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# A guide to conducting research in laboratory medicine

FOR THE IFCC TASK FORCE  
FOR YOUNG SCIENTISTS

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# Introduction to the research guide

*"Science is composed of aggregated facts from which one can create general laws and conclusions"*

**Charles Darwin**

## 1.1. Introduction

The aim of this publication is to provide insight into the research process and an overview of the strengths and weaknesses of different research methods to young scientists at various levels of their profession and career. This book is 'nectar' of the vast experience of well renowned scientists and senior members of leading healthcare organisations sharing their overall vision related to research methodology.

The contents of the Guide are divided into a total ten chapters including this introduction. The titles are well designed and elaborated from "Why is research in laboratory medicine Important?" to "Auditing of research and planning for the future".

The publication provides answers to the following questions:

- What is research and its methodology?
- How it is submitted and what requirements are essential?
- How is research evaluation organised and practised?
- What are the various ways of presenting research findings?
- How should research be audited to plan for the future?

The target audience is Young scientists; Laboratorians; Clinical chemists; and Pathologists together with any others at an early stage of research in laboratory medicine.

## 1.2. The IFCC-Task Force for Young Scientists (TF-YS)

The International Federation of Clinical Chemistry & Laboratory Medicine (IFCC) constituted its Task Force for Young Scientists (TF-YS) in 2010. The specific objectives

of TF-YS are networking; training; participation; and multidisciplinary exchanges. The method of operation of TF-YS includes organising educational sessions in different congresses of IFCC and its Member Societies; addressing the perspectives and principles of Laboratory Management and Leadership; and other activities such as interviews, surveys, trainings, mentorship and publications. Thus, TF-YS is devoted to preparing young scientists for their future careers in Laboratory Medicine and healthcare practices.

The suggestion of preparing this Guide arose from the discussion following a TF-YS symposium entitled 'Research design and methodology – identification of need', which was held in Jodhpur, India in December 2014.

## 1.3. The need for "A guide to conducting research in laboratory medicine"

Research means "a careful investigation or inquiry especially through search for new facts in any branch of knowledge." The purpose of research is to discover answers to questions through the application of scientific procedures to find out the truth which is hidden and which has not yet been discovered. There are numerous reasons to conduct research, including:

- To provide answers to practical problems
- To provide a service to society (and patients in the case of medical research)
- To do some creative work and challenge yourself
- To attain respectability with peers in your profession
- To comply with educational curricula, directives and requirements
- To gain a research degree along with its consequential benefits
- To improve future employment prospects

Research underpins the basis for many government policies in our economic system as a means to improve the standard of living for society. In the case of medical research the benefits are aimed at improving the health of individual patients and the overall wellbeing of society. Medical research can be classified into two main categories:

- Primary research (basic, clinical, and epidemiological)
- Secondary research (meta-analysis and review).

## 1.4. Conducting research

Conducting research comprises a series of logical sequential steps:

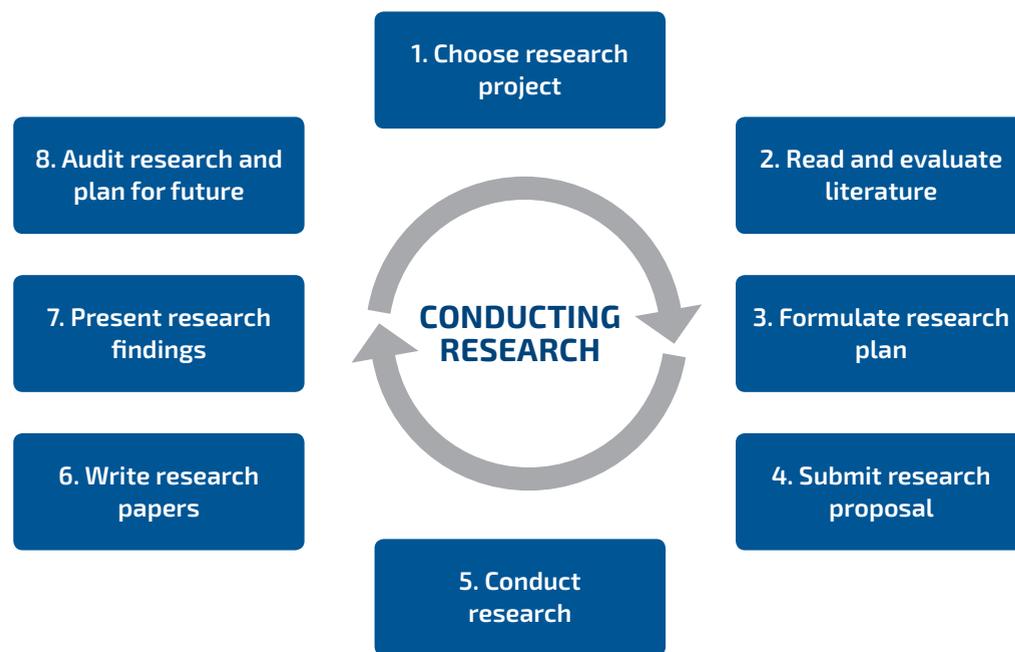




- Define the research problem and choose a research project
- Read and evaluate the literature to discover what is known
- Formulate a hypothesis leading to a research plan
- Submit the research proposal for critical appraisal and possible funding support
- Conduct the research including data collection, testing hypothesis and reaching conclusions by analysing and evaluating the data
- Write research papers to share findings with the scientific community
- Present research findings through oral or poster presentations in scientific meetings
- Audit the outcome of the research and plan for the future

This series of steps may be consider as a cycle (Figure 1.1) since the outcome of the final step will often prompt a further research question.

**Figure 1.1. | Conducting research**



### 1.5. Expected outcomes from the guide

This guide will provide the new researcher with an understanding of the major types of medical research and provide a basis for designing a research study. By careful reading of the guide, students may understand the research process including:

- The identification of a suitable research topic
- Specifying the research purpose
- Searching the literature
- Preparing a research proposal, including assessment criteria and associated timelines
- Conducting the research
- Evaluating data and drawing conclusions to answer research questions.
- Preparing a final research report,

In summary, by following this guide young scientists should be in a position to prepare a high quality research proposal.

# Why is research in laboratory medicine important?

## 2.1. What is medical research?

There is no universal definition of medical research. A simple and convenient way to think of medical research is as 'the acquisition and application of knowledge in the field of human medicine'.

The above description is broad, allowing for medical research to be performed by a wide range of scientists and health professionals, with different education and training, in settings varying from a pure science laboratory to the patient.

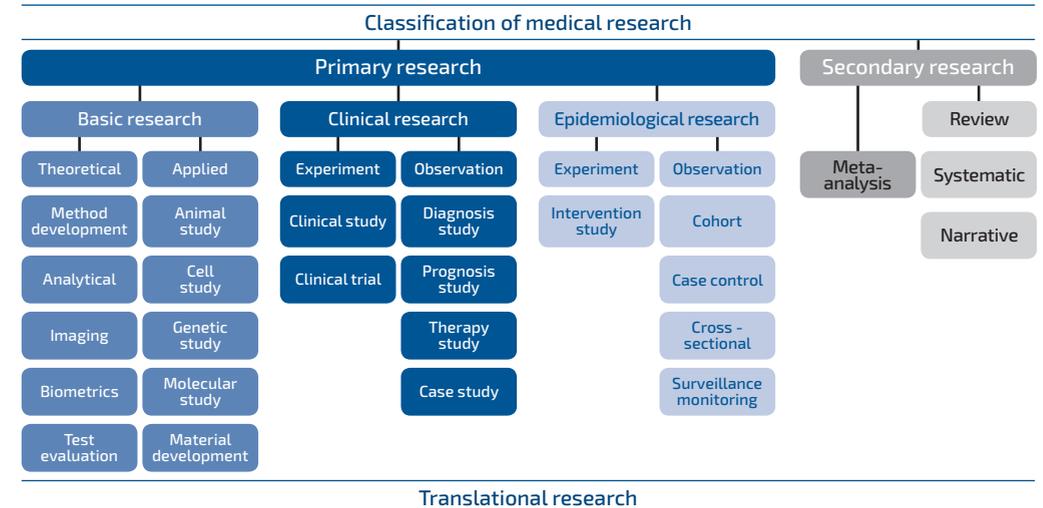
The aims of medical research are also broad, including:

- Understanding normal physiology and the pathophysiology of disease
- Understanding the impact of genetic and external factors on human health
- Keeping populations and patients well for longer
- Diagnosing and managing disease in populations and patients
- Designing and evaluating new therapeutic interventions
- Health economics

## 2.2. What are the types of medical research?

Medical research may be classified in a number of ways. The one that will be used in this chapter is summarised in Figure 2.1 and is described below. The first distinction is between primary research, which is performed in discreet studies, and secondary research which is based on comparing and evaluating literature reports of primary research.

Figure 2.1. | Classification of medical research



## PRIMARY RESEARCH

Primary research may be broken down into three subdivisions:

**Basic research** is usually quite a long way removed from the patient or the clinic, and is often carried out by non-medical scientists working in universities or research institutes. At a theoretical level basic research employs pure sciences to develop methods or equipment that may be useful when used in a clinical context. Applied basic research involves the study of animals, cells, genes and molecules to understand the pathophysiology of disease. Applied basic research may also involve the development of new or modified materials for specific applications. As basic research moves towards the clinical arena it often involves medical doctors and may be considered as pre-clinical research.

**Clinical research** is carried out by healthcare professionals in collaboration with medical doctors. Patients or members of the public may be active participants in clinical research and so there are strict rules about getting their consent for involvement. There are also ethical guidelines for performing clinical research and laboratory medicine specialists should learn about local and national ethical guidelines at an early stage in their research career. Clinical research may be experimental, involving interventions or therapies, ideally in placebo controlled double blind clinical trials. Clinical research may also involve observational studies that evaluate improved



diagnosis, prognosis or therapy for defined groups of patients.

**Epidemiological research** focuses on patterns of illness and disease in groups of patients. Epidemiological research often involves comparing measured parameters or clinical observations in 'test' and 'control' groups. A number of models are available for such research, including cohort, case control and cross-sectional studies. Another form of epidemiological research looks at patterns in populations and through surveillance and monitoring may find associations between diet or environmental factors and disease. Such an association is not proof of a cause: effect relationship but it can open up more targeted research investigations.

### SECONDARY RESEARCH

Secondary research has gained in popularity and credibility in recent years because it is capable of producing evidence based recommendations that can be used in clinical practice. Secondary research, as the name implies, involves a detailed survey of the scientific and clinical literature to identify high quality publications in a specified area of study. These publications are evaluated using strict criteria and graded practical recommendations are made from the evaluation. The publications of high quality are examined in detail in one of two ways.

By combining published quantitative data from several studies it is possible to increase the statistical power of the increased number of observations. This increases the confidence with which a conclusion may be drawn from experimental data. Typically, meta-analyses are used to increase the number of patients studied so that the true value of a therapy or intervention may be determined.

