QUALITY IMPROVEMENT STRATEGIES IN COMPLEX SPINE SURGERY FOCUSED ON VALUE-BASED CARE

Rajiv K. Sethi, MD

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CHAPTER 1

GENERAL INTRODUCTION

GENERAL INTRODUCTION

Adult spinal deformity (ASD) has become an area of major focus over the past 20 years, and major advances in the surgical management have occurred. As the complexities of the spinal deformities that exist in these patients are becoming understood, ASD is increasingly being recognized as a heterogeneous disease entity that extends far beyond a seemingly benign adolescent idiopathic scoliosis that persists into adulthood [1]. Spinal alignment is important for maintenance of an upright posture, protection of neural elements, and stability of the axial skeleton. ASD includes scoliosis, sagittal malalignment, kyphosis, spondylolisthesis, rotatory subluxation, and axial plane deformity. Scoliosis is a deformity of the spine in the coronal plane or frontal plane. Kyphosis is deformity in the sagittal plane, which can significantly compromise upright posture. Axial deformity may lead to significant rotation of the spine and ribs.

Malalignment of the spine may occur between two adjacent vertebra, or segmentally, or within regions of the spine (cervical, thoracic, and lumbar), or globally between the upper spine and the sacrum. Deformity in the adult spine may be longstanding and a sequelae of deformity from childhood. Spinal deformity in the adult may also arise de novo or result from degenerative changes in the intervertebral discs and facet joints that result in asymmetric collapse of the motion segments with segmental and regional deformity [2].

Patients with ASD seek treatment with a chief complaint of back and leg pain, neural symptoms including leg weakness and numbness, functional limitations including difficulty standing in an upright posture, and exercise or ambulation intolerance. This may cause functional limitations in activities of daily living as well as a measurable compromise of mental health including anxiety, depression, dissatisfaction with appearance, and associated limitations of social function [3].

Many developed countries, including the United States, are experiencing an unprecedented shift toward an aging population. With an expanding elderly population, the cost conundrum will expand and become more significant. Although spinal deformity has impact across all ages, it disproportionately affects the elderly. Schwab and colleagues reported a 68% prevalence of scoliosis in volunteers older than 60 years [4].

ASD is associated with a high financial and clinical burden on society. ASD care thus requires improved insights in costs and its drivers as a critical step toward the improvement of value, i.e., the ratio between delivered health outcome and associated costs [5]. A key Belgian study identified sources of variability of care. Their data identifies significant opportunity for adopting a more standardized evidence-based workflow of preoperative examinations and corresponding actions depending on the comorbidities of the patient, following the guideline-based approaches [6].

Value-based care pathways and the study of health economics form a natural intersection where principles between the two coalesce and provide further direction for new and interesting research in care pathways for patients. While the United States remains entrenched in fee for service medicine, the need for value-based care pathways has become ever more apparent for the future [7]. In 2020, the conundrum of an expensive healthcare system that cannot provide basic care to one third of its citizens has reared its ugly head during the COVID pandemic [8].

The Dutch example of management of complex patients in a systematic fashion has led the value-based initiative amongst the most developed European health care systems[9]. The author of this thesis has studied the Dutch example for many years and has found that it can provide much needed antidotes to the conundrums posed by fee for service medicine in the United States. The field of adult spinal deformity surgery has provided the arena where the fields of value-based care and health care economics intersect. The author has published many peer-reviewed manuscripts in the area of improvement and health services approaches to reduce complications for adult spinal deformity patients. Much of this research has echoed the principles of value-based spinal research emanating from the Netherlands [10-11]. The intersection of this work with health economics is now emerging and recent analyses in the care of the spinal patient bring this front and center [12-14].

COMPLEX SPINE SURGERY

This thesis is a summary of a decade of quality improvement initiatives to reduce significant complications in complex spine surgery. This includes complications such as readmissions, re-operations, and medical complications leading to inferior outcomes. From a healthcare economics perspective, we will describe why quality improvement strategies are tied to cost effectiveness for payors and governments.

QUALITY AND SAFETY IN COMPLEX SPINE CARE

In the context of complex spinal surgery, quality is defined as the degree of excellence of care and safety is defined as the reduction of harm to a patient. In the setting of adult spinal deformity surgery, high complication rates are known and therefore reduction of harm strategies are needed.

QUALITY IMPROVEMENT STRATEGIES

Quality improvement strategies can include the application of lean methodology to reduce variation in care processes. These strategies can also include strategies to enhance risk stratification of factors known to be tied to complications. Finally, measurement of improvement is another important tool necessary in quality improvement strategies.

AIMS AND OUTLINE

The general aim of this thesis is to develop and evaluate approaches for improvement of quality and safety in complex spine surgery.

OUTLINE OF THIS THESIS

This thesis consists of a total of 9 chapters, including the General Introduction, and the Summary and General Discussion. In Chapter 1, the General Introduction, an overview of complex spine surgery is detailed and sets the scene for the studies described in Chapters 2-8.

Specific research aims:

1. To introduce lean concepts from manufacturing industry to spine surgery (Chapter 2)
2. To evaluate the impact of a team and systems approach on patient safety in complex spine surgery (Chapter 3 & 4)
3. To develop models for predicting complications and improving safety in patients undergoing complex spine surgery (Chapter 5 & 6)
4. To explore the global perspective of team-based strategies on the value equation (Chapter 7)
5. To discuss what telemedicine can contribute to the spine team approach in light of the Covid-19 pandemic (Chapter 8)

Finally, in Chapter 9 General Discussion, the results of this thesis are summarized, and the main findings are discussed. Their implications for generalizability, for clinical practice, and future research are presented.

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CHAPTER 2

USING LEAN PROCESS IMPROVEMENT TO ENHANCE SAFETY AND VALUE IN ORTHOPAEDIC SURGERY: THE CASE OF SPINE SURGERY

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Vijay Yanamadala
Douglas C Burton
Robert Shay Bess

J Am Acad Orthop Surg. 2017 Nov;25(11)

The manufacturing industry developed lean methodology to increase output while decreasing costs. Lean methods revolutionized manufacturing in Japan, where productivity gains led to Japanese domination of the manufacturing industry in the late 20th century.[1] Today, American manufacturing companies that use lean methods include Boeing, Intel, Ford, Nike, Caterpillar, John Deere, and Kimberly-Clark. The service industry has also adopted lean methodologies, although the core strategies must be modified to fit the service paradigm. Prominent examples of service industry companies that have used lean management include Southwest Airlines, Taco Bell, Fujitsu, and Walmart. Motivated by the productivity and customer satisfaction gains made with the use of lean methods in the manufacturing and service sectors, several health care organizations have attempted to adopt these methods in patient care.[2]

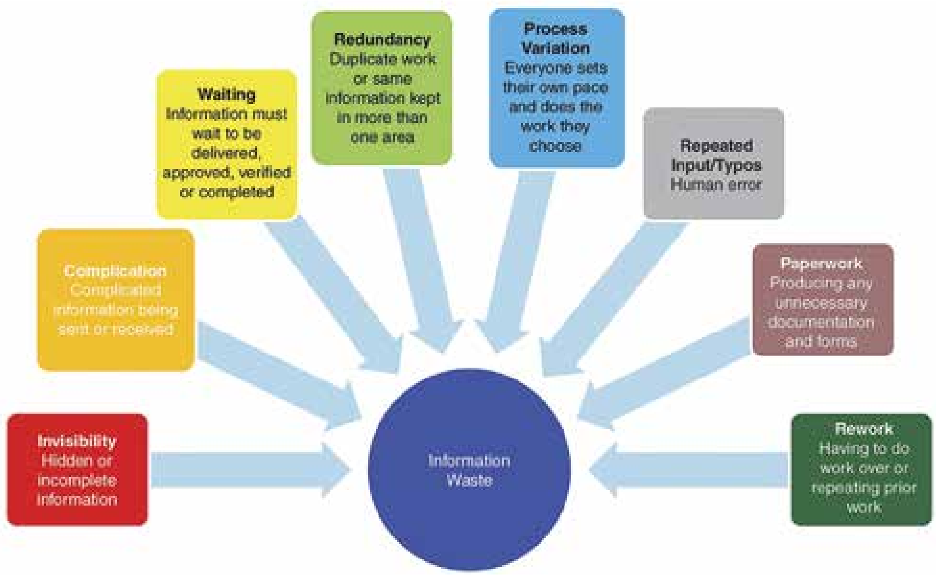
PRINCIPLES OF LEAN METHODOLOGY

Many of the principles of the lean methodology originated in Japan, particularly in the Toyota Production System (TPS).[3] Lean methods center around continuous process improvement through incremental change (kaizen in Japanese),[4] systematic elimination of waste, prevention of mistakes, and empowerment of every worker to stop the process if a deficiency is discovered in the system. TPS hinges on the just-in-time principle, whereby production should perfectly match customer demand. At a granular level of production, TPS aims to perfectly match demand at each step of production to prevent waste.

Lean management relies on the development of so-called standard work, which is based on the concept that any process can be categorized into discrete steps. Each work step is then detailed according to (1) the responsible operator, or the person conducting the work; (2) the task, or the work itself; and (3) a check process to ensure that the work is performed at the expected level. Taiichi Ohno, one of the originators of lean methods, famously said, "Without standards, there can be no improvement".[2] Any work process is thus defined by the standard work. Subsequent incremental improvements are made in each discrete step of the process to improve the entire process. Ohno defined five aspects of a lean process: (1) defining value, in which managers are responsible for identifying what is valuable to the customer; (2) value stream mapping, whereby managers outline the standard process from the standpoint of the value delivered in each step of the process; (3) flow optimization to maximize the value delivered at each step; (4) pull, whereby demand at the next step of a process drives the flow of the previous step in the process; and (5) continuous improvement through serial, incremental changes.[5]

In the service industry, the concepts of continuous improvement6 and respect for people are central to the application of lean management. The focus remains on the reduction of waste. In the service and information industries, waste can be categorized into eight discrete types similar to the seven areas defined for waste in the manufacturing industry[2] (Figure 1). In health care, the principles of preventing mistakes and maximizing customer value are particularly important.[7]

FIGURE 1. Diagram showing the eight types of information waste, adapted from Taiichi Ohno's original seven areas of waste.



2

LEAN METHODS IN HEALTH CARE

Lean methods have been implemented in nearly every type of healthcare facility, from trauma hospitals to pediatric centers; in systems ranging from large health systems, [8 9] and academic centers[10] to regional medical centers[11 12] and ambulatory centers;[13] and in fields such as nursing care,[14] laboratory,[15] pathology,[16] and radiology.[17] These methods have proved particularly powerful in surgical arenas, including implant procurement,[18] perioperative care,[19] and standardization of operating room management and work flow.[20]

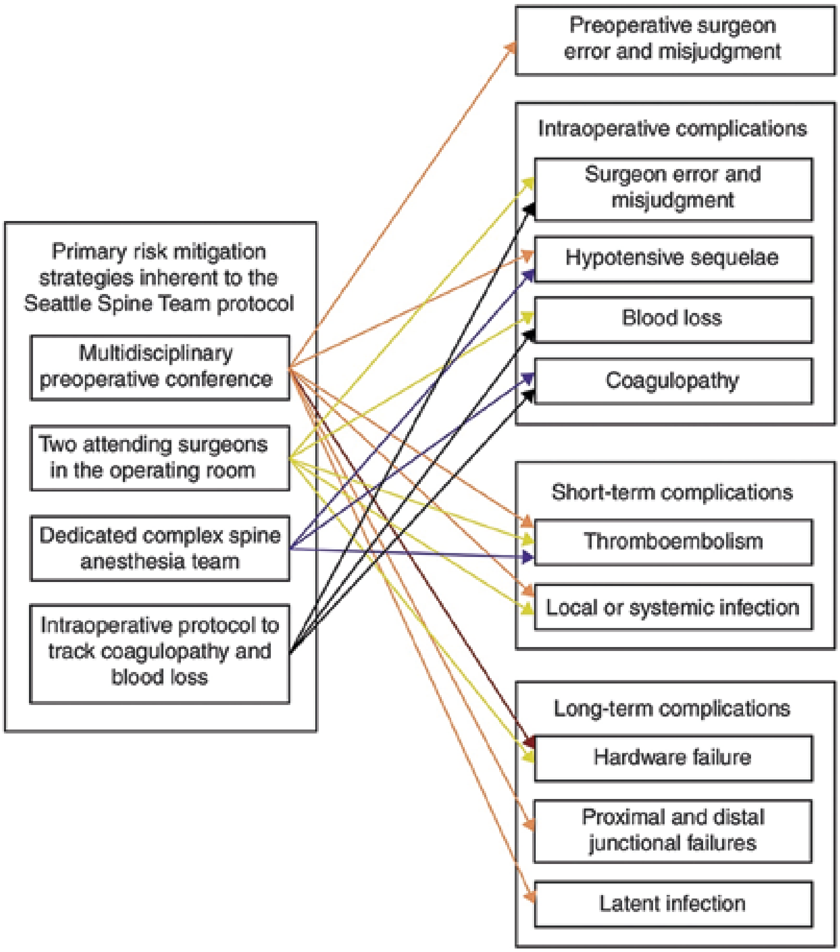
One of the first healthcare institutions that implemented lean methods is Virginia Mason Medical Center in Seattle, Washington.[2] Beginning in 2002, the institution systematically applied lean methods throughout the medical center with dramatic results. The Virginia Mason Production System (VMPS)[21] is an adaptation of TPS to health care. As a result of the VMPS, the incidence of ventilator associated pneumonia decreased from 34 cases with five deaths in 2002 to 4 cases with one death in 2004, with subsequent annual savings of $500,000. [2] Over the next decade, targeted value-focused improvements throughout Virginia Mason Medical Center led to systematic reductions in cost and medical errors, [20-22] extending into orthopaedic surgery and spine surgery.[23]

The Pittsburgh Regional Health Initiative similarly implemented lean methods centered around the reduction of defects in the region's medical centers. One of the most striking findings related to this effort of using lean principles was the reduction of central line infections by up to 90% within 1 year of implementation.[2] ThedaCare, a hospital group in Wisconsin, saw similar gains in productivity and quality through the implementation of lean methods[24] centered on the reduction of defects, improved efficiency, and a culture of change and respect for people. ThedaCare reported $3.3 million overall institutional savings attributable to reduced waste in 2004 through the implementation of basic lean principles.[24]

These examples demonstrate that successful implementation of lean management depends on the adoption of a culture that empowers each person to examine processes and implement incremental changes to enable continuous process improvement.

The highest levels of leadership within the lean system must be involved in creating and supporting a culture of change within the organization. Leadership within the lean system must also enable a systematic approach to analyzing current processes, devising changes, and assessing the results of process improvements. Because lean processes are continually evolving, the VMPS uses a system to track implemented changes and the subsequent effects of these changes on the work process over time.

FIGURE 2. Diagram showing the key components of the Seattle Spine Team approach.



Each process is designed specifically to optimize and standardize preoperative, intraoperative, and postoperative care for patients undergoing complex spine surgery. (Adapted with permission from Buchlak QD, Yanamadala V, Leveque JC, Sethi R: Complication avoidance with pre-operative screening: Insights from the Seattle spine team. Curr Rev Musculoskelet Med 2016;9[3]:316-326.)

LEAN METHODS IN SPINE SURGERY

Reported rates of intraoperative adverse events in complex spine surgery and spine deformity surgery are as high as 10%.[25–32] Overall complication rates range from 25% to 80%,[33] including intraoperative and postoperative mortality; transient and permanent neurologic deficits; myocardial infarction; systemic infection, including pneumonia and urinary tract infection; and surgical site infection. Therefore, the standardized protocols that are part of lean process improvement offer potential benefits in the field of complex spine surgery. The Seattle Spine Team approach is an example of the systematic utilization of lean methods in complex spine surgery.[34] Although many centers have developed individualized protocols to address individual complications,[35–39] the Seattle Spine Team approach[40] uses a value stream map that incorporates preoperative, perioperative, and postoperative care into a single process to improve the quality and ultimately the value of care delivered to the patient (Figure 2).

In the Seattle Spine Team approach, the first goal is defining value, as is the case in all forms of lean methodology. This process requires a multidisciplinary approach involving the key service providers (eg, surgeons, anesthesiologists, physiatrists, internists, pain specialists, nurses, operating room staff, physician assistants) and the customer (ie, the patient). Participating together in a rapid process improvement workshop, the key service providers collectively define the value, which in this approach is defined as delivering the safest and most effective complex spine surgery at the lowest cost.

The next step involves the creation of a value stream map, which delineates each of the steps involved in delivering the defined value. This iterative process results in the creation of a current state map. Each area is studied in detail to identify waste in the process. Depending on the focus of a particular improvement process, each step is delineated as broadly or as specifically as necessary. For example, in the value stream map, the patient's intraoperative care is delineated broadly, whereas the postoperative care is depicted granularly. Thus, this particular value stream map allows focused intervention at the level of the patient's postoperative care. Each part of the postoperative care is delineated with respect to the person performing the task, the task performed, how it is performed, and how it is evaluated. The first step, as depicted in the value stream, is performed by the admitting nurse (RN) on postoperative day (POD) 0. The nurse carries out admission documentation and regular patient checks as depicted in the box. Each step in this value stream may be performed in parallel or in series with respect to the other steps, and hence they are not depicted with any particular ordering scheme. All steps must be completed for the discharge process to take place.

After a value stream map is created, each step is studied rigorously. A method such as the VMPS involves the assessment of waste from the standpoint of time, resources, and personnel. Managers quantify the time, resources, and personnel required for each step and identify any sources of waste in the process. Next, areas of possible intervention for improvement are identified and visually overlaid onto the value stream map.

The mapping of areas for improvement requires direct communication with the personnel involved in each process to ensure best-practice process improvement. The people involved in the tasks (eg, nurse, physician assistant, physical therapist) are interviewed in the setting of a process improvement workshop. They identify areas where tasks are hindered by the existing processes. These insights are documented as clouds on the value stream map as seen in Supplemental Digital Content 2. Color coding allows stratification of areas for improvement according to any number of subcategories, including by the operator, the location of the task, or the timing of the task.

A future state map is then created to identify the ideal value stream that is expected to exist after appropriate process improvements have been made. The future state value stream is codified as standard work, meaning that each part of the value stream is specifically defined at a granular level, a responsible operator is assigned for each step, and performance of proper quality checks is ensured (Figure 3). This codification of the work process ensures that the new value stream will actually be performed and that improvements will be maintained over time.

After the desired interventions are implemented by ground-level personnel, the time, resources, and personnel required for each step are again quantified. Assessment of these parameters over time enables managers to judge the level of improvement and its sustainability. When the future state is achieved, it becomes the new current state from which further improvements can be made in turn. Thus, the value stream map creates a guide for improvement, and the series of current state and future state maps provide a timeline of improvements in the process. This method allows for seamless integration of improvements in a way that individual improvement programs would not afford.

FIGURE 3. Chart showing the standard process for the work of the patient's nurse on the day of discharge. Each operator involved in a given process has an associated standard process that defines the specific operator's responsibilities within the overall process.

Quality Check	Safety Precaution	Standard WIP

Purpose: Standardization of discharge process for complex spine patients
Related Policies or Evidence

Roles/Work Units Who Must Adopt This Proces:	Task Time:
Spine clinic PA, RN, Inpatient RN	13 minutes

STEP Add quality, safety or WIP symbols as needed	OPERATOR List role responsible for each task	TASK DESCRIPTION	TOOLS/SUPPLIES REQUIRED Fill in as needed to explain use of specific tool or supply Add photos if valuable to provide clear instructions
1	Outpatient RN	Track upcoming complex spine/fusion discharges	Charts notes, talk with PAs, attend weekly surgical team huddle
2	Outpatient RN	Gather materials for discharge teaching	Print departure and postoperative pathway
3	Outpatient RN	Do discharge teaching with patient, either day before or day of discharge	None
4	Outpatient RN	Document teaching done in outpatient RN note using template	Computer
5	Outpatient RN	Notify inpatient RN when teaching complete	None

PA = physician assistant, RN = registered nurse, WIP = work in progress

Although codification of the work process facilitates continual improvement through serial change, ultimately a culture of change at the organizational level is required to successfully implement this paradigm. At Virginia Mason Medical Center, where the Seattle Spine Team approach was implemented, the overall complication rate for complex spine surgery was reduced from 52% to 16%.[40,41] Importantly, this rate was sustained over a 5-year period through continuous improvement of preoperative screening, intraoperative communication, and postoperative care pathways.[35] Without the support of a culture of change and continued observation, these changes could have reverted over time.

One example of an area in which lean management can translate directly to success in complex spine care is reducing the need for unplanned secondary surgery.[40,41] The creation of value streams in which all team members are aligned can lead to enhanced communication preoperatively and intraoperatively. The optimization of preoperative communication means that important patient factors, such as obesity, smoking, and suboptimal bone density, can be appropriately managed before surgery. Intraoperatively, surgical teams can standardize their communication according to team-based protocols. We think that the implementation of these types of processes at Virginia Mason Medical Center ultimately explains the substantial decrease in complications leading to the need for secondary surgery.

THE FUTURE OF LEAN METHODS IN ORTHOPAEDIC SURGERY

Systemwide improvements are crucial to the improvement of value in complex orthopaedic surgery.[6] The Seattle Spine Team experience demonstrates that lean methods are effective in reducing complications and improving the value of care delivered. Each center must develop its own value stream upon which to base its process improvements. Although the Seattle Spine Team approach offers a guide to the development of such a system, direct implementation of this approach without attention to an individual center's culture, practices, and patient population will likely lead to a suboptimal process. Individualized improvement processes at each center where complex orthopaedic surgery is performed will ultimately lead to global process improvement in the field.

Lean methodology can be employed first to reduce variation within orthopaedic centers. Implant inventory and processing is an important function in which the implementation of standard work processes can result in substantial reduction of waste and inefficiency.[20] A standard process has been developed at Virginia Mason Medical Center to understand the indications for both simple and complex spine surgery.[23] In this process, all proposed lumbar fusion and adult spinal deformity surgical procedures are expected to undergo a multidisciplinary approval process in which all healthcare professionals are given an equal voice and the indications are standardized according to the best possible implementation of evidence-based medicine. The equal votes of all healthcare professionals involved in the process embodies the concept of respect for people that is central to the lean methodology. Finally, lean methods can be applied to reduce variation among the order sets of orthopaedic surgeons in any given center, such as in the use of drugs (eg, antibiotics, tranexamic acid, pharmacologic thromboembolic prophylaxis), devices (eg, types of hip and knee implants), and postoperative mobilization protocols. The use of rapid process improvement workshops can allow for the variability that is necessary for safe patient care while eliminating unnecessarily variable processes that can add waste, contribute to inefficiency, and result in a negative patient experience.

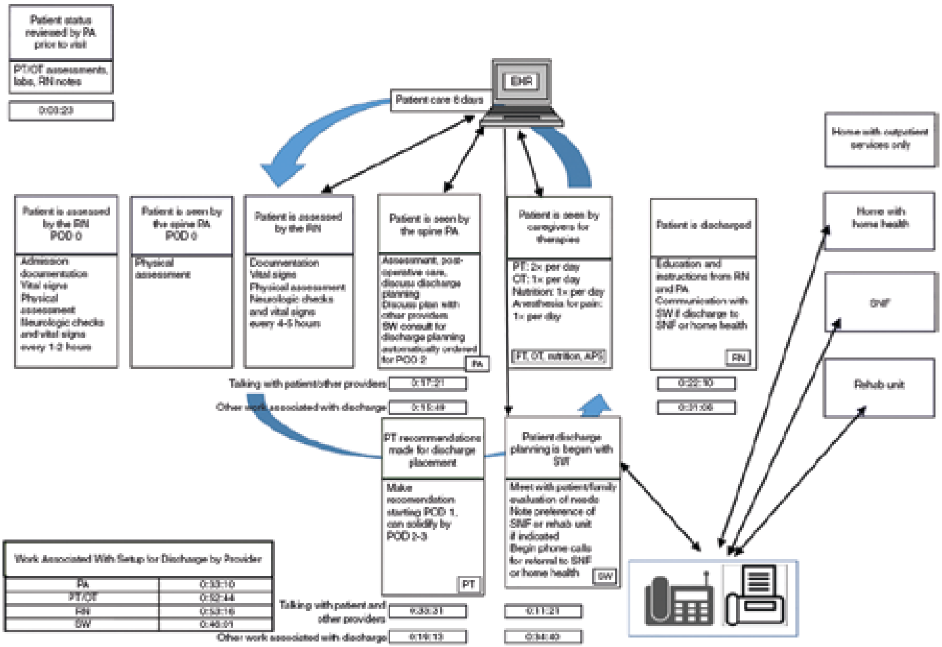
SUMMARY

Lean methodology has evolved from its origins in manufacturing and has been applied broadly in health care. Specific examples of implementation in complex spine surgery and orthopaedic surgery demonstrate that lean methods can assist surgeons and centers as they attempt to enhance the safety and value of orthopaedic care.

2

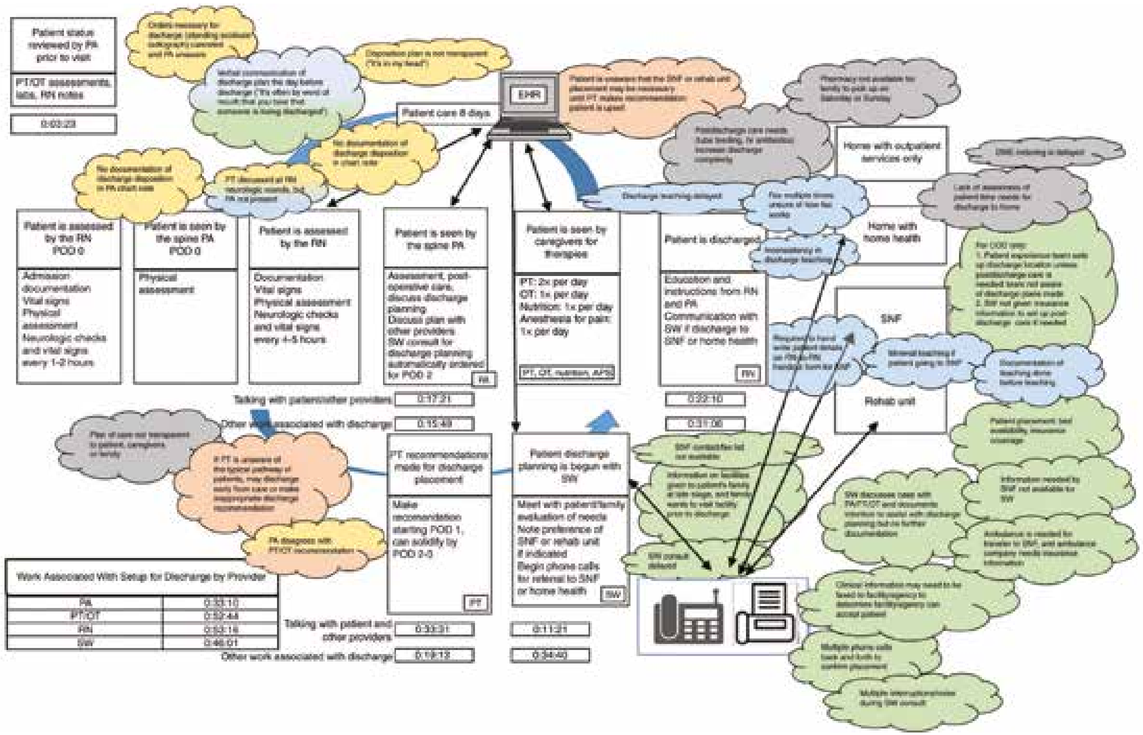
SUPPLEMENTAL MATERIAL

SUPPLEMENTAL FIGURE 1. Current state map showing the discharge process after complex spine surgery.



Each step of the process is discretely identified with a description of the steps involved and the responsible operator, or the person who carries out the task. The steps of the process may be done in parallel or in series and are depicted as independent events. Time stamps indicate the mean time that a particular task or subtask requires (these times are averages of three of more samplings). In the lower left corner of the diagram, we depict the total time required for all tasks during the entire duration of the postoperative process as stratified by operator (ie, PA, PT/OT, RN, SW). The fax machine and phone icons depict modes of communciation for achieving the associated tasks. The blue, curved lines represent information flow, and the double-sided arrows reflect two-way communication. APS = acute pain service, EHR = electronic health record, PA = physician assistant, POD = post operative day, PT = physical therapist, OT = occupational therapist, RN = registered nurse, SNF = skilled nursing facility, SW = social worker.

