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Evaluation of the Free Diagnostics Scheme in Andhra Pradesh

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WHO validation mission team of experts for evaluation of 'Free Diagnostics Scheme' in Andhra Pradesh

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List of acronyms

AH:	Area Hospital
AIIMS:	All India Institute of Medical Sciences
ANC:	Antenatal Care
ANM:	Auxiliary Nurse Midwife
APVVP:	Andhra Pradesh Vaidya Vidhan Parishad
ASHA:	Accredited Social Health Activist
ASO/ASLO:	Anti-Streptolysin O
AYUSH:	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
B.Urea:	Blood Urea
BIS:	Bureau of Indian Standards
Blood C/S:	Blood Culture and Sensitivity
CAG:	Comptroller and Auditor General
CBC:	Complete Blood Count
CD:	Compact Disk
CDS:	Central Drug Store
CGHS:	Central Government Health Scheme
CHC:	Community Health Centre
CMC:	Christian Medical College
CRP:	C-Reactive Protein
CT:	Computed Tomography
DCA:	Drugs Control Administration
DCHS:	District Coordinator of Hospital services

DH:	District Hospital
DIO:	District Immunisation Officer
DLC:	Differential Leucocyte Count
DMHO:	District Medical Health Officer
DMLT:	Diploma in Medical Laboratory Technology
DPM:	District Programme Manager
ELISA:	Enzyme Linked Immunosorbent Assay
EQAS:	External Quality Assurance Scheme
FDS:	Free Diagnostics Scheme
FMO:	First Medical Officer
FNAC:	Fine Needle Aspiration Cytology
GoI:	Government of India
H&FW:	Health and Family Welfare
HbA1C:	Glycosylated Haemoglobin
HDS:	Hospital Development Society
HIV:	Human Immunodeficiency Virus
ICTC:	Integrated Counselling and Testing Centre
ID:	Identification
IEC:	Information Education Communication
ILD:	Inter-Laboratory Delivery
ILPT:	Inter-Laboratory Proficiency Testing
INR:	International Normalized Ratio
INR:	Indian Rupee
IPD:	In-Patient Department

IQC:	Internal Quality Control
ISO:	International Organisation for Standardization
IT:	Information Technology
JSSK:	Janani Shishu Suraksha Karyakram
KFT:	Kidney Function Tests
KGH:	King George Hospital
KP:	Knowledge Partner
KPI:	Key Performance Indicator
L1:	Level 1
L2:	Level 2
L3:	Level 3
LFT:	Liver Function Tests
LJ:	Levey Jennings
MIS:	Management Information System
MO:	Medical Officer
MoU:	Memorandum of Understanding
MP:	Malarial Parasite
MPHW:	Multi-Purpose Health Worker
MS:	Medical Superintendent
NABL:	National Accreditation Board for Testing and Calibration Laboratories
NTR:	NT Rama Rao
OOPE:	Out-of-Pocket Expenditure
OPD:	Out-Patient Department
PHC:	Primary Health Centre

PMSMA:	Pradhan Mantri Surakshit Matritva Abhiyan
PT:	Prothrombin Time
QA QT:	Quality Assurance Quality Team
RA:	Rheumatoid Arthritis
RBS:	Random Blood Sugar
RNTCP:	Revised National Tuberculosis Control Programme
S.Bilirubin:	Serum Bilirubin
Semi-Auto:	Semi-Automated
SGOT:	Serum Glutamic Oxaloacetic Transaminase
SGPT:	Serum Glutamate Pyruvate Transaminase
SMS:	Short Message Service
SOP:	Standard Operating Procedure
T3:	Tri-Iodothyronine
T4:	Thyroxine
TAT:	Turnaround Time
TB:	Tuberculosis
TH:	Tertiary Hospital
TLC:	Total Leucocyte Count
TSH:	Thyroid Stimulating Hormone
Urine R/M:	Urine Routine and Microscopy

Executive summary

A. Background

India has a public health system with a stated commitment to providing universal access to free healthcare. Substantial investments in the National Health Mission (NHM) have resulted in improvement of access and coverage in public health facilities. However, diagnostic services are still largely unavailable in public health facilities hampering evidence-based care and delivery of essential and universal healthcare. Out-of-pocket expenditures on diagnostics continues to be high and an area of concern. The private sector catering to the diagnostics needs of majority of the population is dominated by unorganized players due to lack of a strong regulatory framework.

The National Health Policy 2017 recognises that making available good quality, free diagnostics at public health facilities is one of the most effective way for achieving the goal of providing universal healthcare. To address the urgent need for accessible and quality diagnostics in public health facilities, the Ministry of Health and Family Welfare, Government of India under the aegis of National Health Mission launched the Free Diagnostics Scheme in July 2015. The scheme is intended to provide a set of essential diagnostics at various levels of care so that providers can make rational decisions regarding treatment and patients can benefit by getting their tests conducted within the facility free of cost. The government envisages that this health intervention will reduce both direct costs and out-of-pocket expenditure.

Under this scheme, the National Health Mission is supporting all states to provide essential diagnostics – Laboratory and Radiology at their public health facilities, free of cost. The range of tests offered in the public health facilities are categorized by the level of care, that is, primary health centres (PHCs) offer 19 laboratory tests, and community health centres (CHCs) with 39 laboratory and radiology tests and sub-district and district hospitals offer 57 laboratory and radiology tests A set of implementation guidelines has been formulated by the Ministry of Health and Family Welfare for states to ensure the availability of basic diagnostics services at public health facilities.

Since states have varying capacities in provision of diagnostics, they are adopting different models to ensure availability of requisite diagnostics at the public health facilities. Few states like Rajasthan and Madhya Pradesh are strengthening their in-house capacities while Maharashtra and Assam have recently done a state-wide rollout of laboratory services under public private partnership arrangement. Odisha and Meghalaya are also in the process of implementing the scheme in public private partnership mode. Tripura has opted for a complete in-house model for implementing the Free Diagnostics Scheme in the state.

Andhra Pradesh is the first state which has done a state-wide rollout of both laboratory and radiology services using a hybrid model. The services under the public private partnership were launched by the state on 1st January 2016 under a new flagship scheme called NTR Vaidya Pariksha scheme. The state government is providing free of cost laboratory and radiology services at public health facilities through private partners. 60% funding for the scheme is supported by NHM and the rest 40% by the state government.

B. Methodology used for evaluation

WHO conducted an evaluation of the laboratory services under NTR Vaidya Pariksha scheme in Andhra Pradesh. The laboratory services provided under this scheme and by the in-house laboratories were evaluated for access, quality, utilization, patient satisfaction and out-of-pocket expenditure. In addition, NTR Vaidya Pariksha scheme was assessed for cost efficiency, monitoring mechanisms and adherence to the prescribed clauses in the scheme. For the evaluation, a primary survey was conducted and secondary data were analysed. The primary survey was done in two districts – Krishna and Visakhapatnam, where a total of twenty government health facilities were surveyed -- four PHCs, four CHCs, one AH and one DH in each of the two districts. A central drug store was visited in one district. Six laboratories of the service provider were also included in the survey. In addition, interviews were conducted with state and district officials of the Department of Health and Family Welfare; and with senior management and district teams of the service provider.

For assessment of laboratory services at health facilities, focus group discussions /key informant interviews were conducted with doctors (including Administrators). Structured interviews were conducted with laboratory technicians of in-house laboratories and phlebotomists and Inter-Laboratory Delivery (ILD) personnel of the service provider. 120 patients with laboratory test reports (service provider's reports with/without in-house reports) were interviewed across various government health facilities.

At the service provider's laboratories, semi-structured interviews were carried out with Pathologists/Microbiologists, laboratory managers, laboratory technicians and other staff.

The central drug store was assessed for supply chain for in-house laboratory services. At the central drug store, Deputy Executive Engineer, Pharmacist and Data Entry Operator were interviewed.

In addition to interviews and focus group discussions, relevant observational data at government health facilities, service provider's laboratories and the central drug store were also collected during the visits. Interviews were conducted with senior state officials of the Department of Health, Medical and Family Welfare and their teams -- Principal Secretary, Commissioner, Director General - Drug Control Administration, Commissioner – AP Vaidya Vidhan Parishad, Director - Public Health and Family Welfare and the nodal person for NTR Vaidya Pariksha scheme. District health officials including District Coordinators of Hospital Services and District Health and Medical Officers were also interviewed in the two surveyed districts. Interviews were done with senior management of the service provider and its teams from the two districts.

In addition to the primary survey, secondary data on laboratory services – both for in-house and service provider was collected from the state government and the service provider respectively. Other relevant documents like Agreement with the service provider, MIS reports, test reports, quality control registers etc. were also reviewed.

After data collection, relevant data was entered in Microsoft Excel and analysed.

Following were the key areas for evaluation:

i. Access to laboratory services – service provider's and in-house
   - Total number of government health facilities (DHs, AHs, CHCs and PHCs) serviced by the service provider and turnaround time for commencement of its services.
   - Total number of patients who availed diagnostic services through service provider's and in-house laboratories and total number of tests conducted, test mix, patient to test ratio etc.
   - Availability of services of the service provider and in-house laboratories.
   - Synergy of services of in-house laboratories with those of the service provider.

ii. Quality of laboratory services – service provider's and in-house
   - Quality assurance at laboratories: Equipment (adequacy and availability), human resources, training, standard operating procedures, quality of processes, supply chain management, internal quality control (IQC), external quality assurance scheme (EQAS), readiness of service provider for NABL accreditation etc.
   - Test results: Incidence of erroneous results, repeat sampling, abnormal results; and relay of information to clinicians about critical results.
   - Clinician satisfaction: Quality and turnaround time of test reports; change in availability of tests; accuracy of diagnosis; clinical outcomes etc.
   - Patient satisfaction: Out-of-pocket expenditure, waiting time, comfort during sampling procedure, turnaround time for receiving test reports etc.

iii. Monitoring of services
   - Monitoring by government: Feedback/grievance mechanism, periodic reviews/audits, surprise visits, data validation, tests which are being outsourced despite in-house capacity, penalties to private providers etc.
   - Monitoring by private provider: Allocation of resources for monitoring, feedback, surprise visits, audits etc.
   - Third party monitoring

iv. Adherence of service provider to Agreement clauses

v. Satisfaction of service provider
   - Payments: Procedure for submitting bills for reimbursement, periodicity and mode of payments, challenges (if any) in receiving payments etc.
   - Support from government for rollout of services: Provision of requisite infrastructure etc.

vi. Cost efficiency of NTR Vaidya Pariksha scheme
   - Minimum assured volume
   - Comparative analysis of cost of NTR Vaidya Pariksha scheme (cost per patient) with the CGHS model (cost per test)

C. Key findings

1. Key factors contributing to success of NTR Vaidya Pariksha scheme: State government's high political commitment towards the scheme, strong leadership, constant oversight and monitoring, and commitment to budgetary allocations; a speedy rollout of the scheme throughout the state within a period of three months combined with a phased operationalization of services at various levels of facilities; continuous efforts of the service provider for improving quality of services; and extensive awareness campaigns have all contributed to the successful implementation of the scheme.

2. Improvement in access to laboratory services and reduction in OOPE subsequent to implementation of NTR Vaidya Pariksha scheme: The expanded basket of tests available through the service provider has led to improvement in access to laboratory services. As a result, 6 581 430 patients have been tested and 19 934 620 tests have been conducted from January 2016 to June 2017. There was an increase in the total number of patients in OPD by 15% during 2015-16 to 2016-17 and 5% during 2014-15 to 2015-16. Further, the total number of patients in IPD increased by 29% during 2015-16 to 2016-17 and by 16% during 2014-15 to 2015-16.

A survey commissioned by the state government revealed that per capita out-of-pocket expenditure on diagnostics across public and private sectors reduced by 55% -- from INR 860.54 in 2015 to INR 388 in year 2017. In public sector alone, it decreased by 81% -- from INR 32 in year 2015 to INR 6 in year 2017. Average out-of-pocket expenditure per patient on diagnostics for chronic diseases in public sector decreased by 40% in this period.

Also, the savings on out-of-pocket expenditure on tests provided through NTR Vaidya Pariksha scheme amounted to INR 228 crores in the period of January 2016 (from period of roll out of the scheme) – June 2017. The savings were calculated as money saved by patients on tests which were made available through the NTR Vaidya Pariksha scheme; the assumption was that the patients would have got these tests done from private laboratories in absence of availability of these tests at the government health facilities.

3. Operational model of NTR Vaidya Pariksha scheme: Under NTR Vaidya Pariksha scheme, a single service provider has been selected through competitive bidding to provide designated laboratory tests at all the 8 DHs, 35 AHs, 192 CHCs and 1125 PHCs. The basket of tests offered by in-house laboratories and NTR Vaidya Pariksha scheme is complementary. The in-house laboratories are providing 10 to 12 basic and mostly rapid kit tests at all levels of facilities. NTR Vaidya Pariksha scheme adds a wide range of tests (42 in total) to the menu including few advanced tests. The range of tests provided under the scheme varies with the level of the facility. In PHCs - 7 basic tests, in CHCs - 21 routine tests and in AHs and DHs - 40 tests including routine and few advanced tests have been made available through the service provider.

For providing services under NTR Vaidya Pariksha scheme, the service provider has set up 104 laboratories outside the government health facilities for conducting tests. The sampling of patients is done inside the government health facilities by the phlebotomists of the service provider. The reports are also dispatched at the government health facilities. The 104 laboratories are categorized as L1, L2 and L3. L1 (mother laboratories) provide routine and

all designated advanced tests, L2 provide routine and few advanced tests and L3 laboratories provide only routine tests.

4. Coverage of services under NTR Vaidya Pariksha scheme:

a. Coverage of government health facilities: The service provider achieved almost 100% coverage within 60 days in DHs and AHs, 120 days in CHCs and 150 days in PHCs from the time of signing the Agreement with the state government (November 2015).

b. Coverage of patients: Under the NTR Vaidya Pariksha scheme, 6 581 430 patients have been tested and 19 934 620 tests have been conducted by the service provider since the launch in January 2016 till June 2017.

- **Coverage of patients at different levels of facilities:** Maximum number of patients were tested at PHCs (52%) followed by CHCs (30%), AHs (12%) and DHs (6%). Similar pattern was observed for total number of tests conducted – 41% at PHCs, 33% at CHCs, 16% at AHs and 10% at DHs. The percentage of patients tested (out of total number of patients at all facilities) in this period was 9.8%. The percentage of patients tested (out of total number of patients) was highest in CHCs (10.7%) and lowest in DHs (8.8%). The patient-to-test ratio was highest in DHs (4.91) and lowest in PHCs (2.43).The patient profile at DHs is comparatively more morbid and a higher percentage of patients require tests, whereas PHCs and CHCs cater to less severe disease profiles and therefore lesser percentage of patients require tests. However, the percentage of tests conducted was higher in PHCs/CHCs compared to DHs. A higher patient-to-test ratio observed in DHs compared to CHCs and PHCs corroborates with the profile of patients at the respective facilities.

- **Coverage of patients in outpatient and inpatient departments:** When data for outpatients and inpatients was analysed, it was observed that of the total number of patients tested, 98% were outpatients and 2% were inpatients. Maximum percentage of inpatients were tested in DHs which aligns with its largest share of inpatients among all types of facilities. In DHs, the percentage of inpatients tested (out of total number of inpatients) was also higher than the percentage of outpatients tested (out of total number of outpatients) corroborating with the fact that inpatient department caters to more severe morbidities. In AHs and CHCs, the percentage of outpatients tested (out of total number of outpatients) was higher. The patient-to-test ratio was higher for inpatients compared to outpatients which is again in line with the morbidity profile of inpatients.

c. Monthly and yearly trends in uptake of services at the government health facilities:

Monthly trends: The uptake of services under NTR Vaidya Pariksha scheme by doctors at the government health facilities required focused efforts by the state government. Subsequent to these efforts, the uptake increased steeply and peaked in July 2016 -- 4 months after the complete rollout. The percentage of patients tested (of total number of patients) increased from 9.9% (March 2016) to 13.7% (July 2016). The number of patients tested increased by 72% and number of tests conducted increased by 42% during March – July 2016. Many screening camps were also organized during this period. After uptake of services reached a peak in July 2016, there was a drastic fall in percentage of patients

tested (of total number of patients) mainly at PHCs and CHCs in August 2016. The fall was probably due to the state government's efforts towards rationalization of usage of services by doctors at the government health facilities. The screening camps were also discontinued by the state government. A new equilibrium was achieved in utilization of services especially at PHCs and CHCs, percentage of patients tested (of total number of patients) across all types of facilities reduced from 13.7% (July 2016) to an average of 9.4% (August 2016 – May 2017). However, in June 2017, a steep increase was again observed in percentage of patients tested (of total number of patients) -- 12% of total patients were tested in June 2017. The utilization of services showed seasonal variations at all types of facilities. DHs were least affected by the seasonal variations.

Yearly trends: In the comparison of data (March–June) for 2016 and 2017, a decrease of 1% in the total number of patients at the government health facilities was seen in 2017. However, the decrease in utilization of services under NTR Vaidya Pariksha scheme from 2016 to 2017 was significantly higher as reflected in decrease in number of patients tested (by 13%) and number of tests conducted (by 17%). There was reduction in percentage of patients tested (out of total number of patients) from 2016 (12.1%) to 2017 (10.7%). The fall in utilisation of services in 2017 was seen in PHCs, CHCs and AHs. On the contrary, utilisation of services increased in DHs in 2017. These trends were probably an outcome of the state government's intervention for optimising utilization of services in July 2016.

5. Service delivery by service provider

a. Sampling services at government health facilities: Under NTR Vaidya Pariksha scheme, the service provider had stationed its phlebotomists at all the surveyed health facilities. The phlebotomists followed a structured process flow for sampling, registration and labelling. In the health facilities, all designated tests were being provided by the service provider on all working days except for few instances of service breakdown. Phlebotomists were stationed round-the-clock for sampling of emergency cases only in DHs. Inconsistencies in cold chain were observed at a few surveyed facilities. Biomedical waste guidelines were not followed in most of the surveyed facilities. In the surveyed facilities with position of in-house laboratory technician vacant, the phlebotomist of the service provider did not conduct all in-house tests. The phlebotomists of the service provider and the in-house laboratory technicians worked mostly in a synergistic manner at the surveyed facilities. There was provision for sample pick-up on urgent basis at DHs and AHs but not at PHCs and CHCs. The availability of sampling services was not hampered by long distances of health facilities from the laboratories except in case of few remote locations. According to state officials, in the initial stages, there were several gaps in operations and quality of services under NTR Vaidya Pariksha scheme such as sampling processes, cold chain maintenance, transportation of samples etc.; many of these challenges have been addressed to a great extent with joint efforts of the state government and the service provider.

b. Test reports: Test reports were e-mailed to the health facilities by the service provider as soon as they were generated at the laboratories. Printed reports were delivered to health facilities by the ILD staff; and were dispatched to patients or doctors by phlebotomists of the service provider. The reports after printing were dispatched from the laboratory of the service provider within 2–5 hours of generation, which led to delays for IPD patients. Reports of routine tests were mostly delivered after one day of sampling. In case of advanced tests, the

time of delivery varied from 3–7 days depending on the type of test. Reports for emergency samples were communicated to the health facilities in majority of CHCs, and all AHs and DHs. The test results in the critical range were informed occasionally at AHs and DHs and rarely at PHCs and CHCs. Average waiting time in the queue for receiving reports was 5–10 minutes for outpatients across the facilities.

c. Turnaround time: The turnaround time of a test is evaluated as the time between registration of patient's sample for a test at the primary testing/receiving laboratory and dispatch of electronic report for that test to the government health facility, as per the Agreement between the state government and service provider. However, the turnaround time should be calculated from the time of sample collection to the time of electronic dispatch of report. After few months of launch of the scheme, the state government relaxed the penalty criterion by adding one day to the prescribed turnaround time for each test.

Turnaround time was significantly delayed for most tests in the initial months of rollout and slowly improved due to continual efforts of service provider as well as close monitoring by the state government. Data shows that turnaround time improved significantly from July to August 2016 -- percentage of tests reported within stipulated turnaround time increased from 89.7% to 96.7%. The state government had started levying heavy penalties on the service provider from July 2016 onwards for delayed turnaround time and that could have led to more intense efforts at the service provider's end to improve turnaround time. The turnaround time was delayed more in AHs and DHs than PHCs and CHCs. The delay in AHs and DHs was mostly for advanced tests. Few critical tests were also delayed.

6. Patterns of tests under NTR Vaidya Pariksha scheme: The average percentage of prescriptions with single test in the duration of 18 months of the scheme implementation was 31% and that with two tests was 23%. It was observed in some of the surveyed CHCs that RPR (a very cheap test) was ordered as a single test for many ANC women. The test was done in the in-house laboratories prior to rollout of the NTR Vaidya Pariksha scheme. Also, most of the advanced tests were found to be under-utilised. An average of 6% of tests ordered were of higher cost (CGHS rate INR 121 and above) and 54% of tests ordered were of lower cost (CGHS rate INR 58 and below) during January 2016–June 2017. Some tests, especially few advanced tests showed a decreasing trend in the uptake, which corroborated with lower satisfaction of clinicians with accuracy and turnaround time of these tests.

7. Laboratories of service provider: Out of the 104 laboratories of the service provider, 97 were newly set up which enabled standardisation of infrastructure and processes across these laboratories as well as cost efficiency for the service provider. The new laboratories were set up through a Franchisee model on a cost and revenue sharing basis.

a. Equipment: In the surveyed laboratories, the equipment for most of the tests was found to be appropriate and adequate. L3 laboratories were found to be equipped with haematology analyzer, biochemistry analyzer and urine analyzer; L2 laboratories with haematology analyzer, semi/fully automated biochemistry analyzer or both, PT analyzer, urine analyzer, electrolyte analyzer and HbA1C nycocard reader. L1 laboratories had haematology analyzer, semi/fully automated biochemistry analyzer or both, PT analyzer, urine analyzer, electrolyte analyzer and HbA1c nycocard reader. Few L1 laboratories had HPLC for HbA1c, electrophoresis machine for haemoglobin electrophoresis, histopathology equipment and requisite set-up for manual testing for urine and blood cultures and drug

sensitivity. Most of the equipment was routinely calibrated. Equipment breakdown was rectified mostly on the same day or within one day. In all the surveyed laboratories, power back-up was present.

b. Reagents and consumables: An inventory management system was in place at all the surveyed laboratories. There were rare instances of stock-outs. The equipment used closed system reagents; reagents and consumables were found to be of good quality, in adequate stock and were stored at requisite temperatures. According to the state officials, the reagents used in the initial stages were of suboptimal quality.

c. Human resources: Each district had a pathologist, 12 out of 13 districts had a biochemist (MD/PhD) and 4 out of 13 districts had a microbiologist (MD/PhD). The total number of laboratory technicians in the 104 laboratories was 393, out of which 196 were senior laboratory technicians with more than 3 years of work experience and 197 were junior laboratory technicians. There were sufficient number of technicians in the laboratories and had 1–5 years of experience. All tests except microscopy for advanced tests were conducted by laboratory technicians with no supervision by diagnosticians. The quality control (IQC and EQAS) was also managed by the laboratory technicians. Quality Assurance Quality Team managers sometimes assisted the laboratory technicians in troubleshooting for testing errors and equipment repair. During the survey, it was found that most of the laboratory technicians were adequately informed about conducting tests, running controls, maintenance of records and to some extent troubleshooting. However, they were neither sufficiently equipped nor supervised for identifying and managing erroneous results; they continued testing even when there were erroneous results due to technical problems in equipment, testing methodology etc. They were also not trained adequately on corrective and preventive actions required for managing out-of-range internal and external quality controls. The service provider has instituted a central quality team which managed quality control, inspection of laboratories and NABL accreditation etc. The team however did not play any significant role in training, supervision etc.

d. Training: The service provider had not instituted a training structure and curriculum for its laboratory technicians, phlebotomists and other staff. Training was ad-hoc and was conducted by Quality Assurance Quality Team managers only at the time of induction. In addition, training for ISO certification was organized for administrative and managerial staff, quality assurance quality team managers and select senior laboratory technicians.

e. Quality control: The 104 laboratories were certified under ISO 9001 and BIS and participated in EQAS and established IQC for select tests. The service provider established IQC within 1 month of setting up of the respective laboratories and started participating in EQAS after 4 months of rollout of the scheme. The state government penalised the service provider for delay in initiation of EQAS. Out of 42 tests, IQC was carried out for 25 tests (mainly routine tests) and EQAS for 31 tests. Inter-laboratory comparisons were also carried out for few tests periodically. Standard operating procedures were not in place except for running the equipment. The service provider was mandated to get all its laboratories accredited under NABL within 3 years of signing of the Agreement. At the time of survey, the service provider was in the process of getting all seven mother laboratories NABL accredited. However, 16 tests, mainly advanced tests have not been included in the scope of accreditation.

