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## **EDUCATION**

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### **Reflections in the research pool – a paramedic experience in clinical research and the Master of Emergency Health degree**

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While clinical research has become a vital component in developing the paramedic's professional role, it is an essential element that has not been readily embraced by paramedics or service providers to date. This is demonstrated by the paucity of paramedic clinical research available in peer-reviewed literature compared to other health disciplines such as nursing and medicine. Until very recently, paramedics have relied upon those other disciplines to provide any new learning and support in the development of their own craft, while inadvertently allowing their practice to be influenced by disciplines which do not necessarily have a comprehensive understanding of the unique environment within which paramedics operate.

This paper provides a simple guide to clinical research in the prehospital arena and suggests a framework to enable and encourage paramedics to become involved in the future direction and evolution of their clinical practice and professionalism. It is also a reflection of the authors' personal experiences as the first two Mobile Intensive Care Ambulance (MICA) Paramedics in Victoria, to complete the Monash University Master of Emergency Health degree in 2008.

The Masters program provides a very workable platform from which to engage in postgraduate study through off-campus mode, with strong university staff support and flexibility of study days being the key factors in the program which enable paramedics to progress their study and career paths while working in an Ambulance Service. Students can engage in this course with the knowledge that their efforts will provide a significant qualification while offering both intrinsic and extrinsic opportunities for personal and professional development. The modules within the MEH degree are geared towards personal direction and developmental need, which is a refreshing side-effect of post graduate study. Rather than engaging in study that is task oriented (and often relevance-unknown), the Masters program at Monash provides students with selection components that meet their specific objectives while being flexible enough to allow streaming in business/management, clinical or education fields.

Independently we both opted to select research and education units, followed by a clinical research project unit (to provide an articulation into PhD studies). In retrospect, we both felt that the clinical research unit provided significant value-adding to both the financial and practical aspects of the course as well as allowing us to demonstrate our academic ability to the fullest.

Clinical research provides an enigmatic environment for paramedics through its capacity to provide creative scope and direction for the exploration of concepts and ideas, albeit within the confines of some very strict operating procedures.

The novice researcher enters the field with an idea that has irritated their cerebrum like a grain of sand in an oyster, and is given the time and freedom to develop this pearl within the structure provided by good clinical research principles. These principles are clearly defined within long standing tradition, found in the university faculty handbooks, publications and websites. They provide a framework for the conduct of clinical research. However, the biggest factors affecting individual progression through the research project include time management, logistics, and attention to detail, ensuring compliance with relevant organizational policies, and knowing where to seek the best assistance.

While there is an abundance of quality publications detailing research principles and practice, in addition to those that you will be required to read as essential texts, there are occasional gems to be found in your university library and bookshops. These can provide additional insight and inspiration through their content, and may also convey a more simple understanding of a complex subject to the reader. It is an important first step in the research process to fully understand and explore what it is that you have become involved in. However, be objective when evaluating “recommended” texts and also seek out those that meet your personal needs, as they will provide a more congenial learning experience.

Clinical research is a cyclic process (much like the clinical decision making process), which feeds back into itself in order to perpetuate knowledge. This is best represented in Figure 1 as a framework for conducting study. This provides a structure upon which the many elements of the process can be arrayed, examined and linked to demonstrate completeness and adherence to quality.

