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Value-based Health Care

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Value-based Health Care: Moving Beyond "Minimum Clinically Important Difference" to a Tiered System of Evaluating Successful Clinical Outcomes

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Health care value is defined as health outcomes that matter to patients achieved per dollar spent [8]. The challenge in implementing a system that rewards value is finding an accurate way to measure those outcomes that matter to patients. While current attempts by payers at rewarding value, including those by Centers for Medicare & Medicaid Services (CMS), focus on structural (electronic health record implementation) or process measures (preoperative antibiotic use), no current approach captures the outcomes most important to patients—increased function, decreased pain, and improved quality-of-life. In order to successfully assess the range of postoperative clinical outcomes, we propose a "tiered evaluation system" that may have potential to be used to better reward value.

While outcome measures are wide in scope and capture a variety of constructs, validated patient-reported outcome measures (PROMs) are patient-derived; thus, these instruments may be the best direct measure of outcomes most important to patients. While changes in PROM scores from pre to posttreatment may offer insight into the value of the intervention, a question remains as to what constitutes a clinically important improvement in health outcomes from the patient's perspective.

First described in 1989 by Jaeschke and colleagues [3], the minimum clinically important difference (MCID) was introduced as a way to better evaluate the clinical relevance of changes in scores of quality-of-life instruments. Since then, there has been ongoing debate as to the best approach of calculating the MCID. Two commonly used techniques are the distribution-based and anchor-based methods. Distribution-based methods use a statistical approach, such as defining an MCID as a PROM change larger than one-half standard deviation in size, while anchor-based methods determine clinically important differences based on surveys of patients' own impressions of benefit or satisfaction. While there continues to be debate about which method is more appropriate, the MCID concept overall still remains a focus in research geared towards value-based health care and PROM evaluation. Various orthopaedic studies have sought to investigate the MCID for orthopaedic procedures across different subspecialties [5]. This moves PROMs from the research into the clinical domain, and while the best methodology for deriving MCID has not yet been determined, there is also

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opportunity for critically assessing what role MCID plays in evaluating clinical improvement for patients as part of the value equation.

Another problem with the MCID is what its first letter signifies: Minimum. When considering major elective surgery—such as what many orthopaedic surgeons offer their patients—it seems reasonable to expect at least a "minimum" level of clinical improvement. Recognizing this, the Outcome Measures in Rheumatology - Osteoarthritis Research Society International Initiative suggested categorizing patients following treatment for arthritis as high responders, moderate responders, and nonresponders [7]. They distinguished the groups using predetermined algorithms by evaluating absolute and relative changes in patient self-reported pain, function, and global assessment following a number of interventions such as NSAIDs or an intra-articular specific drug. A nuanced approach like this is appealing when compared to evaluating MCID alone.

An alternative to determining treatment success from the patient's view is the Patient Acceptable Symptom State (PASS) [1], an anchor-based approach to evaluating outcomes rooted in patient satisfaction and the binary outcome of whether or not a patient is satisfied with his or her current symptom state. PASS differs from the MCID in that it focuses on patient satisfaction at its core and not strictly on symptoms, such as pain. It is worth noting the inherent difficulties in measuring patient satisfaction with a single question. Assessment of satisfaction may vary depending on the research question and/or a number of patient factors such as pretreatment expectations or psychosocial status [9]. Thus, we caution against relying on PASS alone and believe that it should be evaluated in consideration with other measures of clinical significance.

Another framework that differs from both MCID and PASS is the Substantial Clinical Benefit (SCB) outcome target, which has been used in evaluating the management of spinal disorders, [2], total joint replacement [4], and hip arthroscopy [6]. The SCB differs from the MCID and PASS in that it is considered the upper threshold of outcome improvement, while the MCID is the minimum improvement believed to be clinically relevant. The SCB offers an innovative approach to recognizing outcomes well above the minimum that are clinically relevant; however, this method has yet to gain notable traction. This may be as result of an overreliance on MCID, which has the benefit of primacy in the meaningful outcome evidence-base. Additionally, because SCB is relatively novel, clinical researchers may not understand the importance of this measure. We believe that SCB, MCID, and PASS are not mutually exclusive and can be assessed in relation to each other.

It is worth noting that there has been no unifying approach in the literature that attempts to bring together MCID, PASS, SCB, or other clinical outcome level approaches in a robust evaluation model. Ultimately, we believe that a more-nuanced understanding of clinically important outcome improvement will lead to higher value care, as surgeons strive to define levels of clinical improvement (whether an MCID, a SCB, or some other designation) that denotes treatment success, while consuming the same or fewer resources.

We believe a tiered system may be the best way to do this.

Our proposed tiered approach, similar in style to Pham and colleagues [7], might begin with a binary "pass/fail" designation following surgery with those passing being defined as at least achieving the MCID. This ensures that, at a minimum, patients improve at least by an amount they considered important. Once that has been exceeded, degrees of success can be further quantified using tools like the PASS and the SCB. Utilizing the high responder, moderate responder, and nonresponder framework as a guide, we contend that meeting MCID should be a minimum goal of any intervention; achieving PASS should be the objective; and reaching SCB should signify a superior outcome.

As with any framework, its limitations—both now and in the future—should be considered. Indeed, the framework rests on reaching consensus of how best to measure MCID, PASS, and SCB. For example, as noted earlier, satisfaction is often challenging to measure and subject to individualized patient expectations [9]. This limitation should be considered, but it should also encourage surgeons to focus on communication skills in helping set reasonable expectations preoperatively. Risk-adjusting satisfaction may also be a method of addressing this concern. Overall, while measuring satisfaction (and therein, PASS), as well as MCID and SCB, is challenging, it is a discussion and debate we feel surgeons should be leading—not policymakers or other stakeholders not involved in the direct hands-on delivery of high value care. Value-based payment models are likely to become ever more prevalent, so it behooves us to set our own standards as much as possible.

While our proposed "tiered evaluation system" addresses the numerator of the value equation, it is crucial to consider the impact of our proposal on the denominator, or healthcare dollars spent. By focusing on achieving clinically significant outcome improvement utilizing our innovative approach, surgeons may need to utilize greater

resources up front in conducting preoperative evaluations and spend more time setting expectations. However, we argue that the degree of increase in dollars spent will be lower than the improvement in health outcomes achieved. Therefore, this approach to measuring clinical improvement will lead to higher value care, which should be rewarded financially in value-based payment models.

To date, surgeons have focused much of their attention on determining the bare minimum change in PROMs that signifies clinical success. However, as value-based payment and delivery models become more prevalent, the need for a more-nuanced approach to classifying the range of successful clinical outcomes is warranted. Our proposed "tiered evaluation system" offers one potential solution that evaluates and differentiates variation in successful clinical outcomes.

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