PREHOSPITAL RESEARCH
an introduction

A BOOKLET BY THE FALCK FOUNDATION TO PROMOTE PREHOSPITAL RESEARCH

Logo and graphical identity

The Falck Foundation is an independent institution that has the aim to promote research in prehospital emergency medicine. The Falck Foundation has created a logo with a unique look that distinguishes itself from the Foundation's main sponsor, the Falck Group. This is in no way intended to conceal the fact that the Foundation receives financial support from the Falck Group, but rather to emphasise the Foundation's scientific independence. Graphically, the Foundation has chosen a simple pictogram representing the two capital F's in the name of the Falck Foundation, set in a blue-orange colour combination.

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Content

1. Introduction 3
2. Prehospital systems 5
3. Prehospital research 9
4. Ethical aspects 13
5. Research areas 17
6. Literature search 19
7. Matching research components 25
8. Prepared for the statistician? 29
9. Research funding 33
10. Tips and tricks 37
11. Roadmap for prehospital research 43
12. Falck Foundation 45
13. Further reading 47

1. Introduction

Within the field of emergency medicine, the prehospital context is a relatively new specialty. The most appropriate research methods still have to be established and the academic culture is still in development. Nevertheless, it is clear that the enthusiasm to conduct prehospital research is growing and that an increasing number of young prehospital professionals are reporting on their research activities. We now need to advance from descriptive studies to ones that explore and find answers to our many important questions.

The field of Emergency Medical Services (EMS) is in need of dedicated researchers who will commit their careers to developing and refining methodologies that will allow the next generation of EMS investigators to make major breakthroughs. All this with the goal to improve patient outcomes.

The main aim of this booklet is to stimulate, facilitate and prepare junior investigators to perform their initial studies in prehospital research. The information presented here is provided by experienced researchers and intends to contribute to ongoing improvements in the quality of prehospital research.

The Falck Foundation supports the development of prehospital research by means of a research grant scheme, the annual Sophus Falck Abstract Awards, and via regular pre-congress research workshops, as well as through congress sessions and lectures. All activities are exclusively in the domain of prehospital research.

This booklet is yet another initiative directed at the main objective of the Falck Foundation: *to promote and support prehospital research*. The booklet is a joint initiative of the members of the Medical Advisory Board of the Falck Foundation and is endorsed by the Governing Council of the Falck Foundation. It is anticipated that the information provided in this booklet, and attendance at the Falck Foundation prehospital research workshops, will result in a higher quality of the abstracts submitted at the conferences, and in valuable research proposals and publications. More importantly, the research outcomes should result in improved and more effective prehospital patient care worldwide.

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2. Prehospital systems

When starting a pre-hospital research project, you need to take into account the typical characteristics of the pre-hospital system in which the study is conducted. Depending on the components of your particular prehospital system, the results of your study can also be relevant for other prehospital systems.

Some history

Prehospital care started more than 2000 years ago. In those days, soldiers were transported to a location where they could be treated for their wounds. During World War II it became clear that basic medical treatment on the battlefield increases the survival of soldiers. Based on this evidence, the care for civilians was also initiated outside the hospital setting. In 1958, Peter Safar demonstrated the importance of prehospital resuscitation. This led to the widespread introduction of prehospital care in many parts of the world. In 1966 a report published by the National Academy of Sciences and the National Research Council mentioned several inadequacies related to these early prehospital systems. For example, there were no treatment protocols, too few trained personnel, inadequate means of communication, poor equipment, and a lack of research to evaluate the prehospital care. Since then, a wide range of legislative and other initiatives have had an important impact on licensure, certification, registration, equipment, personnel and the as a consequence the quality of prehospital care has improved.

Differences between countries

A prehospital system encompasses a complex network of coordinated services that provide care to the community that it serves. At the same time, many countries have different laws and regulations regarding how to provide such care. Moreover, prehospital systems show great diversity due to the socio-cultural, political, geographic and religious differences between countries.

The main differences relate to those in the building blocks of the system:

- the telephone number
- the dispatch centre
- the mode of transport
- the destination of the patient

Within each of these building blocks, there are more differences with regard to:

- the educational level of the staff
- the number of tiers
- the prehospital intervals

The telephone number

Within the European Union (EU), the emergency number **112** is the sole telephone number used for prehospital emergencies in eleven of the member states (Denmark, Finland, the Netherlands, Romania, Cyprus, Estonia, Luxembourg, Poland, Slovenia, Spain and Sweden). In these countries, it is not necessary to dial an area code and the 112 calls are free of charge. In the rest of the EU, as well as in the rest of the world, different national emergency telephone numbers are in use.

The dispatch centre
A dispatch centre may cover a region or a sub-region, generally depending on the size of the population encompassed in a particular geographical area.

Two models are in place to handle a medical emergency call in a dispatch centre:

- medical consultation is immediately available,
- the call is received at an integrated dispatch centre and then transferred to a second-line dispatch centre for medical consultation. In these integrated dispatch centres, emergency medical services, the fire brigade and the police work together to handle incoming emergency calls. This is becoming the most frequently used model in the EU.

The telephone call to a dispatch centre should result in the dispatch of the right resources in the appropriate time to the right patient. To enable this, the dispatcher has to identify the type of need, decide on prioritisation and select the most appropriate response.

Within this relatively uniform structure, considerable diversity exists with regard to, for example, caller identification, calls handling, and needs assessment procedures. Dispatchers may also give assistance to the caller or to the responding team. Another point of diversity is that the education and post-qualification training of the dispatchers is still not standardised.

To describe the performance of dispatch centres, a common terminology, a key dataset for health monitoring and benchmarking, and a number of supplementary parameters, have been defined.

Modes of transport
Various modes are available to transport prehospital care providers to the scene and to transport patients to an appropriate facility. The most common examples are traditional ambulances, medical mobile units and helicopters. Alternative transport modes are bicycles, motorbikes and hovercrafts. Not all modes of transport are used for patients; some are used to transport a medical team only.
At the moment, a single European standard for ambulances exist (EN-1789). However, it is voluntary for the member countries if they use the standard, and therefore EU-experiences large differences regarding ambulance design. The Council of the European Union does not play a role in the organisation of healthcare in the individual member states. In the United States, ambulances that comply with a minimal federal standard for ambulance design are authorised to wear the Star-of-Life symbol.

Patient destination
Two models are used to determine which healthcare facility the patient will be taken to:

- the patient is transported to the *nearest* facility and may be transferred to another facility as and when required. In some systems the nearest facility is not necessarily a hospital and can also be, for example, a general practitioner, or a medical outpost.
- the patient is transported to the most *appropriate* facility for definitive care. This model has been shown to improve outcome in patients with myocardial

infarction and severe traumatic brain injury. In some countries, however, the law states that the patient must be transported to the nearest facility.

Communication of information at the receiving facility has major implications for the subsequent hospital treatment and care of the patient. Efficient patient handover between healthcare workers requires a seamless transfer of relevant information and clinical responsibility. Recently developed communication facilitating aids include SBAR (Situation, Background, Assessment, Recommendation) and IMIST-AMBO (Identification, Medical complaint, Information, Signs, Treatment, Allergies, Medication, Background, Other issues).

Response level

In general, four categories of prehospital practitioners, or a combination of these categories, will determine the response level:

- first responders
- paramedics
- nurses
- physicians

In most European countries, physicians and nurses are generally present in prehospital care. In other European countries, and in most parts of the United States, paramedics are most often present.

Although the educational levels of these categories of personnel are standardised in most countries, there are large differences between countries. A current trend is to give basic training to all prehospital practitioners and additional training to some of them so that they can provide more advanced care to certain patient groups, for example those with myocardial infarction or multiple traumas. The debate continues as to which combination of practitioners, and their related educational levels, will yield the best results in prehospital care. Therefore, also this remains an interesting area of research.

Tiered systems

When only one category of prehospital practitioners, whether paramedic, nurse, physician, or emergency medical technician, is working in prehospital care, this is called a single-tiered prehospital system. When practitioners with multiple education levels are involved in prehospital emergency care, this is called a multiple-tiered prehospital system. In France and Germany, for example, paramedics carry out their tasks together with the physician: this is a two-tiered system. In Belgium, the first responders, nurses and physicians are all involved in prehospital care: this is a three-tiered system.

The prehospital intervals

The three main response intervals are:

- the prehospital interval: this is the time between the occurrence of the incident and arrival at the receiving facility
- the emergency medical dispatch (EMD) response interval: this is the time between the moment that the emergency call is answered and the moment that the resources are dispatched and the call is terminated
- the emergency medical system (EMS) unit response interval: this is the time between activation of the EMS response unit and their arrival at the scene.

Due to the differences of the building blocks of the prehospital systems, the response level and the tiered system, there is a wide variety in the timelines of prehospital intervals (Figure 1).

