

Presenting Patient-Reported Outcomes to Promote Patient and Clinician Understanding and Use

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Johns Hopkins Schools of Medicine and Public Health

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Communication, Education, and Survivorship**

Johns Hopkins Breast Cancer Program

Presentation to:

Centers for Medicare & Medicaid Services

August 22, 2018

Funded by the Patient-Centered Outcomes Research Institute

Disclosures

- Snyder:
 - Research funding from Genentech to Johns Hopkins
 - Royalties from UptoDate (<\$1000 annually)
- Bantug:
 - Nothing to disclose

Presentation Objectives

- Provide an example of engagement with patients and other stakeholders in research
- Describe findings regarding best practices for graphically displaying patient-reported outcomes (PRO) data to patients and clinicians
 - Regardless of the PRO measure

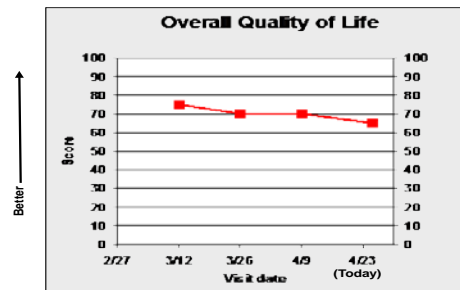
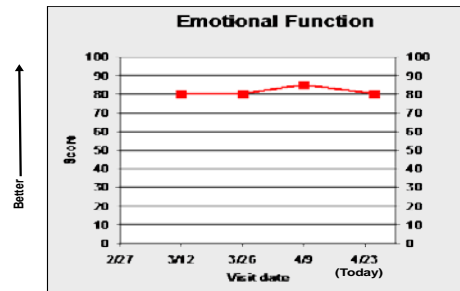
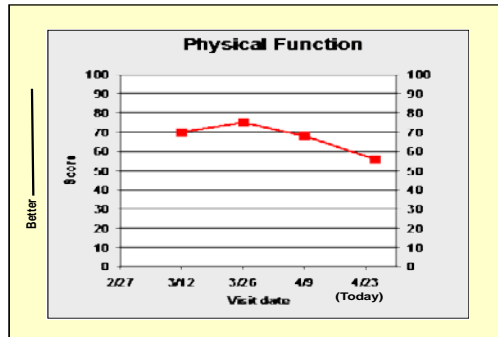
Individual Patient Monitoring

- Promote patient-clinician communication
- Monitor progress
- Inform management

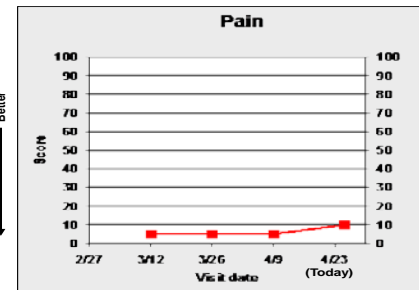
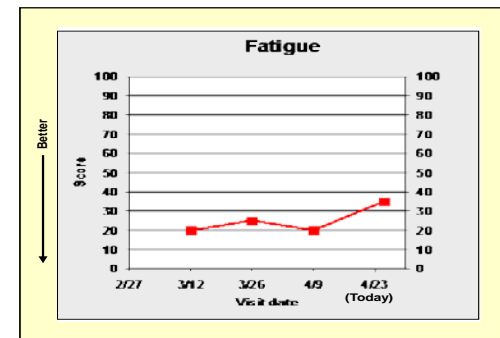
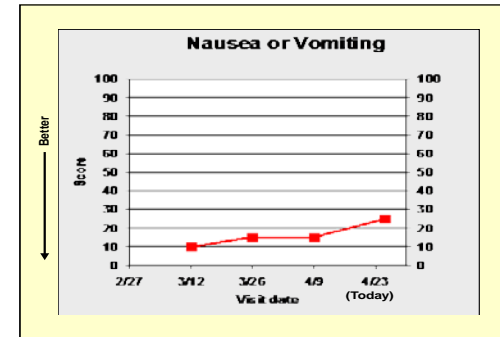


Score Report

Function Scores: Each panel shows scores for the last four visits. High scores represent high levels of functioning. Yellow highlighting indicates concerning scores that have worsened since last visit



Symptom Scores: Each panel shows scores for the last four visits. High scores represent high levels of symptoms. Yellow highlighting indicates concerning scores that have worsened since last visit



Research Study Example

The NEW ENGLAND JOURNAL of MEDICINE

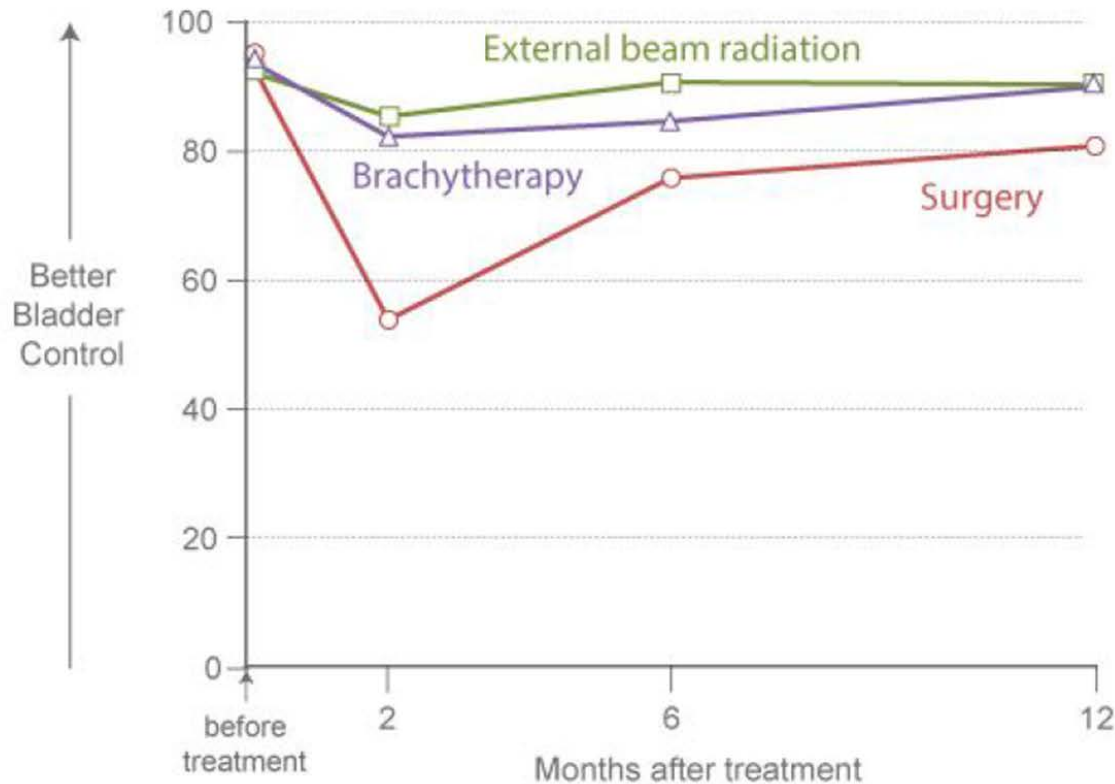
ORIGINAL ARTICLE

Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors

Martin G. Sanda, M.D., Rodney L. Dunn, M.S., Jeff Michalski, M.D., Howard M. Sandler, M.D., Laurel Northouse, R.N., Ph.D., Larry Hembroff, Ph.D., Xihong Lin, Ph.D., Thomas K. Greenfield, Ph.D., Mark S. Litwin, M.D., M.P.H., Christopher S. Saigal, M.D., M.P.H., Arul Mahadevan, M.D., Eric Klein, M.D., Adam Kibel, M.D., Louis L. Pisters, M.D., Deborah Kuban, M.D., Irving Kaplan, M.D., David Wood, M.D., Jay Ciezki, M.D., Nikhil Shah, D.O., and John T. Wei, M.D.

Education Materials/Decision Aids

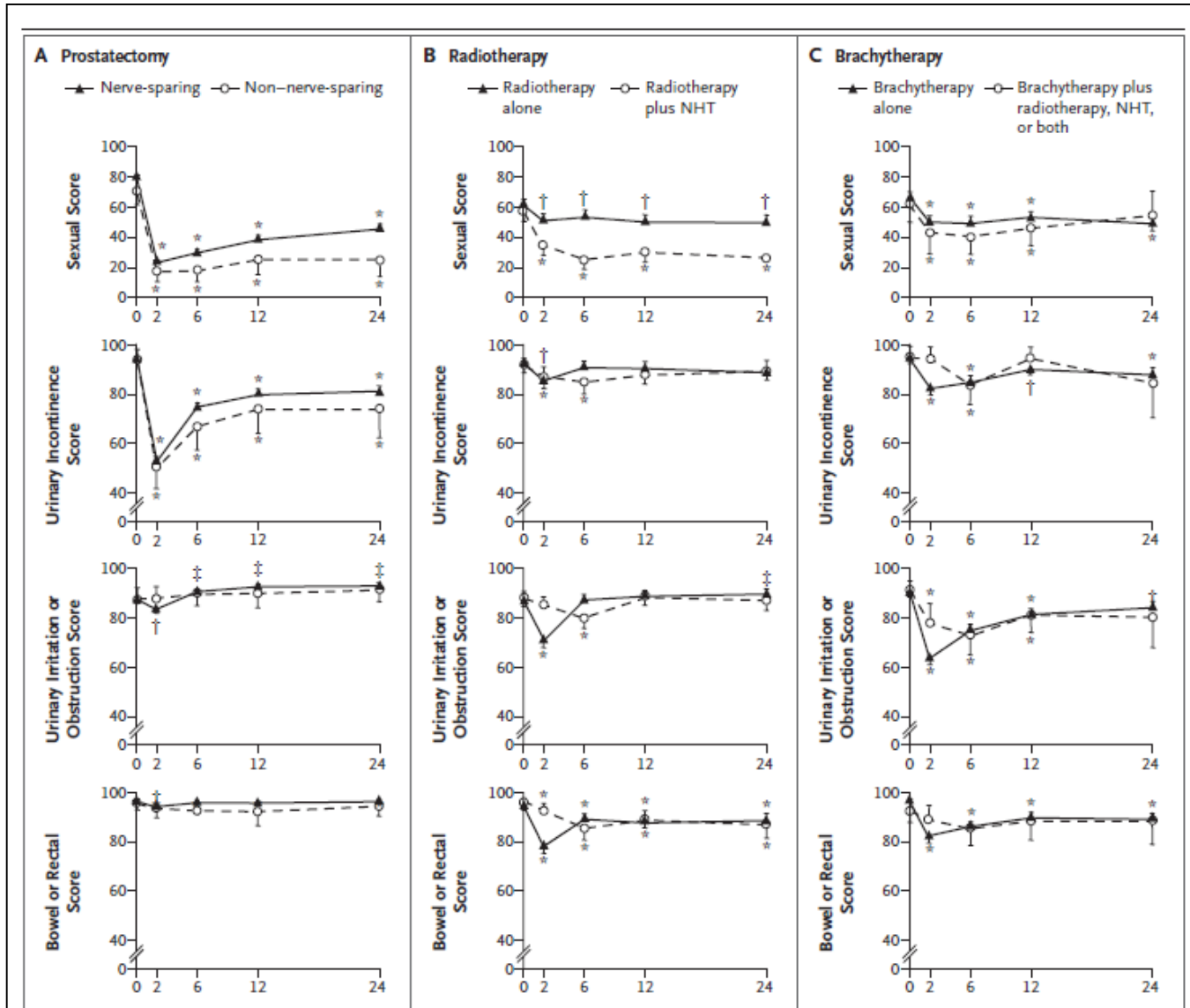
Bladder control in the 12 months after treatment



Summary

- **External beam radiation** and **brachytherapy** cause small bladder problems soon after the treatment, but most patients recover within a year
- **Surgery** causes bigger bladder problems soon after the treatment, but most surgery patients will show some recovery within a year

Journal Publication



The Problem: Variations...

- ...in PRO instruments
 - Over 800 listed in PROQOLID database (<http://proqolid.org/>)
- ...in scoring
 - Higher scores may be better or worse
- ...in scaling
 - E.g, 0-100 vs. normed to 50
- ...in presentation
 - E.g., mean scores vs. responders
 - E.g., graphic vs. tabular

The Problem: Variations...

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- E.g., mean scores vs. responders

- E.g., graphic vs. tabular

Posing a substantial barrier to the interpretation and use of PRO data by patients and clinicians

3-Part Mixed Methods Study

1. To what extent do current practices of PRO reporting limit clinician and patient understanding and use? What are the most/least desirable attributes of current practices?
2. What are novel ways to present PRO results to clinicians and patients to improve their usefulness?
3. Are these novel ways of presenting PROs effective in improving understanding and use of the data?

Stakeholder Engagement

Stakeholder-Driven


Research Questions

- In a recent study of 30 oncologists, almost all participants strongly endorsed the potential value of PROs for enhancing the interpretation of clinical trials, but fewer than half felt comfortable interpreting the PRO results themselves, with lack of standardization in the presentation of PRO data frequently cited as a barrier.
- Research has also shown that some methods for presenting PRO data to patients are more easily understood and more accurately interpreted than others.

- *“I don’t know what the numbers mean,”*
- *“I got confused a bit with the graphs and trying to remember which ones had 100 as good and which had 100 as bad,”*
- *“A score of say, 50, meant one thing on one graph and something different on another one, which I thought was strange.”*


Stakeholder-Driven

Study Design

- 
- All stakeholders included on investigative team
 - Additional stakeholder representation through Stakeholder Advisory Board

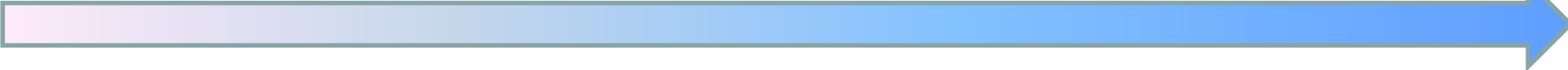
Stakeholder-Driven

**Study
Conduct**

- 
- Broad inclusion of stakeholders as study subjects
 - Stakeholders integrally involved in intervention development

Stakeholder-Driven

**Implementation/
Dissemination**

- 
- In a position to advocate for implementation of study results
 - Active participants in dissemination strategy

How Can We Be Broader?



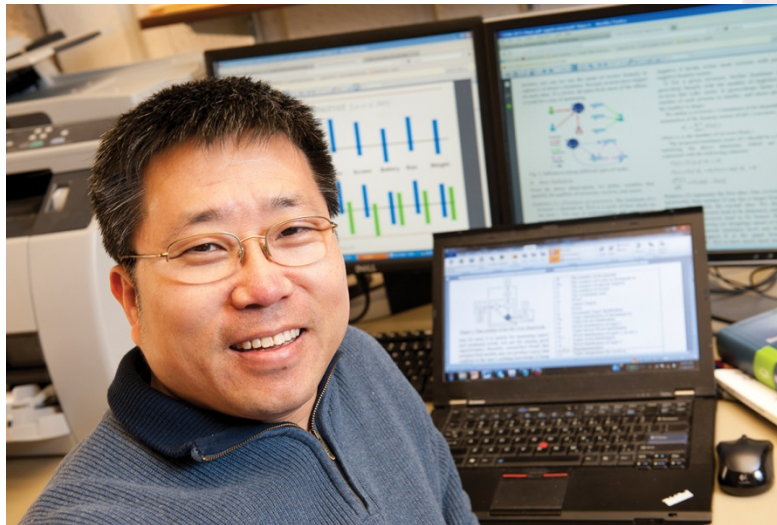
Investigative
Team

Who Are the Stakeholders?

PATIENTS/CAREGIVERS



CLINICIANS



PRO RESEARCHERS

Stakeholders on Study Team

PATIENTS/CAREGIVERS



CLINICIANS

PRO RESEARCHERS

How Can We Be Broader?



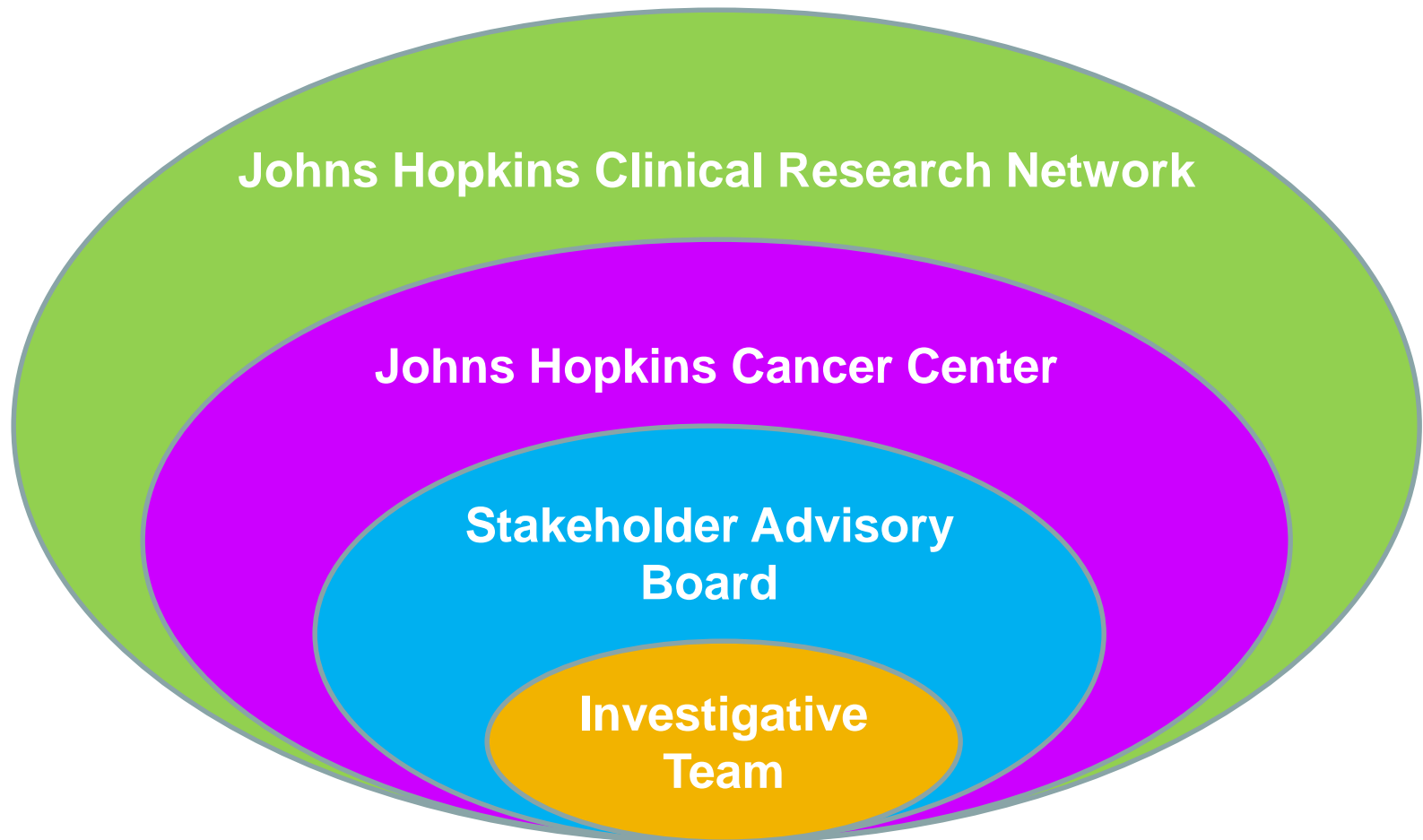
The Stakeholder Advisory Board

A Critical Component

- Provides broader stakeholder perspectives to inform our study design and thereby improve the generalizability of the findings
- Facilitates the successful conduct of our research strategy by facilitating connections to stakeholder groups
- Plays a critical role in disseminating and implementing the findings

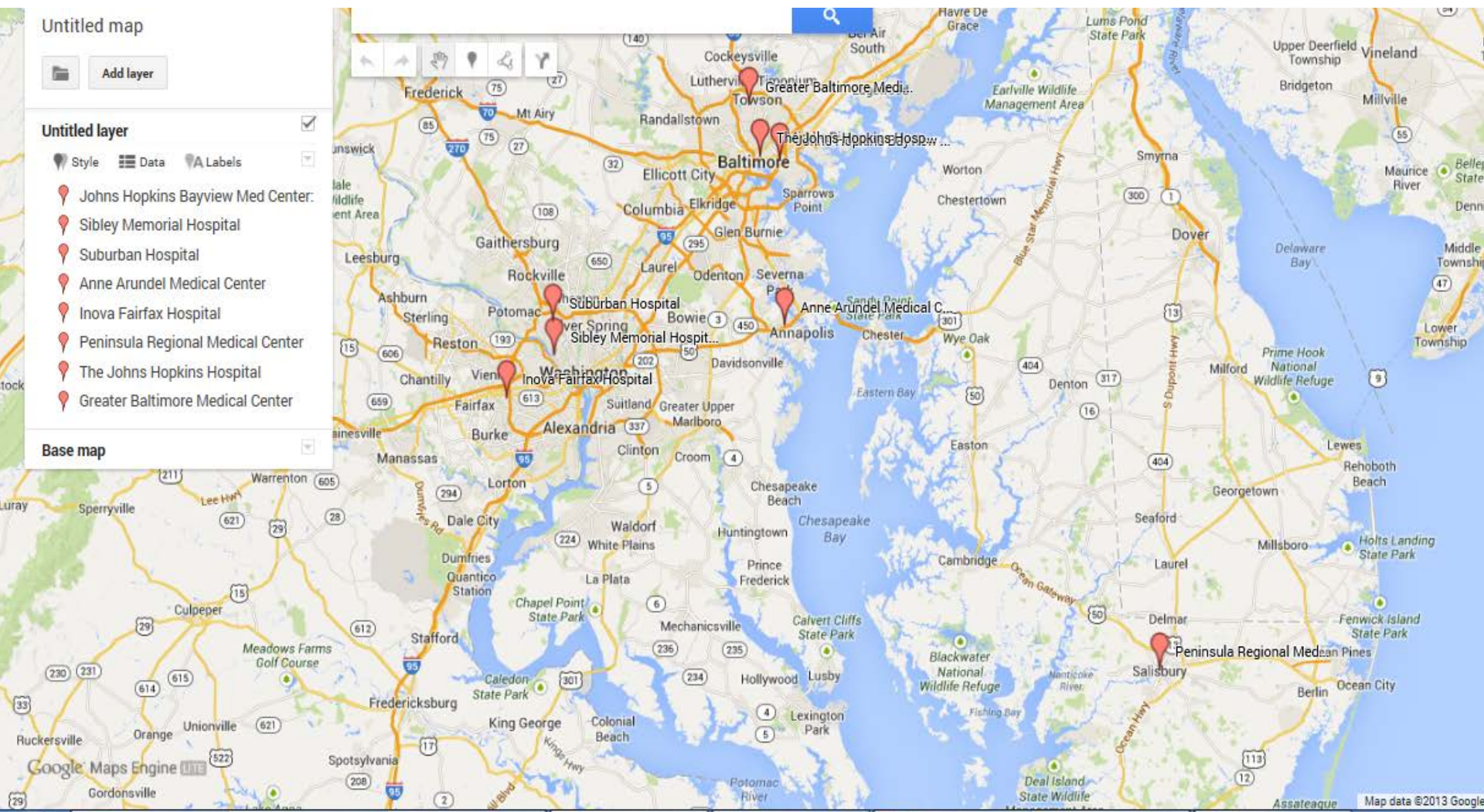
STAKEHOLDER	ROLE
Ellen Stovall	<ul style="list-style-type: none"> •Patient advocate •Assistance with fielding patient surveys •Support for implementation and dissemination
Eden Stotsky-Himelfarb	<ul style="list-style-type: none"> •Patient perspective •Nursing perspective
Matthew Zachary	<ul style="list-style-type: none"> •Patient advocate •Assistance with fielding patient surveys •Marketing background •Social networking and dissemination
Vanessa Hoffman, MPH	<ul style="list-style-type: none"> •Caregiver perspective •Assistance with fielding patient surveys
Patti Ganz, MD	<ul style="list-style-type: none"> •Clinical perspective •PRO researcher and developer perspective •Assistance with fielding clinician surveys
Michael Fisch, MD	<ul style="list-style-type: none"> •Clinical perspective •Assistance with fielding clinician surveys •Journal editor perspective
Ravin Garg, MD	<ul style="list-style-type: none"> •Clinical perspective from community practice •Links with Johns Hopkins Clinical Research Network
Neil Aaronson, PhD	<ul style="list-style-type: none"> •PRO researcher and developer perspective •Journal editor perspective
Bryce Reeve, PhD	<ul style="list-style-type: none"> •PRO researcher and developer perspective •Assistance with fielding PRO researcher surveys •Support for dissemination to PRO research groups

How Can We Be Broader?

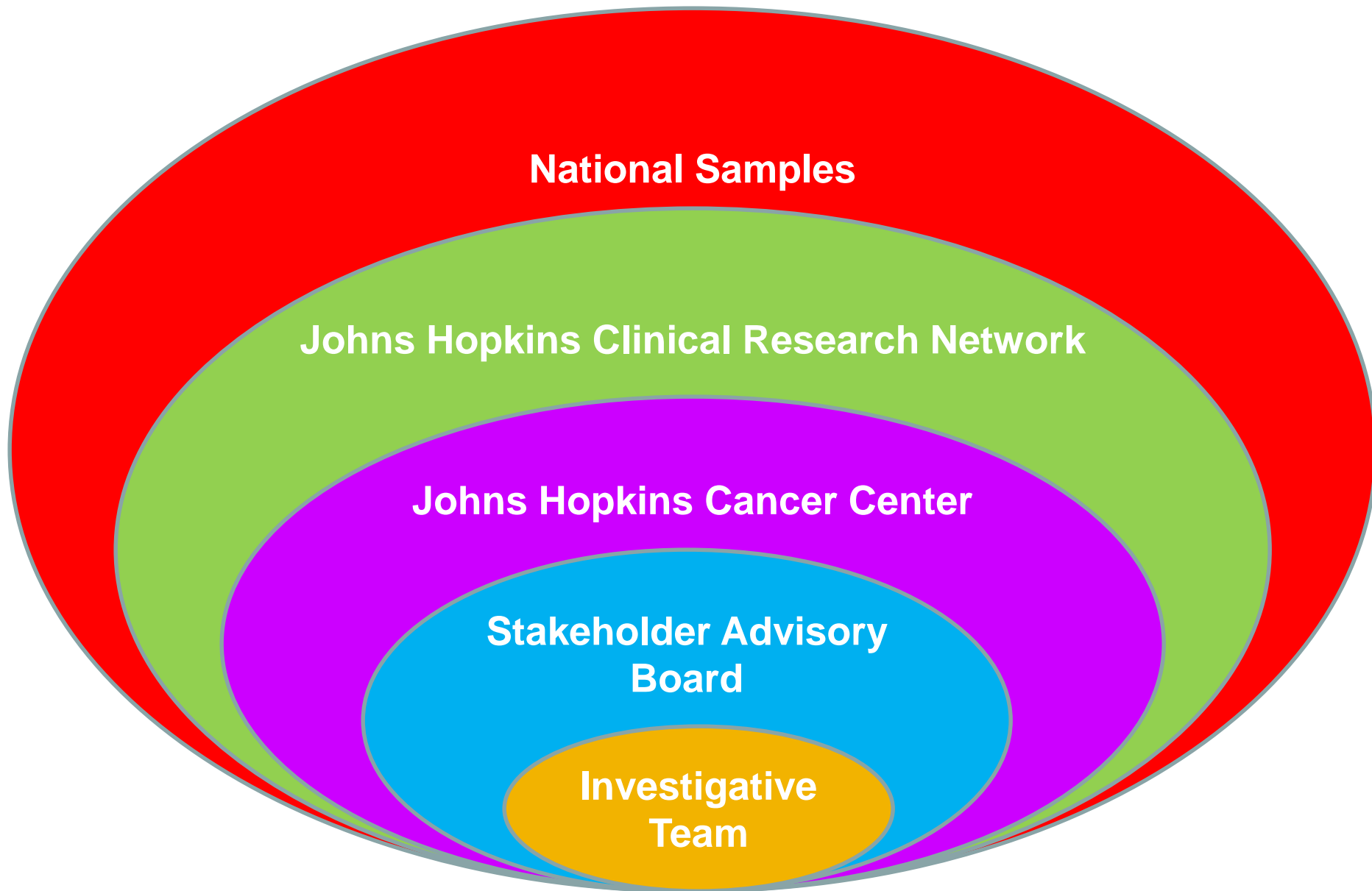


Setting: Parts 1 and 2

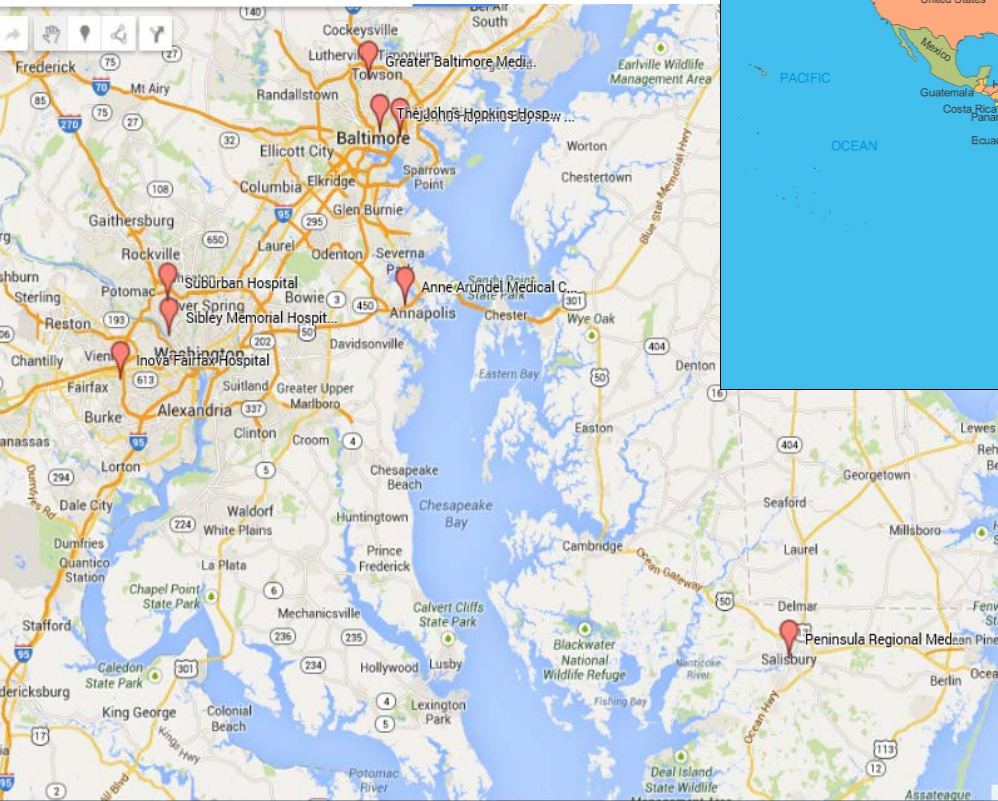
The **Johns Hopkins Clinical Research Network**, a consortium of academic and community medical centers



How Can We Be Broader?



