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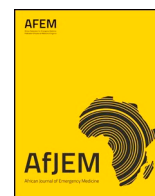
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## Research primer

## Developing a research question: A research primer for low- and middle-income countries

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## ABSTRACT

As demand for emergency care (EC) systems in low- and middle-income countries (LMICs) grows, there is an urgent need to expand the evidence base for clinical and systems interventions in resource limited EC settings. Clinicians are well placed to identify, define and address unanswered research questions using both quantitative and qualitative approaches. This paper summarises established research priorities for global EC and provides a step-wise approach to developing a research question.

Research priorities for global EC broadly fall into two categories: systems-based research and research with a clinical care focus. Systems research is integral to understanding the essential components of safe and effective EC delivery, while clinical research aims to answer questions related to particular disease states, presentations or population groups.

Developing a specific research question requires an enquiring, questioning and critical approach to EC delivery. In quantitative research, use of the PECO formula (Population, Exposure, Comparator, Outcome) can help frame a research question. Qualitative research, which aims to understand, explore and examine, often requires application of a theoretical framework. Writing a brief purpose statement can be a helpful tool to clarify the objectives of a qualitative study.

This paper includes lists of tips, pitfalls and resources to assist EC clinical researchers in developing research questions. Application of these tools and frameworks will assist EC clinicians in resource limited settings to perform impactful research and improve outcomes for patients with acute illness and injury.

## African relevance

- There is an urgent need to expand the evidence base for clinical and systems interventions in resource limited emergency care settings
- Both quantitative and qualitative methods are applicable, and the appropriate methodology will depend on the specific research question.
- Clinicians working in resource limited emergency care settings are well placed to identify and define appropriate and unanswered research questions.

## The International Federation for Emergency Medicine global health research primer

This paper forms part 4 of a series of how to papers, commissioned by the International Federation for Emergency Medicine. It describes the process of deriving a suitable research question. We have also included additional tips and pitfalls that are relevant to emergency medicine researchers.

## Background

Although emergency care (EC) is a well-established discipline in high-income countries (HICs), the development of EC systems globally

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is highly variable [1]. This is despite high-level recognition of the value of EC in resource limited settings, and the potential for timely and effective EC to reduce preventable morbidity and mortality in low- and middle-income countries (LMICs) [2–4].

The evidence base for clinical and systems interventions in developing EC systems remains limited. While there is empirical evidence that many of the leading causes of death and disability-adjusted life years in LMICs can be addressed through EC [3–7], there is a lack of high-quality data supporting specific approaches and interventions. This is despite concerted efforts to raise the profile, output and impact of global EC research [8–12].

Global health (GH) research has traditionally targeted specific disease states and population groups. This has perpetuated a neglect of research into EC systems, which are horizontal in nature and incorporate the full spectrum of illness and injury. A disease-specific approach can be problematic in EC because a large proportion of patients do not receive a definitive diagnosis prior to leaving the emergency department (ED).

Although the volume of literature supporting emergency medicine (EM) practice in HICs has grown exponentially in recent decades, relevance to resource limited contexts cannot be assumed. External generalisability, which refers to the application of research findings beyond the setting and population in which the research was conducted, is a major challenge for clinicians seeking to apply evidenced based care [13,14]. While concerted efforts have been made to curate and disseminate globally-relevant EC research output, most studies originating from LMICs remain observational in nature [8].

The Global Emergency Medicine Literature Review (GEMLR), published annually, provides insights into the breadth and depth of research relevant to global EC practice [8,15]. Among articles disseminated through the GEMLR, ED-based researchers most commonly publish studies pertaining to injury. Communicable disease topics comprise the largest share of studies emanating from non-ED settings. A minority of research output focusses on exacerbations of non-communicable and chronic diseases [8], despite the increasing prevalence of these conditions in LMICs [16].

As demand for EC systems in LMICs accelerates, there is an urgent need to address key knowledge gaps in EM as it is practiced in resource limited settings. Clinicians working at the frontline of EC in LMICs are well placed to identify research questions, and lead studies on locally and globally relevant topics. This paper summarises established research priorities for global EC and provides a step-wise approach to developing a research question.

### Research priorities in emergency care

Research priorities for global EC broadly fall into two categories: systems-based research, and research with a clinical care focus. Systems research is integral to understanding the essential components of safe and effective EC delivery. It is also central to global EC advocacy, in that systems-level evidence is critical to driving the EC development agenda and the integration of EC into overall healthcare services.

