Orthopaedic Knowledge Update®

OKU® 6

Pediatrics

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Pediatrics

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Preface

The sixth edition of *Orthopaedic Knowledge Update®: Pediatrics* is an extension of the previous editions of this series that focuses on musculoskeletal conditions in children and adolescents. This text is written for the experienced orthopaedic practitioner, not the superspecialist or the beginning student.

The goal of *OKU®: Pediatrics 6* is to describe the important developments in pediatric orthopaedics over the past 5 years, while providing core information for each topic. The editors and authors integrated new information with fundamental knowledge to provide an essential resource for the practicing general orthopaedic surgeon and pediatric subspecialist. The annotated reference list at the end of each chapter contains classic articles as well as updated references, with annotations provided for references published within the past 5 years.

Chapters new to the sixth edition include Developmental Biology, Metabolism, Cerebral Palsy: Upper Extremity, High-Energy Injury and Polytrauma, Elbow Trauma, Knee Trauma, and Disaster and Mass Casualty Preparedness.

The quality of this book is directly related to the efforts of the section editors: Brandon Ramo, Benjamin A. Alman, Henry G. Chambers, Charles A. Goldfarb, Vishwas R. Talwalkar, James O. Sanders, Mark R. Sinclair, and Jennifer M. Weiss. These individuals are leaders within the field of orthopaedics and worked hard to ensure that the content of this edition is complete, accurate, and of high quality. We are all indebted to the expert authors who volunteered their time and then spent many hours reviewing the literature and writing these excellent chapters.

The project would not have succeeded without the excellent work of the publications staff of the American Academy of Orthopaedic Surgeons and Wolters Kluwer. Special credit and thanks go to the entire team and in particular to Lisa Claxton Moore and Emily Buccieri. It has been a privilege to participate in this effort.

We hope that the readers find this book to be a useful resource in the treatment of children with musculoskeletal conditions. Suggestions to improve future editions would be appreciated.

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SECTION 1

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CHAPTER 1

Quality, Safety, and Value

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ABSTRACT

The concepts of quality, safety, and value continue to receive attention in the rapidly changing healthcare landscape. An understanding of quality measures and quality improvement methodology, as well as using surgical simulation, implementing checklists, and creating a culture of safety, can improve the quality and safety of orthopaedic surgery. In turn, these efforts in quality and safety will improve patient outcomes and contain costs, thus improving value delivery in orthopaedic surgery.

Keywords: cost; quality; quality improvement; safety; value

INTRODUCTION

During the past decade, increased attention has been directed at improving the value of patient care through higher quality outcomes and improved patient safety. Two reports published by the Institute of Medicine at the beginning of the 21st century raised the collective awareness of patients, payers, hospitals, and providers regarding the importance of quality, safety, and value in the practice of medicine.[1,2] To further this effort, the Pediatric Orthopaedic Society of North America implemented a "Quality, Safety, and Value Initiative" in 2011 to involve society members in providing leadership, education, and direction to discussions on quality, safety, and value taking place both locally and nationally.[3-5] Each concept—quality, safety, and value—will be discussed, including specific applications to pediatric orthopaedic surgery.

Dr. Brighton or an immediate family member serves as a board member, owner, officer, or committee member of the American College of Surgeons and the Pediatric Orthopaedic Society of North America. Dr. Bae or an immediate family member serves as a paid consultant to or is an employee of OrthoPediatrics and serves as a board member, owner, officer, or committee member of the American Academy of Orthopaedic Surgeons, ASSH, and POSNA. Dr. Shah or an immediate family member serves as a board member, owner, officer, or committee member of the American Society for Surgery of the Hand and the Pediatric Orthopaedic Society of North America.

QUALITY

Physicians would universally agree that their top priority is to provide high-quality health care, but a challenging concept remains: What defines quality? The answer depends on who is answering the question and what is important to that individual. It also depends on who is defining quality and how the individual or organization is measuring it. Surgeons frequently refer to quality in the context of low infection, complication, and mortality rates, or adherence to process measures and practice guidelines. Patients and families may view quality from the perspective of rate of recovery and return to function. The Institute of Medicine defined quality as the "degree to which healthcare services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge."[1] In addition, the Institute of Medicine outlined six specific aims for improving health care that are focused on delivering care that is safe, effective, patient centered, timely, efficient, and equitable. In the equation, *value* = (*outcome* + *experience*)/*cost*,[6] quality is a composition of patient outcomes, safety, and patient experience. Improving the quality of care and patient outcomes provides an important opportunity to add value for a given cost.[7]

Quality Improvement

Quality improvement in health care is a systematic, data-guided activity designed to bring about immediate positive change in the delivery of health care in particular settings.[8] Quality improvement methodology is used to incorporate new knowledge into clinical practice and apply this information to fix existing problems in care delivery. The aim is to become more effective, safe, and efficient and continually improve processes of care. Such methodologies and principles originally were designed and implemented in the manufacturing industry and have been applied to health care to provide a framework for improving patient care. Commonly used methodologies include Lean, Six Sigma, and the Model for Improvement.

Lean is a quality improvement methodology that evolved from the Toyota Production System, which was a framework to map out and preserve the processes of value and eliminate waste and inefficiency.[9] One hallmark of the Lean process is the standardization of processes to ensure consistency. The Lean approach requires an understanding of the process, including how the process is intended to work and variations in the process that have evolved across time. This methodology has been used in several healthcare settings to improve the surgical care of patients.[10]

Six Sigma also has its origins in the manufacturing industry. This approach relies on precise and accurate measurements of process and outcomes using the improvement process known by the acronym DMAIC (define, measure, analyze, improve, and control). The problem within a process is defined, any defects are measured, the cause of the defects are analyzed, the process performance is improved by removing the causes of the defects, and the process is controlled to ensure that the defects do not recur. The Six Sigma goal is to identify and reduce error rates to the six sigma level (<3.4 defects per million opportunities).[11] Examples of Six Sigma methodology can be seen in reducing medication administration errors and improving operating room efficiency.[10,12]

Lean Six Sigma is a combination of Lean and Six Sigma principles that is often applied in health care. It aims to improve care by incorporating the Lean principles of eliminating waste and improving efficiency and the Six Sigma approach of pursuing accuracy and effectiveness.