Figure 1

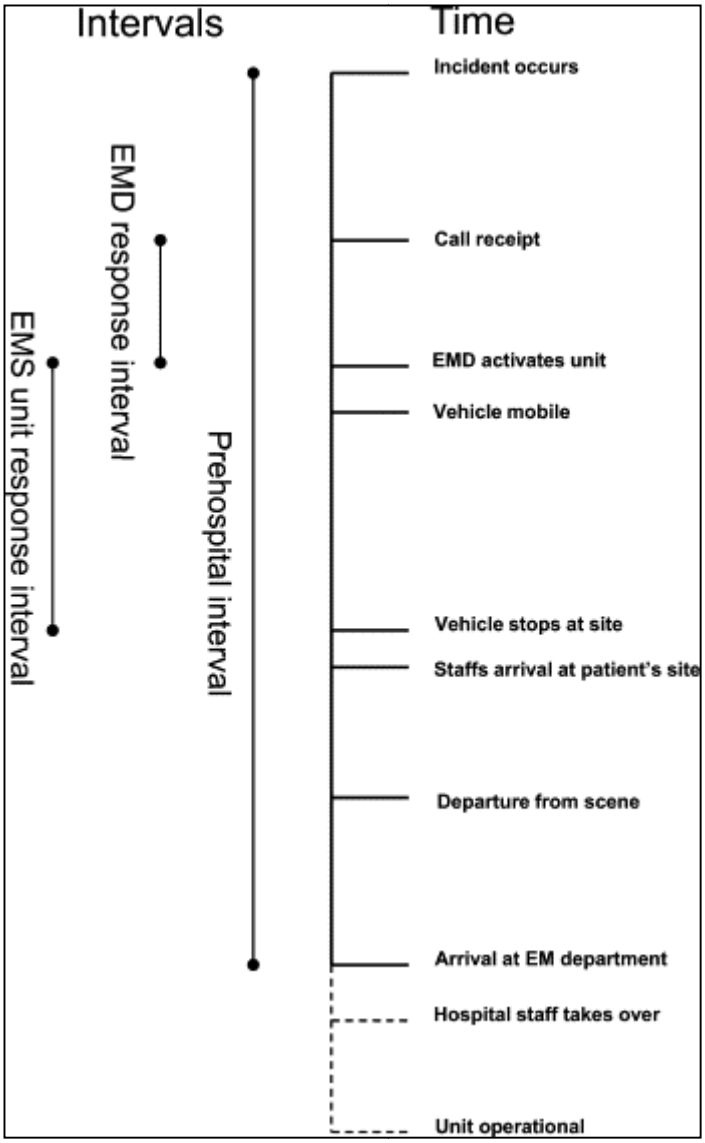

Figure 1: The journey of the patient through the prehospital system and the main response intervals.

Source: Castrén M, Karlsten R, Lippert F, Christensen EF, Bovim E, Kvam AM, et al. Recommended guidelines for reporting on emergency medical dispatch when conducting research in emergency medicine: The Utstein style. Resuscitation. 2008;79:193-7

Information on prehospital systems is relevant for pre-hospital research

Every type of pre-hospital research should take into account the building blocks and characteristics of the emergency medical system where the research takes place. Before starting the research, you need to determine whether the results and conclusions based on a study in your specific system can, or can not, be applied within another context or system. If this is possible, it means that your results are generalizable to other systems. More information on how to determine the generalizability is described in Chapters 6 and 10.

3. Prehospital research

The basis of medical research includes curiosity, a sense of wonder, the desire to understand observations, and the need to have access to facts and data. At the same time, the outcome of research should have some practical consequences in order to be relevant.
In practice, research is conducted for a variety of reasons, such as:

- to describe what is happening,
- to understand what is happening
- to replace subjective impressions with objective data
- to improve the quality of medical interventions
- to obtain political or financial support
- to demonstrate expertise and professionalism.

The bottom line is that medical research is directly or indirectly aimed at providing the best possible care for a patient. It is important to realise that prehospital care is at the start of a long and complex process of diagnosis and treatment. Therefore, the positive effects of outstanding or very fast prehospital care can be rendered useless if subsequent interventions are carried out too late or are inadequate. On the other hand, important adverse events of treatments that started in the prehospital setting may go unnoticed in the hospital.

Evidence of prehospital care
Research in the prehospital domain of emergency medicine, and the implementation of successful research outcomes, contribute to improved patient care. This is particularly true for those individuals in most need of essential and urgent care. However, most of the prehospital issues still need evidence-based solutions. Many of the current working methods are grounded in tradition, or have been transferred from the hospital environment to the prehospital setting. Even in the hospital environment, many of these procedures, techniques and treatments have not yet been properly evaluated to establish their effectiveness. Also, new organisational structures, techniques, technologies and therapies are sometimes introduced without adequate evaluation and unequivocal evidence of their value. In view of the lack of data, it can be debated whether current emergency medical system should be allowed to continue to expand before procedures are in place to monitor and report clinical outcomes, and identify unwanted and adverse effects.

Despite the need for research, the number of studies conducted in the prehospital field is relatively small: in the last decade, only a few hundred articles were published in peer-reviewed journals. In addition, several concerns remain about the quality of the research. Prehospital research is needed that not only shows that prehospital care is beneficial, but also that it is also based on good science. This is important not only for the patients and for those working in the prehospital domain, but also for health care in general – as well as for others involved, politicians, policymakers, and health insurance companies.

Why is there so little prehospital research?
Although there are many reasons for the lack of prehospital research, most of them are related to the setting and the environment. Prehospital care deals with acute events which, by their nature, are unpredictable with regard to place, time and type of

event. There is an almost endless variety of acute incidents, most of which have a low frequency of occurrence. Moreover, there is considerable variety in the settings and the prehospital systems themselves (Chapter 2). Another problem is related to obtaining informed consent from the patient. This problem has both an ethical perspective because the victim is in a dependent or non-responsive state and a practical perspective because it takes time to obtain informed consent whereas the patient is in urgent need of care (Chapter 4).

All these aspects may explain why only about 50% of prehospital research is indexed in electronic medical databases. This may also indicate that much of this research does not meet the standards to be published in a peer-reviewed journal. In fact, less than 1% of all prehospital studies are randomised controlled clinical trials, which is considered the highest level of medical methodology. Generally speaking, in prehospital research, the type of study most often finalised and published, is the case report.

Methodology of prehospital research

The gold standard for clinical research is the randomised controlled trial (RCT), which implies a number of basic conditions, including:

- randomisation
- highly specified protocols
- closely monitored settings
- careful selection of a homogeneous population
- dedicated researchers.

It is difficult to perform an RCT in the prehospital setting because the basic conditions for this type of study are not present. For example, randomisation of individuals requires that all interventions are available on the scene. Obviously, for practical reasons, this is not the case. In addition, most acute incidents have one accepted mode of therapy and no alternative therapy is available for randomisation. In addition, not all hypotheses and questions can be answered using the RCT approach. For example, if one wants to investigate the influence of varying rescue times on patient outcome, it is unthinkable that an ambulance be asked to arrive late simply for research purposes. On the other hand, it can be questioned whether the placebo effect plays a role in an acute setting.

Another methodological problem associated with prehospital research is that unpredictable situations sometimes make it necessary and unavoidable to deviate from the basic study protocol. Also, recordings made in an ambulance of blood pressure level, the Glasgow Coma Scale, pulse oximetry readings and information rated on a visual analogue scale often undergo extreme and rapid fluctuations and may not be reliably recorded. At the same time, emergency personnel trained in research methods are simply not there.

Therefore, it is not surprising that, in many cases, prehospital-related research questions cannot be answered using traditional research models.

Components of good prehospital research

Recent practical experiences in the field of prehospital research have revealed that increased demands on the level of methodology leads to decreased adherence to the research protocol.

Examples of components that enable good quality prehospital research are:

- reliable data
- use of consistent definitions
- well-defined classification systems
- use of validated performance measurements
- risk adjustment parameters to check for confounding factors.

Unfortunately, many of these components are still in various phases of development and there is limited consensus and acceptance of the current definitions, classification systems and performance measures.

4. Ethical aspects

Ethical considerations for clinical research cover three main areas: acquiring informed consent, obtaining approval from an ethics committee, and observing and adhering to the basic principles of beneficence and justice.

Research ethics are based on the principles reported in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. The Nuremberg Code provides for voluntary consent by research subjects to participate or withdraw from the research at any time without prejudice, and with a clear explanation of the risks and benefits.
The Declaration of Helsinki emphasises the need to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of the personal information of research subjects, and for comprehensive research protocols and grounds for waiver of consent. The Belmont Report addresses respect for persons and protection of vulnerable subjects by ensuring compliance to informed consent and the need for beneficence and justice.

It is generally acknowledged that these important ethical principles for hospital-based practice may not be entirely applicable in the pre-hospital environment.

Informed consent
It is required that a person who participates in a research study has been informed about this research in such a manner that the person is able to decide to participate in the research, or to decline participation, without any effect on treatment or the relationship with the treating physician. This process of fully informing the patient and obtaining the answer is called informed consent.

The classical approach to obtaining informed consent is faced with practical problems when applied in the pre-hospital environment. Therefore, in such a setting, there is often a need for a waiver of the usual process of informed consent. The Good Clinical Practice Guidelines of most nations allow enhanced measures to address this problem. The provisions for exemption from informed consent include the following:

- The subjects have life-threatening, time-sensitive medical conditions for which
  - currently available treatments are unproven or unsatisfactory
  - there is reasonable and valid evidence to support the proposed research
- Obtaining valid informed consent is not practically feasible because
  - the medical condition of the subject precludes informed consent
  - the intervention is needed urgently before consent can be obtained
  - the prospective identification of subjects may not be possible
- Opportunity provided for subjects to participate is not in their best interest, especially when
  - a life-threatening situation exists and necessitates intervention
  - the risk involved is minimal or reasonable

- The research cannot be carried out without the waiver of informed consent
- As far as possible, the subject, next-of-kin or legal representative is provided with additional and relevant information after research participation.
- Waiver of informed consent will not adversely affect the rights and future welfare of the subject.
- Measures are put in place for additional protection of rights and welfare of subjects through community consultation, disclosure through public media prior to the research, opportunity for feedback and reporting of the feedback to the ethics committee, post-research public disclosure, and an independent data and safety monitoring board for interim analysis and safety aspects.

Vulnerable populations

Asking for patient consent in the setting of a medical emergency places an unfair burden on an already vulnerable patient. Critically ill patients are vulnerable because their medical condition diminishes their decision-making capacity and their ability to effectively formulate and communicate their needs and wishes. For patients experiencing a health emergency, the capacity to make decisions can be affected by many factors, including medication, stress, emotion, and the illness or injury that has caused the emergency. In addition, the patients will probably feel very dependent on the caregiver who is asking for their permission, which may influence their decision to participate.

Barriers

The ability of the ambulance crew to obtain informed consent from the patient is confronted with several problems and barriers, including:

- extreme situations related to pressure of time and emotions
- absence of relevant information, such as age, medical history or diagnosis
- limitations in available resources
- conflicts at the scene between paramedics and patients, or between family members and patients
- the judgement of paramedics may be impaired due to imminent dangers, inexperience, and stress or fatigue from heavy work schedules.

