Mid-Term Review of District and Medical College Hospital Laboratories in India

Labs for Life Project

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2017

Ministry of Health and Family Welfare, Government of India
In collaboration with
U.S Centers for Disease Control and Prevention (HHS/CDC/CGH)-Division of Global HIV/AIDS, India,
Christian Medical Association of India (CMAI)
and
Becton Dickinson and Company

Acronyms

ABG	:	Arterial Blood Gas
AMC	:	Annual Maintenance Contract
ART	:	Anti-Retroviral Therapy
BD	:	Becton Dickinson
BPL	:	Below Poverty Line
BMW	:	Bio-Medical Waste Management
CAPA	:	Corrective Action Preventive Action
CDC	:	Centre for disease control and Prevention
CLABSI	:	Central Line-associated Bloodstream Infection
CMAI	:	Christian Medical Association of India
CMC	:	Comprehensive Maintenance Contract
EQAP	:	External Quality Assessment Programme
EQAS	:	External Quality Assurance Scheme
FNAC	:	Fine Needle Aspiration Cytology
GLP	:	Good Laboratory Practices
HIV	:	Human Immunodeficiency Virus
HMIS	:	Health Management Information System
ICMR	:	Indian Council of Medical Research
ICTC	:	Integrated Counselling and Testing Centre
IDSP	:	Integrated Disease Surveillance Programme
IHR	:	International Health Regulations
ISO	:	International Organization for Standardization
IPHS	:	Indian Public Health Standards
IQAP	:	Internal Quality Assessment Programme
IQC	:	Internal Quality Control
JSSY	:	Janani Shishu Suraksha Yojna
KPI	:	Key Performance Indicator
LBC	:	Liquid Based Cytology
LIMS	:	Laboratory Information Management System
MoHFW	:	Ministry of Health and Family Welfare
MP	:	Malaria Parasite
MSDS	:	Material Safety Data Sheet
NACP	:	National AIDS Control Programme
NLEP	:	National Leprosy Eradication Program
NHM	:	National Health Mission
NVBDCP	:	National Vector Borne Disease Control Programme
PHEIC	:	Public Health Emergency of International Concern
QI	:	Quality Indicator
RNTCP	:	Revised National Tuberculosis Control Program
SOP	:	Standard Operating Procedure
SPSS	:	Statistical Product and Service Solutions
SSI	:	Surgical Site Infection
STI	:	Sexually Transmitted Infections
TAT	:	Turnaround Time
UTI	:	Urinary Tract Infection
VAP	:	Ventilator Associated Pneumonia
WDI	:	Work Desk Instruction

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Laboratory Services in India

1. Background

Universal access to good-quality health care services without financial hardship is the goal of India's national health policy (MOH 2014). Infectious diseases continue to be a significant cause of morbidity, mortality and socio-economic loss in developing countries like India. While the endemic infections are far from being conquered, newer pathogens have been emerging almost every year alongside known pathogens that have resurfaced in more devastating forms. Early identification, detection, characterization, prevention and control of these agents require laboratory support as an integral part of disease surveillance systems. The burgeoning non-communicable diseases are also a cause of concern.

Laboratory services are fundamental and essential part of a health care system as accurate, reliable and timely laboratory results are critical elements in all aspects of health care, including surveillance and disease control programmes. Though, substantial government efforts and resources have been devoted to the creation of an extensive network of public sector health laboratories in India, they are relatively accorded low priority with allocation of inadequate resources that lead to inadequate quality of service provision. Quality of laboratory services must be ensured through quality management systems which can be achieved by adopting new technologies for the collection, testing and processing, with efficient supply chain management systems and ongoing capacity enhancement of human resource. It is also essential that there is a continuous development, maintenance and update of SOPs, practice of internal quality control, external quality assessment schemes (EQAS) and assessment of performance through internal and external audits. For the above reasons, the laboratory systems have been brought under the purview of ISO. Accreditation to the specific lab standard, ISO 15189 brings the quality systems of a laboratory to the desired level of quality and competence. Considering the very low proportion of voluntarily accredited laboratories in India, it is imperative to instill a culture of quality with in laboratories, if to the basic minimum levels, both in the public and private sector. It is also essential to ensure the provision of adequate and sustainable financial, human and material resources to establishing and maintaining quality laboratory systems across the country.

The Labs for Life project(L4L), a three years partnership initiative of the Ministry of Health and Family Welfare (MoHFW) and the U.S. Centers for Disease Control and Prevention (CDC) was launched in 2014 with the objective of improving the quality of laboratory services, effectiveness, and efficiency of public health laboratories.

Through this collaborative effort, technical assistance is being provided to 20 public health institutions covering 11 districts (both secondary and tertiary) from 7 states representing all 5 national regions (North, South, East, West and North East) to enhance the capacity for

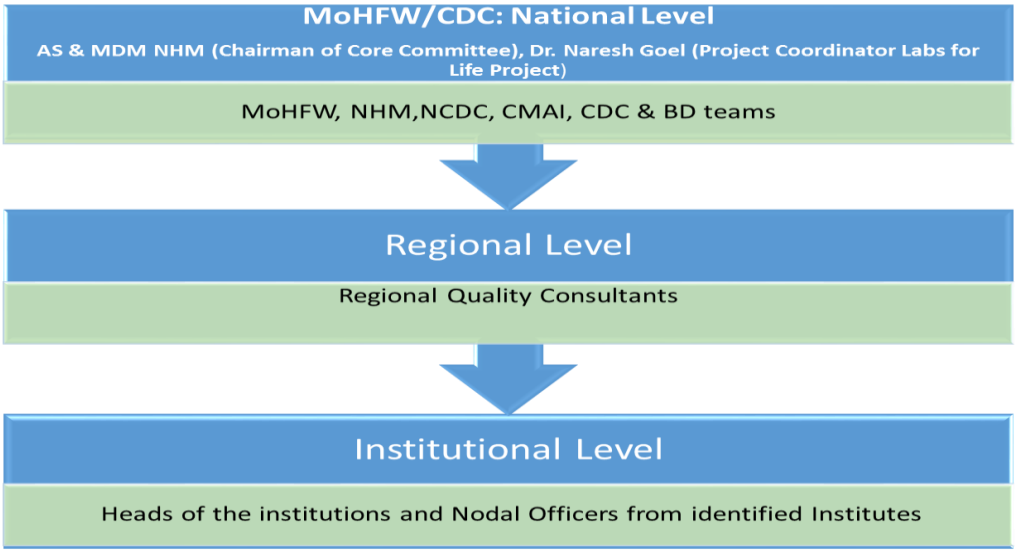
quality diagnosis of communicable and non-communicable diseases in India. CDC India has entered into a co-operative agreement with Christian Medical Association of India (CMAI) to provide technical assistance to Ministry of Health and Family Welfare (MoHFW) for the next three years.

The specific objectives are to, improve the quality of services of 20 identified labs, by at least two additional stars/grades/levels as measured by the checklist (as per MOH grading); strengthen specimen referral mechanism and linkages between various levels of facilities; enhance capacity for diagnosis of communicable diseases; ensure sustainability of interventions through local, state-level and country ownership.

Key activities of the project so far,

Developement of project governance mecahnism: As a first step, the Labs for Life (L4L) project defined the project governing mechanism and developed a structure to spearhead the project activities. At the National level, the core committee under the chairmanship of Additional Secretary, MoHFW is responsible for review, advice and provision of strategic direction to the project. The committee consists of representatives from MoHFW, CDC, BD, CMAI, National Health System resource center and National Health Mission. The committee meets once in a quarter and seven core committee meetings have been conducted so far

At the state level, the Principal Secretary-Health, Mission Director-National Health Mission, Director of Health Services, Director of Medical Education, State Program Managers, State Quality Assurance Officer are among the officials briefed and updated on the project activities. At the district level, District Health Officer, Chief Medical & Health Officer, District quality assurance unit, district program manager are the key stakeholders involved in the planning and implementation of the project. At the Institutional Level, the Principal, Dean, Medical Superintendent, Nodal officers, Head of the laboratories and other concerned officers are involved in the planning and implementation of project activities.



Baseline Assessment, Gap Analysis and State level Dissemination: The objectives of the assessment was to understand the existing laboratory practices, identify areas of gaps/deficiencies, emerging challenges, document best practices, and to decide on the strategies and interventions for implementing quality management systems. All selected laboratories under the project were included in the assessments, conducted from 23rd March to 10th April 2015.

Following the finalization of reports, the findings were disseminated in all the states, with the objective of bringing together all the stakeholders, jointly plan and develop a strategies to address the gaps.

Capacity Building: Based on the situation assessment and gap analysis, followed by series of consultation meetings, the key systemic areas of concerns that can be addressed through capacity building were finalized. These are, facility management and safety, sample collection, documentation, equipment management , calibration and controls, testing methodologies, sample referrals, inventory control, staff training practices, setting and monitoring quality indicators and usage of Information Technology. A comprehensive capacity building plan with central,district and facility wise trainings was developed to guide the planned activities. The plan consists of, Training of Trainers(ToT), district level onsite training, handholding by Regional Quality Consultants, Periodic mentoring visits by the L4L central team, and e-learning initiatives such as webinars. In addition regular advocay with all stakeholders is being done.

- ***Modules Development:*** Five modules on technical areas, such as, Sample Collection and Pre-Analytical Best Practices, Documentation and Record Management, Facility Management and Safety, Equipment Management and Quality Control (2 volumes) have been developed so far, and extensively being used by the participating Institutions.
- ***Training of Trainers: National level workshops on*** Sample Collection and Pre-Analytical Best Practices, Facility Management and Safety, Equipment Management, Documentation and Quality Control were conducted. The objective was to train a pool of Master Trainers who can go back and train their co-workers in their institutions.
- ***Onsite Training:*** Onsite training on "Sample Collection and Pre-Analytical Best Practices, Facility Management and Safety, Equipment Management, Documentation and Quality Control" are regularly being conducted. Technical staff from national programs was also included in the onsite training. On special requests from National Health Mission, a few people from other public health facilities were also trained in some locations. Further training are calendared to ensure a cascading process to reach all the laboratory technical staff of the identified institutions and if possible, beyond.

- ***Webinars: 18*** Webinars have been conducted so far. Technical topics such as, Lab Process Control, Calibrations, Documents and Records, IHR, Infection Control, Bio Medical Waste Management have been covered so far. On an average, around 75-100 participants attended the webinars from across the country.

In addition to addressing the systemic challenges, facility specific interventions were also undertaken in terms of technical advice for lab renovations in several institutions, Bio Medical Waste Management issues etc.

Initiatives to tap the existing resources: A district and state level resource mapping was done by the Regional Quality Consultants to understand the current resources available for laboratory strengthening under various government programs and schemes. Though National health Mission has a mandate to address the infrastructure, human and financial gaps in the public health care system, laboratories have not gained adequate attention so far. To tap the existing available resources under NHM, the project facilitated developing Project Implementation Plan (PIP) in all states to address the resource gaps. As a result, allocations have been made in some states and is being released shortly.

Website: Understanding the unmet need for in-service training for technicians, Labs for life is developing a website with learning resources like training modules, videos and self-learning platforms. Resources like e-tool for Quality Indicators and Statistical Quality Controls are being developed.

2. Objectives of the Mid-Term Review

The specific objectives are,

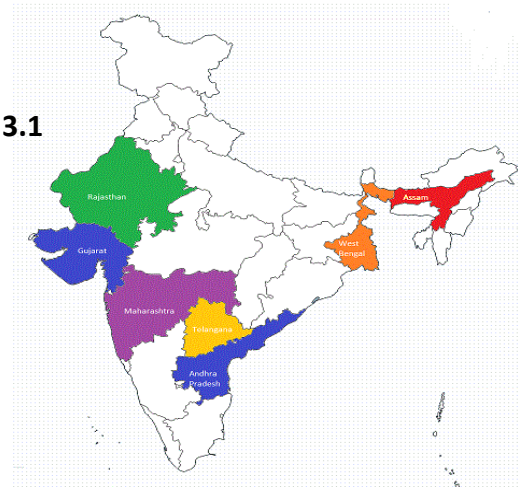
- To review the existing structure and the services provided by the selected laboratories in comparison with baseline.
- To identify facility-specific challenges and systemic areas of need that must be prioritized and addressed.
- To understand the progress, gaps and challenges and the factors facilitating or hindering the progress/achievements.
- To document lessons learned and challenges.
- To formulate facility-specific strategic plan for taking corrective measures and to improve quality management systems.

3. Methodology

Sixteen public health laboratories that includes, 8 each medical college and district hospital laboratories were included selected laboratories under Labs for Life project were included in the assessment. Four laboratories from Gujarat were not included in the mid-term review due to administrative reasons. The geographical distribution of selected states and districts is illustrated in figure-1.

Fig 1: States covered under the project

3.1



Tab 1: States and districts covered

S. No.	States	Districts
1	Maharashtra	Wardha
		Aurangabad
2	Andhra Pradesh	Vishakhapatnam
3	Telangana	Warangal
4	Rajasthan	Jodhpur
		Udaipur
5	Assam	Dibrugarh
6	West Bengal	Darjeeling

3.1 Laboratory site visits using Lab Assessment Tools

The mid-term review was carried out using the same lab assessment tools that were used in the baseline assessment.

- **Medical College Laboratory Assessment Tool**

The medical college assessment was carried out using a validated Medical College Laboratory Assessment Tool for public health laboratories under Integrated Disease Control Programme (IDSP). Appropriate modifications were made to capture elements required under non-microbiological testing disciplines and also non-epidemic prone diseases included in microbiology. Both quantitative and qualitative Information were elicited through staff interviews, observation and record review.

The key components included in the medical college lab assessment tool were,

- Premises and quality
- Specimen Collection

- Bio-safety
- Quality Management System
- Public Health Functions
- Supplies, Equipment
- Budget and finances
- Data Management
- Diagnostic capacities with reference to optimum tertiary care,
- Staff availability
- Staff management
- Training and supervision
- Information Technologies
- Communication.

- **District Hospital Laboratory Assessment Tool**

The district hospitals assessment was carried out using a validated District Hospital Laboratory Assessment Tool, designed by National Health Mission (NHM), Ministry of health and family welfare, Government of India, under Quality Guidelines for District hospitals. This tool is based on ISO, IPHS, and GLP guidelines of ICMR. Additional sheets for General & contact information and summary were added. Both quantitative and qualitative Information were elicited through staff interviews, observation and record review.

The key components included in the District hospital lab assessment tool were,

- Service provision
- Patient rights
- Inputs
- Support services
- Clinical Services
- Infection Control
- Quality Management
- Outcome measurement

3.2 Discussion with key staff and officials

Before administering the tools, a group discussion was conducted among the staff that included the head of the institutions, department head, professional and technical staff. The objectives of the project were explained. In addition, broader details such as, scope of the institution, coverage, and facilities available in general, demographic details, key gaps and challenges of institutions were obtained.

After completion of the assessment, a debriefing session was also conducted. This was mainly to provide a brief summary of the assessment to the institution and to clarify doubts related to the assessment.

3.3 Midterm review Team and Duration

Two independent external assessors, one from BD and one from CDC and one observer from CDC/CMAI/BD constituted the assessment team. Technically qualified personnel, with background of Microbiology/Pathology/Biochemistry with experience in laboratory assessments were chosen.

Two days were allocated for Medical college laboratory assessment. An additional day was given for compiling the data and finalizing the qualitative summary section. For district hospitals, one full day was allocated. An additional day was given for compiling the data and completing the qualitative summary section. The teams arrived in the district a day prior to the assessments.

The midterm review was conducted in 2 phases, starting from 27th September 2016 to 6th October 2016.

3.4 Data Quality Assurance

In order to ensure quality in data collection, process and analysis, a series of activities were carried out that are,

- The tools were tested for correctness in formulae, summation, and consolidation.
- One day orientation was given to the assessors and observers.
- Observers were assigned to facilitate smooth assessment process and ensure impartiality by interaction with the institution and the assessors. The observers were also given training on the tools.
- Direct Observation, Staff and Patient Interviews and Record Reviews were the mechanisms suggested for eliciting data.
- In addition, the Regional Quality Consultants also facilitated in the process.
- The RQCs were given formats in advance to capture the general information of total patient load, department-wise patient load and the contact information of key functionaries.
- After the assessment was over, the tools were cross checked for completeness, summation within subsections and overall summation of score.

3.5 Data Analysis

Both the tools are in Excel file. Each question under each component/sub section carried equal marks and calculated for 100 percent. For Medical college laboratories, the overall score was calculated for 100 marks which is the average of all components with equal weightage. Formulae were developed in excel sheet itself to calculate the scores of sub sections, scores of components and overall score. However, for district hospitals, the overall score was calculated based on the total scores obtained by each laboratory out of the maximum possible score. The component "inputs" is given the highest weightage (19.3%), followed by, quality management (19.0%), Infection Control (17.7%), Support Services (15.4%), Clinical Services (9.5%), Patient Rights (6.9%), Outcome (7.2%), and Service Provision (4.9%). This excel sheets were converted in to SPSS file to carry out further analysis.

During the qualitative data analysis a few overlapping areas were combined that are,

1. Supplies -reagent and equipment- availability and management were analyzed under one category as this reflects common issues that fall under 5.3 of the ISO standard
2. Overall diagnostic capacities.
3. Data Management and Information technologies were combined, as both have overlapping components
4. Staff availability and staff training were combined as both fall under the purview of 5.1 of the ISO standard; personnel.

Table 2: The L4L Medical College Tool: (Modified IDSP) – Specific areas/components and key information under each areas.

Sl No	Key Areas	Information Captured
1	Premises and quality	1. General Infrastructure 2. Availability of utilities: Electricity, backup, running water
2	Specimen Collection	1. Quality of samples: in-house, referral 2. Sampling procedures 3. Request forms: in-house, referral 4. Specimen transportation 5. Specimen tracking 6. Specimen validation 7. Result reporting 8. Referral system
3	Biosafety	1. Building biosecurity 2. Bio-risk management 3. Signage 4. Patient and staff safety

		5. Availability and use of PPE 6. Emergency equipment, first-aid facilities 7. Safety SOPs 8. Safety Training and practice 9. Equipment disinfection 10. Biomedical Waste Disposal
4	Quality Management System	1. Documentation, document control: SOPs, Policies. 2. Internal QC protocols, daily monitoring corrective action protocols, QC trends: All departments 3. External Quality Assurance programs: All depart's 4. Quality Indicators: identification and monitoring
5	Public Health Functions	1. Relationship with IHR 2. Surveillance: Participation, diseases covered, outbreak investigation protocols, emergency sampling and shipping 3. Notification
6	Supplies	1. Inventory Control: Stocks, orders management 2. Use of expired reagents 3. Reagent availability: All departments
7	Equipment	1. Equipment management 2. Preventive Maintenance 3. Calibrations 4. AMC/CMC 5. Availability of user manual and spare parts 6. Equipment availability as per requirement of a tertiary care center
8	Budget and finances	1. Funding principles 2. Reagent/ consumable funding 3. Equipment funding 4. Annual reagent supplies 5. Emergency supplies
9	Data Management	1. Data recording, registers 2. Data validation 3. Critical call-out records 4. Notification records 5. Data archival 6. Computerized data backup
10	Diagnostic capacities with reference to optimum tertiary care: Microbiology	1. Sampling capacities 2. Transportation capacities 3. Bacterial infection 4. Viral Infections 5. Parasitological/ mycological infections 6. Water testing
11	Diagnostic	1. Hematology including cytochemistry, bone marrow,

	capacities with reference to optimum tertiary care:	immunophentyping 2. Histopathology including IHCs 3. Cytology including FNACs, LBC 4. Urine, stool and semen analysis 5. Biochemistry including immunoassays
12	Staff availability, staff management	1. Senior staff 2. Technical staff 3. Support staff 4. Staff Qualifications 5. Staff management 6. HR funding 7. Staff health facilities 8. Professional associations, CMEs
13	Training and supervision	1. Induction training 2. Continuous training 3. Online training 4. Supervision 5. Availability of guidelines: general and specific
14	Information Technologies	**1.** IT hardware availability **2.** Software and licenses **3.** Internet **4.** HIS/ LIS
15	Communication	1. Internal communication 2. External communication 3. IHR compliance and communication 4. Communication with users of the lab 5. Capacity and methods of communication

Table 3: The L4L District Hospital Tool (NHM) – Specific areas/components and key information under each areas.

	Area of Concern	Information Captured
A	Service provision	1. Availability of testing disciplines of laboratory medicine: hematology / biochemistry/ microbiology/ clinical pathology/ microbiology/ serology/cytology/histopathology 2. Availability of national programs 3. Availability of services appropriate to local problems: Infections/ sickle cell anemia/thalassemia/ others
B	Patient rights	1. Availability of information for patients and users regarding lab services 2. Sensitivity to gender, physical disabilities 3. Privacy, Courtesy 4. Confidentiality

		5. Informed consent procedures 6. Complaint redressal system 7. Financial protection: Cashless services to pregnant women and children, availability of prescribed tests, free services to BPL, reimbursement of beneficiaries for tests not available in the lab
C	Inputs	1. Infrastructure: Compatibility of physical infrastructure with the work flow. Power supply 2. Safety measures: Fire 3. Staff availability: Pathologists/ Microbiologists/ Technical staff 4. Staff training 5. Availability of reagents and consumables 6. Availability of equipment
D	Support services	1. Equipment maintenance: Daily maintenance, scheduled maintenance, calibration, AMC/CMC 2. Inventory management: Indenting system, storage, stock verification, emergency purchases 3. Lab safety: Chemical, equipment, fire. Safety of female staff 4. Building maintenance: general upkeep, work stations, furniture, pest control 5. Power backup, running water 6. Compliance to statutory requirements like disease notification 7. HR: Awareness of job descriptions, dress codes, duty rosters 8. Monitoring of outsource services: Laundry, dietary, security
E	Clinical Services	1. Patient identification procedure 2. Referrals: Patients/ samples 3. Record maintenance 4. Disaster management 5. Medico legal cases 6. Pre-analytical: Sample collection procedure 7. Pre-analytical: Sample transportation procedure 8. Analytical: Testing processes, biological reference ranges, critical call outs 9. Post-Analytical: Review of results, reporting formats, report transcription, stat reporting, data archival 10. Post-Analytical: Sample retention, discarding process
F	Infection Control	1. Passive and active culture surveillance of high risk areas 2. Staff immunizations, check ups 3. Hospital Antibiotic policy 4. Hand hygiene protocols 5. Availability and use of personal protective equipment 6. Spill management protocol

		7. Decontamination of equipment 8. Cleaning and disinfection of patient care areas 9. Biomedical Waste management: Segregation at source, sharps disposal 10. Post exposure prophylaxis 11. Liquid wastes management
G	Quality Management	1. Availability of a nodal officer [Quality manager] 2. Surveys of satisfaction: Patients/ referring doctors 3. Availability of Internal Quality Assurance Program 4. Availability of External Quality Assurance Program 5. Corrective action protocols 6. Availability of Standard Operating Procedures 7. Internal Audits 8. Defined Quality Policy 9. Defined Quality Objectives which are monitored 10. Continual improvement protocols
H	Outcome	1. Productivity Indicators e.g. Number of HIV tests done/ 1000 population 2. Proportion of tests done for BPL patients 3. Efficiency Indicators e.g. Z scores, TAT for routine tests, emergency tests 4. Safety Indicators e.g. Percent of critical call outs 5. Service Quality Indicators e.g. waiting time, stock-outs

4. Gap Analysis Results- Medical College Laboratories

4.1 General Information of Selected Laboratories

Eight medical college laboratories from six states were included in the mid-term review. The basic details of the laboratories are given in Table - 2

Table 4: General Information of Selected Medical Colleges

Name of the Institution	MGIMS Wardha, MAH	GMC Aurangabad, MAH	AMC Visakhapatnam, AP	KMC Medical College Warangal TEL	RNT Medical College, Udaipur, Rajasthan	Dr. Sampurnan Medical College, Jodhpur, Rajasthan	Assam Medical College Dibrugarh, Assam	North Bengal Medical College, Darjeeling, West Bengal
District population	**1296157 (2011)**	**3695988 (2011)**	**4288113 (2011)**	**3522644 (2011)**	**3067549 (2011)**	**3685681 (2011)**	**1,326,335 (2011)**	**1,1,846,823 (2011)**
Population Coverage	8774745	18731872	4288113	40,00,000	>3067549	>3685681	>1,326,335	>1,846,823
Total no of beds	770	1177	1300	1070	1000	10000	1500	599
Daily OPD Strength	2107	2473	1536	2880	2217	4528	1,370	1478
OPD strength / year	615634	798239	480868	8,98,575	798120	1630080	16,440	17,736
Laboratory type	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary
SRL/NRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL	SRL
Accreditation Status for HIV	No	NABL	No	No	No	No	NABL	Applied
Number of disciplines	3	3	3	3	3	3	3	3
Total number of samples received/Yr	593164	758441	178488	20,000 – 24,000	2251010	3189171	3,04, 468	1,19, 626
Institution Head	Dr.K.R. Patond	Dr C. B. Mhaske	Dr.T. Radha	Dr.H. Sandhya Rani	Dr.D.P. Singh	DR A.L. BHAT	Dr. R.K. Kotoky	Prof Samir Ghosh
Head: Microbiology	Dr. Vijayshri Deotale	Dr A S Damle	Dr.P.Kamala	Dr.R.Kondal Rao	Dr Anshu Sharma	DR PK KHATRI	Prof. Dr. Lahari Saikia	Prof. Arunabha Sarkar
Head: Pathology	Dr. Nitin gangane	Dr R S Bindu	Dr Bhagya Lakshmi	Dr.H.Sandhya Rani	Dr Sunita Bhargava	DR. A.R KALLA	Prof. Dr. Progyan Saikia	Prof. Bidyut Goswami (Giri)
Head: Biochemistry	Dr. MVR reddy	Dr S B Gaikwad	Dr Raj Kumari	Dr.P.V.Satyanarayana	Dr Ashok Kumar Verma	DR RANJANA MATHUR	Dr. Monigoppa Das (HOD-Incharge)	Prof. Swati Bhattacharya

4.2 Overall Score of Medical College Laboratories

The overall mean score of the medical college laboratories indicated an increase from 50.1 (SD: 13.1) at baseline to 61.7 (SD: 12.3) at midterm. The mid-term score ranges from 81.2% for Medical College Wardha, Maharashtra to 38.6% for Medical College, Warangal, Telangana. The percentage increase is highest for Medical College, Vishakhapatnam (77.1%) and minimum (7.7%) for Medical College, Dibrugarh Assam. The baseline score of Medical College Wardha was the highest and has gone up by 11%. The Medical College Vishakhapatnam recorded higher percentage of increase (77.1%) as compared to 15.6% increase for Medical College, Warangal, though the baseline score was same for both the institutions(33%.).

