Formulation of Research Question and Composing Study Outcomes and Objectives

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Framing an appropriate research question is the most critical and fundamental part of a study. This helps in developing a hypothesis, formulating aims and objectives and methodological execution of the study. Research questions are usually generated by literature backed thorough analysis of the gaps in previous studies and funnelling it to a specific focussed issue. The research question should be framed using the PICO (Population, Intervention/Exposure, Comparator and Outcome) format and should fulfil the FINER (feasible, interesting, novel, ethically sound, and relevant) criteria for practical aspects. Objectives should always be framed in alignment of the research question using SMART (specific, measurable, achievable, realistic and time defined) approach. Outcomes are classified as primary and secondary. It is advisable to have only one primary objective while secondary objectives can be multiple (usually not exceeding five). This paper describes a cascade approach starting from framing the research question and then deciding on the outcomes and study objectives.

Keywords: *Aim, FINER, Hypothesis, PICO, Study design.*

Research question (RQ) is the question or the query which the researcher is trying to answer by conducting an investigation. The formulation of appropriate research question is the most fundamental and critical part of a study. All the further steps of the research i.e., developing a hypothesis, formulating objectives and methodological execution of the study depend upon the framing of the RQ. Composing the objectives and outcomes is the natural progression after framing the RQ in planning a study. Researchers often find it difficult to frame appropriate RQ and objectives from an inviting idea. This paper details the step-by-step systematic conversion of an idea to a valid RQ and translating it further to frame objectives and outcomes.

Getting Ideas for Research

Ideas are everywhere but they have to be converted to a valid RQ. The choice of RQ may be made from the evaluation of previous studies, one's own experiences, from topic of interest or by the need of the time [1]. Most of the ideas for research come from one's perceived gaps in the existing knowledge of a topic. These gaps could be the lack of clear conclusions or insufficient results from previous studies. Identification of such gaps could be taken up as a RQ which would then be used to build on the previous research. Ideas could also be developed from observations made on the previous work. Systematic analysis of this observation after brainstorming may also be one of the methods of finding the correct RQ. Unprecedented circumstances may also yield multiple RQs on a single topic.

Developing Research Question From an Idea

As a rule of thumb, the broad ideas themselves do not form a RQ. They should be chiselled to yield one. This is achieved by an exhaustive and critical analysis of the broad idea by a thorough literature research. The brainstorming would include searching for studies conducted in past on same topic, identifying the lacunae in the existing knowledge or need to replicate the question in different settings, thinking of a hypothesis, and then generating a RQ [2]. Although multiple RQs may stem from a broad idea, it is best to choose only one primary RQ for a particular project (choosing the best RQ is described later). The RQ is the interrogative form of the solution which we are looking. Simply put, it is the purpose of study written in a question format [3]. It has to be specific, focused and clearly defined in terms of population targeted, planned intervention, outcome etc.

For example, while working in pediatric neurology ward, a student observed that there were a large number of children coming with breakthrough seizures. He

brainstormed with peers to analyze the reasons for poor control of seizures in children with epilepsy. One of the RQ which was formed was 'What are the causes of non-compliance of treatment among children with epilepsy at a tertiary-care center?'

ESSENTIAL ELEMENTS OF A RESEARCH QUESTION

The RQs are broadly classified into descriptive and inferential questions based upon the purpose, objective, and clinical context of the study [4]. Various types of RQs along with examples are given in **Table I**.

A RQ has multiple components. The most common approach to address these is referred to as PICO approach, the acronym standing for Population, Intervention/Exposure, Comparator and Outcome [5]. Sometimes Timeframe, and Effect Size are also added to call it as PICOTES approach which makes it more comprehensive. Although most commonly used in the inferential RQ, some of the elements (P and O) are also mandatory in the descriptive RQ. The salient features of PICO elements are explained in **Box I**.

Attributes of a Good Research Question

Some of the framed RQs, although inviting and lucrative are not possible to do. A good RQ once framed, should be assessed using the FINER approach given by Hulley, et al. [6]. It should be feasible, interesting, novel, ethically sound, and relevant. It should be clearly stated and appropriately complex. This audit should be done before the start of the study to avoid wastage of manpower and resources. Doing a pilot study may also help in unearthing real time issues. These attributes are described in the **Table II**. The RQ should be chosen so that it addresses issues common to clinical setup of a particular area, builds upon previous gaps, ethically sound and is doable by the researcher in the given time limit.

Framing a Research Question

The RQ should be written in one's own wording, be appropriately complex and should not be very broad. It should be in question format and complete in itself [7]. One example of research question would be "How efficacious is intravenous phenobarbitone in comparison to intravenous levetiracetam, as a first line drug, in controlling neonatal seizures?" RQ should NOT be framed to provide answer in YES or NO. Binary outcome framing is not a correct approach as decisions in medicine are based on probabilities and cannot be absolute (0 or 100). Some examples of errors in framing RQ are shown below.

