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Setting up the functional pathology laboratory in a hospital attached to a medical institute: An insight from soup to nuts

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ABSTRACT

Context: Laboratory physician's role by and large is confined to diagnostics and academics. Exposure on practical aspects is limited which is nevertheless essential. There is a significant gap in literature on how a four walled space is transformed into functioning laboratory.. We wish to narrate challenges and experiences faced during the process of setting up a diagnostic pathology laboratory attached to a teaching hospital in a rural geographic area.

Materials and Methods: Bulk of data is the authors first-hand experience in setting up the laboratory from October 2019 to July 2021. For specifications and infrastructure related information, guidelines of national and international statutory governing bodies like National Medical Commission (NMC), National Board for Accreditation of Laboratories(NABL), Clinical and Laboratory Standards Institute(CLSI) were referred along with discussion from peers working in established laboratories. Various facets to make a laboratory fully functional were compiled and presented.

Results: A diagnostic pathology laboratory with basic subdivisions had been made functional to cater to healthcare needs of patients keeping in mind the scope for future expansion and growth.

Conclusion: Basic fundamentals of infrastructure, manpower, consumables, vendor and data management are pertinent to even the laboratory associated medical professionals. An integrated and systematic approach with open mind for continual improvement is what it takes to face challenges and set up the diagnostics.

Key Messages: A knowledge and hands on experience of various facets pertaining to a functional laboratory is essential to the practicing pathologists. This article provides the much-needed literature on challenges faced which can be a reference material for others undertaking a similar setting at work.

1. Introduction

Setting up a functional pathology laboratory from inception is an arduous task. A well-planned laboratory provides scope for work to be performed in the most-efficient and safe manner. Adhering to basic minimum requirements of national governing bodies in our country like National Medical Commission (NMC), regulations of accreditation organisations like National Accreditation Board of Laboratories (NABL), a forethought of future expansion, at the same time delivering quality healthcare with available resources, is a challenge for management and laboratory teams specially in developing countries like ours.[1] As academicians, most of us are affiliated to or join medical

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institutes and laboratories where a system is already in place. This limits our work to reporting and administration by and large.[2]

We intent to share our encounters in establishing the lab from inception which not only made us come out of our limited zone of diagnostics, but also made us richer about various aspects of infrastructure, quality testing equipment, finances, cost considerations, procurement of consumables, developing a sustainable inventory, manpower and data management which are imperative to provide quality healthcare.

2. Objectives

To narrate experiences and challenges faced during the process of setting up a functional pathology laboratory attached to a teaching hospital in a rural geographic area, with an intent to provide a reference model to other laboratorians worldwide who would be involved or want to take up a similar undertaking.

3. Materials and Methods

Bulk of data is the authors' first-hand experience on various aspects involved in setting up a pathology laboratory attached to a teaching hospital located in a rural geographic area of South India from October 2020 to July 2021.

Guidelines of regulatory and statutory bodies referred were

1. The National Medical Commission 2019 – Statutory body that sets standards for medical college and hospital requirements and gives accreditation to medical schools in India.[1]
2. National Accreditation Body for testing and Calibration (NABL) – A constituent board of Quality council of India which maintains linkages with international bodies like International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Accreditation Co-operation (APAC) to facilitate global acceptance of its accredited Conformity Accreditation Bodies (CABs).
3. International Organization for Standardization (ISO) 15189 Medical laboratories– a worldwide federation which specifies requirements for quality and competence in medical laboratories and also develops international standards.
4. CLSI (Clinical and Laboratory Standards Institute (CLSI)guidelines- A non-profit global organization that supports development of scientific and clinical standards.
5. Internet-based search engines and online medical literature- For specifications and infrastructure related information.
6. An indispensable data tool was input obtained at various stages by interacting with our peers working from established medical institutes and laboratories all over the country.

Areas covered were: Infrastructure, water and electrical requirements, vendor management system, workflow management, human resource, biomedical waste management, patient and clinical satisfaction, planning the test menu and finances of the laboratory keeping in mind our operational, geographic, cultural and organizational context.

4. Results

Various facets worked upon in setting up the lab are described below keeping in mind our operational, geographic, cultural and organizational context.

Laboratory Infrastructure: Our central laboratory was allotted a floor area of over 10000 square feet to harbour diagnostic departments of Pathology, Biochemistry and Microbiology. Pathology spanned over an area of 4320 square feet. Billing was planned in proximity to the lab for logistic convenience of patients and laboratory personnel. This also facilitated easy communication and dispatch of reports. Phlebotomy was set up at the entrance with four collection counters. Adjacent to it, rest rooms for males and females were planned and an area provided for patients to keep collected urine samples.

