

Outcome scores: what they measure, and what they don't

Overview

- Patient-reported outcome measures (PROMs) are critical for capturing the patient's perspective on health status, which cannot be observed through clinical tests or imaging [48].
- Standardized health-related outcome measures require evidence for change and a way to interpret change within individuals or difference between groups [3].
- The minimum clinically important difference (MCID) defines the smallest amount an outcome must change to be meaningful to patients [46].
- The minimum clinically important difference, the standard error of measurement, and the minimum detectable change are proposed as indicators for the clinical interpretation of test scores [1].
- Lack of consensus in the literature has led to confusion about which measurement properties are relevant, which concepts they represent, and how to assess these measurement properties in terms of design requirements and preferred statistical methods [16].
- Consensus was reached on how a comprehensive research question can be deduced from the design of a reliability study to determine how the results of a study inform us about the quality of the outcome measurement instrument at issue [2].
- An appropriate and validated measure that is suitable for both the particular study population and the reason for collecting the PROMs data should be chosen [6].
- Providing access to PROM scores without clearly understanding how and why surgeons may consider using them can result in expensive and underused systems that add little value [44].
- Reasons for limited use of PROMs by orthopedic surgeons include a lack of knowledge on how to use them and the perception that it is too time-consuming to add to regular clinical routine [45].
- Limitations of PROM use in clinical practice shed light on why PROM use may not always improve patient outcomes and provide considerations for the design and implementation of future PROM initiatives [47].
- PROMIS measures are efficient and precise tools, and their use is expected to continue to increase across medical and surgical specialties as health systems and payers expand their definition of healthcare quality to include patient-reported health outcomes [49].

How It Works

INTERPRETATION AND CLINICAL UTILITY

- The minimum clinically important difference, standard error of measurement, and minimum detectable change are proposed as indicators for the clinical interpretation of test scores [1].
- Scores from tools designed to measure outcomes that matter to patients have been developed over the past 30 years, but few are used routinely at the point of care [21].
- An appropriate and validated measure suitable for the particular study population and the reason for collecting data should be chosen for patient-reported outcome measures [6].

RELIABILITY AND VALIDITY ASSESSMENT

- The two-way mixed-effect analysis of variance model with interaction for the absolute agreement between single scores is recommended to assess test-retest reliability for patient-reported outcome measures [4].
- Consensus was reached on how a comprehensive research question can be deduced from the design of a reliability study to determine how results inform about the quality of the outcome measurement instrument [2].
- The Patient-Reported Outcomes Measurement Information System (PROMIS) item banks demonstrated good reliability across most of the score distributions [43].
- The MOS short form health survey (SF-36) scales met required internal consistency criteria with Cronbach alpha coefficients equaling or exceeding 0.70 in a study conducted in India [33].
- An assessment tool for brachial plexus regional anesthesia performance demonstrated construct validity by reliably discriminating between different levels of training, with senior trainees performing significantly better than junior trainees on the global rating scale [35].

STANDARDIZATION AND DATA COLLECTION

- Current data collection of patient-reported outcome measures is neither uniform nor complete across the world's registries, which may impact data validity and the ability to compare outcomes [8].
- No key measure was identified to capture functional status in advanced musculoskeletal physiotherapy practice, with 15 different tools utilized, highlighting the need for greater standardization of outcome measurement [40].
- Outcomes assessed on numeric rating scales and reported with text-messages on mobile phones provide comparable scores to questionnaires completed with pen and paper [7].

LIMITATIONS AND GAPS

- Physical outcome measures such as range of motion and strength are not as reliable measures as one would think, and are being changed for the use of patient reported outcomes [15].
- All patient-reported outcome measures for intermittent claudication require further validation studies to fill the gaps in their measurement properties [32].

