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RESIDENTS/FELLOWS CLINICAL RESEARCH MODULE
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OBJECTIVES

- To gain basic and practical understanding of common qualitative methods and their applications in health research
- To develop sensitivity to issues of ethics and rigor in qualitative research
- To understand the utility and methods for incorporating qualitative inquiry into medical research using an exemplar

OVERVIEW OF THE SESSION

- Description of a clinical problem that requires qualitative methods to answer
- Description of the spectrum of qualitative methods and general research process
- ➤ Rigor in qualitative methods
- Practice qualitative data analysis
- Explore themes from the exemplar study
 - > Themes
 - > Applications

QUALITATIVE PROJECT EXEMPLAR

- Development of the Cannabis Exposure in Pregnancy Tool (CEPT)
- Pregnant women were recruited through social media advertising
- ➤ In-depth interviews about cannabis, prenatal use, knowledge & beliefs
- Used to inform and validate a tool for prenatal cannabis research



UNDERPINNINGS OF QUALITATIVE RESEARCH

SOURCES: DENZIN & LINCOLN, 1994; MORSE & FIELD, 1995; STREUBERT & CARPENTER, 2011

QUALITATIVE RESEARCH

- Answers a different type of research question from quantitative methods
- Guides practice by exploring experience of persons and health providers in health/illness situations
- Uses systematic modes of questioning, reflecting, sorting, focusing, and writing about human experience

QUALITATIVE RESEARCH

- Variety of methods spectrum
- Stand-alone
- Component within mixed-methods research
 - Strength and rigour should be equivalent to stand-alone



GUIDING METAPHORS

Quantitative

- Deduction
- Objective
- Measurability, calculability & statistics
- Scientific method & hypothesis testing

Qualitative

- Induction
- Subjective
- Language & human experience
- Text, stories & narratives

GUIDING METAPHORS

Quantitative

- Measurement of "truth"
- Impersonal data collection
- Distance from participants

Qualitative

- Open inquiry into perception/experience
- Researcher embedded in data collection
- 。 Closeness to participants

COMPARING THREE COMMON QUALITATIVE METHODS

	Phenomenology (Collaizi, 1978; van Manen, 1984)	Grounded Theory (Glazer & Straus, 1967; Strauss & Corbin, 1998)	Thematic (Boyatzis, 1998)
Aim or Focus	Understanding & describing human experiences or phenomena	Developing a theory about social process	Emergent
Discipline Origin	Philosophy	Sociology	Psychology

	Phenomenology	Grounded Theory	Thematic
Data Collection	In-depth interviews with up to 10 people	Interviews with 20-30 individuals to "saturate" categories & detail a theory	Interviews, focus groups, journals, key informants - until data are "saturated"
Data Analysis	Meaning themes Interpretive memos	Structured coding system: open, axial, selective	Thematic coding; search for themes, ideas
Narrative Form	Evocative, Metaphorical, Anecdotes, Case exemplars	Theory or theoretical model	Description of themes, ideas

Adapted from Creswell, J.W. (1998). Qualitative inquiry and research design: Choosing among five traditions. Thousand Oaks: Sage.



WHAT DO WE ACTUALLY DO IN QUALITATIVE RESEARCH?

Attempt to explore open questions
without imposing underlying
assumptions
about the answers

RESEARCH PROCESS - COMING TO THE RESEARCH QUESTION

- Coming to the question
 - Recognition of need for inquiry: patient-oriented, assumptions-based data; unknowns important to evaluation, public health or service delivery
 - Exploring beginning assumptions about the topic and the research process
- Literature review
 - Topic-driven; identifies/supports rationale
 - Locates question within existing literature and research

RESEARCH PROCESS - SAMPLING

Balance:

- If the sample size too small, it can't achieve theoretical saturation
- If the sample size too large, it can prevent in-depth analysis
- "Purposive" sampling seek people who have direct
 & personal knowledge of the topic
- Exceptional cases "Exemplars"
- Disconfirming cases

RESEARCH PROCESS - GENERATING DATA

- Entering the "field" or the setting where the phenomenon occurs
- Generate data:
 - typically semi-structured or unstructured interviews
 - Focus groups
- Verbatim transcripts of interviews/Focus groups
- Verbatim transcriptions of field notes/observations/insights
- Examination/description of other documents or artifacts

ANALYSIS:

Systematic ways of grouping, or explaining the data

 Not entirely unlike quantitative principles that allow us to explain large numbers of variables and data points

Increases interpretability and answers research question





























Animals









Scenery







People









Nature/outdoors



Subgroup: animals



Subgroup: people



Prof.





