Developing the Research Question and Study Design

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Abstract

Research entails investigation of a problem that results in new information or conclusions. The research process is complex and requires detailed thought, planning, and creativity. The first step in the process is to develop the research question, which describes a gap in knowledge and can be answered through systematic investigation. Several characteristics need to be considered when conceptualizing the research question, including importance, specificity, measurability, and feasibility of the question. The question also should be empirically derived, based on prior knowledge, and be of significant interest to the researcher. Key areas for consideration in formulating the study design include whether the study will be experimental or observational, if the data will be qualitative or quantitative, how frequently data will be collected, and what instrument(s) will be used for data collection. This article outlines the steps involved in developing a research question and designing a study that effectively answers the question.

Introduction

Research, as defined by the Merriam-Webster Dictionary, is an "…investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws" (1). Despite this rather straightforward definition, the research process, especially in science, is complex and entails detailed thought, planning, and creativity.

Identifying the Research Question

The research process begins with formulation of a question based on previous research (2,3), a literature review (2–8), and/or observations (2). The research question is a tool to describe a gap in knowledge (5), and it can be answered through systematic analysis or assessment, ultimately yielding new information (3). Conceptualizing the research question encourages the researcher to consider the study's overall purpose (9). Among the important characteristics to consider when formulating a research question are the importance, specificity, measurability, and feasibility of the question (Table 1) (3). The question should be empirically derived, based on prior knowledge, and be of significant interest to the researcher (3).

Developing and Refining the Research Question

Once a research question has been identified, it must undergo further refinement to help the researcher develop a framework to direct the entire research project (5). According to Bordage (13), absence of a well-defined research question is a common reason for reviewers to reject manuscripts for publication. Therefore, it is paramount for the researcher to spend time crafting a well-written question. Refining the research question can be guided by using one of three similar mnemonic devices:

- PICO (Patient, population, or problem; Intervention or independent variable; Comparison; and Outcome) (14,15)
- PICOM (Patient/Problem, Intervention, Comparison, Outcome, and Methodology) (3)
- PICOT (Population, Intervention, Comparison, Outcome, and Time) (16,17)

Use of PICO/PICOM/PICOT is widely suggested for developing the research question (17) and can aid the researcher in defining a focused question that embodies the previously cited characteristics. Table 2 provides a list of considerations for each component of the mnemonic device and an example of how to apply this process to the nutrition-related problem introduced in Table 1.

Although important and integral to the study, the initial research question rarely is reported in the literature. Instead, researchers develop hypotheses or formal statements based on the research question (18). Hypotheses state a relationship between two or more variables (19) and should be composed so they can be answered as either "true" or "false" based on the results of the experiment (18). Using the nutrition related problem introduced in Table 1, a hypothesis based on this research question might be "LOS will be significantly lower in pediatric burn patients who are provided with an immune-enhancing enteral formula compared to those provided with a standard enteral formula." Not only does a hypothesis define the population of interest (18), but it states the expected results of the study and helps frame the study design (8).

Developing the Study Design

Once the research question and subsequent hypothesis have been developed, the next step is to formulate the study design. Although the study design inherently is considered when developing the research question/hypothesis, specific details are needed. For example, the researcher needs to ask several questions, including:

- Will the study be experimental or observational?
- Will data collected be qualitative or quantitative?
- How often will data be collected?
- What instruments will be used to collect data?

Table 1: Characteristics of a Research Question

Nutrition-related research question: Do pediatric burn patients who are provided with an immune-enhancing enteral formula (e.g., glutamine-enriched) have decreased hospital length of stay (LOS) compared to those provided with a standard pediatric enteral formula?

Characteristic	Definition	How Research Question Fulfills Characteristic
Importance	Relevant to the current problems and issues within the field.	Evidence exists that enteral glutamine should be considered in adult burn patients, although evidence is limited in the pediatric population (10).
Specificity	Identifies the variables and population of interest (3).	Variable: Hospital LOS Population: Pediatric burn patients
Measurability	Concepts in the research question must have a method by which they can be evaluated or assessed (3).	Assess hospital LOS in pediatric burn patients who were provided with either a glutamine-containing enteral formula or a standard enteral formula.
Feasibility	Question must be able to be answered in a realistic time frame, using ethically appropriate methods, and at a reasonable cost (3).	The study design proposed for this study is retrospective: chart reviews will be conducted on pediatric burn patients who were provided with either a glutamine-containing enteral formula or a standard enteral formula. Therefore, the study is realistic from time, ethical, and cost perspectives.
Empirically derived	Concepts in a research question should be based on previous research, a literature review, and/or observations.	A review of the literature yields studies that report an association between enteral glutamine supplementation and decreased LOS in adult burn patients (11,12).
Interest to the researcher	Research requires much time and self-interest. Therefore, the researcher should be passionate about the topic to promote dedication (3).	Not applicable.

