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Quality and Clinical Care Development in Spine Surgery—Connecting the Dots: An Expanded Clinical Narrative

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Abstract

Our health care system is an evidenced-based quality-centric environment. Pursuit of quality is a process that encompasses knowledge development and care advancements through collaboration and expertise. Depicted here is the foundational knowledge, process, and contributions that hallmark successful clinical quality programs. Beginning with methodology, followed by process and form, we create the foundational knowledge and exemplars demonstrating framework and continuum of process in pursuit and attainment of successful clinical quality and care development for patients. Although our protocol has been devised for complex spine care, this could be implemented across all health care specialties to provide individualized and high-quality care for all current and future patients, all while creating a culture of accountability for physicians.

Keywords

quality, outcomes, measurements, metrics, model for improvement, organizational change, accountability

Extraordinary claims require extraordinary evidence.

—Attributed to Carl Sagan

Quality is a concept that is widely adaptable with ability to be applied across infinite settings. However, for the science of medicine and translation to clinical practice, the definition of quality has received the benefit of clear wording. The Institute of Medicine established the definition of quality in the 1990 report, *Medicare: A Strategy for Quality Assurance*.¹ This definition for quality continues today, recognized by the National Academy of Sciences.

Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.^{1(p21)}

This reflects both an operational framework as well as the dynamic and ongoing nature of health care measures and efforts to continuously improve outcomes. Aims for improving clinical quality set by the Institute of Medicine in 2001 are now recognized as Domains of Quality by the Association for Healthcare Research and Quality.² These domains provide mental framework for components of quality care.

Domains of Quality

- *Safe*—avoiding harm
- *Effective*—based on scientific knowledge, care provided to those who may benefit
- *Patient centered*—respectful, responsive, and guided by patient values
- *Timely*—reduction of harmful delay
- *Efficient*—avoid waste, including ideas and energy
- *Equitable*—does not vary based on personal characteristics

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Table 1. Illustration of Common Definitions and Application in Outcome Measures in a Complex Spine Practice.

	Components	Advantage	Common Uses	Example
Observed over expected (O/E) ratio	Observed rate and expected rate	Risk adjustment	Mortality, readmission, length of stay	Observed rate of mortality (3.4%)/ Expected rate of mortality (4.2%) = 0.81 Ratio <1 = better than expected
Standardized infection ratio (SIR)	Recorded infections and predicted infections	Risk adjustment	Hospital-acquired infections	Recorded # of infections (6)/Predicted number of infections (4.632) = 1.30 Ratio >1 = worse than expected
Infection per device days	Number of days a device was utilized and recorded infections	Standardization of denominator	CAUTI, CLABSI	4 infections/2000 device days = 2 infection per 1000 device days
Rate of complication per 1000	Numerator (occurrences), denominator (outcome cases)	Display of low-frequency events, minimize leading zeros	Patient Safety Indicators ⁶ (PSI)	PSI 12—Perioperative pulmonary embolism or deep vein thrombosis rate Numerator 2, denominator 1500; rate per 1000 = 1.33

Abbreviations: CAUTI, catheter-associated urinary tract infection; CLABSI, central line-associated bloodstream infection.

Individual and System Efforts

In improvement of care, traditionally a main focus has been placed on individual practitioner responsibility by emphasizing each and everyone's duty to minimize error and maximize outcomes. The influence of health systems is commonly perceived to be a supervisory and regulatory function rather than serve as a prime participant in efforts to transform care. Creation of a collaborative and trouble-shooting atmosphere can foster practitioner and health system partnership and prevent an "us versus them" mind-set. Development of collaborative processes are essential when seeking to understand and resolve adverse patient events in a collective, facilitated fashion, as is the goal of root cause analyses. Though, the amount of positive impact from a root cause analysis can vary.³ Results, in fact, may obscure meaningful advancements if imbalances are created by a lack of trust or lack of true collaboration and problem solving of individual practitioners and the health system they operate in.

In the field of spine surgery, many entities are now bound by governmental and third-party payors to quantify quality of care. The key is to employ adequate measures to allow for objective assessment of results and derive appropriate countermeasures as needed. Spine care continues to be a befuddling—and expensive—health undertaking due to its complexity and variability, both in types of patient disease as well as interventions. Finding solutions to operationalize quality of spine care is of primary concern for the health care community globally with rising demand for spine services being predictable of older and sicker populations worldwide.⁴

Do Measurements Matter?