**Figure 1: A clinical research framework**

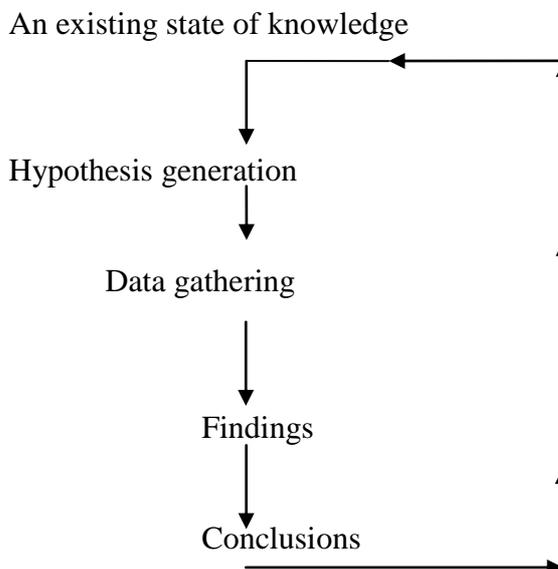


Table 1 provides a three-phase approach to research conduct. The elements constituting each phase represent an approximate order of operations. Even so, multiple elements may be undertaken simultaneously, while some elements rely on completion of others prior to commencement. The importance of displaying the project in the form of a Gantt chart or time line can also help to show the complexity or multiplicity of the project.

**Table 1: The phases of clinical research**

<b>PREPARATION</b>	Define the question Literature review Choose a methodology Draft the protocol Seek funding Ethics submissions
<b>ACTION</b>	Data tools and processes Advertise and recruit participants Data analysis
<b>OUTCOME</b>	Publication strategy Peer reviewed journal article Conference presentation

**The question**

The research question forms the essence of any study and is a carefully distilled synopsis of the “what, who, how and why”. Because it must be necessarily concise, development of the question takes considerable time and involves an original idea being subjected to rigorous examination to find a question that is suitable to study. This part of the process appears simple, yet often produces the most evolution prior to its conclusion as it is a measure of precision. A useful method of refining the question is to use the PICO mnemonic as demonstrated below:<sup>1</sup>

- P** the **P**roblem or **P**atient you plan to study
- I** the **I**ntervention that is of interest
- C** the **C**omparison (treatment or factor)
- O** the **O**utcome that you are seeking to determine

This method helps to formulate the question through specifying each element of the study, and is also useful for identifying the search terms for your literature search.

**The literature review**

It is necessary to examine what is already known about the subject of your research, which a good literature search not only reveals, but also prevents possible replication of previously studied topics. While the task can be a laborious and complicated process of gathering information, which involves reading and sorting many (or few) articles and papers according to relevance and applicability, fortunately, the existence of search engines such as Medline, Ovid, Embase and CINAHL have simplified this process. However, it is equally important to know how each of these databases operate to make sure that you are searching the literature

most effectively. Your university library should be able to provide you with training in these databases, as well as training in bibliographic programs such as EndNote, ProCite or similar. It is crucial to learn how to use the bibliographic programs before you begin researching, as they can save hours of work when it comes to citing and formatting your references. It is also worth considering or developing a search filter such as the Cochrane Prehospital filter which was developed by staff at Monash University DCEHPP to enable streamlined prehospital literature searches.<sup>2</sup> Filters may be customised to narrow or broaden your searches, and can be saved for use on other research projects, or to set up alerts for new literature as it becomes available via the databases with which you set up your alerts.

### **Methodology**

Determining an appropriate methodology for any study requires significant preparation to ensure that quality and capability are measured against one other. It may be necessary to compromise certain aspects of the process to ensure that the study is able to be completed within a timeframe, or that the funding is available to proceed with a more complex agenda. The capability of the researcher and their experience levels are also a factor.

An existing hierarchy of evidence provides a gauge to the novice researcher to attain the best possible results from the study, with the systematic review (or meta-analysis) at the top and anecdotal evidence being the poorest quality.<sup>3</sup> While it is important to ensure that the study is able to demonstrate the highest possible level of relevance amongst your target audience, it is also necessary to consider whether the study will be of a qualitative or quantitative nature.

Simplistically, quantitative studies describe a set of *numerical* data in order to prove or disprove a hypothesis, whereas qualitative studies describe *interpretation* of a situation, or experience.<sup>3,4</sup> Neither is capable of being heralded as a definitively superior study design; rather, each represents the method which is most applicable to the subject that is studied.

### **Determining a protocol**

The protocol document is a synopsis of the entire project, containing all of the relevant details of the study and its logistical structure, including governance and funding. This document is designed to be read and commented on by others who are interested or overseeing the research project. However, it is also a useful tool for self-appraising your own study prior to becoming involved in the complexity of the actual research work.