SUPPLEMENTAL FIGURE 2. Clouds overlaid on the current state map (Supplemental Digital Content 1) showing potential areas for improvement in the discharge process alter complex spine surgery.



Color coding allows us to stratify areas for improvement according to subcategories, including operator, location of the task, or timing of the task. In this case, we have color coded these by operator (yellow = RN; blue = PA; orange = PT; green = case manager and SW; gray = multiple providers). Alter a manager has quantified the time, resources, and personnel required for each granular step of the process, all involved personnel identify sources of waste and targeted interventions to address them. The sources of waste and potential improvements are identified in the clouds associated with their respective parts of the process. The blue, curved lines represent information flow, and the double-sided arrows reflect two-way communication. COE = center of excellence, OME = durable medical equipment, EHR = electronic health record, IV = intraveneus, PA= physician assistant, POD = postoperative day, PT = physical therapist, OT = occupational therapist, RN = registered nurse, SNF = skilled nursing facility, SW = social werker. The fax machine and phone icons depict modes of communication for achieving the associated tasks.

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CHAPTER 3

THE SEATTLE SPINE TEAM APPROACH TO ADULT DEFORMITY SURGERY: A SYSTEMS-BASED APPROACH TO PERIOPERATIVE CARE AND SUBSEQUENT REDUCTION IN PERIOPERATIVE COMPLICATION RATES

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INTRODUCTION

Complications in complex spinal reconstructive surgery in adults are a frequently observed phenomenon [1-8]. The surgical literature contains several reports that document blood loss exceeding a patient's baseline total estimated blood volume sustained during a corrective spinal fusion for scoliosis [9-12]. With the increasing frequency of complex reconstructive surgery for adult spinal deformity, the same phenomenon is being described in this decade [13-16]. Rampersaud et al. [17] studied intraoperative adverse events and related postoperative complications in spine surgery and found an adverse incidence rate of 10.2%. As the evidence mounts that standardized protocols for high-risk spine surgery patients can reduce complications [18-20], spine surgeons are faced with an increasing need to develop strategies and protocols aimed at reducing risk and increasing patient safety. This need is perhaps nowhere greater than in surgical procedures that propose to correct adult spinal deformities, arguably some of the most dangerous and complication-ridden operations in the surgical armamentarium [3,6,21-27].

To date, many strategies are in use to attempt to reduce perioperative complications in adult deformity surgery. These include better preoperative planning strategies, the use of intraoperative vancomycin, and staging [19,28-33]. Although there are isolated strategies for reducing com plications, few centers have studied institutional team protocols and their effect on mitigating complications.

The authors' center changed its approach to adult spinal deformity surgery owing to internal assessment of the complication rates. This approach centers on the use of a live multidisciplinary complex spine conference to assess appropriateness of the proposed surgery. Two attending surgeons are used in the operating room, to increase efficiency and shorten surgical time. The third tenet of the approach uses an intraoperative protocol to manage coagulopathy. This article describes this 3-pronged protocol and tests the hypothesis that the institution of this protocol will lead to a decrease in the incidence of perioperative complication rates.

METHODS

Before instituting a major spine protocol, the attending spinal surgeon would see and book any major spine case. The case was not required for presentation in front of a live multidisciplinary spine conference. In addition, treatment could be done with a physician's assistant or a resident instead of 2 attending surgeons. There was no intra operative protocol to manage or track coagulopathy, and each treatment would be done with an anesthesiologist who was assigned on the day of surgery. A team of complex spine anesthesiologists dedicated to complex adult spinal surgery did not exist. The major spine protocol that was developed is described in this article in preoperative, intraoperative, and postoperative phases. The surgeons in both arms of the study are the same.

MAJOR SPINE PROTOCOL

PREOPERATIVE

Patients referred to the authors' surgical spine clinic who appear to have scoliosis as an underlying diagnosis have a standard set of preoperative studies, including 36-inch anteroposterior and lateral spine films, as well as a dedicated lumbar spine X-ray with flexion-extension views. Patients with symptoms of radiculopathy or neurogenic claudication will also have magnetic resonance imaging of the lumbar spine. Radiographic evaluation includes measurement of sagittal and coronal balance, pelvic parameters, and Cobb angles of major and/or minor curves [34]. A computed tomography scan of the spine and a dual-energy X-ray absorptiometry scan are ordered for potential operative patients. An Oswestry Disability Index and European Quality of Life-5 Dimensions (EQ-5D) questionnaire are obtained for all preoperative patients [35-39].

A patient will enter the researchers' major spine pathway (MSP) by either meeting any of the following criteria: 6 or more levels of fusion; 6 or more hours of case duration; spinal deformity surgery, and/or surgeon expertise deeming the surgery to be sufficiently complex; and significant comorbidities in the cardiac, pulmonary, hemostatic, or neurologic systems. The authors characterize a spinal deformity as scoliosis, kyphosis, or flat-back or any revision case that requires at least 6 levels of fusion. All MSP patients are presented at a monthly conference attended by an internist, a physical medicine and rehabilitation physician, at least 2 members of the dedicated complex spine anesthesiology team, the nurses who coordinate the complex spine patient class, and the operative surgeons. The anesthesiologists and internist review each patient's history and medical issues before the conference. A written summary of the patient's past medical history, relevant laboratory values, screening tests (electrocardiogram, echocardiogram, etc) is then generated and sent via secure e-mail to the conference participants.

Discussion for each patient focuses on both the proposed surgical correction and the preoperative and postoperative medical issues relevant to the patient. Approximately 25% of patients presented at the conference have medical conditions rendering them unsuitable for the extent of surgical treatment proposed; thus a nonoperative plan is generated [40]. Some patients require medical optimization or further studies before a final decision can be made. The surgeon conveys the result of the conference to the patient.

Once a patient has been presented at the conference and deemed a surgical candidate, the surgeon will order any remaining studies described previously, if not already completed. All surgical patients attend a 2-hour class run monthly by clinic nurses and 1 of the spinal deformity surgeons that focuses on the postoperative recovery period and allows for a question-and-answer session. All patients are then engaged in a consent process that includes a discussion of risks including bleeding, infection, proximal junctional kyphosis, rod/hardware failure, postoperative neurologic injury, stroke, death, and blindness during spine surgery [3,41-44].

All patients with normal preoperative coagulation and hematologic panels have 6 U of packed red blood cells and 2 U of thawed plasma typed and crossed. If abnormalities in hematocrit or coagulation are discovered, additional workup involving internal medicine and hematology (if indicated) are completed.

After preliminary clearance by the conference, an internist performs a thorough preoperative evaluation. The need for further cardiac evaluation for these patients is based on American College of Cardiology/American Heart Association guidelines for perioperative risk stratification [45]. Pulmonary function tests are obtained preoperatively as indicated [46].

FIGURE 1. Pain management pathway of major spine patients.

Pre-operative

- Determine current analgesic regimen; convert to IV morphine equivalents
- Patient should take all normally prescribed analgesics up to the surgery (including morning of surgery)
- Determine preoperative pain score (VAS)
- Consider multimodal regimen:
  - gabapentin 900 mg PO
  - acetaminophen 975 mg PO (take note of other acetaminophen containing analgesics that may be taken proximately by the patient to avoid overdose)

Intraoperative

Consider ketamine 0.5 mg/kg bolus followed by 0.1 mg/kg/hr (lean body mass) infusion
Consider long acting opioid titration towards the end of surgery

Post-operative

Patient controlled analgesia (PCA)

- >36 mg IV morphine or equivalent per day:
  - Consider 50% baseline hourly requirement for baseline infusion
  - Demand dosing can commence at 1-2 mg morphine IV q 8 minutes
- >50 mg IV morphine or equivalent per day:
  - Consider continuing ketamine at 0.05-0.1 mg/kg/hr

On post-operative day (POD) 1:

- Wean IV opioid basal infusion and ketamine (if applicable)
- Start long acting enteral opioid (oxycodone ER or morphine ER)
- Can continue with demand dose IV PCA

On POD 2:

- Wean all IV opioids

Other Considerations:

- Consider continuous pulse oximetry.
- For muscle spasms consider baclofen 5-1O mg PO TID prn or diazepam 1-2 mg IV TID prn
- Transfer care back to the primary spina service when patient on stable oral analgesie regimen

IV = intravenous; YAS = visual analog scale; PO = orally; q = every; ER = extended release; TID = 3 times a day

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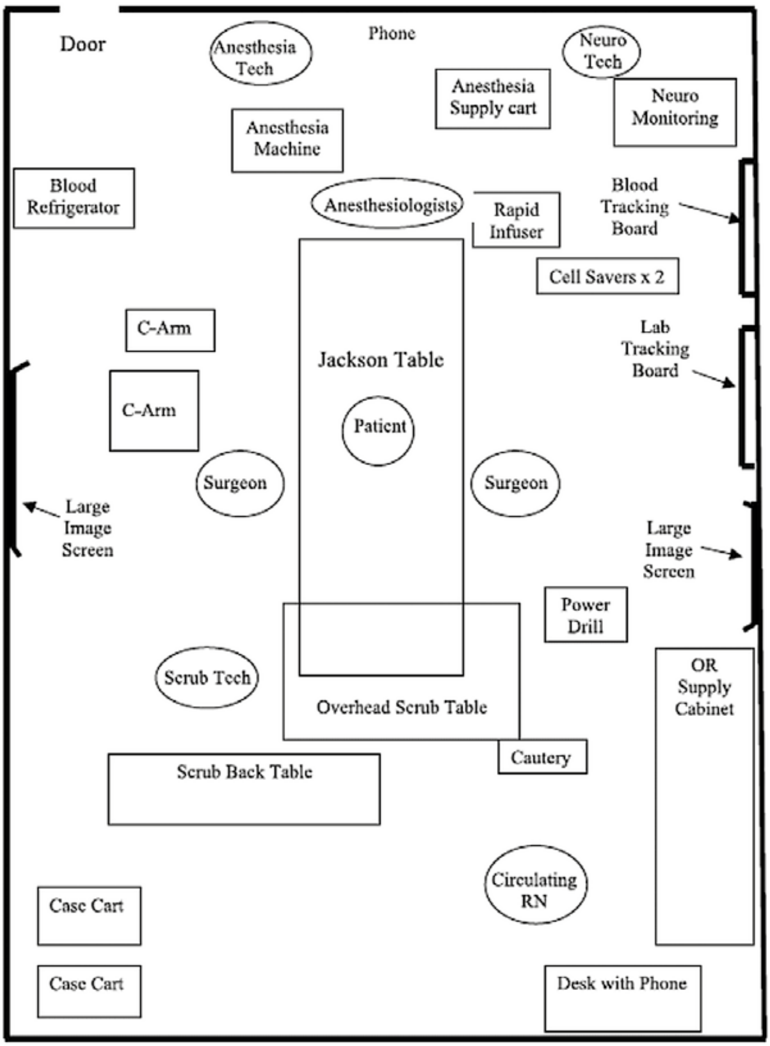
FIGURE 2. The operating room standard layout for a complex spine procedure.



The layout provides zones of operation for the surgeons and scrub technicians, circulating nurse, anesthesia team, and neuromonitoring team. The walls have 2 large-image screens for projection of radiologie studies. The blood-tracking and laboratory value-tracking boards allow visual summaries of the patient' s status for all to see. These boards allow step-by-step clear communication and facilitate decision making during critical hourly team discussions.
Neuro Tech = neurological technician; Neuro Monitoring = neurological monitoring;
Scrub Tech = scrub technician; OR = operating room; RN = registered nurse.

All MSP patients have their analgesia managed post operatively by the Acute Pain Service (Fig. 1), run by the Department of Anesthesiology. The Acute Pain Service in the preoperative area interviews patients to understand their baseline pain and therapy, and to develop a post operative plan. The attending anesthesiologists who run the pain service and supervise their residents and fellows are closely involved with the complex spine team, and therefore are well aware of the unique issues of the patients as well as the importance of early mobilization and communication with members of the daily rounding primary spine team.

Before starting surgery, the surgeon contacts the intensivist who will be accepting the care of the postoperative patient. This discussion serves to alert the intensivist to the presence of the patient, pre-exisiting comorbidities, and the expected surgical course. After surgery, the intensivist will receive an updated patient status directly from the anesthesia team.

INTRAOPERATIVE

Figure 2 depicts the operating room layout. In addition to the standard operating room team, MSP calls for 2 attending surgeons working in tandem; the current practice typically includes a neurosurgeon and orthopedic surgeon with specialized spine training. Both surgeons are viewed as equal members of the surgical team rather than having primary or secondary roles [33]. The researchers also use a 2-member anesthesia team and a dedicated anesthesia technician.

In addition to a standard operating room setup, the MSP calls for a blood-tracking board (Fig. 3) and laboratory tracking board (Fig. 4), which allows the entire operating team to view at a glance the status of coagulation and physiologic laboratory parameters as well as blood product availability. A rapid infuser (Belmont Instruments, Bill erica, MA), 2 cell saver units (1 for each surgeon), and a Masimo pulsoximeter (Masimo Corporation, Irvine, CA) with plethysmographic variability index as well as real time hemoglobin measures [47] and a bispectral index monitor are used.

After induction and central line placement by anesthesia, neuromonitoring leads are placed. It is the authors' standard practice to monitor somatosensory evoked potentials, motor-evoked potentials, and lower extremity electromyography [48-51]. After lead placement, the patient is placed in a Mayfield head holder on a Jackson table [44,52-54].

For cases that will involve a pedicle subtraction osteotomy or fusion extending from the upper thoracic spine to the pelvis, the procedure is planned as a staged operation if the physiological parameters of the patient require this. This decision is made after close discussion with the anesthesiologist based on hourly time points. The primary stage is intended to place most or all of the required instrumentation, whereas the second stage is reserved for the correction and final fixation in cases where the entire operation cannot be safely completed in 1 sitting. The time between scheduled stages is typically 3 to 4 days. In these staged patients, a removable inferior vena cava filter is placed and scheduled for removal 6 to 12 weeks after completion of the surgical procedure [55,56]. Inferior vena cava filters are placed only in patients whose surgery would be staged on different days. All patients are given subcutaneous heparin at 5,000 U, 3 times a day, on postoperative day 1. The researchers routinely ambulate patients between the first and second stages. The practice of inferior vena cava filter placement and the use of subcutaneous heparin were the same in the protocol and no-protocol groups.

Blood product use during major spine surgery is routine and usually commences before evidence of laboratory derangement. Typically, the authors start to transfuse packed red blood cells after estimated blood loss greater than 250 mL in any case in which they plan to complete the entire operation on the same day. This is different from most surgeries that have ongoing blood loss, where laboratory values are measured and replenished with the appropriate blood product. For plasma, the current authors transfuse after 1 to 2 U red blood cells or an international normalized ratio (INR) greater than 1.2. Although not fully characterized, the authors have observed that waiting until the INR is greater than 1.5 to institute plasma or a he matocrit less than 25 leaves the patient in a precarious situation that is associated with amounts of subjective bleeding as well as laboratory derangements that are difficult to correct, such as the INR. The etiology of coagulopathy during major spine surgery is unknown and likely represents both a dilutional as well as consumptive element [57].

Laboratory measures are done hourly, including arterial blood gas, hemoglobin and hematocrit, platelet count, prothrombin time and INR, fibrinogen, D-dimer, ionized calcium, and lactate. Working with the laboratory, the au thors established a rapid turnaround for these laboratory values (20 minutes); results are called into the room as they are made available. The values are then transcribed onto a large laboratory tracking board mounted in the operating room. Once all laboratory values for that hour have returned, the surgical team and anesthesiology team pause, the current physiologic state as well as progress in surgery and any challenges in either are reviewed, and a decision is made to proceed or to stage the surgery. Figure 3 demonstrates an example of the laboratory and estimated blood loss results for a patient.

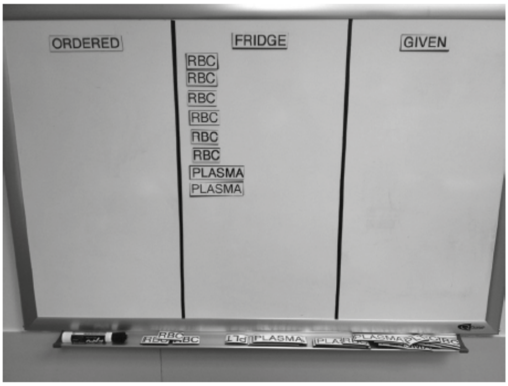
FIGURE 3. Example of the visual control for laboratory values and estimated blood loss (EBL).

Time	Suction Canister	Cell Saver EBL	Field Irrigation	Total EBL	Hct	pH / BE	PT / INR	Platelet Count	Fibrinogen D-Dimer
9:00	N/A	N/A	N/A	N/A	33	7.38/-2.9	13.7/1.1	108	798/2.74
10:03	550	100	0	650	30	7.35/-4.5	14.2/1.1	100	647/2.65
11:00	650	550	0	1200	29	7.38/-3.6	15.3/1.2	95	497/ 2.94
12:00	800	1250	0	2050	31	7.34/-4.2	16.4/1.3	90	411/2.92
13:04	1300	1700	0	3000	21	7.31/-4.8	18.1/1.5	110	335/2.93
14:01	1500	2000	0	3500	31	7.30/-4.5	17.3/1.4	125	280/ 3.95
15:05	1600	2200	0	3800	29	7.33/-4.1	17.0/1.4	103	290/7.49

Hourly calculation of blood loss [(suction canister + cell saver canister) - irrigation] and key acid-base, red blood cell, and coagulation parameters are displayed. N/A = not available; Hct = hematocrit; BE = base excess; PT = prothrombin time; INR = international normalized ratio.

3

FIGURE 4. The blood-tracking board at the beginning of the case.



Per protocol, 6 U packed red cells (RBC) and 2 U thawed plasma are in the refrigerator in the room. Thawed plasma is available to avoid delay in the case of progressive consumptive coagulopathy. As units are administered, the corresponding magnet is moved to the Given column. If additional blood products are ordered, additional magnets representing the units ordered are added to that column. When the ordered product arrives in the room and placed in the refrigerator, the corresponding magnet is move to the Fridge column. Thus, visual control of the status of all blood products is provided to the team.

POSTOPERATIVE

Near the conclusion of the surgery, the anesthesiologist contacts the intensivist to give a person-to-person report of the events of surgery and blood loss and the physiologic state of the patient. Extubation is routinely attempted in the operating room. The researchers rarely keep patients intubated and transport to the intensive care unit. Patients are observed overnight in the intensive care unit with strict control of hematocrit, coagulation factors, and platelet count. The vast majority of patients can be transferred to a general care floor on postoperative day 1. They are mobilized with physical therapy over the next 1 to 3 days and are discharged to home or a skilled nursing facility between days 4 and 6.

OUTCOME MEASURES

Before 2009, 40 consecutive patients underwent com plex spine without MSP (no-protocol group). In 2010 to 2011, 124 consecutive patients were completed with MSP (protocol group). All patients in this study were followed postoperatively by an independent research team at the Group Health Research Institute, who examined medical records and readmission data for 90 days from the date of surgery. Measures included return to operating room, wound infection, thromboembolic complications, post operative neurologic deficit including stroke, urinary tract infection, and mortality. Comparison between pre-MSP and post-MSP patient outcomes were made with Student t test.

RESULTS

The no-protocol group (pre-MSP) had a mean age of 62 years (range, 39 to 84 years) that was similar to the protocol group's mean of 64 years (range, 18 to 84 years). Overall complication rates in the protocol group were significantly lower, with a total complication rate of 16%, versus the no protocol group's total complication rate of 52% ($p < .001$). The protocol group showed significantly lower return rates to the operating room during the perioperative 30-day period (0.8% vs. 12.5%; $p < .001$). The protocol group also had lower rates of wound infection requiring debridement (1.6% vs. 7.5%), lower rates of deep vein thrombosis/pulmonary embolism (3.2% vs. 10%), and lower rates of postoperative neurological complications (0.5% vs. 2.5%), although these measures did not reach statistical significance. The protocol group had dramatically lower rates of urinary tract infection requiring antibiotics (9.7% vs. 32.5%; $p < .001$) (Table 1).

Table 2 lists the demographics and surgical approaches used in each group. The table demonstrates that anterior approaches were more represented in the no protocol group and minimally invasive **(MIS)** lateral approaches for anterior fusion were more common in the protocol group. The protocol group had a greater number of 3-column osteotomies (not significant).

Table 3 shows specific reasons for return to the operating room within 90 days of the index operation. The post operative day for each event (calculated as the number of days from the index procedure) is also shown. None of the cases in Table 3 had anterior or MIS lateral approaches. All wound infections were posterior.

TABLE 1. Spine team approach.

	No Protocol (%)	Protocol (%)	p
Overall complication rate	52	16	< .001
Return to the operating room	12.5	0.8	< .001
Wound infection	7.5	1.6	NS
Deep vein thrombosis/pulmonary embolism	10	3.2	NS
Postoperative neurologic deficit	2.5	0.5	NS
Urinary tract infection	32.5	9.7	< .001

NS = not significant.

3

TABLE 2. Demographics and surgical approaches of protocol and no-protocol groups.

	No Protocol (N = 40)	No Protocol (N = 124)	p
Age, mean	62	64	1.0
Levels fused, mean	11	13	.92
Anterior and posterior approaches, n (%)	10 (25)	12 (10)	.029
Posterior alone (TLIF) with Smith Petersen osteotomies, n (%)	30 (75)	93 (75)	1.0
Lateral (XLIF) + posterior, n (%)	0	19 (15)	.004
Cases staged on different days, n (%)	10 (25)	31 (25)	1.0
Three-column osteotomies, n (%)	3 (7.5)	19 (15)	.29

TLIF = Transforaminal Lumbar Interbody Fusion; XLIF = minimally invasive extreme lateral interbody fusion.

TABLE 3. Reasons for return to operating room within 90 days of index operation, and postoperative day.

No-protocol group
Irrigation and debridement of wound infection, POD 13
Irrigation and debridement of wound infection, POD 23
Irrigation and debridement of wound infection, POD 17
Neurological deficit requiring hardware revision (extruded TLIF graft), POD 3
Leg pain caused by pedicle screw breach, POD 3
Protocol group
Neurological deficit caused by stenosis at L3 PSO closure site, POD 1

POD = postoperative day; PSO = Pedicle Subtraction Osteotomy;
TLIF = Transforaminal Lumbar Interbody Fusion. `

DISCUSSION

The results of this study indicate that a concerted collaborative approach consisting of a dual-attending surgeon team, a complete preoperative screening process, and a robust intraoperative protocol for managing coagulopathy can significantly reduce perioperative complication rates and enhance patient safety in patients undergoing complex spinal reconstructions for adult spinal deformity. Other institutions have described the need for organized system processes [18] to diminish the significant risk associated with these surgical procedures [6,58,59], but to our knowledge the current report is the first analysis of system approaches and their direct effect at reducing this extreme risk of complications.

The primary strengths of this study lie in the standardized nature of the protocol described and the breadth of factors that it covers. All patients who were enrolled in the major spine pathway had minimal variability in surgeons, preoperative clearance protocol, intraoperative anesthetic team, and postoperative management. The intraoperative protocol for managing coagulopathy has likewise been standardized across the institution and is not subject to variation between anesthesiologists.

To our knowledge this is the first study to describe the use of a multidisciplinary live preoperative conference to clear adult deformity patients for surgery. The author' group previously reported that approximately 25% of patients presented here [40] were not deemed suitable candidates for major reconstructions owing to pulmonary and cardiac co-morbidities. Conference discussions are predicated on the belief that both non-surgeon members (eg, internal medicine, anesthesia) and surgeon members of the committee have equal power to decide the suitability of a case; yet this flexibility to remove politics and economic incentives from the discussion may not be applicable to all institutions.

Coagulopathy is a ubiquitous phenomenon in adult spinal deformity surgery, but only a few protocols have been offered to track and manage this vexing problem [9,12-15,57]. The authors describe a clear and robust protocol to manage intraoperative coagulopathy during advanced spinal reconstructive surgery. Their experience also demonstrated that the success of this protocol depends on institutional administrative support in addition to approval from anesthesiology, surgical services, and the institutional blood bank.

Tables 2 and 3 demonstrate the surgical characteristics and specific complications of each group. Both groups had a similar number of cases that were staged on different days. Whereas the no-protocol group had more anterior surgery, it had fewer cases in which a 3-column osteotomy was used. The protocol group had more lateral surgery, but it also had a higher number of more complex osteotomies that are more prone to complications. Nevertheless, the protocol group had had far fewer complications owing to the standardized system processes espoused by this analysis.

One of the significantly reduced complications was that of urinary tract infection. There was no difference in the handling of urinary catheters during the entire study period. The authors believe that the significantly reduced urinary tract infection rate in the protocol group demonstrates improved mobilization, which is a surrogate measure of overall complications.

One weakness of this study deals with the composition of the 2 groups. Because the study involved a lengthy time period, the authors have seen a shift away from traditional anterior surgery, as has been seen at many centers owing to the described morbidity of the anterior approach [60-64]. The authors think that the team approach espoused by this analysis clearly demonstrates improvement in perioperative complication rates. Decreased anterior approaches could certainly add to this phenomenon, but they cannot solely be responsible for the significant improvement in perioperative complication rates.

This study had several additional weaknesses, the first of which arises from the incentive structure for the physicians involved in the study. All physicians at the authors' medical center are paid a salaried wage. This freedom from direct financial reimbursement could present a bias toward conservatism in case selection. This weakness may also limit the applicability of this protocol to institutions that are reimbursed directly by case volume. Second, the researchers have found that organizing and running a live multidisciplinary preoperative screening conference requires protected time for physicians, which may not be a feasible option at all institutions. They think that such a conference will happen if it is part of a required checklist to proceed to complex spinal surgery. Third, the current coagulopathy protocol requires obtaining hourly intraoperative laboratory values, which adds a moderate cost to an already expensive surgical procedure and suggests the need for institutional support that is willing to absorb these costs. This financial requirement may therefore limit the ability to adopt this protocol at all institutions. Although the up-front costs of instituting the entire protocol will be high, the authors hypothesize that significant cost savings and increased patient safety will occur in the long run as fewer expensive complications leading to hospital readmission are encountered. Further economic data are under review by the current research team; a detailed analysis of this will be forthcoming. Either way, the authors of this article believe that increasing costs up front to standardize protocols will increase patient safety with adult spinal deformity patients undergoing surgery. It is their hope that further analyses such as this one will be published, stressing protocol and improved patient safety. Such an analysis can be directly given to the hospital administrator as justification for increased resources.

Finally, a central tenet of the authors' approach is that the team protocol carries weight over the individual, and thus all surgeons and anesthetists adhere to the uniform protocols described here when performing complex spine cases. This uniformity may not be possible in an institution in which there are a large number of department members with varying seniority, and may also therefore interfere with resident and fellow education. The authors are affiliated with a large tertiary care academic medical center in which residents are an integral part of the curriculum. Orthopedic or neurosurgical residents are welcome to scrub adult spinal deformity cases with the understanding that the protocol calls for 2 attending surgeons in any case that fits MSP criteria. The authors recommend an approach as detailed by Ames et al. [33] in a large training institution for highly complex cases such as those involving pedicle subtraction osteotomy.

Current rates of complications in adult spinal deformity surgery remain unacceptably high, and system approaches can reduce complications and mitigate risk. To our knowledge this is the first study demonstrating the positive effect of a live multidisciplinary preoperative conference, a dual-attending surgeon approach in the operating room, and a thorough intraoperative protocol for the management of coagulopathy and resulting significant reduction of perioperative complication rates.

