DEPARTMENT OF SPORTS SCIENCE AND CLINICAL BIOMECHANICS

Interpretation

Vodcast 1

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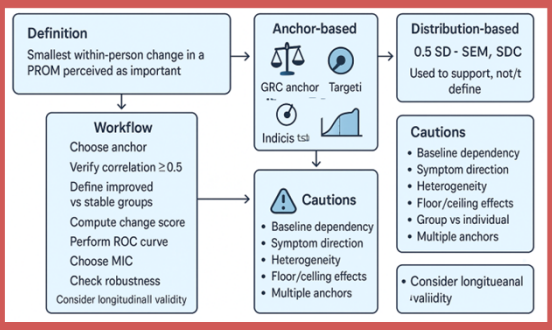
Overview

- What is interpretation
- The concept of *Minimal Important Change*
- Related concepts
- Overview of MIC methods
- Classical MIC methods:
  - Distribution-based methods and their limitation
  - Mean change method
  - Difference in mean change method



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Interpretation

Definition

"The degree to which one can assign qualitative meaning - that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores"

Cosmin 2011

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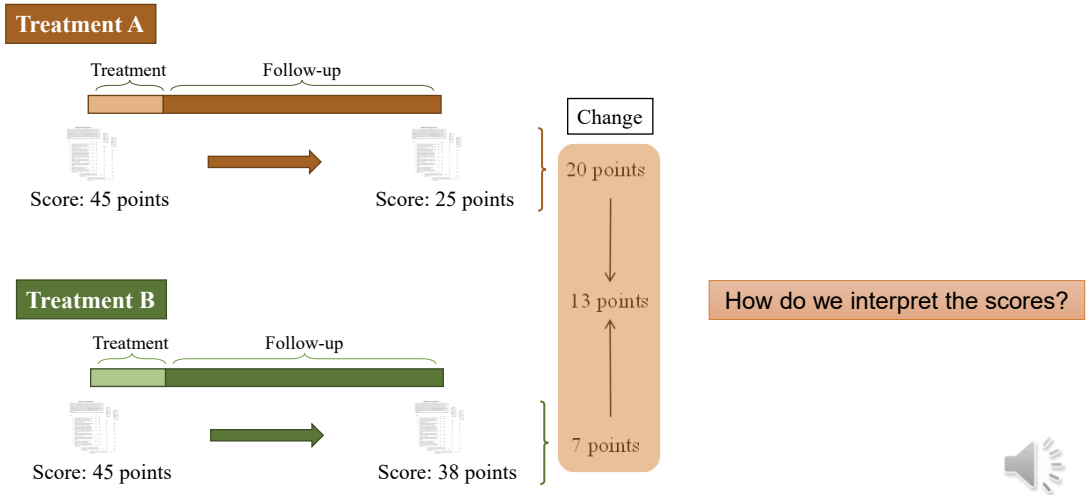
Interpretation



How do we interpret the scores?

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Minimal Important Change (MIC)

Definition

"The smallest change in score in the construct to be measured which patients perceive as important"

Detailed definition

"A threshold for a minimal within-person change over time above which patients perceive themselves importantly changed"

Three important components:

- A threshold for a *minimal* change above which patients perceive themselves as changed
- A change that is considered *important* to patients
- A *within-patient change* over time

MIC is the smallest change in score that you **WANT** to detect with the instrument

Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *Journal of Clinical Epidemiology*. 2010;63(7):737-745
Terwee CB, Peipert JD, Chapman R, et al. Minimal important change (MIC): a conceptual clarification and systematic review of MIC estimates of PROMIS measures. 2021. Qual Life Res.

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Minimal Important Change

MID/MIC/MCID/MCIC

MI = Minimal important
MCI = Minimal clinically important
D = difference
C = change

MID used by the Guyatt group (US)

MIC used by COSMIN

COSMIN

Change: within-patient or within-group change
Difference: between-patients or between-groups change

Much confusion – always look at the methodology to determine what a study is reporting

Guyatt et al., Mayo Clin Proc (2002); van der Roer et al., Spine (2006); De Vet et al., Health Qual Life Out (2006); Terluin et al., J. Clin. Epid. (2015); Dekker et al., Osteoarthritis and Cartilage (2023)

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Related concepts

Concepts measuring change *larger than minimum*:

- Clinically Significant Change (1)
- Sufficiently Important Difference (2)
- Smallest Worthwhile Effect (3)
- Patients Acceptable Symptom State (4)



Concepts which are *different to the MIC*:

- Smallest/Minimal Detectable Change →

Is the smallest change in score that can be detected statistically with some degree of certainty (e.g., 95 or 90%), based on the standard error of measurement (SEM) or limits of agreement from a test–retest reliability design

1. Jacobson, N. et al. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research.
2. Barrett, B., et al. (2005). Sufficiently important difference: Expanding the framework of clinical significance.
3. Ferreira, M. et al. (2012). A critical review of methods used to determine the smallest worthwhile effect of interventions for low back pain.
4. Pham T et al. (2009) Patient acceptable symptomatic state (PASS).