Beneficence and justice

Beneficence addresses the risk-benefit ratio. Risks for the research subjects should be kept to the absolute minimum required for completing the research. The types of risks that need to be considered include physical, psychological, legal, economic, social and financial aspects. Benefit to the individual patient cannot be guaranteed at the time of the conduct of the research. However, there needs to be some evidence of potential benefit, for example by previous animal-based studies or human studies carried out in different environments. Valid arguments should be in place that future patients, or society as a whole, may benefit from the proposed research.

Justice, on the other hand, addresses the need for the distribution of benefit. The research should not include bias in subject selection or discrimination on the grounds of gender, ethnicity, and societal or cultural identity. Justice refers to the principle of fairness and unbiased behaviour by the investigators in the recruitment of study participants. Any exploitation of disadvantaged groups so that advantaged groups may benefit is totally unacceptable. The research investigators need to demonstrate

that vulnerable groups are not unfairly discriminated against in the selection of subjects for a trial, or allocation to a treatment arm.

Role of the ethics committee

Ethical approval is required for any research activity that encompasses collection, use and disclosure of information based on data collected from patients. For this reason, ethics committees, or institutional review boards, are in place to ensure that:

- the autonomy of the subject is respected
- a well-defined benefit would result from this research
- vulnerable subjects would be protected, such as children and prisoners
- peer review is provided for the research proposals.

In different communities, the ethics committee may vary in their practice and procedures. However, most committees require the research team to submit an application using standardised forms. Some projects, such as chart reviews and surveys, may be classified as having a minimal risk and be eligible for quick approval.

At the other end of the spectrum, multi-centre research presents specific challenges and potential delays in obtaining ethics approval. The principal investigator, site investigators and the research administrator at each site must obtain approval from the ethics committee at their respective institutions. The various institutions may have differing local requirements, such as the use of specific terminology in the consent forms.

Ethics committees usually scrutinise the following criteria before granting approval:

- The research design and methodology
- The data planned to be collected need to comply with the research aims
- The risks to the patient are minimised and reasonable in relation to the expected benefits, including the benefit of knowledge gained.
- There is no undue bias in subject selection.
- Informed consent is sought and documented. In case a waiver of consent is required, the grounds for waiver need to be clearly detailed.
- The privacy of subjects and confidentiality of the data are strictly maintained.
- Plans are clearly in place for independent data monitoring and safety.
- The measures to safeguard the rights and welfare of vulnerable subjects are in place.

In many communities, emergency ambulance services do not come under the jurisdiction of any specific medical institution. Instead, they form part of the civilian rescue services, civil defence forces, or fire brigades. It is highly unusual for the parent agency to have their own ethics committee. Principal investigators working with these services usually apply to their own medical institution for support from the ethics committee.

Medication board

In some studies, the approval of a medication board is also needed when the medication board is a separate body.

Certification of researchers
Investigators need to be certified according to the Good Clinical Practice guidelines in their own community and in at least one good research ethics program. An example of such a program is the Collaborative IRB Training Initiative (CITI) Human Subjects Training Program, a subscription service that provides education on research ethics. Before prehospital research is started, every member of the research team has to be aware of all the ethical issues pertaining to the research and be able to implement those measures.

Collection of informed consent forms
After consent has been given, the consent forms are collected and stored by the principal investigator, or at the institution where the data are collected.

5. Research areas

When considering the start of prehospital research, it is important to realise that the research topic should not be limited to prehospital cure. These topics are less popular than trauma and resuscitation and also deserve research initiatives.
In the domain of prehospital research, the four main research areas are:

- Prevention
- First responder care
- Prehospital system
- Outcome.

Within each of these areas, numerous research topics can be identified.

Prevention
A main role of every prehospital provider is to contribute to the prevention of illness or injury. Information regarding the aetiology of illnesses and injuries, or the effects of preventive measures, can be routinely collected. Studies related to this topic allow to determine the dangers of newly introduced 'fads and crazes', or the effect of preventive measures. Prehospital data can be very useful for the development of preventive regulations. A typical example is the reduction of traumatic brain injuries by wearing a helmet when cycling.

First responder care
If an illness or injury cannot be prevented, the next best approach is to ensure that first responders are able to respond appropriately. The first responder can be a layperson or a health professional, such as a general practitioner or home-care nurse. Studies in this area can investigate their roles using various equipment or by applying various therapies. A typical example is the use of Automated External Defibrillators (AED) by first responders.

Prehospital system
Because this relates to the core business of emergency medicine, most studies focus on this area. This includes: access to the system, paramedics versus ambulance nurses, helicopter versus ambulance transport, the use of various devices and equipment, and the effects of training and skill maintenance. Many issues still need to be investigated. For example, studies are needed to determine the cost-effectiveness and public value of prehospital services, scoring methods, severity scales, quality indicators and a variety of outcome measures. A typical example is to measure and evaluate the efficacy of a prehospital system.

Outcome
Many outcome parameters are defined in prehospital research. At the same time, it is important to understand which interventions and which other factors may determine outcome. Research topics include medical supervision of the prehospital care by general practitioners and emergency physicians, and the impact of assistance by mobile emergency groups or telemedicine. A typical example is to measure and evaluate what influence the introduction of the specialty of emergency medicine has had on patient outcome.

6. Literature search

A literature review is an analysis of prior research to identify the “who, what, where, and whys” of the chosen topic area. Knowledge of previously published literature is essential to effectively complete new research. A literature review enables you to identify those articles which are relevant to the topic of interest, including the most recent studies. The literature review also helps to clarify and redefine your final research question. The three main types of literature review are:

- the traditional, or narrative, review
- the meta-analysis, or quantitative systematic review
- the systematic literature search

The narrative review does not follow strict systematic methods of literature search and is therefore prone to bias. On the other hand, narrative reviews are relatively easy and can be carried out fairly quickly. In most cases, a robust narrative review will be sufficient to prepare for a prehospital study.
The meta-analysis combines the data from several studies. This type of review summarises in a structured manner the data from several studies with respect to a specific health problem, or the effect of one single treatment or intervention. A meta-analysis is research in its own right. A well-performed meta-analysis can result in a peer-reviewed publication.
The aim of a systematic literature review is to produce a state-of-the-art publication. The systematic review represents the top of the hierarchy in the pyramid of evidence-based medicine (Figure 2). In most institutions, a PhD study has to be based on a systematic literature search.

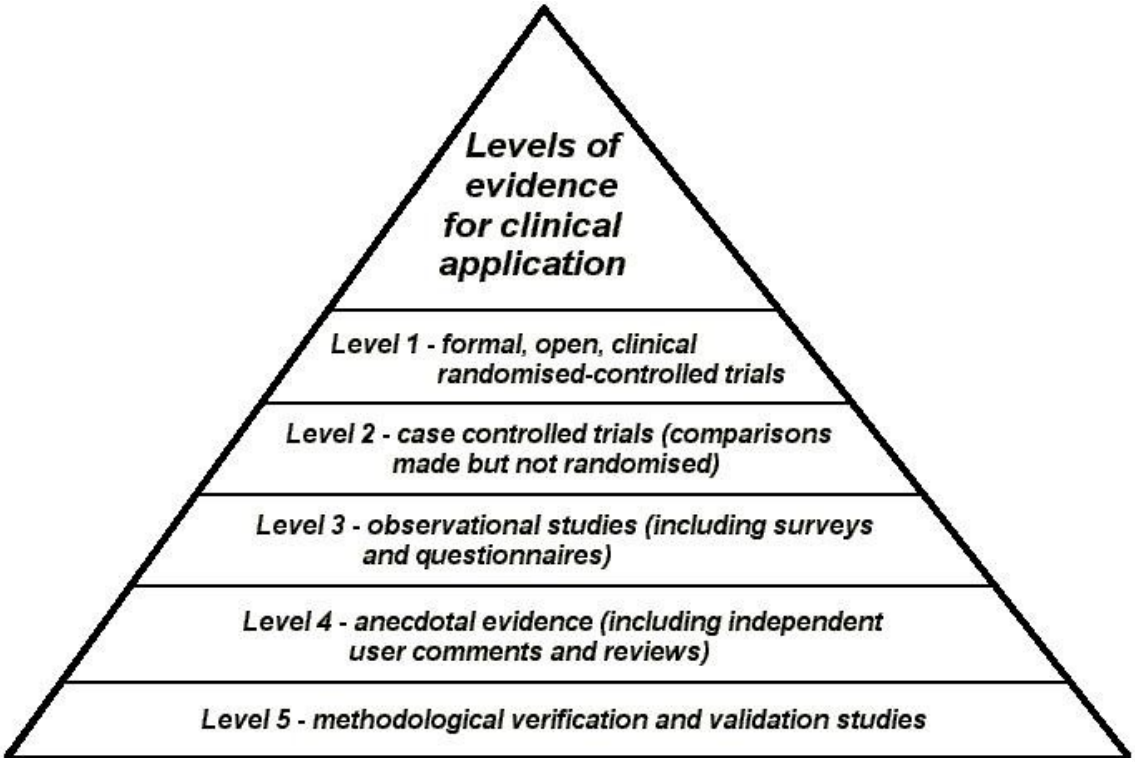

Figure 2: Hierarchy of evidence. Source: Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, Guyatt GH,Harbour RT, Haugh MC, Henry D, et al: Grading quality of evidence and strength of recommendations. BMJ 2004, 328:1490.

A systematic literature search is the most scholarly method of literature review. The systematic approach minimises bias and allows a thorough, objective and reproducible literature search. A systematic literature search should be conducted in five phases to result in a publication of a review article.
Three phases are described in this chapter, and the other two are described in Chapter 7.
Should you decide to publish your results based on a systematic review, you should be aware that you have to go through each and every phase. However, should you only need relevant background information for your research topic, the guidelines for phases 1 to 3 will provide you with the tools to conduct a narrative review.