The Model for Improvement is another example of a quality improvement methodology that provides a framework for improving a process or a system.[13] The model contains four essential components: an aim, measurement, change ideas, and tests of change. The first three components are examined by three key questions: (1) What are we trying to accomplish? (2) How will we know that a change is an improvement? and (3) What changes can we make that will result in an improvement? The final component involves using a technique for rapid testing and learning from change known as the plan-do-study-act cycle (**Figure 1**). Using a series of

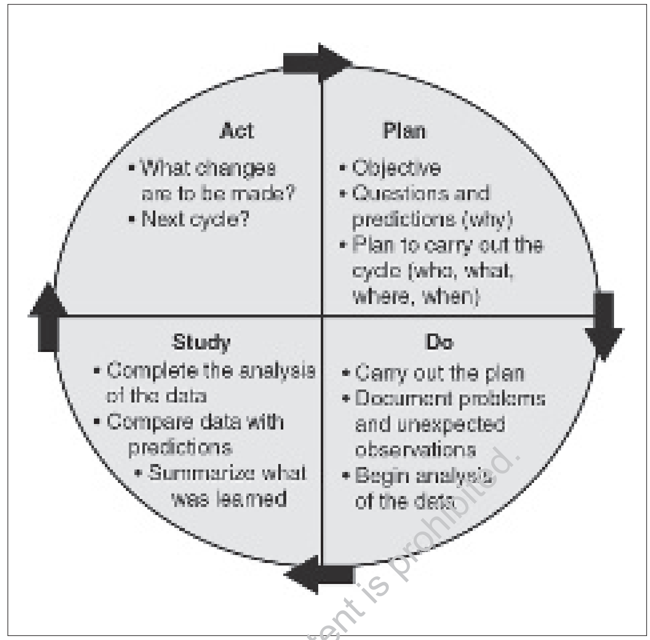

FIGURE 1 Illustration of the plan-do-study-act cycle for learning and improvement.

small plan-do-study-act cycles, changes on a larger scale can be made to improve and sustain improved patient care across time.

There are a number of examples of using quality improvement methodology in pediatric orthopaedic surgery. A 2017 article described an education and training program instituted at Boston Children's Hospital to reduce cast saw injuries.[14] Another example is the institutional investigation demonstrating that a dedicated orthopaedic trauma operating room in a pediatric trauma center was associated with fewer after-hours procedures, decreased wait time to the surgical procedure, reduced length of hospitalization, and lower cost.[15] The authors of a 2018 study, using the Model for Improvement quality improvement methodology, were able to implement evidence-based protocols for the treatment of pediatric supracondylar humerus fractures and distal radius buckle fractures to improve practice recommendations and reduce practice variation.[16] Some clinical examples of the application of quality improvement methodology [15,17-22] are listed in **Table 1**.

Quality Indicators and Measures

Quality indicators refer to a set of clear, measurable items that are ideally related to outcome. Numerous public and private agencies have already begun to define, measure, and report on healthcare quality.[23,24] In a systematic review of the pediatric orthopaedic surgery literature, researchers found mortality, postoperative complications, revision surgery, and readmission rates as the most commonly referenced quality indicators.[25]

TABLE 1

Examples of the Application of Quality Improvement Methodology to Patient Care

Methodology	Example
Improving efficiency of processes (streamlining)	Improving operating room efficiency, use of a dedicated orthopaedic trauma operating room in a pediatric trauma center
Eliminating waste associated with the process (logistics)	MRI use in musculoskeletal infection
Reducing errors and adverse events (safety)	Eliminating cast saw injuries
Decreasing variation in choosing and using processes (utilization and standardization)	Best-practice guidelines for high-risk spine surgery
Improving communication within the healthcare team (use of checklists)	Use of an intraoperative neuromonitoring checklist
Improving systematization of the process (care pathways)	Rapid recovery care pathways in adolescent idiopathic scoliosis
Maximizing health improvement (outcomes)	Patient-reported outcomes (PROMIS, PODCI)
Enhancing the patient's experience of care (satisfaction)	Patient satisfaction scores

PODCI = Pediatric Outcomes Data Collection Instrument, PROMIS = Patient-Reported Outcomes Measurement Information System

Adapted with permission from Jevsevar DS: Health system perspective: Variation, costs, and physician behavior. *J Pediatr Orthop* 2015;35(5 suppl 1):S14-S19.

Defining and measuring quality is essential to identify gaps in performance, make changes, and monitor and compare long-term performance. Process measures require defined criteria that can be determined by nationally derived evidence-based guidelines, institutional guidelines, or consensus guidelines. These often serve as surrogates to define the quality of care and may include compliance with clinical care pathways or adherence to evidence-based guidelines, with limited effect on value. Measures of patient expectations, satisfaction, function, and patient-reported outcomes all can be used to measure outcomes, yet no universal set of outcomes measures exist to clearly define the quality of care being delivered. The ideal measures should be clearly defined, easily obtainable, and risk adjusted to discriminate among levels of quality. The concept of standardization of outcomes measures remains on the near horizon.[26]

PATIENT SAFETY

Beginning with the Institute of Medicine report "To Err Is Human: Building a Safe Health System,"[2] recognizing the magnitude and scope of preventable errors and adverse events has led to the modern patient safety movement.[27] This movement has shifted focus away from individual errors because complications or adverse outcomes resulting from careless or technically incompetent providers are rare. Rather, current efforts aim to optimize care delivery systems, using principles such as standardization, simplification, reducing reliance on memory or experience, and crisis resource management.[27] Currently, patient safety is defined as the prevention and mitigation of harm caused by errors of omission or commission that are associated with health care, which involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur, before they reach the patient.

In pediatric orthopaedics, the first level of improving patient safety involves improving technical performance and minimizing technical error. Surgical simulation is an example of how performance may be improved through iterative, deliberate practice of surgery without patient risk.[28] Simulation training to improve technical performance has been used in several orthopaedic surgical disciplines, ranging from arthroscopy to complex spine surgery.[29-32] Although high-fidelity, virtual reality simulation trainers are available, effective training may be imparted with low-fidelity models focused on fundamental orthopaedic procedures. For example, recent publications highlight the use of a simple distal radius fracture cast model for improving both proficiency and safety in closed fracture treatment, cast application, and cast removal.[33,34] One simulation curriculum using this model was found to significantly decrease the rate of complications and, in doing so, yielded an 11:1 return on investment.[14] The authors of a 2019 study further reported that simulation training for distal radius fractures decreases the risk of loss of reduction and improves radiographic outcomes.[35]

