The Global Assessment of Pain and Related Symptoms

John T. Farrar, MD, MSCE

Departments of Epidemiology, Anesthesia, and Neurology

Center for Clinical Epidemiology and Biostatistics

University of Pennsylvania

Components of a Question

- Dimension(s) covered
- Type of question
  - (e.g., rating, change, agreement)
- Time frame
  - (e.g., days, months, last visit, start of study)
- Scale used to collect response
  - (e.g., NRS, VAS, verbal, change scale)
- Collected from whom?
  - (e.g., patient, doctor, family, insurance adjuster)

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Global Questions - Terminology in the Literature

- global indicator
- global measure
- global perception of change
- global impression of change
- global response
- global assessment
- overall status
- single-item response
- medication performance
- transition question
- patient satisfaction

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What do we mean by “global”?

Webster’s Collegiate Dictionary:

Global is defined as

- **universal or**
- **comprehensive**

Global = Overall?

~~**Satisfaction**~~ **is not the same thing**

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Global Question - What Dimension?

- Global Status

- Global Health
- Global Quality of Life?

- Overall Mood
- Overall Function
- Global Pain

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Global Question – Rating vs Change

- Global Rating
  - 0-10 NRS, VRS, VAS?
  - Verbal

Overall how would you rate your quality of life:

0__1__2__3__4__5__6__7__8__9__10

Worst Possible — Best Possible

- Global Change (Transition)
  - Numeric scales are harder to interpret
  - Verbal scales have meaning and is easier to clinically interpret

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Global Change (Transition) – Time Frame

- Hour, day, month, year
- Since last visit, change in medication
- Start of study

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The Association Between the Brief Pain Inventory and the Patient Global Impression of Change

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RCT Study Description
Pregabalin - Multiple Diseases

- Data on 2,724 subjects from 10 recently completed placebo-controlled clinical trials of pregabalin

- Diabetic neuropathy (3), postherpetic neuralgia (3), chronic low back pain (2), fibromyalgia (1) and osteoarthritis (2).

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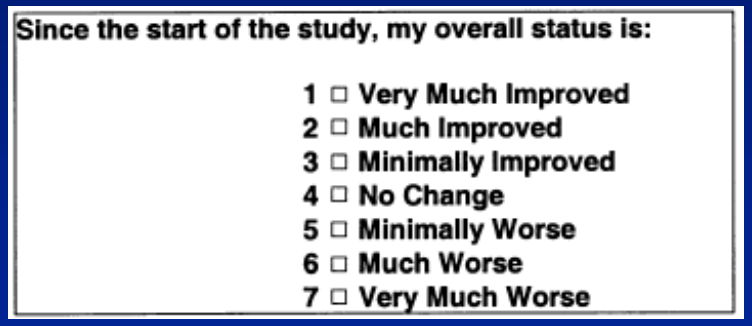
Study Description - Pregabalin (cont)

- All studies measured pain intensity (0-10 NRS)

0__1__2__3__4__5__6__7__8__9__10

and patients global impression of change (PGIC)



Since the start of the study, my overall status is:

1 ☐ Very Much Improved
2 ☐ Much Improved
3 ☐ Minimally Improved
4 ☐ No Change
5 ☐ Minimally Worse
6 ☐ Much Worse
7 ☐ Very Much Worse

- Compared change in pain intensity (PI-NRS) to the PGIC level

Farrar JT, Young Jr. JP, LaMoreaux L, Werth JL, Poole RM: Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94(2): 149-158.

*Supported by Pfizer and NCI-R01-CA73797

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Important Issues in the Analysis of Pain Intensity Data

- Are pain data consistent across studies?
- How do patient's interpret Likert pain scales?
- What cut-off value is the best representation of clinical importance?
- How should the data be analyzed?
- How should the data be presented to be most clinically useful?

