RESEARCH SERIES

Clinical research in emergency medicine: putting it together

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The difficulties in conducting good clinical research in emergency medicine can be overcome. This article will begin by identifying the main difficulties faced by the emergency medicine researcher. It will then discuss some solutions through the development and application of the research protocol. Finally, recommendations will be made with regard to writing for publication.

THE PROBLEMS

The impediments to conducting clinical research in North America have been identified as inadequate training, insufficient time and inadequate funding.[1] This has many similarities with emergency medicine experience in the United Kingdom.

The new researcher in this specialty has to confront problems that arise from their lack of knowledge and experience about research issues. What is a good research question? What is a good research protocol? There is a risk that enthusiasm can obscure reason causing the clinician to become involved in projects that are hopelessly over ambitious. Potential problems pervade the process through to publication. This may be compounded by being unable to judge between good and bad advice.

Academic emergency medicine in the UK has largely been confined to very few centres. Those working in these units will have good opportunities for advice and support for their ideas and to be involved in the development of the projects of others. The majority struggle elsewhere. Within the specialty expert supervision is thin, funding is difficult to acquire, and the academic environment not supportive. There is a paucity of courses and learning materials for research, particularly relating to emergency medicine research issues. Obtaining funding presents particular difficulties to those not familiar with the process.

The emergency medicine environment is highly pressurised, immediate, emotional, and often overburdened. Time for research is therefore at particular risk of interruption, where there is time at all. Ethical issues abound[2] particularly relating to informed consent. Staff rotate making it extremely difficult to see a project through in one setting. There is also the perceived and, in some cases, real need to have research publications as a rite of passage to promotion to clinical posts. The temptation is to go for the quick and dirty study rather than use the project to produce work of higher quality and value and learn from that experience.

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The researcher may need to overcome distraction, deviation, despondency, disinterest, and dishonesty (in a variety of guises) in themselves and in those around them in the course of their research journey toward the truth.

Is it not surprising that consultants and registrars become frustrated, exhausted, and disillusioned and their progress often slow?

SOME SOLUTIONS

> Knowledge is of two kinds. We know a subject ourselves, or we know where we can find the information about it.
>
> Dr Samuel Johnson

Though some contend that research can only be learned through an apprenticeship, written material and courses can add to the knowledge on which experience is built. A bibliography is to be found at the end of this paper that can be accessed directly through most medical libraries or through interlibrary loans. You are also referred to the other papers in this series. Many universities are running masters in science degrees that incorporate supervised research modules. They usually require a half day per week attendance (in term time), and the modules last less than one year. They can usually be undertaken without commitment to the full degree. This offers excellent opportunities to learn and participate in research in a disciplined environment for those not wanting to go on to a research degree or as an introduction for those who do.

The research question

In developing a research project the first issue is the research question. This often comes from critical thinking in clinical practice[3], reading (widely), journal clubs, teaching, and collaboration. Whether the question is a good one can be summed up in the mnemonic FINER[4] meaning feasible, interesting to the investigator, novel, ethical, and relevant.

Whether the question is novel and relevant has to be assessed through a literature search and the question put in context. Does a study need repeating? Is there a new relevant slant? A discussion then with an expert in that particular

Box 1

A well defined question will make a good protocol easier to write, enable focused data collection and manipulation, and facilitate clearer conclusions.

Box 2 Stages in research supervision

- Establish rapport
- Establish current context
- Scope and purpose of present meeting
- Problems, results, etc, discussed
- Decisions needed
- Decisions taken and next task identified
- Evaluation, summary, and disengagement
- Notes on supervision made and filed.

Box 3

A well designed protocol will help with ethical approval, data collection and manipulation, writing and publication.

field will enable a valued judgement to be made. Be wary of those that try to put you off or advise you to do other projects for wrong or poorly thought out reasons.

Research supervision

The point of turning the question into a research protocol is where the novice should seek supervision.[5] This can be critical to the success of a research project. A balance can be struck between the knowledge and experience of the researcher and the complexity of the study required to answer the question when determining the need for a supervisor. A good supervisor may be found in the emergency medicine department but occasionally other specialties including university departments have helpful personnel. The working relationship should be one of mutual benefit, the emergency clinician gains in the quality of their research activity and the supervisor spreads their scope and productivity.