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CHAPTER 4

A SYSTEMATIC MULTIDISCIPLINARY INITIATIVE FOR REDUCING THE RISK OF COMPLICATIONS IN ADULT SCOLIOSIS SURGERY

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INTRODUCTION

Complex spine surgeries in the treatment of adult spinal deformity (ASD) are challenging procedures with high rates of intraoperative and postoperative morbidity, including wound infections and neurological injuries, and death.[4,7,8,14,15,18,19,21,23,24] The rates of major and minor complications for these procedures range from 10% to almost 90%.[14,19,21] There might be opportunities to decrease such risk in complex spine surgery. Many organizations have developed focused protocols aimed at reducing specific complications individually.[1,2] A growing body of literature suggests that standardized systematic protocols can reduce complication rates across surgical disciplines.[12,13,22,24] The implementation of a comprehensive multidisciplinary and systematic approach designed to decrease the full constellation of complications related to spine surgery might contribute to improved care quality and patient outcomes.

We recently published the Seattle Spine Team Protocol,[20] which is among the first in the field designed to reduce the risk of the most common complications simultaneously. In this study, we rigorously analyzed our data from complex spine surgeries before and after the implementation of this comprehensive multidisciplinary protocol.

American health systems, hospitals, and practitioners are under increasing pressure to move away from fee-for-service–based health care delivery and toward delivering value-driven health care by maximizing quality and safety while holding costs constant.[16] As requests for transparent high-quality data increase and patients seek institutions that deliver the "best" care,[11] efforts to improve quality and safety in health care are more important than ever. Innovative multidisciplinary and system-focused approaches represent opportunities for achieving improvements in quality and safety across all fields of medicine.[9]

METHODS

STUDY DESIGN AND POPULATION

We conducted a retrospective cohort study of patients who underwent complex spinal surgery between July 1, 2008, and December 31, 2012. The study was a retrospective review of a series of consecutive cases. Complex spinal surgery was defined here as an operation that required either 6 or more levels of vertebral fusion or more than 3 levels of vertebral fusion in a patient with multiple comorbidities. All the patients were members of Group Health Cooperative, an integrated delivery system in the Pacific Northwest. All of the operations were conducted at Virginia Mason Medical Center in Seattle, Washington. The total possible study population included women and men aged 18–85 years with a primary diagnosis of scoliosis (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] 737.1–737.3[6]). We identified 42,609 patients with a diagnosis of scoliosis who were potentially eligible for this study cohort.

IDENTIFICATION OF COMPLEX SPINE SURGERIES

Among the 42,609 patients with a diagnosis of scoliosis, we identified a subset of them who underwent a complex spine surgery during the study period. Because these procedures are not easily identifiable through billing procedure codes, we used a 2-step approach to capture these cases. First, using automated health record data, we limited the cohort of patients with scoliosis to those who had at least 2 visits to a spinal surgeon 1 year and underwent subsequent multilevel spine fusion surgery, as identified by Current Procedural Terminology (CPT) codes (22532–22819 [spinal fusion], 63710 [graft repair of spine], 22849–2285 [addition of spinal implants], and/or 81.0 [spinal fusion3]), during our study period. We then used medical record chart abstraction to review the operative reports to determine whether the procedure met our study definition of a complex spine procedure.

For a patient to have undergone spinal surgery, a minimum of 2 neurosurgical visits would have been required, because the preoperative and postoperative visits are separate visits from the actual surgery. Any patients with an absence of 2 neurosurgical visits would not be considered to have undergone spinal surgery and were ineligible for inclusion in our retrospective cohort study on postoperative complications.

There were 666 patients with at least 2 visits to a spine surgeon and subsequent procedure codes for spinal surgery who therefore met our criteria for further chart abstraction review. A trained chart abstractor reviewed all electronic health records (EHRs) of these 666 potential cases. For each surgical case, we abstracted the presence of staged procedures, extent and location of the spinal fusion, the surgeon(s), estimated blood loss, and surgical approach (posterior, anterior, lateral, and combinations). As a result of this review, we excluded 499 patients since their procedure was not considered complex spinal surgery because it involved less extensive fusion procedures, involved fusions to the cervical spine, was for a surgical indication other than scoliosis (e.g., surgery related to recent fracture or cancer), or it was an index procedure conducted at an outside medical facility. If multiple procedures occurred during the study period, the first complex spinal surgery was considered the index spinal surgery. The study cohort therefore comprised 140 patients with scoliosis who had undergone a qualifying complex spine surgery.

PATIENT CHARACTERISTICS

Patient age at the time of surgery and patient sex were available from Group Health Cooperative enrollment and demographic records.17 Comorbidity and health indicators, including body mass index, current smoking status, and history of myocardial infarction, diabetes, osteoporosis, depression, previous surgical intervention, and/or spondylolisthesis, were assessed from the 2 years before surgery. Charlson/Deyo comorbidity scores were calculated using 1 year of previous health care utilization data at the time of surgery.10 Intervention Exposure: Implementation of a Standardized Systematic Protocol In 2010, we implemented a standardized systematic protocol at Group Health Cooperative and Virginia Mason Medical Center to mitigate the risk of complications after complex spinal surgery. The key elements of the protocol included the following.20

COMPLEX SPINAL SURGERY CONFERENCE

Before surgery, each potential surgical case is presented to a multidisciplinary spine conference with clinicians representing neurosurgery, anesthesia, orthopedics, internal medicine, behavioral health, and nursing. For each case, potential surgical interventions and patient suitability for surgery are discussed among the team. Surgery is delayed for patients not currently suitable for it (e.g., those who require smoking cessation, weight loss, or further medical consultation).

PATIENT EDUCATION COURSE

Each patient approved for surgery attends a mandatory education course for patients and their caregivers that reviews preparation for the surgery and postoperative care.

DUAL-SURGEON APPROACH

For each surgical intervention, 2 attending surgeons with training in neurosurgery and orthopedics perform the procedure concurrently.

DEDICATED SPECIALIST COMPLEX SPINE ANESTHESIA TEAM

These members of the team play an integral role in the review of each case before, during, and after the multidisciplinary conference and during surgery.

INTRAOPERATIVE PATIENT MONITORING

Patient values for coagulopathy and estimated blood loss are monitored routinely and documented on a whiteboard visible to all operating room members to assess patient stability during the surgery. Intraoperative communication strategies, such as taking an hourly pause for the surgeons and anesthesiologist to review laboratory values and patient status, were also standardized and built into the protocol.

This initiative was designed to maximize patient safety and mitigate the risk of complications, primarily through identifying potential risk factors early, opening clear lines of communication between providers, and standardizing intraoperative protocols to reduce variability. Surgery is delayed for patients not currently suitable for it (e.g., those who require smoking cessation, weight loss, or further medical consultation) and potentially denied for those who are unable to complete medical optimization. Additional detail on the specifics of the protocol were published by Sethi et al.20 in 2014 and Buchlak et al.5 in 2016.

The goal of this evaluation was to compare patient complication rates in 2008–2010 (the preintervention period) to complication rates in 2011–2012 (the postintervention period) after full implementation of these system improvements in late 2010.

OUTCOME MEASURES: SURGICAL COMPLICATIONS

Surgical complications were categorized as those that occurred within the first 30 days (1–30 days) or up to 1 year (31–365 days) from the index complex spine surgery. Complications of interest were specified a priori using available literature on surgical complications from complex spinal surgery.14,21 Complications were identified through a combination of CPT and ICD-9-CM codes in administrative claims data and EHR review. Complications assessed included postoperative blindness (identified through EHRs only), postoperative CSF leak (ICD-9-CM 339.8, 348.4, 389.0, or 792.0), myocardial infarction (ICD9-CM 410), stroke (ICD-9-CM 435), deep venous thrombosis (DVT) (ICD-9-CM 453.40), pulmonary embolism (PE) (ICD-9-CM 415.1), infections, including wound infection (ICD-9-CM 958.3) and pneumonia (ICD-9-CM 486), surgical failure, including implant failure (EHR only) and revision surgery (CPT code 22532, 22819, or 63710), readmission to the hospital (any claim for an inpatient hospital stay in the year after surgery), and death (recorded in the Group Health Research Institute or Washington State death registry).

STATISTICAL ANALYSIS

The analysis compared complication rates after complex spinal surgery conducted within the preintervention period (2008–2010) to those within the postintervention period (2011–2012) to assess the effects of implementing our systematic spine care protocol intervention. We calculated descriptive statistics of patient characteristics overall and stratified according to study period. We used chi-square tests and Wilcoxon rank-sum tests to assess differences in characteristics between patients who underwent a procedure in the pre-implementation period and those whose surgery was within the postimplementation period.

The primary outcome was an overall composite measure defined as the occurrence of any of the prespecified complications and further defined as complications within 30 days and 1 year after the index surgery. If a patient experienced more than 1 complication, only 1 event was counted in the overall composite measure of any complication. Although postoperative blindness is an a priori complication of interest, we had no such complication in our study population and hence did not include blindness as an outcome in the reported results.

Surgical complication rates are presented as the number and proportion of patients with a complication within 30 days and 1 year after surgery. We used a modified Poisson regression model to estimate the relative risk (RR) and 95% confidence interval (CI) of the primary outcome measure (any complication) to compare surgeries performed in 2011–2012 relative to those performed in 2008– 2010. The regression model was adjusted for age (< 65 vs ≥ 65) and Charlson/Deyo comorbidity score (0 vs ≥ 1). RRs were estimated only for the composite outcome measure. We did not test for statistical significance between rates of individual complications because they were quite low, and it would not be possible to control for important confounders such as age and comorbidity. Therefore, we chose to conduct statistical testing only for our primary outcome composite measure. All analyses were conducted using Stata 12.0 (StataCorp).

INSTITUTIONAL REVIEW BOARD APPROVAL

This study was conducted with approval from our institutional review board and was granted a waiver of written consent. All study procedures were compliant with the Health Insurance Portability and Accountability Act.

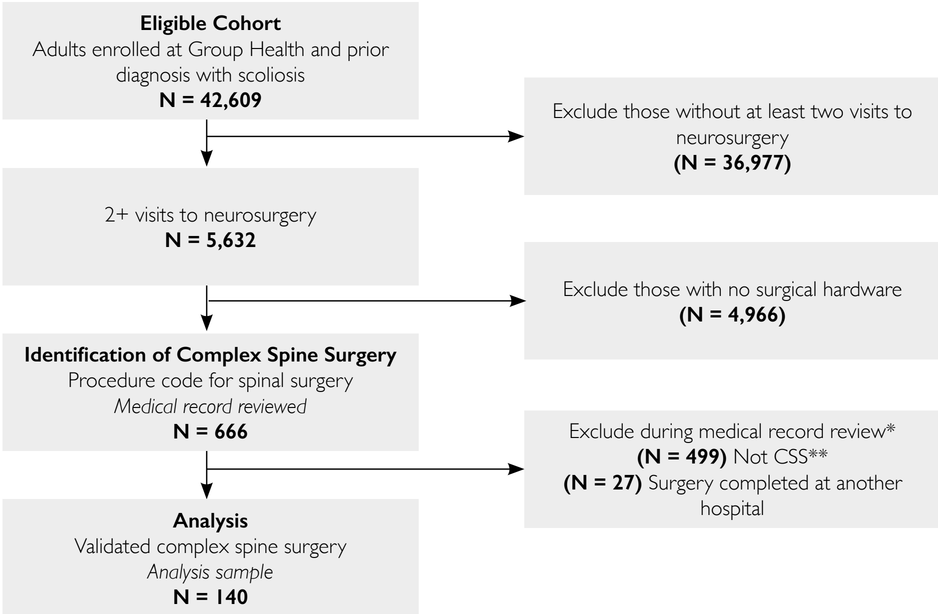
RESULTS

The study population included 42,609 adult men and women with a diagnosis of scoliosis (Fig. 1). Of those with scoliosis, 5632 patients had 2 visits to a spinal surgeon. Among this cohort, we identified 666 patients who underwent any spine fusion surgery, and after chart review, 140 patients were found to have undergone complex spine surgery and made up our study sample for the analysis.

The study population was 74% female, accounting for 65% of the patients in the preintervention period and 84% in the postintervention period ($p = 0.01$) (Table 1). Patients who underwent surgery in the postintervention period were more likely to have been a current or recent smoker at the time of their assessment for surgery, more likely to have undergone a previous spinal fusion surgery, and less likely to have been diagnosed with diabetes or previous myocardial infarction, but these differences were not statistically significant.

Surgery characteristics were similar among patients in the preintervention and postintervention periods. On average, the length of hospital stay for the index surgery was 7.6 days. Almost half (46%) of the surgeries were planned as 2-stage procedures. The number of levels of fusion planned was higher in the postimplementation period; 88% planned ≥ 6 levels of fusion compared with 73% in the pre-implementation period ($p = 0.02$).

FIGURE 1. CONSORT diagram of patients included for evaluation of complex spine surgery.



*Patients might have had both exclusions (exclusion identified in the EHR is listed). **Not complex spine surgery (CSS) (1 stage, < 4 levels of fusion; fusion includes cervical spine, scoliosis not indicated, or fracture indicated).

The most common complication within 30 days after surgery was CSF leak (Table 2). There were declines in nearly all complications within 30 days after surgery in the postintervention period compared to those in the preintervention period. The most notable reduction was in the 30-day complication rate, primarily because of declines in DVT, PE, wound infection, and return to surgery. There were 4 deaths overall, 3 of which occurred in patients who underwent surgery in the preintervention period.

In the multivariate adjusted model, patients who underwent complex spine surgery in the postintervention period had a statistically significant 51% decrease in the risk of any complication within 30 days after surgery compared with those who underwent surgery in the preintervention period (RR 0.49 [95% CI 0.30–0.78]); this analysis was adjusted for age and comorbidity status (Table 3). The difference in risk of complications within 1 year between the preintervention and postintervention periods was not statistically significant (RR 0.98 [95% CI 0.55–1.77]).

TABLE 1. Characteristics of patients who underwent complex spine surgery, overall and according to intervention period.

Characteristics	Overall (n = 140)	Preintervention Period (n = 71)	Postintervention Period (n = 69)	p Value
Patients				
Sex (% female)	74	65	84	0.01
Age (mean [SD]) (yrs)	63,7 (12,1)	62,0 (13,4)	65,5 (10,5)	0.09
Body mass index (mean [SD]) ()	27,4 (5,5)	28,0 (5,6)	26,8 (5,3)	0.24
Personal medical history (%)				
Smoking	24	20	29	0.20
Diabetes	12	16	9	0.22
Myocardial infarction	9	11	7	0.41
Depression	19	18	19	0.94
Osteoporosis	15	13	17	0.44
Spondylolisthesis	59	63	54	0.24
Previous spinal fusion surgery	19	14	25	0.11
Charlson/Deyo comorbidity score				
0	49	45	52	0.43
1-2	34	39	29	
≥3	17	15	19	
Surgery				
Hospital stay (mean [SD]) (days)	7.6 (4.3)	7.7(4.3)	7.5 (4,4)	0.65
Stages, planned (%)				
1	54	55	54	0.88
2	46	45	56	
Levels of fusion, planned (%)				
<6	20	26	12	0.02
≥6	81	73	88	

TABLE 2. Complication rates after complex spine surgery 30 days and 1 year after surgery, according to study period

Complication	No. of Patients (%)			
	30 Days		1 Yr	
	Preintervention Period	Postintervention Period	Preintervention Period	Postintervention Period
Immediate				
Blindness	0 (0)	0 (0)	NA	NA
CSF leak	13 (18)	12 (17)	NA	NA
Cardiovascular				
Myocardial infarction	3 (4)	0 (0)	0 (0)	0 (0)
Stroke	1 (1)	1 (1)	0 (0)	1 (1)
DVT/PE	7 (10)	2 (3)	3 (4)	3 (4)
Infection				
Wound infection	6 (8)	0 (0)	2 (3)	1 (1)
Pneumonia	4 (6)	1 (2)	2 (3)	3 (4)
Surgical failure				
Implant failure	3 (4)	0 (0)	3 (4)	1 (1)
Return to surgery	4 (6)	1 (1)	5 (7)	2 (3)
Other	0 (0)	1 (1)	0 (0)	0 (0)
Readmission to hospital	7 (10)	5 (7)	14 (20)	12 (17)
Death	1 (1)	0 (0)	2 (3)	1 (1)

NA = not applicable.

TABLE 3. Risk of any complication 30 days and 1 year after complex spine surgery, according to study period

Any Overall Complication	No. of Patients (%)		RR (95% CI)*
	Preintervention Period	Postintervention Period	
30 days	34 (48)	17 (25)	0.49 (0.30-0.78)
1 yr	19 (27)	16 (23)	0.98 (0.55-1.77)

*Analyses were adjusted for age (<65 or ≥ 65 years) and Charlson/Deyo comorbidity score (0 or ≥1).

DISCUSSION

The systematic multidisciplinary initiative analyzed here is an evidence-based and scientific solution for improving quality and safety in complex spine surgery care. We conducted a retrospective review of a series of consecutive cases, collected data on several potential confounding factors, accounted for patient differences, and found reductions in overall complication rates within 30 days of surgery.

This work contributes to the advancement of health care quality and practice with a specific focus on surgery. The results suggest that our risk mitigation and quality improvement strategies designed to improve patient safety yielded a 51% reduction in surgical complications within the first 30 days after complex spine surgery. The study revealed decreases in rates of DVT, wound infection, and return to surgery. However, sustained reductions in complication rates were not seen 1 year after surgery, which suggests that the quality improvement measures had an effect on improving patient safety within 30 days of surgery but not within the ensuing year. Our results suggest that quality improvement initiatives can help in the delivery of safer complex spine surgery to patients with scoliosis.

Overall rates of complications at our institution remain lower than benchmarks in the literature. We found 30-day mortality rates of 1% in the preintervention period and 0% in the postintervention period and 1-year mortality rates of 3% in the preintervention period but only 1% in the postintervention period; previous studies have reported 30-day mortality rates as high as 4%.14 The review of patients during the preoperative multidisciplinary spine conference helps to determine the suitability of patients for major surgical intervention and enables patients to be optimized for the procedure. Sometimes surgery is deferred until medical health improves. This preoperative review is an important part of the risk management protocol aimed at improving patient safety.20

Having a minimum of 2 board-certified neurosurgeons with 10 years of practice experience, a board-certified orthopedic spine surgeon with 10 years of practice experience, 2 board-certified anesthesiologists with specialty training in neuroanesthesia with 10 years of practice experience, 2 board-certified physiatrists, and 1 internist underpins our protocol. We do feel, however, that experience is built with time at each individual institution; thus, rather than stringent experience requirements, only consistent attendance to and involvement with patients with complex spine conditions should be required at centers that desire to build such a multidisciplinary preoperative screening conference. Each center will then need to validate its own outcomes and improve the decision-making process over time.

The primary limitations of this study are that it was retrospective, it was conducted at a single institution, and we could not control for some differences, including sex and levels of surgical fusion planned. In addition, we could not fully account for the increase in surgeon and anesthesiologist experience as the study progressed. We did all that we could to eliminate sampling bias by applying objective patient-selection criteria, which were applicable across the 2 study periods.

We elected to include DVT/PE in a single category to represent "thrombotic" complications. The number of these complications was quite low (10 within the 30-day period and 6 within the 1-year period), so further parsing was unlikely to provide statistical benefit. In addition, to truly represent the clinical scenario, we likely would have needed to separate upper-extremity DVT from lower extremity DVT and potentially incidental PE discovered on postoperative spine CT from clinically significant PE potentially requiring anticoagulation. We feel that an assessment of thrombotic complications is important but also that the broad categorization used might have more accurately represented the types of complications that our patients face and that can be affected by the use of a systemic protocol.

A key element of this protocol is better patient selection. We have designed and evaluated a protocol that consists of a number of preoperative and intraoperative components. We have evaluated the protocol as an entire system. It would be beneficial to investigate the effects of the individual protocol components separately to compare and separate, for example, the effects of the patient-selection process versus the effects of the refined intraoperative methods. The study we conducted was an initial step and assisted in answering our initial research questions. More granular and detailed research that can address the specific effects of individual protocol components is a possibility for future work.

IMPLICATIONS FOR PRACTICE

System-based improvements in complex spinal surgery reduce the short-term postoperative risk of complications and death. We suggest that complex spine surgery practitioners and administrators consider designing and implementing systematic approaches to improve the safety of the services they offer. Our experience might be transferrable to the management of perioperative processes in other complex surgical fields and might help contribute to further reductions in complication rates within these other specialties.

As hospitals and practitioners are faced with increasing pressure to maximize quality and as patients are motivated to seek the best care, implementing structured systematic multidisciplinary approaches to delivering surgical care might become a safer standard. We encourage other institutions and practitioners to develop their own comprehensive approaches to reviewing the appropriateness and risk of surgical care for their patients. These types of systematic approaches to improving quality and mitigating risk might set institutions apart as health care quality leaders.

DIRECTIONS FOR FUTURE RESEARCH

The results of this evaluation have revealed a number of possible avenues for future research. Future studies might increase statistical power and address additional issues of confounding by leveraging larger surgical registries or by combining data from multiple institutions. It might also be useful to conduct similar investigations in larger populations to better differentiate longer-term differences in complication rates or those in populations within other institutions or health systems to determine reproducibility and generalizability for attaining meaningful improvements in both short- and long-term treatment outcomes.

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CHAPTER 5

THE SEATTLE SPINE SCORE: PREDICTING 30-DAY COMPLICATION RISK IN ADULT SPINAL DEFORMITY SURGERY

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INTRODUCTION

The population of patients with spinal deformity requiring surgical treatment is growing [1,2]. With the move towards value-based care, surgical care for these patients is being rewarded for higher quality with controlled cost [2–4]. Efforts to improve the accuracy of surgical decision-making and to develop data-driven risk stratification methods are likely to improve patient safety and outcomes, and thereby increase the overall quality and value of spine surgery care.

Complex spine surgery, defined as a procedure involving six or more levels of spinal fusion, is a high-risk undertaking with high complication rates. Complication rates range from 10 percent up to 80 percent [5–12], and are often associated with increased hospital stay, cost and long-term morbidity [9,10,12]. These complications occur as a result of a complex web of social, physiological and environmental factors [13].

Preoperative assessment of complication risk in complex spine surgery is often based on broad prevalence rates and retrospective percentage statistics. The development of debiasing strategies in high-risk medical decision making has the potential to increase service quality and patient safety. Debiasing involves moving away from intuitive processing towards processing that is more analytical, evidence-based and system-supported [14]. Robust predictive models are one method to improve risk assessment and achieve gains in service quality. While work on predictive modeling in spine surgery is progressing [15–20], the application of data-driven methods for accurately and reliably predicting surgical risk and patient complications in spine surgery is rare.

The purpose of this study was to generate and calibrate a statistical model to predict the risk of 30-day complications associated with complex spine surgery. The utility of the model was maximized by focusing on preoperative variables that were readily available and easily measurable. We hypothesized that a statistical model developed using preoperative patient characteristics would accurately predict the likelihood of 30-day complications. We used the predictive model to develop a decision support system (DSS) with a quantified output representing the risk of complication within 30 days of surgery. We performed an evaluation experiment to assess the utility of this statistical model-driven DSS in helping physicians involved in the delivery of complex spine surgical care to identify patients who were at higher or lower risk of postoperative complications. We hypothesized that the additional information provided by the DSS would increase the capability of physicians to accurately predict whether patients would or would not go on to experience postoperative complications.

METHOD

PREDICTIVE MODELING AND DSS DEVELOPMENT

PARTICIPANTS AND DATA COLLECTION

This retrospective predictive modeling study included a total of 136 consecutive spine deformity patients. Inclusion criteria were as follows. Patients were (1) at least 18 years of age, (2) diagnosed with adult spinal deformity with a coronal lumbar or thoracic curve greater than 40 degrees and/or significant sagittal plane imbalance with SVA greater than 10 cm and LL-PI mismatch of 20 degrees or greater, and (3) treated with a spinal fusion procedure involving six or more vertebral levels. All patients underwent a complex spine procedure involving a posterior approach. A subset of cases had a secondary minimally invasive lateral approach for anterior fusion. Surgeries were performed at a single high-volume institution in the United States with a large multistate referral pattern for adult spinal deformity cases. Data was collated for all cases based on queries of the institution's data warehouse and abstraction of electronic medical records (EMR). Abstraction was conducted by two trained abstractors. A random sample of 15% of cases was selected to assess the accuracy of chart abstraction. Inter-rater data concordance was 100%.

PREDICTIVE MODEL DEVELOPMENT

The primary outcome of interest was the occurrence of a complication event within 30 days of surgery. A complication event was defined as a patient experiencing one or more of the following: cardiac event including myocardial infarction, pneumothorax, pneumonia, wound infection, wound dehiscence, urinary tract infection, pulmonary embolism, thromboembolism, unplanned return to surgery and death. The presence of any complication was coded "1" and absence was coded "0". Multiple complications were not additive.

Univariate and multivariate logistic regression analyses (LRA) were conducted to predict the probability of a postoperative complication event. The odds ratio of each risk factor was indicated. A set of theoretically and clinically relevant potential predictive variables was devised based upon the expertise and recommendations of five senior surgeons. Potential predictive variables needed to be captured adequately within the EMR for inclusion in this study. Potential predictors included age, gender, BMI, a history of smoking, and a preoperative diagnosis of hypertension, anxiety, depression, diabetes, bipolar disorder, Parkinson's disease, cancer, and anemia.

Summary statistics were calculated, including frequency and percentage statistics for categorical variables and means and standard deviations for continuous variables. In assessing the magnitude of associations, we calculated odds ratios and 95% confidence intervals. For the multivariate LRA, we included variables that (1) were clinically relevant or (2) achieved a univariate significance level of 0.2 or less, in line with the methods of other predictive modeling researchers [21].

To achieve sufficient power in multivariate LRA, the model must be based on a sample size that is at least 10 times the number of predictors [22]. In this case, the sample size was sufficient to substantially exceed this minimum benchmark. The final model contained seven predictor variables (BMI, age, gender, smoking status, and a preoperative diagnosis of diabetes, hypertension, or anemia) and was based on 136 cases.

Multivariate LRA models were considered significant if they achieved a p value less than 0.05. To calibrate the models and establish an indicator of their performance, discrimination between high- and low-risk patients was assessed using the area under the receiver operating curve (AUROC). The model was developed in line with predictive model development guidelines [13,23–25]. Analyses were conducted using SPSS (SPSS, Chicago, IL).

Three multivariate models were developed and their relative quality was assessed. Model calibration measures how closely actual outcomes align with those predicted by the model. Calibration was measured using the Hosmer-Lemeshow Chi-square statistic [21,26]. Model quality was assessed by reviewing the (1) model's chi-square statistic, (2) percentage of correct predictions, and (3) Nagelkerke's pseudo-R2. The model that demonstrated the best fit and the highest percentage of correct predictions was selected for subsequent validation and experimental evaluation.

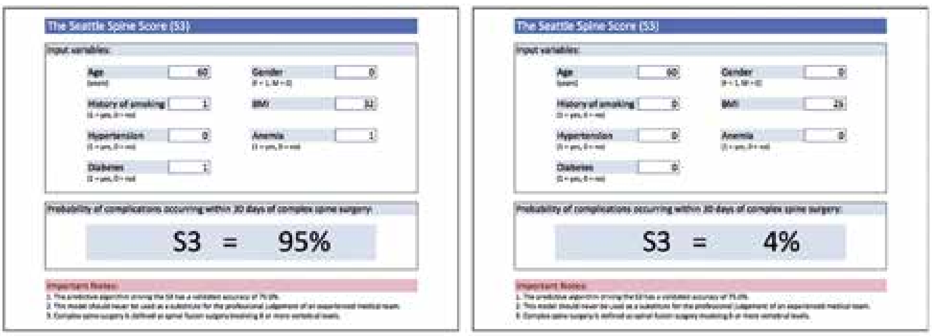
To validate the model, we divided our dataset into five distinct sets. In line with the process articulated by Assman, Cullen & Schulte (2002) [21], combinations of four of these five sets were used for generating the model and training the algorithms. The final set was used for testing the performance of the models on unknown data. This validation process was conducted for every possible 4-part, 1-part combination [21]. This internal validation process showed that the performance of the model was robust. Results in each of the subsets did not differ substantially from the model derived from the full data set.

A predictive algorithm was developed using the beta coefficients and the constant of the model based on the full dataset.

