Module 3 Developing the Study The Basics of Study Design



Learning Objectives

By the end of this module the student will:

- 1. Recognize different types of research methods
- 2. Understand the steps involved in moving a research question into a research study.
- 3. Understand that their research methods and study design are determined by the questions they wish to ask.



Now that you have decided on a topic for your question, you need to design the research methods by which you will actually ask and answer your questions.



Step 1: Is this a basic sciences study or one in which you will work with people?

Basic Sciences. Work with genes, cells, tissues, or animals. (e.g. testing a new drug to see if it is safe). Conducted in a very controlled environment.

People or cultures: are your looking at a specific group of people (e.g. people with spinal cord injury) or a whole group of people (e.g. people who live in Appalachia or Kentucky or the USA)?



Step 2: How will you ask your question?

Quantitative type research.

- "What is happening?"
- This is standardized and generalizable.
- Refers to the systematic experimental investigation of some phenomena in which statistical, mathematical or computational techniques will be used.



Step 2: How will you ask your question?

Quantitative type research continued.

- The process of measurement (blood pressure, distance, weight) is the primary focus.
- These measurements will be examined mathematically to determine if there is a difference between two our more groups.



Step 2: How will you ask your question?

Quantitative type research continued.

- Type of data collected: measurements (numbers), surveys, questionnaires
 - Example: Measure blood levels for people with diabetes who are trying a new drug.
 - Example: Survey that concludes that the average patient has to wait two hours in the waiting room of a certain doctor before being selected.



Step 2: How will you ask your question?

Qualitative type research.

- "Why is it happening?"
- Is aimed at gathering an in-depth understanding of human behavior and the reasons for the behavior or beliefs of individuals.
- The qualitative method often investigates the why and how of decision making, not just what, where, when. This form of research asks its questions in a manner that does not involve mathematical models.



Step 2: How will you ask your question?

Qualitative type research.

- Qualitative researchers typically rely on the following methods for gathering information:
 - Participant observation
 - Focus groups
 - Structured and semi-structured interviews
 - Non-participant observation
 - Field Notes and Reflexive Journals
 - Analysis of documents and materials.



Step 2: How will you ask your question?

Qualitative type research continued.

- Involves analysis of data such as words (e.g., from interviews), pictures (e.g., video), or objects (e.g., an artifact).
 - Because of the time consuming manner by which the information/data is collected, qualitative research uses smaller but focused samples.
- Example: Explore why people with diabetes are not taking the new medication even though it helps their illness.



Step 2: How will you ask your question?

- Complementary: includes both qualitative and quantitative methods.
 - Example: Through a survey we discover that 50% of men over the age of 60 were unsure of their families' health history. After the survey we decide to begin interviewing a group of men over the age of 60 to discuss their knowledge of the health histories of their family members. We hope to learn why they are or are not aware of this information.



What do people with spinal cord injury (SCI) who live in rural Kentucky need to improve their quality of life?

- A Qualitative study: Needs assessment of this group, which involved interviewing representative people.
- Complementary study that emerged from the needs assessment: How accessible are Kentucky state parks for persons in wheelchairs?
 - Measurements were made and numbers recorded



Overall Question was: What do people with SCI, who live in rural Kentucky, need to improve their quality of life?

- A Qualitative study asked: What are the issues people who use wheelchairs need to think about when traveling?
- Persons were interviewed to collect their thoughts and concerns about what they need when they are planning a trip.



Overall Question: What are the obstacles to and supports for participation when people with stroke who live in rural Kentucky return home?

- ❖ Qualitative study: interviews to gather info about how they transitioned back into their communities, and what their perspectives were on obstacles and supports (needs assessment)
- Quantitative component: use of the Stroke Impact Scale, to provide a quantitative assessment of the impact (characterizes the group)



Research questions that are emerging from the needs assessment of people with stroke.

- How is their quality of life affected by participating in a support group? (complementary design)
- Can we reduce the waiting time for people to acquire acute care after onset of stroke through an educational public health campaign? (quantitative design)
- What are the differences in experiences between people in urban areas and people in rural areas upon returning to their communities? (qualitative design)



Step 3: Develop the methods.

A. Who will do what?

 Research usually involves a team working together. Each person who helps on the study has a role to fill and these roles should be spelled out before you start your project.



Step 3: Develop the methods:

B. <u>Sample Size</u>: How many cells, animals or people will you need to study in order to make useful conclusions from your work?

Quantitative Research:

- Power analysis: helps estimate the sample size that needs to collected/recruited in order for the results to reach a level of confidence that can be comfortably reported.
- A statistician can help you with this.



Step 3: Develop the Methods:

Sample Size in Qualitative research:

- Saturation: In qualitative studies the goal is to reach saturation of information. You continue to recruit and interview participants until you don't hear significantly new information.
- This will be different for each study.



Step 3: Develop the Methods

- C. What type of measurements will you collect?
 - **Quantitative study: Examples:**
 - Measurements (numbers): examples: blood pressure, strength, balance, levels of a certain chemical in a person's blood, average income of a certain group of persons.
 - Surveys and questionnaires: Quality of life, self report of disability, pain levels



Step 3: Develop the Methods:

C. What type of measurements will you collect?

Qualitative study: Examples:

Words (e.g., from interviews)

Pictures (e.g., video)

Objects (e.g., an artifact).



Step 3: Develop the Methods. Institutional Review Board (IRB)

- If you are working with people there are additional forms you will need to have approved by an IRB.
 - Involves developing Consent forms (forms that state the person agrees to be part of the study, that they understand what the study is about and what is being asked of them)
 - Involves having all of your methods approved to make sure they are safe to use with people.



Step 3: Develop the Methods. Institutional Review Board (IRB).

Why is the IRB process important?

- The IRB process is there to make sure the welfare of each participant is taken care of.
- It protects the person from harm as well as protects the information they give you from being used inappropriately.



Example of a Quantitative study:

- ❖ After collecting the surveys from 100 men over the age of 60 about their knowledge of their family health histories, you want to analyze the data.
- ❖ You may conduct descriptive statistics to look at averages and frequencies. For example how many men knew their father's health history. What is their average level of comfort in knowing their father's health history (i.e. 1 not at all, 4 completely).



Example of Quantitative study continued:

- After you can describe the data you may want to statistically compare things like: Do single men differ in their knowledge of family health histories from married men? Do men with chronic health conditions know more about family health history than health men?
- This statistical analysis is conducted using computer software.



Example of Qualitative study:

- As you interview men related to their knowledge of family health history you will being analysis using line by line analysis of the transcribed interviews. As you go along words and ideas begin to jump out as important.
- As you analyze more interviews you look to see similarities and differences of the stories. You keep analyzing as interviews are completed.



Example of Qualitative study continued:

By constant comparison between interviews, developing codes and categories you can begin to understand the experience of your participants and see patterns in their experiences.



Developing the Study: Summary

- Frame the question (what, why, where, when, how)
- Determine the best methods to address the question
 - Basic science----Human-----Societal
 - Qualitative-----Quantitative-----Complementary
- Organize the team
- Internal Review Board: Subjects protection



Short Research Module Survey

Please follow the link below to a short survey that will give us feedback about the training module you just finished. Your answers are completely confidential and we will not contact you for any additional information. Your feedback is important to us and will allow us to modify this module as needed.

https://docs.google.com/spreadsheet/viewform?formkey=dHh KODVLMzM5VE9vaEJGMGZ0ZzJXX1E6MQ



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