Guidelines for IMMPACT 4 re: MCID work

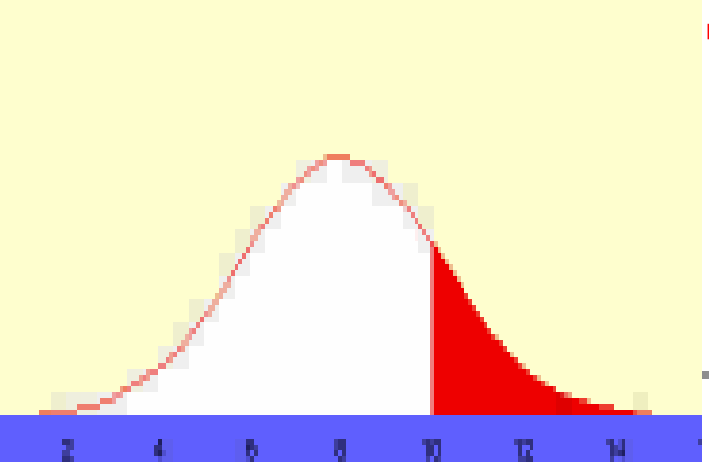
IMMPACT 4 meeting

June 10-12, 2004

Orientation to the 1 SEM

1 SEM

- Formula:
  - SEM = Standard deviation * sqrt(1- r_{xx})
  - Where r_{xx} = test retest reliability from that study population
  - Standard deviation is a baseline distribution in that sample

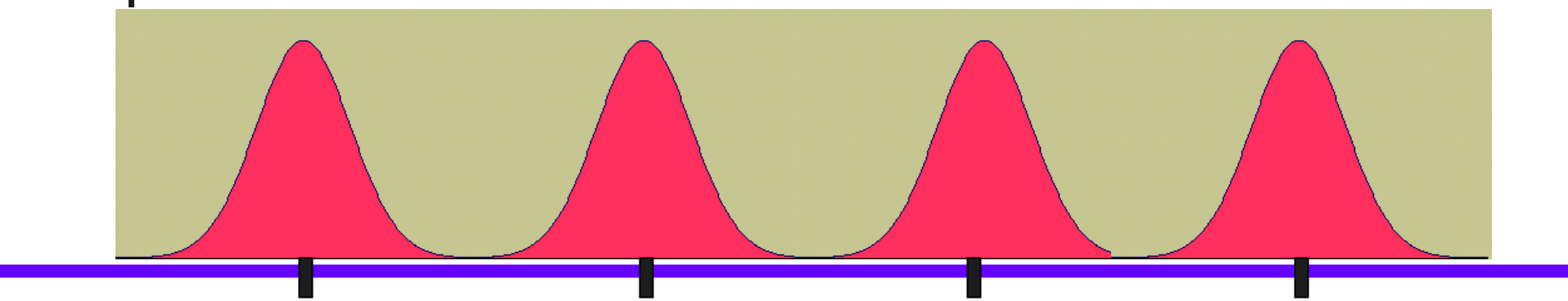


The Standard Error of Measurement (SEM)

$$SEM = s_x \sqrt{1 - r_{xx}}$$

- Fixed characteristic of a measure that is not sample-dependent
- Expressed in the **original metric** of the measure

What is a SEM?