8. Quality of test results under the NTR Vaidya Pariksha scheme: In the initial stages of the rollout, there were several complaints from the clinicians about inaccuracy of test results. Few steps were taken by the service provider to improve the accuracy of tests. Doctors ordered for repeat testing when the test results of service provider were found to be inaccurate or did not correlate with the clinical picture. The percentage of out-of-reference range test results was found to be alarmingly low (overall 0% in initial 4 months and 0-1.3% for inpatients throughout). The sample rejection rate at service provider's laboratories was found to be abnormally low (0-0.63%).

9. Satisfaction of doctors with services of the NTR Vaidya Pariksha scheme and in-house laboratories: The doctors interviewed at the surveyed government health facilities were more satisfied with quality of services of in-house laboratories compared to the service provider's. On a scale of 1-5, most doctors at PHCs and CHCs rated quality of tests under NTR Vaidya Pariksha between 4-5 and at AHs and DHs between 3-4. For in-house laboratories, majority of doctors rated the quality between 4-5 across different types of facilities. With respect to availability of tests, doctors were equally or more satisfied with the service provider's services compared to in-house laboratories. Availability was rated 3 by most of the doctors at PHCs and CHCs for both in-house laboratories and the NTR Vaidya Pariksha scheme. At AHs and DHs, majority of doctors rated availability of tests under the scheme at 4-5 and in-house laboratories at 4. According to the doctors at the health facilities, the expanded basket of tests available through the service provider was leading to improved patient care, lesser OOPE and higher patient satisfaction. According to the doctors in few facilities, some patients were still going to private laboratories but the percentage had reduced significantly.

10. Patient satisfaction: In the patient satisfaction survey, it was found that majority (over 95%) of patients were satisfied with services of both NTR Vaidya Pariksha scheme and in-house laboratories. The availability of tests, waiting time, turnaround time of reports, comfort during sampling, behaviour of staff and cleanliness of the facilities were found to be satisfactory by the patients. None of the patients had paid any fee for the tests.

11. Monitoring of the NTR Vaidya Pariksha scheme

a. Monitoring by the state government: The state government instituted a robust monitoring framework since the beginning of the scheme rollout.

- A dashboard reflecting real-time data on utilization of services was made available.
- State-level review meetings were conducted every month in which key government officials and service provider representatives participated.
- The state programme implementation unit was engaged in the first year of the rollout for close monitoring of the scheme.
- The state government leveraged the Drug Control Administration (DCA) for inspection of laboratories of the service provider.
- District health officials were engaged in supervising the scheme.
- Penalties were levied on the service provider for not meeting certain contractual clauses, such as turnaround time and EQAS.

However, the validation of data of services provided under NTR Vaidya Pariksha scheme was found to be suboptimal. The heads of health facilities and district health officials did not

monitor the scheme closely. Also, the existing mechanism for checking whether tests of registered patients were conducted or not needs strengthening.

The state government worked closely with the service provider for eliminating the teething issues. The state government also adopted a participative instead of imposing approach with the service provider for implementation of the scheme.

b. Monitoring by the service provider: The service provider monitored its services through central and district teams. The quality assurance quality team managers were responsible for supervising quality assurance in laboratories, troubleshooting for analytical processes, training of laboratory technicians, addressing concerns of clinicians about accuracy of test results, checking maintenance of records in the laboratories, ensuring adherence to biomedical waste management etc. In each district, there was a team of 2–3 diagnosticians, conducting validation of test results, reporting and monitoring of IQC. The central quality team inspected the laboratories.

The feedback mechanisms at the government health facilities and at district levels were found to be informal and inconsistent. At some facilities, district teams of the service provider took informal feedback from doctors about its services. In few cases, corrective actions were taken to address concerns of the doctors. The service provider had set up a call centre on request of the state government for grievance redressal, which was found to be non-functional.

12. Information, Education and Communication: The state government in association with the service provider launched extensive campaigns for creating awareness about the NTR Vaidya Pariksha scheme. Various channels were used for the purpose, such as posters, pamphlets, banners, inserts, ANMs and ASHAs, 104 services, Mandal meetings etc.

13. Budget allocation: The central and the state governments contributed 60% and 40% of the budget, respectively for the NTR Vaidya Pariksha scheme. In the financial year 2015-16 (January–March 2016), the budget allocated was INR 75 crore; in 2016-17 it was INR 105.75 crore; and in 2017-18 the budget was INR 105.75 crore. The expenditure in 2015-16 (January–March 2016) was INR 12.47 crore; and in 2016-17 it was INR 101.75 crore. For in-house laboratory services, 100 percent of the cost was borne by the state government.

14. Minimum assured volume for NTR Vaidya Pariksha scheme: A daily minimum assured volume of 12,000 patients was committed to the service provider by the state in the signed Agreement. The daily minimum assured volume was not achieved in the first 2 months for almost 100% of days as the scheme was rolled out only in DHs and AHs in the first month and partially in CHCs and PHCs in the second month. After the complete rollout, the number of days in a month when minimum assured volume was not met averaged to 3.9. If the minimum assured volume would have been committed on a monthly instead of daily basis, then the total patients tested in a month far exceeded the daily minimum assured volumes of the entire month (5%–88% for various months). Similarly, if minimum assured volume would have been committed on a yearly instead of daily basis, the total minimum assured volume from time of complete roll out in March 2106 till June 2017 exceeded the total daily minimum assured volumes of this period by 27%. However, for this period (March 2016 - June 2017), the government incurred an extra cost for patients who were not tested

but billed by the service provider in lieu of unmet daily minimum assured volumes. The extra cost paid was 2.7% over and above the cost for tested patients.

15. Comparison of cost-per-patient and cost-per-test (CGHS) models and factors influencing the cost difference: It was observed that rationalization of service utilisation in July 2016 led to a marked improvement in cost efficiency of the scheme compared to the previous months. When compared with cost-per-test model (CGHS), cost-per-patient model of NTR Vaidya Pariksha scheme turned out to be 7.5% more expensive in the period of March 2016 (rollout completed) - June 2017 when cost of logistics was not included; and 3.4% more expensive when cost of logistics under NTR Vaidya Pariksha scheme was added to the CGHS costs. However, in certain months, cost of per-patient model was lesser than the cost of per-test model. An interplay of several factors resulted in improved cost-efficiency during these months – rationalization (reduction) of percentage of patients tested (out of total number of patients) in PHCs and CHCs; higher patient-to-test ratios in PHCs, CHCs, AHs and DHs; and increased proportion of tests in the upper quartile (INR 121 in CGHS rate) and decreased proportion in the lower quartile of cost (INR 58 in CGHS rate).

16. Adherence to clauses in the Agreement: There are certain clauses in the Agreement which were not implemented by the service provider, such as submission of standard operating procedures for various processes, auditing of laboratories by a third party NABL accredited laboratory etc. Payments to the service provider were made according to the clauses mentioned in the Agreement signed by the two parties. Payments to the service provider were electronically transferred by the state government. A weekly payment cycle was recommended in the Agreement, however making weekly payments proved to be challenging as the penalties were levied on a monthly basis. The payment cycle was found to be of 40 days in most cases with longest duration of 120 days. Penalties were levied for delayed turnaround time and non-performance of EQAS or EQAS out-of-range for more than 2% of tests.

17. Status of in-house laboratories and their synergy with services under the NTR Vaidya Pariksha scheme

a. Synergy of in-house laboratory services with NTR Vaidya Pariksha scheme: The state delineated the tests that would be done in-house and that would be outsourced at the outset. It was found during the survey that in-house laboratories continue to provide most of the designated tests and uptake of in-house tests increased after introduction of the NTR Vaidya Pariksha scheme. At the same time, it was found that after rollout of the scheme, supply of reagents/kits was stopped altogether for a few tests across facilities. Not all designated tests were available at in-house laboratories; availability of tests varied according to the availability of laboratory technicians, equipment and supply of reagents. In PHCs, where designated tests were unavailable, patients and ANC women were referred to the nearest government facility. The patients had to travel long distances at times for basic tests like haemoglobin and blood grouping.

b. Status of in-house laboratories

Equipment: Basic equipment was available for testing at most of the laboratories. In some CHCs, new semi-automated biochemistry analysers were lying unused and patients had to

go to private laboratories for emergency tests. The equipment were repaired by the Biomedical Maintenance Programme team and minor problems were fixed within 2-5 days.

Human resources: In the surveyed facilities, all CHCs, 5 out of 8 PHCs, 1 AH and both DHs, there was adequate manpower. Across the state, 200 PHCs did not have an in-house laboratory technician.

Reagents and consumables: Technicians were responsible for maintaining the stock of reagents and consumables. In most of the facilities, the stock orders were placed quarterly. The stock was usually delivered within 2–7 days by the central drug store to the facility. Cold chain was maintained during transportation of the supply to the health facility. In occasional cases, the transportation from the central warehouse to the central drug store took longer. Stock-out situations were frequent in the facilities. A shortage of sugar strips was found at most of the surveyed facilities. In case of unavailability of the required stock at the central drug store, the facilities purchased from local drug stores. However, if those stocks were available in the central drug store, the facilities were restricted from purchasing locally, even if indent and transportation time were high. There were no mechanisms for ensuring quality in local procurement.

Cold storage was inadequate in some facilities. None of the facilities had an inventory management system in place.

Quality of laboratory processes: The observed sampling technique was mostly found accurate. Registration, labelling and reports were handwritten and prone to errors. The test reports were mostly validated by the government laboratory technicians. Several gaps were observed in sampling, testing and reporting of tests at the surveyed in-house laboratories. The turnaround time (time from sample collection to report dispatch to the patients) for most tests was 10 minutes–2 hours.

Quality control: There were no set quality assurance mechanisms for the in-house laboratories (except for few tests done under RNTCP, ICTC and malaria control programme) even at district hospitals.

Feedback mechanisms: In most facilities, there was no organized feedback collection system in the in-house laboratories for patients, doctors and other staff of the government health facilities. Complaint boxes for patients seen in few facilities were unused.

D. Conclusions and Recommendations

The state government has accomplished its objective of providing free and accessible laboratory services to patients visiting the government health facilities to a large extent through the NTR Vaidya Pariksha scheme. The scheme has reached a certain level of maturity in terms of geographical reach, volume of services provided and management.

Key enablers for successful implementation of NTR Vaidya Pariksha scheme

i. High political and administrative commitment; leadership; and adequate budgetary allocations by the state government.
ii. Rapid rollout of services with a phased approach.
iii. Availability of all designated tests at all facilities.
iv. Delivery of services through newly set-up laboratories, which enabled operational efficiency in the services as well as cost efficiency for the service provider.
v. Concerted and intensive efforts by the state government for overcoming initial resistance of doctors to prescribe tests to the service provider under the new scheme.
vi. Timely payments to the service provider and levying of penalties when required.
vii. Establishment of a robust monitoring framework by the state government since beginning of rollout of the scheme.
viii. Continual improvement in quality of services by the service provider through IQC, EQAS and NABL accreditation (on the anvil).
ix. Clear delineation by the state government of the tests that would be done in-house and those that would be outsourced at the outset.
x. Intensive IEC campaigns by the state government to increase awareness about the scheme among the populations.
xi. The state government's synergistic (not imposing) way of working with the service provider; and service provider's compliance with suggestions from the state government for improvement of its services.

Recommendations

There are certain aspects of the scheme where there is scope for improvement and some issues that require immediate attention for strengthened functioning of the scheme. There are some recommendations for the state government for further improvement of the scheme, and for the Ministry of Health and Family Welfare for guiding potential rollout of the Free Diagnostics scheme in other states.

Recommendations for the state government

1. Scope of services and service utilization

i. It is suggested that the government develops a clear strategy and institutes monitoring mechanisms to avoid unwarranted fluctuations in utilisation of services by doctors.

ii. Utilisation of 'individual tests' should be monitored closely by the state government as well as by the service provider.

iii. To enable adequate utilisation of services among doctors, the service provider should improve upon certain aspects of its services (especially related to advanced tests), build confidence among doctors/district officials about quality of its services, and take periodic feedback from them.

iv. It is suggested that the state government assesses tests that could be reassigned to the in-house laboratories; especially tests which are high-volume and low-cost. Also, the supply of reagents/kits for tests for which in-house capacity exists should be maintained rather than redirecting the tests to the service provider.

v. Adequate oversight is recommended for tests which are being conducted in-house and through the service provider at individual facilities.

2. Operations

i. Cold chain for sample storage needs to be strengthened at all levels -- during storage of samples at the government health facility prior to dispatch, transportation from health facilities to primary receiving laboratories and transportation from L2 to L1 (mother laboratories).

ii. Electronic records should be maintained for sample rejection, repeat orders by doctors, equipment breakdown and unavailability of sampling services.

iii. It is suggested that printing stations are made available by the service provider at AHs and DHs to enable printing of reports within the hospitals, as and when the reports are ready. The government may provide a safe place for installing printing station at these facilities.

iv. The biomedical waste management at sampling stations of service provider in the government health facilities should be improved and monitored – non-functional needle destroyers should be replaced; colour-coded dustbins and bags should be made available at PHCs and CHCs; and it should be ensured that the phlebotomists wear complete personal protective gear.

3. Turnaround time

i. It is recommended that the current definition of turnaround time is revised -- pre-analytical time (time from collection of sample to initiation of testing) is incorporated in the existing definition of turnaround time and closely monitored.

ii. For assessing efficiency of processes at different stages of the sample cycle in terms of turnaround time, it is suggested that the state government monitors pre-analytical, analytical and post-analytical turnaround times, separately.

iii. The test results which fall in critical range should be automatically recorded and sent through automated messaging system to the concerned doctors within 30 minutes of validation of the reports. It is also recommended that the state government ensures that printed test reports are provided to the government health facilities within the stipulated time.

iv. The state government should work with the service provider to bring down turnaround time for many advanced and emergency tests.

v. It is suggested that for monitoring turnaround time, a robust IT system is put in place which tracks the sample status almost instantaneously. The IT system should be integrated between health facilities, local laboratories and mother laboratories; and each case should be closed only after generation of the report and its final receipt by the patient.

4. Quality assurance

i. It is recommended that the service provider makes focused efforts for building capacity across various categories of staff as most of the laboratories are functioning without direct supervision of a diagnostician.

ii. The auto-approval of test results should be made robust and valid by the service provider through the use of algorithms for the auto-approval process.

iii. Precision testing should be incorporated to keep a check on accuracy of processes used by laboratory technicians.

iv. The laboratory technicians should be advised not to conduct tests on erroneous equipment or when results are erroneous due to unknown causes until the problem is rectified.

v. The state government and service provider are advised to monitor out-of-reference range test results for individual tests and for each level of facility. Monthly analytical reports should be analyzed by the state government.

vi. The quality team of the service provider should be strengthened and play a larger role in training, preparation of standard operating procedures, supervision of processes and quality control in the laboratories, monitoring of any significant deviations in test results, management of out-of-range IQC and EQAS results etc.

vii. The quality control (IQC and EQAS) should be established for ALL, not select tests. Monthly reports should be shared with the government on percentage of out-of-range IQC and EQAS and percentage of IQC and EQAS for which requisite corrective and preventive actions were taken.

viii. An independent body should review the appropriateness of corrective and preventive actions for quality control, erroneous results etc.

ix. The criteria for sample rejection should be defined in the MIS of the service provider and laboratory technicians should be trained accordingly on identification of criteria for sample rejection.

x. The service provider should prepare and implement a schedule for periodic internal and external audits of ALL its laboratories, using stringent protocols.

xi. The service provider should immediately initiate the accreditation process of ALL its laboratories. The scope of NABL accreditation needs to be expanded to include ALL tests.

5. Supervision and monitoring

i. It is suggested that a dedicated resource (nodal officer) be appointed by each facility to oversee services under the NTR Vaidya Pariksha scheme. This resource should carry out validation of patient data for the scheme, supervise availability and quality of services and handle grievances related to services under the scheme.

ii. It is recommended that the administrators at health facilities and district health officials take up a larger role in monitoring of services at the health facility level. They should assess monthly analytical reports on availability and utilisation of service provider's services at individual government health facilities; and quality assurance at service provider's laboratories.

iii. The state government should ensure capacity building of the state-level officials responsible for monitoring the scheme and authorising payments.

iv. The dashboard should be strengthened to include percentage of patients tested (out of total number of patients); a facility-level drill down and separate analyses for PHCs, CHCs, AHs, DHs and OPD/IPD for existing indicators; monthly figures in addition to the currently available real-time and to-date figures; and weekly and monthly MIS data analytics and reports (in the form of statistical reports, charts and data summary visuals) for better monitoring and supervision. It is suggested that MIS data be combined with periodic surveys/ inspection reports of government health facilities and service provider's laboratories to enable the state government to maintain an even more vigilant supervision of the scheme. Reports from analytics of laboratory services should be integrated with data on medicines prescribed, pharmacy usage and other relevant parameters.

v. The records of all patients availing laboratory services both at the in-house laboratory and through service provider should to be captured electronically in one single integrated MIS at the government health facility itself. The state government is in the process of implementing EHR. Once implemented, EHR application could be leveraged for the same.

vi. It is imperative to use a single patient identity for patients availing laboratory services to maintain uniformity in identification of new and repeat patients.

vii. Validation of data of the number of patients tested, number of tests conducted and test reports received should be strengthened at the health facility level.

viii. It is suggested that test ordering patterns of doctors should be closely monitored through analytical reports and periodic audits. There is a room for strengthening protocols for evidence-based practices for prescribing diagnostic tests.

ix. An expert committee consisting of government pathologists/ biochemists/ microbiologists/ or other experts and relevant stakeholders should be constituted to monitor the technical aspects of the service provider's laboratories periodically.

x. The service provider should provide access to the state government to view real-time laboratory information system of all its laboratories. A dedicated resource

assigned by the government can randomly check in the system the tests conducted at the service provider's laboratories and the test reports.

xi. All government health facilities should maintain attendance register/biometric attendance for the service provider's phlebotomists. The records should be regularly checked by the facility administrators as well as district health officials.

xii. The government should continue to conduct periodic security audit of the service provider's IT systems for data security and confidentiality.

xiii. The grievance redressal mechanism at health facilities should be strengthened.

xiv. Periodic patient satisfaction surveys should be conducted for assessing patients' experiences with the services under NTR Vaidya Pariksha scheme.

6. Contract management

i. The primacy of responsibilities of the contractor (signing authority) vis-à-vis franchised laboratories (sub-contractors) including quality control, supervision, penalties to the franchisees; and accountability of the service provider in regular monitoring of franchisees and for meeting performance requirements and quality of services rendered by them needs to be monitored.

ii. It is recommended that the Agreement includes 'more detailed' description of certain crucial aspects such as mutual roles/responsibilities and obligations of the government and service provider; project governance mechanism; supervision and monitoring mechanism; use of IT in monitoring and data analytics (morbidity tracking); contract management including payment procedures; and operational aspects of key processes including but not limited to sample collection, sample transportation including quality of storage and cold chain, sample processing etc.

iii. It is suggested that the critical aspects of public private partnership structure i.e. detailed description of outputs and standards including performance indicators and penalties in case of shortfall in performance at various stages are defined. The penalty framework and events of default should be more elaborate in line with the standard concession Agreements already available. It is recommended to add few more KPIs (for penalty) and monitoring indicators. A suggestive list of KPIs and monitoring indicators has been developed by WHO evaluation team (Annexure I) for consideration by state authorities.

iv. The scope of 'breakdown of services' should encompass 'unavailability of accurate testing' and 'unavailability of any designated tests', besides 'unavailability of sampling services'.

v. Currently the penalty on quality control only includes EQAS 'not performed'. It is suggested that 'inability to perform IQC' should also be incorporated in the penalty clause. Along with this, appropriate preventive and corrective actions for IQC and EQAS could also be monitored.

vi. The Agreement should specify the number of days in a month for which the service provider needs to station phlebotomists at each type of facility.

vii. It may be considered that the ‘cost per sample’ in the Agreement is changed to ‘cost per patient’.

viii. Considering that the penalty clauses are monthly, the payment cycle should be made monthly instead of weekly in the Agreement.

ix. For the period till NABL accreditation is accomplished, the Agreement should clearly specify the technology of equipment to be used for each kind of test, quality of reagents to be used for testing and internal control, mechanisms of IQC and EQAS, agencies for EQAS, cold chain monitoring and transportation of samples. Minimum qualifications and training structure for the service provider’s staff should also be outlined. An effort should be made to move to quality assured/WHO prequalified reagents and diagnostics in the future.

x. The penalty clause on unavailability of sampling services should be revised. Penalty should be levied on the service provider if its ‘sampling services’ or ‘any of the designated tests’ are unavailable at the government health facilities for more than a ‘total of 3 working days’ in a month, instead of penalising unavailability of sampling services only for ‘more than 3 days at a stretch’. This leaves room for unavailability of services for short but frequent intervals.

xi. It is suggested that turnaround time is defined as per the best industry practices (to indicate time taken from sample collection to report availability) and should incorporate pre-analytical turnaround time.

xii. It is suggested that turnaround time for critical results (within 3 hours of ‘dispatch’) is revised in the Agreement.

xiii. The minimum volume should be assured on monthly/yearly basis rather than daily-basis in interest of cost efficiency of the scheme. Also, the methodology for calculation of minimum assured volume could be revised. Instead of assigning ‘absolute diagnostic load’ at each type of facility as minimum assured volume; it could be calculated as a percentage of patient load at health facilities. Based on level of care provided at different types of health facilities and data from few states, the minimum assured volume of diagnostic load could be kept at 8% of total patient load for DHs and AHs and 5% for CHCs and PHCs.

xiv. Grievance handling mechanism should be clearly defined in the Agreement.

xv. It is suggested that the state government assesses tests that could be reassigned to the in-house laboratories; especially tests which are high-volume and low-cost like TLC, DLC and Rapid tests (e.g. RPR and Dengue Rapid Test).

7. Adherence to Agreement clauses

The service provider has complied with most of the clauses in the Agreement. There are a few clauses which have not been implemented so far, for which closer oversight is required:

i. The phlebotomists of service provider should conduct ALL tests assigned to in-house laboratory in health facilities where position of the in-house laboratory technician is vacant.

ii. The service provider is suggested to declare the list of empanelled laboratories to the state government.

iii. The service provider should prepare and submit standard operating procedures on sample transportation, storage and testing processes to the state government; declare human resources and equipment at each laboratory; share detailed logistics plan; and maintain complete records of critical test results and inform doctors about the same.

iv. The service provider is recommended to submit reports to the state government on the unavailability of sampling services at the government health facilities.

v. The service provider should get ALL its laboratories audited by a third party NABL accredited laboratory.

vi. Blood culture test should be conducted on automated blood culture system.

vii. The service provider should make provision for serum calcium test.

8. In-house laboratories

i. It is suggested that the in-house laboratories have an upgradation of infrastructure and provision of power back-up and cold storage.

ii. The supply of reagents (especially for blood sugar test) to in-house laboratories should be maintained.

iii. Capacity building of the in-house laboratory technicians is suggested through quarterly trainings, competency assessment and use of standard operating procedures in the laboratories. In addition, the administrator/ another doctor at the facility should be trained on basic concepts of laboratory and should be made responsible for supervising the functioning of the laboratory for processes, reagents and consumables, inventory management, equipment etc.

iv. The in-house laboratories could adopt few best practices of the service provider including registration, labelling, sampling and report dispatch. The reports should be given to the patients in a printed form instead of writing on the OPD slip or a piece of paper.

v. Uniformity and quality in local procurement of reagents is recommended.

Recommendations for the Ministry of Health and Family Welfare for potential implementation of Free Diagnostics Scheme in other states

1. Key enablers for successful implementation of the NTR Vaidya Pariksha scheme for potential adoption by other states: It is recommended that the enablers which facilitated successful implementation of NTR Vaidya Pariksha scheme in Andhra Pradesh (listed in the beginning of this section) are adopted by other states.

2. Agreement between the state government and service provider

Some key observations and recommendations from a detailed analysis of the Agreement between the state government and service provider for the NTR Vaidya Pariksha scheme are mentioned in the section on recommendations for the state (point 6). These could be used by the Ministry of Health and Family Welfare to inform similar programmes in other states.

3. Cost efficiency

i. States should strengthen in-house laboratories at PHCs for low-end and rapid tests, and utilize the budget more optimally in purchasing advanced tests at CHCs and above from the service provider**.** Also, states should build their in-house capacity at all levels of facilities by procuring equipment for tests which are high volume and require minimal expertise. This would strengthen the capacity of public health system in providing basic health services in the long run. The advanced tests from service provider would help in improving efficient purchase of services (tests) under the capitation mode.

ii. It is suggested that a detailed financial analysis or value-for-money (VFM) analysis/cost-benefit analysis of NTR Vaidya Pariksha scheme is done to understand if it would be more efficient to purchase higher level tests from CHC level and upwards rather than low-end tests at the PHC level, through capitation mode; whether per capita rate could be different for various levels of facilities; and which of the two – per capita or per test model is more cost effective. It is also recommended to carry out a comparative analysis of cost of running in-house laboratories with the cost of NTR Vaidya Pariksha scheme for cost efficiency in terms of utilisation of services of each type. The learning could enable other states to prepare a robust financial model for planning its diagnostic services.

iii. States should conduct an in-depth assessment of tests required at various levels of facilities to be incorporated in the Agreement to avoid extra costs incurred in lieu of addition of tests after the Agreement is signed.

iv. It is suggested that a few tests (listed in Annexure II) are added in the current list of Free Diagnostics Scheme guidelines. These additional tests would help in improving efficient purchase of services (tests) under the capitation mode and further improve the healthcare delivery services at each level with great benefits to the catchment populations.

v. Minimum assured volume should be applicable only after complete rollout of the services in the defined geography.

