

EPIC Study



Experiences of Participants In Clinical trials

“Patient-reported outcomes in the Experiences of Participants in Clinical Trials (EPIC) Study”

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Investigative Team



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Overview

- Goals of EPIC study
- Adaptation and selection of PROMIS databank items
- Selected results from focus groups and cognitive testing

Background

- Most studies of participants in clinical trials are from single trials or single diseases
- Few if any studies have explored experiences of participants before, during, and post-trial
- Particular interest in experiences of uninsured compared with insured participants

Selected Research Questions

1. Do research participants think that trials provide medical care?
2. What are participants' evaluations of the trial care quality?
3. Does insurance status affect perceptions of trial care quality, access to care, and outcomes?
4. What happens to participants after their participation in a trial ends?



EPIC Methodology

- Sample (Expected n=1000)
 - Adult, English-speaking, current participants
 - Phase IIIb, IV
 - >20 Chronic illnesses
 - Any protocol length, but must end by Dec 31 2008
- Study sites
 - Over 50 sites
 - Multiple trials
 - Sites/trials incented to recruit participants
 - CISCRP acts as site management team

DATA COLLECTION

- Qualitative: Focus groups and Cognitive Testing
- Longitudinal Survey Data Collection
 - Wave 1 – Current trial participants
 - Wave 2 – At trial exit
 - Wave 3 – 6 months post-trial

The PROMIS Promise

The PROMIS project is producing item banks that will be used for both computerized-adaptive testing (CAT) as well as fixed length surveys to assess health-related quality of life domains.

This preliminary short-form includes items measuring physical functioning, fatigue, depressive symptoms, and pain. It was created for use by Joel Weissman (Massachusetts General) in an NIH-funded study investigating the effects of clinical trial participation on subsequent access to care. Selection of the items was based on preliminary analyses of data collected for the first wave of PROMIS in 2006.

Questions about this short-form should be directed to David Cella, Ph.D. (PI of Statistical Coordinator Center) by phone (847-570-7370) or email (d-cella@northwestern.edu).

PROMIS Short Form (25 items + 1) for EPIC Study

- General health (selected by EPIC team)
 - 1 item
- Functional
 - 6 items
- Emotional
 - 12 items
- Pain
 - 6 items

General Health Item

F1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>

Function Items

	Without Any Difficulty	With A Little Difficulty	With Some Difficulty	With Much Difficulty	Unable To Do
a. Are you able to dress yourself, including tying shoelaces and doing buttons?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. Are you able to walk a block on flat ground?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. Are you able to do chores such as vacuuming or yardwork?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

	Not At All	Very Little	Some-what	Quite A Lot	Cannot Do
a. Does your health now limit you in climbing one flight of stairs?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. Does your health now limit you in walking more than one mile?	0 <input type="checkbox"/>	<input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Emotional Health Items (selected from 12)

In the past 7 days,...

	Never	Rarely	Someti mes	Often	Always
a. I felt worthless.	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. I felt helpless.	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

In the past 7 days,...

	Never	Rarely	Someti mes	Often	Always
a. How often did you feel tired?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. How often did you experience extreme exhaustion?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

Pain Items

In the past 7 days, how intense was your pain at its worst?

Had No Pain	Mild	Moderate	Severe	Very Severe
0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

In the past 7 days,...

	Not At All	A Little Bit	Somewhat	Quite a Bit	Very Much
a. How much did pain interfere with your ability to participate in leisure activities?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. How much did pain interfere with your close personal relationships??	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. How much did pain interfere with your sleep?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
d. How much did pain interfere with your household chores?	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
e. Overall, how much did pain interfere					

How do people with chronic health conditions decide on an overall health self-rating?

Using Cognitive Interviews to Assess Measurement Quality:

21 Cognitive Interviews conducted in person and by phone, 2007

**--When you rate your overall health, do you include your [NAME CHRONIC CONDITION] as part of your overall health?
--Explain why/why not.**

Selected Comments

“I would say that overall, in general, my health is “good.” If I wasn’t depressed, I’d say my... uh, overall health is probably “very good” to “excellent.” But since I am depressed, and I have the depression and it’s, you know, it has a lot of effects, I’d have to drop it to “good.”

