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ROLE OF LABORATORY SERVICES IN RESEARCH– AN EXPERIENCE SHARING

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ABSTRACT

Diagnostic Laboratories in a hospital perform a range of tests which supports diagnosis and treatment. Laboratory data provides enormous potential for research. Laboratory professionals help with research from interpretation of clinical data to the analysis of structure and function of even the newly discovered proteins. This retrospective observational study looks for the involvement and role of laboratory data in research projects submitted for review by the Institutional Human Ethics Committee (IHEC) for the past one year. The involvement of diagnostic laboratory services in research projects approved by the Institutional human Ethics committee, during the Oct'2012- Sep'2013 was collected using a standard proforma. The data was analysed statistically.The results indicated that less than 30% of the research projected submitted to IHEC had involved the services of diagnostic laboratories. 74% of these studies were observational. It was also observed that the usage of clinical biochemistry laboratory predominates over other disciplines. However the special investigations were rarely utilized. Research projects in diagnostic departments have primarily used their own laboratory services. An awareness programme among the investigators about the diagnostic facilities available at the institution will enhance the researchers to expand their research for comprehensive utilization of diagnostic services.

INTRODUCTION

Laboratory diagnosis has a visible place at all levels of healthcare & research, dominated by medical biochemistry activity. In recent decades, the role of laboratory professionals has undergone a radical change, which calls for their importance in standardization & accuracy in interpretation of test results[1, 2]. Extensive coordination and cooperation between the laboratory professionals and the clinicians would help to improve the quality of research in terms of selection of tests and to introduce special investigations[3]. This study was aimed at analyzing the role of laboratory services in carrying out successful research projects and to our best of knowledge this is first of its kind in India and this will reveal the importance of laboratory services in carrying out research projects.

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Objectives

To study the role of laboratory services in the research projects approved by the IHEC.

To find out areas lacking usage of laboratory services for research & to improve the effective usage of laboratory services.

METHODOLOGY

This is a descriptive study. The use of diagnostic laboratory services in research projects approved by the Institutional human Ethics committee, during the Oct'2012- Sep'2013 was collected using a standard proforma by the investigators (1-3) who are IHEC members & the anonymised raw data was analysed by the investigator number 4 who is a non-IHEC member.

Inclusion criteria

Research projects involving diagnostic laboratory services.

Exclusion criteria

Research projects which did not have completedocumentation.

The data was analyzed statistically.

RESULTS

The results indicated that less than 30% of the research projected submitted to IHEC had involved the services of diagnostic laboratories. During the specified period about 100 proposals have utilized the laboratory services out of which 74% were observational studies, 21% were case reports, 5% were interventional studies (Figure 1).

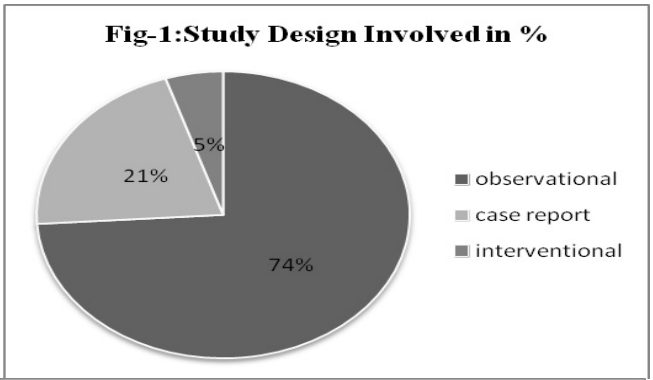
Among laboratory services the principal discipline utilized was clinical Biochemistry (49.8%), followed by Pathology (28.3%) which included clinical pathology, haematology, histopathology as well as cytopathology sections and Microbiology (21.9%) which included clinical microbiology as well as serology sections (Figure 2).