Next portion of the lab was provided with restricted access. Pathology section had segregated areas allotted for haematology, cytology, clinical pathology and histopathology grossing and tissue processing. Haematology and histopathology were allotted larger area considering the scope of introducing immunohistochemistry, FISH, flow cytometry and high-end coagulation testing. A room was dedicated to FNAC with adequate ventilation and privacy. The record room, inventory, cold storage, staff & technician's rooms, restrooms and centrifuge rooms were commonly shared.

An adequate power supply and backup with timely audits by the electrical team, multiple sockets for instruments and microscopes, pipelines for water supply, segregated drains, comfortable working slabs, storage space and good ventilation were accounted for. A pit of 1.5x1.5 metres was excavated in a designated ground area and a ten feet long 'C' shaped pipe was placed. Area surrounding the pipe was filled with a mixture of charcoal, salt and earth reactivation compound. Frequent checks were scheduled by the electrical team for keeping ground resistance value below 3 volts at all times. Centralized air condition was commissioned for the entire lab at 25 degrees Celsius. Water supply was checked to set up a controlled pH of around 7, which is ideal for laboratory work, chemical reactions and to constitute buffers. Wash basins measuring 3 x 2 feet were installed in each section. Primary source of water supply to the laboratory was commissioned from

overhead tanks, which also catered to water demands of the hospital. Taps in rest rooms for patients, staff, technicians and each diagnostic sub divisions were the first ones to be commissioned. Eventually, all permanent water connections were made functional.

An effluent treatment plant (ETP) was set up to direct waste generated before final drainage, in accordance with requirement of National Accreditation Board for Hospitals (NABH) guidelines. Eye wash station, water sprinklers, emergency exit, fire alarms and extinguishers, signages and codes of practice were formulated. The microbiology faculty took initiative of organizing sessions at regular intervals and monitoring protocols for biomedical waste management. A reference model is provided. [Figure 1]

Vendor Management System: Process of vendor selection went through the following stages [Figure 2] in co-ordination with lab manager, purchase department and faculty.

Equipment**:** Decision to purchase, acquire on rental basis or procure a refurbished equipment along with consumables, accessories, service contracts for maintenance, and software was taken by lab heads in conjunction with management representatives. When making this decision, repair costs, service, maintenance contracts and depreciation costs were factored. [Figure 3]

In the "cocoon" phase, a three-part haematology analyser, a semi-automated urine analyser, centrifuges, binocular microscopes, coagulometer and necessary consumables (reagents and supplies) were procured. Instruments were delivered in a phased approach based upon size, urgency and time required for validation. On delivery, lab team was responsible for overseeing vendor installation process based on manufacturer's recommendations. Every instrument delivered was referenced against purchase order before installation. On arrival, it was ensured that contents of equipment package were in accordance with manual. Before installation, verification of necessities like power, area, ventilation and water supply were fulfilled as per manufacturer's instructions. Air conditioning system was evaluated to maintain temperature and humidity levels within acceptable limits. Accuracy and precision checks were completed followed by technician training, which enabled samples to be run without compromise on quality of results. A dedicated logbook was kept for schedule and activities of preventive maintenance, function checks and records of calibration. Asset tags, Inventory logs and standard operating procedures (SOP) were made after referring instrument manual.

Over months, as test volumes increased, a five-part haematology analyser was procured. With increase in surgeries and outpatient procedures, histopathology testing was initiated. This necessitated purchase of a rotary microtome, tissue processor, water bath, incubator, tissue flotation bath, slide cabinets and hot plate. Similar procurement and documentation procedures were followed as mentioned above**.** [Key points - Table 1]

Consumables: During the preliminary phase, they were divided into one time purchase and continuous supply. One-time purchase was for phlebotomy couches, beds for FNAC room, plastic racks and cabinets, rotating stools, ergonomic chairs, working tables, centrifuges, refrigerators, staining & processing related glassware, incubator, pipette set and biomedical waste bins. Vacutainers, urine collection bottles, cotton roll, syringes, glass slides, cover slips, reagents and stains, micro tips and stationary were purchased on need basis. [Key points - Table 2].

Test menu: Initially a test request form was formatted to provide basic haematology and clinical pathology investigations - complete hemogram, ESR, blood grouping and urine routine, fluid analysis, pap smears and FNACs [Figure 4]. In the preliminary stage, there was little clarity on level of specialised tests that might be required. Hence, we entered into a Memorandum of Understanding (MOU) with a sister concern laboratory affiliated under the same management for outsourcing specialised tests. As patient inflow improved, test menu was upgraded and expanded to include specialized cytology and histopathology services. Over time, we have been able to limit outsourcing to only specialised tests such has IHC, flow cytometry and molecular pathology.

