

# Bounded Estimates and Other Considerations in Determining the MID

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# Responsiveness to Change

- HRQOL measures should be responsive to interventions that change HRQOL
- Evaluating responsiveness requires assessing HRQOL relative to an external indicator of change (anchor)

# Two Essential Elements

1. External (not HRQOL measure being evaluated) indicator of change (Anchor)
2. Amount of HRQOL change among those determined to have changed on anchor, relative to noise (variance).

# Kinds of Anchors

- Self-report
- Clinician or other report
- Clinical parameter
- Clinical intervention

# Self-Report Anchor (A)

Overall has there been any change in your asthma since the beginning of the study?

*Much improved; Moderately improved; Minimally improved*

No change

*Much worse; Moderately worse; Minimally worse*

# Examples of Other Anchors

## Clinician report

- How is Jan's physical health now compared to 4 weeks ago?

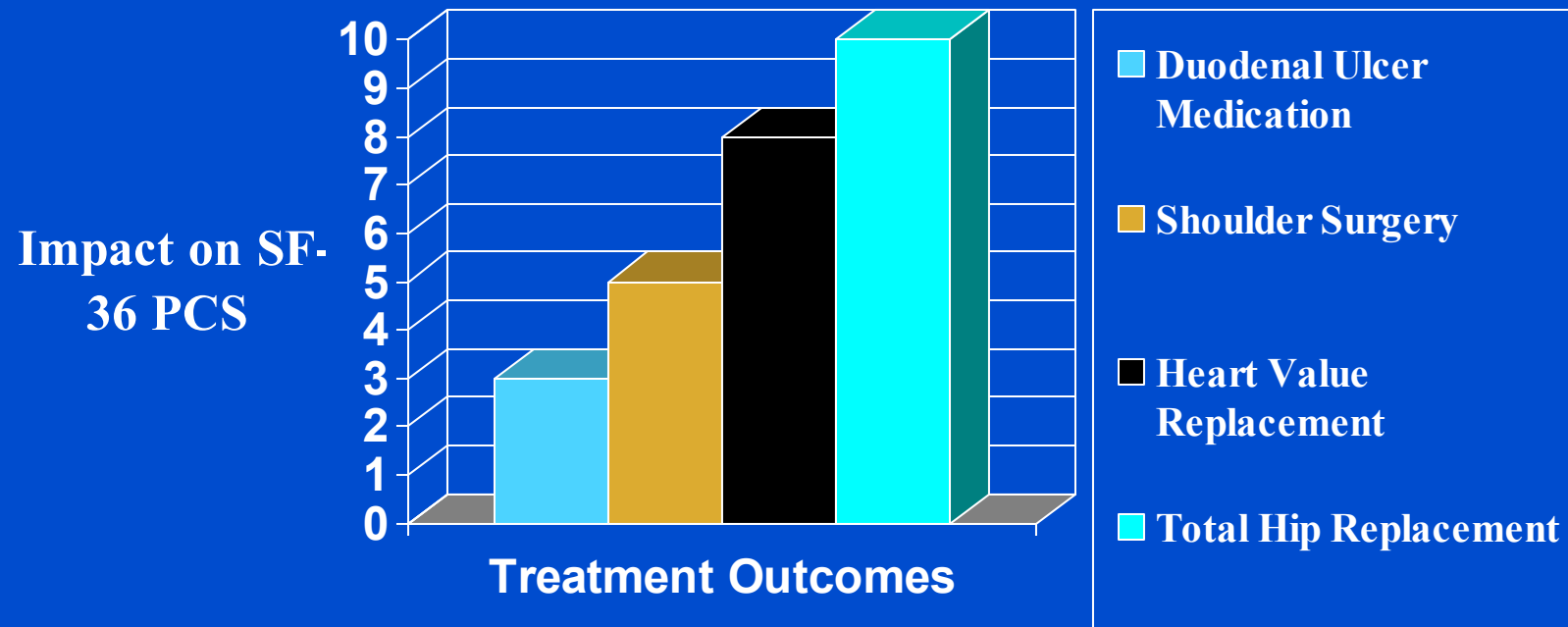
## Clinical parameter

- Change from CDC Stage A to B
- Became seizure free

## Clinical intervention

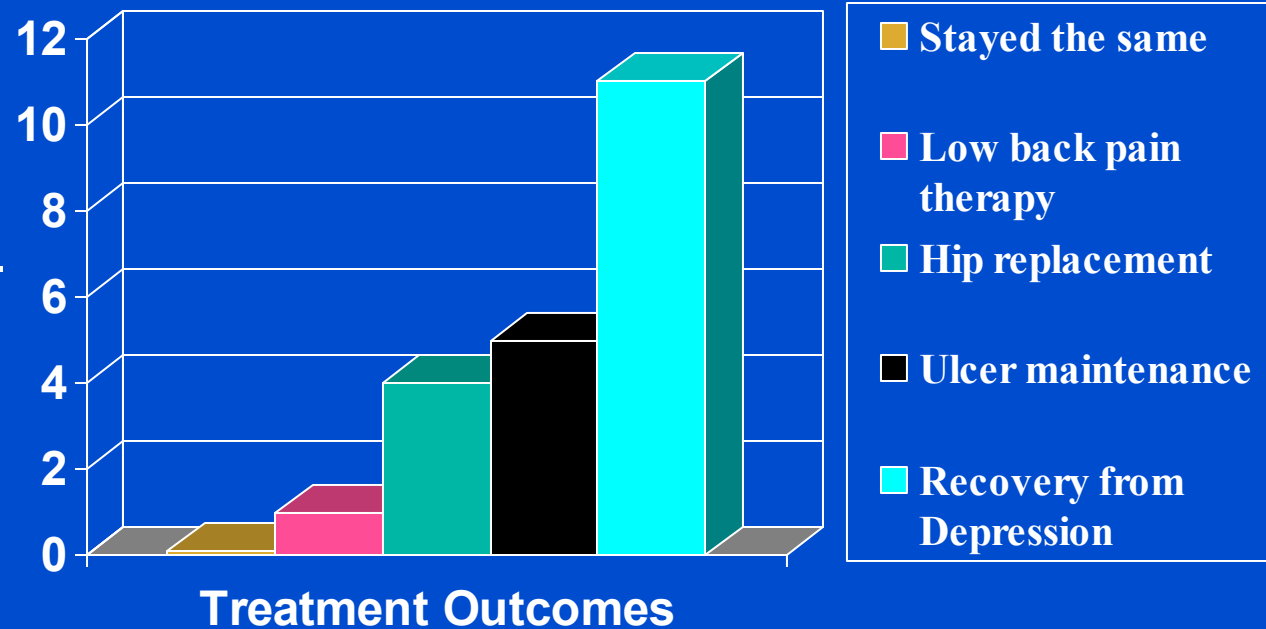
- Before and after Prozac

# Change and Responsiveness in PCS Depends on Treatment



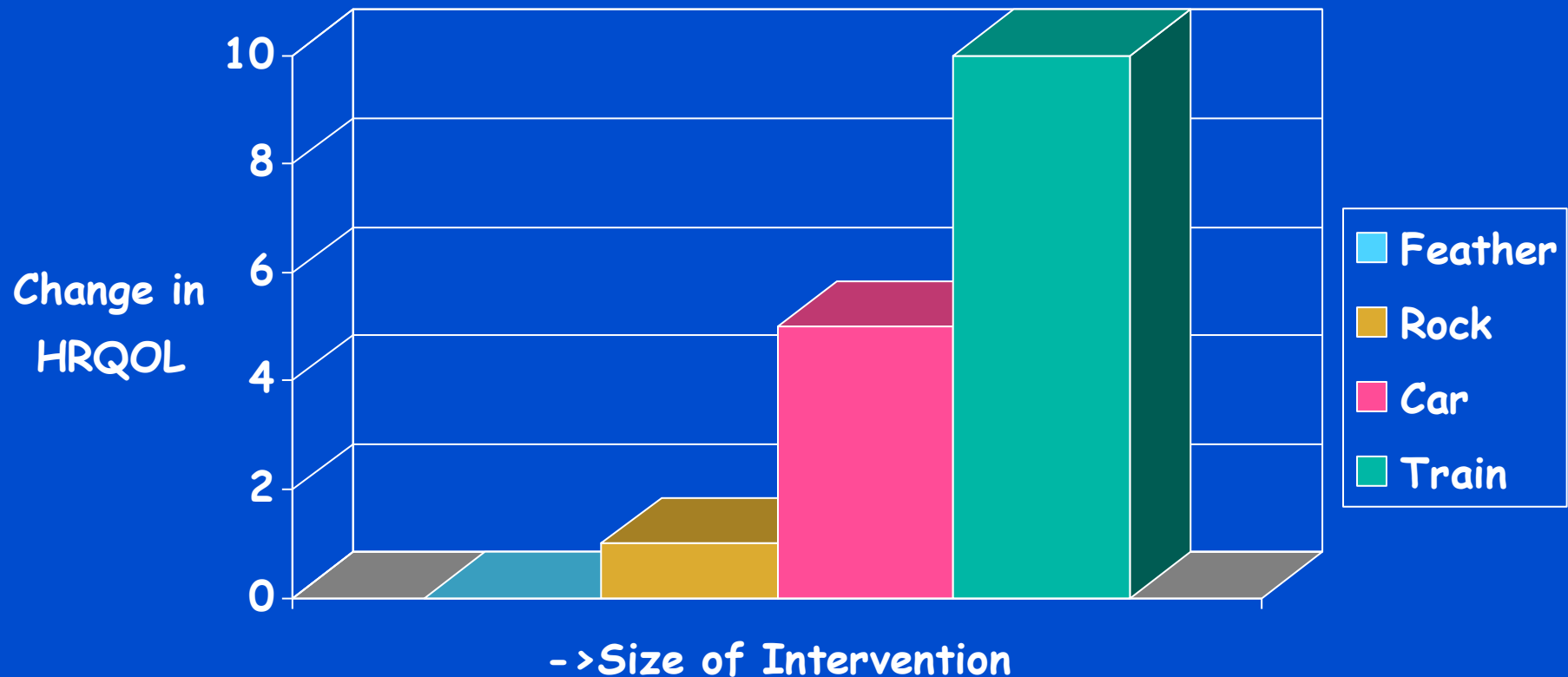
# Change and Responsiveness in MCS Depends on Treatment

