



Clinical Importance: The OMERACT Perspective

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Background

- OMERACT: Outcome MEasurement in Rheumatoid Arthritis Clinical Trials.
 - Meet every two years re: outcomes in RCT's
 - Set research agenda for subsequent two years
- OMERACT 5: Toulouse, May 2000.
 - MCID determination for core set of outcomes in RA, OA, OP, Back pain
 - Based on “the Beaton cube”



OMERACT Filter

- All measures, approaches must pass the OMERACT Filter....(Boers, 1998)
 - *Truth*
 - *Discrimination*
 - *Feasibility*
- Same filter holds for trying to find MCID



Approach to MCID

- 1) What methods are out there?
- 2) How do you find those studies in literature searches?
- 3) What are they able to tell us about important changes in core set of measures?
- 4) Future directions – LDAS.



1. What are the methods? (Wells, 2001)

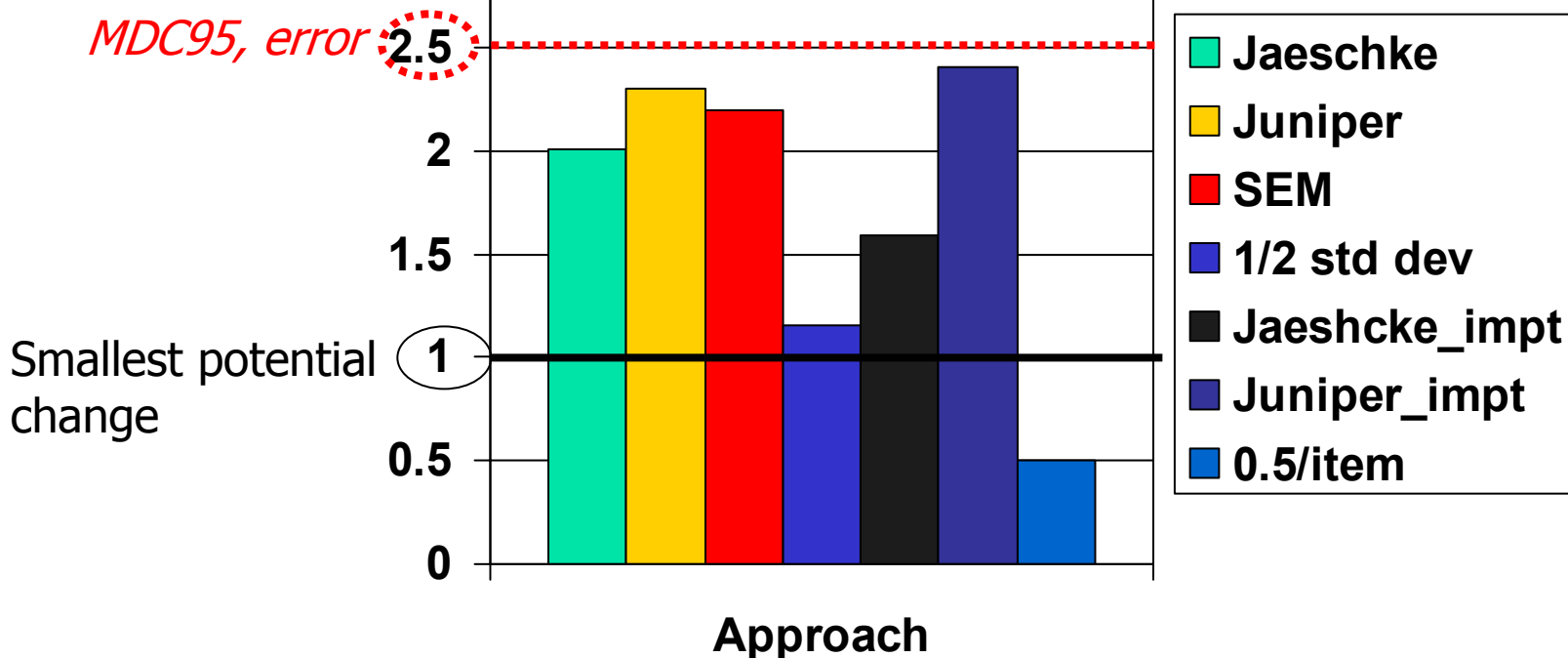
- Patient perspectives.
 - Comparison to global rating (Jaeschke, 1989; Juniper, 1994)
 - Patient conversations (Redelmeier, 1993)
- Clinician perspectives
 - Consensus groups
 - Paper patient ratings (Goldsmith, 1993)
 - Patient scenarios
 - Prognostic rating (Stratford, 1998)
- Data driven (SEM, $\frac{1}{2}$ standard deviation)
- Ability to discern important improvements
 - Achievement of treatment goals (Riddle, 1998)
 - Improvement criteria (achieving ACR20, EULAR/DAS)