Indistinct location



















Colour











angry/sad/negative

melancholy

neutral

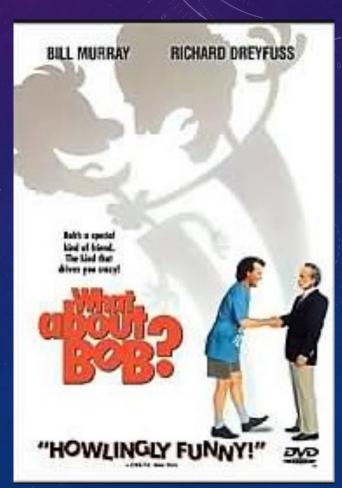
happy/positive

RESEARCH PROCESS (CON'T)

- "Analyze", synthesize, interpret text
 - Process depends on research approach
 - May work in research teams
 - May use computer software to manage large volumes of text
 - Typically involves multiple readings of the text over time, comparing initial and emerging "codes", and building concepts and themes

UNIQUE ETHICAL CONSIDERATIONS:

- Protecting anonymity & confidentiality
 - Small sample size
 - Participants may recognize themselves
- Researcher / clinician role distinctions
 - Prepare to offer referrals for emotional support or follow-up if necessary
 - Qualitative interviews may be therapeutic



SUMMARY

 The guiding metaphors and assumptions are different for qualitative and quantitative research

Research processes are similar

 There are unique ethical considerations when conducting qualitative research

CRITERIA TO JUDGE QUALITATIVE RESEARCH

SOURCE: SALE & BRAZIL . A STRATEGY TO IDENTIFY CRITICAL APPRAISAL CRITERIA.

QUALITY & QUANTITY 2004, 38: 351–365,

Rigor: How to appraise qualitative research?

Reliability Validity
Generalizability,
Representative
Samples

- Because the underlying philosophy differs;
- The judgement criteria must also differ

CRITERION: TRUTH VALUE

Credibility

VS.

Internal Validity

- <u>Triangulation</u> of: Sources;
 Methods; Investigators;
 Theory/perspective
- Member Checking; Use of Quotations
- Negative Case analysis;
 Disconfirming case search
- Ethical review; Informed consent procedures described; protection of privacy ensured

CRITERION: TRUTH VALUE

Transferability

VS.

External Validity (generalizability)

- DESCIPTION and RATIONALE provided for:
 - Phenomenon of study/Study context
 - Specific method chosen
 - Sampling procedure/strategy and participants
 - Raw data description and format
 - Analysis methods/coding
 - Saturation/ closing accrual

CRITERION: CONSISTENCY

Dependability

VS.

Reliability

External Audit of research process conducted

 An independent researcher well-versed in qualitative methods audits the paper trail and provides final agreement or suggested alterations.

CRITERION: NEUTRALITY

Confirmability vs.
Objectivity

- External Audit of Data reconstruction of the data
- Bracketing or statement of researcher(s)' assumptions/biases or perspective(s)
- Demonstration of negative case analysis and spectrum of states/behaviours/ experiences sought out

SUMMARY

- Criteria to assess qualitative research:
 - Credibility
 - Transferability
 - Dependability
 - Confirmability

Source: Sale & Brazil . A Strategy to Identify Critical Appraisal Criteria. *Quality & Quantity* 2004, **38:** 351–365,

REVISITING THE PROJECT EXEMPLAR

- Problem: i) Lack of knowledge of the beliefs, experiences, attitudes of pregnant cannabis users ii) Need a more valid measure of cannabis use in pregnancy
- Highly inconsistent evidence due primarily to poor measurement
- Current estimates of use are based on evaluation in routine practice
 - Inconsistent: not systematically collected
 - Women under-report to physicians (about 36% accuracy)
- Existing tools geared toward non-pregnant populations
 - Wording and context may not apply
- ➤ Biological tests do not accurately measure long-term, or low exposure which may still be important for infant and maternal outcomes