4. Operational efficiency

Other states could avoid teething problems which compromise quality of services in the initial stages of rollout by taking requisite measures before the services are rolled out. These measures are outlined below:

i. The service provider should be given 90-120 days for initiation of rollout of services. The services should be rolled out in a phased manner. The laboratories could start full-fledged services in 1% of facilities in each district for 2 weeks before they extend their services to rest of the facilities. In parallel, the service provider could do a dry-run for 2 weeks at all government health facilities.

ii. In the preparatory phase of the rollout, the following measures can enable a smooth implementation:

   a. Laboratories should be inspected by the service provider and the state government before they become operational. Quality control systems should be instituted in the preparatory phase.

   b. The training structure and curriculum for laboratory technicians should be in place and presented to the government.

   c. Requisite infrastructure, tracking systems and details of processes to be tracked should be in place for monitoring as per monitoring indicators so that requisite monitoring could be initiated as soon as the services become operational.

   d. State should build capacity for monitoring of the scheme at all levels including facility level.

   e. Procurement and adequate testing of equipment, ice boxes, needle destroyers, reagents etc. should be complete and results of testing should have been assessed.

   f. Doctors should be sensitised about introduction of services of private provider (s) right at the outset.

iii. The monitoring indicators should be used for monitoring services from beginning of the rollout. The states should closely monitor all aspects of services.

1. Background

India has a public health system with a stated commitment to providing universal access to free care. Substantial investments in the National Health Mission (NHM) have resulted in improvement of access and coverage in public health facilities. However, diagnostic services are still largely unavailable in public health facilities hampering evidence-based care and delivery of essential and universal healthcare. Expenditure on diagnostics continues to be an area of concern. Under the National Rural Health Mission (NRHM), free care in public hospitals has been extended to a select set of conditions for maternity, newborn and infant care as part of the Janani Suraksha Yojana, Janani Shishu Suraksha Karyakram and for disease control programmes. For other services, user fees especially for diagnostics continued. Out-of-pocket expenditures on drugs and diagnostics have been prohibitively high, one of the highest in the world.[1] The private sector catering to the diagnostics needs of majority of the population is dominated by unorganized players due to lack of entry barriers in absence of a strong regulatory framework.

The National Health Policy 2017 recognizes that making available good quality, free diagnostics at public health facilities is one of the most effective way for achieving the goal of providing universal healthcare. The policy stipulates that the free diagnostics basket should include all that is needed for comprehensive primary care, including care for chronic illnesses, in the assured set of services. At the tertiary care level too, at least for inpatients and outpatients in geriatric and chronic care segments, most diagnostics should be free or subsidized with fair price selling mechanisms for most and some co-payments for the well-to-do individuals. The policy endorses that the public hospitals should provide universal access to a progressively wide array of free diagnostics with suitable leeway to the states to suit their context. The policy seeks to eliminate the risks of inappropriate treatment by maintaining adequate standards of diagnosis and treatment. The policy also recommends to stimulating innovation and discovery of more affordable and appropriate points of care diagnostics as also robust medical equipment for use in the rural and remote areas.[2]

To address the urgent need for accessible and quality diagnostics at public health facilities, the Ministry of Health and Family Welfare, Government of India under the aegis of NHM launched the Free Diagnostics Scheme in July 2015. The scheme is intended to provide a set of essential diagnostics at various levels of care so that providers can make rational decisions regarding treatment and patients benefit by getting their tests conducted within the facility free of cost. The government envisages that this health intervention will reduce both direct costs and out-of-pocket expenditure.

Under this scheme, NHM is supporting all states to provide essential diagnostics – laboratory and radiology at their public health facilities, free of cost. The range of tests offered in the public health facilities are in accordance with the level of care; primary health centres (PHCs) offer 19 laboratory tests, community health centres (CHCs) provide 39

[1] Market research report: India Diagnostic Laboratories. Market Outlook to 2021 Growing Prevalence of Diseases and Launch of Technologically Advanced Procedures to Drive Growth. February 2017. Ken Research.

[2] National Health Policy 2017 document

laboratory and radiology tests including ultrasound and X-ray, and hospitals offer 57 laboratory and radiology tests including CT scan.

Ministry of Health and Family Welfare has formulated guidelines for providing states with a broad framework for implementing the Free Diagnostics Scheme to ensure the availability of basic diagnostics services at public health facilities. The guidelines suggest alternative models supported by innovative technologies which states can adopt based on local context. The guidelines advice the states to prioritize strengthening in-house laboratory services appropriate to the level of care and till the time readiness is established, to judiciously consider outsourcing some categories of diagnostics.

Since states have varying capacities in provision of diagnostics, they are adopting different models to ensure availability of requisite diagnostics at the public health facilities. Few states like Rajasthan and Madhya Pradesh are strengthening their in-house capacities through equipment procurement, enhancing human resources and improving supply chain of reagents and consumables. In Rajasthan, the Free Diagnostics Scheme is being implemented as part of a state scheme called Mukhyamantri Nishulk Janch Yojana. According to a study conducted by WHO in the two states, the scheme has contributed to increased utilisation of public health facilities in these states. In Madhya Pradesh and Rajasthan, the total number of outpatients and inpatients increased by 106% and 31% respectively within 2 years of rollout of the scheme.[3] Maharashtra and Uttar Pradesh have recently done a state-wide rollout of laboratory services under public private partnership arrangement. Uttar Pradesh has adopted the per-test payment model while Maharashtra is paying on a per-patient basis. Assam, Odisha and Meghalaya are also in the process of implementing the scheme in public private partnership mode. Assam and Meghalaya are planning to outsource all tests at all facilities, whereas Odisha is planning to outsource only advanced tests and will conduct routine tests in its in-house laboratories. Tripura has opted for a complete in-house model for implementing the Free Diagnostics Scheme in the state.

Andhra Pradesh is the first state which has done a state-wide rollout of both laboratory and radiology services using a hybrid model. The diagnostic services have been contracted out under public private partnerships and at the same time, the in-house capacities are being utilized in a complementary and synergistic manner enabling provision of comprehensive diagnostic services in the state.

The services under the public private partnership were launched by the state on 1 January 2016 under a new flagship scheme called NTR Vaidya Pariksha scheme. Under this scheme, the state government is providing laboratory and radiology services at public health facilities through private partners. The services are free-of-cost for all beneficiaries visiting these facilities. NHM is supporting the state by funding 60% of the scheme's budget; the remaining 40% is contributed by the state government.

[3] Impact evaluation (IE) of the Free Diagnostics Scheme by the governments of Rajasthan and Madhya Pradesh, including trends in out-of-pocket (OOP) payments in healthcare. WHO Country Office for India. August 2016.

Laboratory services under the NTR Vaidya Pariksha scheme have been outsourced to a single service provider – Medall Healthcare Pvt. Ltd. The service provider was selected by the state government through a competitive bidding process. They provide seven laboratory tests at each of the 1125 PHCs, 21 tests at 192 CHCs and 40 tests at 35 AHs and 8 DHs. The radiology services for X-Rays and CT scans are rendered by another service provider. The service provider carries out reporting of X-rays remotely through tele-radiology for public health facilities where X-ray machines are available. The tele-reporting services for X-rays are operational at 57 government health facilities – 20 CHCs, 30 AHs and seven DHs. They provide CT scan services at nine hospitals – four AHs and five DHs. The service provider has set up and is managing CT scan centre inside four hospitals and reporting of CT scan is done remotely. In five hospitals, the service provider only provides tele-reporting of CT scans. Over 7 000 000 people have benefited through NTR Vaidya Pariksha scheme from the time of rollout in January 2016 till June 2017. Around 20 000 000 laboratory tests have been conducted for 6 500 000 patients; and over 600 000 X-rays and over 40 000 CT scans have been reported.[4] The reimbursement to the service providers is done on a per-patient basis for one time sampling, X-ray or CT scan.

WHO conducted an evaluation of laboratory services under NTR Vaidya Pariksha scheme during February–July 2017 on request of the Ministry of Health and Family Welfare, Government of India.

[4] Source: State government's data

2. Methodology

2.1 Objectives of the evaluation

The objectives of the evaluation were as follows:

a. To assess the access to laboratory services for the patients at government health facilities under NTR Vaidya Pariksha scheme and at in-house laboratories.

b. To assess the quality of laboratory services provided to patients at government health facilities.

c. To evaluate cost efficiency of laboratory services under NTR Vaidya Pariksha scheme.

d. To assess OOPE incurred by patients on laboratory services.

e. To evaluate service provider's compliance to the prescribed clauses in the Agreement signed with the state government.

f. To review NTR Vaidya Pariksha scheme in context of the ongoing health system strengthening efforts and advice the Government of India on the way forward for achieving universal health coverage.

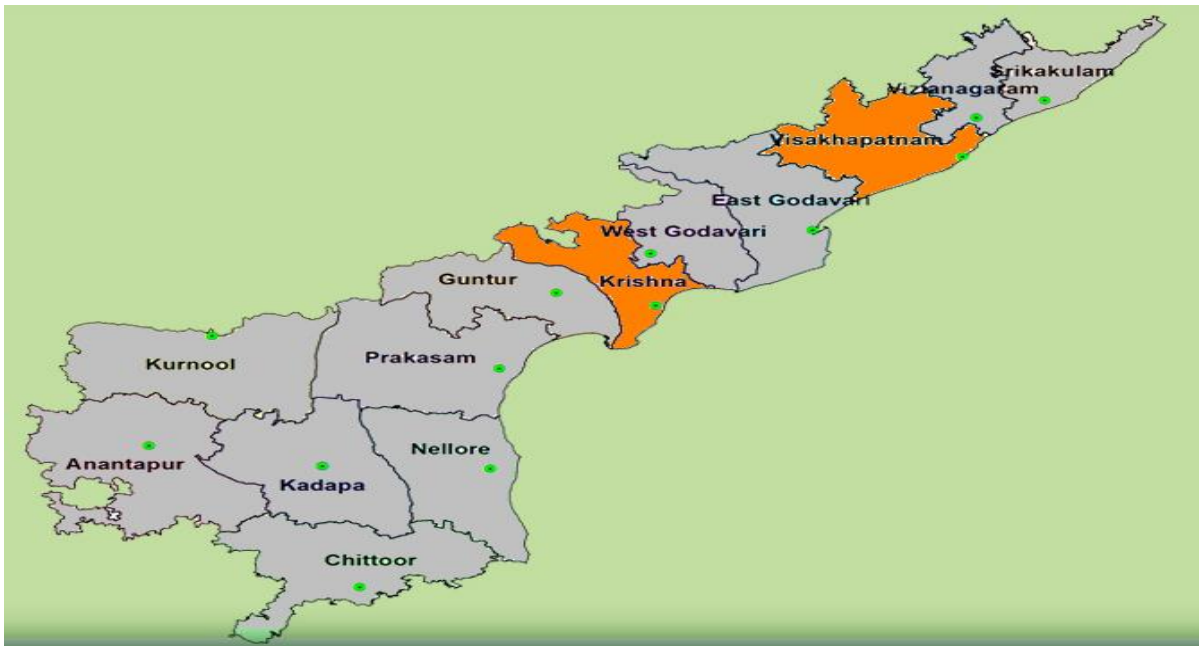
2.2 Study design

2.2.1 Sample design

Andhra Pradesh has 13 districts and 1125 PHCs, 192 CHCs, 35 AHs and eight DHs. For the primary survey, two districts – Krishna and Visakhapatnam (figure 1) were selected based on their infant mortality rate (IMR). Visakhapatnam has higher IMR and Krishna has lower IMR compared to the state average. Visakhapatnam was also selected to have representation of its tribal population in the sample. In each of the two districts, four PHCs, four CHCs, one AH and one DH were surveyed. In the two survey districts, both urban and rural areas were covered and in one district, tribal areas were also covered. A total of 20 government health facilities were, thus, covered for the evaluation. A central drug store was also visited in district Krishna.

In addition, six laboratories of service providers (three in each district) catering to the government health facilities under NTR Vaidya Pariksha scheme were surveyed. All three categories of laboratories were covered – mother laboratories (L1 laboratories), laboratories catering to DH/AH (L2 laboratories) and laboratories catering to CHCs and PHCs (L3 laboratories).

Figure 1: Survey districts



2.2.2 Data collection and analysis

In the surveyed facilities, services of service providers as well as in-house laboratories were assessed. In each of these facilities, focus group discussions/key informant interviews were conducted with doctors (including administrators). Structured interviews were also conducted with laboratory technicians of in-house laboratories and phlebotomists and inter-laboratory delivery (ILD) personnel of the service provider. 120 patients with laboratory test reports (service provider's reports with/without in-house reports) were interviewed across various government health facilities.

At the service provider's laboratories, semi-structured interviews were carried out with pathologists/microbiologists, laboratory managers, laboratory technicians and other staff. The central drug store was assessed for supply chain for in-house laboratory services. At the central drug store, deputy executive engineer, pharmacist and data entry operator were interviewed.

In addition to interviews and focus group discussions, relevant observational data regarding infrastructure and processes at government health facilities, service provider's laboratories and the central drug store were also collected during the visits.

Interviews were conducted with senior state officials of the Department of Health, Medical and Family Welfare and their teams – principal secretary, commissioner, director general – drug control administration, commissioner – AP Vaidya Vidhan Parishad, director – Public Health and Family Welfare and the nodal person for NTR Vaidya Pariksha scheme. District health officials including district coordinators of hospital services and district health and medical officers were also interviewed in the two surveyed districts. Interviews were done with senior management of the service provider and its teams from the two districts.

In addition to the primary survey, secondary data on laboratory services – both for in-house and service provider was collected from the state government and the service provider, respectively. Other relevant documents like Agreement with the service provider, MIS reports, test reports, quality control registers etc., were also reviewed.

After data collection, relevant data was entered in Microsoft Excel and analysed.

2.3 Key areas for evaluation

Following were the key areas for evaluation:

i. Access to laboratory services – service provider's and in-house

- Total number of government health facilities (DHs, AHs, CHCs and PHCs) serviced by the service provider and turnaround time for commencement of its services.
- Total number of patients who availed diagnostic services through the service provider and in-house laboratories and total number of tests conducted, test mix, patient to test ratio etc.
- Availability of services of the service provider and in-house laboratories.
- Synergy of services of in-house laboratories with those of the service provider.

ii. Quality of laboratory services – service provider's and in-house

- Quality assurance at laboratories: Equipment (adequacy and availability), human resources, training, standard operating procedures, quality of processes, supply chain management, internal quality control (IQC), external quality assurance scheme (EQAS), readiness of service provider for NABL accreditation etc.
- Test results: Incidence of erroneous results, repeat sampling, abnormal results and relay of information to clinicians about critical results.
- Clinician satisfaction: Quality and turnaround time of test reports, change in availability of tests, accuracy of diagnosis, clinical outcomes etc.
- Patient satisfaction: OOPE, waiting time, comfort during sampling procedure, turnaround time for receiving test reports etc.

iii. Monitoring of services

- Monitoring by government: Feedback/grievance mechanism, periodic reviews/audits, surprise visits, data validation, tests which are being outsourced despite in-house capacity, penalties to private providers etc.
- Monitoring by private provider: Allocation of resources for monitoring, feedback, surprise visits, audits etc.
- Third party monitoring

iv. Adherence of service provider to the Agreement clauses

v. Satisfaction of the service provider

- Payments: Procedure for submitting bills for reimbursement, periodicity and mode of payments, challenges (if any) in receiving payments etc.
- Support from the government for rollout of services: Provision of requisite infrastructure etc.

vi. Cost efficiency of NTR Vaidya Pariksha scheme

- Minimum assured volume
- Comparative analysis of cost of NTR Vaidya Pariksha scheme (cost per patient) with the CGHS model (cost per test)

3. Key findings

3.1 Positive attributes of the scheme

i. The scheme has improved access to laboratory services – 6 581 430 patients have been tested and 19 934 620 tests done at government health facilities across the state through NTR Vaidya Pariksha scheme from January 2016 to June 2017.

ii. Expanded basket of tests available through the service provider has led to improved patient care. Per capita OOPE on diagnostics has reduced by 55% from 2015 to 2017 across public and private sectors. The total number of patients in OPD and IPD increased by 5% and 16%, respectively from 2014-15 to 2015-16 and by 15% and 29%, respectively, from 2015-16 to 2016-17. There is an increased confidence in the government health facilities among people. Women and tribal patients (58% and 5%, respectively of total patients tested) in particular have benefited from the scheme.

iii. Patients are overall satisfied with the laboratory services at the health facilities.

iv. Clinicians are mostly satisfied with the quality and availability of tests under the scheme.

v. There has been high political and administrative commitment and leadership from the state government.

vi. Adequate budgetary allocations were made by the state government for the first and second year of services.

vii. The rollout was phased – services were started in DHs and AHs in the first month, CHCs and PHCs were commenced in the second third month, respectively. Services were rolled out at all designated government health facilities (1156 PHCs, 192 CHCs, 35 AHs and eight DHs) within 5 months of signing the Agreement. Though there were teething issues, a phased approach facilitated a relatively smoother rollout. Facilities in remote/tribal/hilly areas are also being serviced.

viii. All designated tests have been made available at all facilities. The service provider is delivering services through 104 laboratories out of which 97 were newly set up. The newly set-up laboratories enabled operational as well as cost efficiencies for the service provider.

ix. The state government made concerted and intensive efforts in overcoming initial resistance of doctors to prescribe tests to the service provider under the new scheme which resulted in a steady increase in uptake of services under the scheme.

x. Payments to the service provider were mostly made in 40-day intervals with occasional longer intervals. The penalties were levied when required, for example, for delayed turnaround time of reports and delayed initiation of EQAS motivated the service provider to tighten its systems and establish EQAS.

xi. The state government has instituted a robust monitoring framework since beginning of rollout of the scheme. A dashboard reflecting real-time data on utilization of services has been made available; state-level monthly review meetings are being conducted where key government officials and service provider representatives participate. The state programme implementation unit was engaged in the initial 1 year of the rollout for close monitoring of the scheme. The state government leveraged the drug control administration (DCA) for inspection of laboratories of the service provider. District health officials have also been engaged for supervising the scheme. The service provider too has been monitoring the services through central and district teams.

xii. The state government has mostly worked in a synergistic than an imposing manner with the service provider. The service provider too has been compliant in incorporating suggestions from the state government for continual improvement of its services, especially their quality. IQC and EQAS have been established in all 104 laboratories for select tests. NABL accreditation of mother laboratories has also been initiated.

xiii. At the outset, the state delineated the tests which would be done in-house and those which would be outsourced. The in-house laboratories continue to provide most of designated tests and uptake of in-house tests has increased after introduction of NTR Vaidya Pariksha scheme.

xiv. The state government launched massive IEC campaigns to increase awareness about the scheme among the populations.

3.2 Operational model

The government health facilities offer a range of laboratory tests through NTR Vaidya Pariksha scheme and through their in-house laboratories. The laboratory services under NTR Vaidya Pariksha scheme have been made available by a single service (private) provider. The basket of tests offered by in-house laboratories and NTR Vaidya Pariksha scheme are different. The in-house laboratories are providing 10–12 basic and mostly rapid kit tests at all levels of facilities. NTR Vaidya Pariksha scheme is complementing the services of in-house laboratories with hematology and biochemistry tests as well as few advanced tests. The range of tests provided under NTR Vaidya Pariksha scheme varies according to the level of the facility. In PHCs, only seven basic tests are provided, 21 routine tests in CHCs and 40 tests in AHs and DHs are provided, including routine as well as few advanced tests.

The list of tests available at each level of facility through in-house laboratories and NTR Vaidya Pariksha scheme is given in table 1 below.

Table 1: List of laboratory tests available at each level of facility through in-house laboratories and NTR Vaidya Pariksha scheme

S. No.	Name of the test	Tests available in in-house laboratories
1	Haemoglobin	✓
2	MP slide method/malaria rapid test	✓
3	ESR	✓
4	Clotting time and bleeding time	✓
5	Blood group	✓
6	Blood sugar	✓
7	HIV test	✓
8	Sputum for AFB	✓
9	Urine sugar and albumin	✓
10	Urine pregnancy test	✓
11	HBsAg	✓
12	TLC	Not available in PHC
13	DLC	Not available in PHC
14	Urine microscopy	Not available in PHC
15	Peripheral blood film	Not available in PHC/CHC
16	RPR rapid test	Not available in PHC/CHC

Tests available under NTR Vaidya Pariksha scheme				
		NTR Vaidya Pariksha scheme – PHC	**NTR Vaidya Pariksha scheme – CHC**	**NTR Vaidya Pariksha scheme – AH/DH**
1	TLC			
2	DLC			
3	Platelet count			
4	S. bilirubin (T)			
5	Rapid plasma reagin (RPR)			
6	Dengue rapid test			
7	Stool for ova/cyst			
8	CBC			
9	Prothrombin time test and INR			
10	Serum creatinine			
11	S. bilirubin (D)			
12	Blood urea			
13	SGPT			
14	S. alkaline phosphatase			
15	S. total protein			
16	S. albumin			
17	S. amylase			
18	S. total cholesterol			
19	S. triglycerides			
20	S.VLDL			
21	S. HDL			

		NTR Vaidya Pariksha scheme – PHC	NTR Vaidya Pariksha scheme – CHC	NTR Vaidya Pariksha scheme – AH/DH
22	Urine complete by strip method			
23	Peripheral blood smear			
24	Total eosinophil count			
25	Coomb's test – direct			
26	Coomb's test - indirect			
27	S. uric acid			
28	Rheumatoid factor			
29	Anti streptolysin			
30	S. CRP			
31	S.calcium/potassium/sodium			
32	Troponin - I/troponin - T			
33	S. LDH			
34	TSH			
35	HbA1C			
36	Fluid (CSF, ascitic, pleural) cell count and biochemistry			
37	Semen analysis sperm count			
38	Blood culture			
39	Urine culture			
40	Histopathology			
41	Cytology			
42	Bone marrow aspiration			

The services of in-house laboratories and NTR Vaidya Pariksha scheme can be availed only by patients visiting the government health facilities. Patients who require testing are prescribed tests by the doctors at these facilities. Depending on which tests are prescribed, patients avail services of in-house laboratories or NTR Vaidya Pariksha scheme or both.

The in-house laboratories are located within the government health facilities while the service provider's laboratories have been set up outside the health facilities at varying distances. The sampling of patients for tests under NTR Vaidya Pariksha is carried out in the government health facilities. The service provider has set up sampling stations at all facilities where sampling and report dispatch are done by its phlebotomists. The samples collected by phlebotomists are transported to its laboratories for testing. The reports are emailed to the health facilities immediately after report generation at the service provider's laboratories. Printed reports are also provided to the health facilities after printing at service provider's laboratories. The printed reports are dispatched to the patients or doctors by the phlebotomists of the service provider stationed at the health facilities. Sample transportation from the government health facilities and printed report delivery to the facilities are done by ILD staff of the service provider.

The service provider has created extensive infrastructure for providing services under NTR Vaidya Pariksha scheme. 104 laboratories have been set up to provide services to the designated government health facilities – 1125 PHCs, 192 CHCs, 35 AHs and eight DHs. The 104 laboratories are categorized as L1 (mother laboratories), L2 and L3. All the 97 L2 and L3 laboratories were newly established adjoining all DHs and AHs, and select CHCs. The seven L1 laboratories were already existing and operational and were acquired by the service provider.

All routine tests for neighbouring PHCs and CHCs are conducted at the L3 laboratories; all routine tests for adjoining DHs/AHs and for neighbouring PHCs and CHCs are conducted at L2 laboratories; and advanced tests such as cultures, cytology, histopathology, TSH, fluid examination and HbA1C for AHs and DHs of multiple districts as well as all routine tests for neighbouring PHCs and CHCs are performed at L1 (mother laboratories). L1 laboratories have a diagnostician stationed at the laboratories, whereas L2 and L3 laboratories are staffed by laboratory technicians and laboratory managers. The samples for advanced tests from AHs and DHs are registered at the primary receiving laboratory (L2) and then transported to the mother laboratory (L1). Few advanced tests in some districts are outsourced by the service provider to private laboratories.

