

## Original Research Article

# Situation analysis of medical laboratories in primary health centres

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### ABSTRACT

**Background:** This study was conducted with the objective to assess the medical laboratories attached with primary health centres (PHCs) focusing on the current needs, gaps and to understand the utilization pattern of the laboratory services. There are hardly any relevant studies that are known to have investigated the functioning of laboratories attached with PHCs based on quality of service they are providing.

**Methods:** This study was a cross sectional study based on observations and assessment made at 33 randomly selected medical laboratories attached with PHCs in Ahmedabad district, Gujarat. Checklist adapted from National Quality Assurance Standards (NQAS) and Indian Public Health Standards (IPHS) were used as a tool for data collection.

**Results:** Though all the laboratories have been found to be functioning effectively based on the indicators in this study, some of the laboratories were not performing basic important tests like rapid plasma reagin (RPR) (18%) and hepatitis B surface antigen (HbSAg) (21%). None of the laboratories attached to the PHCs under study performed Widal test. There was very low utilization of urinary pregnancy test (UPT) (1.81%) in the first quarter of the year.

**Conclusions:** Although most of the indicators reflect satisfactory performance of the laboratories, there exists certain gaps and needs that are essential in provision of quality laboratory services in the primary level of health care. The laboratory information management system (LIMS) was the major issue in the laboratories.

**Keywords:** Medical laboratory, Primary health centre, Public health laboratory

### INTRODUCTION

Medical laboratory services are an essential component of disease diagnosis, treatment, monitoring response to treatment, disease surveillance programs and clinical research in a country. Use of diagnostic techniques helps in early diagnosis enabling appropriate and prompt intervention thereby reducing overall disease burden and promoting health. In India, public health laboratory services are available and differ with the three tier public health system; the primary, secondary and tertiary. It includes different types of laboratories under the vertical disease control program as well as laboratories functioning at the huge network of health facilities such as primary health centres (PHCs), community health centres (CHCs), sub-district hospitals, district hospitals and medical college hospitals.

The contribution of laboratory investigations in primary health care is of utmost importance in diagnosing diseases. Medical laboratory services in primary health care are a fundamental constituent of health systems in developing countries but often neglected due to lack of supervision. Their main role in public health, disease control and surveillance, and patient management is often poorly recognized by governments and donors.<sup>1</sup> The understanding of Indian diagnostic services provisioning has certain literature gaps.<sup>2</sup> To achieve success in the programs related to health, a good understanding of the country's laboratory services is needed.<sup>3</sup>

Medical laboratory services play an important role in strengthening the medical care in a health system and help in medical decision-making which have an impact on the nation's health status. A proper diagnosis can not only

improve the treatment procedures and hence the clinical outcomes, but can also bring down the cost of treatment by minimizing the use of the syndromic approach to treat minor ailments. Laboratory support facilities together with other infrastructural facilities are the key factors that determine the utilization of health services.

This study is based on situational analysis of the medical laboratories of PHCs in Ahmedabad district of Gujarat, focusing on the current usage, needs, gaps and assessment. The study also center on whether new procedures and technologies have been introduced and if obsolete procedures have been replaced by more up-to-date techniques for safe and accurate performance of basic laboratory techniques in the laboratories of PHCs.

## **METHODS**

### ***Study design and study area***

This study was a cross sectional descriptive study based on observations and assessment made at laboratories attached with selected PHCs in Gujarat, during the period from February 2019 to June 2019.

### ***Sample size and sampling***

The study sample for this study was laboratories attached with randomly selected functional PHCs in various blocks of Ahmedabad district. 33 laboratories formed the sample size for this study.