Fig 2: Overall Score of Medical College Laboratories

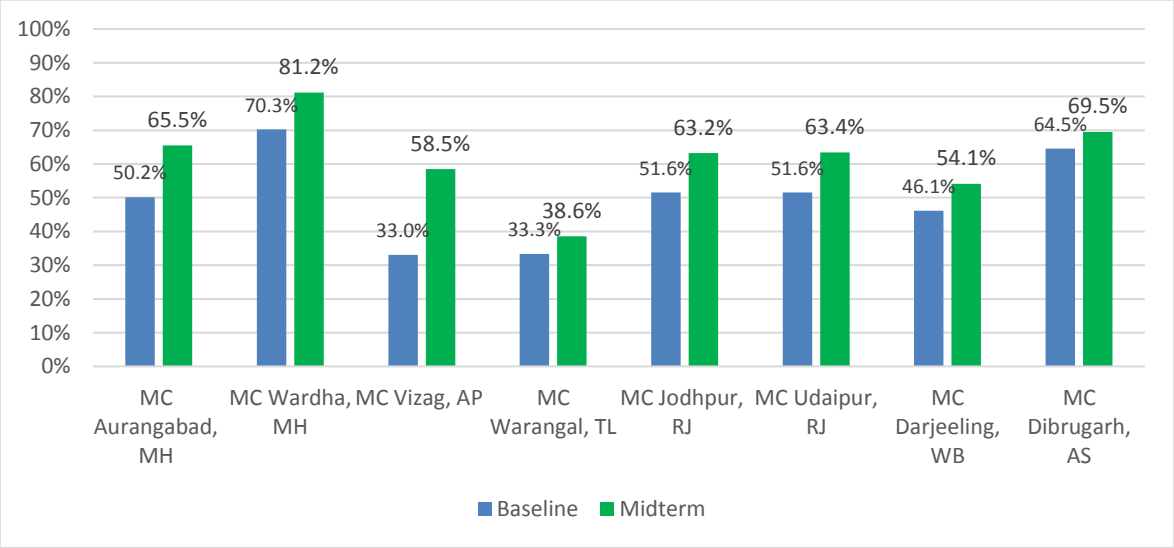
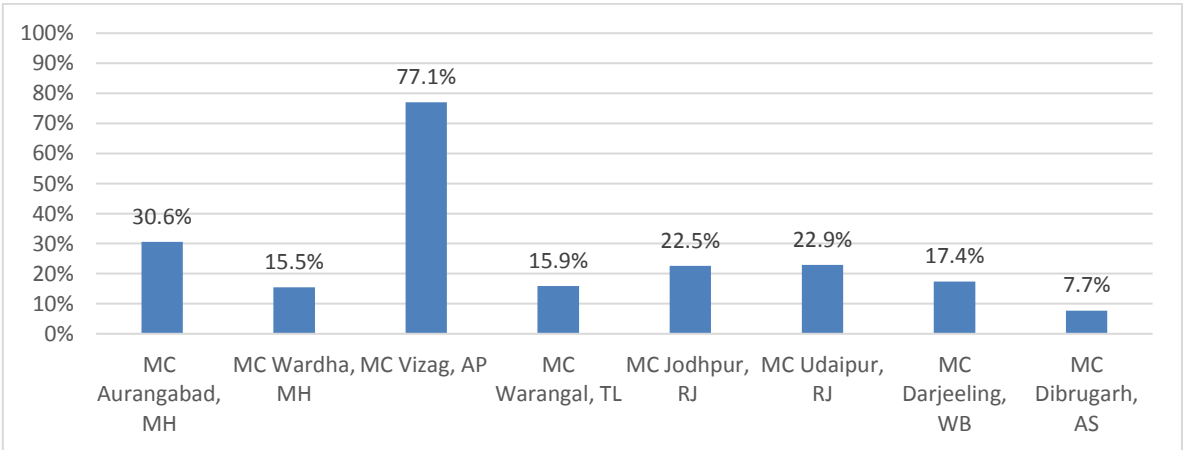


Fig 3: Percentage of increase from the BL - Overall Score

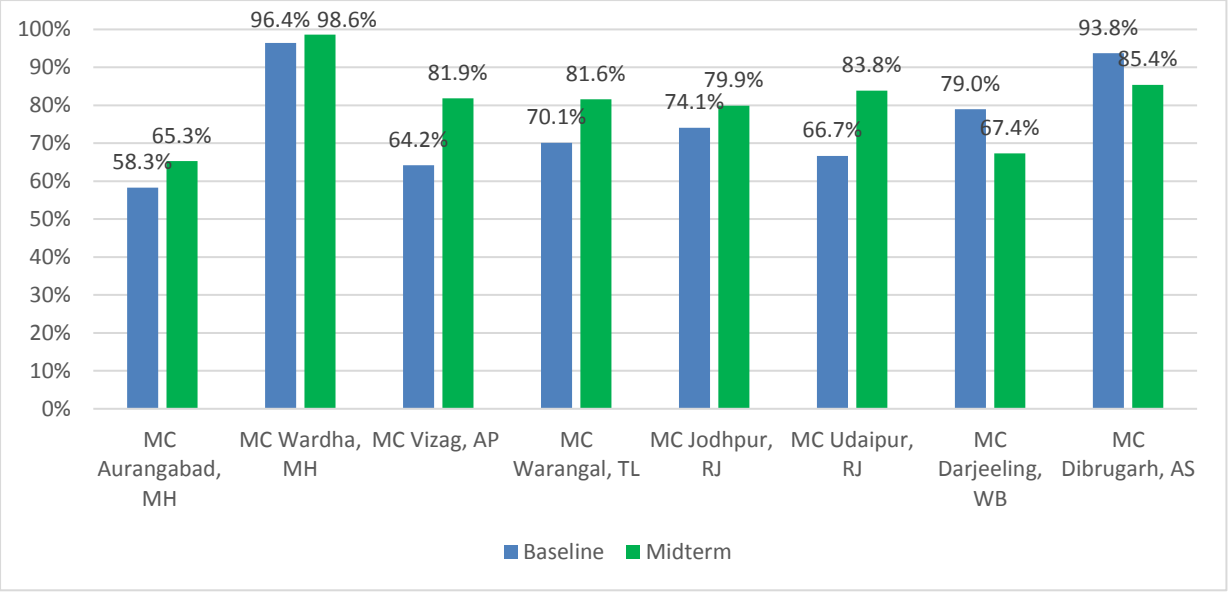


4.3 Premises Quality

The premises quality includes, general infrastructure including availability and upkeep of technical and support rooms, and availability of utilities, such as electricity, backup and running water. The average score for premises quality recorded an increase from 75.3% (SD: 13.7) at baseline to 80.5% (SD: 10.5) at midterm. The midterm review score ranges from 98.6% for Medical College, Wardha, Maharashtra to 65.3% for Medical College, Aurangabad.

Medical Colleges, Vizag and Udaipur have shown an increase, as both these labs have been allocated new premises. The Medical Colleges, Dibrugarh and Darjeeling indicated a slight decrease at midterm from baseline. In these places, there were 2 major earthquakes which resulted in cracks. The relatively new building is also developing areas of seepage. Medical College, Dibrugarh has also recorded a significant increase in patient load compromising the collection premises and possibly accounts for the part of the decline. MC Vizag has both biochemistry and hematology functioning out of the new building. More importance needs to be given to the premises by NBMC Darjeeling.

Fig 4: Premises Quality



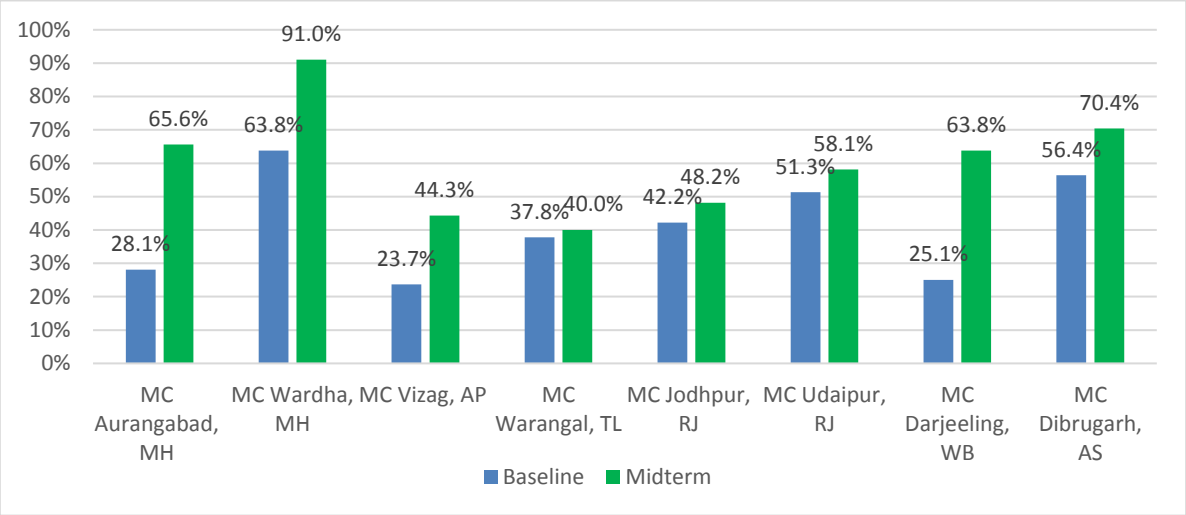
4.4 Specimen collection, Recording and Handling

This component includes, Quality of samples: in-house, referral, Sampling procedures, Request forms (in-house & referral), specimen transportation, specimen tracking, specimen validation, result reporting, and referral systems.

The average score of this component indicated an increase from 41.1 (SD: 15.1) at baseline to 60.2 (SD: 16.5) at midterm. The midterm score of medical colleges ranges from 91% for

Medical College, Wardha, Maharashtra to 40% for Medical College, KMC Warangal. Medical college Aurangabad recorded a significant increase from 28.1% to 65.6%. In terms of Specimen collection, Recording and Handling, the Labs for Life project had done a ToT and several on-site trainings in all the participating labs. Dummy arms have been given to all districts for continued trainings in blood sample collection. However, MC Jodhpur shows the least progress and the highest challenge with 5 institutions under one umbrella, several collection points and a very large patient load.

Fig 5: Specimen collection, recording and handling

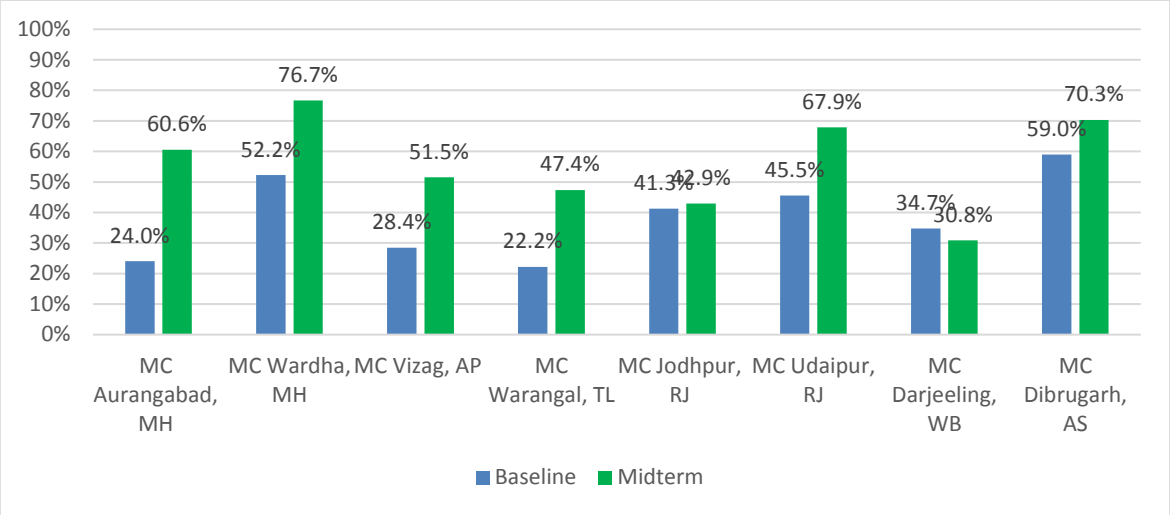


4.5 Biosafety

Bio-safety includes, building bio-security, bio-risk management, signage, patient and staff safety, availability and use of PPE, emergency equipment, first-aid facilities, safety SOPs, safety training and practices, equipment disinfection and Biomedical Waste management.

The average score for biosafety indicated an increase from 38.4% (SD: 13.4) at the baseline to 56.0% (SD: 15.6) at midterm. Labs for Life conducted a workshop on Facility Management and Safety aimed at the upper management from state and districts, institutional and lab decision makers. Following this, safety audits were performed and trainings for frontline workers done. The score ranges from 76.7% for Medical College, Wardha, Maharashtra to 30.8% for Medical College, Darjeeling. There has been a decrease in the midterm score of the Medical College, Darjeeling from baseline. Jodhpur records only minimum increase. Bio-safety has been found to be largely associated with the work load and awareness. Disproportionately large work load and lack of streamlining of work contributes towards the low scores. Active support of the institutions is very much required to correct the shortcomings. A robust Hospital Infection Control committee can also address this to a large extent.

Fig 6: Biosafety



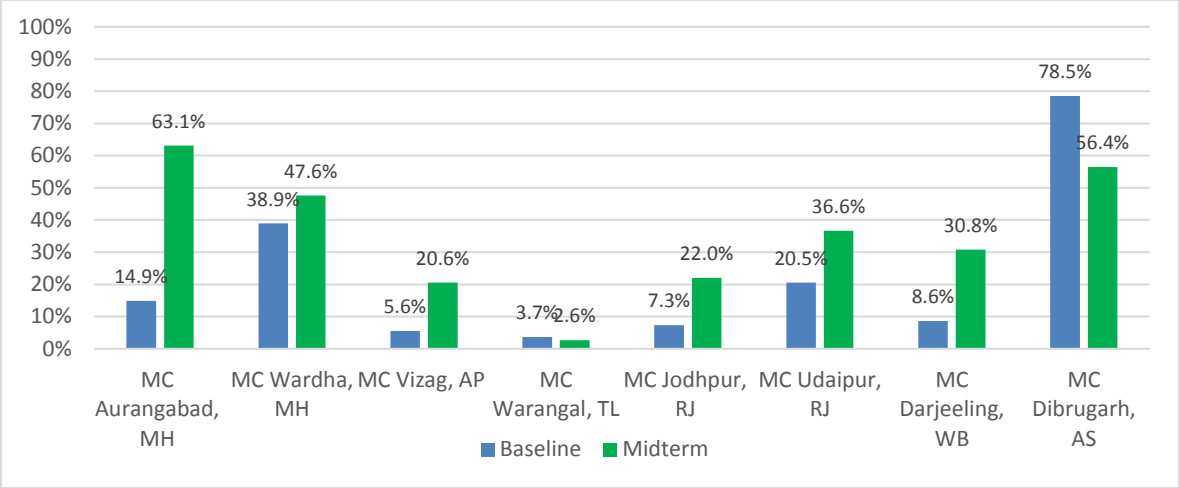
4.6 Quality management

Quality Management System (QMS) includes, documentation processes, internal QC protocols, daily monitoring corrective action protocols, monitoring QC trends in all departments, External Quality Assurance program in all departments, definition and monitoring of Quality Indicators.

The average score for quality management of all laboratories indicated an increase from 22.3% (SD: 25.4) at baseline to 35.0% (SD: 20.2) at midterm. The score for Quality Management in the midterm ranges from 63.1% for Medical College, Aurangabad, Maharashtra to 2.6% for Medical College, Warangal. The percentage of increase was more than 100% for Medical colleges, Aurangabad, Vishakhapatnam, Darjeeling and Jodhpur. The midterm score of medical college Dibrugarh showed a decrease from baseline to midterm (78.5% to 56.4%). A few labs were not having control materials and inadequate monitoring of available controls was observed. In Warangal, the IQC practices are available only in the biochemistry department. EQAS was not available anywhere. The documentation practices also were grossly inadequate.

Both components of this aspect, Quality Controls and Documentation were addressed through multiple levels of trainings by Labs for Life. As the concepts are new and effort intensive, it might take more time for changes to be evidenced. Additionally, the availability and uninterrupted supply of control materials and registering in EQAS programs were found to be challenges in several places.

Fig 7: Quality Management

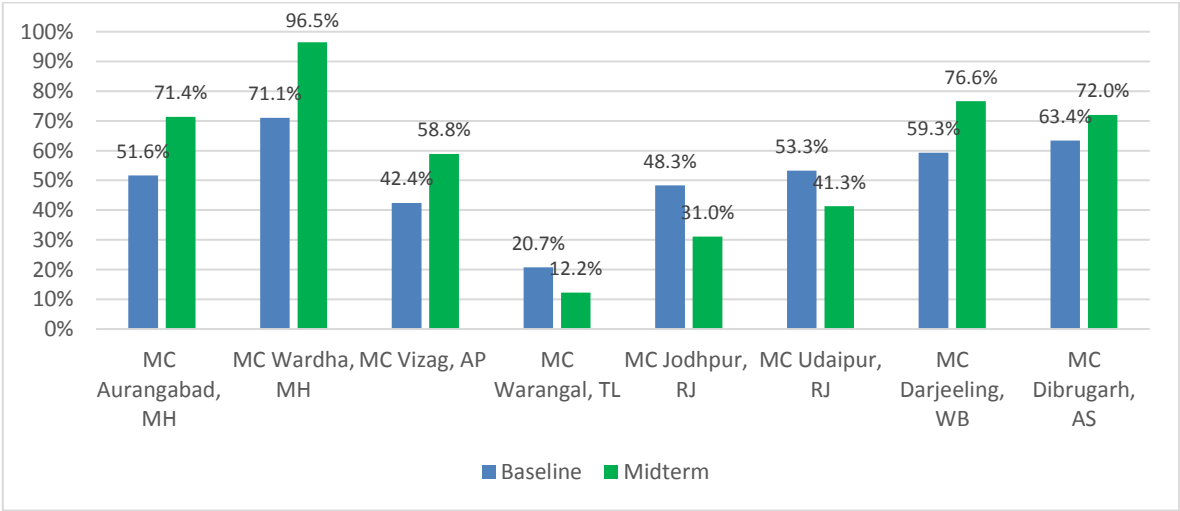


4.7 Public health functions

Public Health functions include, Relationship with IHR, Surveillance: Participation, diseases covered, outbreak investigation protocols, emergency sampling and shipping and Notification.

The average score for public health functions recorded an increased from 51.3% (SD: 15.2) at baseline to 57.5% (SD: 27.5) at midterm review. The score for public health functions in midterm review ranges from 96.5% for Medical College, Wardha to 12.2% for Medical College, Warangal. Medical colleges Warangal, Jodhpur and Udaipur indicated a decline in the score from baseline to midterm. Webinars on Public Health Functions were conducted. Additional interventions are planned.

Fig 8: Public health functions



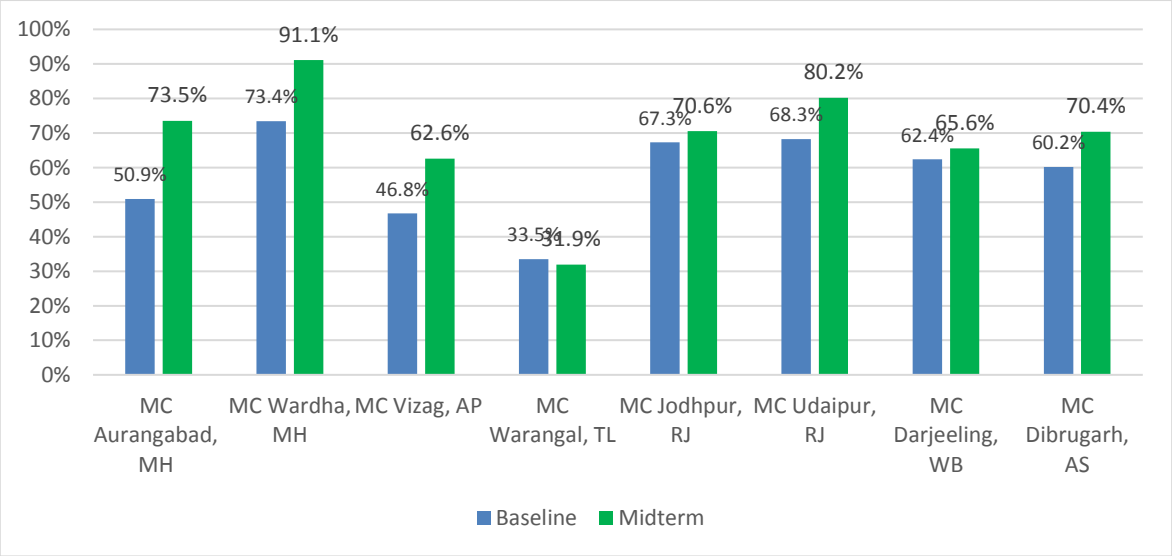
4.8 Supply and equipment management

This component includes, inventory control, stocks, orders management, use of expired reagents, reagent availability, equipment management and preventive maintenance, calibrations, CMC, availability of user manuals and spare parts and equipment availability as per requirement of a tertiary care center.

The average score for supply and equipment management indicated an increase from 57.8% (SD: 13.3) to 68.2 (SD: 17.2) from baseline to midterm review. The score for this component ranges from 91.1% for Medical College, Wardha to 31.9% for Medical College Warangal. All the Medical colleges, except Warangal, showed an increase at midterm review.

None of the institutions except MGIMS have an equipment management program for CMC and calibrations. Some colleges have utilized available funds for calibration of some equipment. Although agencies of the Equipment Management and Maintenance Initiative of NHM have mapped out the equipment in several institutions, the actual support is yet to be given. Stock-outs are also found to be another area of concern. Labs for Life had conducted equipment management workshops for all participant institutions.

Fig 9: Supply and Equipment Management

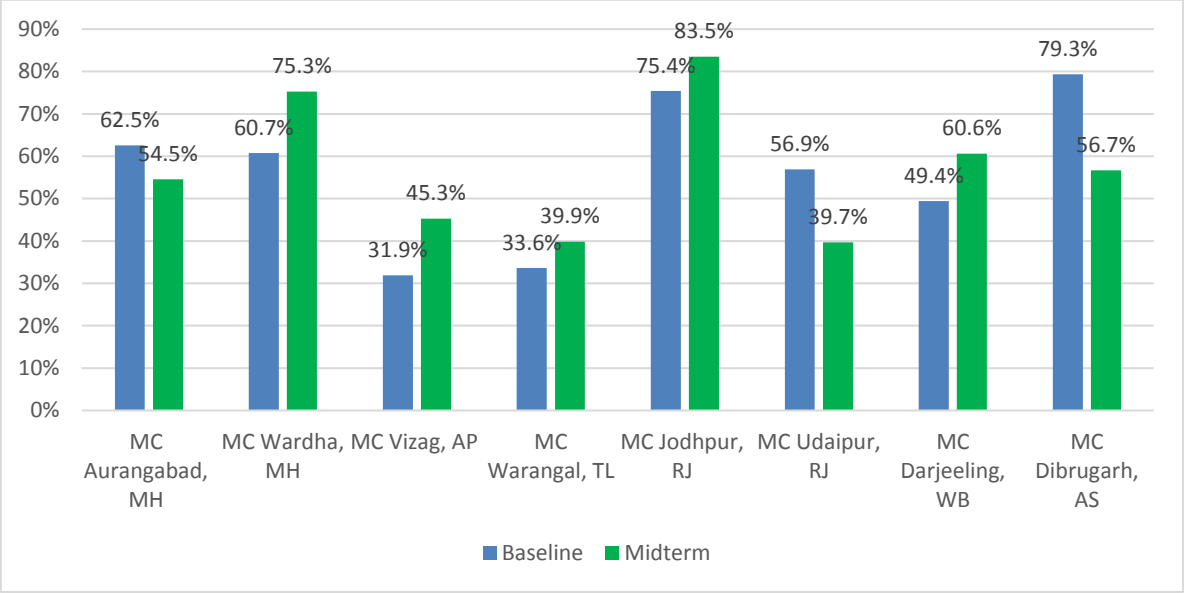


4.9 Equipment availability

This component includes the availability of general and facility specific laboratory equipment. The average score of all laboratories indicated a slight increase from 56.2% (SD: 17.4) to 56.9 (SD: 16.0) from baseline to midterm review. The midterm review score for equipment availability ranges from 83.5% for Medical College, Jodhpur, to 39.7% for

Medical College Udaipur. There has been a decrease from baseline to midterm in medical colleges Aurangabad, Udaipur and Dibrugarh.

