Qualitative Methods and Patient Reported Outcome Measures

Susan C Pitt, MD, MPHS
Assistant Professor of Surgery
University of Wisconsin
Disclosures

• None
Overview

• What is it?
• When is it useful? Why do it?
• Where can I learn more about it?
• How do you do it? Not today
Qualitative Research

“Not everything that can be counted counts.
Not everything that counts can be counted.”

William Bruce Cameron,
“Informal Sociology: A Casual Introduction to Sociological Thinking”
Qualitative Research...What is it?

• Exploratory
Qualitative Research...What is it?

• Used to gain an understanding of underlying reasons, opinions, and motivations
Qualitative Research...What is it?

- Provides insights into the problem or helps to develop ideas or hypotheses for potential quantitative research
Qualitative vs. Quantitative

Qualitative
- Unstructured data
- Summarize, characterize
- Subjective conclusion
- Focus groups

Quantitative
- Structured data
- Statistical analysis
- Objective conclusion
- Survey, “big data”
Qualitative Research...When/why to use it?

- Answers questions like...
  - What is going on here?
  - How is this happening?

- Examines
  - Social constructs
  - Behaviors
  - Interactions
  - Group norms
  - Survey design
  - Meaning
  - Policy implications
Qualitative Methods

Qualitative Research Designs

- In-depth Interviews
- Focus Groups
- Observation
- Projective Techniques
- Ethnography
- Case Studies
- Action Research
- Grounded Theory

Phenomenology, Content analysis, Dimensional analysis, Discourse analysis
Qualitative Methods...Which one???

- Ex: What do patients expect after colon surgery?
- Consult a qualitative expert
- Depends upon:
  - Question being asked
  - Context
  - Accessibility
  - Feasibility
Overview

• **Strengths**
  – Rich data
  – Explain phenomena
  – Dynamic and flexible
  – Investigate complex issues
  – Examine of feelings and motivations
  – Provides insights and generates new ideas
  – Identify/evaluate factors that help solve problems
Overview

• **Weaknesses**
  – Volume of data
  – Time consuming
  – Reliability/replicability
  – Complexity of analysis
  – Interpretation may be subjective
  – Can’t extrapolate to whole population
Hundreds of Specializations and courses in business, computer science, data science, and more.

John W. Creswell

Second Edition

QUALITATIVE INQUIRY & RESEARCH DESIGN
Choosing Among Five Approaches
Patient Reported Outcome Measures : PROM
Patient-Reported Outcomes (PRO)

• Measurement of any aspect of a patient’s health status that comes directly from the patient

...without interpretation of the patient’s response by a physician or anyone else
Assessment of Outcomes

Sources and Examples

Investigator Reported (IRO)
  - Global impression
  - Observation

Physiological
  - Tests (FEV1)
  - Labs (HbA1c)
  - Tumor size

Caregiver Reported
  - HR-QoL
  - Functional Status

Patient Reported (PRO)
  - HR-QoL
  - Symptoms
  - Satisfaction
PRO...When to use them?

• Used to assess:
  – Symptoms (impairments)
  – Functioning (disability)
  – Wellness (health)
  – Quality of life (QOL)**
IRO vs PRO Examples

Investigator Reported

Did they have a good experience?
Did the patient die?
Do the biomarkers indicate success?
Were there complications?

Patient Reported

Were there any long-term complications?
Did they adhere to treatment?
Have symptoms significantly improved?
Did I meet the patient’s own goals?
Did their functional status improve?
What about quality-of-life and mental wellbeing?
Generic vs Targeted PRO

- **Generic**: any population and meant to cover a broad aspect of concept being measured
  - QOL: SF-36, EQ-5D

- **Targeted**: disease, domain, population, or setting-specific assessment of concerns most important to a given population
  - Oxford Hip, AQ20 (IBD)
  - Multidimensional Fatigue Inventory
  - QOL Profile – Senior version
Generic vs Targeted PRO

- Generic instruments (i.e. Health)
  - SF-36
  - SF-12
  - Others...

- Disease oriented instruments (i.e. Cancer)
  - EORTC-QLQ C30
  - FACT-G
  - Others...

- Disease specific (i.e. Colorectal Cancer)
  - EORTC-QLQ CRC29
  - Others...