MIC and difference - methods

Change in…	Approach	Between who…	Concept	Methods	Criteria
Individuals	*Responder*	Change *within* individuals	Responder	MIC: • Distribution-based • Anchor-based • Consensus-based	$\Delta T_1 - T_0 >$ MIC
				$MIC_{individual}$: • Conversation with individuals	$\Delta T_1 - T_0 >$ individual MIC
				Responder criteria	Individuals meets responder criteria
				Goal attainment	Individual achieves goal
		Difference *between* changes within individuals	Tbd	Tbd	Tbd
Groups	*Responder*	*Within-group* change	Proportion of responders	Consensus-based cut-off	Proportion of responders (%ΔA) > cut-off
		Between-group difference in within-group change		Consensus-based cut-off for maximal NNT or minimal RR	NNT < cut-off RR > cut-off
	Group average	*Within-group* change	Average change	MIC	Within-group change ΔA > MIC
		Between-group difference in within-group change		Anchor-based or consensus-based → MCID	Between-group diff. > MCID
				Benefit-harm trade-off or discrete choice experiment → SWE	Between-group diff. > SWE

Tbd = To be determined, NNT = numbers needed to treat, RR = relative risk, SWE = Smallest worthwhile effect, ΔA = within-group change

Dekker et al., Osteoarthritis and Cartilage (2023)

Calculating the MIC

- Many approaches

Generally not recommended

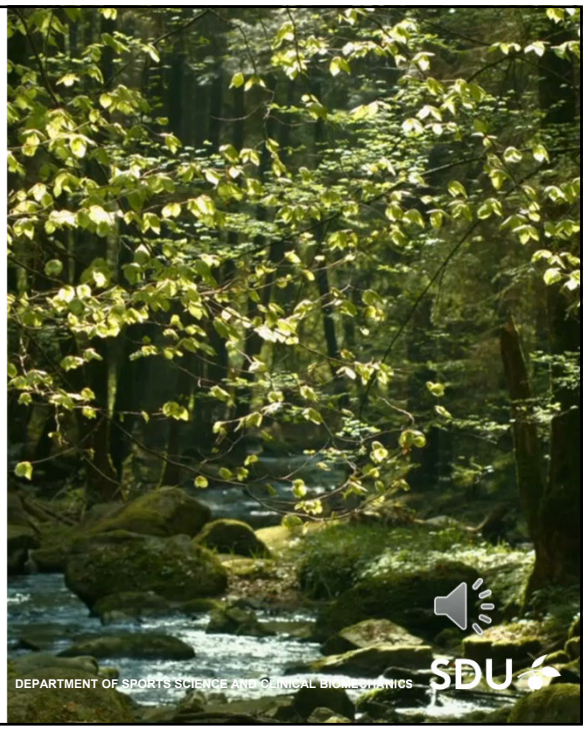
Distribution-based methods

Anchor-based methods

Global Rating of Change

Compared with before receiving treatment, how would you describe your physical abilities now?

- ❑ Much better
- ❑ Better
- ❑ A little better
- ❑ No change
- ❑ A little worse
- ❑ Worse
- ❑ Much worse



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Overview of anchor-based methods

Year	Method	Which change	Short description	Comment	References
1989	**Mean change methods**	Within-group	Mean change score in subgroup	Very common but sensitive to random sampling variation	Jaeschke R et al. Measurement of health status. Ascertaining the minimal clinically important difference. Controlled Clinical Trials.
2007 (1986)	**Receiver operating characteristic (ROC) method**	Within individuals	Classify improved and not-improved with least misclassification	Sensitive to random sampling variation. Cannot include effect modifiers (e.g. baseline score) Wide CI's in small samples	• Deyo RA, Centor RM. Assessing the responsiveness of functional scales to clinical change: an analogy to diagnostic test performance. • de Vet HC et al. Minimally important change determined by a visual method integrating an anchor-based and a distribution-based approach. Quality of Life Research.

