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Technology assessment and cost-effectiveness in orthopedics: how to measure outcomes and deliver value in a constantly changing healthcare environment

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Abstract
Purpose of review The purpose of this study is to review the basic concepts of healthcare value, patient outcome measurement, and cost-effectiveness analyses as they relate to the introduction of new surgical techniques and technologies in the field of orthopedic surgery.
Recent findings An increased focus on financial stewardship in healthcare has resulted in a plethora of cost-effectiveness and patient outcome research. Recent research has made great progress in identifying orthopedic technologies that provide exceptional value and those that do not meet adequate standards for widespread adoption.
Summary As the pace of technological innovation advances in lockstep with an increased focus on value, orthopedic surgeons will need to have a working knowledge of value-based healthcare decision-making. Value-based healthcare and cost-effectiveness analyses can aid orthopedic surgeons in making ethical and fiscally responsible treatment choices for their patients.

Keywords Technology assessment · Cost-effectiveness · Patient-reported outcomes · Time-driven activity-based cost identification · Healthcare · Value

Introduction

Healthcare technology is evolving at a staggering pace, and nowhere is this more evident than in the field of orthopedic surgery. For instance, in 2002, less than 20 orthopedic devices received premarket approval through the US Food and Drug Administration. However, by 2012, this number had risen nearly 400% [1]. Similarly, Medicare payments for outpatient orthopedic procedures (including fees for physician services, surgeon fees, and all payments made on behalf of Medicare patients for outpatient services) increased 64% from 2000 to 2010. Spine and arthroscopic procedures, two groups which experienced substantial innovation over the last decade, accounted for most of this increase [2].

The development of new medical technology is one of the primary driving forces of the enormous increase in healthcare costs [3]. While the long-term gains in clinical outcomes may eventually reduce the overall financial outlay [4], initial capital investment in new technology increases cost in the short- and mid-term [3]. Some technological advances ultimately result in improved patient outcomes, but surgeons must weigh the benefits of new technology against the increased costs resulting from its adoption, especially in a limited resource environment such as the US healthcare system. As such, it is paramount that clinicians ensure that new technologies deliver measurable value for patients prior to widespread adoption and use.

In order to appropriately assess the value added by new technology, the costs and outcomes resulting from this technology must be adequately defined. In the simplest of terms,

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value in healthcare is defined as the ratio of outcomes over cost. It can also be described as health outcomes per dollar spent to achieve those outcomes [5••]. While determining cost is relatively straight forward, establishing the outcomes of a new intervention or medical technology can be more complex. Patient outcomes for a given intervention can vary widely across individual patients and patient populations, and can differ based on the outcome measure(s) utilized, the method with which these outcomes were collected, and the presence of any bias during the collection or analysis process. However, as healthcare payers begin to tighten the reigns on healthcare spending and increase focus on measuring value, outcome reporting has become more and more commonplace. Thus, clinicians will need a thorough understanding of current outcome measures, including collection methods, appropriateness of specific outcome measures in a variety of situations, interpretation of those outcome measures, and development of new measures. Furthermore, it will be necessary to utilize these outcome measures in conjunction with cost analyses to determine the value added, or lack thereof, from new orthopedic technologies.

Outcome measures

Numerous outcome measures have been developed in the recent decades for a variety of medical conditions. Some of these outcome measures are disease- or condition-specific, and some measure general quality of life. While traditional outcome measures such as mortality, complication rate, and return-to-work or return-to-play are still beneficial, there has been a trend toward measuring patient-reported outcomes (PROs). In fact, a variety of patient-reported outcome measures (PROMs) have been developed and validated for nearly every orthopedic injury or pathologic state. Many of these disease-specific PROMs have been validated for additional conditions other than the original condition for which they were created. Moreover, separate measures have been created to measure general quality of life (QoL).

Due to the plethora of outcome measures developed in recent years, it can be challenging to decide which to utilize for a specific condition. While there are numerous factors that must be considered when picking a PROM, it is crucial to ensure that the selected PROM is reliable, responsive, and valid [5••]. Other considerations include cost, method of deployment (i.e., phone, email, paper, etc.), length of the questionnaire, and utilization/comparability in the scientific literature [6–11].