- Domain oriented (i.e. Sexuality)
  - (various)
PRO vs IRO Examples

- Total Knee
  - PRO: pain
  - General
  - IRO: DVT rate

- Prostate surgery
  - PRO: Urinary sx
    - Dz specific
  - IRO: EBL
PROM Overview

• **Strengths**
  – Perspective on treatment effectiveness from patient’s view
  – More systematic than interview
  – Some treatment effects only known to patient
  – Can be used to improved practice
PROM Overview

• Weaknesses
  – Meaningfulness of scores
  – Sensitivity / Specificity
  – Poor validity
  – Unreliable
MORE INFORMATION

http://www.healthmeasures.net/explore-measurement-systems/promis
• Not necessarily exclusive of one another
  – Qualitative → Survey, PRO, CER, Trials
  – PRO → Qualitative, Survey, Trials, CER
Thank You!

Email: spitt@wisc.edu
Twitter: @susieqp8
Survey Science
Definition

- Surveys hard to do well and expensive
  - Is there existing survey data?
  - Is the question appropriate for survey research?
  - Do I have enough funding?

- Ask someone with experience for help
  - Survey Center
  - Attending or researcher
Existing Sources of Data

- Inter-university consortium of political and social research (ICPSR) at the University of Michigan
  - [http://www.icpsr.umich.edu/icpsrweb/ICPSR/](http://www.icpsr.umich.edu/icpsrweb/ICPSR/)
- National health and aging trends study (NHATS)
  - [http://www.nhats.org/](http://www.nhats.org/)
- Health information national trends survey (HINTS)
  - [https://hints.cancer.gov](https://hints.cancer.gov) or @NCIHINTS
- Existing tools: adapt
- School of Public Health
- Survey Center
Characteristics of a Good Survey

• Clear definition
  – Who? What? How?

• Specific content
  – Clear domains of interest

• Standardization of administration
  – Respondent receive same instructions and materials

• Standard scoring procedure
Things to consider

• Cost: Free → $50,000
• Creation
  – Basic
  – Link to other data (respondent information, claims data, biomarkers)
• Purpose
  – Epidemiological Survey
  – Measuring of risk and protective factors
  – Outcomes measures
Things to consider

• Types
  – Self-administered vs Interviews

• Psychometrics: Measurement of properties of a measure
  – Reliability (consistency and stability)
  – Validity: does the test measure what it was designed to measure
    • Content validity
    • Construct validity
Overview

• **Strength**
  – Reach
  – Address many questions / themes
  – Return of investment (hypothesis generation)

• **Weaknesses**
  – Lack of clarity
  – Recall
  – Return on investment (response rate)
Important

• These tools are not necessary exclusive of one another
  – Qualitative → Survey, PRO, CER, Trials
  – PRO → Qualitative, Survey, Trials, CER
  – Survey → Qualitative, PRO, CER, Survey

• Important to build your tool box and know how and when to use your tools
Using patient reported outcomes

1. Patient Reported Outcome
   - Identify issue and population of interest
   - Identify domains of importance to patients

2. Patient Reported Outcome Measure
   - Identify existing PROMs
   - Test for reliability, validity, responsiveness
   - Test feasibility of use

3. Patient Reported Outcome Performance Measure
   - Aggregate PROM data, benchmark
   - Evaluate threats to validity. E.g. exclusions, missing data, poor response rate

“Leadership experience? I have 13 people following me on Twitter!”
PROs

- Health-related quality of life (HRQOL)
- Symptoms
- Function
- Satisfaction with care or symptoms
- Adherence to prescribed medications or other therapy
- Perceived value of treatment
Thank You!

Email: pitt@surgery.wisc.edu
Twitter: @susieqp8
Qualitative Research
Recap: Qualitative Research Process
(Maintaining Consistency)

1. Problem Statement
   Gap found in the literature

2. Research Purpose:
   Understand
   Explain
   Describe
   Illustrate
   Explore
   Conceptualize

3. Research Question:
   Exploratory in nature

4. Research Design:
   Research Plan - logical description of how data would be collected, and analyzed to address the research question(s)

5. Research Approach
   Sampling Strategy
   Data Collection Strategy

6. Philosophical Assumptions OR Paradigm
   Ontology (about reality)
   Epistemology (about knowledge)
   Axiology (about value)

7. Quality Assurance
   Credibility
   Transferability
   Dependability

8. Analysis of Data

9. Presentation and Interpretation of Results
   (Yilmaz, 2013)
The Qualitative Researcher

• Adept at performing a large number of diverse tasks ranging from:
  – Interviewing to observing
  – Interpreting personal and historical documents
  – Intensive self-reflection and introspection
Qualitative Research...What is it?

• Ex: “The goal of this study was to ...[characterize, understand, explain, explore, illustrate, describe, conceptualize]...what patients expect after surgery?”