Measurements provide opportunity to determine a current state and explore mechanisms to identify if change results in actual clinical improvement. Measurements shed light on strengths as well as vulnerabilities and provide decision support for directing resources based on risk. Without measurements what is left

Table 2. Types of Measures Associated With Donabedian Model.

Structure measures	Relate to service, provider, or place. Example: Proportion of board-certified physicians. Access to hybrid operating room (yes/no)
Process measures	Relate to systems or a function. Example: Percentage of patients participating in patient-reported outcomes or percentage of patients with preoperative care planning at multidisciplinary conference
Outcome measures	Relate to impacts of care on the patient. Example: Improvements in functional capacity, 5-year survival, occurrence of complications

is conjecture. Measurements matter in improving clinical care through the provision of evidence of the degree to which services increase likelihood of desired outcome and are consistent with current professional knowledge. Competency in interpretation of common measures, as well as basic definitions, is essential to understanding context of quality and in turn apply assessment of quality to clinical practice. Some common measures are illustrated in Table 1.

Measurements can be categorized by type. A common framework for categorizing by type is described by the Donabedian model.⁵ This model groups measurements into 3 categories: structure, process, and outcome (Table 2).

Data Selection Considerations

When selecting resources for developing measures, establishing baseline, and crafting surveillance, it is helpful to ask the very fundamental question: Is the data meaningful?

Anything can be measured, including the meaningfulness of a measure. The National Quality Forum recognize a structure for measuring usefulness and appropriateness of data and sources.⁷ A few key considerations in evaluation of sources and metrics are the following:

- *Standardization*—Is the measure standardized at the national level?
- *Comparability*—Will the measure be comparable for the population (CMI [case mix index], severity of illness)?
- *Stability*—Is the source for measure stable, what is the longevity of the source?
- *Availability*—Will the measure be available spanning the intended population?
- *Timeliness*—What is the lag time, will the measure be relevant when received?
- *Validity*—Is the measure adequately tested for consistency and accuracy?
- *Distinguishable*—Does the user have experience to know if the measures reflect performance and not shortcoming of information systems?
- *Credibility*—Are the measures audited or do not require audit?

Risk Adjustment ≠ Benchmarking

Risk adjustment can be confused with benchmarking. Risk adjustment and benchmarking complement each other but are not the same. Risk adjustment considers how the patient or health system performed, factoring in severity of illness, present on admission conditions, and demographics for an assessment of outcome. Benchmarking is comparing this performance to other groups performing same measurement. Table 3 offers illustration of a group of health systems utilizing the common measurement of unexpected readmissions within 30 days. Benchmarking compares between the groups. Benchmarking can be performed taking into account similarities and differences of health systems in review of comparative performance. The different disease severities of health systems are expressed by the CMI that help influence the observed to expected ratio of readmissions relative to the size and setting of a hospital.

Data...Now What?

The acquisition of data feels like the journey, when rather it is the starting place. Data must be analyzed and utilized in a regular and ongoing fashion. A good starting point is the question: Does it make sense? Next, *organize* the data, *display* it, and *discuss* it among knowledgeable peers. Compare the data to the “expected,” to benchmarks, and to literature.

Table 3. Benchmarking Example, Measurement With Ability to Compare Between Health Systems.

Health System	CMI	Volume	Academic	O/E Readmission
Health system A	2.51	800	No	1.05
Health system B	1.8	1000	No	0.5
Health system C	3.81	2500	Yes	0.9
Health system D	4.04	3000	Yes	0.3

Abbreviations: CMI, case mix index; O/E, observed over expected ratio.

Can variations be identified? Identify differences and research outliers both positive and negative on the spectrum. *Act* to course correct around clear gaps such as in care planning, communication, or competencies. Develop hypotheses around subtle findings such as would standardizing closure in spine surgery reduce rate of dehiscence? Would implementing nutrition protocol in spine surgery reduce wound dehiscence?