The World Health Organization (WHO) has developed a suite of tools to provide a framework for defining, describing and analysing EC systems, which can be divided into pre-hospital care (at the scene and during transport) and facility-based care [17]. Within this framework, research priorities are focussed on the essential building blocks for systems development: human resources and training; infrastructure and equipment; information/data; leadership and governance, and health financing [5]. Specific to EC systems and separate to service delivery (which intersects with clinical EC research), is an additional building block of processes, which includes EC functions such as triage, patient flow and crowding management, and safety and quality initiatives.

Meaningful clinical EC research embraces service delivery and clinical care operationalised within an EC system, and is therefore different to a traditional vertical disease-specific model of research.

Contemporary work from Africa to define EC sentinel conditions (clinical syndromes that require time-critical, ‘signal function’ interventions to prevent death or disability) has opened up a new field of EC clinical research [18]. These include respiratory failure, shock states, altered mental status, dangerous fever, severe pain and trauma.

Recent work by the same team has developed context-appropriate quality indicators to align with clinical conditions accounting for 75% of mortality in Africa (broadly, trauma, sepsis, lower respiratory tract communicable diseases, asthma and obstetric emergencies) [19]. These tools now enable standardised measurement of clinical service delivery across the African region, and the potential for adaptation and testing in other resource limited settings.

New models of clinical EC research priorities focus on specific population groups, public health and resuscitative care [8]. Vulnerable populations within LMIC communities, such as women, children, refugees and migrants commonly have higher EC needs and may illuminate particular issues and inequalities when studied. Research that describes and analyses resuscitation in resource limited contexts cuts across disease spectrum, EC system building blocks and care-delivery context, which can range from community first-aid to national referral level care [20]. ‘Health security’ is a new global public health concern, referring to transnational disease and climate threats emerging from resource limited settings [21]. As EC is at the frontline of these security concerns, research that focuses on ED disease surveillance and outbreaks can attract attention, including from funders. Further, the ED can be a critical site of measurement and early intervention in public health priorities, such as non-communicable disease, alcohol and drug misuse, mental illness, violence and injury [8].

There is still a substantial gap in knowledge of the burden of EC disease in resource limited settings and descriptive research remains a priority, particularly if consistent tools can be used, such as ‘chief complaint’ categories to enable comparison between countries and across regions [22]. The role and utility of accepted clinical algorithms, predictive tools and decision instruments for common EC clinical presentations such as chest pain or fever/likely sepsis in most resource limited settings is unknown. Testing a tool or clinical intervention developed and validated in HIC settings in new resource limited populations and contexts presents substantial and feasible EC research opportunities. Finally, implementation and quality improvement research has particular relevance for resource limited contexts, as a mechanism for sharing new models of clinical care improvements and highlighting challenges unique to LMIC settings.

For meaning and impact in both EC clinical and systems research, projects must be embedded in local context and engage local experts. Bringing stakeholders together to achieve consensus on research priorities for a country or region can be a useful technique to ensure projects are relevant and context appropriate [23]. Global EC research should aim to improve clinical care and health outcomes, patient experience and expectations, and advocacy capacity. Projects do not need to be expensive, reliant on large data sets or implemented across countries, although studies such as FEAST [24] and CRASH-2 [25] demonstrate that high quality and impactful quantitative research in LMICs is possible. Important and relevant EC publications using qualitative and mixed methods from Africa [26,27] and the Pacific region [28–30], for example, also illustrate that meaningful research can be locally-devised, inexpensive and single-site.

With enhanced understanding of the global burden of emergency illness and injury [6,7], opportunities to design studies of local and global relevance will increase. Given the significant knowledge gaps in global EC, it is critical to have a structured approach to identifying an appropriate and answerable research question.

### Identifying and developing a research question in a resource-limited context

Developing a specific research question requires an enquiring,

questioning and critical approach to EC delivery. In order to generate research questions, clinicians must develop the capacity to recurrently question current clinical practices. Ideally, they are driven by a desire to discover if there are 'better' ways to deliver EC or gaps in the EC literature that need to be answered. In global EC, there is a pantheon of questions that need to be addressed through research, even when the prevailing belief is that these questions have already been answered in well-resourced settings.