DECISION SUPPORT SYSTEM DEVELOPMENT

A DSS was developed to enable the application of the predictive algorithm created. This DSS is an interactive system that applies the exponentiated regression equation, weighting each predictive variable independently. The algorithm was mathematically converted to yield a quantified probability score [24]. The DSS allows for calculation of risk in an individual patient by inputting the value for each of the seven predictor variables. The output of the DSS is a single global percentage statistic, which suggests the likelihood of complications occurring within 30 days for each individual case. Fig. 1 shows the design of the DSS dashboard that was developed. This design adheres to DSS-development guidelines [27,28].

FIGURE 1. Two examples of the OSS interface. One displaying an example of a hypothetical high-risk test case. The other displaying an example of a hypothetical low-risk test case.



EXPERIMENTAL EVALUATION

AIMS AND HYPOTHESES

An experiment was conducted to assess whether the output of the DSS improved the predictive accuracy of expert physicians involved in the delivery of complex spine care. The purpose of this study was to determine the effect of the DSS output (the risk metric) on the ability of physicians to accurately decide whether patients would or would not experience surgical complications as a result of complex spine surgery. The experiment aimed to contribute to building an understanding of whether the output of predictive risk calculators could assist in improving surgical decision-making. It involved collecting and analyzing decision-making data from a sample of senior physicians directly involved in the delivery of complex spine surgical care. Hypotheses guiding the design and implementation of this experimental evaluation study were as follows.

1. Physicians will be more able to correctly identify whether or not patients will go on to experience postoperative complications when they are presented with preoperative patient information along with the probabilistic risk metric than when they are presented with just preoperative patient information alone.
2. The predictions of the model-driven DSS will be more accurate than the predictions of expert physicians when they do not have access to the risk metric.

PARTICIPANTS

Eight senior physicians involved in the delivery of complex spine surgical care participated in this study. Participants included orthopaedic surgeons, neurosurgeons, anaesthesiologists, and physiatrists.

DESIGN

A within-subjects experiment was conducted to gather data on how the risk model affected the quality of physician decision-making. De-identified data was used to create a list of 100 random cases. Data for each case included the seven relevant DSS model input variables. The list consisted of data from 26 surgical cases that experienced postoperative complications within 30 days of surgery and 74 surgical cases that did not experience complications. This list was used in three test conditions. The experimenter sat with participants to mitigate the risk of them using additional resources to aid in the decision making process.

CONDITION X: SURGEON ONLY

In this condition, each physician was asked to predict whether each case would result in complicated outcomes based only on the seven clinical variables presented. Their prediction for each case was recorded as a yes or a no response.

CONDITION Y: SURGEON AND DSS

In this condition, the list of cases presented to physicians contained the DSS risk metric for each case. Physicians were informed of the accuracy of the risk metric. For each case, physicians were asked to decide whether or not postoperative complications were likely. Again, their prediction for each case was recorded as a yes or a no response.

MODEL ONLY CONDITION

The list was analyzed using the DSS. The resulting risk metric was recorded for each case. A DSS probability estimate greater than 0.5 suggested that complications would occur. An estimate less than 0.5 suggested that complications would not occur.

The presentation of stimulus conditions to participants was balanced to control for practice and memory effects. Half of the participant pool was presented with condition X first, followed by condition Y. The other half of the participant pool was presented with condition Y first, followed by condition X. Assignment to these conditions was random. The participant pool provided data for a total of 1600 trials (800 trials in the X-Y condition and 800 trials in the Y-X condition). A power analysis demonstrated that this sample size was sufficient to allow for significance testing.

ANALYSIS

Classification performance was compared to observed patient outcomes. Statistical significance testing was conducted to identify performance differences between conditions. A-prime (A0) statistics were calculated to assess group discrimination sensitivity. An A0 of one indicates perfect performance. This means that participants are able to discriminate between the two patient groups (complications vs. no-complications) accurately every time. An A0 close to zero indicates that participants are not able to distinguish the signal from the noise. As predictive accuracy improves, A0 moves closer to one. Response bias was measured using B00.AB00 of negative one indicates an extreme bias in favour of yes responses. A B00 of zero indicates no bias. A B00 of positive one indicates an extreme bias in favour of no responses [27].

Retrospective evaluation was conducted in accordance with Pick (2008). Retrospective evaluation involved comparing the statistical model predictions with actual outcomes in the retrospective dataset. Each case was assessed by the DSS and a risk classification determination was made to assess the accuracy of the predictive model on the set of cases presented.

ETHICS REVIEW AND APPROVAL

Ethics approval for this predictive modeling and experimental evaluation study was granted by the institution's IRB (IRB file number: IRB15133).

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RESULTS

The mean age of patients was 63.2 years (range 20.0–85.1, SD = 11.2). Mean BMI was 28.5 (range 17.1–47.0, SD = 6.1). Most patients (73.5%) were female, 46.3% had a history of smoking, 55.1% had hypertension, 8.1% had diabetes, and 3.7% had preoperative anemia. Complications occurring within 30 days of surgery were evident in 25.7% of cases.

PREDICTIVE MODELING

Univariate LRA indicated that age, BMI, gender, smoking status and preoperative diagnoses of anemia, diabetes and hypertension were valid predictor variables to be included in the multivariate model. Univariate LRA resulted in the exclusion of the following variables from the multivariate model: Preoperative diagnoses of depression, anxiety, bipolar, Parkinson's disease and cancer.

The multivariate LRA model was significant (v2 = 16.242, $p < 0.05$) and demonstrated a predictive accuracy of 75% (Table 1). The ability of our model to discriminate between those who experienced complication from those who did not was measured using area under the receiver-operating characteristics (AUROC) curve analysis, with an AUROC curve statistic of 1.0 indicating perfect discrimination and 0.5 representing chance. The AUROC statistic obtained by means of the model algorithm was 0.712 ($p < 0.01$), indicating a good level of discriminative functionality (Fig. 2). The risk estimates generated by our model showed very good agreement with the observed incidence of complications (Hosmer-Lemeshow v2 = 3.692, p = 0.884; p should be greater than 0.05), further demonstrating the ability of the model to discriminate between cases that did and did not go on to experience complications. A classification plot is presented in Fig. 3. This provides detailed insight into how well the predictive model classified complicated (1) and uncomplicated (0) cases.

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TABLE 1. Logistic regression analysis statistics for the predictive model developed and used to drive the DSS.

Variable	Predictive Model				
	Coefficient	p	OR	95% OR CI	
				Lower limit	Upper limit
Constant	−5.164	0.004			
Smoking	0.183	0.670	1.200	0.518	2.782
BMI (kg/m^2)	0.111	0.001	1.118	1.044	1.197
Diabetes	0.905	0.210	2.471	0.601	10.153
Age	0.011	0.594	1.012	0.970	1.055
Sex	−0.431	0.386	0.650	0.245	1.720
Hypertension	0.010	0.983	1.010	0.407	2.503
Anemia	0.240	0.815	1.272	0.170	9.522
Model Chi-square (df, p)				16.242 (7, p = 0.023)	
% Correct Predictions					75.00
Nagelkerke R Square					0.165

Note: OR = odds ratio; CI = confidence interval.

FIGURE 2. The receiver operating characteristics curve for the multivariate logistic regression model.

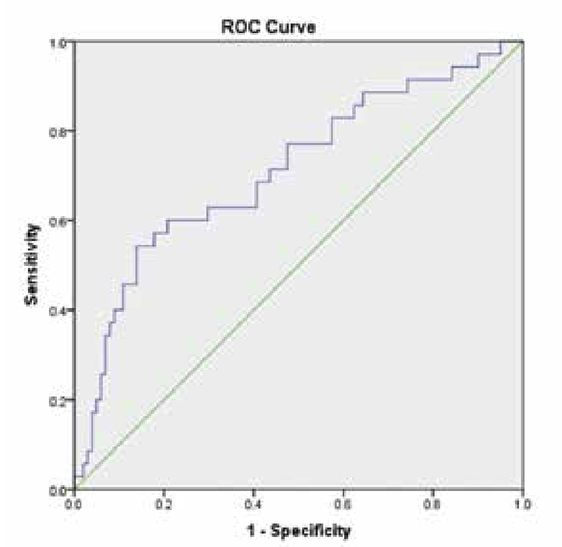

FIGURE 3. Classification plot showing how the model classified cases that did and did not go on to experience postoperative complications.

```
             Observed Groups and Predicted Probabilities

      16 +                                                                                                    +
         I                                                                                                    I
         I                                                                                                    I
F        I             1                                                                                      I
R     12 +             0                                                                                      +
E        I             0                                                                                      I
Q        I             0  1                                                                                   I
U        I             0  1                                                                                   I
E      8 +             0  0                                                                                   +
N        I            10 10                                                                                   I
C        I            00 001                                                                                  I
Y        I          1 00 001                 1          1                                                     I
       4 +        0 00001000   10   0        0          1                                                     +
         I        0100000000 1010 0 0 0      0  0       1                                                     I
         I        0000000000 0000 010001 0   0  01      1 1      1  1   10                                    I
         I       00000000000000000000000 0  101101  0010001  0   01 101 00 1                                  I
Predicted ---------+---------+---------+---------+---------+---------+---------+---------+---------+----------
    Prob: 0       .1        .2        .3        .4        .5        .6        .7        .8        .9         1
   Group: 0000000000000000000000000000000000000000000000000011111111111111111111111111111111111111111111111111

          Predicted Probability is of Membership for 1.00
          The Cut Value is .50
          Symbols: 0 - Postoperative complication/s not experienced
                   1 - Postoperative complication/s experienced
          Each Symbol Represents 1 Case.
```

EXPERIMENTAL EVALUATION

RETROSPECTIVE EVALUATION

When the 100 cases were analyzed by the DSS, it demonstrated a 76% accuracy rate, which was significantly better than chance (50%; v2 = 21.825, $p < 0.01$). A 0.5 threshold was used as the DSS decision making criterion. The DSS was significantly more accurate than participants who were exposed only to the case list that included patient data alone, and were not exposed to the risk metric at all (v2 = 21.825, $p < 0.01$). Participants demonstrated an accuracy of 50%.

THE X-Y CONDITION: BLINDED CASES (X), THEN CASES WITH THE RISK METRIC (Y)

The four participants in this condition were first presented with the list of 100 cases that did not include the DSS risk metric. These participants were subsequently presented with the list of 100 cases that included patient data along with the DSS risk metric. Table 2 presents the results of this test condition.

When participants were first presented with the list of cases that included just preoperative patient data, their predictive accuracy was equal to chance (50.00%). When these participants were then presented with the list of cases that included the risk metric, their predictive accuracy improved significantly to 60.75% (v2 = 9.341, $p < 0.01$).

The proportion of true negatives for these participants increased significantly between stimulus conditions. When presented with the list without the risk metric, the proportion of true negatives was 0.3575. When participants were subsequently presented with the list that included the risk metric, the proportion of true negatives increased significantly to 0.4825 (v2 = 12.812, $p < 0.05$). This indicated an improved ability to accurately identify the patients who did not go on to experience postoperative complications. The proportion of true positives and false negatives did not change significantly in this condition. When participants were first presented with the list of cases without the risk metric, the proportion of false positives was 0.3825. This reduced significantly when participants were presented with the cases accompanied by the risk metric (0.2575; v2 = 13.343, p <

0.05). A false positive occurs when a participant predicts that a patient will experience a postoperative complication and the patient does not. The risk metric significantly reduced this type of prediction error.

Participants presented with just patient data first were not able to discriminate between cases that were likely to experience postoperative complications and those that were not (A0 = 0.0182). When these participants were then presented with the list of cases that included the risk metric, their ability to discriminate between complicated and uncomplicated cases improved significantly (A0 = 0.1151; v2 = 30.150, p < 0.01). Response bias (B00) did not differ between conditions.

TABLE 2. Predictive accuracy statistics for participants who were first presented with case data alone and then were presented with case data accompanied by the risk metric.

	Without risk metric – X (this list presented first)		Without risk metric – Y (this list presented second)		p value*
	n	Proportion	n	Proportion	
Correct	200	0.5000	243	0.6075	0.0022
Incorrect	200	0.5000	157	0.3925	0.0022
TrueNegative	143	0.3575	193	0.4825	0.0003
TruePositive	57	0.1425	44	0.1100	0.1667
FalseNegative	47	0.1175	60	0.1500	0.1772
FalsePositive	153	0.3825	103	0.2575	0.0002
Hit rate		0.1425		0.1100	0.1667
False alarm rate		0.3825		0.2572	0.0002
Sensitivity (A^s)		–0.0182		0.1151	0.0001
Bias (B^N)		0.3181		0.3227	0.8892

*Note: p values test differences in proportion statistics. The standard statistical significance threshold is used here (0.05).

THE Y-X CONDITION: CASES WITH THE RISK METRIC (Y), THEN BLINDED CASES (X)

The four participants in this condition were first presented with the list of 100 cases that included patient data and the DSS risk metric. These participants were subsequently presented with the blinded list of 100 cases, which did not include the DSS risk metric. Table 3 presents the results from this test condition.

When participants were first presented with the list of cases that included patient data along with the risk metric, their predictive accuracy was significantly higher than chance (50.00% compared to 60.50%; v2 = 8.907, p < 0.01). When these participants were then presented with the list of cases that did not include the risk metric, their predictive accuracy remained significantly higher than chance (50.00% compared to 63.50%; v2 = 14.832, p < 0.05), but did not improve significantly (60.50% vs. 63.50%).

The proportion of true negatives, true positives, false negatives and false positives did not change significantly when comparing participant performance on each of the stimulus lists in this Y-X condition.

Participants who were first presented with the list of patient data that included the risk metric demonstrated a low level of sensitivity (A0 = 0.1265). This improved significantly, though, when they were subsequently presented with the list of case data that did not include the riskmetric (A0 = 0.2279;v2 = 14.087, p < 0.05). Participants were more able to discriminate between groups in the blinded condition. This result was counterintuitive and suggested a carry-over effect associated with the risk metric to the blinded condition. Response bias (B”) did not differ between conditions.

TABLE 3. Predictive accuracy statistics for participants who were firstly presented with case data accompanied by the risk metric and then were presented with case data alone.

	Without risk metric – X (this list presented first)		**Without risk metric – Y (this list presented second)**		**p value***
	n	**Proportion**	**n**	**Proportion**	
Correct	242	0.6050	254	0.6350	0.3824
Incorrect	158	0.3950	146	0.3650	0.3824
TrueNegative	201	0.5025	210	0.5250	0.5246
TruePositive	41	0.1025	44	0.1100	0.7309
FalseNegative	63	0.1572	60	0.1500	0.7689
FalsePositive	95	0.2375	86	0.2150	0.4472
Hit rate		0.1025		0.1100	0.7309
False alarm rate		0.2375		0.2150	0.4472
Sensitivity (A^s)		0.1265		0.2279	0.0002
Bias (B^N)		0.2658		0.3263	0.0611

*Note: p values test differences in proportion statistics. The standard statistical significance threshold is used here (0.05).

ANALYSIS BETWEEN X-Y AND Y-X PRESENTATION CONDITIONS

In the X-Y condition, when participants were presented with the blinded stimuli first (patient data only), followed by the stimuli including the risk metric, their predictive performance on the blinded list was equal to chance (0.5000). This suggested that these participants were truly blind and that they experienced no riskmetric-related problem solving advantage.

In the Y-X condition, however, when participants were presented with the blinded stimuli second, after having been exposed to the stimuli including the risk metric, their predictive performance was significantly higher than those completing the same list in the X-Y condition (0.5000 vs. 0.6350; $v2 = 14.832$, $p < 0.01$). This suggested that these participants were not truly blind when presented with the blinded stimulus list that did not include the risk metric. It appears that these participants were able to carry over a problem solving advantage to the blinded stimuli, after having been exposed to the risk metric in the previous stimulus list.

This proposition is also supported by considering the A0 metrics between the X-Y versus the Y-X conditions. The A0 statistic in the X-Y condition for the list that included the risk metric ($A0 = 0.1151$) was essentially equivalent to the A0 statistic in the Y-X condition that included the risk metric ($A0 = 0.1265$). It did not differ significantly. However, the A0 statistic in the Y-X condition for the blinded list (no risk metric presented; $A0 = 0.2279$) was significantly higher than the A0 statistic in the X-Y condition for the same blinded list ($A0 = 0.0182$; $v2 = 81.401$, $p < 0.01$). This, again, suggests that a problem solving advantage was carried over in the Y-X condition when participants were required to complete the list of cases that included the risk metric first, and then were required to complete the list of cases that did not include the risk metric.

When interviewed after the experimental tasks, some participants stated that they were able to spot trends in the data when they were provided with the risk metric along with patient data (e.g., cases with diabetes had a high risk metric). They were able to develop problem solving strategies that they could then employ when considering the subsequent blinded list.

DISCUSSION

Predictive modeling has previously been applied to high-risk surgical procedures [18], although these efforts appear to rarely be translated into usable DSS to effectively support clinical decision making. Systems that have been created in other fields are often complex and involve an intermediate scoring system. Furthermore, they often yield output that is not readily interpretable [13,28,29].

This study was designed to develop a predictive model and an efficiently usable DSS that could accurately predict the likelihood that complex spine surgery patients would experience complications. The study was also designed to determine whether or not this predictive model-driven DSS improved the decision making quality and problem solving performance of senior physicians involved in the delivery of complex spine surgical care. The experiment was focused on evaluating the effect of providing a cognitive aid (a quantified risk metric) on the problem solving process (risk prediction). Results supported the proposed hypotheses and the core proposition of cognitive fit theory.

When physicians were provided the probabilistic risk metric, in addition to preoperative patient information (BMI, sex, age, and diabetes, anemia, hypertension and smoking status), they were more able to accurately predict whether or not patients went on to experience postoperative complications than when surgeons were presented with preoperative patient information alone. The model-driven DSS alone performed better than expert physicians alone, who only had access to the preoperative patient data and did not have access to the risk metric, in correctly identifying the surgical cases that went on to experience postoperative complications. The DSS also performed better than expert physicians even when the physicians had access to the risk metric. The ability of complex spine surgeons to discriminate between cases that went on to experience complications and those that did not, improved when they were exposed to the DSS risk metric. Error avoidance was also improved when surgeons had access to the risk metric.

Cognitive fit theory proposes that when people are presented with a stimulus that aligns with the problem solving domain and task, their problem solving performance improves [30,31]. The probabilistic risk metric is a quantitative synthesis of patient risk factors. This study suggested that it afforded a powerful problem solving advantage for physicians. Results supported the core proposition of cognitive fit theory. When participants were presented with the list of cases without the risk metric, followed by the list of cases with the risk metric, their predictive accuracy improved significantly. Additionally, when they were presented with the list of cases that included the risk metric and then the list of cases without it, their performance on both lists was significantly better than chance. These results suggested that the risk metric helped with the problem solving process, even at a later time when it was not present in a subsequent stimulus list. It appears that the risk metric allowed physicians to spot trends in the data and develop problem solving heuristics that could then be employed at a later time.

The risks of complex spine surgery can be broken down into intraoperative, short-term post-operative, and long-term risks. Intraoperative complications include severe blood loss, surgeon error, coagulopathy, blindness, neurologic injury, hypotensive sequelae and death [32,33]. Short-term complications (within 30 days of surgery) include infection, thromboembolism, reoperation, poor wound healing, hardware-related problems, neurologic problems, and complications arising from comorbid conditions. Long-term complications (more than 90 days after surgery) include infection, pseudoarthrosis, proximal and distal junctional failure, and hardware failure [15,29,34–39]. This study focused on complications presenting within 30 days after surgery because these complications have a direct impact on patient morbidity, mortality, and length of stay [8,40].

We developed a predictive model to assess this risk of complications based on a collection of routinely collected preoperative variables. These variables are easily, affordably, routinely and reliably measured [41]. The model provided good predictive differentiation between high and low risk patients. Our findings align with previous research [16,18]. BMI is a predictor of various complications for patients undergoing spine surgery [42,43] and diabetes is a predictor for the development of postoperative infection after spine surgery [44]. The remaining predictive variables were age, gender, smoking history, preoperative anemia, and hypertension. These variables have been linked to poorer outcomes after surgical intervention [12,17,45,46]. Negative outcomes may not arise directly from any one factor but may instead be the result of interactions amongst a collection of risk factors [13]. The interaction amongst these factors and their differential weighting can be captured in the multivariate predictive modeling process. Despite publications describing an increased risk of complications in patients with a prior history of depression and anxiety [16,46], the addition of these variables into the model decreased the accuracy of predicting postoperative complications in this study. This may have been due to insufficient data. Further studies investigating the predictive power of psychological variables are warranted.

In order to make the predictive statistical model usable for clinicians, a DSS was created. Key design principles guiding the development of our DSS were usability, efficiency, and clarity. The use of well-designed DSS can improve the quality of decision making, facilitate rapid insight, and aid accurate interpretation and planning [47,48]. This DSS generates a real-time, empirically-based, probabilistic estimate of a patient's risk of post-surgical complications with high accuracy.

The complexity of surgical decision making, particularly with regard to the assessment of risk, may lead to the use of cognitive heuristics [49], wherein a limited number of familiar or otherwise salient variables are considered more strongly, based on experience and preference, at the expense of others. Focusing on a small collection of risk factors may yield an inaccurate overall surgical risk assessment and result in suboptimal medical decision making [13]. Human reasoning and decision-making processes in the healthcare setting are often based on the use of heuristics and are compromised by cognitive and affective biases and errors. Consistency of judgment can be low [14,50,51], as biases influence assessments of surgical risk and the nature of the recommendations made to patients [52–54]. Mitigating these biases and errors is an important goal [14]. Factors like fatigue, sleep deprivation and cognitive overload are important determinants that predispose decision makers to the inadvertent tendency towards bias and the increased likelihood of error [14].

Evidence-based medicine involves the application of decision theory to mitigate cognitive limitations and reduce systematic biases and errors [55]. The application of the DSS tool developed here significantly improved the ability of physicians to accurately predict whether or not patients would be likely to experience postoperative complications, suggesting that the DSS was able to positively influence the quality of clinical judgment. By providing a clear prediction of risk, it may allow the surgeon and preoperative surgical review team to allocate more cognitive resources to other necessary considerations that may be more difficult to quantify, including social environment factors, and the specific needs of the patient and their family. This tool may also provide objective evidence of risk to help guide discussion in multidisciplinary preoperative clearance-for-surgery conferences [32,56]. Use of this tool adds negligible cost to the care of a complex spine patient, has the potential to improve outcomes, and is likely to increase the overall value of complex spine care, which may have reimbursement and competitive ramifications in the changing healthcare market [16,19,57]. Finally, this type of tool can facilitate the efficient and clear communication of risks to patients, thereby enhancing the informed consent process.

The predictive DSS developed here was designed for use in adult spinal deformity patients and was derived from a sample of patients at a single institution, limiting the ability to generalize this predictive algorithm to other institutions. It is important to note and consider, though, that inter-institutional generalizability was not the goal of this study. Each institution has its own way of delivering complex spine care and each institution has its own surgery related risk profile [58–60]. Some institutions implement systematic care processes that have been shown to reduce risk and improve patient safety. Other institutions do not. Examples of these risk reduction processes include multidisciplinary patient case review conferences, a dual surgeon approach in the operating room and intraoperative coagulopathy monitoring [32]. Surgical outcomes and systemic risk profiles are likely to differ between institutions due to various factors including perioperative organizational processes, surgeon skill and the degree and quality of postoperative support. Because risk profiles vary by institution, the only forward-looking ways to accurately quantify surgical risk are to either (1) minimize inter-institutional risk variability by ensuring consistent care processes across institutions and then build general predictive models, or (2) generate institution specific predictive risk models to account for each institution's own local risk profile. Large-scale, generalized predictive models based on large datasets from many institutions may be a useful low-fidelity risk assessment tool for institutions unable to create their own local risk models. However, we cannot be confident in the accuracy of these large general models at the local level, unless appropriate validation studies are conducted. While variability in care delivery exists, institution-specific risk modeling is a useful way to accurately quantify risk and confidently provide patients with the most accurate quantified risk assessment information. This analysis underscores the need for each healthcare system to perform similar analyses to maximize the quality of their own risk stratification processes.

A limitation of this study was our classification of the smoking variable, which was split into the categories of "smoker" and "never smoked." Patients in the smoker category were people who had smoked at any point in their life and may have stopped smoking well before their operation. The predictive strength of this variable may be increased by increasing smoking status categorization granularity, as research suggests that health status can improve after smoking cessation [61,62]. This study did not include neurologic complications. The frequency of these outcomes was very low and difficult to characterize. Future studies with larger samples would do well to include this variable.

As the complexity of medical decision making increases [63], this type of evidence-based data-driven DSS tool facilitates accurate risk stratification in complex spine surgery in a way that is clinically useful. DSS can improve the quality, value and safety of complex spine surgery care. The DSS tool's usability, simplicity and accuracy allow it to rapidly become an element of standard practice and to sharpen the accuracy of clinical decision making in favour of patient safety. We advocate for the development of similar predictive DSS at other institutions and for their application as an integral component of a broader systematic approach to patient evaluation.

DISCLOSURES

All authors have reviewed and approved this manuscript and have no relevant financial or other conflicts of interest with regard to this research and its publication.

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CHAPTER 6

QUALITY AND SAFETY IMPROVEMENT INITIATIVES IN COMPLEX SPINE SURGERY

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KEY CONCEPTS IN IMPROVING QUALITY AND SAFETY IN COMPLEX SPINE SURGERY

The number of adult patients with spinal deformity requiring complex surgical treatment is growing. [1,2] Complication rates in the literature have been reported as high as 80% and are potentially preventable. Complicated surgery is associated with increased hospital stay, long-term morbidity [3-10] and increased cost of care. [11,12] Health care expenditure represents a major economic burden globally and costs associated with spine care have garnered the attention of major stakeholder groups. [13-17] As the health system moves toward a value-based future, surgical care for complex spine patients is increasingly being rewarded for generating higher quality outcomes while controlling costs. [18, 2, 19] Requests for transparent quality data are increasing and patients are actively seeking institutions that deliver the best care.[20] In this shifting health care landscape, efforts to improve quality and safety in spine surgery are more important than ever.

MEASUREMENT AND EVALUATION

To improve safety and quality, it is necessary to have access to reliable and accurate data. Robust measurement and evaluation are central to quality improvement. [21] It has been suggested that patient harm is frequently the result of health systems failing to deliver recommended treatments. [22,23] Maintaining accurate records of medical errors is an essential requisite for improving patient safety. [24] Cultivating an organizational climate of safety by explicitly prioritizing safety, improving information flow, providing safety information, and developing appropriate safety procedures improves error reporting in hospitals. [24] Organizational factors associated with high quality and safety performance in academic medical centers include the use of quality and safety account ability systems, a focus on data and results, cultivating a culture of collaboration, developing a shared sense of purpose, and a hands-on leadership style. These organizational factors have been associated with measurable differences in patient-level quality and safety outcomes. [25]

HIGH RELIABILITY SCIENCE

High reliability science is a prominent framework in health care currently for improving quality and safety across the care continuum. High reliability science was developed to effectively manage hazards in industries where errors are rare and the consequences of errors are major and cannot be easily contained (e.g., aviation and nuclear power). It is characterized by consistent levels of high safety performance over substantial periods of time. [26,27] and reflects a desirable operational and service quality state for health care organizations.

Many high reliability studies exist and a collection of high reliability success principles have been identified. These principles come together to collectively describe a particular type of organizational culture in which all stakeholders are aware of even small deviations in, and breaches of, safety processes and protocols. All organizational members are vigilant for changes that may lead to a failure of the system and all are responsible for maintaining high levels of quality and safety performance. [21-30]

It is not always possible to directly apply the high reliability concepts and practices of organizations outside of health care to hospitals and health services. Health care is characterized by complex systems with substantial input and process variability. High reliability methods need to be adapted appropriately for the health care context to manage this variability, in particular the variability of care system inputs. Three key success factors relevant to the health care context appear to be: (1) leaders committing to zero patient harm, (2) a well-functioning and widespread organizational culture of safety, and (3) the broad implementation of effective process improvement tools. [30] It has been suggested that team huddles are integral in sustaining a culture of high reliability in health care. [31] A high reliability maturity framework has been developed to articulate the stages a health service needs to move through to achieve high reliability status. [30]

INSTITUTION-SPECIFIC RISK

Quality performance and risk to the patient vary by institution. [32] Patients are exposed to differing levels of risk depend ing on the institution within which they choose to receive care. [33] This can be due to differing care processes, levels of clinical capability, management practices, and the nature of the institution's care systems and technologies. Quality and safety improvement initiatives may need to vary by institution to achieve comparable improvements, driven by generalizable improvement principles and methods, rather than specific improvement tactics per se.