### **Ethics in research**

Ethics approval within the prehospital emergency care environment is significantly grey due to the variety of situations in which care is provided; yet that same application within a clinical research environment may be rigid and well defined.<sup>3,4</sup> This may sometimes provide a challenge for paramedical researchers in identifying the need for strict adherence to defined ethical principles and conduct. However, it is worth bearing in mind that ethical practice in both clinical and paramedical research exists as a standard to ensure adherence to principles that acknowledge both the rights of the participant and the responsibilities of the researcher in obtaining, handling and utilising personal information.

Confronting the initial stack of papers that constitutes an ethics application is daunting to the uninitiated. At this point it is worth consulting your supervisor, who will be able to guide you and can make the process much less stressful.

It is also important to ensure at this point that your research question is sound, and that your objectives and methods are clear in order to provide the ethics committee with a layperson's plan of your proposed research project. Ethics applications must be simple to read and understand, with translation of research theories and methods conveyed in generic terms. This process is an exercise in working at your own level of understanding, while interpreting information at differing levels for others.

Finally, do be aware that, depending on the type of study and participant group, it may be necessary to gain a number of ethics approvals.

### **Ensuring data confidentiality**

One of the most vital components of any research project is the maintenance of participant confidentiality. This is a legal and ethical requirement which is inflexible, and should not be taken lightly. The data gathered by the researcher may represent a personal means of resolving their question, but its substance is a reflection of the participants' thoughts, their physiology and disease, religious, cultural or physical makeup. As a result, this information may, if revealed, cause harm (real or perceived) to that person, which is why the researcher has a clear obligation to protect the subject from any consequence of their involvement with the study. Each institution has a defined set of policy requirements for the management, storage and security of information, as well as the duration and archival and disposal of that information. It is advisable to obtain this information in the early stages of the research project, and most certainly prior to the collection and recording of data.

### **Developing the appropriate forms**

One of the most important aspects of conducting clinical research is the development of appropriate and concise tools for gathering data, advertising for and attracting participants, while ensuring compliance with the research ethics approvals that have been obtained. Unfortunately, it is quite common for tools which were developed in good faith at the start of the project, to be modified or redeveloped as the project develops. This can occur if they lose their relevance or applicability as the project evolves and/or your understanding of what is required has improved in the process.

There is a vast array of existing data forms and tools available from within the literature, on the Internet, or by seeking the advice of the staff at your university. It is also acceptable and sound practice to contact the author of a study that is relevant to your research, in order to understand why they chose these tools, and to further your own understanding of selecting and applying specific forms or templates to your study. Many authors and researchers are happy to know that others are interested in their work, and are usually open to sharing their experiences of research with novices.

Preparing advertisements for participants is also a governed practice, with specific detail required on each form. This detail can be provided by your university research office as well as forms that relate to consent and information collection.

### **Data collection and analysis**

The collection of pre-data for a clinical study is a vital part of the research process. However, spending hours and effort collecting tainted or irrelevant data is both frustrating and expensive, which is why we offer the following advice to other paramedics (from personal experience) before commencing the process of data collection.

- Utilising paramedics as subjects or participants in a study is not advisable for the novice researcher. This is because there is usually a well documented curiosity as to the endpoints of the research that lead paramedics to sometimes compromise the integrity of the process. They may also inadvertently sway outcome through bias, or carry a latent suspicion of the rationale for participation (an industrial throwback of the politics of ambulance).
- Collecting data from the prehospital environment (patients or paramedic staff) can also present significant challenges to ensure that ethical principles are adhered to. This is mainly because anecdotally, as paramedics by their very nature they are inquisitive and may inadvertently compromise outcomes by seeking to provide a “correct” answer rather than pure data.
- Furthermore, paramedics may be reluctant to participate in clinical research due to suspicions that the outcomes may be used for industrial or political leverage. Therefore the researcher must take great care to reassure the participant that this is not the case.
- Prior to gathering data it is important to consult with a statistician to determine what sample size represents relevance within the study. A variety of texts and short courses exist to provide the novice researcher with a working knowledge of statistics, however, if time is an issue, it is advisable to utilise the services of a statistician.