Choosing the appropriate PROM

As mentioned above, it is critical that PROMs are reliable, responsive, and valid. Reliability refers to the ability of a PROM to give the same result for the same patient state each time it is assessed [9•]. Responsiveness is the ability of a PROM to detect change and depends on score changes in patients who have improved compared to those who have not improved [9•]. Validity refers to the ability of a PROM to measure what it is being utilized to measure [9•]. In addition, PROMs must not just detect change in disease states, but also must be able to differentiate between the minimal detectable change (MDC) and the minimal clinically important difference (MCID). While the MDC is a statistical value, the MCID represents the magnitude of change that would actually be meaningful to a patient [5••, 6]. The MCID is typically used to designate the change in a patient's outcome as improved or not improved [5••]. While there are two different methods commonly utilized to determine the MCID for a given score (anchor-based and distribution-based), each has inherent limitations and the MCID is most effectively measured when both strategies are implemented [5••]. Most importantly, the MCID should be considered in any PROM-based value assessment.

In addition to the inherent properties of each specific PROM, results can vary based on the method of PROM administration. PROMs can be administered face-to-face, using pen and paper, using computer-based entry, online through a web-based form, through the mail, or via telephone. Results can vary based on the PROM administration modality utilized [12]. There are numerous forms of bias that can be introduced via the different modes of administration, and respondent answers can vary according to mode. These findings can have significant implications when using PROMs for value assessments. As such, it is important that a standardized mode of administration is established for each PROM, and that authors report these details in publications. Clinicians and policy makers should keep these details in mind when making important decisions based on PROM data.

In addition to the measurement and psychometric properties of PROMs, one must consider the logistical components of PRO collection. Licensing costs for PROMs range from free (public domain) to exorbitant. Licensing fees for a large patient population may add up quickly, and this should be taken into consideration prior to widespread adoption of a specific PROM. Furthermore, some PROMs require complicated calculations that may require specific software, further adding to the costs. In general, PROMs which are deployable via email, tablet computers in the office environment, or web-based forms are preferred. Similarly, staff and patient "buy-in" is crucial to successful collection of PROs, and efforts to communicate the multiple benefits (both to the individual patient and to patient populations as a whole) of PROs may help to increase participation levels [13].

Anatomic- and disease-specific PROMs

Some orthopedic PROMs were designed to assess patient health states due to a specific joint, or anatomic region, while others were developed to address specific injuries or pathologic conditions. Multiple studies have aimed to identify the most effective of these PROMs. While not inclusive of all region- or disease-specific PROMs, several notable examples are provided below.

The American Shoulder and Elbow Society (ASES) Outcomes Subcommittee studied multiple PROMs relevant to shoulder and elbow surgery and graded them based on their psychometric properties, ease of use, ease of comprehension/interpretation, standardized national/international use, and cost [6]. They recommended that the ASES Subjective Shoulder Score be utilized as the main shoulder-specific PROM in the USA, with the Oxford Shoulder Score serving as an acceptable alternative, especially in Europe [6]. Similarly, they recommended adoption of the Mayo Elbow Performance Score (MEPS) for elbow-related pathology, and the Disabilities of the Arm, Shoulder, and Hand (DASH) score for general upper extremity-related conditions [6]. For rotator cuff-specific PROM, the subcommittee recommended the Western Ontario Rotator Cuff (WORC) Score [6].

In November of 2016, an international multi-specialty consortium of arthritis experts published recommendations for PROMs to utilize in patients with osteoarthritis of the hip and knee. They recommended the short form version of the Knee Injury and Osteoarthritis Score (KOOS-PS) for knee arthritis, and the short form version of the Hip Disability and Osteoarthritis Score (HOOS-PS) for hip arthritis. As neither of these measures include a pain score, the group also recommended the addition of a pain scale along with the HOOS-PS and KOOS-PS in general practice (such as the visual analogue pain scale) [14].

In a separate systematic review of knee-specific PROMs from 44 studies, knee-specific instruments were graded based on their psychometric properties, and recommendations were provided for injury-specific PROMs [15]. For ACL injuries, the authors suggested using the Cincinnati, KOOS, and Lysholm scores. For general knee pain, they recommended the KOOS or International Knee Documentation Committee (IKDC) score, and for anterior knee pain, they recommended the Kujala score [15]. They recommended the Western Ontario Meniscal Evaluation Tool (WOMET) for meniscal injuries, and the IKDC, KOOS, or Lysholm for articular cartilage lesions [15].

