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EDITORIAL

Dilemma of "Randomized Controlled Trial" and "Observational Study" in conducting health research

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Research is a study conducted to prove a specific question or hypothesis. The researcher is any person who engages in the conceptualization of research, study design, data collection, and management of the study concerned. The researcher must have a clear and definite research question in mind which can make a useful contribution to the scientific evidence before is formulated (Diagram 1).

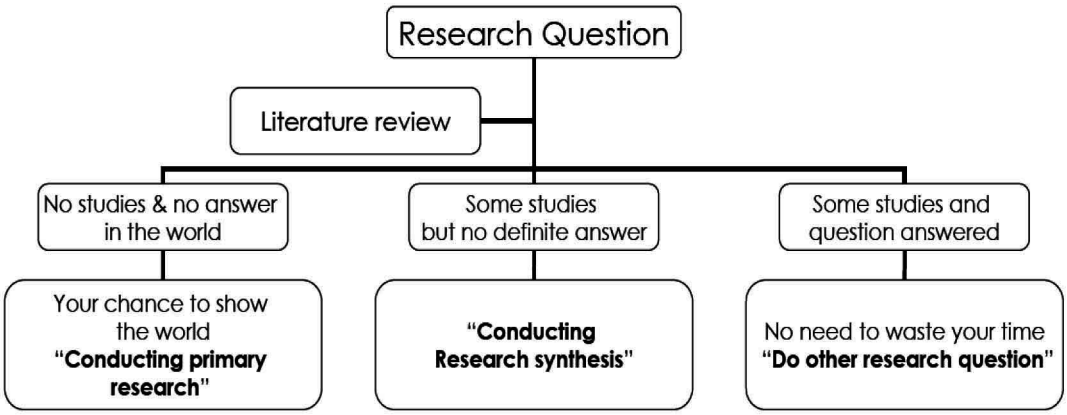

Diagram 1. Research question

Relevance, feasibility, and ethical responsibilities are important characteristics of a good research question. A study design may be relevant and suitable for answering a research question; yet there might be some problems with regard to feasibility and ethical responsibility.

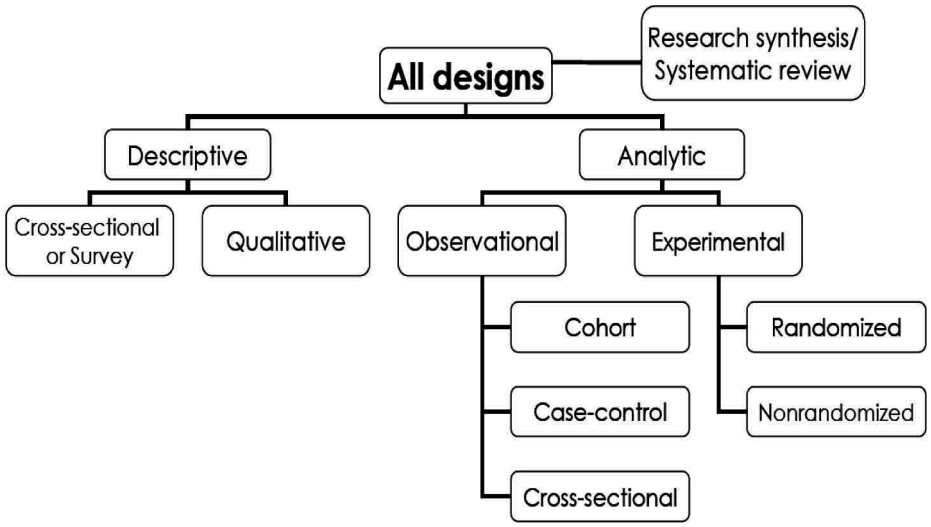

Diagram 2. Study design

Diagram 2 shows a tree of study designs. It is well-known that the randomized controlled trial (RCT) is the most preferable study design. This is due to the fact that RCT is well-planned and allows the exposure or intervention occurring before the outcome leading to strong evidence for "cause-and-effect" as well as controlling for confounders which are the causes of various types of biases, namely selection, performance, detection and attrition biases. However, some research questions are not suitable for RCT due to feasibility or ethical issues, thus a research question become narrow and specific.

In addition, an RCT is standardized in order to achieve an optimal and controlled experimental condition, which differs from that in routine practice. Consumption of time and resources is one of the issues in conducting an RCT because a well-designed research process needs greater input of human resources and any costs happened in the trial should be the responsibility of the research and covered by the research budget, such as treatment costs, compensation for time loss and transportation of the participants, and the cost of management of possible adverse events.

The most common debates in an RCT are small sample size and low power statistics to detect the true positive results between intervention and control. Nevertheless, if the methodological quality of that trial is adequate, it is a chance to make use of it. A systematic review is a kind of scientific activities to synthesize the results of previously conducted researches. It keeps up with the accumulative evidence and allows for objective appraisal of the evidence. An analysis used in systematic review called meta-analysis. It is a statistical technique to combine the findings of previous individual studies. Meta-analysis can enhance the precision of effect estimate, reduce probability of false negative results, and introduce the effective treatment in a timely manner.

Observational study is a study conducted in the natural state of events and conditions. This type of study can be divided further into cross-sectional, cohort, or case-control studies, based on temporal relationship. A cross-sectional study is less expensive and easy to conduct, has a fewer ethical issue, and can identify some potential risk factors for future analytical study. However, it cannot determine the temporal relationship or test etiological hypotheses. A cohort study can overcome the mentioned limitations of cross-sectional study and presents a direct estimate of relative risk of exposure, and has less selection bias due to unknown outcome and no recall bias of exposure. A cohort study is not suitable for rare outcomes and usually faces a problem of drop-outs. These limitations of cohort study become the advantage of case-control study. However, case-control study has common

weaknesses on selection and recall biases as well as potential confounders.

Some research questions are appropriate for RCT or observational study. For example, if we would like to test whether the new treatment is more effective than conventional treatment and no issue of ethical problems, an RCT is the most suitable to test hypothesis. On the other hand, if we hypothesize that delivery at home increases risk of maternal deaths comparing to hospital delivery. We cannot assign a randomization for a woman to deliver at home or hospital as doing so would be unethical and infeasible. Likewise, the research on the accuracy of diagnosis, health policy and system research, or epidemiological research is more apt for an observational study rather than an RCT. As a result, the research question formulated must represent a knowledge gap and shows a need of definite answerable question. Then choosing a study design that is most relevant and appropriate for the research question is a key concern.

In conclusion, relevance, feasibility, and ethical responsibility are essential for selecting the appropriate study design to answer a research question. Whether an RCT or an observational study is selected, the good research methodology is also important. Selection of suitable methods and data sources, understanding of ethical implications of the methodology and providing clear description of data collection process are crucial for proving that the research findings are valid and reliable.