



## ปัญหาที่พบบ่อยในการออกแบบการศึกษาเชิงปริมาณทางวิทยาศาสตร์สุขภาพ ของนักศึกษาระดับบัณฑิตศึกษาในหลักสูตรทางสาธารณสุขศาสตร์

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### บทคัดย่อ

ทักษะการออกแบบการศึกษาเชิงปริมาณทางวิทยาศาสตร์สุขภาพ (Quantitative Health Studies) เป็นการประยุกต์ความรู้ทางวิทยาการระบาด (Epidemiology) และชีวสถิติ (Biostatistics) มากำหนดวิธีการศึกษาเพื่อตอบคำถามวิจัยที่พบในงานการดูแลผู้ป่วยและสุขภาพประชากร การจัดการเรียนการสอนให้เกิดทักษะดังกล่าวเป็นประเด็นความท้าทายสำคัญทั้งต่ออาจารย์ผู้สอนและผู้เรียน โดยเฉพาะอย่างยิ่งในระดับบัณฑิตศึกษา ที่มุ่งเน้นให้ผู้สำเร็จการศึกษามีความสามารถในการทำวิจัย เพื่อประกอบวิชาชีพเป็นนักวิจัยและนักวิชาการได้ อีกทั้งการกำหนดวิธีการศึกษายังมีผลโดยตรงต่อคุณภาพของหลักฐานเชิงประจักษ์จากงานวิจัยที่จะใช้เพื่อการตัดสินใจ การกำหนดนโยบาย และการดำเนินการจัดการสุขภาพประชากร ในบทความวิชาการนี้ ผู้นิพนธ์รวบรวมประเด็นปัญหาที่พบบ่อยจากการตรวจโครงร่างการวิจัยซึ่งเป็นกิจกรรมการเรียนรู้จากประสบการณ์ (Experiential Learning Activity) ของนักศึกษาระดับบัณฑิตศึกษาในหลักสูตรทางสาธารณสุขศาสตร์ ณ มหาวิทยาลัยแห่งหนึ่งในสหรัฐอเมริกา และนำเสนอแนวทางการแก้ไขในแต่ละประเด็น เพื่อให้เกิดการเรียนรู้ทักษะการออกแบบการศึกษาเชิงปริมาณทางวิทยาศาสตร์สุขภาพให้มีประสิทธิภาพยิ่งขึ้น

**คำสำคัญ:** การออกแบบการวิจัย วิธีการทางระบาดวิทยา การสอน



## Common Issues in Design of Quantitative Health Science Studies Among Graduate Students in Public Health Programs

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### Abstract

Skills in designing quantitative health studies require the application of knowledge in epidemiology and biostatistics to define study methods to answer research questions found in patient care and population health management. Instructional design and learning to develop such abilities have been challenging for both instructors and students, especially at the graduate level where the emphasis is on equipping graduates with the competency to conduct health research in their professional practice as researchers and academicians. In addition, the study method has a direct effect on the quality of empirical evidence from research to be used for decision-making, policy formulation, and implementation of population health management. In this academic article, the author provided a summary of frequently encountered issues in quantitative health research proposals which was an experiential learning assignment for graduate students in public health programs at a university in the United States. Suggestions for these issues were also provided to exemplify possible methods to improve teaching and learning skills in designing quantitative health studies.

**Keywords:** Research designs, Epidemiologic method, Pedagogy

### 1. Introduction

Designing quantitative health studies necessitates the application of epidemiology and biostatistics knowledge to create study protocols to address research issues in clinical care and public health management. [1-2] Epidemiology and biostatistics are already complicated in theory, computation, and application due to their nature as highly quantitative disciplines. As a result, when it comes to the challenge of using these two subjects' knowledge to create quantitative research studies that answer real-world research questions, a greater level of application expertise is required, making the process incredibly challenging. [3]



Apart from the aforementioned issue, research methodology also adds to the complexity in achieving the task of designing quantitative health research. Asking the right research question, formulating a testable research objective, providing rationale for study, and determining inclusion and exclusion criteria for participants selection are examples of problematic issues that many students have when they design quantitative studies. [4]

To improve teaching and learning of skills in designing quantitative health studies, information regarding common mistakes in achieving this task is required to identify issues or areas of subjects that need pedagogical improvement. This academic article summarizes commonly encountered issues in quantitative health research proposals which was an experiential learning assignment for graduate students in public health programs at a university in the United States. Suggestions for these issues were also suggested to guide feasible methods to improve teaching and learning skills in designing quantitative health studies.