Phase 1: Ask a clinical question by means of the PICO of PECOT approach
The first phase of a systematic literature search starts by defining your research question. It is helpful to formulate your research question using the PICO strategy that includes the items: Population (P), Intervention (I), Comparison (C), and Outcome (O) measures. For example: in patients with ankle fracture (P), is paracetamol (I) as effective as a non-steroidal anti-inflammatory drug (C) to relieve the pain (O)?
For epidemiologic research you can use the PECOT strategy to define the clinical question: Population (P), Exposure (E), Comparison (C), Outcome (O), and Timeframe (T). For example: in patients with ankle fracture (P), is paracetamol (E), as effective as a non-steroidal anti-inflammatory drug (C) to relieve the pain (O) during prehospital care (T).

This first phase generally has a repetitive, circular process. After your initial search in journals known to publish articles related to your topic of interest, you may well come to the conclusion that your clinical question needs more focus. After you have developed your final definition based on the PICO or PECOT terms, you can start your search strategy.

Phase 2: Search strategy
The second phase involves a search for the best available evidence. Before starting the search, it is important to define which domain of health care your clinical question refers to. Health care domains include, for example, diagnosis, prognosis, etiology, therapy, side-effects, and outcomes.

Data sources
The research question, defined by the PICO or PECOT terms, determines the components of your search strategy. A systematic literature search uses various sources of information, such as Medline, the Cochrane Central Register of Controlled Trials, Embase, CINAHL and PsychINFO.

Specific or sensitive approach
Before starting a literature search, you have to decide whether a specific or a sensitive approach is preferred. Although a specific approach will yield fewer results, you run the risk of missing relevant articles. On the other hand, all retrieved articles will be highly relevant. A sensitive search will yield more results, all of which you will have to read. But not all of the articles will be suitable for further analysis.

Terminology
After selection of the data sources, the relevant terminology has to be selected by means of controlled vocabularies. The advantages of using terms from a controlled vocabulary, which can be considered as a medical thesaurus, are:

- an increase in search efficiency and more focus, while eliminating irrelevant records
- representation of a subject concept, no synonyms are needed
- helps to find relevant articles on a search topic that may not be explicitly mentioned in a title or abstract

However, the controlled vocabulary, including MeSH and Emtree terms, may not always cover new concepts, or all the variability in types of reporting, and all relevant studies.

Too many and too few results
If the search yields too many articles, the PICO terms should be refined, for example by using a controlled vocabulary in the 'subheadings' instead of in the 'major topics'. Also, it may help to use methodological filters, such as PubMed Clinical Queries, SUMSearch2 or the Trip database. Methodological filters will also facilitate your search for high-quality evidence. Using controlled vocabulary in combination with these filters will help to narrow your results to the most relevant articles.

If your search yields only a few articles, you can try and identify additional relevant articles in the reference lists of the retrieved articles. This is called the snowball technique. You can also use a citation database, such as Scopus or Web of Science. Another possibility is to look for the option of 'related articles' in the data sources that you have used. Sometimes you may need to search for unpublished information or 'grey literature' that is available on the internet. You can also look for controlled vocabulary that has already been used in published articles on your subject of interest.

An alternative way of searching is the use of free text in electronic databases. Free text is mainly used when searching for a new topic or disease, because that item is not yet included in a controlled vocabulary. This technique is also useful for a sensitive search approach, or when looking for very recent articles.

***Practical tip**: write down all your choices, selections and experiences during the use of your search strategies, including those which have not worked. In some cases, this information might be requested by a journal before your paper is accepted.*

Phase 3: Appraise the quality of evidence
The third phase of your systematic literature search involves critical appraisal of the evidence reported in the retrieved studies. The quality of evidence reflects the extent to which you can be confident that an estimate of the effect is correct. A large number of approaches are available to appraise the quality of medical evidence. The most common, sensible and transparent approach to grade the quality of evidence has been developed by the GRADE working group. Over 60 major healthcare organisations and publishers use GRADE as a standard when reporting evidence.

The research design is the determining factor of quality: RCTs rank high in the hierarchy of evidence, whereas observational studies rank low.

Factors that lower the quality of evidence are:

- methodological limitations
- inconsistency of the results
- indirectness of the evidence
- imprecision of the results
- publication bias.

Factors that contribute to a higher quality of evidence are:

- large effect size. For example: Compliance with hand hygiene by the proper use of alcohol-based hand rubs can reduce the nosocomial infection rate by as much as 40%.
- evidence of the dose-response gradient. For example: the risk of lung cancer increases with the number of cigarettes smoked per day.

Overview of the key databases and relevant websites for an electronic literature search. All databases have an 'awareness service' that can alert you when new articles are published in your field of study.

Name	**Description**
Medline/PubMed http://www.ncbi.nlm.nih.gov/pubmed/	A service of the US National Library of Medicine that includes journals in the Medline database as well as biomedical articles from other life-science journals. It also includes PreMedline, which references to articles that have been published but are not yet included in the full version of Medline. This is one of the most up to date biomedical databases available
the Cochrane Library http://www.thecochranelibrary.com	Cochrane reviews represent the highest level of evidence on which to base clinical treatment decisions
Embase www.embase.com	Compared to Medline, EMBASE has a more European bias, and only about one-third of the journals are covered in both databases
Cinahl www.ebscohost.com/cinahl/	Covers nursing and allied health journal articles, books, dissertations and conference proceedings
PsychINFO http://www.apa.org/psycinfo/	Contains journal articles, books, dissertations and theses in core psychology disciplines, behavioral sciences and mental health
Scopus http://www.scopus.com/home.url	Scopus is the largest abstract and citation database of peer-reviewed literature and quality web sources with smart tools to track, analyze and visualize research and ensures broad interdisciplinary coverage
Web of Science http://www.webofknowledge.com	Includes three databases: Science Citation Index, Social Science Citation Index, and Arts and Humanities Citation Index
Open Grey http://www.opengrey.eu	System for Information on Grey Literature in Europe
MeSH http://www.ncbi.nlm.nih.gov/mesh	A detailed taxonomy of keywords developed by the National Library of Medicine

SUMSearch2 http://sumsearch.org/	Real-time meta-searches of high-quality medical websites
TripDatabase http://www.tripdatabase.com/	Medical search engine with emphasis on evidence-based medicine and clinical guidelines and queries, including content from Cochrane and Bandolier
GRADE http://www.gradeworkinggroup.org/	Guides users of clinical research information on which studies are likely to be most valid

7. Matching research components

In some ways, doing research is no different from any other household task that needs to be done. For example, when repairing a leaking tap, you should ask yourself “what exactly is the problem?” (research question, or hypothesis), “what instruments do I need?” (method), and “what is the best result that I can achieve?” (publication). A good and realistic match of these components is essential to get the job well done.

Research question
The main intellectual challenge of prehospital research is to define a relevant research question that will add value to the body of knowledge in the prehospital setting. All clinical research, and perhaps even more important prehospital research, starts with a clinically relevant question that has not yet been fully answered. Once you have established that you have posed an original research question and that the issue is relevant, the first step is to conduct a literature search to explore various sources of information. To identify and establish that no similar studies already exist can be a difficult task. On the other hand, the conclusions based on research performed in another prehospital system may not necessarily be applicable to your own prehospital system (Chapter 2). For example: what works in an urban system might have no effect, or may even be harmful, in a rural emergency medical services system. The importance of the answer to a research question is confirmed, when your clinical problem has not been investigated before in a comparable prehospital care system.

Research hypothesis
The next step will generally be the definition of a clear null hypothesis from the research question posed. The core task of science is to create and test hypotheses or assumptions, ultimately leading to the development of a theory that serves to explain and predict. Hypotheses, by their very nature, reflect a point of view. Thus, they remain hypothetical until their validity is tested by experiments. Anything that distorts hypothesis testing is considered to be a form of bias. Because bias can never be completely eliminated, much effort during the preparation of prehospital research goes into detecting, disclosing, and correcting for the biases that are inevitably present when testing the hypothesis. The use of a placebo, randomisation and blinding can help to limit the biases. However, for various ethical reasons, these methodological tools are difficult to manage or to apply in prehospital research (Chapter 9).

Research design
The research design is mainly determined by the topic of research, the research question, and the research hypothesis. First of all, you need to decide whether to undertake qualitative research, or quantitative research, or to apply a mixed-method approach. A mixed-method approach combines qualitative and quantitative research. You need to be aware of the applicability of a particular research methodology. Does the research design match the clinical research question? Sometimes a single-method approach is not always possible. Each research design has its own flaws and limitations, which may have consequences for the methodology used.

Qualitative research

Prehospital research is well suited for qualitative studies based on observations. Qualitative research facilitates the understanding of human experiences and helps to provide more insight into motivation, perceptions and behaviour. This method of research is inductive. This implies that a theory emerges from the data itself, rather than the testing of some theory or hypothesis. Qualitative research generally employs four types of data collection: interviews, observations, document analysis, and analysis of audiovisual material.

Other quantitative studies make use of consensus based on Delphi procedures, or nominal group techniques, or collecting personal experiences during focus studies. To increase the reliability of the research outcome in qualitative studies, several tests are used. This is called triangulation. Qualitative research is a suitable method to answer many innovative research questions.

However, this type of research is still relatively uncommon and most scientific communities, and the majority of journals, prefer a quantitative approach. Therefore, before embarking on qualitative research for the first time, it is strongly advised to talk to researchers who have experience with this type of research and who understand the challenges and pitfalls, as well as the investment of time required to perform qualitative studies and get them published.

Quantitative research

Quantitative research facilitates the understanding of relationships. This classical method of research is used when variables can be measured and relationships between the variables can be examined objectively. Quantitative research studies can have either an experimental or non-experimental design.

During experimental studies, the researcher manipulates the independent variable. for example, by the introduction of an intervention, and measures the effect on the dependent variable. The lack of absolute control over all events and characteristics can obscure or magnify any difference noted after the intervention. For this reason, most experimental studies are very difficult, and some impossible, to perform in the prehospital setting.