### ***Data collection***

Primary data was collected with the help of checklist adapted from National Quality Assurance Standards (NQAS) and Indian Public Health Standards (IPHS) by direct observation and by interviewing laboratory technicians (LTs) working in the selected PHC based laboratories. Secondary data was obtained from the records available in the laboratories.<sup>4,5</sup>

All the selected laboratories were assigned scores using a checklist. The checklist consisted of eight domains/areas of laboratory, aiming to capture information which was necessary to achieve the objectives of the study. These eight areas of concern were further divided into different branches and had specific measurable elements. The measurable elements were assessed by checkpoints. The scores for the laboratories were calculated after assessing the measurable elements, checkpoints and marking compliance. For every checkpoint, 0 was given for no compliance, 1 for partial compliance and 2 for full compliance. The weightage was calculated by adding the scores of each checkpoint under every standard/area of concern and the total score was converted into percentage which reflected the performance of the individual laboratory. The co-relation of scores of all the laboratories was analyzed.

The various areas considered as performance indicators for the assessment of the laboratories are given below.

### ***Services provision***

This area measured the availability of diagnostic services in the laboratory.

### ***Patient rights***

This area measured various aspects such as availability of information or mandated free services provided by the laboratory.

### ***Input***

This area measured the availability of skilled human resource, infrastructure, equipments and instruments and physical safety in the laboratory.

### ***Support services***

It measured the inventory management and equipment maintenance.

### ***Clinical services***

It measured the quality of clinical services such as continuity of care, record keeping and laboratory services.

### ***Infection control***

This area measured for the control of infection such as biomedical waste management, personal protection, disinfection and hand washing.

### ***Quality management***

It is concerned with internal and external quality control of the laboratory.

### ***Outcome***

It measured the performance of the laboratory in terms of efficiency, productivity and clinical care and safety. Data was analyzed using Microsoft excel 2007 and the NQAS and IPHS checklists acted as tool for data collection.<sup>4,5</sup>

Purpose and details of the study were explained to the respondents (LTs) and informed consent was obtained from them. Assurance was given to the respondents on the confidentiality and anonymity of the data collected from them.

## **RESULTS**

The overall scores of the laboratories were above 70 and the mean score was 81.60. There was no significant difference in the scores of all the laboratories.

## Performance indicators

### Service provision

All the laboratories provided services as per IPHS but however it was found that some of them did not perform certain essential laboratory tests (Table 1).<sup>6</sup>

**Table 1: Percentage of PHC laboratories providing essential and basic tests.**

Sl. no.	Lab tests	Laboratories providing essential tests (n=33) (%)
1	Hemoglobin	100
2	CBC	0
3	Malaria parasite	100
4	Blood group	100
5	Urine sugar	100
6	Urine albumin	100
7	UPT	100
8	Blood sugar	100
9	AFB	100
10	HIV	97 (32)
11	VDRL/RPR	82 (27)
12	HbSAg	79 (26)
13	ESR	6 (2)
14	Bleeding and clotting time	100
15	Widal	0

### Patient rights

More than 80% of the laboratories secured full score in the area of patients' rights that include standards like display of laboratory information on all the laboratory tests performed, time of sample and report collection.

### Inputs

Components such as human resources, equipments and laboratory facilities and furniture are adequate and satisfactory in all the laboratories. There are no significant differences among the laboratories.

### Human resource

Among the 33 laboratories, 4 of them had vacant seats and LTs from other PHCs were deputed.

### Infrastructure

Water and electricity were available in all the laboratories. One PHC laboratory was functioning on a rented building. Overall hygiene was maintained in all the laboratories. For safety purpose, all the laboratories were equipped with fire extinguishers. The furniture mentioned in the checklist were available in most of the laboratories and under good condition.

### Basic equipments

Nearly about 50% of laboratories did not have venereal disease research laboratory (VDRL) shaker and digital thermometer. 82% did not have erythrocyte sedimentation rate (ESR) tube (Table 3).

### Support services

Calibration of the instruments were done in regular basis and the standard operating procedures were followed strictly in all the laboratories but there was lack of timely maintenance of equipments in half of the laboratories (Table 2).

