda for the Next Generation of Health Care Information Technology. *I*.

The correlation between EHR data measurements and value is made stronger by the inclusion of this program in the current CMS plan to transition to a Merit-based Incentive Payment System.¹⁵

Needs Finding, Value, and Innovation

At the core of any good innovation is a true human need. There are endless problems within healthcare that need to be overhauled and the process of identifying them can be referred to as “needs finding.” While individual healthcare workers are likely to have long lists of problems that they would like to see fixed, an innovator’s job is to develop an understanding of the entire paradigm and workflow surrounding one area of focus. Through the process of needs finding, an innovator should perform observations and interviews with stakeholders to develop a full picture of the need space. These stakeholders can include patients, multiple types of providers, payers, administrators, and more. An innovator can then use this information to identify the key areas which require improvement.

Value can provide a framework for analyzing pain points. For example, within an identified area:

- How can the quality of care be improved?
- What outcomes do each of the stakeholders care most about?
- What has a significant impact on quality of life?
- Where are the bottlenecks in access?
- What are the most negative parts of an experience?
- Where could stakeholders benefit from more engagement?

These questions identify areas where there is strong potential to increase overall healthcare value, which is essential for successful adoption of an innovation.

Identification

Once a disease state or specific population is determined as an area of focus, a team is likely to discover hundreds of needs that have to be addressed. How does a team select which one to pursue? What frameworks should be used to filter the possibilities?

A primary method of needs screening is to assess potential value-add through the lens of a health economics analysis. Where is ample money spent, with poor outcomes? These areas are ripe for innovation that could lead to positive health economic outcomes. This health economic value is incredibly important to hospital administrators and has a high impact on the likelihood of adoption. Overall, this form

¹⁵ *CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)*. (2016). Baltimore, MD

of value analysis should look at current treatment paradigms and the costs accumulated per patient over time, providing a reference point for the potential value-add of an innovation in this space. Treatments with high rates of complications or poor health outcomes can lead to an accumulation of long-term costs. In this way, innovations that improve patient quality of care can prove beneficial in economic value.

A cost-utility analysis is another form of health economics analysis¹⁰. This model measures health gains in Quality Adjusted Life Years (QALY), which reflects both quality of life and years lived. QALY is a numerical measurement, with incremental QALY gains and costs allowing for a more quantitative assessment of the quality to cost value ratio. An innovation that results in a higher QALY-to-cost ratio than the current standard of care is more likely to lead to a desirable increase in value for the system.

Invention

“Concept screening” is the process of evaluating a solution’s potential strengths and barriers. Thinking through all of the elements necessary for a product’s adoption from the earliest stages of development will prevent teams from investing in an idea that is likely to meet significant barriers. This also requires early consideration of value and its relation to adoption. A solution that adds the most value to a system may be the most likely to succeed.

Implementation

It is also important to consider if the imagined product could eventually make it through a value committee. Many high-tech, over engineered products are too expensive relative to the value they contribute. As much quality as they would add, costs are too high (in both dollars and work burden) for them to succeed. The ratio of quality to cost cannot be overlooked.

Overall, this stage of innovation requires a focus on commercial value and viability, driving the best outcomes at the lowest cost.

Conclusion

The role of value in the US healthcare system continues to grow in significance and complexity. Stakeholder groups will continue to utilize their own definitions and priorities, and new payment models will continue to be implemented. As an innovator, the definitions and models that will have the greatest impact on product adoption remain critical. In emphasizing value, the US can work toward building more accessible, high-quality, and cost-sustainable healthcare systems. Future successful innovations will contribute positive net value as they address compelling unmet clinical needs through a careful balance of quality and cost.



The Modern Orthopedic Morbidity and Mortality Conference: An Instrument for Education and System-Wide Quality Improvement

29

Ayesha Abdeen

Introduction

The Morbidity and Mortality (M&M) Conference, utilized in most medical and surgical departments as a recurring meeting whereby medical errors, adverse events, and deaths are discussed, is intended to educate surgeons and trainees and reduce similar errors in the future. In many institutions, the process involves an environment of blame and shame, whereby attendees find fault with a colleagues' judgment or highlight technical errors. This "Monday morning quarterbacking" is counterproductive and does not ultimately lead to the intended goal of quality improvement.

History of the M&M Conference

The origin of the M&M conference is attributed to Dr. Ernest Armory Codman, a surgeon at the Massachusetts General Hospital from 1904 to 1924 whose "end-result" concept contended surgeons should follow patients long term, evaluate their results, and learn from errors [1, 2]. Codman published the outcomes of 337 cases in his first 5 years in practice detailing 123 errors in a book entitled *A Study in Hospital Efficiency* and led the American College of Surgeons Hospital Standardization Program in 1918 that held hospitals accountable to the public for their outcomes [1, 3]. After merging with other programs, this eventually became what is now known as the Joint Commission on Accreditation of Healthcare Organization (JCAHO)—a not-for-profit organization that provides accreditation for health-care organizations in the United States on the basis of quality and safety standards [1, 4].

A. Abdeen (✉)

Department of Orthopaedic Surgery, Boston Medical Center, Boston, MA, USA

e-mail: ayesha.abdeen@bmc.org

The first reported M&M conference was convened by surgeons, internists, and anesthesiologists in 1935. Philadelphia County Medical Society's Anesthesia Mortality Committee found that 67% of deaths following anesthesia were preventable [1, 5].

Historically, undertones of "blame and shame" have been pervasive in the M&M conference; there has been a central focus on ascribing blame and taking punitive action against individuals [1]. This approach stigmatizes well-intended physicians and does little to reduce the likelihood of the event recurring. The 1999 Institute of Medicine publication *To Err is Human: Building a Safer Health System* highlighted the importance of openly discussing medical errors constructively rather than pursuing a punitive approach [6]. The authors state that "Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing" [6]. This publication heralded a paradigm shift away from ascribing individual blame for medical errors, toward a systems-based approach of assessment and prevention. An analysis of the root cause of an adverse event enables system-wide changes that reduce the likelihood of the event being repeated. These systems-based techniques have been incorporated and reported in the M&M conference in many disciplines including family medicine, cardiology, gastroenterology, oncology, pediatrics, and otolaryngology [7–9]. There is a paucity of literature on the use of a systems-based approach to orthopedic M&M conferences. A contemporary approach can and should be applied to the orthopedic M&M conference in order to transform the process into a systems-based initiative for quality improvement.

The Fundamentals of an Improved Orthopedic M&M Conference Process

The ideal design of an effective, systems-based orthopedic M&M conference process involves the following: (adapted from Tad-y et. Al) [10].

1. A confidential, privileged forum
2. Comprehensive case identification and selection
3. Inter-disciplinary, inter-professional participation
4. Application of standard methodologies (SBAR, Root Cause Analysis)
5. Identification of areas of systems improvement
6. Development of formal channels of interaction with the hospital's division of quality and safety, risk management, Graduate Medical Education office, and peer support
7. Post-conference, closed-loop follow up of problems identified in M&M conference matched with system-wide improvements.

A confidential, privileged forum: Voluntary reporting and transparency in the discussion of a complication are critical to understanding why it occurred and to determine how to prevent recurrence. The potential for litigation poses a barrier to this process. A fundamental feature of M&M conference is that it is a privileged forum subject to peer review protection. "Candid and conscientious evaluation of clinical

practices is a sine qua non of adequate hospital care. To subject these discussions and deliberations to the discovery process... would result in terminating such deliberations. Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit" [11]. The confidentiality and undiscoverable nature of M&M conference must be retained for it to function as a tool for patient safety and quality improvement.

Case Identification and Selection: In order to learn from errors and adverse events, a mandatory reporting system for case presentation at M&M conference is necessary. All cases must be submitted for review including adverse events, mortalities, unexpected return to OR, and near misses. A system reliant exclusively on voluntary report will inevitably result in missing cases. Therefore, an adjunctive automated process should supplement the process with "triggers" for high-risk events (such as venous thromboembolism and post-surgical infections). In our institution, the departmental Quality Improvement Director collates cases submitted by faculty surgeons and trainees. The complication list is further curated from an automated incident reporting system for near misses, readmissions, and re-operations. Cases are selected for presentation at M&M conference. Case selection should strike a balance between learning opportunities and implementation of quality improvement measures. Quality improvement teaching has become a fundamental requirement by the Accreditation Council for Graduate Medical Education (ACGME) in orthopedic residency training [12]. The M&M conference is a good opportunity to impart the principles of quality and safety to trainees and therefore an effective format is for the conference to be led by trainees with faculty sponsor.

Inter-Disciplinary, Inter-Professional Participation

The M&M conference should have interdisciplinary and interprofessional participation, where appropriate, which can include internists, anesthesiologists, radiologists or technicians, members of the allied health care team, other operating room personnel, case management, and therapists. When working in silos, there can be a tendency for each discipline to "defend its authority at the expense of the total system's function- a problem known as sub-optimization" [13]. A collaborative, patient-centered approach can eliminate redundant or conflicting efforts that can threaten patient safety. A multidisciplinary approach with high levels of communication, cooperation, and coordination of patient care will lead to clinical excellence and reliable, high quality care [13].

Application of Standard Methodology

SBAR Framework: A brief synopsis of the case is provided to outline the patient history, procedure/treatment, and adverse event. SBAR stands for Situation, Background, Assessment, and Recommendations, which is a validated tool that has been shown to "improve the overall quality and educational value of the surgical

Table 29.1 After a discussion of the situation and background, the M&M process should include a methodical assessment of the event including root cause analysis. A proposed solution to prevent future similar problems should then be evaluated and enacted with a systems based approach when applicable

Situation: Statement of the problem	– Admitted diagnosis – Statement of procedure or operation-Statement of adverse outcome
Background: Clinical information pertinent to adverse outcome	– Patient history – Indication for intervention— relevant labs and imaging studies—procedural details – Hospital course – Recognition of the complication—management of the complication
– Assessment and analysis: Evaluation of what happened and why	– Error analysis: What happened? Describe sequence of events leading to adverse outcome– Root cause analysis: Why did it occur?
Review of the literature: Evidence-based practice	– Present literature pertinent to the complication
Recommendations: Proposed actions to prevent future similar problem	– Identify how problem could have been prevented or better managed—identify learning point(s) from case

Adapted from Mitchell EI, Lee DY, Aroraa S, et al. SBAR M&M: a feasible, reliable, and valid tool to assess the quality of surgical morbidity and mortality conference presentations. *Am J Surg*, 2012;203(1):26–31

M&M conference: and provides an effective scaffold for case review” [14] (Table 29.1). The SBAR format has been shown to objectively improve resident and faculty engagement the M&M process [8].