In addition, the implementation of checklists has been an important measure to improve patient safety through error prevention. Most notably, the World Health Organization developed the Surgical Safety Checklist in 2008 as part of the Safe Surgery Saves Lives initiative. The checklist seeks to improve patient safety by promoting communication within surgical teams and minimizing the risk of preventable error. Therefore, the checklist provides a list of safety checks to be taken before inducing anesthesia (sign in), just before incision (time out), and at the conclusion of each procedure (sign out). Although compliance with the checklist is still variable, prior investigations have suggested that this simple measure may prevent adverse events and improve patient outcomes.[36,37] Various checklists have been similarly introduced in several orthopaedic subspecialties, including implant arthroplasty, anterior cruciate ligament reconstruction, spine surgery, and hand surgery; future work in pediatric orthopaedics is underway.[21,38-40]

The Safety Culture

Perhaps the most important, yet most challenging and elusive, step toward improving patient safety is to create a culture of safety.[27,41] Pediatric orthopaedic care is a complex and ever-changing field, yet safety cultures have been effectively nurtured in other equally complex industries, such as aviation and manufacturing. Effective individuals and organizations create a culture of safety by (1) acknowledging that errors occur; (2) participating in nonjudgmental mechanisms to identify, understand, and own the root sources of error; (3) recognizing expertise from stakeholders regardless of hierarchy; and (4) embracing changes in practice to minimize errors and potential complications.[42] Prior studies of practicing orthopaedic surgeons have identified that surgeons are concerned about the safety climate in their work environments and are enthusiastic about promoting improved communication and procedural standardization to improve patient safety.[43] These attitudes serve as an important foundation, given the traditional hierarchal structure of surgery and its reliance on autonomous individual providers.

It is critical that this process involve all providers involved in patient care, including the practicing surgeon. Improvement in individual behavior—and a decrease in disruptive behavior—may not only improve team dynamics but also decrease medical error and adverse patient outcomes.[44] Several initiatives have been developed to assist in provider education and training. Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), for example, was developed by the Agency for Healthcare Research and Quality as a comprehensive, evidence-based teamwork system.[45] By providing means for site assessment, team training, implementation, and sustainment of change, TeamSTEPPS can improve team-based behavior and, ultimately, patient safety. Prior application of TeamSTEPPS programs improved perceptions of teamwork and communication and positively influenced clinical performance (eg, nosocomial infection rates and time to successful extracorporeal membrane oxygenation cannulation) in pediatric intensive care units.[46,47] Similar team training may improve patient outcomes and create a sustainable culture of patient safety within pediatric orthopaedics.[48]

Future Directions

Despite widespread efforts to improve patient safety, challenges remain. Some errors, such as wrong-site surgery, seem more refractory to time-outs and other systematic protocols. Systems initiatives that were proven effective in smaller pilot studies have not been appreciated with widespread implementation and generalization. Changing technology, rapidly advancing surgical techniques, organizational silos of healthcare systems, and persistent reliance on individual surgeons to manage patient care likely represent some of the reasons for these challenges. The current reimbursement system in the United States may further add challenges. Providers are typically incentivized and rewarded based on volume, not value. Work is underway to understand variations in compliance with checklists and other safety measures to improve adoption of and adherence to these helpful tools. In addition, continued cultural shifts away from individual autonomy and toward collaborative systems are needed to maximize patient care and safety.

VALUE

For decades, healthcare costs in the United States and other developed countries have steadily risen. In the United States, healthcare expenditures have increased at a greater rate than the economy as a whole for 31 of the past 40 years and now approach 18% of the gross domestic product.[49,50] This percentage is expected to reach 19.6% by 2024.[49] The Institute of Medicine has identified six domains of wasted expenditures including failure of care delivery, failure of care coordination, overtreatment or low-value care, pricing failure, fraud and abuse, and administrative complexity. When considering these six domains, the estimated cost of waste in the US healthcare system ranged from $760 to $935 billion, representing approximately 25% of total healthcare spending.[50]

Health economists have suggested that competition of the wrong type is responsible for this staggering level of waste in the US healthcare system.[51] In healthy competitive markets, motivation to improve efficiency and quality generally results in productive innovation, improved service, and decreased costs. However, in the current healthcare economy, competition occurs at the wrong level and has a poor focus.[51] In this market, costs continue to rise without concomitant improvements in quality. Leading health economists have suggested that competition within the US healthcare sector is a zero-sum game, where value is divided through cost shifting between patients, payers, and providers. Cost shifting increases administrative expenses without net cost reduction or value creation. Value-based competition is lacking in the United States.

How Do We Define and Measure Value?

Value is defined as “the health outcomes achieved per dollar spent” to achieve those outcomes.[6] Most thought leaders emphasize that the health outcomes of interest to patients include both the quality of health care plus patient and family satisfaction. The value of health care is represented by the equation: *value* = (*health outcomes* + *patient satisfaction*)/*cost*.

One of the most difficult challenges in creating value-based competition is measuring value. Outcomes can be measured by a wide variety of quality metrics (patient-related outcome measures, function, and safety), and satisfaction can be measured by a wide variety of service metrics (patient satisfaction, convenience, timeliness, and communication). Although less attention has historically been paid to measuring cost, costs have received increasing scrutiny given the apparent deficiency of financial sophistication in many healthcare provider organizations. Investigations in 2013 and 2018 demonstrated that only 10% to 45% of provider organizations could provide patients and families with cost estimates for common orthopaedic surgical procedures including total hip arthroplasty in adults and percutaneous pinning of distal radius fractures in children.[52,53]

How Do We Measure Patient Outcomes?

Patient-reported outcomes are important for assessing patient satisfaction and clinical outcomes. Some patient-reported outcome measures are generic and appropriate for use in a wide variety of conditions (eg, the Pediatric Quality of Life Inventory). Other patient-reported outcome measures are disease specific and focus on symptoms or side effects of a specific set of diseases, conditions, or treatments (eg, the Scoliosis Research Society Questionnaire). Disease-specific patient-reported outcome measures tend to be more sensitive to treatment-related changes and may help to precisely measure healthcare value.[54]

The advent of computer adaptive testing appears to offer major advantages in determining patient-centered outcomes. The National Institutes of Health has funded the development of the Patient-Reported Outcomes Measurement Information System (PROMIS), a well-used set of computer-adaptive patient-reported outcome measures. The use of PROMIS has increased in the measurement of musculoskeletal health outcomes. In 2014, researchers demonstrated that computerized adaptive testing using the PROMIS physical function item bank reduced testing burden and had a lower ceiling effect compared with a nonadaptive patient-reported outcome measure.[55] Several PROMIS physical function item banks have been validated for use in children.[56,57]

How Do We Measure Costs?