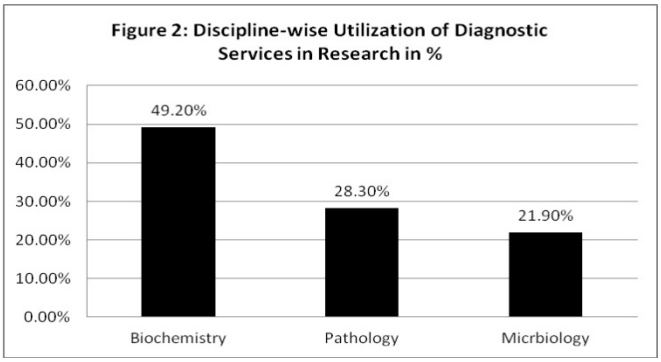
Among the pre and para clinical departments, the microbiology department has utilized the maximum percentage (23%) of laboratory services in the research projects undertaken (Figure 3) and the community medicine department has made minimum usage. However most of the microbiology projects are confined to microbiology laboratory.

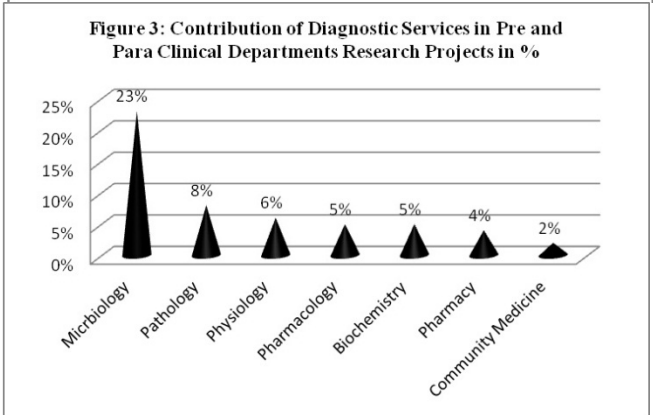
Among the clinical departments, considerable proportion of research projects undertaken by general medicine, obstetrics and gynecology, pediatrics, dermatology, general surgery and nephrology had utilized diagnostic laboratory services (Figure 4).

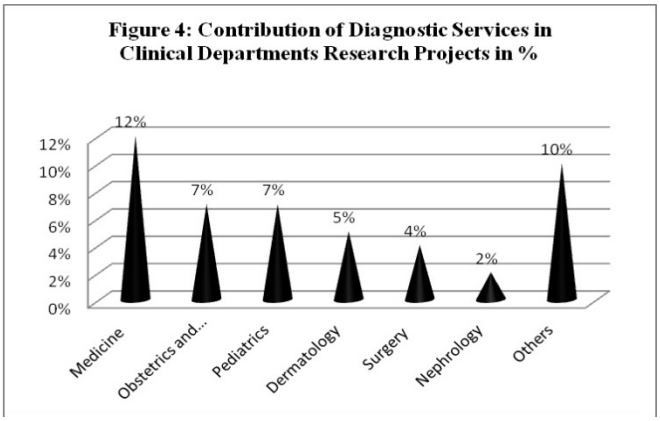
In clinical biochemistry, utilization of routine tests was found to be higher than special investigations. In pathology, clinical pathology section was utilized highest followed by histopathology and cytopathology. (Table1).
Majority of the projects which had used microbiology laboratory services, have utilized bacteriology lab service (75%) than others sections (Table 2).

Among the laboratory departments, intra departmental service utilization was found to be highest with microbiology. The studies involving inter departmental activities had utilized biochemsitry in highest proportion (92%) (Figure 5).