Fig 10: Equipment availability



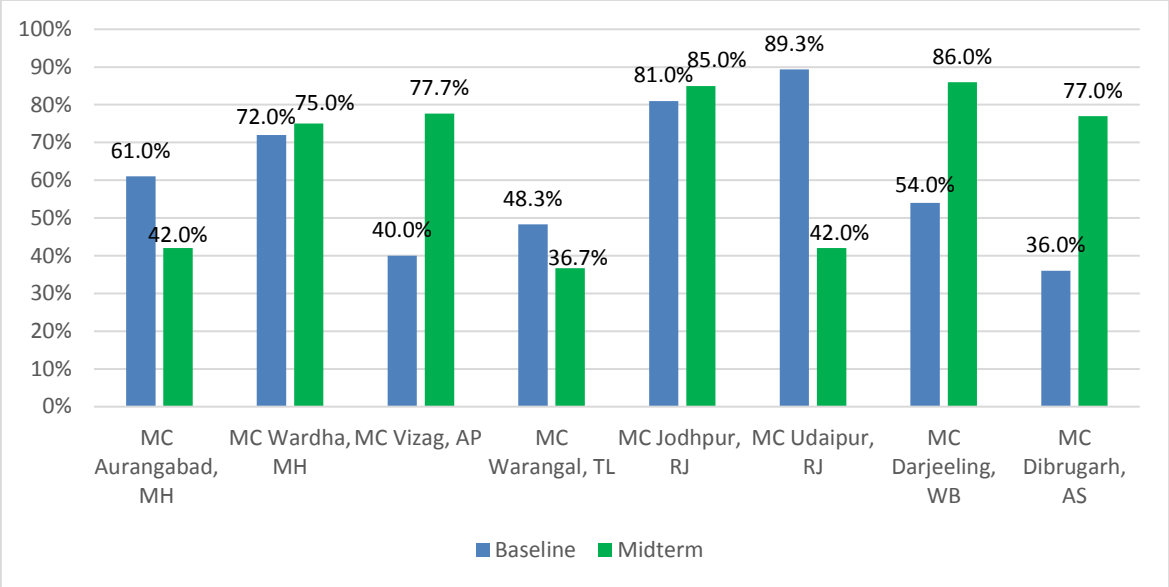
4.10 Budget and Finances

This component includes funding principles for reagents, consumables, equipment, annual reagent supplies and Emergency supplies.

The average score for budget and finances recorded an increase from 60.2% (SD: 19.3) at baseline to 65.2(SD: 21.1) at midterm review. The score for budget and finances for midterm review ranges from 86% for Medical College, Darjeeling to 36.7% for Medical College, Warangal. Medical colleges of Aurangabad, Warangal, Udaipur showed a decline in midterm review score when compared to baseline.

Fluctuating fund allocations result in uncertainty in the service provision as well as unsustainable efforts in maintaining quality. Efforts to map out resources available for Medical Colleges are being attempted. A dedicated lab fund may be considered by all State Medical Education Departments, based upon the menu of tests offered, workload, scientific principles of inventory projections and funds for implementing and maintaining a Quality Management System. A few alternate sources apart from state funding that have emerged are PMSSY funds, project funds through agencies like ICMR,DBT etc., NGOs, old students associations and other development funds. Continuous advocacy is being done in this area. Labs are being sensitized regarding projecting their annual needs and being part of the institutional planning activities.

Fig 11: Budget and Finances

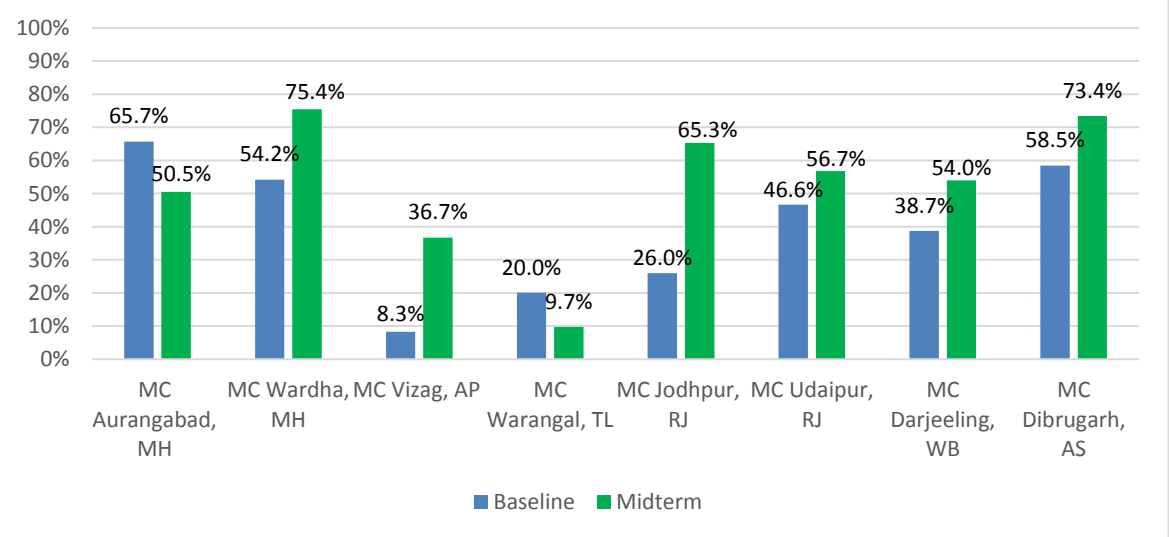


4.11 Data management

This component includes, data recording, registers, data validation, critical call-out records, notification records, data archival and computerized data backup.

The average score for data management indicated an increase from 39.8% (SD: 20.2) at baseline to 52.7% (SD: 21.5) at midterm review. The score for data management in medical colleges ranges from 75.4% for Medical College, Wardha to 9.7% for Medical College, Warangal. The Medical colleges, Warangal, Wardha and Aurangabad showed a decrease in midterm review as compared to baseline.

Fig 12: Data Management



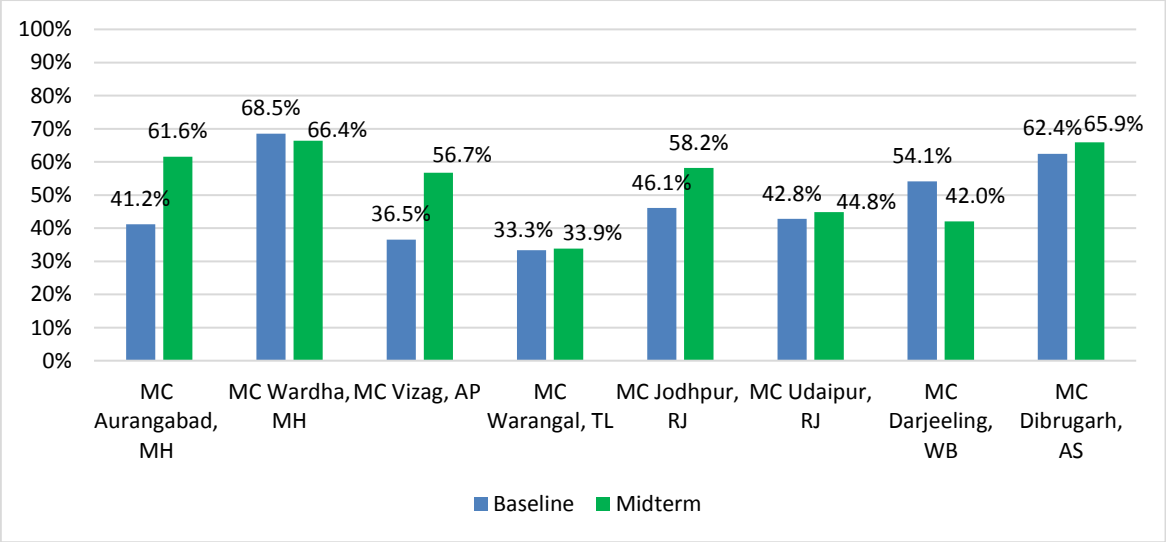
4.12 Microbiological diagnosis capacities: General Microbiology

This microbiology diagnosis capacities include sampling capacities, transportation capacities, and diagnostic capacities in bacterial, viral, parasitological and mycological infections and water testing facilities.

The average score for microbiological diagnosis capacities recorded an increase from 48.1% (SD:12.5) at baseline to 53.7% (SD:12.0) at midterm review. The midterm score for Microbiology diagnosis capacities in medical colleges ranges from 66.4% for Medical College, Wardha, to 33.9% for Medical College, Warangal. Medical college Wardha and Darjeeling showed a decrease at midterm as compared to baseline.

This area needs to be addressed as the need is systemic. Efforts in intervention have to be in consensus and with the support from NCDC, for which a plan has to be drawn up. It is important to note that, unlike the primary and secondary care institutions, the standards of service provision have not been set for medical colleges. Thus what are the mandatory tests, if screening or confirmation is mandated, by what methods etc. are not defined. These issues need to be advocated at the highest levels.

Fig 13: Microbiological Diagnosis Capacities

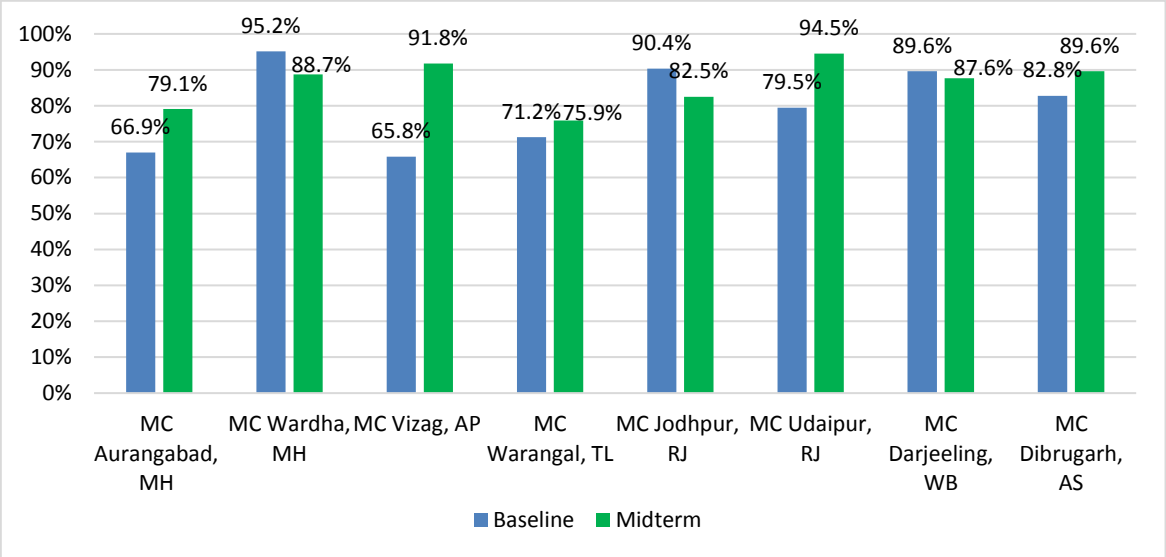


4.13 Diagnosis capacities, clinical lab

The Diagnosis capacities- clinical lab component includes, Hematology including Cyto-chemistry, bone marrow, immunephenotyping, Histopathology including IHCs, Cytology including FNACs, LBC, Urine, stool and semen analysis and Biochemistry including immunoassays.

The overall score for the diagnosis capacity indicated an increase from 80.2% (SD: 11.3) at baseline to 86.2% (SD:6.4) at midterm review. The midterm score for diagnosis capacities-clinical lab ranges from 94.5% for Medical College, Udaipur, to 75.9% each for Medical College, Warangal. The score is above 70% in all the medical colleges' laboratories. As suggested under the microbiological testing capacities, standards to service provision are not set for the pathology and biochemistry too which needs attention.

Fig 14: Diagnosis capacities, clinical lab

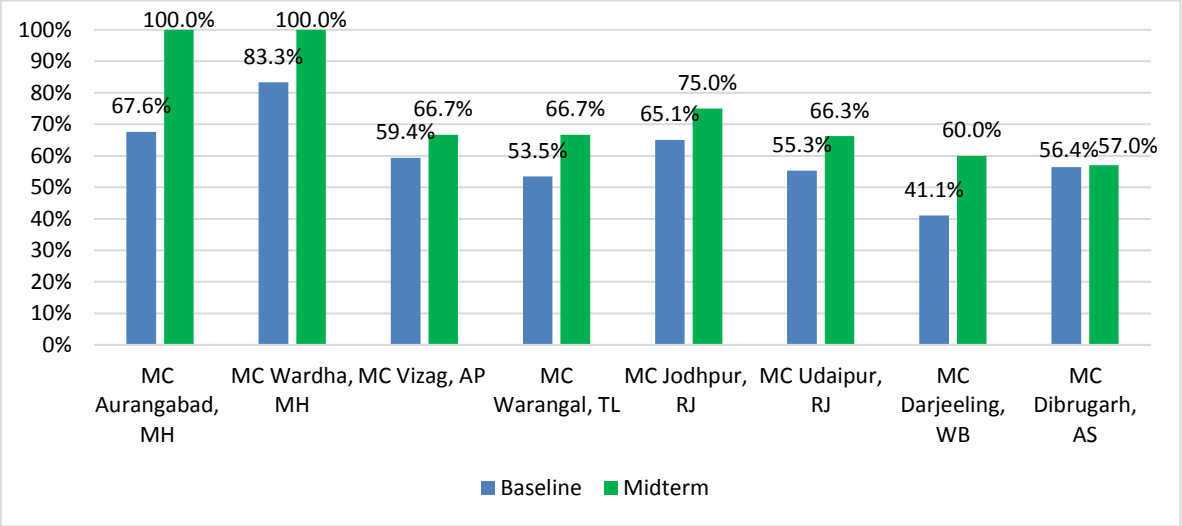


4.14 Staff available in the laboratory

The component, staff availability includes availability of senior staff, Technical staff, Support staff and qualification of the said staff. The average score for the staff availability of all laboratories recorded an increase from 60.2% (SD: 12.3) at baseline to 73.9% (SD: 16.9) at midterm review. The midterm score for staff availability ranges from a maximum 100% for Medical College, Aurangabad and Wardha to 57% for Medical College, Dibrugarh. The midterm score was above 50% for all the medical college laboratories.

The tool has the limitation in that it captures the staff availability as per sanctioned strength. If the sanctioned strength in itself is flawed, the numbers will not reflect the inadequacies. Medical Colleges lack in the staff strength standards. MCI has set numbers of faculty positions and technical and support staff from the perspective of student intake. However, no standards are available for the requisite numbers in terms of bed-strength or OPD walk-ins or lab-load.

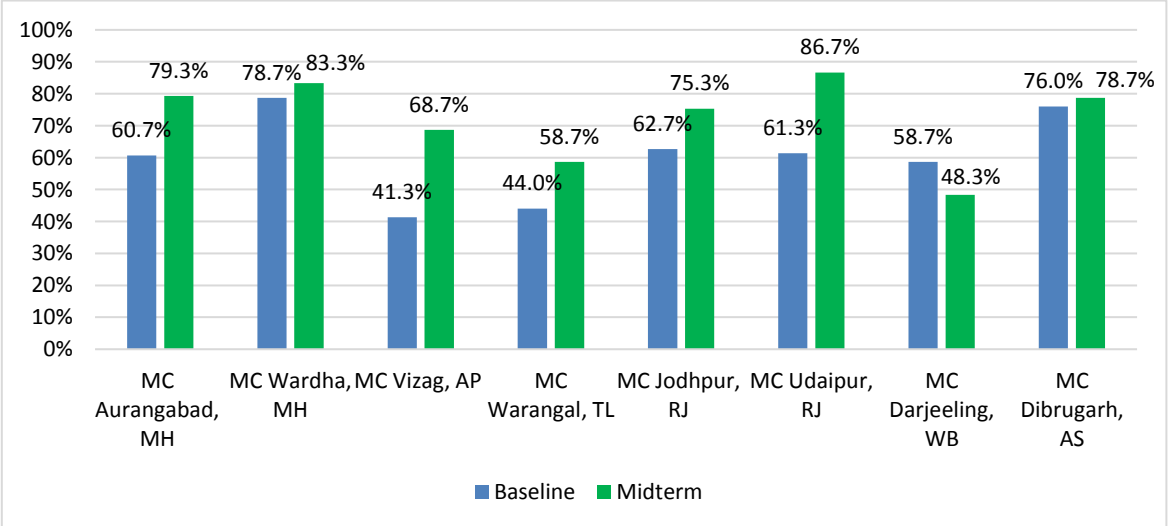
Fig 15: Staff Availability



4.15 Staff management

Staff management includes, HR funding, staff health facilities, professional associations, CMEs. The average score for staff management of all laboratories showed an increase from 60.4% (SD: 13.2) in baseline assessment to 72.4% (SD 13.1) midterm review. The midterm review score for staff management ranges from 86.7% for Medical College, Udaipur, to 48.3% for Medical College, Darjeeling. Medical college Darjeeling indicated a decrease in midterm review. No availability of professional associations for Lab Technicians was noted as point in most places. Thus options of in-service training, capacity building up-gradation on recent advances are lacking. State and institution level policies are required to make this a sustainable and replicable model

Fig 16: Staff management

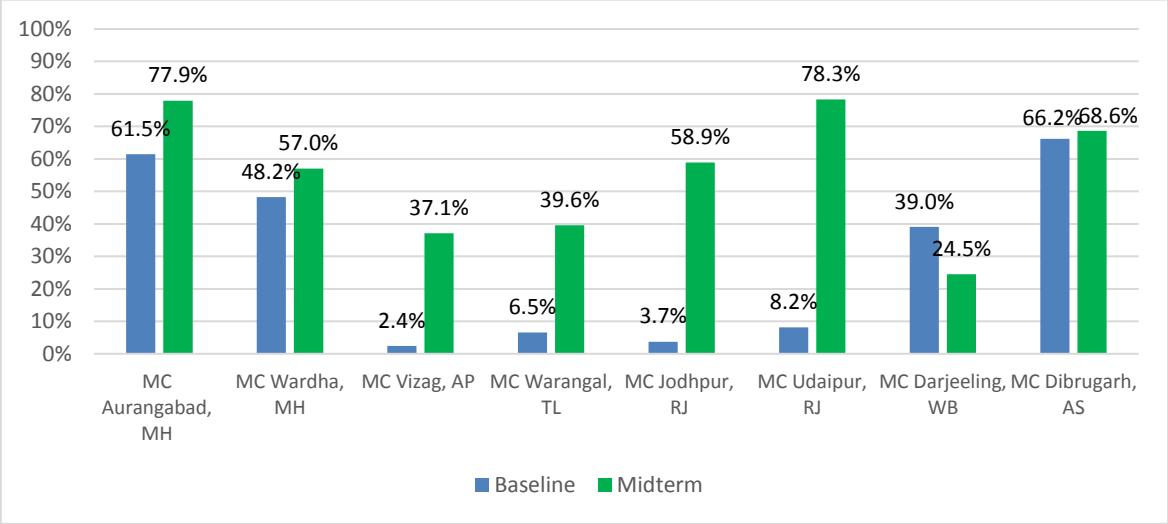


4.16 Training and supervision

The training and supervision component includes, induction training, continuous training, online training, supervision and availability of general and specific guidelines. The average score of training and supervision recorded an increase from 29.5% (SD: 27.2) to 55.2% (SD: 19.9) at midterm review. The score for training and supervision in midterm review ranges from 78.3% for Medical College, Udaipur, to 24.5% for Medical College, Darjeeling.

As most of the components of this could be addressed at the institutional level, there is a very positive change in most institutions. Trainings have become part of the activities of the institution. However, to make it sustainable, fund allocations and calendaring of trainings by the institutions themselves are needed.

Fig 17: Training and Supervision

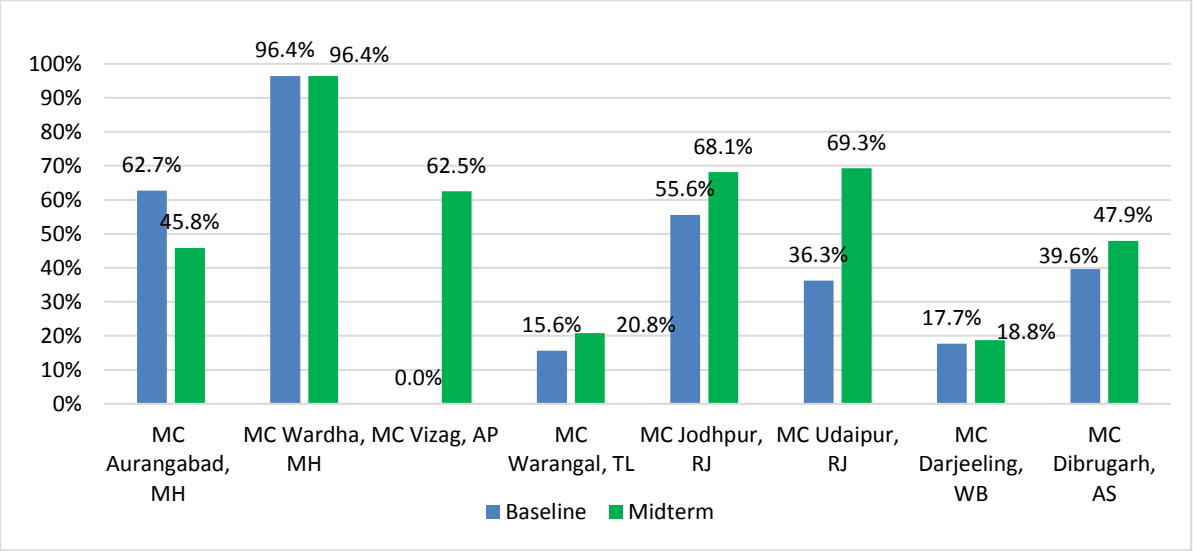


4.17 Information technologies (IT)

The information technology component includes hardware availability, software availability and licenses, internet, and Hospital Information System (HIS)/ Laboratory Information System (LIS).

The average score increased from 40.5% (SD: 30.8) at baseline to 53.7% (SD: 26.1) at midterm review. The midterm score ranges from 96.4% for Medical College, Wardha, to 18.8% for Medical College, Darjeeling. Medical college, Vishakhapatnam showed recorded a significant increase to 62.5% from the baseline score of 0%. Wardha has a robust Lab information system. Most other places have some level of capacities and are in different stages of developing LIS. It is advisable to do this in accordance with ISO 15189 requirements and the process done accordingly.

Fig 18: Information Technology

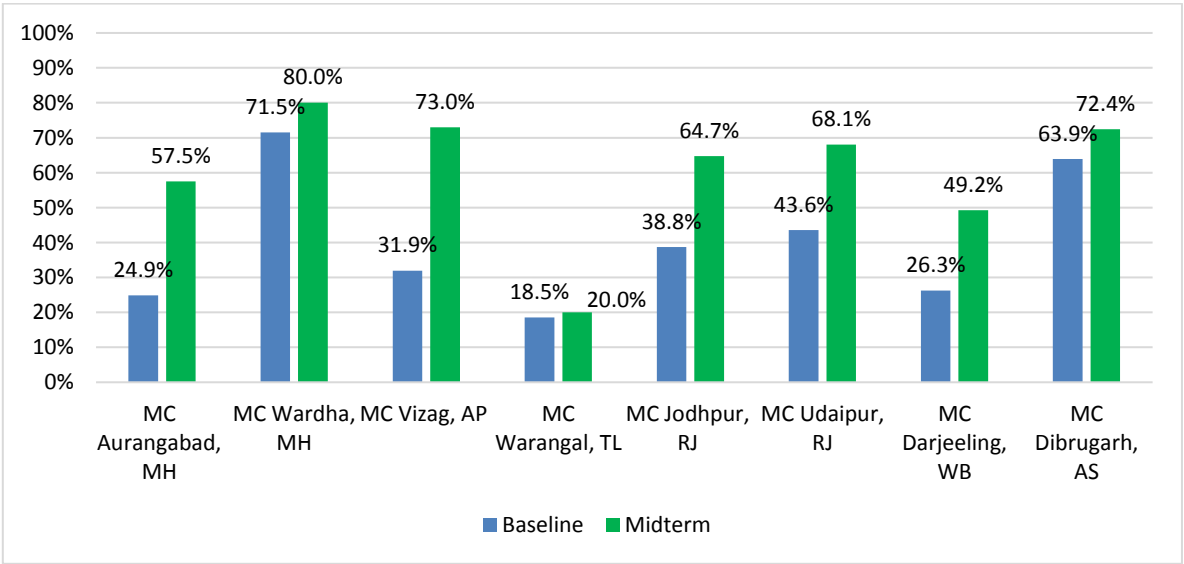


4.18 Communication

This communication component includes internal communication, external communication, document management, IHR compliance and communication, communication with customers and communication capacity.

The average score for communication in all the laboratories showed an increase from 39.9% (SD: 19.0) at baseline assessment to 60.6 % (SD: 19.0) at midterm review. The midterm review score ranges from 80.0% for Medical College, Wardha, to 20% for Medical College, Warangal.

Fig 19: Communication



Though the score has gone up, there is a need for much more effort in this regard. Intra lab, inter lab, inter-department levels of internal communications have to be established. External communications with patients, regulatory bodies, surveillance bodies; district and state authorities need to be established. IHR and PHIEC communications need to understood and complied with.