After a discussion of the situation and background, the M&M presentation should include a methodical assessment of the event including a root cause analysis and classification of the complication.

Root Cause Analysis

Root cause analysis (RCA) is a systematic methodology used in a number of industries to evaluate the cause of accidents and errors and serves as the foundation for improvement measures. “Recognizing and classifying root causes of errors are essential to transition from case-based, singular discussions to organizational change” [1]. The Toyota Motor Corporation is credited as one of the first to describe this process of workplace error analysis. RCA involves a structured, in-depth investigation of the reasons why a particular adverse event may have occurred. The goal is to understand the causes of a systems failure in order to implement corrective actions. There are a number of strategies that can be employed in the RCA. One such technique is the “Five Whys” tool, a simple problem-solving technique that attempts to quickly identify the root of a problem [15].

Clinical Vignette: A 75-year-old female underwent primary total hip arthroplasty. Immediate postoperative neurovascular examination was normal. The patient presented 2 weeks postoperatively with a large fullness in the thigh and a foot drop that was not present upon discharge.

The Five Whys is applied to this case (Table 29.2). This strategy involves asking Why? (or What?) caused this problem which then prompts a series of subsequent questions of “why?” which, when answered sequentially can help to identify the main source of the error [15].

Another technique employed in RCA, often employed in conjunction with the Five Whys methodology, is a Fishbone Diagram (Fig. 29.1). The Fishbone diagram can be used to further refine and classify the root causes contributing to the adverse event.

Table 29.2 The five Whys/root cause analysis

Problem statement –	A 75 –year-old female developed a foot drop 2 weeks after total hip replacement was performed
Why? Why did the patient get a delayed foot drop?-because she developed a hematoma that compressed the sciatic nerve	
Why? Why did the patient get a postoperative hematoma?- because she received excessive anticoagulation	
Why? Why did she receive excessive anticoagulation?—Because she was given Lovenox in addition to rivaroxaban	
Why? Why was she given 2 anticoagulants?—Because both were ordered in the electronic medical record (EMR)	
Why? Why were both anticoagulants ordered in the EMR? Because one order was pre-existing based upon the patient’s medication history and the second was entered automatically with the postoperative order set for total hip arthroplasty	
Why? Why were there 2 orders in the EMR? Because the EMR is not designed to automatically reconcile and notify provider of duplicate orders for anticoagulants	
Root cause(s)	1. EMR not designed to identify redundant anticoagulants and notify providers thereof 2. Human error- failure of provider to recognize two anticoagulants were ordered To validate root causes, ask the following: If you removed this root cause, would this event or problem have been prevented?

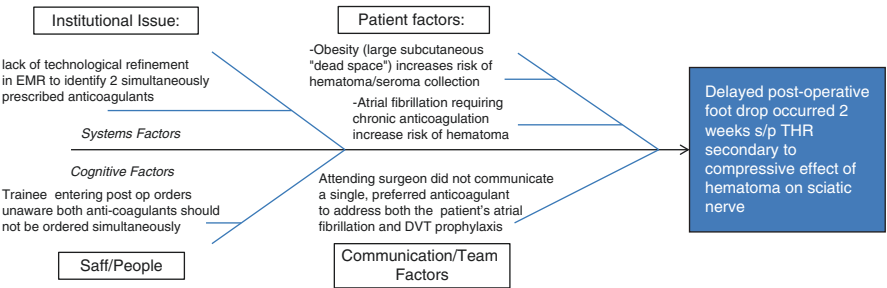


Fig. 29.1 A Fishbone diagram used in the root cause analysis for the Clinical Vignette in which a 75-year-old female undergoing total hip arthroplasty developed a delayed foot drop 2 weeks post-surgery. In this visual method of analysis, the skeleton of the fish is formed by larger bones that categorize the causes of the adverse event (Institutional Issues, Patient Factors, People, Communication) and smaller bones describe the specific causes in each category that may have contributed to the adverse event

Error Classification

Cases should be classified based upon the type of complication in order to assess impact on patient outcome. A number of classification systems exist. The Clavien-Dindo grading system of complications is a helpful tool to categorize the degree of patient harm associated with a given complication [16] (Table 29.3). Error taxonomy helps to determine the appropriate course of action. The requisite corrective action to prevent a complication from recurring is predicated on the severity of the complication as well as the type of root cause of the error. Root causes of errors can be classified as a failure of the individual, a group, or a systems failure.

Evidence-Based assessment: A review of the literature relevant to the complication should be conducted and presented at the M&M conference. Data from Meta-Analyses, Systematic Literature reviews, and Clinical Practice Guidelines should be used to inform and develop quality improvement initiatives.

Identify Areas of Systems Improvement

Alexander Pope wrote “To err is human, to forgive divine” [17]. However, from a societal and legal standpoint, medical errors are unacceptable and often “unforgivable.” As no human is infallible, surgeon errors are paradoxically and simultaneously unacceptable and unavoidable [1]. Durable, effective, and “strong” improvement measures are those that are directed toward systems-based improvements in contrast to “weak” individual-based actions that rely predominantly on human factors.

Table 29.3 Clavien-Dindo classification of complications

Grade 0: No harm	– No harm—Near miss
Grade I: Minor deviation	– Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions— Allowed therapeutic regimens are drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy – Includes wound infections opened at bedside
Grade II: Minor intervention required	– Requiring pharmacological treatment with drugs other than such allowed for grade I complications—includes blood transfusions and TPN
Grade III: Major intervention required	– Requiring surgical, endoscopic, or radiological intervention IIIa: Not under general anesthesia IIIb: Under general anesthesia
Grade IV: Life threatening	– Life-threatening complication requiring ICU management. IVa: Single organ dysfunction (including dialysis) IVb: Multiorgan dysfunction
Grade V: Death	Death

Adapted from Clavien, P.A., et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg, 2009; 250(2):187–96

As we revisit the case vignette of the 75-year-old female with a delayed foot drop due to the pressure effect of a postoperative hematoma, the RCA revealed an error based on individual factors as well as environmental and organizational factors: the trainee entered duplicate anticoagulation orders likely due to lapse in communication with the attending surgeon (individual and team factors). However, the RCA also revealed a number of environmental factors (efficiency pressures, volume of cases, fatigue related to duty hours) as well as an organizational-level vulnerability whereby duplicate orders for anticoagulants were not automatically recognized by the existing EMR. Rather than instructing the care team to improve their communications or reprimanding the trainee for forgetting to reconcile the medication list (weak quality improvement intervention with high likelihood of failure), a strong intervention addresses the shortcomings in the EMR with a reproducible, automated safeguard that notifies a provider when there are duplicate anticoagulants ordered. Advances in Information Technology (IT) can be harnessed to create system-based solutions that reduce the likelihood of medical errors.

Systems-based QI initiatives require adaptive leadership and culture in an institution. When an error occurs, such as a wrong-site surgery, the question should not be “How did that surgeon make such a grave error?” but rather: “What systems were in place to allow that error to occur?” The World Health Organization’s *Safe Surgery Saves Lives* initiative promotes surgical improvement programs to “minimize the most common and avoidable risks endangering the lives and well-being of surgical patients” [18]. The initiative employs a “Safe Surgery Checklist” that has been incorporated in most centers that identifies three critical phases of an operation: (1) **Sign in** before the induction of anesthesia. (2) **Time out** before the incision of the skin. (3) **Sign out** before the patient leaves the operation room. Using such techniques, a system can be designed to inherently reduce, if not eliminate, reliance on human factors in areas where harm can be of great magnitude. Systems that promote inter-disciplinary communication such as standardizing routine peri-operative “huddles” in which a verbal debrief occurs before and after each case can also minimize patient harm that arises from miscommunication among the surgical team [18].

Develop formal channels of interaction with the hospital’s division of quality and safety, risk management, Graduate Medical Education office, and physician peer support: In order for the M&M conference to result in meaningful system-based improvements, there needs to be a collaborative interplay between the quality assurance leaders in the orthopedic department and the hospital’s office of quality and safety as well as risk management. The M&M forum may identify cases that meet criteria for mandatory reporting to the State Medical Board or Department of Public Health. In addition, cases resulting in serious, preventable harm may need to be escalated and evaluated at the institutional level in order to elicit broader, system-wide improvements. In rare instances where negligence—failure to meet the standard of care—was deemed to play a role, input from members of the risk management team should be garnered.

Orthopedic residency training requirements now include mandatory teaching of quality improvement strategies as outlined by the ACGME. A structured curriculum for QI training must be embedded and emphasized in residency training.

System-based problems identified at the M&M conference serve as quality improvement opportunities. Resident participation in such QI projects should be encouraged to both enrich their experience and meet the requisite training guidelines.

The modern M&M conference represents a trifecta of quality improvement, education, and peer support. Traditionally and currently the forum serves as a space in which faculty can seek the counsel of their peers and learn to “accept and deal with errors” [1]. The concept of the physician as the “second victim” of a complication was described by Hilfiker in the New England Journal of Medicine in 1984 in an article entitled “Facing our Mistakes” [19]. The article underscores the emotional stigma experienced by the physician when involved in a medical error. The potential scope of the emotional impact is broad and can result in surgeon burn-out, depression, and post-traumatic stress disorder. Departmental QI leaders can act as liaisons to peer-support providers when appropriate.

