3.5 Determining the research question

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3.5.1 Learning objectives

To understand key factors to consider when determining the question that would be answered by research to resolve an uncertainty in health emergency and disaster risk management (Health EDRM), including:

1. Deciding on the general issue that needs to be studied.
2. Defining a precise research question for the study.
3. Confirming that the study is a priority, will make an important contribution to the existing evidence base and will not waste funding or other resources.

3.5.2 Introduction

The first step when planning, doing or using a research study to resolve an area of uncertainty in Health EDRM is to be clear about what type of information is needed. For example, the issue may relate to how often something happens, why it happens, how to change what would otherwise happen or what might happen when something new is done. The desire may be to try to explain what has already happened or to find ways to improve things in the future. Clarity in this helps, both in the development of the appropriate research question and in the choice of what type of study to use to answer it.

This chapter begins with an outline of some of the types of study that would be suitable for tackling the broad topics, which are discussed in more detail in other chapters. This is followed by a section on defining the research question and the need to ensure that answering this question is a priority and will not waste funding or resources.

3.5.3 Deciding on the broad topic

Research can generally be categorized as observational, in which the study looks at what has already happened or is likely to happen anyway in the future, or experimental, in which it investigates the effect of changing something. Taking the example of the Great East Japan Earthquake in March 2011 and subsequent problems at the Fukushima nuclear power plant *(1)*, observational research might study:

- the number and types of injury caused by the tsunami *(2);*
- the types of people most likely to suffer from subsequent PTSD, anxiety and depression *(3);*
- the consequences of evacuating people from the area near to the power plant *(4)*.

Experimental studies might be used to:

- investigate different ways of treating injuries *(5)* or preventing PTSD *(6);*
- identify effective and efficient methods for risk communication *(7)* and mass evacuation.

Furthermore, with events as rare as major radiological incidents *(8)*, such as Chernobyl and Fukushima, computer-based modelling studies might be used to predict the likely impact of policies such as “shelter in place”.

Deciding on the broad topics that need to be studied allows choices to be made about the type of new research that would be most relevant. Observational studies investigate the consequences of certain events (see Chapters 2.2, 2.3 and 2.4) or risk factors (see Chapter 3.2), whereas experimental studies such as randomized trials (see Chapters 4.1 and 4.3) determine the effect of a new intervention, action or strategy and provide evidence to help people to decide whether it should be implemented in the future.

3.5.4 Defining the research question

For any new study, it is important that the research question is formulated correctly. It is the research question that will:

- underpin the choice as to which type of study to undertake;
- ensure that it is clear what is being investigated;
- ensure that the correct measurement tools are chosen;
- ensure any potential biases are avoided, such as those that might arise if the accumulating findings lead to unplanned changes;
- ensure that, if the study is completed successfully, it will provide a clear answer.

Case Study 3.5.1 provides an example of how a clear question produced a clear answer in an observational study in the aftermath of the Wenchuan earthquake in China in 2008.

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Case Study 3.5.1
Analysis of inpatients and deaths in the West China Hospital of Sichuan University following the Wenchuan earthquake

The 8.0 magnitude earthquake that struck on 12 May 2008 affected nearly 46 million people and caused tremendous loss of life and property. The West China Hospital of Sichuan University is the only large-scale, state-level, general teaching hospital in the disaster area. It acted as the rescue centre for treating severe and complicated injuries caused by the earthquake, the support centre for the hospitals in the disaster area, and the logistics centre for medical teams from other provinces. It treated a total of 2728 injured people: 872 in the emergency department and 1856 admitted as inpatients. Amidst this delivery of health care, opportunities were taken to do research so as to provide evidence to help improve emergency plans for earthquakes and the establishment of state-level regional medical centres.

This research sought to answer questions such as "what were the gender, age, source, distribution of admission time, and types of injury of the patients?" And, "what were the causes of death among those who were admitted to hospital?" An observational study was designed to answer these questions, with clear definitions of what was to be counted and how. The findings were reported in the *Journal of Evidence-based Medicine* later that year *(9)*.