Most healthcare provider organizations measure costs using a cost-to-charge ratio or a relative value unit (RVU). In a cost-to-charge methodology, cost is estimated by multiplying charges set by the hospital charge master, which is a listing of every single procedure that a hospital can provide to its patients, by the cost-to-charge ratio. This type of methodology incorrectly assumes that each type of service consumes indirect costs in the same proportion; it tends to overallocate costs to some services and underallocate costs to others. As an example, a provider organization may falsely assume that procedures with high charges also have high costs. Because charges often reflect organizational pricing and negotiation strategies, the linkage of cost and charge may distort internal cost estimates.

An RVU methodology can theoretically generate refined cost estimates. RVUs are estimates of the relative time, complexity, and value of a service; they are used to more accurately allocate costs to individual procedures and activities. In theory, RVUs can accurately reflect real costs; however, in practice, the allocation methodologies tend to be imprecise. This lack of granularity often leads to unintended cost distortions. As an example, in an RVU methodology, the high cost of a robotic surgical system could be attributed to all surgical procedures rather than the small subset of procedures in urology and gynecology that require its use. It may be possible to improve cost estimates using RVUs with rigorous methodology.

These cost-measurement approaches have obscured value in health care and have led to cost reduction efforts that are incremental, ineffective, and occasionally counterproductive. Most healthcare organizations measure and accumulate costs according to departments, physician specialties, or discrete service lines—a reflection of internal organization and the financing of care. Costs, like outcomes, should instead be measured according to the patient and distributed across the entire care cycle. This type of cost accounting methodology could enable truly structural cost reduction by eliminating non–value-added services, improving capacity utilization, shortening cycle times, providing services in more efficient settings, and so forth.

In 2004, a new accounting technique, time-driven activity-based costing (TDABC), was introduced and has since gained popularity in leading healthcare organizations.[58,59] TDABC assigns costs based on the specific resource time each service or product requires and the unit cost of supplying capacity (labor, equipment, space): *resource cost* = *cost rate* × *time*. The total cost is the sum of each resource cost: ($cost\ rate_A \times time_A$) + ($cost\ rate_B \times time_B$) and so on. In this accounting technique, costs are carefully assigned based on actual labor and equipment utilization.

Data from a 2016 study suggest that TDABC may more accurately reflect costs in orthopaedic surgery than cost-to-charge or RVU methodologies.[60] An investigation published in 2016 suggests that traditional accounting systems that use cost-to-charge or RVU methodologies may overestimate costs associated with many surgical procedures. An investigation of carpal tunnel release in 2019 further demonstrated that TDABC appears to provide the granularity required to identify cost-reduction and value-improvement strategies.[59,61]

The measurement of value is the first step in improving value delivery in health care. Organizations that are able to precisely measure value, effectively eliminate practice pattern variations, and establish efficient clinical pathways will be best positioned to survive ongoing payment reform (eg, pay-for-performance, payment bundling, and accountable care organizations). The American Academy of Orthopaedic Surgeons has advocated the use of evidence-based clinical practice guidelines, which are systematically developed statements designed to support provider decision making in specific clinical scenarios. Such guidelines are based on available scientific evidence and attempt to reduce practice pattern variations and improve patient outcomes.

Standardized clinical assessment and management plans (SCAMPs) represent a promising adjunct to clinical practice guidelines.[62] A SCAMP is a flexible guideline that is designed to reduce practice variability while still permitting physicians the opportunity to exercise clinical judgment and offer treatment that is specific to a patient's clinical situation or personal preferences. SCAMP pathways are designed as decision trees that provide guidance based on the particular clinical scenario, such that management is individualized to the specific condition and patient. The first SCAMPs were developed and implemented at Boston Children's Hospital in 2009. Many features of SCAMPs are similar to the evidence-based care process models developed at the Intermountain Healthcare System in Utah.[63] In concept, either SCAMPS or evidence-based care process models could be seamlessly shared across provider organizations, resulting in rapid dissemination of actionable information. The transferability of these decision-support tools could permit provider organizations not initially involved in the design or implementation to rapidly reduce variation and create value.

SUMMARY

To improve value in pediatric orthopaedic surgery, there must be increased focus on improving outcomes and containing expenditures. Continuous quality measurement and rapid process change are critical aspects of any value improvement model. Although great challenges exist in outcome measurement, cost measurement, and the sharing of best practices across provider organizations, medical organizations, including the Pediatric Orthopaedic Society of North America, have taken a leadership role in uniting efforts across provider organizations.

KEY STUDY POINTS

- Quality in orthopaedic surgery often refers to process measures, patient-reported outcomes, patient experience, or patient safety measures.
- Quality improvement is a data-driven process using methods such as the Model for Improvement, Lean methodology, or Six Sigma to improve care in a particular setting.
- Patient safety is at the core of quality in health care, and activities such as the use of checklists, surgical simulation, and creating a safety culture are examples of methods to prevent harm and reduce errors.
- Value, although difficult to measure, is best thought of as a patient outcome or level of satisfaction achieved per unit of money spent to achieve said outcome.

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CHAPTER 2

Evidence-Based Quality and Outcomes Assessment in Pediatric Orthopaedics

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ABSTRACT

Evidence-based clinical practice guidelines, appropriate use criteria, outcome measures, and patient-reported outcome measures are critical tools to ensure the best clinical care for patients. These guidelines, criteria, and measures will be increasingly integrated into care pathways.

Keywords: appropriate use criteria (AUC); computerized adaptive testing; evidence-based clinical practice guidelines; outcome measures; Patient-Reported Outcomes Measurement Information System (PROMIS)

INTRODUCTION

Critical analysis of clinical care can lead to answers to a wide variety of clinical questions.[1-3] Pierre Charles Alexandre Louis, a French physician, applied the numerical method (early biostatistics) and helped end the practice of bloodletting.[4] The teachings and end result idea advocated by American surgeon Ernest Amory Codman influenced generations of outcomes researchers and inspired the American College of Surgeons and the Joint Commission for the Accreditation of Healthcare Organizations.[5] Randomized clinical trials and prospective study designs may produce the highest quality/lowest bias evidence; these types of studies, along with other forms of evidence, guide clinical care decisions.