## 2. Identifying issues in the design of quantitative health studies

Evidence of the common issues in designing quantitative health studies in this article was compiled from 110 research proposals of graduate students in four public health programs including Advanced Certificate Program in Public Health, Master of Public Health (MPH), Joint Doctor of Medicine, and Master of Public Health (MD-MPH) Program, and Joint Juris Doctor and Master of Public Health (JD-MPH) Program at a university in New York, United States. The public health programs in this analysis were accredited by Council on Education for Public Health, United States. The research proposal was an experiential learning assignment required in a graduate-level course entitled ‘Research Methods for Quantitative Studies’ for seven semesters including the Fall and Spring semesters of the academic year 2018 to 2022, except Fall 2019. A wide variety of topics in quantitative health research were covered, ranging from patient-oriented clinical studies in medicine to public health epidemiological studies. Data collection designs comprised descriptive studies, cross-sectional studies, cohort studies, case-control studies, and randomized controlled trials. With such a wide variety in the four programs, the topics, and proposed data collection designs; this analysis would enable generalizability and usefulness of the findings not only to instructors and students in the field of quantitative research in public health but also to those in the field of quantitative patient-oriented research in medicine and allied health sciences.

## 3. Common issues in designing quantitative health studies

### 3.1 Research question

A key characteristic of a research question is a scientific question that leads to a ‘meaningful answer’. An appropriate research question should be an answerable question that suggests how to answer the question by the scientific method and provides clear implications for decision-making or action. An exemplary issue in asking good research questions was as followed:

**Non-informative question:** *Is sugar consumption related to dental caries (tooth decay)?*

This research question would lead to the ‘yes’ or ‘no’ answer. Assume that the answer from this study is ‘yes, sugar is related to dental caries with statistical significance ( $p < 0.05$ )’. This answer would lead to further questions; such as ‘In what way of the relationship?’ and ‘What is the public health recommendation for this?’. A way to improve the clarity and direction of this research question could be:

**Possible question:** *Does sugar consumption increase the risk of dental caries?*

The question better guides on how it could be answered by cohort data collection approach and analysis of the outcome by risk ratio or rate ratio. In addition, the answer would be more meaningful and leads to decision

making. If the answer is ‘Yes, frequent sugar consumption increases the risk of dental caries by 4 times compared to low consumption.’ The possible recommendation following this evidence would be to avoid sugar consumption to prevent dental caries. If the answer is ‘No’, the decision can then be made that sugar can be consumed without concern about caries occurrence.

### 3.2 Research objective

Unlike the research question which is an interrogative statement and more concise, the research objective is a detailed statement of purpose that provides more information regarding the defined study population, relevant independent factor, relevant comparison, and outcome. An exemplary issue in writing the research objective was as followed:

**Research question:** *Is azithromycin or doxycycline more effective in reducing fever in children with scrub typhus?*

**Non-informative research objective:** *To study the effectiveness of azithromycin and doxycycline in reducing fever in children with scrub typhus.*

**Informative research objective:** *To compare the time duration (number of hours) that fever is reduced to 37.5 Celcius degrees by azithromycin and doxycycline in pediatric patients diagnosed with scrub typhus.*

The non-informative objective statement shows a typical pitfall in writing a research objective by copying the research question and changing from an interrogative statement into an affirmative sentence. This does not provide additional details beyond the research question and is considered to be redundant. Moreover, instead of using ‘to study’, other more definitive verbs (e.g., compare) should be used to better clarify the aim of the study.

The informative research objective, in contrast, defines the patient domain to include only pediatric patients with the medical diagnosis of scrub typhus. This objective also guides the way to measure the outcome by measuring the period of the temperature reduction from fever down to a certain degree Celsius.



### 3.3 Research hypothesis

The research hypothesis in the research proposal is a scientifically-sound statement of possible findings. The research hypothesis is required only when hypothesis testing is being undertaken in the study. Descriptive studies—such as case reports, case series, and descriptive cross-sectional studies—do not require statement of research hypothesis. The followings are examples to clarify this point.

**Research question:** *What is the prevalence of hypertension in the elderly living in the town of Garden City?*

**Research hypothesis:** *No need as the aim of the study is not to test any hypothesis but rather to identify the prevalence of hypertension.*

A statement of research hypothesis is appropriate for studies that aim to test a hypothesis or evaluate an association. The followings are examples of research questions requiring a statement of hypothesis in the research proposal.

**Example 1:** Testing hypothesis regarding the difference

**Research question:** *Is there a significant difference in weight and height of 6-year-old children with different dental caries statuses?*

**Possible research hypothesis:** *Caries-free children are likely to have significantly greater weight and height compared to children with dental caries.*

**Example 2:** Evaluating an association

**Research question:** *What is the effect of smoking on the occurrence of lung cancer?*

**Research hypothesis:** *Smoking increases the risk of lung cancer.*

### 3.4 Background and rationale

#### (a) Lacking description of the health problem of interest with supporting evidence

One important question that the researcher should answer or explain in the study rationale is ‘why this health problem is important and leads to the current study?’. However, many proposals in this analysis showed that the importance of health problems was simply stated from the researchers’ points of view which might not be evidence-based or scientific. Several quantitative measures can be considered to accentuate the importance of the health problem under investigation. For example, instead of simply stating that ‘Hypertension is an important public health problem.’, the quantitative measure of prevalence—an epidemiological measure of disease frequency—can be a piece of evidence that shows the magnitude of hypertension in the study setting. Thus, the importance of this disease can be alternatively described as ‘In this township, the prevalence of hypertension among older adults aged 35 to 59 years old in 2021 was 40



percent.’ This statement implies that 4 out of every 10 older adults in this setting had hypertension from a previous survey and clearly shows the importance of this disease to be investigated in the current study.

