MIXED METHODS IN COMPARATIVE EFFECTIVENESS RESEARCH

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OVERVIEW

- Quantitative, qualitative and mixed methods – key differences
- When and why to use mixed methods (or not)
- Applying mixed methods to CER and PCOR
  - Using qualitative methods to focus on the patient experience and the intervention
- Benefits of using mixed methods
- Challenges of using mixed methods

DEFINING “MIXED METHODS”

- My definition: “Mixed methods” research: use of at least one quantitative data collection method and at least one qualitative data collection method, to answer the same overarching research question
- Sometimes used to describe using different kinds of data collection from either quantitative or qualitative methods
- We will use my definition today
QUANT & QUAL – KEY DIFFERENCES

- The obvious difference – numerical v. textual data; numbers v. words (and images)
- Different traditions/epistemologies
  - Quantitative: draws primarily from “hard sciences” and from “positivist” epistemology
  - Qualitative: draws from “social sciences” and history and from “grounded theory” epistemology
  - Abraham Kaplan – context of justification v. context of discovery – note that both are important
- Concretely -- closed ended v. open ended questions

DATA COLLECTION OPTIONS

<table>
<thead>
<tr>
<th>QUALITATIVE</th>
<th>QUANTITATIVE</th>
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<td>Primary</td>
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<td></td>
<td>Surveys with only or almost only closed-ended questions</td>
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<td>Key informant interviews</td>
<td>Abstraction of discrete information from records</td>
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<td>Cognitive interviews</td>
<td>Secondary</td>
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<td>Focus groups</td>
<td>Using existing compendia of quantitative data</td>
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<td>Observation</td>
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<td>Secondary</td>
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<td>Gathering documents or images</td>
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In a mixed method study, you have, therefore, a very wide choice of data collection options and can combine them in a variety of ways. These choices need to be driven primarily by your research question. Specifically,
- The variables/topics related to your research question
- What is already known and what is not about your variables/topics
- Your research subjects and their likely response to different data collection methods
**DATA COLLECTION OPTIONS**

**Different combinations**
- Using qualitative approaches to confirm or further explore existing quantitative data
- Using both qualitative and quantitative methods to explore the same variables
- Using qualitative methods to identify key variables for further study
- Using qualitative methods to explore some variables and quantitative methods to explore others – likely combination in CER

**QUANT & QUAL – KEY DIFFERENCES**

- Analyzing data
  - **Quantitative**: focus on descriptive and inferential statistics
    - Note desire for a large "n" and interval/ratio data whenever possible to widen range of available statistical tests and have a better chance of finding significance
  - **Qualitative**: focus on identification of themes and patterns in language
    - Can be very systematic and rigorous through use of formal coding of text as a basis for analysis
    - More “impressionistic” analysis is only appropriate when you have a small amount of data

**DATA ANALYSIS IN MIXED METHODS**

- Qualitative and quantitative data can be analyzed together, but this is not common (yet)
- Typically, we use analytic methods appropriate to our data collection strategy
- Each of our analyses must, therefore, meet standards of rigor specific to the overall approach
- The key when not analyzing together is how we
  - **Use each form of analysis**
  - **Integrate our INTERPRETATION of our analyses**
WHY USE MIXED METHODS?

In health services research, and in clinical research, this question is typically about why we should add qualitative methods to quantitative methods; in that case, you do this when:
- Your question has rarely been asked or has been asked with questionable results
- You want the strength of multiple methods triangulation
- Only some, if any, of your variables are easily quantifiable at this stage of inquiry
- To “illuminate the black box” of relationships defined only in statistical terms
- To hear from people who are rarely reached effectively by typical quantitative approaches (e.g. vulnerable patients, front line health workers)

But for qualitative researchers, the equally important question is, why add quantitative method; you may want to do this when:
- You want to build on a base of existing quantitative data that is highly relevant to your research question AND you trust it and can relatively easily gain access to it
- OR you recognize that (for good reasons and bad) the credibility of your research will improve if you add numbers
- Your goal is to build more valid and reliable quantitative measures and data collection instruments, such as surveys

In comparative effectiveness research, and in particular Patient Centered Outcomes Research (PCOR)
- Increasingly, researchers are being asked to focus on outcomes that are
  - Are of importance to patients (and sometimes family)
  - May be reported by patients (PROMs)
- In addition, since this research is intended to support treatment choices of patients as well as clinicians, researchers are asked to
  - Clearly describe how treatments and their effects are experienced by patients, and sometimes clinicians
WHY USE MIXED METHODS?