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How It Is Used

- Clinicians can use the minimum clinically important difference, standard error of measurement, and minimum detectable change to interpret test scores [1].
- Standardized health-related outcome measures require evidence for change and a method to interpret change within individuals or differences between groups [3].
- Clinicians must be cautious when accepting a minimal clinically important difference score at face value due to wide variability in established scores for a single outcome scale [5].
- Outcomes assessed on numeric rating scales via text messages on mobile phones provide comparable scores to those completed with pen and paper questionnaires [7].
- Investigators can choose thresholds to dichotomize responses on health-related quality of life measures based on absolute scores or change scores to facilitate interpretation [10].
- Promoting ownership and correct use of the measure by clinicians can improve practice and the quality of care through patient-reported outcome measure data use in clinical decision-making [11].
- The minimal important difference is not an immutable characteristic and may vary by population and context, meaning no single minimal important difference is valid for all study applications [14].
- Routine use of patient-reported outcome measures has the potential to help transform healthcare [18].
- High variability in scale choice and the use of measures not validated in pediatrics make comparative outcomes research difficult in the pediatric sports population [19].
- High-quality systematic reviews on measurement instruments are advocated to recommend the best available outcome measurement instrument [20].
- Few outcome measurement tools have been used routinely at the point of care despite being developed over the past 30 years [21].
- Further studies are needed to provide validated outcome measures to ensure the accuracy of reported results and conclusions after rib fracture [22].
- Comparative effectiveness research requires accurate assessments of patient numbers, follow-up completeness, clinical outcomes, and care settings [34].
- Recommendations for the selection of patient-assessed measures of health outcome are needed [36].
- Limiting follow-up to automated methods has the potential to transform the design and conduct of outcome-based research to provide substantially better research value in large prospective cohorts [38].
- There are challenges in using patient-reported outcomes in clinical practice [39].
- The routine use of patient-reported outcomes in clinical practice is assessed for its impact on the process of care, patients' and professionals' experiences of care, and health outcomes [42].

Interpreting the Results

MEASUREMENT PROPERTIES AND RELIABILITY

- Consensus was reached on deducing a comprehensive research question from the design of a reliability study to determine how results inform the quality of an outcome measurement instrument [2].
- The two-way mixed-effect analysis of variance model with interaction for the absolute agreement between single scores is recommended for assessing test-retest reliability of patient-reported outcome measures [4].
- Range of motion and strength are not as reliable measures as one would think [15].

MINIMAL CLINICALLY IMPORTANT DIFFERENCE (MCID)

- Clinicians must be cautious in accepting an MCID score at face value given the wide variability of established MCID scores available for a single outcome scale [5].
- The recommended approach for estimating the minimal important difference is to use several anchor-based methods with relevant clinical or patient-based indicators, examine distribution-based estimates as supportive information, and triangulate on a single value or small range of values [9].
- The Minimal Clinically Important Difference (MCID) is a point estimate that should always be reported with its associated 95% CI, as there is no basis for considering a sample-derived MCID a singular threshold to be crossed [12].
- The minimal clinically important difference (MCID) is an imperfect solution to a complicated problem, and different methods used to calculate MCID lead to highly heterogeneous values [13].
- The minimal important difference (MID) is not an immutable characteristic but may vary by population and context, and no one MID may be valid for all study applications [14].
- The minimal clinically important difference (MCID) is a low bar that patients do not seek when undergoing surgery; instead, they aim for substantial clinical benefit or a patient acceptable symptom state (PASS) [17].
- The calculation of the minimal clinically important difference (MCID) needs to be correlated with changes in scores on the rating scale and external anchors [24].
- A systematic approach exists to triangulate on the Minimal Clinically Important Difference (MCID) using both distribution-based and anchor-based methods [29].

REPORTING AND INTERPRETATION FRAMEWORKS

- Outcomes assessed on numeric rating scales and reported with text-messages on mobile phones or with questionnaires completed with pen and paper provide comparable scores [7].
- Investigators can choose thresholds to dichotomize responses on HRQL based on absolute scores or change scores to facilitate interpretation [10].
- A standardized reporting of patient-reported outcome measures (PROMs) has been proposed that incorporates the minimum clinically important difference (MCID) and the patient acceptable symptom state (PASS), introducing a 'clinical relevance ratio' to report the proportion of patients achieving clinical importance rather than relying solely on mean changes [23].

- Routine use of patient reported outcome measures (PROMs) has the potential to help transform healthcare [18].