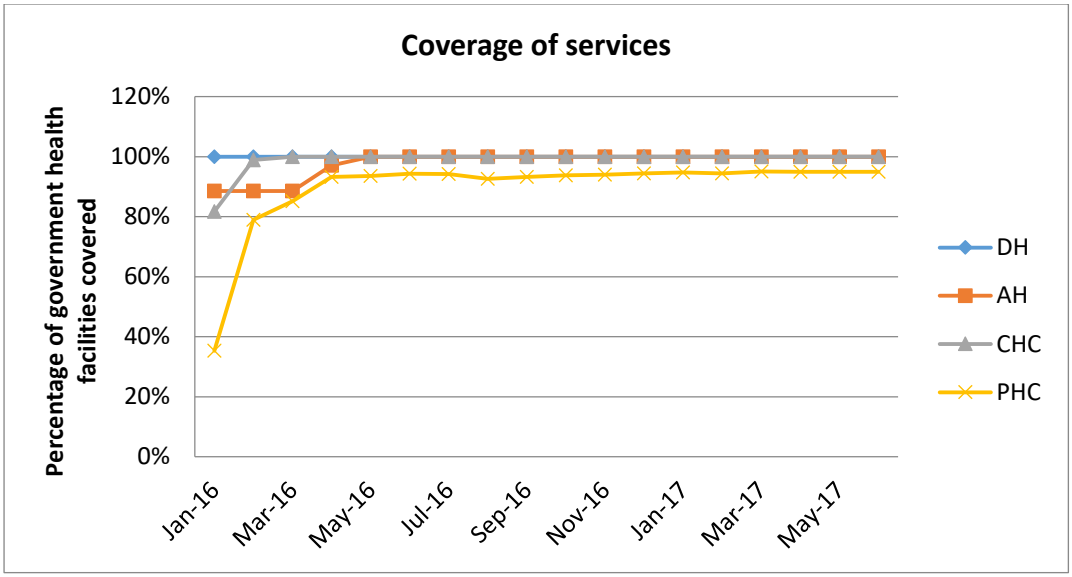
The service provider has also set up a district reporting centre in each district. In these centres, diagnosticians remotely carry out validation of test results and of IQC results of all laboratories in their respective districts. They also report few tests, such as peripheral smears, fluid examination and semen analysis.

3.3 Service coverage under NTR Vaidya Pariksha scheme

3.3.1 Coverage of government health facilities

The service provider was given the mandate to roll out the scheme in 8 DHs, 35 AHs, 192 CHCs and 1125 PHCs. The scheme was launched within 54 days of signing of the Agreement. 100% coverage was achieved for DHs within the first month of launch itself. All AHs and CHCs were covered by the third month and approximately 95% of PHCs were covered by the fourth month (figure 2).

Figure 2: Coverage of government health facilities under NTR Vaidya Pariksha scheme



Source: Service provider's data

3.3.2 Coverage of patients

NTR Vaidya Pariksha scheme has achieved a considerable reach among the target populations. A total of 6 581 430 patients were tested by the service provider since the launch of the scheme in January 2016 till June 2017. Maximum number of patients were tested at PHCs (52%), followed by CHCs (30%), AHs (12%) and DHs (6%) (table 2).

The percentage of patients tested out of the total number of patients who visited the health facilities was 9.8%. This percentage was the highest in CHCs (10.7%), followed by AHs (10.5%), PHCs (9.4%) and DHs (8.8%) (table 2). Intuitively, the percentage of patients tested (out of the total patients) at DHs should have been significantly higher than that at CHCs and PHCs. DHs offer advanced care and there is a higher proportion of patients presenting with severe morbidities, whereas PHCs and CHCs cater to primary care and basic illnesses, and require diagnostic tests for a smaller percentage of patients.

A total of 19 934 620 tests were conducted by the service provider since the launch of the scheme in January 2016 till June 2017. Maximum number of tests were conducted at PHCs (41%), followed by CHCs (33%), AHs (16%) and DHs (10%) (table 2). This is aligned with the fact that maximum number of patients was tested at PHCs followed by CHCs, AHs and DHs.

Overall patient-to-test ratio (average number of tests conducted per patient) was 3.03. The ratio was highest in DHs (4.91), followed by AHs (3.74), CHCs (3.36) and PHCs (2.43) (table 2). This is in line with profile of patients and level of care provided at respective types of health facilities.

Table 2: Type of facility-wise coverage

Type of facility	Total number of patients tested and percentage share	Total number of tests conducted and percentage share	Patient to test ratio	Percentage of patients tested (number of patients tested/total number of patients who visited health facilities)
All facilities	6 581 430	19 934 620	3.03	9.8%
DH	407 567 (6%)	1 999 176 (10%)	4.91	8.8%
AH	830 664 (12%)	3 103 787 (16%)	3.74	10.5%
CHC	1 974 707 (30%)	6 636 655 (33%)	3.36	10.7%
PHC	3 368 492 (52%)	8 195 002 (41%)	2.43	9.4%

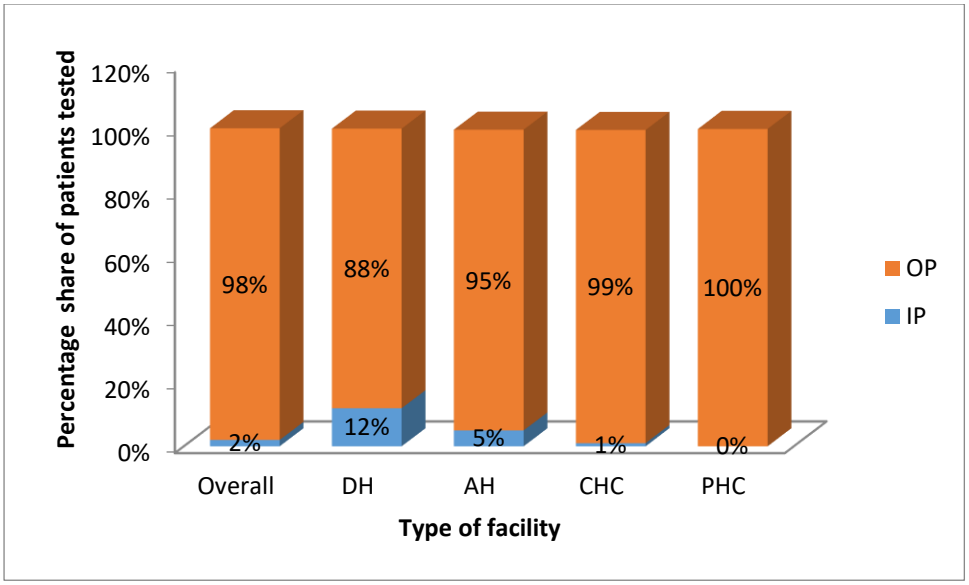
Source: State government and service provider's data

These parameters were also analyzed separately for outpatients and inpatients. Emergency patients were included in inpatients. Of the total number of patients tested under NTR Vaidya Pariksha scheme, 98% were outpatients and 2% were inpatients (figure 3). The percentage shares of outpatients (among total patients tested) in DHs, AHs, CHCs and PHCs were 88%, 95%, 99% and 100%, respectively (figure 3). The percentage share of inpatients (among total patients tested) was much more in DHs (12%) compared to AHs (5%) and CHCs (1%) (figure 3).

The tests conducted for outpatients and inpatients were 97% and 3%, respectively, of the total number of tests conducted (figure 4). The percentage shares of tests conducted for outpatients in DHs, AHs, CHCs and PHCs were 85%, 94%, 98% and 100%, respectively (figure 4). The percentage share of tests conducted for inpatients was much more in DHs (15%) compared to AHs (6%) (figure 4).

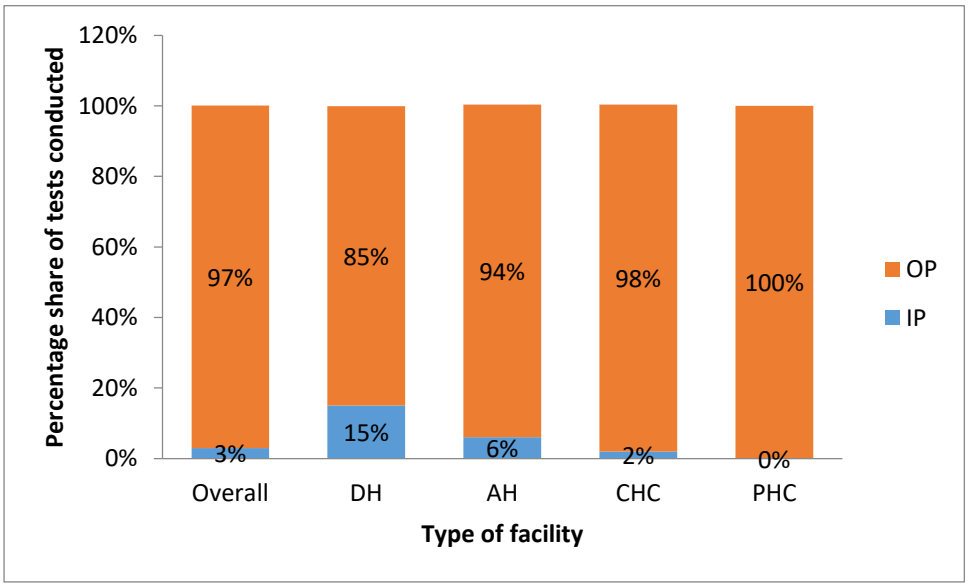
The maximum percentage share of inpatients among total patients tested and total number of tests conducted in DHs matches the highest inpatient load at these facilities. Also, patients admitted in DHs have more severe morbidities compared to those admitted in AHs. On the other hand, fewer patients with less severe morbidities are admitted in CHCs. Also, pregnant women who have delivered or are about to deliver constitute a large proportion of inpatients in CHCs.

Figure 3: Percentage share of patients tested – outpatients (OP) and inpatients (IP)



Source: Service provider's data

Figure 4: Percentage share of tests conducted – outpatients (OP) and inpatients (IP)



Source: State government and service provider's data

The patient-to-test ratio for outpatients and inpatients was 4.73 and 6.23, respectively in DHs; 3.72 and 4.05, respectively in AHs; 3.35 and 4.09, respectively in CHCs; and 2.43 (outpatients) in PHCs (table 3). This fits well with the profile of inpatients and outpatients at health facilities – the former usually requiring more tests than the latter. Also, as mentioned earlier, the inpatients in DHs have more severe morbidities and therefore require maximum number of tests per patient while CHCs and PHCs cater to relatively less morbid patients.

Table 3: Patient-to-test ratio – outpatients and inpatients

	DH	AH	CHC	PHC
OP	4.73	3.72	3.35	2.43
IP	6.23	4.05	4.09	-

Source: Service provider's data

The percentage of inpatients tested (out of total inpatients) was 12.4% in DHs, 5% in AHs, and 2% in CHCs. The fact that DHs cater to patients with most morbidity in IPD is reflected in the highest percentage of inpatients tested out of the total number of inpatients at these facilities compared to AHs and CHCs. However, the percentage of outpatients tested (out of total outpatients) in each kind of facility do not correlate with the profile of patients at these facilities. A significantly higher percentage of outpatients (out of total outpatients) were tested in CHCs (11.3%) and PHCs (9.7%) compared to DHs (8.5%). In AHs, the percentage of patients tested was same as in CHCs (11.3%) (table 4). The percentage should have been higher in AHs than in CHCs, considering that AHs offer more advanced care and cater to a higher disease burden than CHCs.

Table 4: Percentage of patients tested (patients tested/total number of patients) – outpatients and inpatients

	DH	AH	CHC	PHC
OP	8.5%	11.3%	11.3%	9.7%
IP	12.4%	5.0%	2.0%	-

Source: Service provider's data

3.3.3 Inter-district comparison

Inter-district comparison was carried out for total number of patients tested, tests conducted, percentage of patients tested (out of total patients) and patient-to-test ratio. Data for these parameters were compared across all districts and based on this analysis, districts were categorized into quartiles. For total number of patients tested and total number of tests conducted, data was compared for each month across all kinds of facilities. For patient-to-test ratios and percentage of patients tested, average for all months was compared for each type of facility as these two parameters vary with the type of facility.

Table 5 lists the districts in upper and lower quartile. Tables 6, 7 and 8 highlight districts in lower quartile (in red) and upper quartile (in yellow).

It was observed that for total number of patients tested and total number of tests conducted, there was an overlap among most of the districts in the two quartiles. Also, all districts falling in lower quartile for total number of patients tested and tests conducted were those with remote and hilly locations, and tribal populations. The patient-to-test ratios were, however, higher in most of tribal districts.

Table 5: Inter-district comparison – districts in upper and lower quartiles

	Number of patients tested	Number of tests conducted	Percentage of patients tested (number of patients tested/total number of patients at the facilities)	Patient-to-test ratio
Upper quartile	Ananthpur, East Godavari, Guntur, Krishna and West Godavari	Ananthpur, East Godavari,Guntur, Krishna and West Godavari		Krishna and Vizianagram (DHs); East Godavari and Prakasam (AHs); East Godavari, Visakhapatnam and Vizianagaram (CHCs and PHCs)
Lower quartile	Srikakulam, Visakhapatnam and Vizianagaram	Prakasam, Srikakulam, Visakhapatnam and Vizianagaram		Guntur and Kadapa (DHs); Chittoor, Guntur and Kadapa (AHs); Ananthpur, Kurnool and Srikakulam (CHCs); Chittoor, Kurnool and Srikakulam (PHCs)

Source: Service provider's data

Table 6: Inter-district comparison of number of patients tested

Inter-district comparison of patient load (patients tested)													
	Ananthapur	Chittoor	East Godavari	Guntur	Kadapa	Krishna	Kurnool	Nellore	Prakasam	Srikakulam	Visakapatnam	Vizianagaram	West Godavari
Jan-16	6507	3653	1857	5978	3648	1534	1982	2682	4821	998	1026	1562	3051
Feb-16	28211	15691	8101	15079	11434	17815	15197	10854	16225	8064	6030	8769	17901
Mar-16	44334	22800	21532	27866	19420	35927	27177	21149	27722	20173	15178	19962	39251
Apr-16	52228	28268	27889	28535	27195	32947	30861	23708	34536	19205	20906	19403	48337
May-16	62719	42480	33458	37108	32068	46701	33293	32433	58367	24135	26634	19052	49252
Jun-16	65390	37199	41743	41538	32426	52488	37450	37247	53669	31886	32937	25293	50672
Jul-16	64916	27156	55439	52866	39177	51795	40233	40681	50815	39396	35427	31951	57898
Aug-16	38208	25372	29743	28485	32207	30564	18642	25459	23042	14687	21094	16803	35485
Sep-16	40739	27836	34180	33451	34135	42644	22333	23588	19405	18709	23754	15283	31318
Oct-16	41409	26912	35819	38049	36719	45083	23264	23729	22954	21708	22990	14696	35400
Nov-16	40807	27784	27045	36094	33827	34246	26431	24252	19841	17463	19576	14236	34531
Dec-16	43150	29200	24362	32876	34766	32675	28106	25937	19408	13829	17636	14991	33939
Jan-17	39697	28593	22830	32806	33899	30252	26271	21864	19865	10764	13115	12935	33197
Feb-17	40895	29125	24411	32840	32162	28089	24282	23281	21186	14361	12219	14378	32457
Mar-17	44987	33398	29364	33893	30261	33663	27635	25366	23868	14528	15723	14833	37130
Apr-17	39288	31877	28462	32815	26990	31515	29635	25240	21900	10324	15455	12824	34591
May-17	43116	37600	33248	44025	31753	37945	33461	32541	28605	14245	21302	15260	40580
Jun-17	44635	37453	38796	44449	30350	37754	31255	37148	29274	15341	20165	18557	37760

Source: Service provider's data

Table 7: Inter-district comparison of number of tests conducted

Inter-district comparison for test load													
	Ananthapur	Chittoor	East Godavari	Guntur	Kadapa	Krishna	Kurnool	Nellore	Prakasam	Srikakulam	Visakapatnam	Vizianagaram	West Godavari
Jan-16	18759	16603	11696	21050	12334	7566	10061	12116	16745	5460	7414	10746	16668
Feb-16	72862	53661	40728	53336	31295	71007	51229	41752	57211	30732	30390	37422	77284
Mar-16	109533	66445	90740	91375	52048	126453	77113	74753	94647	61677	65944	82748	158466
Apr-16	112626	69960	99073	83870	66080	105608	72469	75294	102751	50341	73415	66390	170442
May-16	137398	113763	116512	105365	81025	141987	84758	80612	159537	62205	86677	68650	170916
Jun-16	143653	95585	143371	122657	87393	152617	88758	89100	164101	81154	114939	97993	187722
Jul-16	147706	72148	178915	159912	106267	170644	90012	93836	156522	86854	123066	120307	211665
Aug-16	93602	68041	109135	97948	87949	108991	54553	70544	75988	37209	83324	67397	142617
Sep-16	115542	96759	120775	110004	94923	144036	61792	69356	61812	45046	95845	60134	121769
Oct-16	113312	79769	125430	123668	107180	143099	65321	68646	72907	47604	91477	58229	134518
Nov-16	104690	78033	99719	108387	95735	111252	73647	67024	62808	40784	81246	59176	124975
Dec-16	111017	78601	90497	94923	96555	100041	75802	71116	61181	33200	70343	59531	123707
Jan-17	103808	80674	89926	98732	93382	93322	69392	65287	63191	28780	54547	51812	117024
Feb-17	106183	83572	93609	98842	84899	89604	67310	70068	67503	49091	51671	54803	117205
Mar-17	112061	92080	108516	98330	82655	101209	71165	71037	78257	38502	64722	53490	132577
Apr-17	97449	82986	99459	88358	73751	86275	72523	63236	70458	25549	65031	44549	112537
May-17	105716	95750	106881	116039	86351	101955	78056	70902	87167	31010	76141	53318	127333
Jun-17	107527	92185	124415	117129	81787	101746	74418	75310	85785	35668	71593	63042	123466

Source: Service provider's data

Table 8: Inter-district comparison of patient-to-test ratio

Inter-district comparison of Patient-to-test ratio													
Facility	Ananthapur	Chittoor	East Godavari	Guntur	Kadapa	Krishna	Kurnool	Nellore	Prakasam	Srikakulam	Visakapatnam	Vizianagaram	West Godavari
DH		4.6	5.2	3.6	4.1	5.7	5.0					6.2	5.5
AH	3.3	3.3	4.4	3.1	2.0	3.5	3.4	3.7	4.4	3.9	5.8	3.9	4.1
CHC	2.3	3.2	4.0	3.3	3.3	3.5	3.2	3.3	3.4	3.0	4.3	4.2	4.5
PHC	2.2	2.1	2.7	2.5	2.3	2.5	2.0	2.1	2.4	2.1	3.0	3.2	2.7

Source: Service provider's data

3.3.4 Monthly trends

Anecdotal evidence suggests that in the initial stages of rollout, there was resistance among doctors for ordering tests through the service provider due to their existing practice of referring patients to local private laboratories. The state government undertook stringent measures to increase the uptake of services under NTR Vaidya Pariksha scheme. State officials conducted weekly video conferences with doctors and district officers for monitoring utilization of services, kept a close watch on and followed up regularly with facilities with underutilization of services. During this period, the service provider also encouraged the doctors to prescribe tests to more patients. Because of these focused efforts, the uptake of services increased – total number of patients tested, tests conducted and percentage of patients tested (out of total patients) increased significantly in each type of facility from the time of rollout and peaked (increased by 2-3 times) in July 2016 (figures 5, 7 and 11).

Data for the peak period of July 2016 was compared to that of March 2016 (by when the rollout was almost completed in all types of facilities). The total number of patients tested increased by 250 000 (72%) and total number of tests conducted increased by 560 000 (49%). Total number of patients who visited government health facilities increased by 900 000 (29%) (figure 13). This indicates a sharp uptake in services, more so for total number of patients tested than for total number of tests conducted (figure 5 and 7).

Data for increase in uptake of services was also studied for each type of facility from time of rollout at each level (more than 85% rollout) till the peak in July 2016. The total number of patients tested increased in DHs by 235%, 213% in AHs, 202% in CHCs and 208% in PHCs. In the same period, total number of tests conducted increased in DHs by 178%, in AHs by

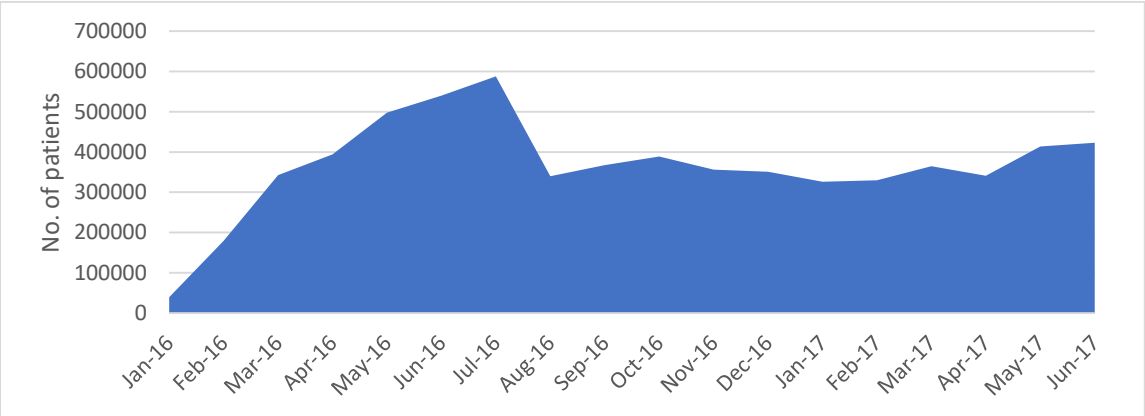
197%, in CHCs by 120% and in PHCs by 76% (figure 6 and 8). Many screening camps were organized in schools, communities etc., on request of district health officers or doctors of government health facilities. The population tested through these camps was counted in the respective PHC or CHC of the concerned area. This contributed to an increase in the numbers at the PHCs and CHCs.

The increase in total number of patients tested was more than the increase in total number of tests conducted at PHCs and CHCs and relatively lesser at DHs.

The percentage of patients tested (out of total patients) from January 2016 to July 2016 increased in DHs from 4.1% to 9.3%, in AHs from 5.9% to 10%, in CHCs from 7.1% to 15.3% and in PHCs from 8.6% to 14.4%. The data indicates that uptake of services increased the most in CHCs, followed by PHCs (figure 6 and 8).

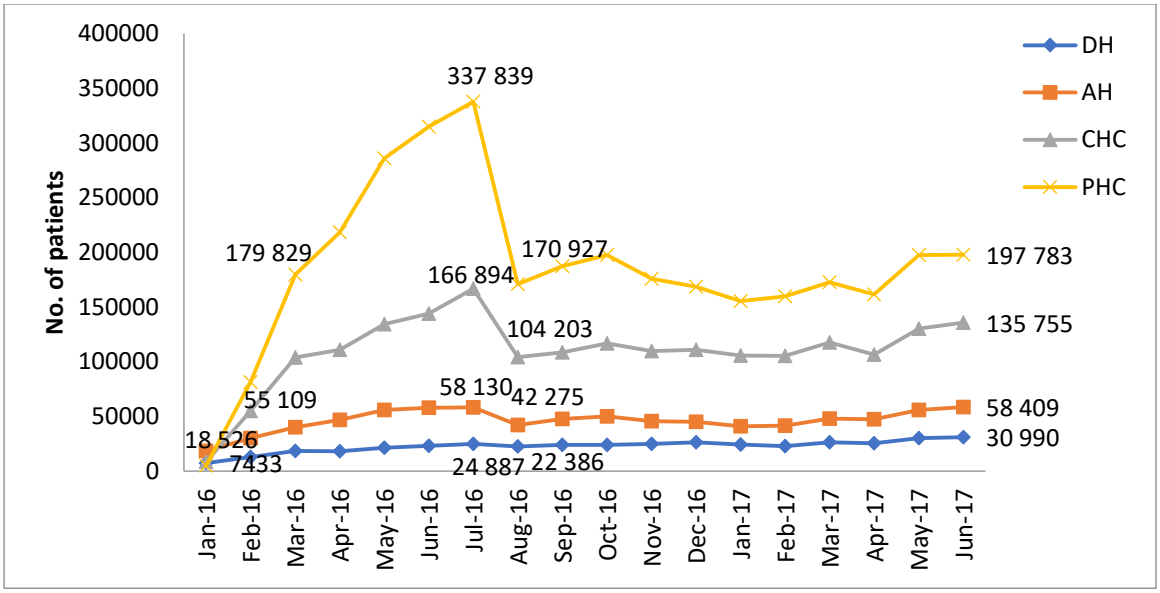
In all types of facilities, the patient-to-test ratio was the highest in the first month of rollout (January for DHs, AHs, CHCs and February for PHCs) after which a significant fall was seen in the next few months. The ratios were compared from the respective commencement of the rollout to July 2016. The ratios fell from 4.3 to 2.9 across different types of facilities, from 6.2 to 5.2 in DHs, from 3.8 to 3.6 in AHs, from 4.7 to 3.3 in CHCs and from 2.7 to 2.5 in PHCs (figure 9 and 10). This corroborates with the finding above of a much higher increase in the total number of patients tested compared to the total number of tests conducted in this period. During the survey, it was found that initially, few doctors prescribed many tests to patients, when some of these tests were not required.