Table 2: Application of PICO/PICOM/PICOT Components of a Research Question

P	I	C	O	M	T
Patient, Population, or Problem	Intervention or Independent Variable	Comparison	Outcome	Methodology	Time
What patient, population, or problem will be studied? **Pediatric burn patients**	What intervention or exposure of interest will be studied? **Immune-enhancing enteral formulas (e.g. , glutamine-enriched)**	What will be the comparison? **Standard pediatric enteral formulas**	What will be the variable of interest? **Hospital length of stay**	How will the data be collected? **Retrospective medical chart review**	When will the outcome be assessed? **Medical charts of both pediatric burn patients provided with immune-enhancing enteral formulas and those provided with standard enteral formulas will be reviewed once, after discharge**

Final research question: Do pediatric burn patients who are provided with an immune-enhancing enteral formula (e.g., glutamine-enriched) have decreased hospital length of stay compared to those provided with a standard pediatric enteral formula?

Adapted from Heddle (16).

Experimental Versus Observational

Study designs can be divided into two primary categories: experimental and observational (Figure 1) (4,20). Experimental studies are characterized by alteration of the independent variable and evaluation of the effect of this change on the dependent variable(s) (4). The randomized, controlled trial (RCT) is an example of an experimental study design that is considered the gold standard in research methodology (20). The typical overall goal of an RCT is to investigate the efficacy of a certain intervention or treatment by comparing treated study participants with those who were untreated (i.e., control group) (21,22). RCTs are characterized by random assignment of the intervention or treatment (22), and according to Hanson, they are the strongest study design to test for cause and effect (20).

Randomization eliminates the effect of confounding variables, such as demographics. However, when an RCT does not assign participants randomly to study groups, instead using other methods such as date of birth or order of participant recruitment, the study is considered a quasi-RCT (20). Caution is warranted with interpreting results of quasi-RCTs because the observed difference between groups cannot be attributed with certainty to the treatment or intervention (21). Instead, confounding variables that were not controlled for with randomization might be involved.

Unlike experimental study designs, observational study designs seek to determine relationships between variables that have not been altered (4). Examples of observational studies include cohort and case-control. Cohort studies are considered the gold standard of observational studies (20). In a cohort study, a group of individuals is followed forward in time to observe participant experiences, with disease being the most commonly studied outcome (22). At the beginning of the study, study participants are assumed to be free of disease and are recruited based on treatment status or presence/absence of a certain factor or exposure (22). The individuals then are followed prospectively to identify the outcome of interest (20,22). Cohort studies can be considered as tools to identify the potential cause of a disease (21). Although well-suited to establish an association between exposure and outcome, cohort studies are unable to establish causality among variables (21).

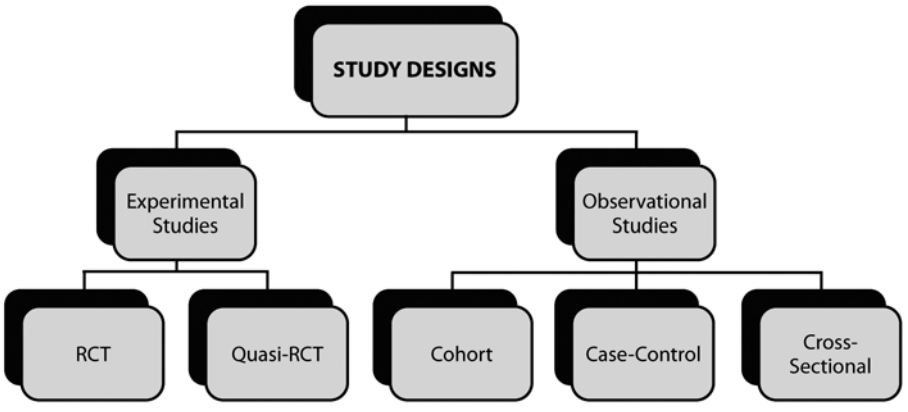
Case-control studies are another type of observational study that identify possible contributing factors to a disease or condition, but unlike cohort studies, the observations are made retrospectively (21,22). Briefly, exposure status is compared between "cases" that develop the outcome of interest and "controls" that do not have the outcome (20–22). Case-control studies are ideal for outcomes that are rare (20–22) and are less expensive and time-intensive than cohort studies (22). However, similar to a cohort study, a limitation with the case-control study design is that causation cannot be established; only associations can be made between the factor and the outcome of interest (21).

Qualitative Versus Quantitative

Scientific research can be either qualitative or quantitative, and both approaches commonly are used in the same study (4). Data collected using qualitative research approaches are characterized by words; numbers are indicative of quantitative data (4). Qualitative data collection is suited best for studies that strive to evaluate social occurrences, such as behaviors and attitudes, in a natural setting (2,6). For example, understanding how Native Americans who have diabetes perceive the American health system and manage their disease would be evaluated best using qualitative approaches, such as a focus group (23). In this example, researchers asked for opinions and experiences of Native Americans who had diabetes in a small group discussion. Although this type of data is considered subjective and may not be applicable to other populations, it is more comprehensive than data elicited from a survey.

