Research methodology: Study types

Editorial

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Different study designs are applied in research fields, and sufficient knowledge of study types may help design the research methodology. Type of study is referred to as one of various methods for obtaining data information collected by researchers depending on their goals, and the questions they're trying to answer. This simply means that several study types can answer the study question, but which is the most appropriate? There are two main categories of studies; observational and experimental. Observational studies involve collecting, and analyzing data without researcher' intervention (*i.e.*, the experimental execution of a certain plan); while experimental studies require researcher intervention. When researchers want to answer a specific question related to a certain topic, they may choose an observational approach, or experimental design. The present editorial aims to clarify the important differences between study types to select the best one answering the study question, or confirming/denying the study hypothesis.

How to write a research question?

During clinical practice and/or reading literature, the researcher finds a problem that is worth solving. One of the most essential steps in problem solving is developing a study question/hypothesis. It directs the investigation, provides a clear focused goal, and addresses a problem or issue that researchers attempt to answer. In 2007, Brian Hulley created the FINER model that stands for the characteristics of a study question[1]. The FINER criteria aren't just a checklist, *i.e.*, they are essential elements ensuring a strong impact and meaningful study. The criteria included 1) **f**easibility where the question is within the researchers' abilities, and resources, 2) **i**nteresting to reviewers, and other colleagues to conduct similar researches, 3) **n**ovel providing new insights and may help confirm existing research, 4) **e**thical where the study participants provide their informed consent, are informed with the study results, and receive the appropriate management, 5) **r**elevant where the researchers choose topics related to their society's health problems.

To start with, there are two primary types of research questions: qualitative and quantitative. A qualitative question seeks exploration of the study topic, *e.g.*, Is schistosomiasis *haematobium* associated with cancer bladder? Are natural products of value in treatment of schistosomiasis *mansoni*? On the other hand, quantitative is an objective question that aims to prove or deny a hypothesis, *e.g.*, What type of cancer bladder is most commonly associated with schistosomiasis *haematobium* in Egypt? Does oil extract of *N. sativa* exhibit inhibitory effects on *Schistosoma* adults in comparison to Praziquantel? Of note, the study question should be directly stated under the subtitle 'Background' in the article's 'Abstract' (the study rationale).

Research type: Is it observational or experimental?

Observational studies help researchers expand existing knowledge regarding a specific topic, while experimental studies present and provide solutions for existing problems. Most commonly, basic observational research seeks to answer "how, what, and why" fulfilling a sense of curiosity. On the other hand, there are three types of applied research: 1) action to help researchers find practical solutions to a health problem, 2) evaluation to help authorities make an informed decision, and 3) developmental to create a new diagnostic tool, identify novel drug targets or develop new drugs, and implementation of a control measure. Of note, both research types (basic and applied) overlap when observed results provide a foundational understanding to encourage researchers conduct experimental research.

In addition to reviews (literature, systematic, meta-analysis), case reports or series reports are the best examples of basic observational studies that offer a cost-saving approach, and provide additional information for further analysis and hypothesis. However, researchers are not able to determine a clear conclusion after reporting a case or series. Accordingly, they are encouraged to perform in-depth observational studies to gather data on a topic, and the recorded results are comparatively analyzed. By analysis, researchers can determine correlations between different variables, and exposure-outcome(s) relationship.

The most commonly utilized in-depth observational studies are case-control, cohort, and cross-sectional studies. An ecological study is a common term used by Clinical Epidemiology staff to understand exposure-outcome(s) relationship at a population level, *e.g.*, smoking and cancer. Such studies differ from the previously mentioned studies in that the unit analysis being studied is the community, *i.e.*, relationship is generalized to population, not study participants. On the other hand, the experimental approach is utilized

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for conducting a controlled randomized study in either laboratory animals, or human (clinical trial). All studies should utilize either PEO or PICOT framework[2]. While the 1st framework stands for population, exposure, and outcome(s), two additional issues are included in the 2nd (comparison group, and time frame), and intervention replaces exposure. Advantages for experimental approach include strong variable control, broad application across different conditions, feasible actionable results relevant to the study question, and foundational use for further studies.

Case-control studies are designed when researchers investigate the cause(s) of a disease, *i.e.*, the study starts with an observational outcome. Researchers compare and analyze variables of two groups in which the 1st group exhibits a certain outcome (cases), and the 2nd does not exhibit this outcome (controls). In such studies, attributable risks are calculated. The study objective is to determine if an association exists between exposure, and a certain outcome. Distinguished by the method used to select controls, there are two types; matched and non-matched. Matching indicates equal numbers and equal frequency of attributable risk factors, (sex, age, residence, *etc*.). For example, if the research question: Is schistosomiasis *haematobium* related to cancer bladder in Egypt? The study recruits 2 groups in which the 1st includes apparently healthy individuals (controls), while the 2nd is for patients with cancer bladder (cases). These studies are inexpensive, quick to conduct (short time), require fewer sample size than other studies, and more useful when the disease is rare. However, disadvantages include dependance on inaccurate records to determine degree of exposure, difficulty in identification or selection of the controls, and occurrence of potential bias since the study is not blind. Additionally, due to its small size, the results obtained only apply to specific populations, *i.e.*, not standardized to be generalizable. Meanwhile, because these studies collect data after disease occurrence, they are considered retrospective, *i.e.*, it is a study limitation. Notably, this design offers less support for exposure-outcome hypothesis than the longer cohort design, but provides stronger evidence than a cross-sectional study.