When seeking supervision think widely and consider the important attributes of a good supervisor; an experienced researcher, one who knows their weaknesses and can advise accordingly, has an interest in the subject matter, and can establish a rapport with the researcher.[6] It has been said that good supervisors are usually busy people and so when meeting them it is advisable to have an idea of what you want from the outset. Box 2 summarises an efficient format for meetings.

Apart from help with project design, a good supervisor will have knowledge of other facilities such as statistical advice and local funding opportunities, which can be critical to the successful completion of a study. Negotiating ethical issues may be simplified. In addition the name of a reputable researcher involved in the study can influence funding and cooperation from others. Good supervision not only offers a better chance of success but can make the project a more fruitful learning experience.

It is worth mentioning here the fear that many have for sharing research ideas. There are unscrupulous individuals

Research question(s)	Simple, and clear statement (ideally in one sentence)
Significance of the study	An introduction using evidence to explain why the study needs to be done
Hypothesis	Anticipated outcome of the study
Setting	Setting where research is conducted
Methodological approach	Observational/experimental, prospective/retrospective, etc.
Selection of subjects	
Inclusion criteria	Criteria defining group to be studied
Exclusion criteria	Particular criteria to exclude subjects from the group for study
Sampling/randomisation methods	
Measurement of input and outcome variables	
Materials used	For example, drugs
Procedures used	What/how procedures are to be performed
Data collection	
Who	With their credentials
Tools used	For example, forms, scoring methods
Untoward events	How to manage anticipated difficulties
Statistical issues	
Sample size estimation	
Analytical approach	
Ethical issues	How addressed. Consent forms
Funding issues	
Pilot data	
Time scale	A proposed time sheet

Figure 1 Issues for the research protocol.

Box 4 Examples where pilot studies may help

- Assessing the ease of recruitment or follow up of subjects.
- Assessing issues around taking measurements; accuracy, consistency,
- Practical issues?
  - for example, is the information reliably recorded in the patient case notes?
- Ensuring data record forms are useable, filled in as intended, and legible.
- Survey methods
  - Questionnaire design—legibility, ambiguity, understanding, gaps and validity, refining questions.
  - Interview methods—similar issues around question development
- Where a number of people are conducting the study are they conducting the research in the same way? A dress rehearsal is offered.
- Getting more knowledge about the issues being studied, for example, to assist with estimating the number of cases needed for the study.
- Data management. Having some data to manage will help identify features that could make the final analysis more difficult.

sufficiently driven to poach research any way along the road to completion. They are usually readily identified and avoided. There is much more to be gained from collaboration than isolation in research, however it is important to remain central to the conduct of your project and take responsibility for its progress.

The study protocol

The study protocol will represent the way in which the answers to the question will be sought.[7–9] It is necessary for ethical approval, funding applications, registering the project with the research and development department in the trust, and other formal communications about the study. It is critical therefore to take time and effort to get this right before starting. It is often extremely difficult, sometimes impossible, to rescue a project from a poor protocol (again good supervision can be critical). This enforced discipline is extremely important for the successful completion of the study and will constitute much of the content of any subsequent publications. The prior literature review may help in indicating the methods and techniques that could gainfully be used in your methodology. The key parts to a study protocol are summarised in figure 1.

The challenge will be to find an efficient, effective, ethical, and workable process. It has to be emphasised that statistical issues are better addressed at the planning stage.[10] Another important issue is how the data are collected.[11] There is occasionally a temptation to collect too much data in the hope that they will be useful. Great care needs to be taken as this can lead to a loss of focus in the project and it increases the amount of work needed, which is likely to be fruitless. The researcher also has to be wary of running into problems with multiple hypothesis testing and finding a statistically significant result where a real difference is not present. No more data should be collected than are relevant to the interpretation of the study in the context of the research question. The data collection forms need to be concise, clear, and understood.

Clearly the logistical issues with working through the study have to be addressed before starting. Will there be enough patients recruited in your environment considering dissenters and others lost to follow up (if applicable)? Will you be able to complete the project in the time frame needed? Are there enough people conducting the study who are technically able to obtain measurements? Is there enough money or any other insurmountable reason why the scope of the study may be beyond the local capabilities? Where such difficulties might arise it is important be tenacious in the pursuit of their solutions.