In the most straightforward type of experimental study, some participants are given the new intervention, while others act as a control group, continuing to receive the routine care. Many randomized trials use this simple, comparative design in which half the participants are randomly allocated to a new therapy and the other half receive usual care (see Chapter 4.1). The following paragraphs illustrate how the same basic topic for a piece of research would require different types of comparative study depending on the precise research question that is asked about the effects of the intervention.

The illustrative example is fish oil for treating PTSD, which was studied in a randomized trial after the Great East Japan Earthquake (see Case Study 4.1.1). If the broader topic is whether fish oil alleviates PTSD among people exposed to a disaster, there are many different possible comparisons that could be made, each answering a different research question, as discussed below.

Fish oil versus control
In this comparison, some participants would be allocated to take fish oil capsules and others would be asked to avoid them. In some studies, a placebo, or "dummy" capsule, might be given so that the participants and those looking after them or measuring their outcomes do not know who is receiving the fish oil. This simple design would answer the question "does taking fish oil have more or less benefit than not taking it?". However, it will not show whether fish oil is better, worse or the same as taking a different therapy or using a different type of intervention.

Fish oil versus another intervention
If there is an acceptable alternative to the intervention being tested, comparing that intervention with no intervention is unlikely to help decision makers who are trying to choose between the intervention and an alternative they would routinely use. In this PTSD example, if routine practice is to provide counselling, then answering a question about fish oil versus no intervention is not helpful. Instead, a comparison of fish oil versus counselling would answer the question "does taking fish oil have more or less benefit than counselling?" However, it will not show whether fish oil might provide further benefit if it was given in addition to the counselling.

Counselling plus fish oil versus counselling alone
If counselling would be routinely used to prevent or treat PTSD, the previous comparison would investigate whether it might be worth replacing it with fish oil. However, people might be cautious about changing practice. To overcome this, a study would be needed in which everyone continues to be provided with counselling but some receive fish oil in addition. This would then answer the question "does fish oil bring any additional benefit to the normal management of PTSD?"

Immediate fish oil versus delayed fish oil
In some circumstances, the uncertainty might be about whether something should happen immediately or can be delayed. For example, the fish oil might be given straight away or delayed for a few weeks. During those few weeks, the measurement of PTSD would provide information that is the same as that from the first example above, when one group of people are receiving the fish oil and another group are avoiding it. However, after those first few weeks, both groups will have been given fish oil, just at different times. This design would show whether fish oil should be given immediately or later. However, it leaves some participants exposed to a no-intervention period before the delayed fish oil is given, and this might not be acceptable if an alternative, such as counselling, is available. This might raise ethical issues (see Chapters 3.4 and 6.4). In such a case, the comparison might need to become immediate fish oil versus counselling followed by fish oil, so that everyone is being offered something straight away.

There are even more possible permutations for this topic than the examples given above, including whether different sequences of fish oil and counselling have different effects, and the most appropriate dose or type of fish oil product. However, these examples illustrate how different research questions need different comparisons and so different types of study. They also show that if the research question is not carefully defined, the resulting study might not be of an appropriate design and so might fail to produce a meaningful answer.

People designing an experimental study need to decide whether to compare a new intervention, action or strategy against no intervention or against an alternative, or if the new intervention should be added to something that is already used. A study of the effects of a combination might also be used to investigate the sequence in which the components are given.

3.5.5 Avoiding research waste

Once a research question has been clearly defined, the researcher needs to be confident that the study will fill an important gap and ensure that it will not contribute to research waste *(10)*. In the context of Health EDRM, research waste could mean that doing the research actually does more harm than good by diverting resources that could be used for other purposes or by hampering the response and relief effort. It is important, therefore, to ensure that answering the research question is of sufficient priority to justify doing the study. Sometimes, working through the following steps leads to the research question being changed, in order to improve it and increase its relevance. One of the steps in determining this might be to do a scoping review (Chapter 3.6).