A systematic review aims to provide an exhaustive summary of current literature relevant to a specific research question. A systematic review uses an objective and transparent approach for research evaluation in order to minimise bias. While many systematic reviews are based on an explicit quantitative data, there are also qualitative reviews which adhere to the same standards for gathering, analysing and reporting evidence. The Cochrane Database of Systematic Reviews provides a valuable library of systematic reviews across all of clinical medicine

### TRANSLATIONAL RESEARCH

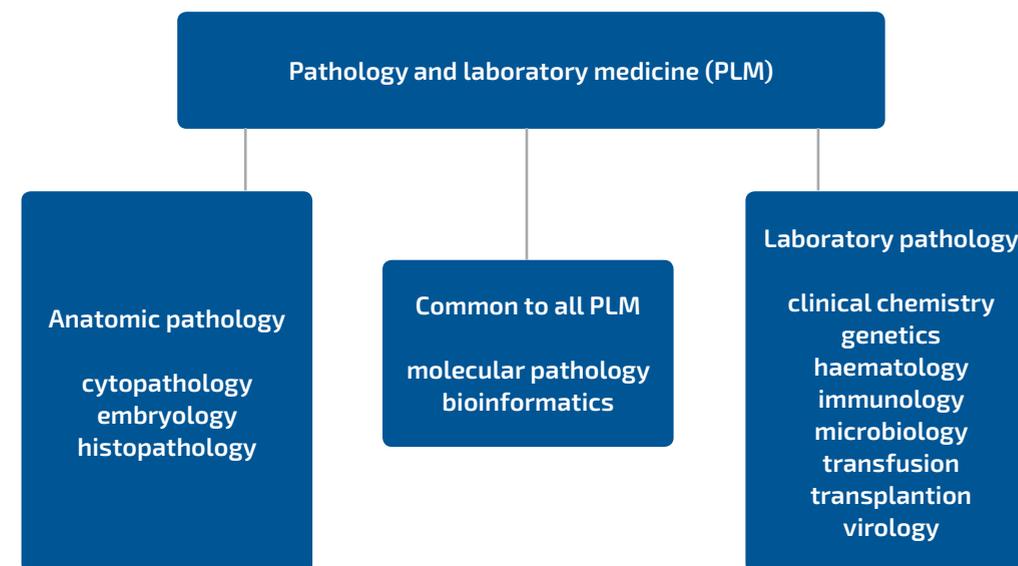
Translational research applies findings from other forms of research in order to enhance human health and well-being and facilitate improved clinical outcomes. The term 'from bench to bedside' has often been used to describe translational research but this is an oversimplification because in most cases basic research will need to be further developed through clinical or epidemiological research before it can be translated into routine clinical practice. Translational research includes adopting best

practice, including the implementation of evidence based guidelines. Increasingly, cost-effectiveness is an essential component of translational research. It follows from the above that the skills required for transitional research may be different from those used in the other forms of research with companies and health economists making a significant contribution.

### 2.3. What is Laboratory medicine?

Laboratory medicine is a term that has different meanings in different countries. For the purposes of this chapter laboratory medicine (known in some countries as clinical pathology) will be regarded as distinct from anatomic pathology, although everything written in this booklet about research in laboratory medicine applies equally to anatomic pathology. Figure 2.2 illustrates the sub-specialties of laboratory medicine and anatomic pathology and indicates the common sub-specialties on molecular

Figure 2.2. | A simple classification of pathology and laboratory medicine





pathology and bioinformatics.

## **2.4. Why is research in laboratory medicine Important?**

Research has always been a key component of laboratory medicine. Today, research is probably more important than at any time in the past. In considering why research is important it is reasonable to consider the benefits of that research to different healthcare stakeholders.

### **IMPORTANCE TO PATIENTS**

The primary purpose of medical research is to improve the clinical outcome and/or the clinical experience for the patient. By contributing to and embracing research findings Laboratory Medicine specialists can ensure that the services provided are always up to date and appropriate to the local healthcare environment. In this way patients will benefit from:

- High quality results delivered and reported in a timely manner
- Adoption of patient centred care and a move towards personalised medicine
- Compliance with local, national and international clinical guidelines
- Improved patient safety that can facilitate improved clinical outcomes

### **IMPORTANCE TO USERS OF THE SERVICE**

Laboratory Medicine supports virtually all branches of clinical medicine. The impact of research means that the optimal use of laboratory medicine services is constantly changing. A two-way communication between the laboratory medicine specialist and the various clinical specialists is important to ensure that the laboratory can always offer high quality services that are fit for clinical purpose. Research findings may influence users of laboratory medicine services in several ways, including:

- The introduction of new biomarker tests
- More rapid turnaround time for results
- Improved reporting of results, including calculated or estimated parameters
- Innovation in the availability of testing, including point of care testing

### **IMPORTANCE TO COMMISSIONERS OF HEALTHCARE SERVICES**

Laboratory medicine services are organised and provided within both public and private healthcare systems. In both situations there will be a body that is responsible for commissioning or contracting laboratory medicine services for its patients and clients. The active involvement of the laboratory medicine specialist in clinical research will reassure the commissioners that:

- Services will be up to date and targeted to meet clinical need
- Services will be of high quality in pre-analytical, analytical and post-analytical phases
- There is a willingness to embrace new findings and methods of service delivery
- There is an appreciation of the need for improving clinical and cost effectiveness

### **IMPORTANCE TO THE INTERNATIONAL COMMUNITY**

'Globalisation' is a word that is overused. However, in terms of medical research it is vital that research findings can be shared quickly in a format that can be understood and acted upon by researchers from anywhere in the world. The publication of research findings in a peer reviewed journal is the recommended methodology. Increasingly, there is growth of open-access electronic journals that publish research findings rapidly without time or financial constraints to the reader. The publication of medical research:

- Increases the global body of knowledge
- Reduces duplication of effort
- Facilitates value for financial investment
- Encourages international collaboration between research groups with similar interests.

### **IMPORTANCE TO THE PROFESSION**

The results from laboratory medicine investigations influence a high percentage of all clinical decisions, placing laboratory medicine at the centre of the multidisciplinary healthcare team. Nevertheless, the true contribution of laboratory medicine to modern healthcare is often underestimated. Collaborative research provides an opportunity to reinforce the centrality of laboratory medicine services as that research may:

- Increase knowledge and understanding of pathophysiology
- Emphasise the role of Laboratory Medicine in diagnostic and/or therapeutic algorithms
- Facilitate the implementation of evidence based clinical guidelines
- Shorten the patient pathway with benefits to both clinical and cost effectiveness

### **IMPORTANCE TO THE INDIVIDUAL RESEARCHER**

The individual laboratory medicine specialist stands to gain from participation in research in several ways, including:

- Greater understanding of the contribution of laboratory medicine to healthcare



- Development of a reputation as an informed and valued source of collaboration
- Generation of a research portfolio that improves future employability
- Appreciation of personal strengths and weaknesses in a competitive research environment

## REFERENCES

Medical research. Wikipedia. [https://en.wikipedia.org/wiki/Medical\\_research](https://en.wikipedia.org/wiki/Medical_research)

Clinical trials and medical research. NHS Choices. [www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx)

Röhrig B, du Prei JB, Wachtlin D, Blettner M. Types of study in medical research. *Dtsch Arztebl Int* 2009; 106: 262-8

Rubio DM, Schoenbaum EE, Lee LS, Schteingart DE, Marantz PR, Anderson KE et al. Defining translational research: implications for training. *Acad Med* 2010; 85: 470-5

The Cochrane Library. [www.cochranelibrary.com](http://www.cochranelibrary.com)

## Choosing a suitable research project

### 3.1. Factors that stimulate research projects

There are many factors that may give rise to a medical research project. It is convenient to consider these in two categories:

#### GENERAL FACTORS

Most medical research starts with a question or a practical problem for which there is no available answer. These questions or problems may arise from several different sources, including:

- A matter that is topical in the media or national / international research community
- An intellectual challenge
- An area perceived to be important to healthcare
- An area of practice, which has been identified as in need of improvement
- Follow-on from previous research observations or findings
- A priority area identified by government or funding agencies, including research charities

There are different ways to address research questions. For example, the following types of investigation may be prompted by the research question or problem:

- The need to identify the cause of a condition or phenomenon
- The desire to test a hypothesis derived from sound principles
- The development of methodology that will improve the outcome of investigation
- The adoption of improved practices in healthcare

In the context of laboratory medicine the research questions or practical problems centre on trying to improve the quality and/or the clinical relevance of laboratory medicine to patient investigation and care. As Chapter 2 has explained research projects often involve

- Learning more about the pathophysiology of disease
- Developing new methods to aid the diagnosis, prognosis and therapy of individuals
- Identifying patterns of disease and suggesting reasons for those patterns
- Comparing methods or treatment regimens to improve clinical outcomes
- Translating research findings into improved clinical practice

#### PERSONAL FACTORS

It may be a daunting task for the new researcher to assimilate all of the general factors listed above. Therefore, he/she should consider whether personal factors or interests may help to refine their choice of project. A research project which has strong personal appeal to the researcher is likely to cause him/her to be more motivated and committed to seeing it to a successful conclusion. Personal factors that may influence choice include areas:

- Of interest derived from family or personal experience
- Of local significance or interest
- Identified from reading literature or scientific media
- Suggested by peers and/or the local research team
- Suggested by users of the local laboratory medicine service

Having identified one or more potential topics of personal interest the researcher should ensure that the outline topic can comply with two key considerations:

**Simplicity:** The ideal research project addresses a clear question in such a way that the researcher knows when he/she has obtained an answer to that question. It is a common mistake to make research projects and proposals too complex or too open-ended in order to impress others. Simplicity of design is a major factor in predicting likely success.

**Flexibility:** A research project may be simple in design but it should not be so narrow that a single setback can derail it completely. Research rarely follows a smooth and predictable path. A degree of flexibility will be required in all research. That flexibility is best directed in terms of different ways to answer the fundamental research question or problem'



Preparation of an outline research plan is a valuable next step as this may be applied to address whether the identified project is important and practicable.

### 3.2. Importance of the research project

It is easy to make the general statement that all research is important because it adds to the body of scientific knowledge and because it helps the personal development of the researcher. However, the reality is that modern research is conducted in a highly competitive environment. Therefore research projects are likely to be assessed by peers and by funding institutions in terms of their ability to answer two related questions about the importance of the research:

#### IS THE RESEARCH WORTH DOING?

**Nature of research:** The nature of the research proposed to answer the question or problem is a major factor in assessing importance. Therefore, research that is based on testing a new hypothesis derived from earlier findings is likely to be assessed as more important than a 'fishing' research project that measures lots of parameters in the hope that something 'may turn up'.

**Originality:** Research originality may lie in the scientific underpinning of the research project and/or in the methodology that is employed to address the research question or problem. A truly original research project will usually be considered more important than 'me too' research that reproduces already published research findings. However, if the clinical relevance is high then there is value (and importance) in confirming research findings and or adding to the weight of research that may help to change clinical practice. In the international arena confirming research findings in a local population may be important in that locality, although less so to an international audience.

**Clinical relevance:** In laboratory medicine even basic research should be designed to obtain knowledge or to develop methods that have a clinical context. In clinical and epidemiological research the clinical relevance should be increasingly clear and in translational research the main focus of the research is putting research findings into clinical practice. There is an interesting debate about relative importance of different clinical research. From the perspective of society and health administration research into major diseases such as diabetes and cancer will always be considered important. On the other hand the individual patient with a rare genetic disorder will have a different assessment of clinical relevance. In reality clinical relevance may often be determined by local priorities or the source of funding for the research.