Setting: Part 3



Internet survey only

Internet survey supplemented with
1-on-1 in-depth interviews

Key Lessons

- Determine who the stakeholders are early on
- Include stakeholders in every step of the process
- Be broad
- Select stakeholders who can facilitate successful study conduct and effective dissemination

ONLINE FIRST NOVEMBER 9, 2017

How We Do It

Partnering with stakeholders using an example patient-reported outcomes project

Claire Snyder, PhD,^{abc} Katherine Smith, PhD,^{bc} Elliott Tolbert, PhD,^{ab} Elissa Bantug, MHS,^c Michael Brundage, MD, MSc,^d and the PRO Data Presentation Stakeholder Advisory Board[†]

Johns Hopkins University^aSchool of Medicine and ^bBloomberg School of Public Health, and ^cSidney Kimmel Comprehensive Cancer Center, in Baltimore, Maryland; and ^dQueens Cancer Research Institute, Kingston, Ontario, Canada

3-Part Mixed Methods Study

- 1. To what extent do current practices of PRO reporting limit clinician and patient understanding and use? What are the most/least desirable attributes of current practices?**
2. What are novel ways to present PRO results to clinicians and patients to improve their usefulness?
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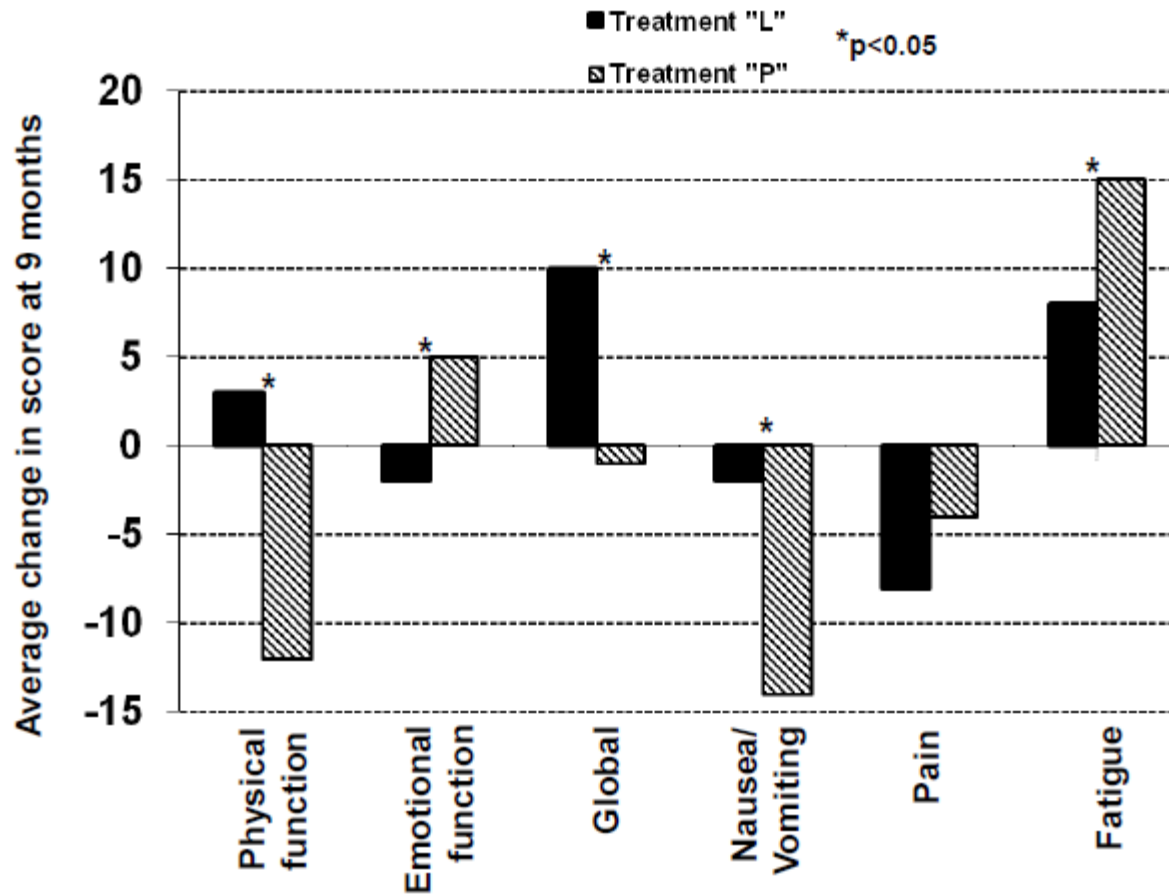
Part 1: Objectives

- To evaluate patient and clinician comprehension of PRO data using existing presentation approaches
- To obtain qualitative feedback on attributes of different presentation formats found to be either helpful or challenging

Each bar represents the average change in score at nine months.

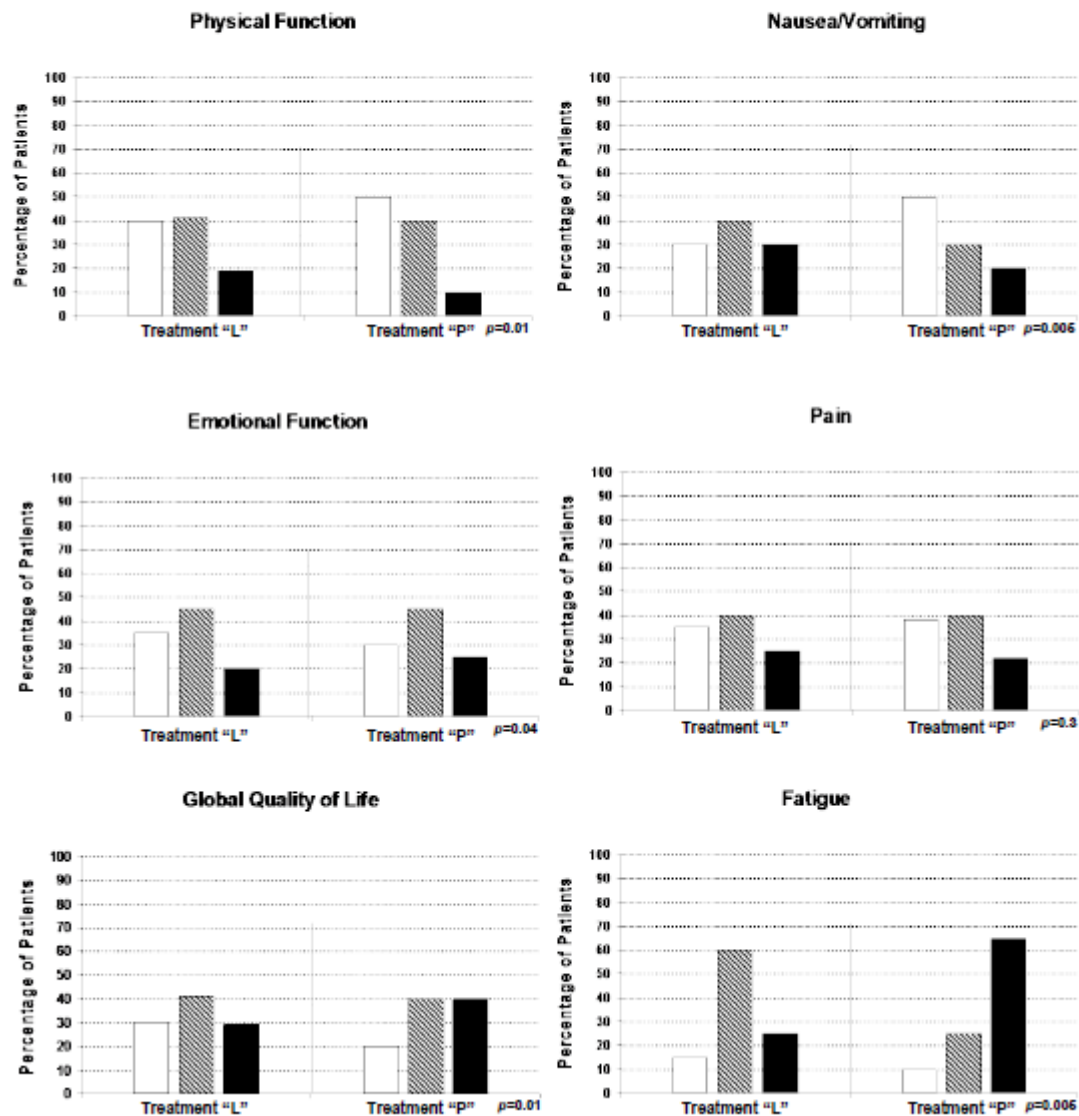
A bar below the "0" line represents improved scores (better functioning or improved symptoms), on average, at nine months compared with prior to starting treatment.

Statistically significant differences between treatments are shown with an *.



The bars represent the percentage of patients that show improved, stable, or worsened scores at nine months. Improved or worsened is defined as a 10 point change (scale range 0-100). "p-values" less than 0.05 are considered significant differences between treatments.

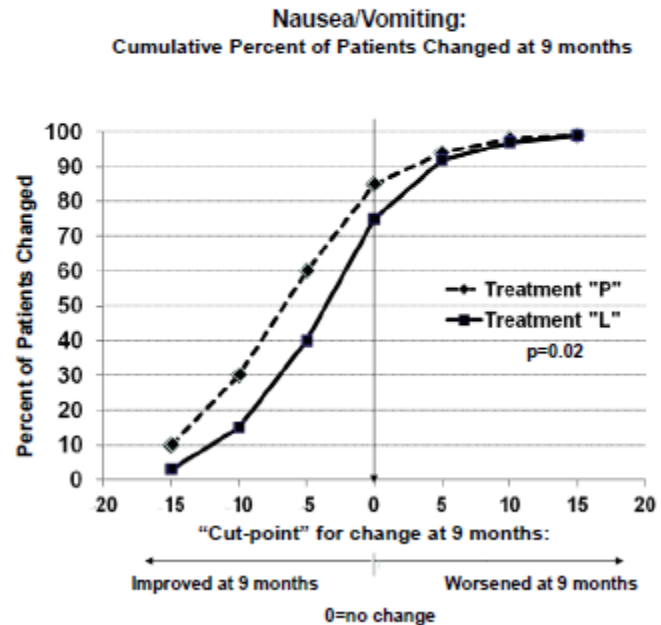
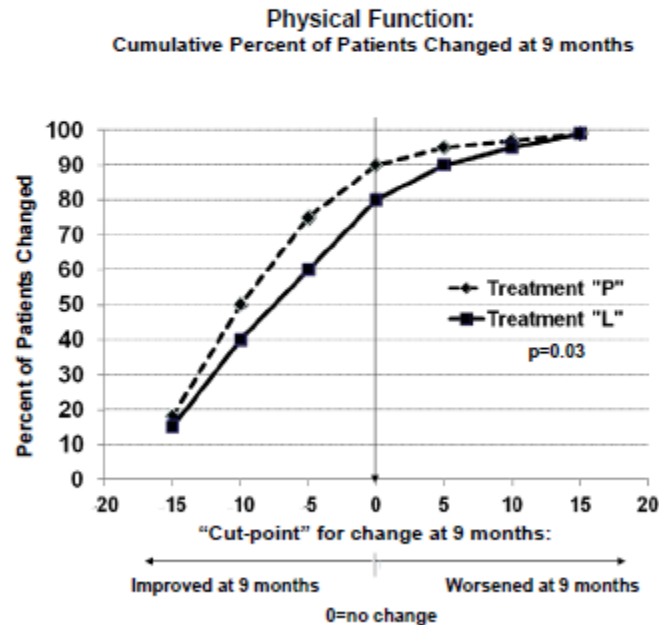
Improved at 9 months
 Stable at 9 months
 Worsened at 9 months



The curves represent the cumulative percentage of patients that show a change in scores at nine months.

Various thresholds (up to 15 points improved) for calculating the percentage of patients changing from baseline are shown across the x-axis.

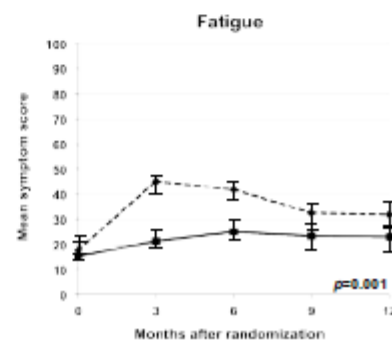
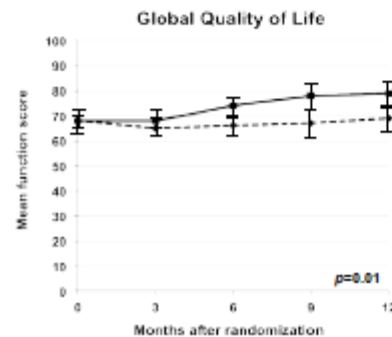
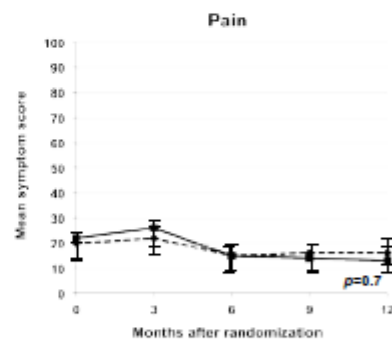
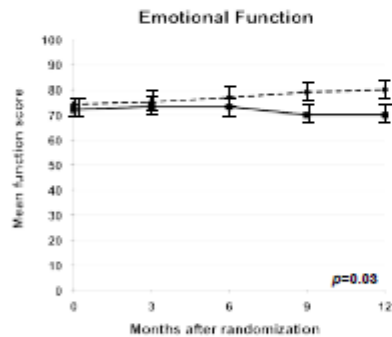
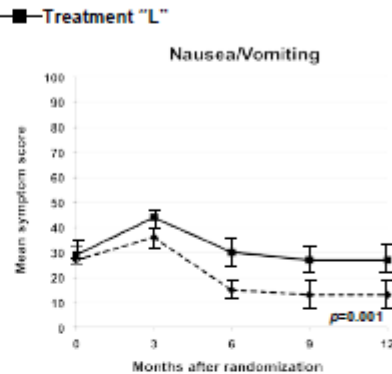
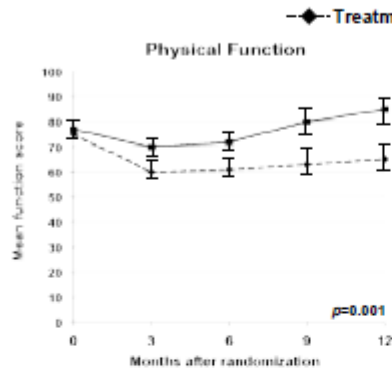
"p-values" less than 0.05 are considered significant differences between treatments.



The lines represent the average (mean) scores of patients on each treatment at baseline (0) and at each assessment point up to 12 months. The vertical bars represent variation in the scores at each point (95% confidence limits around the average scores). "p-values" less than 0.05 indicate significant differences between treatments.

Higher scores represent better function or global QOL

Higher scores represent a higher level of symptoms (greater symptom burden)



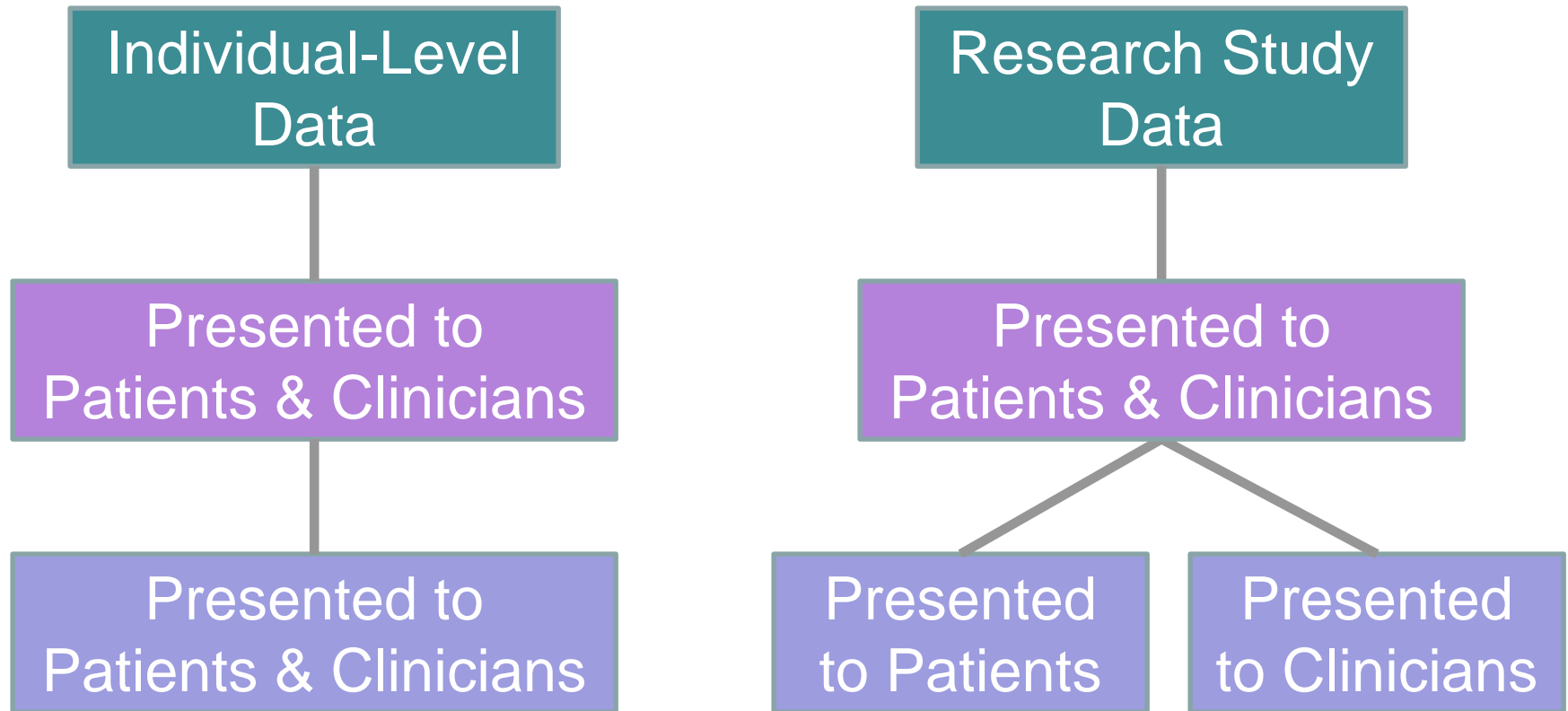
Also shown

- normed to population average
- plain (without confidence limits)

Part 1 Conclusions

- Wide variation in accuracy of interpretation for both patients (36%-100%) and clinicians (56%-100%)
- Some confused by direction changes
- Many improvements suggested
- Patients were most likely to prefer simple line graphs
- Clinicians preferred line graphs with norms or confidence intervals, but rated simple line graphs best

One Key Part 1 Finding



Communicating patient-reported outcome scores using graphic formats: results from a mixed-methods evaluation

Michael D. Brundage¹ · Katherine C. Smith^{2,3} · Emily A. Little⁴ · Elissa T. Bantug² · Claire F. Snyder^{2,3,4} · The PRO Data Presentation Stakeholder Advisory Board

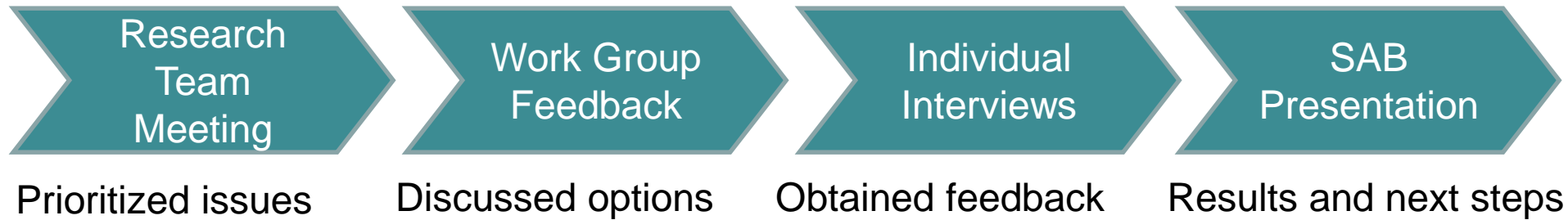
3-Part Mixed Methods Study

1. To what extent do current practices of PRO reporting limit clinician and patient understanding and use? What are the most/least desirable attributes of current practices?
2. **What are novel ways to present PRO results to clinicians and patients to improve their usefulness?**
3. Are these novel ways of presenting PROs effective in improving understanding and use of the data?

Part 2: Objectives

- Develop candidate best practice approaches for presenting PRO data
- An iterative working group process to obtain stakeholder input on approaches to improve PRO presentation

Approach



Work Group Organization

Stream 1: Individual-Patient Level Data

Goal: Format suitable for paper context, with potential for additional functionalities in an electronic context

Work Group: approximately 8 patients, 4 clinicians

In-Depth Individual Interviews: approximately 20 patients, 10 clinicians

Research
Team
Meeting

Work Group
Feedback

Individual
Interviews

SAB
Presentation

Stream 2: Group-Level Data for Communication

Goal: Format suitable for patient education materials designed to communicate results of comparative studies reporting patient-reported outcomes

Work Group: approximately 8 patients, 2 clinicians

In-Depth Interviews: approximately 20 patients, 10 clinicians

Research
Team
Meeting

Work Group
Feedback

Individual
Interviews

SAB
Presentation

Stream 3: Publication Data

Goal: Format suitable for peer-reviewed publications of comparative studies reporting patient-reported outcomes

Work Group: approximately 6 clinicians

In-Depth Interviews: approximately 20 clinicians

Research
Team
Meeting

Work Group
Feedback

Individual
Interviews

SAB
Presentation

Research Data: Issues to Address

- Line graphs only, or line graphs and others?
- Approaches to directional consistency
- Approaches to common representation independent of PRO measure scaling
- Approaches to highlighting statistical significance
- Approaches to highlighting clinical significance

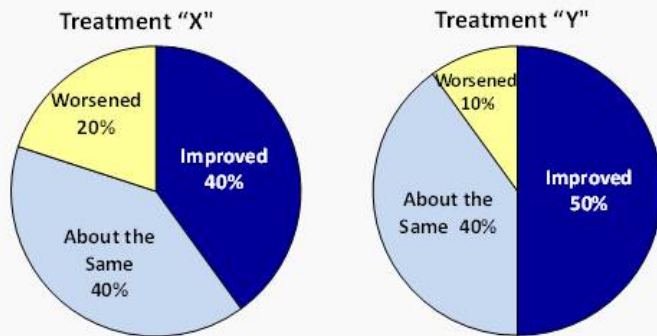
Patient Formats Developed for Testing in Part 3

- Proportion Formats
 - Pie charts
 - Bar charts
 - Icon arrays

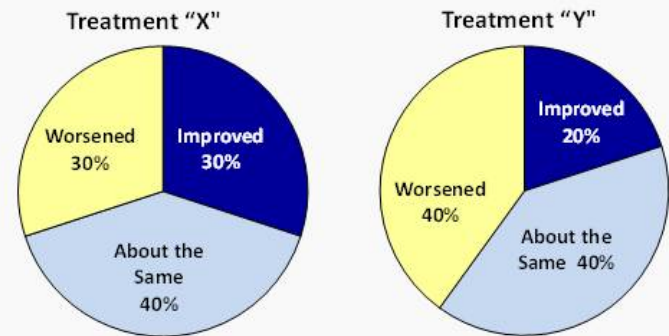
Pies

Status of 100 patients 9 months after starting treatment

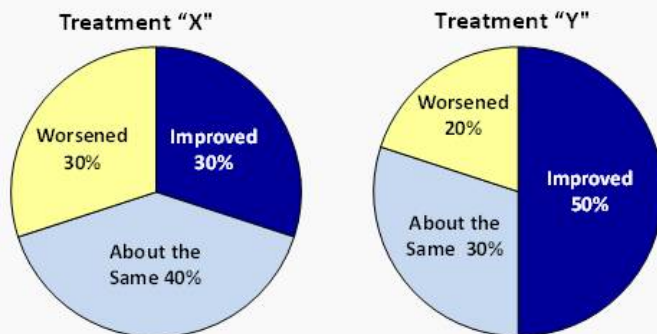
Ability to Do Physical Activities



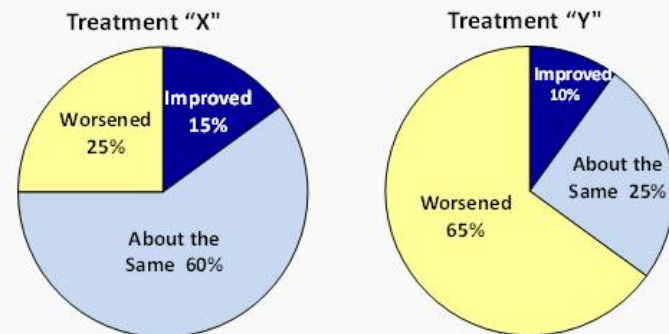
Emotional Well-Being



Pain

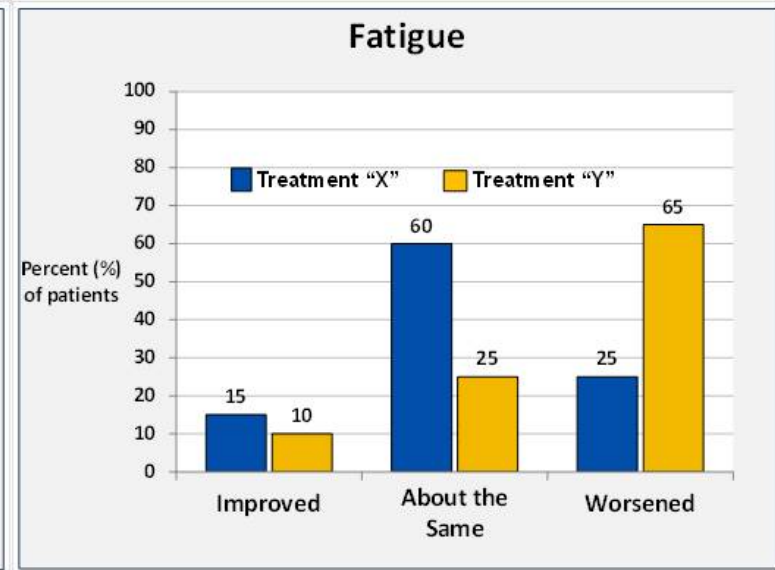
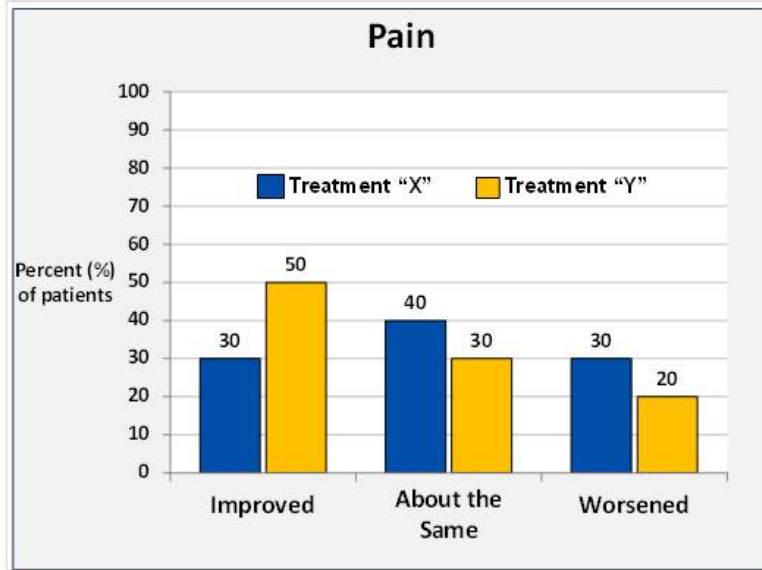
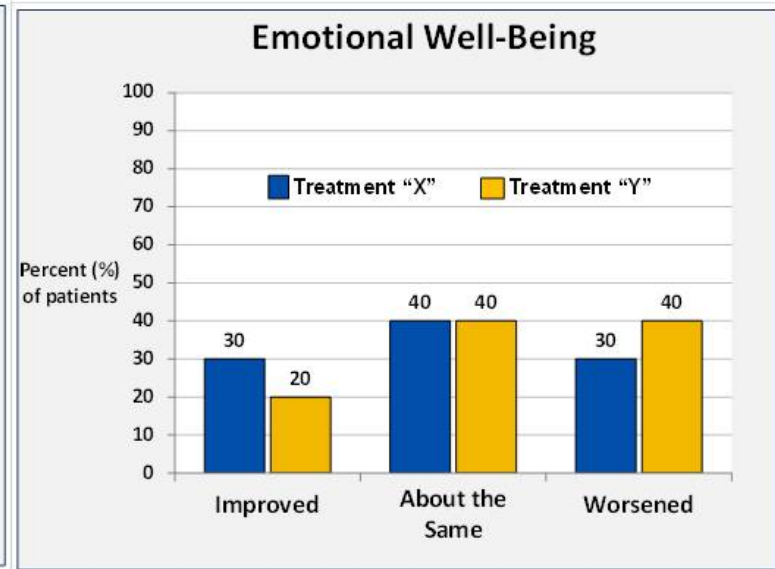
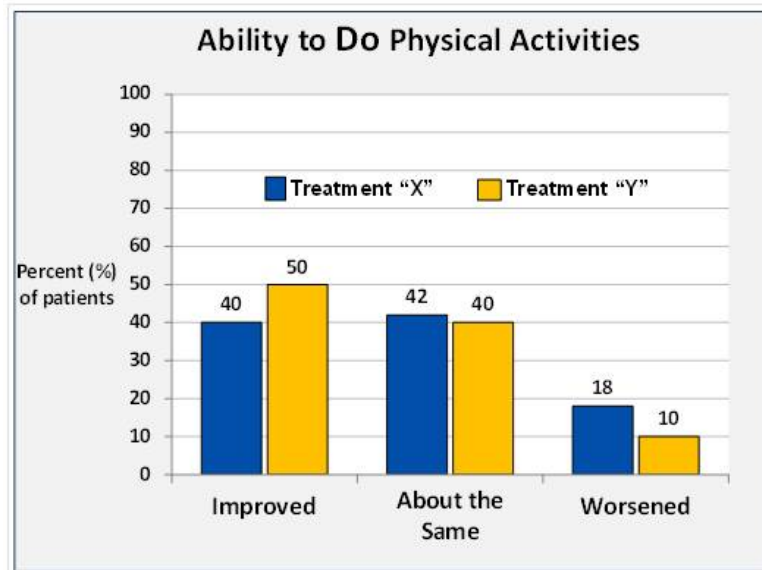