OVERVIEW AND METHOD:

- Objective: To explore knowledge attitudes and beliefs about cannabis among pregnant women
 - > To inform education and intervention (not just what, but how)
 - To develop a valid measurement tool for antenatal cannabis exposure
- > Social media recruitment
- > Semi-structured interviews; audiotaped and transcribed
- Thematic analysis (mixed with qualitative validation and reliability methods



QUALITATIVE DATA ANALYSIS HOW TO

CODING STRATEGIES

- Scan each sentence for words or phrase that strikes you as significant
- What to code?
 - Behaviours; Events; Activities; States (loneliness, depression)
 - Strategies or tactics (doing X in order to...)
 - Relationships; adaptations
 - Conditions or constraints
 - Consequences
 - Settings
 - Meanings example: chilling out relaxing, not doing much, or social interaction with peers – CONTEXT!
 - (Adapted from Bogdan and Biklen, 1992; Strauss, 1987; Mason, 1996; and Gibbs, 2006)

CODING STRATEGIES

- What to look for:
 - Word repetitions; Keywords in context
 - Metaphors and analogies
 - Transitions and connectors: "since"; "because"; "as" etc.
- Missing words or information:
 - Is there anything that you would expect to see but don't?
 - Continua of states, emotions or experiences...
 what about other points on the continuum?

CODING STRATEGIES

- Group concepts by similarities and differences
- Label concepts (to what do these quotes speak?)
 and look for ties/similarities
- Constant Comparison
 - With each new addition, compare to previously coded examples and ask "does this fit?"
- Examine uncoded text to ensure it's not a new concept

CODING STRATEGIES

- Label grouped concepts sub-processes- what explains or predicts the concepts in the group
- Facts before theories
- Explore how the concepts are related visualizations, maps and diagrams can be helpful

"I take my meds but I still have bad days. I know the moment I wake up if it's going to be a bad day. I'm really fidgety and distracted and resentful. I can't even sit out here on bad days. I get too resentful when people walk by and don't help. I know it doesn't make sense, and that I don't have a right to be resentful, but I still get angry. I can't keep a job because of the bad days. I just get too verbal when I'm agitated. I don't even realize I'm doing it. I realize it later.

But when it's happening, I don't know it's happening. It's like when I'm in the picture, I can't see the picture."



"He makes me want to know about little things, so that I can teach him. Like when we sit by this lake, I wish I knew what kind of turtle that was, so I could tell him. And I want to figure out what kind of duck that is, so I can tell him all about it the next time we come."

"What do you want most for him?"

"Whatever his dreams are, I'm down to ride for him."

"What's your biggest fear

for him?"

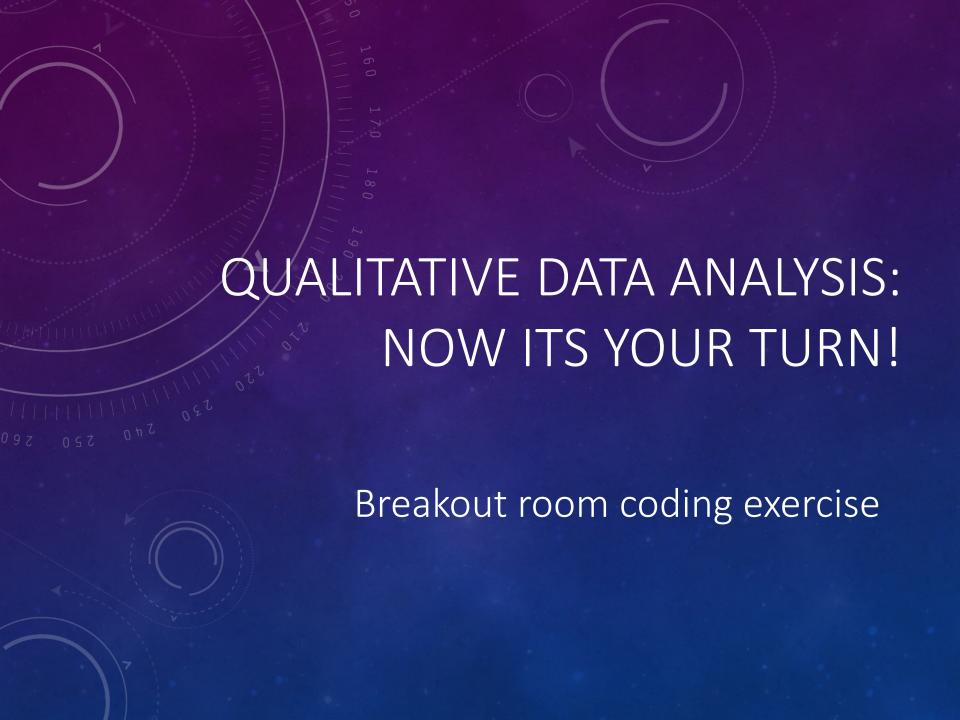
"That he won't try.