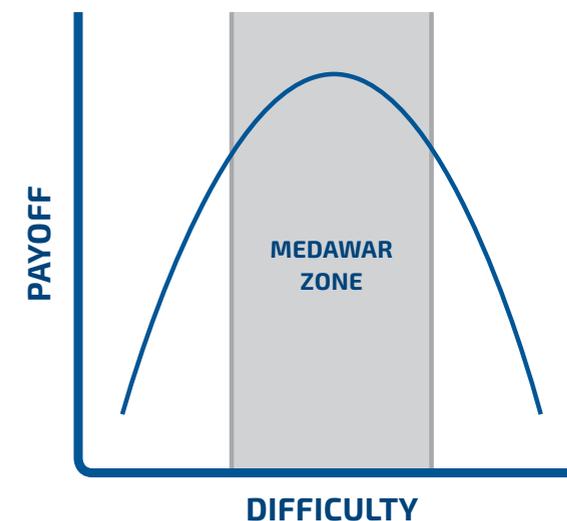
#### WHAT IS THE LIKELY IMPACT OF THE RESEARCH?

Research is often unpredictable. Therefore, it is difficult to assess the likely impact of a research project with great confidence. It is normal practice to take an optimistic view about the proposed research and in such circumstances the likely impact may be assessed by addressing the following four supporting questions:

- Will the research move forward knowledge and understanding?
- What specific outcomes is the research likely to deliver?
- Who will benefit from the research?
- Is the research like to improve clinical practice?

A convenient tool for assessing the importance of a research project is to consider where it may fit in relation to the Medawar Zone (Figure 3.1). This zone is named after Peter Medawar, a Nobel prize-winning medical researcher who was active from the 1940s to the 1960s, who suggested that there seems to be a certain time when scientific questions are ripe for answering, whereas other questions remain elusive and out-of-reach from investigation. Although it is a qualitative and subjective concept any research project may be assessed in terms of its likely payoff (impact) against the difficulty involved in performing the research. This simple tool may help to answer the question 'is the research worth doing'?

Figure 3.1. | A simple classification of pathology and laboratory medicine





### 3.3. Practicability of the research project

Having designed a high quality personal research project that is assessed to be important the final area to be addressed is practicability. In other words 'is it possible for me to perform this research project in my current role'? There are four considerations in addressing practicability:

#### FACILITIES

The facilities required to undertake a successful research project in laboratory medicine include:

- The fabric, utility services and access to the laboratory in which the research will be performed
- The availability of clinical material (e.g. specimens from or patients of defined clinical status)
- The scientific and computing equipment required to undertake the research together with protected research time to use that equipment
- The availability of appropriate consumables

#### PERSONNEL

Modern research is increasingly collaborative in nature. In order for research to be successful it is necessary to have personnel support in a number of areas:

- A director or head of department who has created a research ethos and environment
- Peers with similar research interests who can be involved in detailed discussion
- Clinical colleagues who will support the research, including the provision of appropriate clinical material
- Skilled technologists and informatics experts who can support specific components of the research

#### PERMISSION

Modern research often requires one or more forms of permission or authorisation, including:

- Agreement in advance from all research collaborators to participate as specified
- Ethical permission from the local, and maybe the national, ethics committee
- Informed consent from patients or volunteers who will participate in the research
- Licences to work with animals, radioactivity or infectious materials

#### FINANCE

Research funding support is often the stumbling block to undertaking a research project. This topic is addressed in detail in Chapter 6. All research requires funding and it is normally a condition of support from collaborators that their contribution to the research will be funded adequately. Finance is required to support one or more of the following research areas:

- The salary and 'on costs' of employing the researcher and/or research technical support
- The cost of consumables
- The cost of hiring specialised equipment or facilities, including informatics
- The capital cost of any equipment that may not be available
- The cost of obtaining suitable clinical material (e.g. reimbursing expenses for volunteers)
- Overheads for the research institution and for allowing for attendance at meetings and conferences

### 3.4. Research supervision and mentoring

All researchers will require support to help them deliver a successful outcome to their research. This support can be provided either as supervision or as mentoring. Depending on the stage of their career individual researchers will require a different balance between these two forms of support. Individuals who are new to research will require substantial supervision while established researchers running their own programmes will benefit most from mentoring. There is no fixed relationship between supervision and mentoring and since the needs of a researcher will change over time it is possible for one person to act first as a supervisor and later as a mentor.

#### SUPERVISION

The supervision of research students is essential for a successful outcome. It comprises a process of fostering and enhancing learning, research and communication by the student with the aim of achieving research quality, effectiveness and productivity. An effective research supervisor encourages inquiry by the student, explores and challenges ideas and provides resources (intellectual and financial). The supervisor gains from the relationship by advancing his/her own knowledge, learning and reputation. Although the traditional model is of a 1:1 relationship between student and supervisor other models are also common.

The research supervisor is usually an experienced researcher who is expert in the



specific area of the research project. Commonly, the supervisor has contributed to the design of the research project, obtained funding for it and provides the facilities to enable the project to proceed. Under these circumstances the supervisor may select the research student, manage research, monitor research and ensure that it is evaluated and reported.

The dynamics between a researcher and his/her supervisor are crucial to a productive relationship and both parties should consider if a harmonious partnership is likely to develop. For both parties this is a key component of choosing a research project.

### MENTORING

One definition of mentoring is 'a dynamic reciprocal relationship environment between an advanced career researcher (mentor) and a less experienced individual (mentee), aimed at promoting the development of both.' The relationship is not as closely linked as supervision and the mentor focuses more on supporting the mentee researcher than on the fine detail of the research project. Therefore, the mentor in laboratory medicine need not be expert in the specifics of an individual project though he/she will need to understand the research and clinical context. Table 3.1 shows the characteristics of a successful relationship.

**Table 3.1. | The characteristics of a successful mentor: mentee relationship**

CHARACTERISTICS OF A SUCCESSFUL MENTOR: MENTEE RELATIONSHIP	
Mentor	Mentee
Interest in serving as a mentor	Definition of the support and help needed
Flexibility to make a definite commitment of time and effort	Recognition that one mentor may not meet all your mentoring needs
Ability to recognise and support the needs of the mentee	Recognition that your needs for mentoring change over time
Knowledge and experience in the area in which you are acting as a mentor	Ability to accept and commitment to work through meaningful advice and criticism

Academic and research institutes appreciate the value of mentoring as a contributor to high quality research outputs. It is not an easy relationship and training in mentoring and coaching is now widely available.

### 3.5. References

Loehle, C. 1990. A guide to increased creativity in research inspiration or perspiration? *BioScience* 1990; 40:123-129

Cohen L, Manion L, Morrison K. *Research methods in education*. 7<sup>th</sup> Edition, 2011, Routledge, ISBN-13: 978-0415583367

Medical Sciences Board. Code of practice for supervisors. Radcliffe Department of Medicine, University of Oxford, UK. [www.rdm.ox.ac.uk/code-of-practice-for-supervisors](http://www.rdm.ox.ac.uk/code-of-practice-for-supervisors)

Bettmann M. Choosing a research project and a research mentor. *Circulation* 2009; 119: 1832-35

## Reading and evaluating the scientific literature

### 4.1. Literature study

A literature study is a fundamental part of the planning and implementing of any research project. A researcher may only be able to plan a meaningful project if he has made a careful study of the literature in connection with his field of research beforehand.

The most important reason for a literature study is to become acquainted with theories, definitions, previous relevant research, etc. in connection with a specific subject or problem area. On the basis of the accumulated information, a researcher gets a clearer view of the nature of the issue and is able to outline or demarcate the problem positively and to set hypotheses.

From the literature, the researcher usually gets an indication of the most effective procedures, measuring instruments and methods of analysis that can be used. This knowledge enables the researcher to plan the project accurately. A thorough study of the literature also helps the researcher to understand the actuality of the intended research. If it turns out that the research envisaged has already been done and that the "problem" has been solved satisfactorily, no purpose will be served by repeating the work.

Review articles are a rich source of information. These articles are usually written by an expert or a pioneer in the subject area. For newcomers to a field, it is recommended that they first read some review articles in order to understand the big picture. Thereafter, scrutinize the most recent literature. In particular, try to highlight the divergent points of view chronologically to enable the reader to sense immediately in which direction the proposed research is headed.

### 4.2. Questions that need to be answered when reading a publication

There are six questions that one should be able to answer when reading a research article – these six questions also deal with different parts of the paper.

**Why?** The study question – considers the aims of the study. One should always consider the reasons for the study and must determine whether sufficient evidence is presented to justify the study.

**How?** Study methodology – considers the methods used in the study. One needs to critically review the methodology used and decide whether it is valid for obtaining a correct result.

**Who?** The study population – considers the analyses of the results. One must decide whether the sample used is representative enough of the population to extrapolate the results back to the larger population.

**What?** Treatments and outcomes – considers the analyses of the results. One must ascertain whether the treatments applied are clearly defined and whether the response variables are appropriate.

**How many?** Outcomes – considers the analysis of the results and the conclusions. One must consider whether the sample size is sufficient and whether the significance ascribed to the results is correct.

**So what?** Overall significance – considers the conclusions. One must decide: what is the overall significance of the reported findings.

### 4.3. Critical appraisal of an article

As a scientist one must learn to critically appraise published articles. Critical appraisal is a systematic process used to identify the strengths and weaknesses of a research article in order to assess the usefulness and validity of research findings. This is important as it will determine whether you will use the article in your thesis/protocol/publication.

The concept of critical appraisal has largely grown out of the evidence-based health care movement. It fits into the cycle of getting evidence into practice. This means improving the quality and cost effectiveness of health care by finding the best available research evidence on the outcomes of health care interventions, and basing decisions on health care upon it.

In practice this translates as:

- Finding the evidence (searching the most appropriate databases)
- Carefully checking the validity of the research (critical appraisal)



- Applying the lessons learnt from the evidence to patient care (getting research into practice)

Critical appraisal means being able to look at a piece of research in an objective and structured way to decide how valid it is compared to other research.

The **Abstract** should contain everything that is important in the study which includes the reason for the study, methods used, results and significance of the findings. The abstract is usually read first and will make you decide whether it is worth reading the entire article.

The aim of the study should clearly be stated in the **Introduction**. Is the study's research question relevant? In a causal study the relationship between exposure and outcome is attempted to be clarified. In a descriptive study, one delineates the facts or contents which are going to be measured and attempts to infer the findings to a target population. In addition to the aim/objectives the author should provide some background and current understanding of the problem in the Introduction.

In the section of **Materials and Methods**, the contents of measurement should be provided. One should be able to judge the validity of these measurements and therefore the investigator should explicitly state the determinants of each measurement. This should include the name and model number of the measuring instrument as well as QA/QC procedures used with the measurement. Determine whether appropriate controls were used or not. In clinical studies assess whether the inclusion and exclusion criteria are relevant. In human and animal studies it should be stated that ethical approval was obtained.

In the **Results** section it should be determined whether the statistical analysis was performed properly. Are the results presented correctly?

For the **Discussion** determine whether appropriate explanations are provided. This should be done using knowledge of the subject area. The question to be answered is whether the objective set in the Introduction was accomplished. Most importantly what do they conclude from this finding. Does the study add anything new? Do the data justify the conclusions?