PREDICTIVE MODELING AND CLINICAL DECISION SUPPORT

Predictive clinical decision support is having an increasing impact in the field of risk stratification in complex spine surgery. Researchers are building accurate multivariate predictive models that can be applied to clinical practice in the form of decision support systems (DSS). Bekelis et al. created a statistical model to predict complications in spine surgery based on data from 13,660 patient cases. The model's out come variables included 30-day postoperative risk of stroke, myocardial infarction (MI), wound infection, urinary tract infection (UTI), death, deep vein thrombosis (DVT), pulmonary embolism, and unplanned return to surgery. Predictors were preoperative patient characteristics. The model was able to successfully discriminate between cases that did and did not experience complications. Areas under the receiver operating characteristics curves for each of the out come variables ranged from moderate to high. [34]

Other teams are also developing predictive decision support tools to improve quality and safety in complex spine surgery in their own contexts.[35] These predictive methods are able to aggregate the totality of an institution's clinical practice data, taking into account an institution's own organizational risk profile to generate highly accurate predictive statistical models. These models, when applied as DSS drive more accurate risk stratification and result in surgical care processes that are more data-driven and evidence-based. They help to mitigate the risk of detrimental clinical decision making biases. [36] They can be used to inform and improve the decision making of (1) the clinical team during preoperative evaluation and (2) the patient during the informed consent process.[35] These have the potential to improve clinical decision-making processes and the quality of decisions made, achieving incremental patient safety improvements. [37, 38]

OUTCOMES

Outcome measures and measures of quality accompanying surgical spine interventions include: (1) definable perioperative events that patients experience, including complications, mortality and morbidity, readmissions and reoperations, (2) key process measures, and (3) validated, standardized questionnaires designed to evaluate patient-reported care effectiveness and functional outcomes. [21,39] Rigorous collection and reporting of outcome metrics allow for informed decision making and comparison of performance variability across health care systems and medical centers. Furthermore, appraisal of surgical outcomes against health care expenditures yields relevant information about the ultimate value of care received by the patient. [40,41] Two of the most substantial challenges facing value-based health care is the absence of standardized outcome reporting metrics and lack of diagnostic clarity. Since 2007, twenty-two standard sets of outcome measurements have been proposed by the International Consortium for Health Outcomes Measurement (ICHOM),[42] including a defined set of parameters for standardized outcome reporting in the management of low back pain. [43]

However, great variability in captured and reported spinal surgery outcomes still exists between medical facilities and clinical registries. For instance, The Quality Outcomes Database (QOD), formerly known as the National Neurosurgery Quality and Outcomes Database (N 2QOD-Spine Care), [44,45] collects unique surgical spine measures that have been approved by the Centers for Medicare and Medicaid Services (CMS).[46] Meanwhile, the Scoliosis Research Society (SRS)-22 questionnaire is one of several Health-Related Quality of Life (HRQOL) measures routinely administered in multiple medical centers across the US to evaluate patient outcomes following adult spinal deformity surgery. [47-49] The Spine Adverse Events Severity System (SAVES) is a standardized assessment tool designed to assist surgeons in recording adverse events. [50] Recent collaborative efforts between the American Academy of Physical Medicine and Rehabilitation and the American Association of Neurological Surgeons led to the development of the new Spine Quality Outcomes Database (SQOD). Slated to launch in 2017, SQOD is designed to streamline data collection and align with the expectations of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). [51] A number of other initiatives have also been launched to build prospective databases to better track surgical outcomes and quality performance across institutions systematically in spine surgery. These initiatives include the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), [52-54] and Washington State's Spine Surgical Care and Outcomes Assessment Program (SCOAP). [55,56]

Institutional participation in NSQIP has been linked with reduced surgical complication rates across specialties and reduced cost of care. [57,58] The NSQIP provides an excellent model for capturing data on surgical outcomes. However, it has been suggested that some hospitals do not have the required infrastructure necessary to capture clinical and 30-day outcome data and to contribute to the initiative. [59]

Broad-based measurement of health care performance and outcomes is key to quality and safety improvement and clinical databases represent powerful ways of providing such data. However, there is a risk that these initiatives can face challenges with administration, leadership, data collection and data accuracy,[60,61] which may degrade their utility and value. Organizations managing clinical registries must be vigilant and effective in appropriately assessing these risks to maximize the return on invested time and data for all stakeholders involved and to achieve safer care for patients. A systematic review evaluating the impact of spine registries on the quality of spine care and patient outcomes suggested a lack of evidence supporting the proposition that registries have impacted the quality of spine care. A collection of recommendations were presented to improve the quality of registries and their potential to improve patient outcomes. [62]

In the past, patient outcomes were represented by surgical complications and disease-specific outcome measures, such as radiographic correction. [63] Complications and other adverse outcomes are typically captured during these three phases: perioperative, short-term (within 90 days of surgery), or long-term (greater than 90 days after surgery). Perioperative complications associated with complex spine surgery include severe blood loss, coagulopathy, hypotensive sequelae and surgeon error or misjudgment. Short-term complications include wound infection, thromboembolic complications, unplanned return to the operating room, neurologic deficit including stroke, poor wound healing, continued postoperative pain requiring reoperation, mortality, and urinary tract infection. Long-term complications include latent infection, implant fatigue and failure, pseudarthrosis, and junctional failures. [35]

Over the last decade, numerous studies have demonstrated the value of patient-reported outcome measures (PROMs) in providing information about functional outcomes and mental health. Patient-reported outcome instruments relevant to spine surgery include the Oswestry Disability Index (ODI), [64] the Patient-Reported Outcomes Measurement Information System (PROMI S), [65] the short form 12-item survey (SF-12), the EuroQol EQ-SD, the neck disability index (NDI), [66,67] the Zung depression scale, the Modified Somatic Perception Questionnaire (MSPQ) to measure anxiety, and the SRS- 22. [39,68] Outcome measures also include the patient 's return to work timeline, rates of readmission within 30 days after discharge, rates of emergency department visits within 30 days of discharge, length of hospital stay, [69] patient satisfaction with the care provided, and patient satisfaction with the surgical outcome. [39] Patient satisfaction is an important aspect of care quality, however it appears that patient satisfaction is not strongly associated with improvement in quality of life and disability after surgery. [39]

Readmission within 30 days has been targeted by the US government as a key surgical quality measure. [70]

Quality and safety improvement initiatives should consider standardizing a set of process and outcome measures that are relevant for the improvement efforts being proposed. Mant [71] suggested that process measures are sensitive and direct measures of quality, while outcome measures reflect all aspects of care, including variables that are difficult to measure. Outcome measure performance can be affected by case mix, patient population characteristics, chance and data collection processes, as well as quality of care. [71] Recent efforts have demonstrated tremendous value in long-term gathering of patient-reported outcome measures following complex spine surgery. Continued research in this area will prove to be useful for clinicians and hospital administrators. The following section considers prominent quality improvement approaches and examples of initiatives that are relevant to complex spine surgery.

PROTOCOL DEVELOPMENT, STANDARDIZATION, AND PERFORMANCE

Quality improvement is key to the future of surgery. [72] Quality and safety improvement initiatives in spine surgery have recently been designed, evaluated and published by multiple care teams. These initiatives have focused on a spectrum of improvement domains, including implementing checklists, [69] improving clinical decision making, [35] emphasizing multidisciplinary approaches, and improving communication and information flows. [73] Multiple recent quality and safety improvement initiatives in spine surgery are reviewed here and avenues for future improvement are considered.

Many examples of focused quality improvement studies exist in the field of spine surgery, including investigations of surgical planning strategies, intraoperative vancomycin use, surgical staging, neurologic monitoring, bone morphogenetic protein, and two attending surgeons. [74-81] However, published examples of systematic *multidisciplinary* improvement initiatives in complex spine surgery are rare. [73, 82] Groups have developed protocols to reduce specific surgical complications individually [74,75] but, increasingly, research suggests that comprehensive, standardized, systematic perioperative care protocols can reduce the rates of multiple complications holistically. [76, 83-85] The resultant decrease in the constellation of complications associated with spine surgery has the potential to improve care quality and patient outcomes, reduce cost and generate improved health care value.

The American College of Surgeons has articulated four guiding principles for quality improvement. These principles are:

1. "Setting standards individualized to patient groups and backed by research or consensus to define the basic standards of care for a group of patients"
2. "Building the right infrastructure for each program by describing staffing levels, specialty mix, equipment and the importance of checklists and pathways to guide the care of patients according to these standards"
3. "Committing to measurement of performance against the standards by using rigorous data from medical charts with post-discharge tracking, which is risk adjusted and continuously updated"
4. "Creating a verification process, which occurs through external peer review and site visits in a standardized format that allows the hospital to be directly assessed by peers evaluating their performance against the standards" (Rikkers et al., 2014, p. 567) [72,86]

Presented below are examples that demonstrate real-world implantation of these guiding principles, with a description of their methods, implementation, and results.

THE SEATTLE SPINE TEAM PROTOCOL

The Seattle Spine Team Protocol is a standardized quality and safety improvement initiative designed to mitigate the risk of complications following complex spine surgery. It is based on the principles of continuous improvement [87-89] and the Toyota production system [90,91] and focuses on identifying potential risk factors, improving team communication, and standardizing perioperative processes. The protocol primarily aims to improve the quality of surgical outcomes. The key components of the protocol include the following:

A MULTIDISCIPLINARY REVIEW CONFERENCE

The multidisciplinary conference involves the presentation and review of every case by a team of clinicians representing neurosurgery, anesthesia, orthopedics, internal medicine, behavioral health, and nursing. Patient suitability for surgery and potential pre-surgical interventions are discussed amongst the team for each case presented.

A PATIENT EDUCATION COURSE

The patient education course includes patients and their caregivers. Nurses review the surgery preparation and post operative care processes with patients in a group setting in order to provide realistic patient expectations for recovery.

A DUAL-SURGEON INTRAOPERATIVE APPROACH

The dual-surgeon approach involves two attending surgeons with training in neurosurgery and orthopedic surgery con currently performing the complex spine procedure.

A SPECIALIZED AND DEDICATED COMPLEX SPINE ANESTHESIA TEAM

The specialized anesthesia team possesses substantial com plex spine surgery experience and is involved in every complex spine case. They are integral to the review and preoperative assessment of every case during the conference as well as providing anesthesia support during surgery.

INTRAOPERATIVE PATIENT MONITORING

Intraoperative patient monitoring involves the regular and timely collection of critical data during the procedure to facilitate safe intraoperative decision making. Data on coagulopathy and blood loss are collected and displayed in the operating room for all to see. The surgical team regularly pauses to review laboratory values and the patient's status.

Details of the protocol and initial data on outcomes after implantation were first published by Sethi et al. in 2014. [73] Further detail associated with the preoperative component of the protocol was published by Buchlak et al. in 2016. [35] An evaluation of the Seattle Spine Team Protocol suggested that the implementation of this systematic multidisciplinary quality improvement initiative was associated with a significant reduction in complication rates. Patients exposed to the improved protocol experienced significantly lower rates of unplanned return to the operating room. They also experienced significantly lower rates of wound infection, DVT and pulmonary embolism, postoperative neurological complications, and UTI. [73]

A collection of key factors have been integral to the success of the protocol. It was created by a multidisciplinary team as a result of a “stop-the- line” event. A comprehensive review of the system was initiated, guided by process improvement principles and techniques. The improvement team conducted a comprehensive review of current research, the care system and organizational factors and engaged in a detailed protocol redesign process. The team also defined and benchmarked clear performance measures. Improvement efforts were allocated sufficient resources by organizational and institutional leadership. The protocol is subject to continuous evaluation, review, and improvement over time. Perioperative performance data is collected, tracked, and analyzed. All employees involved in the delivery of the protocol are empowered and encouraged to highlight potential risks and to suggest improvement. These improvement suggestions are considered thoughtfully by the team, discussed, trialed, and implemented. [35]

QUALITY AND SAFETY IMPROVEMENT AT JOHNS HOPKINS MEDICINE

Pronovost et al. [92] discussed the implementation of a quality and safety performance improvement initiative at Johns Hopkins Medicine, guided by the principles of high reliability science and a tailored conceptual model. [93] The goal of the initiative was to ensure that patients received recommended care at least 96% of the time. Targeted core measures included (1) cardiac surgery glucose control, (2) surgery patients on beta-blocker therapy before admission who received beta-blocker treatment during the perioperative period, (3) urinary catheter removed on postoperative day 1 or 2, (4) acute myocardial infarction percutaneous coronary intervention within 90 minutes, (5) provision of heart failure discharge instructions, (6) blood cultures performed for pneumonia patients in the emergency department before initial antibiotics received in hospital, and (7) children’s asthma care home management plan. A tiered organizational design was set up to implement the initiative. Each tier (system, hospital, department, unit) incorporated a similar organization of people with the right skills, quarantined time and accountability for the performance of the initiative. A governance structure was set up to oversee the initiative and monitor vertical inter-tier connections . Horizontal connections were also facilitated to share information and social norms between clinical teams. Five hospitals participated in the initiative. A set of core measures was developed to assess performance. The leadership team defined and communicated clear goals and measures for the initiative. The initiative was well structured, resourced, and enabled with a clear view to building the right organizational capabilities. Improvement groups were multidisciplinary, involving physicians, nurses, information technology staff, quality improvement staff and process improvement specialists. Baseline measures were taken for performance metrics and these metrics were monitored throughout the initiative. Clinical workgroups were formed to examine processes and identify barriers and best practices. Standard process improvement tools were used by improvement teams to analyze failures and improvement opportunities. Transparent reporting was established, taking the form of a hospital-level dashboard that displayed performance on core measures by month. When a hospital fell below the 96% threshold a performance review process was activated. Repeatedly missing performance targets progressively escalated the performance review process. This quality and safety improvement initiative led to improved performance on the core care process measures. Six of the seven targeted measures met or exceeded the 96% performance threshold after implementation and some hos pitals involved received industry awards. [92]

SURGICAL CHECKLISTS

The implementation of surgical checklists as quality and safety improvement tools has been widespread. Research suggests that the full (rather than partial) implementation of checklists, including sign-in, time-out, and sign-out is associated with reduced complications after surgery. [94] Mayer et al. [94] demonstrated a 14% reduction in complications associated with full checklist implementation and Kwok et al. [95] showed a significant reduction in surgical complications with the implementation of surgical checklists. A systematic review conducted by Russ et al. [96] suggested that checklists improve teamwork and communication in the operating room. Research conducted in the UK suggested that improving the communication and interaction of surgical, anesthetic, and intensive care teams reduced the risk of avoidable surgical mortality. [21] Not all studies assessing the utility of checklists have been so optimistic , however. Urbach et al.'s study showed a significant reduction in complications in six hospitals countered by a significant increase in three other participating hospitals, and demonstrated no significant reduction in 30-day mortality.

Checklists and decision support frameworks from high technology industries have been used to improve the quality and safety of the handover process from surgery to intensive care. These methods have been shown to reduce technical errors, handover information omissions, and handover time. [97]

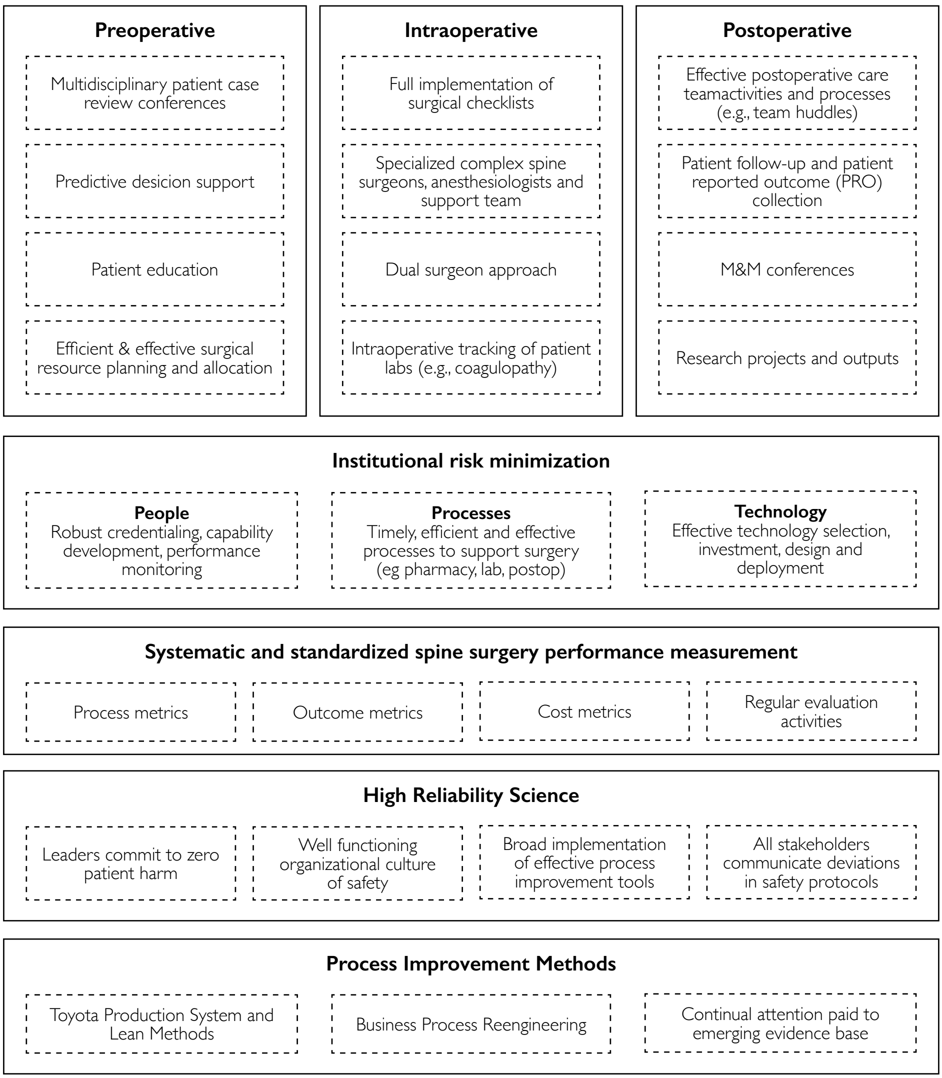
THE SURGICAL INFECTION PREVENTION PROJECT AND THE SURGICAL CARE IMPROVEMENT PROJECT

Surgery-related infection prevention is an area of quality improvement that has received substantial attention in the literature. Research efforts have been focused on (1) assessing antibiotic type, efficacy, and timing and (2) developing new infection prevention approaches. [98] Prophylactic antibiotic treatment has been linked with shorter hospital stays, less patient discomfort, and reduced cost of care [99,100] Studies have suggested that the timing of antibiotic administration is a risk factor for infection and these findings have led to the inclusion and refinement of infection prevention cues in surgical checklists and timeout processes. [59, 101-104]

Major surgical quality improvement initiatives were implemented by the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention in the United States to decrease morbidity and mortality resulting from postoperative surgical site infections. These initiatives included the Surgical Infection Prevention Project (SIPP) and the Surgical Care Improvement Project (SCIP). [59,105] The SIPP involved a 1-year collaboration between 56 hospitals and 43 Medicare Quality Improvement Organizations, which tested SSI prevention approaches and facilitated the spread of improvement approaches between health services. [59] Participating hospitals showed improved antibiotic timing, antimicrobial selection, and duration of antibiotic therapy. These hospitals also improved on a range of process measures designed to reduce SSis. Overall, these hospitals demonstrated a 27% reduction in their SSI rates on average. [106] The success of the SIPP led to the implementation of the SCIP. The SCIP expanded efforts to standardize approaches to prevent four key categories of surgical complication: infection, venous thromboembolism, cardiac events, and respiratory complications. The SCIP articulated a clear set of process and outcome performance measures. [59,107,108] Multiple research articles suggested that adherence to SCIP guidelines was associated with reduced SSI rates, [109,110] while some stood in opposition to this link. [1 11, 104] Pastor et al. [112] suggested that the SCIP measures are not enough to prevent

SSis in some contexts and Awad [113] stated that additional factors are important and necessary in reducing complications, including the capability of the surgical team, and the promulgation of an organizational culture of quality and safety.

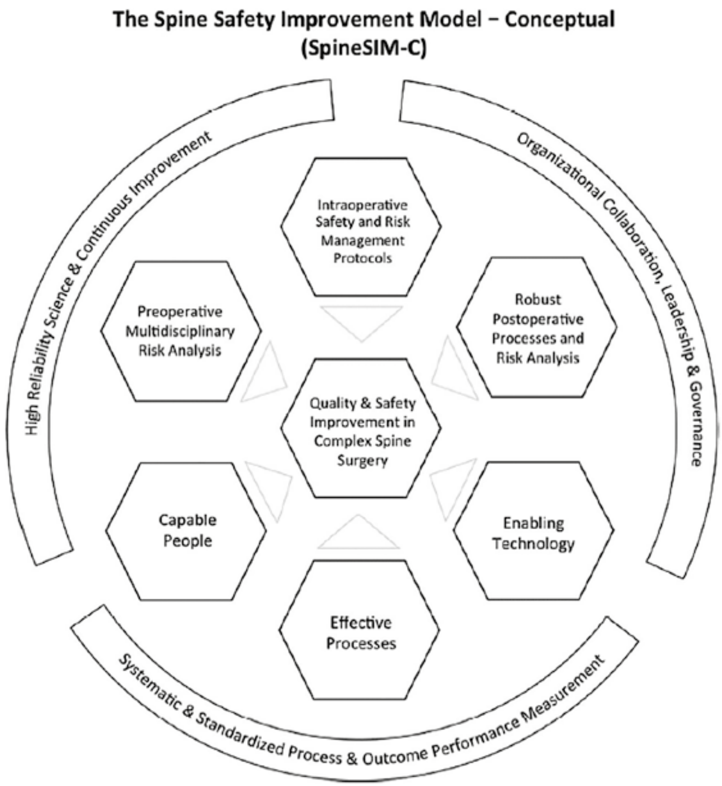
FIGURE 1. The SpineSIM-D: a detailed synthesis of key success factors for achieving quality and safety improvement in complex spine surgery, weaving together improvement approaches that operate at the individual, team, and organizational levels.



KEY SUCCESS FACTORS

A detailed conceptualization of key success factors for achieving quality and safety improvement in complex spine surgery is presented in Figure 1. This detailed Spine Safety Improvement Model (SpineSIM-D) aggregates insights from the research and improvement initiatives reviewed. It weaves together improvement approaches that operate at the individual, team, and organizational levels to generate a comprehensive approach to delivering the best, high value, spine care. The components of the Seattle Spine Team Protocol [73, 35] are evident in the three broad stages of the patient care continuum. Improvement and performance monitoring methods that are relevant and important across the entire care continuum underpin the care delivery process in the model.

FIGURE 2. The SpineSIM-C: a distilled conceptual model to guide organizational quality and safety improvement initiatives in complex spine surgery.



CONCLUSION AND FUTURE DIRECTIONS

Quality and safety improvement initiatives and approaches have been reviewed and analyzed, with a particular focus on their relevance to complex spine surgery. A key component of quality and safety improvement initiatives, from high reliability science to the Toyota production system and the Seattle Spine Team Protocol, is the presence of a multi disciplinary improvement approach and the empowerment of all participants in the operative care process, across all levels of seniority, to identify improvement opportunities. Figure 2 distills the core concepts of the SpineSIM-D, and lessons learned, to generate a complementary conceptual model, the SpineSIM-C, which may be used to guide future organizational quality and safety improvement initiatives in complex spine surgery.

Risk reduction can clearly be achieved by focusing on specific components of clinical care. Many studies have demonstrated reductions in complication rates as a result of improvement in focused clinical care processes (e.g., infection prevention). However, this is not enough. Focused components of best practice clinical care should be coupled with systematic multidisciplinary organizational and broader process improvement efforts to achieve maximal quality and safety improvements in spine surgery. The potential for highly skilled clinicians to deliver the best patient outcomes through evidence-based clinical practice may be inhibited if broader organizational approaches to risk mitigation, communication, leadership, patient management, and process improvement are suboptimal.

Well-designed quality and safety improvement initiatives that adhere to ACS guidelines and evidence-based methods can reduce the risk of poor patient outcomes in spine surgery. Quality and safety improvements in spine surgery appear to have been achieved with multidisciplinary proto col designs based on the principles of continuous improvement and full (not partial) implementation of surgical checklists. It appears that systematic, multidisciplinary approaches to the delivery and refinement of surgical care is essential in maximizing quality, safety, and value in complex spine surgery. Future research may focus on the potential for applying predictive modeling and other innovative technologies to achieve further quality and safety improvements.

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CHAPTER 7

IMPROVING COMPLEX PEDIATRIE AND ADULT SPINE CARE WHILE EMBRACING THE VALUE EQUATION

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INTRODUCTION

The value of health care interventions is increasingly a part of the decision-making process by payer groups and government bodies in a world of ever growing focus on resource use in health care. Value is defined as the quotient of outcomes to cost. Both pediatric and adult spinal deformity surgeries are among the most expensive procedures offered today. With high variability in both outcomes and costs in spine surgery today, surgeons will be expected to consider long-term cost effectiveness when comparing treatment options. Herein, we discuss methods to help standardize protocols for patient safety and effectiveness as a means to improve outcomes, reduce unnecessary costs and ultimately drive up the value of complex spine care. Ultimately, systemwide improvements will be crucial to the improvement of value delivered in complex spine surgery.

This manuscript will describe standard pathways in pediatric and adult complex spine care specifically focusing on methods to achieve these pathways. We will describe team-based strategies to improve health care specifically documenting the experience of a pediatric spine OR team with further emphasis on the cultural aspects of team building. Finally we will address the topic of two attending surgeons, mentoring, and continuous improvement of outcomes via registry experience.

STANDARDIZATION AND STANDARD PATHWAYS: THE PEDIATRIC EXPERIENCE

Transition to more standardized postoperative care pathways following posterior spinal fusion for adolescent idiopathic scoliosis have increased in popularity based on the homogeneity of this patient population and the potential benefits offered by less variability in care. A variety of published techniques exist to guide hospitals in the creation of a postoperative pathway including more standardized methods focused on limiting wasted steps (ie, LEAN/Six Sigma) [1-3] and creating standardized processes involving stakeholders from multiple service lines [4-11]. Much of this work has been championed in complex adult spine cases by Rajiv Sethi and his team in Seattle and has led to the designation of "centers of excellence" by American payer groups where complex spine cases are referred to centers on the basis of quality and value. Commonalities exist among these pathways. Patients are typically sent to the surgical floor rather than the intensive care unit [12] and are initially placed on intravenous (IV) narcotics/antispasmodics for pain control. Oral intake, usually with liquids beginning immediately after surgery, is advanced as tolerated rather than waiting on a return of bowel function. Transition to oral pain medications occurs early, usually as soon as the patient is tolerating liquids, often on postoperative day (POD) 1. An epidural catheter is usually avoided because of difficulty mobilizing patients. Published pathways encourage regular physical therapy two to three times per day and ambulation beginning as soon as POD 0 [9] or POD 1 [4-6,8,10]. Aggressive bowel regimens are begun on POD 1 and patients are typically discharged before their first bowel movement. Expectations are established regarding length of stay beforehand, with most patients being discharged on the second or third postoperative day. All published reports have shown low complication rates and few returns to the system for gastrointestinal or pain control problems. Cost savings with these strategies will come through reductions in length of stay and potential improvement in readmissions.

STANDARDIZATION AND STANDARD PATHWAYS: THE ADULT EXPERIENCE

As surgeons, we have a tendency to focus on preoperative and intraoperative optimization as a means of decreasing complications. It is important that both of these pathways have intersecting value streams and bring all team members to the discussion. From the patient's standpoint, however, the most relevant timepoints may be the in-hospital stay and the postoperative recovery. Efforts to standardize the discharge and recovery pathway for patients have been successful in general and gynecologic surgery, primarily through the use of Enhanced Recovery After Surgery (ERAS) protocols [13,14]. These protocols include a focus on early ambulation, early removal of drains, and a standardized follow-up plan to ensure that early complications are captured and treated. These types of in-hospital pathways have been applied to pediatric scoliosis patients with improvements in length of stay without an increase in complications or readmissions [9,11,15]. These early discharges lead to a significant cost savings, and one that may eclipse savings derived from changes to intraoperative variables [9,15,16].