Limitations and Pitfalls

MEASUREMENT PROPERTIES AND RELIABILITY

- Lack of consensus in the literature has led to confusion about which measurement properties are relevant, which concepts they represent, and how to assess these properties in terms of design requirements and preferred statistical methods [16].
- To assess test-retest reliability for patient-reported outcome measures, the two-way mixed-effect analysis of variance model with interaction for the absolute agreement between single scores is recommended [4].
- Consensus was reached on how a comprehensive research question can be deduced from the design of a reliability study to determine how the results inform about the quality of the outcome measurement instrument [2].
- A 10-item computerized adaptive test (CAT) eliminated floor and decreased ceiling effects, achieving a small standard error (≤ 2.2) across scores from 20 to 50 with reliability ≥ 0.95 for a representative US sample [31].

MINIMAL CLINICALLY IMPORTANT DIFFERENCE (MCID)

- The recommended approach is to estimate the minimal important difference based on several anchor-based methods with relevant clinical or patient-based indicators, examine various distribution-based estimates as supportive information, and triangulate on a single value or small range of values [9].
- MCIDs expressed as effect sizes reduce bias, which mainly results from dependency on the baseline score [41].
- Researchers, clinicians, and healthcare policy decision makers can consider using a specific instrument to evaluate the design, conduct, and analysis of studies estimating anchor based minimal important differences [30].

DATA COLLECTION AND STANDARDIZATION

- The current data collection of patient-reported outcome measures (PROMs) is neither uniform nor complete across the world's registries, which may impact data validity and the ability to compare outcomes [8].
- The high variability in scale choice and the use of measures not validated in pediatrics make comparative outcomes research difficult [19].
- Only 57% of primary medical providers are using patient reported outcome measures within their practice, with the information largely used for research rather than clinical decision-making [27].
- Further studies are needed to provide validated outcome measures to ensure accuracy of the reported results and conclusions [22].

CLINICAL APPLICATION AND INTERPRETATION

- The authors propose using the minimum clinically important difference, the standard error of measurement, and the minimum detectable change as indicators for the clinical interpretation of test scores [1].
- Integrating standardized patient-reported outcomes into routine orthopaedic visits is feasible and improves practice efficiency by providing actionable objective data for shared decision-making [26].
- The ability to collect patient-reported outcome (PRO) data in real time and share this information with patients to inform clinical decision making represents the future of value-based healthcare, moving beyond research-focused assessments to guide treatment consistent with patient preferences [25].
- Promoting ownership and correct use of the measure by clinicians can potentially improve practice and the quality of care provided through patient-reported outcome measure data use in clinical decision-making [11].

Key Evidence

- [L5] The authors propose using the minimum clinically important difference, the standard error of measurement, and the minimum detectable change as indicators for the clinical interpretation of test scores. [1] ([10.1136/bjsports-2012-091704](#))
- [Paper] Consensus was reached on how a comprehensive research question can be deduced from the design of a reliability study to determine how the results of a study inform us about the quality of the outcome measurement instrument at issue. [2] ([10.1186/s12874-020-01179-5](#))
- [L4] Standardized health-related outcome measures require evidence for change and a way to interpret change within individuals or difference between groups. [3] ([10.1016/j.rdc.2018.01.011](#))
- [L5] To assess test-retest reliability for patient-reported outcome measures, the two-way mixed-effect analysis of variance model with interaction for the absolute agreement between single scores is recommended. [4] ([10.1007/s11136-018-2076-0](#))
- [L5] Clinicians must be cautious in accepting an MCID score at face value given the wide variability of established MCID scores available for a single outcome scale. [5] ([10.1179/2042618612y.0000000001](#))
- [Paper] An appropriate and validated measure that is suitable for both the particular study population and the reason for collecting the PROMs data should be chosen. [6] ([10.1136/bmj.c186](#))
- [L4] Outcomes assessed on numeric rating scales and reported with text-messages on mobile phones or with questionnaires completed with pen and paper provide comparable scores. [7] ([10.1186/1471-2288-14-52](#))
- [L4] The current data collection of patient-reported outcome measures (PROMs) is neither uniform nor complete across the world's registries, which may impact data validity and the ability to compare outcomes. [8] ([10.1097/corr.0000000000001918](#))
- [L5] The recommended approach is to estimate the minimal important difference based on several anchor-based methods, with relevant clinical or patient-based indicators, and to examine various distribution-based estimates (i.e., effect size, standardized response mean, standard error of measurement) as supportive

information, and then to triangulate on a single value or small range of values for the MID. [9] ([10.1186/1477-7525-4-70](#))