Critically appraising an article will therefore assist in determining what the relevance of the research is to one's own research.

#### 4.4. References

Du Prel J-P, Röhrig B, Blettner M. Critical appraisal of scientific articles. Dtsch Arztebl Int 2009; 106:100-105.

Young JM, Solomon MJ. How to critically appraise an article. Nat Clin Pract Gastroenterol Hepatol 2009; 6:82-91.

## Formulating a research plan

### 5.1. What is a research plan?

A research plan is a short document, which sets out initial thoughts on a research project in a logical and concise manner. It is a concept paper, which may be shared, in confidence, with peers and potential collaborators. Several iterations of a research plan may be necessary before it may be considered as complete.

A research plan in laboratory medicine includes the considered opinion of its author in a research area of his/her choice. It is supported by evidence from the scientific and/or medical literature. It may be constructed in the following format:

- The research question
- The hypotheses
- Aims and objectives
- Research design

A research plan is not a formal research proposal, although it may well be the foundation document from which a detailed research proposal may be developed. Having a coherent research plan may help to make the process of writing a research proposal easier and quicker.

### 5.2. The research question

All research should start with one or more research questions. The research question seeks to address the general point of 'What am I proposing to do?' It sets out a problem that can be challenged, examined and analysed in a logical and systematic manner. Superficially this may seem like a simple task but the construction of a well-defined

research question can have a big impact on the design of a research proposal, its chances of securing funding, and the likelihood of a successful outcome.

The research question needs to be focussed, relating to a specific study in a defined situation. In laboratory medicine the research question should have a clinical context. The starting point for the research question comes from a detailed knowledge of the researcher; what he/she has learned from studying the literature; and what gaps or problems have been identified that may be solved by the research to be undertaken. As explained in Chapter 3 the chosen research project should be both important and practicable. One question that the researcher should ask him/herself is 'will my research question' avoid the response of 'so what?'

There are a number of criteria that may be used to help in formulating a research question in laboratory medicine. Of these the PICOT approach is one of the most widely used. Using this approach the research question should be formulated in terms of:

- P**opulation to be studied
- I**ntervention of interest
- C**omparator for the intervention
- O**utcome that will be assessed
- T**ime frame over which outcomes will be assessed

Not all research involves intervention and so the abbreviations **I**ndicator and **C**ontrol may be more appropriate in these circumstances.

Once the research question has been framed in line with the PICOT approach the next stage is to ask whether the research question can be translated into a proposal that meets the FINER criteria. This means assessing whether the resulting project will be:

- F**easible to perform
- I**nteresting for the researcher and the user
- N**ovel in the local or wider context
- E**thical to undertake
- R**elevant to clinical practice

Having satisfied him/herself that the research question accords with PICOT and FINER criteria the researcher would be well advised to seek the opinion of peers before deciding on the final version.

An illustration of a 'good' and a 'poor' research question are included in Table 5.1.



**Table 5.1. | An example of a 'good' and 'poor' research question**

'Good' research question	'Poor' research question
Is it possible within one year to develop a mass spectrometric method to improve the specificity of measuring serum 'rhubarb' in order to better understand its significance as a biomarker of the risk of developing pre-eclampsia?	Does the measurement of serum 'rhubarb' have any relevance in the investigation of pre-eclampsia?

### 5.3. The hypotheses

A well-thought-out and focused research question leads directly into one or more hypotheses. What predictions can the researcher anticipate will arise as a consequence of answering the research question? Testing the hypotheses (predictions) becomes the justification for the research.

Hypotheses are much more than hunches or guesses. They have their foundation in scientific knowledge and principles backed up by the experience and vision of the researcher. Strong hypotheses:

- Provide insight into the research question
- Are testable and measurable by the proposed experiments
- Are capable of being challenged and addressed by others using a different approach

Normally, no more than three primary hypotheses should be proposed for a research study. A proposal that is hypothesis-driven is more likely to be supported than a "fishing expedition" or a primarily descriptive study.

An illustration of a 'good' and a 'poor' hypothesis are included in Table 5.2.

**Table 5.2. | An example of a 'good' and a 'poor' hypothesis**

'Good' hypothesis	'Poor' hypothesis
A reverse phase packing bed can be used to extract 'rhubarb' from serum using a 96 well format and small volumes of eluant that are capable of automated injection into the liquid chromatography system	A method can be designed to isolate 'rhubarb' from serum

### 5.4. Aims and objectives

In simple terms the aims of the research proposal are to test the hypotheses that have been developed. Therefore, there should be one aim for each hypothesis. The aims are short, broad statements of the outcomes desired from testing each hypothesis. Aims should emphasise what is to be accomplished and not how it is to be accomplished. If the research question and the hypotheses are well constructed then the aims will be relatively simple to compose.

An illustration of a 'good' and a 'poor' aim are included in Table 5.3.

**Table 5.3. | An example of a 'good' and a 'poor' aim**

'Good' aim	'Poor' aim
To devise and evaluate a reverse phase method for the extraction of 'rhubarb' from serum using a 96 well format and small volumes of eluant that are capable of automated injection into the liquid chromatography system	To explore a variety of methods to extract 'rhubarb' from serum prior to liquid chromatography.

Each aim should be broken down into one or more objectives. These are the specific tasks that you are going to undertake in order to meet the aim. Deciding on objectives for the research plan can be difficult because of the unpredictable nature of research. However, it is worth investing time into establishing relevant objectives because



these will determine the methodology that will be employed once the research plan is implemented.

There is a useful mnemonic to help construct appropriate objectives. They should be SMART:

- S**pecific – target a specific area for improvement
- M**easurable – as an indicator of progress
- A**chievable – within the local research environment
- R**elevant – to the aim that it qualifies
- T**ime-related – specify when the result(s) can be achieved.

An illustration of a 'good' and 'poor' objective are included in Table 5.4.

**Table 5.4. | An example of a 'good' and a 'poor' objective.**

'Good' objective	'Poor' objective
Within three months to determine the percentage and precision of recovery of 'rhubarb' from human pregnancy serum using micro-columns of OASIS HPL solid phase and a methanol /water based eluant	To explore a range of solid phase extraction systems to see which of them can extract 'rhubarb' from serum

## 5.5. Research design

In a short research plan it is not necessary to detail all the investigations that will be performed. The research design is the framework created to enable the researcher to map out the logical sequence of investigations to be performed to achieve each of the objectives. As part of this process the researcher should list all the equipment and consumables that will be required and to identify any items that will need to be obtained in order for the research to proceed. This process will enable the researcher to reassure him/herself that all the investigations are practicable within the research environment and the timescale allowed for the research. It will also provide sufficient information for collaborators and peers to understand the plan of investigation.

There are many ways to classify research design. However, such theory can be

confusing and the researcher will do well to focus on the particular framework of investigations needed for his/her study.

A flowchart diagram is a useful way to set out the research design.

## 5.6. References

Aslam S, Emmanuel P. Formulating a researchable question: A critical step for facilitating good clinical research. *Indian J Sex Transm Dis.* 2010; 31: 47–50

Thabane L, Thomas T, Ye C, Paul J. Posing the research question: not so simple. *Can J Anaesth* 2009; 56:71-79

PICO. Formulate an answerable question. University of Oxford  
[http://learntech.physiol.ox.ac.uk/cochrane\\_tutorial/cochlibd0e84.php](http://learntech.physiol.ox.ac.uk/cochrane_tutorial/cochlibd0e84.php)

SMART criteria. Wikipedia  
[https://en.wikipedia.org/wiki/SMART\\_criteria](https://en.wikipedia.org/wiki/SMART_criteria)

Research design. Wikipedia  
[https://en.wikipedia.org/wiki/Research\\_design](https://en.wikipedia.org/wiki/Research_design)

# Submitting a research proposal for external approval and funding

## 6.1. Preparation

Preparation is the key to a successful outcome when submitting a research proposal for external approval and funding. To reach this stage you should already have:

- Chosen a suitable research project (Chapter 3)
- Read and evaluated the scientific literature (Chapter 4)
- Formulated a research plan (Chapter 5)

The next step is to select a suitable organisation to receive your formal research proposal and to customise your research plan to comply with the requirements of that organisation.

## 6.2. Some simple truths

Securing research funding support in laboratory medicine is likely to be a competitive process. Therefore, it is sensible to acknowledge a few simple truths at the outset of preparing your research proposal:

- There are always more applications than available funding
- Preliminary screening of research proposals is often done quickly by experts in screening not in the specific science
- Screeners are looking for reasons to exclude applications
  - Stick to the rules, length, time lines etc.
  - Match the funding guidelines as closely as possible
- Referees are volunteers and busy. They may also be close competitors
- Unrealistic proposals or claims are easily spotted by referees
- In Laboratory Medicine successful outcomes should link to better patient care

## 6.3. Ten steps on the 'road to success'

Figure 6.1 sets out a simple 'road map', which should increase the chances of a successful outcome to the submitted research proposal. There are ten steps:

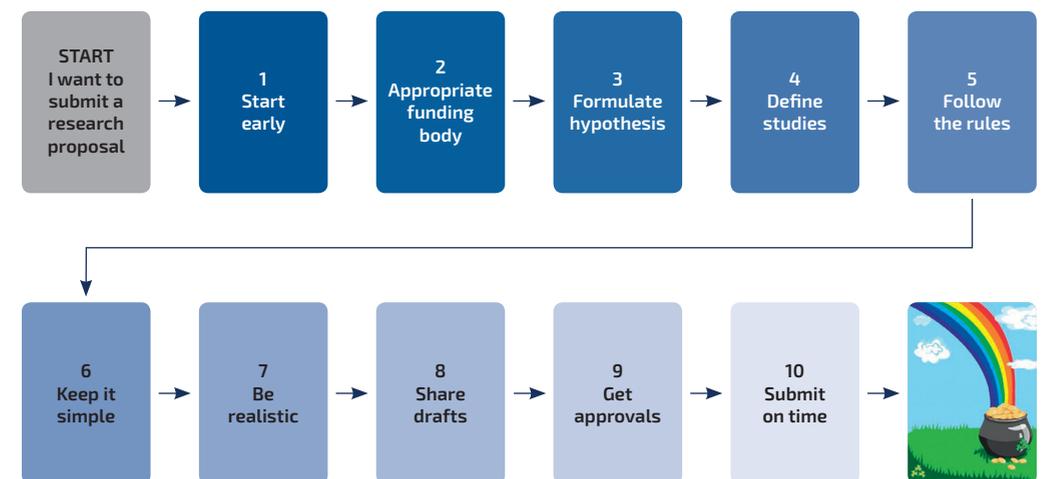
### 1. Start early

Drafting a successful research proposal takes a long time (~6 months). Actions include:

- Performing the literature review
- Recruiting collaborators
- Formulating specific research questions
- Getting ethical approval
- Producing a first draft
- Sharing with busy colleagues
- Getting feedback from busy colleagues
- Producing the final draft of correct length with figures
- Obtaining co-author and institutional approvals
- Submitting on time

If the preparation steps have already been taken and a research plan is available then the time may be reduced but it is unwise to rush preparing a research proposal.

Figure 6.1. | A road to success?