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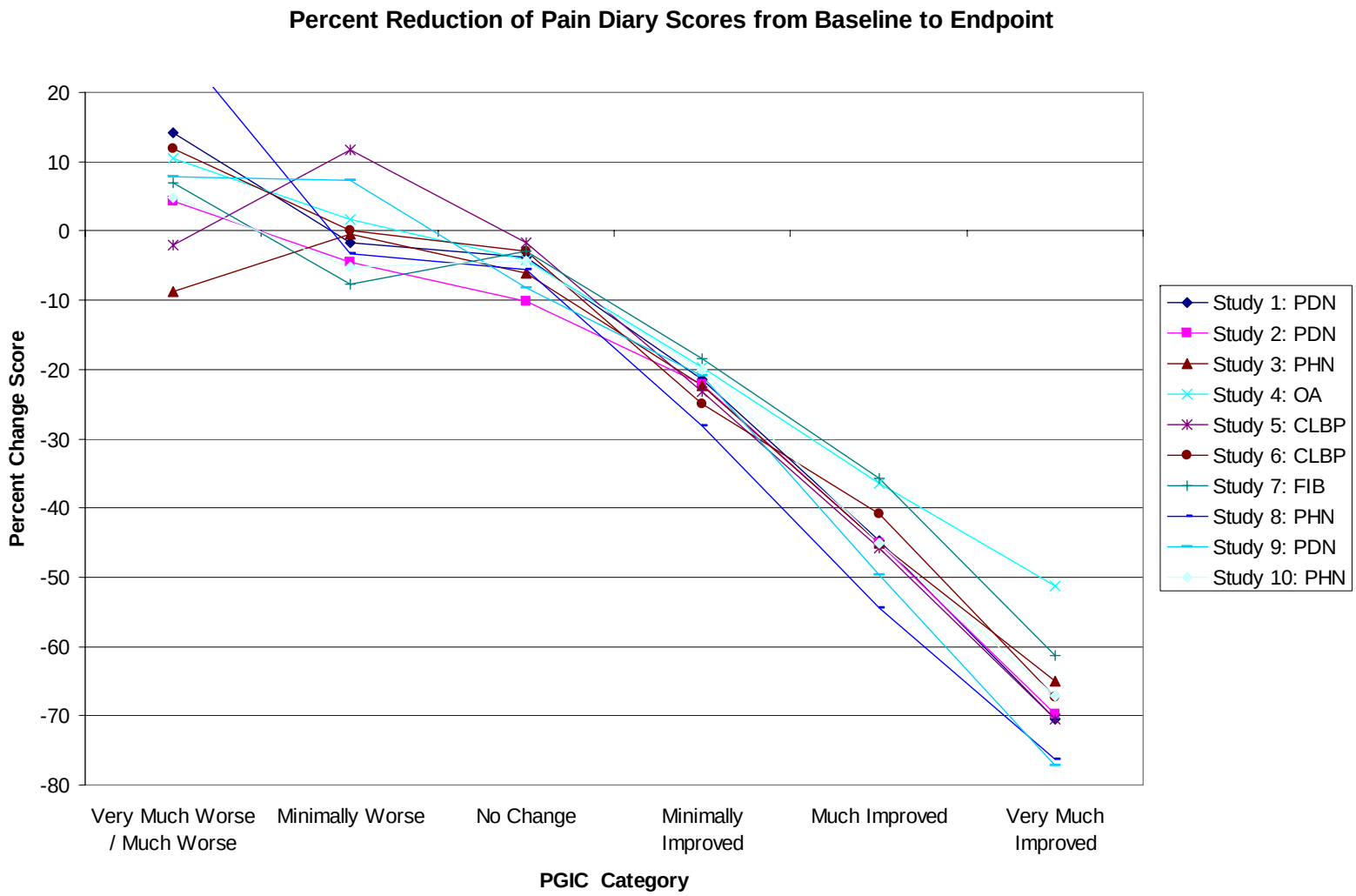
Are Pain Data Consistent With PGIC Across Ten Studies? Yes



How Do Patient's Report Change Using the NRS Pain Scales?

- Possible Interpretations
  - Raw pain intensity difference (PID)
  - Percent pain intensity difference (%PID)
- How does this compare to the PGIC?