In order to identify a relevant knowledge gap for EC practice in a resource limited context, prospective researchers should first apply the following question:

*"Is this diagnostic or treatment approach, which is (or is not) supported by research in a well-resourced setting, ...*

1. *Relevant to my local epidemiology*
2. *Relevant to my emergency department*
3. *Available*
4. *Feasible*
5. *Safe*
6. *Effective*
7. *Good value for money*
8. *Culturally appropriate, and*
9. *Of a public health benefit*

*...in my resource-limited setting?"*

If the initial answer to some of these questions is "yes" or "I don't know", then it is appropriate to determine whether these questions have already been answered validly for comparable resource limited EC settings. This requires an exploratory search of the literature.

Should the question be found to be *appropriate and unanswered*, the next step is to frame the question in such a way that it can be addressed using research methodology. Broadly speaking, comparative research in global EC may be conducted using a quantitative approach, qualitative approach or both (mixed-methods).

## Quantitative approach

If using a quantitative approach to answer a question of comparison (or difference or association) between groups, the research question elements that need to be defined are explained below. It is important to understand that by defining these elements the researcher will generate both the research question and the research aim simultaneously. The two are fundamentally the same in structure. The only difference is that one is written as a question, and the other is written as an intended action (i.e. "The aim of this study is/was to.....").

Preliminary research on an aspect of EC that has not yet been considered (e.g. in a country where emergency care is a relatively new focus of healthcare) may be undertaken without focusing on a comparison. For example, it may be of interest to determine and describe the epidemiology or burden of one or more conditions relevant to EC.

### Box 1

Examples of quantitative research questions.

- 'Among severely injured (triaged as category one on arrival) adult (greater than 18 years old) patients presenting to your ED (P=Population), are those arriving by ambulance (E = Exposure), compared to those not arriving by ambulance (C=Comparator), more likely to survive to hospital discharge (O=Outcome)?'
- 'For adult patients presenting to your ED with chest pain (P=Population), is having a raised troponin level (E=Exposure), versus not having a raised troponin level (C=Comparator) associated with death at 30 days (O=Outcome)?'
- 'For adult patients presenting to your ED following a drug overdose with a GCS less than 9 on arrival (P=Population), does endotracheal intubation (I=Intervention), compared to no endotracheal intubation (C=Comparator), lead to a reduced length of stay in hospital (O=Outcome)?'

## Population (P)

The participants in a study (the study sample) should represent the population for which the study question is relevant, and to which its answer (the study results) is applicable. The next step is to define which study participants (e.g. patients) are accessible from both a practical and ethical point of view (e.g. able to provide informed consent, not pregnant, adults etc.). These constraints will be more specifically defined by the inclusion and exclusion criteria of the subsequent study.

The study sample (e.g. patients) may be defined by one or more of the following: age, presenting complaint, diagnosis, severity of illness or care setting.

## Exposure (E)

The exposure variable of interest needs to be identified (from the study question), and its type (e.g. binary, continuous, etc.) defined. Where the exposure is controlled, the study design is labelled as a 'trial' and the exposure is called an 'intervention' (I).

In observational quantitative designs (not trials), the exposure variable is labelled as such. For every variable where an exposure exists (e.g. drug A or smoker or road traffic incident or triage category 1), there is at least one possible observation for the same variable where the exposure does not exist (e.g. drug B or non-smoker or falls and assaults or triage category 2 or 3, respectively). This can be labelled the comparator (C).

The intervention (controlled, as in a trial) or exposure (not controlled, as in an observational study) may be defined by one or more of the following: type of treatment (drug, procedure, therapy); new diagnostic test; an abnormal test result; delivery of treatment (who, where?); or risk factor. The comparator may then be defined as any of the following: treatment which is the standard of care; alternative or placebo; an old diagnostic test; a normal test result; an alternative delivery mode for a treatment; or the absence of a risk factor.

## Outcome (O)

The outcome variable of interest needs to be identified (from the study question) and its type (e.g. binary, continuous, ordinal, etc.) also defined. For every subject, the outcome variable may have a 'positive' observation (e.g. survival to discharge, hospital length of stay of more than seven days, Injury Severity Score of more than 12 recorded at discharge, pain score less than 4 at one hour following ED presentation) and at least one possible 'non-positive' observation for the same variable where the outcome does not exist (e.g., death in hospital, hospital length of stay of less than seven days, Injury Severity Score of less than 12 recorded at discharge, pain score greater than or equal to 4 at one hour following ED presentation, respectively). Where possible, a well-defined time point should be included in the definition of the outcome.

Examples of outcome measures include improvement of symptoms, healing, side effects and complications, improvement in the processes or timing of care, survival, length of hospital stay, cost-effectiveness or benefits for the service provider.