5. Key observations and Recommendations (Medical Colleges)

The following are the key observations and recommendations by the assessors, based on the results from quantitative assessment, site observations, group discussion and interviews with different stakeholders in the institutions. The observations and related recommendations are given institution's wise.

Table 5: Government Medical College, Aurangabad, Maharashtra

Government Medical College, Aurangabad, Maharashtra		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• Space is adequate with specific areas designated. • No Parasitology unit. • Washrooms need to be cleaner. Whitewash & repair needed in OPD area. • No UPS for analyzers in OPD area. • Air-conditioning absent in OPD or nonfunctional. • Waiting area before sample collection gets very crowded at peak load. • In OPD labs storage not organized. • Changing room & wash rooms absent in OPD labs.	• Parasitology unit to be created. • All analytical equipment to be on UPS. • Air-conditioning to be provided and to be kept functional in lab and sample collection area. • Storage space to be demarcated. • Waiting area workflow to be streamlined to avoid overcrowding. • Whitewash and repair to be done periodically or on need basis. • Washrooms need to be cleaner.
Specimen Collection, recording and handling	• Time of collection, clinical history not captured especially from IPD. • No monitoring of sample volume and temperature adequacy. • Verified Sample transportation box not available. • Test requisition via HIS for OPD samples, hard copy for IPD; very limited details mentioned on TRF. Name of sampler, time of collection, address, clinical history, medication history etc, not mentioned on TRF. • No SOP for data management. • No provision of sample referral if services discontinued. • Specimens not labeled with 2 identifiers. In clinical pathology no	• Common sample collection center for all the units must be implemented to ensure better monitoring and high output, with fewer errors and less manpower. • Containers to be used as per the vendor guideline or standard textbooks. • Monitoring of sample volume and temperature adequacy to be done. Sample volume risks to be measured according to tests. • To use validated transportation box for transportation of samples. • TRFs should be duly filled-Name of sampler, time of collection, address, clinical history, medication history etc.

	numbering on container; in most only registration number mentioned. • Procedure for processing of sample and retention not defined to ensure testing is done on within stability and correct integrity of sample.	• SOP on data management to be made. • Provision of sample referral to be made. • All samples to be properly labelled with 2identifiers • Procedure for processing of sample and retention to be defined that ensures testing is done on within stability and correct integrity of sample.
Biosafety	• Bio risk assessment not done. • All exits not marked by proper, illuminated signs. • Fire evacuation plan not evidenced. • There is no central service for lab coats/lab linen washing. • Emergency equipment availability- fire blankets not available; no record for use of these equipment. • First aid box does not have instruction sheet, safety pins, mouth piece, sterile eye-pads with attachment bandages & band aids. • Methods in packaging and triple-packaging of a sample are not clearly defined and followed especially for ward samples. • MSDS for chemicals used not displayed. Lid covered infectious waste disposal containers not used. Pathology and Biochemistry: Apart from the above, restricted entry into labs not effectively implemented especially in OPD area. • Staff moving outside lab area with lab coats. • Lid covered infectious waste disposal containers not used. • Dedicated special containers not used for solvents (Toluene, Xylene, etc.). Emergency exits not available.	• Bio-risk assessment to be done. Restricted entry into labs to be effectively implemented especially in OPD area. • All exits to be marked by proper, illuminated signs. • Fire evacuation plan to be made and displayed. • A central service for lab coats/lab linen washing to be started. • Emergency equipment availability to be ensured; record for use of these equipment kept. • First aid box to have instruction sheet, safety pins, mouth piece, sterile eye-pads with attachment bandages & band aids. • Methods in packaging and triple-packaging of a sample to be clearly defined and followed especially for ward samples. • Staff should not move outside lab area with lab coats. • MSDS for chemicals to be displayed. • Covered infectious waste disposal containers to be used. Dedicated special containers to be used for solvents (Toluene, Xylene, etc.).

Quality Management	• That staff has read and understood the current SOPs, is not evidenced. • All reagent lots not undergoing acceptance testing. • IQC & EQA protocols, review, trending, LJs and corrective actions not evidenced from records. • Quality indicators not defined and regularly monitored in pathology and Biochemistry	• Staff to record in 'read and understood' once SOPs are read. • All reagent lots to undergo acceptance testing. • IQC & EQA protocols, review, trending, LJs and corrective actions to be made and effectively maintained. • Quality indicators to be defined and monitored regularly.
Public Health Functions	• Relationship of the lab with IHR not evidenced.	• Relationship of the lab with IHR to be established. Staff trainings to be planned for improving awareness. • IHR interactions policy to be reviewed, trained and implemented.
Supplies, equipment availability and Management	• Overall satisfactory in Microbiology. • Inventory management not adequate to ensure continuity of lab services; a major concern.	• , Blood culture analyzers and Automatic AST analyzers may be considered , • ATCC strain of Candida should be made available. • CMC to be preferred instead of AMC for the equipment; as found delay with payments after repair of instruments. • IQ, OQ and PQ of all the instruments must be considered. • Periodic training commitments from vendor should be included in the CMC contract. • Reagent availability to be ensured for continuity of lab services Electronic inventory management may be considered. •
Budget and Finances	• Budgetary projections not based on test, facility and equipment needs, quality assurance procedures and materials. • Reagent availability and timely repair a major concern. • In pathology and biochemistry, there are inadequate number of functional	• Budgetary projections to be based on test, facility and equipment needs, and quality assurance procedures and materials. • Adequate number of functional equipment to ensure consistent service levels should be assured.

	equipment to ensure consistent service levels. • Back-up plans for getting tests done from outside in case of equipment failure not evidenced.	• Back-up plans for getting tests done from outside in case of equipment failure to be made. • Reagent availability and timely repair to be streamlined.
Data Management and IT	• Inadequate Laboratory Data management policies and procedures. • Immediate notification of critical values not being done.	• Policy and procedures covering Laboratory Data management & access restriction, ensuring integrity and security to be made available. • Immediate notification of critical values to be done.
Diagnostic capacities	• Bacterial, viral and parasitic infections tests not available as per checklist • No separate parasitic unit. • Flowcytometery for immunophenotyping not done. • Hb electrophoresis not done. FDP, D-Dimer. LBC PAP & HPV not done. Calcium & phosphorus not done in urine. HbA1c, Urinary micro albumin not done. Creatinine clearance not done.	• All bacterial, viral & parasitic infections tests to be made available to meet local needs. • Parasitic unit may be created. • Flowcytometery for immunophenotyping, FDP, D-Dimer,LBC PAP & HPV may be considered in Pathology. • HbA1c, Calcium & phosphorus in urine, urinary micro albumin, Creatinine clearance may considered in biochemistry and relevant immunoassay testing may be started as per the institutions requirement, and considering that this is a tertiary care facility.
Staff availability, training and management	• Post exposure prophylaxis guidelines (PEP) not pinned on the wall. • Trainings not planned to meet the job requirements; pre/post training assessment not done. • Pathology and microbiology have not defined the job descriptions for various staff categories, which are understood and noted by the staff.	• Post exposure prophylaxis guidelines (PEP) to be pinned on the wall. • Trainings should be planned to meet the job requirements; pre/post training assessment done. • Lab has to define job descriptions for various staff categories, which are understood and noted by the staff.

Communications	Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services is a good practice to start • Communication with district and state authorities and regulatory bodies can be started. Understanding and availing funds, understanding the equipment and inventory management practices instituted by state needs to be understood for effective utilization of resources. • Disease notification practices can also be improved by understanding the disease surveillance requirements at national and international levels.

Table 6: Mahatma Gandhi Institute of Medical Sciences, Wardha, Maharashtra

Mahatma Gandhi Institute of Medical Sciences, Wardha, Maharashtra		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	**Microbiology:** • Premises are well maintained. • Quality policy not displayed in any department. **Pathology:** • Tube light placed on the working bench in Cytology lab/FNAC room. • Tea machine found in Histopathology lab. • Expired needles found in FNAC room. • Medicine collection centre ward was too crowded with patients all around. • Staff at the central collection centre is unaware about PEP guidelines. • Order of draw not available to the phlebotomists.	• Need to place a fire extinguisher in the laboratory within reachable limit as burners are used in the lab. • Signage for exit. Applicable for all departments. • Display timings for collection of samples, collection of reports in local language in all the lab premises. • Hazardous practices like loosely fixed lights must be changed • Medicine collection centre should display working hours in local language. Order of draw must be displayed. Patients need to be called in sequence and must queue up in waiting area. • Central collection centre should have first aid box, spill kit. • PEP guidelines awareness should be imparted as trainings and should be displayed in local language wherever relevant. • Closed collection such as evacuated tube may be used as an infection control practice
Specimen Collection, recording and handling	**Microbiology:** • Overall satisfactory. **Pathology:** • Need a lot of improvement in histopathology. • Samples are transported in open trays in biochemistry	• Samples should be collected and stored in appropriate leak proof containers. The practice of open containers in histopathology can lead to hazards of formalin vapour and needs to be addressed. • Recording and handling of samples and requisition forms needs to be done in organized manner.

		• Need for transportation in a closed box. • Standardized skin disinfection procedure must be followed for blood collection by phlebotomists.
Biosafety	• Bio risk management exercise not carried out. • Sample storage in serology needed improvement and is implemented immediately. • In pathology, samples and forms are placed inappropriately where samples are leaked on the forms.	• Bio-risk management exercise should be performed and documented and accessible to the staff. • Bio risk matrix should be used. Monitoring must be performed on regular / periodic basis. • Finding should be discussed in the management review meetings. • Organized and systematic way to handle samples and requisition forms recommended. • Pictogram awareness to be created for all lab chemicals
Quality Management	• Microbiology has good QMS and QI practices. **Pathology:** • IQC in Haematology not available. Master list of documents unavailable. • Results such as urine routine test and its findings are directly transferred to LIMS without recording in the registers. • Instrument calibration not done in haematology for Cell counters. • QI monitoring to be started in Pathology and biochemistry	• Inventory for IQC material must be strictly followed. • Haemostasis QC needs to be performed. • Staff need to read and understand SOP and need documentation for the same. • SOPs need revision and procedure must be standardized and followed diligently. • For IQC breaks in CBC, a process of repeating retained samples may be employed. But this cannot replace the IQC as a mechanism of performance evaluation. • Retained sample evaluation maybe done for assessing storage if the lab reports samples after storage • Results should be traceable. Hence a system of registers may be adopted for manual testing

		where back-up data is not available either as print outs or on an equipment. • Documentation needs to be improved for the following; equipment maintenance logs, IQC protocols, calibration data, sample retention, corrective actions for EQAS. • Transcription errors should be checked for cases when samples are sent out for testing, due to breakdown and when results are copied from externally generated reports to LIMS
Public Health Functions	• Participates in disease surveillance. • Notification done and L forms sent to IDSP	• MGIMS has a significant presence in the district and can be involved in the Infection control AMR activities of the district
Supplies, equipment availability and Management	• Sterile screw capped wide mouth plastic containers for sputum samples are not available. • Glass slides reused for Gram stain. • Haematology QC not available. • Plastic sealed containers not available for histopathology samples. • Asset coding or unique identification number as per institutional coding not done for various equipment.	• Sterile screw capped wide mouth plastic containers for sputum samples should be used for all specimen types. • Need for fully automated new updated version of instruments in Haematology. • Replace old, not in use instruments. • Asset coding/ unique ID system for all equipment required
Budget and Finances	• Resources, in general is not a constraint but challenges to carry out tests like LBC as it is not cost effective compared to manual PAP. • Consent form not taken for OPD patients on whom FNAC is performed.	• LBC is recommended that is more sensitive and produces superior results though cost may be a concern • Informed consent may be mandated wherever necessary
Data Management and IT	• Good LIMS integrated to HIS.	• It would be helpful to incorporate advancements such as alerts for critical results, delta checking etc. so that they can be communicated on time and also for emergency samples
Diagnostic capacities	Adequate	• May upgrade as required, especially microbiology

Staff availability, training and management	• Adequate staff • Training records not found.	• Induction training to be carried out. • Training calendar to be prepared on the basis of staff assessment and training needs. • Regular internal/external training must be considered for all technical and supervisory staff including housekeeping (especially for biosafety). • Technical staff competency assessment to be carried out once a year and accordingly training to be provided and must be documented.
Communications	• Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services is a good practice to start • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.

Table 7: Andhra Medical College, Visakhapatnam, Andhra Pradesh

Andhra Medical College, Visakhapatnam, Andhra Pradesh		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	**Microbiology:** • The new lab designated for microbiology does not have sufficient space to accommodate decontamination, washing and sterilization procedures, as it involves installation of 2 autoclaves, hot air ovens, place for handling glassware' etc. • The place where sterilization and decontamination is done is old as is in need of renovation. • Many unnecessary articles including expired reagents are kept in the area. **Pathology:** • Patient testing is done in a new lab with sufficient space. • However, sample transport is not streamlined and patients are walking inside the testing area with samples. **Biochemistry:** • Premises are satisfactory.	• Decontamination, washing and sterilization may be retained in the present place, where sufficient space is available. • Sterile activities like plate pouring, storage of prepared media etc. may be shifted to the new lab. • A robust system should be thought out and implemented so that there will not be any break in transport of materials, to and from the new lab to the sterilization and decontamination area. • The sterilization and decontamination area should be properly cleaned, unwanted items discarded and renovated. • The rest of the diagnostic work should be shifted to the new lab without delay as the current lab does not have temperature control. • If a microbiology department is running properly, the media and reagents required at a time is high and consequently a large storage facility will be required. • It is recommended that a cold room is made available rather than 6 or 7 large refrigerators. • In **pathology**, proper arrangements should be made for single point receipt of samples, and subsequent transport to the lab.
Specimen Collection, recording and handling	**Microbiology** • Specimen is received in the first floor of the microbiology department. It is difficult for patients to find the place. • Specimen containers used are not	• Sample reception should be located in the new lab at a single point for all departments (central sample reception) where it is accessible to the patient.

	standard. • Test requests do not have critical information such as details of the specimen, patient etc. • No system for sample storage on receipt or for retesting at a later time. • No standard procedures for specimen handling. • Specimen processed without any standard protocol. • No work register maintained for specimen processing. • More than optimum number of samples processed in a single medium resulting in failure to interpret the growth. • Special media for epidemic prone diseases such as cholera, typhoid, food poisoning etc. not used routinely. • Sufficient biochemical media not available for routine use. **Pathology and Biochemistry** • No standard procedures implemented. • Proper work registers not maintained. • Reports are directly entered into the test request form as report to patient. No information maintained in the lab. • Specimen receipt is not proper. Patients are walking inside the testing area with samples.	• Sample storage refrigerators should be available and samples stored in it wherever more than 30 minutes delay occurs or as per standard guidelines Sample storage refrigerator should be available in the lab for storing samples before and after processing. • The first cubicle of the new microbiology lab may be allocated for receiving microbiology samples from the central sample reception. Temporary storage, serum separation for serology, register entry and numbering etc. can be done here. • Proper sample containers and collection tubes should be used. • A standard request form should be introduced with proper awareness among the clinicians to give a properly filled request. • SOPs should be written using standard protocols and implemented to correct observations above **Pathology and Biochemistry** • Proper arrangements should be made for single point receipt of samples, and subsequent transport to the lab. • All documents as mentioned above (Test Request Forms, Accessioning registers) to be implemented. • Training should be given to staff on maintenance of proper registers in the lab. • Preanalytical errors shall be minimized when we have the sample collection manual in place

		and implemented. • Clotting to be monitored before centrifugation and work instructions needs to be available. • A unique numbering system will have to be evolved with SOPs for accessioning: transportation, segregation and preparation of samples, applying acceptance criteria, repeat sample requests wherever warranted.
Biosafety	• Staff was found to be extremely careless in handling patient samples. • Instances of staff throwing syringe with sample on the table, walking around with uncapped syringes, unattended spillages were seen. • Splashes inside the testing area not attended.	• Repeated training should be given to the staff to increase the morale. • Supervisory staff should be designated to monitor compliance to biosafety practices. • A proper biosafety cabinet, certified as per EN12469/NSF49, should be installed in microbiology.
Quality Management	• Quality management system not implemented. • QC for antibiotic susceptibility not done even though the control bacterial strains are available. • No work record is maintained in the lab. • Staff who is knowledgeable in NABL standards is available. • No IQC/EQAS in pathology (hematololgy, cytology or histopathology) Documentation needs improvement. SOPS should be read and understood **Biochemistry** • Biochemistry lab has improved significantly from the baseline. • Automation has been ushered in. • Staff motivation is high. • Biochemistry has both Internal and External Quality Control programs which is lacking in pathology. • Biochemistry EQAS reports have improved considerably from the last	• An SOP for the entire testing sequence should be developed and implemented. • The documents should include; Sample collection manual, Sample rejection criteria, procedures for processing sub-optimal samples which cannot be rejected, sample repeat procedure, Sample storage procedures, sample retention criteria, disposal procedures, SOPs for all sample processing and antimicrobial susceptibility testing, documentation of all these activities with registers where required. • As knowledgeable staff is available in the department, any lack of quality system need to be addressed in this light. • A time bound action plan may be developed for the implementation of QS, and monitored at regular intervals for compliance.

	review. • A few parameters like Sodium and Potassium show consistent outliers in EQAS. • Glucose testing for several patients is done using calorimeter. This is for logistic reasons. • The auto analyser used for evening reporting is less well controlled. Other semi-automated systems are also in use. • The Speciality Wing has a Chemiluminescence Immunoassay Equipment. No Internal or External Control mechanisms are available for this. Though the technicians here are very enthusiastic, they need training in Quality Assurance. • The lab does not have a deep freeze. This has been requested for.	• Once the quality systems are in place enrolment in EQAS should be done. **Pathology** • IQC and EQAS in all aspects of testing to be started at the earliest in pathology **Biochemistry** • Training in IQC monitoring is required. • EQAS maybe better monitored especially for persistent outliers like electrolytes • As the calorimeter is not controlled it is best to be avoided • The multiple methods of analysis in biochemistry have to be brought under the QC protocols. Protocols of harmonization should be developed and implemented. An SOP for this may be developed and implemented. • The issue of the lab in the speciality wing needs to be addressed and this brought under the supervision of the main lab, possibly by have SRs rotation. Internal Controls may be provided and all the equipment enrolled in EQAS • Provision of a deep freeze may be considered
Public Health Functions	• Staff is generally active in epidemic surveillance activities but no proper network exist as envisaged under IDSP. • The institution does not have any mechanism for receiving samples of epidemic prone diseases from the field or lower institutions like PHC or CHC. • There are no links with any technically superior institution for aid in technical advice, referral of a	• Proper network should be initiated with institutions in the area which the MCH is serving. • Regular communication should be maintained with clinicians in peripheral institutions to facilitate better detection of epidemic prone diseases. • A referral institution should be identified and communications opened, which can be used as a support institution for the lab.

	sample, referral of organism for identification or for advanced testing like diphtheria toxigenicity testing. • Prepared special media for detection of pathogens like Salmonella, Shigella, V. cholera are not available when need and is not used.	• Usage of special media should be incorporated in the SOPs and should be available at all times.
Supplies, equipment availability and Management	• Since the microbiology lab is located in the old building under the principal, confusion exist in procurement of reagents and equipment for patient testing and for student purposes. • Availability of reagents was reported as a problem. • Management of media and reagents not proper. Media, more than 5 years after expiry was found. • Sufficient media and reagents for routine testing is not being prepared. • Proper weighing balance not available. The one in use is very old. • Laminar flow cabinet for media preparation not available. • Plastic Petri dishes are used even for AST. Plates are old, discoloured and warped.	**Microbiology:** • Once the microbiology lab is shifted to the new premises in the Central Lab, all requirements for patient testing should be met through the MS. • Management of reagents should be streamlined. Expired reagents should be discarded and proper stock maintained. Regular monitoring of stock position and expiry dates should be done. • Immediate steps should be taken to purchase a laminar flow cabinet, digital weighing balance. • As the quantity of media in routine use need to be increased, larger horizontal autoclaves may be purchased as required. • Though it is more expensive, plastic pert dishes may be replaced with glass to maintain quality **Pathology and Biochemistry:** • The Speciality wing also has a dialysis unit. However, the semi-automated equipment used in reporting the tests is not under any quality assurance mechanisms. A good CMC, Calibration program may be looked into.
Budget and Finances	• No earmarked budget is available for the lab.	• Steps should be taken to fix an annual budget for the lab, taking into account the recurring expenses and capital expenses projected for the subsequent year.

Data Management and IT	• Improper numbering systems. Unique id of sample is available only in microbiology. • Report issuing system is chaotic. • Hospital Information System is under implementation.	• The majority of the current issues will be sorted out once the HIS is implemented. However, as the entire system is new, a robust accessioning system should be developed, taking into account the need for a UID, ease of use of the id in the lab, identification of samples between different departments etc. As the HIS is at least one year away, an interim manual system of accessioning, which can be smoothly changed over to computerized HIS, should be implemented immediately.
Diagnostic capacities	**Microbiology:** • The lab is capable of doing all tests required at the level of MCH. However, because of the many sub-standard practices mentioned above, for e.g., no special media for epidemic prone diseases, the actual diagnostic capability is limited. **Pathology:** • No coagulation tests available. • No Hb electrophoresis available • Semen analysis performed in the infertility lab in the hospital and is unsupervised • Manual TLC done directly from smears as the 3 part analyser is not working • ESR tubes are reused and without adequate washing **Biochemistry:** • Hb A1C not available. Serum Electrophoresis not available • CSF proteins are done by an obsolete method.	• Standard practices should be enforced in the lab to make it function at the optimum level. • • Better methods of analysis may be sought wherever non-standardized methods are employed • Coagulation tests, Serum and Hb Electrophoresis with Hb A1C may be considered. • A robust equipment management program needs to be developed to avoid long breakdowns. • More haematology automation is required to manage the workload • Disposable ESR tubes may be used, especially as an infection control practice • Semen analysis may be brought under the purview of the pathology lab
Staff availability, training and management	• In general, staff (Faculty) availability was not a problem, with most of the sanctioned posts filled. However, there is a 20% vacancy of LTs.	• Necessary steps to be taken to fill the vacancies, and to provide additional staff through HDS, where required.

	• Additional staff required. • Training is required in many aspects as mentioned previously.	
Communications	• Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services is a good practice to start • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.
Other Observations	• There doesn't seem to be any lack of cooperation between the staff, and other staff members are active in the process. The administration is very supportive of the whole process.	

Table 8: Kakatiya Medical College, Warangal

Kakatiya Medical College, Warangal		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• Old building with sufficient space, but poorly organized in some places. • Walls, doors, windows need painting and maintenance. • More importantly, cleaning is not adequate. Cleaning in the institution is outsourced. The corridors and general areas are regularly cleaned. However, very little cleaning is done inside the labs. • No air-conditioning in required areas. Considering the fact that temperature can go up to 42oC, a/c is mandatory in microbiology culture room. • Inadequate cold storage facility. • The locations of the exits are very inappropriate. The pathology area has no quick exits at all.	• Painting and maintenance need to be done. • Minor reorganization with clearing of unnecessary items which are spread out need to be done. Proper cleaning of the lab should be done. • Air conditioners should be installed where required. • One cold room each for Biochemistry and Microbiology should be installed for proper storage of media and reagents. (mandatory for microbiology, optional for biochemistry) • Structural alterations if possible should be considered in view of safety.
Specimen Collection, recording and handling	• Improper specimen containers used for sample collection. • Improper container and media for blood culture. • No system for sample storage on receipt or for retesting at a later time. • No standard procedures for specimen handling. • Specimen processed without any standard protocol. • No work register maintained for specimen processing. • Improper media used for specimen processing. • More than optimum number of samples processed in a single medium. • No special media for epidemic prone diseases such as cholera, typhoid, food poisoning etc. • Blood culture discarded in 24 hrs.	• The staff should be trained in an institution which follows standard protocols and have all quality systems in place. • The entire system of testing should be replaced, and a new system with quality control, based on the training given should be implemented. • Sample transport system should be fully implemented. Additional training and monitoring of staff at the point of sample collection should be done • Specimen quality needs to be monitored, with acceptance rejection criteria. • Centrifugation protocol for serum tubes shall minimize the fibrin clots and threads.