Figure 5: Monthly trends in total number of patients tested



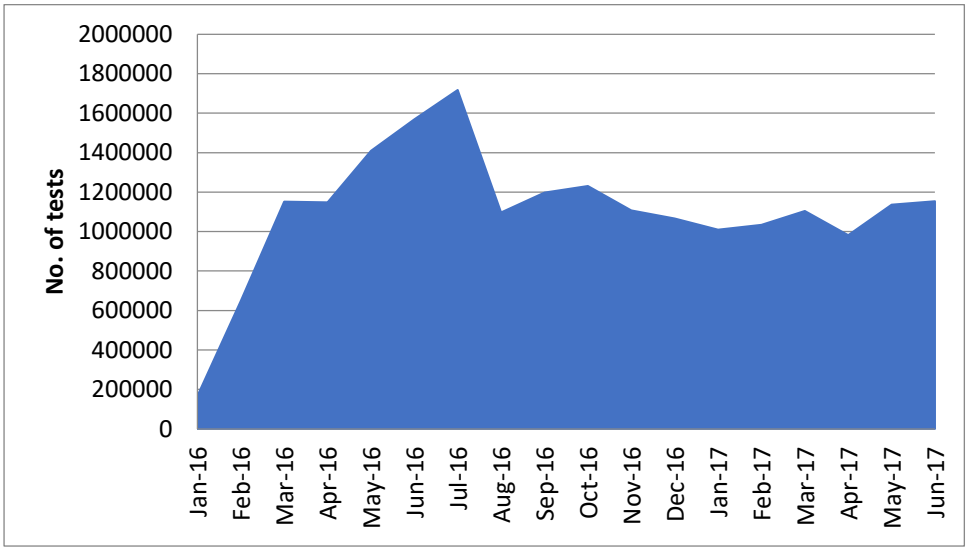
Source: Service provider's data

Figure 6: Monthly trends in total number of patients tested at each kind of facility



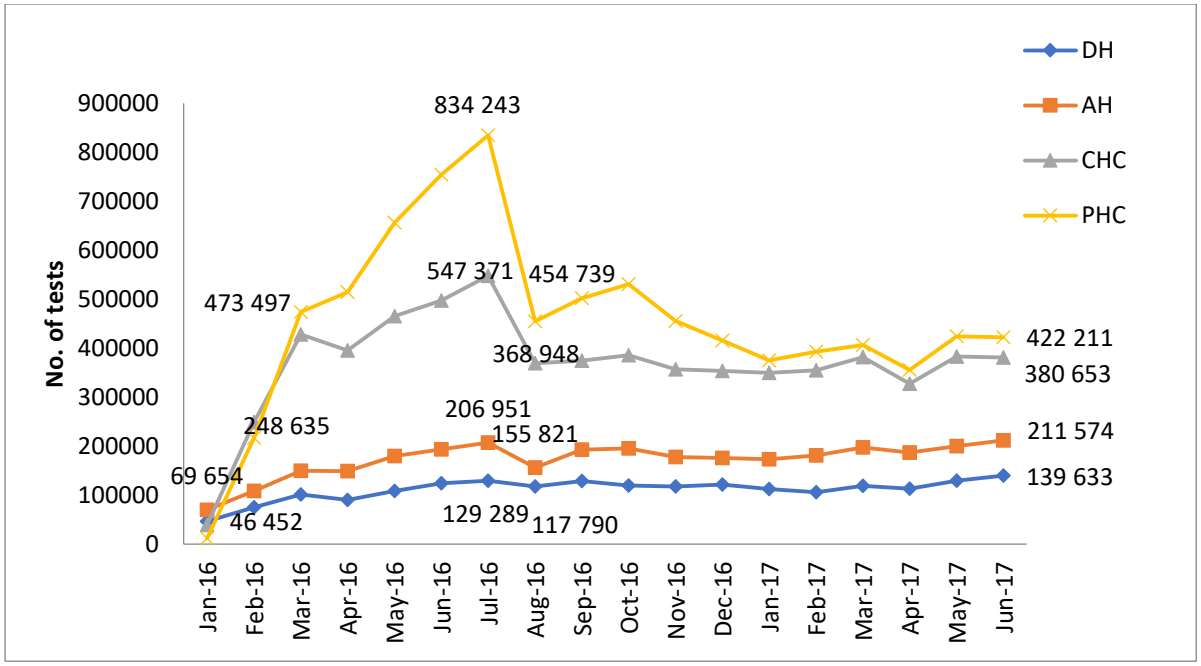
Source: Service provider's data

Figure 7: Monthly trends in total number of tests conducted



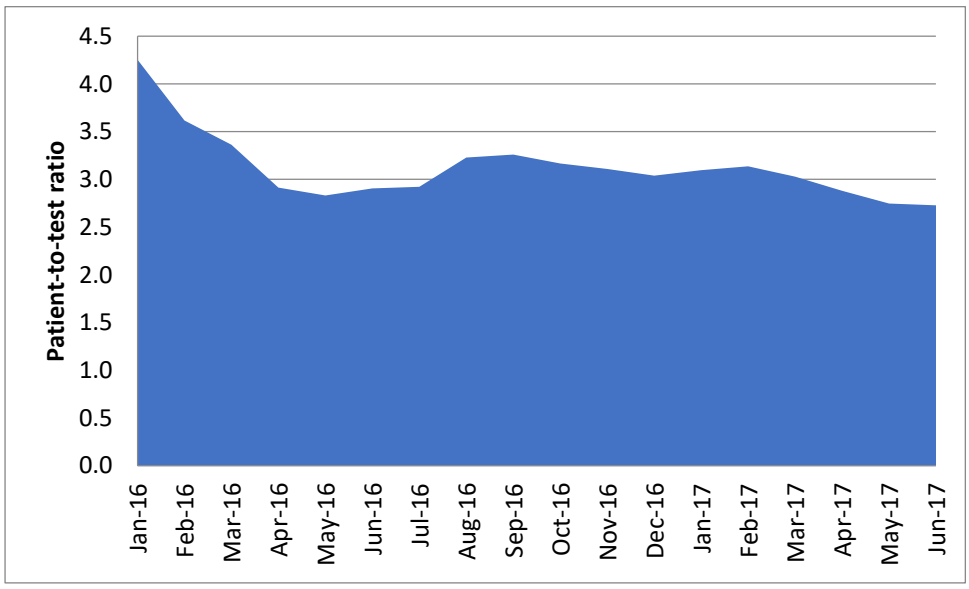
Source: Service provider's data

Figure 8: Monthly trends in total number of tests conducted at each type of facility



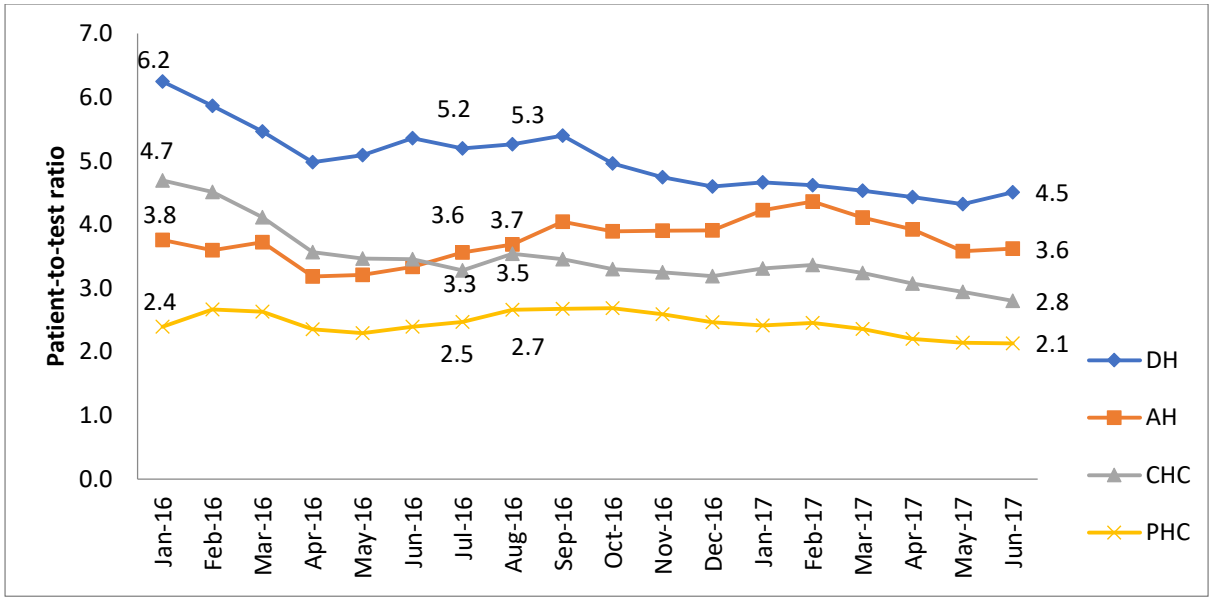
Source: Service provider's data

Figure 9: Monthly trends in patient-to-test ratio



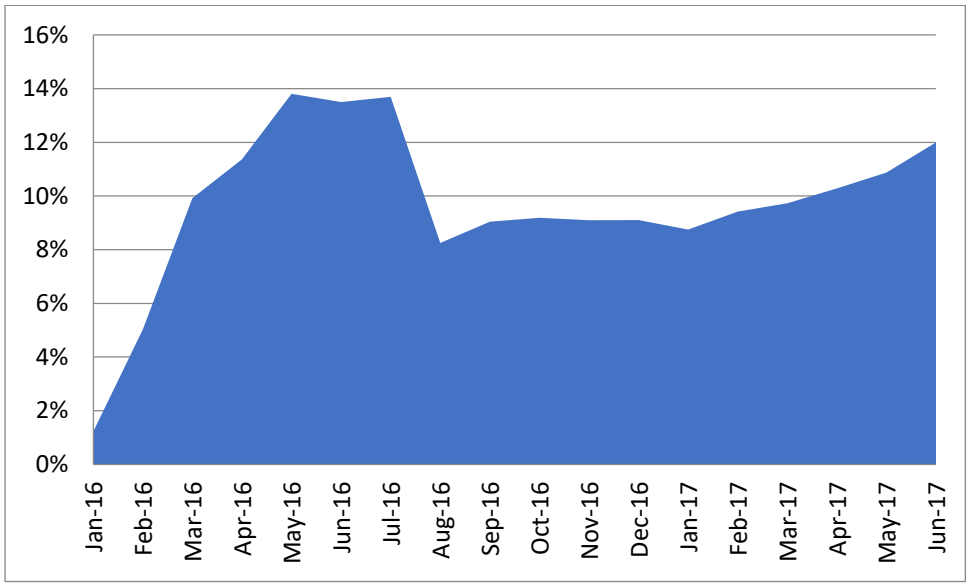
Source: Service provider's data

Figure 10: Monthly trends in patient-to-test ratio at each type of facility



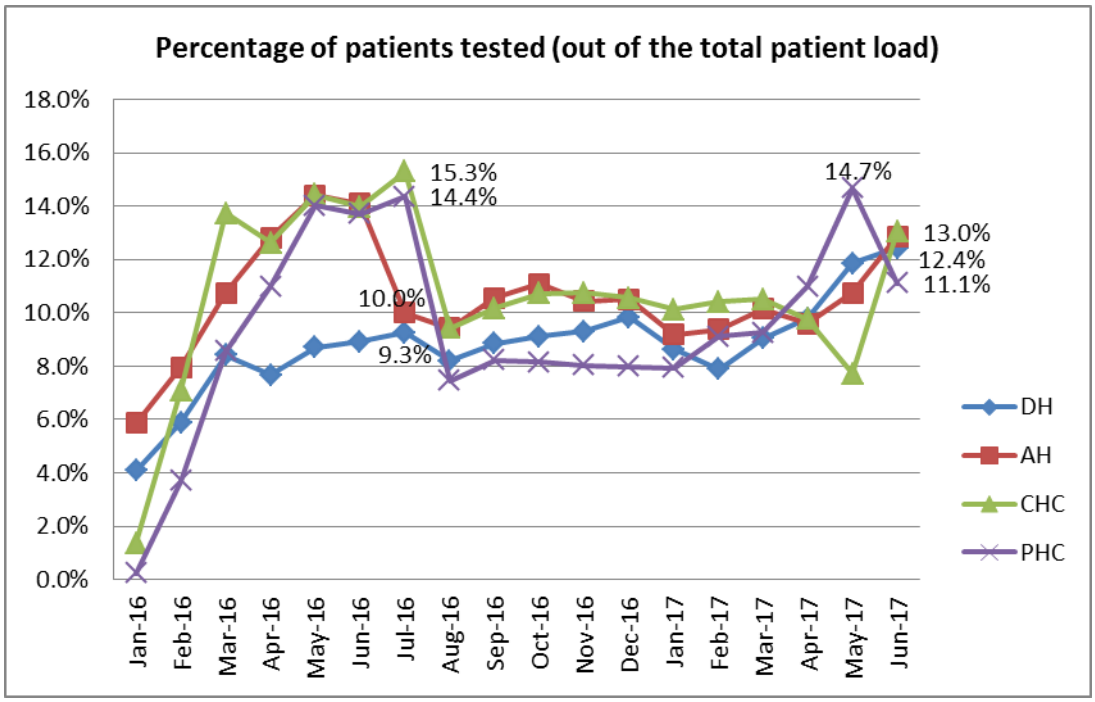
Source: Service provider's data

Figure 11: Monthly trends in percentage of patients tested (out of total patients)



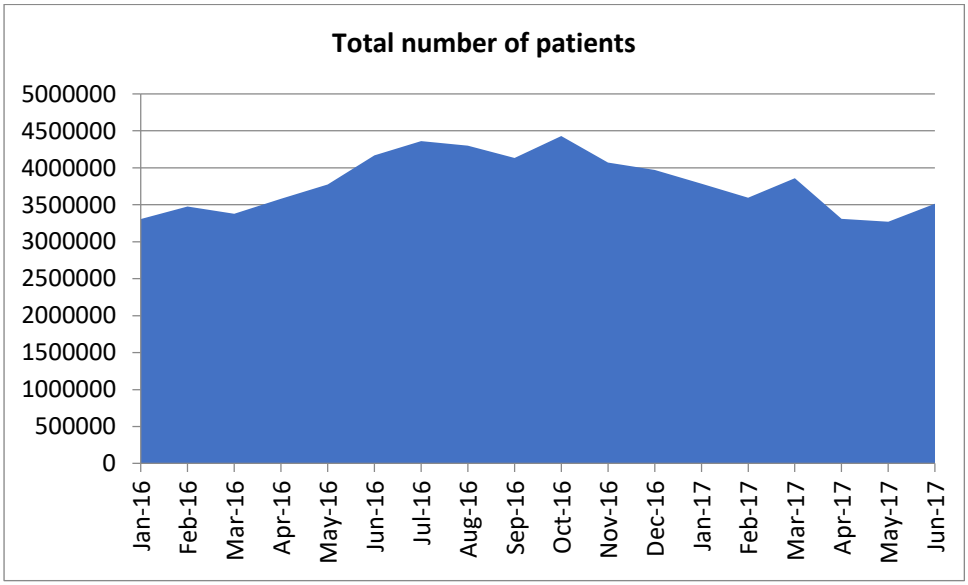
Source: Service provider's data

Figure 12: Monthly trends in percentage of patients tested (out of total patients) at each type of facility



Source: Service provider's data

Figure 13: Monthly trends in total number of patients who visited government health facilities



Further to facilitating a substantial increase in uptake of services within the first 7 months of rollout as clearly reflected in the increase in percentage of patients tested (out of total patients), the total number of patients tested and tests conducted, the state government moved to the next level of rationalizing the utilization of services by keeping a check on the percentage of patients (out of total patients) who were ordered tests. The doctors at government health facilities were directed by the state government in July 2016 not to prescribe tests to more than 10–15% of outpatients. The screening camps were also discontinued. As a result, there was a considerable drop in the total number of patients

tested (42%) and total number of tests conducted (36%) from July 2016 to August 2016 (table 9). The percentage of patients tested (out of total patients) also reduced from 13.7% to 8.2% (table 11). This drop could not have been due to seasonal variation as May–September is the peak season for weather-related illnesses. Also, the total number of patients who visited the health facilities reduced only by 1% from July 2016 to August 2016. The patient-to-test ratio increased by 10% (0.3 points) in this period (table 9). This could indicate that the tests were now being prescribed only to patients who needed them.

The fall in total number of patients tested and tests conducted was more significant in PHCs and CHCs compared to DHs and AHs. The reduction in total number of patients tested and total number of tests conducted in PHCs was 49% and 45%, respectively, followed by CHCs – 38% and 33%, respectively, and AHs – 27% and 25%, respectively. In DHs, the reduction in total number of patients tested and tests conducted was much lesser – 10% and 9%, respectively. In DHs and AHs, the reduction was seen only in outpatients; inpatients on the contrary saw an increase. In CHCs, the reduction was seen in both outpatients and inpatients with lesser reduction in inpatients compared to outpatients (table 10).

The drop in the percentage of patients tested (out of total patients) was the most significant in PHCs (from 14.4% to 7.5%) and CHCs (from 15.3% to 9.4%) and minimal in DHs (from 9.3% to 8.2%) and AHs (from 10% to 9.4%) (table 12).

Patient-to-test ratio increased in August 2016 compared to July 2016. The increase in patient-to-test ratio was the highest in PHCs (8%) and CHCs (8%) followed by AHs (4%) and DHs (1%) (table 9). The increase in overall patient-to-test ratio was more in outpatients (10%) than inpatients (5%). In AHs, the patient-to-test ratio increased in outpatients by 4% and reduced in inpatients by 3%. CHCs saw an increase in the ratio in both outpatients (8%) and inpatients (6%). In DHs, the ratio reduced marginally in outpatients (1%) and increased in inpatients (8%). In PHCs, the ratio in outpatients increased by 8% (table 10).

Data was also analyzed for change in prescription of individual tests from July 2016 to August 2016. In PHCs, the prescription of all types of tests reduced in number from July 2016 to August 2016, including a significant transient reduction (for August 2016) in prescription of dengue test. This transient fall was seen in the peak season of dengue. The tests for dengue again increased in PHCs in September-October 2016 to almost same value as July 2016 corroborating with high season of the disease. Prescription of platelet count test (a supportive test used for detecting low platelet count in suspected dengue patients) did not bounce back. The demand for this test did not pick up after falling in August 2016. In CHCs, prescription of dengue test increased and of all other tests reduced.

Among outpatients at DHs, prescription of dengue test and platelet count test increased, corroborating with the high season of dengue. Few other tests, such as urine culture and peripheral blood smear also increased in number. However, prescription of other advanced tests such as blood culture, histopathology, cytology, fluid examination and semen analysis reduced transiently in August 2016. Since these advanced tests are ordered only when required, there is a possibility that these tests were sent to private laboratories in the same month. Also, serum electrolytes reduced by 20%, troponin by 42%, HbA1C by 18% and TSH by 38%. The most common routine tests, such as CBC, serum creatinine, serum bilirubin, did not decrease or showed slight reduction. Possibly, the doctors reacted to the state government’s intervention of rationalizing utilization of services by reducing prescription of

advanced and IPD tests; these tests, too, did not meet expectations of the doctors in terms of accuracy and/or turnaround time. In AHs, the prescription of dengue and platelet count tests increased. However, unlike DHs, AHs showed an increase in tests like blood culture, fluid examination, prothrombin time and troponin. Tests, such as urine culture, serum electrolytes, histopathology, and cytology, showed reduction. TSH and HbA1C reduced by 28% and 36%, respectively. The most common routine tests, such as CBC, serum creatinine and serum bilirubin also showed significant reduction.

The changes in parameters from July 2016 to August 2016 suggest that the state government's intervention for rationalization of services worked well for PHCs and CHCs where there was a probable overuse of services. A significant reduction in the percentage of patients tested (out of total patients), total number of patients tested and tests conducted as well as an improved patient-to-test ratio in these facilities even over the next few months indicate that a new equilibrium was created in utilization of services at PHCs and CHCs. DHs, on the other hand were not affected except a transient reduction in prescription of advanced tests.

Table 9: Percentage change in total number of patients, total number of patients tested, tests conducted and patient-to-test ratio from July 2016 to August 2016

	Total number of patients	Total number of patients tested	Total number of tests conducted	Patient-to-test ratio
All facilities	-5%	-42%	-36%	+10%
DH	2%	-10%	-9%	+1%
AH	-23%	-27%	-25%	+4%
CHC	1%	-38%	-33%	+8%
PHC	-4%	-49%	-45%	+8%

Source: State government and service provider's data

Table 10: Percentage change in total number of patients tested, tests conducted and patient-to-test ratio from July 2016 to August 2016 – OPD and IPD

		Total number of patients tested	Total number of tests conducted	Patient-to-test ratio
All facilities	OPD	-43%	-37%	10%
	IPD	0.05%	6%	5%
DH	OPD	-12%	-13%	-1%
	IPD	5%	12%	8%
AH	OPD	-29%	-26%	4%
	IPD	16%	12%	-3%
CHC	OPD	-38%	-33%	8%
	IPD	-29%	-24%	6%
PHC	OPD	-49%	-45%	8%

Source: Service provider's data

Table 11: Percentage of patients tested (total number of patients tested/total patients) in July 2016 and August 2016

	July 2016	August 2016
All facilities	13.7%	8.2%
DH	9.3%	8.2%
AH	10.0%	9.4%
CHC	15.3%	9.4%
PHC	14.4%	7.5%

Source: State government and service provider's data

Table 12: Percentage of patients tested (total number of patients tested/total patients) in July 2016 and August 2016 – OPD and IPD

		July 2016	August 2016
All facilities	OPD	14%	9%
	IPD	22%	10%
DH	OPD	9%	8%
	IPD	12%	13%
AH	OPD	11%	10%
	IPD	5%	4%
CHC	OPD	16%	10%
	IPD	3%	2%
PHC	OPD	15%	8%

Source: State government and service provider's data

During this period, the state government also intensified the monitoring the quality of services. The percentage of tests with results outside normal reference range were very low till July 2016 and increased drastically from 8% in July 2016 to 33% in August 2016. The increase was the most significant in CHCs (from 8% to 42%) (table 13). All kinds of tests showed an increase in the percentage of results with abnormal values.

Table 13: Percentage of tests with results outside normal reference range in July 2016 and August 2016

	July 2016	August 2016
All facilities	8%	33%
DH	9%	35%
AH	10%	37%
CHC	8%	42%
PHC	8%	24%

Source: Service provider's data

After a significant fall in August 2016 in the percentage of patients tested (out of total patients), total number of patients tested and tests conducted, an upward trend was observed in the next two months in these parameters (figures 5, 7 and 11). The patient-to-test ratio remained high (figure 9). During the period August 2016–October 2016, the total number of patients did not show any significant change. This indicates that the uptake of services by the doctors increased slightly, possibly because of seasonal infections.

During November 2016–January 2017, there was a fall in the total number of patients at health facilities and a parallel fall in the percentage of patients tested (out of total patients), total number of patients tested, tests conducted and patient-to-test ratio (figure 5, 7, 9 and 11). The decreasing trend corroborated with the waning of seasonal infections. The decrease in this period was not seen in DHs for any of the parameters. In AHs, CHCs and PHCs, the reduction in the total number of patients tested was less compared to reduction in the total number of tests conducted (figure 6 and 8).

In February 2017, an ascending trend was seen in the total number of patients at health facilities, percentage of patients tested (out of total patients), total number of patients tested and tests conducted; followed by a significant increase in these parameters during May 2017–June 2017 (figure 5, 7 and 11) corroborating with the commencement of period of seasonal infections. The total number of patients tested increased by a higher percentage than the total number of tests conducted which is also reflected in reduction in patient-to-test ratio during this period (figure 5, 7 and 9). The significant increase in the percentage of patients tested (out of total patients) during May 2017–June 2017 at all types of facilities (figure 12) implies higher usage of services during the period of seasonal infections. However, more analysis and closer monitoring are required to assess if the trend is moving towards overuse of services at PHCs and CHCs.

3.3.5 Year-on-year trends

A comparison was done between data for 2016 and 2017 for various parameters – percentage of patients tested (out of total patients), total number of patients tested, tests conducted and patient-to-test ratio. For this comparison, period of March 2016 – June 2016 for both years was considered. This is because secondary data was collected till June 2017; and January and February were excluded as the rollout in PHCs was completed in March 2016 only.