**Table 2: Percentage of PHC laboratories showing support services.**

S. no.	Indicators	Percentage of PHC laboratories (n=33) (%)
1	Calibration of the instruments done on regular basis	88 (29)
2	Up to date instructions followed	73 (24)
3	Timely maintenance	47 (15)

**Table 3: Percentage of basic equipments in the laboratories.**

S. no.	Equipments	Laboratories with availability of basic equipments (n=33) (%)
1	Microscope	100
2	Slide storage box	100
3	Glucometer	100
4	Sahli's hemoglobinometer	100
5	Refrigerator	97 (32)
6	Spirit lamp	97 (32)
7	Needle destroyer	82 (27)
8	Micropipette	76 (25)
9	Centrifuge	76 (25)
10	VDRL shaker	52 (17)
11	Digital thermometer	48 (16)
12	ESR tube	18 (6)

### Clinical services

Majority of the laboratories scored high in provision of clinical services. In the facility level, all the criteria/requirements were being met for clinical services.

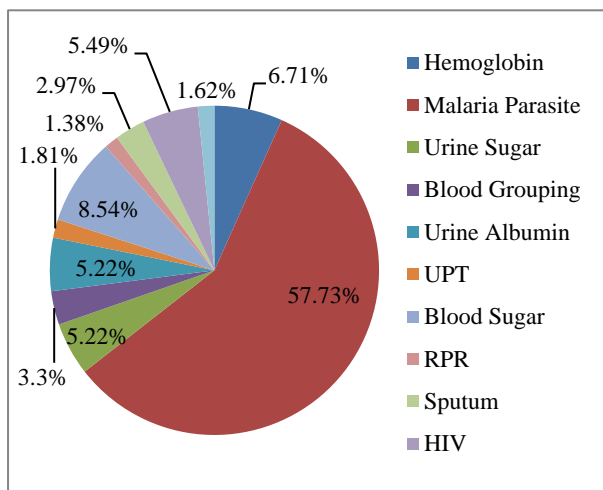
### Infection control

Most of the laboratories were having facilities for controlling the infections like wash basin, water supply,

disinfectant/soaps, color coded waste bins and display of hand washing techniques. LTs in 28 (85%) laboratories wore laboratory attire and LTs in 20 (60%) laboratories wore gloves during work.

### Quality management

The laboratories carried out the task of quality management very diligently. All the laboratories secured full score in quality management area, which included: well designed, implemented and maintained quality management system (QMS); well established protocol for regular monitoring of proper calibrations and functions of instruments, reagents and documentation; operation of laboratory equipments only by authorized personnel; manuals for use and maintenance of equipments; clean and well maintained work area, procedure for storage and disposal of hazardous sample as per biomedical waste management (BMW) rules; standard operating procedure (SOP) for sample collection, tests, storage, disposal and transportation; preparation of a weekly and monthly report in authorized format on timely basis and sending it to reporting authority.



**Figure 1: Service utilization pattern of different tests performed in the laboratories of PHCs during first quarter of 2019 (in percentage).**

### Outcome

Three indicators were used to determine the outcome of a laboratory: productivity (number of Hb test done per ANC and no. of test done per 100 patients on monthly basis); clinical care and safety (number of Hb reported less than 7 gm% and number of rapid diagnostic kits discarded due to unsatisfactory reasons on monthly basis); and efficiency (number of stock out of incidences of reagents and kits on monthly basis)

All laboratories performed satisfactorily for productivity and clinical care and safety. 33% of them did not maintain the record for stock out of reagents thereby, lagging behind in efficiency.

### Service delivery in the first quarter (service utilization)

The secondary data from the first quarter (from January 2019 to April 2019) depicted that malaria parasite test was the highly utilized test among the laboratories. The least utilized tests were RPR, HbSAg and UPT. None of the laboratories performed Widal test (Figure 1).

### DISCUSSION

With the intention to know and understand the scenario of the medical laboratories in primary level of health care in Ahmedabad district, this study was undertaken as to how their functioning influences the healthcare delivery system in the rural areas and it was found that there are certain gaps and needs. Although all the PHC laboratories have been found to be functioning satisfactorily, there are still certain areas, as the indicators suggest that needs attention to enhance the healthcare service.