Clinician's satisfaction was reviewed by frequent feedbacks and updated Directory of Services (DOS) accordingly. Till date, test menu undergoes a timely scrutiny based on care givers demands and patient needs.

Laboratory Personnel**:** To begin with, a senior lab manager having around ten years of experience and six qualified lab technicians recruited (two seniors) each with degree in medical laboratory technology. The team managed workload in the laboratory as a whole. (Pathology, Biochemistry, Microbiology and Phlebotomy). There were three consultant pathologists to begin with. Attenders were commonly shared between lab and casualty. Eventually need for improving staffing was felt. Lab being twenty-four hours functional, additional technicians and attenders were appointed to work in shifts (general, mid-morning and night) in allocated departments. Technicians were trained in various aspects of laboratory operations including importance of documentation and quality assurance.

Data management: Headmost computers, printer and registers were procured. A master register was the single point of entry for test requests and details. Eventually, as individual sections diversified separate registers were maintained. To begin with, results were manually entered, reports cross verified by consultants and signed before dispatch. Verbal communication, dispatch of reports, stock and equipment maintenance related records were kept. Daily check lists and logs were designed as per individual tests and workflow. Standardized and verified

Fig. 1: Reference floor plan for a pathology laboratory

Fig. 2: Implementation of avendor management system

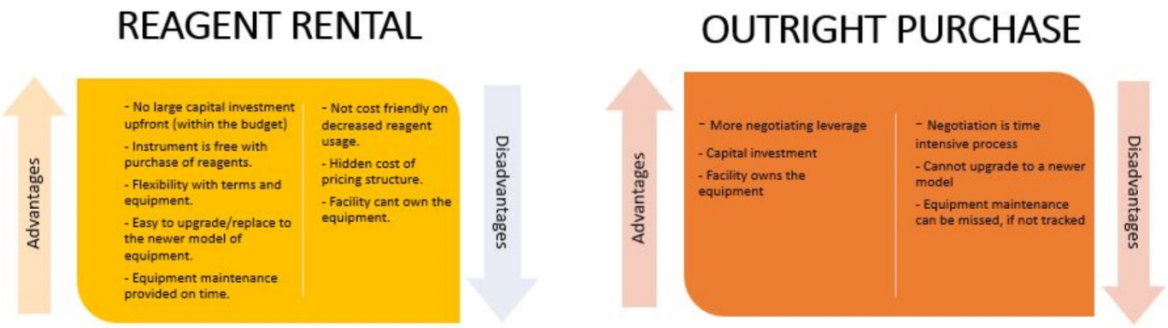

Fig. 3: Equipment procurement: reagent rental v/s outright purchase

Fig. 4: Sample requisition form for pathology

staining procedures and SOPs were displayed at workplace. Laboratory Information Management System (LIMS) was introduced, which enhanced productivity significantly by faster billing, reducing clerical work, giving better evaluation of workload, conduct audits and easy retrieval. This also enabled an electronic inventory process for indents.

In this way a systematised operational laboratory was functional by multidisciplinary effort. Our laboratory, envisions being one of the finest of its type. [Figure 5]

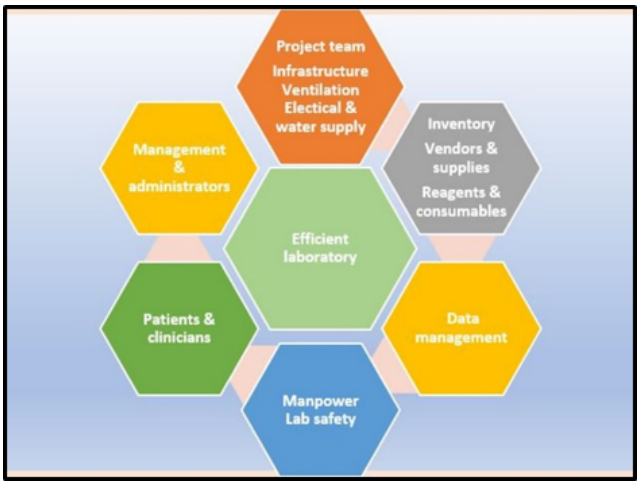

Fig. 5: Key factors in setting up a medical laboratory for quality patient care.

Table 1: Laboratory Equipment key points

	• Purchase Order for equipment must include all details including provision of the IQ, OQ and PQ certifications. Often, the contract does not include key components and the user has to pay for them at a later date.
Nuggets	• Initiate the Annual Maintenance Contracts (AMC) and Comprehensive Maintenance contracts (CMC) to ensure best possible service • Must for each equipment - asset label, file/ folder with specific documents inclusive of those required for accreditation. The latter to be collected from the service engineers & supplier at the time of installation.

