
Patient-Reported Data: Qualitative Research and Questionnaire Design

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Variables Used in Clinical Research

- Traditionally, clinical research has employed “hard” endpoints
- Important & clinically relevant, relatively easy to measure from sources other than the study participant
 - Death
 - Biological variables (blood pressure, cholesterol)
- Sometimes (increasingly!) we need to obtain information directly from the study participants
 - Shift in focus from mortality and morbidity to health-related quality of life, values and preferences, and satisfaction



Predictors and Covariates

- Clinical characteristics
 - medical history
 - co-morbid conditions
 - symptoms and prior treatments
- Sociodemographic characteristics
 - Race/ethnicity
 - Socioeconomic status
 - Cultural context
- ***Attitudes, knowledge and beliefs*** about condition and/or treatments



Patient-Reported Outcomes

- Clinical symptoms experienced after an intervention
- Impairments associated with these symptoms
- Impact of symptoms/impairments on health-related quality of life
- Preferences and values associated with outcomes
- Satisfaction with processes and outcomes of care



How do we Define and Measure these Variables?

Qualitative data – a great place to start ...

Qualitative research differs from quantitative research

- seeks to gain a rich and nuanced understanding of a phenomenon in a small number of individuals
- rather than seeking statistical precision by assessing a limited range of information in a large group of people.

Qualitative research is often hypothesis generating.



Uses of Qualitative/Formative Studies for Clinical Research

- To develop conceptual models that describe the patient-related attitudes and behaviors factors/“grounded theory”
 - Theories emerge from data
- To create quantitative measures of patient-reported data
 - Identifies important domains that need to be addressed
- To develop effective educational interventions

Qualitative analyses can be the end product.



Types and Sources of Qualitative Data

- Open-ended questions on quantitative surveys
 - Other: (specify) _____
 - Why or why not? _____
- Focus group interviews
- One-on-one qualitative interviews
- Other types of qualitative data
 - Observation of physician / patient interactions



Focus Group Interviews

- 8 to 10 participants
- Trained moderator with discussion guide
 - Discussion guide with prompts
- Advantages
 - Group members react to each other and generate ideas
 - Data from a lot of participants at once
- Disadvantages
 - One person can dominate
 - Complicated to arrange



One-on-One Qualitative Interviews

- Trained interviewer with interview guide
- Discussion guide with prompts
- Advantages
 - More detailed information
 - Useful for sensitive information
 - Easier to co-ordinate
 - Able to elicit information from less vocal individuals
- Disadvantages
 - No “riffing” on ideas from other participants
 - Many more transcripts to review!



Hysterectomy

Q: How has your bleeding affected your day-to-day activities?

“It affected my entire . . . month! Because I would be pre-menstrual, and then I would have a week of such heavy bleeding, I mean, the middle of the day . . . I really couldn’t leave the house. And usually it just started, and I would have SUCH heavy bleeding, and I would go through Super Tampax and super tampons, and, and . . . I was wearing rubber pants, and . . . everything, trying to have a normal life.”



Prenatal Testing Study

Q: Studies have shown that African American women are less likely to have prenatal diagnostic testing than white women. What might be some of the reasons?

“I think of Tuskegee . . . I do wonder sometimes, you know, when they’re doing things, if I’m the next guinea pig. I mean, that’s always in the back of my mind. I don’t care how many years pass by. I still think that if anyone could do something like that to a people in the name of science, what’s different today than it was then?”

“Because it gets down to your values . . . about whether or not you would choose to abort the baby.”



Induction of Labor

Q. How did you feel when you were told that your labor would be induced?

“I was angry. I didn't know how I was going to get through [it] because my whole birth picture was like I was moving, and I was in a tub. And now I was hooked up to these things. And I was stunned when she said I had to keep it in me the whole time. I thought, oh, you'd get a little bit of Pitocin, and then you'd be walking around. And then they were like, "No. This machine is on you the whole time.”



Inter-pregnancy Interval

Q: In this country, about half of all pregnancies aren't planned. What do you think about this? Why do you think this might be?

“Things happen, even if you're on birth control sometimes you get pregnant, so why bother [planning]?”

“I used birth control ... I had a condom and the morning after pill ... So these were just my babies – they were meant to be. I mean, I could have chosen to have an abortion. But honestly, I felt like, ‘Well, hell, you know, they've already made it through two rounds.’ These were just meant to be my babies.”



Conducting Qualitative Analysis

- Hours and hours of tape recordings
- Recordings are transcribed and translated (budget for this!)
- Goal of analysis is to allow themes to emerge by looking for commonalities in the information obtained from different participants in different focus groups or qualitative interviews.



Conducting Qualitative Analysis

- Parcel transcripts into “bits” of information, each communicating a thought or view.
- Develop code list
- 2 to 3 people assign codes to bits
- Code assignments discussed and revised
- Code list is updated as new concepts emerge



Coding Grid Example (Hysterectomy)

What did you think about as you were deciding whether or not to have a hysterectomy?

I never had any plans on having children. I never really wanted kids.	5e
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I was trying to avoid pain. I'm such a weenie.	3g
--	----

I didn't really want to go into menopause	6d
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Conducting Qualitative Analysis

- Software (ATLAS.ti, NVivo, Nudist, Excel) is used to group statements and identify emergent themes



Can Qualitative Studies be Published?