Model for Health Care Improvement

It is inevitable, on making data actionable, that opportunities will surface to practitioners involved in such a quality process. The Institute for Healthcare Improvement offers a model for improvement.⁸ The model begins with asking, “What are we trying to improve?” Followed by, “How will we know if the change is an improvement?” and “What change can we make that will result in improvement?” This provides process for clarifying aim, defining improvement, and to hone in on what changes could be made to accomplish. This is followed by testing if a proposed change will meet the intended goal. The framework for testing a proposed change is known as “Plan-Do-Study-Act”:

- Develop plan to test a change (*Plan*)
- Carry out the process being tested (*Do*)
- Observe and gather the results (*Study*)
- Determine modifications, make recommendations for further study or implement process, that is, plan for next step: modify, adopt, or abandon (*Act*)

Model for Organizational Change

Change can be difficult to achieve let alone sustain. Utilizing a model for structuring organizational change is helpful for assuring support for success. One model is Lewin’s model of change theory.⁹ In the Lewin model of change theory, change is grouped into phases beginning with “unfreezing,” followed by “change,” and lastly “refreeze.”

- *Stage 1*—Unfreeze: Organize participation and support (buy in). Groups prepare for acceptance and plan for change.
- *Stage 2*—Change: Change is accepted, and new paths adopted. There is alignment around change.
- *Stage 3*—Refreeze: Change becomes the new norm, processes are evaluated for adherence (process measures) and recognized (positive or resulting in course correction) ensuring new ways are anchored into culture.

Initial planning for each area of change, including supports to sustain, is key to successful implementation and sustainment of organizational change.

Applying the Principles to Complex Spine Surgery

Complex spine surgery has evolved to an increasingly commonplace procedure category and in such has become a major focal point of quality improvement initiatives. Nationally, a number of measurements have come to life beyond the usual mortality and deep surgical site infections that are increasingly governing how we practice. Examples of these are shown in Table 4.¹⁰

To effect change, a number of concepts hold promise to connect the power of a healthcare system with each of its providers toward the mutual goal of creating a fact based collaborative and continuous learning environment intent on continuous self-improvement. Relatively simple program implementations for a complex spine service have afforded beneficial results. The following are a number of such measures the authors have found to be helpful in their practices.

Quality and Outcomes Conferences

Most hospitals around the world feature some form of regular morbidity and mortality reviews, some more formal than others. The morbidity and mortality reviews usually rely on a more or less voluntary self-reporting system or extracted complications from a hospital data bank.¹¹ Such conferences are a desirable foundation for inter- and intradisciplinary communication and provide a hopefully blame-free learning opportunity for all in attendance. As such conferences are established, the goal is to develop input and reporting systems, remain current with peer review and analysis of adverse events. Reliance on individualized self-reporting or hospital registries may lead to significant underreporting of actual adverse events. Use of a

Table 4. Common Outcome Measurements.

Mortality
Readmission
Surgical site infection
Reintervention (ie, unplanned additional surgery)
Patient Safety Indicator (PSI)—PSI 02 Death rate in low-mortality Diagnosis Related Groups (DRGs)
PSI 03 Pressure ulcer rate
PSI 04 Death rate among surgical inpatients with serious treatable complications
PSI 05 Retained surgical item or unretrieved device fragment count
PSI 06 Iatrogenic pneumothorax rate
PSI 07 Central venous catheter-related blood stream infection rate
PSI 08 In-hospital fall with hip fracture rate
PSI 09 Perioperative hemorrhage or hematoma rate
PSI 10 Postoperative acute kidney injury requiring dialysis
PSI 11 Postoperative respiratory failure rate
PSI 12 Perioperative pulmonary embolism or deep vein thrombosis rate
PSI 13 Postoperative sepsis rate
PSI 14 Postoperative wound dehiscence rate
PSI 15 Unrecognized abdominopelvic accidental puncture or laceration rate

dedicated reporting system and a resource professional such as a “Quality Nurse” at the intersection of care providers and hospital administration has been described as a desirable resource to professionalize, provide a clinical lens for surveillance process, and operationalize learnings from conference.

Beyond regular case conferences, routine and standardized outcome review is the cornerstone of clinical quality efforts. Outcome review is 2-fold: (1) publication of measurements and (2) review of cases for context and identification of opportunity for improvement. One can exist without the other; however, publication of measurements without review is of limited utility. Review of cases without measurements lacks evidence and context. Publication of measurements with case review context provides the foundation for evidence-based clinical improvements and ability to measure if a change results in improvement. Ideally, measurement review in conjunction with M&M case review provides context and stimulus promotes intervention.

The following is a case study of clinical care development in partnership with clinical quality program.

