

Approaches for Estimating Minimally Important Differences

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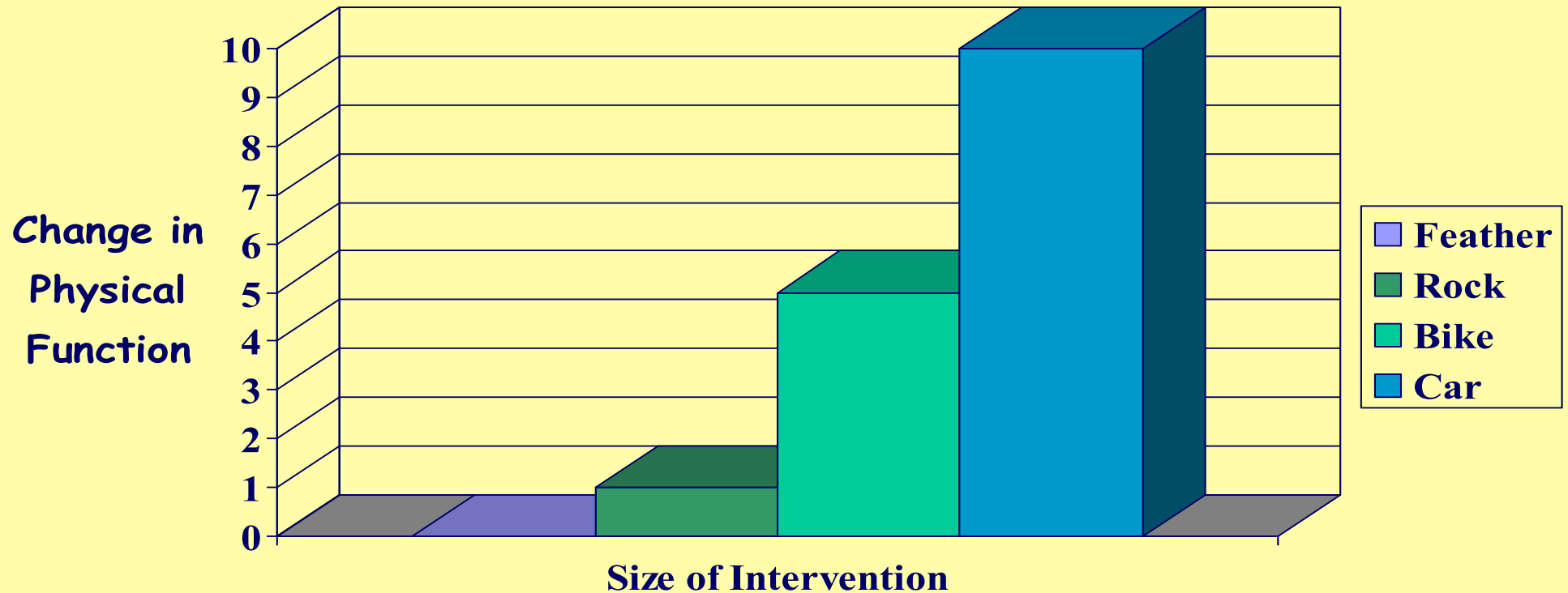
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Minimal Clinically Important Differences in COPD