- Clinical journals traditionally interested in quantitative, clinical outcomes.
- Over the past decade, staggering increase in publications using health-related quality of life and other patient-reported outcomes as primary endpoints.
- Qualitative studies more difficult to publish, although the numbers of these studies also have been increasing.



Using Qualitative Data to Create Questionnaires

- Fine tune conceptual framework
- Content/domains identified
- Search for existing measures!!
- Develop new scales
 - Identify important questions to ask
 - Wording of questions
 - Response options



How to Design a Good Questionnaire

- Crystallize your research question and study hypotheses
- Clearly define predictors, covariates and outcomes
- Search the literature and ask colleagues for published, validated scales that measure these variables
- Include new items as needed, taking care to word them unambiguously
- If necessary, create new scales (and proceed with caution!)
- Conduct reliability and validity testing for new scales



Developing New Items: Be Specific

Rather than this:

How much education do you have?

- ☐ Elementary school
- ☐ High school
- ☐ College

Try this:

What is the highest level of education you have completed?

- ☐ No formal education
- ☐ Less than a high school degree
- ☐ High school graduate, GED or equivalent
- ☐ Some college, junior college or vocational school
- ☐ College graduate
- ☐ Professional or graduate degree



Developing New Items: Be Comprehensive

Rather than this:

What type of delivery did you have?

- ☐ Vaginal
- ☐ Cesarean

Try this:

Which of the following best describes the type of delivery you had?

- ☐ Spontaneous vaginal delivery (no forceps or vacuum)
- ☐ Vaginal delivery with vacuum
- ☐ Vaginal delivery with forceps
- ☐ Cesarean delivery (C-section)
- ☐ Other, specify: _____



Use Exhaustive & Mutually Exclusive Response Options

What is your total yearly household income (before taxes)?

- ☐ Less than \$25,000
- ☐ \$25,001 - \$50,000
- ☐ \$50,001 - \$100,000
- ☐ \$100,001 - \$150,000
- ☐ Over \$150,000



Beware of Cognitively Burdensome Items

Please rank the following sources of information according to how helpful they were to you in making your prenatal testing decision.

- ☐ Your midwife or obstetrician
- ☐ A genetics counselor
- ☐ A group class taught by a health care professional
- ☐ Written material given to you by your healthcare providers
- ☐ Your friends and relatives
- ☐ The internet



Instead ...

How helpful were each of these sources?

Your genetic counselor

- ☐ Very helpful
- ☐ Somewhat helpful
- ☐ Not helpful
- ☐ Does not apply



Make Sure Responses Answer the Question

Have you been in pain in the last week?

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Frequently
- ☐ Always

Correct question: Over the past week, how often have you been in pain?



Be Specific About Time Frame

During the past 4 weeks,* how much of the time have your pelvic problems interfered with normal social activities, like visiting with friends or relatives?

- ☐ All of time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

*Recall period should be 4 weeks or less



Don't Use “Double Barreled” Questions



How satisfied were you with
the care you received from
the doctors and nurses?



Attitudes: Agreement with Statements

1. It is important for me to know if my fetus has Down syndrome.
2. In my culture we learn to accept what we are given.



Likert Scales

- ☐ Strongly/mostly disagree
- ☐ Somewhat disagree
- ☐ Neither agree nor disagree
- ☐ Somewhat agree
- ☐ Strongly/mostly agree



What's the Problem?

In general, what time is best for contacting survey respondents? (check one)

- ☐ Morning
- ☐ Afternoon
- ☐ Weekdays
- ☐ Weekends



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Problem: answer options are not mutually exclusive; not exhaustive (no eve & night option)



What's the Problem?

Approximately what proportion of your patients do you believe has substance-abuse problems? (check one)

- ☐ 5%
- ☐ 10%
- ☐ 15%
- ☐ 20%
- ☐ 25%



What's the Problem?

Approximately what proportion of your patients do you believe has substance-abuse problems? (check one)

- ☐ 5%
- ☐ 10%
- ☐ 15%
- ☐ 20%
- ☐ 25%

Problem: providing close-ended scale "gives away" what you think is the right answer (this one may be best to leave open-ended and let the R put in the number they think is right)



What's the Problem?

Please indicate how much you agree or disagree with the following statement:

Physicians care too much about money and don't spend enough time with patients.

- ☐ Strongly/mostly disagree
- ☐ Somewhat disagree
- ☐ Neither agree nor disagree
- ☐ Somewhat agree
- ☐ Strongly/mostly agree



What's the Problem?

Please indicate how much you agree or disagree with the following statement:

Physicians care too much about money and don't spend enough time with patients.

- ☐ Strongly/mostly disagree
- ☐ Somewhat disagree
- ☐ Neither agree nor disagree
- ☐ Somewhat agree
- ☐ Strongly/mostly agree

Problem: double-barreled question



Compiling the Survey Instrument

- Make a list of variables
 - Predictors, outcomes, potential confounders
 - Double check that each is included in your analysis plan
- Collect existing measures
- Create new items and scales
- Standardize and group items with similar response options
- Organize the flow of the interview
- Add text for transitions
- Pretest, revise, throw out as many items as you can, test again



Other Things to Consider

- Mode of administration
 - Self-administered
 - Computer/web/e-mail
 - Regular mail
 - Specific location
 - Interviewer-administered
 - Face-to-face
 - Telephone
- Use of proxy (getting information about an individual from someone else)
- Languages
- Confidentiality



Have FUN!

And keep in mind that no matter how much you plan ahead, and how well you design your questionnaire, each study will bring new challenges . . .