Post-conference, closed-loop follow-up of problems identified in M&M conference matched with a system-wide improvement measure: An effective M&M conference involves a robust closed-loop process whereby problems identified in the conference are paired with durable, reproducible solutions operationalized with lasting effect. Mechanisms to ensure active case follow-up are critically important. In some departments, an automated web-based reporting system of managing adverse events and evaluating trends exists. A quality “dashboard” within a department or service is another emerging strategy to monitor and address trends identified in the M&M. Other mechanisms include enlisting faculty, residents, and/or dedicated personnel to formulate system-based changes when indicated. The M&M conference should be used as a data gathering tool using the SBAR framework to identify and develop actionable items to be addressed in an evidenced-based, consensus-based manner. System-based changes need to occur at an intradepartmental, interdepartmental, or institutional level on a case-by-case basis. Evaluation of performance in the larger context of state, national, and international databases is important for best practice benchmarking. A number of such national quality improvement programs exist in the United States including the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), the Quality and Accountability Study from the University Health System Consortium (UHSC), and the Hospital Safety Score from the Leapfrog Group. The National Reporting and Learning System (NRLS), a voluntary, national reporting system for the National Health System in England and Wales is currently the largest and most comprehensive reporting system for medical errors in the world.

Summary

The modern M&M conference is a structured forum for the review of complications. Implementation of the SBAR framework is an effective method that engages faculty and trainees and improves the educational impact. Corrective actions that address individual physician factors are less likely to be successful to prevent future errors when compared to system-based safeguards that are embedded into the

work-flow. The over-arching goal of the M&M conference is to create effective, evidence-based, patient-centered quality improvement initiatives. The contemporary M&M conference enables surgeons to be better through a collaborative, multi-disciplinary, and systems-based approach, with ongoing quality improvement efforts ultimately improving patient care.

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Janice M. Bonsu, Anna Farrell, and Carmen Quatman

Introduction

One in two Americans live with a diagnosed musculoskeletal condition, costing an estimated \$213 billion in healthcare expenditures [1]. Routine perioperative care is essential to orthopedic management and is associated with improved recovery and high patient satisfaction [2–4]. However, there are disparities in access to timely, specialized orthopedic care, usually affecting rural populations [5]. Access to orthopedic medical care has traditionally been limited by a number of factors, including geographic limitations [6] and an inadequate orthopedic workforce in some communities [7]. Orthopedic telehealth interventions have expanded healthcare services to previously underserved communities [8, 9]. Telehealth is an integrative form of telecommunications to connect patients to providers in a virtual environment and overcome certain barriers to standard in-person clinical experiences. Quality improvement (QI) techniques have led to innovative telehealth opportunities for orthopedics.

In 2020, as a result of the global Covid-19 pandemic, many healthcare systems were required to rapidly pivot and integrate telehealth for musculoskeletal care [10–14]. Prior to the pandemic, orthopedic telehealth was not well utilized due to technology constraints, concerns for patient outcomes, and lack of national policies and reimbursement for musculoskeletal telehealth care. With the pressure from the global pandemic to rapidly incorporate telehealth into musculoskeletal practices, there have been swift advancements in knowledge and utilization for this type of care. Over time, many practices have converted to integrated options of both telehealth and in-person evaluation experiences.

J. M. Bonsu (✉) · A. Farrell · C. Quatman

Department of Orthopaedics, The Ohio State University Wexner Medical Center,
Columbus, OH, USA

e-mail: jbonsu2@emory.edu; Anna.Farrell@osumc.edu; Carmen.Quatman@osumc.edu

Table 30.1 Quality improvement processes using the PDSA framework

PDSA	Tasks
<i>Plan</i> : Identify a change to test in this cycle	Gather background information to determine the current state of the problem Identify and engage stakeholders Define questions and predictions Plan data collection
<i>Do</i> : Test the change on a small scale	Execute plan Document problems Collect data
<i>Study</i> : Study the outcomes and what was learned from this cycle	Data analysis Compare data to predictions Summarize what was learned Identify the root cause of the problems
<i>Act</i> : Determine an aim for the next change cycle	Formulate new hypothesis Adjust processes to test new hypotheses Decide whether the change can be implemented Plan and identify an aim for the next cycle

Many healthcare systems adopted telehealth “on the fly” without sufficient evidence, technology, or even training for providers and patients. This hasty adoption led to a chaotic experience for patients and clinicians scrambling to provide the safest care possible in an environment where state-wide and national quarantine parameters were in place.

QI techniques are particularly useful to allow for rapid integration and adoption of telehealth for health systems. The Plan-Do-Study-Act (PDSA) cycle is a theoretical framework used to theorize, develop, assess, and establish QI initiatives (Table 30.1). Within this model, iterative, small-scale testing allows stakeholders to review the proposed intervention and adjust it according to feedback and preliminary results before widescale adoption [15].

Example of a Telehealth Quality Improvement Experience

In 2020, a large tertiary academic hospital for musculoskeletal patients used the PDSA framework (Table 30.1) to rapidly implement telehealth. Four iterative PDSA cycles were conducted to assess the landscape, implement phone-based telehealth visits, implement video-based telehealth visits, and ultimately shift the practice of telehealth visits from phone to video formats, when possible.

The aims, actions, and reflections are from a “Telehealth Task Force,” established in March 2020 at an urban, academic medical center. The task force was composed of orthopedic, podiatry, and sports medicine clinicians, as well as staff, billers/coders, informatics specialists, medical students, and scheduling assistants. The first Plan-Do-Study-Act was performed in a rapid cycle with weekly evaluations to optimize strategies over time (March 15, 2020-July 1, 2020). After completion of the weekly rapid cycle evaluations, monthly sustainability meetings were completed through October 2020 and shared with hospital leadership and stakeholders (Fig. 30.1).

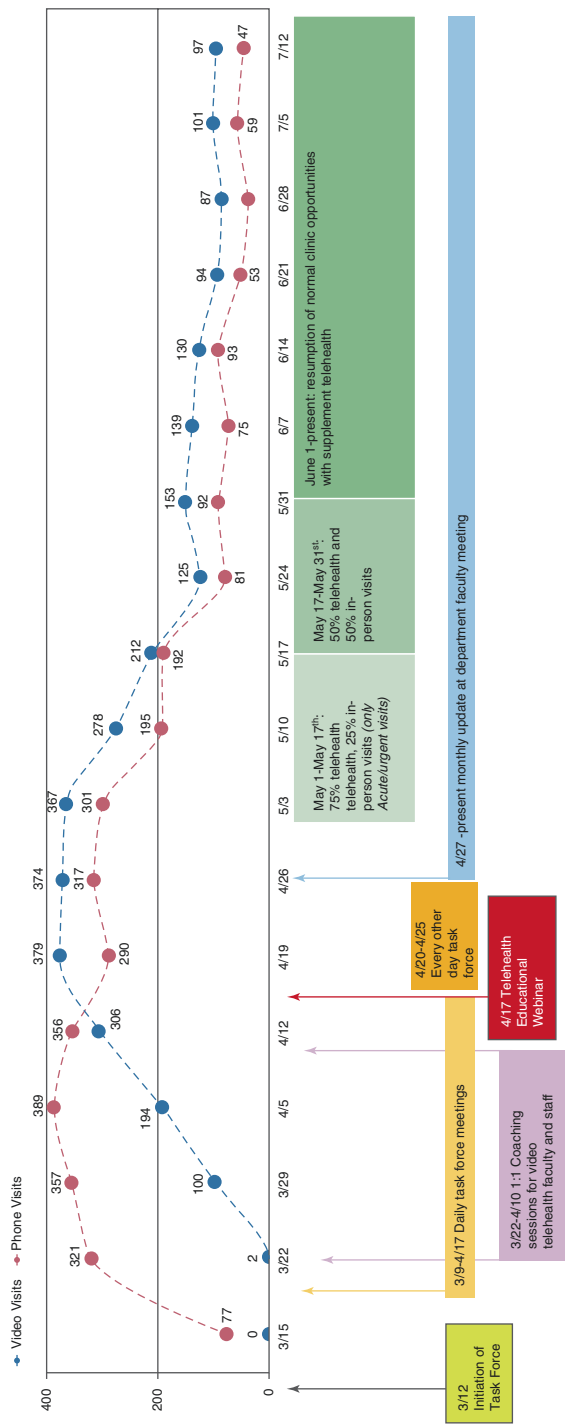


Fig. 30.1 6-month timeline of results from the rapid implementation of musculoskeletal telehealth demonstrating the conversion from predominantly phone based to predominantly video-based telehealth visits following the educational webinar intervention

Plan

After assessing the readiness for adoption of musculoskeletal telehealth, the task force strategized phone-based and video-based telehealth by holding a focus group for schedulers and surgeons adopting phone-based telehealth encounters to understand key stakeholders' opinions and concerns (Fig. 30.1). A special presentation by an external orthopedic surgeon who had been conducting musculoskeletal telehealth for over two years, provided significant guidance and feedback in the early adoption phase. In addition, a systematic review of the current literature was performed in the first two weeks of the initial uptake of telehealth to provide evidence-based guidelines to clinicians. Early in telehealth adoption, rules and regulations around what programs were considered HIPPA compliant were specifically addressed and re-evaluated over the entire QI cycle. Planned telehealth coaching sessions were conducted daily over four weeks to facilitate video telehealth implementation and increase healthcare provider comfort with software video platforms.

Do

A daily task force meeting was established to educate, evaluate, and troubleshoot any challenges that stakeholders encountered. During peak build up phase (March–April 2020), an average of 50 individuals attended. Telehealth coaching by physician champions was performed to gain buy-in and establish provider comfort with the video platforms. Common themes of feedback from the coaching sessions were shared to disseminate information widely and encourage broad adoption. Following over 80 video telehealth visits, a guerilla-marketing styled campaign was enacted in which video-visit adopters would share stories of their patient interactions and feedback. A formal telehealth educational webinar was offered to all stakeholders involved in musculoskeletal care to educate clinicians about best telehealth practices and provide systematic review findings regarding telehealth patient satisfaction and outcomes.