Fatigue



Bars

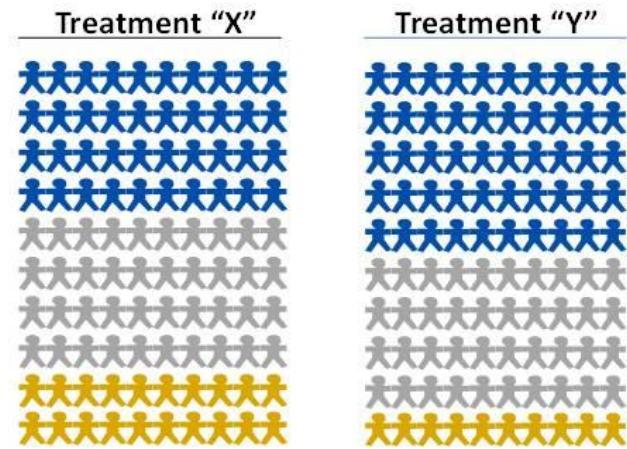
Status of 100 patients 9 months after starting treatment



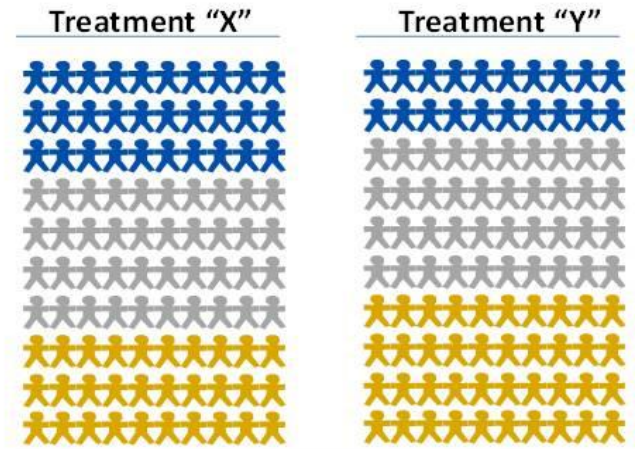
Icons

Status of 100 patients 9 months after starting treatment

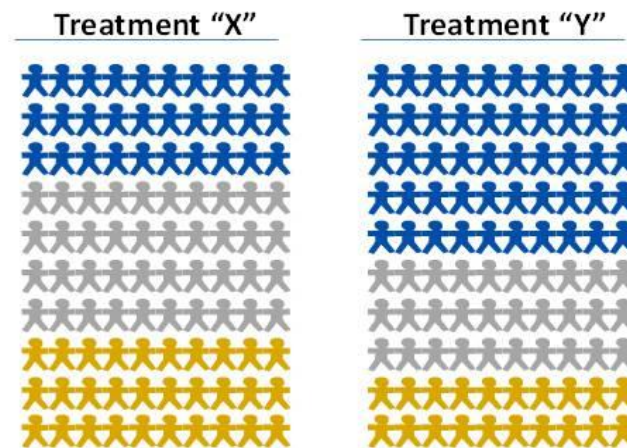
Ability to Do Physical Activities



Emotional Well-Being

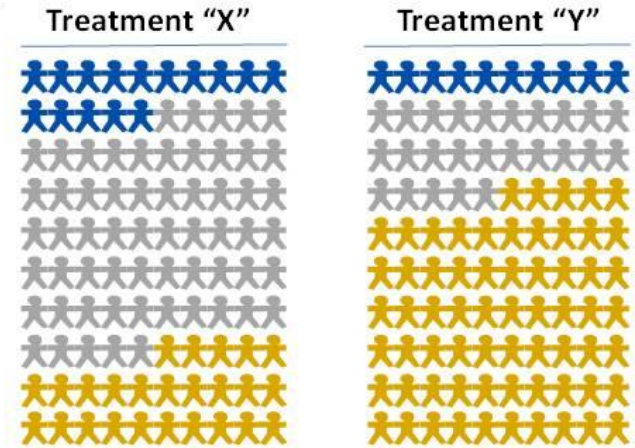


Pain



- Improved
- About the same
- Worsened

Fatigue

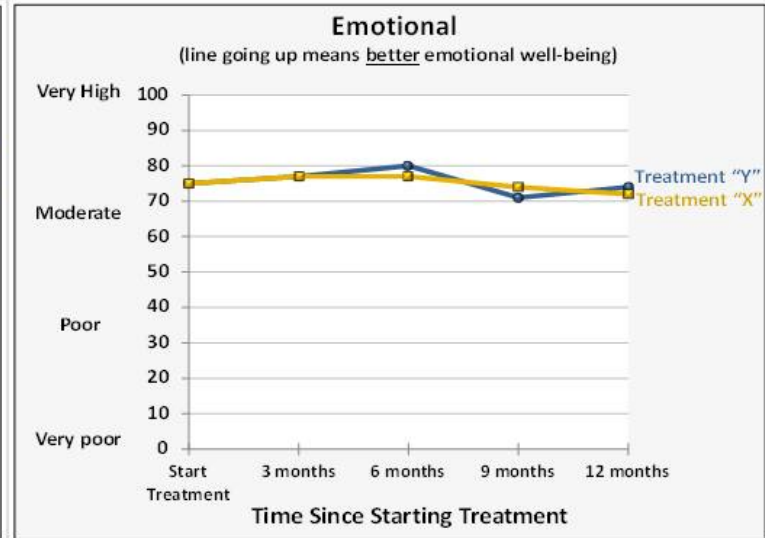
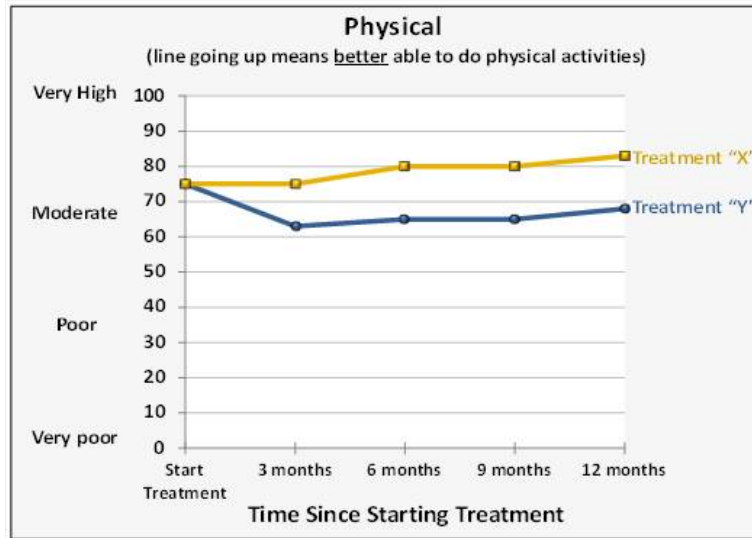


Patient Formats Developed for Testing in Part 3

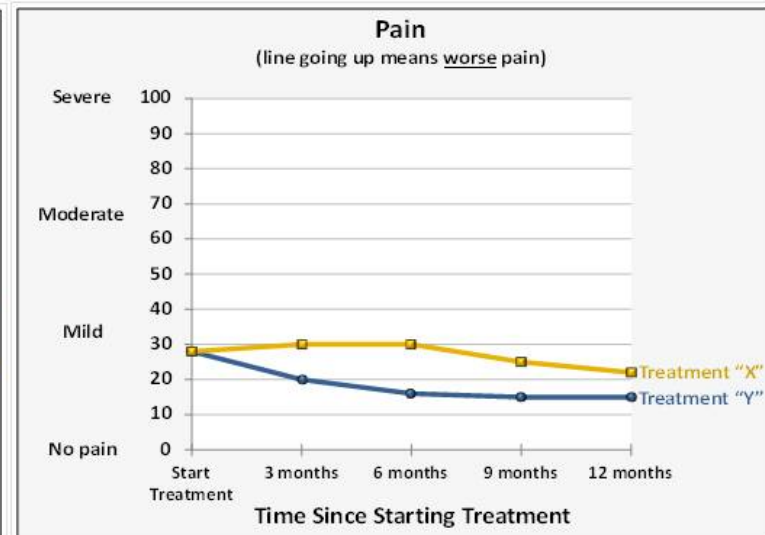
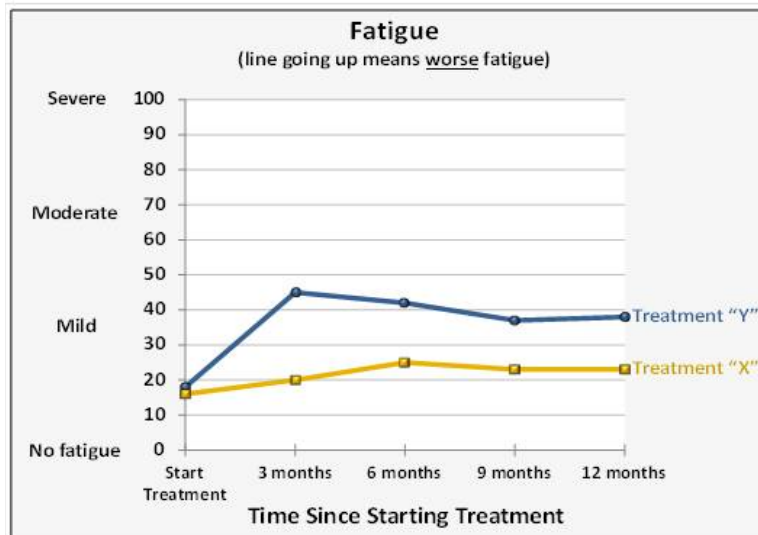
- Proportion Formats
 - Pie charts
 - Bar charts
 - Icon arrays
- Line Graphs of Mean Scores Over Time
 - “More” Line Graphs: higher scores indicate more of an outcome
 - “Better” Line Graphs: higher scores indicate a better outcome
 - Normed Line Graphs: normed to a population average

“More” Line Graphs

Patient's Functioning

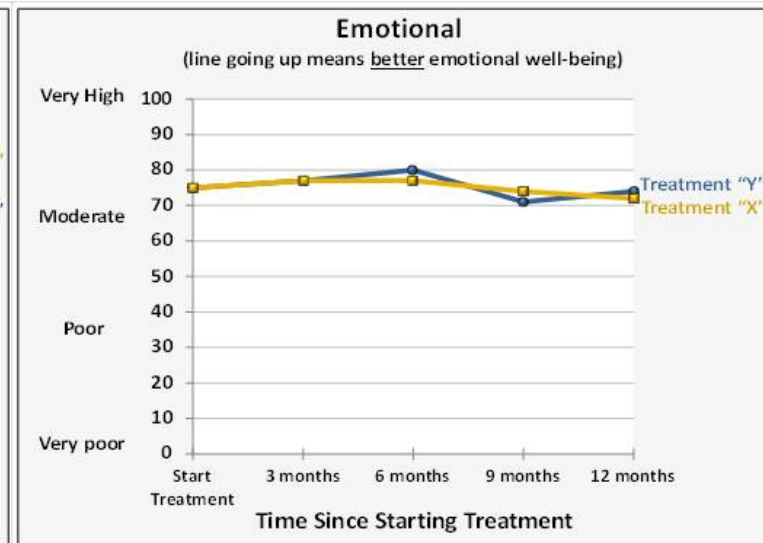
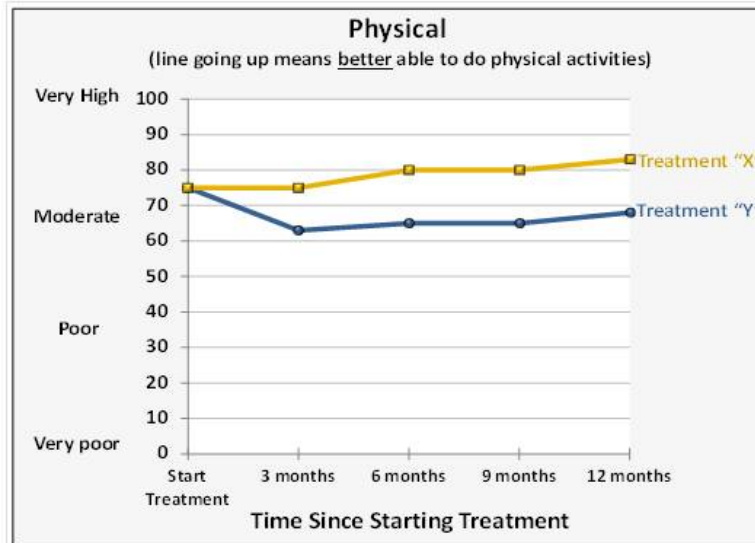


Patient's Symptoms

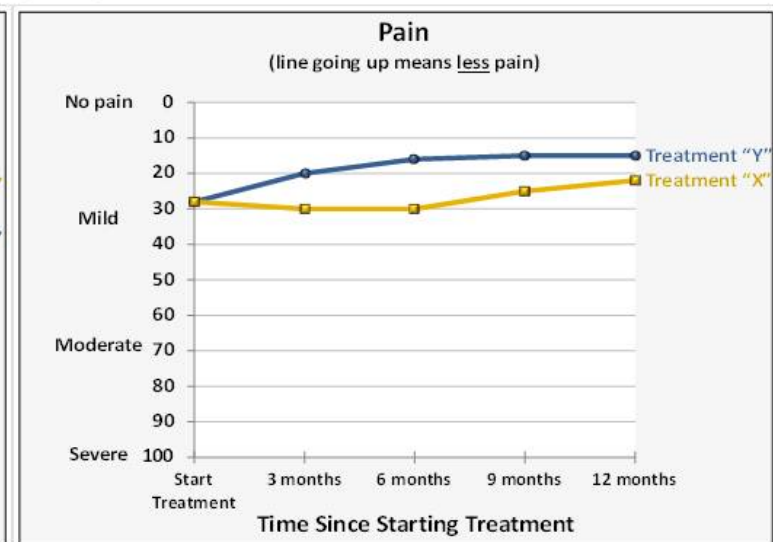
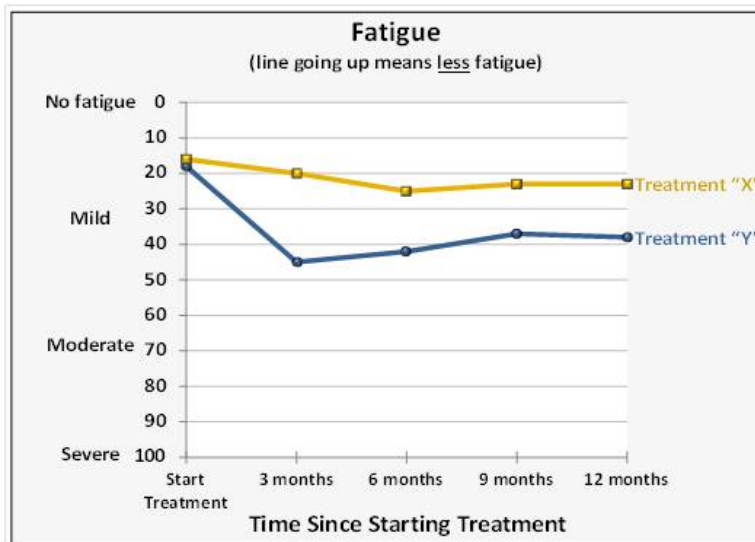


“Better” Line Graphs

Patient's Functioning

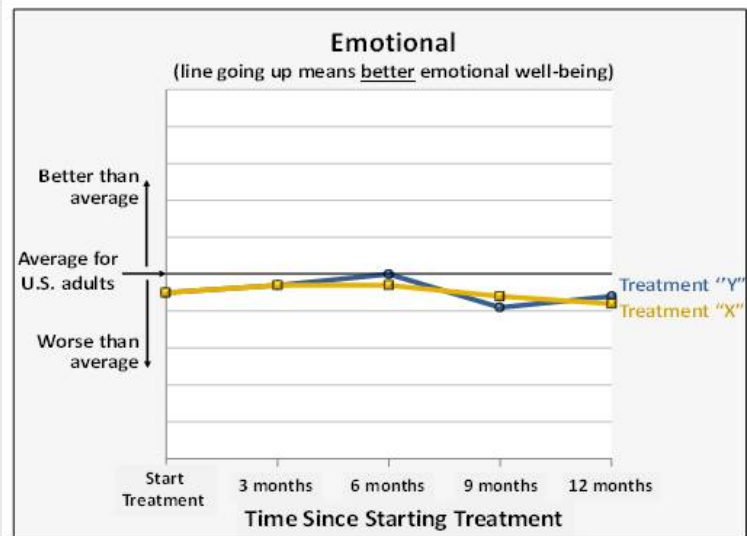
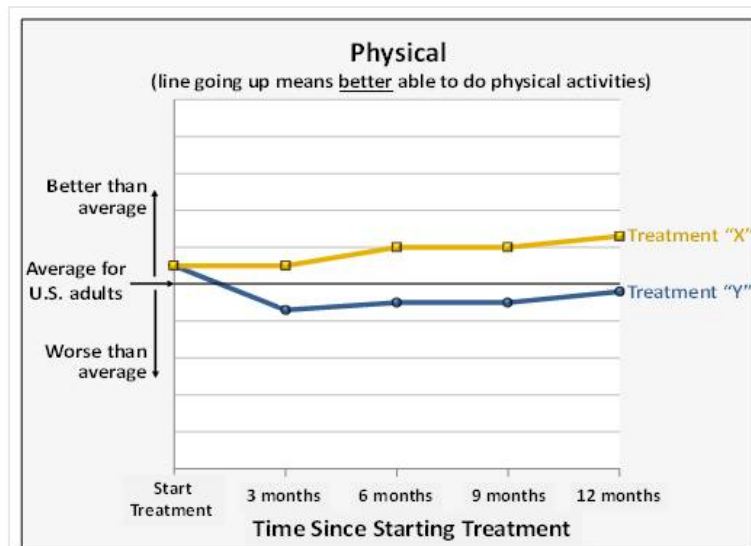


Patient's Symptoms

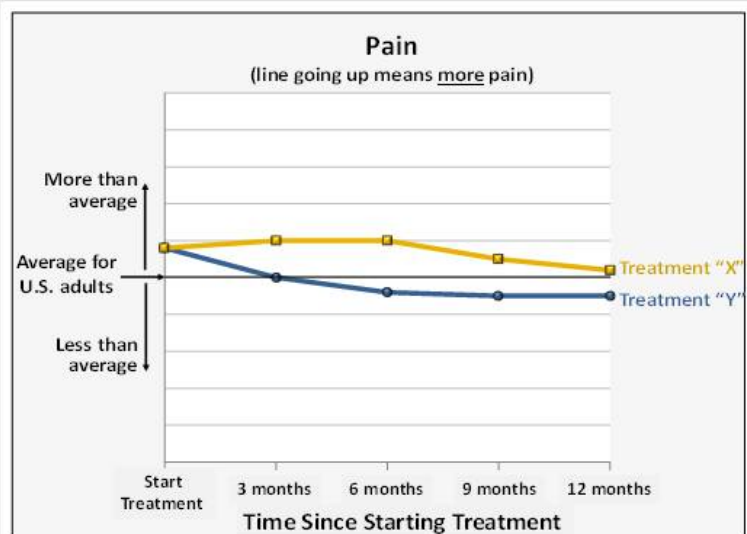
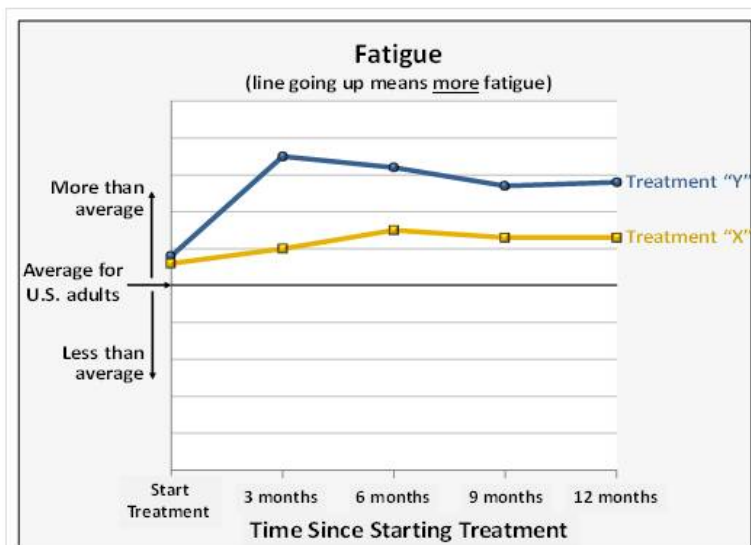


Normed Line Graphs

Patient's Functioning



Patient's Symptoms

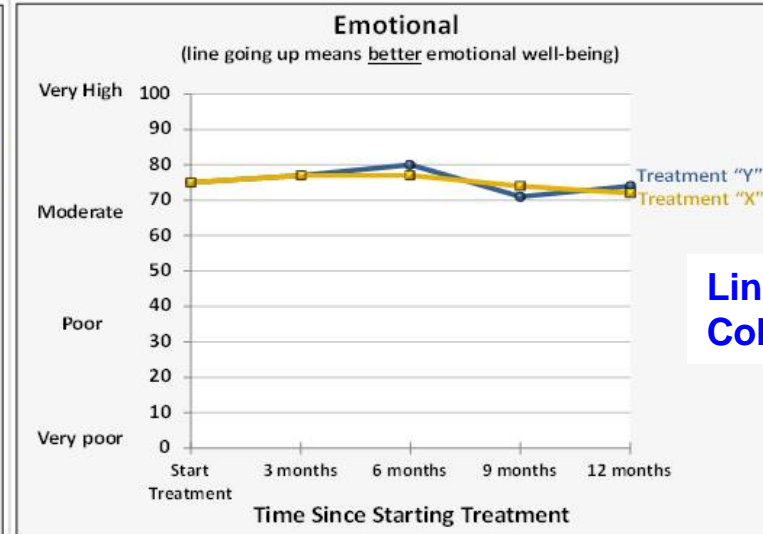
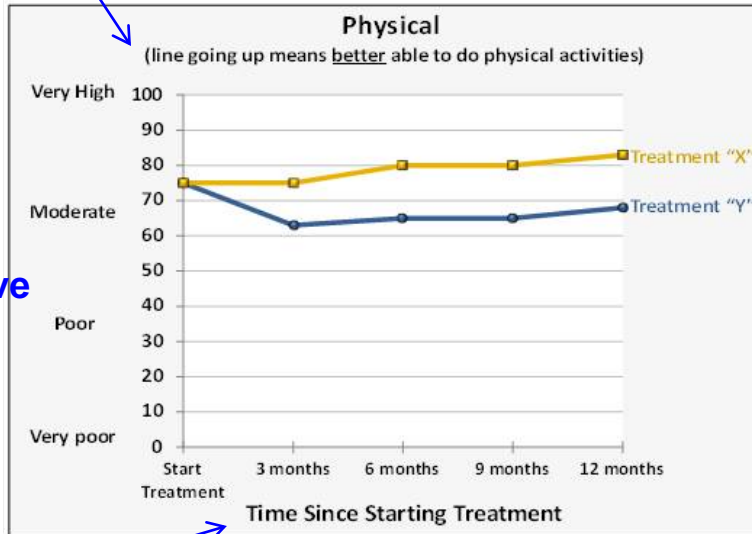


Patient's Functioning

Labels for directionality

Y-axis descriptive labels

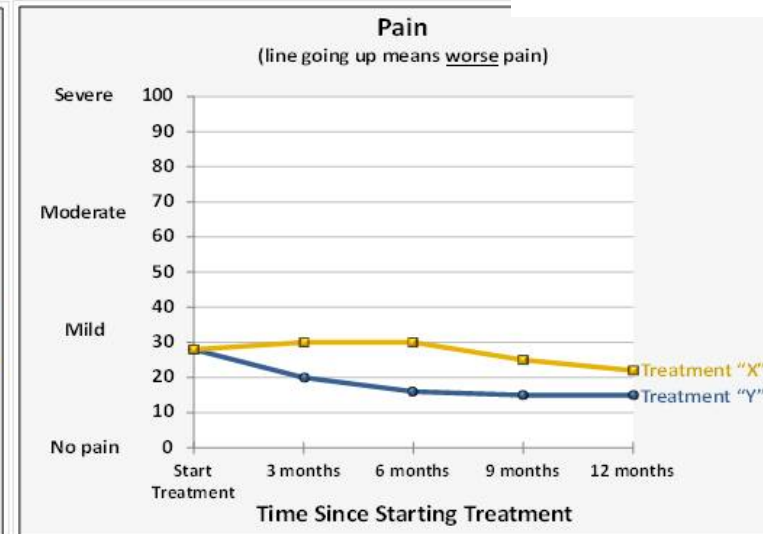
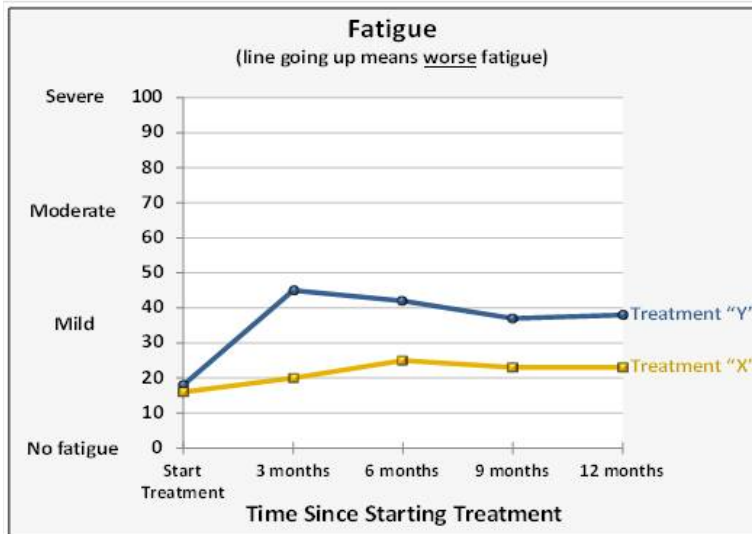
Clear x-axis wording



Line Labels Color

Patient's Symptoms

Separate domains with different directionality



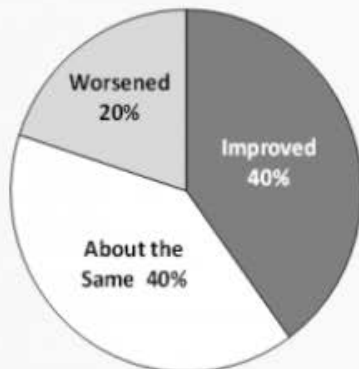
Clinician Formats Developed for Testing in Part 3

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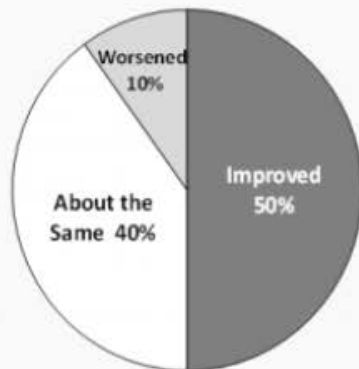
Status of 100 patients 9 months after starting treatment

Ability to Do Physical Activities

Treatment "X"



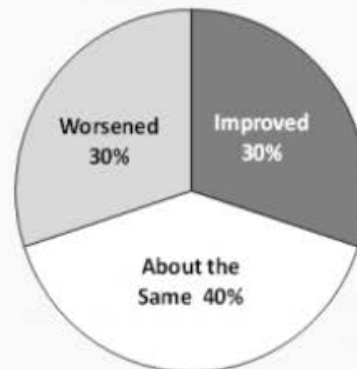
Treatment "Y"



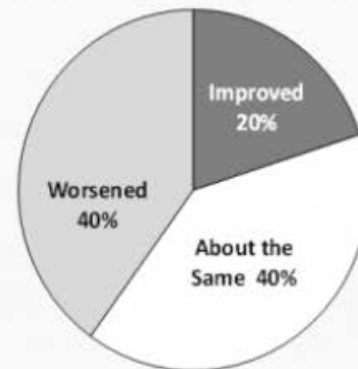
$p=0.10$

Emotional Well-Being

Treatment "X"