- In addition, especially for projects funded by PCORI, you have to involve patients and other stakeholders (specifically clinicians) throughout the research process
- Qualitative methods can help you describe and assess the short-term effectiveness of how you choose to involve patients and stakeholders
- Everyone is “feeling their way” in this area, but there will, nonetheless, be expectations that researchers take “patient-centered” seriously

WHY USE MIXED METHODS?

- So, in comparative effectiveness research:
  - Quantitative measurements good for
    - Assessing and comparing the profile of samples assigned to different interventions (or none)
    - Tracking important outcomes that are quantifiable (including PROMs)
  - Qualitative measurements good for
    - Describing the interventions in action (not in theory)
    - Assessing implementation fidelity
    - Describing patients' experience of the interventions and their results
    - Assessing the actual involvement of patients and other stakeholders throughout the research process

WHY USE MIXED METHODS?

- In disseminating comparative effectiveness research:
  - Quantitative measurements good for
    - Presenting results in the numerical, statistical way that many people expect and trust
  - Qualitative measurements good for
    - Again, describing the interventions in action (not in theory)
    - Providing specific examples of how differences between interventions are experienced by both patients and clinicians
    - Even though people say they want just numbers, in fact they love and respond to stories!
Since I am not a clinical researcher, I will use a “hypothetical” example that has, however, been the subject of CER.

Comparing the effectiveness of:
- Beginning with prescription medications only v. Beginning with insertion of a stent
- For people with coronary artery disease

There are lots of purely quantitative studies of this question;
- Why add a qualitative component?

We do CER or PCOR because we want to inform actual decisions made by patients and clinicians (preferably shared decisions) with strong evidence.

This must involve paying attention not only to clinical results but also patient preferences and values.

Patients know more not only about their preferences and values but about which preferences and values arise for them in a given clinical situation.

To learn about this we might:
- Conduct in-depth interviews or focus groups with patients enrolled in both arms of the study (and their family members if appropriate)
- Conduct in-depth interviews with clinicians to explore their response to the intervention as well as how they are seeing their patients’ response
- Potentially, observe the intervention “in action”, e.g. tape, transcribe and analyze clinician-patient interactions directly both to confirm that the intervention is being implemented with fidelity and to gather information about clinician and patient responses
It can be argued that this kind of information will make for more effective dissemination and actual adoption of evidence-based guidance.

- We will be able to advise both patients and clinicians of what issues might arise for them as they make a choice, including but going beyond the traditional "risks" and "benefits".

In addition:

- While we will have randomly assigned patients, patients in the two arms may differ in terms of key unmeasured characteristics, for example, how willing they are to wait for results, specifically a reduction in symptoms.
- It may be important to track patients' reports of "how it is going" (especially in the medication only arm).

Examples continued:

- We can find out, for those in the "stent" arm, how people feel immediately after surgery, some time after surgery, and whether, in general, they think that the surgery was "worth it."
- A certain proportion of people who are started on medications eventually need to get a stent; it would be useful to get information on the reactions of people who have a "delayed" stent — are they okay with having waited? Annoyed? Upset?
APPLYING MIXED METHODS IN CER: A NON CLINICAL EXAMPLE

- Current study in which I am directly involved
  - Funded by AHRQ
  - Randomized trial of the use of “public deliberation” to get input from the public on the USE of comparative effectiveness research
  - Examines four different methods of public deliberation and a control
- The largest study ever done of public deliberation in health

What is public deliberation: bringing together groups of citizens to:
- Identify the ethical issues and social values that have to be addressed around a policy-related question
- Provide a way for these citizens to weigh in on their values and preferences around this question
- Distinguishing features of public deliberation (compared to say a poll or a town meeting):
  - People get information about the policy question (in plain English)
  - People discuss their views and give “reasoned justification” for them
  - Note – they do not have to reach consensus

Lead organization – American Institutes for Research
Multiple organizational and individual partners
The question addressed:

Should individual patients and/or their doctors be able to make any health decisions no matter what the evidence of medical effectiveness shows, or should society ever specify some boundaries for these decisions?
APPLYING MIXED METHODS IN CER: A NON CLINICAL EXAMPLE

- Randomized trial of four different methods of doing public deliberation against a control group and each other
- Study involved over 1300 research subjects and 76 public deliberation groups
- Sample varies in terms of age, gender, race/ethnicity, educational level; groups did not include health professionals
- Major issue – how do we evaluate the process and outcomes of the deliberations?