Study

Focus groups identified the following common concerns from schedulers, surgeons, and trainees: coordinating telehealth appointments with central scheduling and information technology, effects on patient outcomes, and compromised quality of surgical training. Specific to phone-based visits, the inability to visualize patients limited clinicians' ability to conduct post-operative wound checks, complete physical exams, and build rapport among new patients. Feedback from the video telehealth coaching revealed challenges in creating the best environment strategies (lighting or backgrounds), camera angles, speaking volume (headset vs. external

microphone), and specific language used to direct physical exam maneuvers. Patients with special needs (interpreters, caregiver support, vision or hearing challenges) proved difficult to treat with telehealth and often led to immediate referral for in-person evaluations. Over time, clinic schedulers reported a greater efficiency in scheduling telehealth visits, and remarked that clinic ran more efficiently. However, they reflected on the time-consuming new responsibility of troubleshooting unreliable internet connections and directing new patients on how to use the mobile applications. Although the patient “intake” was performed by physician extenders to enable providers to stay on schedule, it could be time consuming to orient technology-naïve patients on how to use the mobile app for video visits. Clinicians expressed difficulty in explaining medical imaging to patients in video visits and were eager to identify a validated method to conduct physical exams. Stakeholder interviews noted that patients appreciated the convenience of the video telehealth encounters, especially with their concerns of safety for avoiding environmental contact with COVID-19.

Act

The adoption of telehealth comes with unique challenges that differed for each type of patient encounter. Phone visits proved insufficient for most new patient encounters, wound checks, and overall ability to understand patient function and motion. Video telehealth was found to be associated with better patient care. Additionally, we recognized a need for standardization and recommendations of “best telehealth practice guidelines” for musculoskeletal clinicians.

Key Takeaways

- Rapid implementation of telehealth is possible and can be optimized with strategic stakeholder PDSA cycles.
- Quick feedback opportunities led to immediate system changes to aid provider and patient experiences.
- Physician/Provider lead champions were critical to elevate concerns for stakeholders (i.e., scheduling, technology, documentation, equipment).
- Coaching sessions to improve comfort level of providers with telehealth platforms were critical to quick uptake.
- Providers prioritizing evaluation appropriateness of specific patients for telehealth (both patient/caregiver comfort and provider ability to follow the injury by virtual experience) were helpful to sustain telehealth utilization.
- Continual dashboard feedback on individual and specialty specific utilization of telehealth allowed for early identification of teams that needed further support/coaching in telehealth uptake.

Discussion

Prior to the COVID-19 pandemic, options were limited for patients and providers to use telehealth for musculoskeletal care. Global implementation and adoption of telehealth have led to musculoskeletal telehealth use for consults [16–19], triage care [16, 20], follow-up care [21–26], and patient rehabilitation [27–30]. Guidelines for completing an effective virtual physical examination are now available [31], and increased comfort level by patients and providers has been documented across many healthcare domains [32].

Enhancing the patient experience, improving population health, reducing costs, and improving the work life of health care providers significantly influence health-care system decision-making [33]. Telehealth is positioned to impact patient experience and improve patient satisfaction, has the potential to reduce costs (value), and improve population health by breaking down travel and access barriers for patient population [11, 34]. Improving the work-life for healthcare providers is pivotal for sustained adoption of telehealth for healthcare systems. Rapidly evolving outcomes research around telehealth is changing the landscape for future growth in telehealth. QI strategies provide a foundation for healthcare systems to adopt, sustain, and optimize telehealth for our communities.

Telehealth and Patient Satisfaction

A systematic review demonstrated an association between patient outcomes and patient satisfaction scores across multiple specialties including gastrointestinal, radiology, and pulmonology [35]. There are equivalent or improved patient outcomes for musculoskeletal telehealth patient visits as compared to standard musculoskeletal visits [14, 17, 18, 22, 23, 26, 29, 36–42]. There are several different vantage points from which patient clinical outcomes can be evaluated outlined in Table 30.2.

Ware et al. created a classification system to measure patient satisfaction which includes eight components: (1) interpersonal communications, (2) technical quality of care, (3) accessibility and convenience, (4) efficacy/outcomes of care, (5) continuity of care, (6) physical environment, (7) finances, and (8) availability [43]. Although the physical clinical environments is important to general patient satisfaction [44], musculoskeletal telehealth interventions are able to achieve similar ratings of patient satisfaction [45–47]. One study reported a statistically significant favorability toward the telehealth intervention, especially after total joint replacements [26]. Even in instances where lower satisfaction was recorded,

Table 30.2 Patient outcome measurement scales

Activities of daily living
Pain scores
Range of motion
Quality of life

Table 30.3 Musculoskeletal telehealth patient satisfaction

Factors influencing patient satisfaction
Decreased need for patient/caregiver time off work
Reductions in travel time and/or distance traveled
Expanded access to specialty care
Optimal visit length

patients still stated they would engage with telehealth services again [48]. Patients reported the following contributors to their satisfaction of musculoskeletal telehealth interventions, listed in Table 30.3.

Telehealth and Clinician Satisfaction

Clinical efficiency, including time saved by office staff and patient wait times, overwhelmingly favors telehealth across many medical specialties. Among patients with chronic obstructive pulmonary disease, a patient population with a high rate of hospital use, telehealth interventions were found to significantly decrease emergency department visits, hospital admissions, and contact with specialized nurses [49, 50]. Similarly, musculoskeletal telehealth patients spend less time waiting for appointments without significant differences in patient evaluation accuracy or patient adherence to patient care plans [8, 26, 39, 51–53].

Difficulty in performing the physical exam is one of the most common reasons for transition from virtual to in-person care [54]. While in-person physical exams are ideal and allow for easy visualization and evaluation of strength and motion, technologic advances have improved telehealth assessments and allow for data capture that may not be as easy in the in-person environment. For example, telehealth goniometry assessments (motion assessments) are effective [55], as well as digital photography for the hip, knee, elbow, and shoulder [56].

Telehealth Value-based Considerations

Among a diverse population including cardiac and neurologic patients, telehealth consultations uniformly increased office efficiency and cost savings associated with referrals, surgical case consults, and time savings for inner-city general practices and specialty clinics [57].

In systematic reviews of other specialties, patients and providers found cost savings related to telehealth [58–60]. A 2019 randomized controlled trial reported lower costs to both musculoskeletal surgery patients and hospitals [61]. These findings corroborate a 2018 study by Rosner et al. reporting a mean savings of \$656.52 per musculoskeletal patient [62]. In fact, significantly fewer telehealth musculoskeletal patients required time off from work to attend their appointments compared to the control group [23]. Parkes et al. noted that their musculoskeletal telehealth population had fewer transportation needs, lower fuel costs, and reduced parking fees [63]. Musculoskeletal patient time and distance traveled have also been reported as

reduced with the telehealthcare provision [23, 25]. Wade et al. reported that while 61% ($n = 36$) of studies across medical specialties found telehealth interventions to be more cost-effective, 31% of studies reported greater costs [64]. Further analysis by Wade et al. suggested that less cost-effective telehealth interventions were more likely to be delivering services to rural areas. However, even among the more rural populations, who may incur a higher start-up cost for technology, reductions in travel and time for patients across specialties have an equally valuable economic impact [19, 65, 66]. Given the diversity of telehealth interventions, patient populations served, and the various dimensions in a cost-analysis, it is difficult to conclude with certainty the universal cost-effectiveness of telehealth.

Barriers to Telehealth

Previous barriers to telehealth, such as insurance reimbursements, state laws, and technological challenges were facilitated almost overnight due to the COVID-19 pandemic. This allowed for the field of musculoskeletal health to overcome many challenges to widespread telehealth adoption. Although a 2010 report from the World Health Organization found that telehealth is most advantageous to patients of low socioeconomic status [67], interventions targeting these populations [68] are scarce. However, not all studies include details regarding patient health insurance status, which when controlling for other confounding variables has been associated with likelihood of using telehealth [69]. Additionally, many telehealth studies report mean patient ages to be middle ages and thus may not accurately capture the experiences of older age demographics who may be utilizing these platforms. Although one-third of pediatric medical problems involve the musculoskeletal system [70], there is a dearth of literature analyzing telehealth interventions among pediatric patients. For further evolution of telehealth care, it is critical to determine how to leverage telehealth interventions for patient consults, follow-up encounters, and post-operative rehabilitation while also expanding access to care and promoting patient recovery.

While telehealth holds potential to increase healthcare access for some, it should be noted that its use can effectively marginalize other posing barriers through limited accessibility features [10], technology access, and literacy. Most studies present minimal information regarding the sociodemographic, disability status, insurance status, and language barriers, which all greatly influence technology accessibility. Patients who speak languages other than English and Spanish have been reported as less likely to partake in telehealth encounters [69]. A preliminary study evaluating one demographic variable reported that linguistic and cultural barriers prevented at least 90% of non-Native English speaking patients from understanding the following words: consent, autonomy, telehealth, videoconference, and electronic records [71].

Pincus et al. found that 40% of pediatric musculoskeletal telehealth patients had diagnoses of cerebral palsy, intellectual disability, or other congenital syndromes. They postulated that the cost and time savings associated with telehealth were likely

attributable to the inconvenience of patient transport [72]. Despite this benefit, few telehealth interventions specifically cater to patients who have speech, cognitive, and physical disorders or those who are blind or deaf [73]. There remains a further need to evaluate interventions targeted to under-researched populations, such as pediatric patients, non-Native English speaking patients, patients of low socioeconomic status, and patients with disabilities.

Future Directions

Future research and quality improvement initiatives should evaluate various non-contact physical exams for common musculoskeletal complaints. These efforts will establish confidence in patient safety and increase willingness to engage in musculoskeletal telehealth. Directing future research to more clearly define factors influencing surgeon/clinician and patient telehealth satisfaction and adoption will more likely expand telehealth opportunities to different populations. Many satisfaction assessment scales being used in the current literature for telehealth are not validated [10]. Some instruments used do not effectively distinguish whether patients are satisfied with their treatment, their interaction with the provider, or the modality of health service delivery. It is important that surgeon and patient satisfaction be considered for effective integration of musculoskeletal telehealth long term [74, 75]. Although much research has been conducted on the influence of musculoskeletal telehealth on patient satisfaction, there is great variability in the methodology used to assess patient satisfaction. Likert or Likert-similar scales are most commonly used, while 1–10 scoring, yes/no, visual analog scale, and extended responses also can be used. A portion of questionnaires assessed satisfaction on a global level, such as “I was satisfied with the services I received,” while others evaluate patient satisfaction specific to certain elements of the telehealth experience. Considering the vast array of scoring and assessment techniques, the challenges and benefits of each method should be considered. Developing universal, validated metrics to measure satisfaction among patients will enable generalizability of intervention results.