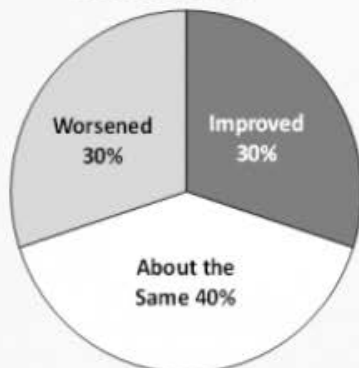
Treatment "Y"



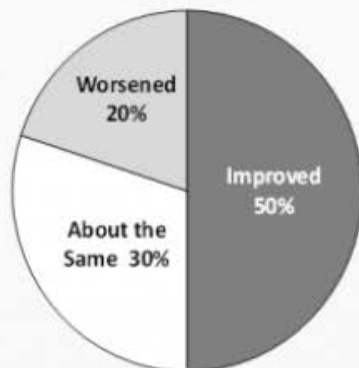
$p=0.04$

Pain

Treatment "X"



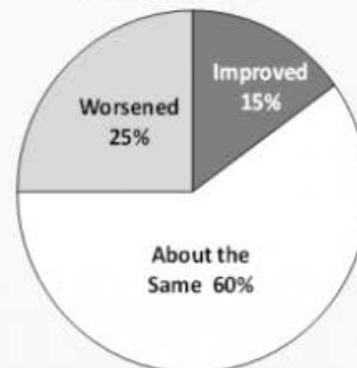
Treatment "Y"



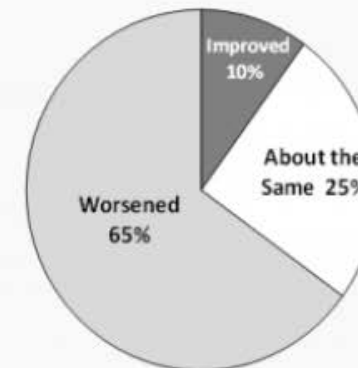
$p=0.01$

Fatigue

Treatment "X"



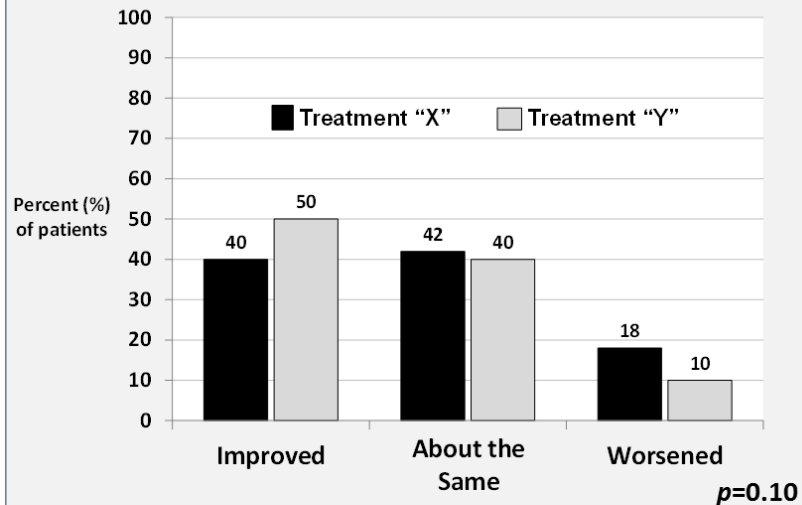
Treatment "Y"



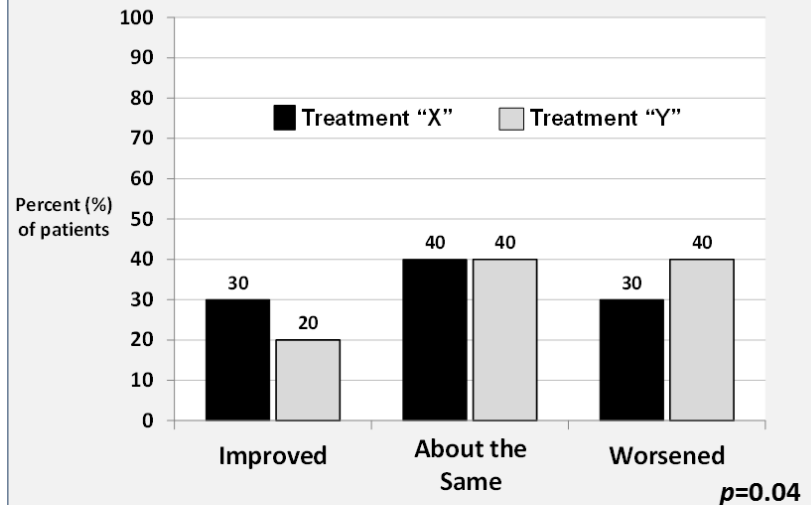
$p=0.001$

Status of 100 patients 9 months after starting treatment

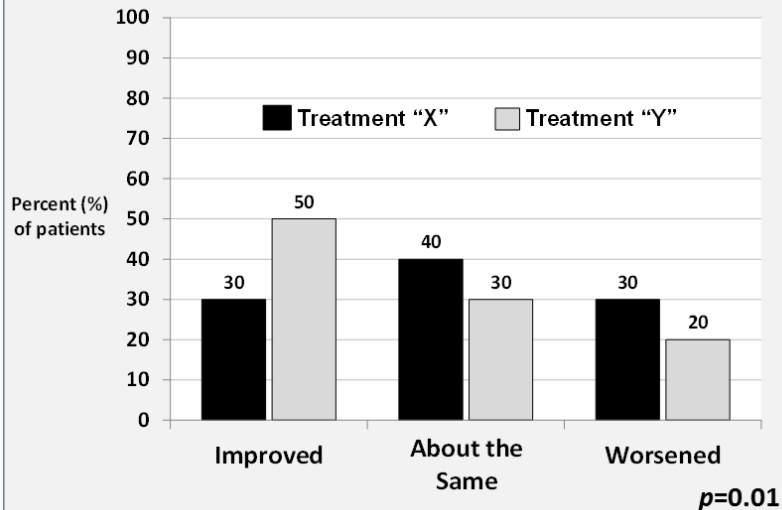
Ability to Do Physical Activities



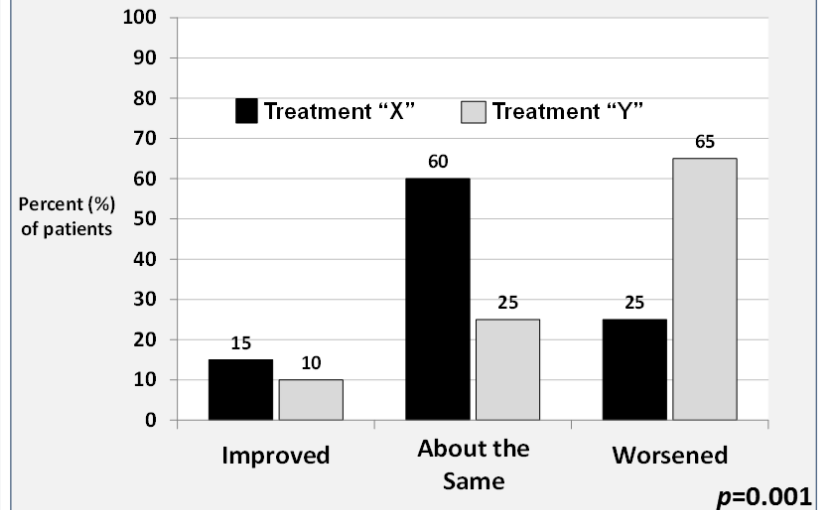
Emotional Well-Being



Pain

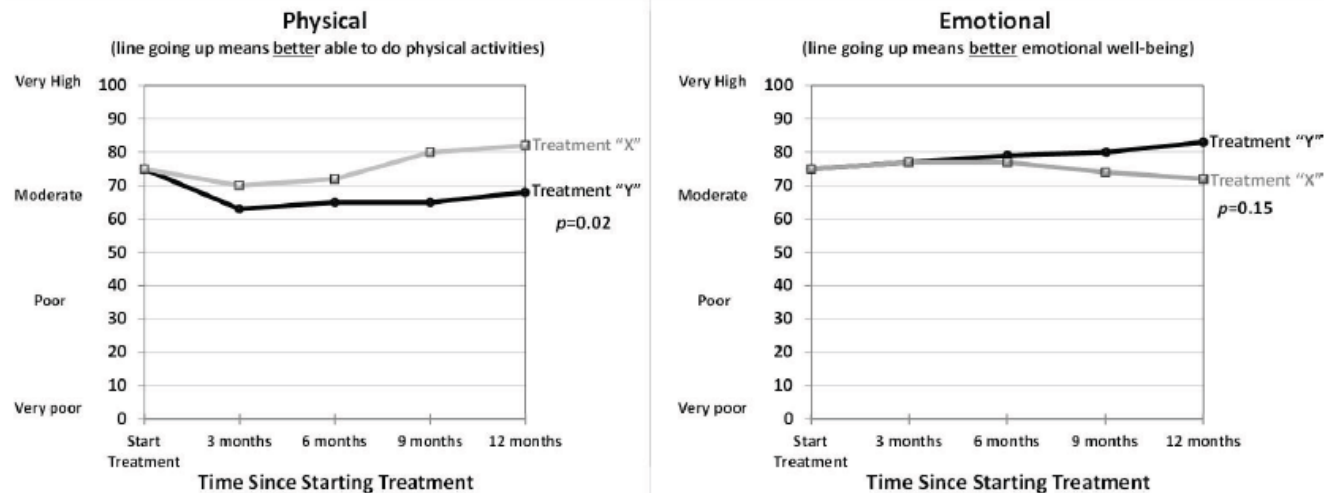


Fatigue

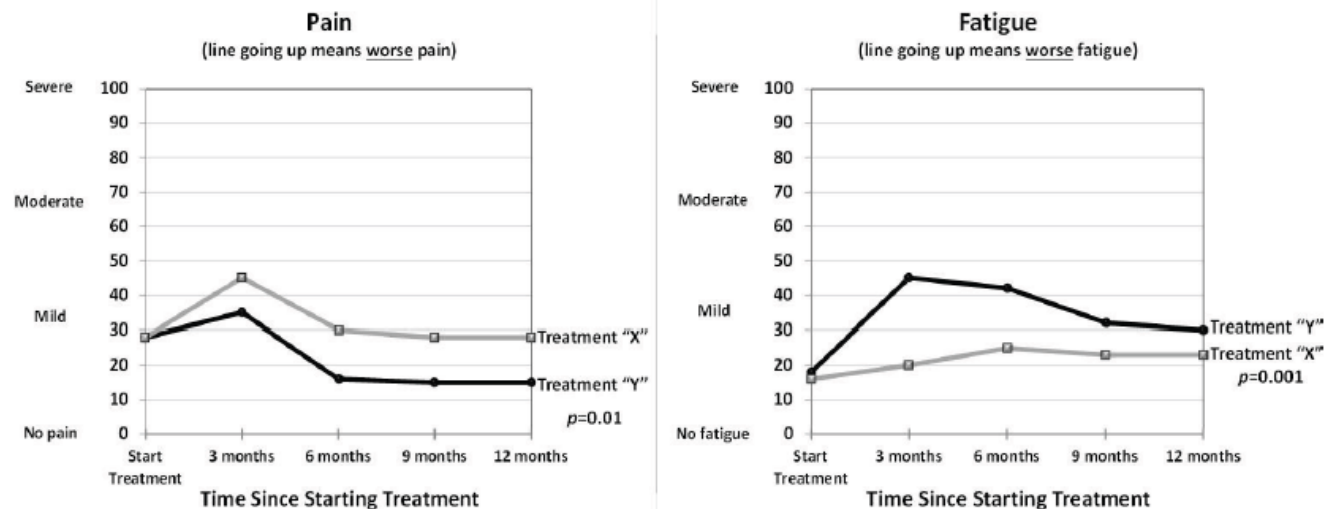


Line Graphs: “More” Format

Patient's Functioning



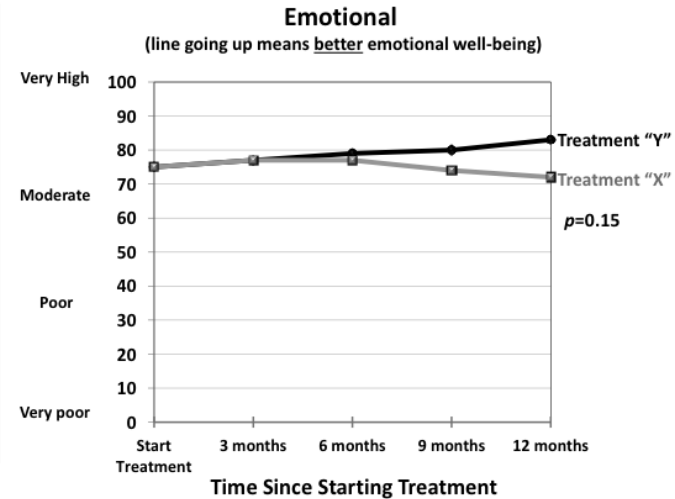
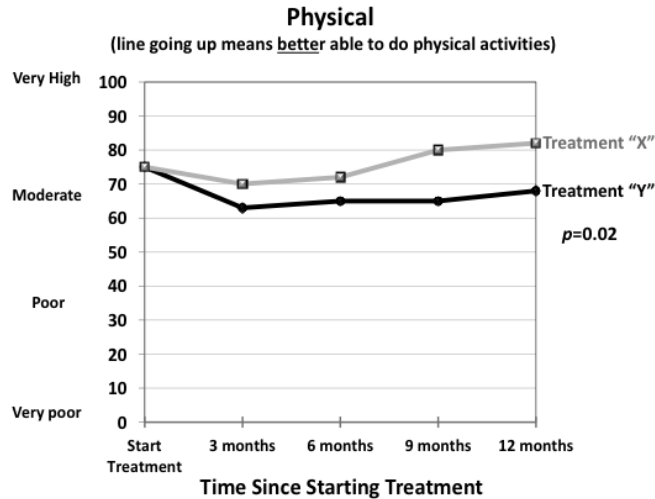
Patient's Symptoms



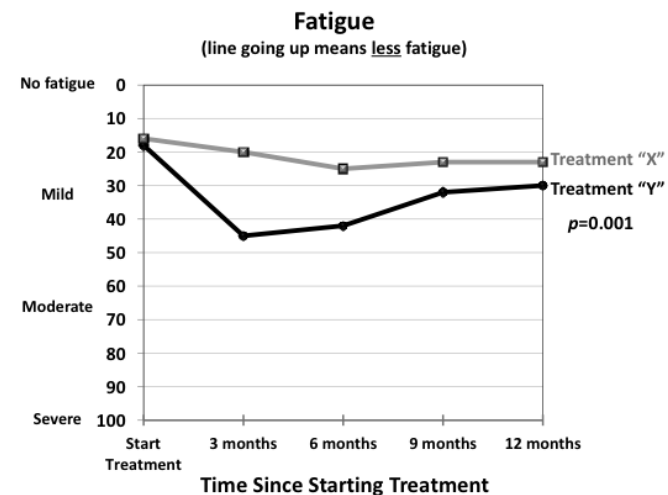
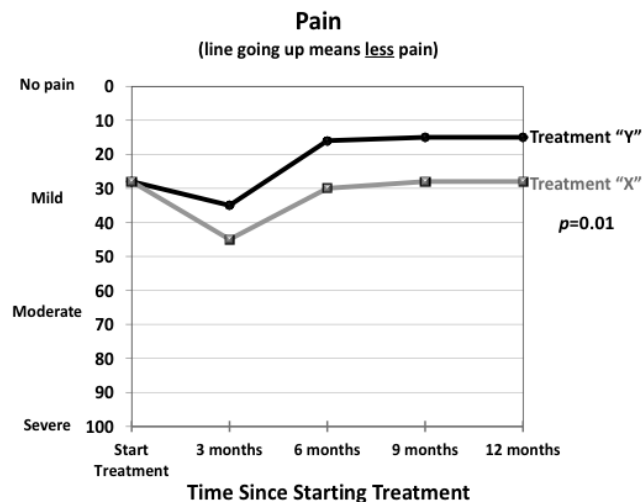
Legend: For all graphs, p -values are for between-treatment differences over time.

Line Graphs: “Better” Format

Patient's Functioning



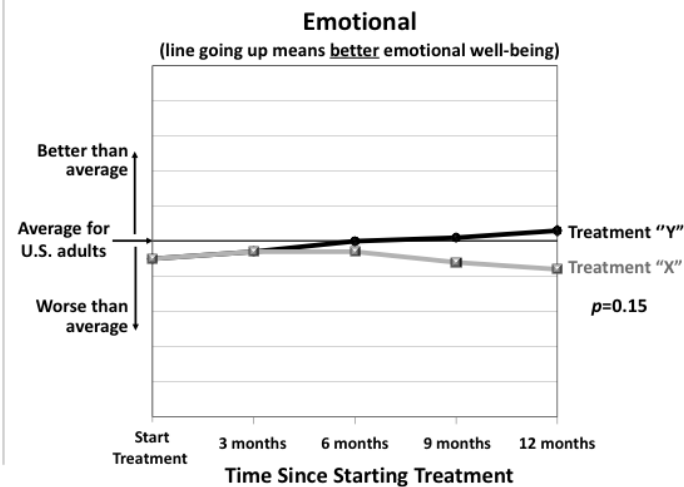
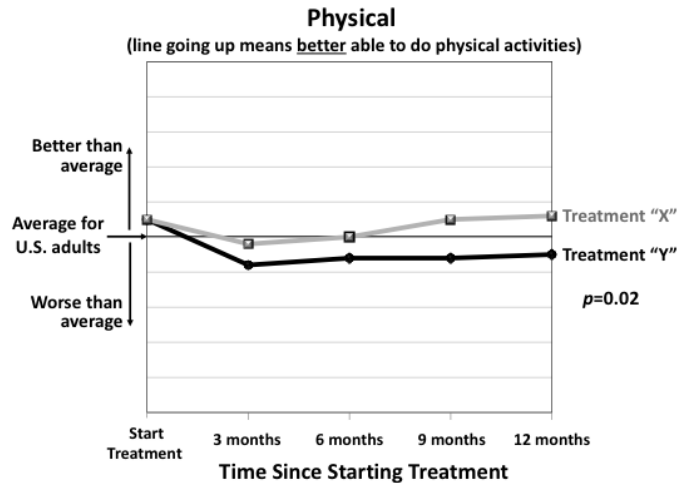
Patient's Symptoms



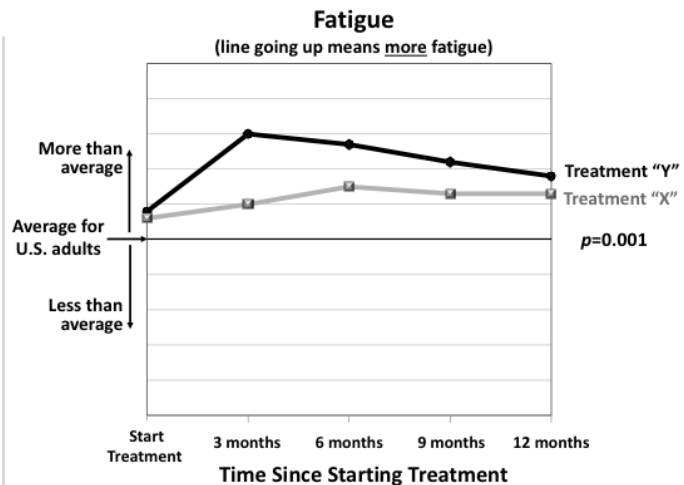
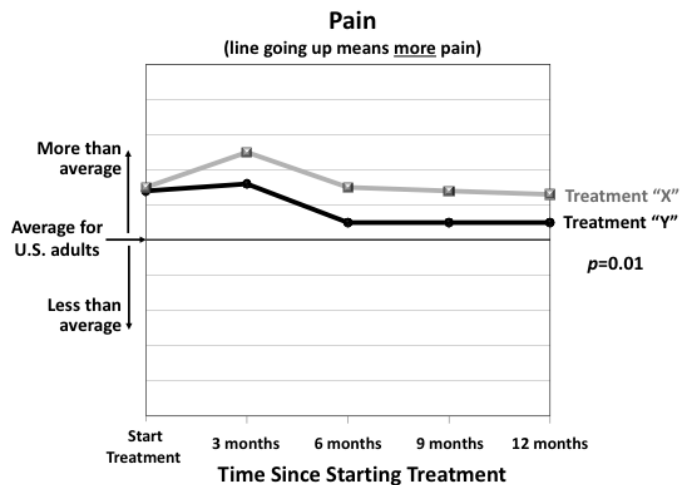
Legend: For all graphs, p -values are for between-treatment differences over time.

Line Graphs: “Normed” Format

Patient’s Functioning



Patient’s Symptoms



Legend: For all graphs, p -values are for between-treatment differences over time.

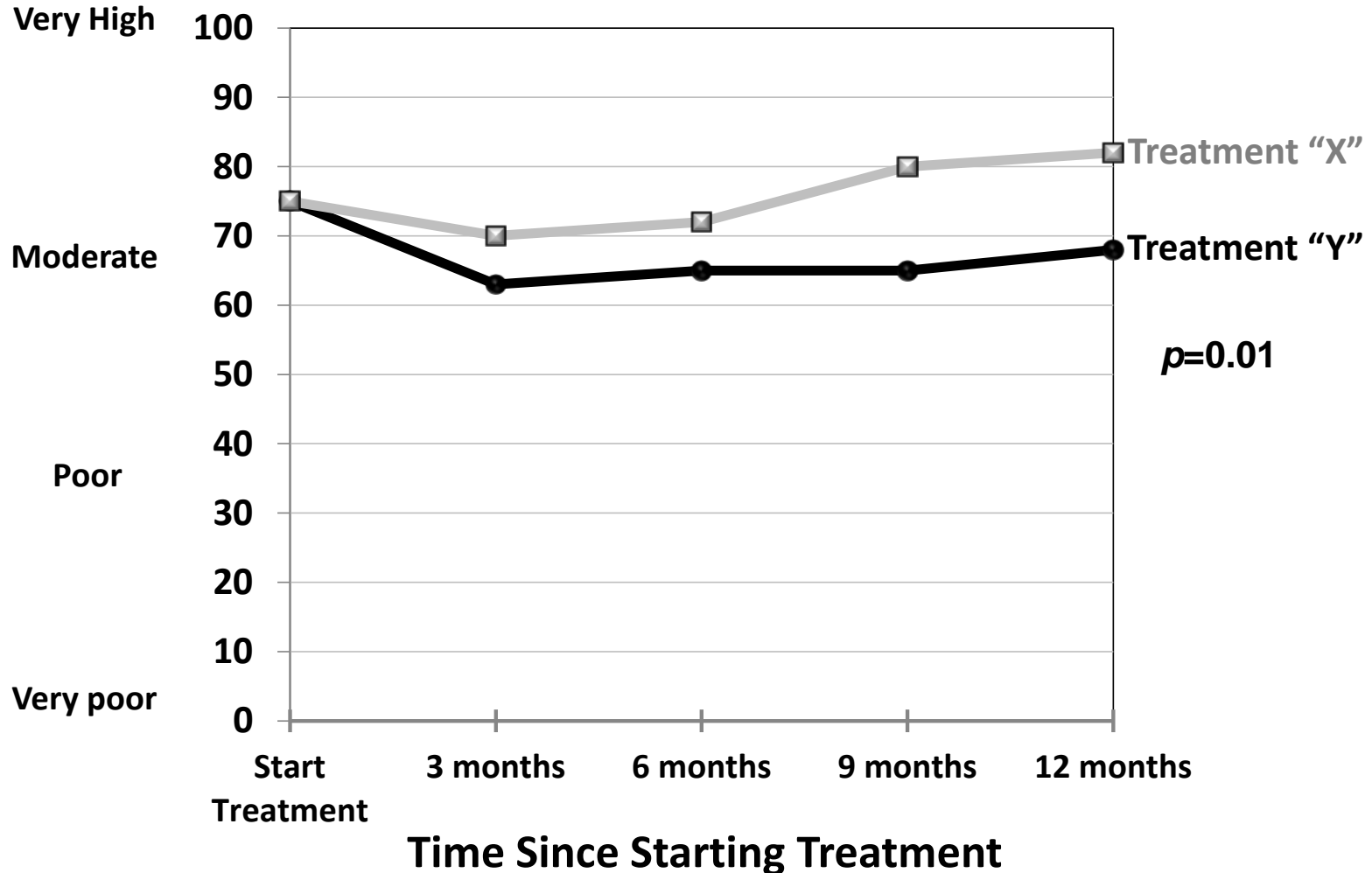
Three Additional Variations on Lines for Clinicians

- “Plain lines” – average scores over time
- “Clinical Significance” – asterisks added
- “Confidence Limits” – added

Line Graphs: “Plain”

Physical

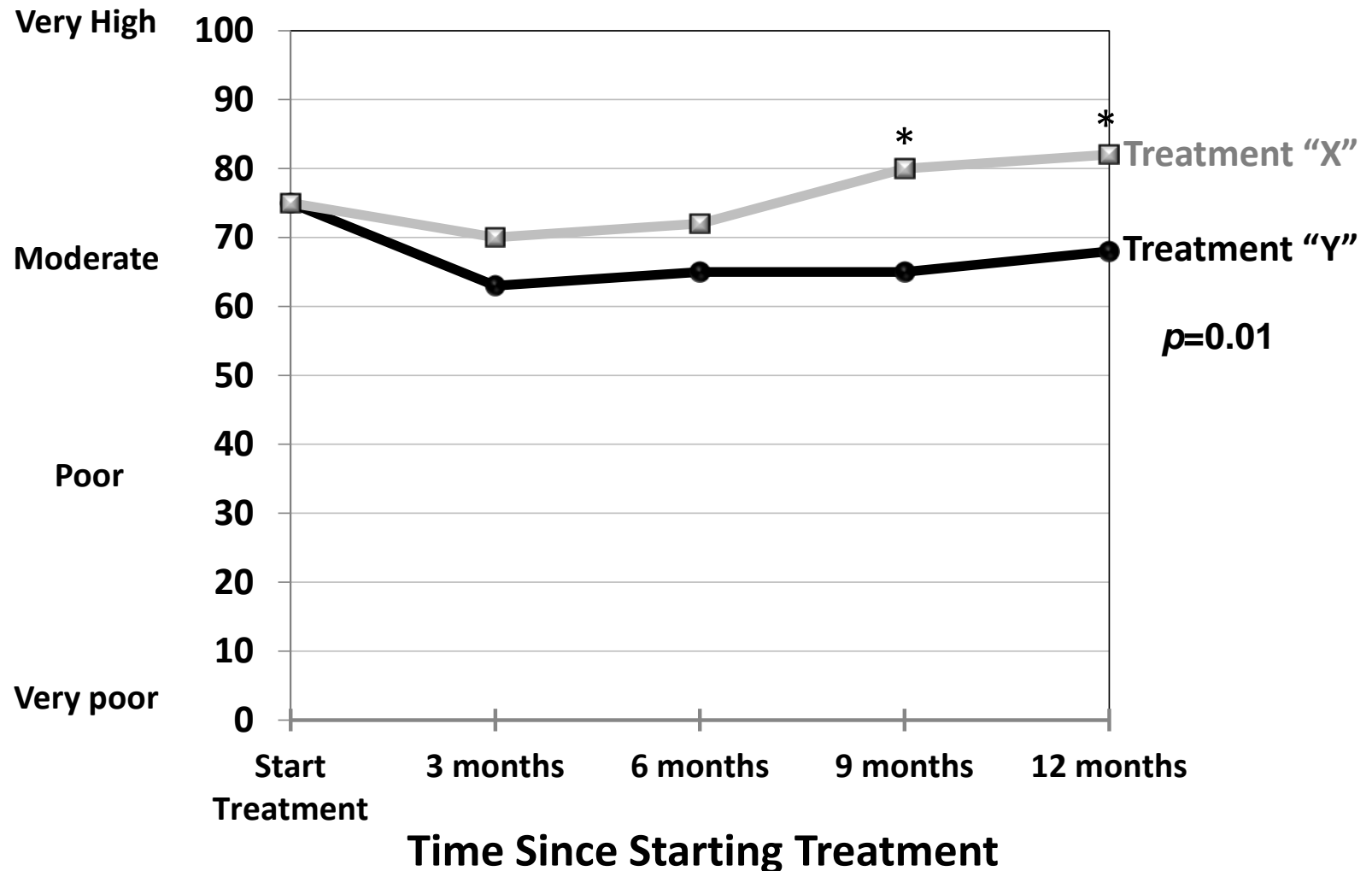
(line going up means better able to do physical activities)



Line Graphs: “Clinical Significance”