Box 5

Do not leave organisational issues to chance.

As doctors rotate around departments, collaboration with colleagues becomes essential for the completion of the study. It is therefore important to decide on the need for assistance at the stage of protocol development. Collaborators involved early intellectually buy into the design of the project and are later in a better position to satisfy criteria for paper authorship. The overall learning from the study is also enhanced. Nevertheless someone has to lead the project and have the final say on important issues.

So meetings to discuss development and progress are inclusive. As doctors rotate they slot into the data collection part of the study in the relevant institution. Having this overseen by a permanent member of staff clearly smoothes changeovers. Different aspects of the study being performed by different members also reduces the time load. Good teamwork will lighten the load.

Funding

Research funding is a competitive process. Mackway-Jones[12] will discuss this in a later article in the series. A good research question and a good protocol will assist greatly in submitting the relevant information and making the application competitive. The advocacy of a supervisor with an established research record is likely to help. Look also beyond funding organisations to commercial enterprises, charities, research prizes, grants as well as within the trust, which may have monies allocated to support research projects. A good supervisor may offer valuable advice as may a department for research and development.

The role of the pilot study

A pilot study does not answer the research question but can assess the methodology proposed for the full study. It is better to find fault before the full scale study is implemented. A pilot study can also make it easier to write submissions for funding or approval and have them accepted because the probable direction and difficulties of the study are better understood (box 4).

It might be better to assess different aspects of the study through different pilots. With the knowledge gained you are in a better position to consider the optimal technique or process required to carry out the study.

Note that if the results from the pilot are to be incorporated into the larger study there are statistical implications.

Working through the study

Previous stages have required creativity and judgement. This stage demands tenacity, discipline, and honesty. It is quite possible that there will be unforeseen problems with the conduct of the study and these will need to be managed as they develop.

Do not miss opportunities to help the study along. The full knowledge of other members of staff that the study is under way (and for example their assistance in recruiting subjects) can be very useful. Feeding back to staff the results of local research and the demonstration of the benefit of applied results in that setting can help to develop a culture to facilitate research. Be sure to keep your data collection forms in a safe and accessible place, not where they might be thrown out by the cleaner.

WRITING FOR PUBLICATION

General points

At this stage you will appreciate having a tightly defined research question, thought carefully through the research protocol, and gained statistical advice at an early stage. Before sitting down to write though it is worth answering Smith's basic questions[13];

- What do I have to say?
- Is it worth saying?
- What is the right format?
- What is the right audience for the message?
- What is the right journal for the message?

Most scientific papers follow the IMRaD structure[14]; Introduction (what question was asked), Methods (how was it studied), Results (what was found), and Discussion (what do the findings mean). Before writing the paper it is therefore essential to read the instructions to authors published by the journal as there are differences between journals.

Writing the paper will be made easier if the study is founded on a literature review and follows a well worked out protocol. Style is important to author, editor, and reader. The latter wants to be able to understand the article and remember that for some English will not be their first language. They do not want to be irritated by ambiguities or inaccuracies. Brevity is desired by most editors and readers but not at the expense of clarity. Remember that style can influence the likelihood of publication.

Read and re-read your text. After successive drafts the quality of the work is honed closer to perfection. Have others read the paper and give them specific instructions, for example, comment on content, proof reading. This is usually a necessary part of writing. Again beware of bad advice that will deviate the article from your message or your target audience.

The introduction takes us back to the foundation of the study and the first literature review. It should contain a systematically conducted review of the results of previously published studies briefly putting the current study into context.[15] The question asked should be clear and succinct. Readers should be told why this is an important study.

Weakness in the method section is the most common cause for a paper to be rejected.[16] This section should be sufficiently descriptive to enable the suitably qualified reader to accurately repeat the study. Therefore clear descriptions should be made of the key components of the study including the tests and accepted points for significance. How were issues around subject numbers and power determined? How were ethical issues addressed?

The reader wants to understand how close the results come to the truth and estimate the relevance of the results to their own area of work. Gaps in the method section will increase uncertainty thereby reducing the impact of your work.