	Antimicrobial susceptibility done using improper media and without any validation. • Potentially 100% error in reporting due to the above observations. **Biochemistry and Pathology** • All points mentioned under microbiology pertaining to pathology such as lack of sample collection guidelines was observed here. • System where staff brings samples to the lab instead of patients is being implemented. But still patients are seen walking with samples. • Improper filling of EDTA tubes seen.	• Collecting & transferring samples from bottles to vials increases the chance of haemolysis. • May consider using disposable tubes with clot activators, whereby avoiding the pre-analytical errors.
Biosafety	• Very poor practices seen in the lab which can be hazardous. • No biosafety cabinet for TB work. Laminar flowsare used for bacteriology and TB work, multiplying the risk involved. • Poor handling of samples, ESR tubes. • Blood spilled and dried on equipment, work surfaces.	• Bench level training should be given to technicians for handling infectious materials safely. • Same level of training should be given to supervisory staff for sustained implementation. • Proper protocols should be in place to avoid spillages and to clean up immediately in the event of a spillage. • Cleaning protocols for end of day and weekly cleaning should be implemented. • Recent BMW guidelines to be made available and trained.
Quality Management	• No quality systems in place. • Substandard procedures used for sample processing, without the correction of which, no quality improvement can be made. • QC run in auto analyser. But no attempt made to correct consistent QC failures. Assays run in semi-automated or manual system without any QC. • Supervisory staff still not sure of QC serum, calibrator, standard etc.	• The following documents should be prepared and implemented; Sample collection manual, Sample rejection criteria, procedures for processing sub-optimal samples which cannot be rejected, sample repeat procedure, Sample storage procedures, sample retention criteria, disposal procedures, SOPs for all sample processing and antimicrobial susceptibility

		testing, documentation of all these activities with registers where required. • Training as should be given in all aspects of quality management. • Once the Quality System is implemented, enrolment for EQAS should be considered. • Validation of new kits and documentation to be practiced
Public Health Functions	• No network as envisaged under IDSP or IHR exist. • Staff unaware of the required networking, need of network or the role of the institution in the network. • Special media for the detection of epidemic prone diseases not available routinely. • Capability of identifying the pathogens (sufficient biochemical tests, antisera) does not exist. • Not capable of doing antimicrobial susceptibility, advise clinicians on the local antibiotic resistance patterns or formulating an antibiotic policy.	• Advanced training required in all aspects, possibility with the help of IDSP personnel who have more expertise in Public Health Functions.
Supplies, equipment availability and Management	**Microbiology:** • Conflicting information given. On one hand it was reported that all routine reagents are available. On specific enquiry on non-availability of certain reagents, difficulty in communicating the need to higher ups, lack of supply even after multiple requests, inability to influence the purchase of required reagents etc., can be seen. • No proper system for the management of reagents. • Culture medium essential for antimicrobial sensitivity testing not available even after more than 1 year of assessment and reporting. • Staff directly involved with testing patient samples does not have a say in the indenting or selection of reagents.	• An indent should be prepared taking into consideration all the needs and the required items purchased. • System should be in place where the requirements for patient testing are met in a reasonable time frame. • Staff involved with patient testing should be able to indent and procure the required items. • Essential equipment should be installed without delay. • To have Standby instruments in full working condition and compared for the optimal performance. • Service personnel details to be updated and kept available to all

	• Essential equipment such as temperature control in the testing area, sufficient cold storage facility, biosafety cabinets etc., are not present. • Even minor equipment are outdated. Wooden test tube racks, old warped and discoloured plastic Petri dishes etc., in use. **Pathology and Biochemistry:** • No grossing station or proper ventilation where histopathology samples are handled. • No UPS for the Automated tissue Processor • No equipment management program available. No documented daily maintenance, calibration, CMC • Several equipment are seen broken down with no definite plans for repair. • No downtime monitoring • No understanding about the functioning of equipment. Not availing tech support adequately.	staff in the section. • Preventive maintenance logs to be documented. • CMC calibration program to be initiated for all equipment analytical and non-analytical.
Budget and Finances	• No designated budget for the lab. • No adjustment of budget based on projected requirements.	• Proposal to be made to administration to provide a minimum budget allocation for the lab. • The requirements of the lab needs to be mapped out, cost analysed and projected annually. • Training is required for this both at the technical and administrative levels.
Data Management and IT	• No LIMS or HIS.	• Proper software with require hardware and networking to be implemented. • The mapping is being done by Reliance. • The LIMS should be in consensus with the ISO standard

Diagnostic capacities	• Limited test menu. Much lower than expected of a Medical College. • Does not have reagents and expertise for giving a complete report for even routine samples. • RDTs done instead of ELISA test for HBsAg. • Compared to the patient load in the hospital, low number of patients referred to the lab for special pathology investigations. • Many non-standard techniques of reporting, especially in pathology. Hb is screened using paper and at best Sahlis method. Counts assessed only from smears. • This being an important tertiary care institution should have IHCs, flow cytometry and other advanced diagnostic tests, not available. • Several unsupervised labs, tests seen	• Additional training need to be done and reagents and equipment procured to increase the test menu. • In the available equipment, test menu can be expanded to the fullest capability of the analyser. • Reagents to be monitored for the expiry and shelf life. • Non-standard testing practices like Sahli's should be avoided All tests should be supervised and validated by an authorized signatory
Staff availability, training and management	• Staff availability in general was not a problem. • The qualifications of the technicians seems to be a major problem. It was reported that there are technicians who can't even read or write. Through some policy of the Government even lab assistants are promoted based on their service as LTs. This issue was seen in the District Hospital also. • Staff being present for the entire duration of working hours is a problem.	• An attempt may be made to bring this to the notice of high level administrators so that the qualifications and expertise of LTs will be set at par to the rest of the country. • Extensive training is required at all levels of staff, especially in microbiology; the details of which are mentioned previously. • Lab personnel can volunteer in the improvement activities such as record keeping, stock availability, expiry verification • Job descriptions for staff is essential and so is fixing and monitoring the time of work as both are ambiguous.
Communications	• Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in

		the form of advisory services is a good practice to start • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.
Any Other Area	• A great rift is seen where some areas are declared as under the control of Principal and some aspects under the Medical Superintendent. But in many cases, there is no responsibility or control by either in many aspects of patient testing; staff, reagents, maintenance, management etc. • Central lab where part of pathology work is being carried out is totally uncontrolled. The lab is not supervised by the pathology department.	• Routine CMEs and Seminars shall be conducted. • A calendar of events for the academic activities is achievable with the database which gets generated.

Table 9: Dr. Sampurnanand Medical College, Jodhpur, Rajasthan

Dr. Sampurnanand Medical College, Jodhpur, Rajasthan		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• The medical college and the associated hospitals have adequate space and infrastructure, but certain areas such as sample collection, Microbiology requires more space for smooth working.	• Collection areas to be redesigned. • Microbiology labs in all facilities need more space and adequate lab design. As it is, constructions are going on in MGM and it is understood that provision to this end will be taken care of. In the other hospitals too, it will be provided as much as possible.
Specimen Collection, recording and handling	• Sample collection areas are separate from the labs in most of the places. Also there is good signage for the sample collection areas. • Best practices of Phlebotomy are not followed. Serum tubes are drawn in Non-standard container rendering centrifugation suboptimal. • High chances of NSI and infections due to spillage are observed. • Needle burner / Sharp container either not available or not working in many of the places. No Spill kit/ First Aid Kit available. • No safe sample transportation system available to protect sample integrity and infection control.	• Best practices in phlebotomy to be followed. • Recommended containers to be considered for sample integrity. • Biomedical Waste management and infection control processes to be streamlined. • A safe sample transportation system to be defined and executed • It is proposed by the review team that the collection be supervised in rotation by all the 3 departments to encourage ownership and enforce the pre-analytical best practices across the departments.
Biosafety	• There are colour coded bags/bins available in all hospitals but segregation at source needs improvement. • Staff not aware of spill management and BMW guidelines. • Sharps were not disposed properly. • Disinfectant (Sodium hypochlorite) was not available/ freshly prepared / date of preparation not written. • The laboratories were not equipped with fire-fighting equipment and did not have any escape plan. • Spill kit and eye wash stations were not available in most of the sites.	• Staff needs to be trained for BMW practices for segregation of waste at source. • Biomedical Waste management and infection control processes to be streamlined.

Quality Management	• Few of the laboratories have started developing SOP's and work instructions, although extensive efforts are required. • Although the staff is aware of quality controls and calibration but most of the laboratories do not have internal and external quality assurance in place. • Lack of Quality management system is evident, although efforts can be observed at certain places.	• SOPs need to be developed, read and understood by all the staff. • Inventory system should be strengthened. EQAS should be started at the earliest. • A well-defined and documented QMS should be implemented with the full involvement of the higher management.
Public Health Functions	• Laboratories are not aware of International Health Regulations (IHR) and criteria defining Public Health Emergency of International Concerns. • There are no written guidelines conforming to National/International requirements for specimen collection, packing and shipping. • Laboratories are not part of any committee related to public health event/outbreak management; although the lab is carrying out select viral diseases. • Laboratories are not sharing antimicrobial susceptibility pattern with the clinicians	• Awareness and compliance of all laboratories to IHR • Expand the scope of surveillance activities as per state and national guidelines. • Laboratories should regularly share pattern of antimicrobial susceptibility and resistance, should also develop policy to minimise use of antimicrobials.
Supplies, equipment availability and Management	• Laboratories have adequate infrastructure/equipment for the load of the patients catered to. However, equipment management is inadequate, no preventive maintenance schedules, no CMC-AMC /Calibration, no breakdown downtime tracking	• A comprehensive equipment management program involving all the levels of functionaries, to make available, define, implement and monitor equipment management is to be developed and implemented
Budget and Finances	• Adequate funding &budget allocation for routine & specialized testing. • Finances are available under various heads as per state govt. policies.	• Better coordination within administration and department will help iron out issues
Data Management and IT	Most of the laboratories are managing and maintaining records manually and but some of them have also started using laboratory information system as the institution is in the process of adopting LIS for the entire institution, presently being piloted in one hospital. SOPs are also not available on data	• The institution is working on expanding the scope of HIS/LIS, it may be done as per ISO guidelines to enable optimum utilization. • Age and Gender-wise mapping may be adopted as an immediate measure. • Delta-monitoring option may be

	management, including data recording and storage.	very helpful. • Bilateral interfacing, incorporation of testing algorithms may be looked into.
Diagnostic capacities	Most of the laboratories in the institution have adequate space and infrastructure, equipment, availability of testing kits and dedicated staff to support continuous testing	• Training of lab staff to improve the quality of testing & reporting. • Junior technical staff requires capacity building in many areas such as testing, lab safety and adherence to BMW guidelines.
Staff availability, training and management	• The staff at most of the laboratories are not adequately trained on various areas, such as sample collection and transportation, disinfection, BMW, fire safety etc. It was observed that training modules and training aids were not available at the point of sample collection and testing. Retention of trained staff also is a problem as it is not in the purview of the College and hospital administration. An inadequacy in numbers as well as training was pointed out by the team.	• Staff training: The principal has assigned the HOD pathology to head a team to do calendared in-service training for all technical staff involved in patent sample reporting. A subcommittee may be formed to this end. • The training should cover all aspects of QSE. A training calendar may be prepared to include at least the following: Sample Collection, Equipment Management, Quality Controls, Documentation, Safety and Inventory Control. • Staff availability: Needs to be addressed. However, it is up to the institution to make interim arrangements to enable smooth functioning. Pooling of the existing staff, staff motivation, LIS enablement & staff rotations may be looked into to solve this.
Communications	Communication channels need improvement	• Channels of communication within the lab, among the labs, among department's especially clinical departments need to be improved. • Communication with patients in the form of advisory services is a good practice to start Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national & international levels.

Table 10: RNT Medical College and MB Govt. Hospital, Udaipur, Rajasthan

RNT Medical College and MB Govt. Hospital, Udaipur, Rajasthan		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• New building for laboratories has adequate space & ventilation along with demarcated area for various tests & staff. However tests which are not under MNJY would be done in old lab / current setup. • Lab has space constraint and their HIV testing Laboratory functioning in a classroom as a stop gap arrangement. Hence quality and confidentiality is serious concern along with BMW issues.	• Laboratory should expedite shifting to new building. Appropriate lab design should be ensured. • HIV testing laboratories should be urgently shifted to a better place and their testing procedure should be strictly done as per NACO guidelines. • Current setup should be monitored and maintained well after shifting to new lab. • Histopathology set up also need attention for occupational safety.
Specimen Collection, recording and handling	• There are centralized collection facilities for all the three laboratories at the hospital. • It has sufficient number of signage & display of user friendly IEC material; recording & handling is done as per the guidelines. • Spirit swabs were kept in open container and some BMW colour coded bins were missing/not available. • Staff vaccination was not available	• BMW needs to be strengthened. • Procurement of BMW 2016 supplies should be expedited • Continuous and regular Bio-Medical Waste Management and Healthcare Infection Control training should be arranged for Health care workers & supervised by Health Infection Control team & HOD of respective department. • Vaccination for Staff should be initiated.
Biosafety	• Biosafety needs to be strengthened along with provision of laminar flow for sputum sample for AFB & TB culture. • A dedicated separate area /lab /room should be identified for mycology work (culture & sensitivity).	• Biosafety Cabinets should be installed.
Quality Management	• Quality Manual, SOPs were available in pathology and biochemistry, However staff is enthusiastic to bring positive changes in quality assurance and is	• Quality Manual, SOPs & documentation of test procedures along with routine internal & external quality

	trying to incorporate internal and external checks. In Biochemistry IQC and EQA's is done but there are supply issues.	controls should be maintained all the incidents & accidents should be recorded. • CLSI (Recent guidelines should be followed for AST). • Quality management training, antibiotic stewardship training may be provided to the staff. • IQC breaks in between should be avoided in biochemistry • Pathology should start QC programs in all aspects
Public Health Functions	• Testing of all notifiable public health diseases is the responsibility of microbiology lab. • Lab must maintain record of such tests and it should be displayed and available to assessment whenever needed. • They may coordinate with public health specialist for the same.	• Better coordination with public health specialist along with proper documentation warranted. • IEC material may be used for the same. • IHR and PHEIC should be familiarized
Supplies, equipment availability and Management	• **Microbiology** Lab does not have proper Biosafety cabinet / laminar flow in main microbiology lab. Non Functional equipment's kept in the lab since a very long time. • **Pathology:** Laboratory has good quality equipment. The breaks for IQC supply were observed. • **Biochemistry:** Management of laboratory is very good. However there are issues related to supply of reagents and QC (Administrative issue)	**Microbiology:** • Laboratory should ensure condemnation of non-functioning equipment and it should be time bound. • Space can be utilized for expansion of microbiology testing. • Laboratory can look for BSC in new lab / existing lab if required. **Pathology and Biochemistry:** • Supply chain needs to be strengthened and timely delivery of the supplies / requirement should be ensured. • Ensure continuous supply chain without break (Reagent & QC). • Most equipment are available in biochemistry. • In pathology, some cell counters are old and may be replaced.

		• Grossing station, filing cabinets (slides, records) are required in pathology • A fully automated coagulation analyser may be considered • Labs should work with RMSCL or similar agencies for equipment CMC and calibration
Budget and Finances	• The finances have come down drastically from the last year. However, there seems to be adequate funding and budget for specialized tests like PCR for swine flu. Finances are available under various heads as per state govt. policies.	• Better coordination with administration and accounts is required • Positive Involvement will be required with Accounts & Admin for Strengthening the lab departments
Data Management and IT	• Records are well maintained manually and were in good condition. However, computerized data management/LIS /HIS should be introduced.	• Introduction of LIS / HIS as in define time frame. • Arogya online may be provided with the TA to make the LIS optimal.
Diagnostic capacities	• Lab has a capacity to do all the routine testing, however, they can develop their parasitology, mycology, TB labs and molecular testing for viral diseases such as HBs, and HIV can be introduced. • Pathology and Biochemistry departments have all routine tests.	• Services can be expanded further in view of patient welfare. • Automation in bacteriology warranted. • In biochemistry, HbA1c, Protein Electrophoresis etc. may be considered in the scope of testing for which electrophoresis systems and HPLCs respectively may be purchased. • Hb Electrophoresis may be considered as this is the thalassemia region.
Staff availability, training and management	• Staff has recently joined and needs supervision and guidance. • Work load is surprisingly low as compared to patient population. BMWM transport has to be ensured within stipulated time period.	• Continuous and refresher trainings should be a part of process for the institute. • Training on spill management, BMW, disinfection and fire safety should be given to all the staff including housekeeping.

Communications	• Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services is a good practice to start • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.

Table 11: Assam Medical College, Dibrugarh, Assam

Assam Medical College, Dibrugarh, Assam		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• Overall, the condition of building in all sections is good except for few areas where there is seepage and cracks on the roof and walls. • The central collection area is situated in close proximity to laboratories. There are adequate numbers of rooms for technical activities. However, there is inadequate space for patient waiting in sample collection and report collection area. The number of chairs is very limited in comparison to the number of patients. • The average waiting time for patient registration is high. Appropriate measures may be taken to ensure patient rights.	• Adequate amenities for the patients in the sample collection area. Waiting time to be monitored and effective corrective actions to be taken to reduce the same. • As no. of patients has seemingly doubled since last year and the load is increasing, the Sample collection area requires further expansion with required amenities for patients and staff.
Specimen Collection, recording and handling	• A central collection centre is situated very close to the laboratories. Sample acceptance and rejection criteria for blood samples are well-defined and displayed. But the same for other samples are missing e.g. body fluids, urine, stool etc. • The test request form does not contain name of the sampler and few forms did not give time of collection. • There are no documented procedures for storage of primary samples, acceptance of unfit samples in certain circumstances and communication in the report stating compromise on test results with unfit sample. • It was observed that sample container for few samples e.g. urine, contained only Patient's hospital ID and no other patient identifier. • The technical staff did not follow infection control practices in phlebotomy area.	• Test and sample specific acceptance and rejection criteria to be developed, displayed, documented and monitored for corrective actions. • Sample collection manual should address the policy and procedure for primary sample storage and transportation, testing of compromised samples. • Proper labelling of urine samples with at least three identifiers are recommended. Phlebotomists should be trained on the infection control practices, aseptic technique and phlebotomy technique as per WHO and CLSI guidelines. • Monthly meeting with the clinicians and laboratory concerned should be continued for the feedback and improvements in the pre-

	• The staff kept the needle of syringe exposed on the table before collection and recapped the needle with both hands after collection. • The staff did not follow the steps of venepuncture as written in primary sample collection manual. • The samples are not transported in a closed container.	analytical practices. • All the departments need to strictly follow Non-confirming events documentation and take corrective and preventive measures. • Training to be done through Labs for Life.
Biosafety	• Overall, the lab building biosecurity is addressed appropriately. • There is effective separation of incompatible activities in technical areas. • Wherever necessary, signage and labels have been placed. However, with regard to fire safety, fire exit plan is not visible, inadequate fire extinguishers and exit signs are not marked appropriately. • The personal protective equipment is available and used appropriately. However, there is no log book for use and maintenance of safety equipment. • There is availability of first aid box in which few more additions can be done e.g. sterile eye pads, first-aid manual and mouth piece for mouth-to-mouth resuscitation. • Adequate number of safety trainings has been organized and safety procedures are available except procedures for glassware and equipment washing and protection against specific infectious agents. • Equipment disinfection and sterilization is not followed adequately in all departments. • Regarding Biomedical waste management, waste from all the departments is being segregated appropriately except cytology where needles were discarded in green bag. • The color-coded bins are available at	• There should be fire exit plan displayed in all the floors, including all closed areas and corridors. • Fire exit routers to be properly marked as per Fire safety guideline. Adequate number of fire extinguishers to be installed in all vulnerable areas. • All staff should be sensitized on used of fire extinguishers and other safety equipment. Fire and disaster training and drills are essential periodically. • A log book for safety equipment with periodic check plan is recommended. • Arrangements to be made for disposal of general wastes. • Chemical indicators for every batch and biological indicators for at least once in a month to be used in autoclave as recommended in the 2016 BMW guidelines. For biological & chemical treatment indicator supply should be adequate for uninterrupted services. • Sensitization of staff on using PPE, periodic health check-up for the staff are recommended. • The team does not recommend use of the treated water/sledge for irrigation/agricultural purposes because of various

	points of use. • The BMW bags are not transported in a closed trolley. In BMW plant, general waste disposal is not addressed. It is discarded in open on the ground. The BMW plant is currently operating an effluent treatment plant, solid waste disposal with autoclaves and shredders, incinerator facility and kitchen waste compactor. • The water and sledge obtained after effluent treatment are appropriately treated. • There is also a lack of use of chemical/biological indicators for autoclave Quality control. • The BMW plant workers were not wearing adequate PPE. It is also recommended to provide them with regular trainings and copy of updated BMW rules 2016. • The team could not find health check-up records of BMW plant workers.	factors not being tested e.g. viral load or radioactivity. Only coliform testing is not enough for recycling purposes.
Quality Management	• **Microbiology:** Overall, QMS is established. Quality manual, QSPs, SOPs, Work desk instructions and other relevant documents and records are available. • Quality objectives are clearly defined and quality indicators are being monitored regularly. However, it is advised to keep changing the quality indicators from time to time for effective quality improvement. • There is regular participation in formal EQA programs. Internal Quality assurance program is established with few areas of improvement e.g. batch validation in preparation of borderline reactive control in serology lab, IQA program in AMLU, non-existent QC for Versatrek/BACTEC. • **Pathology:** Quality Manual, few QSPs and few SOPs are available. Quality	• IQC material to be made available for all instruments used for testing in all the disciplines. • A documented QC plan to be developed and displayed for staff awareness. QC to be run as per policy before testing patients' sample, monitor the results with control chart, corrective actions to be taken in case of IQC is out of range. • It is recommended to monitor the QC results as per the lab mean and SD. A parallel testing may be employed for new lots of QCs. • Lab should participate in EQA programs for all the tests available. In case of non-availability of a proper EQA program, lab should formulate a process of verifying the accuracy

	indicators are defined but not measured. • The lab participates in formal EQA program but not for all parameters. No root cause analysis or corrective or preventive actions documented for any outliers. • There is a lack of well-defined Internal Quality Assurance program. There is availability of QC materials in haematology but there is no monitoring, no LJ graphs or CV trends. • **Biochemistry:** Quality Manual, QSPs and SOPs are available. Quality indicators are defined but not measured • The lab participates in formal EQA program but not for all parameters. No root cause analysis or corrective or preventive actions documented for any outliers. • There is a lack of Internal Quality Assurance program. There is availability of QC materials but there are no LJ graphs or monitoring CV trends.	of results through exchange of samples • Root cause analysis and effective corrective actions to be taken in case of any outlier. • Lack of availability of Quality Controls in some areas due to supply breaks
Public Health Functions	• Most of the diseases are being notified to concerned authorities. There is regular participation in disease surveillance activities and emergency public health sampling/outbreak management. • The microbiology lab regularly analyses AST patterns in the area and provides the same to the clinicians. • However, there is a complete lack of knowledge on IHR and PHEIC.	• Display of disease surveillance data (Prevalence &prevention) will be appreciated on the notice board/digital display for public/patient. • The AMC being a very strong presence in the region, may also help the DH and CHCs with infection control and AMR surveillance.
Supplies, Equipment Availability and management	• **Microbiology:** The inventory management is satisfactory with maintenance and updating of stock register. • Most of the reagents are available. However, there is no system to monitor the quantity of reagents used	• It is recommended to develop and practice an appropriate and uniform inventory management including lot verification of new reagent/QC material. • Adequate and appropriate equipment management policies,

	and project the availability of critical reagents in the next 3 months. • Equipment management in documented. However, not all equipment are labelled appropriately or under AMC/CMC. There are few equipment with no record of calibration e.g. BSC, versatrek or BACTEC. • **Pathology:** The inventory management is not adequate. No documentation of current or required stock. No monitoring of lag time or Quality checking while receiving. There is no regular supply of QC materials in haematology. Equipment management is not adequate. There is no process of equipment verification, AMC/CMC or calibration. • **Biochemistry:** The documentation for inventory management is adequate. No evaluation of reagents/suppliers is done. No lot verification of QC/reagents is done. Equipment management is not adequate. There is no process of equipment verification, AMC/CMC or quality check after calibration and preventive maintenance.	processes and procedures are recommended.
Budget Finance	• Most of the requirements are met through hospital funds. The lab also has contributions from national programs and projects. • There is no shortage of supplies except in QCs. • There is no budgetary projections based on needs of the user. • The labs are also not involved in providing technical specifications for procurement.	• The labs are recommended to participate in actively providing technical specifications for purchase of new equipment or reagent.
Data Management and IT	• The data is electronically maintained till sample registration. However, it is manual afterwards.	• Appropriate data management processes and procedures are recommended including defining

	• There is no uniform policy on data management although documented procedures are available in microbiology department. • Data validation is done but there are no documents for authorization to change patient data or supervising clerical errors. • There is lack of defined critical levels and lack of processes and procedures for immediate notification of physicians in case of critical results. • The computer systems are available and HIS installed till patient registration in sample collection area. However, labs do not have electronic LIS. All data entries are transcribed manually onto computer systems for data backup. • There are no software licenses or equivalent. Internet is available but slow in speed.	critical alerts and immediate notification. • Electronic LIS may be considered for all labs considering the scope of work of the lab.
Diagnostic Capacities	• There is a wide umbrella of parameters done by all departments.	• Few tests may be considered e.g. MAT for leptospira, TPHA for syphilis and expansion of mycology and anaerobic culture subject to local prevalence in Microbiology HB electrophoresis, FDP, D-Dimer, Liquid based cytology, HPV DNA may be considered in • **Pathology.** 2. ABG and a wider menu of biochemical tests also may be considered as per requirement.
Staff Availability, Training and Management	• In general, all labs have adequate number of staff. Personal files are maintained but there is a lack of competency evaluation of staff. • Quality managers are designated for all labs. However, the training of Quality manager is inadequate in terms of ISO 15189:2012. • The staff is immunized for Hep B. There	• Staff health check-ups and titer checks after immunization are recommended. Competency evaluation recommended. • ISO trainings for Quality Managers recommended. • Awareness and training on Quality control, IHR, PHEIC and public health functions of lab are

	are no documented records for their titre levels. • The health check-ups are also not undertaken actively for staff. There are a number of trainings given to staff as documented in labs. However, the trainings are not followed by adequate post-training assessments. • There is also lack of training on Quality Control and public health functions. Disease specific guidelines are available at labs.	recommended.
Communications	There are established internal and external communication systems. Mainly through office letters, mobile connections. However, telecom facilities are not available. Patient satisfaction surveys are conducted only by Microbiology department. Although, feedback/complaints are collected but there are no documented records that they are addressed.	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services patient feedback, complaint redressal systems etc. can be started • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.