Prehospital research lends itself better to non-experimental studies. However, most events that are investigated in the prehospital setting are sporadic, beyond control, and unpredictable. In a non-experimental design, events are monitored and analysed without an attempt to manipulate or alter the outcome. Non-experimental studies cannot define cause-and-effect relationships. For non-experimental studies, several designs are available:

- A cross-sectional non-experimental design measures all variables during a narrow time window and provides data on the prevalence of an outcome or other variables within a population. Such research provides a picture of the current status of a problem.
- A longitudinal non-experimental design follows a group of subjects over time. This type of study is better suited to determine a cause-effect relationship.
- Case-control studies identify subjects based on the presence or absence of an outcome and then, in retrospect, try to determine what differences might account for the occurrence of this outcome.
- Cohort studies identify subjects and then expose them to a treatment.

Non-experimental studies are important in the cycle of research: the problem, or the current status of a research topic, has to be defined before changes can be proposed and the effects of changes can be studied. Non-experimental designs are useful to generate and refine questions, rather than solving problems.

Some examples of quantitative research:

Randomised controlled trial (RCT)
You want to investigate whether, in patients with acute coronary syndrome in the prehospital phase, 6 liters of oxygen per minute via a concentration mask or titrated oxygen therapy to achieve an oxygen saturation of 93-96% makes a difference in outcome. For this study, you have to define how, and how many, patients will be randomised to each of the study arms, what outcome parameters will be studied, and at what time intervals.

See also: Ranchord AM, et al. High-concentration versus titrated oxygen therapy in ST-elevation myocardial infarction: a pilot randomized controlled trial. American Heart Journal 2012;163:168-75.

Cohort study
You are interested in determining the frequency and characteristics of prehospital deaths compared with hospital deaths in a subpopulation with a severe injury. For this, you can choose a population-based cohort study using person-based linkage of a nationwide hospital discharge register with death certificate data. The subpopulation prehospital deaths can be identified from autopsied out-of-hospital deaths with injury as the underlying cause. In addition, the parameters of the study need to be defined, for instance, the injury severity score. The different cohorts can then be compared.

See also: Gedeborg et al. Prehospital injury deaths. Strengthening the case for prevention: nationwide cohort study. Journal of Trauma and Acute Care Surgery 2012; 72:756-72.

Cross-sectional study
You would like to identify actions that might improve pain management in a pre-hospital setting. For this study you could choose to investigate how pain was assessed and managed in all pre-hospital acute myocardial infarctions during a defined period of time. Outcomes are pain assessment, improvement in pain scores, and administration of analgesics. The study can demonstrate limitations in the assessment and treatment of pain, and also whether the assessment of pain was associated with more effective treatment.

See also: Siriwardena et al. Exploratory cross-sectional study of factors associated with pre-hospital management of pain. Journal of Evaluation in Clinical Practice 2010;16:1269-75.

Case-control study
You are interested in assessing the effect of early prehospital implementation of moderate hypothermia on neurologic outcome in patients recovering from cardiac arrest. The control group is a number of patients in cardiorespiratory arrest who were resuscitated in your EMS system before a prehospital hypothermia protocol was established. The second study group includes the same patients after the induction of hypothermia. Neurologic outcome, using well-defined parameters, can then be compared between the two groups.

See also: Torres et al. Prehospital induction of moderate hypothermia after cardiac resuscitation can increase survival without neurological impairment. Emergencias 2012;24:7-12.

Retrospective and prospective studies
Quantitative research designs can be either retrospective or prospective. A retrospective design allows to further refine a research question, to understand which data are available and needed, and to provide preliminary data regarding the research question and the hypothesis. A prospective experimental design is best used for mature research questions and hypotheses.

Outcome
When the objective of the prehospital research includes outcome parameters, you have to select one or more of the 6-D outcome parameters. Several validated outcome scales are available for each of the outcome parameters.

- Death or survival. A definition of the endpoints for death or survival has to be established: arrival in the hospital, discharge from the emergency room, discharge from the hospital after one year. Note that the mortality in your study has to be directly attributable to the initial condition.
- Disease. This is the deterioration of impaired physiology by objectively measured signs of altered physiology.
- Disability. This is a change in the functional status of the patient in terms of the ability to live independently and the daily quality of life at home, at work, or during leisure.
- Discomfort. This expresses uncomfortable symptoms such as pain, nausea, vertigo, or shortness of breath.
- Dissatisfaction or satisfaction. This expresses whether the expectations of the patients, or their families, are met.
- Destitution. This measures the financial consequences of health care for the patient and society.

Some terms used in this chapter:

Null hypothesis is defined to conclude that there is no relationship between two measured phenomena. If the null hypothesis is rejected, it can be assumed that there is a relationship between the two phenomena, which should stimulate further studies.

Blinding and bias: Blinding is important to prevent the researcher, or the study participants, being influenced by the observations during the test. In a blinded test, the outcome of the test only becomes available when the study has been completed. Thus, blinding aims to prevent bias related to the researcher, or study participants.

Prevalance is the percentage of persons with a well-defined condition within a total population.

8. Chapter 8
Prepared for the statistician

To find the most appropriate methodology for your study, you should consult a statistician in the early preparation phase of your research. This will help you make the right methodological decisions. However, remember that statisticians have a different type of expertise than clinicians. Therefore, before consulting a statistician, you should compile a total package of all aspects of the research to allow the statistician to fully appreciate and understand all your questions. During this consultation, fatal flaws or mistakes are often identified in the statistical procedures, data collection methods and the study methodology. Only after all the statistical issues have been addressed and resolved can the research be started.

Describe the clinical problem

It is best to clearly describe the clinical problem and provide some relevant articles selected from your literature search. Describe the aim of the research and make clear which part of the aims have not been investigated before, at least according to your understanding of the literature.

Data collection

It is important that the statistician knows, in measureable terms and variables, exactly what you want to describe, measure or compare. Different types of measurements are available that can be used in research.

Categorical data

These data are generated when each measurement can only belong to one of a number of distinct categories of the variable.

- Nominal measurement relates to categories that can be named and assigned a simple numerical code. For example: gender or nationality.
- Ordinal measurements allow sorting of the data based on a ranking system. For example: the Likert scale. The numbers of the Likert scale (for example: 0, 1, 2, 3, 4, 5) do not quantify the differences between the categories.

Continuous data

These data are derived when the variable takes a numerical value.

- Interval data is measured along a scale in which each position is equidistant from one another. The zero is arbitrarily chosen. For example: temperature in ^{o}C.
- In ratio measurement there is always an absolute zero and measurement varies continuously without intervals. For example: the weight or height of a patient.

Each type of data has its advantages and disadvantages concerning measurability and feasibility. Each type is also linked to specific statistical methods.

Data can be derived from existing registries or collected by means of previously used and validated questionnaires. In some situations, the measurement instruments have to be developed and validated. Whatever the case, it is important to perform a pilot study to test the availability and reliability of data, taken from existing or new registries.

You should also provide the statistician with a definition of all the variables you plan to measure, as well as the method of data coding and data input. Because data input generates at least 1% of changes to that data, double input of data by two independent persons is recommended.

When measurements have to be made, have a realistic plan regarding who will perform the measurements, at what time points, and with which instruments. In some situations, different persons may perform the measurements. Standardisation of the measurements and adequate training of the persons making the measurements are essential, otherwise inter-observer variability can decrease the accuracy and reliability of the data and jeopardise the results.

Although all these procedures are time consuming, they are essential to have your manuscript accepted and published in a renowned peer-reviewed journal.

Type of statistics

Based on the type of measurements, the type of statistics that best suit your study should also be defined.

- Descriptive statistics are used to describe data by means of frequency, average and median. Descriptive statistics describe single variables.
- Inferential statistics help to explore relationships between variables. The type of measurement, the type of relationship and the distribution of the data will dictate the choice of the statistical test.
    - Normally distributed data are used for parametric tests.
    - Not-normally distributed data are used for non-parametric tests.

The use of predictive value, risk reduction, numbers needed to treat, numbers needed to harm, or a Kaplan-Meier survival plot make the statistics more clinically applicable.

Sample size

The statistician should help to define the sample size required, by calculating the power of a study. The power of study is the probability that it will detect a statistically significant difference. If the expected difference of an intervention is a 100% effect compared with a 0% effect without that intervention, a very small study would be sufficient. In most studies, however, the expected difference is much smaller and a small study would be unlikely to have sufficient power to produce a result with statistical significance.

Estimation of the potential effect of the intervention is complex: even small changes in the estimated effect may have a significant impact on the sample size. When possible, previously published data are used to estimate the effect. The advice of a statistician is essential when dealing with this problem.

There is also an ethical aspect related to the calculation of a sample size: if a too small number is calculated, the research will never reach its goal. If a too large number is calculated, too many patients will be studied with related potential risks, and/or there is a waste of time and money.

Statistical significance and clinical relevance

What also needs to be discussed with the statistician is the relationship between statistical significance and clinical relevance, and to define what is a clinically relevant outcome. Significance testing is based on the assumption that we can never be 100% certain of our findings. The significance level describes how certain we are about what the data is telling us.

If a study is too small, the results are unlikely to be statistically significant even if the intervention actually works. Conversely, a large study may find a statistically significant difference that is too small to have any clinical relevance. A well-known example is the effect of steroids on spinal injury. Although a statistical difference was found between the groups, the clinical relevance of the better outcome was futile. The issues of both statistical significance and clinical relevance have to be discussed in advance with the research supervisor and other relevant authorities in this field.

Other issues

Additional issues to discuss with the statistician are potential ethical problems, financial aspects, the time frame, and co-authorship. Before submitting an application for funding, the costs of statistical advice and statistical analysis have to be discussed and estimated. If no funding is available, the costs of a statistical consultation may lead to the conclusion that the research cannot be started.

Make clear arrangements about the time frame for data collection and statistical analyses, as well as establishing who will write the final paper for publication. Agree on the order of authorship, including the ranking of the statistician. Some institutes include the statistician as co-author, whereas others refer to the statistician in the Acknowledgements section of the manuscript.

Some terms used in this chapter

Inter-observer variability: indicates the systematic differences between the various observers involved. For example, one physician may consistently score patients at a higher risk level than other physicians.

Parametric and non-parametric tests: When the study item is normally distributed among the population, the parametric method is used. If the distribution is not normally distributed, non-parametric methods are used.