Table 2: Consumables: Key points

Nuggets	• In a less-than-organized lab environment a track on usage must be kept and indent placed in planned phases to avoid over ordering and out-of-stock scenarios. • Ensure that Supplies received are from standard companies and with an acceptable expiry date

5. Discussion

"A neat and orderly laboratory is unlikely. It is, after all, so much a place of false starts and multiple attempts**."** said Isaac Asimov an American writer and Professor of Biochemistry at Boston University. The various facts and facets involved in setting up a functional lab are described keeping in mind our operational, geographic, cultural and organizational context.

5.1. Infrastructure & planning

Primary objective of the central laboratory floor plan was: to permit a smooth work flow, reduce walking distance and improve visibility for effective management of operations.[3,4] A good infrastructure isn't complete without considering safety aspects of space and personnel. Earthing' or grounding is one such feature to protect equipment from electrical faults (prevent and stabilize over voltage) and save lives which was taken care of in the initial stages. Centralized air condition was commissioned for the entire lab as the ideal temperature required for most equipment is below 25 degrees Celsius. An uninterrupted water supply is a prerequisite for any laboratory. Water with a controlled pH of around 7 is ideal for laboratory work, chemical reactions and to constitute buffers. For the biochemistry lab distilled or reverse osmosis water is a mandate. The water was checked for pH and quality by sending samples to the accredited chemical analysis testing centre and we continue to do the same once every three months. Codes of practice and guidelines were formulated which specified safe work practices as per NABH.[5] Scope of future expansion and accreditation must be factored for during the initial stages.

5.2. Consumables & procurement

Equipment procurement constitutes a large capital expenditure for a laboratory. Range of investigations, estimated workload, competency of human resources, quality assurance and safety factors must be accounted for.[6] Well-functioning equipment in compliance with infrastructure and allotted budget is a prerequisite. Equipment selection must be phased to provide basic services and cover the intended test menu.[7] As a part of installation, it is the vendor's responsibility to carry out assembly of items, whether a complex modular build or a simple "plug-and-play" device, and perform electrical safety tests. Support of a good biomedical department is essential.[7,8] Erratic power supply, intermittent air conditioning, protecting the equipment from dust will be problems faced when the building is under construction. The same was also observation of authors who had gone through a similar experience.[4,7]

Consumables are an indispensable component without which work comes to a halt. Initial teething problems were faced as our hospital is located in a remote location from

city. Vendor management must be a top priority from initial stages to ensure timely supply of reagents and consumables. It takes a while to put systems in place as distance and logistics must be considered. The purchase department and lab manager must work hand in hand to stabilize the same until periodic indents starts being placed at fixed intervals based on consumption to minimize expiry.[2]

5.3. Laboratory services

Services of a healthcare lab must meet clinical needs of the population it serves, and avoid delays in diagnosis that could have a negative effect on patient outcome. Our target population was largely the rural population from surrounding districts. Designing a test menu must be of the first exercises undertaken. Ordering practices are affected markedly by a laboratory's requisition which must be well designed and organized to steer clear of misinterpretation and errors.[9] Weighing the number of tests being ordered to cost per test expenditure before introducing new tests in house can avoid hoarding and expiry of expensive reagents. Restriction of the Directory of Services (DOS)with available tests in the initial stages rather than being over ambitious was one of the lessons we learnt.

Medical laboratories contribute to education and research, information technology design implementation, and quality improvement.[10]A diagnostic laboratory requires well trained, skilled and motivated staff to perform activities and meet professional standards under local circumstances.[6,11] A productive team encompassing attenders, information technology, clerical staff, technicians and pathologists is crucial. There is paucity of guidelines in literature on how professional human-resource requirements for a pathology laboratory should be calculated.[11]A laboratory has various entry points for employment depending on candidates' training and level of work complexity.[12]We took a use-based approach for staffing of laboratory as per Workload Indicators of Staffing Need (WISN), WHO 2015.[6,11]

5.4. Integration with technology & data management

Technical backup is necessary for a seamless workflow.[2,13] Creating a culture of quality with emphasis on adoption of quality assurance and proficiency programmes by repeated reinforcement, monitoring and training sessions to the laboratory personnel is a must. Introduction of the Laboratory management system -LMS enables robust reporting and verification of results that easily reached point of care in an accurate and instant fashion.[14,15] Though early operational stages posed challenges, we realized that significant opportunities will also present to optimize various operational components, delivering diagnostic information at optimal turnaround times.[16,17]

6. Conclusion

As doctors involved in healthcare, our experience gave insights into various facets of infrastructure, equipment, manpower, vendor systems, data management and finances which are an integral part of a well-functioning laboratory but are often overlooked. Awareness about these aspects can make us better laboratory physicians handling both diagnostics and administration with equal competence.

7. Conflict of Interest

There are no conflicts of interest in this article.

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