- [L5] Investigators can choose thresholds to dichotomize responses on HRQL based on absolute scores or change scores to facilitate interpretation. [10] ([10.1186/1477-7525-4-62](#))
- [L2] This could promote ownership and correct use of the measure by clinicians, potentially improving practice and the quality of care provided through patient-reported outcome measure data use in clinical decision-making. [11] ([10.1177/0269216313491619](#))
- [L5] The Minimal Clinically Important Difference (MCID) is a point estimate that should always be reported with its associated 95% CI, as there is no basis for considering a sample-derived MCID a singular threshold to be crossed. [12] ([10.1177/03635465231189223](#))
- [L5] The minimal clinically important difference (MCID) is an imperfect solution to a complicated problem, and different methods used to calculate MCID lead to highly heterogeneous values. [13] ([10.1177/03635465231189222](#))
- [L5] The minimal important difference (MID) is not an immutable characteristic but may vary by population and context, and no one MID may be valid for all study applications. [14] ([10.1016/j.jclinepi.2007.03.012](#))
- [Paper] Physical outcome measures are being changed for the use of patient reported outcomes, and range of motion and strength are not as reliable measures as one would think. [15] ([10.1016/j.injury.2019.11.017](#))
- [L5] Lack of consensus in the literature has lead to confusion about which measurement properties are relevant, which concepts they represent, and how to assess these measurement properties in terms of design requirements and preferred statistical methods. [16] ([10.1016/j.jclinepi.2010.02.006](#))
- [L5] The minimal clinically important difference (MCID) is a low bar that patients do not seek when undergoing surgery; instead, they aim for substantial clinical benefit or a patient acceptable symptom state (PASS). [17] ([10.1016/j.arthro.2023.10.014](#))
- [L5] Routine use of patient reported outcome measures (PROMs) has the potential to help transform healthcare. [18] ([10.1136/bmj.f167](#))
- [L4] The high variability in scale choice and the use of measures not validated in pediatrics make comparative outcomes research difficult. [19] ([10.1177/2325967119s00036](#))
- [L5] They advocate for conducting high quality systematic reviews on measurement instruments in which the best available outcome measurement instrument is recommended. [20] ([10.1590/bjpt-rbf.2014.0143](#))
- [L5] Scores of tools to measure outcomes that matter to patients have been developed over the past 30 years but few are used routinely at the point of care. [21] ([10.1136/bmj.g7818](#))
- [L2] Further studies are needed to provide validated outcome measures to ensure accuracy of the reported results and conclusions. [22] ([10.1016/j.injury.2019.07.002](#))
- [L5] The authors propose a standardized reporting of patient-reported outcome measures (PROMs) that incorporates the minimum clinically important difference (MCID) and the patient acceptable symptom state (PASS), introducing a 'clinical relevance ratio' to report the proportion of patients achieving clinical importance rather than relying solely on mean changes. [23] ([10.2106/jbjs.21.00030](#))