Table I Types of Research Questions and Their Characteristics [4]

Type	*Purpose*	*Example*
Descriptive	Intends to seek measurement of a phenomenon in a defined population. Usually covers only one variable and provides result in frequencies.	What is the prevalence of scabies in primary school children in village 'X'?
Inferential	Aims at drawing inference of an exposure, intervention, or laboratory test on a sample of defined population. It involves a minimum of two variables– Independent and Dependent (one each).	What is the effect of applying chlorhexidine on umbilical cord in decreasing neonatal mortality and neonatal sepsis?
Causal	Intends to seek the association of exposure of a causative factor in a defined population as compared to comparator.	What is the association of developing retinopathy of prematurity (ROP) in preterm neonates with receiving 100% oxygen therapy?
Diagnostic (descriptive)	Seeks to describe the measurement of a phenomenon related to the diagnostic test in a defined population.	What is the sensitivity of CRP in the diagnosis of late onset sepsis in neonates weighing less than 1500 grams at birth?
Diagnostic (analytical)	Seeks to analyze which out of the two diagnostic tests is better in picking a particular phenomenon in a sample of defined population.	What is the predictive value of procalcitonin compared to CRP for diagnosing late onset neonatal sepsis in VLBW neonates?
Prognostic	Intends to find the measure of the prognostic value of a marker in a defined population predisposed to a particular disease.	What is the risk of poor neurodevelopmental outcome in ELBW neonates having received intensive phototherapy for more than 72 hours?
Qualitative	Intends to find explanations of the defined phenomenon which are not possible to quantify in a specific population. The questions are usually broad and open-ended.	What are the perceptions of the mothers who have undergone preterm delivery regarding the usage of donor human milk in their offspring?

Box I PICO Elements in a Research Question

Population of Interest, **P**atient or **P**roblem to be discussed in the descriptive RQ

Description: The study population characteristics need to be clearly defined so that there is no ambiguity.

Example:

- Preterm neonates < 32 wk gestation
- Neonates requiring umbilical arterial catheter (UAC)
- VLBW Neonates having suspected early onset sepsis

Intervention or Exposure

The primary variable whose effect is investigated in the defined population. Could be an intervention (drug, treatment, procedure) or an exposure.

Example:

- Delayed cord clamping for 60s
- Positioning a high UAC
- Estimating use of CRP in first 24h

Comparator or **C**ontrol

An alternative condition to compare the primary variable. Could be the gold standard or placebo.

Example:

- Immediate cord clamping
- Positioning a low UAC
- Estimating procalcitonin in first 24h

Outcome

The expression that will be assessed at the end point of the study.

Example:

- Incidence of intraventricular hemorrhage
- Complications related to UAC
- Detection of culture proven neonatal sepsis

Table II Attributes of a Good Research Question - FINER

F	Feasible	Ensure the availability of appropriate and adequate • Participants to be enrolled • Adequate manpower • Time to complete the study • Funds • Equipment • Expertise in the investigator
I	Interesting	Getting the answer of the RQ should arouse interest in the investigator, colleagues, readers and community
N	Novel	RQ should address to the unexplored areas of a topic The answer to RQ should extend, annul or confirm the previous findings RQ of other studies should not simply be copy pasted because of ease of doing
E	Ethically sound	Mandatory to get ethical approval for the authorities for any study Should not pose harm to the subjects Should follow the principles of Declaration of Helsinki
R	Relevant	The RQ should arise from issues raised from local problems The research should contribute to: • Scientific knowledge • Clinical and health policy • Future research

Example 1

Incorrectly framed: In preterm neonates less than 30 weeks, does formula feeding predispose to necrotizing enterocolitis (NEC)?

Reason: RQ should not have a binary outcome.

Correct: What is the relationship of formula feeding with NEC in preterm neonate less than 30 weeks?

Example 2

Incorrectly framed: What measures are being taken to prevent postoperative wound infection undergoing emergency surgeries?

Reason: Too simple and broad, should be appropriately complex.

Correct: What are the risk factors associated with deep surgical site infection following laparotomy for acute perforation peritonitis?

FORMULATING THE OUTCOMES

The writing of RQ should be followed by the framing of study outcomes and objectives. Outcomes are the measurable endpoints of the objectives which are monitored during the study and occurrence (or absence) of these indicate that result has been achieved. They should originate and be in alignment with the study objectives. It is of utmost importance to *a priori* define an outcome as well as a standard validated method to measure it as a particular entity may be definable or measurable by variable methods. The outcomes should be clearly written such that anyone can easily understand the nature of what is being measured and replicate the measurements at their research settings. The ideal outcomes should be reproducible under same conditions and have minimum inter observer difference, and valid i.e. should measure what they intend to measure. The primary outcome is the most important measurable endpoint and should correspond to the primary objective.