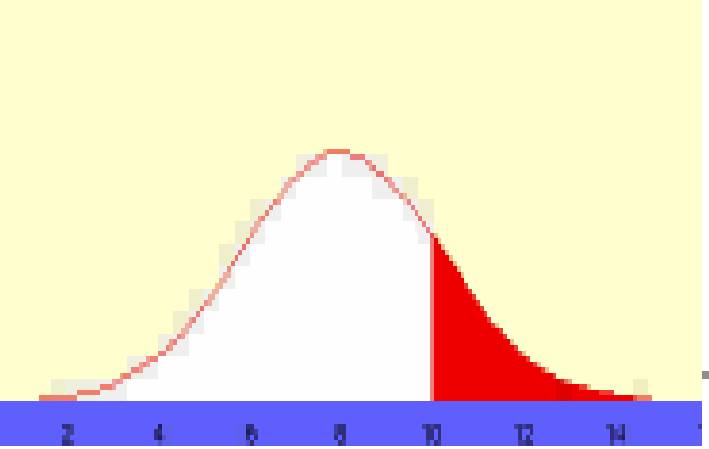


Mary's True Score

Jim's True Score

Gary's True Score

Kim's True Score



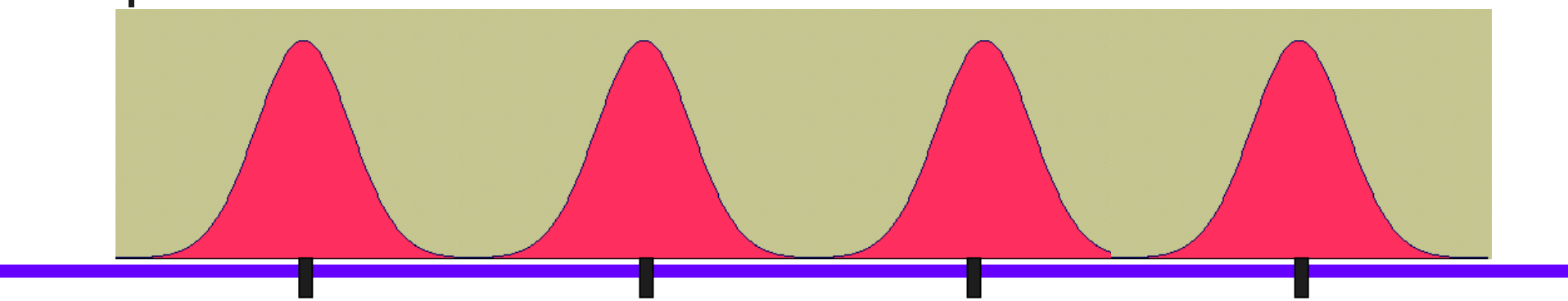
How Many SEMs = Important Individual Change?

1 SEM

1.96 SEM

2.77 SEM

What is a SEM?



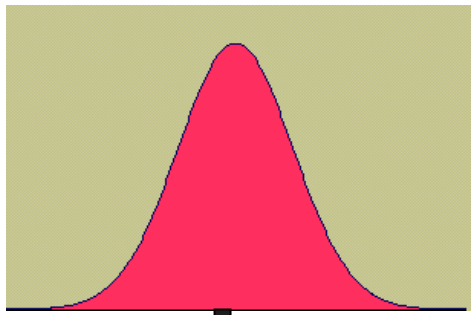
Mary's True Score

Jim's True Score

Gary's True Score

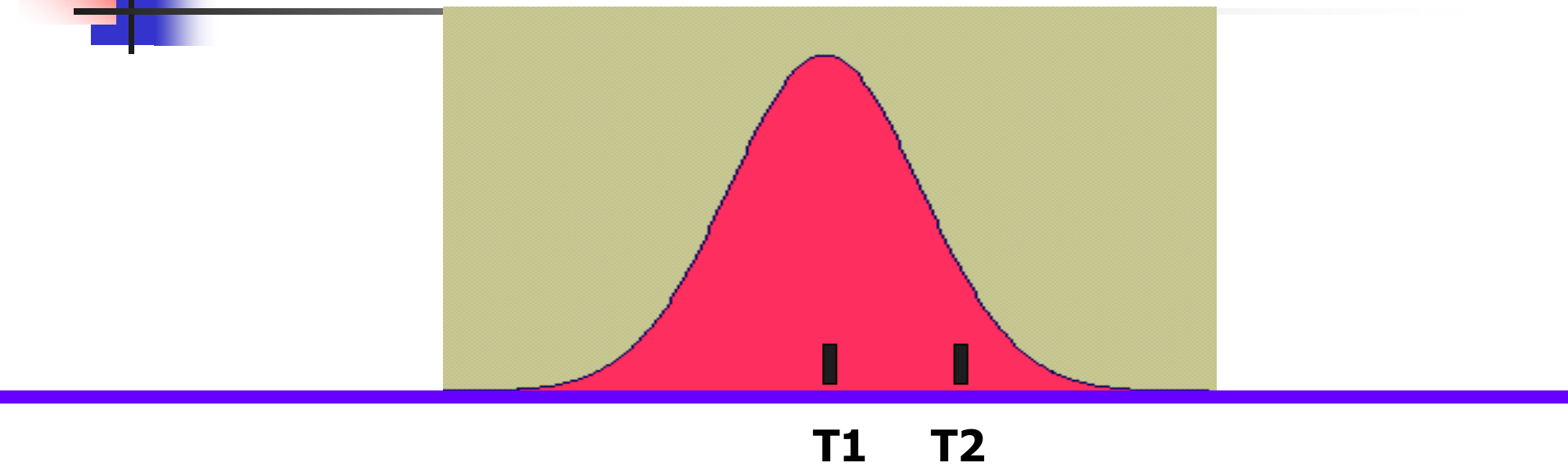
Kim's True Score

What is a SEM?



Gary's
True
Score

Why 1SEM?



Gary's

Time 1 & Time2 Scores

Potential indicators for studies of MCID

- Review of some of the literature (not comprehensive)
- Gain opinion of the face validity of each of these for use in MCID work in Pain clinical trials

Principles….