Sample size is the number of measurements required to calculate a significant difference between the study groups.

Validated instrument is a tool that has been tested to confirm that it does measure what it should measure, irrespective of the circumstances. For example: a standardized questionnaire. A validated instrument is considered to be reliable.

Confounding factor is a factor that cannot be separated from other factors being investigated. If confounding factors are present in a study, it is often impossible to draw any conclusion about the individual roles of the factors and the confounding factors.

9. Research funding

In some cases, you may be able to perform a pilot study, or other small prehospital studies, without the need to apply for external funding to support the work. For example, this may be possible for junior investigators associated with departments that can provide access to the necessary resources. However, at some point in your career, you will probably need to seek partial or full funding to carry out research activities.

The process of obtaining external research funding starts with determining a project budget that accurately describes the costs associated with carrying out the research. Then you need to identify potential funding sources and complete the application process. When research funds are obtained, they need to be appropriately managed in accordance with relevant guidelines from your institution, as well as those of the funder.

Determining the research project budget
The first step in the funding process is to determine the budget for your research project. Once the research question, study design and methodology have been clarified, you must carefully consider the potential costs associated with carrying out the project. Categories of costs to consider include salaries, equipment and supplies, various fees, presentations at scientific meetings, and institutional overhead costs.

Salary support
Depending on the scope and type of research, there may be multiple individuals involved in carrying out different parts of the research. Each of these tasks needs to be described, together with an estimate of the amount of time that each will involve. If you have the overall responsibility for the project, you may have to carry out most of the work. A statistician will probably assist with the research design and data analysis, and research assistants may assist with patient enrolment, data collection, data extraction, or other tasks. Generally, the amount of effort required will be expressed as a percentage of the individual's overall work load and salary. Limits are generally imposed by the funding source on the percentage and overall salary costs that research staff can receive.

Equipment and supplies
Some studies may involve specialised equipment and supplies, the costs of which can be included in the research budget. However, some funding sources have restrictions as to what type of equipment and supplies may be included in the funding budget. For example, equipment and supplies used in the routine operation of an ambulance service, but which are also used for a research project, may or may not be allowed in the proposal budget, depending on the guidelines of the individual funding source. Similar restrictions may also apply to computers and other types of office equipment.

Fees
If the research requires access to proprietary datasets with their associated user fees, these may be included in the research proposal budget. Some institutions charge a fee for the study protocol to be reviewed by the ethics board. Generally, these fees can be included as a line item in the budget.

Presentation-related costs
Costs associated with the presentation of results at a scientific meeting, and publication of the findings in manuscript form, may also be included in the research proposal budget. These costs may also include travel costs and accommodation for the investigator, and registration fees for the conference. Costs associated with publication may include submission fees at open source journals.

Institutional overhead
Many academic institutions charge overhead costs to the investigators conducting research within the institution. These overhead charges generally go towards the cost of resources shared by many investigators, including facility operational costs, administration and, in some cases, statistical support and other resources. Institutional overhead costs are often calculated as a fixed percentage of the direct charges described above, and may accrue to more than 60% in some institutions. Funding sources may or may not cover institutional overhead costs, or may have a ceiling as to how much overhead costs they will support.

Sources of research funding
Research funding can be obtained from a variety of sources, which differ between countries. Academic institutions often have funds that academic investigators can apply for in order to support their research efforts. Information about these funds can usually be obtained from the centralised research administration or academic affairs office of the institution.
Other sources of funding outside of your own institution fall into three main categories: public funding sources, private philanthropic foundations, and industry.

- Public funding of biomedical research is often coordinated by a national agency or office of the Ministry of Health, but may be coordinated by different agencies according to topic area, and depending on the country or region. Information about these sources of funding is usually available from the websites of the agencies responsible for funding in the investigator's area of interest. In some countries, the national public funding agency for research has specific research agendas. You can check their website to see whether your research idea fits into such an agenda.
- Private philanthropic foundations are typically mission-based organisations that support research and other activities in specific areas. Information about funding from such organisations is usually available through databases on research funding that may be maintained by universities and other research organisations. Also, you may need to search on the Internet to identify relevant funding opportunities.
- Industry funding is another source that investigators may consider. Companies that produce equipment, supplies or pharmaceuticals often look for investigators at external institutions to carry out objective studies on their products. This can be a potential opportunity for funds if you can find companies with products related to your area of research.

Process of application
Although most funding applications will probably ask for similar information about the research aims, methodology and budget, each application is unique. Some funding sources may want information that others do not, or information may need to be presented in different ways. Make sure to carefully review each funding application and understand what information needs to be included and how it should be presented.

Practical tip: *Paying careful attention to these details will increase the chance of receiving a favourable review.*

Reusing elements from prior funding applications may be an efficient strategy when submitting multiple applications. However, care should be taken to modify sections as required, so that they are relevant to each application.

Particular attention should be paid to the budget to ensure that it matches the scope of the work described in the methodology of the research. In other words, if you are projecting that it will take 9 months to carry out and complete the research, then the budget should reflect 9 months of costs and not more than this. That being said, the estimates for the amount of time necessary to carry out the work should be realistic and allow for adequate time to carry out the work. Make sure that all costs included in the budget are allowed by the funding agency and that individual line items do not exceed allowable levels or violate any other restrictions.

Depending on the size and scope of the project, you may need to apply for multiple funding sources. If this is the case, it is important to indicate in the application that you are applying for partial funding and that other funding sources will also be sought. Anticipate that you may be asked to include the entire project budget in addition to the partial budget that you are applying for.

Before finalising the budget for the project, it has to be reviewed by the senior research supervisor and by the other individuals who will receive funding for work carried out within your project. Ensure that they are all in agreement with the description of the scope of work and the budget allocation for that work.

Funding sources may require that funding recipients be affiliated to an academic organisation and that the funding be received and managed by the research grants management office within the institution. If this is the case, you need to have the grant application reviewed by the research grants management office prior to submission. The grants management office will probably also be able to help you develop your budget and ensure that it is correct and appropriate.

Exceeding the funding limits
If the project budget exceeds the limit of what a particular funding agency will provide, several options are available on how to proceed. You can consider scaling back the scope of the project in order to reduce costs. For example, carry out a pilot study that can then be used as the basis for a larger research project. You can also consider additional funding sources, each of which might provide partial funding.

However, funding agencies may require that the project be fully funded as a condition for releasing their partial funding. If the aim of the research involves testing new equipment or a novel application of existing equipment, the equipment manufacturer may partially or fully cover the cost of the equipment and other related costs.

Managing research funding

Once a grant has been awarded, it is important to review the terms of the funding to understand the expectations of the funding agency regarding the management of the funds.

This includes the frequency and content of progress reports, the timing of the disbursements of funds, and the way in which the funding organisation should be acknowledged in subsequent publications resulting from the work.

If the grant is being managed by the grant management office at the investigator's institution, they will be able to help coordinate these issues. However, if you are managing the grant yourself, you will need to pay careful attention these details. This is especially important if any modifications are made to the research protocol, or if any other adaptations in the project change the way that the grant funding is being allocated.

For example: amounts of money being allocated to salary versus equipment and supplies. Any modifications will most likely need to be communicated to and discussed with the funding organisation.

10. Tips and tricks

Research in the pre-hospital domain is difficult and a thorough preparation is a key factor for success, as is described in the previous chapters.

Preparation also includes reflection on your own motivation to do research, understanding the research environment, and organising a supportive research environment. The preparation process can easily take 6 months or longer. But this can be fun and exciting, something like preparing for a long and demanding journey.
In traditional research some construction errors are usually quickly detected and can be repaired while a study is in progress. However, this is not possible in pre-hospital research because such research takes place in a more dynamic and complex setting. It often takes a considerable period of time before a fatal error in the research design is detected.

Understanding motivation and consequences
It is important to define your motivation to do research and reflect on the consequences beforehand. People are motivated to do research for many reasons, including reasons such as following a family tradition, curiosity, ambition, compensation for earlier frustrations, as a compulsory task in an educational program, or as a career target ("publish or perish").

Each of these motivations will have a different effect on your perception of doing the research. For example: If you start research merely out of curiosity, you have to accept the fact that you are indulging yourself in a project that has no clearly defined end. To prevent this from happening, you may decide to redefine your motivation so that you have better control over your research activities and research time.
If you are faced with a compulsory research task as part of your education during a defined period of time, then you need to plan your topic within a strict timeline. However, you may decide to request for an extension of the time allowed for this task, to allow you to develop a more substantial research plan.

After questioning yourself about your real motivations, the answers can help you to understand the demands the research will make on your time, finances, leisure activities, as hobbies and sports, and relationships with family and friends. Research is a very time-consuming activity. Understanding your motivation will also help you become aware of the amount of time you are prepared to devote to the total process between preparation and the publication of your results, and to discuss this with the people you are close to. It also helps to determine how you will cope with the frustrations or delays in your planning. Proper management of the balance between research activities, other obligations and private life, will help you to enjoy doing research.

The supervisor
As early as possible, you should obtain the support of a supervisor who has sufficient expertise, and who has enough time left to supervise research in the pre-hospital domain. Unfortunately, even experienced researchers may have no understanding of the complex, dynamic and assertive environment in which your prehospital research has to be carried out. Although traditional researchers will generally promote intervention trials, testing of a null hypothesis, randomised controlled trials or

outcome studies, even experienced researchers and prestigious international research groups have often failed in doing this in the prehospital setting. It is very helpful to consult experienced researchers, as well as various professionals who have extensive practical understanding of the prehospital setting.

Activity log

From the moment that you decide to start working on a study, you should make regular notes about all your communications, and archive all formal and informal communications. This is important for later reporting and also to support the reproducibility of your study.

The research topic

Especially in prehospital research, you may look for a topic in an unexplored area or you may fit your study within on-going research activities. This choice will mainly depend on your motivation and personal objectives. If you are planning a research-oriented career, it is better to try and move in uncharted territory, or “walk on untouched snow”. In prehospital research, many areas still need to be explored. On the other hand, if you need to comply with your educational demands, it is much easier to fit your study within on-going research.