All comparative studies, using a quantitative study design (i.e. trial or observational studies) will demand a clear articulation of the study question by defining Population (P), Exposure (E) and Outcome (O). Variations on this approach have been previously described in research methods training courses and publications, and can be referred to as the PECO or PICO (Population, Exposure/Intervention, Comparator, Outcome) framework [31]. Examples of study questions formulated according to this framework are provided in **Box 1**.

Study questions best answered using this quantitative approach will often be obvious because they include one of the following question words: “Does....?”, “How much....”, “How many....?” or “How long....?” Alternatively, many questions relevant to global EC, are naturally framed to ask “How....?” or “Why...?” The answers to these equally important, and complementary, study questions are best answered using a qualitative study design.

## Qualitative approach

Qualitative research is driven by the participants and their data. It is inductive, hypothesis generating and embraces complexity and the ‘whole world’ view of participants [32]. Unlike positivist quantitative research, which assumes an objective truth that can be reached through robust study, qualitative research acknowledges that truth is constructed through social, environmental, cultural, gendered and other lenses. For this reason, research in resource limited contexts can be well suited to qualitative methods, and clinician researchers in LMICs are often relieved to discover that exploring the challenges and complexity of their local environments is both valuable and impactful.

The key steps to developing a qualitative study question are as follows:

### Define the scope of the research and its purpose

Qualitative research seeks to understand, explore and examine. Developing a purpose statement can help clarify what is being investigated and the purpose of the study. Questions that can assist in formalising a purpose statement include:

- what is being investigated/what is the phenomenon or process under study and why?
- what is the role of the researcher?
- what type of inquiry will be needed and why?
- who are the participants?

A helpful script for writing a purpose statement is:

*The purpose of this qualitative study is to \_\_\_\_\_ (explore/understand/describe etc.) the \_\_\_\_\_ (core process or phenomenon under study) in \_\_\_\_\_ (the participants) at \_\_\_\_\_ (the research site) [33].*

Qualitative research is useful for exploring the perspectives of EC providers and patients, and may provide insights into why EC interventions and outcomes do not conform to expectations, particularly in challenging or complex resource limited settings [34]. Real-life frustrations in EC systems development and clinical care delivery can become excellent stimuli for qualitative research questions.

## Box 2

Examples of qualitative research questions.

‘What are the barriers and enablers to first aid care provision for trauma victims in urban environments in Papua New Guinea?’  
 ‘How do new EM specialist doctors experience and understand leadership roles in LMICs in South East Asia?’  
 ‘How can we improve pain management for children attending the national hospital ED in Botswana?’  
 ‘What is the role of gender in determining career progression in emergency medicine in sub-Saharan Africa?’  
 ‘Why are pre-hospital providers not following clinical guidelines for obstetric haemorrhage in East Timor?’

## Articulate the research question

Refining the research question narrows the purpose of the research. Words that should appear in qualitative research questions include ‘explore’, ‘examine’, ‘understand’, ‘discover’, ‘evaluate’, ‘describe’ and ‘generate’. These words differ from research questions in quantitative research, which seek to determine ‘association’, ‘cause’, ‘effect’ and ‘relationship’. Examples of qualitative research questions are provided in **Box 2**.

## Consider a theoretical approach

Theories and theoretical frameworks can assist in clarifying the research question and the methodology required to address it. Applying known theoretical approaches to qualitative studies in resource limited environments assists to improve structure and rigour in the research [35]. Useful theoretical approaches in global EC research include ‘phenomenology’ (concerned with individuals and their experience) [36], ‘grounded theory’ (building a new theory ‘from the ground up’) [37], and ‘action research’ (with the dual aims of collective study and collaborative action to bring about positive and desirable change) [38]. Simple qualitative description of health behaviours and experiences is a simpler and recommended approach where time and research capacity are limited [39].

Importantly, qualitative research should be iterative and reflexive. This means that research questions and techniques can change over time, and should be responsive to the qualitative data that is being generated and the perspectives and biases of the researcher. Unlike in quantitative research where the study aims to eliminate all bias and create a supposed objective environment, qualitative research embraces and seeks to respond to unexpected ideas and new influences within the research process [40].

Finally, many research questions in global EC require both quantitative and qualitative methods to adequately answer them. Mixed methods research uses the strengths of both approaches. The examples provided earlier in this paper from the Pacific region, regarding trauma care in Fiji [30], asthma management in Papua New Guinea [28] and triage in the Solomon Islands [29], have all used a qualitative ‘action research’ framework to explore the implementation science, and simple quantitative methods to measure outcomes. In Africa, mixed methods have been used to describe and evaluate a training program [26], and to analyse the introduction of a new process for trauma data collection [27]. These approaches are highly acceptable and have great utility in resource limited contexts; they provide rich data on the real-life experiences, outcomes and challenges involved with implementing a new intervention to improve clinical care or develop an EC system.