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It is important for orthopaedic surgeons to review the use of evidence for clinical care, with an emphasis on evidence-based clinical practice guidelines (CPGs), appropriate use criteria (AUC), and outcome measures, including those from the Patient-Reported Outcomes Measurement Information System (PROMIS) and computerized adaptive testing.

CLINICAL PRACTICE GUIDELINES AND SYSTEMATIC REVIEWS

The Institute of Medicine has called for the increased use of CPGs to reduce practice variation, improve quality of care, and decrease inefficiencies.[6-8] A CPG is a "systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances."[7,8]

Historically, guidelines have been based on the consensus of expert groups, but consensus guidelines have several potential limitations: (1) Many guidelines do not consider all evidence. (2) Evidence integration and quality ranking may be flawed. (3) There may be a lack of transparency about conflicts of interest. (4) Results may not be reproducible by other groups. To address these limitations, the American Academy of Orthopaedic Surgeons (AAOS) guidelines are based on a systematic review of the literature and follow a rigorous, transparent, and reproducible methodology that meets all of the Institute of Medicine standards for developing trustworthy guidelines[9] (**Table 1**).

Clinical content experts develop systematically outlined research questions that define the patient, intervention, comparison, and outcome (PICO). Experts in the field of evidence analysis review the literature comprehensively, rank the quality of the study design and the risk of bias of the articles, and ensure that the evidence review is transparent, reproducible, reviewed by others, and updated.

TABLE 1

Institute of Medicine Standards for Evidence-Based Clinical Practice Guidelines

- Transparency
- Management of conflicts of interest
- Composition of the guideline group
- Standards for systematic reviews
- Establishing evidence foundations for and rating strength of recommendations
- Standard form for the articulation of the recommendations
- External review
- Updating

Overview: AAOS Guidelines and Systematic Review Process

For topics in which the published evidence contains a broad range of high-level/low-bias evidence, the CPG is an appropriate analysis. In cases in which the published evidence is not as robust to support a full CPG, a systematic review may be the best analysis. The AAOS addresses bias beginning with the selection of CPG and systematic review work group members, who function as the clinical content experts. Applicants with financial conflicts of interest related to the CPG or systematic review topic cannot participate if the conflict occurred within 1 year of the start date of the CPG or systematic review development, or if an immediate family member has a relevant financial conflict. In addition, all CPG or systematic review development group members sign an attestation form agreeing to remain free of relevant financial conflicts for 1 year following the publication of the CPG or the systematic review.

Physician and clinician groups (clinical experts) prepare CPGs and systematic reviews with the assistance of the AAOS Department of Clinical Quality and Value (expert evidence methodologists). These evidence methodologists include data analysts, health economics and outcomes research experts, and statisticians. As the physician experts, the CPG or systematic review work group defines the scope of the CPG or systematic review by creating PICO questions that direct the literature search. The medical librarian creates and executes the search or searches. The supporting group of expert methodologists reviews all abstracts, reviews pertinent full-text articles, and evaluates the quality of studies meeting the inclusion criteria. They also abstract, analyze, interpret, and summarize the relevant data for each PICO question and prepare the initial draft for the final work group meeting.

After completion of the systematic reviews, physician CPG work groups meet in person to participate in a 1-day meeting to develop the recommendations. To complete their charges, the physician experts and methodologists evaluate and integrate all material to develop the final recommendations. The final recommendations and rationales are edited, written, and voted on by the clinician work group. The CPG or systematic research work group may approve additional edits to the rationales via subsequent webinar meetings. The draft CPG or systematic review recommendations and rationales receive final review by the methodologists to ensure consistency with the data. The draft is then completed and subsequently undergoes a period of peer review.

After peer review and editing, the CPG or systematic review draft is distributed for public commentary. Thereafter, the AAOS Committee on Evidence-Based Quality and Value, AAOS Council on Research and Quality, and the AAOS Board of Directors sequentially approve the draft CPG or systematic review. All AAOS CPGs are reviewed and updated or retired approximately every 5 years. The process of AAOS CPG or systematic review development incorporates the benefits from clinical physician expertise and the statistical knowledge and interpretation of methodologists without conflict. The process also includes an extensive review process offering the opportunity for more than 200 clinical physician experts to provide input before publication. This process minimizes bias, enhances transparency, and ensures the highest level of accuracy for interpretation of the evidence.

The language used in the recommendations is based on the quality of the evidence, and a star system is used for ranking the strength of the recommendation based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE, more stars = greater strength; **Table 2**).

The AAOS has developed 20 evidence-based CPGs since 2007; 7 have clinical applicability to pediatric and adolescent care, and 3 are focused specifically on pediatric orthopaedics (**Table 3**). These guidelines can be accessed through the OrthoGuidelines website; a free mobile application is available (http://www.orthoguidelines.org/).

APPROPRIATE USE CRITERIA

The randomized clinical trial serves as the benchmark for clinical research, but these trials are complicated, expensive, and time-intensive and labor-intensive. Because they are performed under ideal circumstances, the results are not always generalizable. In many technical fields, including orthopaedic surgery, randomized clinical trials are complex (thereby limiting their construction and recruitment); may not have broad external applicability; or simply are not available. CPGs rely on higher-level evidence, but in many fields, higher-level evidence may be lacking. In areas in which the evidence base is less robust, AUC may be especially valuable. In 1986, a method was introduced for the detailed assessment of the appropriateness of medical

TABLE 2

American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guideline Strength of Recommendation Descriptions

Strength of Recommendation	Overall Strength Of Evidence	Description of Evidence Quality	Strength Visual
Strong	**Strong or moderate**	Evidence from two or more high-quality studies with consistent findings for recommending for or against the intervention. Or Rec is upgraded from moderate using the EtD framework	★★★★
Moderate	**Strong. Moderate or limited**	Evidence from two or more moderate-quality studies with consistent findings, or evidence from a single high-quality study for recommending for or against the intervention. Or Rec is upgraded or downgraded from limited or strong using the EtD framework.	★★★☆
Limited	**Limited or moderate**	Evidence from one or more low-quality studies with consistent findings or evidence from a single moderate-quality study recommending for or against the intervention. Or Rec is downgraded from moderate using the EtD framework.	★★☆☆
Consensus	**No reliable evidence**	There is no supporting evidence, or higher quality evidence was downgraded due to major concerns addressed in the EtD framework. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion.	★☆☆☆

Reproduced from the American Academy of Orthopaedic Surgeons: *Appropriate Use Criteria Methodology*. Rosemont, IL, American Academy of Orthopaedic Surgeons, 2019. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/methodology/cpg-methodology.pdf. Accessed June 30, 2020.