If he doesn't try, I'll be hurt.

Cause then we'll never
know how far he'd get."



https://www.facebook.com/humansofnewyork?fref=nf





- > Safety
 - It's safe because...
 - It's natural so it's safe
 - my/her kids are fine, so it's safe
 - > Safer than smoking, drinking, prescriptions
 - Not enough evidence to say it's not safe
 - Different modes have different safety

"I would think that edibles and lotions and liquid CBD capsules even, they're most likely more safe to take during pregnancy considering ... you're taking out the smoking of the equation, that's the part that most people have a big problem with"

"my son turned out perfect! Healthy baby boy weighing 8.6 ... the most calmest baby ever! Doesn't cry, he's a happy baby and healthy."





- > Perceived medical benefit
 - > Perceived effectiveness for various conditions

"I'm off antipsychotics, benzodiazepines, amphetamines, sedatives, and all painkillers, replaced by 2-3 grams medical marijuana a day....And I mean, 27 weeks so far, and baby looks good"

"I had really bad morning sickness and it really helped me with that, but it helped me with my mental health, like anxiety and stuff, or insomnia, and loss of appetite."

- Misinformation/distrust
 - Circle of trust includes sources that confirm beliefs (being "educated")
 - Different forms have different safety
 - Placenta or mother's body filters THC
 - Some mistrust of science/pharma

"I 100% preferred taking a puff or two of the lovely Mary Jane rather than chemically-made, unnatural Tylenol pills when I was sore or feeling stressful mood-swings or headaches... It's Mother Nature's medicine and 100% beats any doctor. I've been to."

"I trust smoking a plant while pregnant more than a vaccine that is suggested nowadays."



> Stigma

- Physicians being open about it reduces perception of stigma
- ➤ Acknowledging some benefits reduces stigma → less biasing of response

"[if the doctor acknowledged that it was useful in some cases]...If they were open to talk about it and they were educated on it and they knew how... We could have a conversation, and an educated one, I would be really happy."

CONTENT ANALYSIS FOR TOOL

Some assumptions were right, but MANY lessons learned



THEME APPLICATIONS FOR TOOL

- Women change patterns of use in pregnancy lower dose, frequent use
- Understanding of dose depends on personal factors, frequency of use, mode of consumption, perception of safety and utility
- Stigma still high, and non-judgmental approach is key to unbiased reporting
 - Must allow an 'accidental exposure' category
 - Medicinal use perceived as more acceptable
- Cognitive function?
- Exposure takes many forms: frequency, dose, mode of exposure/consumption, timing in pregnancy

CEPT ONLINE

CEPT Online



IMPLICATIONS

- > The population has a unique outlook and set of beliefs
 - affects health behavior
 - crucial to understand for effective education/intervention
- ➤ Although some of our assumptions were correct, without the full qualitative exploration, we would not have a valid tool!
- > We can:
 - estimate the magnitude of the problem (essential for resource allocation)
 - > accurately study effects (without misclassification)
 - inform clinical and public health communication and education

PUBLISHING QUALITATIVE RESULTS

Reporting guidelines for qualitative research:

COREQ checklist: available online

http://www.equator-network.org/reporting-guidelines/coreq/

Sale and Brazil (2004) criteria can be very useful for publication as wells as in critical appraisal of research you might come across while informing your practice or summarizing evidence

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Our participants





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FEEDBACK & QUESTIONS

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