The results section is an opportunity to guide the reader to the relevant information relating to the research question(s) and emphasise the important findings. It is important therefore for this section to describe the findings and not just display them through a series of charts or tables. They will then be interpreted and put into context in the following discussion section.

Some prefer to start with the results that are easier to interpret. Descriptive results, range and central tendency and tests of significance usually follow in that order. It is important to emphasise the size of any differences as well as their significance. Any unexpected findings are then described. Tables and diagrams should be as simple as is required to demonstrate the data without further reference to the text. Photographs should be presented with anonymity or following the consent of the subjects and specimens provided with an adjacent scale.

The objective in the discussion section is to present the results in the context of the established literature in a clear and balanced way. This is often done poorly, which led Doherty and Smith[17] to propose a structure for the discussion section of scientific papers (see box 6).

Box 6

- Statement of principal findings
- Strengths and weaknesses of the study
- Strengths and weaknesses in relation to other studies, discussing particularly any differences in results
- Meaning of the study: possible mechanisms and implications for clinicians or policy makers
- Unanswered questions and future research

Box 7 Key points in writing the paper

- Have a well thought out, planned and run research protocol.
- Consider Smith's five points before writing
- Be accurate in structuring the article—read the advice to authors for the target journal before starting
- Be clear, simple, and brief in your style
- Be honest and balanced in your conclusions
- Expect to improve the quality of the writing with careful repeated reading and revision by you and others.

The title is the first point of contact for the reader and it needs to invite them to read further. It has to be clear, simple, and brief avoiding sensationalism. Avoid also the temptation to cover the whole paper in the title. The *British Medical Journal* has recently advised more declarative titles while in the past there have been requests by others not to do so.

Who should be credited with authorship has been clearly laid out by the Vancouver Group.[18] They should include those that have made a substantial contribution to all of the following stages;

- the concept and design of the study or the analysis and interpretation,
- drafting the article or revising it for important intellectual content
- the final approval of the version to be published.

In other words they should be able to defend the work publicly. These guidelines followed controversies where coauthors refused to take responsibility for papers later found to be fraudulent.

Some researchers consider the Vancouver proposals to be unworkable and too restrictive. A recently implemented idea that has been introduced in the *British Medical Journal* is for authors to list their contribution.[19]

CONCLUSION

It is clear that each stage in the conduct of research if done well will make the conduct of the following stages easier to undertake as well as increase the probability of publication.

The problems with research in emergency medicine can be overcome. There is knowledge contained in written materials and courses, particularly in masters in science research modules for those not wishing to go on to an MD and for those that do. Good supervision from contacts in or outside emergency medicine should be sought by all inexperienced researchers. There is much to be gained from this in all stages of the research process, not only increasing the prospect of success but also to make the project a more fruitful learning experience. Collaboration when organised well makes for lighter work and efficiency. Successful research is going to demand imagination, creativity, judgement, teamwork, tenacity, communication skills, and confidence. Interestingly these

are also good qualities for the many other areas of endeavour in emergency medicine.