You also need to understand why you want to investigate a particular topic. Very often you need a cascade of “why” questions or “what do I really want to know” questions before you really understand why the preferred research area, or research topic, makes sense as a study objective. During this process you may come to the conclusion that it is better to change or re-focus the study area, topic or question (Chapter 6).

The research question

As emphasised in this booklet, defining the research question is probably the most critical part of your preparations. A well-defined and simple question is more likely to provide a well-defined and clear answer. Many studies have failed because, at the beginning of the study, the questions were too complicated or the wrong questions were asked.

The study question may be reformulated many times. An effective question is the basis of your study and should provide you with a clear and relevant answer. When the study question is being reformulated, always ask yourself the ”so what?” question. In other words, would anyone be interested in knowing the answer, would any editor be willing to publish a paper on this item, or would anyone take the time to read the final publication. What is the added value of the answer to the current body of knowledge? In your quest for the perfect study question you will discover that it is helpful to also discuss all this outside your immediate study environment, for example with friends, family, and during sports or social activities. Most non-researchers will be open-minded and may offer helpful remarks and suggestions that will help to refine your study question.

The time spent on defining the study question is not lost time. A good study question will allow you to precisely define, and limit, the amount of data that you need to collect to answer your question. This makes data collection easier, faster and more reliable. Less data also means less work and time spent on analysing and reporting (Chapters 6 and 7).

From an initial question to a research question:

One day a student came to me and said he was fascinated by the gum-elastic bougie. This is an endotracheal tube introducer that he saw being used during a difficult intubation by a helicopter team.
For his study period, his plan was to investigate whether this device indeed facilitated difficult prehospital intubation. My immediate answer was that the device is used in 2-5% of the prehospital intubations and that in 80-90% of these cases in which it was impossible without the device, it was possible to intubate using the bougie.
I also asked him the 'so what?' question: Why would anyone be interested in this, speculative, answer. After a number of sessions, the two study questions became:

Is the rate of difficult intubations for an experienced anaesthesiologist in the prehospital setting higher compared to that in an in-hospital setting, and, In the case of a difficult intubation does the anaesthesiologist follow the same difficult airway procedures outside the hospital as inside the hospital?

The results of the study could have practical value for new members of the helicopter team and the out-of-hospital difficult airway protocol.

Involve the pre-hospital study environment
After you have found a supervisor, examined the literature and defined the study question, you need to get the study environment involved. Again, although this is a time-consuming activity, it is a rewarding period in which you gain a better understanding of the practical applicability of your study aims.
Many practical problems will arise during these contacts which, generally, can be solved with a creative approach. Sometimes you need to redefine the study question or change your study instruments, timing and finances. These types of solutions will help you to finalise the study.

Try and talk to different people at all levels, including nurses, physicians, laboratory staff, receptionists, as well representatives of all other parties that can be involved with, connected to or even represent potential barriers to your study. These parties sometimes include all levels of management and the trade union representatives. For some studies it may be worthwhile to contact patients in your field of interest. Be very communicative and ask for feedback about the study issue, the study question, the study method and the study embedding. It may be helpful to give one or more presentations to the persons most directly involved in or affected by the study.

These contacts will not only help you, and them, to understand the complexity of a simple question, but will also help to establish important relationships in your study domain. These contacts will help you understand the structure and culture of your study environment and the feasibility of the proposed study design. At this stage it may happen that you realise that you need some clearer definitions of some, or all, elements in your study to ensure that everyone involved is speaking the same language. In this phase you may decide that some incentives are needed, for example free ice-cream after the inclusion of each 20th patient. Or that ongoing PR

campaign is needed, including newsletters, on-site posters, or tweets to keep everyone aware and updated about your study.

Pre-mortem analysis

At a certain moment, probably several months later that expected, you may feel that you are well prepared. Your study question is clear-cut, your study instruments have been tested and validated, you are an expert on the current literature, and you have become good friends with many persons in the study environment. Although this has taken considerable time, you have learned a lot and feel confident that you can start your journey in a well-prepared way. However, one thing still needs to be done.

This is the pre-mortem analysis. In a pre-mortem analysis you envisage the scenario that your study has failed completely and you try to analyse the reasons for this disastrous result. You should try and do a pre-mortem analysis together with several other people. By taking time to discuss this negative outcome, you begin to understand where the weak points of your study may still be: have you been too optimistic about the number of patients to be included; which expectations have not been tested; and which previously defined problems have not been addressed? Although the pre-mortem analysis will take some extra time, you will be even better prepared when entering the pre-hospital domain.

Performing the study

Based on this extensive preparation, you will find that you are able to deal with most of the obstacles during the study, that your are able to collect sufficient good-quality data, that you will be able to stay focused when other side issues appear, and that you have adequate support from your study environment. Also, you realise that it might have been disastrous if you had started your study just a few weeks after formulating your initial idea for research.

Writing your article

Many books, CD-ROMs and internet sides are available to help you to write a paper. Writing a manuscript is a step-by-step process that follows a different order than when you are reading a manuscript.

For pre-hospital studies a clear description of the setting, as well as the methods and materials used, is very important. The study setting should allow readers from other settings to understand the characteristics of your prehospital environment in a concise and clear manner.

The methods and materials should describe how you have finally organised your study. Although you may have changed the original design of your study many times, you should not describe all the failures, changes and frustrations in your paper, but only report the ultimate route of success.

When the sections describing the study setting, as well as the methods and materials used are completed, you can start with the results, tables and figures. However, before putting anything on paper, it is important to carefully analyse all the data and arrive at a preliminary overall conclusion about the answers that these data will provide.

Also, explore whether other messages are concealed in the data and whether these messages are relevant for the conclusion of your study. If not, you should not focus on this. In your enthusiasm, you may run the risk of making suggestions about what

your study may imply in the unexplored area of prehospital study ("What else can we do now that we know this?"). Such a discussion distracts from the focus of your manuscript and should be avoided. The support of your supervisor and study environment is essential at this moment.

Always check the most recent literature when your are writing the discussion section.
Only when the discussion is finished you can write the introduction and abstract.
At some time during the writing process, you may considering writing two separate papers based on the collected data. Generally, this is not recommended. The process of your first publication usually takes so much time that you may have no more time, or interest, in the second publication Alternatively, another group may have published on the same topic, or your interest is now focused on a next-level study. In such a dilemma it helps to focus on your initial study question and related data.

Time efficacy

The approach of undertaking extensive preparations before starting each phase of your study may seem laborious and time consuming. This approach will, however, help to prevent you from starting a study that might fail and will also allow you to step away from the study without any serious consequences. On the other hand, when walking this path, you will see that it is in fact a very pleasant and easy-going way to prepare yourself while other business continues as usual. This approach will almost guarantee that your research will receive funding and that the results will be published in due time (Figure 3).

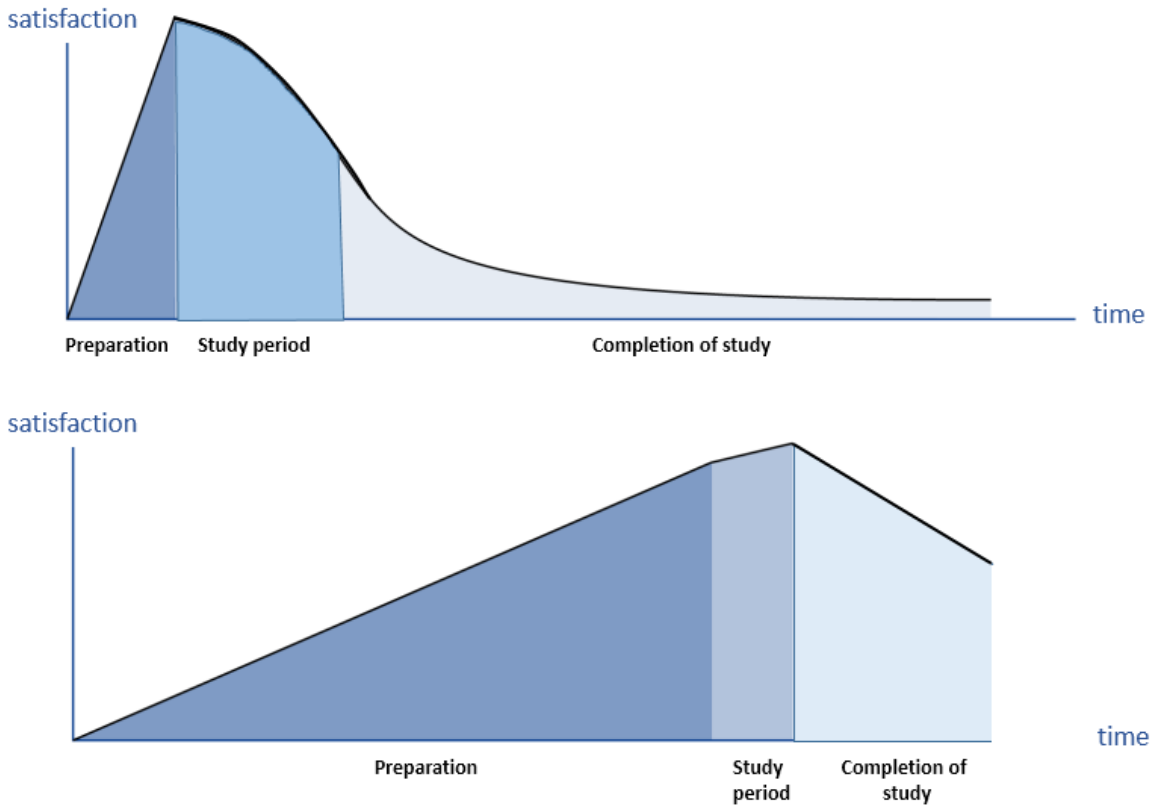

Figure 3: Schematic presentation of time commitment and results based on the usual way of starting a study with limited preparation and after extensive preparations, as mentioned in this chapter. Note that, although the total time spent is identical, the satisfaction of conducting research remains higher when the preparations are sufficiently deep and extensive.