Health-related quality of life measures

Quality of life (QoL) measures are more generic instruments that are intended to track changes in the general quality of life and health state of patients. Three groups of QoL measures are most commonly utilized: (1) the Short Form health surveys (SF-36, SF-12, SF-6D), (2) the Veteran-Rand surveys (VR-36, VR-12), and (3) the European Quality of Life Score (EQ-5D). The SF-36 is a 36-question survey that covers eight domains of health including physical and mental components. It is widely used but has limited value in cost-utility analyses due to failure to incorporate preference weighting. Furthermore, its relatively lengthy 36 questions can negatively affect patients' willingness to participate. Thus, the SF-6D (preference weighted and easily converted to quality-adjusted life years, or QALYs) is often more applicable for cost-utility studies, and the SF-12 is more easily used for routine clinical follow-ups and registry use [5••, 14, 16]. The VR-36 and VR-12 are similar to the Short Form surveys, and results from the VR-12 are easily converted to or compared to SF-12 scores. While the EQ-5D is relatively widely used and preference rated, there are some concerns about a ceiling effect with the EQ-5D, and there is questionable agreement between the EQ-5D and the SF PROMs. As such, the SF-12, SF-6D, and VR-12 are recommended as general QoL PROMs. Of these listed, only the VR-12 is license free and only the SF-6D is preference weighted [5••, 14, 16]. It should be noted that these generic quality of life scores are unable to provide the type of precision needed to differentiate between subtle differences in surgical technique, although they may be able to compare broadly amongst widely different medical diseases and treatments [9•].

PROMIS

The Patient-Reported Outcome Measurement Information System (PROMIS) is a unique PRO system aimed at measuring patients' physical, mental, and emotional health [17••]. PROMIS was developed as a National Institutes of Health (NIH) initiative and is gradually being utilized by surgeons around the world. The uniqueness of the PROMIS system is that it adapts based on patient answers, so that only follow-up questions are based on earlier responses from the patient. This decreases the investment for the patient and theoretically improves patient compliance with the system. The PROMIS system contains over 120 questions but efficiently assigns only relevant questions [17••]. However, further research will need to determine which questions are valid and responsive for the gamut of orthopedic conditions [6].

Cost

After the outcomes associated with a new orthopedic technology have been determined, the next step in value assessment is to measure the cost. Traditionally, cost identification has been performed using a ratio of cost to charges or using relative value units (RVU). When using a cost to charges ratio, costs are allocated in direct proportion to charges for a particular service. This method is relatively straightforward and easy to use, but is often inaccurate and mistakenly assigns costs proportionally across widely heterogeneous procedures. With RVU-based costing, total costs are divided by total RVUs to obtain cost per RVU. This value is then multiplied by the RVUs billed to determine the cost for a procedure or physician service [18••]. These cost identification methods were usually adequate in the "cost plus" system of reimbursement, in which payers reimbursed providers and hospitals proportionate to their calculated costs, such that a minimum profit margin was built in. However, as capitated and bundled reimbursement systems become more commonplace, accurate methods of cost identification will be needed to more precisely identify inefficiencies and cost-saving opportunities within the healthcare delivery system [5••, 17••, 18••, 19–21].

Cost identification using time-driven activity-based costing

Recent studies have espoused the benefits of the time-driven activity-based cost (TDABC) identification method [18••, 19–21]. TDABC methodology consists of identifying the costs of a resource per unit of time (usually minutes) and multiplying the cost rate by the amount of time the resource is used. It can be utilized in the inpatient or outpatient setting and incorporates personnel costs (physicians, nurses, clerks, technicians, etc.), equipment costs, and supply costs [18••, 21]. It involves accurate process diagrams and accurate calculation of personnel and equipment costs per unit of time measure. TDABC allows for a much more detailed breakdown of costs throughout different phases in an episode of care and has been used at several institutions to significantly reduce costs and improve efficiency [22–25].

