

Quantifying Probability of Benefit

When is a patient feeling better? When is a patient feeling good?

What is "probability of benefit" and how can we measure it for a new technology?

Most often, clinical studies use validated patient-reported outcomes (PROs) to measure improvements in pain, function, or quality of life among the study participants. It's important to select the right PROs for your technology, the disease or pathology being treated, and your research questions. Most PROs produce a score on a scale of 0-100 or 0-10.

For many patients and decision-makers evaluating clinical evidence, the statement "pain is reduced by 30 points on average with this new treatment" is not very meaningful. However, a statement such as "80% of patients have a significant reduction in pain" is more easily understood and more impactful; but, what counts as a significant reduction?

Researchers calculate thresholds based on clinical data and additional patient feedback to help answer this question across a wide variety of treatment types. Three common thresholds used are:



Figure 1. Example of 3 patients who all have a pretreatment (baseline) function score of 20. After treatment, Patient 1 improves to a score of 40, meeting the MCID of 20. Patient 2 improves to a score of 70, meeting the SCB of 50 and exceeding the PASS of 50. Patient 3 improves to a score of 50, exceeding the MCID and meeting the PASS.

MCID – minimal clinically important difference – the threshold for the minimal improvement, from pretreatment to post-treatment, that is considered to be impactful

SCB – substantial clinical benefit – the change in score, from pre-treatment to post-treatment, that is considered to be a dramatic improvement

PASS – patient-acceptable symptom state – the minimum score that patients find satisfactory

Metrics such as these allow clinical researchers to calculate and report the percentage of participants in a clinical study who experience a meaningful improvement (MCID or SCB) or achieve a satisfactory result (PASS). These proportions (and their confidence intervals) represent one way to measure the probability of benefit for a new healthcare technology. Be careful when applying these metrics though! It is important to ensure similarity between the patients/treatments in your study and those used to calculate the MCID, SCB, or PASS thresholds.

By: Jason Inzana, PhD | Director of Science and Innovation | Telos Partners, LLC

jinzana@telospartnersllc.com www.telospartnersllc.com

For some additional reading and examples of these calculations:

Roos EM et al.. It is good to feel better, but better to feel good: whether a patient finds treatment 'successful' or not depends on the questions researchers ask. *Br J Sports Med.* 2019;53(23):1474-1478.

Tashjian R. Editorial Commentary: The Alphabet Soup of Understanding Clinical Shoulder Research: MCID (Minimal Clinically Important Difference), PASS (Patient Acceptable Symptomatic State), SCB (Substantial Clinical Benefit), and Now...MOI (Maximal Outcome Improvement). *Arthroscopy*. 2020;36(7):1811-1812.

Nwachukwu BU et al. . Defining the Clinically Meaningful Outcomes for Arthroscopic Treatment of Femoroacetabular Impingement Syndrome at Minimum 5-Year Follow-up. Am J Sports Med. 2020;48(4):901-907.