TABLE 3

Published American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines

Acute Compartment Syndrome (2018) AUC
Anesthesia and Analgesia in TJA (2020) CPG Endorsement
Anterior Cruciate Ligament Injuries (2014) AUC
Carpal Tunnel Syndrome (2016) AUC
Distal Radius Fractures (2009) AUC
Glenohumeral Joint Osteoarthritis (2020)
Hip Fractures in the Elderly (2014) AUC
Limb Salvage or Early Amputation (2019) AUC
Osteoarthritis of the Hip (2017) AUC
Osteoarthritis of the Knee (Arthroplasty) (2015) AUC
Osteoarthritis of the Knee (Non-Arthroplasty) (2013) AUC
Osteochondritis Dissecans (2010) AUC
Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months (2014) AUC
Pediatric Diaphyseal Femur Fractures (2015)
Pediatric Supracondylar Humerus Fractures (2011) AUC
Periprosthetic Joint Infections (2019)
Prevention of Orthopaedic Implant Infection in Patients Undergoing Dental Procedures (2012) AUC
Psychosocial Factors Influencing Trauma Recovery (2019)
Rotator Cuff Injuries (2019) AUC
Surgical Site Infections (2018) AUC
Tranexamic Acid in Total Joint Arthroplasty (2018) CPG Endorsement
Use of Imaging Prior to Referral to a Musculoskeletal Oncologist (2018) CPG Endorsement
Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty (2011)

Reproduced from the American Academy of Orthopaedic Surgeons: *OrthoGuidelines*. Rosemont, IL, American Academy of Orthopaedic Surgeons, 2020. Availabel at: http://www.orthoguidelines.org/guidelines. Accessed June 30, 2020.

technologies based on the concept that synthesizing expert medical opinion could simultaneously incorporate the knowledge gained from randomized clinical trials with that of clinical experience.[10] Expert panels were asked to rate the appropriateness of different interventions where "appropriate was defined to mean that the expected health benefit (ie, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity)…exceeded the expected negative consequences (ie, mortality, morbidity, anxiety of anticipating the procedure, pain produced by the procedure, time lost from work) by a sufficiently wide margin that the procedure was worth doing [exclusive of cost]."

This early concept developed into the RAND/UCLA Appropriateness Method, which was developed by the RAND Corporation and clinicians at the University of California at Los Angeles (UCLA) as an instrument primarily designed to measure the overuse and underuse of medical and surgical procedures.[11,12]

Whereas a CPG indicates, based on best evidence, whether a given intervention is associated with a desirable outcome, the AUC indicates when (ie, in what specific clinical situation) the same intervention is best applied. The purpose of the AUC is to help determine the appropriateness of CPG recommendations for the heterogeneous patient populations routinely seen in practice. The best available scientific evidence is synthesized with collective expert opinion on topics where benchmark, randomized clinical trials are not available or are inadequately detailed for identifying distinct patient types. When there is evidence corroborated by consensus that expected benefits substantially outweigh potential risks, exclusive of cost, a procedure is determined to be appropriate. The AAOS uses the RAND/UCLA Appropriateness Method. The process includes the following steps: reviewing the results of the evidence analysis, compiling a list of clinical vignettes, and having an expert panel composed of representatives from multiple medical specialties determine the appropriateness of each of the clinical indications for treatment; classification is stratified as appropriate, may be appropriate, or is rarely appropriate.

In 2014, two AAOS AUC documents directly relevant to pediatric orthopaedic surgery were published: one addressing the management of pediatric supracondylar humerus fractures[13] and one on pediatric supracondylar fractures with vascular injury.[14] These follow the CPG on the treatment of pediatric supracondylar humerus fractures published by the AAOS in 2011.[15] There are also other AUCs that are applicable to the pediatric orthopaedic patient population, including anterior cruciate ligament injury prevention and treatment (two AUCs), osteochondritis dissecans, developmental dysplasia of the hip in infants up to 6 months of age for generalists and orthopaedic specialists (two AUCs), prevention of orthopaedic implant infection in patients undergoing dental procedures, and surgical site infections.

In developing an AAOS AUC document (and in keeping with the RAND/UCLA Appropriateness Method), a writing panel made up of orthopaedic specialists who have expertise in treating the specific condition is assembled. The panel follows the following guiding principles: Patient scenarios must include a broad spectrum of patients who may be eligible for treatment of pediatric supracondylar humerus fractures (comprehensive). Patient indications must classify patients into a unique

TABLE 4

Interpreting the Nine-Point Appropriateness Scale

Rating	Explanation
7-9	**Appropriate:** Appropriate for the indication provided, meaning treatment **is** generally acceptable and **is** a reasonable approach for the indication and **is** likely to improve the patient's health outcomes or survival.
4-6	**May Be Appropriate:** Uncertain for the indication provided, meaning treatment **may** be acceptable and **may** be a reasonable approach for the indication, but with uncertainty implying that more research and/or patient information is needed to further classify the indication.
1-3	**Rarely Appropriate:** Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e. procedure is not generally acceptable and is not generally reasonable for the indication).

Reproduced from the American Academy of Orthopaedic Surgeons: *Appropriate Use Criteria Methodology.* Rosemont, IL, American Academy of Orthopaedic Surgeons, 2019. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/methodology/auc-methodology_v1.1.pdf. Accessed June 30, 2020.

scenario (mutually exclusive). Patient indications must consistently classify similar patients into the same scenario (reliable, valid indicators).

The writing panel develops the scenarios by categorizing patients in terms of indications evident during the clinical decision-making process. These scenarios rely on definitions and general assumptions, mutually agreed on by the writing panel during the development of the scenarios. These definitions and assumptions are necessary to provide consistency in the interpretation of the clinical scenarios among experts voting on the scenarios and readers using the final criteria. The writing panel then organizes these indications into a matrix of clinical scenarios that address all combinations of the classifications.

When the work of the writing panel is completed, a separate independent voting panel is formed, composed of approximately 50% specialists and 50% nonspecialists (a specialist is defined as an orthopaedic surgeon who treats the condition addressed in the AUC that is under study). The panel uses a modified Delphi process to determine appropriateness ratings. The objective of this process is not to force consensus, but rather to determine whether discrepancies in the ratings are the result of actual clinical disagreement over the use of a procedure. The appropriateness of each scenario is rated as shown in **Table 4**. Following the final (second) round of voting, the final levels of appropriateness are determined as shown in **Tables 5** and **6**. Web-based AUC applications are available at the AAOS website. An example of the AUC application for pediatric supracondylar humerus fractures[16] is shown in **Figure 1**. The RAND/UCLA Appropriateness Method has now been used and studied in many procedural disciplines beyond orthopaedic surgery and found to be reliable.