Physical

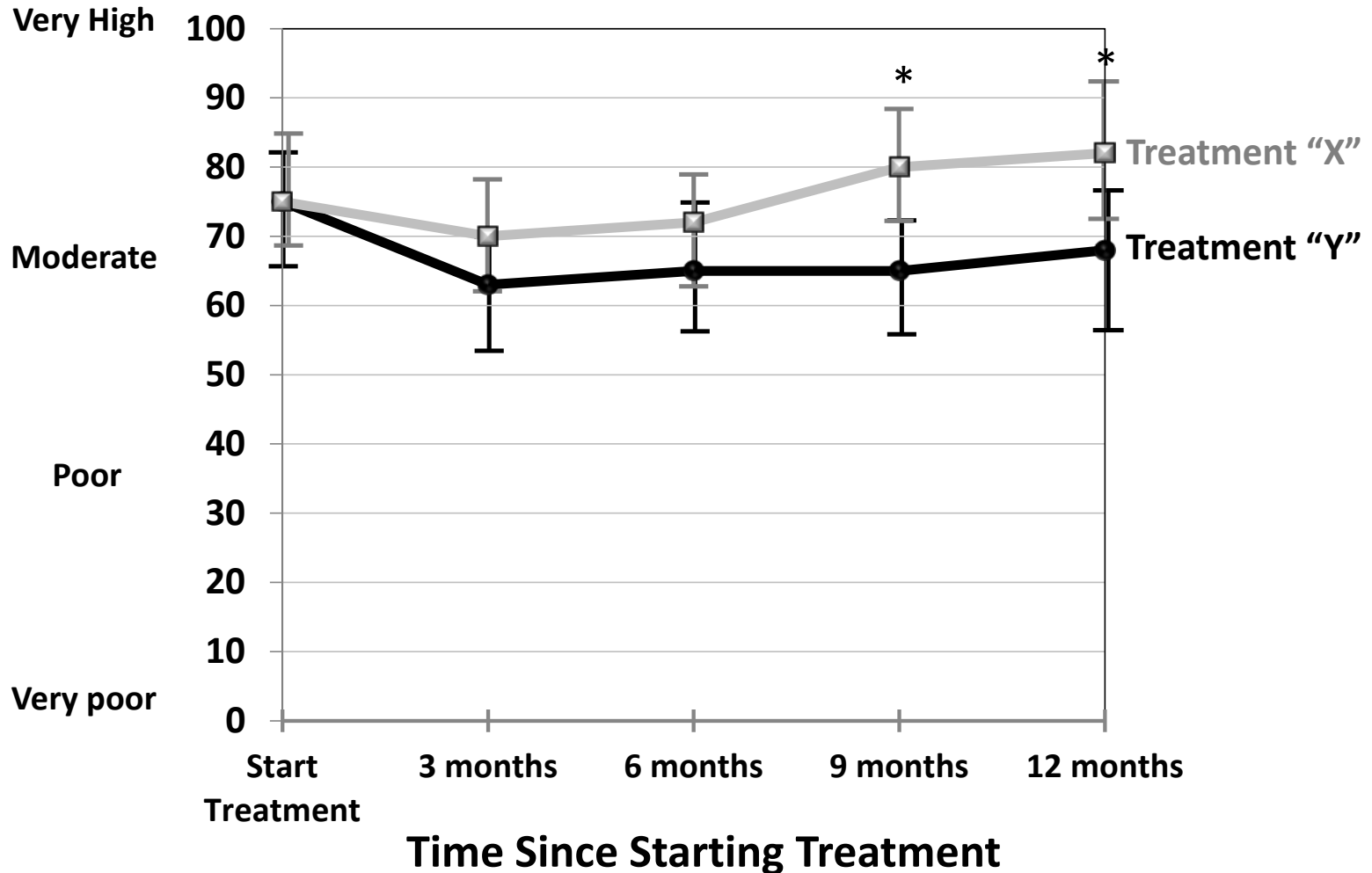
(line going up means better able to do physical activities)



Line Graphs: “Confidence Limits”

Physical

(line going up means better able to do physical activities)



ORIGINAL ARTICLE

Engaging stakeholders to improve presentation of patient-reported outcomes data in clinical practice

Katherine C. Smith^{1,4} · Michael D. Brundage² · Elliott Tolbert³ · Emily A. Little³ ·
Elissa T. Bantug⁴ · Claire E. Snyder^{3,4} · PRO Data Presentation Stakeholder
Advisory Board

Received: 25 November 2015 / Accepted: 24 April 2016
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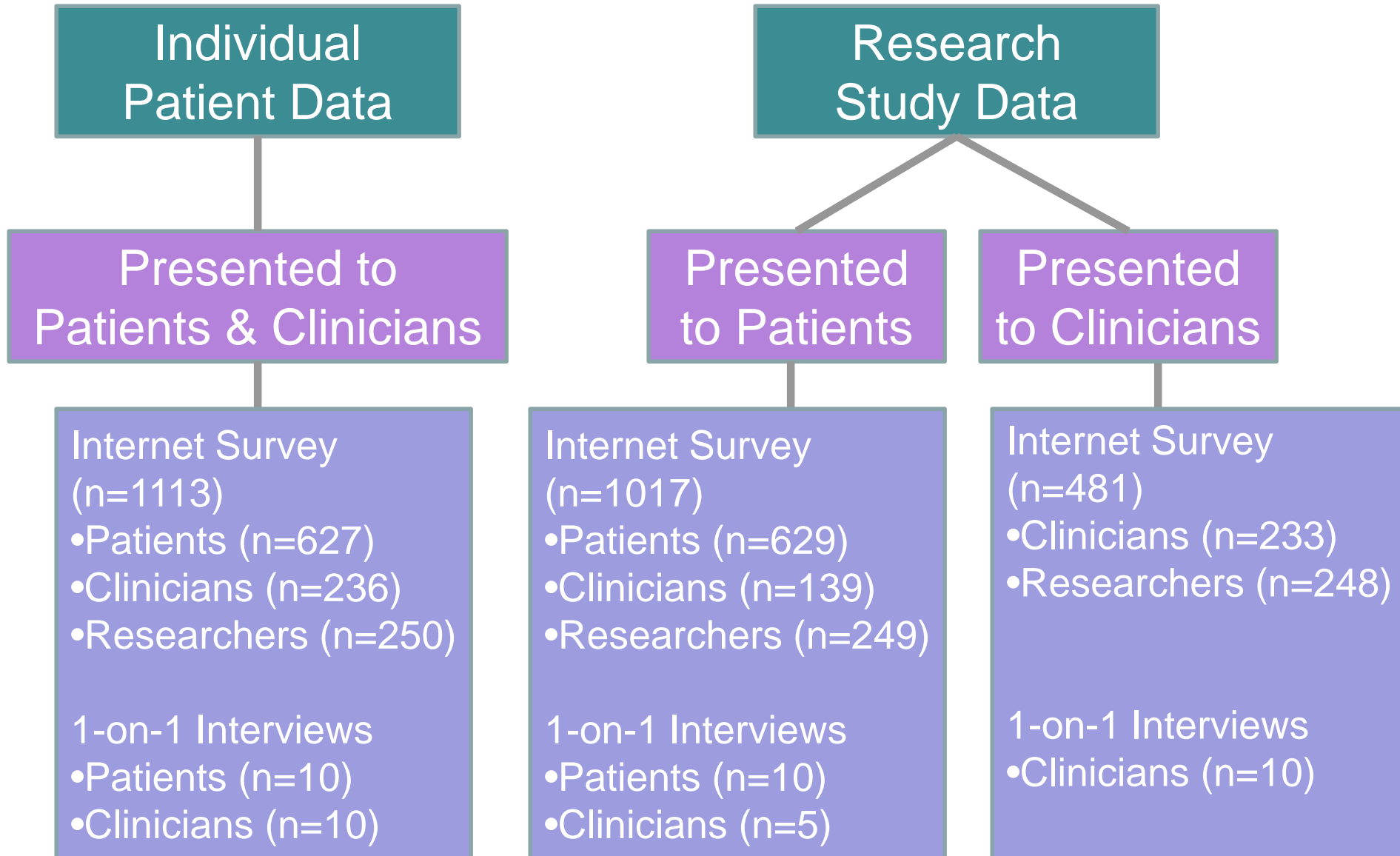
3-Part Mixed Methods Study

1. To what extent do current practices of PRO reporting limit clinician and patient understanding and use? What are the most/least desirable attributes of current practices?
2. What are novel ways to present PRO results to clinicians and patients to improve their usefulness?
3. **Are these novel ways of presenting PROs effective in improving understanding and use of the data?**

Study Population

	Internet Survey	One-on-One Interviews
Cancer Patients/ Survivors	<ul style="list-style-type: none"> Self-reported cancer history 	<ul style="list-style-type: none"> ≤30% of any cancer type Completed acute treatment ≥10% <than college degree ≥30% from Johns Hopkins; ≥30% from other sites
Clinicians	<ul style="list-style-type: none"> Self-identified cancer provider in one of the relevant specialties 	<ul style="list-style-type: none"> Oncologist in active practice (medical, radiation, surgical, gynecologic/urologist, nurse practitioner/physicians assistant, fellow) ≥30% from Johns Hopkins; ≥30% from other sites
PRO Researchers	<ul style="list-style-type: none"> Self-identified 	Not applicable

Approach



Survey Design

- Comparators developed based on results from Parts 1 and 2
- Interpretation accuracy questions
 - Data and questions held constant for format order
 - Data and questions change between formats
 - Survey alerted when format changed
- Clarity ratings on each format
- Open-ended comments
- Select the “Most Useful”
- In-person interviews “think aloud”

Analysis

- Descriptive summary of accuracy questions and clarity ratings
- Chi-square/Fisher's exact testing of "Most Useful"
- Multivariable GEE logistic regression
 - Interpretation accuracy
 - Clarity ratings
 - (adjusting for relevant covariates)
- Qualitative analysis of "think aloud" responses and online comments

Research Data for
Patients:
RESULTS

Final Sample

	Internet Survey	One-on-One Interviews
Cancer Patients/ Survivors	N=629 <ul style="list-style-type: none"> • mean age: 58 • 87% female • 94% white • 23% < college grad • 46% ≤5 years from diagnosis • 56% breast cancer 	N=10 <ul style="list-style-type: none"> • 30% < college grad • 30% breast • 30% from Johns Hopkins 70% from other sites • 70% female • 90% white
Clinicians	N=139 <ul style="list-style-type: none"> • mean age: 44 • 54% female • 70% white • mean years in practice: 16 • 44% medical oncologists 	N=5 <ul style="list-style-type: none"> • ≥1 from each specialty category • 60% from Johns Hopkins 40% from other sites
PRO Researchers	N=249 <ul style="list-style-type: none"> • mean age: 45 • 67% female • 79% white • 46% > 10 years experience 	Not applicable

6 Versions: Each Proportion Format Shown Either Before Or After 1 of 3 Line Graph Types

	Format 1	Format 2	Format 3	Format 4
Version 1	Pies	Bars	Icons	Line Graphs ("More")
Version 2	Bars	Icons	Pies	Line Graphs (Normed)
Version 3	Icons	Pies	Bars	Line Graphs ("Better")
Version 4	Line Graphs ("More")	Pies	Bars	Icons
Version 5	Line Graphs (Normed)	Bars	Icons	Pies
Version 6	Line Graphs ("Better")	Icons	Pies	Bars

Accuracy of Interpretation – Proportions

First Format	Second Format	Third Format
1. At 9 months, on which treatment did more patients <u>improve</u> with regard to doing PHYSICAL activities?	1. At 9 months, on which treatment did more patients <u>improve</u> with regard to EMOTIONAL well-being?	1. At 9 months, on which treatment did more patients stay <u>about the same</u> with regard to FATIGUE?
2. At 9 months, on which treatment did more patients <u>worsen</u> with regard to PAIN?	Not applicable	Not applicable

**Answer
Choices:**

**Treatment
"X"**

**Treatment
"Y"**

**Treatments are
about the same**

Accuracy of Interpretation – Line Graphs

Randomly Assigned Line Graph Set

1. At 12 months, on which treatment are patients better able to do PHYSICAL activities?
2. At 12 months, on which treatment do patients report better EMOTIONAL well-being?
3. At 12 months, on which treatment do patients report worse FATIGUE?

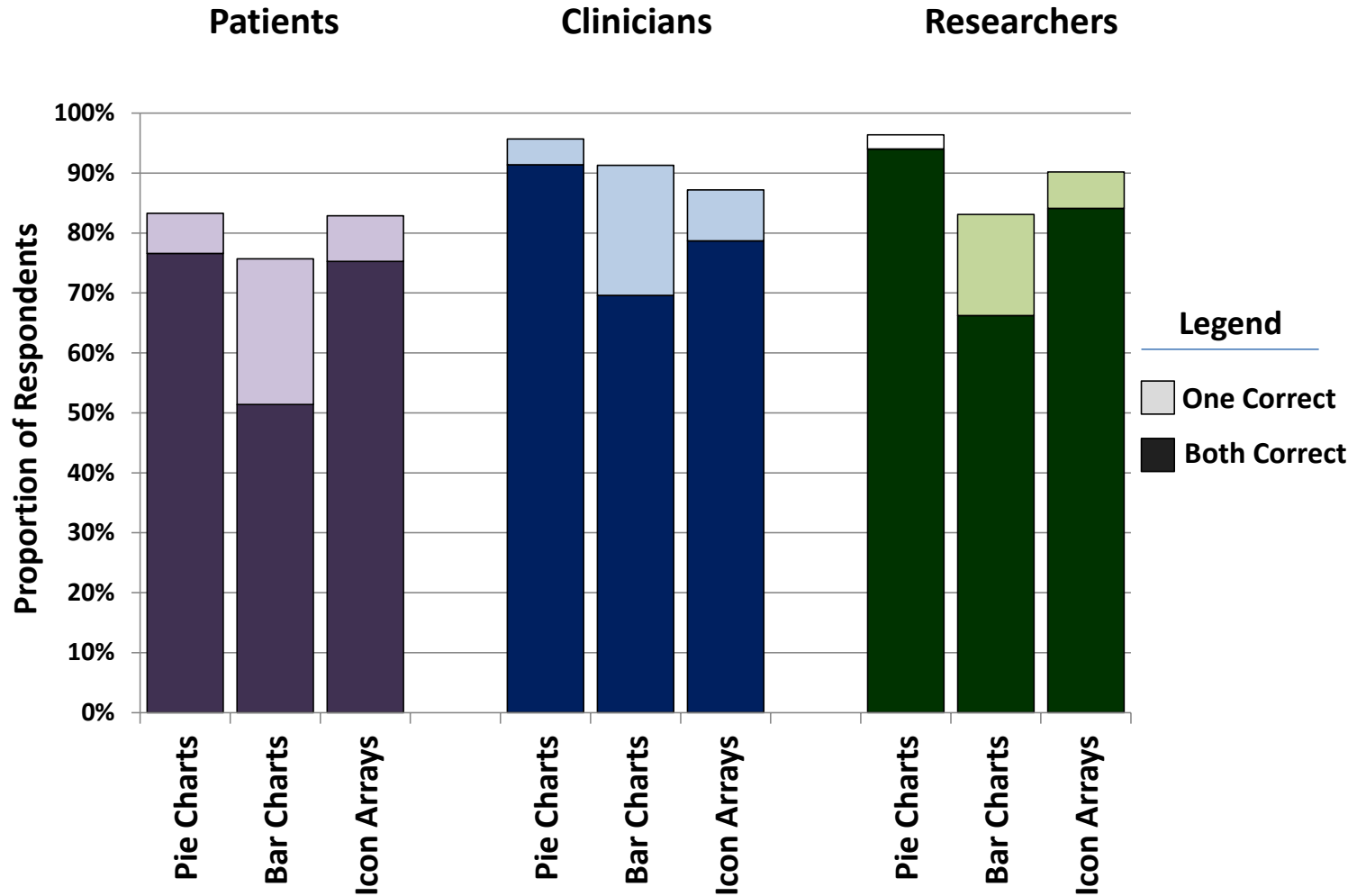
**Answer
Choices:**

**Treatment
"X"**

**Treatment
"Y"**

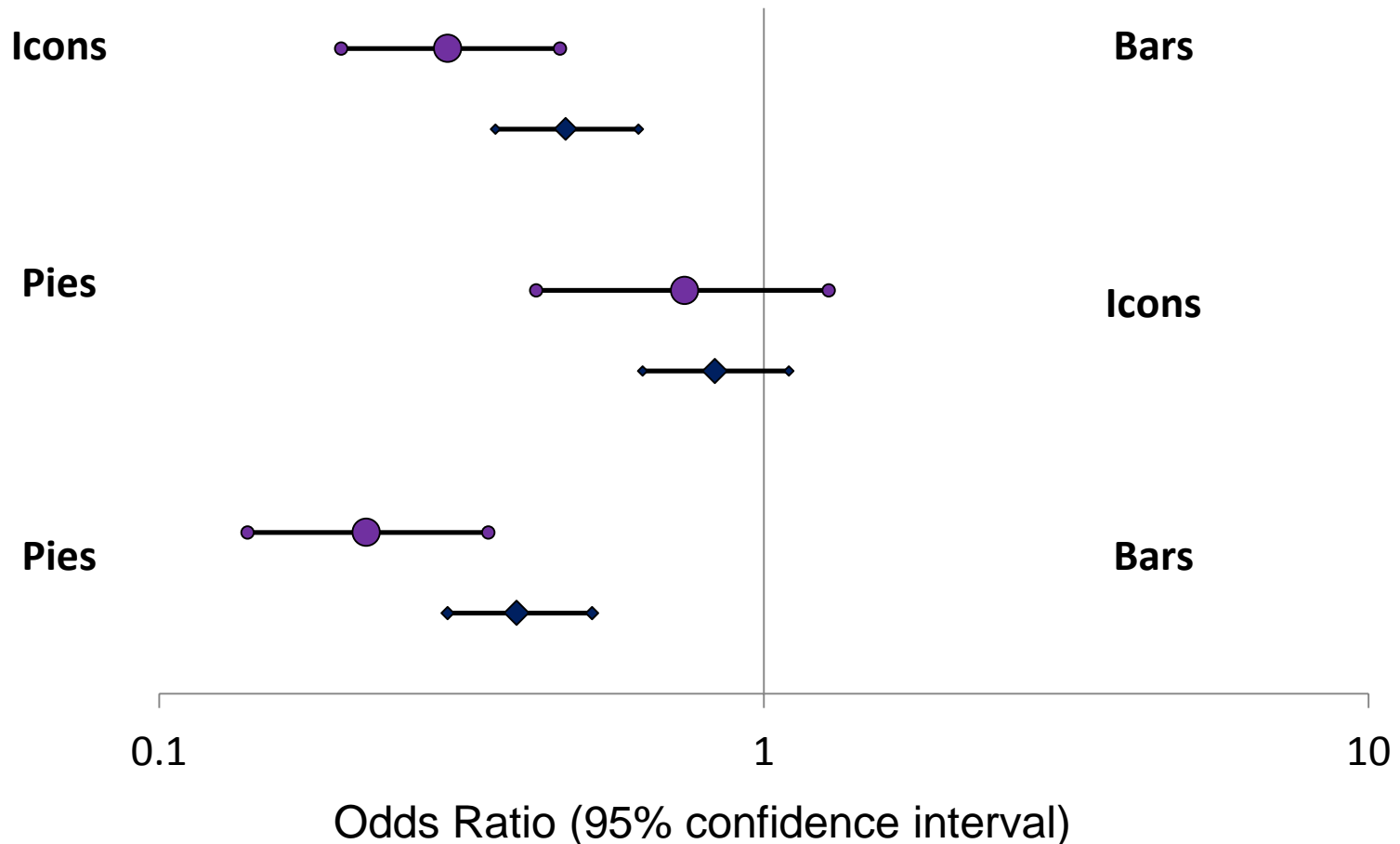
**Treatments are
about the same**

Accuracy of Interpretation: Proportions

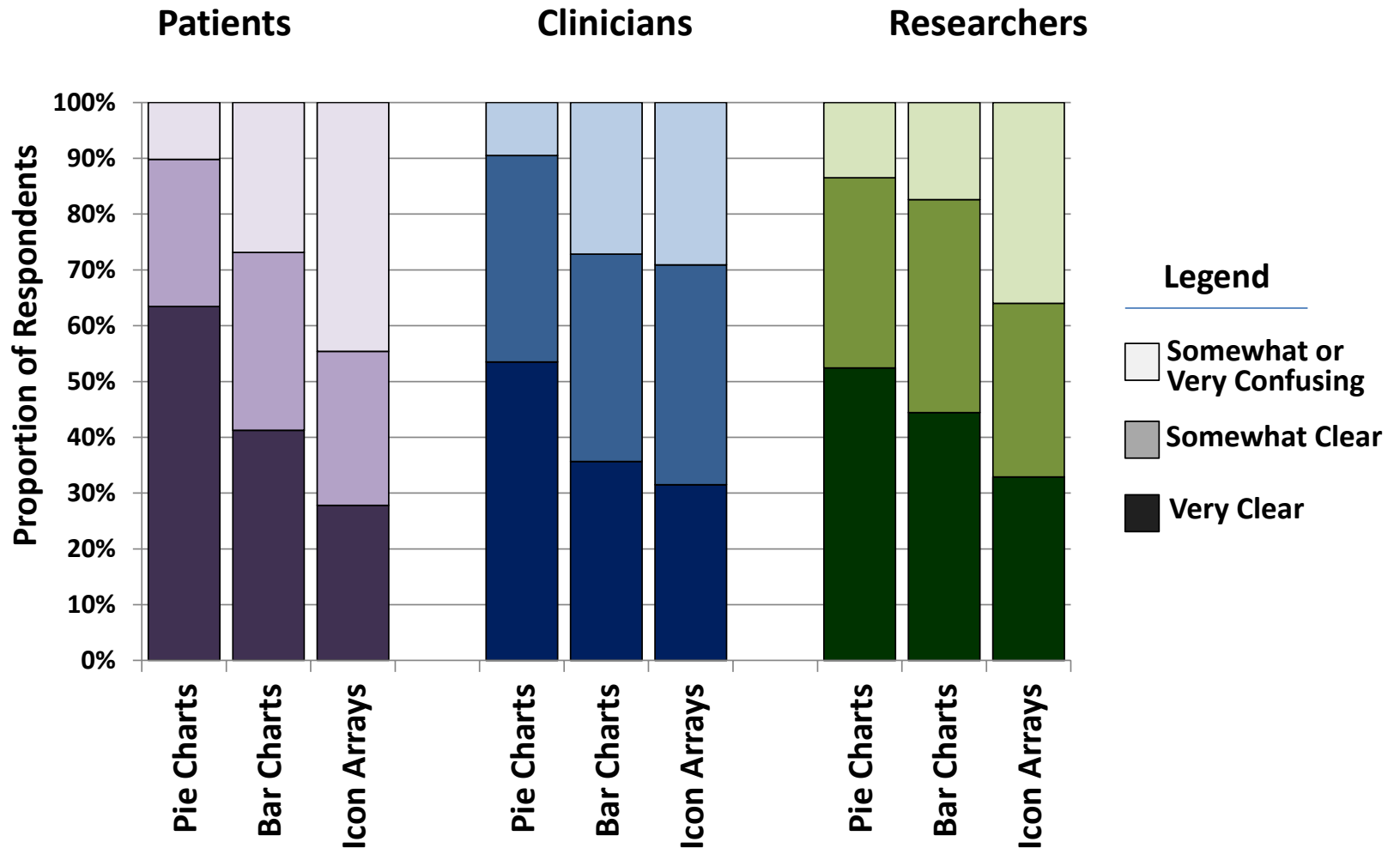


Accuracy of Interpretation: Proportions

- = Correct Answer for First Format Seen
- ◆ = Correct Answer for All Format Questions



