SeeingTheta

ISOQOL 2026

PRAGUE · ORAL SESSION 208: MEANINGFUL CHANGE

An Evidential Framework for Evaluating Anchor Measures in Meaningful Change Research

Anchors are grouping tools. Appraise them as grouping tools.

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PRESENTED BY Piper Fromy, SeeingTheta · 20 October 2026

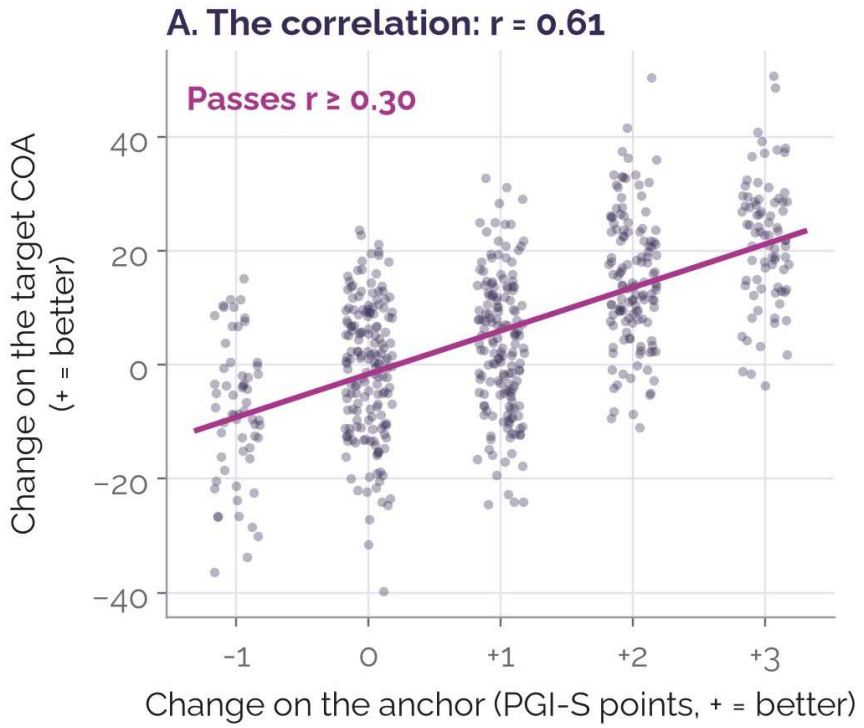


Our anchor is the PGI-S. Its change correlation with the target COA is r = 0.61.

That clears the usual r ≥ 0.30 bar with room to spare. Would you use it to set a meaningful change threshold?

Simulated data: a hypothetical trial, N = 600. The same anchor appears again on slides 3, 7 and 8.

Why a correlation is not enough



Simulated data, same hypothetical trial (N = 600). Curves: distribution of target COA change within each PGI-S change group.

Only 51% of anchor-based studies report any empirical association at all (Zhang et al. 2023).

A strong correlation can come from the far-apart groups, while neighbouring groups overlap.

The premise: what is an anchor for?

“Anchor measures in meaningful change analyses have the sole purpose **of stratifying patients into distinct and interpretable change groups with respect to change in the concept of interest.”**

ANCHOR RESPONSE OPTIONS

What the instrument offers. For the PGI-S: None, Mild, Moderate, Severe, Very severe.

A property of the instrument.

ANCHOR GROUPINGS

What the analysis builds from them: “no change”, “1 point better”, “2 points better”.

A property of the analysis. Meaningful change methods work on these.

So judge an anchor by the groups it produces, not by one statistic.

The framework: three necessary conditions

PURPOSE **Sort patients into distinct, interpretable groups with respect to change in the concept of interest**

1 Construct linkage

Does it measure the same thing?

1.1 Conceptual alignment
Instrument review. The gate.

1.2 Cross-sectional association
Quantitative

1.3 Longitudinal association
Quantitative. Necessary, not sufficient.

2 Meaningfulness

Do its steps mean something to patients?