### **Database management**

It is necessary to have at least a fundamental understanding of some of the software applications that are available to researchers when engaging in this activity. At various points in the process it may be advisable to utilise the skills of others to assist in compiling and disseminating large amounts of data. Some of the programs that will be required are:

- Microsoft or Open Office Word processing programs – for writing reports
- Microsoft or Open Office spreadsheet programs – for the compilation of graphs, charts and presentation of data
- Microsoft or Open Office slide presentation programs – for presentation purposes
- SPSS – statistical analysis program - for the interpretation and representation of data
- EndNote, ProCite or Reference Manager etc. – for those lengthy reference lists

Each of these programs will assist in the task of recording, collating, interpreting and displaying information concisely, and each program is relatively easy to use.

Physical data must be locked in a secure location for the specified time and manner determined by the ethics committee and/or other organisational information management policy requirements. Ongoing information such as data tables can be stored electronically. However, to avoid loss of your critical data, it is highly recommended that you save at least three separate backup sources of the same information on either: USB, CD/DVD, laptop/PC hard drive or other storage medium.

### **Study management**

Without doubt, the research journey is best undertaken with a competent, supportive and relevantly qualified supervisor. In other words, this mentor will need to have specific qualities to assist you in pursuing your goal. They must have the patience of a saint, the expertise to support your needs, the understanding to cope with your doubts, and they must be able to share the passion of your quest in order to obtain the best possible results.

### **Publication strategies**

As the study approaches completion and the research question has been answered, information gathered from the study can then be disseminated to its relevant audience.

Publication and presentation of your findings by peer review are two powerful means of disseminating your research. This type of review is valued among researchers as it provides credibility through the rigour of the review process.

It is worth seeking out a variety of relevant journals in which to publish, as the experience of peer review and understanding of the specific author requirements for each journal is of great value. Keep in mind that the review and publication process can be lengthy, with revisions often being required to meet the expectations of the reviewing journal.

As vast amounts of literature are submitted for publication each year it may be difficult to have your research accepted by some of the more prestigious journals, even after multiple revisions of your work. It is also worth noting that, regardless of the journal's prestige, your research may gain better recognition in a publication that is more specific to your particular field of research.

Conferences also provide the opportunity for a less formal process of peer review as the researcher's capabilities are conveyed to a wider audience of their peers, and often involve travel (nationally or internationally). These experiences can be both personally and professionally rewarding, as they provide networking and development opportunities while enabling participation in awards for presentations.

### **The future of paramedic research**

As paramedic practice is evolving rapidly, the need for paramedics to conduct high quality research has never been more urgent in order to guide the craft and secure its future. At this time, the future is a blank page awaiting those who are willing to make the effort to define what it is, and what could be, through engagement in research activity. Those who perceive the factors of professionalism, employment security and ongoing clinical development within the future of paramedic practice must also acknowledge the place of clinical research in securing that future; industrially, clinically and politically.

### **Useful resources**

#### **Texts:**

- Johnstone M-J. *Effective Writing for Health Professionals*. Allen & Unwin, 2004.
- Hickson M. *Research Handbook for Health Care Professionals*. Blackwell Publishing, 2008.
- DeAngelis C. *An introduction to Clinical Research*. Oxford University Press, 1990.

- Booth WC, Colomb GG, Williams JM. *The Craft of Research*. University of Chicago Press, 2003.
- Anon. *A Guide to Good Research Practice*. Monash University Department of Epidemiology and Preventative Medicine, 2006.

**Websites:**

[www.jephc.com](http://www.jephc.com)

[www.monash.edu.au](http://www.monash.edu.au)

[www.nhmrc.gov.au](http://www.nhmrc.gov.au)

[www.cochranepdhf.org](http://www.cochranepdhf.org)

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4. DeAngelis, C., *An introduction to clinical research*. 1990, Oxford: Oxford university press.