Conclusion

As COVID-19 has galvanized a rapid adoption of telehealth techniques, bias due to excitement of novel approaches may influence methodology, assessments, and outcomes [10]. Nevertheless, studies support that telehealth can provide a reliable and acceptable model of musculoskeletal healthcare delivery, particularly when patients are not able to travel to clinic. While telehealth will not replace traditional in-person visits due to the inherent nature of orthopedics/musculoskeletal problems, it serves as a great service for a select group of patients who may have mobility or transport limitations. Using the structured PDSA format of quality improvement, one can strategically implement telehealth innovation in any organization. The key factor in

utilizing the PDSA model is the routine assessment of what was learned and what can be changed. Sustaining patient interest and trust in musculoskeletal telehealth will require ongoing stakeholder engagement and quality improvement strategies.

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Using Quality Improvement to Enhance Geriatric Fracture Care

31

Althea Anne Perez, Mitchell T. Gray, and Carmen Quatman

Introduction

The population of individuals over 65 in the United States will reach 70.3 million by 2030. As a result, the annual number of hip fractures in the US could reach 666 million by 2030 [1]. With a rising population of older adults, there is a critical need to improve current healthcare models to create sustainable improvements in efficiency, quality, and cost of care [2]. Quality improvement (QI) strategies provide a platform to improve morbidity, mortality, and quality of life for older patients. The management of geriatric fracture care is complex, often requiring a multidisciplinary approach to deliver comprehensive care.

Understanding the specific musculoskeletal concerns related to the geriatric population helps guide approaches to improve the quality of patient care. With an age associated decline in mobility, strength, and stress response, older adults who are predisposed to poor bone quality have an increased risk of falls and subsequent fracture [3]. The health system can intervene and address the comorbid conditions that elevate a patient's mortality risk and adverse outcomes in the perioperative period [4–9]. Cognitive impairment, frailty, immobility, delirium, and home environment all play a role in outcomes following fracture in geriatric patients. Additionally, older adults are at risk of losing independence and they may need special consideration for biopsychosocial needs such as additional home support,

A. A. Perez

Department of Orthopaedics, University of Cincinnati, Cincinnati, OH, USA

e-mail: AltheaAnne.Perez@osumc.edu

M. T. Gray

Indiana University School of Medicine, Indianapolis, IN, USA

C. Quatman (✉)

Department of Orthopaedic Surgery, Ohio State University Wexner Medical Center, Columbus, OH, USA

e-mail: Carmen.quatman@osumc.edu

financial challenges, and difficulty with finding transportation for care [10]. Dedicated co-management teams including the orthogeriatric model of care have proven to reduce mortality in this vulnerable population. Addressing patient malnutrition, frailty, polypharmacy, delirium, and depression can significantly affect overall outcomes for geriatric fracture patients [3, 10].

While healthcare systems have widely recognized the need to improve efficiency and cost while preserving safety and quality across all patient populations, the adoption and implementation of recognized safe practices for geriatric patients remain a challenge. Standardized protocols and policies for these patients should be a priority for healthcare providers and policy makers [2, 11]. Using QI techniques, health systems can identify and address gaps in care for geriatric orthopedic patients. This chapter illustrates the utility of QI to identify care gaps and implement solutions to improve the delivery of care for geriatric fracture patients.

Gaps in the Continuum of Care

There are many “touchpoints” for patients within the healthcare experience as outlined in Fig. 31.1 [3]. Despite advances in technology and transition to electronic medical records (EMR), healthcare for older adults is often fragmented. Care coordination can also be challenged by the inability to centralize patient information, especially with patient transfers from tertiary hospitals and nursing facilities without EMR compatibility. Patients or caregivers are often the primary channels of

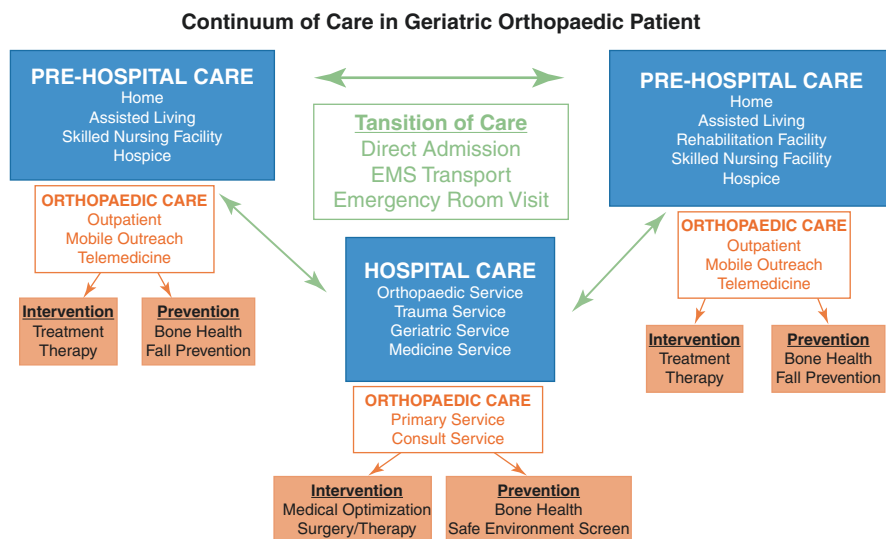


Fig. 31.1 Outline of the continuum of care for geriatric orthopedic patients. Reprinted by permission from [Springer]: Current Geriatrics Reports, “Geriatric Orthopaedics: a New Paradigm for Management of Older Patients” by Quatman et al. 2017 [3]

translation for medication history, prior medical and social history, and exchange of medical information such as outside imaging. Patients who sustain hip fractures may find themselves under the care of two to 10 different care teams over the course of six months following an operation [12, 13]. For a geriatric patient who has limited functional capacity or ancillary support, this process can lead to oversights in patient management. Further gaps in care can occur if the patient and/or caregiver has dementia or cognitive impairment. When care is coordinated seamlessly across these transitional points (hospital, transitional care, home care), there is a significant reduction in hospital readmissions and mortality and improved functional recovery after fracture [14]. Optimal care depends on the coordination of patients and their caregivers; involving these critical team members can ensure success in care transition [13, 15].

Since fracture management frequently requires urgent treatment, relying on the patient and caregiver's detail of events is a vital yet challenging exercise for providers. It is paramount that medical teams, "go to gemba" (visit the place where work is being performed) and truly understand the patient journey and frontline experiences to improve care through QI initiatives. For the geriatric fracture patient, this starts by understanding the mechanism of injury, location of where injury happened (i.e., home), as this critical information can help with care planning and future injury prevention strategies (Pre-hospital phase of care Fig. 31.1). Once patients arrive to the hospital/clinical care environment, further management proceeds based on the type of fracture and disability that may be associated with it. Even if surgery is not needed, geriatric fracture patients may need to be admitted to the hospital for physical therapy, mobility assistance, pain control, and monitoring of clinical conditions. The "APGAR SCORE" was developed to help enhance the quality of life for geriatric hip fracture patients, but perhaps it could have a wider scope approach to all geriatric fracture patients [16]. As part of the "APGAR SCORE," there is emphasis of Alimentation (and nutrition), Polypharmacy, Gait, Advance care planning, addressing Reversible cognitive impairment, maximizing Social support, remediating Cataracts (or other visual impairments), addressing Osteoporosis, and ensuring Referrals for multidisciplinary care and safe Environments after discharge [16]. Much of the APGAR SCORE for hip fracture patients encompasses the biopsychosocial needs that should be addressed in order for all geriatric fracture patients to have the best outcomes. Below are various challenges along the continuum of care for geriatric fracture patients that QI initiatives could address.

Acute Phase

Immediate and efficient care from the onset of a geriatric fracture can be challenging to coordinate. Appropriate patient optimization relies on surgical clearance from consultant teams and management of relevant medical comorbidities. Poor medical optimization in older hip fracture patients is associated with a 28% increased relative risk of mortality and longer time to full recovery after surgery [17, 18]. While there is substantial clinical benefit to comprehensively optimize patients for surgery,

management of certain fractures requires timely operative fixation. The lack of streamlined hospital protocols specific to geriatric patients can delay time to surgery and worsen outcomes. For example, in the United States, a typical model of care starts in the emergency department (ED) and is transferred to a medical or surgical provider. The patient may have several different consulting teams in addition to a primary provider as they are medically optimized. Minimization of the critical time to surgery for certain fracture types requires a protocol-driven coordinated effort from multiple medical services. In the hip fracture population, surgery within 24-h of presentation lowers the odds of mortality and decreases 30-day complications [19]. This information can help guide systems-based protocols with an emphasis on streamlining the ED to operating room process.

Several studies have shown success with co-management strategies in geriatric hip fracture patients, addressing limitations found in single service management of these complex patients. Co-management teams comprised of orthopedic surgeons and geriatricians decrease length of stay, readmission rates, time to surgery [20], complication rates, and mortality rates compared to single service management [21–25]. The benefits of co-management extend to providers beyond geriatricians [26], as co-management with hospitalists [27], as well as clinical nurse specialists [28] is also advantageous. Additionally, harms common to geriatric patients such as adverse drug reactions in the inpatient setting can be reduced with this combined model of care [29]. Streamlined protocols that provide efficient care for these patients are under-practiced but essential in geriatric hip fracture management.

Along with co-management strategies, care bundle interventions improve pain control and delirium management in the perioperative period [30]. Care bundle strategies create a short consistent group of interventions, usually five or fewer evidence-based suggestions, that allow for a more standardized practice of clinical medicine [31]. Chuan et al. found that implementation of a protocol to standardized pain management, avoiding high risk drug classes, and educating care teams reduced delirium in hip fracture patients. Other protocols have focused on identifying polypharmacy, fluid imbalance, and blood pressure control in the perioperative period with similar reductions in delirium [32, 33]. These studies demonstrate the utility of care bundles in geriatric fracture care and can serve as a model for future QI projects.