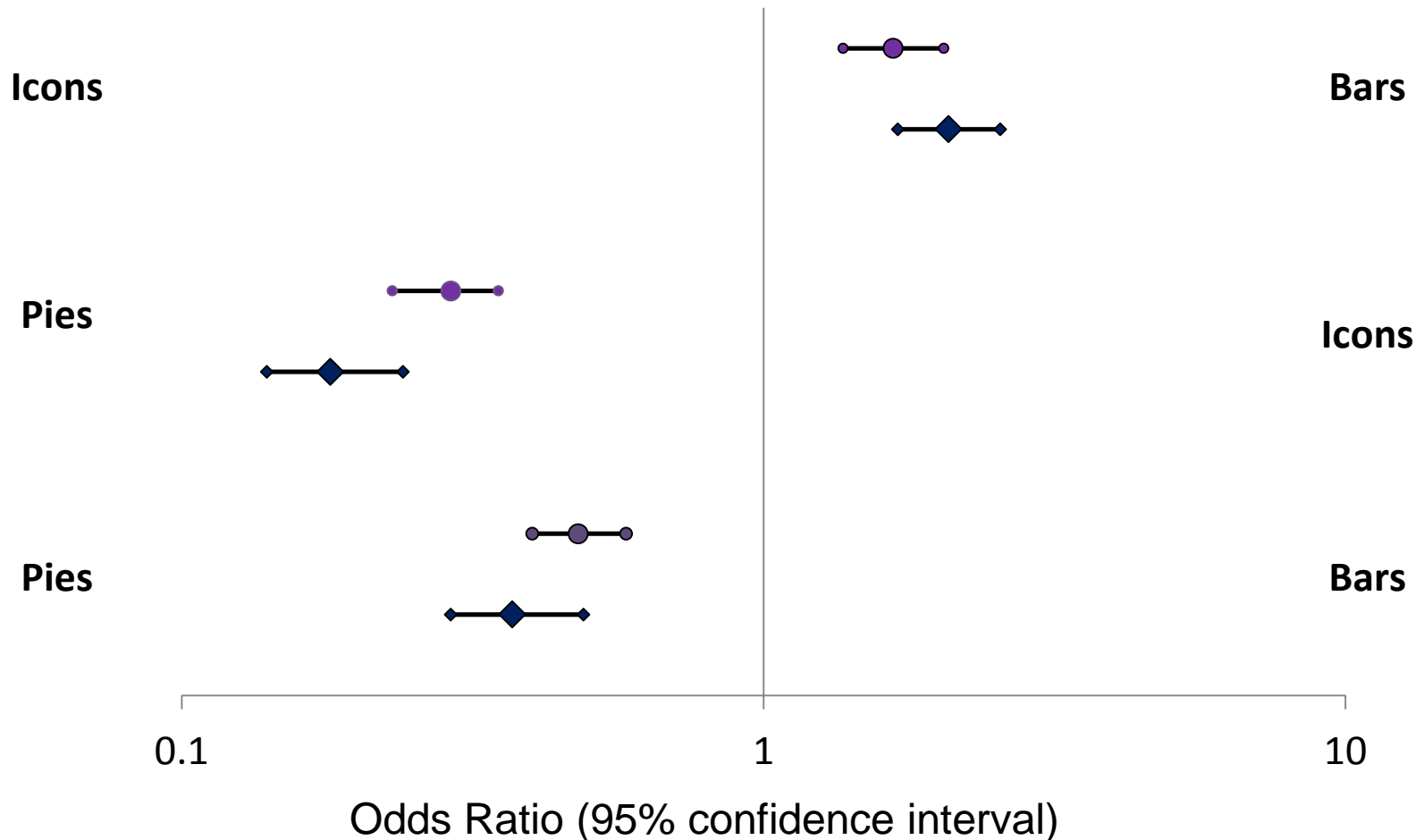
Clarity: Proportions



Clarity Ratings: Proportions

● = Rated “Very” Clear

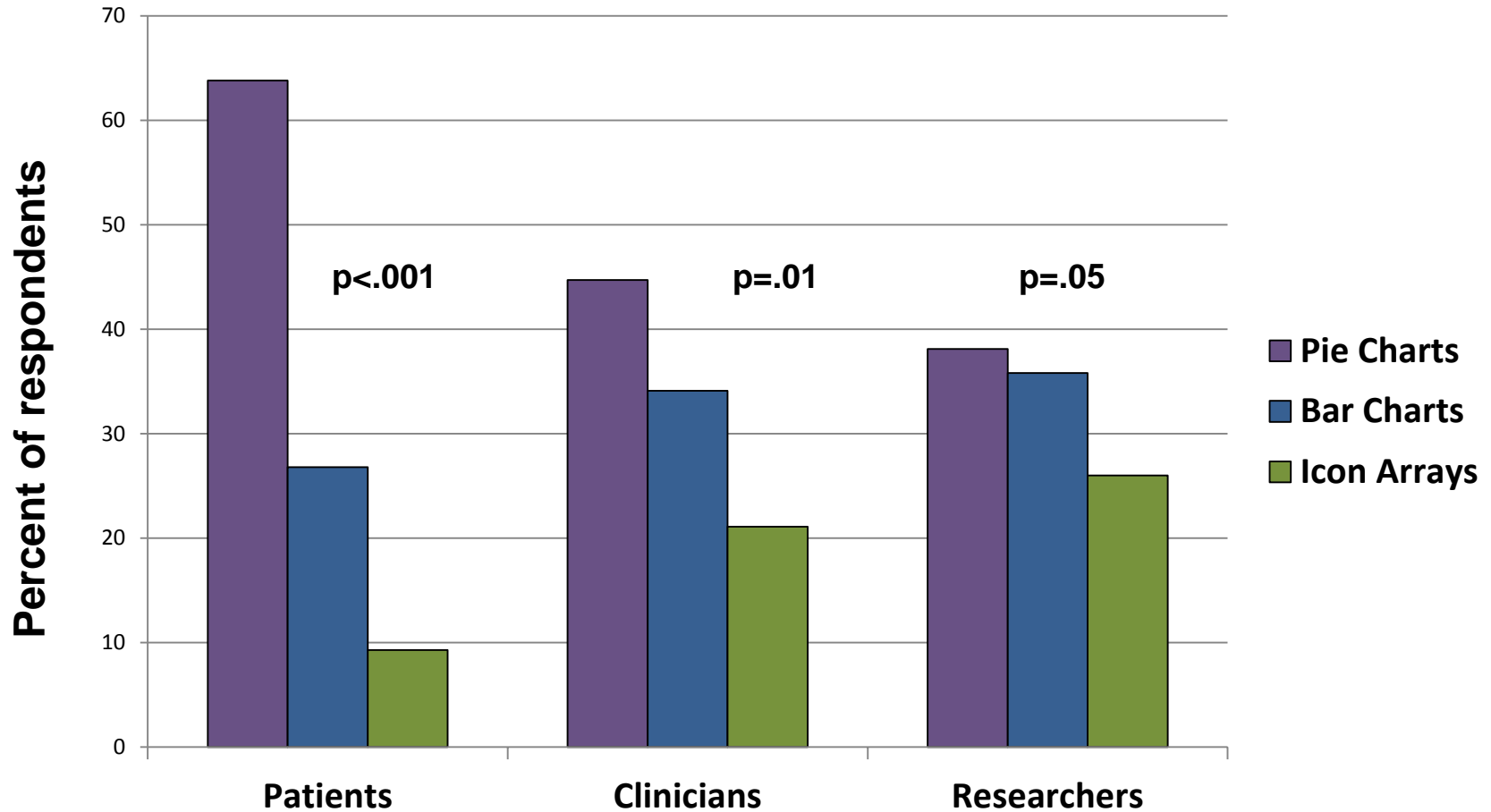
◆ = Rated “Very” or “Somewhat” Clear



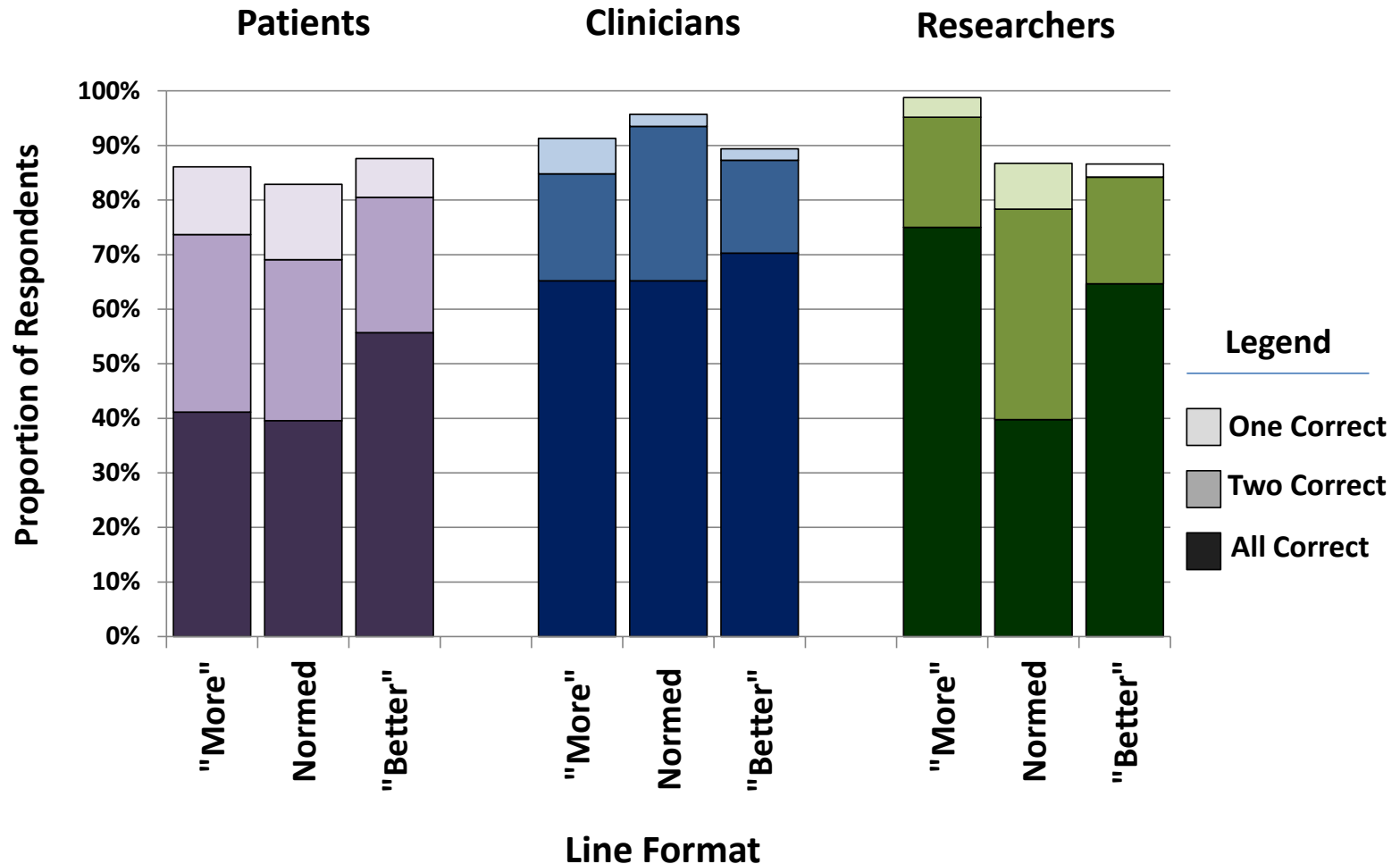
Selected Quotes: Proportions

PIES	BARs	ICONS
POSITIVE <i>"Pie charts are always easy."</i> <i>"The colors work well and it is immediately clear which treatment is better on each pie"</i>	POSITIVE <i>"Easy to compare treatments side by side in column graph."</i> <i>"Very crisp, visually clean and it's easy to extract information"</i>	POSITIVE <i>"Represent people which too often gets lost in looking at cancer statistics"</i> <i>"Cute and pleasant, and manage to convey the information in a clear and concise way"</i>
NEGATIVE <i>"Very difficult to interpret"</i> <i>"The only time a pie chart is appropriate is at a bakers' convention"</i>	NEGATIVE <i>"You have to concentrate to ascertain what they mean"</i> <i>"Too clinical looking for the everyday patient"</i>	NEGATIVE <i>"Wouldn't want to have to sit and count the little people"</i> <i>"Looks overwhelming and very busy - which makes it hard to interpret"</i>

Selected Most Useful: Proportions

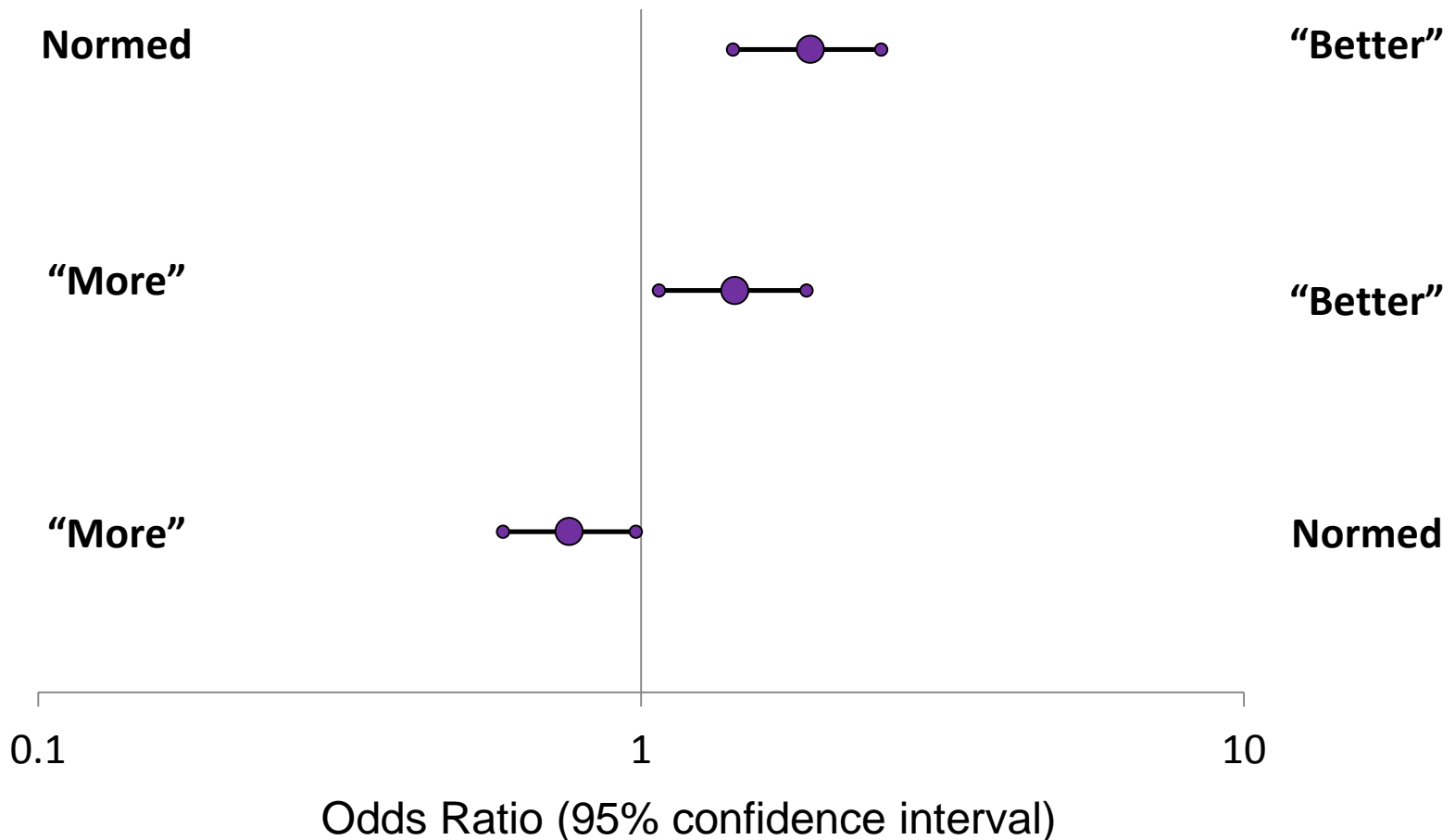


Accuracy of Interpretation: Line Graphs

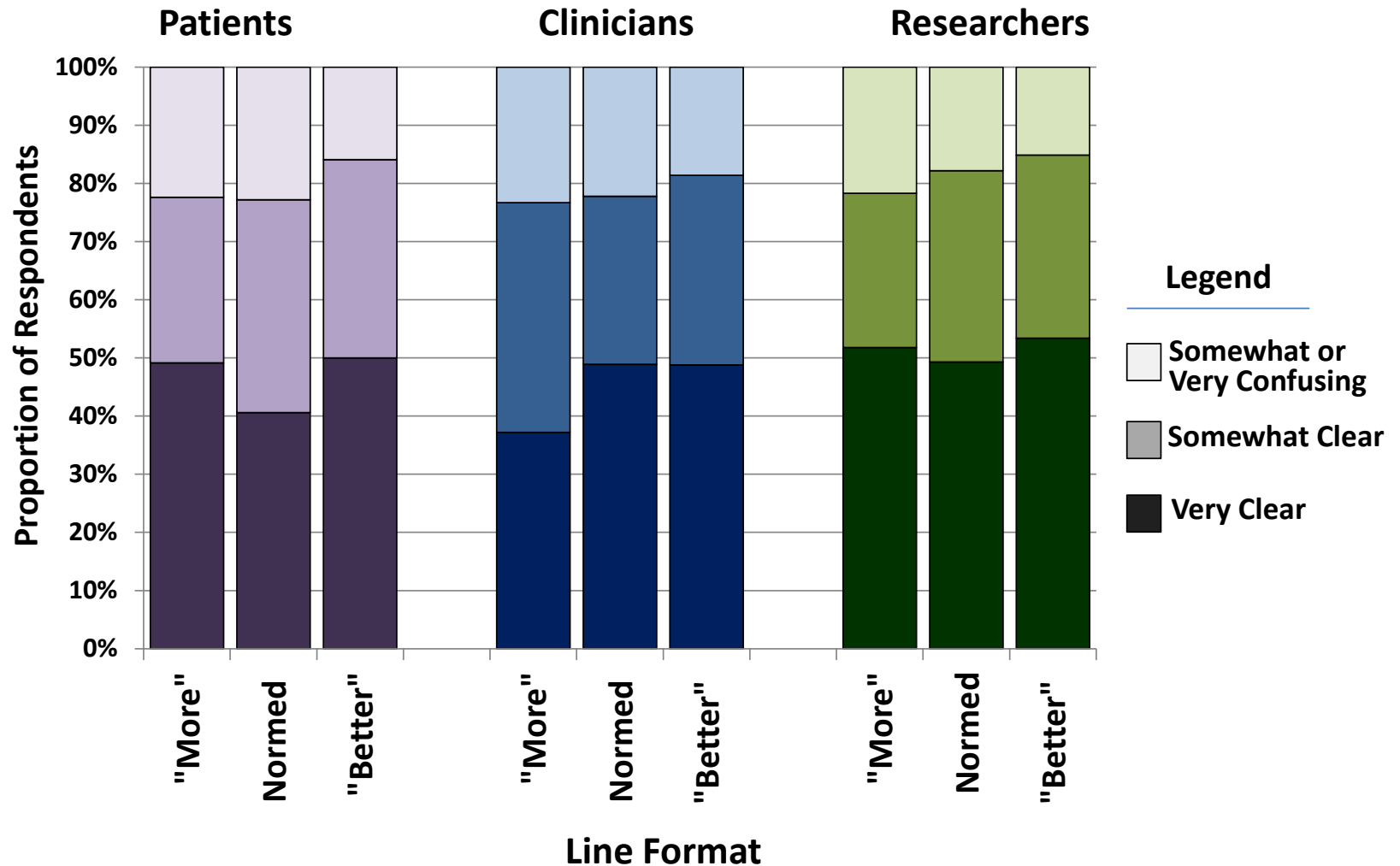


Accuracy of Interpretation: Line Graphs

● = Correct Answers



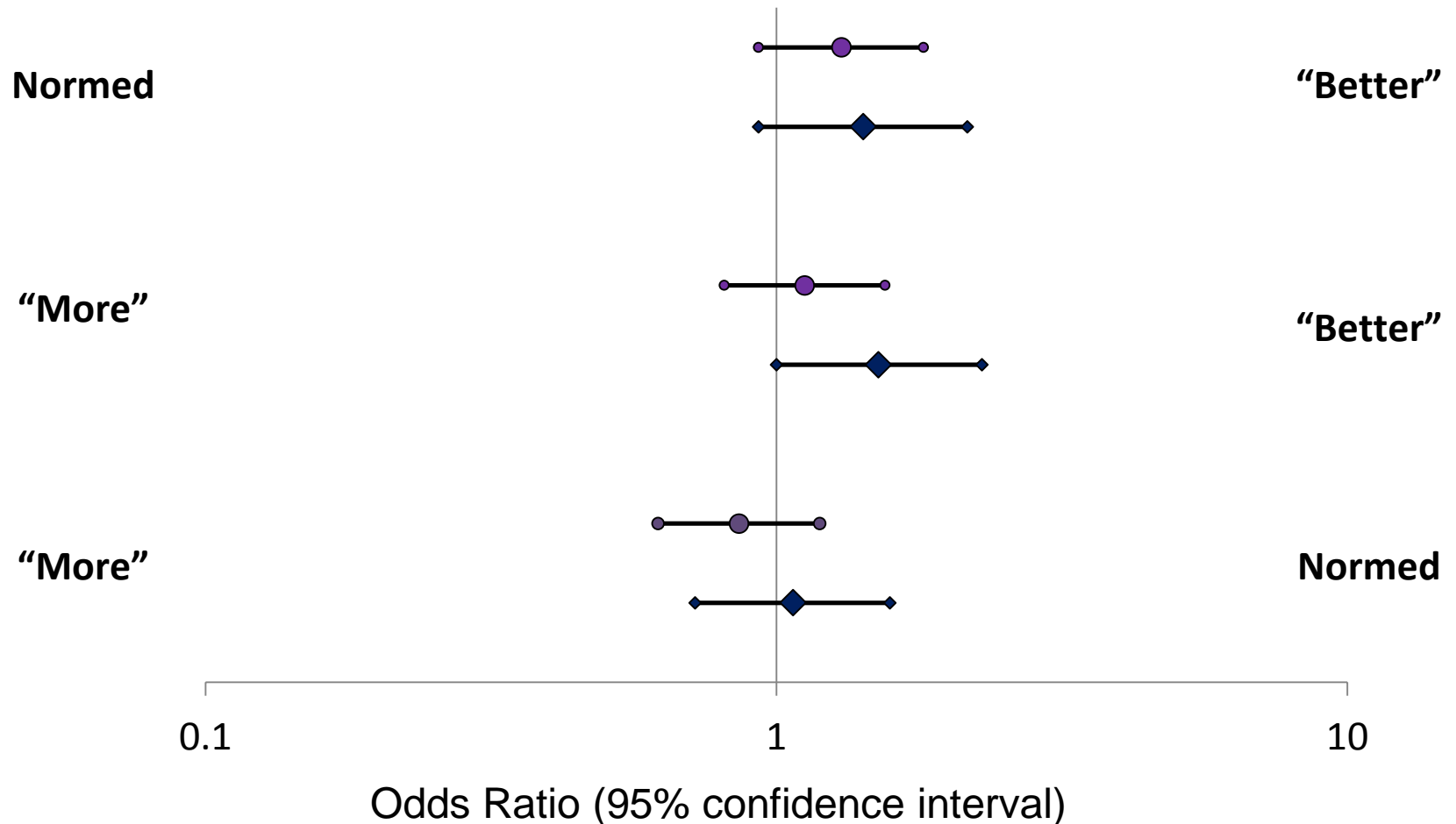
Clarity: Line Graphs



Clarity Ratings: Line Graphs

● = Rated “Very” Clear

◆ = Rated “Very” or “Somewhat” Clear



Selected Quotes: Line Graphs

POSITIVE

“The time dependency is great. Could show, for example if the relative differences are getting farther apart or not, rather than that someone else picked a single, arbitrary date.” [P; re. “more” lines]

“Good to demonstrate changes over time.” [R, re. “better” lines]

NEGATIVE

“The fact that the positive/negative scale changes between functioning and symptoms (so that ‘up’ means different things) makes error much, much more likely in interpreting these graphs.” [P, re. “more” lines]

“How is the average for US adults calculated?” [R, re. normed lines]

Summary

- Pie charts
 - Most accurately interpreted
 - Most likely to be rated clear
 - Rated best for proportions
- Line graphs with higher always indicating better outcomes
 - More accurately interpreted
 - More likely to be rated clear than “more” line graphs

Tolbert E, Brundage M, Bantug E, Blackford AL, Smith K, Snyder C; PRO Data Presentation Stakeholder Advisory Board. Picture This: Presenting Longitudinal Patient-Reported Outcome Research Study Results to Patients. Med Decis Making. 2018; *In press*.

Tolbert E, Brundage M, Bantug E, Blackford AL, Smith K, Snyder C; PRO Data Presentation Stakeholder Advisory Board. In Proportion: Approaches for Displaying Patient-reported Outcome Research Study Results as Percentages Responding to Treatment; *Under review*.

Research Data for
Publication:
RESULTS

Final Sample

	Internet Survey	One-on-One Interviews
Clinicians	<p>N=233</p> <ul style="list-style-type: none">• mean age: 41• 55% female• mean years in practice: 16• 55% medical oncologists	<p>N=10</p> <ul style="list-style-type: none">• 3 surgical oncologists;• ≥1 from each specialty category• 5 from Johns Hopkins• 5 from other sites
PRO Researchers	<p>N=248</p> <ul style="list-style-type: none">• mean age: 43• 63% female• 38% > 10 years experience• 37% psychology / sociology• 35% clinician / clinician scientist	Not applicable

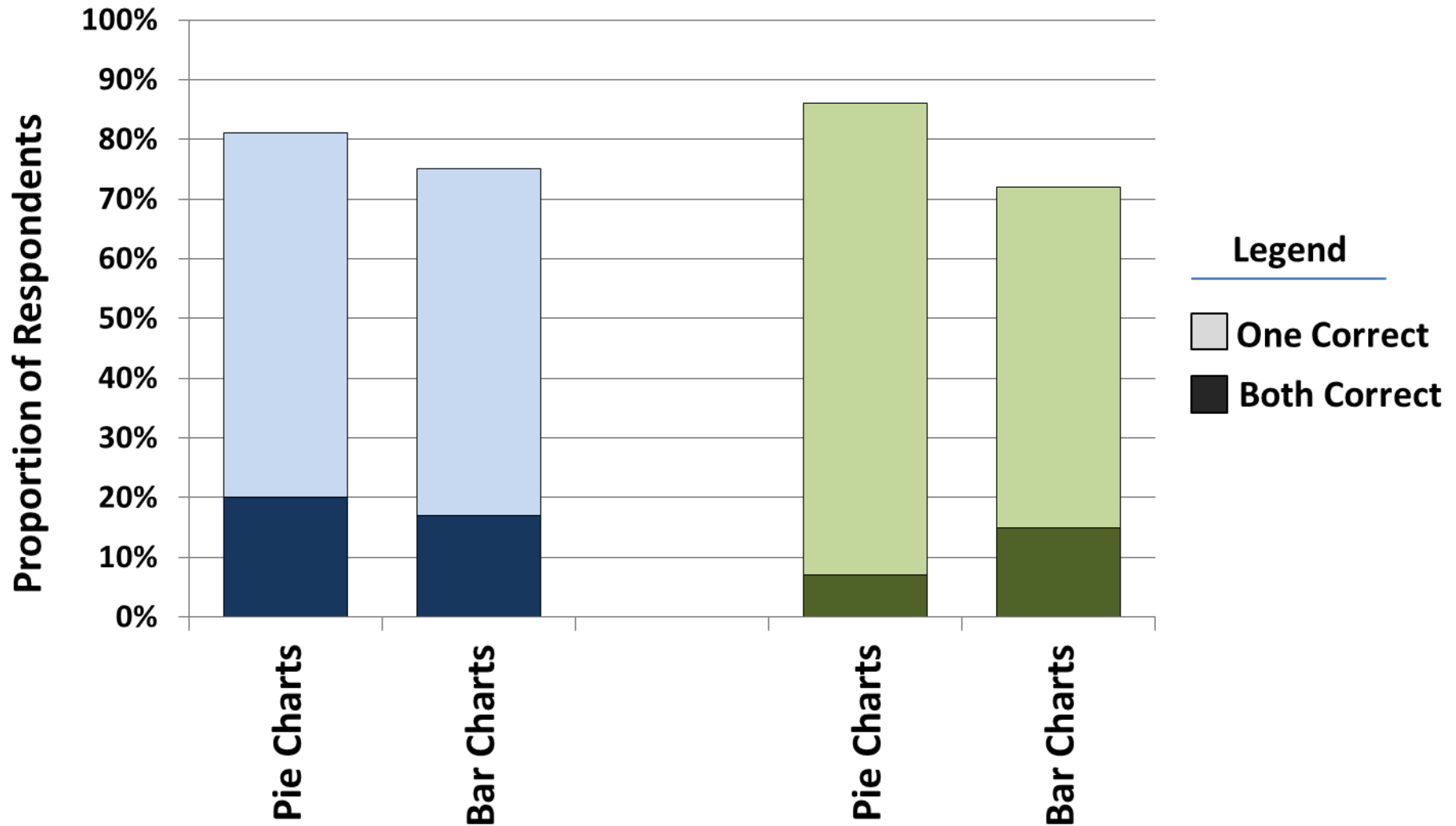
Overview of Presentation Order

	Line Graphs of Average Scores			Proportions Changed	
	Format 1	Format 2	Format 3	Format 4	Format 5
Version 1	Confidence Limits	Clinical Significance	Plain	Pies	Bars
Version 2	Plain	Confidence Limits	Clinical Significance	Pies	Bars
Version 3	Clinical Significance	Plain	Confidence Limits	Pies	Bars
Ver. 4-6	As per 1-3, lines normed to 50			Pies	Bars
Ver. 6-9	As per 1-3, “More” symptom scores			Pies	Bars
Ver. 10-18	As per 1-9			Bars	Pies

Accuracy of Interpretation: Proportions

Clinicians

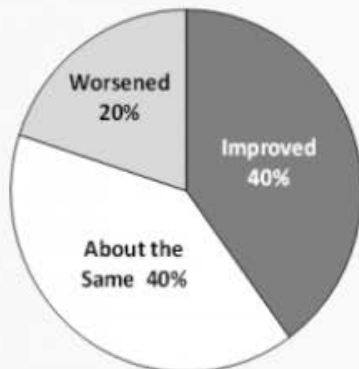
Researchers



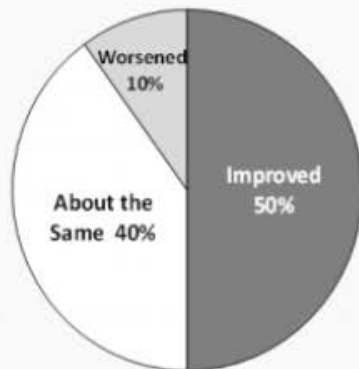
Status of 100 patients 9 months after starting treatment

Ability to Do Physical Activities

Treatment "X"



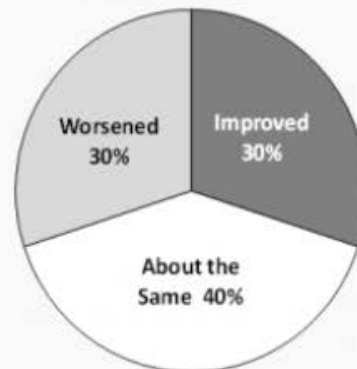
Treatment "Y"



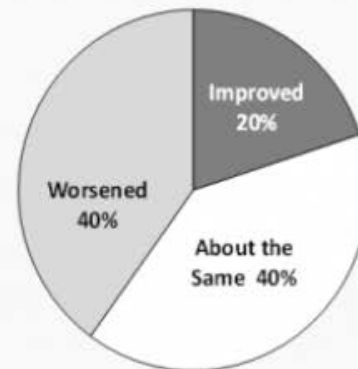
$p=0.10$

Emotional Well-Being

Treatment "X"



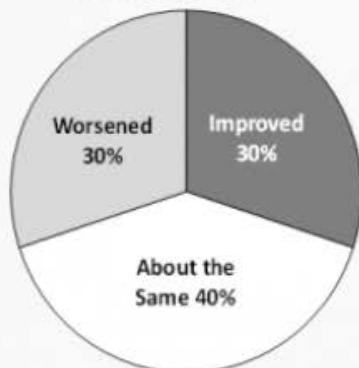
Treatment "Y"



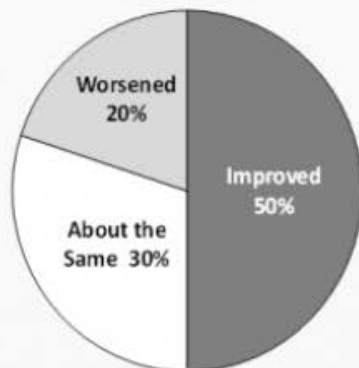
$p=0.04$

Pain

Treatment "X"



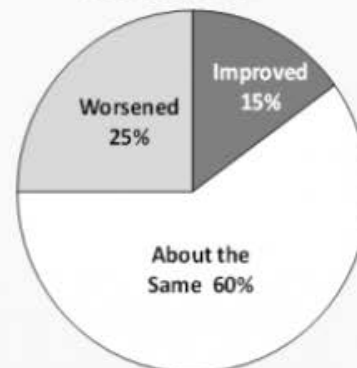
Treatment "Y"



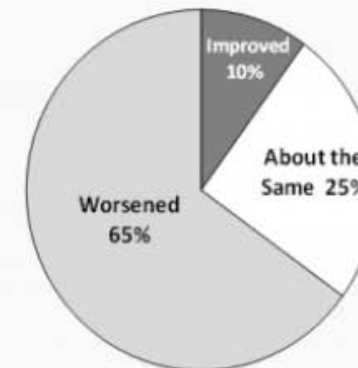
$p=0.01$

Fatigue

Treatment "X"



Treatment "Y"