Wyrwich, 2003



Do methods matter? ...*Yes*

MCID value for pain NRS



test-retest = 0.85 (Gaston-Johannson, 1996),
Minimal detectable change (95%) = $1.96 * 1.41 * s \text{ dev}'n * \sqrt{1-0.85} = 2.5$

Does it matter? ...*Yes.*

MCID Approach	MCID Value	Number “improved”*	% of sample “improved”
SEM _(t-rt)	2.2	67	40.6
½ std dev’n	1.15	85	50.9
0.5/item	0.5	120	72.7
Jaeschke	2.01	67	40.6
Juniper	2.3	85	50.9
Juniper + impt	2.4	67	40.6
MDC-95	2.5	67	40.6

* “improved” = change in pain score > this MCID threshold, n=172



2) Finding MCID studies in literature

- MCID most often found in studies of responsiveness
- OMERACT approach was to use “the Cube” to sort through responsiveness studies for those addressing important change.



Use of the cube.

- Finding important changes in studies of responsiveness (Beaton, 2001)
 - Kind of change defined by 3 features
 - Decided: Only those specifically addressing important change are of interest to MCID determination.



Features defining change

Setting: Who is the focus?

- groups
- individuals

Which scores are contrasted?

- differences between?
- changes within?
- both?

What kind of change?

Minimum
potentially
detectable

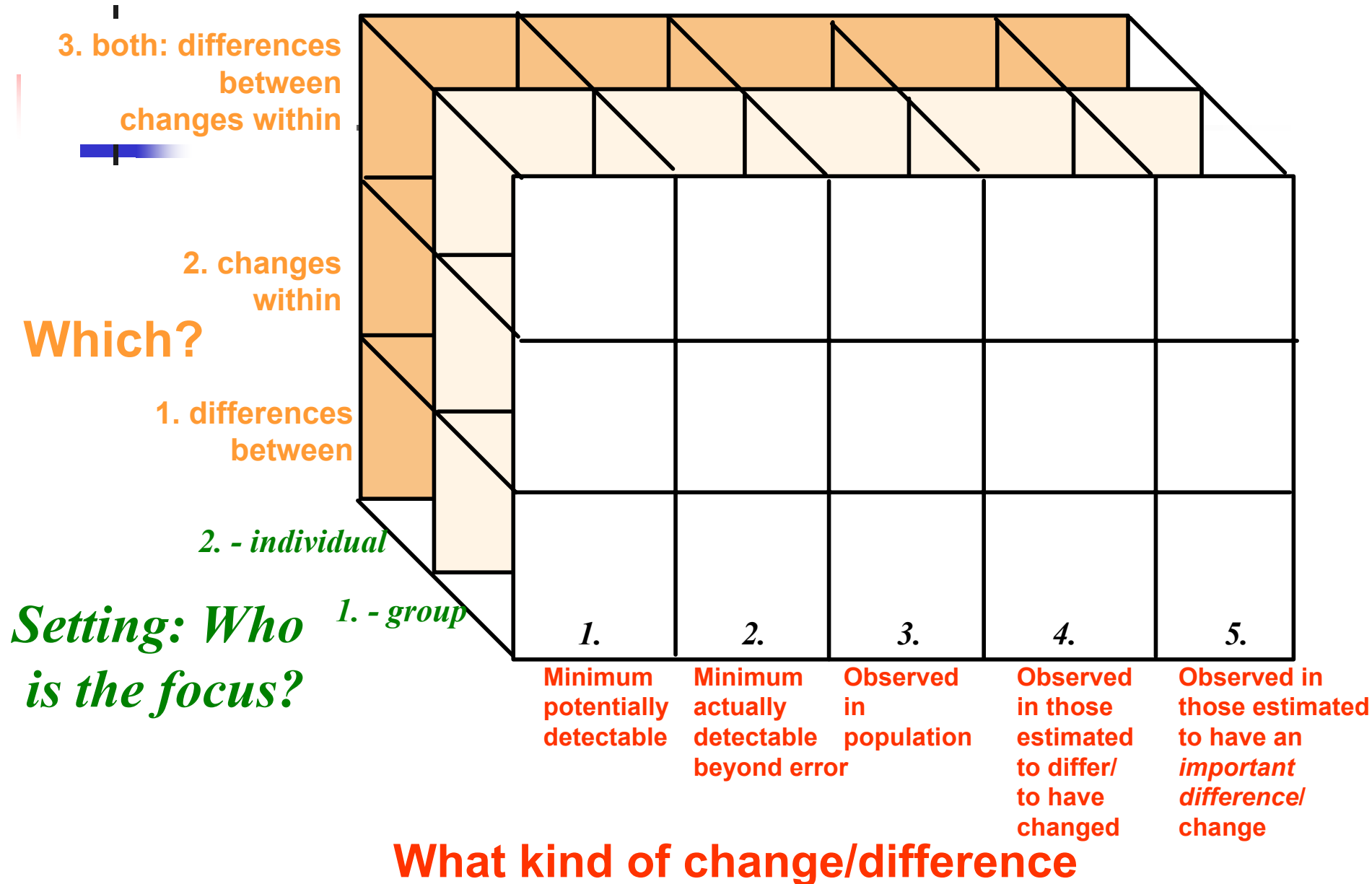
Minimum
actually
detectable
beyond error