The adult population presents novel challenges to the application of these pathways, however. Numerous studies have demonstrated that increasing age is associated with an elevated risk of discharge to a nonhome facility even for nonfusion lumbar procedures.[17-19] Adult patients have more complicating medical issues that delay discharge to home or require discharge to a rehabilitation facility, including delirium, increased risk of urinary retention, decreased ambulation, and an increased comorbidity score [17,19-21]. The complexity of these patients may require development of comanagement pathways coordinating care between surgical and medical teams, analogous to the care typically provided for pediatric patients by an orthopedic spine team and general pediatric service. Early attempts at co-management for geriatric patients have led to promising results, with a decrease in immobilization time after surgery, a shorter length of stay, and an increase in the number of patients discharged to home rather than another inpatient facility [22].

LEAN OPERATING ROOM TEAMS

Lean methodology developed in the manufacturing industry as a way to increase output while decreasing costs. These methods are increasingly being used in health care to similarly drive value through improving outcomes while decreasing costs. At a major tertiary children's hospital in the United States, the spine team created an interdisciplinary, dedicated team for spinal fusion for scoliosis. Members developed standardized protocols for anesthetic management, transport, patient positioning, prep, draping, imaging, and wake-up. These protocols were initially implemented with a small interdisciplinary team, including one surgeon (Phase 1), then expanded (Phase 2). The team compared Dedicated Team cases to cases performed without a Dedicated Team (Casual Team). Because of the heterogeneous nature of PSF for scoliosis, they developed a novel case categorization system: Category 1 - relatively homogeneous, patients with <1 2 level fusion, no osteotomies, and body mass index <25; Category 2 - more heterogeneous, patients with >1 2 level fusion, and/or >1 osteotomy, and/or body mass index >25. Dedicated Team cases used significantly less OR time for both Category 1 and 2 ($p<0.001$). In Category 1 cases, the average reduction was 111.4 minutes (29.7%);

in Category 2 cases, it was 76.9 minutes (18.5%). The effect of the Dedicated Team was scalable: the reduction in OR time was significant in both Phase 1 and 2 ($p<0.001$). The Dedicated team cases had no complications. Cost reduction averaged $8900 for Category 1 and $6000 for Category 2 cases. By creating a Dedicated Team and standardizing several aspects of PSFs for scoliosis, the team achieved a large reduction in OR time. This increase in team efficiency was significant, consistent, and scalable. The team now routinely complete two Category 1 PSFs in the same OR with the same team in standard block time (unpublished results). As clinical teams embrace LEAN principles to reduce waste and enhance cost effectiveness, it also behooves others like implant companies and hospital administrations to lower costs and deliver greater value to the patient.

TEAM-BASED APPROACHES

Building a cohesive team is crucial for the coordination of care for patients undergoing these complex surgeries. Comprehensive Unit Based Safety Program (CUSP) were originally developed as a framework for improving safety and teamwork in the intensive care unit (ICU) setting (ahrq.gov). After remarkable success in reducing rates of central line-associated bloodstream infections (CLABSIs) and catheter-associated urinary tract infections (CAUTIs) across hundreds of ICUs [23, 24], CUSP has now been adapted to many health care settings. Implementation of CUSPs in perioperative care has been associated with lower surgical site infection (SSI) rates, fewer surgical errors, fewer operating room delays, and improvements in surgical unit culture [25-28]. Surgical CUSP implementation addresses two critical barriers to surgical outcomes improvement: (1) protocols and checklists used to standardize practice, although necessary, are not sufficient to maximize quality and safety [29-32], and (2) poor teamwork and communication culture, while associated with worse surgical outcomes, are challenging to address [33-37].

The training elements of CUSP programs provide team members with core concepts of process defect identification and teamwork/communication known to enhance surgical safety culture [37,38]. Each multidisciplinary CUSP team with members ranging from scrub technicians, to surgical and anesthesia attendings then engages in creating a front-line provider driven learning health systems infrastructure within the unit [38,39].

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This is accomplished through developing strategies for briefing/debriefing on surgical cases[40,41], collecting reliable data for surveillance, and building trust-accountability processes [27]. Researchers affiliated with the Safety in Spine Surgery Program (S3P) and the Pediatric Orthopedic Society of North America Quality Safety Value Initiative (POSNA QSVI) have been actively studying CUSP implementation in complex spine surgery units with promising preliminary results in SSI prevention, culture, and other quality metrics.

CONTINUOUS MENTORSHIP AND DUAL ATTENDING APPROACHES

The breadth and complexity of techniques in deformity surgery has grown in recent years. As a result, more trainees are completing multiple fellowships [42-45]. There is also increased interest in the role that the first assistant plays in surgical outcomes [46,47]. Some authors have reported shorter operative times and less blood loss with a dual surgeon strategy [48,49], whereas others have not found such advantages [50]. One aspect of dual surgeon surgery not assessed in current literature is the potential of an accelerated learning curve for junior surgeons. Another aspect that is not addressed by the literature is the seniority or experience of each of the two attending surgeons when dual attending surgeon approaches are discussed.

There is currently no test of neuromuscular aptitude during the selection of spine fellows by programs or for more prestigious memberships like the Scoliosis Research Society. Future educational assessments need to be standardized and developed around such skills that are essential for spinal deformity surgeons. Also, many fellowships vary in the experience they provide their respective fellows. This may not be known to the fellow applicant or to the practice that hires the spine fellowship graduate.

Cahill et al. [51] showed increasing surgeon experience is related to better surgical outcomes. Perhaps a paradigm shift is needed in which senior surgeons commit time to the continued training of junior partners during the initial years of the younger surgeon's practice. The reality of fee-for-service medicine in the United States often precludes this in many centers.

Responsibilities can be shifted from the senior to junior surgeon during complex cases. Initially the senior surgeon takes the lead on complex cases. The decision making is gradually shifted to the junior partner, with the senior surgeon providing a supportive role during subsequent cases. Over time, the junior surgeon accumulates knowledge from the senior partner and can pass that experience on to the next junior surgeon. The model allows early career surgeons to have ultimate responsibility for their patients while providing a senior surgeon "safety net" to facilitate patient safety during the junior surgeon's learning curve. Recognition of the safety and value added to patient care through accommodative reimbursement is paramount to surgeon support of such a model. As discussed above, payment models do not adjust for this type of training and many senior surgeons would be seen as "less productive" when helping junior partners since they are not doing their own cases.

TRACKING OUTCOME METRICS THROUGH DASHBOARDS

Efforts to improve value while maintaining quality in complex pediatric and adult spine care are critical to control costs, provide access and ensure sustainability. The electronic medical record (EMR) provides robust, readily accessible data for analysis and evidence-based decision making, but assembling the myriad of information in an effective, useful way was challenging. A dashboard is a data-driven clinical decision support tool that can query, assemble, and distill multiple databases and present a visual representation of key performance indicators in a single report, much like the dashboard display in your automobile. These easy-to-read, color-coded clinical decision supporttools can be usedto promote data-driven decision making and improve adherence to evidence-based practice guidelines, organizational goals, manage specific conditions, or monitor concerted efforts for complication reduction. The dashboard as a reporting application fits well into the valuebased health care model promoted by Porter [52].

The five basic principles regarding dashboards are as follows: type of database integration, visual properties (color coded, intuitive, allowing at-a-glance interpretation), purpose (benchmarking, notification or warning, feedback for clinical decision making), time focus (retrospective, real-time, or predictive), and type of process monitored (patient safety, structure, process, or outcomes oriented) [53]. Numerous authors have described EMR integration, methodology of dashboard development, physician engagement, actionable intelligence, usage principles, and continuous improvement of the dashboard that are critical for success that ultimately enhances learner performance, patient care, and outcomes [54,55].

Dashboards have been used in the corporate suite for institutional decision making and now at all levels of health care organizations. Successful use of dashboards has improved workflow in patient care departments, such as emergency rooms, operative suites, and maternity wards and to support clinical decision making.

Two applications for dashboards in spine surgery are discussed here. The Harms Study Group comprises 10 institutions of high-volume pediatric spinal deformity surgery and prospectively collects demographic, radiographic, and patient-related outcomes data, as well as intra- and postoperative process measures and complications. Dashboards reports are circulated biannually to allow surgeons to gauge their performance and outcomes benchmarked relative to the group and determine adherence to best practice guidelines. These dashboards have improved operative times, decreased intraoperative blood loss, and decreased length of stay after implantation and sustained improvement or reduction three and five years later [56]. Furthermore, the dashboards have identified high performers who can help formulate best practice guidelines and, alternatively, have highlighted outliers more prone to complications and practice variability that have taken advantage of opportunities to improve quality and standardize processes. The Department of Neurosurgery at the University of California, Los Angeles, created a quality dashboard and demonstrated that it was a powerful tool to help manage process measures, quality and safety, patient satisfaction, improvement strategies, and monitor impact [57].

Concerns about dashboards include human and capital expenditure, sustainability, user anxiety, use of this information to compare providers or institutions in a negative light, information overload, and technology overload. Furthermore, ongoing efforts should be made to ensure that the data being collected is, in fact, an accurate and timely representation of the process or outcome being measured or studied. Although there is concern about the loss of physician autonomy in an era where more spinal surgeons are employed, active involvement of surgeons in the creation of dashboard metrics based on the principles of evidence-based medicine will enhance safety, quality, and value.

RIGOROUSLY MONITORING OUTCOMES THROUGH REGISTRIES

Standardization of treatment outcomes measurement, including systematic and continuous outcome monitoring from a patient's perspective is important to assess the value of care delivered, that is, outcomes relative to cost, and future reimbursement [52]. Treatment outcomes are thought to matter most to patients, reflect the end result of all aspects of care [52], and could be regarded as a proxy for quality of care. In two recent AOSpine knowledge forum deformity studies concerning the appropriateness of surgical care for adolescents with idiopathic scoliosis and adults with spinal deformity, international consensus was reached to systematically monitor patient-related outcomes (ie, patient-reported outcome measures [PROMs] and clinician-based outcome measures), including factors for risk assessment and surgical planning [58]. In order to support the evolvement of appropriateness of care, patient outcomes should be closely monitored and prospectively documented in a registry [58].

Outcomes monitoring through a registry is expected to contribute to quality improvement. An outcome registry is an organized system that uses observational study methods [59]. The data could be used to describe care patterns, including appropriateness of care and disparities in the delivery of care [59]. Although promising, the systematic review showed a lack of evidence that outcome registries actually have an impact on the quality of spine care [59]. In order to improve the quality of evidence of current outcome registries, various recommendations were reported. These recommendations are related to the organization and methodology of a (spine) outcome registry, the outcomes and related contributing casemix and risk factors that should be registered, data analysis, reporting of results, and practical issues.

Following these recommendations, outcome registries could serve different goals: individual patient care evaluation, continuous evaluation of quality of care delivered in a defined subgroup of patients, case-mix, and risk-corrected benchmark between professionals and institutions, value based health care, research (eg comparative effectiveness), and more specifically decision support. To enhance standardization and the quality of spine deformity care, we recently reached international consensus on a standard set of outcomes for adolescents and young adults (AYA) with a spine deformity undergoing reconstructive surgery [60]. Currently, we perform a large project to achieve a comparable international consensus-based standard set of outcomes for adult spine deformity, based on a systematic review [61].

In Sint Maartenskliniek (a Netherlands-based clinic), all patients undergoing spine deformity surgery are systematically monitored over time and registered in an online web system since March 2014 that is connected to the patients' electronic medical records. Routinely, for AYA undergoing deformity surgery, relevant patient characteristics and outcomes following the standard set [60], radiologic, and perioperative parameters are measured and captured. Recently, the short-term outcomes of surgery at one-year follow-up were presented [60]. The clinical relevancy of patient-reported outcomes is determined by means of previously reported minimal clinical important changes (condition-specific health-related quality of life; Scoliosis Research Societye22r questionnaire scores) and a satisfactory symptom state, comparable to healthy persons (ODI v2.1a). Patients undergoing surgery for idiopathic scoliosis experience a relevant improvement in functioning, health related quality of life, self-image, and satisfaction. The number of registered complications and revision surgeries are relatively low [60]. A two-year follow-up study is currently being performed.

CONCLUSIONS

Critically examining value is a crucial component of improving the delivery of complex spine care. Improving value in turn requires us to examine both quality and cost of care. Value can be improved through either the improvement of quality or the reduction of cost. However, as we have demonstrated, many value-based initiatives simultaneously address both of these contributors to the value equation. Standardization and team-based approaches simultaneously strive to deliver consistent high-quality results while reducing unnecessary costs that do not contribute to the desired outcomes. Similarly, eliminating variability through lean methods and continuous process improvement can lead to ever-increasing value. In an era of value-conscious care, surgeons have the unique opportunity to drive these initiatives in a way that is focused on delivering the best patient care possible. The authors of this study represent pediatric and adult academic complex spine surgeons. Many of the authors focus on health services research where systems are studied in detail. Sethi et al. have recently published their algorithmic approach for a spine safety improvement model [62,63]. Figure 1 demonstrates the conceptual framework and Figure 2 demonstrates a more detailed analysis. Dashboards and registries will allow users to assess whether the items in Figure 2 are leading to less variability and more predictable outcomes. It is clear from this work that multiple interweaving efforts as those discussed in this manuscript will enhance the patient experience and increase value. Without surgeon leadership in this arena, suboptimal solutions may result from the isolated intervention of regulatory bodies or payer groups. The cooperative development of standardized, team-based approaches in complex spine surgery will lead to the high-quality, high-value care for patients.

FIGURE 1. The Spine Safety Improvement Model-Conceptual (SpineSIM-C). Adapted with permission from Sethj R et al. Quality and safety improvement initiatives in complex spine surgery. Semin Spine Surg 2017.

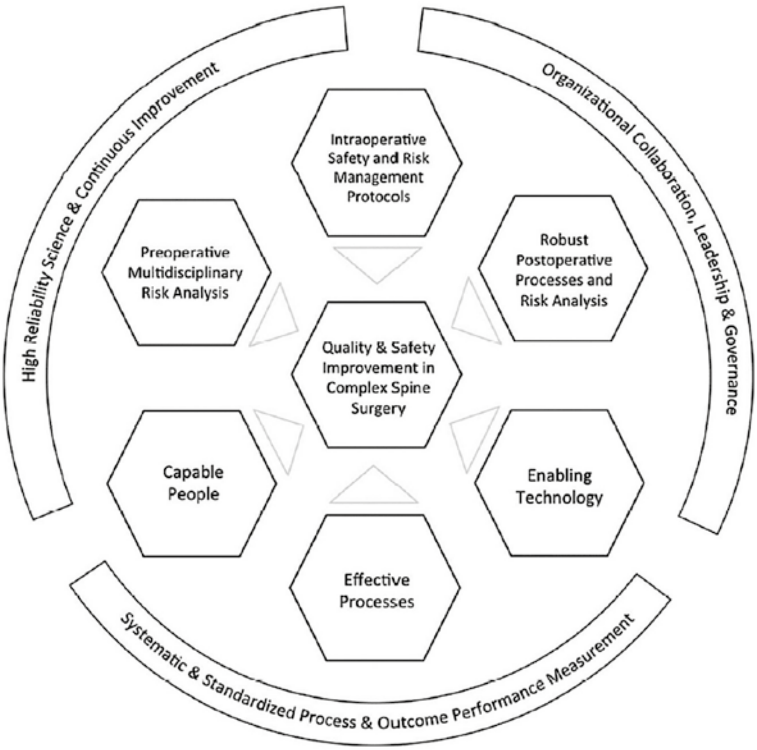

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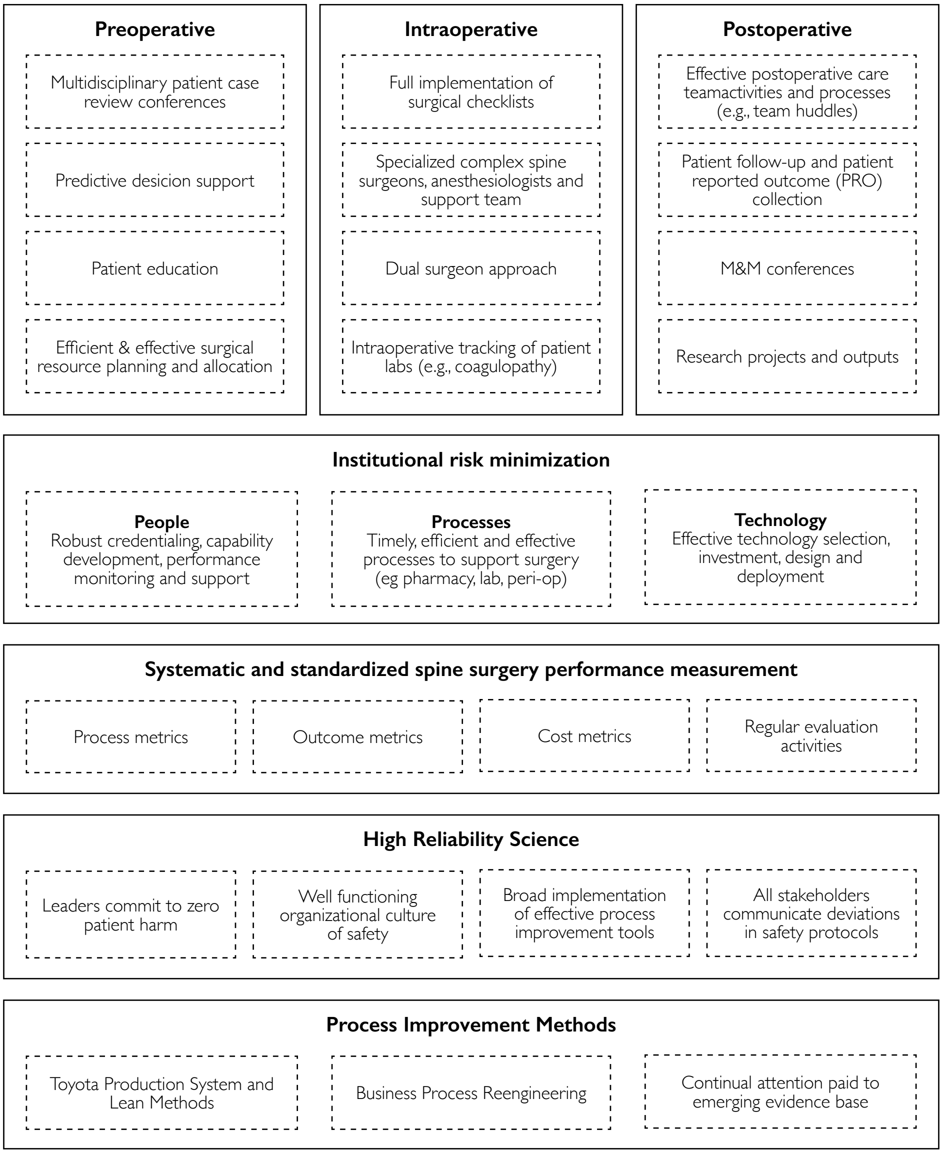
FIGURE 2. The Spine Safety Improvement Model-Detail e d (SpineSIM-D). Adapted with permission from Sethi R et al. Quality and safety improvement initiatives in complex spine surgery. Semin Spine Surg 2017.



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CHAPTER 8

HOW ONE HEALTH SYSTEM COMBINES TELEMEDICINE AND HANDS-ON CARE

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Until the Covid-19 pandemic struck, surgical patients in the U.S. had been increasingly traveling to designated Centers of Excellence, health systems that met stringent criteria for providing exceptional, high-value care for specific procedures such as knee replacement and spinal surgery. In some cases, large employers such as Walmart entered into contracts with the COE providers to care for their employees, whose travel to the specified provider for evaluation and, if needed, surgery, would be fully covered. In other cases, patients would travel from afar using other coverage to receive this specialized care.

Our institution, Virginia Mason, along with others including Geisinger, the Mayo Clinic, and Johns Hopkins are designated Centers of Excellence. Among the services patients have traveled to us for are complex spine surgeries, one of the most challenging procedures.

By shutting down most travel, the pandemic might have put an end to such programs, at least for the duration . But at Virginia Mason, prior investments in telemedicine technology for virtual patient encounters and virtual multidisciplinary perioperative clinical-team conferences have allowed us to continue providing surgery and other spine care to both local and remote patients traveling from hundreds or thousands of miles away, as well as to enhance virtual patient care broadly.

THE SPINE TEAM APPROACH

Based in Seattle, we were among the first organizations to confront the Covid-19 pandemic and, as such, had no blueprint to guide our response . Regulatory guidelines were constantly evolving and there were widespread shortages of personal protective equipment (PPE). Travel restrictions were keeping patients from many states away from Seattle and, fearing infection with the novel virus, local patients were deferring needed care. A ban on elective procedures resulted in precipitous and profound decreases in clinical care revenue and financial pressures were intensifying.

The pandemic forced us to quickly respond to novel clinical challenges, but we also needed to develop new ways to coordinate our sophisticated care teams and to safely engage with patients, including those traveling to Virginia Mason for complex spine surgery.

Like many leading organizations, Virginia Mason emphasizes a multidisciplinary approach to value based care, which focuses on improving outcomes while reducing costs. The "Seattle Spine Team Approach" is a fully developed example of such comprehensive and condition-specific care. This model involves pre-surgical team conferences (now held virtually) that include orthopedic surgeons, neurosurgeons, physiatrists, pain medicine specialists, specialty-trained nurses and physician assistants, hospitalists , psychologists, and anesthesiologists . These conferences, along with the requirement that two attending surgeons are present during complex spine surgeries and the institution of a tailored intraoperative anesthesia protocol, have resulted in a three-fold reduction in major complications in the most complex spinal procedures. Many team members see these conference as the cornerstone of the entire spine care program.

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When a patient is referred for spine surgery, the team holds a virtual "patient clearance" conference to evaluate whether he or she will decisively benefit from the procedure or may be as effectively treated without it. (In our prior studies of in-person visits where referred patients were presumed to need lumbar surgery, we found that 58% in fact didn't need it.) For those patients found to be good candidates for surgery, the team conducts a risk stratification to determine which require immediate surgery and begins pre-surgical "optimization," evaluating patients for surgical risk factors such as obesity, diabetes or smoking. In non-urgent cases, the team postpones surgery to allow time to address these.

Our clinicians have embraced the virtual conference format. We have seen increased attendance and continued engaged discussion by our clinical staff. Further, providers who rotate between clinical sites can attend these more easily than the previous physical meetings. As a result, the spine team has now committed to all-virtual patient-clearance conferences as its "new normal" and expects to continue with these virtual conferences even after restrictions on in-person meetings are lifted .

COMBINING VIRTUAL AND HANDS-ON CARE

A recent case illustrates how we are integrating traditional destination care and new virtual care models. A 57-year-old man from Alaska had been experiencing progressive weakness in his arms and legs and for several weeks was unable to get timely outpatient evaluation because of the pandemic. As his symptoms became severe, his local doctor referred him to one of our physicians. The team held a virtual care conference and the same day a consultation with his local doctor, determining that the patient would require complex cervical spine reconstructive surgery. Within a day of those meetings, the patient was on a plane from Alaska to Seattle where he was scheduled to undergo immediate surgery at Virginia Mason. Two weeks later, the patient returned to Alaska and all further communication with the patient and his local doctor has been conducted virtually. Within three months after surgery, the patient had regained full use of his arms and legs and returned to work. We are continuing to follow him through serial virtual visits that include his surgeon, specialized spine physician assistants, rehab physicians and pharmacy.

While the pandemic hasn't substantially interrupted our destination care program for patients needing urgent specialized spinal surgery, it has underscored the less dramatic, but equally important element of the program - it's focus on identifying candidates for surgery who in fact can be effectively managed without it. It's now clear that, going forward, many nonsurgical patients could receive a comprehensive evaluation and treatment without physically traveling to Seatt le. These patients can be managed virtually by our non-operative spine specialists and continue their treatment plan without travel-related interruption. With virtual multidisciplinary care we have actually increased access to quality care while, with the decrease in required travel, dramatically reducing the costs of evaluation and treatment .

Acknowledging the terrible human suffering and financial toll of Covid-19, we anticipate some positive lasting changes. Virtual multidisciplinary conferences and telemedicine allow us to provide our model of care to all patients, not just those in COE programs. For patients back home after surgery, telemedicine allows for close and timely follow-up without the burden of travel. Virtual multidisciplinary conferences can improve care by allowing same-day, real-time assessments of the urgency of patients' needs and facilitating immediate triage. In addition, they can serve as a consult resource for patients' local providers. The potential silver lining of the current Covid crisis may be its role as a catalyst to enable a better paradigm of value-based care.

CHAPTER 9

SUMMARY AND GENERAL DISCUSSION

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SUMMARY AND GENERAL DISCUSSION

Many developed countries, including the United States, are experiencing an unprecedented shift toward an aging population. Adult Spinal Deformity (ASD) is increasingly being recognized as a heterogeneous disease entity that extends far beyond a seemingly benign adolescent idiopathic scoliosis that persists into adulthood, and it disproportionately affects the elderly. It is associated with a high financial and clinical burden on society. With an expanding elderly population, ASD has become an area of major research and quality improvement focus over the past 20 years, and major advances in the surgical management have occurred. As the complexities of the spinal deformities that exist in these patients are becoming understood, the cost conundrum will expand and become more significant. ASD care thus requires improved insights in costs and its drivers as a critical step toward the improvement of value, i.e., the ratio between delivered health outcome and associated costs.

The general aim of the research presented in this thesis is to develop and evaluate approaches for improvement of quality and safety in complex spine surgery with a focus on value-based care.

The importance of this work is underscored by variability in care pathways, cost conundrums in the setting of more patients seeking treatment for ASD. Quality improvement is key to the future of surgery. Quality is defined as the degree of excellence of care (as measured with outcomes of care) and safety is defined as the reduction of harm to a patient (disutility of care). Quality and safety improvement initiatives in spine surgery have recently been designed, evaluated, and published by multiple care teams and have been presented in this thesis. These initiatives have focused on a spectrum of improvement domains, including implementing checklists, improving clinical decision making, emphasizing multidisciplinary approaches, and improving communication and information flows. Multiple recent quality and safety improvement initiatives in spine surgery have been reviewed here and avenues for future improvement are considered.

Many examples of quality improvement studies focusing on one aspect exist in the field of spine surgery, including investigations of surgical planning strategies, intraoperative vancomycin use to reduce the rate of post-operative wound infections, surgical staging, intra-operative neurologic monitoring to reduce the incidence of neurologic injury, use of intra-operative bone morphogenetic protein to reduce the rate of pseudoarthrosis, and operating with two attending surgeons. The complexity of ASD as an entity in combination with the complexity of the decision making and complexity of the operating room environment require a systems approach to improving outcomes and with that to improve the value of care. The published examples of systematic multidisciplinary systems improvement initiatives in complex spine surgery are increasingly demonstrating the generalizability of these approaches. Groups have developed protocols to reduce specific surgical complications individually and, increasingly, research suggests that comprehensive, standardized, systematic perioperative care protocols can reduce the rates of multiple complications holistically. [16, 17] The resultant decrease in the constellation of complications associated with spine surgery has the potential to improve care quality and patient outcomes, reduce cost and generate improved healthcare value. Future research should evaluate each of these areas separately and within the context of different healthcare systems in well- developed high-quality systems like those in Seattle and Nijmegen.

SPECIFIC RESEARCH AIM 1: TO INTRODUCE LEAN CONCEPTS FROM MANUFACTURING INDUSTRY TO SPINE SURGERY

SUMMARY OF MAIN FINDINGS

Chapter 2 of this thesis describes systemwide LEAN processes and how this can be applied to the surgical treatment of a patient with a complex spinal problem to reduce error and waste and start the process of value-based transformation. [9] The manufacturing industry developed lean methodology to increase output while decreasing costs. Lean methods revolutionized manufacturing in Japan, where productivity gains led to Japanese domination of the manufacturing industry in the late 20th century. Motivated by the productivity and customer satisfaction gains made with the use of lean methods in the manufacturing and service sectors, several healthcare organizations have adopted these methods in patient care including the Virginia Mason Medical Center in Seattle where the author of this thesis is currently employed. Lean methodology can be employed to reduce variation in approach, treatment, and outcomes within orthopaedic centers.