TDABC consists of seven main steps: (1) Select the medical condition—with surgical conditions, this usually includes a discrete surgical procedure and associated visits. For chronic conditions, a time period of 12 months is usually chosen. (2) Define the care delivery value chain —this includes every service and activity that a patient participates in for the defined medical condition. (3) Development of process maps—this detailed map includes every step that a patient goes through. (4) Process time estimation—this involves documenting the amount of time each resource is used. For a surgeon, this can include the time spent talking with the patient, time spent in preoperative planning, time spent dictating, and time spent billing or documenting. (5) Estimate resource costs—the cost of each resource utilized is calculated. For personnel, it involves calculating the total salary and benefits for the entire year. The cost of administrators, managers, and other personnel without direct involvement in patient care is usually distributed amongst all personnel that they manage. (6) Calculate resource capacity and unit cost rates—the total cost of a resource for the year is divided by the practical capacity of that resource. For personnel, the practical capacity is considered 80% of the theoretical capacity (which accounts for break time and any other time that the person is not working). For equipment, the total number of minutes or total number of tests performed on a yearly basis is calculated. Total costs are then divided by total units (e.g., total salary and benefits divided by number of minutes worked per year) to obtain a cost per unit (usually dollars per minute). (7) Calculate total cost of patient care—total costs are calculated by multiplying the unit cost of each resource by the time the resource was used [20, 21].

There are some unique challenges associated with TDABC methodology. Process mapping can be time and resource intensive, and measuring the exact time a resource is utilized can be difficult. Further, most process maps must be developed from scratch as TDABC has not yet been widely instituted. However, there is a significant potential upside, as TDABC provides a more accurate representation of actual costs than most traditional costing methods. TDABC allows medical conditions to be analyzed according to the different phases of treatment (e.g., preoperative, operative, and postoperative) or as one aggregated episode of care. Identifying even small areas of cost reduction may improve the financial viability of care delivery in capitated and bundled reimbursement systems and accurate cost identification allows for more accurate value assessment when considering new technologies [18••, 21].

Cost-effectiveness, cost-utility, and cost-benefit analyses

After appropriate cost identification, cost-effectiveness, cost-utility, and cost-benefit analyses provide a means to compare the cost of medical interventions with the health benefits gained [26]. Cost-effectiveness analyses use objective outcomes to compare two different interventions (e.g., union rate of both-bone forearm fractures in operatively and non-operatively treated fractures). Cost-effectiveness studies often report incremental gains in the form of an incremental cost-effectiveness ratio (ICER). Cost-effectiveness analyses can be performed across a wide variety of objective outcomes as long as the interventions compared both results in the same type of outcome. Notably, cost-effectiveness analyses do not take into account PROs or patient preferences [5••].

Cost-utility analyses, on the other hand, utilize patient-centric and subjective measures of health, such as PROs [5••, 27]. Often, cost-utility analyses are reported in terms of quality-adjusted life years (QALYs) gained per unit cost [27]. These assessments of patient health utility states take patient preference into account and are becoming more popular in the orthopedic literature [27]. In fact, the US Panel on Cost-Effectiveness in Health and Medicine recommends using cost-utility analyses for medical decision assessment [27]. It should be noted that PROMs used in cost-utility analyses must have a QoL subdomain or some method of measuring general health.

Cost-benefit analyses attempt to compare the benefits gained to the initial cost of intervention [5••]. This type of analysis does not compare objective or subjective health outcomes to cost, but rather the ultimate financial benefit compared to the financial cost [27]. Often, cost-benefit analyses compare the cost of intervention to the cost that patients are willing to pay for a certain health state.

Case studies

Many recently published studies have performed cost and value analyses of new orthopedic technology. Several examples are provided below.

Meniscal scaffold procedures

The use of meniscal scaffolds is one emerging technology in orthopedics. Meniscus injuries can have devastating consequences, and multiple salvage procedures have been proposed. One study evaluated the socioeconomic effect of scaffold procedures for irreparable meniscal tears using Markov models with Monte Carlo simulations. The authors concluded that meniscal scaffold procedures were not cost-effective at a willingness to pay of 20,000 euros (approximately $21,000 US dollars in 2016). However, the authors acknowledged limitations in their models and suggested that changes in the costs of meniscal scaffold procedures or better information on quality of life prior to meniscal procedures could affect the outcomes [28].