APPLYING MIXED METHODS IN CER: A NON CLINICAL EXAMPLE

- Two parallel data collection and analysis efforts
- Quantitative: collection and analysis of pre- and post-survey of all subjects
  - Demographics
  - Knowledge about CER and case studies used in the deliberative groups
  - Attitudes/beliefs toward CER and how it is used
  - Reports on experience in the deliberative groups (not for control group)

APPLYING MIXED METHODS IN CER: A NON CLINICAL EXAMPLE

- Qualitative methods:
  - Taping and transcription of ALL the deliberative groups
  - Development of a parsimonious set of “codes” that focus on the opinions of participants and how they change in response to the group process and case studies used
  - Coding, with rigorous inter-rater reliability checks and team discussions
  - Development of “memos” on individual codes and on specific combinations of codes
APPLYING MIXED METHODS IN CER: A NON CLINICAL EXAMPLE

- Qualitative methods:
  - All leads to “making meaning” regarding what people said and what influenced what they said
  - Themes and patterns are identified (as in quantitative analysis)
  - For example, we examine how responses vary by deliberative methods and how they vary depending on what case is being discussed
  - Also, we examine to what extent the process was “faithful” to the principles of public deliberation
  - We pay attention to what shows up most often but we do NOT quantify

This analysis is going on right now

The next phase will involve some integration of the quantitative and qualitative data:

- For example, we are using quantitative results on the quality of the deliberative experience to select particular groups for a “deep dive”
- We may also want to relate the changes we see in our outcomes (knowledge and attitudes measured through surveys) to what happened in the groups – e.g. when did big shifts in opinion occur and what might have been the triggers

BENEFITS OF MIXED METHODS

- Allows you to use the most appropriate method for a particular research question, issue or study population
- Allows you to confirm, or disconfirm, the information you are getting from different methods and sources
- Generally leads to much higher quality measurement:
  - “Behind every quantity there must lie a quality”
BENEFITS OF MIXED METHODS

- You can address not only “what” but “how” and even “why”
- Supports interdisciplinary work: by including multiple methods, it is easier to engage a range of clinicians and social scientists in your work

CHALLENGES IN MIXED METHODS

Pulling together the right research team
- Need all methods represented strongly
- Need everyone to be
  - Respectful of the other method
  - Willing to learn about the other method
- This is likely to mean an interdisciplinary team
- The alternative is for someone with expertise in one area to “go it alone” on an unfamiliar method
  - High risk approach, but sometimes there is no alternative

Pulling together the right research team
- What specific qualitative skills are needed?
  - Specifying a purposive sample in detail
  - Getting access to key informants
  - Developing interview protocols with really open ended questions
  - Conducting interviews so respondents are forthcoming and honest
  - Similarly, developing focus groups moderator guides
  - Conducting focus groups – means that in addition to raising questions you have to carefully watch and manage the group interaction
Pulling together the right research team

What specific qualitative skills are needed?
- Developing a coding list that covers the bases without being too long and detailed
- Using and refining the codes, preferably with appropriate computer software
- Querying the program to gather together key sections of text, by individual codes or combinations
- Identifying themes; testing themes
- Making meaning!

Where do you find people with these skills (or at least some of them)?

People from the following disciplines are most likely to have these skills:
- Anthropology
- Sociology
- Political Science
- Marketing and Consumer Behavior

People comfortable with “applied” research are more likely to fit into your team

This implies good leadership/management

Regular interactions/communications

Most likely, realistically, slightly more resources because many people cannot “silo” themselves
Dealing with anomalies in the results

- What if you are using multiple methods to look at the same general issues (e.g., our example) AND
- You get different results depending on the methods
- This is “the elephant in the room” in mixed methods

May require re-examination of every step in the research process to see if an explanation can be found in terms of methodological flaws

May reflect the reality that depending on how something is looked at (perspective) it looks different – the parable of the five blind men using touch alone to describe an elephant

Ultimately, this may involve more research