“I think of everything together – the diabetes, my [44.00] OCD [obsessive-compulsive disorder], my social disorders, my arthritis – I mean, I think about it all in one big picture. ”

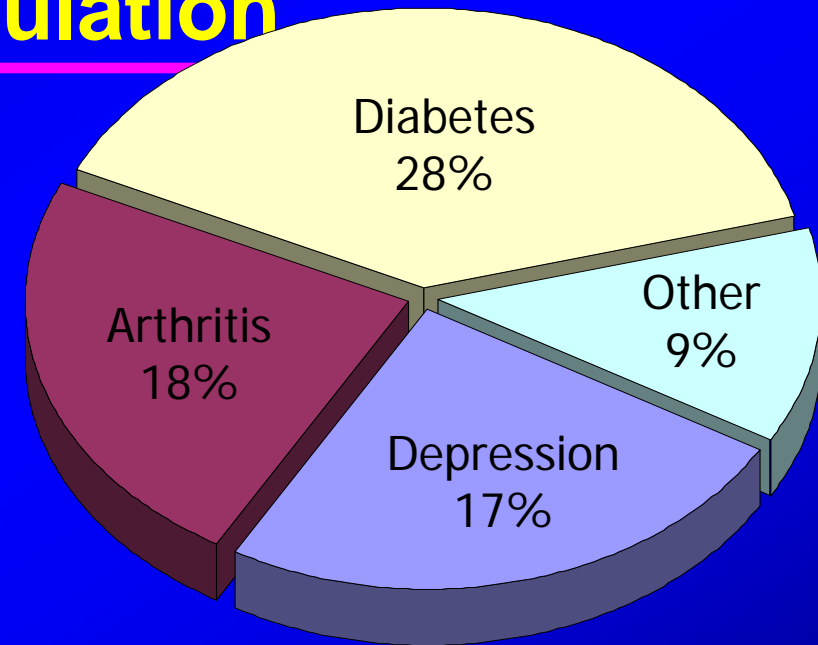


Focus group locations





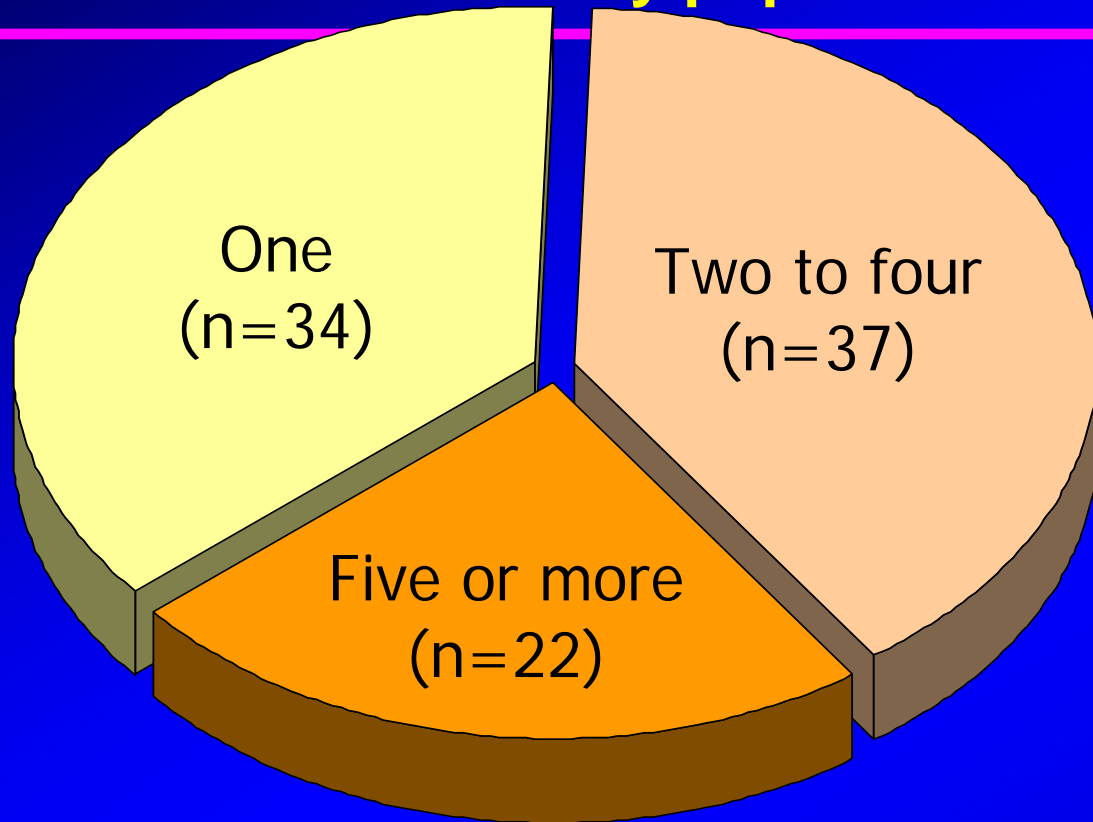
Study population



CONDITIONS

- ❑ 8% currently uninsured
- ❑ 19% uninsured in the last 12 months
- ❑ 26% did not get a prescription filled due to cost in the last 12 months
- ❑ 21% skipped a test or treatment due to cost in the last 12 months
- ❑ 68% of participants had enrolled in more than one medical research study