2.1 Category interpretability
Qualitative, clinical input
PLAN IN PROTOCOL

2.2 Transition meaningfulness
Qualitative, targeted item
PLAN IN PROTOCOL

2.3 Within-group coherence
Targeted item
PLAN IN PROTOCOL

3 Discrimination

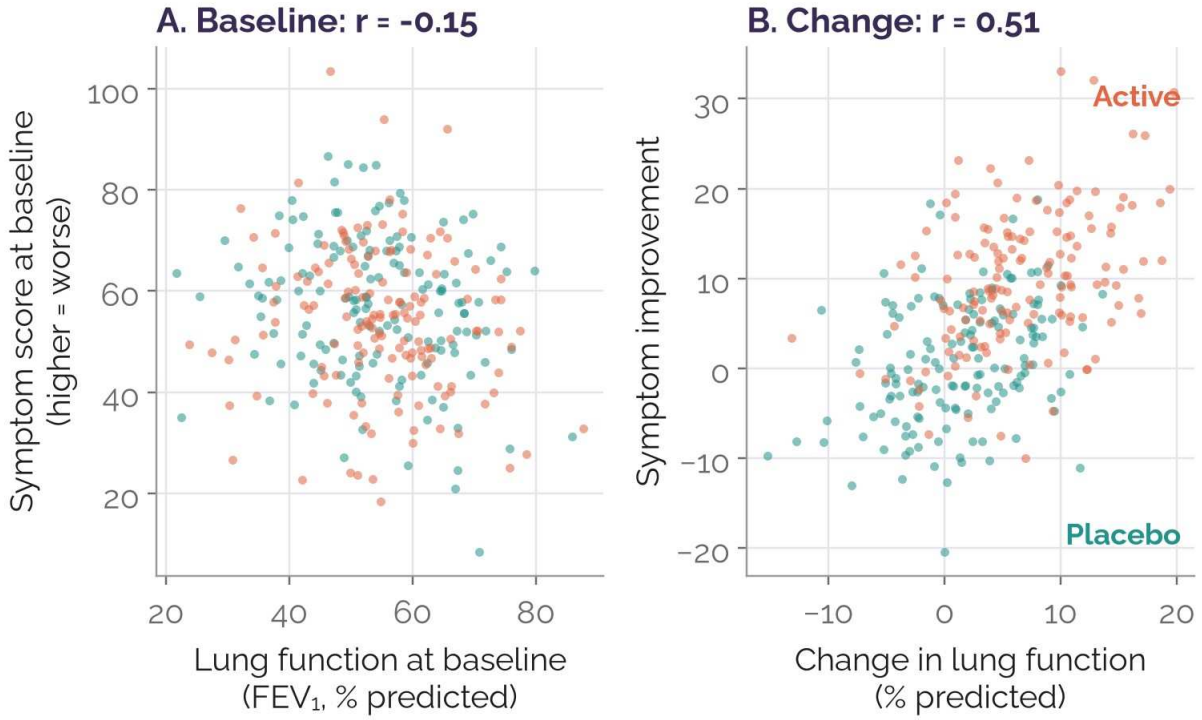
Does it separate neighbouring groups?

3.1 Response option discrimination
Quantitative, one time point

3.2 Grouping discrimination
Quantitative, change scores

Each numbered item is one row of the evidence documentation form.

1 · Construct linkage: change correlations can be misleading



1.1 Conceptual alignment is the gate

Same domain, same perspective, similar recall. If the constructs differ, no statistic rescues the anchor.

1.2 Check one time point first

Do anchor and COA agree at baseline? Here they barely do (r = −0.15).