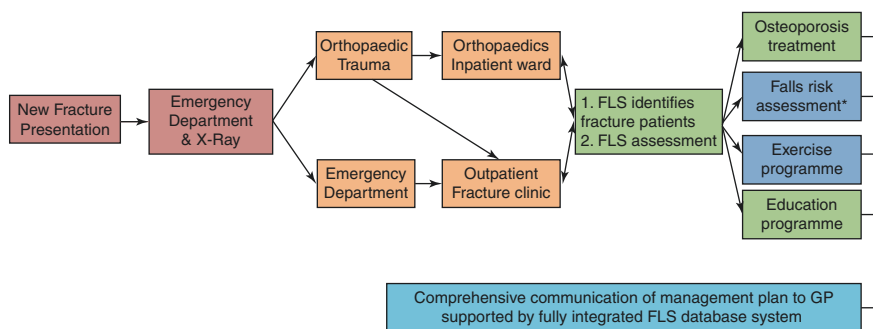
Patients undergoing surgical management in setting of an acute fracture endure a major physiologic stress to the body. Elderly patients with limited physiologic reserve can be at risk for poor outcomes if they are not nutritionally optimized [34]. Some studies cite up to 50% of geriatric patients as malnourished when they present with a hip fracture [35]. Various factors can contribute to further iatrogenic compromise of nutrition while in the hospital setting. Delays in surgical management, post-operative delirium, availability of familiar and satisfactory food options, vision difficulties or physical impairment can all limit appropriate nutritional status of patients. The literature is clear regarding the impacts of malnutrition in the geriatric population, with implications on wound healing, strength, balance, and fracture healing [36]. Older adults experience higher rates of falls, higher risks of failing to perform ADLs [37], loss of independence status, and increased rates of in-patient mortality in the setting of malnourishment. Duncan et al. reduced both in-hospital

and 4-month mortality with dietetic assistance to manage nutritional needs for geriatric hip fracture patients [38]. Dixon et al. systematically and prospectively outlined the pre-operative in-patient nutritional practices of hip fracture patients in England [39]. Their results contradicted previous belief that cognitively impaired patients receive less in-hospital nutritional support, and less than 30% of admitted patients in their cohort were at risk for malnutrition. While it is unclear the exact incidence of malnutrition in the geriatric population, clinicians should be aware of its implications in fracture management and introduce strategies to maximize nutritional support.

Long-Term Management and Prevention

While the best long-term solution to address morbidity and mortality in the geriatric fracture population is implementation of fall prevention strategies, once a fall occurs, there is a critical window of time to minimize additional risks. Up to half of hip fracture patients have history of prior fractures in the months to years prior to their presentation, serving as a harbinger for future fracture risk [40, 41]. These “sentinel events” should not be ignored and present an opportunity for the health system to intervene, altering the risk profile of these patients. Prospective QI measures after insufficiency fractures have enhanced patient recognition of their disease process, improved follow-up duration, and increased regular rates of bone mineral density testing [42].

Secondary preventative strategies such as Fracture Liaison Services (FLS) and American Orthopaedic Association’s Own the Bone registry [43–45] are useful services that improve assessment, treatment, and appropriate follow-up for geriatric patients with fragility fractures (Fig. 31.2) [46]. Senay et al. studied long-term follow-up with FLS implementation for fragility fracture patients and noted an 86% enrollment of patients in anti-osteoporotic medical treatment [47]. The re-fracture



* Older patients, where appropriate, are identified and referred for falls assessment

Fig. 31.2 Diagram emphasizing the structure of a hospital-based fracture liaison service. Reprinted from “Capture the Fracture: a Best Practice Framework and global campaign to break the fragility fracture cycle” by Akesson et al. under the creative commons license [45]

rate in their cohort was 4.3% over a 2-year follow-up interval with significantly improved pain scores, functional scores, and a trend toward improved quality of life. Future study of FLS implementation with control groups could better quantify the effectiveness of this strategy in geriatric fracture care. Compliance of anti-osteoporotic medication is a challenge and although there are many benefits of pharmacologic fracture prevention including decreased mortality risk, the utilization of these medications requires identification of patients for treatment, prescription, and patient compliance with medications. These medications can be difficult to remember to take consistently if prescribed orally because they are often once a week or once a month use (Table 31.1) [48]. In addition, many of the anti-absorptive medications are expensive, not universally covered by insurance and require self-injection daily. Balasubramanian et al. found that 20% of women and <5% of men following insufficiency fractures underwent DXA evaluation in the following year [49]. While some results highlight the low rates of pharmacologic and diagnostic osteoporosis management for geriatric patients following a fracture, this provides an opportunity for researchers to create novel solutions for this gap in treatment.

Discharge planning and social optimization following a geriatric fracture are challenging tasks. Safe mobility, medical optimization, and optimized care transitions should be a primary focus when approaching discharge [10]. This process should start as early as admission, as it has implications on readmission rates and lengths of stay [50, 51]. Pitzul et al. discovered that while inpatient rehabilitation has higher initial costs, the risk of 1-year of readmission and mortality was higher in those discharged directly to the community [52]. Protocols that include early rehabilitation programs and discharge planning can lead to lower implant failure rates, lower rates of delirium, and greater ability to discharge home safely [53].

Table 31.1 Guidelines outlining Bone Health specific medications. Reprinted from Insufficiency Fractures. In: Miller T.L., Kaeding C.C. Stress Fractures in Athletes. By Quatman et al. [48]

Generic drug	Brand	Administration	Duration	After completion
Alendronate sodium	Fosamax	1/week orally	4–5 years	Drug holiday (2–3 years)
Ibandronate sodium	Boniva	1–2/month orally	4–5 years	Drug holiday (2–3 years)
Risedronate sodium	Actonel	1/day up to 1/week orally	4–5 years	Drug holiday (2–3 years)
Zoledronic acid	Reclast	1/year Infusion	3 years	Drug holiday (2–3 years)
Calcitonin-Salmon	Fortical/Miacalcin	SubQ, IM, nasal	4–5 years	Drug holiday (2–3 years)
Denosumab	Prolia	2/year infusion, renal disease pts.	3 years	Drug holiday (2–3 years)
Raloxifene	Evista	1/day orally	4–5 years	Drug holiday (2–3 years)
Teriparatide	Forteo	1 SubQ injection daily	2 years (lifetime)	Follow with prolia or bisphosphonate
Abaloparatide	Tymlos	1 SubQ injection daily	18 months–2 years (lifetime)	Follow with Prolia or bisphosphonate

Following definitive surgical intervention, orthopedic surgeons provide weight bearing precaution recommendations, follow-up intervals, wound care instructions, and expectations for recovery. Physical therapists often determine whether a patient has the capacity to meet functional needs at home or requires higher levels of care, a crucial step in preventing readmission or further harms [54–56]. Falls can be avoided with accurate assessment of the home environment and rehabilitation assistance tailored toward the patients' needs. Social work, occupational therapy, and other providers can offer additional assistance to ensure a safe home environment. Recovery after a hip fracture extends well beyond what is provided in the surgical hospital setting, often lasting for more than 1 year [57, 58]. As with many aspects of geriatric care, organized protocols are necessary to ensure regular follow-up and closely monitor adherence to the given plan. Thoughtful and standardized discharge planning after a geriatric fracture is an essential task to provide quality care, with QI initiatives poised to ensure reproducible outcomes.

Addressing biopsychosocial factors for geriatric hip fracture patients can have lasting implications on outcomes in the perioperative and postoperative period. The incidence of depression, delirium, and cognitive impairment at the time of injury in geriatric hip fracture patients is estimated to be 29%, 49%, and 47%, respectively [59]. Several studies outline the ties between mental health and fracture related outcomes, highlighting the associated delays in recovery [60], prolonged hospital stays [61], and trends toward elevated risk of mortality when these conditions are not addressed [62]. Following a fracture, patients commonly experience decreased quality of life, increased fear of falling [63], pain [64], and delirium [65]. In the hip fracture population, depression is the most commonly diagnosed psychiatric disorder [66]. Cognitive impairment, psychologic stress, and anxiety are known contributors to depression and should be evaluated upon patient admission. Eleuteri et al. recommend these mental health factors be reassessed during patient follow-up at 90 days, and 1 year and 2 years from admission [67]. Standardized measurement tools such as the EQ-5D form with Visual Analog Scale (VAS) [68], and ADL measurement tools [64] can aid in assessing pain, health related quality of life, and function. The Geriatric Depression Scale is another tool to assess depression in this population [69]. Patients admitted for hip fracture management who had twice-weekly counseling sessions had a reduction in symptoms of depression and anxiety [70]. Patients with greater levels of emotional distress at admission experience greater improvements in quality of life and reduction of pain with counseling. Thus, treating mental health in the perioperative period has a role in mitigating poor patient-reported outcomes for geriatric fracture patients.

Given the estimated increase of incidence in hip fractures to 500,000 cases/year by 2040, policy makers have significant incentives to consider cost-minimization strategies to improve effective and efficient care for these patients. Adeyemi et al. found that total annual direct medical costs associated with hip fractures were \$50,508 per patient, with a yearly estimate of \$5.96 billion to the US healthcare system [71]. Inpatient and skilled nursing facility services accounted for 76% of the estimated cost per patient (\$44,135/patient). In response to these extraordinary costs, Alternative Payment Models (APMs) were launched, creating a shift in care

to prioritize value over volume. Hospital costs account for 44–47% of direct cost for hip fracture patients, and the consolidation of payment sources is reported to decrease the total cost of care [72]. Where the patient once stood as the “middle-man” in the payment scheme, paying each provider for their individual contribution, APMs now act as a central payer. APMs may offer opportunities in the future for improved cost effectiveness; however current evidence to support utilization of APMs is limited at this time.

One form of APM for the geriatric population is the application of Bundled Payment for Care Improvement (BPCI). BPCI programs for patients undergoing arthroplasty for hip fracture demonstrated decreased 90-day costs and length of stay with increased home discharge rates [73, 74]. The Center for Medicare and Medicaid Services (CMS) planned to instate the first nationwide model for bundled payments in fracture care in 2018, aimed at patients undergoing repair of hip or femur fractures. However, the implementation was halted due to reimbursement concerns particularly for medically complex patients. Instead, CMS is trialing elective utilization of BCPI models, attempting to overcome barriers to application on a national level [75]. The presence of these successful models foreshadows the future advancement of QI initiatives designed for cost-minimization in geriatric fracture care.