Table III Examples of Research Questions (RQ) Integration With Objectives

Parameter	*Example 1 (descriptive study)*	*Example 2 (case-control study)*	*Example 3 (cross sectional)*
RQ	What is the magnitude of typhoid fever in under-five children in region A?	What is the impact of malnutrition on clinical recovery in under-five children with typhoid fever?	What is the diagnostic role of Typhidot-M test as compared to blood culture in the diagnosis of typhoid fever in under-five children in first week of illness?
Aim	To study the proportion of under-five children with confirmed diagnosis of typhoid fever in 'X' hospital.	To compare the outcome of typhoid fever in malnourished vs normal children	To ascertain the diagnostic accuracy of Typhidot-M against blood culture for early diagnosis of typhoid fever
Primary objective	To document the proportion of children with typhoid fever among total hospitalized children	To compare the duration of hospitalization between undernourished and normal children with typhoid fever	To estimate the predictive value of Typhidot M for diagnosis of typhoid fever as compared to blood culture
Secondary objectives	• Rate of complications • Mortality	• Rate of complication • Mortality	• Sensitivity • Specificity

The study design and sample size are also based upon the primary outcome of the study. The additional measurable endpoints pertaining to the secondary objectives are called as secondary outcomes. Usually outcomes are analyzed independently but 'composite outcomes' can be used when the individual occurrences are rare, correlate with each other or a combination is more informative as compared to an isolated outcome [12]. Mortality or bronchopulmonary dysplasia is a composite outcome used in RQs pertaining to respiratory support in neonates; death or presence of a severe neuro-development impairment (blindness, deafness, motor or cognitive disability) by two years of age is another example of composite outcome used in assessing long term impact of various interventions in extremely low birth weight neonates.

STUDY OBJECTIVES

The RQ tells us that what we are planning to do. The objectives of the study give us accurate description of the steps about how we are going to achieve what we had thought of in the RQ. The objectives serve as milestones for the ultimate goal [8,9]. The objectives are classified as primary and secondary. The primary objective is the most important endpoint and should reflect the RQ. The additional endpoints which we want to study are termed as secondary objectives. It is better to have only one primary objective for a particular RQ. Secondary objectives can be multiple; however, should not exceed five.

Framing the Objectives

Objectives are written in single infinitive sentence format starting with the word 'To' using SMART format. They should be specific, measurable, achievable, realistic and time defined [10]. The action verbs from Bloom's measurable verb list e.g. determine, compare, verify, establish etc. should be used in the framing of the objective [11]. The objectives dictate the type of study design and help in developing the methodology section of the protocol. We should avoid writing too many objectives and should have a clear flow between the RQ and objectives as shown in **Table III**. The relationship between the individual objectives should have a synergistic impact [8,9].

CONCLUSION

The formulation of RQ is most critical and fundamental part of a study which should be done carefully and scientifically. Framing of objectives is a natural corollary after finalizing the research questions. Defining the outcome (mostly in the form of a numerical measurable expression) is a necessary intermediary between the two processes. A summary of the process of developing a research question and translating it into outcomes and objectives is exemplified (**Table IV)**.

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Table IV Systematic Framing of the Research Question and Study Objective

Steps	*Example*
Choose an interesting general topic	Typhoid fever
Extend your knowledge on the topic by consulting several resources	Brief review of treatment of typhoid Fever The antibiotics currently used for treatment of typhoid infections include fluoroquinolones, cephalosporins and macrolides. All lead to therapeutic response, but with variable duration of achieving defervescence. Azithromycin is increasingly being used but recent data about its efficacy in early resolution of fever has not been tested.
Likely research questions	Q1. What is the efficacy of oral azithromycin in treatment of typhoid fever? Q2. What is the comparative rate of recovery following treatment with fluroquinolone and cephalosporins in children with proven typhoid fever? Q3. What is the advantage of polytherapy over monotherapy in typhoid fever?
Brainstorming of the research questions after discussing with mentors and experts	To compare the efficacy of azithromycin and fluoroquinolones for treating typhoid fever in children
Frame an appropriate research question/ hypothesis	What is the efficacy of azithromycin in treating typhoid fever in children compared to ciprofloxacin?
Check for PICO elements:	• Population: Children with typhoid fever • Intervention: Azithromycin • Comparator: Ciprofloxacin • Outcome: Efficacy
Test for practicality	The study is feasible, interesting, novel, ethically sound and relevant (FINER).
Study design	Randomized control trial
Outcomes	Efficacy can be measured in terms of duration of hospitalization, proportion of non-responders, or patient satisfaction.
Primary objective	To compare the duration of hospitalization in children receiving azithromycin or ciprofloxacin for treating uncomplicated typhoid fever
Secondary objectives	To study the proportion of non-responders in children receiving azithromycin vs ciprofloxacin. To compare the satisfaction of parents in two treatment groups

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