Total joint replacement

Hip and knee arthroplasty procedures are two of the most common and costly orthopedic procedures performed in the USA, and arthroplasty of other joints is being increasingly performed. New technology in arthroplasty tends to be very costly, especially in the initial stages of adoption. As such, numerous studies have examined the economic value of arthroplasty innovations.

Markov decision analysis was used to investigate the cost-effectiveness of robot-assisted unicompartmental knee arthroplasty in one study [29]. They considered revision rates, hospital volume, and costs to determine what factors may make robot-assisted unicompartmental knee arthroplasty cost-effective. The authors calculated that robot-assisted arthroplasty would be cost-effective at high-volume centers with slightly improved outcomes (0.06 QALYs) and an incremental cost of $47,180 per QALY. At lower volume centers, traditional unicompartmental arthroplasty was the more cost-effective choice [29].

The cost-effectiveness of total ankle arthroplasty has also been evaluated, comparing it with ankle fusion or nonoperative management for the treatment of end-stage ankle arthritis [30]. The authors concluded that total ankle arthroplasty was the most cost-effective strategy, with an incremental cost of $14,500 per QALY compared to nonoperative management. Furthermore, total ankle arthroplasty resulted in a $5900 lifetime savings over nonoperative management and an $800 lifetime savings over ankle fusion [30]. This study elegantly illustrates the point that orthopedic technology with high initial cost may eventually provide greater cost-effectiveness and value in the long term.

Another study analyzed the cost-effectiveness of hypothetical innovation in traditional total knee arthroplasty. Using a validated computer model and Medicare claim data, the authors reported that new implants offering at least a 50% decrease in long-term failure rates at less than or equal to 50% increased costs resulted in incremental costs of less than $100,000 per QALY. However, innovations resulting in less than a 50% decrease in long-term failure rates were not considered cost-effective according to World Health Organization guidelines [4].

The cost-effectiveness of reverse total shoulder arthroplasty for rotator cuff tears that were considered large or massive in patients over the age of 65 years old has also been analyzed [16]. Rotator cuff repair was the most cost-effective option, as reverse total shoulder arthroplasty resulted in an equivalent gain in QALYs (11.7) at a higher cost ($37,500) compared to rotator cuff repair ($22,300). While nonoperative treatment resulted in lower average costs ($11,300), it also resulted in lower QALYs gained (11.02). The authors recommended against the use of reverse total shoulder arthroplasty as a first line treatment for large and massive rotator cuff tears in elderly patients but suggested that a better understanding of factors leading to re-tear may allow a more individualized treatment algorithm [16].

Imaging

Orthopedic imaging is another high-cost piece of the healthcare pie, and increased focus has been placed on measuring the value of various imaging modalities across a range of orthopedic conditions.

For diagnostic magnetic resonance imaging (MRI) in the setting of meniscal tear, a cost-utility analysis using a willingness-to-pay of $50,000 per QALY showed that MRI to confirm positive physical exam findings in traumatic tears was cost-effective, while history and physical alone was the preferred strategy for degenerative meniscal tears [31].

A similar study was used to assess the cost-utility of MRI in diagnosing hip conditions. They found that hip MRI rarely influenced treatment decisions and calculated the cumulative cost of obtaining MRIs for one treatment decision to be $59,296 when the suspected diagnosis was not mentioned.

However, when MRI was used to confirm a specific diagnosis, the cumulative cost to influence a treatment decision was only $2383. As such, the authors recommended developing an algorithm that would guide MRI utilization based on physical exam, radiographic, and history and physical parameters [32].

Conclusion

In summary, technological advances in orthopedic surgery can be extremely costly. However, many of these technologies have the potential to make a significant impact on patient outcomes. As initial costs may be offset by long-term cost savings, and significant improvement in patient outcomes may outweigh the added cost, orthopedic surgeons must work diligently to determine the value added by these new technologies. As increased financial scrutiny is placed on medical decision-making, it will be crucial to used evidence-based guidelines to identify the most valuable and cost-effective technologies for patients.

Compliance with ethical standards

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All other authors declare no conflict of interest.

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