Table 12: North Bengal Medical College and hospital, Darjeeling, West Bengal

North Bengal Medical College and hospital, Darjeeling, West Bengal		
Area of Concern	**Summary/ Observations**	**Recommendations**
Premises Quality	• The hospital has adequate work space. The condition of building needs attention, cracks were seen on the pillars and walls, temporarily supported by wooden beams. Seepage was also observed in some laboratory areas. • Air-conditioning is inadequate and not available in all critical areas inside the lab. • There is no power back up in most of the departments. Sometimes shortage of running water is reported. • The hospital premises surrounding labs are found to be dirty with Bio-medical waste was found scattered in the premises, including infectious waste. • Staff amenities are inadequate, staff rooms are found untidy and condemned material was lying on the benches.	• Basic infrastructure need to be strengthened for safety purpose. Major cleanliness is needed in hospital premises as well as the laboratories • Adequate security personnel or system to be deputed to prevent stray animals and unauthorized people from entering into all technical areas. Installation of CCTV camera is required for security purposes. Safety audit is also important • Improvement in air-conditioning especially in all critical area to be strengthened. • Installation of emergency power backup maybe considered. • Considering the workload, the sitting arrangement for patients in the waiting area needs to be strengthened. Separate queues for males and females may be considered. Note: Earthquake prone area, the corridors are supported by wooden beams. This may be looked into.
Specimen Collection, recording and handling	• SOPs are prepared in Biochemistry and Pathology and SOP of Microbiology is under process. • The laboratory is reporting the result in a printed uniform format with Biological reference interval printed in it. • There are no system of collecting clinical history of patients except Histopathology and Cytology. • The name of the sampler and the time of sample collection is not mentioned	• SOPs should be prepared and implemented in all the departments, staff should be aware of all relevant procedures, flow charts to be displayed in local language. • Relevant clinical history from patients should be incorporated in the test request form. • The test request form should contain the signature of the sampler as well as the time of

	in the test request form. • There is no process implemented for testing and reporting of urgent samples, critical and alert values are not reported on urgent basis to the clinicians. • Sample rejection criteria are defined, but not followed and monitored by the departments, except Biochemistry. • Sample collection process and all other relevant flow charts were displayed in the sample collection area. • Secondary samples are not labelled in the Biochemistry department. • Sample collection process is not as per SOP. • There is no sample referral system available through lab.	sample collection. • The lab may extend the service for reporting urgent samples, critical values may be reported to the concerned clinician at the earliest, in the interest of patient care. • Sample rejection criteria needs to be followed, documented and monitored for improvement. • Secondary samples/split samples should be labelled properly to avoid sample identification error. • Sample integrity should be set as Quality Indicator. % defects or Non-conforming events in collection must be captured to monitor and improve the collection process
Biosafety	• Biohazard symbols not displayed where required. • Exits are not clearly marked • No First-Aid kits or fire safety equipment available. • No procedures explained for maintenance of basic personal hygiene or lab cleaning and disinfection. • Equipment disinfection & sterilization inadequate. • BMW disposal system not in place. • Sharp disposal containers not available • Fire safety inadequate • Emergency safety kits (e.g. Spill kits) not available. • Adequate safety training not provided to the staff. • Bio safety cabinet not working	• Biohazard symbols must be displayed where required. • Exits should be clearly marked as per the Fire safety guideline. Fire training and drills are essential periodically. • First-Aid kits or fire safety equipment should be made available. • Procedures must be in place for maintenance of basic personal hygiene or lab cleaning and disinfection. • Equipment disinfection & sterilization schedule must be established. • BMW management guidelines must be implemented. • Sharps disposal containers to be made available • Adequate fire safety and emergency safety (e.g. Spill kits) measures need to be addressed. • Bio safety cabinets should be in place

Quality Management	• The lab has quality manual containing the Quality Policy and measurable Quality Objectives. Microbiology is under process to develop the Quality Manual. • IQC material is regularly being used in Biochemistry department; control charts are being prepared and monitored. Effective corrective actions have been taken in case of any error. In haematology, IQC is run, LJ chart prepared and monitored for corrective actions. There is no IQC available in Clinical path, Histopathology and cytology. No batch wise validation is being done for serological tests and immunoassays. • The lab has enrolled for EQA programme for clinical chemistry, clinical haematology, bacteriology, TB, HIV, and VDRL. But no reports available as the programs just started. No EQA is available for Histopathology, Cytology and Clinical pathology.	• Regular sensitization programme to be conducted on the Quality Manual, Quality Policy and Objective. Quality Policy and Objectives may be displayed in the lab. • IQC material to be made available to all tests and sections on regular basis. The IQC results are to be monitored by preparing control charts, effective corrective actions to be taken in case of the control value is out of range. • The lab should enrol for EQA programme for all the sections. In case a formal EQA programme is not available, the lab should develop its own protocol to cross check the accuracy by exchange of samples
Public Health Functions	• The hospital participated in most (NACP, NVBDCP, RNTCP, JSSY, and STI) of the national public health programmes. Notification of diseases is routinely done by the laboratories • The lab is in contact with state and other local authorities on disease surveillance programme, the health camps are regular being organized as per the requirements of the community. • All notiifiable diseases are reported as per regulation to the concerned authorities. • No awareness of IHR or PHEIC	• Guidelines and training programs for IHR & PHIEC may be made available and implemented. • It is recommended to study the surveillance of AST pattern of community infections, information to the local clinicians.
Supplies, equipment availability and Management	• AMCs of some critical instruments are not available. • Maintenance logbooks of instruments are being maintained, down time of the	• AMC/CMC and Calibration should be scheduled and implemented • Calibration of instruments and equipment to be done

	equipment's are being recorded and monitored for further improvement. • Calibration of all major equipment, as well as the ancillary instruments, example, micropipette, centrifuge, water bath, etc., are not there • Supplies are adequate, proper stock management and indenting procedures are in place. • Validations of new reagents lots are not done after receiving. • All the equipment in SRL are calibrated and preparing for NABL accreditation. • No automated tissue processor • available in pathology • No coagulation testing systems available	• All critical regents should be checked by running IQC or a known previous sample, records of the same to be maintained, acceptable range to be defined. • Automated tissue processing and coagulation system may be procured • A new Fully Automated analyser for Clinical Chemistry may be procured as the existing one is old • CLIA may be procured for Immunoassay tests • HPLC system for HBA1c may be considered
Budget and Finances	• Budgetary projections are made by laboratory based on test, facility and equipment needs, and quality assurance procedures and materials. Microbiology has already in the process to procure automated Bacterial culture and AST system.	• It is suggested to allocate more funds to procure new equipment as per the workload of the laboratory.
Data Management and IT	• Data maintained as hard copies • All procedures, manuals and documents are saved into computer system, but there is no provision for data backup. • Internet facilities are made available in all the departments. • The Lab doesn't have a functional intercom system for interdepartmental communication.	• Computerized data backup may be considered for data safety. Data entry operators are required. • HMIS or LIMS may be considered to manage workflow. • A functional intercom system may be installed for effective interdepartmental communication.
Diagnostic capacities	• Inadequate in microbiology. • Frozen sections not available in histopathology • LBC not available in cytology • Coagulation tests not available • Microbiology section has BSL III lab for TB.	• The bacteriological processing needs to be strengthened. Serology for Hepatitis profile needs to be done ELISA. The lab may introduce TORCH profile. All facilities to monitor the hospital infection control activities may be considered. In mycology section, culture may be started. Parasitology section may be

		strengthened. • Coagulation, LBC and Flow cytometry may be included in pathology department.
Staff availability, training and management	• The staff was enthusiastic and eager to learn. • There is an extreme shortage of technical and support staff. Almost all the functions are run by the DMLT students. • Training of staff inadequate in all levels.	• Filling up of vacancies and provision of adequate staff. • Appropriate capacity building efforts may be planned. • Induction training programme should be conducted on SOPs, infection control practices and PEP, Safety and BMW management, Fire and disaster management. • Periodical Health assessment for staff should be done. • Competency assessment for the staff should be conducted at least once in a year. • Formation of active infection control & BMW committees to ensure segregation, transportation of BMW and infection control required.
Communications	• Communication channels can be better	• Channels of communication within the lab, among the labs, among departments- especially clinical departments - may be improved. • Communication with patients in the form of advisory services, feedback and complaint redressals etc. are good practices to start • Communication with district and state authorities and regulatory bodies can be started. Disease notification practices can be improved by understanding the disease surveillance requirements at national and international levels.

6. GAP Analysis results - District Hospital Laboratories

6.1 General Information of Selected Laboratories

Eight district hospital laboratories that were selected from six states in the country were included in the assessment. The basic details of the laboratories are given in the following

Table 13: General Information of Selected District Hospitals.

Name of the Institution	General District Hospital Wardha Maharashtra	SDH Vaijapur Aurangabad, Maharashtra	Govt. District Hospital, Anakapalle Vishakhapatnam A.P	Area Hospital Jangaon, Warangal	Satellite District Hospital, Chandpole Udaipur Rajasthan	Paota Government District Hospital Jodhpur, Rajasthan	Moran Tiloi CHC Dibrugarh Assam	Darjeeling District Hospital Darjeeling, West Bengal
State	Maharashtra	Maharashtra	Andhra Pradesh	Telangana	Rajasthan	Rajasthan	Assam	West Bengal
District	Wardha	Aurangabad	Visakhapatnam	Warangal	Udaipur	Jodhpur	Dibrugarh	Darjeeling
City/Town	Wardha	Aurangabad	Visakhapatnam	Warangal	Udaipur	Jodhpur	Moran Tiloi	Darjeeling
Dean/ Institution head	Dr. Purshottam Mandvi	Dr. Mudkhedkar	Dr. S.V.R. Kumari, MS DGO	Dr K Padma,	Dr. A.K. Berva	Dr. Ashok Singh Rathore	Dr. REBA KUMAR SAIKIA	Dr. Saikat Pradhan
District Population	1296157 (2011)	3695988 (2011)	4288113 (2011)	3522644 (2011)	3067549 (2011)	3685681 (2011)	1,326,335 (2011)	1,1,846,823 (2011)
Beds Strength	240	100	100	100	100	150	30	400
No of outpatients (March 2015-Feb 2016)	303360	83000	248,317	146000	257333	98254	33902	91,496
Laboratory Type	District	Sub District	District	Sub district	District	District	CHC	District level
Number of samples annually	101089	59777	106371	70612	120088	68882	5916	82928
Lab Head	Dr. Swati Patil	Dr. Sanjay Jadhav	Dr. R. Ramadas	Dr. Ganesh Babu	Dr. Rekha Bhandari	Dr. Lokesh Mehta	Dr SWAGATHA BHARATI	Dr. Renuka Chhetri
Nodal Officer	Dr. Swati Patil	Dr. Sanjay Jadhav	Dr S.V.R. Kumari	Dr. Ganesh Babu	Dr. Naresh Singhal	Dr. Kulbir Chopra	Dr Swagatha Bharti	Dr. Renuka Chhetri

6.2 Overall Institution Score

The overall score comprises of components such as, Service Provision, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management and Outcome/KPI monitoring.

As mentioned earlier, The component "Inputs" is given the highest weightage (19.3%) followed by, quality management(19.0%), Infection Control (17.7%), Support Services (15.4%), Clinical Services (9.5%), Patient Rights (6.9%), Outcome (7.2%), and Service Provision (4.9%).

The overall mean score of all the district hospital laboratories indicated an increase from 33.0(SD: 6.7) at baseline assessment to 56.3(SD: 8.5) at midterm review. The average midterm score of district hospitals ranges from 65.4% for District Hospital, Darjeeling to 42.0% for district hospital, Aurangabad.

Fig 20: Overall Score

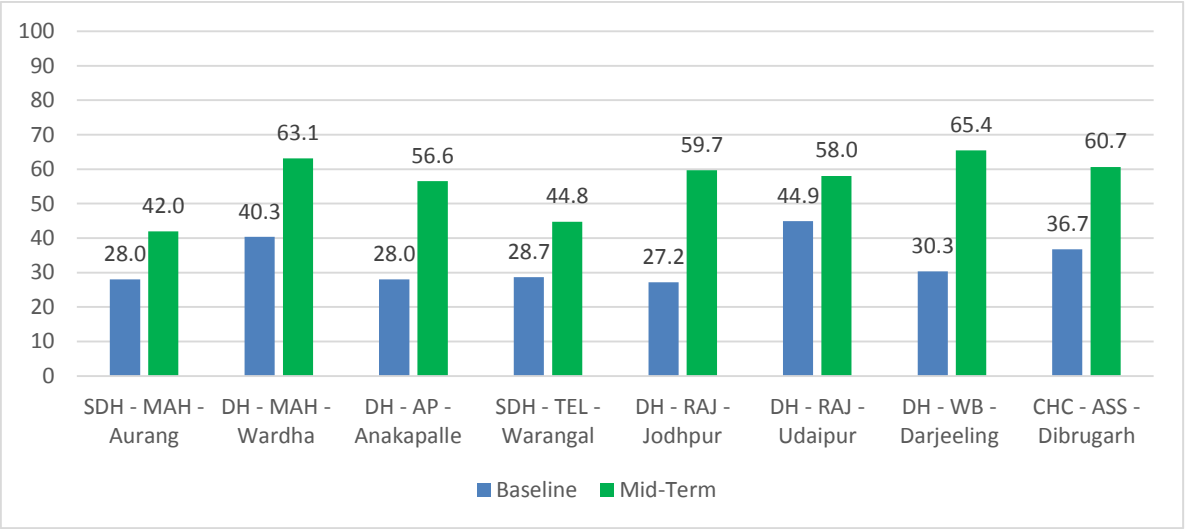
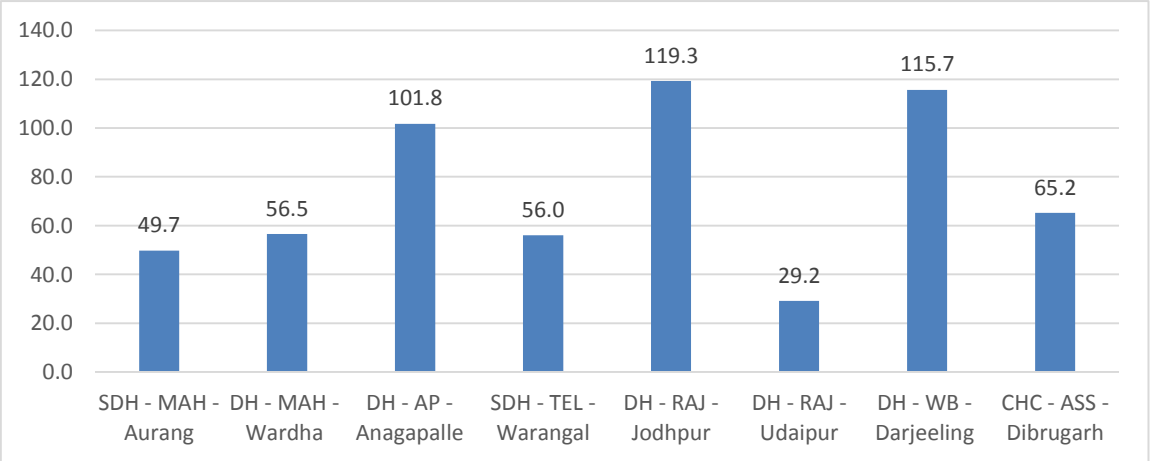


Fig 21: Percentage of change

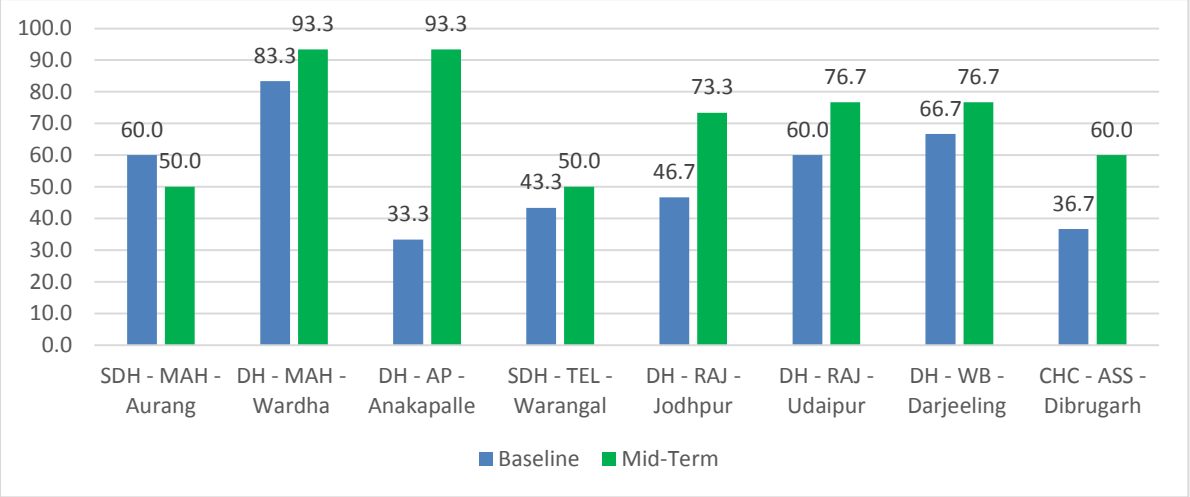


The percentage of increase is maximum (119. 3%) for district hospital, Jodhpur and minimum (29.2%) for district hospital Udaipur. A key observation here is the availability of pathologists that made a difference in DH Wardha, DH, Eden Darjeeling, CHC Moran Tiloi, Dibrugarh, DH Udaipur. Additional inputs in infrastructure and equipment also enhanced scores.

6.3 Service provision

The service provision component includes, availability of testing disciplines of laboratory medicine such as, hematology, biochemistry, microbiology, clinical pathology, microbiology, serology, cytology, histopathology; availability of national programs, availability of services appropriate to local problems(Infections/ sickle cell anemia/thalassemia/ others).

Fig 22: Service Provision



The overall score for service provision indicated an increase from 53.8% (SD: 16.9) at baseline to 71.7% (SD: 17.2) at midterm review. The midterm score for service provision ranges from 93.3% for District Hospital, Anakapalle and Wardha to 50.0% for Warangal and Aurangabad. SDH Vijapur, Aurangabad, recorded a decrease in midterm score from 60% to 50%. District hospital, Anakapalle recorded a significant increase in service provision basically due to the roll out of Free Diagnostic Services Initiative.

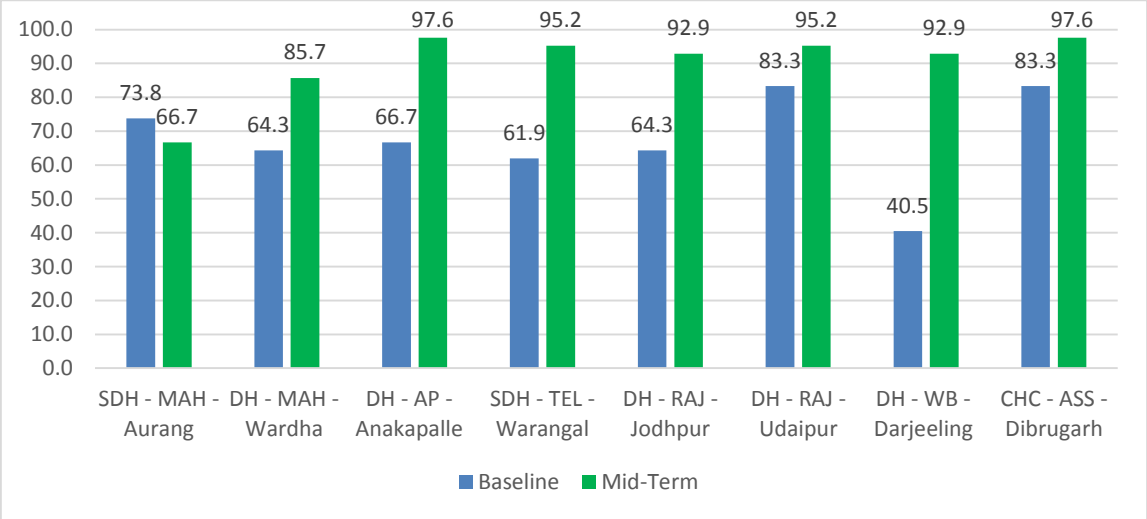
6.4 Patient rights

Patient rights comprise of, availability of information for patients and users regarding lab services, sensitivity to gender, physical disabilities, privacy, courtesy, confidentiality, informed consent procedures, complaint redressal system, financial protection (mandatory

cashless services to pregnant women and children), availability of prescribed tests, free services to BPL, reimbursement of beneficiaries for tests not available in the lab.

The overall score for patient rights showed an increase from 67.3% (SD: 13.8) at baseline assessment to 90.5% (SD: 10.3) at midterm review. The midterm score for patient rights ranges from 97.6% each for District Hospital, Anakapalle and district hospital, Dibrugarh to 66.7% for district hospital, Aurangabad. The midterm score is above 80% for all the laboratories of hospitals except Aurangabad, which recorded a decline from 73.8% to 66.7%. As these were soft interventions, action at the level of labs and institution heads was sufficient to bring about most of the necessary changes. Handholding by the Regional Quality Consultants provided the necessary impetus.

Fig 23: Patient rights

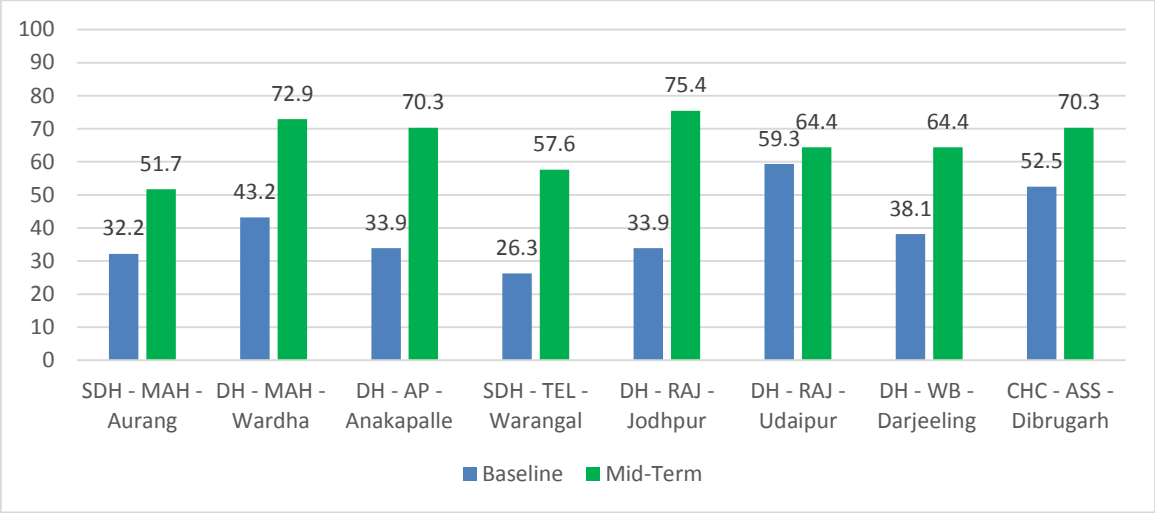


6.5 Inputs

Inputs comprise of, infrastructure adequacy: compatibility of physical infrastructure with the work flow, power supply, safety measures: fire safety equipment, staff availability: pathologists/ microbiologists/ technical staff, staff training, availability of reagents and consumables and availability of equipment.

The average score for inputs indicated an increase from 39.9% (SD: 11.1) at baseline assessment to 65.9(SD: 8.0) at midterm review. The midterm score for inputs ranges from 75.4% for District Hospital, Jodhpur to 51.7% for District hospital, Aurangabad. Both Jodhpur and Anakapalle recorded remarkable increase in inputs due new premises or addition of equipment or staff. Availability of pathologist has proved to be a distinct advantage in consolidating all available inputs into outputs.

Fig 24: Inputs

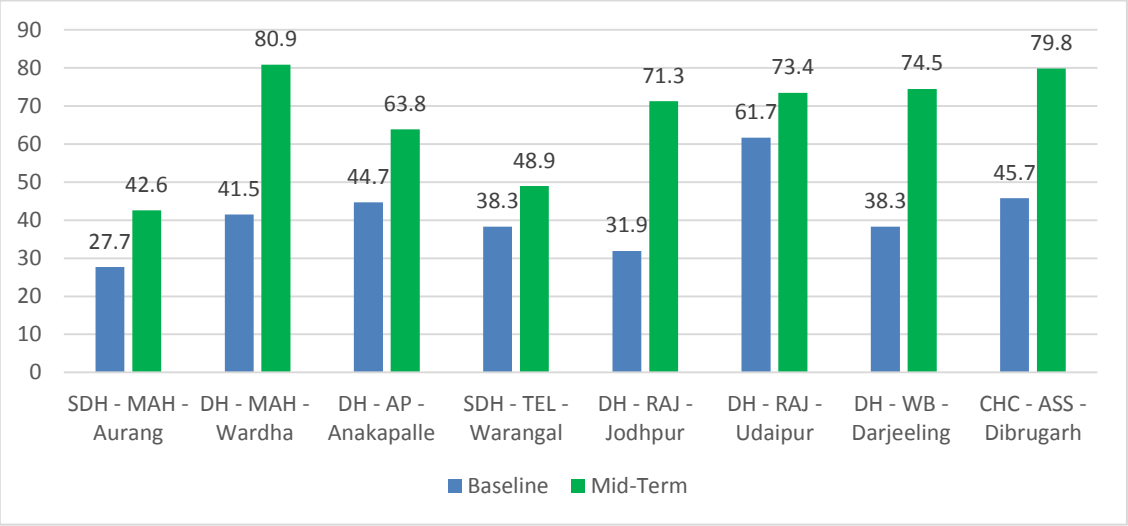


6.6 Support services

This component includes, Equipment maintenance; daily maintenance, scheduled maintenance, calibration and availability of AMC/CMC, Inventory management; Indenting system, storage, stock verification and emergency purchases, Lab safety; bio-safety, chemical, equipment, fire safety and safety of female staff, building maintenance; general upkeep, work stations, furniture, pest control, power back-up and running water, compliance to statutory requirements like disease notification, HR: Awareness of job descriptions, dress codes, duty rosters, monitoring of outsourced services: Laundry, dietary, security.