In contrast, quantitative data collection is most appropriate for experimental studies, such as an RCT. Quantitative studies generally require more standardized methods than do qualitative studies and rely heavily on statistical analyses (2,6). An example of quantitative data collection is the assessment of fluid and body composition changes after gastric bypass surgery (24). The data collected in this example were objective and included urine, serum, and body weight, which were analyzed using statistical procedures and yielded data that described the participants in the study in terms of their changes after gastric bypass surgery. Overall, quantitative data yield information that is succinct and relatively free of bias (provided the samples are analyzed according to

Figure 1: Study designs



RCT: randomized, controlled trial
Adapted from Hanson (20).

protocol), but such data cannot describe how the changes occurred. That interpretation is up to the researchers. In summary, neither research method is superior to the other, with studies often employing both. The choice of which to use depends on the specific research question and hypothesis.

Frequency of Data Collection

The frequency and timing of data collection are important logistical considerations. Both time and finances dictate how often data are collected and the study duration. In the cross-sectional study, which is the shortest study design, data are collected at one time point only. Because individuals are not followed long term, such an observational design is considered "a snapshot in time" and is not sufficient to establish causal relationships. However, one advantage of a cross-sectional study design is its simplicity and relatively low expenses because no follow-up is needed. In addition, determination of associations between exposure and disease is possible (25), which can lead to more in-depth follow-up studies, such as an RCT. In contrast, the longitudinal study is characterized by data collection at more than one time point. Study participants are followed for days to years, depending on the needs of the study, and a longitudinal design allows the establishment of causal relationships, if the study is an RCT. However, because study participants are followed long-term, studies can be time-intensive and, therefore, costly. In sum, the frequency of data collection is an important consideration when planning the study design, and time constraints, budget, and the research question/hypothesis determine the necessary timetable.

Instrumentation

The choice of tool(s) for data collection might be one of the most important features of the study design. The research question primarily determines the type of instrument(s) needed. Examples of study instruments include surveys, assay kits, and clinical assessment tools. First, the researcher must decide if he or she will develop a new instrument or use an existing one (8). Perusing the literature can help identify if a tool has been developed that fits the scope of the study. However, researchers should not select an existing tool based solely on convenience (8), because such a choice could jeopardize study results if the instrument is not appropriate. It is beneficial to use existing instruments for which the reliability and validity have been established to make possible comparisons between studies (8). However, if existing instruments are not appropriate for the study, the researcher must modify an existing instrument, create a new instrument, or use an existing instrument in a manner that has not been done previously. For any of these options, the researcher must describe clearly what was done so that the validity can be assessed (8) and future researchers who wish to replicate the study have a specific path to follow. Overall, study results are only as reliable as the chosen instrumentation. Therefore, prudent research and selection from all available options is recommended.

Outcomes Research

Outcomes research emerged in the early 1980s as a tool to evaluate the effectiveness of health care services and has changed how the health care system evaluates end results of procedures, treatments, interventions, and programs (26). Unlike the RCT, which determines efficacy through controlled conditions, outcomes research measures the effectiveness of services in "real life" settings (27,28). Typically, assessed outcome categories include: clinical, patient, and cost (27). Clinical outcomes are concerned with health status and examples include mortality, symptoms, and clinical events (26,27). Patient outcomes are characterized by a response to an intervention and examples include survival, symptom relief, LOS, and nutrition status (27). Cost outcomes, as would be expected, are concerned with the financial aspects and include what it costs to initiate the intervention or procedure and the cost ramifications of the resulting outcome (27).

Results of outcomes research are applicable to both health care providers and patients. For example, clinicians and patients can glean information (e.g., benefits, risks) to help guide an informed decision about treatment options (26,28,29). Data from outcomes research also can aid health care providers in the development and/or improvement of protocols, programs, and clinical guidelines for the most effective care. More specifically, dietitians can incorporate outcomes research into their daily work routine, thereby playing an active role in improving health care outcomes and patient experiences. Including outcomes research in current practice should not be perceived as a laborious task. It does not require large populations or expensive equipment; rather, it requires information from daily activities (30). For example, using medical records, a clinical dietitian could assess if those who receive a nutrition consultation have decreased nutritional complications or LOS. Other parameters that a dietitian could assess include:

- Patient satisfaction with hospital meals
- Clinical outcomes in patients who receive immune-enhancing enteral formulas
- Weight status in postgastric bypass surgery patients who attend support group sessions
- Glycosylated hemoglobin values in patients with diabetes who attend outpatient diabetes education sessions

Outcomes research assesses the effectiveness of health care interventions and programs, and in an ever-changing health care environment, this methodology is integral for the determination of what works and what does not. Data that support the use of interventions and programs represent a powerful tool to ensure that the services provided by the dietitian are sustainable.

Conclusion

Developing a scientific research study is not a static process; rather, it evolves continuously with completion of each step. The process begins with the identification and refinement of the

research question. Detailed attention to this step is essential because it forms the framework for the overall study, and a well-written question can increase the chance for publication success. Once the research question has been developed, the researcher should pay attention to the details of the study design. The overall research question helps to guide the process, along with consideration of whether the study will be experimental or observational, the data will be primarily qualitative or quantitative, how often data will be collected, and what instrument(s) will be used to collect data. Good researchers spend a significant amount of time thinking about and developing these initial steps because they form the basis for the entire research project and if well done, can result in useful and novel data.

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