There was 1% decrease in the total number of patients at government health facilities in 2017 (March–June), compared to year 2016 (March 2016–June 2016). However, decrease in utilization of services under NTR Vaidya Pariksha scheme from year 2016 to 2017 was significantly higher (13% in total number of patients tested and 17% in total number of tests conducted). This indicates that utilization of laboratory services under NTR Vaidya Pariksha scheme decreased from 2016 to 2017. This is also evident from the reduction in percentage of patients tested (out of total number of patients), which decreased from 12.1% in year 2016 to 10.7% in year 2017. The decrease in utilization of laboratory services was mainly seen in CHCs and AHs. The percentage of patients tested (out of total patients) in CHCs reduced significantly from 13.7% (2016) to 10.3% (2017). The total number of patients in CHCs increased by 37%, while the total number of patients tested reduced by 1% and number of tests conducted reduced by 18%. In AHs, the percentage of patients tested (out of total patients) reduced from 13% (2016) to 10.8% (2017). The total number of patients in these facilities increased by 26%, while total number of patients tested only increased by 4% and

number of tests conducted increased by 19%. The reduction in utilization of services from 2016 to 2017, especially at CHCs, could again point to a possible overuse of services in 2016 which was optimized at a later stage in these facilities. In DHs, the demand for services under NTR Vaidya Pariksha scheme did not reduce and rather increased from year 2016 and 2017 indicating that the services would have been optimally utilized in 2016. The percentage of patients tested (out of total patients) in DHs increased from 8.4% (2016) to 10.8% (2017). The total number of patients in these facilities increased by 10%, and at the same time the total number of patients tested and number of tests conducted increased by 39% and 18%, respectively. In PHCs, the total number of patients and total number of patients tested and tests conducted decreased proportionately (23%, 27% and 33%, respectively). The percentage of patients tested (out of total patients) in these PHCs reduced from 11.8% to 11.5%. However, PHCs had shown a significant fall in the percentage of patients tested (out of total patients) in August 2016 (March 2016–June 2016). The percentage of patients tested in PHCs again picked up in 2017 and matched with that of March 2016–June 2016 (table 14 and 15).

The total number of patients tested and tests conducted decreased among outpatients by 14% and 18%, respectively and increased among inpatients by 16% and 1%, respectively in 2017 (table 16).

The patient-to-test ratio in 2017 was significantly lower compared to the corresponding months in 2016 in DHs, CHCs and PHCs. In AHs, the trend was reverse. In DHs, CHCs and PHCs, the ratios were mostly lower in 2017 for both inpatients and outpatients, while in AHs, the ratios were higher for both inpatients and outpatients in 2017 (table 17 and 18). Reduction in patient-to-test ratio is also reflected in a significant increase in single test prescriptions from average of 30% in 2016 to 38% in 2017. According to the service provider, the AYUSH doctors at CHCs overprescribed the number of tests in the initial stages of rollout.

Table 14: Percentage change in total number of patients, total number of patients tested and tests conducted from 2016 to 2017 (March-June 2016 and March-June 2017)

	Total number of patients	Total number of patients tested	Total number of tests conducted
All facilities	-1%	-13%	-17%
DH	10%	39%	18%
AH	26%	4%	19%
CHC	37%	-1%	-18%
PHC	-23%	-27%	-33%

Source: State government and service provider's data

Table 15: Change in percentage of patients tested (out of total patients) from 2016 to 2017 (March-June 2016 and March-June 2017)

	Average percentage of patients tested from March-June 2016	Average percentage of patients tested from March-June 2017
Overall	12.1%	10.7%
DH	8.4%	10.8%
AH	13%	10.8%
CHC	13.7%	10.3%
PHC	11.8%	11.5%

Source: State government and service provider's data

Table 16: Percentage change in total number of patients tested and tests conducted from 2016 to 2017 (March-June 2016 and March-June 2017) – OPD and IPD

		Total number of patients tested	Total number of tests conducted
All facilities	OPD	-14%	-18%
	IPD	16%	1%
DH	OPD	38%	18%
	IPD	44%	20%
AH	OPD	2%	16%
	IPD	60%	72%
CHC	OPD	0%	-16%
	IPD	-43%	-66%
PHC	OPD	-27%	-33%

Source: Service provider's data

Table 17: Month-on-month comparison of patient-to-test ratio (2016 and 2017)

	DH	AH	CHC	PHC
January	-1.6	0.5	-1.4	0.0
February	-1.2	0.8	-1.1	-0.2
March	-0.9	0.4	-0.9	-0.3
April	-0.5	0.7	-0.5	-0.2
May	-0.8	0.4	-0.5	-0.1
June	-0.8	0.3	-0.7	-0.3

Source: Service provider's data

Table 18: Month-on-month comparison of patient-to-test ratio in OPD and IPD (2016 and 2017)

		DH	AH	CHC	PHC
January	OP	-1.8	0.4	-1.4	0.0
	IP	-0.2	1.2	-2.8	-
February	OP	-1.3	0.7	-1.1	-0.2
	IP	-0.7	1.1	-2.3	-
March	OP	-0.9	0.4	-0.8	-0.3
	IP	-1.3	0.5	-2.4	-
April	OP	-0.5	0.7	-0.5	-0.2
	IP	-1.8	0.6	-2.0	-
May	OP	-0.8	0.4	-0.5	-0.1
	IP	-0.6	0.2	-1.9	-
June	OP	-0.7	0.3	-0.6	-0.3
	IP	-0.9	0.0	-1.5	-

Source: Service provider's data

3.3.6 Profile of patients

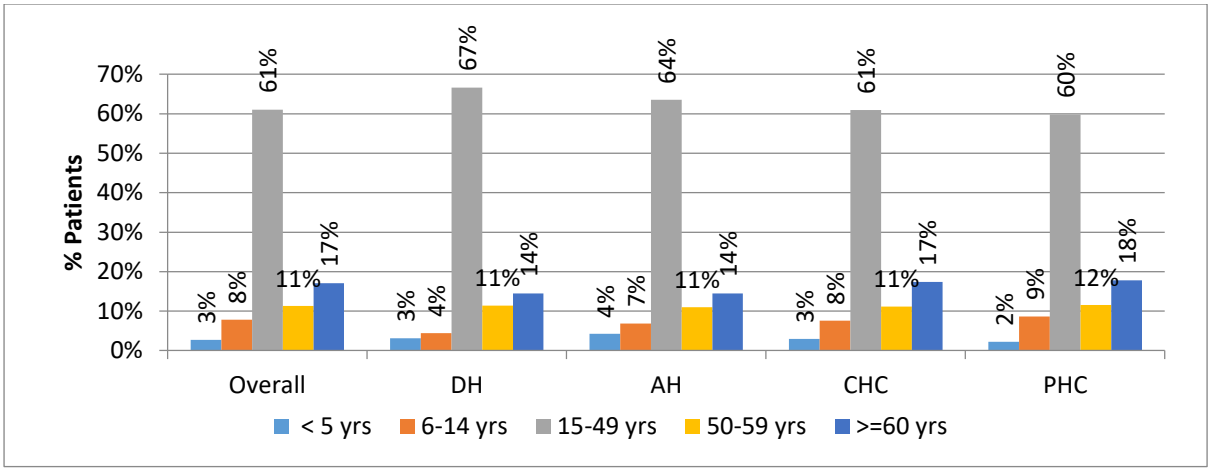
Age distribution

Among patients tested under NTR Vaidya Pariksha scheme during January 2016–June 2017, 3% were children up to 5 years of age, 8% were between 6–14 years, 61% between 15–49 years, 11% between 50–59 years and 17% were of 60 years and above. Maximum number of patients in the age group 15–49 years could be explained by a high number of women in the age group who visit health facilities for delivery. The percentage of patients tested in the age group 15–49 years were higher in DHs (67%) and AHs (64%) compared to CHCs (61%) and PHCs (60%) (figure 14).

A higher percentage of geriatric population was tested in CHCs and PHCs as compared to DHs and AHs. This corroborates with the fact that geriatric patients with chronic diseases visit nearby CHCs and PHCs for regular follow-ups (figure 14).

In DHs, the percentage of children under the age of 14 years was the least as compared to the other types of facilities. Also, percentage of children below 5 years was slightly lesser in PHCs as compared to the other types of facilities (figure 14).

Figure 14: Age-wise distribution of patients tested under NTR Vaidya Pariksha scheme



Source: Service provider's data

Inter-district comparison for age-group distribution of patients shows that the percentage of children under 14 years who used services under NTR Vaidya Pariksha scheme was the least in Krishna, Nellore and Srikakulam districts (table 19).

Table 19: Inter-district comparison for age group distribution of patients

District name	Age<=5 years	Age 6–14 years	Age 15–49 years	Age 50–59 years	Age >=60 years
All districts	3%	8%	61%	11%	17%
Ananthapur	4%	9%	61%	10%	16%
Chittoor	3%	7%	60%	11%	19%
East Godavari	3%	9%	62%	11%	15%
Guntur	2%	8%	62%	11%	17%
Kadapa	4%	10%	59%	11%	17%
Krishna	2%	6%	61%	13%	18%
Kurnool	3%	8%	67%	9%	13%
Nellore	1%	5%	57%	14%	23%
Prakasam	4%	7%	54%	13%	22%
Srikakulam	2%	7%	61%	12%	17%
Visakapatnam	3%	10%	65%	10%	12%
Vizianagaram	3%	13%	60%	10%	14%
West Godavari	2%	7%	63%	11%	17%

Source: Service provider's data

Gender distribution

Among patients tested under the scheme, female patients comprised 58% of the total patients. The percentage of women tested gradually increased in the last few months (February 2017–June 2017). The percentage of female patients varied from 55% to 60% in various districts.

Tribal patients

Tribal patients comprised 5% of the total patients tested under NTR Vaidya Pariksha scheme. The tribal belts are primarily located in six districts. The number of tribal patients tested decreased by 17% from 2016 (March-June) to 2017 (March-June). Maximum fall was seen in Srikakulam (50%). On the other hand, Kurnool and East Godavari saw an increase in the number of tribal patients tested (30% and 14%, respectively) (table 20).

Table 20: Total number of tribal patients tested with comparison of years 2016 and 2017

District	Total number of tribal patients tested till June 2017	Percentage of tribal patients out of total patients tested till June 2017	Percentage change in total number of tribal patients tested from 2016 (March-June) to 2017 (March-June)
All districts	346 931	5%	-17%
West Godavari	97 479	14%	-36%
Vizianagaram	73 206	24%	-31%
East Godavari	72 729	13%	14%
Kurnool	49 188	12%	30%
Visakhapatnam	42 853	13%	-7%
Srikakulam	11 476	3%	-50%

Source: Service provider's data

3.4 Service delivery

3.4.1 Sample collection at government health facilities

The service provider is providing sampling services at all health facilities, except few remote PHCs. Sampling stations have been set up at these facilities by the service provider, which are staffed by its phlebotomists. These phlebotomists carry out registration, collection, labelling, storage and dispatching samples. In DHs, the phlebotomists are stationed round-the-clock. In AHs, CHCs and PHCs, Sundays and public holidays are non-working, however they are available on call in AHs.

According to the service provider, 1467 phlebotomists were stationed at 1360 government health facilities under NTR Vaidya Pariksha scheme. The number of phlebotomists stationed by the service provider at each of the government health facilities was adequate. On an average, 3-4 phlebotomists were stationed on shift duties in DHs and AHs, two in most of the CHCs and one in all PHCs and few CHCs. In eight PHCs in Visakhapatnam, the phlebotomists were sent on alternate days because of remote location or unavailability of doctor at the PHCs. During the survey, it was observed that one phlebotomist was stationed at all PHCs and 1-3 were stationed at CHCs (3-in-1 CHC, 2-in-3 CHCs and 1-in-4 CHCs). One CHC was found to be overstaffed with three phlebotomists, and one phlebotomist was also conducting some of the in-house tests (rapid kit tests) despite the availability of two in-

house technicians who were doing only paper work. One phlebotomist was sitting with the doctor and filling requisition forms. The samples collected on the day of visit were only four, indicating the need for rational staffing by the service provider and close supervision by the administrators at government health facilities. In one AH, there were three phlebotomists and in the other AH there was only one. In the latter AH, the state government had not officially informed the service provider about its upgradation from CHC. Six phlebotomists were stationed (on shift duties) in one DH and three in the other DH (on shift duties). In DH with six phlebotomists, more phlebotomists were provided during OPD hours to manage the heavy patient load. It was observed that only one phlebotomist out of the four stationed during OPD hours was drawing samples and the others were documenting registration, dispatching report and sample. Availability of only one phlebotomist for sampling was leading to long waiting time for patients in the queue.

In most of the facilities, the phlebotomists were available for sampling on all working days. Many facilities reported that the service provider's phlebotomists did not take many leaves; and a replacement was provided in case of absence. In one PHC, the phlebotomist was reported to be unavailable for one day on two instances. In one CHC, the phlebotomist had quit, and a replacement was provided for few days. However, during the transition there was no phlebotomist for three days at the facility. In another PHC, the phlebotomist was unavailable for 4-5 days in a month and no replacement was provided by the service provider. In four out of eight PHCs, replacement was not sent by the service provider and in two of these PHCs, the in-house laboratory technician carried out sampling for the service provider's tests. In CHCs with two phlebotomists, the other phlebotomist stationed at CHC managed the sampling in the absence of one phlebotomist. In remaining four CHCs with one phlebotomist, replacement was not sent in three CHCs. In two out of the three CHCs, the in-house laboratory technician carried out sampling. In one AH (which was still a CHC in the service provider's list), no replacement was sent during the absence of a phlebotomist. Many times, in case of unavailability of a phlebotomist at a CHC/PHC, service provider shifted its phlebotomist from another PHC, thus leaving the latter facility without a phlebotomist. Hence, replacement of phlebotomists needs to be ensured universally by the service provider without compromising sampling services anywhere.

At several facilities, there was no communication to the staff at government facilities about the absence of service provider's phlebotomists. Attendance records for phlebotomists were maintained in some of the government health facilities (four out of eight PHCs, two out of eight CHCs and none of the AHs and DHs). Since phlebotomists' attendance records are not available at all health facilities, the state government cannot accurately estimate and closely monitor breakdown of sampling services at these facilities.

In all facilities, except one DH, one AH and one CHC, sampling area was common for service provider's and in-house laboratory staff. In five out of eight PHCs, seven out of eight CHCs and one AH, there was no dedicated sampling area and sampling was carried out in the testing laboratory itself.

All facilities had a waiting area which was common for in-house laboratory and service provider. The waiting area was clean in all facilities. The waiting area in PHCs and CHCs was the same as that for OPD rooms. It was observed that a few PHCs (two out of eight) and CHCs (three out of eight) did not have adequate space for patients waiting in the queue. In many PHCs (five out of eight) and CHCs (five out of eight); and in one out of two DHs,

seating in the waiting area was not adequate. There was no separate counter for patient registration in any of the surveyed facilities. The registrations were carried out in the sampling area. The reports were also dispatched at the same station except one DH which had a dedicated report dispatch counter.

The timings for sample collection were 9:00–16:00 in four out of eight PHCs and seven out of eight CHCs. In other four PHCs, one CHC and one AH, the timings were 9:00–14:00. In the other AH, the timings were 9:00–16:00; and in DHs, services were provided round-the-clock. The timings for laboratory services were not displayed in any facility. In one of the surveyed PHCs, the government health facility sent the data of that day to the state government by 14:30 and patients reaching afterwards were refused services although sample was dispatched after an hour. These patients were called on the next day for providing their samples.

There were no tests which were available to patients only on specific days. This means that patients could get all the prescribed tests done in the same visit. On Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) day which is on the 9th of every month, the ANC case load was very high across facilities leading to a higher test load.

In all facilities, all designated tests were provided by the service provider. However, occasional breakdown of services was observed in terms of unavailability of individual tests. In one AH, tests for serum bilirubin and serum creatinine were not available many times in the initial stages of the rollout. In the other AH, TSH was not available for 10 days at a stretch a few months before the survey. In three facilities, CBC was not available for one day. In Visakhapatnam, a CHC was upgraded to AH but the list of tests provided by the service provider was not upgraded yet. In the other AH, fluid examination and FNAC were not provided. Also, in both DHs, bone marrow examination was not provided and in all surveyed AHs and DHs, no provision had been made for a pathologist to collect sample for FNAC. In the initial stages of the rollout, cultures were not made available at one DH and one AH. When made available, turnaround time for the culture report was 15 days and therefore the test was not useful. A few days before the survey, blood culture bottles were not supplied on two occasions in one of the surveyed DH. A surveyed AH reported unavailability of select tests such as fluid examination, blood culture in the initial stages of the rollout. The medical superintendent informed the higher authorities about the unavailability of services. In the other AH, the tests provided were of CHC level as it had recently been upgraded from CHC. It is important that the service provider is provided official communication by the state government about upgradation of any facility so that the service provider can make provision for requisite tests according to the new status of the facility.

In most facilities, consumables for sampling were found to be adequate in number and of good quality. In two CHCs, plain tubes, PT tubes and urine pots were not in adequate quantity.

Sampling methodology of the service provider's phlebotomists was found to be accurate in facilities wherever it was observed. The samples were labelled properly using pre-printed barcodes. Barcodes were also put on the patient's requisition form, registration register and batch sheet. However, in one DH, labelling was not done by the phlebotomist at the time of sampling; samples with patients' requisition forms were handed over to the registration staff for registration and labelling.

There was a provision for round-the-clock sampling for emergency cases in one AH and both DHs. In AHs, it was found that when phlebotomists were not physically present in the hospital, the doctors did not call the service provider for sampling even if there was a requirement. There was no provision for round-the-clock sampling for emergency cases at PHCs and CHCs except in one CHC where phlebotomist was on call till 20:00, but had never been called so far.

It was observed that phlebotomists of the service provider did not wear complete personal protective gear, majority of them only wore laboratory coat and did not wear mask and gloves. Biomedical waste guidelines were being partly followed in all the surveyed AHs and DHs. In majority of the surveyed PHCs and CHCs, these guidelines were not followed. The colour-coded waste bags were missing. It was observed in many facilities (all types) that phlebotomists were removing needles by hand, recapping the needles or keeping the uncapped needles aside without breaking. The needle cutter was not working in many facilities.

In Visakhapatnam, seven PHCs (out of 87) had zero samples for at least three months since the time the programme was rolled out. In majority of cases, the reasons cited for zero samples were difficulty in recruiting phlebotomists in remote locations and absence of government doctors at the PHCs. In few of these PHCs, the phlebotomists went only 2-3 times a week because of unavailability of doctors.

Cold chain is a crucial component for maintaining sample integrity. It was maintained well at many of the surveyed facilities where samples were kept in a cool box containing ice packs. At the same time, inconsistencies in cold chain were observed at a few facilities. The samples were usually lying in PHCs and CHCs for up to five hours after sample collection and for up to two hours in AHs and DHs. The samples were found to be lying at room temperature at many facilities. At a CHC and a PHC, the ice-pack in cool box containing samples was found to be at room temperature. At a PHC, there was no cool box and a plastic box containing ice packs was used. In a DH, the cool box used for storage of samples did not have adequate number of ice packs. The service provider needs to make significant efforts towards improvement in cold chain maintenance with close monitoring by the state government.

According to state officials, there were several challenges in the initial few months of the rollout – the processes of sample collection, labelling, storage and transportation were not streamlined and were prone to errors. For example, there were sample mix-ups due to labels coming off the tubes. Also, there were leakages of samples from the containers. The sampling methodology was poor and a large percentage of samples were unfit for testing (haemolysed/clotted/insufficient quantity). The service provider on request of the state government studied the processes at reputed institutes like CMC and AIIMS and adopted some of their best practices for improving its processes. Many processes are now streamlined. During the survey, it was observed that the service provider's phlebotomists followed a structured process flow for registration of patients; and collection, labelling, storage and dispatch of samples at the government health facilities. Blood samples are collected in vacutainers. An acknowledgement slip is given to the patients for report collection. Cold chain remains a challenge though.

Some other challenges which were noted were that the service provider changed its phlebotomists frequently at many facilities; many of the phlebotomists were not adequately qualified; night shift phlebotomists did not have a place to sleep in hospitals and 10–20% PHCs did not even have a place for the phlebotomists to sit.

3.4.2 Transportation of samples

After samples are collected at government health facilities, they are transported to the nearest laboratories for testing. The ILD staff of the service provider picks up samples from the facilities and transport them to the testing laboratories. In all surveyed facilities, except one PHC, samples were always picked up on the same day. In one PHC, samples were not picked up on the same day on two instances and the samples were refrigerated at the PHC. The PHC was informed by the service provider about the inability to pick up the samples. This shows that there is a good coordination between health facilities and the service provider regarding sample pick-up.

According to information provided by the service provider, samples were picked up once from PHCs and far-off CHCs (far from testing laboratories), twice from nearby CHCs and every 1–1.5 hours from AHs and DHs. Based on information provided by phlebotomists at the surveyed facilities, in five out of eight PHCs, four out of eight CHCs and one out of two AHs, the sample pick was once and in remaining three PHCs and four CHCs, the pick-up was done twice. At the other AH and both DHs, samples were picked up within 1.5–2 hours or earlier if batch of 12 samples was ready.

Based on information provided by the service provider, 296 ILD staff managed transportation of samples from and delivery of reports to the government health facilities under NTR Vaidya Pariksha scheme across the state. In the surveyed districts, one ILD staff each was assigned for every DH and most of the AHs and few CHCs. For PHCs and remaining CHCs, each ILD staff was assigned 3–6 facilities. The staff route for PHCs and CHCs was analyzed for two regions in each of the two surveyed districts for sample pick-up time. In PHCs, the sample pick-up time was 11:30–14:30 and in CHCs with twice a day pick-up, the first pick-up was done at 11:30–12:00. Sampling services were unavailable for the second half of the day in PHCs where samples were dispatched as early as 11:30. None of the government health facilities kept a record of delays in sample pick-up. The samples from PHCs and CHCs reached the primary testing laboratories at different times varying from 13:00–17:15. This resulted in prolonged pre-analytical time for patients' samples.

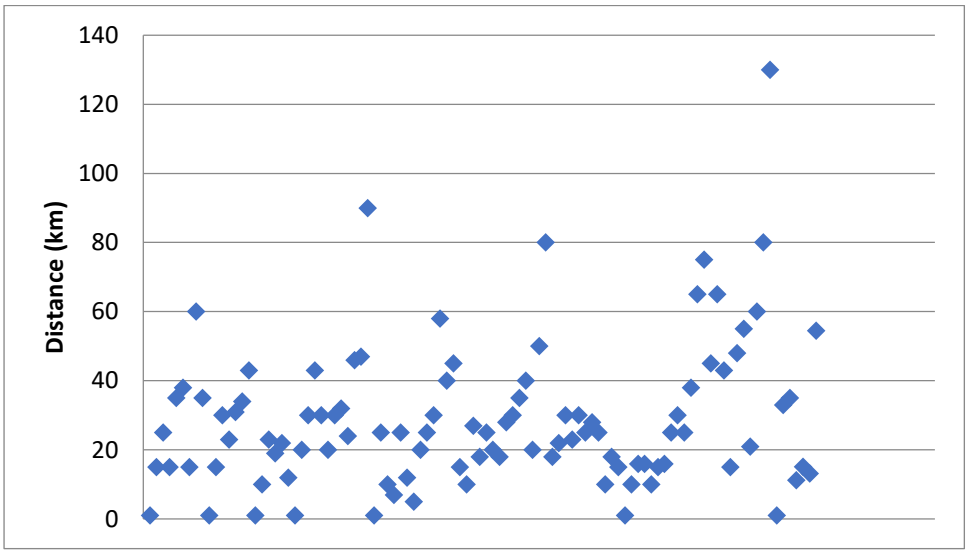
In the surveyed facilities, there was a provision for emergency sample pick-up in one AH and both DHs. There was no provision for pick-up of emergency samples on an urgent basis in all PHCs and five out of eight CHCs. In one CHC, the supervisor picked up any emergency samples during his regular visit to the CHC. The service provider needs to draw up a plan for picking up emergency samples, especially from CHCs.

On analysis of data of distances of government health facilities from the testing laboratories, it was found that the distance varied from 1 km to 130 km in Visakhapatnam (figure 15) and from 0.5 km to 55 km in Krishna (figure 16). Each laboratory has been set up near one health facility and the remaining health facilities are at varying distances from the laboratory. All laboratories catering to DHs and AHs have been set up within 1.5 km range. Other laboratories have been set up within 2 km of select CHCs. Distances of PHCs and CHCs from their respective testing laboratories did not affect the availability of sampling services,

except in case of few remote locations. For instance, not all PHCs which did not send any samples for many months were located far from their respective laboratories.