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2015	**Predictive modelling (PM)**	Within individuals	Logistic regression using dichotomized transition ratings	Similar result to ROC method but more precise	Terluin B et al. Minimal important change (MIC) based on a predictive modeling approach was more precise than MIC based on ROC analysis. J Clin Epidemiol.
2017	**Adjusted predictive modelling (APM)**	Within individuals	Adjusts for proportion improved other than 50%	Improvement of predictive modelling	Terluin B et al. Minimal important change (MIC) based on a predictive modeling approach was more precise than MIC based on ROC analysis. J Clin Epidemiol.
2022	**Improved adjusted predictive modelling (IAPM)**	Within individuals	Takes reliability of the anchor into account	Improvement of APM modelling	Terluin B et al. Improved adjusted minimal important change took reliability of transition ratings into account. Journal of Clinical Epidemiology

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2022	**Longitudinal item response theory**	Within individuals	Based on IRT model	Similar precision to IAPM and LCFA	Bjorner JB et al. Establishing thresholds for meaningful within-individual change using longitudinal item response theory. Qual Life Res

Not recommended as computational difficult

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2022/2024	**Present State Bias in transition ratings**	-	Based on LCFA model	Determines PSB which is useful for evaluating MIC and model selection in LCFA	• Terluin B et al. Present state bias in transition ratings was accurately estimated in simulated and real data. Journal of Clinical Epidemiology • Terluin B et al. Effect of present state bias on minimal important change estimates: a simulation study. Qual Life Res
2023	**Longitudinal confirmatory factor analysis (LCFA)**	Within individuals	Based on LCFA model for ordinal indicators	Similar precision to IAPM	Terluin B et al. Estimating anchor-based minimal important change using longitudinal confirmatory factor analysis. Qual Life Res.

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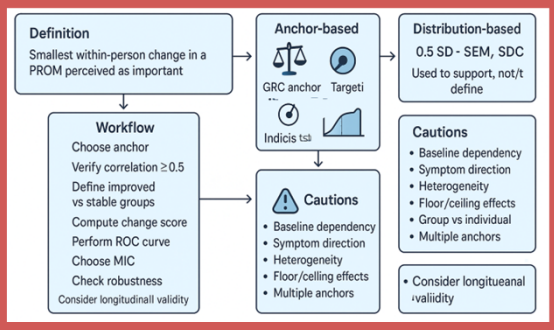

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Distribution-based methods

Use statistical parameters, such as the standard deviation (SD) or standard error of measurement (SEM) for estimating the MIC value

A variety of methods exists → see Crosby *et al.* and 'Responsiveness vodcast'

E.g. $MIC = 1 \times SEM$ or $MIC = \frac{1}{2} \times SD$

If MIC is defined as $1 \times SEM$ the SDC will always (by definition) be larger than the MIC, because:

$$SDC = 1.96 \times \sqrt{2} \times SEM$$

This would mean that one can never distinguish important change from measurement error in individual patients (the same is true for 0.5 x SD).

Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *Journal of Clinical Epidemiology*. 2003;56(5):395-407.
Terluin et al. J Clin Epidemiol. 2017

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Distribution-based methods

Limitation

- Do not provide a good indication of the ***importance*** of the observed change
- Are measures of *magnitude*

Not recommended for MIC determination

Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *Journal of Clinical Epidemiology*. 2003;56(5):395-407.

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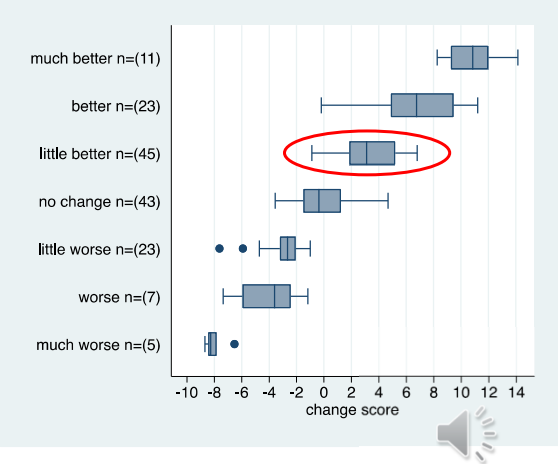
Mean change method

Mean value of the change score in patients reporting a minimal improvement



Carrasco-Labra A et al. Minimal important difference estimates for patient-reported outcomes: A systematic survey. J Clin Epidemiol. 2021

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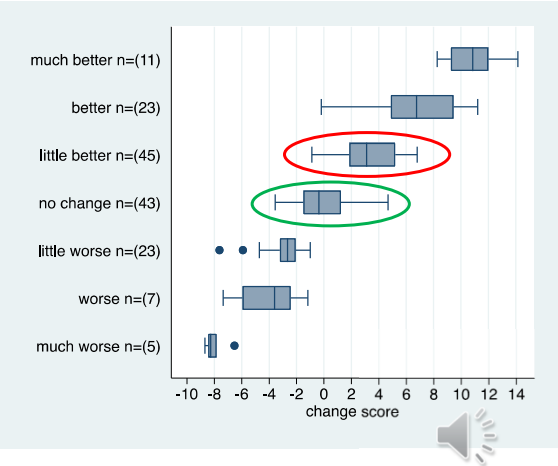
Difference in mean change method

The difference in means value of the change score between patients reporting a minimal improvement and patients reporting no change



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Video 2

- We will look at other selected methods in more details



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