Beach House, Bal Harbor, Florida

National Jewish Medical and Research Center

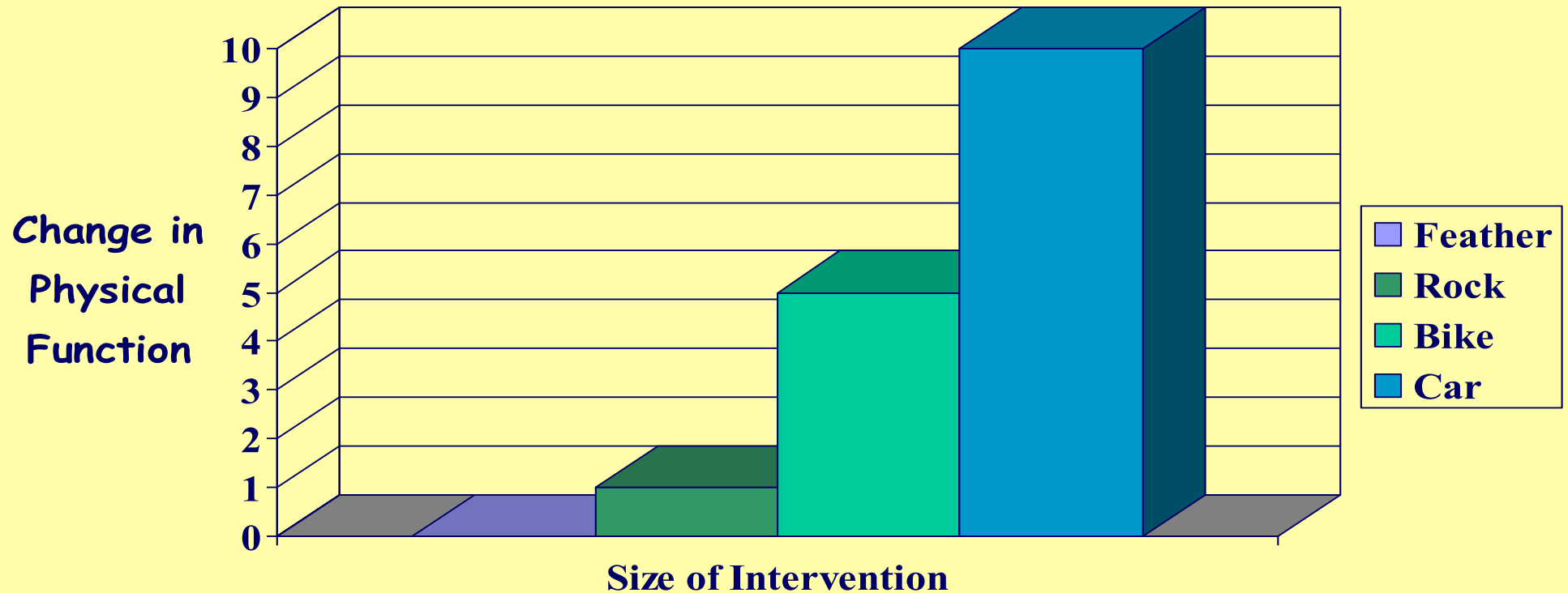
Magnitude of HRQOL Change Should Parallel Underlying Change