## 2. Choose an appropriate funding body

All research funding bodies have written criteria to describe the type of application they may fund. They will not fund outside these criteria. Examples of such criteria include:

- Basic science / translational science / clinical practice
- Research in a specific area (e.g. cardiac disease, cancer etc.)
- Collaborative research – link with clinical teams and patients
- International partnership
- Minimum / maximum age of applicant
- Minimum / maximum length of research project
- Funding of equipment and/or salaries
- Maximum funding possible
- Need for shared or matching funding

## 3. Formulate an hypothesis for your research

As explained in Chapter 3 it is worthwhile to formulate an hypothesis for your research and explain it in your proposal.

- The approach of " I believe 'X', if this proposal is successful the outcome will be 'Y' and the benefit (to patients) will be 'Z'"
- Avoid 'fishing expeditions': "We will do this research in the hope of finding something that will shed light on 'X'"
- Aim for a clinical end-point which will improve outcomes / benefit patient experience / improve cost effectiveness

The hypothesis for your research should be included at the end of the Introduction section of the proposal.

## 4. Define the studies required

From your research plan you will already have an outline of the studies that you wish to perform and the methods that you wish to use.

- These should be described in detail in the proposal:
  - Use literature as a guide
  - Wherever possible use pilot study data
- Use of a flowchart can be helpful
- For each study estimate:
  - Patients / animals/ cell cultures involved
  - Equipment and consumables required
  - Input needed from collaborators
  - Likely time to completion (allowing for false starts)
  - Expected outcome / indices of success

- Assess whether the full range of studies will be possible within the timescale / budget allowed by the funding body

## 5. Follow the rules

Funding bodies usually have strict rules relating to the structure and layout of applications.

- These rules include:
  - Section headings
  - Maximum word length in each heading
  - Maximum number of figures / tables
  - Maximum number of references
  - Type of experiment
  - Equipment / staffing allowed
- Failure to follow the rules is a reason for rejection of your proposal

## 6. Keep it simple

To get as far as referees the proposal must be intelligible to non-experts who may perform the initial screen of the proposal

- Avoid:
  - Too much jargon / too many abbreviations
  - Long complex sentences
  - Deviating from the purpose of the proposal
  - Hyperbole or criticism of other researchers
- Use:
  - Simple language
  - Reviews where possible
  - Figures and diagrams where possible
- Anticipate:
  - Likely referees and quote accurately from their studies

## 7. Be realistic in your proposal

In your research proposal it is natural to try to impress the reader. However, unrealistic proposals are as dismissed along with bad proposals. Experts in assessing research proposals can judge:

- How long studies will take
- If they are adequately powered
- If they have a realistic expectation of completion
- Whether claimed outcomes are achievable
- How much they will cost



### 8. Share drafts with others

You may think that you have written the 'perfect' proposal. In reality you haven't because you are too close to it and cannot see the flaws. Therefore you should share early drafts with:

- Research collaborators
- Colleagues / peers who will respect confidentiality
- Lay people e.g. family or patients

You should be willing to accept constructive criticism, amend the proposal and check with critics that the edited version is an improvement.

### 9. Get approvals

All research proposals require signatures of approval on the final document.

Approvals will include:

- Support of co-authors and collaborators
- Supervisor / head of department
- Backing of employing institution

Approvals may include:

- Ethical approval
- Evidence of suitable licences (e.g. animals)

Approvals take time, this is reduced if individuals have seen early drafts and/or are primed to expect document on a set date

### 10. Submit on time

You should never miss the deadline for submission of your research proposal. To do so will exclude your proposal from consideration and mean that you have wasted or lost months of preparation. Try to submit a day or two ahead of the deadline because this will allow you:

- Breathing space to address any last minute problems
- To go to front of pile, read when reviewer is fresh

You should send your proposal with a simple covering letter, and if possible check that it has arrived. At this stage all you can do is wait but you are entitled to allow yourself a small celebration for completing the process.

## 6.4. Structure of research proposal

Each research funding organisation will have its own specific requirements for submitting a research proposal, often contained in an application form. The specific requirements must be met in full and these should be identified and worked towards

once a decision has been taken on the organisation to which the application will be submitted.

Although the structure, sequence and nomenclature used in application forms may differ the content is fairly generic and is illustrated in Table 6.1.

**Table 6.1. | Generic information required in a research proposal**

Section of research proposal	Comment
Title of proposal	Concise and not too technical
Names of applicants	Specifying principal investigator
Aims and objectives of proposal	Succinct and SMART
Summary of proposal	Both lay and technical summaries
Introduction	Background to the proposal
Hypotheses	Scientific basis of the proposal
Plan of Investigation	Detailed research plan with time lines
Data analysis	Including statistical methods
Expected outcomes	If hypotheses are proven
Expected benefits	To patients and/or service users
Finances requested	Staff, equipment and consumables
Justification for finances	To assure value for money
References	Key scientific literature
Curriculum vitae of applicants	Including publications and grants held
Approvals	Evidence of ethical approval + licences
Letters of support	From collaborators, employers

## 6.5. Evaluating feedback

The various organisations that fund research in Laboratory Medicine have different criteria and rules for responding to the applicant once the proposal has been evaluated. Applicants should understand the nature of the feedback that they are likely to receive. The different responses may include:

### UNQUALIFIED APPROVAL

From the applicants perspective this is the best possible outcome. It indicates that having evaluated the comments of referees the funding organisation accepts



every detail of the proposal and has agreed to fund everything that was suggested and requested. Such unqualified approval is not a common response to a research proposal.

### QUALIFIED APPROVAL

This form of feedback is fairly normal. It indicates that having seen the comments from the referees the funding organisation approves the proposal subject to certain conditions. Those conditions may relate to small changes in the nature of the proposed research, amendment of the suggested timescale and/or the level of funding support available. The applicant will be invited to accept the modifications as a condition of overall approval.

### REQUEST FOR CLARIFICATION OR ADDITIONAL INFORMATION

Feedback in this category indicates that the referees and the funding organisation like the fundamentals of the proposal but do not fully understand the detail and/or wish to suggest some changes to the proposal. The applicant will be invited to comment on one or more specific points. In such circumstances the way in which the applicant responds will determine whether the proposal is subsequently accepted or rejected. The applicant may challenge some of the specific points raised but should only do so if he/she can produce an evidence-based response. The aim of this dialogue between applicant and funding organisation is to improve the research proposal and so help to increase the chances of a successful outcome.

### REJECTION

For many funding organisations the rejection of a research proposal is the most common outcome in a competitive research environment. Rejection of a proposal will be a disappointment to the applicant but it does not necessarily mean that it was a poor proposal. Research proposals may be rejected for a variety of reasons including:

- It is scientifically or technically invalid or unachievable
- It lacks clarity or detail
- It lacks originality
- It lacks ethical or other necessary approval
- It is inappropriate to the criteria set by the funding body
- It is of insufficient importance in comparison with other proposals
- It did not score sufficiently highly in comparison with other proposals
- The applicants do not have a track record of research achievement

The feedback should enable the applicant to understand the reason for rejection. He/she may feel disappointed or aggrieved but there is no merit in challenging the decision once it has been made. For the young and inexperienced researcher it is worth remembering that:

- It is normal to fail first time
- Even experienced researchers rarely achieve 50% success
- Feedback should be seen as a learning experience
- The second proposal is much easier than the first!

## 6.6. References

All grant awarding bodies will provide specific information and advice on how to prepare and submit a research proposal. Applicants should study the appropriate document from the grant awarding body to which they will submit their application. The following are general references.

How to write a grant proposal.  
[www.wiki.how/Write-a-Grant-Proposal](http://www.wiki.how/Write-a-Grant-Proposal)

Points to bear in mind when preparing a grant application. The Wellcome Trust.  
[www.wellcome.ac.uk/Funding/Biomedical-science/Application-information/wtvm052727.htm](http://www.wellcome.ac.uk/Funding/Biomedical-science/Application-information/wtvm052727.htm)

Grant proposals (or give me the money). The Writing Center  
<http://writingcenter.unc.edu/handouts/grant-proposals-or-give-me-the-money/>

Grant writing. National Institute for Health.  
[www.cc.nih.gov/training/resources/grant\\_writing.html](http://www.cc.nih.gov/training/resources/grant_writing.html)

# Conducting research investigations and analysing findings



## 7.1. Planning for implementation

Having acquired the resources required to undertake your research investigation you are now at the implementation stage. There is a temptation to 'dive in' and start conducting experiments. However, time spent planning proper investigations is time well spent since planning will help to design an investigation that will have the best chance of completion without error and of producing data that can be analysed in a meaningful way to deliver firm conclusions that will be accepted by peers. There are four components in planning to implement a research investigation:

### 1. Listing requirements

Making a list of what you require for an investigation is an obvious step. Every investigation will have different requirements but they are all likely to include:

- Material for investigation: patients, blood specimens; animals, cell lines etc.
- Equipment: preparatory, analytical, computing, storage etc.
- Consumables: reagents, laboratory ware, disposal etc.
- Facilities and staff: access to facilities and availability of staff when needed etc.

There is no point in commencing the investigation until everything is to hand.

### 2. Planning for data acquisition and recording

The investigation will generate data. As part of planning it is necessary to define the nature of that data, how it will be acquired and stored.

- Nature of data required: measurements; quantity; units etc.
- Method of data acquisition: manual; automatic; quantitative; qualitative etc.
- Data storage: data store; format; accessibility; flexibility; security etc.

### 3. Planning for the analysis of results, including statistics

Having planned to acquire and store the correct data you should also plan how you are going to analyse it and display the results of the analysis.

- Preparation: table; database, spreadsheet; etc.
- Statistical test; see Table 7.1
- Statistics package
- Presentation: table; figure; chart; plot etc.

### 4. Conducting pilot investigations

Pilot investigations are a useful way to test that the planning has been comprehensive. Pilot investigations also help to confirm that equipment is working and to clarify timing and logistics.

## 7.2. Methods and equipment

The choice of methods will have been planned at the research proposal stage. The suitability and availability of the equipment required to undertake the investigations will have been confirmed as part of planning for the investigation. If possible a pilot investigation will have been performed to assess timing and logistics. The final step before starting the investigation is checking the performance characteristics of the equipment.

Most equipment requires to be calibrated. This means that its performance needs to be compared with an independent standard. A simple example is the calibration of a micro-pipette where the volume of water dispensed can be weighed on a suitable balance, which itself has been calibrated. Other examples of calibration relate to standards of time, temperature, mass, electrical conductivity etc. Calibration is the basis of ensuring an accurate result when the equipment is applied to the test investigation.

In addition to accuracy it is necessary to know the imprecision (uncertainty) of measurement of the equipment used. Using the example of the micro-pipette the imprecision can be calculated by weighing the water dispensed from repeated use of the same pipette. Clearly, the imprecision of measurement should be as small as possible in order to reduce its impact on the difference between test and control. Data from the calibration and assessment of all the equipment to be used in the investigation should be recorded and dated. It is the responsibility of the researcher to obtain this data since it will underpin the results obtained and the conclusions drawn from the investigation.



### 7.3. Conducting research investigations

After all the preparation the time has finally arrived to conduct the research investigation. It is at this stage that the value of that preparation becomes apparent. You have already selected and tested your methods and equipment and you may have been able to conduct a pilot investigation to optimise the test investigation. Therefore, the researcher can proceed with confidence knowing that risks have been minimised. This is important because precious material (e.g. patients or samples) will now be committed to the investigation.