The average score for support services in the district hospitals recorded an increase from 41.2% (SD: 10.3) at baseline to 66.9% (SD: 14.2) at midterm review. The midterm score for support services vary from 80.9% each for District Hospital, Wardha to 42.6% for sub-divisional hospital, Aurangabad. The majority of the district hospitals scored above 60% except Aurnagabad, and Warangal. None of the institutions have an equipment management program for CMC and Calibrations. Although agencies of the Equipment Management and Maintenance Initiative of NHM have mapped out the equipment in several institutions, the actual support is yet to be given. Stock-outs are another area of concern. Labs for Life has done multiple levels of trainings in equipment management and safety. Mentoring and hand-holding in staff management issues are ongoing. Training in inventory management is planned.

Fig 25: Support Services

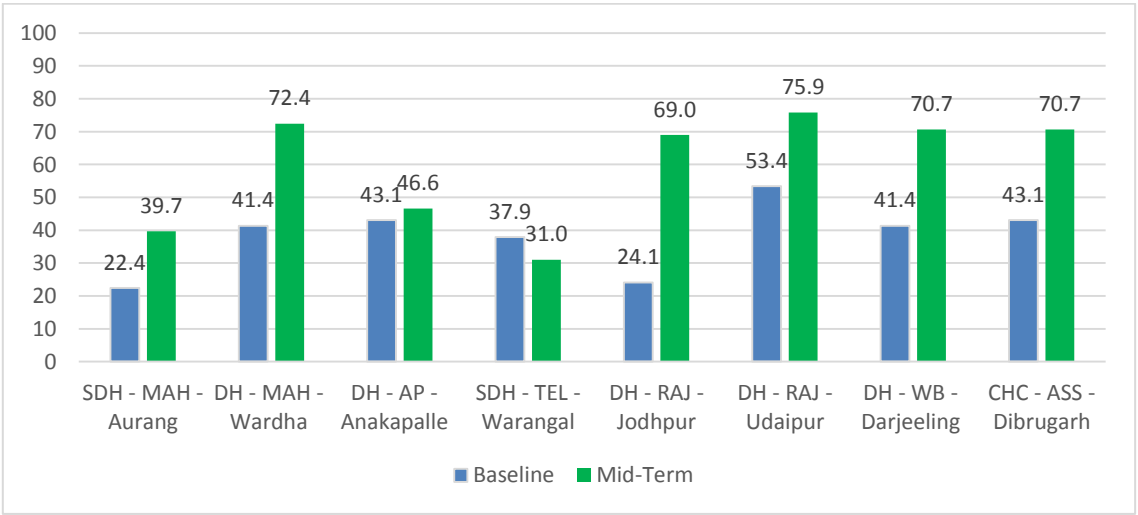


6.7 Clinical Services

Clinical services consist of, patient identification procedures, referrals (patients/ samples), record maintenance, disaster management, medico legal cases, pre-analytical: sample collection procedure, pre-analytical: sample transportation procedure, analytical: Testing processes, biological reference ranges, critical call outs, post-Analytical: Review of results. reporting formats, report transcription, stat reporting, data archival, and post-Analytical: sample retention and discarding process.

The average score for clinical services in the district hospitals indicated an increase from 38.4% (SD: 10.3) at baseline to 59.5(SD: 17.5) at midterm review. The score for clinical services vary between 75.9% for District Hospital, Udaipur and 31.0% in SDH, Warangal.

Fig 26: Clinical Services



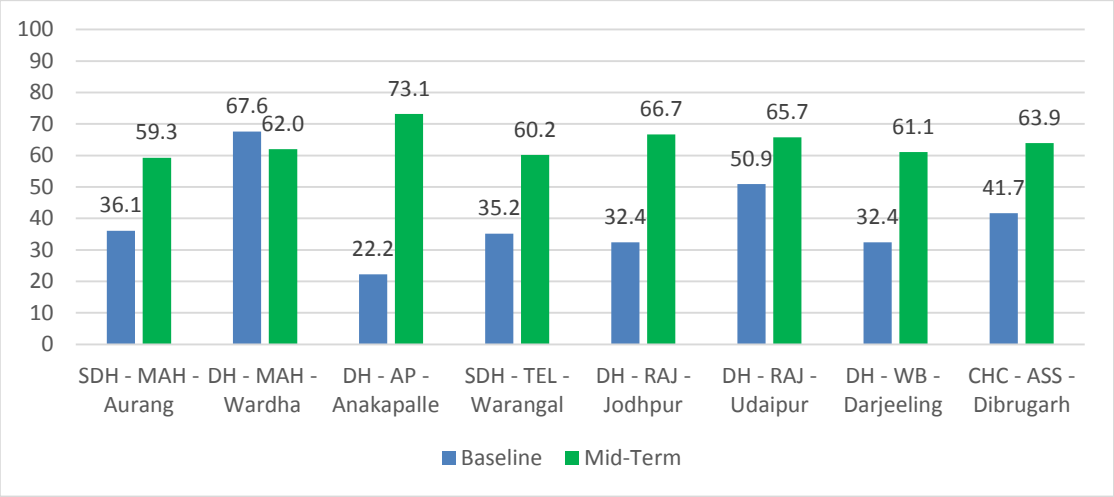
Labs for Life gave multiple levels of trainings in Sample Collection and Pre-analytical practices. Standard testing practices are being taken up by Quality Coordinator and Regional Quality Consultants. Post –analytical aspects are also being addressed. Initiation of computerization and installation of LIS can streamline the process of pre-analytical, analytical and post-analytical processes. Allocations through PIP can help in this regard.

6.8 Infection Control

Infection control includes, passive and active culture surveillance of high risk areas, staff immunizations, check ups, hospital Antibiotic policy, hand hygiene protocols, availability and use of personal protective equipment, spill management protocol, decontamination of equipment, cleaning and disinfection of patient care areas, biomedical waste management: Segregation at source, sharps disposal, post exposure prophylaxis and liquid waste management. The average score for infection control in district hospital showed an increase from 39.8% (SD: 13.9) at baseline to 64.0 (SD: 4.5) at midterm review respectively. The score for infection control ranges from 73.1% each for District Hospital, Anakapalle to 59.3% for District Hospital, Aurangabad. The percentage of increase was highest for district hospital Anakapalle followed by Jodhpur. Anakapalle also awarded the second place in the Kayakalp award scheme.

Labs for Life has done several trainings in infection control especially with regard to Bio Medical Waste Management. NHM PIPs have allocated funds in some hospitals for purchase of disposable collection and ESR tubes, staff vaccinations, triple bucket cleaning systems etc. to aid in the infection control process.

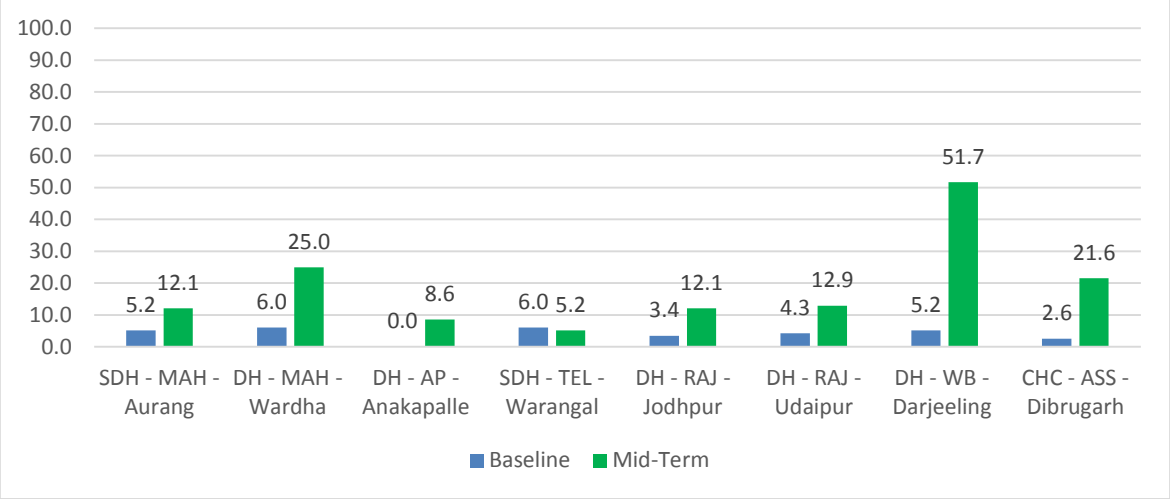
Fig 27: Infection Control



6.9 Quality Management

Quality management includes, availability of a nodal officer [Quality Manager], surveys of satisfaction among patients/ referring doctors, availability of internal quality assurance program(IQAP), availability of external quality assurance program(EQAP), corrective action protocols, availability of standard operating procedures(SOP), internal audits, defined quality policy, defined quality objectives which are monitored and continual improvement protocols.

Fig 28: Quality Management



Both components of this aspect, Quality Controls and Documentation were addressed through multiple levels of trainings by Labs for Life. As the concepts are new and effort intensive, it might take more time for changes to be evidenced. Additionally, the availability and uninterrupted supply of control materials and registering in EQAS programs were found to be challenges in several places.

The average score for quality management recorded an increase from 4.1% (SD: 2.0) at baseline assessment to 18.6 (SD: 14.9) at midterm review. The midterm score for quality management component ranges from 51.7% for District Hospital, Darjeeling to 5.2% for SDH, Warangal.

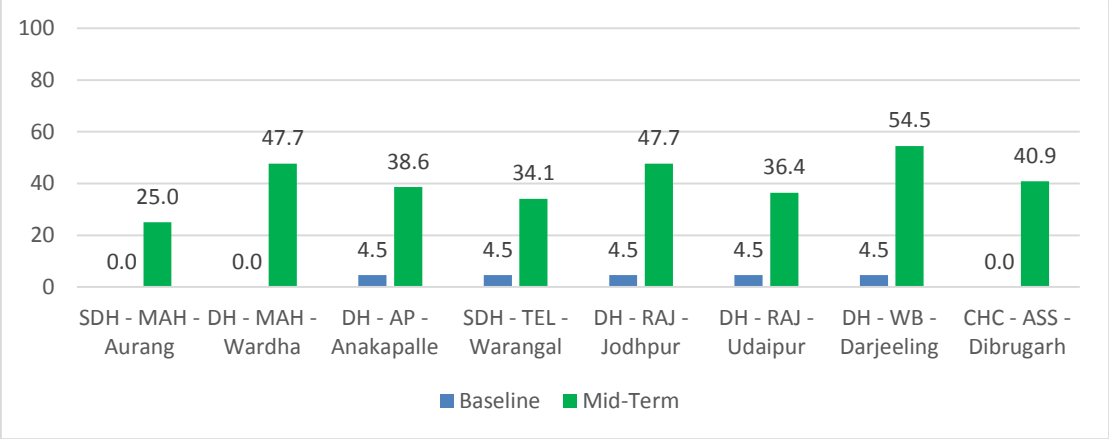
The district hospital, Darjeeling recorded the highest percentage of increase followed by Dibrugarh. DH Darjeeling has money allocations through NHM PIP FY15-16 which got the process of IQC and EQAS initiated there. Rajasthan has state provision of IQCs, though irregular. PIP allocations are to be availed and used for this as well as EQAS registration. Maharashtra also has allocations for quality management. Assam PIPs are being worked out. West Bengal has resubmitted PIP through supplementary. Telangana and Andhra have no PIP allocations and state government funds are awaited.

6.10 Outcome monitoring

Outcome measurement indicates, developing productivity indicators e.g. Number of HIV tests done/ 1000 population , proportion of tests done for BPL patients, efficiency Indicators e.g. Z scores, TAT for routine tests, emergency tests, safety Indicators e.g. Percent of critical call outs and service quality Indicators e.g. waiting time, stock-outs.

The average outcome score indicated an increase from 2.8% (SD: 2.4) at baseline to 40.6% (SD: 9.3) at midterm review. The midterm score for outcome ranges from 54.5% each for district hospital, Darjeeling to 25% in SDH Aurangabad. Overall, there is a significant increase in midterm score for all the laboratories in district hospitals. Most of the service uptake data is being captured regularly. However, monitoring these data as indicators is being started now. Along with this, quality indicators will also be captured as percent defect as per ISO: 15189

Fig 29: Outcome measurement



7. Key observations and Recommendations

District Hospital Laboratories

The following are the key observations and recommendations by the assessors, based on the results from quantitative assessment, site observations, group discussion and interviews with different stakeholders in the institutions. The observations and related recommendations are given institution's wise.

Table 14: SDH Vaijapur

SDH Vaijapur		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• Laboratory services are not offered in night regularly. • Biochemistry & Hematology analyzers not functional. • All tests, as required by IPHS & National Programs not available: Cholesterol (lipid profile), OT test for residual urine in water, CSF protein & sugar, Iodometry titration. • Microbiological services not available- KOH for fungus, Bacteriological examination of water. • Cytology services not available. • Clinical Pathology services not available- Bile salts & bile pigments in urine, Semen analysis, and Hanging drop for Cholera, Occult blood, CSF analysis, aspirated fluids cell count. • Turnaround time not defined and calculated.	• The score is less than baseline now. The reason to be understood. • Laboratory services to be offered as per the IPHS guidelines. • Biochemistry & Hematology analyzers to be kept functional. • All tests, as required by IPHS & National Programs to be made available. • Turnaround time to be defined and displayed. Take immediate action • Help of GMC Aurangabad to be sought in streamlining.
Patient Rights	• Sample collection site should allow patient privacy and separate queue for females (only 1 collection site), • No phlebotomy chair is available. • Reports are not provided in printed formats.	• Sample collection to be in segregated area that should allow patient privacy and separate queue for females (at least 2 collection sites), • At least 2 phlebotomy chairs should be made available. • Registration and reporting area to be separate. • The water testing premises have been allocated. Have to evolve a

		mechanism for upgrading.
Inputs	• No secure storage of TRF/reports. • No complaint box or grievance redressal system exists. Sample collection, registration, payment & reporting done within lab area. Long queue in peak time. • No telephone/intercom available in lab. Unidirectional flow absent. BMW guidelines not followed effectively. • Segregation done but not handed over to authorize vendor, instead burned in the facility. • Fire Safety deficient- fire extinguishers are expired, staff training not provided. • Many test as per guideline are not available and patient is refused. No sample referral done. • Housekeeping staff put blue bag in black bag- later all in one bag. No record of training evidenced. • Many kits not available. E.g. CRP, RA, HBsAg, many biochemistry kits • Centrifuge does not have adequate speed setting options. • Only one fridge available for reagent storage. No sample storage fridge available	• Important to have a dedicated Pathologist. • Phone connection to be availed. • TRF & reports to have printable formats and stored for at least 1 year. Better to use computerized system. • Complaint box or grievance redressal system to be established. • Lab to have unidirectional flow, with sample collection, registration, payment & reporting to be done in area segregated by space or time and should be outside lab area. • BMW guidelines to be followed effectively. Take immediate action. • Fire Safety compliance to be improved; fire extinguisher recharged and staff to be trained. • All tests/kits should be made available and sample referral done, if needed. • A new centrifuge and storage refrigerator are needed.

Support Services	• No AMC/ CMC, calibrations. • Many bottles & containers not labeled. • Date of opening & reconstitution not mentioned. • No monitoring done of environmental conditions. Temperature not controlled in labs and sample collection area. • Restricted entry not effectively implemented, since collection also done in lab. • Staff is not aware of their role and responsibilities (no defined job description). • Doctor, technician and support staff do not adhere to their respective dress code.	• CMC for equipment to be done; calibrate as required. Equipment management program rolled out by the state must be availed. • Staff to be trained on equipment labeling, downtime monitoring, preventive maintenance. • Monitoring to be done of environmental conditions and temperature controlled in labs and sample collection area. • Restricted entry to be effectively implemented. • Staff to be made aware of their role and responsibilities (define job description). • Doctor, technician and support staff to adhere to their respective dress code. • Inventory management training required
Clinical Services	• No referral system evidenced for tests not performed. • No handover mechanism evidenced during shift change. • Printed formats for requisition and reporting are not available. • No disaster management plan evidenced. • Request forms do not contain information on: type of primary sample, time of primary sample collection and date and time of receipt of sample by laboratory. • Instructions for primary sample collection not evidenced. • Two identifiers not used for labeling samples. • No system for transportation evidenced for samples collected in ward and transported to lab, to ensure timely receipt at correct temperature. TAT not defined and monitored	• Referral system to be defined for tests not performed. The hospital should participate in the Free Diagnostic Services Initiative being rolled out • Handing over mechanism to be established at shift change. • Printed formats for requisition and reporting to be made available. • Disaster management plan to be created. • Request form to contain information: type of primary sample, time of primary sample collection and date and time of receipt of sample by laboratory. • Instructions for primary sample collection to be created. • Two identifiers to be used for labelling samples. • System for transportation for samples collected in ward and transported to lab, to ensure timely receipt at correct temperature to be established.

		• TAT to be defined and monitored. Take immediate action • The entire processing sequence from proper request forms, unique ID of samples, processing registers, report issuing and handling of tests not done in the institution, should be streamlined with proper documentation. • Initiation of computerization can help in this regard.
Infection Control	• There is no provision of periodic medical checkups and immunization of staff. • Regular monitoring of infection control practices. Antiseptic Solutions not available • Transportation of bio medical waste is not done in closed container/trolley	• Provision of periodic medical checkups and immunization of staff to be created. • Regular monitoring of infection control practices to be done. • Availability of Antiseptic Solutions should be ensured. • Transportation of bio medical waste to be done in closed container/trolley. • PPE, Disposable collection tubes, ESR tubes to be procured continuously. • HIC program should be initiated to address these comprehensively. • Equipment decontamination program should be started. • BMW trainings to be done. • BMW operator to be contacted and briefed about the requirements.

Quality Management	• There is good initiation with SOPs being displayed, some protocols written. However, there has to have improvements in QMS. • There is no designated departmental nodal person for coordinating Quality Assurance activities. • Facility has not established internal quality assurance program. • Facility has not established external assurance programs. • Standard operating procedures not available. • Facility has not mapped its critical processes, do not enumerate nonconformities and takes timely corrective actions to improve processes. • The facility has not defined its quality objectives or monitor them. • Continuous quality improvement in services not effectively implemented in all aspects.	• A designated departmental nodal person for coordinating Quality is required. • Quality Assurance activities to be identified. • Facility to establish internal quality assurance program. PIP funds should be availed and used optimally. • Facility to establish external assurance programs. Maharashtra has allocated funds for EQAS. This should be tapped into. • Standard operating procedures to be made available for all testing and non-testing activities. • Facility to map its critical processes, enumerate nonconformities and take timely corrective actions to improve processes. • The facility has to define its quality objectives and monitor them. • Continuous quality improvement in services to be effectively implemented in all aspects.
Outcome	• The outcome measurement has been initiated. • Facility does not map most productivity Indicators on monthly basis, as required.	• Facility to measure most productivity Indicators on monthly basis, as required.
Risk Management (as per ISO 15189:2012)	• Not aware of the concept and need, hence not done	• Staff to be trained on Risk management. Then review the processes and specify mitigating strategies
Competency Assessment of staff (as per ISO 15189:2012)	• Not aware of the concept and need, hence not done	• Staff to be trained on Competency Assessment. To be done depending on roles and responsibilities.

Table 15 District Hospital, Wardha

District Hospital, Wardha		
Area of Concern	**Summary**	**Recommendations**
Service Provision	Overall service provision is excellent.	• It is recommended that the lab reports are provided in an electronic/printed format. • Timing of report collection to be displayed near patient area.
Patient Rights	• Patient rights are taken care of and well managed.	• Confidentiality of patient reports should be maintained which currently is a problem as reports are mentioned on the requisition forms. • Complaint / feedback forms also need to be displayed near patient waiting / collection area.
Inputs	• Overall Satisfactory except few recommendations are made considering improvement in workflow and safety aspects.	Additional collection counter should be made available when the patients flow is high so that patient waiting queue and time is not too long. Back up phlebotomist should be available. • Phlebotomy chairs for collection should be provided to for comfort of patient and phlebotomist. • Department need to have signage's to permit safe escape to its occupant at time of fire. Fire exits should be clearly visible and routes to reach exit need to be marked. • Fire extinguisher should be available in the lab and Staff should be competent for operating fire extinguisher.
Support Services	• Services provided and offered are mostly acceptable with few gaps that need to be addressed as mentioned in recommendation.	• All equipment should be covered under CMC including preventive maintenance. All the major and minor equipment/ instruments should be calibrated. Equipment management initiative of NHM which has been rolled out by the state, to be checked ot and followed through • Instructions/flowcharts for operation and maintenance of equipment should be available with staff.

		• Each lot of reagents has to be checked against earlier tested in use reagent lot or with suitable reference material before being placed in service and result should be recorded. • Role and Responsibility documents must be prepared and shared with staff. • Additional refrigerator for storage of samples is recommended.

Clinical Services	• Needs improvement	• Laboratory should have system to record the identity of person collecting the primary sample.
		• Sample transportation time, temperature must be documented
		  ○ Carrier specified for transportation (closed box for storing sample) should be made available.
		  ○ Laboratory must have defined retention period and disposal of used sample.
		• Strengthen documentation and records practices.
		• The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation.
		• Initiation of computerization can help in this regard.

Infection Control	• Need to be focused as an area of improvement.	• Infection control score is less than baseline and needs to be addressed immediately. • Staff is not immunized and Periodic medical checkups of the staff should be considered. • Alcohol based Hand rub and antiseptic solution should be available. • Proper Decontamination of instruments after use should be carried out.

		• PPE, Disposable collection tubes, ESR tubes to be procured continuously. • HIC program should be initiated to address these comprehensively. • Equipment decontamination program should be started. • BMW trainings to be done. BMW operator to be contacted and briefed about the requirements.
Quality Management	• Need to be focused as an area of improvement.	• IQA and EQA procedures must be well established. • PIP allocations to be used for uninterrupted IQC supply. • EQAS to be started availing NHM funds for the state. • Quality objectives must be established, monitored and reviewed periodically for continuous improvement. • Documentation is to be strengthened. Training in QCs and documentation to be continued
Outcome	• Need to be focused as an area of improvement.	• The facility must measure and analyze - Productivity Indicators , - Clinical Care & Safety Indicators, Efficiency Indicators and service quality indicators in compliance with State/National benchmarks
Risk Management (as per ISO 15189:2012)	• No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	• No awareness	• Staff need to be assessed periodically /six months and based on this a re-training may be required.

Table 16: District Hospital, Paota, Jodhpur, Rajasthan

District Hospital, Paota, Jodhpur, Rajasthan		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• Laboratory provides basic services for biochemistry, hematology and serology. • Basic services for Microbiology is not available. • The District Hospital has been taken over by the medical college and is in the transition phase.	• Facility can increase the scope of testing by using its resources. • Basic microbiology tests can be added as the hospital has current/ temporary lab in charge who is MD Microbiology. • Availing one resident on rotation basis from SNT Jodhpur to be considered.
Patient Rights	• The hospital provides services to the adjoining urban and rural areas. • Most of the facilities are available for patient comfort e.g. ramp, toilet and drinking water. • All the facilities are available under one roof.	• Report confidentiality needs to be strengthened. • HIV testing should be done by pre-test and posttest counseling.
Inputs	• The lab has recruited 8 new contract technicians recently. However, technical supervisory staff are not available; either pathologist or microbiologist. • The lab has adequate patient waiting area, toilet facility and sample collection area. • The lab has space constrains in the testing area as well as space is limited for free lab staff movement. • Lab has granite work benches for most of the testing except serology which is carried out on wooden table. • All the staff is not trained on Fire safety. • Lab does not have permanent housekeeping staff. • The lab does not have separate area for sputum processing or staining. • Stains were partially available	• Serology work station should have granite/ non-corrosive top which can be disinfected regularly. • Staff should be trained for fire safety. • Pathologist/ Microbiologist could be appointed for appropriate monitoring of daily working. Effort must be taken to post the microbiologist in the lab full time. • As the hospital has been brought under the purview of the SN Medical College, SRs may be requested for, from the college • The newly recruited technical staff should be trained in Quality System Essentials • Proper drainage and plumbing should be made available. • As the lab is too small to handle the volume of work, relocation has been suggested. The allocated rooms can be designed as per lab design specifications. PIP allocations may be

	and not labelled. • The effluent from the biochemistry analyzer is collected in a bucket and manually disposed as there is no drainage.	also considered in bringing in the changes suggested.
Support Services	• Equipment were found clean and well maintained. The equipment which were not in use were properly labeled. • Equipment are not covered under AMC and are not calibrated. • There is no uniform labelling for equipment. • Eye washing station/ process not available. • There is no temperature monitoring of the refrigerator. • 5 part analyzer has been nonfunctional for a long time	• Laboratory should have AMC and CMC for all equipment and records should be maintained. Equipment CMC Calibration has been rolled out by the state, to be followed through. • All equipment should be calibrated and labeled; • Hematology analyzer requires immediate calibration. • Lab should have digital temperature monitoring instrument. • A downtime monitoring system should be enabled
Clinical Services	• Lab is giving equipment print outs to the patient, as uniform reporting formats are not available. This results in inadequate data archival. • Staff is not aware of disaster plan. • Blood samples are not uniformly labeled.	• Lab should develop uniform reporting format. • Reporting formats should be as per ISO guidelines. • Strengthen documentation and records practices. • All data should be archived for future reference. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard. Computers can be made available through PIP allocation
Infection Control	• Hand wash area are available with hand wash instructions in the lab area. • Infection control practices are	• All lab staff should be vaccinated and records maintained. • PPE, Disposable collection tubes, ESR tubes to be procured continuously.

	not adequate, selective samples are collected for surveillance and sent to referral lab for testing. • There are no records for vaccination.	• HIC program should be initiated to address these comprehensively. • Equipment decontamination program should be started. • BMW trainings to be done
Quality Management	• The lab is conducting testing in all basic areas, maintaining records for internal QC in biochemistry whereas such records are not available in other testing areas. • The lab has developed work instructions for limited number of tests but detailed SOP's and work instructions were not available for most of the testing including sample collection, transportation and validation. • There is no procedure for monitoring equipment time • No dedicated Quality Manager available in the lab. • No EQA's available in any testing discipline.	• The lab should develop SOP's and work instructions for full test menu. • Equipment breakdown time should monitored and reviewed. • Lab should restart IQC program in Hematology and get enrolled in EQAS in all areas.PIP allocations to be used for uninterrupted IQC supply and get EQAS started. • Documentation is to be strengthened. • Training in QCs and documentation to be continued
Outcome	• The lab has all data for calculation of productivity indicators. Efficiency indicators are not monitored. • Clinical care and service indicators are available, but not as dashboards.	• Lab may capture all the performance indicators as dash boards for easy monitoring.
Risk Management (as per ISO 15189:2012)	No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	No awareness	• Staff need to be assessed periodically /six months and based on this a re-training may be required.