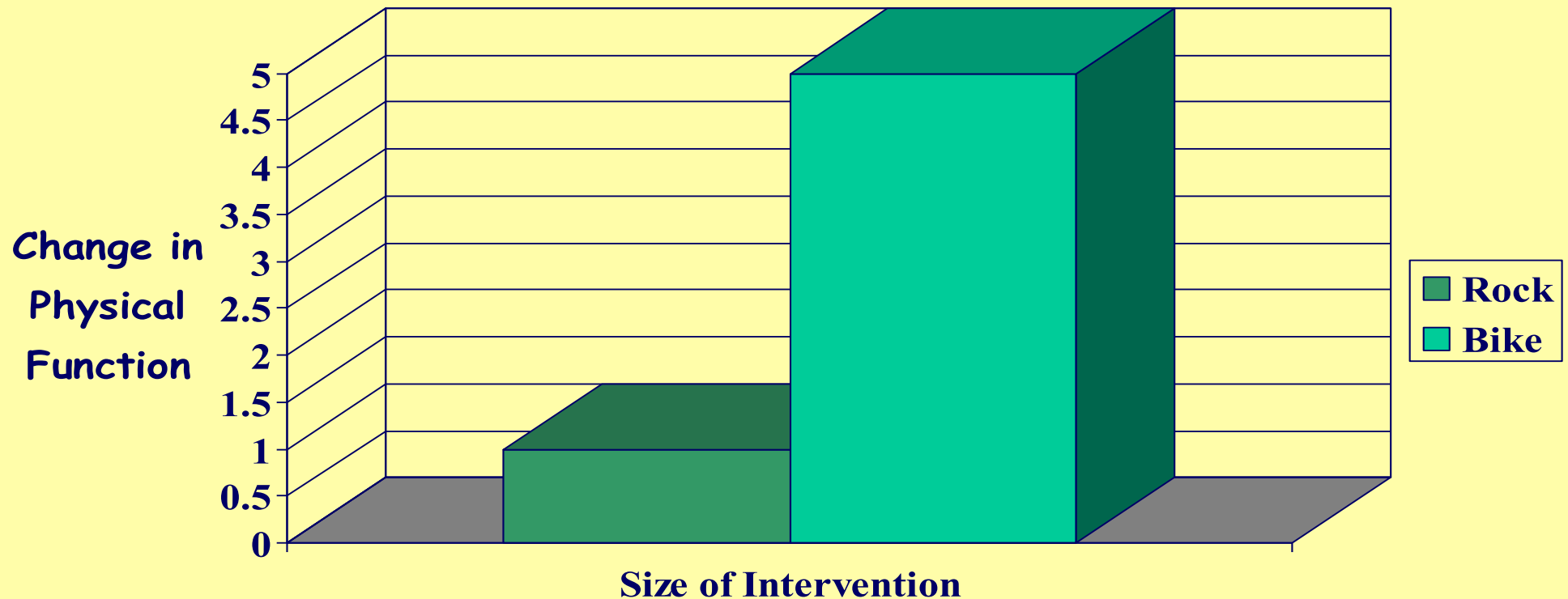
How Evaluated

- ◆ External anchor to determine there has been “minimal” change
 - Self-report
 - Provider report
 - Clinical measure
 - Intervention
- ◆ Estimate change in HRQOL among those with minimal change on anchor

Change in Physical Function by Size of Intervention



Some Anchors are Better than Others for MID Estimation



Self-Report Anchor

- ◆ People who report a “minimal” change
- ◆ How is your physical health now compared to 4 weeks ago?
- ◆ *Much improved; Moderately Improved;*
- ◆ *Minimally Improved;*
- ◆ *No Change;*
- ◆ *Minimally Worse;*
- ◆ *Moderately Worse; Much Worse*

Example Use of Self-Report Anchor in COPD

- ◆ Compared to Jack, my ability to walk is:
 - Much better; Somewhat better; A little bit better; About the same; A little bit worse; Somewhat worse; Much worse
- ◆ Determined how much actual walking distance had to differ, on average, for patients to rate themselves as walking either *a little bit better* or “*a little bit worse*.”

Redelmeier, D. A. et al., 1997, Am J Respir Crit Care Med

Example with Multiple Anchors

- ◆ 693 RA clinical trial participants evaluated at baseline and 6-weeks post-treatment.
- ◆ Five anchors:
 - 1) patient global self-report;
 - 2) physician global report;
 - 3) pain self-report;
 - 4) joint swelling;
 - 5) joint tenderness

Kosinski, M. et al. (2000). Determining minimally important changes in generic and disease-specific health-related quality of life questionnaires in clinical trials of rheumatoid arthritis. Arthritis and Rheumatism, 43, 1478-1487.

Patient and Physician global reports

- ◆ How the patient is doing, considering all the ways that RA affects him/her?

Very good (asymptomatic and no limitation of normal activities)

Good (mild symptoms and no limitation of normal activities)

Fair (moderate symptoms and limitation of normal activities)

Poor (severe symptoms and inability to carry out most normal activities)

Very poor (very severe symptoms that are intolerable and inability to carry out normal activities)

Pain self-report

- ◆ 10 centimeter visual analog scale
- ◆ 0 = no pain, 10 = severe pain

Threshold on Self-Report and Physician Report Anchors Used for MID estimation

- ◆ Patient and physician global reports
 - Improvement of 1 level over time.
- ◆ Pain self-report
 - Improvement of 1-20% over time.

Joint swelling and tenderness anchors

- ◆ Number of swollen and tender joints
- ◆ Threshold for MID estimation = 1-20% improvement over time

Recommendations

- ◆ Use multiple anchors
- ◆ Use anchors that represent minimal change
- ◆ Report average across anchors and studies, range, and SD
- ◆ Consider that it can be easier to conclude that a difference is clearly or obviously important than it is to say one is always unimportant (grey area).



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Appendix: Terminology

- ◆ Minimally Important Difference (MID)
- ◆ Minimal difference (MD)
- ◆ Minimally Detectable Difference (MDD)
- ◆ Clinically Important Difference (CID)