Observed
in
population

Observed
in those
estimated
to differ/
to have
changed

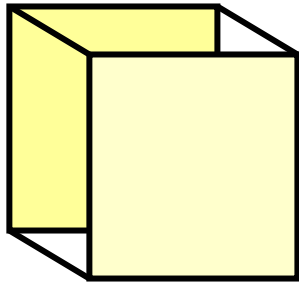
Observed in
those estimated
to have an
*important
difference/*
change

Change/differences in studies of responsiveness





Cells in the cube

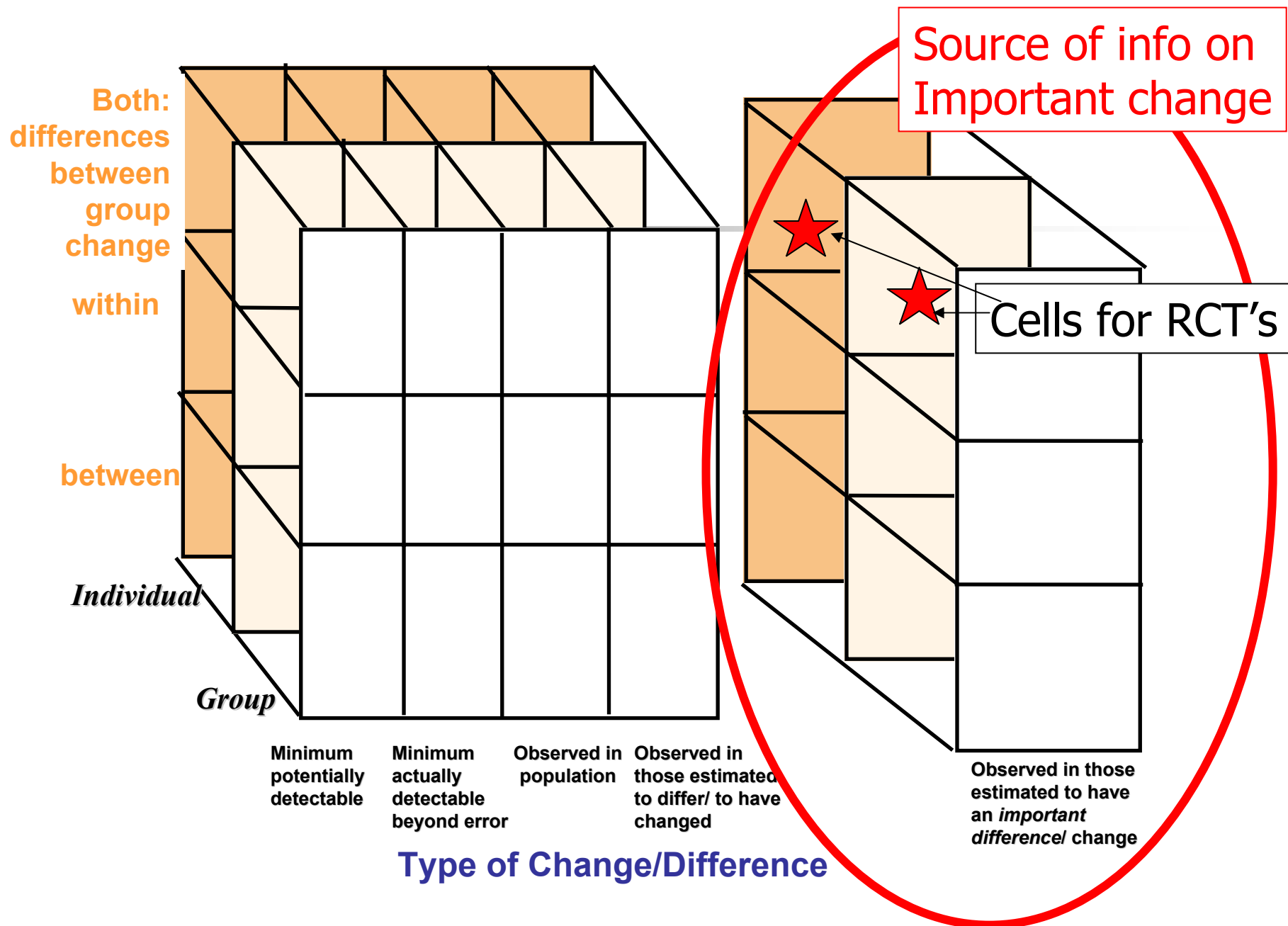


- Each cell in cube = valid type of change/difference for a study of responsiveness
- Not every cell can tell us about MCID.



3. What can these studies tell us about MCID

- Studies of responsiveness fit into appropriate cell
- Focused only on those addressing important change.
- Therefore focus on the “far right” end of the cube to find studies addressing important change





Roland-Morris Scale Findings

Bombardier, 2001

	Important change	
	Individual	Group
Both: differences between change within	★ (consensus: 2-3, not >5)	★
Within	Stratford: 2-8 Riddle: 3-13 [Stratford: 5 for scores 6-20]	Stratford: 7.2 Riddle: 7.6 [Deyo: 4.4]
Between		