- Try > 1 approach, aim for convergence across methods
- Report SEM using test-retest reliability
- Separate analysis for improvement and deterioration
- Consider checking MCID values across tertiles of distribution
- Choose analytic methods that could yield individual level results
  - ROC analysis > mean change score within minimally changed group

Global scale (Jaeshchke, 1989/Juniper 1994)

"Has there been a change in your level of *fatigue* since your last visit?"

Worse Same Better

If worse of better. 

Jaeschke, 1989; Juniper, 1994

-7	A very great deal worse
-6	A great deal worse
-5	A good deal worse
-4	Moderately worse
-3	Somewhat worse
-2	A little worse
-1	Almost the same, hardly any worse at all

7	A very great deal better
6	A great deal better
5	A good deal better
4	Moderately better
3	Somewhat better
2	A little better
1	Almost the same, hardly any better at all

Juniper used 2,3

Subgroup with small, but important change

MCID = mean change score in those with a small but important change

Global indicator (Hagg, 2003)

Compared to before my treatment my pain is…

- Much better
- Better
- Unchanged
- Worse
- Much worse

- MCID = mean change for those better versus unchanged

Global indicator (Farrar, 2001)

- Since the start of the study, my overall status is…
  - Very much improved
  - Much improved
  - Minimally improved
  - No chang
  - Minimally worse
  - Much worse
  - Very much worse

Global indicators (Kosinski, 2000)

- 5 point transitional scales of change in…
  - Patient Global Change Item on RA Changes
  - Patient Global Change Item on overall health
  - Physician Global Change Item on RA

- MCID = mean change score in scale among patients in the "improved" group

Concordant pt/clinician view (Stratford & Riddle, 98)

- Jaeschke 15 point scale
- Indicator: > 5/7 rating by both patient and clinician

- MCID: ROC analysis of change score for those with concordant improvement vs not.

Also used by Deyo & Inui, shorter scale

Global indicators questions

- Should they be related to same concept as the target scale?
  - Jaeshchke, 1989; Juniper, 1994
- Should it be very global….so are you better?
  - Supported by those hoping that a change relates to overall benefit & well being
- What breadth of response options?
  - 5, 7, 11, 15?

Meeting treatment goals (Riddle & Stratford, 1998)

- Set treatment goals at onset, negotiated with the patient
- At discharge, verify if patient has met these treatment goals
- MCID: Best change score (ROC) for differentiating those meeting goals versus not

Consider dropping this one for pain, it might not be as related to change in pain

Clinical indicators (Kosinski, 2000)

- Number of tender joints
  - No change = < 1% decrease in count
  - Small Improvement = 1-20% decrease in count
- Number of swollen joints
  - No change = < 1% decrease in count
  - Small Improvement = 1-20% decrease in count
- MCID = mean change score in scale among patients in the "improved" group

Need clinical categories for Pain….ie, depression category shifts, cortisol levels?

Clinical indicators (Deyo & Inui)

- ARA disease classification
  - Shift in ARA classification level = improvement in disease.
- MCID = mean change in those with a disease improvement

Clinical indicators for pain

- Shift in VonKorff chronic pain grades
- Clinical indicators are hard to define

Indicators measured at t1 & t2

- Is your pain at a level where you can forget about it and do what you need to do in your day?
  - Improved group: Baseline = no; follow-up = yes
  - MCID: ROC analysis looking for best change differentiating those transitioning from no-yes from others.

Indicators measured at t1 & t2

- Bed Disability days
- Restricted activity days
- Work loss days

- MCID: ROC on people with no/1-2days/one week/normative data or more versus others

Treatment of known efficacy

- Distribution of change in those undergoing care of known efficacy
  - Set lower percentile distribution, 5^{th}, 25^{th} percentile

- Use to explore validity of 30% change etc, there should be consistency if it is effective care

Satisfaction (JN Katz, Stucki)

- Katz: Satisfaction with outcome of care
  - > 8/10 on satisfaction scale = definitely improved. Used for responsiveness
  - MCID: Could also use ROC analysis for most accurate change related to high satisfaction

- Stucki: Categorical satisfaction: very sat/somewhat sat/somewhat sat/very dissatisfied
  - Change in those in somewhat satisfied minus unsatisfied after spinal stenosis.

Adequate pain control (Lee, 2003)

- Focus was on 'major' clinical improvement
- Did you have adequate pain relief?
  - Yes = definitely improved
- Would you accept analgesic now?
  - Yes before, no now = improved.

- MCID: ROC analysis for best change in pain discriminating between improved vs.unimproved groups.

Use of rescue meds (Farrar, 2003)

- Cancer pain research
- Need to use rescue medication = failure for pain to be reduced an important amount

- MCID: ROC analysis of change scores to determine most accurate discriminating value