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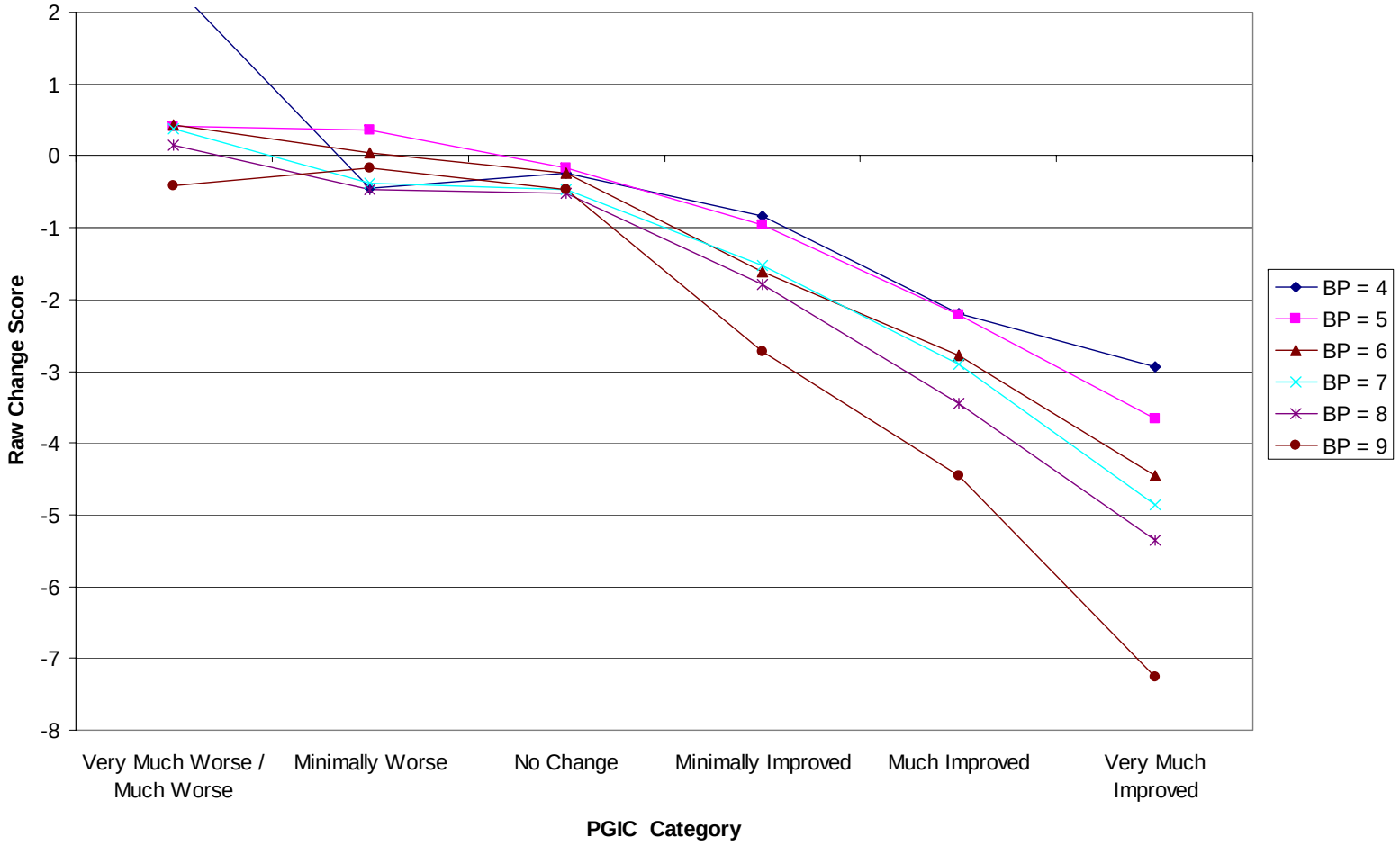