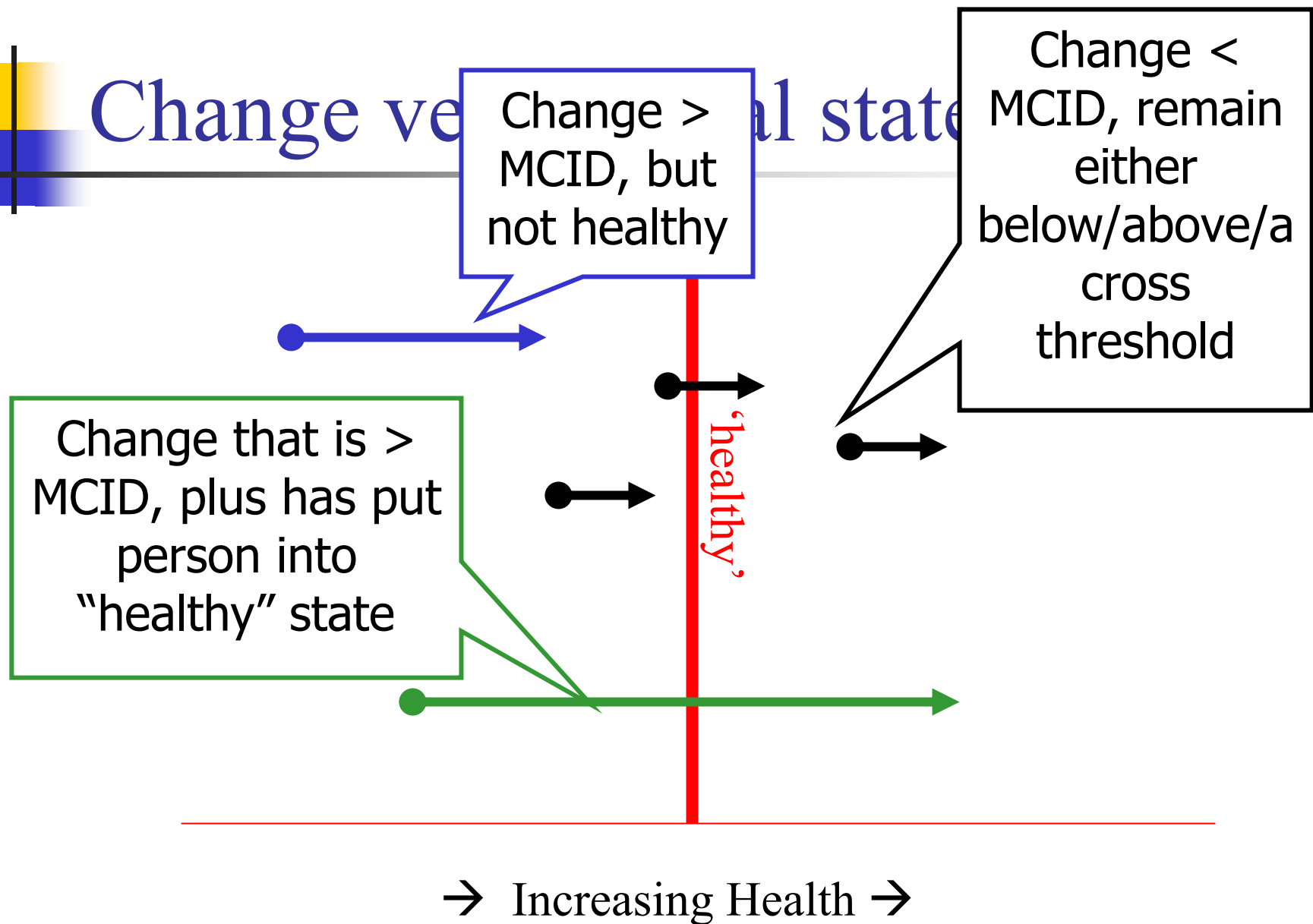
[] – studies where same method was considered important by other authors



MCID's

- Varied in magnitude across....
 - Different methods
 - Different baseline scores (Riddle 98; Stratford 98; Stucki, 96, Hagg 2003)
 - Positive versus negative change (Hagg, 2003)
- Focus was limited to...
 - minimal change
 - Change alone, not where people ended up (Farrar, 2000; Jacobson, 1999)

Change velocity and state





New directions for OMERACT

- 2000 vote (Wells, 2001):
 - Look at major clinically relevant/important differences rather than minimal
 - Is minimal enough?
 - Link to clinical situations: ie, change related to successful analgesic use (Lee, 2003; Farrar, 2003)
 - Look at final state – what level is a success?
 - Use patient and consensus opinion



4. New at OMERACT → *LDAS*

- OMERACT 5-7 (2000-4)
- ***LDAS: Low Disease Activity States***
 - “that state which is deemed a useful target of treatment by both physician and patient, given current treatment possibilities and limitations”
~ OMERACT 6
 - defines the final state ~ where people land
 - Not complete remission (DAS28 <2.6)



LDAS

- LDAS established for each of core set measures
 - ie. NRS Pain $< 2/10$
 - Others: swollen joints, tender joints, HAQ, physician global, patient global, ESR
- **Successful response**: complete remission (defined)
 - OR** 5/7 core set measures achieve LDAS
 - ** aggregation across measures.



Lessons from OMERACT?

- Be aware of methodological MCID issues
 - Not as variable for Pain NRS, more so for HRQOL
 - MCID method used, baseline score, +ve vs. –ve change
- Consider the most appropriate target?
 - Measurement error? Or MCID? Or Major response?
- Consider exploring LDAS concept – final state across 5/7 measures
 - Aggregation also allows people to be “responders” with coping, adjusting, adaptation – not just pain elimination



Summary

- “Science should be kept as simple as possible but no simpler” ~ Albert Einstein.
- MCID is elusive, but important
 - likely context-specific
 - look for consistency across methods, timing, treatments, etc to increase confidence in a single MCID value

Greetings from OMERACT 7

Asilomar Conference Center

Monterey, California

May 12-14, 2004

