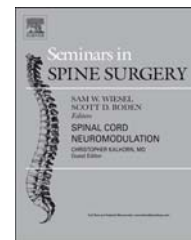




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Quality and safety improvement initiatives in complex spine surgery

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ABSTRACT

The global health policy landscape is shifting. Health care is moving toward a value-based system with emphasis on reduced adverse events, improved patient outcomes, and increased cost efficiency. Studies have demonstrated that complex adult lumbar scoliosis surgery is accompanied by high variability in complication rates, which may be prevented with improved delivery of evidence-based care. In particular, standardized, systematic, multidisciplinary perioperative care protocols have been shown to significantly reduce the likelihood of a spectrum of negative outcomes associated with complex adult lumbar scoliosis surgery. This paper presents a review and analysis of multiple quality and safety improvement initiatives and methodologies in adult complex spine surgery. Achieving maximal quality and safety improvements in this field appears to require clinicians to go beyond focusing on specific elements of clinical practice and pay attention to optimizing the perioperative system. Two novel conceptual models were developed: the SpineSIM-D and the SpineSIM-C. They synthesize key success factors operating at the individual, team, and organizational levels to guide future quality and safety improvement initiatives. 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.

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1. 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 morbidity³⁻¹⁰ 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

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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.

1.1. 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 accountability 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

1.2. 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.²⁷⁻³⁰

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

1.3. Institution-specific risk

Quality performance and risk to the patient vary by institution.³² Patients are exposed to differing levels of risk depending 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.

1.4. 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 outcome 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 outcome 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 DSS have the potential to improve clinical decision-making processes and the quality of decisions made, achieving incremental patient safety improvements.^{37,38}

1.5. 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

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