Is the answer already out there?

Before embarking on a new study, it is important to review the existing research to ensure that the research question has not been answered already. Reviewing the existing research might also help when designing the new study, by enabling researchers to draw on practical lessons learned from earlier studies *(11)*. Doing a systematic review (see Chapter 2.6) or finding one that has already been done by others (see Chapters 3.7 and 6.2) should help to clarify the topics to be investigated and determine the precise research question to answer. For example, Case Study 3.5.2 describes the Cochrane Review of the health effects of electric fans during heatwaves, which concluded with the suggestion for a randomized trial that would focus in particular on people living in nursing homes *(12)*.

Case Study 3.5.2
Health effects of electric fans during heatwaves

As heatwaves become more common, their devastating effects on health are likely to increase. For example, during the heatwave that occurred in Europe in August 2003, an additional 30 000 people may have died. People will often use electric fans to help them feel more comfortable as temperatures rise, and a systematic review *(12)* was prepared to provide evidence on their effects on health to help inform England's national heatwave plan in the run up to the London Olympics of 2012. This review found that the existing research was not able to confirm or refute the potential benefits and harms of using an electric fan during a heatwave. It highlighted a lack of reliable evidence on whether or not people with a fan were more or less likely to survive the heatwave. This is of concern because fans work by encouraging the evaporation of sweat, which can lead to dehydration, which can be particularly dangerous for vulnerable groups such as children and the elderly. When air temperatures are above 35 °C, it is postulated that the fan might actually contribute to heat gain by blowing hot air onto the body. The review highlighted that one way to resolve this uncertainty would be to conduct a new, high quality study and it proposed the following design for this:

Population: Adults of any age with or without co-morbidity who are likely to be representative of general population, with a particular focus on participants aged ≥65 years in residential or care homes; during a heatwave.

Comparison: Electric fan versus routine care.

Outcomes: Use of healthcare services, heat-related illnesses, deaths and self-report comfort.

Design: Randomized trial, possibly a cluster trial with randomization of specific settings (such as care homes) or areas (such as small geographic regions).

3.5.6 Is the research a priority?

Identifying priorities for research is challenging in any area, as discussed in Chapter 2.7. However, this is particularly true in Health EDRM where the range of evidence needed and the complexity of emergency response make it difficult to prioritize key questions that might provide the decision makers and those making choices about interventions, actions and strategies with the evidence they need. Case Study 3.5.3 describes a priority setting exercise which was led by Evidence Aid to identify a set of 30 questions used to prioritize the conducting or updating of systematic reviews *(13)*.

Case Study 3.5.3
Identifying the highest priority systematic reviews of humanitarian action

During 2011 to 2013, Evidence Aid worked with a group of partners on a priority setting exercise for systematic reviews, producing a priority list of research questions for new or updated systematic reviews. The process included contributions from representatives of, among others, Action Contre La Faim, ALNAP, Centers for Disease Control and Prevention (USA), Centre for Global Health Trinity College Dublin, Department for International Development (United Kingdom), International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières (including the Epicentre-Paris), Merlin, Nutrition Works, Public Health England, Save the Children, UNICEF, UN Office for the Coordination of Humanitarian Affairs, WHO and World Vision.

The exercise identified 30 priorities for up-to-date systematic reviews of the effects of interventions, actions and strategies on health outcomes, which would be particularly relevant to those involved in Health EDRM at an international level. It built on a needs assessment that had identified a couple of hundred relevant research questions, which were grouped under 43 themes. Ten themes were prioritized through an online survey and the questions attached to these themes were discussed at a face-to-face meeting in London, United Kingdom in May 2013, leading to the generation of the list of 30 highest priority questions *(13)*.