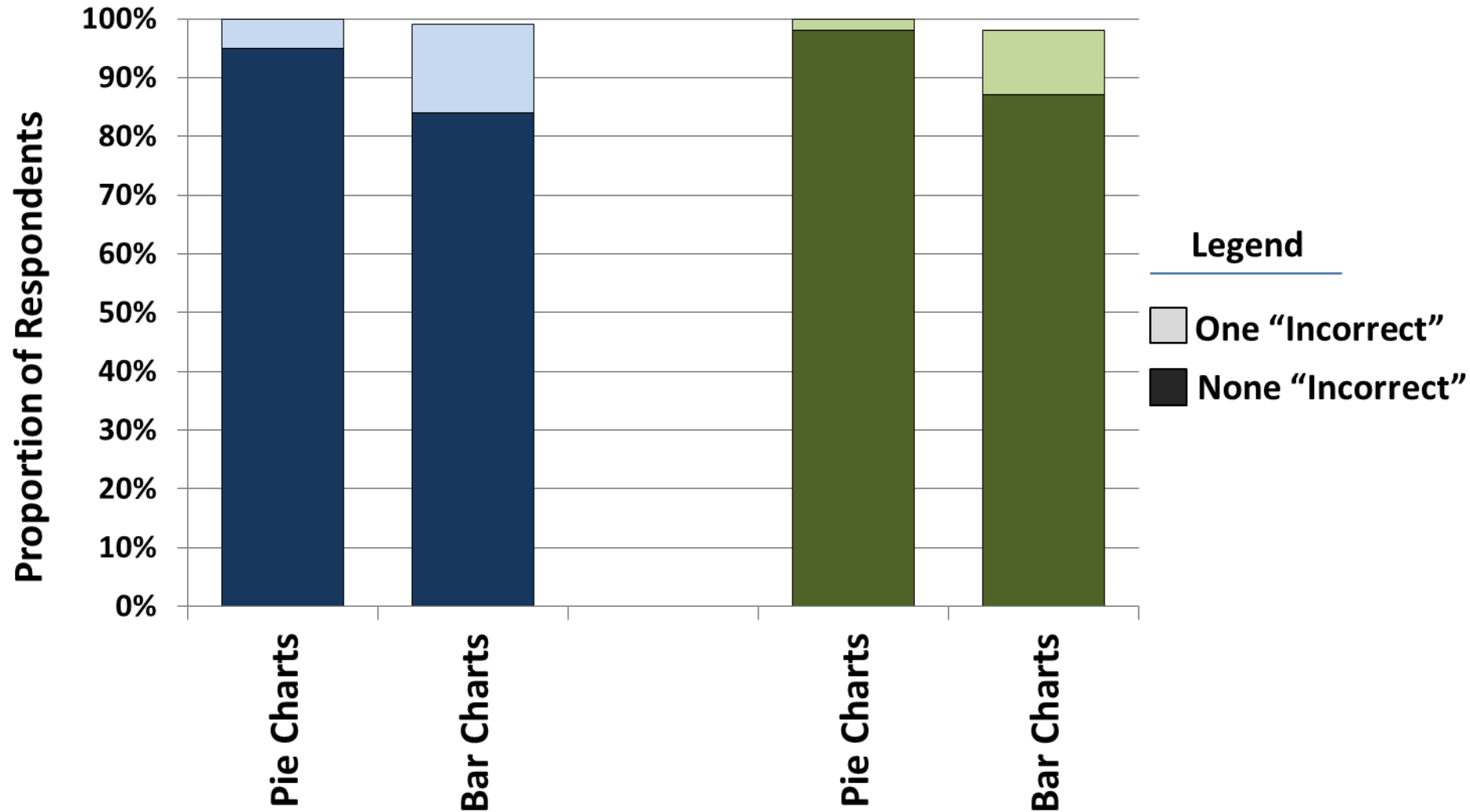


$p=0.001$

Accuracy of Interpretation: Proportions

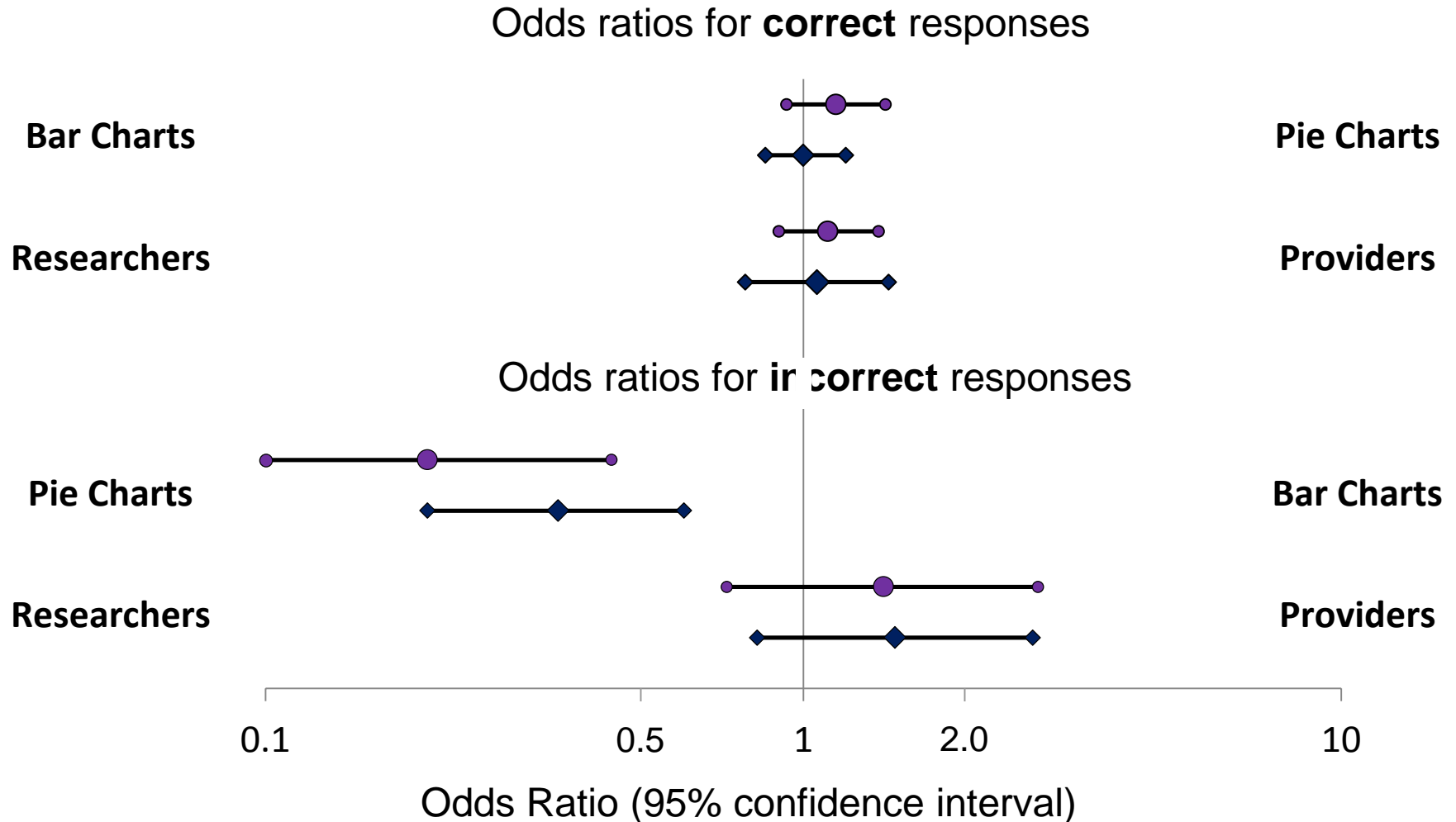
Clinicians

Researchers



Accuracy of Interpretation: Proportions

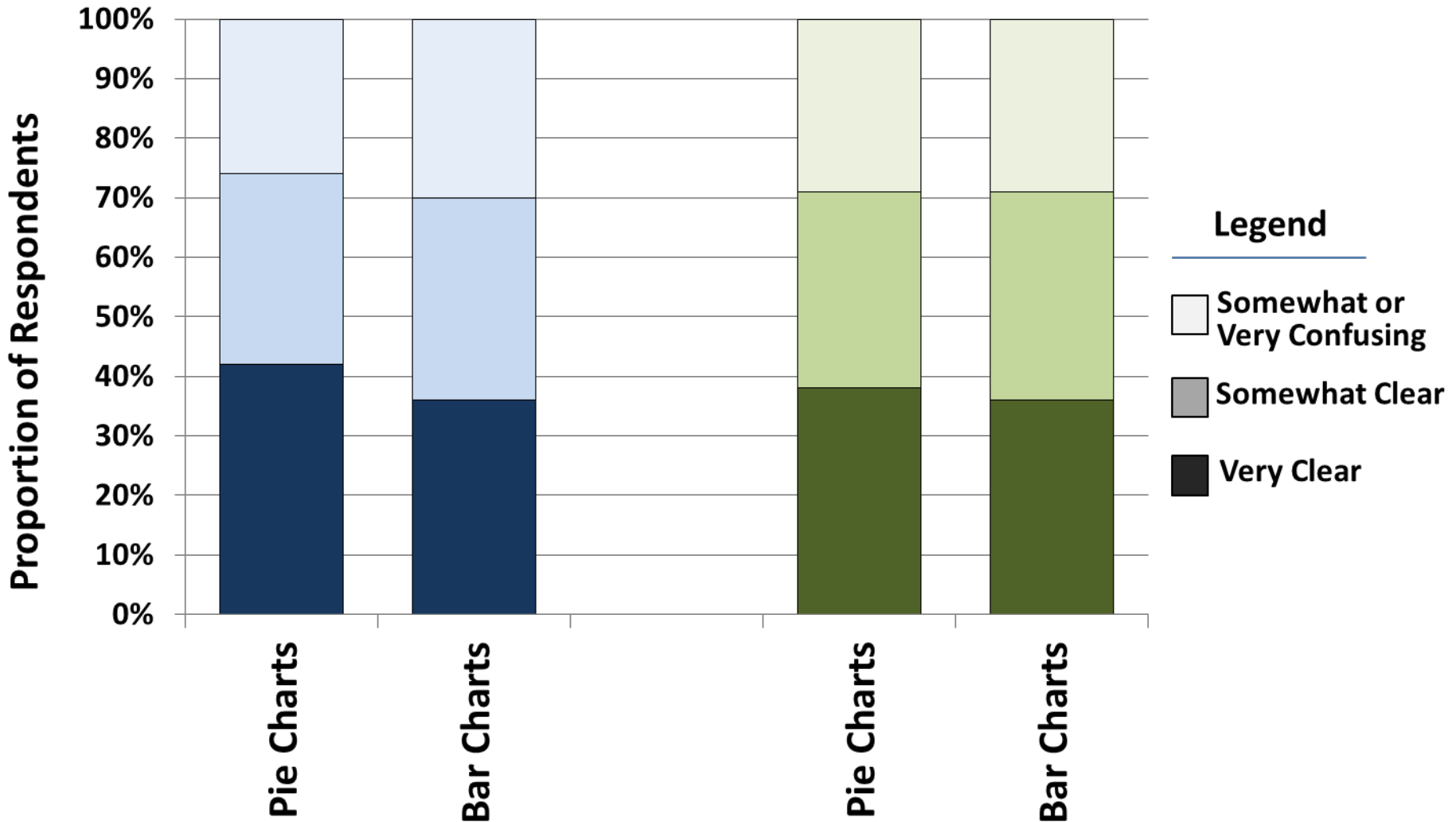
- = First Format Seen
- ◆ = All Format Questions



Clarity: Proportions

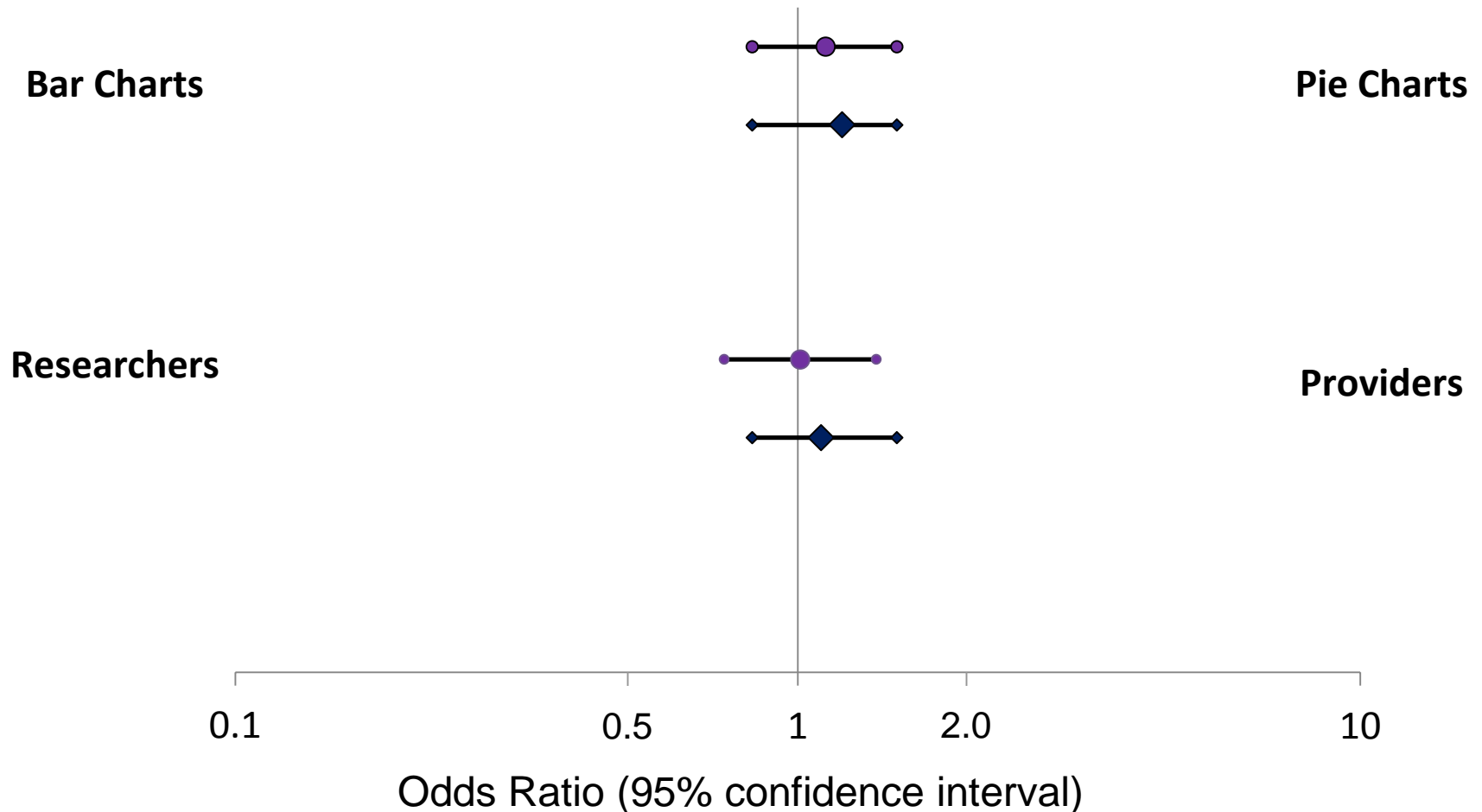
Clinicians

Researchers



Clarity Ratings: Proportions

- = Rated “Very” Clear
- ◆ = Rated “Very” or “Somewhat” Clear



Selected Quotes: Proportions

PIES

POSITIVE

“A pie chart is always easier on the eye”

“I think it’s just easier for my brain to see and compare the two charts...the bar graph takes me a little bit longer to compare treatments”

NEGATIVE

“It’s not a format that I’m used to seeing to have the data presented and so it did catch me off guard initially”

“Bar graph is easier to describe patient results compared to the pie graph”

BARS

POSITIVE

“I find this graph to be much easier to read than the pie charts”

“(Bar charts)...can show each category, improved, about the same or worsened, head to head against the two treatment...for pie graphs you have to bounce back and forth to see the direct comparisons”

NEGATIVE

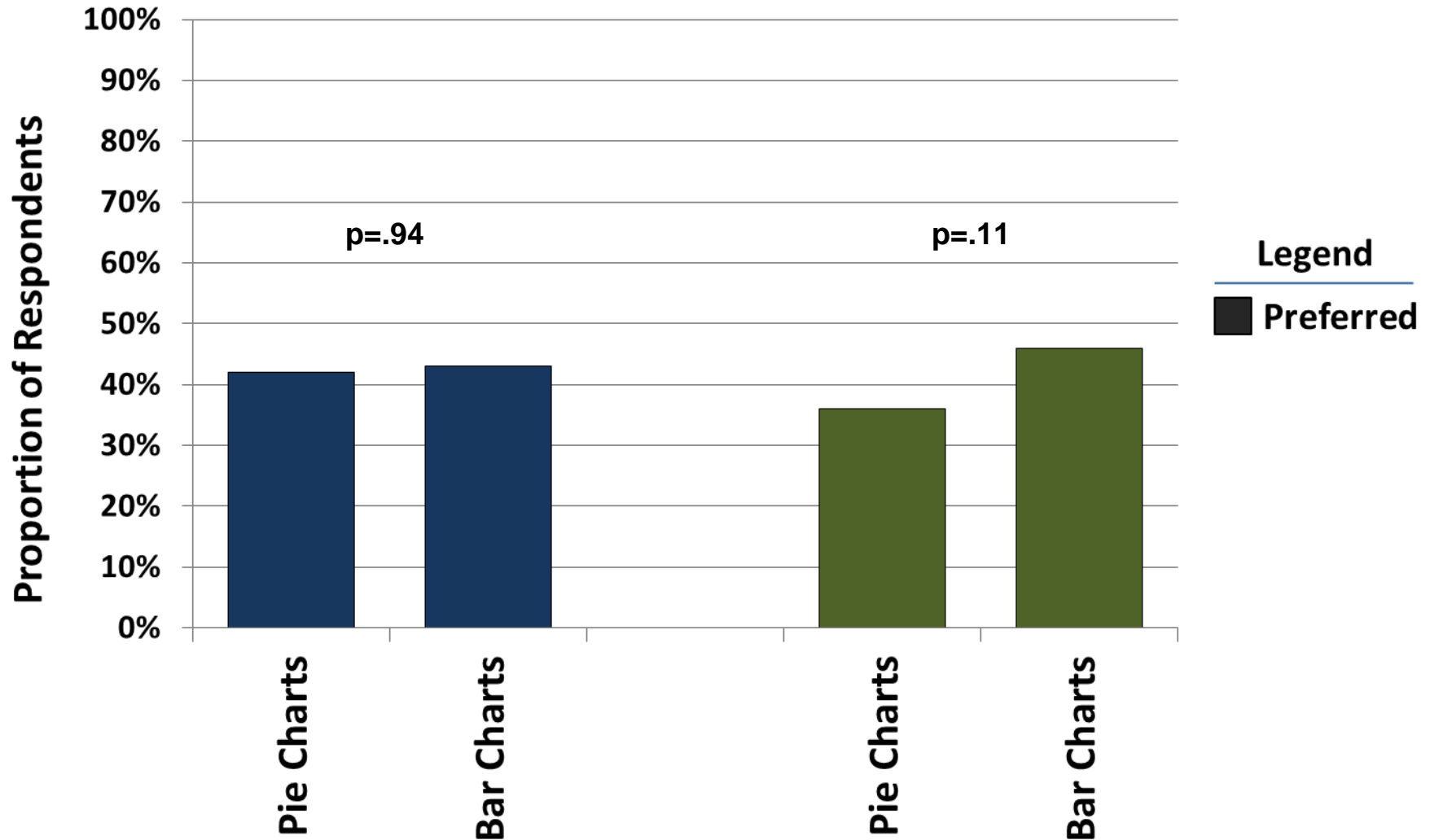
“The bar graph takes me a little bit longer to compare the two (treatments)”

“I find these bar charts to be difficult to interpret. They take more time and likely are going to be more prone to error in interpretation”

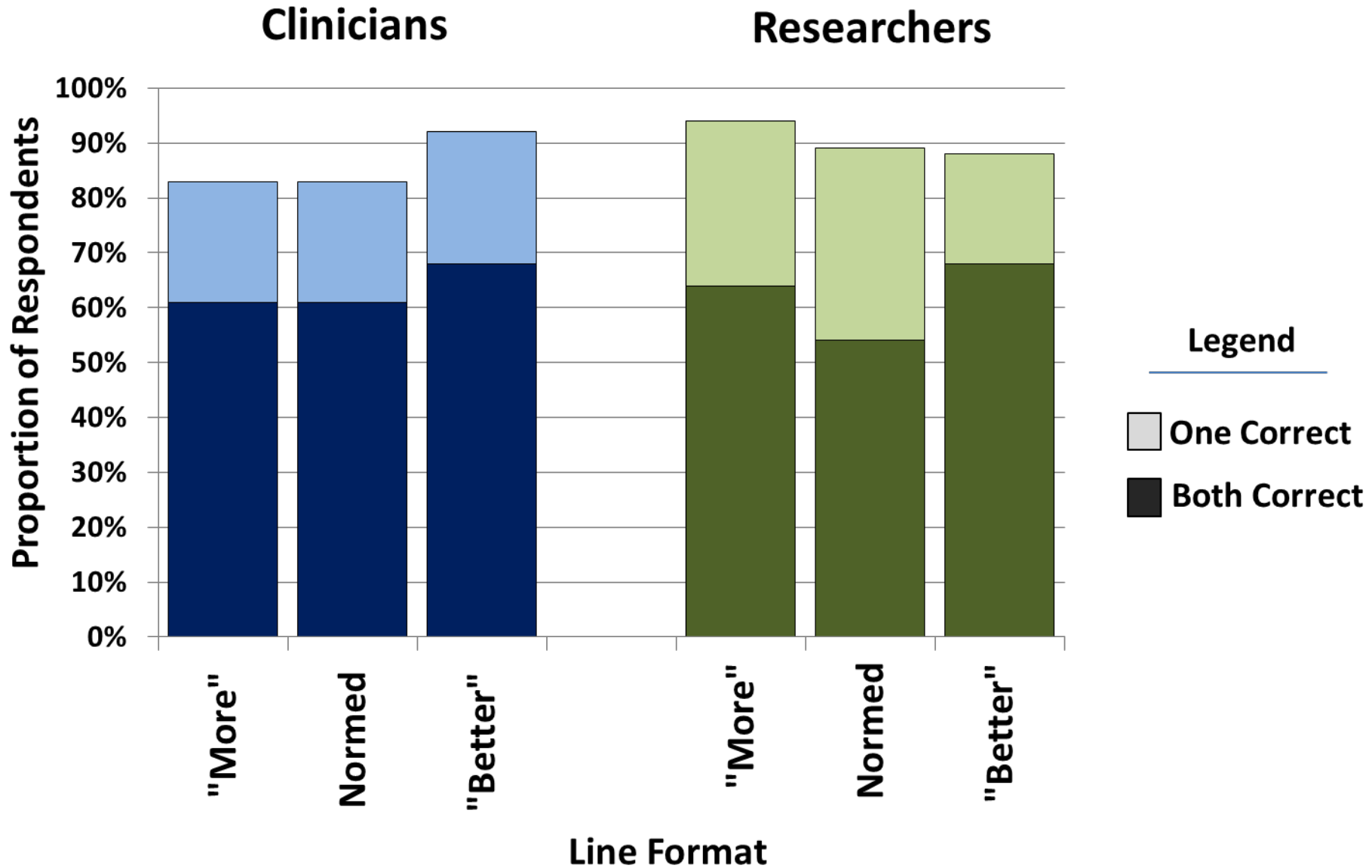
Selected Most Useful: Proportions

Clinicians

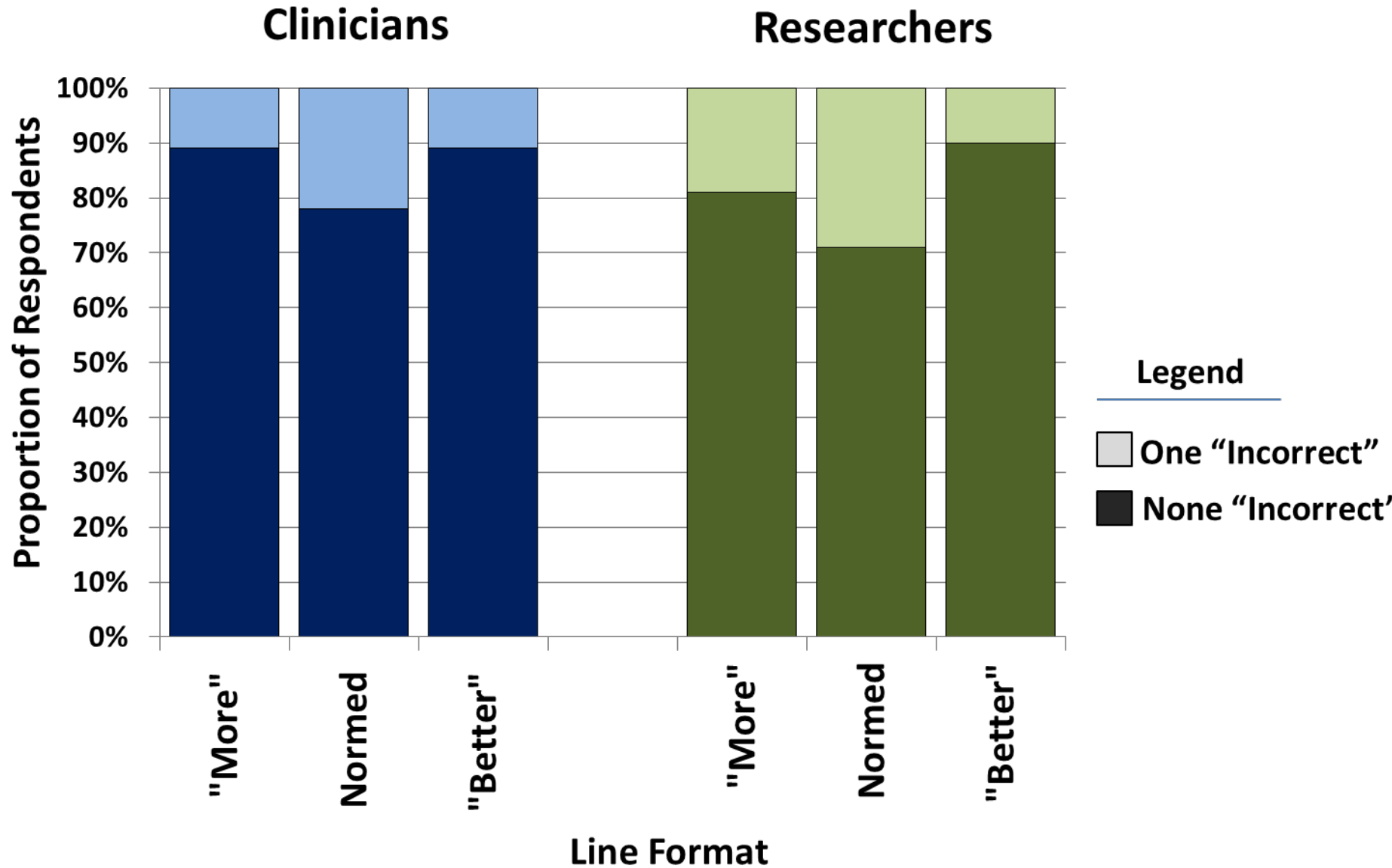
Researchers



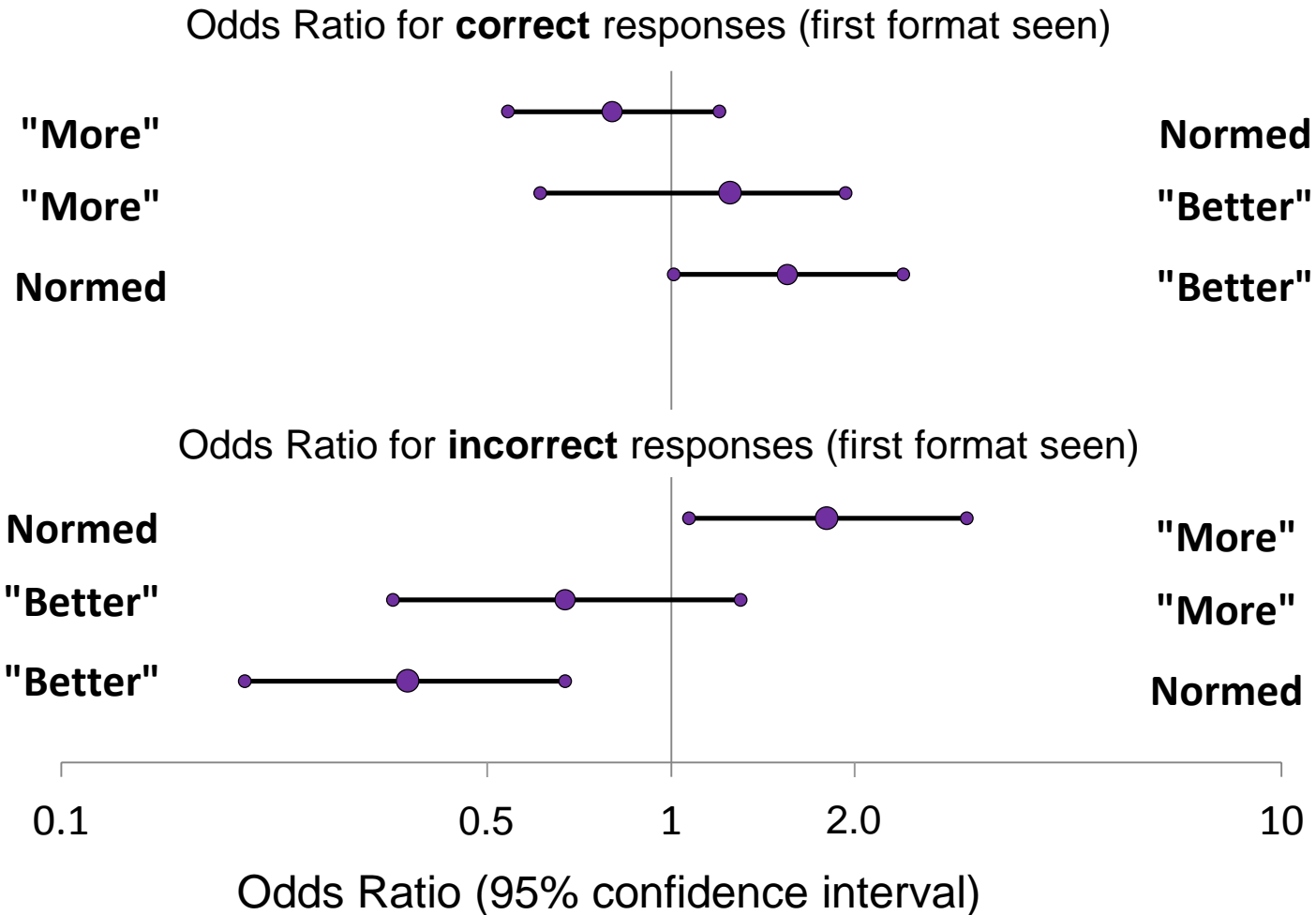
Accuracy of Interpretation: Lines



Accuracy of Interpretation: Lines



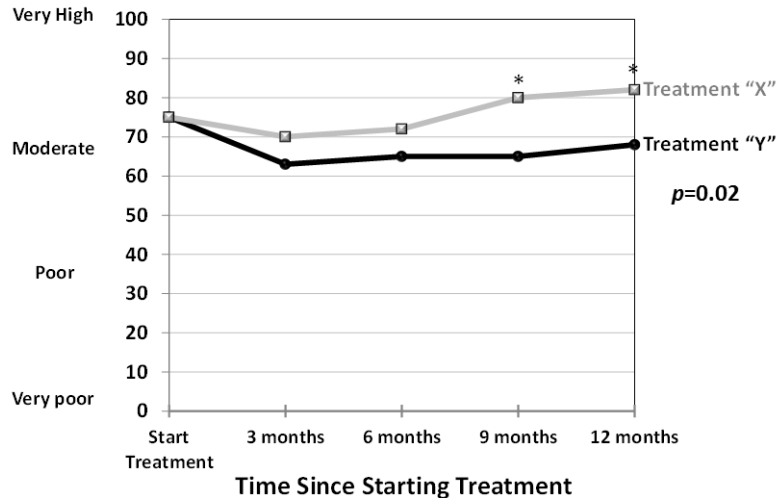
Accuracy of Interpretation: Lines



Patient's Functioning

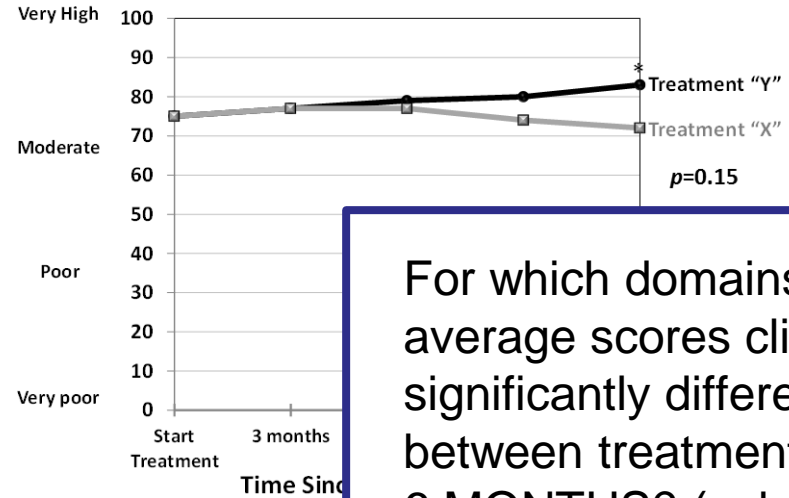
Physical

(line going up means better able to do physical activities)