Many research investigations involve repeated measurement, which may only be possible in batches. In such circumstances every effort should be made to reduce inter-batch variability. This can be achieved by meticulous attention to every detail of the procedure. In particular the balance between control and test samples should be the same in every batch. The inclusion of identical control samples in each batch provide the opportunity for objective quality assessment.

### 7.4. Recording research investigations

The recording of a research investigation is a critical part of research governance because this record contains the data that is the evidence arising from the investigation. Record keeping should be timely, systematic and comprehensive because it is possible that an external source may ask to audit the research or examine a specific data set.

The classical way to record investigations is to create a research book. There is an entry for each day of the project in which contains:

- Date and name of researcher
- Detailed study performed
- Raw data from study, including print-out from equipment
- Summary arising from raw data
- Comments
- Signature of researcher

Such a record cannot easily be changed at a later date.

Today most research records are kept in an electronic format, often in a series of files or folders. The same approach should be adopted as for the research book. The advantages of electronic records lie in convenience, the ability to perform data analysis directly from the record, and the ability to back-up the record in the interests of data security. From a research governance perspective the disadvantage of

electronic records may lie in capturing raw data and in the ease with which changes can be made at a later date.

There is no excuse for the researcher who does not keep detailed records. Without the evidence from the investigations there is always the risk that the researcher may be accused of unprofessional practice or even fraud.

### 7.5. Analysing data

Data analysis is a structured process of inspecting, cleaning, and transforming data with the goal of discovering useful information. In effect, this information represents a result from the investigation.

Prior to analysis the required data has been collected and recorded. The next stage is data processing, which may involve transferring the raw data into groups, rows or columns as part of a database or spreadsheet. It may become apparent that the data is incomplete, contain duplicates or errors. The data should be cleaned to remove all invalid data and a record should be kept of the data that was removed and the reasons for removal.

Data transformation entails converting the cleaned data into a form where it can be examined using statistical or other objective methodology. A simple example of data transformation is to convert individual data points from a group study into a mean or median, with confidence limits.

Different analytical techniques may be applied to the transformed data. In medical research the transformed data is usually numeric, lending itself to formal statistical analysis. However, the data from a survey or case study may be qualitative rather than quantitative in which case data analysis may involve pattern identification. Further consideration of the techniques used for data analysis are beyond the scope of this text.

The methodology used to display analysed data is part of the reporting process and is considered in more detail in Chapter 8. It is usual to display the transformed data, together with a confidence limit and the level of statistical significance. Display can be in tables or in a range of figures that include plots and charts.

The timing of data analysis depends on the research methodology. In a clinical trial, especially one that is 'blind' to the researcher no data analysis is possible until the research investigation is complete. Conversely, in basic research it may be possible to perform exploratory data analysis at an earlier stage in order to seek reassurance about the quality of the data collected or the detailed research methodology.



## 7.6. Statistics

A detailed consideration of the use of statistics in medical research is beyond the scope of this short booklet. There are inexpensive specialist texts on medical statistics; most researchers will have access to a statistician for advice or practical assistance; and many academic institutions run courses on statistics for research. Different research questions require different statistical tests and so it is important that the choice of the correct statistical test is made at the planning stage of conducting a research investigation. Planning for statistical analysis will help the researcher to determine both the nature of data to be collected and the quantity of data required to give power to the study so that the statistical analysis may produce a clear outcome.

The importance of statistics becomes apparent when the researcher presents his/her findings to peers or submits a manuscript for publication. The use of inappropriate or invalid statistical methods is easily spotted and can result in dismissal of the research findings.

A simple way to classify statistical tests is shown in Table 7.1. This is based on the text recommended in the References section at the end of this chapter.

**Table 7.1. | Simple classification of statistical tests**

Nature of statistical test	Example of statistical test
Describing data	Percentage; mean; median; standard deviation; coefficient of variation. Parametric or non-parametric
Testing confidence	Confidence intervals; p values
Testing difference	Parametric: t test Non-parametric: Mann-Whitney test Chi-squared test
Comparing risk	Risk; Odds ratio; risk ratio; risk reduction; number needed to treat
Analysing relationships	Correlation; regression
Analysing survival	Kaplan-Meier plots
Analysing clinical investigations	Sensitivity; specificity; predictive value; level of agreement

## 7.7. Drawing conclusions

Once the results of the investigation have been analysed it is time to draw conclusions. This process will be considerably easier if the investigation was planned to include adequate sample size, a suitable control and the testing of a single variable. In such circumstances the results are likely to demonstrate whether there is a statistically significant difference between the test and the control arms of the investigation.

If there is a 'positive' outcome to the investigation it is possible to conclude that there is a significant difference between test and control. However, by itself that finding may not be sufficient to justify the hypothesis that was tested in the investigation. This is because there may be more than one explanation for the positive result. Researchers are often quick to reach conclusions that are beyond their results, especially if the results are in line with their original hypothesis.

To illustrate this dilemma one has only to look to recent literature to find many studies that have demonstrated statistically significant vitamin D deficiency in a range of common chronic diseases. It is possible to conclude that there is a difference but it is not possible to conclude that vitamin D deficiency is the cause of the chronic disease. Indeed it may be that the chronic disease is responsible for the vitamin D deficiency. This cause or effect phenomenon is common in medical research and may prompt the valid conclusion that further research is required to differentiate between the possible explanations for the observed results.

The over-interpretation of results can lead to a high quality investigation being disregarded by peers. The inexperienced researcher would do well to follow a systematic approach to drawing conclusions from his/her results:

- Record the result of the investigation performed
- List all possible explanations for the observed result
- Use scientific knowledge to reduce the number of possible explanations
- Reach a conclusion based on the number of valid explanations that remain
- Discuss the process used to reach the conclusion with your research supervisor or mentor

## 7.8. References

Estieite R. Medical Research Essentials. 2014  
McGraw Hill Education. ISBN 978-0-07-178164-0

Data analysis. Wikipedia.  
[https://en.wikipedia.org/wiki/Data\\_analysis](https://en.wikipedia.org/wiki/Data_analysis)

Harris M, Taylor G. Medical Statistics Made Easy 3<sup>rd</sup> Edition 2014.  
Scion Publishing Ltd. ISBN-13: 978-1907904035

# Writing research papers for publication



## 8.1 Why publish your research results?

No job is finished until the paperwork is done. Thus, scientific work is doing its job only when it is published. A published research work will serve several objectives:

- As evidence that a research work has actually been conducted and accomplished.
- Providing confidence that the work is able to pass the scrutinised process by peer-reviewers.
- As information and resource to other researchers in the field.
- As way of obtaining external awards, as being cited by other researchers, getting attention of sponsors for further studies or post-doctoral positions, etc.
- As credit points to support your career. Although important, this should not be the main objective of publishing a paper, as you may tend to contribute information, which is not quite meaningful.
- As way of obtaining research grants. A good publication track record is a must-have requirement when applying research grants.
- As way of obtaining additional income. If your research is purchased after being published, this may serve not just recognition but also financial benefit.
- Of foremost importance, your motivation for publication shall be to make a meaningful contribution to the understanding and development of research in your field.

## 8.2. Initial preparation

Some tools can be recommended for writing a manuscript. For example, collaborative editing of documents online is possible with tools such as Google Docs, Google Drive

or Dropbox. The use of track changes helps this editing process. It is also suggested to use electronic reference software. Nowadays, open source software can be easily downloaded and used (for further explanation, go to Section 8.8).

Besides preparing tools for the authors in writing the manuscript, it is also necessary to decide a suitable journal as a target for the submission. Although the best journal with the highest impact factor or the greatest prestige is a common desire of most authors, other journals with good readership and reputation can possibly be a more realistic target. Basically a target journal should be selected, so that the proper writing style for the manuscript can be started. Information related to "Instructions for Authors" or "Author's Guideline" should be obtained, understood and complied with (for further explanation, go to Section 8.6). Mistakes will prolong the reviewing process. The common mistakes are failure to fulfill at least one requirement as described in the Instruction for Authors or the detailed checklist of manuscript preparation, which occurs to about one third of submitted papers.

## 8.3. Choosing the most suitable journal

The easiest way to publish your work is self-publishing your paper online. This is not just the easiest but also the cheapest way as it is absolutely zero cost. Several preprint servers are available for this like *arXiv* or *Nature Precedings*. However, recognition for your work by other scientists in the field will be minimal as the self-publishing submission does not have a filtering process by experts in the field.

Therefore, a peer-reviewed journal, is still considered the most legitimate way of publishing research works as it has the process of going through the eyes of the experts in the field. Most peer-reviewed journals are recognized publications, and the community members of a certain research field usually know many, if not all, the other major players in the field.

Considerations for choosing the most suitable publication for your research work include:

- Scope of the journal: It is important to choose a journal, which covers works of other scientists related to your area of research. You may not want your paper to be published in a journal of which the readers do not appreciate the contents of your research work. Moreover, your paper may also be subject to rejection by the editors.
- Language used: English would be the language of choice. Journals using local languages, which are not considered one of the major international languages, are less likely to be quoted by other scientists. The less quoted, the less your work is recognised.



- Credibility of the journal: is it frequently cited by other publications; does it have credible editors and reviewers?
- Length of process starting from submission of paper until actual publishing. This is perhaps the major drawback of submitting to a peer-reviewed journal: it may take more than a year until it is actually published.

## 8.4. Authorship

Authorship of a research publication may be a sensitive issue and so should be addressed clearly. The authors included and the order of appearance should be decided based on the contribution of each author. The International Committee of Medical Journal Editors recommends the following four criteria for eligibility as an author:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## 8.5. The process of submitting research work to a journal

After choosing the most suitable journal to your research subject, you should:

- Read the "Instructions for Authors" part of the journal, as you would not want to find yourself spending your time submitting your work only to be rejected because you did not pay enough attention to the requirements of the editors. Specific requirements like layout, font type, length of article, process of submission, *etc.*, are usually part of such instruction. Failure to comply with the journal's requirements is the most common reason a paper gets rejected by the editors.
- Prepare the draft manuscript (Section 8.6), share it with co-authors and edit to accommodate their feedback.
- Ask one or more colleagues and/or professors to review your research paper before submitting. They may find matters, which you missed like spelling errors, typographical errors, clarity of writing, conciseness, *etc.*
- Make a final check on content and presentation.
- Submit the paper. Be sure to use the right channel or address. While we are now in the digital era, some editors may still require printed copies.

## 8.6. Content and preparation of a manuscript

All journals have their specific instruction, which every author should follow. In general, however, all manuscripts contain the following sections:

### 1. Title and abstract

The title should be concise and descriptive. It has to be self-explanatory and create interest in the manuscript. Potential readers will find the article by scanning through lists of titles. Therefore, your title should be attractive enough to gain readers' attention. The title should include keywords listed in the manuscript. Generally, the title is best left for last when writing a paper. After the abstract and keywords are written, it is easier to develop a title.

The abstract reflects an overview of your manuscript, highlighting the major findings and conclusions. An abstract provides the first impression and influence to the editor to consider the submitted manuscript. It also provides the first impression and influence to the reviewer during the reviewing process. Therefore, the abstract should attract the readers to go further. Poorly written abstracts will likely diminish readers' interest in the work. Abstracts may be structured or unstructured, but should be written concisely without references and should never exceed the allowed number of words.