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REFERENCES

1 **Kelly WN**, Randolph MA, eds. *Careers in clinical research: obstacles and opportunities*. Washington DC: National Academy Press, 1994.
2 **Nee PA**, Griffiths RD Ethical considerations in accident and emergency research. *Emerg Med J* (in press).
3 **Wyatt J**, Guly H. Identifying the research question and planning the project. *Emerg Med J* (in press).
4 **Hully SB**, Cummings SR. *Designing clinical research*. Baltimore: Williams and Wilkins, 1988.
5 **Foex BA**. Research for higher degrees. *Emerg Med J* (in press).
6 **Brown G**, Atkins M. *Effective teaching in higher education*. London: Methuen, 1988.
7 **Clancy M**. Overview of research designs. *Emerg Med J* (in press).
8 **Mann C**. Research design II. Cohort, cross sectional, and case-control studies. *Emerg Med J* (in press).
9 **Kendall JM**. Designing a research project: randomised controlled trials and their principles. *Emerg Med J* (in press).
10 **Carley S**, Lecky F. Statistical considerations for research. *Emerg Med J* (in press).
11 **O'Columb**, Haji-Michael P, Nightingale P. Data collection in the emergency setting. *Emerg Med J* (in press).
12 **Mackway Jones K**. Seeking funding for research. *Emerg Med J* (in press).
13 **Smith R**. Introduction. In: Hall GM. *How to write a paper*. Nottingham: BMJ Publishing, 1994.
14 **Paton A**. Write a paper. In: Reece D, ed. *How to do it: 3*. 3rd edn: London: BMJ Publishing, 1995
15 **Chalmers I**. Improving the quality and dissemination of reviews of clinical research. In: Lock SP, ed. *The future of medical journals: in commemoration of 150 years of the British Medical Journal*. London: BMJ Publishing, 1991.
16 **Hawkins C**, Sorgi M. *Research. How to plan, speak and write about it.* Berlin: Springer-Verlag, 1985.
17 **Doherty M**, Smith R. The case for structuring the discussion of scientific papers. *BMJ* 1999;**318**:1224–5.
18 **International Committee of Medical Journal Editors**. Guidelines on authorship. *BMJ* 1985;**291**:722.
19 **Smith R**. Authorship: time for a paradigm shift? *BMJ* 1997;**314**:99.

BIBLIOGRAPHY

General issues

Hully SB, Cummings SR. *Designing clinical research*. Baltimore: Williams and Wilkins, 1988.
Crombie IK, Davies HTO. *Research in heath care*. Chichester: Wiley, 1996.
Bailey DM. *Research for the health professional. A practical guide.* Philadelphia: FA Davis, 1997.
Oyster CK, Hanten PA, Llorens LA. *Introduction to research. A guide for the health science professional.* London: JB Lippincot, 1987.
Pogar S, Thomas SA. *Introduction to research in the health sciences.* 3rd edn. Melbourne: Churchill Livingstone, 1995. A series currently running in the journal of *Academic Emergency Medicine* beginning with; Research fundamentals; Getting from hypothesis to manuscript: An overview of the skill required for success in research. *Acad Emerg Med* 1998;**5**:924–9.
Khan CR. Picking a research problem. The critical decision. *N Engl J Med* 1994;**330**:1530–3.

Reviewing the medical literature

A current series in *JAMA*: User's guides to the medical literature. This started with; Oxman AD, Sackett DL, Guyatt GH. User's guides to the medical literature I. How to get started. *JAMA* 1993:**270**:2093–5.
Sackett DL, Haynes RB, Guyatt GH, *et al*. *Clinical epidaemiology: a basic science for clinical medicine.* 2nd edn. Boston: Little, Brown, 1991.

Questionnaire design

Oppenheim AN. *Questionnaire design and attitude measurement*. New York: Basic Books, 1966.

Methodological issues

Lowe D. *Planning for medical research. A practical guide to research methods*. Congleton: Astraglobe Ltd, 1993.
Brodie DA, Williams JG, Glynn Owens R. *Research methods for the health sciences.* Singapore: Harwood Academic, 1994.
Shapiro SH, Louis TA. *Clinical trials. Issues and approaches*.New York: Marcel Dekker, 1983.
Campbell DT, Stanley JC. *Experimental and quasi-experimental designs for research.* Boston: Houghton Miffin, 1963.

Statistical issues

Bland M. *An Introduction to Medical Statistics*. 2nd edn. Oxford: Oxford Medical Publications, 1995.
Campbell MJ, Machin DI. *Medical statistics. A common sense approach.* 2nd edn. Chichester: Wiley, 1993.

Funding

Howie J. Apply for a research grant. In: *How to do it.* Vol 1. 2nd edn. Plymouth: Latimer Trent, 1985.

Ethics

Royal College of Physicians of London. *Guidelines on the practice of ethics committees in medical research involving human subjects.* 3rd edn. London: Royal College of Physicians of London, August 1996.
Evans E, Evans M. *A decent proposal. Ethical review of clinical research.* Chichester: Wiley, 1996.

Writing

Driscoll P. How to write a paper. *J Emerg Med* 1997;**14**:65–9.
Hawkins C, Sorgi M. *Research. How to plan, speak and write about it*. Berlin: Springer Verlag, 1985.

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Notes