Emotional

(line going up means better emotional well-being)

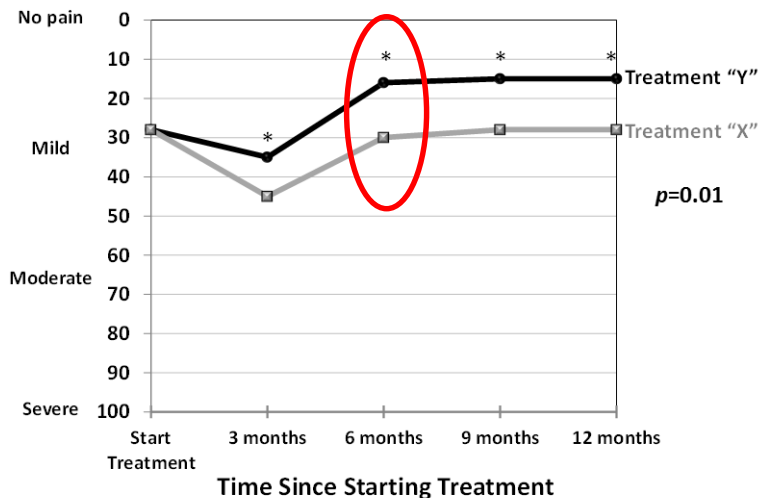


For which domains are average scores clinically significantly different between treatments at 6 MONTHS? (select any that apply)

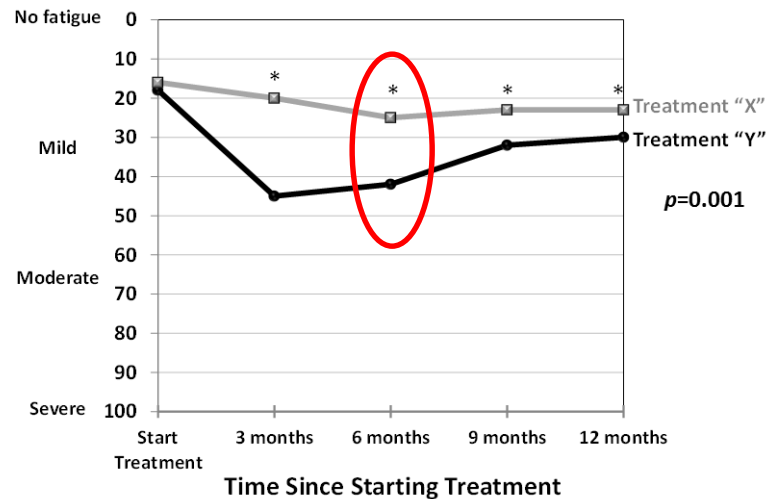
Patient's Symptoms

Pain

(line going up means less pain)



(line going up means less fatigue)



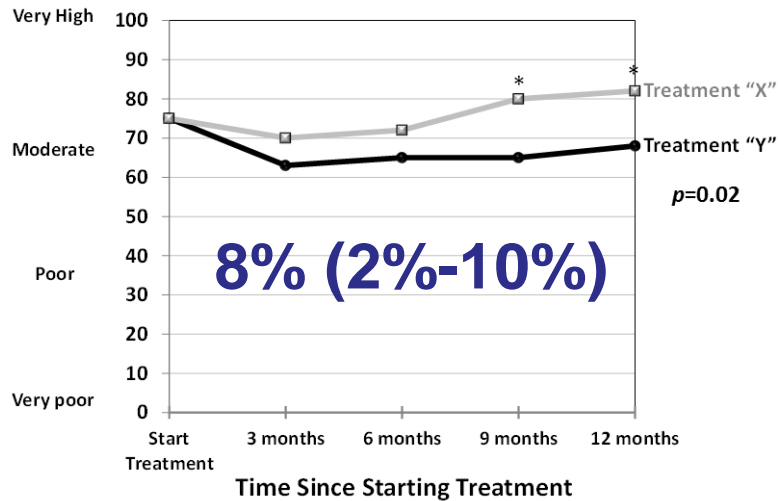
Legend: For all graphs, p -values are for between-treatment differences over time.

*indicates differences between treatments that are clinically important

Patient's Functioning

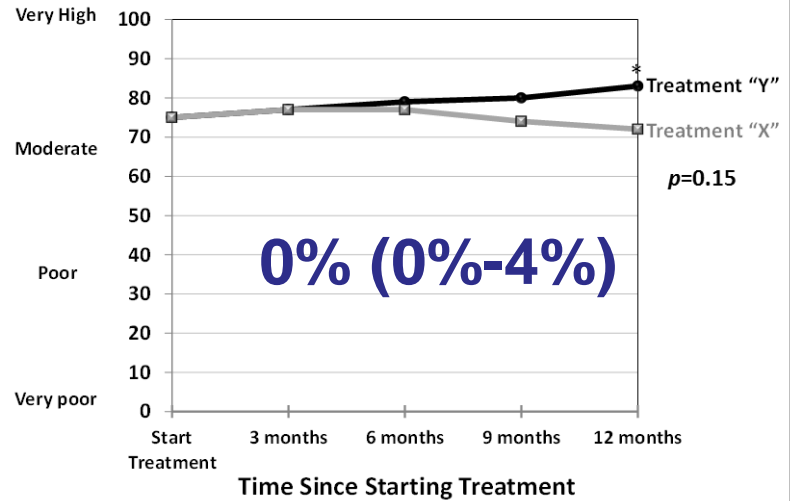
Physical

(line going up means better able to do physical activities)



Emotional

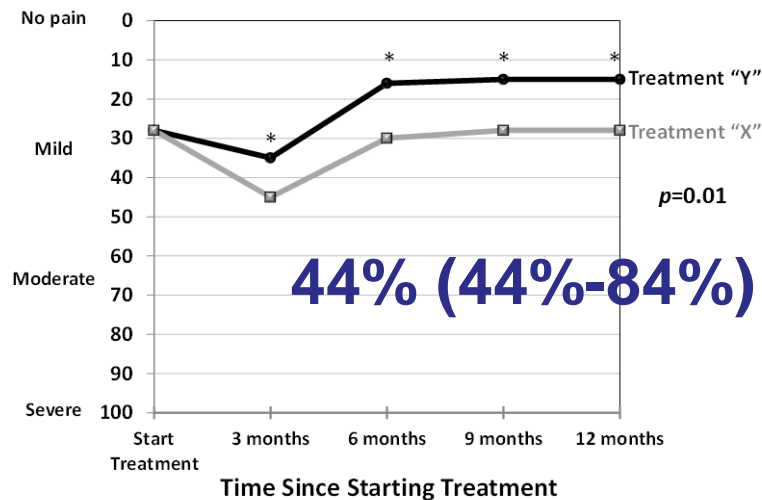
(line going up means better emotional well-being)



Patient's Symptoms

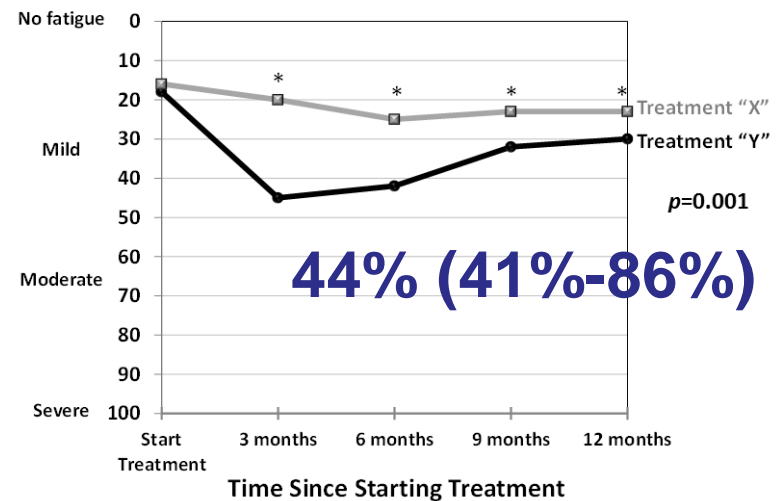
Pain

(line going up means less pain)



Fatigue

(line going up means Less fatigue)



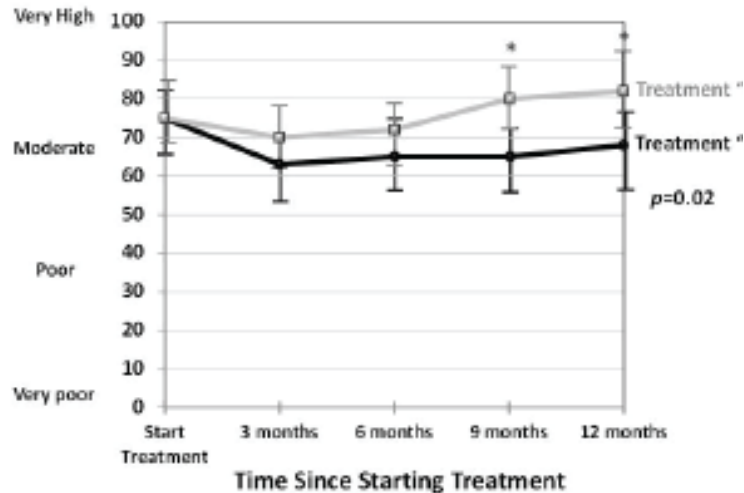
Legend: For all graphs, p -values are for between-treatment differences over time.

*indicates differences between treatments that are clinically important

Patient's Functioning

Physical

(line going up means better able to do physical activities)

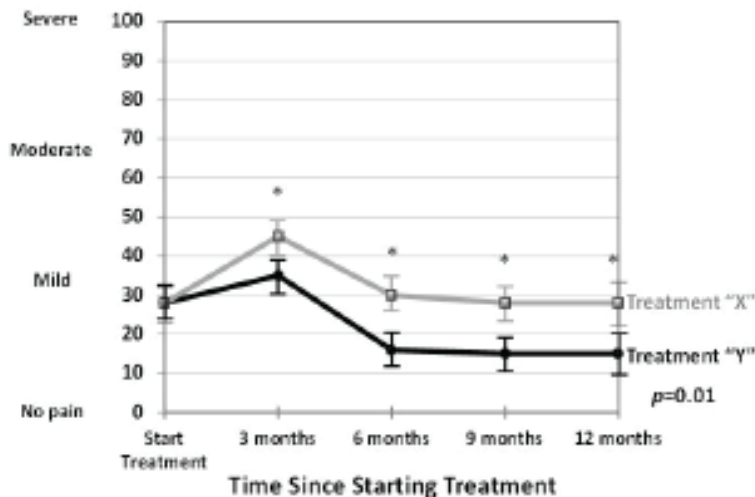


For FATIGUE, at which time points are average scores statistically significantly different between treatments? (select any that apply)

Patient's Symptoms

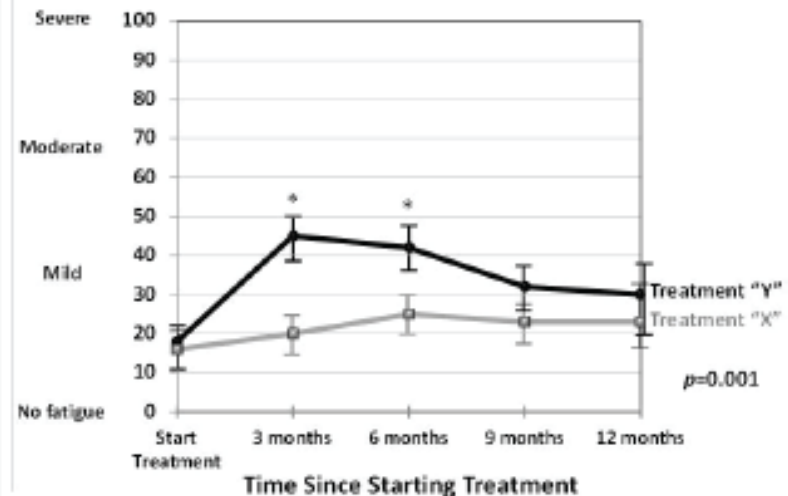
Pain

(line going up means worse pain)



Fatigue

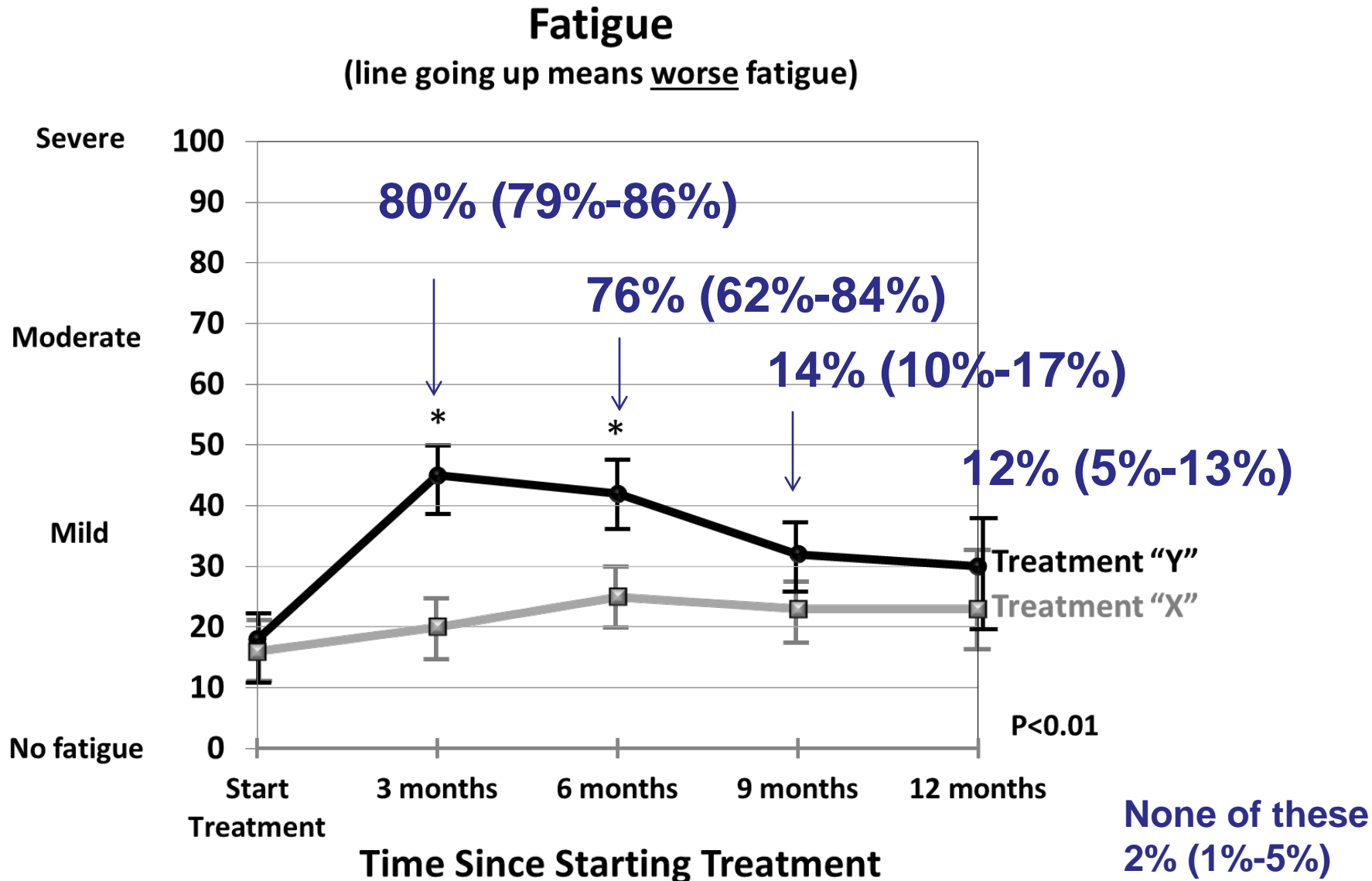
(line going up means worse fatigue)



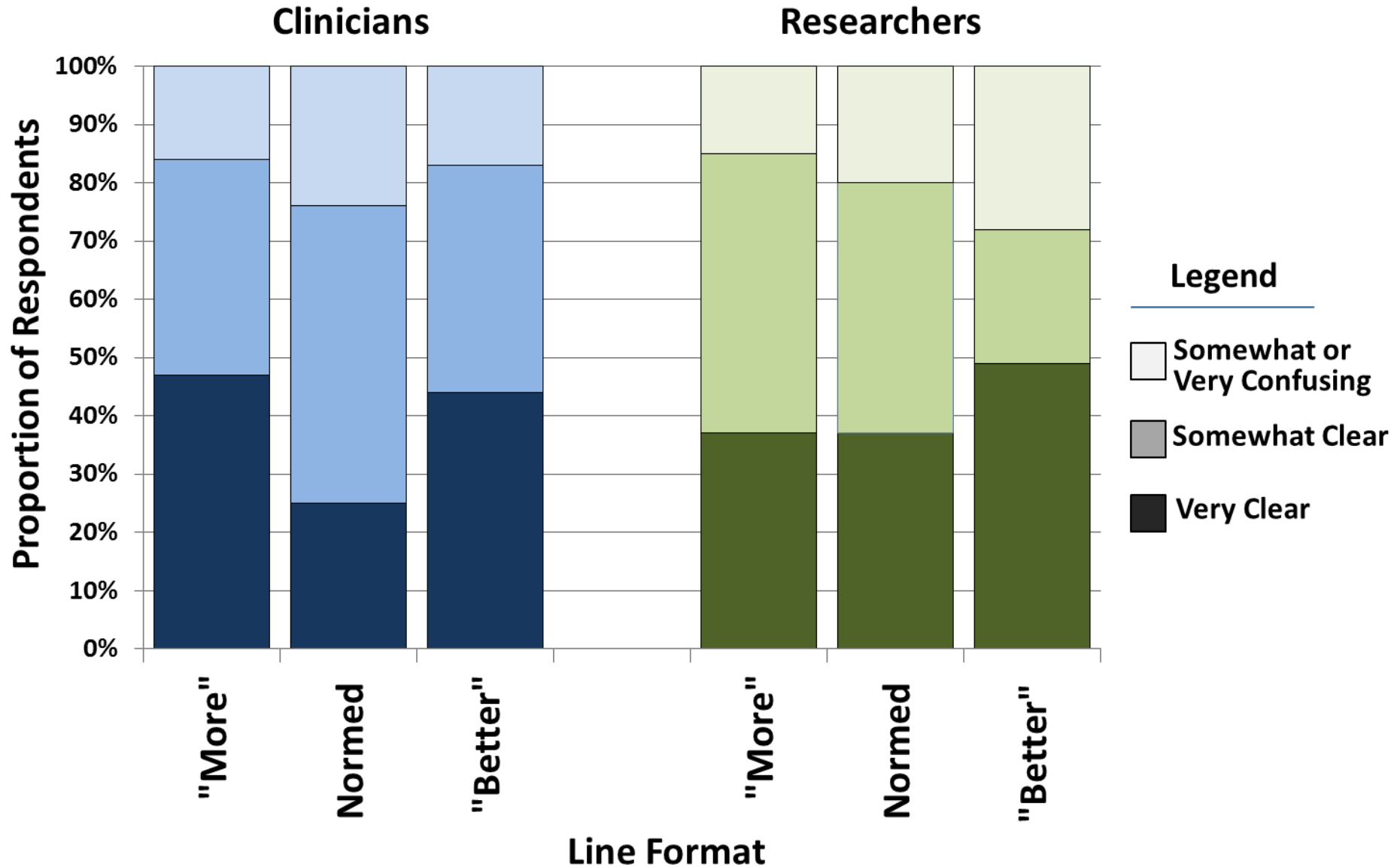
Legend: For all graphs, p -values are for between-treatment differences over time.

* = differences between treatments that were determined to be clinically important. Vertical lines indicate 95% confidence limits

% of Respondents by Time Point (range across groups and formats)

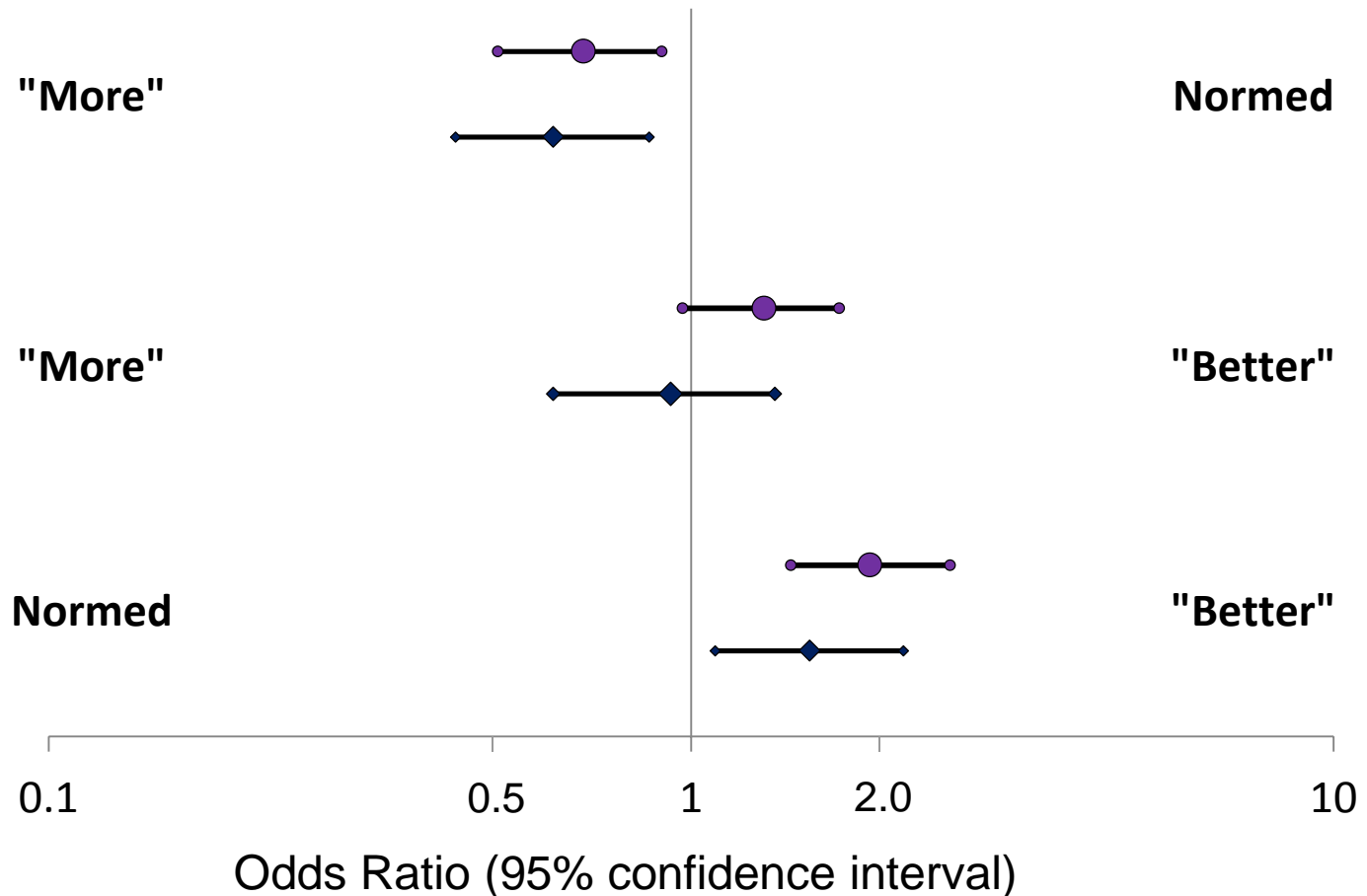


Clarity Ratings: Lines



Clarity Ratings: Lines

- = Rated "Very Clear"
- ◆ = Rated "Very or Somewhat Clear"



Selected Quotes: Line Graphs

MORE: *“They are somewhat confusing...whether it’s physical or fatigue is in one graph lower and in one graph higher...requires very close attention to detail”*

BETTER: *“This one is more confusing in that severe fatigue is at the bottom as opposed to the top...my inclination would be that as fatigue worsens it would go up”*

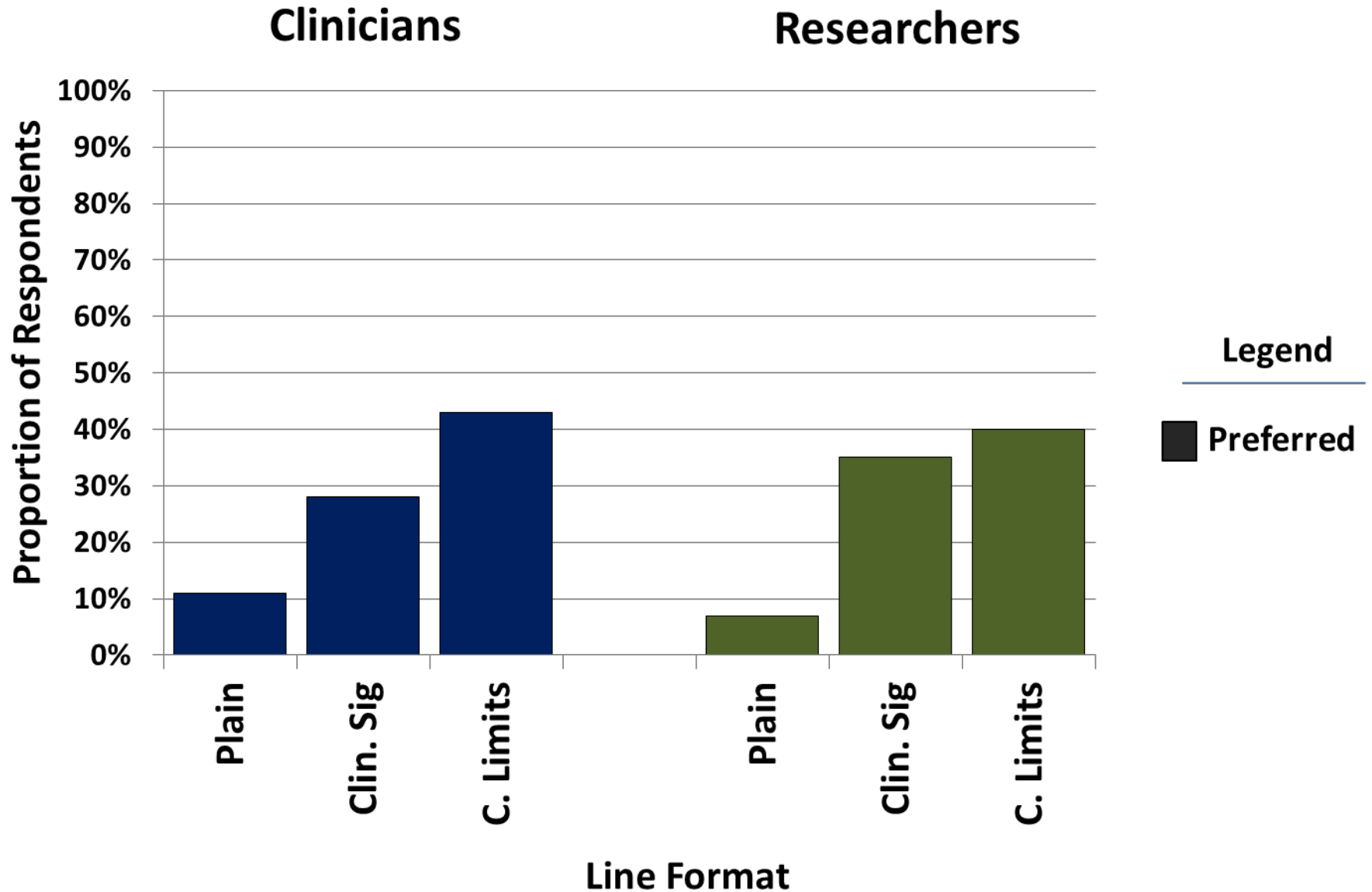
BETTER: *“Reviewing the graph, I understand the scale now and it was fairly simple to figure out”*

NORMED: *“The contrast between treatments is clear, but the magnitude of the effect is absent”*

CLINICAL SIGNIFICANCE: *“I believe the asterisk format is the easiest in showing patient results without the confidence intervals”*

CONFIDENCE LIMITS: *“I felt that they offer more statistical information that is helpful to the clinicians”*

Selected Most Useful: Lines



Summary

- Proportions
 - Both clinicians and researchers **unlikely** to pick “**incorrect**” treatment
 - Odds of an incorrect answer significantly higher with bar charts
 - Clarity ratings did not significantly differ between pie and bar charts
 - Researchers tended toward picking bar charts as preferred
- Line graphs
 - Normed graphs more likely to be interpreted **incorrectly**
 - Normed graphs less likely to be rated clear
 - Inclusion of clinical importance or statistical significance appreciated

Presenting comparative study PRO results to clinicians and researchers: beyond the eye of the beholder

Michael Brundage^{1,8} · Amanda Blackford² · Elliott Tolbert^{3,4} · Katherine Smith^{5,7} · Elissa Bantug⁷ · Claire Snyder^{3,6,7} · PRO Data Presentation Stakeholder Advisory Board (various names and locations)

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Next Steps

Stakeholder-Driven Evidence-Based Standards

- PCORI-Funded Meetings & Conferences contract
- Modified-Delphi approach
- Broader group of stakeholders
- Taking these data, and data from other studies, to develop PRO data presentation recommendations for the three different applications

Paper reporting on recommendations is under review

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