### 2. Introduction

The introduction should be brief and informative, describing the background of the subject matter reported in the paper; the rationale for the study; and the aim/hypothesis of study described. A crisp introduction is an essential ingredient of a good paper. Therefore, the introduction should tell what is known and what is unknown. The introduction should review and reference previously reported research but should not include data or conclusions from the research being reported.

### 3. Methods

The methods section should contain enough information to allow readers to understand the way in which the research was performed; to evaluate the findings, and to compare the study results with other published studies. The section should describe both experimental and statistical methods. The level of detail should be sufficient to enable others to reproduce the work described. Detailed descriptions of already published methods may be referenced. When preparing the manuscript it may be convenient to write the methods section after the results section to ensure that all relevant methods are included.

### 4. Results

The results section should be presented in the most concise format possible to provide



a clear description of the experimental findings without interpretation. Research data should be presented, processed and analysed, including statistical analysis where appropriate. Figures and tables are valuable tools to support data presentation and should be arranged in a logical sequence to support the descriptive text. The results section is the core of the research manuscript and many authors find it helpful to write this section before the supporting sections.

## 5. Discussion

The discussion section should start by stating the strength of the study and its major findings. The interpretations of results and the significance of the reported findings can be compared to other published data. Data should not be repeated in this section. Data should not be over-interpreted and the limitations of the study should be articulated. At the end of the paragraph, a conclusion should be provided to tell the significance of the study and its potential impact in the related field. In laboratory medicine there is usually a clinical context for the conclusion.

## 6. References

The references section is important because it defines the previously published research that you have used to design your research project, interpret the results, draw conclusions and put into clinical context. All journals define the way in which references should be presented, usually in accordance with international convention. Only key references should be listed.

## 8.7 Electronic reference management

Technology has made it possible for researchers to save, retrieve and quote references related to their publications in a simple manner. Several 'reference managers' or 'citation managers' are available free on the internet. The choice for each researcher may depend on individual preferences. Most also provide features for researchers' social media, which allows sharing of references between researchers or even formation of a collaboration between a peer group of researchers or a public group. Tutorials are also available on the internet to familiarise oneself with the major reference managers

In general, the reference managers enable the researcher to:

- Keep and store across devices, search and sort references, documents and notes in one place, down to the keyword.
- Tailor citation and bibliographies according to individual needs.
- Share and collaborate. This can be performed for either public or private sharing of reading lists, references or even full-text articles. Collaboration in writing a manuscript is often possible using these applications.

- Showcase a work.
- Keep statistics of your work: who, when, from where, how frequent are your papers cited or downloaded.
- Trace researchers and activities of other researchers on the same subject.

Below are some applications available on the internet, which can be downloaded free:

- Mendeley ([www.mendeley.com](http://www.mendeley.com))
- Zotero ([www.zotero.org](http://www.zotero.org))
- EndNote basic (<http://endnote.com/product-details/basic>)
- Docear ([www.docear.org](http://www.docear.org))
- ProQuest Flow (<https://flow.proquest.com/>)

## 8.8. Ethical considerations

Ethical violation in medical research is not uncommon, including in research publication. Researchers need to pay attention in order not to expose themselves to accusations of unethical conduct, which may damage an author's integrity. References to ethics in medical publishing can be found either in the form of books or articles.

Kerstin Stenius classifies ethical issues into seven categories:

Carelessness: citation bias, understatement, negligence.

Redundant publication: same tables or literature review reports without noting prior source.

Unfair authorship: failure to include eligible authors.

Undeclared conflict of interest: failure to cite funding source.

Human/animal subjects violations: no approval from Review Board or Ethics Committee

Plagiarism: reproducing others' work or ideas without citing the original source.

Other frauds: fabrication or falsification of data, misappropriation of others ideas or plans given in confidence.

## 8.9. The review process

Manuscripts are seldom accepted after initial submission. Most of the time, the author will be asked to make revisions based on the comments of referees. The editor may ask you to revise your paper, but as long as there is no statement of clear rejection, then it is always a positive review. Respond precisely and constructively to the requirements of the editor, although you are the one who knows most about your research work. Even if the journal finally still rejects your paper, you can still submit your work to other publications.



## 8.10 References:

Bavdekar SB. Authorship issues. Lung India 2012; 29:76-80

Binder R, Friedli A, Fuentes-Afflick E. The new academic environment and faculty misconduct. 2015; Acad. Med. [Epub ahead of print] doi:10.1097/ACM.0000000000000956

Boyd JC, Rifai N, Annesley TM. Preparation of manuscripts for publication: Improving your chances for success. Clin Chem 2009; 55: 1259-1264

Cook DA. Twelve tips for getting your manuscript published. Med Teach 2015; 38: 41-50

Derntl M. Basics of research paper writing and publishing. Int. J. Technology Enhanced Learning. 2014; 6: 105-123

Jha KN. How to write articles that get published. J Clin Diagn Res 2014; 8: XG01-XG03

Members of the ICMJE. 2013. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. <http://www.icmje.org/icmje-recommendations.pdf>

Stenius K. Workshop on scientific integrity and ethical issues in publishing. AIDS 2010: Slide of the XVIII International AIDS Conference 2010 July 18-23, Vienna, Austria. [https://www.iasociety.org/Web/WebContent/File/AIDS2010\\_Scientific\\_Integrity\\_Workshop\\_presentation.pdf](https://www.iasociety.org/Web/WebContent/File/AIDS2010_Scientific_Integrity_Workshop_presentation.pdf)

# Delivering research findings as oral or poster presentations

## 9.1. Introduction

Presentations at scientific meetings are formal and one should keep in mind that you are not presenting to novices on the subject, but rather to a group of very well informed experts, who are really interested in the new knowledge that they can gain from your presentation. Poster presentations at scientific meetings are more informal, though one should keep in mind that the audience remains the same.

The fact that the audience is well informed experts should however never discourage any young scientist to present at scientific meetings, as most well balanced good scientists of stature will also use the opportunity at scientific meetings to positively criticise and build the self-esteem of a young researcher rather than breaking them down. You should keep in mind, however, that all of this will happen with the unspoken golden rule that science is much bigger than any scientist and that the value of solid good scientific argumentation and facts are not negotiable.

Normally all scientific presentations should have the basic structure of scientific documentation and very strict time limitations will regulate the extent of discussion of each of these subheadings. It is however not necessary to guide the audience every time exactly as to which subheading will be discussed next. Remember the most important part of any scientific presentation that is based on research is the results and the discussion of the results.

## 9.2. Oral presentations

### GENERAL GUIDELINES

The following guidelines will ensure that a scientific presentation conveys the correct image of professionalism, thoroughness and scientific accuracy:

- Professional appearance – wear the right clothes (neat, formal, comfortable)
- Art of communication – it is important to be able to communicate effectively with your audience. Things to take into account include; self-image, voice enhancement, enthusiasm, pausing and even a bit of dramatising can help break the boring monotony of a scientific presentation.
- Knowledge of the podium and the facilities in the lecture hall enables the presenter to make use and control all of these facilities in order to support the presentation optimally.
- Do not put all the text on the screen and read it off. Neither should you read all the text from a piece of paper. Recognise the audience. Make use of a pointer whilst presenting the material to the audience.
- Always ensure that the support material is of exceptional quality. Refer to the 'do's and don'ts' of PowerPoint presentations below.
- Don't use irrelevant support material e.g. include photos of your wildlife photography or your family/pet.
- Don't ever be apologetic – this refers to anything even if you have a cold.
- Refrain from irritating manners/habits – do not use excessive hand signs, don't move around so much that it is disturbing, don't use wavering introductory words such as uh, now etc.
- When you have a graph on a slide, explain the axes and indicate what you are talking about.
- Stick to the time limitation. A rule of thumb is that 1 minute should be allocated per slide (excludes title slide and thank you slide)
- Before presenting practice, practice, practice. Be sure you can pronounce unfamiliar words.
- If possible project your presentation in a large room to see that colours project as they should. Use the speakers preview room to see that formatting did not change. Check compatibility between Mac and other word processors.
- If the Chairperson introduces you and gives the title of your presentation -do not repeat.

Make sure you have two copies of your talk or email it to yourself or place it in Dropbox so that you do not get the nasty surprise of your talk vanishing.



## POWERPOINT GUIDELINES

- Show data numbers prominently.
- Framing of graphs is not recommended as too many lines are confusing.
- Use lower case lettering: reads faster and takes up less space.
- Titles should preferably be placed on the left, rather than in the middle, because our eyes are accustomed to read from left to right.
- Use only one background colour throughout the presentation.
- Use the same font size for headings on different slides. Good size for headings is 32 and rest of the text 24. Too small text is unreadable.
- Use a font that is plain and will reflect clearly e.g. Arial/Arial narrow.
- Make sure that the contrast between the background and the text colour is good – use dark colours on a light background and light colours on a dark background.
- Place all the headings and text parts on the same height.
- Preferably do not use red and green together as colour blind people will not be able to read the writing.
- Rule of thumb is 5 lines, each with 5 words per slide. Do not have full sentences.
- Include a slide with an appropriate picture or graph for every 5<sup>th</sup> slide.
- Make use of pictures, graphs, flow charts etc. rather than text and numbers to help tell the story.
- Beware of setting a fixed time to slide before it automatically goes on. If there is a glitch it could lead to problems.
- Condition the audience by using the same colour on graphs for a specific analyte i.e. colour is associated to a certain parameter.

## PRESENTATION OF DIFFERENT DATA TYPES ON SLIDES

- *Text*: the design of a text slide should be simple. Use key words
- *Table*: these are usually very busy, thus highlight numbers of importance
- *Bar charts*: ideal to compare statistical data. Stacked bar charts indicate percentage composition.
- *Line graphs*: it is excellently suitable for dynamic comparisons and therefore may be used to indicate a tendency of change over a specific time period or what the relationship between variables is.
- *Pie charts*: is normally very easy to understand, excellent for presentation of relative values and composition.
- *Scatter charts*: indicates distribution of values.
- *Area charts*: express proportional representation, it is often used to indicate and

interpret statistical differences as well.

- *Clip art*: can express feelings, attitudes, and experiences.
- *Maps*: are used to indicate distribution, location, etc. Good for epidemiological data.
- *Photos*: provides three dimensional images, clinical photos, microscope photos. See that the enlargement is provided. All photos should be presented and taken at the same magnification.
- *Moving images/Videos/internet*: make sure that it works.