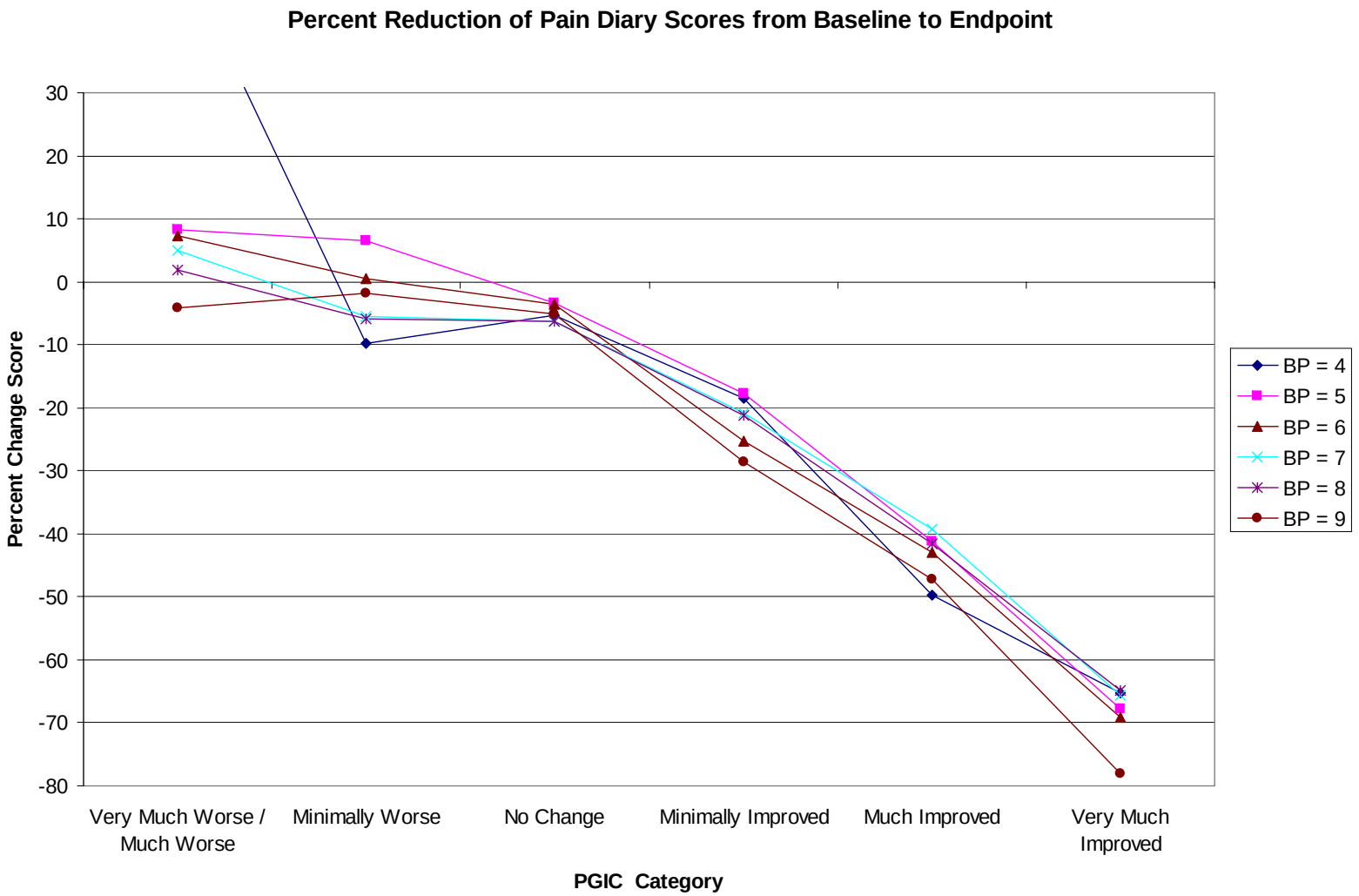
Pain Intensity Difference Values Separate When Stratified by Baseline Pain Intensity