Implant inventory and processing is an important function in which the implementation of standard work processes can result in substantial reduction of waste and inefficiency. A standard process has been developed at Virginia Mason Medical Center to understand the indications for both simple and complex spine surgery. In this process, all proposed lumbar fusion and adult spinal deformity surgical procedures are expected to undergo a multidisciplinary approval process in which all healthcare professionals are given an equal voice and the indications are standardized according to the best possible implementation of evidence-based medicine.

A limitation is that the approach of lean methodology cannot be applied in all settings. The more a process can be described in a linear fashion, the more suitable it is for standardization and standard operating procedures. Especially due to the heterogeneity of ASD, and the (non-linear) complexity of the individual patient, not all aspects relevant to decision making or treatment can or should therefore be standardized. Having said that, there must be control of major variables and clinical operators in order to enhance cooperation. The generalizability of the approach of lean methodology and systems approach is seen across different industries including manufacturing and health care, thus highlighting its baseline utility.

FUTURE RESEARCH

The current study has focused on the health care system in Washington state, United States of America. The large differences in health care systems across the world (funding, incentives, staffing, culture etc.) may be expected to strongly influence how quality and safety improvement strategies can be successful (or not). This study was a first that used the approaches of mean methodology and complex systems to evaluate the value of surgical treatment in patients with ASD. Further studies should focus on how lessons learned may be implemented and adapted to the local context and environment, to compare results, to reduce practice variation and in such a way that patients across the world may benefit.

SPECIFIC RESEARCH AIM 2: TO EVALUATE THE IMPACT OF A TEAM AND SYSTEMS APPROACH ON PATIENT SAFETY IN COMPLEX SPINE SURGERY

SUMMARY OF MAIN FINDINGS

Chapter 3 describes the Seattle Spine Team Approach. [10] Complications in complex spinal reconstructive surgery in adults are a frequently observed phenomenon. As the evidence mounts that standardized protocols for high-risk spine surgery patients can reduce complications, spine surgeons are faced with an increasing need to develop strategies and protocols aimed at reducing risk and increasing patient safety. This need is perhaps nowhere greater than in surgical procedures that propose to correct adult spinal deformities, arguably some of the most dangerous and complication-ridden operations in the surgical armamentarium. In chapter 3 two comparable historic cohorts from one institution were studied, and the results indicate that a concerted collaborative approach consisting of a dual attending surgeon team, a complete preoperative screening process, and a robust intraoperative protocol for managing coagulopathy significantly reduced all perioperative complication rates from 52 to 16%, including reduction of unplanned return to the operating room form 12,5% to 0,8%, and reduction in infection rates requiring surgery from 7.5% to 1,6%. This systematic quality improvement effort demonstrated that it can enhance patient safety in patients undergoing complex spinal reconstructions for adult spinal deformity.

Chapter 4 describes the nature of systematic processes from a health services perspective and the nature of complication reduction strategy. [11] The Group Health Research Institute and Virginia Mason Medical Center implemented a systematic multidisciplinary protocol, the Seattle Spine Team Protocol, in 2010. This protocol involves the following elements: 1) a comprehensive multidisciplinary conference including clinicians from neurosurgery, anesthesia, orthopedics, internal medicine, behavioral health, and nursing, collaboratively deciding on each patient's suitability for surgery; 2) a mandatory patient education course that reviews the risks of surgery, preparation for the surgery, and postoperative care;

3) a dual-attending-surgeon approach involving 1 neurosurgeon and 1 orthopedic spine surgeon; 4) a dedicated specialist complex spine anesthesia team; and 5) rigorous intraoperative monitoring of a patient's blood loss and coagulopathy. The authors

identified 71 patients who underwent complex spine surgery involving fusion of 6 or more levels before implementation of the protocol (surgery between 2008 and 2010) and 69 patients who underwent complex spine surgery after the implementation of the protocol (2010 and 2012). All patient demographic variables, including age, sex, body mass index, smoking status, diagnosis of diabetes and/or osteoporosis, previous surgery, and the nature of the spinal deformity, were comprehensively assessed. Patients who underwent surgery after implementation of the Seattle Spine Team Protocol had a statistically significant reduction (relative risk 0.49 [95% CI 0.30–0.78]) in all measured complications, including cardiovascular events, wound infections, other perioperative infections, and implant failures within 30 days after surgery; the analysis was adjusted for age and Charlson comorbidity score. A trend toward fewer deaths in this group was also found.

The primary limitations of this study are that it was a retrospective analysis, it was conducted at a single institution, and we could not control for some differences, including sex and levels of surgical fusion planned. In addition, we could not fully account for the increase in surgeon and anesthesiologist experience as the study progressed. We did all that we could to eliminate sampling bias by applying objective patient-selection criteria, which were applicable across the 2 study periods.

Another limitation of this study is that it focusses on the short term 'disutility of health care' and does not study long term outcomes ('sustainability of health'). Long term complication rates can be up to 40% [18] such as non-union, implant failure and, proximal junctional failures. Recent studies, such as the NIH funded ASLS study [19] have demonstrated that although the re-operation rate is high, five-year results seem to be sustainable, and cost effective. [20]

FUTURE RESEARCH

The current trend in mismatch between the large burden of disease, societal demand and limited available resources of health care systems will continue. This is extremely relevant for patients with ASD due to the continuously aging population age, and rising costs of spinal surgery.

Improving patient selection and identifying the appropriate (surgical) treatment for these patients is paramount and should be given high research priority to reducing costs and disutility of heath care (e.g. complications) whilst improving outcomes.

Large data sets based on outcome registries [21] (such as the American Spine registry [22]), in which the AOASD patient profile [23], including the standard outcome set for ASD [24] are implemented, and that are automatically linked to Electronic Medical Records will be essential to describe care patterns, including appropriateness of care and disparities in the delivery of care. Registry data could also be used to understand variations in treatment and outcomes, and to identify patient profiles and surgical approaches that predict poor or successful outcomes and with that to ultimately increase the value of care delivered. To evaluate this advanced statistics and machine learning techniques may be used as tools to analyze these large data sets and to compare between hospitals and countries.

SPECIFIC RESEARCH AIM 3: TO DEVELOP MODELS FOR PREDICTING COMPLICATIONS AND IMPROVING SAFETY IN PATIENTS UNDERGOING COMPLEX SPINE SURGERY

SUMMARY OF MAIN FINDINGS

Chapter 5 brings forward the concept of predictive analytics specifically to enhance the value equation and begin the discussion of predictive analytics coupled with healthcare economics [12]. The population of patients with spinal deformity requiring surgical treatment is growing. With the move towards value based care, surgical care for these patients is being rewarded for higher quality with controlled cost.

Efforts to improve the selection of appropriate patients by improving accuracy of surgical decision-making and development of data-driven risk stratification methods are likely to improve patient safety and outcomes, and thereby will increase the overall quality and value of spine surgery care. This study has demonstrated that an internally validated model, including seven routinely collected risk factors, namely age, smoking, hypertension, diabetes, female gender, high BMI, and anemia as input for the "Seattle Spine Score" (3S), can predict risk of complications and post-operative wound infections, with a predictive accuracy of 75%.

Evidence-based medicine involves the application of decision theory to mitigate cognitive limitations and reduce systematic biases and errors. The application of the decision support tool significantly improved the ability of physicians to accurately predict whether or not patients would be likely to experience postoperative complications, suggesting that the tool was able to positively influence the quality of clinical judgment. By providing a clear prediction of risk, it may allow the surgeon and preoperative surgical review team to allocate more cognitive resources to other necessary considerations that may be more difficult to quantify, including social environment factors, and the specific needs of the patient and their family. This tool may also provide objective evidence of risk to help guide discussion in multidisciplinary preoperative clearance-for- surgery conferences. Use of this tool adds negligible cost to the care of a complex spine patient, has the potential to improve outcomes, and is likely to increase the overall value of complex spine care.

Chapter 6 is devoted to the description of the wide field of quality improvement and the methodologies that can be applied to health economic aspects of care delivery. [13] Two novel conceptual models were developed: the Spine Safety Improvement Model-Detailed (SpineSIM-D) and the Spine Safety Improvement Model-conceptual (SpineSIM-C). They synthesize key success factors operating at the individual, team, and organizational levels to guide future quality and safety improvement initiatives. SpineSIM-D includes aspects of the patient pathway, institutional processes, consistent and systematic capturing of outcome data, commitment to data driven science, and continuous improvement methodology.

Comprehensive, systematic perioperative protocols that are multidisciplinary in nature appear to be rare in the field of complex spine surgery and have the potential to further improve quality and safety thereby meeting the requirements of health care's value-driven future. Complicated and complex surgery is associated with increased hospital stay, long-term morbidity and increased cost of care. Health care expenditure represents a major economic burden globally and costs associated with spine care have garnered the attention of major stakeholder groups. As the health system moves toward a value-based future, surgical care for complex spine patients is increasingly being rewarded for generating higher quality outcomes while controlling costs. Requests for transparent quality data are increasing and patients are actively seeking institutions that deliver the best care. In this shifting health care landscape, efforts to improve quality and safety in spine surgery are more important than ever.

FUTURE RESEARCH

The conceptual and detailed framework described above take a holistic systems view, from a bio- psychosocial perspective, to improving patient safety and quality. Improving safety benefits every individual patient, it reduces negative outliers, and reduces unforeseen costs due to complications. Improving quality leads to improved outcomes. Improving both safety and quality will lead to improved outcomes at reduced costs, the essence of value-based health care, relevant to all health care systems and societies across the globe. This can only be achieved by taking a holistic systems-based approach, rather than a reductionist approach which tackles each individual aspect without recognizing the impact on other parts of the system. Although this framework was developed in a specific (US) health care system, it seems likely to be applicable to all health care systems, where each aspect may be weighed differently according to the local context.

Future studies should include external validation of the risk model to generalize to common clinical practice. Furthermore, from a holistic perspective, pre-operative psychological (e.g. expectations, depressed mood, catastrophizing) and social factors (e.g. social support) should be included as potential risk factors. To enhance standardization the AOSpine ASD patient profile could be used. [23] As such, a comprehensive decision support tool could be developed using advanced statistics and that follows the recommendations as stated by Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) Initiative. [25]

SPECIFIC RESEARCH AIM 4: TO EXPLORE THE GLOBAL PERSPECTIVE OF TEAM-BASED STRATEGIES ON THE VALUE EQUATION

SUMMARY OF MAIN FINDINGS

Chapter 7 brings to light the international efforts in the space of value-based care for spinal conditions and highlights the Dutch American collaboration between Nijmegen and Seattle. [14] Following on from the previous chapter, multiple aspects in the SpineSIM-C and SpineSIM-D frameworks are explored from institutions across the globe. The experience and results of multiple efforts are reported, including the effects of implementing standardized patient pathways, lean operating room teams, team-based approaches (including comprehensive safety programs), continuous mentorship and dual surgeon operating teams, and continuous tracking and reporting of outcome metrics. Standardization of treatment outcomes measurement, including systematic and continuous outcome monitoring from a patient's perspective is important to assess the value of care delivered, that is, outcomes relative to cost, and future reimbursement. Treatment outcomes are thought to matter most to patients, reflect the end result of all aspects of care, and could be regarded as a proxy for quality of care. In recent AOSpine knowledge forum deformity studies [23,24,26] concerning the appropriateness of surgical care for adolescents with idiopathic scoliosis and adults with spinal deformity, international consensus was reached to systematically monitor patient-related outcomes (i.e. patient-reported outcome measures [PROMs] and clinician-based outcome measures), including factors for risk assessment and surgical planning. In order to support the evolvement of appropriateness of care, patient outcomes should be closely monitored and prospectively documented in a registry. An outcome registry is an organized system that uses observational study methods. Outcomes monitoring through an outcomes registry is expected to contribute to quality improvement. The data could be used to describe care patterns, including appropriateness of care and disparities in the delivery of care.

Dashboards and registries will allow users to assess whether the items in this study are leading to less variability and more predictable outcomes. It is clear from this work that multiple interweaving efforts as those discussed in this manuscript will enhance the patient experience and increase value. A limitation is that this work needs funding and institutional support. Thus, in a resource-stricken environment, this model may be difficult to fund. This is a major limitation and can lead to a lack of generalizability of the approach. However, using dashboard and registries can help the practicing surgeon and clinician improve their work and maintain involvement in daily improvement strategies.

Institutional and national registries and quality assurance systems can provide 'real life data' rather than evidence from cohort studies or RCT's. In the Netherlands, the mandatory national arthroplasty registry [27] has been able to track outcomes since 2007, with over 95% of implants tracked annually. The value of such registries was demonstrated when the first signs of problems with the ASR hip resurfacing implants [28] came from the Australian hip registry.

Implementing systems-based improvement strategies requires 'up front' financial investments and consistent institutional support. In most health care systems across the globe, this can be challenging, as the beneficiary of improving the value-based equation may be the future patient and society but is not always aligned with other stakeholders such as the health care provider or the payer.

FUTURE RESEARCH

As the cost of health care is increasing, regulators are increasingly requiring monitoring of outcome data. Recently the American Food and Drug Administration (FDA) has accepted data from registries as relevant and mandatory for allowing surgical innovations to be applied in the United States. Similarly, in Europe, the Medical Device Regulation [29] requires consistent post-market surveillance of all medical implants, including spinal implants.

However, most of these registry data is currently used to evaluate past interventions. In future, large data sets based on registries that implement standard outcome sets [24], that are automatically linked to Electronic Medical Records, and combined with other data sets (such as billing data, mortality data) will b e essential for identifying patient profiles and surgical approaches that predict poor or successful outcomes. As the data collected becomes more granular, machine learning techniques may be tools to analyze these large and complex data sets and may help build prognostic (decision support) tools. These tools can be expected to significantly help identify which patient benefits most from which intervention at the optimal cost.

Ultimately, this leads to improved value-based spine care.

SPECIFIC RESEARCH AIM 5: TO DISCUSS WHAT TELEMEDICINE CAN CONTRIBUTE TO THE SPINE TEAM APPROACH IN LIGHT OF THE COVID-19 PANDEMIC

SUMMARY OF MAIN FINDINGS

Chapter 8 provides the recent real-life example of what happens to value based care during the COVID- 19 pandemic during which this PhD thesis was completed (15). This was published by the *Harvard Business Review* and highlights the use of telemedicine to deliver the same care described in this introduction. Until the Covid-19 pandemic struck, surgical patients in the U.S. had been increasingly traveling to designated Centers of Excellence (COE), health systems that met stringent criteria for providing exceptional, high-value care for specific procedures such as knee replacement and spinal surgery. In some cases, large employers such as Walmart entered into contracts with the COE providers to care for their employees, whose travel to the specified provider for evaluation and, if needed, surgery, would be fully covered. In other cases, patients would travel from afar using other coverage to receive this specialized care. Virginia Mason, along with others including Geisinger, the Mayo Clinic, and Johns Hopkins are designated Centers of Excellence. Among the services patients have traveled for are complex spine surgeries, one of the most challenging procedures. By shutting down most travel, the pandemic might have put an end to such programs, at least for the duration. But at Virginia Mason, prior investments in telemedicine technology for virtual patient encounters and virtual multidisciplinary perioperative clinical team conferences have allowed them to continue providing surgery and other spine care to both local and remote patients traveling from hundreds or thousands of miles away, as well as to enhance virtual patient care broadly.

FUTURE RESEARCH

The Covid-19 pandemic has helped accelerate the implementation of telemedicine. With the increasing ability and acceptance to have online multidisciplinary meetings between health care professionals, and between health care professionals and patients, telemedicine is no longer the future, but has arrived. The next iterative steps that should have high research priority, will include remote monitoring, whether with traditional methods such as radiographs, or novel methods such as using wearables. This new data may well accelerate all developments described in the previous chapters, especially those focused on risk factors, outcome measurements and quality control, leading to better outcomes at lower costs and improved predictive analytics, ultimately benefitting our patients.

CONCLUSION

This thesis has described the development and evaluation of approaches for improvement of quality and safety in complex spine surgery. The data collected has revealed that the use of lean methodology, team approaches, risk stratification scores, predictive analytics and registries can enhance quality and safety and therefore should be the bedrock of value-based strategies to not only enhance patient safety but also address important health economic challenges for payors, regulators, and governments.

The COVID-19 pandemic was one of the greatest global challenges in the recent history of mankind. It has forced us to consider the ugly face of health inequality and cost conundrums on a much deeper level. This thesis brings forward overarching themes and stresses the importance of international collaboration in understanding health economics and value-based care algorithms as we work towards a better world where the most costly episodes of care can be improved and delivered on a more equal scale.

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SUMMARY (ENGLISH)

This thesis is a summary of a decade of quality improvement initiatives to reduce significant complications in complex spine surgery. This includes complications such as readmissions, re-operations, and medical complications leading to inferior outcomes. From a healthcare economics perspective, we demonstrate how improvement strategies are tied to cost effectiveness for payors and governments.

Quality improvement strategies can include the application of lean methodology to reduce variation in care processes. These strategies can also include strategies to enhance risk stratification of factors known to be tied to complications. Finally, measurement of improvement is another important tool necessary in quality improvement strategies.

The Dutch example of management of complex patients in a systematic fashion has led the value-based initiative amongst the most developed European health care systems. The author of this thesis has studied the Dutch example for many years and has found that it can provide much needed antidotes to the conundrums posed by fee for service medicine in the United States. The field of adult spinal deformity surgery has provided the arena where the fields of value-based care and health care economics intersect. The author has published peer reviewed manuscripts in the area of improvement and health services approaches to reduce complications for adult spinal deformity patients. Much of this research has echoed the principles of value-based spinal research emanating from the Netherlands. The intersection of this work with health economics is now emerging and recent analyses in the care of the spinal patient bring this front and center.

While the United States remains entrenched in fee for service medicine, the need for value-based care pathways has become ever more apparent for the future. In 2020, the conundrum of an expensive healthcare system that cannot provide basic care to one third of its citizens has reared its ugly head during the COVID pandemic. The importance of learning health economics and value-based care with a Dutch perspective becomes ever more relevant.

SAMENVATTING (DUTCH)

Dit proefschrift bevat een samenvatting van een decennium aan kwaliteitsverbeteringsinitiatieven met als doel om een relevante vermindering van complicaties te realiseren bij complexe wervelkolomoperaties. Hierbij gaat het om complicaties zoals heropnames, re-operaties en medische complicaties die tot inferieure behandelresultaten leiden. Vanuit een gezondheidseconomisch perspectief is geëvalueerd hoe verbeteringsstrategieën zijn gekoppeld aan kosteneffectiviteit voor de betalers en overheden.

De toepassing van de Lean-methodiek is een strategie voor kwaliteitsverbetering, waarbij variatie in zorgprocessen kan worden verminderd. Voorts kan deze methodiek ook strategieën omvatten om risicostratificatie toe te passen, door factoren te identificeren waarvan bekend zijn dat ze samenhangen met complicaties. Ten slotte is het meten van behandeluitkomsten een ander belangrijk middel dat nodig is voor kwaliteitsverbetering.

Nederlandse voorbeelden van systematische behandeling van complexe patiënten hebben geleid tot waarden gedreven initiatieven (value-based health care [VBHC]). Dit is ook het uitgangspunt in het Integraal Zorg Akkoord. Daarmee zijn de Nederlandse VBHC-initiatieven één van de meest vooraanstaande binnen één van de meest ontwikkelde Europese gezondheidszorgstelsels. De auteur van dit proefschrift heeft vele jaren verschillende Nederlandse voorbeelden bestudeerd en is tot de conclusie gekomen dat die kunnen bijdragen aan een oplossing voor vraagstukken die worden veroorzaakt door zogenaamde 'fee for service' (vergoeding 'per behandeling') geneeskunde in de Verenigde Staten. De complexe chirurgische behandeling van volwassen met spinale deformiteiten is een goed voorbeeld waar op waarde gebaseerde zorg en gezondheidseconomie bij elkaar komen. Voor dit proefschrift zijn meerdere studies uitgevoerd en gepubliceerd in peer-reviewed tijdschriften, op het gebied van kwaliteitsverbetering om complicaties te verminderen bij volwassenen met spinale deformiteiten die een operatie ondergaan. Veel van deze studies weerspiegelen het onderzoek uit Nederland dat gebaseerd is op principes van waarden gedreven zorg en deze principes zijn samengebracht binnen het domein van de complexe spinale wervelkolomchirurgie. De samenkomst van dit werk met gezondheidseconomie is momenteel in opkomst en huidige analyses in de zorg voor de patiënt met een wervelkolomaandoening brengen dit naar de voorgrond.

Hoewel in de Verenigde Staten 'fee for service' geneeskunde verankerd blijft, is voor de toekomst de behoefte aan op waarden gebaseerde zorgpaden steeds duidelijker. In 2020, tijdens de wereldwijde COVID-pandemie, bleek een duur gezondheidszorgsysteem zoals dat van de Verenigde Staten voor een derde van haar bevolking geen basiszorg te kunnen bieden. Het leren van gezondheidseconomie en van waarden gedreven zorg vanuit een Nederlands perspectief, zoals ook verankerd in het Integraal Zorg Akkoord, wordt daarmee steeds belangrijker en relevant.

APPENDIX

DATA MANAGEMENT

LIST OF PUBLICATIONS AND CONFERENCE PRESENTATIONS

ACKNOWLEDGEMENTS

ABOUT THE AUTHOR

PHD PORTFOLIO

DATA MANAGEMENT

This thesis is based on the results of multiple retrospective studies. The medical and ethical Institutional Review Board at the Benaroya Research Institute at Virginia Mason has given approval to conduct these studies.

This project is stored on the Neuroscience Institute at Virginia Mason's department server: G:\NSI\Admin\Sethi.

The patient data for the analyses of the studies as presented in chapters 2-8 is stored on the departments' G-drive (G:\NSI\Share\Research\IRB Documents).

The data will be saved for 15 years after termination of the study. Using these patient data in future research is only possible after a renewed permission by the patient as recorded in the informed consent or an IRB waiver. The datasets analyzed during these studies are available from the corresponding author on reasonable request.

LIST OF PUBLICATIONS AND CONFERENCE PRESENTATIONS

JOURNALS

1. DePledge L, Louie PK, Drolet CE, Shen J, Nemani VM, Leveque JA, **Sethi RK**. Incidence, Etiology and Time Course of Delays to Adult Spinal Deformity Surgery: A Single-Center Experience. Spine Deform. 2023 Feb 11:1–8. doi: 10.1007/s43390-023-00658-1.
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BOOKS & BOOK CHAPTERS

1. **Sethi RK**, Wright AK, Vitale MG. Value-Based Approaches to Spine Care: Sustainable Practices in an Era of Over-Utilization, 2020.
2. Vitale M, **Sethi RK**, Wang K. Safety in Spine Surgery: Transforming Patient Care and Optimizing Outcomes, 2019.

3. Friedman A, Leveque J, Wright AK, Buchlak Q, Bauer JM, **Sethi R**. Evaluation and Optimization of the Adult and Pediatric Spine Patients Preoperatively and Perioperatively to Improve Outcome. Textbook of Spinal Surgery, 4th Edition Wolters Kluwer Health,2018.
4. Lebl D, **Sethi RK**, Harris MB, Anderson, P. Clearing the Cervical Spine. Spine Trauma, 2011.
5. **Sethi RK**, Bradford DS, Metz L. The History of Disc Arthroplasty. Spinal Arthoplasty, 2008.
6. **Sethi RK**, Harris MB, and Wood K. Thoracic Spine Fractures: Operative and Nonoperative Management. Surgical Management of Orthopaedic Trauma,2006.
7. **Sethi RK**, Yeon H, and Harris MB. Spinal Imaging in Cervical Trauma. Clearing the Cervical Spine, 2006.
8. Yeon H, **Sethi RK**, and Harris MB. Evaluation and Early Management of Spinal Injury in a Polytrauma Patient. Orthopaedic Trauma, 2006.
9. **Sethi RK**, Harris MB, Anderson P. Clearing the Cervical Spine. Current Controversies. Spine Trauma, 2006.
10. **Sethi RK**, Aggarwal S, Rubash HE, Shanbhag AS. Total Hip Replacement: Osteolysis – Incidence and Clinical Presentation. Joint Replacements and Bone Resorption: Pathology, Biomaterials and Clinical Picture, July 2005.
11. Im G, **Sethi RK**, Rubash HE, et al. Osteolysis in Total Hip Arthroplasty: Biological and Clinical Aspects. Hip Replacement: Current Trends and Controversies, July 2002.

OTHER PUBLICATIONS

1. **Sethi RK**, Karhade AV, Glenn MG, Kaplan GS. How One Health System Combines Telemedicine and Hands-on Care. Harvard Business Review. July 2020.
2. **Sethi RK**, Nemani V, Shaffrey C, Lenke L, Sponseller P. Reimagining Medical Conferences for a Virtual Setting. Harvard Business Review. December 2020.

CONFERENCE PRESENTATIONS

1. **Sethi RK**. Myelopathy in the Setting of Adult Cervical Deformity. Scoliosis Research Society. 57^{th} Annual Meeting. Stockholm, Sweden. September 14, 2022.
2. **Sethi RK.** Technology and Value-based Care in 2022. Safety in Spine Surgery Month Webinar. The Safety in Spine Surgery Project. April 21, 2022.
3. **Sethi RK.** New Directions in Value-Based Healthcare. Daniel R. Benson Lectureship, UC Davis Orthopaedic Grand Rounds. December 14, 2021.
4. **Sethi RK.** 21^{st} Argentine Spine Congress – Argentinean Society of Spine Pathology. Live transmission to Buenos Aires, Argentina. October 27, 2021.

5. **Sethi RK.** Leveraging the Quality/Value Equation with Navigation and Robotics in Complex Spine Surgery. 10th Annual UCSF Techniques in Complex Spine Surgery, Las Vegas, NV, Nov 5-6, 2021.
6. **Sethi RK.** SST Approach. Safety in Spine Surgery Month Online CME. April 29,2021.
7. **Sethi RK.** Appropriateness and Safety in ASD surgery: Leveraging Expertise in Time of Global Crisis. Scientific Conference of the Canadian Spine Society. February 17,2021.
8. **Sethi RK.** 3D Printed Guides: A Cheaper Alternative. 27th International Meeting on Advanced Spine Techniques. July 11, 2020.
9. **Sethi RK.** Adult Deformity Surgery Challenges in 2020; Safety is Paramount. AANS/CNS Annual Meeting. Las Vegas, NV. March 5-8, 2020.
10. **Sethi RK.** The Seattle Spine Team Approach. University of Toronto Neurosurgery Grand Rounds, Toronto, CA. January 10, 2020.
11. **Sethi RK.** High-Grade Lumbo-Sacral Spondylolisthesis. Weill Cornell Brain and Spine Center, 4th Principles and Techniques of Complex Spinal Reconstruction, March 23, 2019.
12. **Sethi RK.** Highlights of Preoperative Planning for Complex Adult Spinal Deformity. Federation of Spine Association Specialty Day, Las Vegas, NV, March 16,2019.
13. **Sethi RK.** What Are Some Strategies for Managing ASD in a Bundled System? Scoliosis Research Society, Bologna, Italy, October 10-13, 2018.
14. **Sethi RK.** Introduction to the New Paradigms in Global Complex Spine Care. Scoliosis Research Society, Bologna, Italy, October 10-13, 2018.
15. **Sethi RK.** Building High Functioning, Resilient Teams. Scoliosis Research Society, Bologna, Italy, October 10-13, 2018.
16. **Sethi RK**. How Do You Build a “Center of Excellence” from the Payor Perspective? International Meeting on Advanced Spine Techniques, Los Angeles, CA, July 11-14, 2018.
17. **Sethi RK.** Systems Reform to Enhance Safety and Optimize Outcomes in Complex Deformity Surgery. Federation of Spine Associations, New Orleans, LA, March 10,2018.
18. **Sethi RK.** Reducing Complications of Surgery: Safety and Value. AAOS, New Orleans, LA, March 7, 2018.
19. **Sethi RK**. Pre-op Patient Assessment, When is it Over My Head and When Do I Ask for Help? Scoliosis Research Society, Philadelphia, PA, September 5-8, 2017.
20. **Sethi RK**. Potential Hematological Problems and Planning for Blood Loss in Complex Spinal Deformity Surgery (Multidisciplinary Pre-op Optimization). Scoliosis Research Society, Philadelphia, PA, September 5-8, 2017.