Practical tip: *A definition of the basic message of your data helps you to define an elevator pitch: You summarise the aim of your study, the results and conclusion, in a concise form that you can relate during one minute, as though you are explaining all this to a fellow passenger in an elevator. This elevator pitch helps you to focus on a precise report of the data analysis and discussion sections.*

Mistakes and pitfalls

During preparation of the study

- not being fully aware of why you want to do this study
- not a good study issue
- not a good study question
- no knowledge of the recent literature
- no good embedding in the local environment

These mistakes and pitfalls generally result in unclear, irrelevant and unembedded questions

During organisation of the study

- no feedback and lack of flexible problem-solving
- no involvement of the environment
- no records of the on-going organisation
- no minutes of the meetings

These mistakes and pitfalls result in a non-relevant study that starts without adequate information, consensus, structure and support

During writing the study paper

- start writing before the data analysis
- write as you read
- aiming for two or more publications from one study
- no focus on the results and adding extra ideas and associations
- plan insufficient time for writing

These mistakes and pitfalls result in a non-focused study without a clear story line

11. Roadmap for prehospital research

A roadmap of your research project, and a well-considered time frame, will help you to anticipate, plan and prioritise your activities.

A roadmap for prehospital research has 4 major phases:

- orientation: you are willing and able to do a relevant study on a subject that has captured your interest
- preparation: you define and elaborate on all the components of the study
- operationalization: you perform the study
- reporting: you write the manuscript and prepare it for publication

During each of these phases several activities will need your attention. Some activities only need doing once, but most need intermittent or regular attention during the course of the study project. Often a feed-back circle arises. For example: after a literature search you may realise that you need to redefine the initial research question, which you probably had considered to be original and indispensable.
All these activities are discussed in the chapters of this booklet.

These activities include:

- defining the study question (Chapters 3, 5, 7, 10)
- literature search (Chapter 6)
- contact with the pre-hospital system (Chapters 2, 3, 7, 10)
- introspection (Chapter 3, 10)
- finances, funding and budgets (Chapter 9)
- data collection (Chapters 2, 3, 10)
- statistician (Chapter 8)
- ethical considerations (Chapter 4)
- research proposal (Chapters 2, 4, 5, 6, 7)
- pre-mortem analysis (Chapter 10)
- publication (Chapters 2, 10)
- supervisor (Chapter 10)

Figure 4 presents an example of a roadmap for a prehospital study.

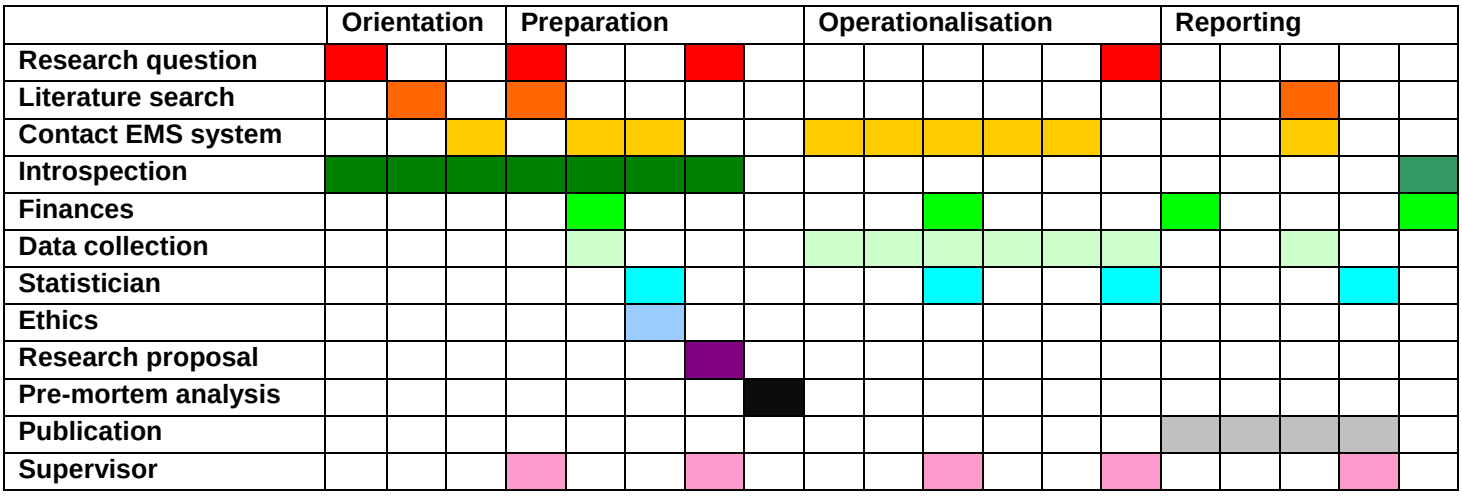

Figure 4: An example of a roadmap for prehospital research

The amount of time needed for each activity needs to be realistically anticipated by the researcher based on logical and realistic assumptions. Also taking into account the time needed for other activities, such as examinations and/or holidays.

In this example of a prehospital study, during the **orientation phase** you decided on a preliminary research question, area or topic. Some relevant literature is studied for orientation purposes (a narrative literature search) and the issue is informally discussed with people who are familiar with the EMS system. Then you decide whether the study topic really is worthwhile and feasible, and whether starting the study can fit within your personal situation.

During the **preparation phase**, you find a supervisor as soon as possible. Based on a more extensive systematic literature search, and a better understanding of the EMS system, you formulate a research question or hypothesis (PICO or PECOD). The study question is the basis for the identification and preparation of data sources and measurement instruments. Then, the outcome parameters and study design are selected. The preparation phase is the period in which you communicate with people in your study environment about the relevance of the study, its practical aspects, and the generalisation of the study outcome.

A statistician is consulted, financial arrangements and budgeting are completed, and the ethical issues have been inventoried. All activities in this phase are logged. In the light of the new information and deeper understanding of the pre-hospital environment, it often happens that the study question, data sources, measurement instruments, and study design may have to be adapted. Sometimes, the research question itself has to be reformulated. At this stage you may even decide that you do not want to do research.

The preparation phase ends with the writing of the research proposal.

The **operationalization phase** starts after the pre-mortem analysis: this is a final test analysis to ensure that all the pitfalls, limitations and methodological imperfections have been identified and worked through. Data are collected, and you keep good contact with colleagues in the pre-hospital domain to monitor any flaws or deviations from the study protocol. You maintain regular contact with your supervisor and the statistician. You also make sure that you stay within the allocated budget.

During the **writing phase**, you define the basic message of the manuscript (the elevator pitch). Always take into account the most recently published literature, the advice of colleagues working in the prehospital area, and of your statistician and supervisor. After you have submitted your manuscript, make a final financial overview of the study costs and inform, as required, the organisations that have supported the research, either financially, with equipment or materials.
You can also reflect on the entire project and consider the possibility of the next step forward as a researcher in prehospital care.

12. Falck Foundation

The Falck Foundation is a non-profit entity established under Belgian Law, financially supported by the international emergency medicine company Falck, but operating independently from the Falck company. The Falck Foundation was established in 2008 by the Falck Group with the objective to promote scientific research and education in the field of prehospital care delivery.

The Foundation fulfils its objective by supporting scientific study and education, and by giving incentives for researchers to publish abstracts at renowned emergency medicine conferences.

Support is given in the form of grants for research projects and as the Sophus Falck Abstract Award. The latter is awarded at the International Conference on Emergency Medicine (ICEM) and the Foundation also presents the award at the annual European Society Emergency Medicine Conference (EUSEM). At most of these conferences, the members of the medical advisory board organise interactive sessions on how to set-up research on prehospital emergency medical care.

Organisation
The activities of the Falck Foundation are carried out by the Medical Advisory Board. The members of the Board are internationally renowned scientists and professors in emergency medicine.

The Medical Advisory Board of the Falck Foundation consists of Prof. Phillip Anderson (Boston, USA), Prof. Marc Sabbe (Leuven, Belgium), Dr. Joost Bierens (Vught, the Netherlands), Prof. Maaret Castrén (Helsinki, Finland), Prof. Venkataraman Anantharaman (Singapore), Dr. Jana Šeblová (Prague, Czech Republic) and Dr. Jan Christiaen (Antwerp, Belgium). Falck's chief of health care policy as well as the research director of the Lundbeck Foundation participates in the meetings ad hoc.
The governing board of the Falck Foundation is the General Council, which consists of the Anders Larsen (Falck Emergency Europe), Ole Qvist Pedersen (Group Public Affairs), and Dr. Jan Christiaen, director of Falck Ambuce (Belgium) and initiator of the Falck Foundation.
The Falck Foundation is supported by a professional team that organises the meetings, as well as the administration of applications and grants, the website and travel arrangements, and also controls the budget. Rune Andersen from Falck is in charge of this secretariat.

Study grants and support
Applications for study grants follow the Falck Foundation guidelines and application schemes. These are available on the Foundation's website Evaluation of each application is based on a rating system that requires an objective score in order to be awarded the requested grant. If approved, the Medical Advisory Board will support the grant, together with proposals for improving the study project. Projects that are not approved receive feedback to improve the application should the applicant wish to re-submit at a later date.

Recommendations for grants are finally approved by the General Council, which is responsible for the overall budget.
After a grant has been approved, the investigators are requested to make regular reports to the Medical Advisory Board.

The Sophus Falck Abstract Award
The Sophus Falck Abstract Award is handed out at the congresses of the International Conference on Emergency Medicine (ICEM) and the Mediterranean Emergency Medicine Congress (MEMC). Both are biannual congresses and one of these meetings takes place each year. It is awarded to the best abstract entered in the category Emergency Prehospital Care. In addition to the prize money, the winners also receive a Sophus Falck Award statuette, especially designed by the Danish artist Lene Steffensen.

Figure 5: The Abstract Award, designed by Lene Steffensen

This booklet, as well as more information about the Falck Foundation can be found on the website www.falckfoundation.com

13. Further reading

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Notes during the Falck Foundation Prehospital Workshop

Notes during the Falck Foundation Prehospital Workshop