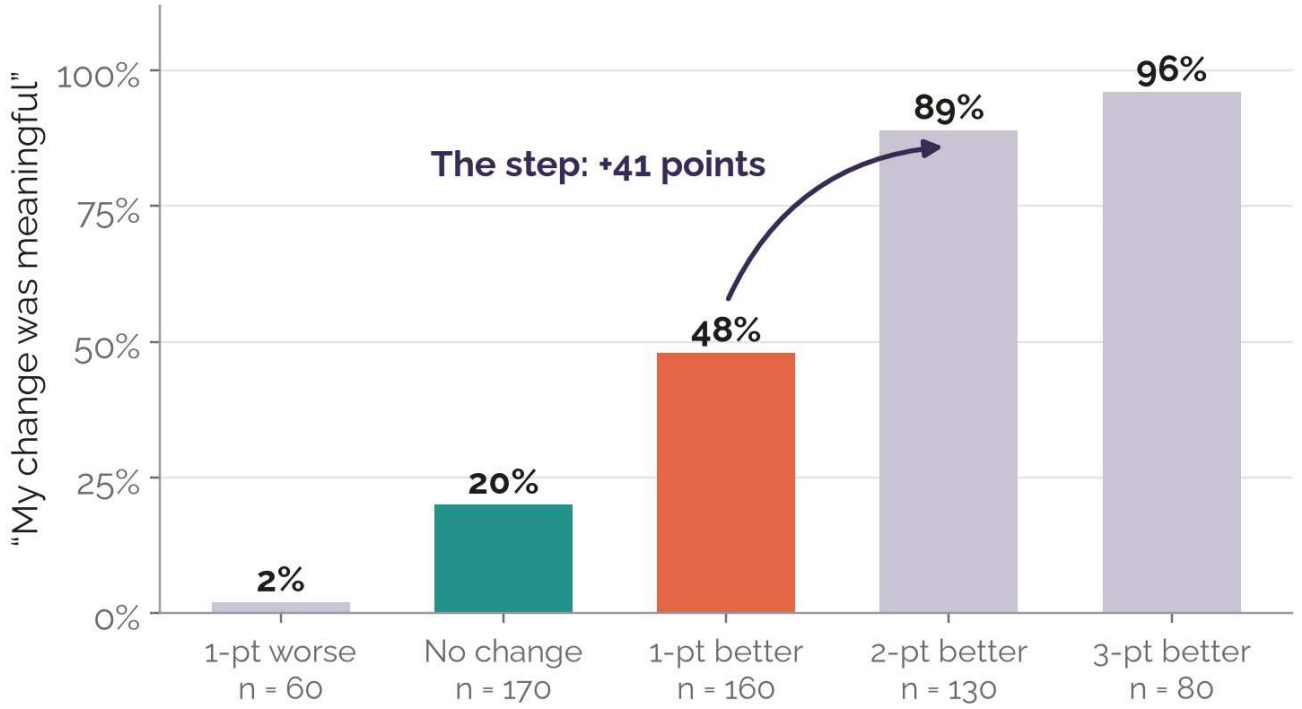
1.3 Change correlation: necessary, not sufficient

Both improve with treatment, so their changes correlate (r = 0.51). Moving together is not measuring the same thing.

Simulated: placebo-controlled trial, N = 300. The pattern follows reports for lung function and symptoms in COPD (Jones et al. 2011, 2012; Leidy et al. 2014).

Two measures can change together without measuring the same thing.

2 · Meaningfulness: ask the patients



Simulated data, same hypothetical trial (N = 600). Item at follow-up: "Has your change been meaningful?"

WHAT IT COSTS

One item at each follow-up visit. A few probes in interviews you may already run.

WHAT YOU GET

Patients tell you which group is meaningful: 48% at 1 point, 89% at 2 points.

IF YOU SKIP IT

A 1-point threshold counts patients as improved. 52% of that group say their change was not meaningful.