- [L5] The calculation of the minimal clinically important difference (MCID) needs to be correlated with changes in scores on the rating scale and external anchors. [24] ([10.1177/03635465231193405](#))
- [L5] The ability to collect patient-reported outcome (PRO) data in real time and share this information with patients to inform clinical decision making represents the future of value-based healthcare, moving beyond research-focused assessments to guide treatment consistent with patient preferences. [25] ([10.1007/s11999-016-4813-4](#))
- [L4] The authors conclude that integrating standardized patient-reported outcomes into routine orthopaedic visits is feasible and improves practice efficiency by providing actionable objective data for shared decision-making. [26] ([10.1007/s11999-013-3143-z](#))
- [L4] Only 57% of primary medical providers are using patient reported outcome measures within their practice, with the information largely used for research rather than clinical decision-making. [27] ([10.1177/2325967119s00107](#))
- [L5] The authors describe a systematic approach to triangulate on the Minimal Clinically Important Difference (MCID) using both distribution-based and anchor-based methods. [29] ([10.1016/j.apmr.2019.12.008](#))
- [L4] Researchers, clinicians, and healthcare policy decision makers can consider using this instrument to evaluate the design, conduct, and analysis of studies estimating anchor based minimal important differences. [30] ([10.1136/bmj.m1714](#))
- [L5] A 10-item CAT eliminated floor and decreased ceiling effects, achieving a small standard error (≤ 2.2) across scores from 20 to 50 with reliability ≥ 0.95 for a representative US sample. [31] ([10.1016/j.jclinepi.2006.06.025](#))
- [L1] However, all PROMs require further validation studies to fill the gaps in their measurement properties. [32] ([10.1016/j.ejvs.2014.12.002](#))
- [L4] The questionnaire was well understood by the respondents, and all scales met the required internal consistency criteria with Cronbach alpha coefficients equaling or exceeding 0.70. [33] ([10.4103/0970-0218.106623](#))
- [L5] Comparative effectiveness research requires accurate assessments of patient numbers, follow-up completeness, clinical outcomes, and care settings. [34] ([10.1007/s11999-013-3194-1](#))
- [L4] The assessment tool demonstrated construct validity by reliably discriminating between different levels of training, as senior trainees performed significantly better than junior trainees on the global rating scale. [35] ([10.1016/j.rapm.2006.10.009](#))
- [L4] Recommendations for the selection of patient assessed measures of health outcome are needed. [36] ([10.1136/bmj.324.7351.1417](#))
- [L2] Limiting follow-up to automated methods may have the potential to transform the way that outcome-based research is designed and conducted to provide substantially better research value in large prospective cohorts. [38] ([10.2106/jbjs.19.00531](#))
- [L5] However, there are a number of challenges in using patient-reported outcomes in clinical practice. [39] ([10.1007/s11136-008-9379-5](#))

- [L2] No key measure was identified to capture functional status, with 15 different tools utilized, highlighting the need for greater standardization of outcome measurement in musculoskeletal clinical practice, service evaluation and research. [40] ([10.1002/msc.1200](#))
- [Paper] MCIDs expressed as effect sizes reduce bias, which mainly results from dependency on the baseline score. [41] ([10.1016/j.jclinepi.2016.11.016](#))
- [Paper] The objectives are to assess the impact of the routine use of patient-reported outcomes in clinical practice on the process of care, patients' and professionals' experiences of care, and health outcomes. [42] ([10.1002/14651858.cd011589](#))
- [L5] All item banks demonstrated good reliability across most of the score distributions. [43] ([10.1016/j.jclinepi.2010.04.011](#))
- [L4] Providing access to PROM scores without clearly understanding how and why surgeons may consider using them can result in expensive and underused systems that add little value. [44] ([10.1097/corr.0000000000002059](#))
- [L4] The reasons provided included a lack of knowledge on how to use PROMs and the perception that it is too time-consuming to add to regular clinical routine. [45] ([10.1186/s13018-020-02135-1](#))
- [Paper] The MCID defines the smallest amount an outcome must change to be meaningful to patients. [46] ([10.1001/jama.2014.13128](#))
- [L4] These limitations shed some light on why PROM use may not always improve patient outcomes and provide considerations for the design and implementation of future PROM initiatives. [47] ([10.1007/s11136-021-03003-z](#))
- [L5] This editorial argues that Patient Reported Outcome Measures (PROMs) are critical for capturing the patient's perspective on health status, which cannot be observed through clinical tests or imaging. [48] ([10.1136/bjsports-2014-093707](#))
- [L4] PROMIS measures are efficient and precise tools, and their use is expected to continue to increase across medical and surgical specialties as health systems and payers expand their definition of healthcare quality to include patient-reported health outcomes. [49] ([10.5435/jaaos-d-24-00432](#))

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