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There is a reasonable body of literature on the setting of priorities in healthcare research *(14)* and some attention has been paid to this issue in the context of Health EDRM. For example, the Radiological/Nuclear Threat Countermeasures Working Group identified and prioritized 18 areas for further attention in relation to radiological or nuclear threat countermeasures *(15)*. A formal process has also been developed for conducting a rapid review to identify research priorities, especially in regard to infectious disease outbreaks *(16)*. This resonates with the ethics of doing research (Chapters 3.4 and 6.4). Murray and Kessel highlighted the need for agreement on the prioritization process because

- Undertaking health and social research to help facilitate disaster risk reduction and disaster risk management is vitally important to increase preparedness to respond to disasters, to enable the most effective action to be taken once disasters have occurred and to understand better the consequences of disasters *(17)*.

UNICEF also stressed the need for formal methods of research prioritization in 2011:

- The efficiency of knowledge generation and dissemination at both the global and country levels is diminished by a lack of coordinated, systematic planning and rigorous evaluations. Insufficient coordination among HQ [UNICEF headquarters], ROs [regional offices] and COs [country offices] in establishing research priorities and planning evaluations detracts from development of a focused research agenda in ECD [early childhood development] and results in missed opportunities to leverage resources for more rigorous, longer-term country-specific and multi-country evaluations. Current processes at the country and global levels do not facilitate sequencing of evaluations into formative and summative stages. *(18)*

The framework presented in Table 3.5.1 can help when deciding on the relevance and relative priority of a new piece of research. This was suggested in a report on the impact evaluations that are already available or are needed for humanitarian assistance, prepared by Evidence Aid and the International Initiative for Impact Evaluation (3ie).

Table 3.5.1. Framework for planning an impact evaluation *(19)*

Item	Things to consider
Feasibility of undertaking impact evaluations	Consider methodological difficulties (for example in finding comparison groups), operational difficulties (for example in defining and delivering the policies, interventions, actions or strategies to be evaluated) or institutional difficulties (for example unwillingness to evaluate).
What to evaluate?	Consider whether the impact evaluation should be of a topic that will be particularly easy or difficult to evaluate. For example, it might be relatively easy to do a randomized trial of a specific medical procedure for treating cholera but examining a complex intervention to improve the protection of women and children in a displaced person camp might require the assessment of a range of difficult-to-measure outcomes (such as gender-based violence, dignity and livelihoods).

Item	Things to consider
Use of existing evidence when prioritizing individual impact evaluations	Consider whether to focus on areas with little or no existing research or areas with a relatively large amount of research that is not sufficiently reliable or robust.
Creating review standards	Review the existing evidence to confirm that there is sufficient uncertainty to justify a new study and, when it is complete, place its findings in the context of other relevant studies, to provide users with an up-to-date summary of the evidence base.
Choosing the interventions to evaluate – innovation	Consider whether to focus on innovative interventions or those that are already in wide use.
Choosing the interventions to evaluate – relationship with the development sector	Consider whether to focus on interventions where there is considerable overlap with the development sector.
Choosing the interventions to evaluate – uncertainty, controversy and debate	Consider whether to focus on policies or interventions with considerable uncertainty, controversy or debate about their relative effects.
Choosing the populations to study	Consider whether to focus on particular subgroups of people (such as vulnerable or disadvantaged), or the population as a whole.
Settings for the impact evaluations	Consider whether to focus on sudden-onset disasters (possibly with the need to put some impact evaluations 'on the shelf' for future events) or for ongoing protracted emergencies.
Phases for the impact evaluations	Consider whether to focus on impact evaluations in resilience, risk reduction, immediate short-term response, or prolonged response or engagement.
Choosing the outcomes to measure	Consider whether an existing core outcome set should be used, or a new one developed (see below). In the absence of a core outcome set, identify and measure those outcomes that will be most helpful to future decision makers.
Methodology research	Consider whether research into the methods to be used in the study could be embedded in the study, for example in a SWAT (Study Within A Trial) *(20)*.
Impact evaluation of the impact evaluations	Consider whether the study should include an evaluation (either by the research team working on the study or by someone independent) of the impact of the study on future policy, practice and outcomes.
Dissemination and implementation of findings	Consider having an implementation or knowledge translation plan, which should include how best to reach key decision makers and how the findings might be made available to those who took part in the study.