#### (b) Gap of knowledge

A careful review of related research and information is an important step before identifying the gap of knowledge. Nonetheless, it was often found that the researchers had not carefully reviewed relevant studies before stating that there had never been a study on their research questions before. In many published articles, the gap of knowledge stated in the introductory part also contradicted the information in the discussion part as the authors stated that the research topics had scarcely been investigated but later provided a comparison of their results with those from several previous studies.

#### (c) Expected benefits of study results

Lack of clarity in identifying the expected benefits of study results is one of the issues that could be found in the introduction part of the research proposals. Many students simply stated that the results of their studies could be useful for improving public health policy. However, this statement is too general and did not provide direction for the anticipated use of research results. To improve the clarity of the expected benefits, information including ‘who’ (anticipated stakeholders), should ‘do what’, and ‘how’ should be clarified to provide the possible uses of anticipated results.

### 3.5 Research methods

#### (a) Inclusion and exclusion criteria

The selection of the study participants must be relevant to the research question and objective. Inclusion criteria are how the study populations are selected for the current study. After participants are selected based on the inclusion criteria, study participants are re-assessed by exclusion criteria to exclude those who may not be able to practically participate in the study. Thus, inclusion criteria are applied to obtain a tentative pool of participants before re-assessment using exclusion criteria. Nonetheless, a common pitfall in defining inclusion and exclusion criteria was the misconception that exclusion criteria are the opposite of inclusion criteria. For example, if the inclusion criterion was to include female participants for the investigation of risk factors for breast cancer, the exclusion criterion was falsely defined as excluding male participants from the study. This exclusion criterion was not valid since males would not be included from the start when the inclusion criterion was applied and there would not be any male participants to be later excluded. Examples of appropriate definitions of inclusion and exclusion criteria are as followed:

**Example 1:** *A case-control study was to be conducted to assess whether breastfeeding can prevent breast cancer later in life.*

**Inclusion criteria:**

(1) *Women utilizing the same routine breast cancer diagnosis service at a certain hospital. (Those*



*being diagnosed with breast cancer becomes a ‘case’, while the others not being diagnosed with breast cancer becomes ‘control’.)*

*(2) These women must be eligible to breastfeed their babies (and had either breastfed or not breastfed their babies).*

**Exclusion criteria:**

*(1) Do not consent to participate in the current study.*

*(2) Do not answer the question about the past breastfeeding practice.*

**Example 2:** *An intervention study was to be conducted to assess the therapeutic effectiveness of Remdisivir in the treatment of COVID-19*

**Eligible criteria** (combining inclusion and exclusion criteria):

*Patients who are hospitalized due to COVID-19 from July to October 2020 at X Hospital, and have clinical conditions that can be considered for prescribing Remdisivir. Consent to participate in the study must be obtained from relatives of the patients before participating in the study.*

**Example 3:** *A retrospective cohort study is to be conducted to assess whether the risk of SARS-CoV-2 infection varied by race among residents in Nassau County, New York.*

*Inclusion criteria: The residents of all races in Nassau County who were at risk of SARS-CoV-2 infection from May to December 2020.*

*Exclusion criteria: The residents who moved out of the area or could not be follow-up until the end of the study.*

**(b) Lack of comparison group in analytical studies**

Having a comparison group is a key element in analytical studies that are applied to evaluate the relationship or association between independent variables or exposure variables and the health outcomes. Analytical studies in quantitative health research include analytical cross-sectional studies, cohort studies, case-control studies, randomized controlled trials, and non-randomized trials with comparison groups. [5] The comparison group is defined according to the data collection design. For example, in the cohort study, an index group is defined as a group of participants at-risk of outcome who are exposed to a certain agent (e.g., smokers) while a comparison group is a group of those without such exposure (e.g., non-smokers). In a case-control study, ‘cases’ are defined as participants with the study outcome while ‘controls’ are those without the outcome that represents the exposure level in the source population from which both cases and controls are sampled. Lacking the comparison group would result in an inability to evaluate the association. An example of proposed study protocols without comparison groups is as followed:



**Example:** *The following cohort study aimed to evaluate an association between inadequate sleep and depression among undergraduate students at a university in the academic year 2021.*

**An inclusion criterion:** *Undergraduate students who do not have adequate sleep at night.*

From this example, the exposure variable was the inadequacy of sleep and the outcome was depression. To evaluate this association, a comparison was needed and students with adequate sleep must be included.

### Conclusion

From this analysis, the most common pitfalls in designing quantitative health research included (a) the unclear conception of research questions, objectives, and research hypotheses, (b) lack of clarity in study rationale, and (c) pitfalls in designs comprising inappropriate participant selection criteria and lack of comparison groups in analytical studies. It is recommended that students should be provided with exemplary proposals as case studies that vary by design, different types of pitfalls, and possible solutions for correcting the pitfalls so that they can learn to avoid making these mistakes.

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