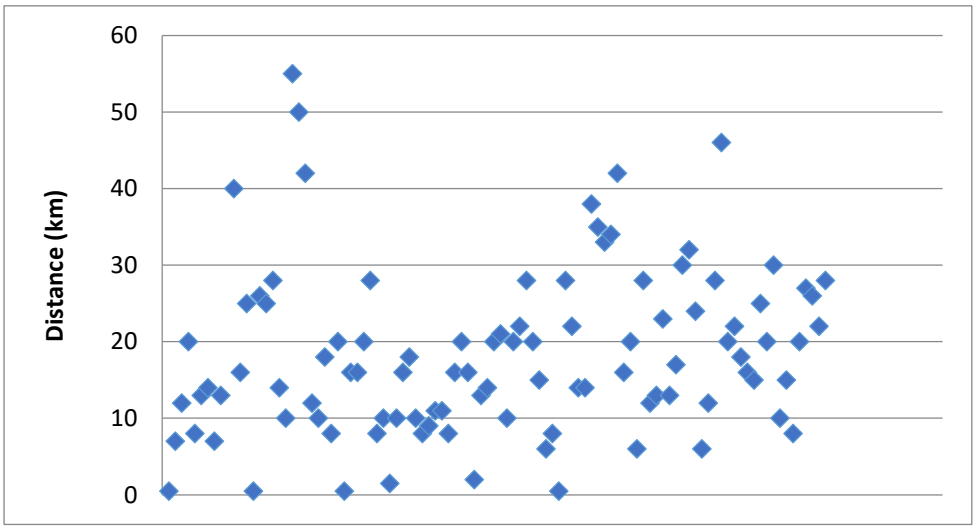
As mentioned earlier, samples are transported by ILD staff to the primary receiving laboratories. Couriers are used for transporting samples to the mother laboratory situated in a different district. Time taken by the ILD staff to transport samples to the primary receiving laboratories varies between 1–4.5 hours. The phlebotomist and the ILD staff travel halfway each for sample transportation in East Godavari and Kurnool, the remote tribal areas of Visakhapatnam.

Figure 15: Distribution of distances (km) of government health facilities from testing laboratories in Visakhapatnam district



Source: Service provider's data

Figure 16: Distribution of distances (km) of government health facilities from testing laboratories in Krishna district



Source: Service provider's data

Samples from AHs and DHs for advanced tests such as cultures, fluid examination, histopathology, cytology, TSH and HbA1C are transported to mother laboratories in seven districts of Andhra Pradesh, and Chennai. The transportation time varies from 3 to 12 hours (Table 21).

Table 21: Time taken for transportation of samples to mother laboratories in same or different district for advanced tests (cultures, cytology, histopathology and TSH)

District from which samples are transported	District to which samples are transported (mother laboratory/outsourcing laboratory)	Time taken for transportation (in hours)
Ananthapur	Kurnool	8
Chittoor	Kadapa and Chennai (Tamil Nadu)	8
Guntur	Prakasam	3
Kadapa	Kadapa and Chennai (Tamil Nadu)	1 hour (TSH) and 12 hours (histopathology, cytology, cultures)
Krishna	Prakasam	5
Kurnool	Kurnool	2
Nellore	Prakasam	5
Prakasam	Prakasam	1
Srikakulam	Visakapatnam	8
Visakapatnam	Visakapatnam	2
Vizianagaram	Visakapatnam	8
West Godavari	East Godavari and Chennai (Tamil Nadu)	8 hours (culture, TSH) and 12 hours (histopathology, cytology)
East Godavari	East Godavari and Chennai (Tamil Nadu)	6 hours (culture, TSH) and 12 hours (histopathology, cytology)

Source: Service provider's data

The ILD personnel picked up the samples and transported these in a cool box. As observed for sample storage at health facilities, cold chain was not found to be foolproof during transportation of samples. In one surveyed PHC, ILD staff did not carry an ice pack in the box and no spare pack was found in the refrigerator at the PHC either. Also, at some places where ILD staff was transporting samples from L2 laboratories to mother laboratories of the same district, sample integrity was compromised for advanced tests, such as urine culture and fluid analysis. For transportation to mother laboratories of different districts, couriers were used and the cold chain was compromised.

The service provider is now planning to equip its laboratories with thermometers for measuring temperature of samples at the time of receipt.

3.4.3 Test reports

Reports for the tests done under NTR Vaidya Pariksha scheme were e-mailed to the health facilities by the service provider's laboratories as soon as the reports were generated at the laboratories. In addition, printed reports were delivered to health facilities by ILD staff; and were dispatched to patients or doctors by phlebotomists of the service provider.

It was observed that the doctors did not access their emails for reports. In AHs and DHs, the reports were printed and dispatched from service provider's laboratories after 2–5 hours of report generation leading to delays for IPD patients. In many PHCs and CHCs, printed reports from the service provider's laboratories reached late, on the next working day.

In the surveyed facilities, all PHCs, six out of eight CHCs and one AH received printed reports once a day between 9:00 and 12:00. The remaining two CHCs, other AH and one DH received printed reports twice a day. The other DH printed reports at the facility itself at the printing station installed by the service provider. For inpatients in one CHC, reports were received within 2–3 hours of sample dispatch. In absence of printing stations at most of the facilities and doctors not accessing reports over emails, it becomes imperative that the printed reports are delivered at health facilities in time by the service provider.

It was also observed that patients' reports were printed only when results for all tests were ready. For patients prescribed only routine tests, the printed reports were delivered on the next day of sampling. However, for patients who were prescribed both routine and advanced tests, the electronic and printed reports were given only once all test results were ready. For example, for patients who were prescribed CBC (a routine test) and TSH (an advanced test), both electronic and printed reports were received at facilities after three days. Printed report for CBC was otherwise mostly available the next day, if only CBC was prescribed or it was prescribed with other routine tests. The service provider needs to ensure that reports are dispatched for individual tests as and when they are ready instead of waiting for the reports for advanced tests.

There were few instances of delays (1–2 days) in delivery of reports for routine tests. In one PHC and few CHCs, reports for samples which were dispatched after 16:00 were delivered to the facilities next day at 16:00 or after two days. One PHC reported that sometimes ILD staff did not deliver reports in which case they checked reports over e-mail. In few CHCs, the service provider's phlebotomists asked the patients to collect the report after two days of sample collection. In one AH, reports of TSH and HbA1c were received after three days and for Peripheral blood smear after four days.

In DH with the printing station, reports of patients who were prescribed only routine tests were printed on the same day for morning samples, and on the next day for samples collected later. Reports for TSH were received and printed after three days, peripheral blood smear after one day, FNAC after five days, histopathology after seven days, fluid examination after 2–3 days, and blood culture after seven days. In the other DH, reports for TSH were delivered after 2–5 days, peripheral blood smear after five days, FNAC after 3–5 days, fluid examination after a day and urine and blood cultures after five days. Delay in

receipt of reports for advanced tests in DHs where morbidity among patients is high, warrants requisite action from the service provider.

Reports for emergency samples were communicated to the health facility on priority in five out of eight CHCs and all AHs and DHs. In one PHC, there was an instance when report for platelet count was provided within six hours of sample collection. The service provider informed the reports for emergency tests to the health facility either over the phone, or through emails (in case of CHCs) or through printed reports (in case of AHs and DHs) within 3–6 hours of sample collection.

In AHs and DHs, the service provider informed its phlebotomist/staff nurse about critical results within two hours of sample dispatch. The critical reports were communicated telephonically. In the initial stages of one DH, critical results were informed the next day. The service provider did not inform PHCs and CHCs about critical results except for two instances in two CHCs – once for suspected leukaemia. During periods of high patient load for tests, such as rainy season or epidemics, service provider's laboratory technicians found it difficult to inform clinicians about critical results. There was an instance when a PHC doctor called the service provider's laboratory to find about a report for suspected low platelet count and he was not given information by the laboratory technician reason cited for which was heavy work load. At the service provider's laboratories, it was found that the laboratory technicians informed the facilities only occasionally about critical results.

None of the surveyed facilities except one DH had a printing station. Average waiting time for patients in the queue for collecting reports across facilities was 5–10 minutes for outpatients. In a DH, printing station was available; however instead of printing the reports beforehand, the staff printed them only when patients showed their registration slips. Thus, it increased the waiting time to 15–45 minutes. In one CHC andone AH, and both DHs there was a separate staff (phlebotomist) of the service provider for dispatching the report. Records of the test reports were maintained in the service provider's laboratory information system, but not at the health facilities. If misplaced, the reports could be printed again at the laboratories.

3.4.4 Turnaround time

Based on the Agreement between the state government and the service provider, turnaround time of a test is calculated as time between registration of patient's sample for a test at the primary testing/receiving laboratory and dispatch of electronic report for that test to the government health facility. However, the definition is inaccurate as the turnaround time should be calculated from the time of sample collection to the time of electronic dispatch of report. The prescribed turnaround time is different for each test depending on the time required for testing. The delay in turnaround time for even a single test of a patient is counted as delayed turnaround time. If the turnaround time is delayed for more than 5% of patients, 100% amount is deducted for all patients whose tests crossed the prescribed turnaround time. If percentage of patients is less than 5%, then 25% amount is deducted for all patients whose tests crossed the prescribed turnaround time. The state government relaxed the prescribed limit of turnaround time by 1 day for all tests and hence the penalty is levied on turnaround time +1 day.

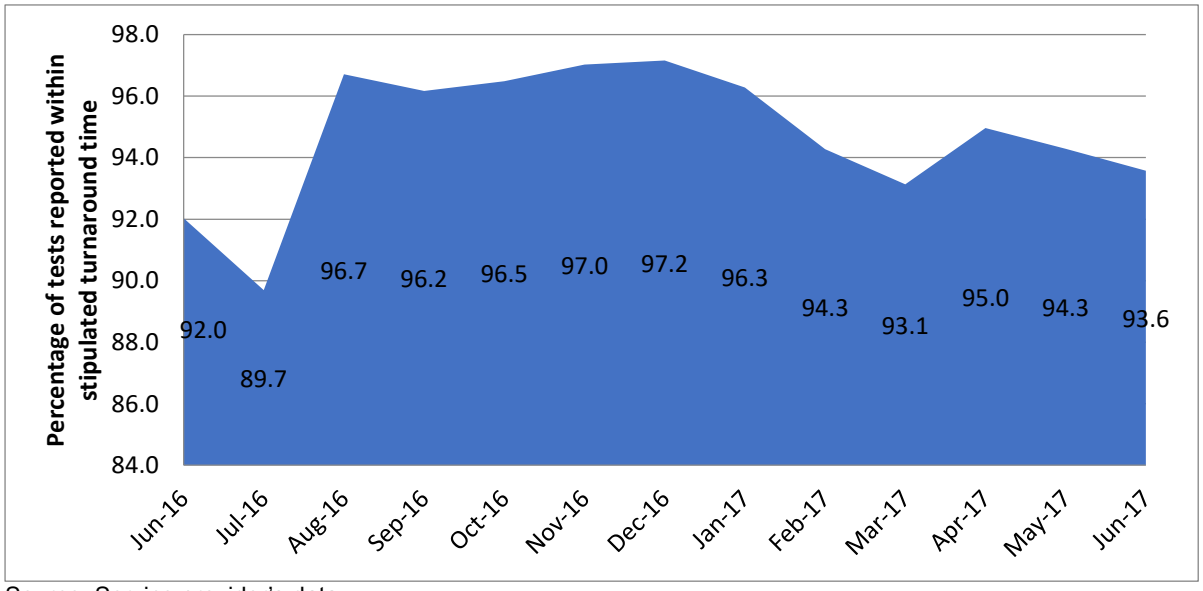
The data of turnaround time was made available by the service provider from June 2016. According to the government officials and service provider, turnaround time was significantly

delayed for most tests in the initial months of rollout and slowly improved owing to continual efforts of service provider as well as close monitoring by the state government.

Data shows that turnaround time improved significantly from July to August 2016 – percentage of tests reported within stipulated turnaround time increased from 89.7% to 96.7% (figure 16). The state government had started levying heavy penalties on the service provider from July 2016 onwards for delayed turnaround time, leading to more dedicated efforts at the service provider's end to improve the turnaround time. However, from January 2017, the percentage of tests reported within stipulated turnaround time again started falling and varied between 93.1% and 95% (figure 17). As per the documents received from the state government, no penalties were levied during February–March 2017 (information on penalties was made available only till March 2017).

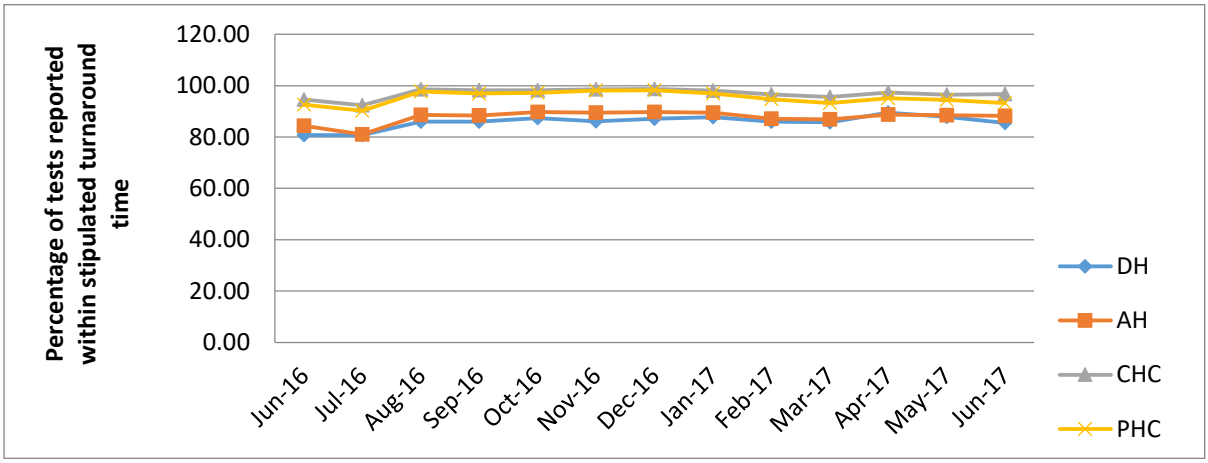
During the period of January 2016–June 2017, turnaround time was delayed more in AHs and DHs than in PHCs and CHCs (figure 18). The delay in AHs and DHs was mostly for advanced tests. Also, during periods of high patient load for tests, such as rainy season or during epidemics, the service provider found it difficult to manage the turnaround time, implying that the service provider needs to plan in advance for such times.

Figure 17: Percentage of tests reported within stipulated turnaround time



Source: Service provider's data

Figure 18: Percentage of tests reported within stipulated turnaround time at each type of facility



Source: Service provider's data

The data was also studied for the turnaround time of individual tests at each type of facility. In AHs and DHs, the turnaround time for blood culture, urine culture, fluid examination and coomb's indirect test was delayed for more than 80% of the tests. For cytology, histopathology, peripheral smear and coomb's direct test, the turnaround time was delayed by more than 50% of tests. For other tests, such as platelet count, prothrombin time, HbA1C, serum LDH, semen analysis, troponin I, troponin T and TSH, the turnaround time was delayed for 15–50% of tests (table 22 and 23).

Cultures are provided by the service provider only in three districts in Andhra Pradesh and Chennai. This leads to delay in transportation of these samples from other districts by 8–12 hours. Few mother laboratories also outsource advanced tests to other private laboratories. The reports from these laboratories are received at the service provider's mother laboratories, approved by the diagnosticians there and then entered in the software. The entire process leads to a delay in releasing the reports by 1–2 days. Delays were also seen for tests which required transportation to the mother laboratories. For instance, for Coomb's tests, the laboratory technicians could not be trained adequately and therefore the tests had to be sent to the mother laboratories.

Samples for tests like fluid examination, peripheral blood smear and urine culture were received at L2 laboratories and were transported to the mother laboratories for testing without any processing. The long pre-analytical time for these tests led to loss of sample integrity as well as increased the turnaround time for test reports.

In CHCs, the turnaround time for platelet count and prothrombin time was delayed for 15–25% of tests. In PHCs, the turnaround time for platelet count was delayed for 15–25% of tests. For other routine tests, the turnaround time was either within the prescribed limit or delayed for up to 15% of the tests (table 22 and 23).

Table 22: Number of tests for which the turnaround time was delayed at each type of facility

	Total tests	Turnaround time delayed for 5–15% of the tests	Turnaround time delayed for 15–50% of the tests	Turnaround time delayed for >50% of the tests	Turnaround time delayed for >80% of the tests
DH	40	9	9	3	4
AH	40	16	9	4	3
CHC	21	0	2	0	0
PHC	7	0	1	0	0

Source: Service provider's data

Table 23: List of tests for which the turnaround time was delayed at each type of facility

	Turnaround time delayed for 15–50% of tests	Turnaround time delayed for >50% of tests	Turnaround time delayed for >80% of tests
DH and AH	Platelet count, prothrombin time, HbA1C, S.LDH, semen analysis, troponin I, troponin T and TSH	Coomb's direct, cytology histopathology and peripheral smear	Blood culture, urine culture, coomb's indirect (DH), fluid examination
CHC	Platelet count, prothrombin time (turnaround time delayed for 15–25% of the tests)	-	-
PHC	Platelet count (turnaround time delayed for 15–25% of the tests)	-	-

Source: Service provider's data

With impetus from the state government, the service provider stepped up its efforts to overcome the delays in the turnaround time – operational efficiency was improved and monitoring of the turnaround time was intensified at every level. To this end, the service provider increased the number of ILD staff for reducing transportation time of the samples. The pick up of samples was increased to twice a day from once a day at many CHCs**.** The number of diagnosticians (including part-time) were increased for faster validation of test results. New machines with faster processing speeds were installed in the laboratories. For example, for TSH, semi-automated analyzer was replaced with fully automated analyzer. The service provider also started the process of establishing infrastructure for conducting blood and urine cultures in more districts. The work flow in laboratories was improved, for

example, samples with different turnaround time were segregated in colour-coded racks. Monitoring of the turnaround time was made more robust by engaging all levels of service provider's team in supervising turnaround time on a daily basis for each facility. District operations managers, quality assurance team managers and general manager and planner-cum-coordinator (corporate office) worked as a team to keep a close watch on the turnaround time. The laboratory technicians were also instructed to work towards achieving stipulated turnaround time. Due to these efforts, the turnaround time for blood culture, urine culture and histopathology witnessed slight improvement.

3.4.5 Synergies with services of in-house laboratories

Some good synergies were found between services of the in-house laboratories and service provider in making requisite tests available for the patients at the government health facilities. Twelve tests assigned strictly to the in-house laboratories were conducted at all facilities. However, additional three tests in CHCs (TLC, DLC and urine microscopy) and four tests in AHs and DHs (TLC, DLC, urine microscopy and peripheral blood film) which were designated to in-house laboratories were not conducted at most facilities and instead directed to the service provider.

Other tests, such as CBC, TSH etc., for which the in-house capacity was inadequate in many facilities, were assigned to the service provider and they were made available at all facilities. The synergy was evident in a large percentage of patients utilising both in-house and service provider's services in the same visit for different tests. In the surveyed AHs and DHs, CBC and TSH tests for ANC women were done through the service provider and tests for HIV, HBsAg, blood grouping, urine routine examination etc., were done at the in-house laboratories. Subsequent follow-ups of haemoglobin and urine routine tests for these women were done at the in-house laboratories. Similar synergies were noted for laboratory tests done for patients with different diseases.

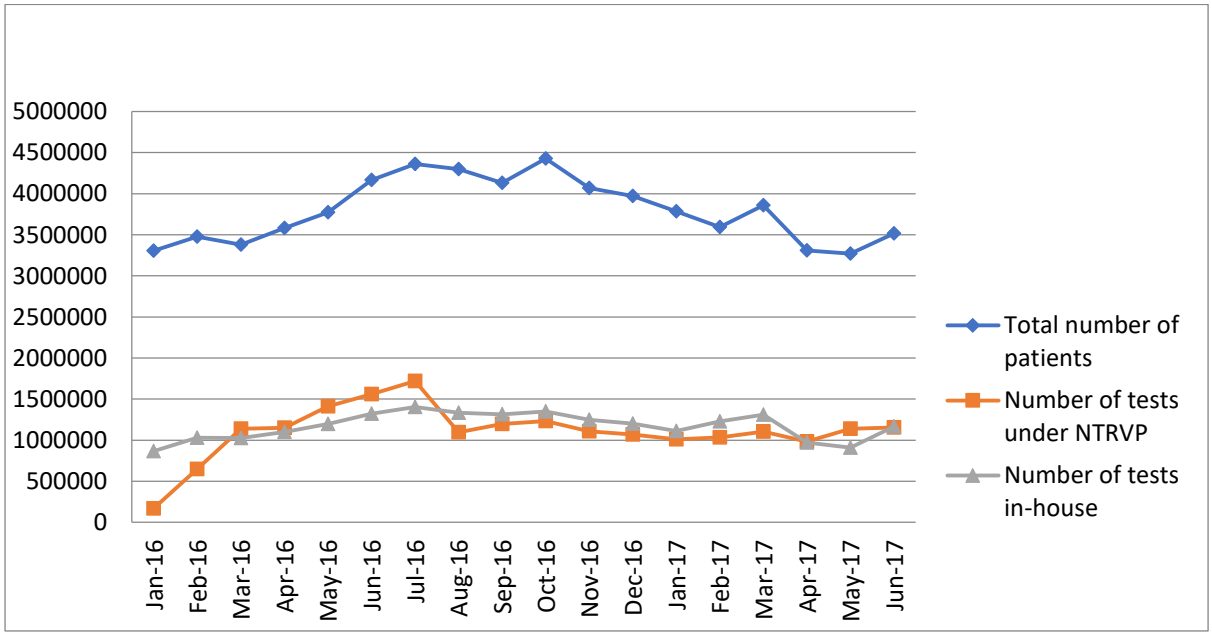
However, there were few tests for which the in-house capacity existed but they were outsourced for the service provider. In few PHCs and CHCs, TLC, DLC, dengue rapid test and RPR were done prior to rollout of services under NTR Vaidya Pariksha scheme and were discontinued. Analysis of relevant secondary data shows that ordering of RPR test increased by 113% in CHCs and 3% in PHCs from the last year. It was also observed during the primary survey that many ANC women were prescribed RPR as a single-test prescription. In an AH, haemoglobin, TLC, DLC, ESR, blood urea, serum creatinine, serum bilirubin and RPR were discontinued because of availability of these tests with the service provider and because the in-house laboratory technician was not available for last few months; the blood bank laboratory technician conducted limited tests. In one DH, there was discontinuation of platelet count and CBC (tested previously on cell counter in the in-house laboratory); blood urea, serum creatinine, cholesterol, serum bilirubin, serum uric acid, serum calcium (tested on a calorimeter in the in-house laboratory); RA factor, CRP, ASO (rapid kit method), RPR, urine – bile salts/pigments/ketone bodies and stool examination. According to doctors at this DH, the laboratory technicians had become complacent after availability of tests through the service provider. In the other DH, routine biochemistry tests using semi-automated analyzer and CBC on cell counter were still being carried out. RA factor, CRP and ASO using rapid kit method had been discontinued. Also, when doctors prescribed tests which were exclusively in the service provider's list, they would also include those tests which they would have prescribed through the in-house laboratory. For example,

they would add CBC in the service provider's list instead of getting haemoglobin, TLC, DLC done from the in-house laboratory; and add LFT instead of going for in-house biochemistry. Also, when blood sugar test was unavailable in-house, the doctors would get HbA1C (a more expensive test) from the service provider for indicative sugar values. The reason cited by doctors for relaying tests available in-house to the service provider was that the service provider receives payment on per-patient basis, and it was therefore prudent to include as many tests as required for a patient in the service provider's list. In fact, from the perspective of service provider's cost efficiency and long-term sustainability of the scheme, it is imprudent to redirect those tests to the service provider which can be done in the in-house laboratories.

According to doctors at the government health facilities, the quality of services of in-house laboratories was not adversely affected in any way after the introduction of the service provider's services. In fact, in one DH, new equipment was procured after the launch of NTR Vaidya Pariksha scheme and quality of tests improved.

Monthly trends in the number of tests conducted under the NTR Vaidya Pariksha scheme and the number of tests conducted by in-house laboratories was studied from the rollout of the NTRVP scheme in January 2016 till June 2017. It was observed that after August 2016, monthly trends (including seasonal variations) in the number of tests conducted under NTR Vaidya Pariksha scheme were found to be similar to that of in-house laboratories. A sharp decline in the number of tests conducted under the NTR Vaidya Pariksha scheme from July to August 2016 was not observed for in-house tests (figure 19). The trends of number of patients who visited the government health facilities have already been discussed earlier.

Figure 19: Monthly trends of tests conducted at in-house laboratories and under NTR Vaidya Pariksha scheme and total number of patients who visited government health facilities



The total number of patients who visited health facilities increased from 2014-15 to 2016-17. The increase was significantly higher from 2015-16 to 2016-17, compared to 2014-15 to 2015-16 in CHCs, AHs and DHs. The total number of patients in OPD and IPD increased by

5% and 16%, respectively, from 2014-15 to 2015-16 and by 15% and 29%, respectively, from year 2015-16 to 2016-17.

A comparison was done between the uptake of in-house tests (2016-17) and service provider's tests (August 2016–June 2017, extrapolated to a year). Data of January–July 2016 for the NTR Vaidya Pariksha scheme was not included for comparison of uptake of tests as rationalization of services under NTR Vaidya Pariksha scheme was undertaken in July 2016.

The uptake was calculated as ratio of total number of tests conducted to total number of patients who visited the health facilities.[5] The uptake of in-house tests and service provider's tests was almost the same – around 31% each (table 24). A similar demand for in-house and service provider's tests suggests that there was a huge unmet demand for tests among patients visiting the government health facilities which was fulfilled by the new scheme.