Examples of Quality Improvement in Geriatric Orthopedic Fracture Care

There are many examples of successful QI programs in geriatric fracture care. Current practice guidelines from programs such as American Academy of Orthopaedic Surgeons (AAOS), American Orthopaedic Association’s “Own the Bone” campaign, and the National Health Service tariff program have highlighted the problems that exist and strategies that can improve outcomes for geriatric patients. Successful implementation of QI initiatives that target the entire continuum of care can streamline and optimize care for older patients as well as decrease transition in care gaps. Coordination of the geriatric multidisciplinary team and the creation of more cost-effective programs to encourage medical center adherence are two recent advances in QI related applications.

On a global scale, medical centers in different countries have successfully implemented secondary prevention of fragility fractures. The United States, Australia, Canada, and UK developed the “fracture liaison service” model of care in the late 1990s. Fracture programs have significantly improved rates of osteoporosis screening, education, and treatment, effectively resulting in significant reductions in re-fracture risk and post-fracture mortality [76].

Other initiatives have offered financial benefits to encourage hospital compliance with national standards, which have improved integrated models of fracture care. For example, The Best Practice Tariff, initiated in 2010, offered hospitals a “bonus” payment for every hip fracture patient that was managed according to National Hip Fracture Database standards [77]. The QI initiatives created in response to the tariff

resulted in reduced time to surgery, increased OR availability to meet the demand, and reduced mortality [78].

National databases such as the National Hip Fracture Database, or the ACS NSQIP, are excellent resources that can be used by providers for auditing purposes and to compare themselves to other providers. In addition, the International Geriatric Fracture Society has set designated standards of care to also improve patient outcomes for geriatric fractures [79]. These resources can provide national benchmark information that can be used to optimize patient care and outcomes [80]. Sepehri et al. surveyed NSQIP and found that patient enrollment in standardized hip fracture programs from 2016 to 2017 demonstrated 30-day improvement in mortality [81].

The initiatives mentioned above are just a few examples of successfully implemented quality improvement projects in geriatric orthopedic fracture care. The majority of QI research has focused on the hip fracture population given its relation to elevated morbidity and mortality, however future work that focuses on QI initiatives for all geriatric fractures may significantly improve care as well.

Keys to Success

In September 2016, the Global Fragility Fracture Network explored how global/regional organizations improve aspects of care and published a “Global Call to Action with the support of multiple other geriatric societies.” Four elements were recommended: (1) promote clinical recommendations; (2) establish national fracture registry; (3) increase number and capabilities of case management/FLS; and (4) improve diagnosis of and communications about patients with vertebral fractures [82]. Global and regional initiatives by internationally respected societies can provide motivation and a standard for healthcare providers to become certified and recognized for their efforts in geriatric fracture care. Basu et al. suggest six keys to providing a successful geriatric hip fracture program including program leadership from an orthopedic and medical physician, co-management, standardized sets and protocols, collegial relationships of other team members, early surgical intervention, and a strategy for continuous quality improvement [83]. Continuing to identify and improve these gaps in care will provide an excellent framework toward improving the quality of geriatric fracture care.

Conclusion

Quality improvement can optimize fracture care for geriatric patients. Currently, there are many opportunities for multidisciplinary team-based QI initiatives that can improve short- and long-term outcomes for patients. While this chapter outlines numerous examples of successful QI programs in geriatric orthopedics, there are many gaps in care that require further study. QI can and should be employed by all providers to continually improve care across geriatric fracture management.

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Orthopedic Surgeons as Managers and Leaders: Developing the Right Culture

32

Steven L. Frick and Serena S. Hu

What Is the Definition of Leadership?

There are multiple definitions, but in the orthopedic surgery realm, it can be defined as organizing a group of surgeons and healthcare co-workers to work together to achieve common patient care, professional, scientific, and educational goals. Every surgeon is a leader each time they set foot in an operating room or clinic to deliver clinical care to patients, as that work cannot be accomplished without a group of people working together to achieve a surgical outcome or a successful outpatient clinic visit. Organizing groups of surgeons into a team to carry out larger group, practice, departmental, or hospital goals, or even national organizational goals, involves leadership tasks that can be similar or different than that of the clinical surgeon leader. Understanding and recognizing these differences can be an important part of developing as a surgeon leader [1].

What Is the Definition of Organizational Culture?

Orthopedic leadership is about setting standards and holding others accountable to them. It involves personal commitment, character, courage, and communication [1]. Character has been described as how you treat those who cannot do anything for you. The culture of an organization describes the character of a group of people and how they think and act as a collective. A company of strong character has a culture that promotes treating all people well, not just the ones who can pay them or provide something of value to them. The right culture in a medical organization is one committed above all else to the welfare of individual patients, as well as collectively to

S. L. Frick (✉) · S. S. Hu

Department of Orthopaedic Surgery, Stanford University School of Medicine, Center for Academic Medicine, Palo Alto, CA, USA

e-mail: Sfrick01@stanford.edu; Shu3@stanford.edu

the health of a community or a country, above the enrichment of individual physicians or a physician's group. But particularly at a time where burnout and professional dissatisfaction are at high levels among orthopedic surgeons, leaders need to also recognize the health, emotional and professional fulfillment needs of their group members. Surgeons who are energized and excited about their work and career will provide better care for patients. A focus on having the right culture, led by team members with the right character, leads to the development of trust by individuals within the group and those external to the group—in our case, the patients who we care for, our peers who we work with, and the administrative leaders of hospitals and other organizations we interact with. The centuries-old dedication to the patient-first mentality embodied in the Hippocratic oath can have unintended adverse consequences for physicians in the modern era. The current focus on patient satisfaction over patient healthcare outcomes can also lead to physician frustration and feelings of abandonment by administrative leadership if the patient is viewed as “always right” and the physician perspective is not appreciated. Surgeon leaders need to understand, empathize, and support front-line surgeons who are working hard to provide optimal patient health outcomes.

Is There a Difference Between Managing People and Leading People?

Managing can be defined as getting people to accomplish tasks and meet goals, while leadership involves inspiring people and setting the goals. Managers identify and define problems and work on solving the problems. They also are organizers of people and may be charged with hiring and firing staff. Leaders prepare organizations for change and help them deal with change. Leaders tolerate chaos, while managers appreciate organization and work to avoid chaos. In a famous essay entitled “What leaders really do,” John Kotter [2] described management as coping with complexity, while leadership is about coping with change. Good managers bring order and consistency to an organization, leading to high quality and profitable products. Leadership brings about change and dealing with change in a competitive and volatile world. Managers organize and staff an organization to carry out plans and devise systems to implement plans. In reality, managers have to lead, and leaders have to manage, and while linguists may argue about the semantics, managing and leading are overlapping roles. Gardner [3] thought that leaders and managers are often doing similar tasks. The six differences he saw between leaders and managers were: (1) leaders think longer term, (2) leaders grasp relationships to larger realities, as a part of a larger entity or even entities external to the larger organization, (3) leaders reach and influence constituents beyond their own jurisdiction, outside their own organization, (4) leaders put a heavy emphasis on the intangibles of vision, values, and motivation, (5) leaders have the political skill to cope with the conflicting requirements of multiple constituencies, and (6) leaders think in terms of renewal and the inevitability of change.

Leadership Is About Selecting and Aligning People, Then Motivating and Inspiring Them

For organizations to be successful, leadership development is viewed as an important requirement. Creating a culture of leadership means that leaders will recruit other people with leadership interest and potential and guide them on a career path that provides opportunities for development of skills and perspectives that prepare them for leadership roles. These activities that develop leadership skills and potential may not be activities that generate revenues, so successful organizations need to understand that an investment in leadership development may come with a short-term loss of revenue potential. Often the pathway to develop surgeon leaders involves exposing team members with leadership potential to educational programs and activities that temporarily pull them away from traditional revenue generation, such as clinic visits and surgical cases. These activities include advanced degrees, business and leadership educational programs, service on national organization committees and boards as volunteers, and participation in traveling fellowships or other specific leadership development programs. Leaders need to encourage young faculty with leadership potential to explore these opportunities and invest the time early in their career, so that they'll be prepared when leadership opportunities present. Kotter noted that the ultimate act of leadership is to "institutionalize" a leadership-centered culture where leadership development is prioritized [2].

Know Thyself

For those who are considering a career as a leader in orthopedic surgery, a common component of all leadership development programs is to first know yourself. There are multiple types of personalities as well as leadership styles, and individuals should strive to develop a leadership style that is congruent with their own personality and way of interacting with other people. Authenticity and being viewed as "genuine" lead to the development of trust. Without trust, followership cannot be developed. Trust has been described as like oxygen—when it is present, it is unnoticed, but when absent, all are acutely aware [4]. There are multiple personality inventory tools available for those who aspire to leadership. In addition, seeking personal coaching can help one to better understand individual personality traits and leadership skills. One characteristic described by Goldman has been termed as emotional intelligence [5]. This has the components of self-awareness, self-regulation, self-motivation, empathy, and social skills. These are important qualities to consider in understanding strengths and weaknesses as an individual on a journey towards leadership. Trust develops when leaders act with integrity: doing what they say they will do, holding confidential information they promise to keep confidential, and not delegating work to others that the leader is not willing to also do.

Know Your People

Adam Grant [6] has written about givers, takers, matchers, and fakers. Most people are matchers, meaning they will do something for you if you do something for them. Givers are selfless yet can be both the most productive and non-productive individuals. Leaders need to be aware of individuals on their teams who are takers (selfishly motivated) and fakers- those who want to be regarded as selfless / givers but whose motives are actually selfish. Fakers can often also be dishonest in fulfilling professional duties, and dishonesty has no place in medicine. Selfish and/or dishonest team members can poison morale and destroy cohesiveness, leading Robert Sutton [7] to write *The No Asshole Rule*, a book that notes how leaders who do not hire or tolerate jerks or bullies will create a better place for people to work. Organizational culture is created by both the behaviors that leaders encourage but also those that are tolerated; thus, to have a good culture leaders need to know how their people behave, set expectations, and correct bad behavior. The challenge for a leader is to avoid deluding yourself into thinking that people are intrinsically better or worse than they really are; rather it is to find ways to bring out the best in followers while minimizing the worst [8].

