



Best practice guidelines

WASP (Write a Scientific Paper): The role of the pathology department in clinical research

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ABSTRACT

The pathology laboratory is the hub of investigatory medical care, and constitutes an invaluable asset for clinical research. A number of disciplines fall under the cap of a pathology laboratory. Researchers may gain access to such services provided ethical and laboratory administrative permissions have been granted. While establishing the research budget it is essential to have a clear understanding of what goes on behind the path lab curtains as this may impinge on what can and cannot be done, financially and otherwise. Indeed, the process is far more complex than just handing a specimen and obtaining the respective result. Infrastructure, material and human resources need to be quantified and their respective costing identified. Liaison with the laboratory section personnel facilitates the smooth provision of service and research outcomes.

1. Introduction

Pathology is defined by the Oxford dictionary as “*the science of the causes and effects of diseases, especially the branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic or forensic purposes*” [1]. The pathology laboratory is the hub of investigatory medical care and an invaluable asset for clinical research. The laboratory can provide a number of valuable investigative information, from a basic routine test result to a more complex histological result. This information may be used for any type of research, provided ethical and administrative permissions have been granted. In fact, whether a surgical team is conducting a case study on a patient with an abnormal histological tissue finding, or whether an endocrinologist wishes to evaluate the glucose regulatory trend of all registered diabetic patients, or whether an epidemiologist wishes to conduct a health examination survey, all would require assistance and active input from the path lab. Therefore having an understanding of the services provided and ‘what goes behind the scenes’ of the pathology laboratory is a must prior to conducting any kind of investigatory clinical research.

2. Services provided by the pathology laboratory

A number of disciplines fall under the cap of a pathology laboratory.

1. **Cellular pathology:** examines tissue specimens from patients which were either surgically removed during an operation or during a post-mortem examination [2].
2. **Clinical chemistry:** analyses body fluids (such as blood, urine) for diagnostic and therapeutic purposes [3].
3. **Haematology:** provides routine and urgent automated blood counting and morphological profiling as well as coagulation screening [4].
4. **Medical Microbiology:** provides diagnostic bacteriology, mycology, parasitology, virology and mycobacteriology testing [5].
5. **Molecular diagnostics:** analyses biological markers (genome and proteome) to diagnose a disease, predict disease course and enable selection of treatments as well as monitor effectiveness of therapies [6]. The range of molecular diagnostics will vary from one laboratory to another.
6. **Transfusion medicine:** performs blood grouping, antibody screening and blood/blood products provision [4].
7. **Genetics:** provides molecular genetic testing. The range of genetic testing will also vary from one laboratory to another.
8. **Immunology:** provides diagnostic immunology testing which may include: autoimmunity, allergy serology, immunodeficiency, neuroimmunology, immunochemistry and infectious immunology [7]. The range of immunology testing will similarly vary from one laboratory to another.
9. **Emergency services:** a number of diagnostic testing can be

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provided out of normal working hours due to emergency scenarios. These tests might include: full blood count, coagulation screening (INR and partial thromboplastin time), and cross match for blood transfusion, amongst others.

3. Utilizing the pathology laboratory for research purposes

Research is the bread and butter of a number of individuals from different sectors of medicine, as well as a requirement to achieve certain undergraduate and postgraduate degrees. Most clinical research requires a number of laboratory tests for quantitative analysis. However, unless the researcher has access to the required technology to perform the clinical tests himself/herself, the already established hospital pathology laboratory will need to be used. It is thus essential for the researcher to identify the procedure pathway and protocols that enable this. Although different pathology departments will have different procedures and protocols, the basic principles are the same, as discussed below. Due to various constraints, pathology departments may only accept research studies that have a positive cost-utility analysis, or are of scientific interest leading to eventual patient benefit.

The researcher needs to have a research proposal accepted by an institute or authority, with the corresponding ethical approval before approaching the pathology department administration. It is essential for the researcher to understand that there is more than just handing out a specimen sample to the laboratory and getting its respective result. A number of 'hidden' administrative procedures and laboratory occur before such a result is achievable. The researcher should therefore enquire about these procedures and incorporate them into the research budget. Costs that need to be covered include, but are not limited to:

- Infrastructure resources (use of premises, utilities etc.)
- Actual material resources (kits, equipment etc.)
- Human resources (hours dedicated by laboratory staff to research)

Specific forms and procedures may be available to which the researcher needs to adhere. These forms will require the name and number of tests that the researcher is requesting to be performed at the laboratory. It is essential that the researcher establishes an estimate of the total number of tests to be conducted. This is important for the administrative management so as to estimate the resources (such as reagent kits, human resources hours) required for the research study. Bench fees along with consumable costs and human resources costs may be applicable for any research study to be conducted at the pathology department. These should all be included as part of the research budget.

4. Conclusion

The researcher needs to acknowledge the role of the laboratory service as an integral component of the research proposal as well as to budget the respective costing. Establishing permission to utilize such service while adhering to the procedures and protocols is essential. Liaison with the laboratory section personnel is required to ensure smooth provision of service, which includes appropriate notification of samples to be sent to the laboratory and appropriate identification of such specimens.

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The inspiration for this series of papers arises from the international Write a Scientific Paper course (WASP - <http://www.ithams.com/wasp>) [8,9]. Indeed, all of the topics in the papers in this WASP Best Practice Guideline series are discussed in the WASP course.

Conflict of interest statement

There are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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