# Why is research in laboratory medicine important?

# 2.1. What is medical research?

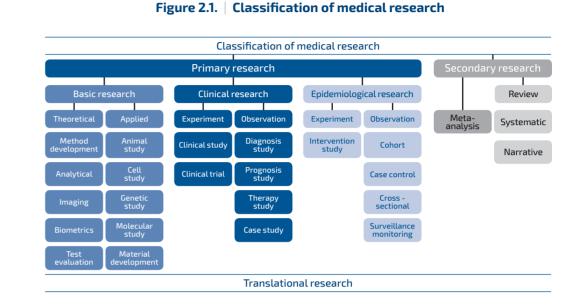
There is no universal definition of medical research. A simple and convenient way to think of medical research is as 'the acquisition and application of knowledge in the field of human medicine'.

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.



# 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

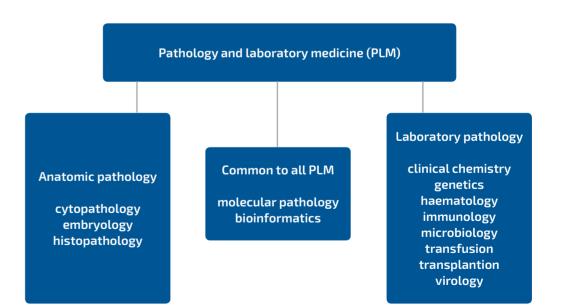
## **TRANSLATIONAL RESEARCH**

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

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- 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

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