Mixed Methods Study Design

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1. Approaches
   a. Qualitative first, then quantitative
   b. Quantitative first, then qualitative
   c. Concurrent

2. Quantitative designs, strengths & weaknesses
   Deductive data collection and statistical analysis techniques, such as clinical trials or cohort studies, that seek to examine variables that can be measured numerically. Quantitative studies yield numerical data and typically a priori hypotheses, but may be hard to generalize.

3. Qualitative designs, strengths & weaknesses
   Inductive data collection and analysis techniques, such as ethnography or focus groups, that seek to understand meaning and context. Qualitative studies yield rich, grounded data and new hypotheses, but may be hard to generalize.

4. Examples
   a. Qualitative first, then quantitative
   b. Quantitative first, then qualitative
   c. Concurrent

5. Developing a mixed methods team

6. Publishing mixed methods research

References
QUANTITATIVE STUDY TYPES

Quantitative designs are specified at the outset, typically along with a priori hypotheses. Analyses usually involve descriptive and inferential statistics.

A. Case reports & case series
   *Detailed descriptions of an individual case or cases, without an explicit control group.*
   May be useful for generating new hypotheses, or for describing unusual or new diseases. Particularly prone to selection bias and confounding.

B. Ecologic studies
   *Comparisons of factors, using group data (as opposed to data on individuals).* Efficient use of available data for generating hypotheses or a "bottom line" assessment of strong relationships. Any link between exposure and outcome must be inferred, since individual data is not collected. May lead to "ecologic fallacy" of falsely attributing causation to confounding factors.

C. Cross-sectional (prevalence) studies
   *The relationship between an outcome and other factors of interest is compared, in a defined population, at one point in time.* Efficient in that exposure and outcome data are collected at one time. The argument for a causal relationship is weakened by the lack of a temporal relationship between the predictor and outcome variables. Best design for determining prevalence.

D. Case control studies
   *Cases of an outcome and suitable controls are compared with respect to past exposures or other factors of interest.* Efficient for a rare disease. The temporal relationship of exposure and outcome is an issue here, too. The control group must be representative of the population from which the cases are chosen. Measurement of exposure must be similar for cases and controls. Watch for ascertainment and recall biases.

E. Cohort studies
   *A defined group is followed over time for the development of an outcome thought to be related to a prior exposure.* Typically, an exposed and an un-exposed group are then compared for their relative risk of disease. Can provide temporal evidence for a causal relationship, since exposure precedes the outcome. Costly for rare diseases, or diseases with a long latency. Attrition may cause bias.

F. Clinical trials
   *Eligible subjects are assigned randomly to receive either treatment or serve as a control, and are followed for the development of the outcome of interest.* Most like an experiment. Strongest evidence for causality. Selection factors may decrease generalizability. Expensive. Ethical issues.
QUALITATIVE STUDY TYPES

Often qualitative designs involve multiple methods. The use of multiple data sources and multiple analysts is called "triangulation," and helps to assure the trustworthiness of the findings. Typically qualitative study designs evolve over time in an iterative fashion based on the initial findings. Analyses involve a combination of editing, templates or immersion/crystallization.

A. Participant observation

*Immersion of the researcher in the area of study; fieldnotes based on observations.*

B. Interviews (key informant, depth, informal)

*Talking with informants. Often recorded for later analysis.*
Provides the perspective of those being studied. Selection of key informants can dramatically alter findings, as can relationships and hidden agendas.

C. Focus groups

*Moderated discussion among homogeneous or heterogeneous groups of 4-12 people.*
Provides a shared perspective stimulated by prompts and other participants. Selection of participants and the group process affects findings. Seldom good for sensitive topics.

D. Text analysis

*Analysis of printed or electronic materials.*
Useful if the needed information exists in this form.

E. Participatory inquiry

*Involving the participants in forming the question, designing and conducting the study, interpreting and disseminating the findings.*
The process develops trust and helps to assure the relevance of the findings to participants. May be challenging to convey the learning outside of the group.

F. (Comparative) case studies

*Integrating multiple data sources to provide an in-depth evaluation of a particular case. Comparative case studies then perform analyses across cases.*
Useful for generating insight into multifactorial problems or understanding the effects of complex interventions. Selection of cases is key. Challenging to identify over-arching lessons.
Integrative Studies

A. Review Articles
An author summarizes data and experience on a topic, and makes recommendations. Review articles or editorials often incorporate useful clinical insights from the author, but are particularly prone to the biases of the writer. This is particularly true for non-peer reviewed articles.

B. Meta Analysis
All published original research relevant to a specific question is examined using explicit criteria for quality and validity. Data from studies meeting inclusion criteria are summarized or pooled. This approach is less subject to the biases of the writer than the typical review article, and can be useful in increasing statistical power when multiple small studies have yielded conflicting results. Make sure that you agree with how the question is focused, the inclusion/exclusion criteria, and weighting schemes.

C. Decision Analysis
A technique for specifying alternate choices for managing a clinical problem and for quantitating and comparing the outcomes from different approaches. Decision analyses can help specify multistep clinical decisions, provide a bottom line recommendation, and demonstrate the sensitivity of the optimal choice of different assumptions. They are dependent on the logic and adequacy of specification of their decision trees, the quality of data upon which they are based, including information on the value or "utility" placed on various outcomes.

D. Economic Analyses
Cost effectiveness analyses compare the costs and health care outcomes of alternate decisions or health care policies cost benefit analyses go further, in that outcomes are valued in monetary terms. Like decision analyses, economic analyses are highly dependent on the logic and adequacy of specification of the costs and outcomes, the quality of the cost, outcome, and utility data upon which they are based, and the assumptions made in the analyses.

E. Clinical Policies or Guidelines
A technique for using explicit guidelines for gathering and interpreting available information to develop an approach to a particular clinical problem. Most clinical practice guidelines produce a general recommendation for most cases, along with options for tailoring the recommendation to fit individual circumstances. Guidelines that are developed using explicit rules for examining the scientific evidence for clinical decisions can provide a very useful synthesis of information, and can identify particular criteria for deviating from the policy in individual cases. Policies that are developed by a group of "experts" without explicit specification of their rules are subject to bias.
ASSESSMENT OF THE VALIDITY OF THE STUDY

Examine potential sources of error and ask:

How (in what direction) would the threats to validity affect the findings?
Were potential sources of error adequately controlled in the design and analysis?
How do validity concerns affect your interpretation or application of the data?

POTENTIAL SOURCES OF ERROR

A. CHANCE: Random error in sampling from a population.
   1. Type I (alpha) error: The probability of falsely saying that there is a difference between two populations.
   2. Type II (beta) error: The probability of falsely saying that there is no difference between two populations.

B. BIAS: Systematic distortion
   1. Selection bias
      - Systematic slant in how subjects are assembled or retained for study
   2. Information bias
      - Systematic distortion from inaccuracy in measurement or classification of study variables

C. CONFOUNDING: Misattribution of cause and effect
   Cause                              Effect
   Confounder

REDUCING THE CHANCE OF ERROR

In the Design
1. Study design appropriate for the question B,C
2. Adequate power A
3. Complete accounting of eligible patients B1
4. Verification of information B2
5. Blinding B2
6. Multiple control groups B,C
7. Randomization C
8. Restriction C
9. Matching C

In the Analysis
1. Best case / worst case scenario B,C
2. Sensitivity analysis B,C
3. Adjustment B1,C
4. Mathematical modeling C

A Reduces the role of chance; B1 Reduces selection bias; B2 Reduces information bias; C Reduces confounding