Define the Why or Purpose of the Group

When tasked with leading a group of orthopedic surgeons, it can be helpful to explain and have your team members understand why teamwork, practice goals, or departmental initiatives are important. Simon Sinek [9] has written about this with the advice to “Start with Why.” Motivating individuals to work together towards a common goal can be easier to accomplish if all the team members know why the goal is important, and why your organization is striving to achieve them. Sinek has described the golden circle of starting with why, which then leads to how the goals will be accomplished and in what way. In healthcare, we have the advantage of our professional commitment to the welfare of patients above personal gain or desires, and thus the “why” of our mission is often self-evident. There may be other initiatives above and beyond patient care, however, that your team will need clarity on the “why.” Once you have defined “why” and team members understand your purpose, cause or beliefs, you can then move to “how” the organization you lead will achieve goals [10]. According to Sinek, continuing to understand and focus on the “why” brings clarity and allows you to keep your organization focused on its mission and long-term goals. In another book, he noted that it is not enough to only know the “why” of your organization, you must also know your people (“who”) and realize that they are much more than an expendable resource. Good leaders must truly care about those entrusted to their care. Being competent is simply not enough. His book *Leaders Eat Last* [11] describes leaders as people who put their own interests aside to protect others and lead them into the future. They would sacrifice “what is theirs” to save “what is ours” and would never sacrifice “what is ours” to save “what is theirs.” This speaks to what Jim Collins [12] has described as the highest level of

leadership (level 5), the cornerstone of which is unselfishness. Selfishness is a destructive quality for a leader and a culture. In a weak culture, we veer away from doing the right thing in favor of doing the thing that is right for oneself. In strong cultures, employees form similar attachments and an identity as a part of belonging to the organization. This is the value of uniforms or company logos on attire and merchandise to instill a sense of pride in membership and a sense of belonging. Successful leaders understand that leadership is about helping others, not about helping yourself.

On Competition Versus Collaboration in Medicine

Enemies fight. Friends cooperate [11]. It's important to get to know people outside of the professional environment, and to see and treat each other as human beings instead of competitors. Learning what you have in common can facilitate cooperation as opposed to competition. Building relationships leads to better communication, a better understanding of one another's issues, and the opportunity for collaboration. There may still be disagreement, or we might discover that collaboration is not possible, but without a relationship and communication with each side listening to the other, it is difficult to imagine that collaboration and cooperation can occur. Leaders need to give people a reason to work together and commit to excellence together. Competition is desirable in a capitalistic healthcare system and may be inevitable, but it often leads to considerations of competitors as less talented, less intelligent, less competent, and less skilled based on limited information. When leaders hear these kinds of comments, efforts to improve communication and collaborate in areas where competition for revenues does not exist can result in relationships that allow corrections to these assumptions. This can create opportunities for professional collaborations to improve access to care, research, and education.

Leaders Understand the Basic Needs of the People That They Work with Including the Need for Income, Stable Job, Housing, Health Care, and Ability to Take Care of Their Families

From *On Leadership* by John Gardner [3].

Leaders help people believe that they can be effective and that goals are within their reach. Leadership involves revitalizing shared values and beliefs to accomplish effective group action. Gardner says that the word manager indicates an individual who holds a directed post in an organization, tasked with presiding over the processes by which the organization functions, allocating resources prudently, and making the best possible use of people. He described the tasks of leadership as envisioning goals, affirming values, regeneration of values, motivating, and managing. In order to achieve a workable unity, the leader must develop trust, be able to explain what the problem is and how to do certain things, and to serve as a symbol or role model. The leader also is tasked with representing the group and must foster

a sense of renewal. Leaders can be delegators of some of these tasks, but they are still responsible for making sure that the tasks are completed. Leaders need to enable and empower team members, by sharing information and making it possible for followers to obtain education, by sharing power and responsibility, by building the confidence of followers to achieve individual and team goals, by removing barriers to the release of individual skills and talent, and by seeking and providing resources followers need to accomplish goals. Conflicts inevitably arise, and one role of the leader is to resolve conflicts. An essential description of leadership is that leaders point people in the right direction and tell them to get moving. This is about setting expectations and having high expectations for accomplishment by members of the team. Gardner also notes that the concept of accountability is as important as the concept of leadership [3].

Be A Contrarian

Advice from *A Contrarian's Guide to Leadership* by Steven Sample [8].

What follows are excerpted ideas from Sample's book: Learn to think gray and free, meaning don't form an opinion about an important matter until you've heard all the relevant facts and arguments, or until circumstances force you to form an opinion with incomplete information. Avoid a black and white, win-lose, succeed-fail binary approach whenever possible. Remember that Friedrich Nietzsche noted that people tend to believe that which they sense is strongly believed by others. A well-developed ability to think gray is the best defense a leader can have against this assault on intellectual independence. The leader should have an inner circle of advisors founded on mutual understanding and trust, a concept he described as having a "few trusted lieutenants." Having trusted colleagues from different backgrounds can help ensure the leader hears multiple viewpoints before making decisions, and sometimes decision-making processes can be improved by appointing a person or a group of people to take a contrary opinion (some refer to this as designating a "red-team").

Become an artful listener. This also helps with maintaining the intellectual independence of the leader. Artful listening enables the leader to see things through the eyes of followers, while at the same time seeing things from their own unique perspective—sample described this as seeing double. When an outside person is appointed to lead an organization, unless the organization is in crisis, sample recommends a period of artful listening, which some have called a listening tour [13] after taking a new job, to understand the issues facing the organization and the culture of the organization before taking a hands-on decision-making approach.

Decision-making is a critical part of the leader's job, and an important way leaders exercise their power. Sample advises two general rules for his decision-making approach: (1) never make a decision yourself that can reasonably be delegated to a trusted lieutenant and (2) never make a decision today that can be reasonably put off until tomorrow [8]. US President Calvin Coolidge reportedly would first ask "how much time do I have to make this decision?" when presented with an important

decision to make. Sample described decision-making as bringing together the finest traits of contrarian leadership—thinking gray and free, artful listening, delegating authority while retaining ultimate responsibility, artful procrastination, ignoring sunk costs, taking luck into account, and finally listening to one’s inner voice.

There are some things that leaders should be committed to that are critical for their own personal character, and for the culture and values of their organization. Sample called this “knowing which hill you’re willing to die on” [8]. Some battles are not worth the costs. Morally there are choices to be made, and the leader needs to be able to triage these decisions and decide which hill he or she is willing to die on. These may be ethical issues involving honesty, compassion, altruism, empathy, and loyalty.

Work for Those Who Work for You

If your direct reports are successful, then you will be successful. Teddy Roosevelt is quoted as stating the best executive is the one who recruits the most competent people around, tells them what the leader wants done, and then gets out of the way so they can do it. Surgeons in particular seem to respond well in our experience to this leadership style.

Mutual self-interest is a powerful way to bond people together, especially through tough times. Monetary rewards alone are often not enough. Punishment is generally a losing strategy for leadership. Leaders don’t really run organizations, but they lead individual followers who collectively give motion and substance to the organization of which the leader is the head.

There’s a difference between “being president” versus “doing president” [8]: many people want the job and the title, but they may not be willing to do the work that the job or title requires. Be aware of this when developing leaders and look for those individuals who do the work without complaining or procrastinating. These individuals may not recognize their own leadership potential and may respond well to increased responsibilities. All with significant leadership roles understand that leaders are often charged with doing seemingly trivial activities that are important for group cohesiveness. Effective leaders want to do the job, not just carry the title.

Promote Innovation, Improvement, and a Focus on Getting Better Every Day by Using Peer Review

Orthopedic leaders should define metrics that are important for success, and then measure them. That which gets measured can be improved. Creating an expectation that surgical care has the highest quality in places that are innovating, performing original research, participating in peer review processes, and educating future generations is an important orthopedic leadership task. We should all strive to be life-long learners, and to provide better care tomorrow than we did today. Having humility, recognizing that there is much we do not know, can help drive research

and innovation. Leading weekly surgical preoperative and postoperative case review conferences with peer evaluation is a tried-and-true method to raise standards of care and promote surgical innovation and quality. All surgeons should create a system of peer review of their cases to seek advice and constructive criticism. No matter the size of your group, all of you are smarter than one of you. Although peer review conferences are associated with academic programs, any group can set up peer review processes.

Value Diversity

Orthopedic groups and divisions should strive to provide excellent orthopedic surgical care to all patients in their community. Access to care is important and reflecting the community your group serves can facilitate patients feeling more comfortable seeking care with your group. A diverse group offers improved decision-making, as diversity of prior experience, upbringing, cultural and religious backgrounds, and educational experiences can widen the options considered for major decisions and facilitate improved decision-making [14]. Our profession has long been dominated by white, male leaders, and in medicine, orthopedic surgery has been among the slowest specialties to change and value diversity by positioning underrepresented groups in leadership positions. Being a leader in an orthopedic group now requires a commitment to diversity, equity, and inclusion, recognizing past inequities and working to improve them by offering opportunities to surgeons from underrepresented groups to not only participate, but also to prosper, develop, and lead [15]. Those changes are occurring now, and the principles and concepts reviewed above can help this new group of orthopedic leaders succeed and advance our profession.

Conclusion—Developing the Right Culture

A commonly cited leadership phrase is “culture eats strategy for lunch” [16]. Strategic plans, brilliant ideas, matrixes of organizational charts, and ambitious operational goals are ineffective if there are not committed, hard-working people willing to do the daily work needed to advance your group. Patient communication workshops often teach “they won’t care how much you know, unless they know how much you care”—the same holds true for your practice colleagues and staff. Leaders develop work environments where people interact professionally, trust each other, communicate well, surface and address problems, and identify and resolve conflicts. Successful orthopedic leaders develop cultures focused on doing the right thing for patients, for staff, and for surgeons, and create work environments allowing for professional fulfillment and enjoyment of work, where turnover is minimal. Team members want to remain on the team for the internal rewards of job satisfaction and commitment to purpose as much as for appropriately aligned external rewards (compensation, career advancement, titles, and promotions). Considering

the ideas and principles outlined in this chapter can help orthopedic surgeons develop leadership skills individually and within their groups, resulting in organizations with cultures focused on excellence, professionalism, and teamwork that will serve the interests of patients, society, and our profession.

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