Case Study: Protocols in Complex Spine Surgery Aimed to Prevent Postoperative Complications

In an effort to address complications following complex spine procedures, the most common reasons for patient readmissions and return to the operating room were regularly reviewed and analyzed over a period of 2 years. Paired with outcome measurements, 4 areas of opportunity were identified and assessed for clinical opportunities in care planning: (1) postoperative respiratory complications; (2) postoperative wound complications; (3) intractable pain; and (4) DVT (deep vein thrombosis)/PE (pulmonary embolism). As a result, 5 initiatives were developed.

“Back to Basics” Protocol

Observation: Avoidable postoperative pulmonary complications. Elevated temperatures and fever work-ups with utilization of chest radiographs that identified “nonspecific atelectasis” were a relatively common occurrence.

Idea: Promote regular simple active breathing exercises by implementing incentive spirometry use (10 times per hour while awake) as well as specific deep breathing diaphragm mobilization exercises. Prior to implementation, advance practice nurses as well as nursing leadership provided education to staff and clinic nurses related to the significance and reasoning for use. This education was essential to ensure that nursing had an adequate understanding of the rationale and importance of this therapy and could, in turn, provide patient education in the clinics and on the units. This program was started before any elective surgery during preoperative education session and then continued for the acute phase hospitalization through home use until return to the hospital for a wound check at 3 weeks postoperatively. Compliance was tracked through daily rounding

and electronic medical record data capture as part of a more active patient participation program in early recovery.

Multimodal Pain Management

Observation: Preventable readmission and delayed discharges related to inadequate pain management.

Idea: To install an effective preoperative, perioperative, and postoperative pharmacologic and nonpharmacologic regimen to be instituted on all elective complex spine patients. A dedicated comprehensive complex spine order set was generated in the electronic medical record to assure accurate and consistent use of desirable medication regimens outlined for consistent provider use. In addition, nursing was instructed how to utilize multitiered pain management orders and encourage the use of conservative, nonpharmacologic pain management tools. This is an ongoing effort and has been a challenge due to widely variable opiate tolerance of patients as well as their baseline health status. It is also affected by cost consideration for some helpful medications, such as intravenous acetaminophen and liposomal-based bupivacaine, which limit their regular availability in everyday practice. Nevertheless, creative application of a “multimodal” pain management program has become a culture of care focus with ongoing efforts to find optimal solutions for any and all patient and their various specific needs and challenges.

Mobilization Initiative

Observation: Avoidable postoperative complications such as DVT/PE.

Idea: Routine early mobilization of postoperative patients through implementation of a nurse-led initiative focused on avoidance of prolonged bedrest following complex spine surgery. Nursing education focused on the benefits of mobilization and troubleshooting for challenging patient situations and included routine preoperative patient and spouse education. Expectations included assisting patient out of bed to a chair by 0700 AM as well as documentation of mobilization (ie, each time patient is out of bed) with description of activity (ie, physical therapy, marched at bedside, etc). This program has become ingrained in the everyday culture of postoperative spine care and removed the expectation that it was the sole responsibility of a few specialized physical therapists to mobilize patients. The current atmosphere is one where all patient arena providers feel a sense of participation in the desirable return of complex spine surgery patients to a more functional status at the earliest point in time. Beneficial health care effects in terms of reduction of VTE events are ongoing as modifications of chemical prophylaxis are underway and are being monitored in terms of associated risks of such an intervention.

Nutrition Protocol

Observation: Avoidable postoperative nutrition-related complications such as wound breakdown.

Idea: Implementation of a nurse led initiative that focused on preoperative and postoperative nutrition guidance, management, and care. Nutrition screening using simple clinical and few serologic parameters was conducted in the preoperative setting to identify patients at risk for wound complications and to identify nutrition needs as well as supplying information and resources to patients regarding how to meet those needs (ie, nutritional supplementation, dietary changes, and referral for nutritional consult). The hospital system supported these measures in conjunction with a sponsoring industrial partner by making protein drinks available for 5 days preoperatively and 5 days postoperatively in identified “at-risk patients” and monitoring compliance.

Glycemic Control Initiative

Observation: Preventable postoperative complications for complex spine patients.

Idea: Focus on tighter blood glucose management in the preoperative, perioperative, and postoperative stages. Concerted preoperative efforts included clinic nursing staff screening patients for HgA1c higher than 7. These patients were provided education regarding possible complications associated with the surgical procedures as well as effective methods for avoidance. Referrals were made to Endocrinology for strategizing medication management as well as working with patients’ primary care physicians to optimize HgA1c prior to surgery for elective cases.