The technology used or the complexity of the tests done were general and basic in the laboratories requiring low resources and the minimum manpower needed was one LT per laboratory (according to the IPHS guidelines). However, during the interview, LTs from all 33 laboratories expressed that there is a dire need of laboratory assistants as they have to multitask and are overburdened by having to switch between performing diagnostic tests and feeding the data in the LIMS. Even in a study it was found that manpower and infrastructure in PHCs are lacking. Though they have adequate number of medical officers but lacks in paramedical staffs such as laboratory technicians.<sup>6</sup>

In current study, every PHC had one room for laboratory and the sizes of the laboratories were not uniform. Water and electricity supply was available in all laboratories and were equipped with fire extinguishers for the safety. Color coded waste bins were in place for proper biomedical waste management.

According to IPHS guidelines, standard list of laboratory tests are given for PHCs.<sup>5</sup> A study on IPHS awareness amongst health care providers in PHCs found that they did not adhere to the IPHS and the management was unaware and unclear of them.<sup>7</sup>

In this study also, certain tests are not at all performed in some laboratories and UPT have been utilized in very less number in the first quarter of the year. The underutilization of such tests in PHCs raises questions. Among the disease specific tests, Widal test was not performed in any of the laboratories. Utilization of RPR tests in 17 laboratories and HbSAg tests in 7 laboratories were not registered in the first quarter. Blood sample based tests like complete blood count (CBC) were not performed and the samples were sent to the higher centres for analysis. Along with that, erythrocyte sedimentation rate (ESR) test was also not carried out in the laboratories as included in the IPHS.



Among the non-blood sample tests, urine albumin and urine sugar had been carried out in all the laboratories.

In an article, it is mentioned that ensuring basic laboratory services at PHCs not only improves the quality of medical care but is also capable of creating a greater demand for essential drugs at the facility. This in turn can improve the potential of the PHC as a centre providing primary healthcare.<sup>8</sup>

The LIMS in the PHC laboratories was the major issue faced by the LTs. 90% of the LTs gave their feedback on LIMS expressing that the software used was not user friendly. There were several issues such as poor or lack of internet connection, having to feed unnecessary data etc. In many of the laboratories, the data entry was done in registers as the LIMS was not being used due to software upgradation. There is a necessity for a separate computer only for laboratory purpose according to the LTs. There was practical difficulty in sharing the only computer available in the PHC by every staff. All of them suggested the need for a separate assistant for data entry into the LIMS. In some laboratories, logistics was the issue as there was mismatch of demand and supply in both quality and quantity of kits and reagents. Although the LTs are satisfied with the adequate training they are provided with, they said that they need to be given more training to be competent in their field.

According to an article, the most difficult challenges facing public health laboratory system in developing countries are acute shortage of workforce capacity, due to limited number of trained and skilled personnel; poorly maintained physical infrastructure and inadequate supply of electricity and water; lack of equipment maintenance; weak supply-chain management systems for consumables and reagents; and lack of leadership and policies for standards. Laboratory strategic planning is the way for resource-poor countries to set standards, directions and make decisions on allocating capital and persons to achieve sustainable standards for quality laboratory services. To establish an effective strategic planning, situational analysis of the existing laboratory network in the country by using standard approaches must be carried out.<sup>1</sup>

## CONCLUSION

The contribution of laboratory investigations in primary health care is of utmost importance in diagnosing diseases. Facilities like laboratory support along with other infrastructural facilities are major factors impacting the utilization of health services.

According to the findings of this study the laboratories attached to the PHCs are operating as per IPHS standards though few aspects need attention. Essential diagnostic tests such as RPR, HbSAg and UPT tests were the least

utilized tests in the laboratories in the first quarter. None of the laboratories attached to the PHCs were performing Widal test. The problem faced by LTs with LIMS also needs to be addressed. LIMS software needs to be more user-friendly for the entry of laboratory data. The PHCs need good internet connection with robust IT system. The proper management of logistics in these laboratories needs attention to avoid mismatch of supply and demand for reagents and kits. According to the LTs, the government should encourage the laboratories to focus on calibration and timely maintenance of instruments and more training should be provided to them to improve competency in the field. It is evident from this study that among the indicators, the area of service provision needs to be given attention.

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