## Tips on this topic and pitfalls to avoid

The following tips and potential pitfalls are useful to remember:

- It is essential to ask, frame and record an answerable (focused) research question at the beginning. Otherwise the subsequent efforts to conduct and complete the study will be wasted
- For a comparative, quantitative (not qualitative) research question, always determine the agreed ‘PICO’ before commencing the study.

This will inform the design, the variables upon which data is to be collected, the analysis, the approach to reporting the results, the required sample size and the resources required

- Where multiple outcome variables are to be measured and reported, identify a single primary outcome and define the time point at which this primary outcome is measured
- For interventional studies, it may be necessary to get advice from a statistician to determine if it is feasible to answer the research question using the available sample of patients (in other words, will the sample size be sufficient to demonstrate a difference in outcomes, if one exists)
- Developing an answerable focused research question requires practice and a working knowledge of the subject area
- It is essential to involve a researcher with qualitative research skills early on in your project if this is the approach you are considering

### Additional resources

The reference list below features a number of helpful papers on EC research priorities and methods. Resources of particular relevance include the following:

Duke, in his paper 'How to do a postgraduate research project and write a minor thesis', provides a step-wise approach to designing and conducting a study in a RL context. The article is targeted at postgraduate specialty trainees, but is relevant to all clinician researchers. See reference [39].

In an article published in the *Emergency Medicine Journal*, Wyatt and Guly provide an introduction to EM research, and outline the characteristics of a good EC research question. Although this article is over a decade old, the principles still apply. See reference [41].

*Emergency Medicine Australasia*, like many academic journals, has published a series of primers on EC research (references [42,43,44]). These provide helpful information for prospective EC researchers, particularly those seeking more detailed guidance.

Hulley et al., in their comprehensive reference text 'Designing clinical research', (reference [45]) introduce the FINER criteria: research questions should be Feasible, Interesting, Novel, Ethical and Relevant. See Chapter 2 on 'Conceiving the Research Question and Developing the Study Plan'.

For qualitative research, the work of Erlingsson and Brysiewicz published in the *African Journal of Emergency Medicine* provides an overview of theory, qualitative methods and an approach to qualitative data analysis that is context appropriate. See references [34, 40].

Several EM colleges, societies and professional organisations have also published research primers along with research priority agendas. These can be helpful resources for framing research questions, even if the content is targeted at HICs. Examples include:

- 1 <https://www.emfoundation.org/globalassets/general/pdfs/acep-research-primer-book-pdf.pdf>
- 2 <https://www.saem.org/research/research-resources>
- 3 <https://www.rcem.ac.uk/docs/Research/FINAL%20ranking%20top%2030%20v2.pdf>

Many universities provide free, online resources on research methods. Some general but helpful websites focussed on research question development include:

- 1 <https://www.monash.edu/rlo/research-writing-assignments/understanding-the-assignment/developing-research-questions> (Monash University, Australia)
- 2 <https://www.youtube.com/watch?v=mrWeLJZydUU> (University of Melbourne, Australia)
- 3 <https://www.cebm.net/2014/06/asking-focused-questions/> (Centre for Evidence Based Medicine, University of Oxford, United Kingdom)

There are also a range of research-focussed online resources from Free Open Access Medical Education (FOAM) and Freely Accessible Medical Education (FAME) websites. Relevant examples include:

- 1 <https://dontforgetthebubbles.com/choosing-your-research-topic/>
- 2 <https://badem.co.za/afcem-2018-how-to-get-your-research-published/>

### Conclusion

There is an urgent need to expand the evidence base for clinical and systems interventions in resource limited EC settings. Both quantitative and qualitative methods are applicable, and the appropriate methodology will depend on the specific research question.

Clinicians working in LMIC EDs are well placed to identify and define appropriate and unanswered research questions, ideally using recognised formats such as PEO or PICO. Increasingly, resources are available to support EC research in LMICs, and prospective clinician researchers are encouraged to collaborate with local and global EC colleagues to perform impactful research and improve clinical outcomes for emergency patients.

### Authors' contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: RDM contributed 30%; GMO and GAP 20% each; and TS and NR 15% each. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

### Declaration of competing interest

The authors declared no conflicts of interest.

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