TABLE 5

Defining Agreement and Disagreement for Appropriateness Ratings

Panel Size	Disagreement # of ratings between 1-3 or 7-9	Agreement # of ratings outside of appropriateness rating range
8, 9, 10	≥3	≤2
11, 12, 13	≥4	≤3
14, 15, 16	≥5	≤4

Reproduced from the American Academy of Orthopaedic Surgeons: *Appropriate Use Criteria Methodology.* Rosemont, IL, American Academy of Orthopaedic Surgeons, 2019. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/methodology/auc-methodology_v1.1.pdf. Accessed June 30, 2020.

TABLE 6

Interpreting Final Ratings of Criteria

Level of Appropriateness	Description
Appropriate	Median panel rating between 7 and 9 and no disagreement
May be appropriate	Median panel rating between 4 and 6 and no disagreement or median panel rating between 1 and 9 with disagreement
Rarely appropriate	Median panel rating between 1 and 3 and no disagreement

Adapted with permission of The Rand Corporation, from Fitch K, Bernstein SJ, Aguilar MD: *The Rand/UCLA Appropriateness Method User's Manual.* 2001.

FIGURE 1 The given screenshot shows an example of the American Academy of Orthopaedic Surgeons (AAOS) Appropriate Use Criteria for pediatric supracondylar humerus fractures. (Reproduced from the American Academy of Orthopaedic Surgeons: *Appropriate Use Criteria on Pediatric Supracondylar Humerus Fractures: Treatment*. Rosemont, IL, American Academy of Orthopaedic Surgeons, 2014.)

OUTCOMES ASSESSMENT

Outcomes assessment is important.[17] Ernest Codman is often referred to as the father of outcomes research because of his common-sense notion that every hospital should follow every patient it treats long enough to determine whether the treatment has been successful. If treatment is unsuccessful, Codman advocated that the reason for the failure should be determined to preventing similar failures in the future.[18] Modern outcomes assessment in pediatric orthopaedics is dependent on the interrelated concepts of validity (measuring what is intended to be measured), reliability (measuring it in a reproducible fashion), responsiveness to change (detecting true improvement or worsening), and minimum clinically important difference (MCID; measuring differences that are important to patients and parents).[19] Collectively, these traits of outcome instruments are referred to as psychometrics or psychometric properties. These same principles apply to both traditional clinician-measured parameters (eg, radiographic angles, joint range of motion) and patient-generated measures (both general and disease-specific, health-related quality-of-life instruments).

Validity has several dimensions that must be considered.[20] The simplest is face validity, which amounts to passing the so-called sniff test or duck test. For example, using the Scoliosis Research Society Outcomes Questionnaire as the main outcome measure for a study of pediatric phalangeal neck fractures has no face validity.

Content validity relates to the fact that questions or measurements pertinent to the thing being assessed are appropriately included. The content validity of the Early Onset Scoliosis Questionnaire was established via a process that created questions based on recorded interviews focusing on factors that are important to parents.[21]

Construct validity refers to how consistent the new test or questionnaire seems to be when compared with existing tools that measure similar things. When the Muscular Dystrophy Spine Questionnaire was being developed, its construct validity was established by comparing it with two other established instruments (the Activity Scale for Kids and the Pediatric Outcomes Data Collection Questionnaire).[22]

Criterion validity relates specifically to how well the new measure correlates with an established benchmark (if one exists). In a 2013 study of a new shoulder instability scale, the authors tested its criterion validity by comparing it with the Rowe anterior shoulder instability scale.[23]

The types of reliability commonly assessed are interrater reliability (two or more raters) and intrarater reliability (the same rater on different occasions).[24] Moreover, these types of reliability may involve either continuous or categoric variables. The key aspect of statistical methods aimed at assessing reliability is that they control for chance agreement. The intraclass correlation coefficient is most commonly used for continuous variables, whereas the kappa coefficient (also known as the Cohen kappa) is usually used for categoric variables.[25] Interpretation of reliability data is similarly dictated by the type of data being analyzed (**Tables 7 and 8**).

The concept of responsiveness to change relates to whether the measuring instrument is appropriately able to detect improvement or worsening after a treatment intervention. Ceiling and floor effects play an important role in the responsiveness of a questionnaire. An example of the ceiling effect is when all students taking an examination get an "A" because the test was too easy. An example of the floor effect is when another group of students all get an "F" because the test was too hard. It may seem obvious to clinicians, but it also has been shown that retrospective methods of evaluating responsiveness to change are of little value because they consistently provide overestimates.[26] Responsiveness to change is directly related to effect size.[27]

Effect size refers to the inherent difference in statistically significant and clinically significant outcomes.[28,29] Estimates of the proportion of patients benefiting from a treatment based on effect size and so-called anchor-based approaches

TABLE 7

Fleiss Criteria (Typically Used for Continuous Variables)

ICC ≥ 0.75 = excellent

ICC ≥ 0.40 and <0.75 = fair to good

ICC <0.40 = poor

ICC = intraclass correlation coefficient

Data from Fleiss J, Levin B, Paik MC: *Statistical Methods for Rates and Proportions*, ed 2. New York, NY, John Wiley & Sons, 1981, pp 1-800.

TABLE 8

Criteria of Landis and Koch (Typically Used for Categoric Variables)

<0 = less than chance agreement

0.01-0.20 = slight agreement

0.21-0.40 = fair agreement

0.41-0.60 = moderate agreement

0.61-0.80 = substantial agreement

0.81-0.99 = almost perfect agreement

Adapted by permission of International Biometric Society from Landis JR, Koch GC: The measurement of observer agreement for categorical data. *Biometrics* 1977;33(1):159-174.

such as the MCID have been shown to perform equivalently.[30] The MCID (also known as a minimum important difference) is attractive because it reflects the importance of the patient.[31,32] When the MCID following scoliosis surgery (as measured by the Scoliosis Research Society Outcomes Questionnaire) was assessed, there was a large change in the appearance domain, but minimal change (within measurement error) was noted in the activity domain.[33] It is important to keep in mind that some trials may demonstrate a statistically significant difference in treatment outcome, but the difference may not be meaningful or perceptible to patients. Designing studies to assess MCID ensures outcomes are meaningful to patients.