Study population: Research experience

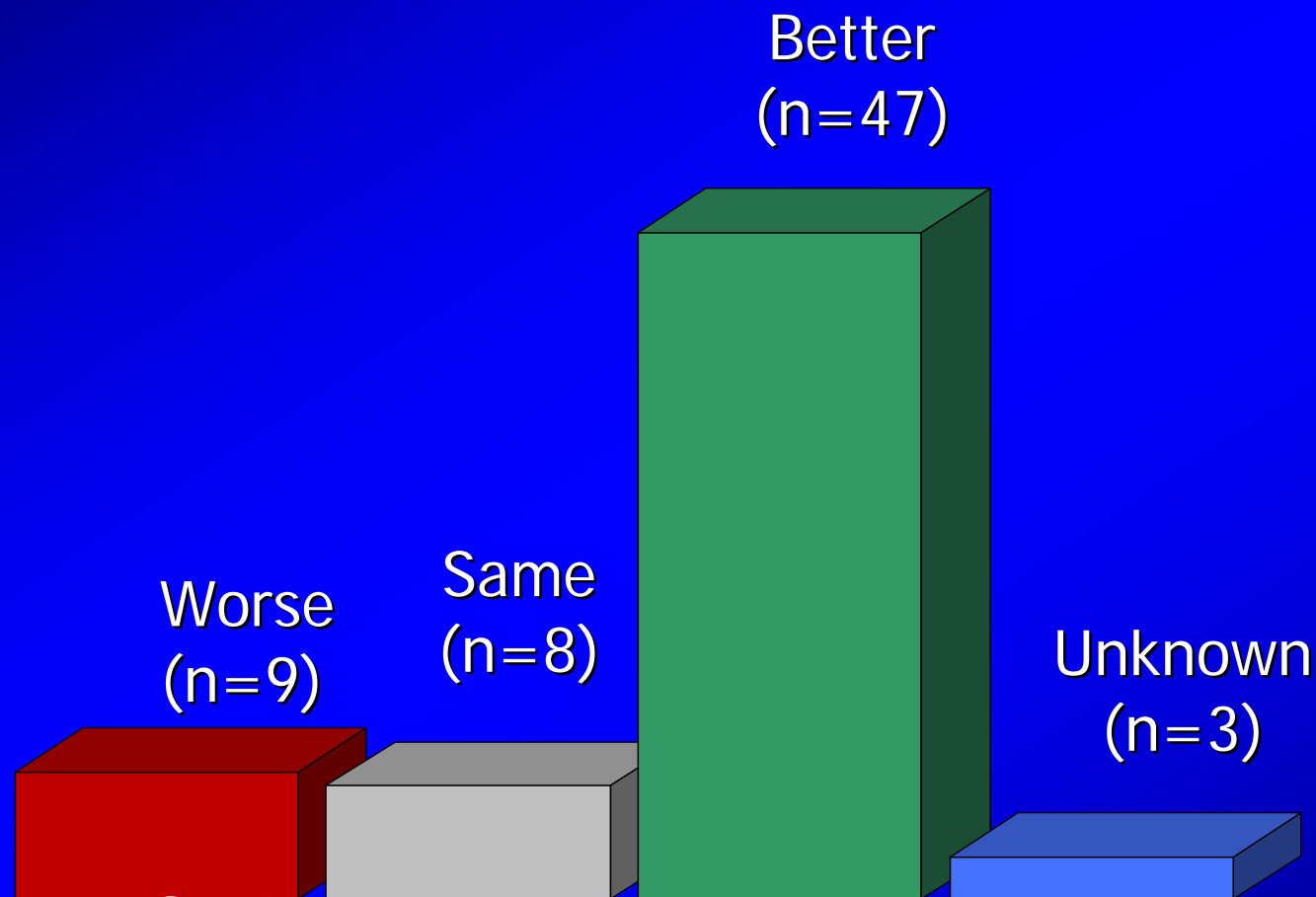


(n=93)