Cohort studies examine one or more cohorts sharing a certain exposure to determine possible outcome(s) over time. Cohort is a group of individuals who share a common characteristic or experience within a defined period. Researchers don't control or manipulate variables, instead, they apply certain inclusion and exclusion criteria for selection of the study participants to monitor the outcome(s) over time. These studies are characterized by larger sample size (generalizable results), can provide insights into possible relationships between variables, do not require controls, and are less expensive than controlled studies. A prospective approach is the gold standard of cohort studies, used to answer research questions demanding extensive time-based observations. It allows for longitudinal observations revealing valuable insights over time, unattainable through other in-depth observational studies. Therefore, it tracks a wide range of variables simultaneously, offering a multifaceted view of the study hypothesis. It is appropriate to understand the temporal sequence of events over time, explore rare or complex phenomena because such phenomena require a longer time to gather sufficient data for meaningful analysis, and to evaluate the effects of multiple variables. However, disadvantages include time-consuming, costly, and high rate of drop-out. In contrast, historic cohort studies look backward in time, *i.e.*, researchers use existing data to trace back the outcomes and exposures. Utilizing existing data reduces time and costs associated with data collection. However, existing data might not be as complete, or tailored to the research question, *i.e.*, associated by selection bias. Besides, inability to control data collection can limit the study's scope. As a parasitological example of using a prospective cohort approach, the researcher tracks a cohort of patients infected with *S. mansoni* to answer the quantitative research question: Will portal hypertension develop with or without treatment? Meanwhile, the study can be conducted in hospital-based historic cohort study in which the researcher uses existing data of a cohort (patients with portal hypertension) to obtain results answering the research question.

Cross-sectional studies usually look for exposure and outcome(s) together at the same time. Such studies allow researchers to analyze multiple variables at the same time, and manipulate the variables. They often use surveys and are well suited for measuring the prevalence rate if the sample is representative. They are also conducted in a specific population to estimate the detection rate (not prevalence). Of note, it is also used to determine the incidence of a certain outcome in a specific population at a set time. These studies are quick, cost-effective, and safe, however; they are not used to determine exposure-outcome relationship, *i.e.*, collected data cannot be used to infer causality. They differ from case-control studies in that they aim to provide data on the target population, whereas case-control studies include only individuals who have developed a specific outcome. These studies are not suitable for rare diseases because of the huge calculated sample size. Of note, studies evaluating the performance of a new diagnostic tool can utilize a cross-sectional study to build up two groups, *e.g.*, negative, and positive *S. mansoni* egg in stool samples, and an additional group including patients with other parasitic infections. Obtained results allow researchers calculating sensitivity, specificity, and diagnostic accuracy.

Most commonly, the term "descriptive analytical study" is used in cohort and cross-sectional studies.

Randomized controlled studies evaluate the efficacy of a new drug, and vaccine candidate. Participants

are randomly assigned in groups *e.g.*, receiving treatment, no treatment, placebo, or drug of choice (for comparison). In some instances, additional groups are included for different doses. Of note, researchers control all variables related to the outcome(s). Such studies use highly controlled conditions with limited variables affecting outcomes, *i.e.*, can determine exposure-outcome relationship. Besides, they provide targeted results applicable for action, evaluation, and development. However, such experimental studies require a long time for follow-up, and the challenge to attain participants availability, *i.e.*, when not all participants complete the study period.

CONCLUDING REMARKS

1. Research question, whether qualitative or quantitative, should fulfill the FINER criteria (feasible, interesting, novel, ethical, and relevant). The following table summarizes commonly used study types according to the research question.

Research question	Study type
Qualitative	• **Case report, literature and systematic reviews:** Describe "What, How, Why? • **Meta-analysis:** Description and analysis.
Quantitative	• **Case-control:** Compare past exposures (retrospective). • **Cohort:** Track exposure to outcome over time (prospective). • **Cross-sectional:** Snapshot of population. • **Randomized controlled trial:** Assess interventions.

2. Two types of research are known, observational or experimental. The latter achieves one of three applications; 1) practical solution to a health problem, 2) making authorized decision, and 3) identification of novel diagnostic, or therapeutic or preventive strategy.
3. The case-control study starts with analysis of the results of outcome(s) to search for their relationship with exposure (retrospective). Its main drawback is small sample size leading to potential bias, and non-generalizable results.
4. The cohort study starts with a shared exposure in one or more cohorts to determine its relation with outcome(s) over time (prospective). Its main drawback is lack of randomization that might lead to bias in exposure-outcome(s) relationship.
5. Cross-sectional study is the only example for analysis of exposure and outcome(s) together at the same time. It is the most useful design utilized to determine prevalence of a disease in a representative sample, and detection rates in a specific target sample size. It can be utilized for evaluation of the performance of a new diagnostic tool.
6. The randomized controlled study is the best design used to evaluate drug efficacy because controlled conditions, and limited variables affecting outcomes are used. It is termed trial if conducted on human, and experimental when involving laboratory animal models. Although it is the only study that determines exposure-outcome relationship, it has several drawbacks, commonly reported in clinical trials, such as participants compliance, potential side effects of the drug under study, and limited availability of participants during the whole period of the trial.

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