## THE TEN RULES FOR MAKING GOOD PRESENTATIONS

- 1. Talk to the audience:** The presenter should know the level of the audience – conference covering a specific topic in an area i.e. presenting to experts in the field who are familiar with the terminology and latest developments vs presenting to an entire pathology group where many only have limited knowledge and therefore the talk will be more basic initially so as to introduce them to the field.
- 2. Less is more:** If the presenter says too much the main message may be lost.
- 3. Only talk when you have something to say:** If you only have preliminary data, do not put in an abstract for an oral presentation but rather opt for a poster. Be sure you have a substantial amount of data that is meaningful. Work that has recently been published or is submitted for publication is usually a good choice.
- 4. Make the take-home message pertinent:** If you were to ask someone a week later what you presented, they should remember three points. If it is not the key points, your emphasis was wrong.
- 5. Be logical:** There should be a flow throughout the talk. The beginning (introduction) is to set the stage; the story is told in the middle; and the end is the big finish with the take home message.
- 6. Treat the floor as a stage:** Presentations should be entertaining but not overdone. If you are not humorous by nature, do not try to be so as it would not work.
- 7. Practice and time your presentation:** Don't go off on a tangent, visual cues should be used to help. The more presentations you give the better you will get.
- 8. Use visuals sparingly but effectively:** Visuals should support what you are saying.
- 9. Review audio and/or videos of your presentations:** These can give problems.
- 10. Provide appropriate acknowledgements:** Can use logos if too many.

Remember that it takes the audience 15 seconds to decide whether your presentation is worth their attention.

## BEFORE PRESENTING

- Introduce yourself to the chair. Provide additional information required e.g. biography, how to pronounce surname before the session starts.



- Make sure that your talk is loaded in the timeslot provided.
- Be on time and stay the entire session.
- Respect the chair's time cues.
- If you do not understand a question, ask for it to be repeated.

### 9.3. Poster presentations

Scientific posters normally contain the same structural layout that one will find with any scientific document. A number of important facts should be considered when planning a poster:

- Selection of information
- Amount of information
- Organisation of content
- Integration of visual elements
- Creation of focus points
- Correct relationship of elements
- Visual acceptance and acceptability

#### POSTER TIPS

- The title is important as it catches the eye first.
- Play around with the layout until it pleases your eye. There is no incorrect layout.
- A poster with a background (not overpowering) will attract more attention than a plain one.
- Check that there are no spelling mistakes.
- Avoid cramming the poster with too much text and Figures/Tables.
- Do not simply make an enlargement of your abstract that was submitted.
- See to it that you put your poster up and keep it up for the scheduled duration.
- Be at your poster during poster viewing times.
- If you decide not to attend the conference withdraw your poster in a timely manner.

A poster presentation should basically include the formal scientific part on the poster itself and whilst you are presenting you should discuss and present your data in a relaxed scientific manner.

Good luck with your presentation!

### 9.4. References

Bourne PE. Ten simple rules for making good oral presentations. PLoS Computational Biology 2007; 3: 593-594.

Erren TC, Bourne PE. Ten simple rules for a good poster presentation. PLoS Computational Biology 2007; 3: 777-7778.

Jadoul M. Ten ways to ruin or market your oral scientific communication. Nephrol Dial Transplant 2001; 16: 2119-2123.

# Auditing research and planning for the future

## 10.1. What is audit?

Audit is a process used to assess the performance of a function or service by comparing it with set criteria. Most people are familiar with financial audit but clinical audit is an essential element of modern healthcare.

A short definition of clinical audit: is 'improving the quality of patient care by looking at current practice and modifying it where necessary'. A more comprehensive definition comes from the UK National Institute for Health and Clinical Excellence:

'Clinical audit is 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.'

Clinical audit can take many forms in modern healthcare. Examples include:

- Assessing facilities for patients compared to guidelines
- Comparing clinical outcomes against national standards
- Comparing patient treatment times against local targets
- Assessing performance against local quality management standards

In laboratory medicine audit is central to quality management. Laboratory accreditation against the international standard ISO 15189:2012 requires laboratory management to define standard operating procedures and performance standards for all laboratory functions. Evidence of compliance with those procedures and standards is obtained by a planned series of audits undertaken by individuals not directly involved in the specific procedure or standard.

The components of audit are:

- Identifying the topic to be audited
- Defining the standards against which the audit will be performed
- Collecting data
- Data analysis to compare performance with standards
- Applying change
- Review impact of change

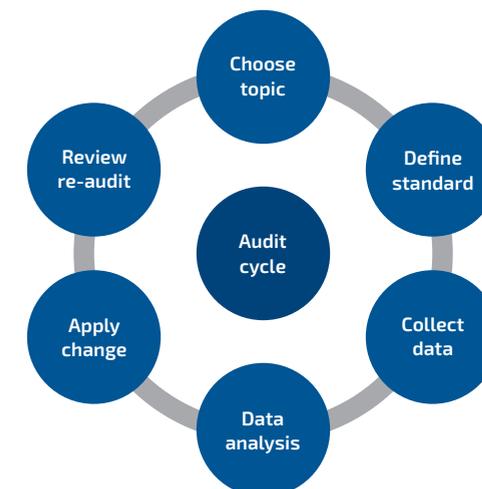
To be of value the audit cycle should be closed, which means reviewing the audit once change has been implemented to confirm that it has addressed the original topic. Therefore, audit may be considered as a continuous rather than a 'one-off' process.

Together these components constitute the well-known audit cycle, depicted in Figure 10.1.

## 10.2. Auditing research

New researchers may often be confused by the difference between research and audit. As a result it is fairly common for a medical student to think that he/she is doing research when he/she is performing a clinical audit. This is because the process involved in research and audit is similar. However, the fundamentals of research and audit differ as may be seen from the statement that: 'Research is concerned with discovering the right thing to do; audit with ensuring that it is done right'. The main differences between research and audit are recorded in Table 10.1.

Figure 10.1. | The audit cycle



**Table 10.1. | Fundamental differences between research and clinical audit**

Research	Clinical audit
Based on hypotheses; creates new knowledge	Based on facts, which form the standards for the audit
Involves novel approaches to problem solving	Involves the application of standard techniques to data
Must comply with research governance, including research ethics	Should be registered with the local clinical audit committee

This section deals with the application of audit techniques to a research project. The application of audit to research is a logical and helpful way to assess the effectiveness of a research project. Auditing research facilitates the optimal use of precious resources and allows for modifications in the project that will help to improve outcomes within the parameters of the original aims and objectives. It is the aims and objectives that form the criteria against which the audit is performed.

To be of value audit of a research project should not be left until the end of the project. At that stage it is too late to realise that one or more aims and objectives have not been met by the investigations performed. There are no hard and fast rules for the timing of audit in a research project but it is logical to perform an audit of performance against an objective when the investigations performed in support of that objective are complete or at an advanced stage. With this approach the general audit cycle may be modified to apply to research audit as depicted in Figure 10.2.

Another consideration to add value to audit of a research project is the involvement of someone other than the primary researcher. For a new researcher it is appropriate for the research supervisor to lead the audit. For a more experienced researcher this is a role for the research mentor.

**Figure 10.2. | Auditing research**



### 10.3. Recording and analysing audit findings

The use of a template is recommended for recording and analysing the findings of audit of a research project. A completed template serves as a record of the audit, which can be held both by the researcher and the person who led the audit. The template can also be used to reassure the employing authority and/or the grant awarding body that the research project is being conducted under good standards of research governance.

There are many variations of template available and researchers may be advised to adopt the template that is preferred locally. Table 10.2 sets out a simple template that can be adapted for any research project. One benefit of the template in Table 10.2 is that it allows for updating following review and re-audit, effectively closing the link. Some research institutions may like to see completed audit templates signed to indicate acceptance of the findings.



**Table 10.2. | Simple template for recording audit of a research project**

<b>Title of research project:</b> [ ]
<b>Date of audit:</b> [ ]
<b>Who was involved in the audit?</b> (List of people including designation) [ ]
<b>Research objective being audited:</b> (This should include a brief description of the reason for selecting the topic) [ ]
<b>Criteria:</b> (This section identifies the aspects which you are going to measure and should be clearly defined) [ ]
<b>Analysis and findings:</b> (This section should outline the level of compliance achieved against the objective and if full compliance not achieved an explanation of why. What was learnt from the data collection?) [ ]
<b>Conclusions and reflections from the audit:</b> (What changes are needed? How will changes be implemented; who will do this and when?) [ ]
<b>Re-audit date:</b> (Suggest appropriate time period for evaluating impact of any change) [ ]
<b>Re-audit findings:</b> (The re-audit report should include the date of second data collection, the Standard achieved and whether further action is required) [ ]

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- A basic research finding that opens up a pathway or mechanism that influences understanding of pathophysiology
- The application of basic research findings to a clinical research project
- Evidence from a clinical research project that can be translated into routine clinical practice
- The opportunity to introduce a new method into the Laboratory Medicine repertoire
- Evidence from an epidemiological research project that prompts a hypothesis to explain a particular association

If the research project matches any of these examples then the researcher may wish to plan for one or more follow-up research projects. Such follow-up projects will involve new research questions and may involve new research collaborators.

Researchers should consider a systematic approach to planning for future research. One way to do this is to modify the cycle and the template adopted for auditing research so that they are applied to review of the original research question. Examples of how this may be achieved are recorded in Figure 10.3 and Table 10.3.

Planning future follow-on research takes the researcher back to earlier in this booklet (Figure 1.1) as he/she will be involved in:

- Reading and evaluating the scientific literature (Chapter 4)
- Formulating a research plan (Chapter 5)
- Submitting a research proposal for external approval and funding (Chapter 6)
- Conducting research investigations and analysing findings (Chapter 7)
- Writing research papers for publication (Chapter 8)
- Delivering research findings as posters or oral communications (Chapter 9)
- Auditing research and planning for the future (Chapter 10)

### 10.4. Planning for the future

The appeal and excitement of research to most scientists lies partly in the satisfaction of proving a hypothesis that may help improve patient care, and partly in the unpredictable nature of research. Even the most tightly designed and controlled research projects are capable of throwing up unexpected results, which stimulate further research questions. It is rare for a research project to finish without the researcher being stimulated to consider 'what happens next?'

Examples of how a successful research outcome in laboratory medicine may stimulate further research questions include:

**Figure 10.3. | Planning future research**



**Table 10.3. | Simple template for identifying follow-up research**

<b>Title of research project:</b> _____
<b>Date of final review:</b> _____
<b>Who was involved in the final review?</b> (List of people including designation) _____
<b>Research question being reviewed:</b> (This should include a brief description of the reason for selecting the topic) _____
<b>Criteria for review:</b> (This section identifies the aspects which you are going to measure and should be clearly defined) _____
<b>Analysis and findings:</b> (This section should outline the level of compliance achieved against the research question. What was learnt from the data collection?) _____
<b>Conclusions and reflections from the review:</b> (What has been achieved? What unanswered questions remain?) _____
<b>Suggested areas for follow-up research:</b> (Suggest preparation required) _____

## 10.5. The final report

Many research funding bodies require a formal report at the end of the project. This report is evaluated to determine the outcomes for the project and whether they delivered value for money. The structure and format of this final report will vary according to the funding body and the researcher should ensure strict compliance. Writing the final report will be easier if the project has been audited as suggested in this Chapter.

## 10.6. References

Burgess R, Moorhead J. New principles for best practice in clinical audit. 2011 CRC Press; 2nd revised edition

Clinical audit explained. NHS Clinical Audit, Effectiveness and Research.  
<http://www.clinical-audit.org.uk>

Clinical audit. Wikipedia.  
[https://en.wikipedia.org/wiki/Clinical\\_audit](https://en.wikipedia.org/wiki/Clinical_audit)

Audit vs research, Guidelines and Audit Implementation Network.  
<http://www.gain-ni.org/index.php/resources/clinical-audit/auditvsresearch>





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