Number of research studies

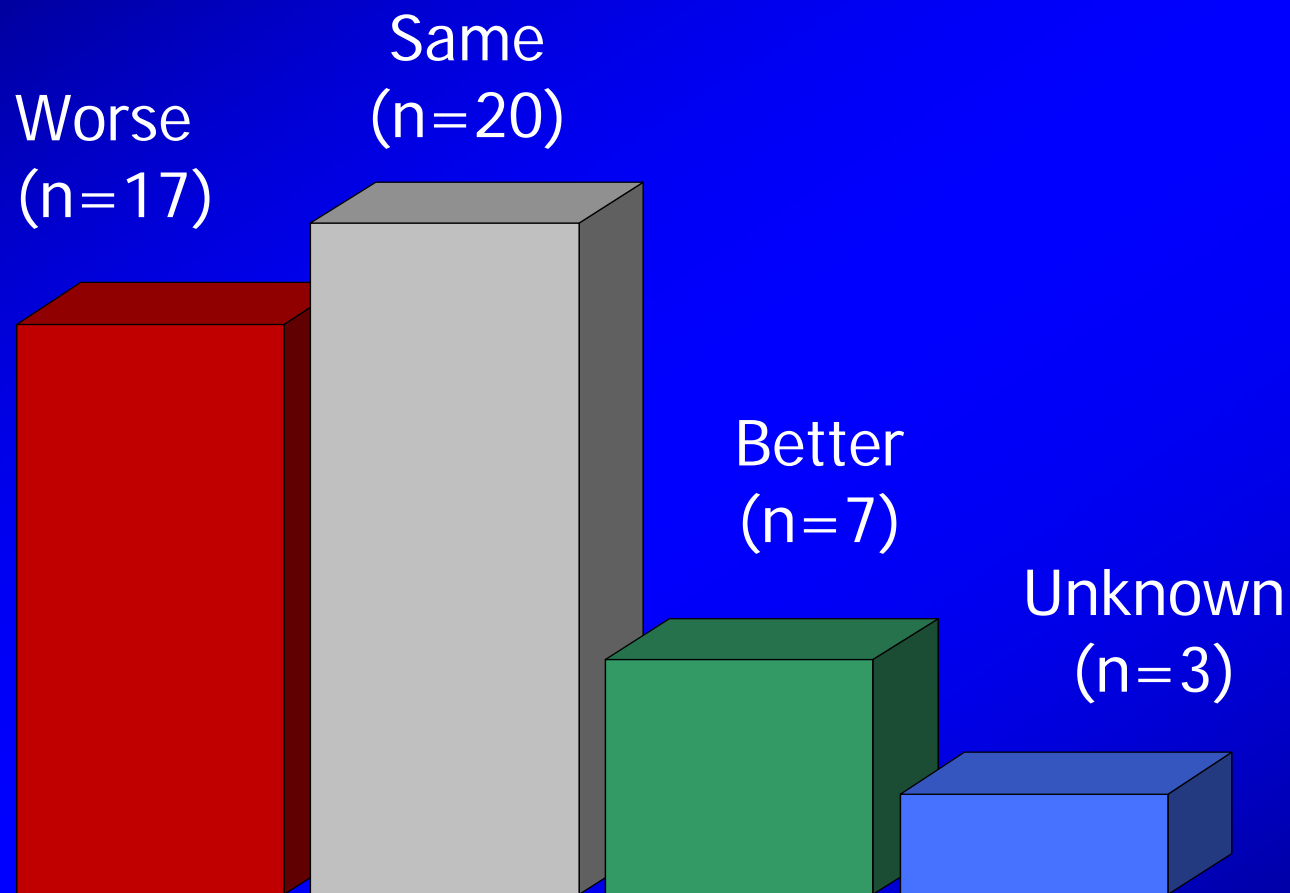
- 81 in a clinical trial testing a drug
- 67 finished at least one clinical trial testing a drug

PTA impact: Health changes during the trial



Self-reported change in health status DURING
most recently completed clinical trial (n=67)

PTA impact: Health after the trial



Self-reported change in health status AFTER
most recently completed clinical trial (n=67)

Trials as a source of medical care

- Participants sought symptomatic relief from clinical trials.
- Many participants reported that their health improved during the trial.
- Most participants thought it was appropriate to compare the quality of trial care to regular care.



Next Steps

- Continue recruitment for survey portion
- Wave 1 (trial entry)
 - Feb - Dec 2008
- Wave 2 (trial exit)
 - April 2008 – Feb 2009
- Wave 3 (6 mos. post trial)
 - Sep 2008 – June 2009
- Final report
 - December 2009