BP=Baseline Pain

Percent Pain Intensity Difference Values Overlap When Stratified by Baseline Pain Intensity



BP=Baseline Pain

Comparing Multi-item Quality of Life and Single Global

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Multi-Item Total Score is Determined by the Weighting of Each Question

- Number of questions
- Structure of questions
  - Sequential
  - Independent components
- Value of the scale used for each question
  - » (0-10); (1-4); (yes-1 : no-0)
- Summary value calculation
  - » Arithmetic
  - » Multiplicative
  - » Regression formula

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Calculated Model of Quality of Life

SF-36 Factor analysis dimensions

- Bodily pain
- Mental health
- Physical-role
- Physical functioning
- Social functioning
- Health transition
- Emotional role
- General health

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Does It Matter When We Ask the Single Global Quality of Life Question?

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Single Item Question

- Single question gives a summary answer
- But single question is considered unreliable.
  - When asked “How are you?” patients respond differently depending on location
    - » In the hallway answer is –> “Fine”
    - » In the exam room –> get a long list of complaints

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Does the Underlying Construct Affect the Answer to Questions?

German Potato Study – Patients were asked two sets of questions

- First set — Answer
  - Are potatoes a german food? — 40% said yes

- Second set
  - Is rice a Chinese food?
  - Is pasta an Italian food?
  - Are potatoes a german food? — 60% said yes

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Study of the Order for the Global Rating of Quality of Life

First question of the SF-36 is Global Health

1. In general, would you say your health is:

Excellent Very good Good Fair Poor

Then administer the rest of the SF-36

Then ask “Considering all these factors:”

37. In general, would you say your health is:

Excellent Very good Good Fair Poor

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Pre-Post Comparison of SF-36 General Health Question

- Conducted as part of a clinical trial of patients with osteoarthritis of the knee
- SF-36 administered as first questionnaire followed by the identical first question again.
- 63 subjects were evaluated
  - Fifty-one (81%) subjects reported the same level of GH before and after the SF-36 evaluation
  - 5 subjects (8%) improved by 1 category
  - 6 subjects (9%) worsened by 1 category, and
  - 1 subject (2%) worsened by 2 levels
- Spearman rank pre - post $r=0.80$, $p<0.0001$

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Spearman Rank Correlations (p-value vs no correlation)

SF36 Subscale	Pre - SF36 Global	Post - SF36 Global
Physical Health	**0.46 (<0.0001)**	0.40 (0.001)
Role Physical	0.27 (0.033)	**0.41 (0.0009)**
Bodily Pain	0.38 (0.002)	0.37 (0.003)
General Health	0.66 (<0.0001)	**0.76 (<0.0001)**
Vitality	0.40 (0.001)	**0.50 (<0.0001)**
Social Function	0.43 (0.0004)	**0.52 (<0.0001)**
Role Emotional	0.22 (0.08)	0.25 (0.05)
Mental Health	0.35 (0.006)	**0.50 (<0.0001)**

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In 5 out of seven subscales there was a closer correlation with the question asked after completing the SF-36

Why Ask Questions (Rather than Read Statements)

The psychometric properties of a question are different than reading a statement.

- Answering a question involves thinking about the response
- The answers to those questions provide data that can be used to better understand the global response
- However, need to avoid patient burn out (i.e. too many questions)

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Global Rating of Quality of Life (Possible Alternative)

- Start with multiple questions:

  Covering all domains to be considered

  – To get subject to think about all areas

  – For use in etiologic and predictive modeling

  – For face and context validity

- Followed by a global question:

  "Considering all of the above…"

  – Allows the subject to integrate the factors

  – Possible use as the primary outcome?

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Survey of Course Participants

- How do you feel about this lecture?

0__1__2__3__4__5__6__7__8__9__10

Complete
Waste of Time

Best Use
of My Time

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Ask the Question a Different Way

- How do you feel about being in a nice place?)

  0__1__2__3__4__5__6__7__8__9__10

  Complete Waste of Time — Best Use of My Time

- How do you feel about being indoors on this warm afternoon
- How do you feel about your significant other doing fun things without you
- How do you feel about spending (wasting?) your day at this meeting.

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Based on All of the Above

- Now, how do you feel about this lecture?

0__1__2__3__4__5__6__7__8__9__10

Complete
Waste of Time

Best Use
of My Time

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Global Impression of Change

- Types
  - –Change (-3 to 0 to +3)
    Much worse to stable to much better
  - –Relief (0 - 100% relief)
  - –Medication Performance
    (poor, fair, good, very good, excellent)
- Also need to pick a time frame

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Global Impression of Change

Since the start of the study

or - over the last _____ (month, week, day)
or - since your last visit

how would you rate your _____

(pain, function, quality of life)

Much worse	Worse	A little worse	No change	A little better	Better	Much better

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Global Impression of Change

Since the start of the study

or - over the last _____ (month, week, day)
or - since your last visit

my overall status is:

Very Much worse	Much worse	Worse	A little Worse	No Change	A little Better	Better	Much better	Very much better

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As a Primary Outcome of a Trial

- Clinical Question:
  Is the benefit (taking into account the possible risk) of the treatment going to make it worthwhile to use in patients?

- Use questionnaire total score or change:
  - Using scoring or modeling
- Or use global question
  - Rating scale or change scale

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Advantages of Global Approach

- Can combine multiple important outcomes
- Allows patients to integrate factors

- Answers the important clinical question

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Advantages of Using Context Multi-question Then Global

- Clarifies the factors that are to be considered
- Ensures patients have at least considered all of the factors into their integrated response
- Provides data to help explain the response
- May allow more consistent comparison across studies
- May allow us to compare across cultures

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Recommendations PGIC (Patient global impression of change)

- Use balanced 7 or 9 point scale
- Overall rating to ensure patient is:
  - Better (how much?)
  - Not worse (balance of effect/ side-effects and no unmeasured side-effects)
- Consider additional global impression of change and global rating questions
  - For pain? For function? For quality of life?
- Consider use as a primary outcome?

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The End