Impact on SF-36 MCS





# Magnitude of HRQOL Change Should Parallel Underlying Change



# Minimal Important Difference (MID)

Some differences between groups or over time may be so small in magnitude that they are not important.

Smallest difference in score that is worth caring about (important).

Change large enough for a clinician to base treatment decisions upon it.

# Two Essential Elements

1. Indicator (not HRQOL measure being evaluated) of “minimal” change (Anchor)
2. Amount of HRQOL change among those determined to have changed on anchor.

# Example Anchor (1)

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*

# MID Varies by Anchor

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.

# Changes in SF-36 Scores Associated with Minimal Change in Anchors

Scale	Self-R	Clin.-R	Pain	Swell	Tender	Mean
PF	8	8	8	<u>6</u>	<u>8</u>	8
Role-P	<u>21</u>	20	<u>11</u>	13	13	16
Pain	<u>15</u>	12	8	12	<u>7</u>	11
GH	<u>4</u>	2	2	3	<u>1</u>	2
EWB	<u>7</u>	5	5	3	<u>1</u>	4
Role-E	<u>18</u>	12	<u>8</u>	16	11	13*
SF	<u>12</u>	9	<u>8</u>	8	10	9
EF	<u>11</u>	10	<u>5</u>	5	8	8
PCS	<u>4</u>	4	<u>3</u>	3	3	3.5*
MCS	<u>5</u>	3	<u>2</u>	3	2	3 <small>14 1/23/18</small>

Samsa et al. (1999, p. 149) said

MID for SF-36 is “typically in the range of 3 to 5 points” (p. 149). { .09- > 0.28 ES }

Samsa, G., Edelman, D., Rothman, M. L., Williams, G. R., Lipscomb, J., & Matchar, D. Pharmacoeconomics, 15, 141-155: 1999.

# MID Determination Complicated By Cumulative Change Over time

Baseline	42
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Year 4	36
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Note: 4-year decline in PCS among US seniors, 1990-94.



-> 1.5 points per year (0.15 SD)



# MID Varies by Starting Position

Same retrospective report of change associated with bigger prospective change for those with more room to change

- Among those who said their physical health was *somewhat worse*, change ranged from -26 points to +3 points for people with high (81-100) versus low (0-20) baseline physical health (Baker et al., 1997, Medical Care).

# Group Average is Different from Individual Change

Average change collapses across individual responses.

Is inference about minimum amount of change that is important for individuals based on a group average reasonable?

What if scale score improved by 4 points for half the people and 0 points for the other half? Is the MID = 2 or 4?

# Value Depends on Cost



A small positive change has greater value if it costs less.

Importance of HRQOL change depends on what it costs to produce it.

# Summary

Identification of MID aids interpretation by providing familiar anchors to unfamiliar units.

Trying to give a single point estimate is too simplistic.

Bounded estimates are necessary given the uncertainty.

## Resource Centers for Minority Aging Research



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# So How Big Are Different Changes?

## Effect size benchmarks

- Small: 0.20-→0.49
- Moderate: 0.50-→0.79
- Large: 0.80 or above