Methods

Ongoing deidentified summary data pertinent to selected quality metrics PSI 11 (postoperative respiratory failure), PSI 12 (postoperative venous thromboembolism VTE), and postoperative surgical site infections were pulled from the hospital database of a dedicated tertiary, quaternary dedicated neurosciences center over a 4-year period (2015-2018). Internal and external validity checks were performed through internal data auditors and a contracted commercial entity (Premier, Charlotte, NC).

Findings

Although undoubtedly multifactorial, the number of wound infections in spine surgery patients at the target institution decreased from the time of program implementation to the present as follows (Table 5).

The efforts involved a coordination between the ambulatory clinics, pre-anesthesia departments, the operating room, post-anesthesia care unit, intensive care unit, and in-patient floors. In comparing pre-implementation year with full year following implementation: PSI 12, Perioperative DVT or PE, reduced 79%; PSI 11, postoperative respiratory failure reduced 45%; surgical site infection reduced 25% (Table 6).

At year 2, these improvements led in removal of hospital acquired condition reimbursement penalty (CMS Hospital

Table 5. Spine Fusion Surgical Site Infection Trend^a.

	2015	2016	2017	2018
Infection rate	1.31%	1.13%	1.00%	0.56%
Numerator (N), denominator (D)	N = 14, D = 1066	N = 14, D = 1234	N = 9, D = 900	N = 5, D = 894

^aSource: National Health Safety Network (NHSN) Surveillance Spine Fusion.

Table 6. Summary of Clinical Areas Overcome by Implementing Quality Improvement Strategies.

Postoperative Complication	Solution	Outcome
Respiratory complications	Incentive spirometry back to basics protocol	Postoperative respiratory failure reduced 45%
Wound complications	Glycemic and nutrition protocol	Surgical site infection reduced 25%
DVT/PE	Mobilization protocol	Perioperative DVT or PE reduced 79%

Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism.

Acquired Conditions Reduction Program), to the financial amount of roughly US\$1 million annually. Additionally, CMS (Hospital Compare) star rating of facility increased by a full star. These initiatives were subsequently recognized by organizational annual quality award. Now in year 3, focus is on sustainment and anchoring the fundamentals of these initiatives into standard of care while continuously monitoring, reviewing, and adapting to meet unique needs of patients receiving complex spine care.

Summary

As previously discussed, utilizing a change model such as the Lewin model of change theory helps ensure the support necessary to maintain, sustain, and expand initiatives. The quality initiative described above met several impediments following the initial success. As part of a review process following this quality initiative we identified barriers of sustainability. Specifically,

- Change in leadership and staffing
- Scope of project
- Disconnect between prioritization by ambulatory versus inpatient setting

Implementation of a multifaceted quality initiative requires the support of many individuals across settings. The above initiative was implemented over the course of a year, at a time when we saw turnover at many leadership levels as well as staffing at the RN level (the strongest driver of this initiative). With rapid turnover and use of temporary, agency, and per diem staffing, the commitment to the program slowed. In addition, the overall scope of this project was wide. With 5 separate

initiatives woven into one larger all-encompassing initiative we found it difficult to perform the audits and continued education necessary to support the program. Last, despite a committed group of individuals in the ambulatory and inpatient setting, each location prioritized the initiative at various levels. For the clinic this initiative was a driving force in the work that RNs were performing. That being said, inpatient nurses were required to meet numerous metrics, only one of which was the above initiative.

Although our complication, readmission, and return to operating room rates remains at an admirable level we continue to find room for ongoing improvement. The challenge remains, how to embark on an ongoing process of course correction without loss of initiative and momentum, especially in times of ever-present cost-cutting efforts by hospital administrations. Recommendations include the development of an interdisciplinary group with representatives from each setting, identification of a champion(s) to support this effort, developing attainable auditing measurements to ensure compliance, and development of a standardized training for onboarding so the initiatives become part of the culture that new staff are presented with. In the big picture perspective having a regular reporting mechanism that is supported and recognized by the overall hospital system and then is duplicated in other facilities within the system can create a setting for ongoing quality initiatives and a sustained drive for improvement as part of the organizational culture—starting with each individual practitioner to the hospital and from there to its health care system.

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