A growing number of orthopaedic researchers are improving instrument development using Rasch analysis. These analytic methods have been applied in a wide variety of fields other than health care, including education, psychology, marketing, and economics.[34] Rasch analysis is a form of item response theory that mathematically models question difficulty and examiner aptitude. Recently, the Pediatric Outcomes Data Collection Instrument was subjected to Rasch analysis for cerebral palsy patients with Gross Motor Function Classification System levels 1 through 3. This process identified several redundant items as well as ceiling effect in all domains except the sports/physical function domain.[34]

PATIENT OUTCOMES: PROMIS, COMPUTERIZED ADAPTIVE TESTING

The National Institutes of Health has funded the development of PROMIS to address deficiencies associated with legacy instruments. The PROMIS marks a new paradigm for measuring patient-reported outcomes that is made possible through computerized adaptive testing. Instead of administering a fixed set of questions that are indivisibly validated (classic test theory),[35] computerized adaptive testing uses computer algorithms to dynamically administer only the most informative questions based on that individual's previous responses from a large question bank until a prespecified level of precision is met. This method paradoxically allows for maximal measurement precision through the fewest possible number of administered questions (typically only three to five per domain).[36,37] Pediatric-specific question banks are available for various domains, including global health, mental health, physical health, and social health[38] (**Table 9**).

Reported benefits of computerized adaptive testing include reduced completion time that lowers the responder burden of the patient;[39,40] increases measurement precision with reduction of ceiling and floor effects;[41-43] and has the ability to add or subtract questions from the item bank without the need to re-create and validate an entirely new scale. The psychometric properties of computerized adaptive testing have outperformed legacy scales in adult orthopaedic patients.[39,41,42,44,45] Studies consistently show high correlation between the PROMIS and traditional instruments, but the PROMIS has increased reliability, decreased test length, and less unexplained variance in baseline studies. However, the responsiveness, or the ability of the PROMIS to detect change after treatment, has not been thoroughly evaluated in all orthopaedic patients, but has demonstrated limited improvement in cerebral palsy patients.[45]

The PROMIS has similarly been applied to pediatric orthopaedic patients to address the current limitations of existing instruments. The PROMIS can be used to assess multiple domains in pediatric patients, of which the most pertinent domains for pediatric orthopaedic patients include physical function, pain interference, anxiety, depression, and global health. The physical function domain may be scored singularly or broken into mobility (23-item question bank) and upper extremity (29-item question bank) domains that share approximately 35% common variance.[46] The PROMIS has shown good reliability in pediatric patients from 8 to 17 years of age, whether completed

TABLE 9

PROMIS Measures for Pediatric Patients (Ages 8 to 17 Years) and Parent Proxy Report (Ages 5 to 7 Years)

Domain	Subdomains
Global health	
Mental health	Cognitive function Emotional distress: anger Emotional distress: anxiety Emotional distress: depressive symptoms Life satisfaction Meaning and purpose Positive affect Psychologic stress experiences
Physical health	Fatigue Pain: behavior Pain: interference Pain quality (affective, sensory) Physical activity Physical activity: mobility Physical activity: upper extremity Physical stress experience Sleep-related disturbance Sleep-related impairment Strength impact
Social health	Peer relationships Family relationships

by the child or for the child by a parent.[47,48] When the parent completes the survey for the child, this is called parent-proxy. In addition, fewer children require parental assistance to complete the survey compared with legacy scales.[49,50] Finally, PROMIS for pediatric patients is available in multiple languages, depending on the domain being evaluated. For example, pain intensity is available in the following languages: Afrikaans, Arabic, Bosnian, Bulgarian, Chinese-Simplified, Chinese-Traditional, Croatian, Czech, Danish, Dutch, Finnish, French, Georgian, German, Greek, Gujarati, Hebrew, Hungarian, Italian, Kannada, Kazakh, Korean, Latvian, Lithuanian, Malay, Malayalam, Marathi, Norwegian, Orya, Polish, Portuguese, Punjabi, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Tamil, Telugu, Thai, Turkish, Ukrainian, Urdu, and Welsh.

The psychometric properties of computerized adaptive testing in pediatric orthopaedic patients have not been extensively researched, but have been compared with legacy scales in certain patient populations. PROMIS pediatric measures of general health have been shown to have excellent convergent and discriminant validity with the KIDSCREEN-10 and the Pediatric Quality of Life 15.[51] In pediatric patients with congenital hand deformities, the PROMIS was found to correlate with the Disabilities of the Arm, Shoulder and Hand score and the Pediatric Outcomes Data Collection Instrument, but was only mildly correlated with the Michigan Hand Questionnaire.[49] In children with cerebral palsy, the PROMIS physical function mobility portion showed good correlation with patient and parent assessments of mobility, but was less responsive to treatment than legacy scales (the Pediatric Outcomes Data Collection Instrument, the Functional Assessment Questionnaire, the Shriners Hospitals for Children with Cerebral Palsy Computer-Adapted Testing Battery) and did not distinguish between Gross Motor Function Measures as well as other instruments.[45,52] The investigators concluded that item-bank expansion may be needed before mobility computerized adaptive testing is applied to patients with cerebral palsy.

Pediatric orthopaedic surgeons should be aware of the PROMIS because it is likely that it will be used as a patient-reported outcome measure in the future. The number of scientific articles assessing or using PROMIS has increased exponentially in the past 10 years from 16 in 2005 to more than 150 in 2015. The measurement properties of the PROMIS appear favorable in adult orthopaedic patients across multiple specialties, but it is not known if they will translate into similar results in pediatric orthopaedic patients.

SUMMARY

Better outcomes for patients are based on evidence-based CPGs, AUC, outcome measures, and the PROMIS.

KEY STUDY POINTS

- Evidence-based CPGs inform patients and clinicians if a given intervention is associated with a desirable outcome.
- AUC documents indicate when (ie, in what specific clinical circumstance) the same intervention is best applied.
- Outcome measure assessments are dependent on the interrelated concepts of validity, reliability, responsiveness to change, and MCID.
- In addition to clinical measures that matter to clinicians, patient-reported outcome measures include variables that are important to patients. An increased emphasis on patient-reported outcome measures and computerized adaptive testing allows clinicians to better understand the effects of interventions on patients.

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