Table 17: Satellite District Hospital, Chandpole Udaipur

Satellite District Hospital, Chandpole Udaipur		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• Laboratory services are adequate for the population it caters. • Laboratory provides basic services for biochemistry, hematology and serology. • Microbiology culture and sensitivity can be started. • Laboratory is facing radiology department without any proper shield or proper protective coverage.	• Patient feedback/ complaint register signage should be displayed and available to patients freely. • Reports can be printed as they have the printing facility.
Patient Rights	• Informed consent, privacy and confidentiality of patients are well maintained. • Basic facilities like toilet, drinking water, seating area and first aid services are available. • Pre and Posttest counseling is available for the designated patients. • Good display of posters and signage's for understanding of patient/ staff.	• Proper sample collection chair should be there.
Inputs	• Laboratory space is inadequate as per patient load and test performs. E.g. No separate area for AFB staining, washing, centrifugation and BMW management. • There is inadequate storage space for reagents and kits. Certain kits were found kept outside the refrigerator. • There is no landline or intercom facility. • Laboratory is planned as per unidirectional flow of services.	• Laboratory area should be increased for carrying out various laboratory related activities like staining, washing, centrifugation etc. • Extra refrigerators should be provided according to the work load. • Functional telephone/ intercom services should be provided for communication. • Fire extinguisher should be provided inside the lab and proper training should be given. • PIP allocations may be considered in bringing in the changes suggested.

	• Safety equipment like fire extinguisher is not inside the lab and staff is not trained on it.	
Support Services	• Equipment's were found clean and maintained. • Equipment are not covered under AMC and are not calibrated. Laboratory is in process of finalizing AMC with one particular company as per govt. directions. • Eye washing station/ process not available. • There is no temperature monitoring of the refrigerator.	• All equipment should be calibrated and labelled. Equipment CMC Calibration has been rolled out by the state, to be followed though • Lab should have digital temperature monitoring instrument. • Calibration records should be maintained.
Clinical Services	• Lab is not giving printed reports to the patient. • Staff is not aware of disaster plan. • Laboratory records are maintained as per the clinical requirement. • Adequate supply of reagents and kits are there.	• Lab should develop uniform reporting format. • Reporting formats should be as per standard guidelines. • Strengthen documentation and records practices. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard. Computers can be made available through PIP allocation.
Infection Control	• Facility does not have formal infection control program/ infection control committee and infection control team. Although infection control practices are followed partially without any formal training or services. • Doctor is aware of antibiotic policy but it has not been defined or established. • Hand hygiene and antisepsis practices were followed as	• Gloves should be changed once it is visibly soiled. • Infection control team should be formed and regular infection control surveillance should be carried out. • Formal training for infection control practices should be provided to all healthcare workers. • Vaccination policy should be formulated. • PPE, Disposable collection tubes, ESR tubes to be procured continuously. • HIC program should be initiated to

	per guidelines.	address these comprehensively. • Equipment decontamination program should be started. • BMW trainings to be done.
Quality Management	• Laboratory has initiated SOP's for various tests and techniques. • Work instructions are well displayed. • No identified quality management program/ officer or team. • Although laboratory has started participating in internal lab comparisons but formal EQAs is not available.	• SOP should be available in time bound manner. • Internal Quality control supply chain needs to be strengthened. • PIP allocations to be used for uninterrupted IQC supply • Laboratory should participate in EQA's for various tests. • Healthcare worker should be provided Quality Management training. • Documentation is to be strengthened. Training in QCs and documentation to be continued.
Outcome	• The lab has all data for all the notifiable diseases and the routine tests done including HIV, TB /AFB, however it cannot be calculated /1000 population as the specialized person is needed.	• Lab may capture all the performance indicators as dash boards for easy monitoring.
Risk Management (as per ISO 15189:2012)	No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	No awareness	• Staff need to be assessed periodically /six months and based on this a re-training may be required.

Table 18: SDH, Jangaon

SDH, Jangaon		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• Limited test menu. • New equipment have been bought and is awaiting commissioning. • Additional tests are expected once all the equipment is operational.	• Necessary steps should be taken to ensure that all the tests expected to be done by a DH is done in the institution. • Finalize the menu of tests that can done in-house. • Make arrangements to outsource the rest.
Patient Rights	• All the basic requirements as per the check list are met. • But the outcome is more cosmetic than functional. Both male and female patients have only a set of 3 or 4 bottles for collecting urine samples. The patients have to take one bottle, collect sample and bring for testing. After testing the patient will have to discard the sample and give the bottle back for the next patient to collect. All this happen in the middle of a crowd of onlookers.	• The privacy part of the patient rights should be implemented in its spirit. • The need for patients to collect their samples in a used container should be avoided. Procurement of disposable collection containers to be enabled ASAP. If unavoidable, make sure sufficient clean bottles are available and arrangements should be made for the cleaning staff to clean and return the bottles for reusing. • Printed reports will eliminate the transcription errors. Test request forms, reporting stationery printing to be enabled.
Inputs	• Infrastructure that is in use is very inadequate. However, additional space has been allocated and is expected to be operational soon. • Staff management is highly inadequate. Altogether 9 LTs are available in the institution including the ones from vertical programs. However, only one LT is available for the lab. • The actual testing is done by a group of students from a nearby college. • Equipment for biochemistry, hematology and serology was	• The new lab under development should be commissioned without delay. Complete the lab renovation at the earliest. • With the availability of new, automated equipment, utilize all equipment optimally. • Additional staff who can man the machines should be posted in the lab. • Staff from various sections shall be trained on multitasking and utilized as per the need. Complete re-orientation of staff needs to be done. The consolidated pool of staff can be trained by Labs for Life for standard practices and quality systems • If sufficient staff is not available in the

	purchased. But, so far only biochemistry analyzer is in operation. But that too not calibrated or used to run all the required tests. • Hematology analyzer was reported to be not in use because of the absence of reagents. Once the reagents supplied with the machine was exhausted, testing was stopped.	institution, steps should be taken to appoint additional staff through HDS. • The practice of depending on untrained students to do diagnostic tests should be stopped. • Personal files with relevant documents including OJT and competency records could give better clarity in responsibilities of the staff. • Sufficient provisions for reagent supply should be made so that all equipment can be used continuously • Record keeping shall be practiced and monitored for improvements. • Internal Audits shall be practiced.
Support Services	• No system exists for regular monitoring, servicing or calibration of equipment. • System for continual supply of reagents not in place.	• System should be in place to ensure proper maintenance of equipment, availability of reagents and consumables, so that the diagnostic work is not interrupted at any point of time. • Equipment CMC Calibration has been rolled out by the state, to be followed through for the maintenance of old equipment • For new equipment, avail tech support from manufacturer. • Inventory management has to be strengthened to avoid stock-outs. Labs for Life will extend the trainings as required.
Clinical Services	• No system exists for the seamless processing of samples or a system of faultless documentation for the same.	• The reason for the score to go below baseline needs to be investigated. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard. If computers are made available, Labs for Life can provide Lab Information System software and train operators,

Infection Control	• Biosafety practices are very inadequate. Even though posters of hand washing, BMW segregation etc., are available, it is not practiced. • Specimen is handled by a group of students. Careless and very dangerous handling of samples seen.	• Additional training should be given to the staff. • Systems should be implemented to decrease the possibility of mishandling. • Supervisory staff with responsibility and necessary authority should be designated to oversee safe practices. • Training and implementation of new BMW shall help and required. PPE's, disposable collection tubes, ESR tubes to be procured continuously. • Waste segregation to be mandated. • Equipment decontamination program should be started. • HIC program should be initiated to address these comprehensively
Quality Management	• Quality system is totally lacking. • QSP is implemented only as part of the vertical programs, in the respective labs.	• Quality Systems should be implemented in its entirety. • State funds for IQC and EQAS to be obtained. • Quality Indicators shall be picked as applicable and worked upon and reviewed for its improvement. • Documentation is to be strengthened
Outcome	• Other than the basic statistics of monthly work done, no assessment of efficiency, productivity or possibilities of further improvement is looked into.	• Once the Quality System is in place and the lab is made functional, regular monitoring of its performance and variation over time should be monitored for further improvement.
Risk Management (as per ISO 15189:2012)	• No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	• No awareness	• Staff need to be assessed periodically /six months and based on this a re-training may be required.

Table 19: District Hospital, Anakapalle

District Hospital, Anakapalle		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• The institution has all the required tests; being done in-house or out sourced. • More tests are being out sourced than those done in the lab.	• Dependency on out sourcing should be reduced gradually. • Rapid card tests like Dengue, Chikungunya and other feasible tests may be done in the lab immediately.
Patient Rights	• Managing patients during the peak hour is challenging, leading to intolerance and being harsh towards patients, occasionally.	• The arrangements should be made such that the patient load is managed well. • Reorientation of the collection area to promote unidirectional flow of activities may be done. • The air-conditioning may be appropriate to the patient traffic. This may be decided in consultation with the PWD engineering division, especially considering the extreme heat conditions in this region
Inputs	• Insufficient sitting arrangements in waiting area. • No patient call out system. • Patients crowding at the door. Patients not managed adequately. • Insufficient collection points, when compared to the load. • Patient flow not unidirectional, leading to unnecessary congestion. • Fire safety not implemented. • No specialist supervisory staff in the lab such as Microbiologist or Pathologist. • Staff not trained properly in maintenance of automated equipment, biomedical waste management, maintenance of lab records etc. • Major lack of equipment for, Microbiology and Serology work.	• Qualified supervisory staff should be appointed for the lab. A trained Pathologist/Microbiologist is required to make real and lasting systemic improvements. • Fire safety measures including installation of fire extinguishers and training should be done ASAP • Increase the seating arrangements for patients. • Patient queuing and call out system should be implemented. • Sample collection for Medall can be separated from the lab collection area, as the samples are not utilized there. • Additional staff should be allocated for sample collection during the peak hours to manage the load. • Arrangements should be made for patients to leave through a separate path than by crossing the incoming patients. • Proper training should be given to staff

		in required areas. • Additional equipment should be introduced for starting, Basic Microbiology and Serology work, as per IPHS norms, if feasible.
Support Services	• Systems for periodic maintenance, break down repairs and timely calibration of equipment are not in place. • Staff not trained or skilled in basic repairs or maintenance of equipment. • No system of monitoring of reagents (quality, expiry, consumption, storage temperature) • No ventilation in the reception and sample collection areas. Insufficient air conditioning. • No eye wash facility present.	• Retraining and delegation of staff with accountability shall be an option for improvement. • Eye wash station to be installed. Eye wash solution with date of preparation could be a temporary option. • Equipment CMC Calibration has been rolled out by the state, but is yet to be done in DH This needs expedition as none of the equipment are calibrated. • Inventory management has to be strengthened to avoid stock-outs.
Clinical Services	• Samples do not have unique identification number. • Management of patient results not standardized. • No documented procedures for Pre-analytical, Analytical or Post analytical activities.	• UHID with immediate effect to be implemented. • Sample quality manual and work instructions or SOPs to be prepared. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard.
Infection Control	• Monitoring of infection control practices can be improved. • Proper facility for hand hygiene (antiseptic soap, elbow taps) not available in all rooms. • Standard protocols for decontamination of work area, equipment etc. after work is not implemented.	• On rotation basis, every lab staff can take turns in monitoring the infection control practices. • A copy of the new BMW guidelines shall be made available and retrained if required. • The management shall make sure there are sufficient needle cutters in working condition. Needle cutter purchase to be understood with reference to the

	• Segregation of BMW not proper. • Needle cutters insufficient.	number of cuts possible, patent load. Sufficient supply should be available to change needle cutters as required. • Disposable collection tubes, ESR tubes to be procured continuously. • A strong HIC program can be initiated. • Equipment decontamination program should be started. BMW trainings to be done.
Quality Management	• No IQCs • No EQAS • QSPs not in place. • No SOPs available for the different activities in the lab. • No Quality Indicators being monitored •	• Quality Systems should be implemented in its entirety. • State funds for IQC and EQAS to be obtained. Both internal and external quality assurance programs to be initiated. • Quality Indicators shall be picked as applicable and worked upon and reviewed for its improvement. Documentation is to be strengthened. • As a team effort framing SOPs can be initiated and completed in due course. Labs for Life RQC shall help in documentation.
Outcome	• The lab does not fully monitor any productivity indicators, Efficiency indicators, Safety indicators or Service quality indicators.	• Once the Quality System is in place and the lab is made functional, regular monitoring of its performance and variation over time should be monitored for further improvement.
Risk Management (as per ISO 15189:2012)	No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	No awareness	• Staff need to be assessed periodically y /six months and based on this a re-training may be required.

Table 19: District Hospital Darjeeling

District Hospital Darjeeling		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• The original lab is under renovation. The lab is shifted near emergency temporarily. Routine Services are adequate except Microbiology n Histopathology. • Demarcated area for Collection/tests. • The Hospital has a designated RNTCP center and ICTC center for TB and HIV diagnosis. • The lab has started FNAC/Cytology testing. Emergency services are also provided on call basis.	• The lab may open Microbiology department or consider sample referrals. • Sample collection for basic microbiology tests can be enabled through trainings. • The lab may also introduce a referral system for histopathology testing. Cytology training for cervical smears can be had and a basic cytology program enabled as the hospital has a pathologist.
Patient Rights	• Patients are not charged for tests. • All national health programs are implemented. • Gender consideration well taken into account. • The hospital has an effective grievance redressal process.	• A ramp may be constructed for disabled patients. • All instructions and signage's to be put up in the local languages also.
Inputs	• The lab has been temporarily shifted due to renovation of the original lab. • The space and infrastructure is adequate in the present lab. • All work areas are demarcated. • Patient waiting area is in corridor. No separate area provided. Sitting area is inadequate. Adequate toilet is there, but not demarcated for male and female. • There is a shortage of storage area. • Collection counters are also inadequate as per workload. • Fire signages are not installed.	• Separate toilets for male and female patients. • Adequate seating arrangement in the waiting area may be provided. • Adequate storage spaces are required considering the workload. • Fire and disaster management plan to be implemented effectively. • Adequate manpower may be provided to the lab for improving the lab services. • Fully Automated instruments may be provided to the lab considering their workload. More collection points to manage load

	Staff training is inadequate for fire and disaster management. • There is a shortage of staff and equipment in laboratory as per workload. • Running water is being made available	
Support Services	• All equipment are calibrated except ELISA readers and all are under AMC.	• Log book and breakdown record of all equipment to be maintained for monitoring of breakdown time. • Equipment performance to be checked internally after calibration. • The Equipment Management Program of NHM should be tapped into
Clinical Services	• Hospital caters to multiple clinical disciplines. • Sample collection/transportation are not as per the SOP. • No referral system for the tests not available in the lab.	• Sensitization programmed for the phlebotomists may be conducted. • The lab may introduce referral system for the tests not done internally. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard. If computers are made available.
Infection Control	• There is no formal and structured infection surveillance system. • This includes surveillance of infection, hand hygiene practices, sterilization and disinfection practices, BMW management and occupational safety of healthcare workers. • There is no antibiotic policy developed for the hospital.	• Implementation of HIC procedures must be considered. • Microbiology lab to be established to implement a good infection control practices, in lab as well as in the hospital. • All the aspects of hospital infection control may be addressed. BMW trainings required

Quality Management	• The lab has documented SOPs and QMSPs for all relevant major activities performed in the lab. But staff are not well aware of those procedures. • There is no IQC available in the lab. No control chart prepared to monitor the result. No corrective and preventive action taken	• Staff training may be initiated on quality management system. More stress to be given to strengthen the quality control of the lab. • IQC procurement once the PIP money is allocated • EQAS registration in hematology and microbiology required • Documentation is to be strengthened.
Outcome	• The lab is monitoring all major quality indicators except some parameters.	• The lab may start monitoring all major indicators required to monitor the performance of the lab and make them available as dashboards.
Risk Management (as per ISO 15189:2012)	No awareness	• Define risk factors for each process / departments followed by assessment, analysis and action plan and corrective action taken.
Competency Assessment of staff (as per ISO 15189:2012)	No awareness	• Staff need to be assessed periodically /six months and based on this a re-training may be required.

Table 21: Moran Tiloi CHC, Dibrugarh

Moran Tiloi CHC, Dibrugarh		
Area of Concern	**Summary**	**Recommendations**
Service Provision	• All lab services are available in routine working hours and few are available even after working hours. • The lab provides hematology, biochemistry, serology and clinical pathology services. However, the number of tests are limited in each area. • No microbiology, cytology or histopathology services are available. • No rapid test kits available for locally prevalent infections/diseases. • All patients are referred to AMC, Dibrugarh for tests which are not available.	• The number of tests can be increased to meet the need of users. • The laboratory may think of expanding its scope by including basic microbiology services. • A sample referral system may be enabled for tests not available. • Sample collection for basic microbiology tests will be enabled through trainings. • Cytology training for cervical smears can be had and a basic cytology program enabled as the hospital has a pathologist
Patient Rights	• The laboratory provides adequate patient information and guidance in terms of signage, instructions, complaint box. • It was observed that there is absence of grievance redressal system at CHC.	• An appropriate grievance /complaint redressal system should be in place.
Inputs	• Lab space is generally adequate with effective separation of incompatible activities. • The lab has only very basic equipment for biochemistry. No cell counter available. • There is provision of basic utilities with scope of improvement in toilet cleanliness and hygiene. • There is no storage area available for lab reagents, records or consumables.	• Appropriate storage space and fire exit with plan are recommended and may be looked into by the hospital administration. • It is understood that more inputs will become available as the PIP money is availed. Equipment (analytical and supporting) purchase will upgrade the lab. This may be expedited

	• In addition, no telephone/intercom services are available for communication. • It has also been seen that fire and lab safety training has been imparted but there is lack of defined fire exit, fire exit plans, safety training records and fire extinguishers; which are very important to ensure safety. • There is one microscope however, not working properly hindering basic microscopy work. • There is lack of availability of equipment for sterilization and disinfection e.g. autoclave.	
Support Services	• The overall condition of furniture is adequate. • Equipment management has been started. However, there is lack of AMC/CMC of equipment and lack of storage space. • There is no verification of new lot of reagents. Lack of security services. • Pest and rodent control is inadequate with stray dogs inside the premises.	• Regular AMC/CMC of analytical equipment is recommended. Equipment management initiative is being rolled out by the state and may be plugged into. • Provision of security services for the facility may be undertaken.

Clinical Services	• The lab has defined a unique identification number for each patient. • There is no defined referral linkage for tests not available in the facility. • No storage space for records. • No awareness on disaster plan. • The lab has not defined critical alert values and not reported on urgent basis. • There is no policy for reporting of urgent samples.	• A centralized Medical record section is recommended. • Referral linkage with other facilities may be undertaken. The lab is advised to define critical alert values and may be reported on urgent basis. • The entire processing sequence from proper request forms, unique id of samples, processing registers, report issuing and handling of tests not done in the institution should be streamlined with proper documentation. • Initiation of computerization can help in this regard.
Infection Control	• There is a system initiated on basic infection control practices in the lab. • The staff are aware of spill management and hand-washing practices. However, there is lack of regular monitoring of infection control practices, environmental surveillance, hospital antibiotic policy, and appropriate PEP and equipment decontamination procedures. • There are color-coded bins but there is lack of color-coded bags except for yellow bag. In addition, BMW site was visited by the team and it was found that although segregation of waste is done but there are violations of BMW rules. The waste especially sharps are discarded in bleach solution but they are manually segregated by	• Appropriate biomedical waste management and infection control practices are recommended. Follow BMW rules 2016 and SPCB guidelines. • A mechanism for collection and disposal of BMW needs to be evolved as there is no authorized collection agency in the district now

	housekeeping staff before disposing in sharps pit. • The burial site is within the facility and very close to labor room and neonatal ward.	
Quality Management	• The lab does not have IQC and EQA programs. • The quality control materials are not available. • The SOPs have been prepared but not for all areas and processes. Overall, the documentation is inadequate. • The SOP on primary sample collection is not updated as per current practice.	• Quality Systems should be implemented in its entirety. • PIP funds for IQC and EQAS are to be channelized at the earliest and training given to the technical staff • Quality Indicators shall be picked as applicable and worked upon and reviewed for its improvement. • Documentation is to be strengthened. As a team effort framing SOPs can be initiated and completed in due course. Labs for Life RQC shall help in documentation
Outcome	• The lab measures few productivity indicators. • However, there is no measurable efficiency, clinical care and safety and service quality indicators.	• The lab is recommended to measure key productivity indicators and project them as dashboards
Risk Management (as per ISO 15189:2012)	Not done.	• Mandated as per ISO 15189:2012
Competency Assessment of staff (as per ISO 15189:2012)	Not done.	• A formal regular scheduled competency assessment may be undertaken for all level of staff for Quality Improvement

8. Conclusion

Laboratory based diagnostics is an integral part of the practice of evidence based medicine covering the spectrum of prevention, screening, detection, treatment and management. For these reasons, the clinical laboratory systems have been brought under the purview of ISO with standards for every laboratory activity. In India, access to quality laboratory services has been a key challenge for the public health system that has adversely affected our capabilities in disease control and patient management. These also have contributed to widespread reliance on private service providers, empirical patient care, irrational diagnostic prescriptions and practices that waste scarce resources.

Labs for Life has been working in 16 public health laboratories; 8 District hospitals and 8 Medical Colleges, in different parts of India since March 2015. Though there has been a significant improvement in many technical areas as compared to baseline information, it is evident from the midterm findings that many aspects require much attention such as responsiveness of institutions to training and the lack thereof, importance of leadership and motivated staff, resource needs, requirements for guidelines and standards and the need for dedicated lab funds, among others.

Among District Hospitals, those with Pathologists and Microbiologists are seen to have utilized the trainings better. Sustained training and capacity building for these staff can enable further improvements in their institutions and beyond. Availability of inputs like quality control material, either through state funds as in Rajasthan or through NHM funds as in West Bengal, have also helped in the improved scores. However, staff motivation is the single most enabling factor. Thus, factors leading to demotivation of staff with consequent reduced output and staff attrition, needs to be addressed at all levels of public health. Quality and infection control protocols need to be implemented as defined by the National Quality Assurance Standards. In an endeavor to be at par with world class laboratories, effort may be made to comply with ISO standards and apply for NABL accreditation.

Medical College laboratories are more complex in organization and function. With different departments responsible primarily for academics at gradual and post-graduate levels, additional responsibilities like service provision and public health functions remain inadequately defined. Appropriate standards and guidelines are essential to guide these tertiary care hospitals regarding the tests that need to be provided, equipment that need to be available and the staff that is required to provide these services. Similarly, quality standard are to be prescribed. The sheer load on these institutions renders any intervention extremely demanding. Microbiology especially, is very challenging since most testing and interpretative aspects have to be manual and need skill and training. Whatever automation can be utilized is also not yet available in most of these hospitals. If efforts are made to

address these, here too, in an endeavor to be at par with world class laboratories, effort can be made to comply with ISO standard and apply for NABL accreditation.

In addition, a quality-assured district model for diagnostics, integrating all levels of public health through a sample referral system, can resolve several issues of non-availability of diagnostics. This needs services with testing menu and quality standards clearly defined and implemented at the respective levels and a robust logistic and IT system. As a case in point, making available at the secondary level, basic microbiology practices, a linking sample collection and transportation system and a tertiary care level with all advanced tests can ensure adequate microbiology laboratory support for the need of the district, which in order will prevent empirical use of antibiotics and spread of Anti-Microbial resistance. Several non-communicable diseases can also be addressed this way.

A comprehensive strategic action plan powered by a National Lab Policy along with committed and focused efforts can bring into effect this model which can then be replicated and scaled up.