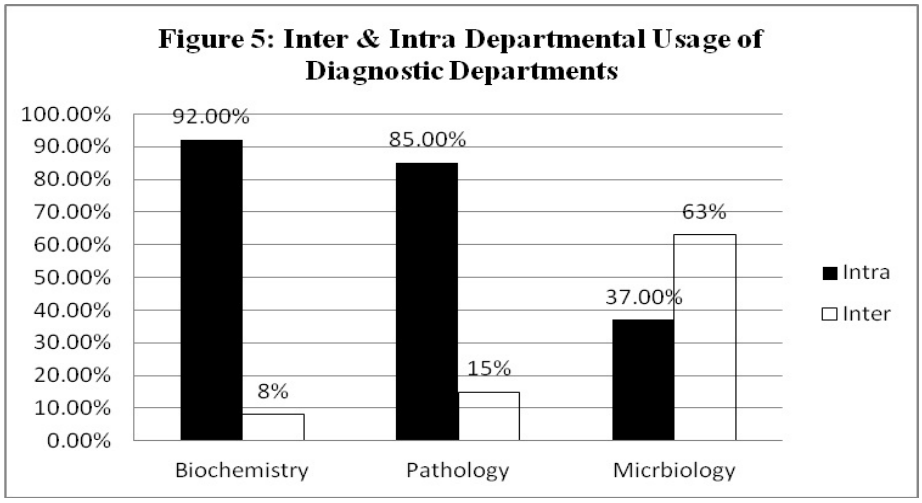


Table 1. Section-wise utilization of Biochemistry and Pathology Departments

Biochemistry Department	
Special	24.57%
Routine	75.42%
Pathology Department	
Clinical Pathology	68.65%
Histopathology	23.88%
Cytology	4.47%
Serology	2.98%

Table 2. Section-wise Utilization of Microbiology Department

Microbiology Department	
Bacteriology	75%
Serology	13.46%
Mycobacteriology	3.85%
Mycology	1.90%
Immunology	5.76%

DISCUSSION

The diagnostic laboratories in health institutions are generally under three disciplines namely biochemistry, pathology and microbiology each of which undertakes numerous tests to aid in diagnosis and prognosis of disease. These laboratories also aid in medical research for both retrospective and prospective projects. In the current study only less than 30% of the projects submitted for IHEC review during the study period have utilized diagnostic services. IHEC receives proposals on medical education and population survey in addition to projects involving experimental work which accounts to the remaining 70 %. The community Medicine department carries out mostly population based epidemiological research which may not require lab services often.

The biochemistry section receives blood and other body fluids for instrumental analysis of blood components, enzymology, toxicology and endocrinology. These are classified as routine and special tests based on the methodology and frequency of request. The routine tests include the chemistry parameters like glucose, urea, creatinine, lipid profile, and liver function tests etc which are received in high numbers and involve simple colorimetry. Hormones, special proteins, tumor markers therapeutic drug monitoring etc which involve complicated technology are classifies as special tests.

The pathology section comprises clinical pathology to perform urinalysis (tests urine for many analytes however, if measuring urine chemicals is required, the specimen is processed in the clinical biochemistry lab) and stool tests, hematology (consisting of automated and manual analysis of blood cells to do full blood counts, and blood films as well as many other specialised tests). Histopathology processes solid tissue removed from the body (biopsies) for evaluation at the microscopic level and surgical pathology examines organs, limbs, tumors, fetuses, and other tissues biopsied in surgery such as breast mastectomys. Cytopathology examines smears of cells from all over the body (such as from the cervix) for

evidence of inflammation, cancer, and other conditions.

Microbiology encompasses five different sciences which include bacteriology, virology, parasitology, immunology and mycology .Microbiology receives almost any clinical specimen, including swabs, feces, urine, blood, sputum, cerebrospinal fluid, synovial fluid, as well as possible infected tissue to look for suspected pathogens which, if found, are further identified based on biochemical tests. Also, sensitivity testing is carried out to determine whether the pathogen is sensitive or resistant to a suggested medicine. Results are reported with the identified organism(s) and the type and amount of drug(s) that should be prescribed for the patient. Parasitology is a microbiology unit that investigates parasites. The most frequently encountered specimen here is faeces. However, blood, urine, sputum, and other samples may also contain parasites. Virology is concerned with identification of viruses in specimens such as blood, urine, and cerebrospinal fluid.

Immunology/Serology uses the concept of antigen-antibody interaction as a diagnostic tool. Compatibility of transplanted organs is also determined.

Among the diagnostic laboratory disciplines, biochemistry has found its highest utility in the research projects of this hospital. This may be attributed to the large number of quantitative tests undertaken by this section compared to the other sections. However routine tests are being employed in most of the projects compared to the special tests. The special tests require complicated technology and hence the assay kits are expensive. Hence expenditure might have been a deciding factor in involving these tests. Awareness on funding agencies and facilitating more grant writing will help the researchers to overcome this problem. It was also observed that research projects in diagnostic departments have primarily used their own laboratory services.

This study concludes that awareness programme among the investigators about the diagnostic facilities available and on funding agencies will facilitate the researchers to expand their research on special investigations also.

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