3.5.7 Choosing the right outcomes to measure

Regardless of the topic chosen, the outcomes measured need to be those that will answer the research question reliably and be most useful to decision makers. Some of the causes of waste in healthcare research generally are the inconsistent measurement of outcomes across studies of the same topic, and selective reporting of the outcomes that have been measured *(9, 21)*. One way to reduce this waste is through the development of agreed, standardized sets of outcomes for research, known as core outcome sets. A core outcome set would help when comparing, contrasting and combining the findings of Health EDRM research. Although a core outcome set is not yet available for humanitarian action, a template has been prepared showing the data that should be reported for acute disaster medical response. This includes 15 data elements with indicators that can be used for research and quality improvement (Case Study 3.5.4). Furthermore, the international COMET Initiative *(22)* provides support for the development and uptake of core outcome sets and has identified more than 300 examples across health and social care *(23-25)*.

Case Study 3.5.4
Template for uniform data reporting of acute medical response in disasters

In order to tackle the lack of standards for collecting and reporting data in research studies on disaster medical management, the Academy for Emergency Management and Disaster Medicine brought together a group of 16 experts in the fields of research, education, ethics and operational aspects of disaster medical management from eight countries in a consensus process. Their aim was to produce a template for uniform data reporting of acute disaster medical response. The intention was to support more accurate completion of reports on disaster medical response, which would in turn contribute scientific evidence and knowledge that could be used to optimize medical response system interventions and improve the outcomes of disaster victims. The template was finalized at a meeting at the Utstein Abbey, on the island of Mosterøy, off the coast of Stavanger, Norway in November 2010. It followed the Utstein model, in which meetings are characterized by strong international collaboration and sponsorship of scientific organizations, using a process of gathering in an isolated intellectual environment experts who engage in well-facilitated discussions. The template contains 15 data elements with indicators, that can be used for both research and quality improvement, and it is available in the journal article *(26)*.

3.5.8 Being research ready

Chapter 3.6 describes how a scoping review might be the next step in moving forward with a piece of research. Sometimes, a pilot or feasibility study might be needed to develop the methods for a definitive research study and to ensure that it can be completed successfully. These might be particularly important steps when planning a study for implementation in a sudden-onset disaster, when it may be necessary to have plans for a prospective study (such as a randomized trial) pre-prepared and ready to

be activated. Without this "on the shelf" study, it might not be possible to do the necessary research, especially if it would take days or weeks to design and activate the study and the need and opportunity for the research would therefore be missed. To overcome this challenge, it might be worth having the study pre-designed and ready to initiate at the appropriate time in the disaster. This is the case with a series of studies funded by the UK's National Institute for Health Research, which will be activated in the event of an influenza pandemic *(27)* and include a randomized trial of steroids for the critically ill *(28)*.

3.5.9 Conclusions

There are many areas of uncertainty in Health EDRM which would benefit from research. However, before embarking on any new study it is important that it is carefully planned and designed. The first step in doing this should be the development of a precise research question to help ensure that the design of the resulting study is appropriate and will produce a relevant, reliable and robust answer.

3.5.10 Key messages

- **Defining a clear research question, including any comparisons that will be made, is vital when planning a research study to fill an evidence gap for Heath EDRM.**
- **Outcomes to be measured and reported should be chosen carefully, in order to allow the study to answer the research question and provide evidence that will influence decision makers.**
- **A review of the existing evidence will help to ensure that the new study is a priority and that the answer to its research question is not available from existing research.**
- **If the study will need to be implemented rapidly (such as in a sudden-onset disaster), a pilot or feasibility study may be necessary and it will be important to have the design "on the shelf" and ready to activate.**

3.5.11 Further reading

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3.5.12 References

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