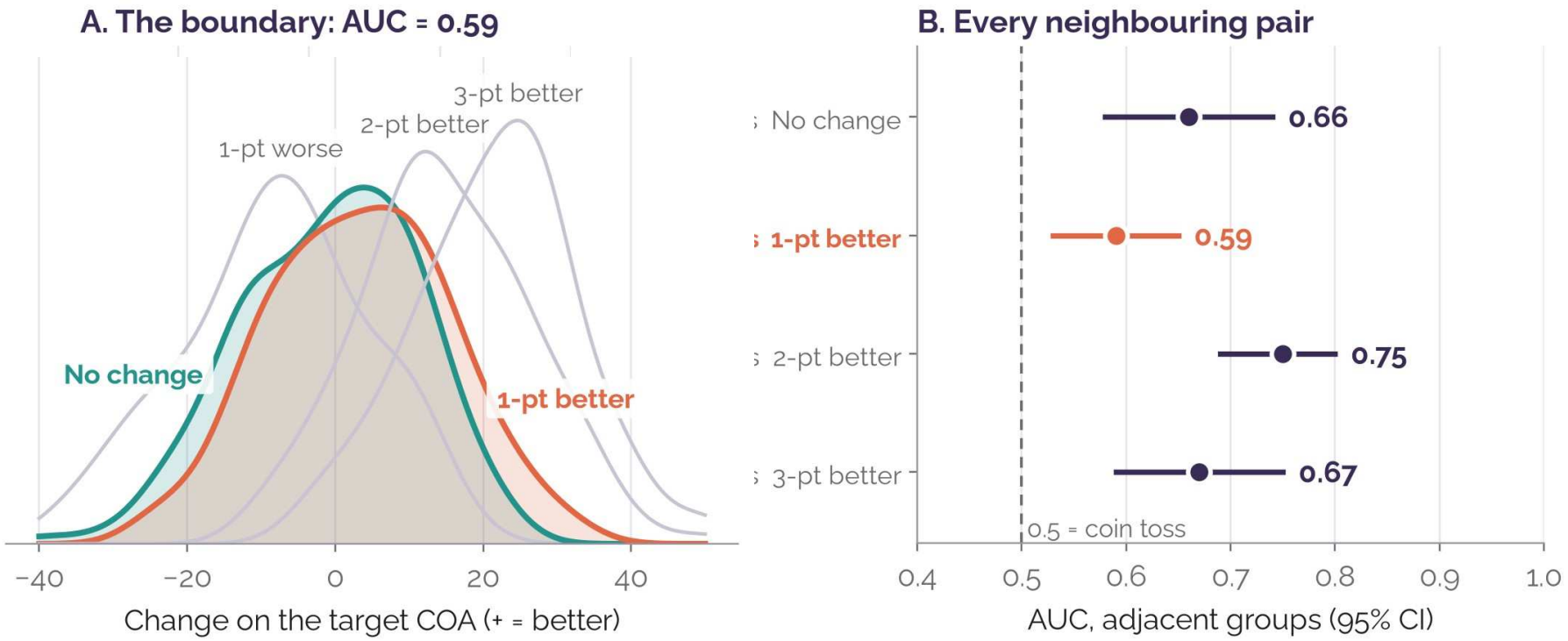
THE PAYOFF

The threshold rests on what patients report, not on an assumed step size.

This is protocol work, not an analysis option. It cannot be added after the data are in.

One question at follow-up shows where meaningful change starts: here, at 2 points.

3 · Discrimination: back to our anchor



Simulated data, same trial (N = 600). AUC: chance that a patient from the higher group improved more than one from the lower group. 95% CI: bootstrap.

Domains 2 and 3 agree: the 1-point group is neither meaningful to patients nor distinct from no change.

Slide 2: r = 0.61, it passes. At the boundary that sets the threshold: AUC = 0.59.

Use it on your own anchor, and on published literature

DOCUMENT YOUR OWN

Protocol: plan items 2.1 to 2.3, because they need new data.
Analysis plan: pre-specify 1.2, 1.3, 3.1 and 3.2. Report: complete every row and justify each gap.

APPRAISE OTHERS'

For peer reviewers, regulators, HTA bodies, and anyone reusing a published threshold. Ask for each item. Missing evidence is a question to answer (rather than an automatic fail).

Item	Evidence presented	Appraisal
1.3 Longitudinal association	Change correlation r = 0.61, with scatter plot	Supports linkage. Not sufficient alone.
2.3 Within-group coherence	"Meaningful": 48% at 1 point, 89% at 2 points	1-point group not coherent. Supports a 2-point grouping.
3.2 Grouping discrimination	Adjacent AUCs with 95% CI. No change vs 1 point: 0.59	1-point group not distinct. Supports a 2-point grouping.

Illustrative excerpt from the draft evidence documentation form, filled in for the simulated anchor.

No cutoffs, by design.
The form sets out the argument for the reader to judge .

The same form documents your anchor and lets you appraise anyone else's.

Thank you.

THREE QUESTIONS FOR ANY ANCHOR

1. Does it measure the same thing as the COA?
2. Do its steps mean something to patients?
3. Does it separate neighbouring groups?

DISCLOSURES

All authors are employees or representatives of the organisations listed on the title slide. They have nothing else to disclose.

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