21. **Sethi RK**. International Expectations to Japanese Spine Surgeons, The View of Scoliosis Research Society. Keynote Speaker. Japanese Scoliosis Society, Sapporo, Japan, August 23-25, 2017.
22. **Sethi RK**. Indications and Pitfalls of ACR for Adult Spine Deformity. Keynote Speaker. Japanese Scoliosis Society, Sapporo, Japan, August 23-25, 2017.
23. **Sethi RK**. The Seattle Approach. Keynote Speaker. Japanese Scoliosis Society, Sapporo, Japan, August 23-25, 2017.
24. **Sethi RK**. The Seattle Spine Team Approach. Massachusetts General Hospital Anesthesia Grand Rounds, Boston, MA, August 3, 2017.
25. **Sethi RK**. Spine Care in 2017 and Beyond: What Can We do To Enhance Safety and Sustainability? , University of Kansas Peltier Lectureship, Kansas City, KS, June 17,2017.
26. **Sethi RK**. Population Health in Spinal Surgery, David Levine Symposium, HSS, New York, NY, June 9, 2017.
27. **Sethi RK**. Strategic Initiatives in Safety and Value for the Scoliosis Research Society. London, England, May 20, 2017.
28. **Sethi RK**. Safety and Value Report to the SRS board. London, England, May 19,2017.
29. **Sethi RK**. System Strategies to Enhance Spinal Surgery Outcomes. Cornell Medical School Complex Spine Techniques, New York, NY, April 8,2017
30. **Sethi RK**. Safe Thoracic Pedicle Screw Placement. Cornell Medical School Complex Spine Techniques, New York, NY, April 8, 2017
31. **Sethi RK**. Risk Stratification in Adult Scoliosis Surgery. AAOS/FOSA, San Diego, CA, March 18, 2017.
32. **Sethi RK**. Complex Techniques in Adult Scoliosis Surgery. AAOS, San Diego, CA, March 17,2017.
33. **Sethi RK**. Dual Surgeon Operating. Keynote Speaker, British Association of Spine Surgeons (BASS), Salford Quays, Manchester, England, March 16,2017.
34. **Sethi RK**. Risk Stratification in Spinal Surgery. Keynote Speaker, British Association of Spine Surgeons (BASS), Salford Quays, Manchester, England, March 15,2017.
35. **Sethi RK**. Dealing with the Crisis of Overutilization in Spine Surgery: The Seattle Approach. Course Chairman, Spine Safety Summit, New York City, NY, February 9-10,2017.
36. **Sethi RK**. What Do Payors Want in Value-Based Healthcare? Course Chairman, Spine Safety Summit, New York City, NY, February 9-10, 2017.

37. **Sethi RK**. The Seattle Approach and What We Can Learn from a Japanese Car Company. Visiting Professor and Keynote Speaker, Hospital for Special Surgery, Cornell Medical School, New York City, NY, February 8, 2017.
38. **Sethi RK**. Why is Spine Safety Such a Hot Topic? Course Chairman, SRS Worldwide Conference on Scoliosis Surgery, Hyderabad, India, January 25-28, 2017.
39. **Sethi RK**. The Seattle Approach: When, How and Why. Course Chairman, SRS Worldwide Conference on Scoliosis Surgery, Hyderabad, India, January 25-28, 2017.
40. **Sethi RK**. Dealing with Neurological Complications. How to Avoid This When Choosing Surgical Approach. Course Chairman, SRS Worldwide Conference on Scoliosis Surgery, Hyderabad, India, January 25-28, 2017.
41. **Sethi RK**. Live Surgical Reconstructive Techniques in Complex Spine Surgery. Course Chairman, New Delhi, India, January 23-25, 2017.
42. **Sethi RK**. How to Use Intraoperative Technology to Assess Alignment in Reconstructive Spinal Surgery; How to Use the Toyota Model in Spinal Surgery. Seattle Science Foundation, Seattle, WA, December 3, 2016.
43. **Sethi RK**. Live Course in Complex Techniques in Spinal Reconstruction. Chairman, Chennai, India, November 7-9, 2016.
44. **Sethi RK**. How to Build a "Center of Excellence" for the Surgical Treatment of Complex Spinal Disorders: the Payor and Patient Perspective. Sixth Annual UCSF Techniques in Complex Spine Surgery Course, La Vegas, Nevada, November 4-6, 2016.
45. **Sethi RK**. Complex Surgical Techniques in the Management of Adult Spinal Deformity. Choosing the Correct Procedure in an Optimized Environment; Adult Spinal Deformity: Classification/Clinical Radiology Assessment; Key Strategies to Avoid Reoperation in Adult Deformity; When to Say "No" to Surgeon for Adult Spinal Deformity. AAOS/SRS, Rosemont, Illinois, September 29-30, 2016.
46. **Sethi RK**. What is LEAN and How Can it be Applied to Spine Care. SRS pre-meeting course, Prague, Czech Republic, September 21, 2016.
47. **Sethi RK**. The Seattle Approach. SRS pre-meeting course, Prague, Czech Republic, September 21, 2016.
48. **Sethi RK**. Risk Stratification in Complex Spine Surgery. Course Chairman, SRS pre-meeting course, Prague, Czech Republic, September 21, 2016.
49. **Sethi RK**. New Techniques for Anterior Column Reconstruction. SRS Worldwide course, Indonesia, Bali, August 12, 2016.

50. **Sethi RK**. How to Reduce Complications in Scoliosis Surgery. Keynote speaker, SRS Worldwide course, Indonesia, Bali, August 11, 2016.
51. **Sethi RK**. Trauma ICL for spinal surgery. Moderator, SRS IMAST, Washington, DC, July 15, 2016.
52. **Sethi RK**. The Seattle Approach to Complex Spine Surgery. Keynote speaker, SRS IMAST, Washington, DC, July 14, 2016.
53. **Sethi RK**. Why Standard Work in Complex Spine Surgery is needed now. ISSG national meeting, Denver, Colorado, May 13, 2016.
54. **Sethi RK**. How to Reduce PJK and Revision Surgeries. Meeting of the Minds, Chicago, Illinois, April 23, 2016.
55. **Sethi RK**. The Seattle Approach and Lessons Learned. Meeting of the Minds, Chicago, Illinois, April 22, 2016.
56. **Sethi RK**. Risk Stratification in Adult Scoliosis Surgery. Keynote speaker, AAOS/FOSA, Orlando, Florida, March 5, 2017.
57. **Sethi RK**. Complex Techniques in Reconstructive Spinal Surgery. AAOS, Orlando, Florida, March 4, 2017.
58. **Sethi RK**. Reducing Complications in Adult Scoliosis Surgery. AAOS, Orlando, Florida, March 3, 2017.
59. **Sethi RK**. Safety in Spine Summit. "Debate: Two Surgeons versus One for Complex Spine Cases: Standard of Care versus the Reality of the RVU Incentivized Environment." And "The Seattle Spine Team Approach: Applying Principles of LEAN and the Toyota Production System to Spine Surgery." Invited Speaker, New York, New York, February 19, 2016.
60. **Sethi RK**. Is Adult Spinal Deformity Surgery Sustainable in the Era of Healthcare Reform? Visiting Professor and Ground Rounds, Columbia University, New York, New York, February 18, 2016.
61. **Sethi RK**. Safety and Value in Adult Spinal Deformity. Sixth Annual Spine Deformity Solutions: A Hands-On Course, SRS/AANS, Las Vegas, Nevada, February 4-6, 2016.
62. **Sethi RK**. The Seattle Approach to Adult Scoliosis Surgery. Keynote Speaker, Cedars Sinai, Las Vegas, Nevada, February 4, 2016.
63. **Sethi RK**. Live Operative Workshop on Current Concepts in Complex Spinal Surgery. Visiting Professor and Chairman, University of Colombo, Sri Lanka, January 21-23, 2016.
64. **Sethi RK**. The Seattle Approach to Adult Scoliosis Surgery. Visiting Professor, University of Colombo, Sri Lanka, January 20, 2016.

65. **Sethi RK**. Is Spinal Deformity Surgery in Adults Sustainable in 2015? Cedars Sinai Grand Rounds, Los Angeles, California, December 16, 2015.
66. **Sethi RK**. Making Adult Spinal Deformity Surgery Sustainable in the Era of Healthcare Reform. Fifth Annual UCSF Techniques in Complex Spine Surgery Course, San Francisco, California, November 6-7, 2015.
67. **Sethi RK**. An Analysis of the Seattle Spine Team Approach for Adult Spinal Deformity from a Health Services and Payor Perspective: Significant Reduction of Post-Surgical Harms Leading to Readmission Achieved Within the First 30 Days. Scoliosis Research Society, Minneapolis, Minnesota, October 3, 2015.
68. **Sethi RK**. When and How to Say "No", the Seattle Approach. Scoliosis Research Society, Minneapolis, Minnesota, October 1, 2015.
69. **Sethi RK**. "Making Spinal Deformity Surgery Sustainable". Scoliosis Research Society, Minneapolis, Minnesota, October 1, 2015.
70. **Sethi RK**. New Minimally Invasive Lateral Approaches to Complex Adult Spinal Deformity Surgery; Avoiding the Anterior Approach. Plenary Keynote speaker, Asia Pacific Spine Summit, Hong Kong, China, September 26, 2015.
71. **Sethi RK**. New Directions in Spinal Deformity Surgery; From Spinopelvic Balance to the Seattle Spine Team Approach. Asia Pacific Spine Summit, Hong Kong, China, September 25, 2015.
72. **Sethi RK**. The Virginia Mason Approach to Complex Spine Surgery. Neurosurgery Grand Rounds, Massachusetts General Hospital, May 7, 2015.
73. **Sethi RK**. The Seattle Spine Team approach. Grand Rounds, Brigham Women's and Children's' Hospital, Boston, Massachusetts, May 6, 2015.
74. **Sethi RK**. Choosing the Correct Procedure in an Optimized Environment; Adult Spinal Deformity: Classification/Clinical Radiology Assessment; Key Strategies to Avoid Reoperation in Adult Deformity; When to Say "No" To Surgeon for Adult Spinal Deformity. Congressio Brasileiro de Coluna, Belottori, Brazil, April 18, 2015.
75. **Sethi RK**. Adult Lumbar Scoliosis: State of the Art Treatment, and Adult Spinal Deformity: Surgical Planning and Complications. American Academic of Orthopedic Surgeons, Las Vegas, Nevada, March 23, 2015.
76. **Sethi RK**. The Seattle Spine Team Approach: Enhancing Outcomes and Safety (keynote address). Stryker Spine Symposium, Miami, Florida, March 20, 2015.

77. **Sethi RK**. Assessing Spinal Pelvic Balance and Evaluation of the Adult Deformity Patient: Assessing Balance Clinically and Radiographically. Deformity Correction Summit, Miami, Florida, February 21, 2015.
78. **Sethi RK**. Complex Spine Surgery. Bangladesh Spine Society Conference. National Institute of Traumatology and Rehabilitation, Dhaka, Bangladesh, January 8-9, 2015.
79. **Sethi RK**. Strategies to Enhance Safety in Complex Spine Surgery. Zorab Symposium, British Scoliosis Research Foundation, London, United Kingdom, December 4, 2014.
80. **Sethi RK**. Technique of Three Column Osteotomy and Perioperative and Intraoperative Management to Optimize Outcomes in Adult Spinal Deformity. 4th Annual UGSF Techniques in Complex Spine Surgery, Las Vegas, Nevada, November 7-8, 2014.
81. **Sethi RK**. The Seattle Spine Team Approach to Complex Spine Surgery. Brown University Grand Rounds, Providence, Rhode Island, October 23, 2014.
82. **Sethi RK**. Complications in Complex Spine Surgery: Avoidance and Management. Medtronic Complex Spine Surgery Seminar, Houston, Texas, October 10, 2014.
83. **Sethi RK**. Multidisciplinary Mechanisms to Target Proximal Junction Kyphosis in Complex Spine Surgery. SRS HIBBS Session, Anchorage, Alaska, September 9, 2014.
84. **Sethi RK**. Minimally invasive treatment for spine fractures. IMAST, Valencia, Spain, July 19, 2014.
85. **Sethi RK**. Multidisciplinary Approaches to Complex Spine Care. IMAST, Valencia, Spain, July 18, 2014.
86. **Sethi RK**. The Seattle Spine Team Approach and Appropriate Care for Complex Spine Patients. Grand rounds speaker, All India Institute for Medical Sciences, New Delhi, India, May 29, 2014.
87. **Sethi RK**. My Approach to the Most Severe Adult Spinal Deformity Case. Keynote speaker, Eurospine, Salzburg Complex Spine Technique Seminar, Salzburg, Austria, May 9, 2014.
88. **Sethi RK**. Multidisciplinary Approaches to Reduce Complications in Complex Spine Surgery. Keynote speaker, Australian Spine Society, Brisbane, Australia, April 11, 2014.
89. **Sethi RK**. How to Choose the Correct Patient for Adult Spinal Deformity Corrective Surgery. SRS Worldwide Course, Kolkata, India, January 25, 2014.
90. **Sethi RK**. How to Avoid Adjacent Segment Lumbar Degeneration. SRS Worldwide Course, Kolkata, India, January 24, 2014.
91. **Sethi RK**. Risk Reduction Strategies in Complex Spinal Surgery. UCSF Complex Spine Symposium, Las Vegas, November 9, 2013.

92. **Sethi RK**. The Seattle Spine Team Approach. IMAST/SRS 2013, Vancouver, BC, Canada, July 11, 2013.
93. **Sethi RK**. Multidisciplinary Approaches to Risk Reduction in Complex Spinal Surgery. Spine Technology and Education Research Group Meeting, Cabo San Lucas, Mexico, June 22, 2013.
94. **Sethi RK**. The SRS Schwab Classification of Adult Deformity and My Approach to Complex Deformity Cases. SRS SILACO-GEER worldwide symposium, Valencia, Spain, May 29, 2013.
95. **Sethi RK**. Planning of Complex Spinal Deformity Cases Using a Modular Implant System, SILACO-GEER worldwide symposium, Valencia, Spain, May 30, 2013.
96. **Sethi RK**. Enhancing Safety in Complex Spine Surgery. The Seattle Approach. Soonchunhyang Korean Spine Society 2013, Seoul, Korea, March 21, 2013.
97. **Sethi RK**. Management of Late Onset Kyphosis. ASSICON 2013, Kochi, India, January 17, 2013.
98. **Sethi RK**. Managing Pedicle Screw Breaches. ASSICON 2013, Kochi, India, January 17, 2013.
99. **Sethi RK**. Multidisciplinary Approaches in Complex Spine Care: Enhancing Safety and Cost Effectiveness. ASSICON 2013, Kochi, India, January 17, 2013.
100. **Sethi RK**. The Virginia Mason/Group Health Complex Spine Research Update. Virginia Mason Grand Rounds, January, 2013.
101. **Sethi RK**. The Virginia Mason Safety Model in Adult Spinal Deformity Surgery. Washington State Orthopaedic Association Annual Meeting, Seattle, Washington, November, 2012.
102. **Sethi RK**. The Importance of Multidisciplinary Care in Complex Adult Spinal Deformity Surgery. UCSF 2nd Annual Complex Spine Meeting, Las Vegas, Nevada, November, 2012.
103. **Sethi RK**. Dual Surgeon Techniques in Pedicle Subtraction Osteotomy. UCSF 2nd Annual Complex Spine Meeting, Las Vegas, Nevada, November, 2012.
104. **Sethi RK**. Enhancing Safety in Adult Spinal Deformity Surgery: The Importance of Collaboration and Multidisciplinary Approaches. Group Health Research Institute, Grand Rounds, Seattle, Washington, September, 2012.
105. **Sethi RK**. Coagulopathy in Adult De Novo Scoliosis Surgery: Timing and Onset of Breakdown of the Coagulation Cascade as Measured by D Dimer and Fibrinogen Levels. IMAST, Istanbul, Turkey, July, 2012.

106. **Sethi RK**. Posterior Approaches to Complex Adult Spinal Deformity: The Importance of Implant System Versatility in the Planning of Complex Cases. ASSICON, New Delhi, India, February, 2012.
107. **Sethi RK**. The Importance of Forums around Safety in Adult Spinal Deformity Surgery. ASSICON, New Delhi, February, 2012.
108. **Sethi RK** et al. A Multidisciplinary Approach to Complex Spinal Surgery. Grand Rounds. Virginia Mason Medical Center, Seattle, Washington, September, 2011.
109. **Sethi RK** et al. A Multidisciplinary Complex Adult Spinal Deformity Conference has a Significant Rejection Rate. IMAST, Copenhagen, Denmark, July, 2011.
110. **Sethi RK**. Posterior Approaches to Complex Adult Spinal Deformity: The Importance of Implant System Versatility in the Planning of Complex Cases. IMAST, Copenhagen, Denmark, July, 2011.
111. **Sethi RK**. Management of Spinal Deformity, From Child to Adult. Group Health Permanente Best Approaches, Kauai, Hawaii, February, 2011.
112. **Sethi RK**. Management of the Adult Spinal Deformity Patient. ASSICON, Mumbai, India, January, 2011.
113. **Sethi RK**, et al. A Dual Orthopaedic-Neurosurgical Attending Approach to Complex Spinal Surgery Significantly Reduces Perioperative Complication Rates. IMAST, Toronto, Canada, July, 2010.
114. **Sethi RK**. Current USA Trends in the Management of a Polytrauma Patient with a Spinal Injury. Grand Rounds, Hinduja Hospital, Mumbai, India, December, 2009.
115. **Sethi RK**, et al. Proximal Junctional Kyphosis and Its Relationship to Cephalad Level of Fusion. IMAST, Paradise Island, Bahamas, July, 2007.
116. **Sethi RK**, Harris MB. The Initial Assessment and Management of the Multiple Trauma Patient with an Associated Spine Injury. Grand Rounds. University of California San Francisco, San Francisco, California, November 23, 2006.
117. **Sethi RK**. Operative Management of T-Type Acetabular Fracture. New England Fracture Forum. Boston, Massachusetts, May 4-5, 2006.
118. **Sethi RK**, Harris MB. The Initial Assessment and Management of the Multiple Trauma Patient with an Associated Spine Injury. Grand Rounds. Apollo Hospital, New Delhi, India, December 6, 2005.

119. LeRoux PD, **Sethi RK**, Elliott JP, et al. Factors Associated with Surgical Complications for Basilar Bifurcation Aneurysms: An Analysis of 101 Patients. Poster presentation. American Association of Neurological Surgeons, Annual Meeting, Philadelphia, Pennsylvania, April 1998.
120. **Sethi RK**. New Directions in the Study of the Epidemiology of Multiple Sclerosis in the Middle East. Fulbright Commission, Amman, Jordan, April 1997.
121. Kaplan GB, Leite-Morris KA, **Sethi RK**, et al. Regulation of G Protein-Mediated Adenylyl Cyclase in Striatum and Cortex of Opiate-Dependent and Opiate Withdrawing Mice. American College of Neuropsychopharmacology, San Juan, Puerto Rico December 1996.

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ABOUT THE AUTHOR

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Brown University, Providence, Rhode Island	B.Sc.; B.A.	1992-1996	Neuroscience, Middle Eastern Studies
Fulbright Scholarship, Washington, DC	Fulbright Scholar	1996-1997	Public Health/ Preventative Medicine
Harvard Medical School, Boston, Massachusetts	M.D.	1997-2001	Medicine
Massachusetts General Hospital, Boston, Massachusetts	Internship	2001-2002	General Surgery
Harvard Combined Program, Boston, Massachusetts	Residency	2002-2006	Orthopaedic Surgery
University of California, San Francisco, California	Fellowship	2006-2007	Complex Spinal Surgery/Scoliosis and Deformity

CONTRIBUTIONS TO SCIENCE

Dr. Sethi's educational pedigree is detailed above. He has been working at Virginia Mason Medical Center for the past 16 years as a spinal surgeon specializing in spine deformity and serving as the executive director of the program in Neurosciences and Spine for the past 9 years. Dr. Sethi's interests in quality improvement and safety strategy began as a result of the observation of high complication rates in the surgical treatment of adult spinal deformity in the 2000- 2010 decade when he began practice. System approaches were a strategy that could be applied to enhance safety and Dr. Sethi began his work utilizing lean management principles, standard work principles and team-based medicine as an approach. This led to multiple publications and work with national and international societies to bring this work to the stage and also form a research network for the study of these principles.

Dr. Sethi has been chair of multiple committees of the Scoliosis Research Society including having served on the Board of Directors from 2017-2019. He is the local host and Program Chair of the annual meeting of the Scoliosis Research Society in Seattle in 2023. Dr. Sethi also serves on the board of the Spine Safety Foundation and the National Spine Health Foundation. Furthermore, Dr. Sethi has been nominated to the scientific advisory boards of several startups that have focused on safety and value in the delivery of spine care in the United States.

The study of value-based health care led the author of this thesis to Nijmegen. A close collaboration with Professor Marinus De Kleuver in many arenas of academic spine programs led to the discussion of work in health economics where further learning and collaboration could be conducted. This was enforced after a visit to Nijmegen where direct interaction and learning occurred for the author with leading figures at Radboud University.

RESEARCH SUPPORT

VMMC, founded in 1920, is a non-profit regional health care system based in Seattle that serves the Pacific Northwest. Virginia Mason employs approximately 5,500 people and includes a 336-bed acute-care hospital; a primary and specialty care group practice of more than 480 physicians; and 8 regional medical centers throughout the Puget Sound area. In partnership with internationally recognized Benaroya Research Institute (BRI), Virginia Mason has 440+ active studies, $5 million annual research portfolio and 80+ studies currently open to enrollment. The Clinical Research Team has 20 study coordinators, 10 research assistants and 11 support staff.

In addition to the research facilities provided by the Benaroya Research Institute and VMMC, this research activity is supported by the neurosurgeon team at NSI, a hospitalist, anesthesiologists, physiatrists from physical medicine and rehabilitation, a research fellow, a visiting research scholar, research program manager, an undergraduate research assistant.

PHD PORTFOLIO

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors. Follow this format for each person.

NAME	POSITION TITLE
Rajiv K. Sethi	Orthopaedic Spinal Surgeon, Medical Director of the Neuroscience Institute at Virginia Mason Medical Center Clinical Professor of Health Services Research University of Washington

Department: Radboud University Medical Center Department of Orthopaedics PhD period: 01/06/2019– 20/10/2023 PhD Supervisor(s): Marinus de Kleuver MD PhD PhD Co-supervisor(s): Miranda L. van Hooff PhD	
TRAINING ACTIVITIES	**HOURS**
COURSES	
University of Washington Health Services course numbers HSERV 600A, HSERV 499A (see explanation below) • 2019, 2021 • Utrecht Scientific Integrity Course, Certificate Obtained, 2023 • CITI (Collaborative Institutional Training Initiative), Human Subjects Protection/Good Clinical Practice and Refresher course, 2021, Valid until 2024	400

SEMINARS	
Medical technology Symposium of Advamed, Health economics seminar, Los Angeles, 2023 • Leadership in Medical Care, Health Economics Symposium, Harvard Univ., Boston, 2019 • Multiple virtual webinars on providing care during the pandemic along resource constraints, including those with Dutch key opinion leaders, 2020-2022	120
CONFERENCES	
• International Meeting of Advanced Spine Techniques, Dublin, Ireland, March 2023 • Scoliosis Research Society, Seattle, USA, September 2023 • International Meeting of Advanced Spine Techniques, Miami, USA, April 2022 • Scoliosis Research Society, Stockholm, Sweden, September 2022 • Spine Safety Summit, New York City, April 2023	175
OTHER	
• Health executive leadership coaching, 3 hours per week for 12 weeks, September-November 2022	36
TEACHING ACTIVITIES	
LECTURING	
• University of Washington Medical School Med Sci 501 and 503, 2019-2023	75
SUPERVISION OF INTERNSHIPS / OTHER	
• Director of Virginia Mason Complex Spine Fellowship, 2019-2023	100
TOTAL	**906**

Courses HSERV 600A and HSERV 499A are both delivered via the University of Washington in Seattle and both courses are centered in the Department of Health Services and Population Health with an emphasis on health economics. Both courses have an independent study allotment with access to faculty for any learning required. In both courses, I studied Time Driven Activity Based Costing (TDABC) as a new methodology that I could use to further my own learning in Health Economics. A majority of the hours cited were spent learning the algorithm of TDABC and creating a study design to use lean management methods and TDABC together to create a new algorithm for the study of value-based healthcare delivery.

POSITIONS AND HONORS

POSITIONS AND EMPLOYMENT

- Group Health Research Institute, Seattle, Washington. Affiliate Investigator Status. 2009-Present.
- University of Washington Department of Health Services, Seattle, Washington, Clinical Professor. 2011-Present.
- Virginia Mason Medical Center, Spinal Surgeon, Neuroscience Institute, and Medical Director, Neuroscience Institute. 2015-Present.

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

2015 – Present	Safety and Value Committee, Scoliosis Research Society, Chair-Elect, 2016-2017
2015 – Present	Safety Committee, Scoliosis Research Society
2015 – Present	IMAST Committee, Scoliosis Research Society
2015 – Present	Washington State Orthopedic Association, Second Vice President
2014 – Present	IMAST and Worldwide Conference Committee, Scoliosis Research Society
2013 – Present	IMAST Committee, Scoliosis Research Society
2012 – Present	Washington State Orthopaedic Association, Board of Directors, Second Vice President
2010 – Present	Scoliosis Research Society (Committees: IMAST, Worldwide Conference, Website, and Adult Deformity)
2010 – Present	North American Spine Society
2009 – Present	Diplomate of the American Board of Orthopaedic Surgery
2006 – Present	American Academy of Orthopaedic Surgeons, Fellow since 2009
2001 – Present	Harvard Medical School Alumni Association, Deans Council
1997 – Present	Fulbright Alumni Association

HONORS AND AWARDS

2014-2015	Seattle's Best Doctors, Seattle Metropolitan, Seattle, Washington
2014	Clinical Excellence Award, Group Health Physicians Annual Meeting, Seattle, Washington

2014	Mary McClinton Award for Patient Safety, Seattle, Washington
2013 – Present	Primary Investigator Grant Award. Dual attending surgeon approach to complex adult spinal deformity surgery, prospective 3 year follow-up study, Group Health Research Institute, Partnership for Innovation Grant, $82,000.
2012-2015	Seattle Best Doctors, Seattle Magazine, Seattle, Washington
2012	Whitecloud Research Award Nominee, Scoliosis Research Society, IMAST, Istanbul, Turkey
2012	Appointment, Board of Directors, Washington State Orthopaedic Association
2011	Associate investigator status, Group Health Research Institute, Seattle WA
2011-2012	Primary Investigator Grant Award. Coagulopathy in adult spinal deformity surgery, intraoperative lab and data analysis based on hourly D dimer and Fibrinogen, Virginia Mason Medical Center, Benaroya Foundation, $63,000.
2010	Research Grant Committee, Website Committee, Adult Deformity Committee, Scoliosis Research Society 2007 - Spinal Surgical Outreach Programmes in India, UAE, Japan, Egypt, Bolivia and Jordan, Harvard Medical International
2006	Chief Resident, Massachusetts General Hospital, Harvard Combined Orthopaedic Surgery Residency, Boston, Massachusetts
2004-2011	Co-Investigator Grant Award. Complex spine surgery outcomes on Group Health Patients treated at 3 Seattle institutions, $100,000, multiple funds including Group Health/UW
2001	New Pathway Curriculum Advising Committee, Harvard Medical School, Boston, Massachusetts
1996	Sigma Xi, Brown University, Providence, Rhode Island
1996	Phi Beta Kappa, Brown University, Providence, Rhode Island
1996	Magna Cum Laude, Brown University, Providence, Rhode Island