The total number of in-house tests conducted and uptake of these tests (calculated as ratio of total number of in-house tests conducted to the total number of patients who visited health facilities) increased after introduction of the NTR Vaidya Pariksha scheme (2015-16 and 2016-17) (table 24). The expanded basket of tests made available at all the government health facilities through the scheme was probably an important catalyst for greater increase in the number of patients who visited the health facilities compared to previous years, as well as for enhanced uptake of the existing in-house laboratory services. The uptake of in-house tests increased in all facilities; however a marginal decrease was seen in DH 2016-17 (table 25).

Table 24: Uptake of in-house tests

	April 2014 - March 2015	April 2015 - March 2016	April 2016 – March 2017
Total number of tests conducted	1 01 86 628	1 20 29 263	1 51 17 620
Total patients who visited health facilities	3 91 87 509	4 14 10 862	4 80 25 866
Uptake of in-house tests (ratio of total number of tests to total number of patients)	0.26	0.29	0.31

Source: State government's data

[5] Percentage of the total number of patients tested could not be used as an indicator of uptake of tests as data of number of patients tested in-house was unavailable.

Table 25: Ratio of in-house tests to total number of patients at each type of facility

	April 2014 – March 2015	April 2015 – March 2016	April 2016 – March 2017
PHC	0.18	0.20	0.21
CHC	0.24	0.29	0.33
AH	0.44	0.52	0.64
DH	0.50	0.61	0.58
Overall	0.26	0.29	0.31

Source: State government's data

These findings corroborated with the primary survey where most of the facilities with in-house laboratory technician, majority of tests assigned for in-house testing were conducted in the in-house laboratories. However, in many facilities, few assigned tests were not conducted due to lack of reagents.

As a contractual responsibility, the service provider is mandated to conduct the in-house tests where the position of in-house laboratory technician is vacant, and when in-house laboratory technician is on leave. Position of the in-house laboratory technician is vacant in 200 out of 1125 PHCs. However, it was found during the survey that in two of the three PHCs where the position of in-house laboratory technician was vacant, the phlebotomist of service provider only carried out few rapid tests. For other tests, such as haemoglobin, patients were referred to the nearest CHC/hospital. In one PHC, the phlebotomist also prepared peripheral smear for malaria which was sent to CHC for examination. In another PHC, only random blood sugar using the glucometer was done by the service provider's phlebotomist and for all other in-house tests, patients were sent to the nearest CHC. In 2 CHCs**,** the phlebotomist performed only emergency tests in the absence of the in-house laboratory technician.

According to the service provider, extra phlebotomists were deployed in some DHs to exclusively handle testing in the in-house laboratories as the sample load was high and positions of in-house laboratory technicians were vacant.

The phlebotomists of the service provider and the in-house laboratory technicians also worked synergistically at health facilities by sharing samples and ensuring that the patients are not pricked separately for tests at service provider's and in-house laboratories. In PHCs and CHCs, sampling for such patients was carried out by phlebotomist of the service provider and the sample was shared with the in-house laboratory technician. In many cases, sample was divided in two tubes, one for service provider and other for in-house laboratory. In few facilities, the in-house laboratory technician only carried out those tests which required finger prick sample and, therefore sample sharing was not required. In one AH, sampling for these patients was carried out by phlebotomist of the service provider as well as the in-house laboratory technician. However, the sample was not divided in two tubes, the requisite quantity of sample was taken by the in-house technician from the sample tube of service provider and tested immediately. In the other AH and DH, sampling areas were

separate and sampling for these patients was carried out by the phlebotomist of the service provider and an extra tube was filled and sent to the in-house laboratory. There is a scope for improvement in the process of sample sharing between service provider's phlebotomists and in-house laboratory technicians. In the other DH, sampling of these patients was carried out separately at service provider's sampling station and in-house sampling station. At a few facilities, the in-house laboratory technician and phlebotomist of service provider also shared work responsibilities in each other's absence.

3.5 Test patterns

Trends and patterns of tests ordered by the clinicians at the government health facilities were analyzed using secondary data. The average percentage of prescriptions with single test in the duration of 18 months of the scheme implementation was 31% and that with two tests was 23%. The percentage of single test prescriptions was the highest in June 2017 (40%). It was observed in some of the surveyed CHCs that RPR (an inexpensive test) was ordered as a single test for many ANC women. The test was performed in the in-house laboratory prior to the rollout of the NTR Vaidya Pariksha scheme.

At the same time, over-prescription of tests was also observed in some cases. At one CHC, all ANC women were prescribed liver and kidney function tests without any indication. Also, according to the service provider, AYUSH doctors at CHCs prescribed almost all biochemistry tests to the majority of patients.

It was found that at many facilities, the service provider encouraged the clinicians to prescribe tests to more patients and to keep the number of tests prescribed to each patient less.

CBC, blood urea and serum creatinine were the top three tests ordered at CHCs, AHs and DHs (tables 27, 28 and 29); in PHCs these were TLC and DLC (table 26)**.** The tests which were underutilised (0–10 tests/month in a facility) in AHs and DHs were blood and urine cultures, Cytology, fluid examination, histopathology, semen examination, Coombs test (direct and indirect) and bone marrow aspiration (tables 28 and 29)

Table 26: Percentage share of tests in PHCs

TLC	25–30%
DLC	22–30%
Platelet count	17–23%
Bilirubin	10–15%
RPR	7–15%
Dengue	4–8%

Source: Service provider's data

Table 27: Percentage share of tests in CHCs

More than 10%	CBC (13–27%)
Between 5–10%	Blood Urea
	S. Creatinine
	S. Bilirubin
	Urine complete analysis
	Dengue (September–October)
Less than 0.2% (lowest quartile)	Stool examination

Source: Service provider's data

Table 28: Percentage share of tests in AHs

	AH IP	AH OP
More than 10%	CBC (18–20%)	CBC (13–18%)
Between 5–10%	Creatinine	Creatinine
	Urea	Urea
	Bilirubin	Bilirubin
	Urine complete	Urine complete
Less than 0.2% (lowest quartile)	Blood C/S	Blood C/S
	Cytology	BMA
	Histopathology	Coombs test (direct and indirect)
	Fluid	Cytology
	Semen	Fluid
	Trop I&T (7 and 9 months)	Histopathology
	Urine C/S	Semen
	Stool	Stool
	BMA	Trop I&T
	RPR	Urine C/S
		RPR
0–10 tests in a month in a facility	Blood C/S (5 months)	
	BMA	
	Coombs test (direct and indirect)	
	Cytology	
	Fluid	
0–10 tests in a month	Histopathology (6 months); highest in the first 2 months; picked up again in March–April 2017.	
	Semen	
	Stool	
	Urine C/S	

Source: Service provider's data

Table 29: Percentage share of tests in DHs

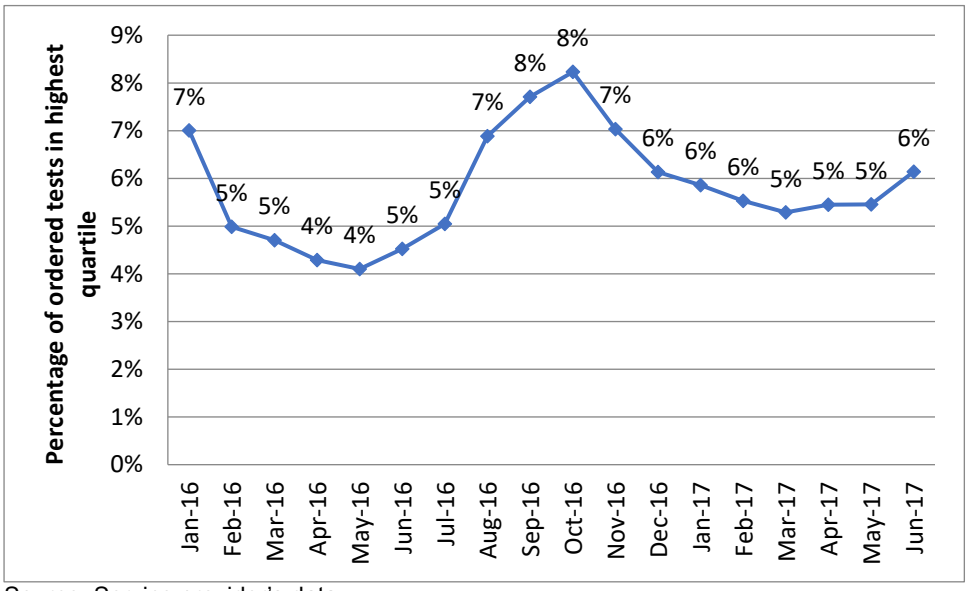
	DH OP	DH IP
More than 10%	CBC (11–15%)	CBC (10–12%)
Between 5–10%	Creatinine	Creatinine
	Urea	Urea
	Bilirubin	Bilirubin
	TSH (5 months; 4 months in 2017)	SGOT
	Urine complete	SGPT
		S. electrolytes
Less than 0.2% (lowest quartile)	Blood C/S	BMA
	BMA	Coombs test (direct and indirect)
	Coombs test (direct and indirect)	Cytology
	Cytology	Histopathology
	Histopathology	Fluid
	Fluid	Semen
	Platelet count	Stool
	Semen	Trop T
	Stool	Urine C/S
	Trop I&T	
	Urine C/S	
0–10 tests in a month in a facility	BMA	BMA
	Cytology (3 months, January–April 2016)	Coombs test indirect
	Fluid	Cytology
		Fluid
		Semen
		Stool

Source: Service provider's data

All tests provided by the service provider were divided into quartiles based on CGHS rates. The percentage of ordered tests which fell in the upper quartile (INR 121 and above) and lower quartile (INR 58 and below) were calculated. It was found that in the study period, 6% of ordered tests fell in the upper quartile of CGHS rates and 54% of ordered tests fell in the lower quartile of CGHS rates. This implies that most tests conducted under the scheme were of low value (cost). This is aligned with the finding that 41% of tests conducted were for patients at PHCs, where only basic routine tests are available through the service provider.

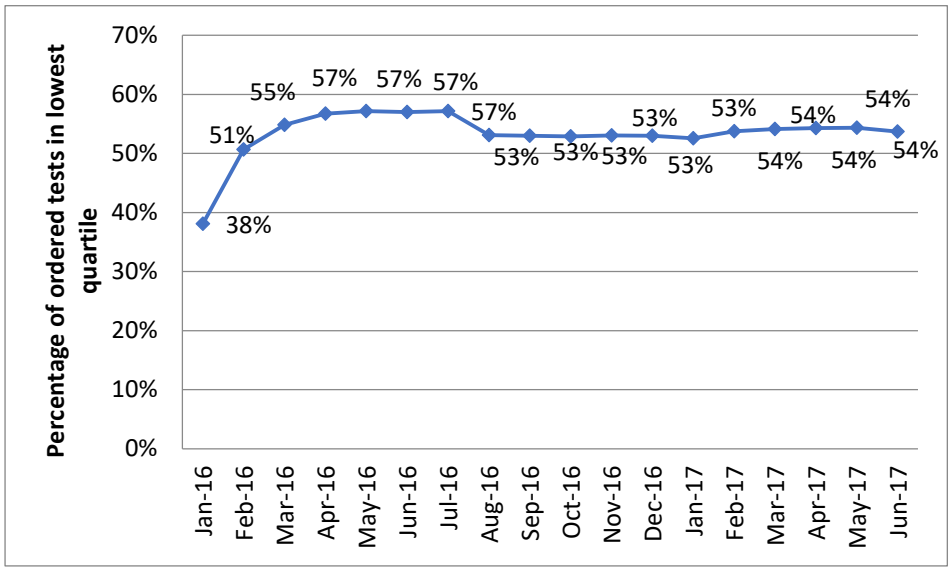
It was observed that percentage of ordered tests in the highest quartile increased from 5% to 7% from July to August 2016 and went up to 8% in October 2016 after which it showed a downward trend (figure 20). On the other hand, the percentage of ordered tests in the lowest quartile reduced from 57% to 53% during July to August 2016 (figure 21). This could be explained by the state government's move towards rationalization of services under the NTR Vaidya Pariksha scheme, as a result of which prescription of unnecessary low-cost tests was curtailed. Also, compared to 2016, the month-on-month percentage of ordered tests in the highest quartile was slightly higher and percentage of ordered tests in the lowest quartile was slightly lower in 2017 (figure 20 and 21).

Figure 20: Monthly trends in percentage of ordered tests in the highest quartile (INR 121 and above in CGHS rate list)



Source: Service provider's data

Figure 21: Monthly trends in percentage of ordered tests in the lowest quartile (INR 58 and below in CGHS rate list)



Source: Service provider's data

Prescription of dengue test and platelet count test was analysed further**.** It was found that the tests ordered for dengue were significantly higher in PHCs compared to other types of health facilities (table 30).

Table 30: Number of dengue tests in January 2016–June 2017

DH	AH	CHC	PHC
18222	58130	173548	425252

Source: Service provider's data

In all types of facilities, the number of prescribed dengue tests increased sharply in June and July 2016 and remained high till November 2016 (except for a transient dip in August 2016) corroborating with the high season of dengue. The platelet count test also showed a similar trend in PHCs, AHs and DHs. The platelet count test was ordered for patients with suspected/confirmed dengue to monitor the platelet count as it could fall because of the infection. The availability of dengue test and platelet count test in PHCs was found to be helpful by the doctors in catering to the local communities.

Yearly trends in prescription patterns

The data of ordered tests was compared for 2016 and 2017 (months of January to June of each year). In DHs and AHs, the uptake increased for troponin, prothrombin time, cytology, histopathology, TSH, HbA1C, dengue and most of the routine tests while it reduced for fluid examination. In DHs, blood culture and peripheral blood smear and in AHs, urine cultures reduced in number (table 31 and 32).

In CHCs, prescription of RPR and dengue increased from 2016 to 2017. All other routine tests, prothrombin time and serum amylase reduced in number. In PHCs, prescription of RPR increased while that of other tests reduced in number (table 33 and 34).

Table 31: Year on year change (2016 and 2017) in number of each type of test in DHs

Overall: +32%				
Tests which increased in 2017	**Percentage increase**		**Tests which decreased in 2017**	**Percentage decrease**
Troponin-I&T	126% and 91%		S. LDH	-2%
Cytology (malignant cells)	117%		Peripheral blood smear	-11%
Dengue rapid test	71%		Serum amylase	-12%
Prothrombin time test and INR	68%		Fluid (CSF/ascitic/pleural) cell count and biochemistry	-16%
Anti streptolysin	59%		Platelet count by cell counter	-16%
Liver and Kidney function tests	27–58%		Blood culture	-18%
Serum electrolytes	52%		Stool for ova and cyst	-40%
TSH	49%		Bone marrow aspiration	-100%
CBC	38%			
S.CRP	36%			
Semen analysis sperm count	32%			
Coombs test – indirect and direct	12% and 23%			
Urine culture	19%			
Urine complete analysis	18%			
HbA1C	14%			
Histopathology	9.2%			
Rheumatoid factor	6.8%			
Lipid profile	4.2%–12.2%			

Source: Service provider's data

Table 32: Year on year change (2016 and 2017) in number of each type of test in AHs

Overall: +35%				
Tests which increased in 2017	**Percentage increase**		**Tests which decreased in 2017**	**Percentage decrease**
Liver and kidney function tests	31%–111%		Fluid (CSF/ascitic/pleural) cell count and biochemistry	-1.37%
Prothrombin time test and INR	108%		Urine culture	-7.19%
Dengue rapid test	94%		Semen analysis sperm count	-7.96%
Serum amylase	74%		Platelet count by cell counter	-10.69%
Histopathology	52%		Coombs test – direct	-17.57%
Serum sodium/potassium/ chloride	49%		Blood culture	-19.02%
Anti streptolysin	48%		Stool for ova and cyst	-40.40%
Troponin - T&I	41% and 17%		Bone marrow aspiration	-80.00%
Cytology (malignant cells)	34%			
Serum LDH	34%			
HbA1C	26%			
TSH	25%			
Rheumatoid factor	25%			
Rapid plasma reagin (RPR)	25%			
Serum CRP	22%			
Lipid profile	11%–23%			
Coombs test – indirect	22%			
Urine complete analysis	15%			
CBC	13%			
Peripheral blood smear	7%			

Source: Service provider's data

Table 33: Year on year change (2016 and 2017) in number of each type of test in CHCs

Overall: -10%				
Tests which increased in 2017	**Percentage increase**		**Tests which decreased in 2017**	**Percentage decrease**
Rapid plasma reagin (RPR)	113%		CBC	-3%
Dengue rapid test	74%		Urine complete analysis	-3%
			Liver and kidney function tests	(-1% to -16%)
			Platelet count by cell counter	-10%
			Lipid profile	(-36% to -53%)
			Serum amylase	-43%
			Stool for ova and cyst	-51%
			Prothrombin time test and INR	-59%

Source: Service provider's data

Table 34: Year on year change (2016 and 2017) in number of each type of test in PHCs

Overall: -33%				
Tests which increased in 2017	**Percentage increase**		**Tests which decreased in 2017**	**Percentage decrease**
Rapid plasma reagin (RPR)	3%		Dengue rapid test	-8%
			Platelet count by cell counter	-31%
			DLC	-38%
			Serum bilirubin	-39%
			TLC	-41%
			Stool for ova and cyst	-56%

Source: Service provider's data

The change in uptake of tests corroborates with some of the primary survey findings like satisfaction of clinicians with accuracy and the turnaround time of the respective tests. For an instance, in one DH, clinicians were not satisfied with the accuracy of results and turnaround time of blood and urine cultures and therefore uptake of these tests had declined. In another DH, clinicians were satisfied with the reports of histopathology and cytology and uptake of these tests increased.

3.6 Effect on patient care, out-of-pocket expenditure and patient satisfaction

According to doctors at health facilities, the expanded basket of tests available through the service provider is leading to improved patient care, lesser out-of-pocket expenditure and a higher patient satisfaction.

3.6.1 Effect on patient care

Before the launch of NTR Vaidya Pariksha scheme, tests available at different types of facilities through their in-house laboratories were very few and a large proportion of patients got themselves tested from private laboratories. Those patients who could not afford tests at private laboratories were referred to hospitals. After the launch of the scheme, majority of patients got their tests done at the government facilities through the service provider.

According to doctors at DHs, various diseases and health conditions were being managed better after availability of tests through the service provider. For example, there is availability of LDH and platelet count for pregnancy induced hypertension patients; tests for suspected cases of rheumatoid arthritis, gout and hypothyroidism; TSH for all C-sections; serum electrolytes for post-operative (especially post-laparotomy) patients and old patients; complete LFT for obstructive jaundice; and CBC, serum creatinine, blood urea, serum bilirubin, SGOT, serum uric acid and urine protein for delivery patients. Also, TSH and histopathology are now available free of cost, which were earlier sent to private laboratories. The methodology used for few tests conducted by the service provider is superior to what was used at in-house laboratories for the same tests. For an instance, in one DH, biochemistry tests were conducted on a calorimeter in the in-house laboratory. Now, these tests are conducted on a fully automated biochemistry analyser by the service provider.

As per doctors in one AH, number of patients visiting the facility had increased because of availability of more tests through the service provider. For example, availability of CBC and TSH enables detailed screening of all pregnant women for anaemia and hypothyroidism. Screening for hypothyroidism is now being carried out for newborns as well. In the other AH, doctors can manage acute abdomen cases better because of availability of complete LFT; earlier only serum bilirubin was available at the in-house laboratory. Dengue detection has increased; and lipid profile is now being prescribed.

In CHCs, doctors informed that the patient load had increased and management of various diseases and health conditions has improved because of availability of more tests –lipid profile, LFT and KFT for patients of diabetes, kidney disease, and hypertension; CBC for screening of pregnant women; and tests for screening for malnutrition among children. Also, earlier few conditions could not be managed at CHCs because of unavailability of tests and were referred to higher government facilities. These can now be managed well at CHCs. For example, C-sections which require LFT, KFT are done; screening of high-risk ANC women using LFT, KFT among other tests is done at CHCs and referrals are made only if the test results are deranged; mild pregnancy induced hypertension cases are identified and their platelet count, urea, creatinine, uric acid are monitored; and newborn jaundice and pedal oedema cases are managed better. A case of leukaemia was also diagnosed at a CHC through the tests provided by the service provider. On the contrary, according to one doctor at a CHC, there was no improvement in care because of availability of service provider's

tests as most patients visiting CHCs required primary care for which few tests were required and those were available in-house. Also, results of these tests were mostly not very deranged in such patients.

According to doctors at PHCs, availability of more tests has enabled patients with poor affordability to get the prescribed tests done at PHCs. There was an increase in demand among patients for tests. Also, management of patients has improved. For an instance, patients with suspected dengue who were earlier referred to hospitals are now being managed at PHCs with availability of dengue screening test and platelet count test. According to a district officer, dengue test (ELISA) was earlier available at teaching hospital only, now the screening is available even at the PHC level. Patient care has also improved through monitoring of platelet counts in dengue cases. In few villages, the entire communities were affected with dengue, and the PHCs could manage this independently because of availability of requisite tests. Patients of jaundice who are referred to teaching hospitals for treatment now get follow-up bilirubin tests done at nearby PHCs. According to a doctor at a PHC, the list of tests made available through the service provider has not led to any improvement in care. For example, all patients with fever did not require TLC, DLC and were prescribed these tests only for their satisfaction.

There are certain tests which the doctors required and were not in the lists of designated tests for both in-house and outsourced services. The tests which were requested to be added in the list were – PHCs: TSH (especially for all ANC women), T3, T4, LFT, KFT, serum creatinine, lipid profile, urine culture; CHCs: TSH, T3,T4 for ANC/other patients, GTT and TORCH for ANC patients, CRP for newborns, HbA1c, semen analysis, RA factor, ASO, serum electrolytes, serum calcium, serum uric acid, CPK MB, LDL, QBC test for malaria; AHs/DHs - T3, T4, Anti-TPA, anti-HCV (for surgical cases), ELISA for HBsAg, Pus C/S, ABG and bone biopsy, monteaux test, QBC test for malaria, serum lipase, serum calcium, CSF ADA.

Because of unavailability of these tests, patients were either referred to higher government facilities or private laboratories for getting the tests done. At 2 surveyed PHCs, patients were referred to nearest CHC/hospital for various tests including TSH, lipid profile, serum creatinine, urine routine examination and urine culture. In another PHC, all pregnant women were referred to the nearest hospital for TSH. At CHCs, patients were referred to a higher facility for TSH, Serum uric acid and HbA1C. Majority of pregnant women were referred for TSH.

On designated bi-weekly ANC days, the number of ANC women visiting the government health facilities was very high. Many women didn't get themselves tested at the government health facilities because of long waiting hours. During visit to one CHC, it was noted that several ANC women ended up going to private laboratories for the same reason.

According to doctors at few facilities, some patients were still going to private laboratories because of various reasons such as unavailability of prescribed tests in the list of designated tests of the service provider/in-house laboratories, lack of trust in the quality of reports of the service provider/in-house laboratories, private laboratories providing reports on the same day and within an hour for emergency cases vis-à-vis service provider giving reports in 1–2 days (in paediatric department of a CHC, the service provider gave reports for emergency bilirubin tests only by 18:00 even if sample was given at 10:00); long waiting time in the

queue for tests on ANC days; and lack of awareness about availability of tests at the government facilities. The percentages of patients going to private laboratories/higher government facilities from the surveyed PHCs were 2–3%, 3%, 1%, 10–20%, 30–40%; in CHCs, the percentages were 5%, 5–20%, 10–20%, 1–2%, 5%, 5–7%, 4–5% 2–5%; in AHs, 2% and 10–20%; and in a DH 20%. Most of the patients who were referred to higher government facilities went to private laboratories.

However, according to the government doctors, the percentage of patients who got their tests done from private laboratories went down in many facilities after rollout of service provider's services. For example, in one PHC, the percentage had come down from 60% to 30–40%. In a CHC, earlier 15–20% patients were going to laboratories outside and now it had reduced to 5%. In another CHC, the percentage had come down from 3–5% to 1%. In one AH, the percentage had come down from 10–20% to 2%. In a DH, 60% patients got themselves tested outside earlier primarily because of unavailability of tests – this had reduced to 20–30% after implementation of the NTR Vaidya Pariksha scheme.

3.6.2 Out-of-pocket expenditure

A survey commissioned by the state government revealed that per capita OOPE on diagnostics across public and private sectors reduced by 55% – from INR 860.54 in 2015 to INR 388 in year 2017. In public sector alone, it decreased by 81% – from INR 32 in year 2015 to INR 6 in year 2017. Average OOPE per patient on diagnostics for chronic diseases in public sector decreased by 40% in this period.

Also, the savings on out-of-pocket expenditure based on average market rates of the laboratory tests amounted to INR 228 crore in the period of January 2016–June 2017. The savings were calculated as money saved by patients on tests which were made available through the NTR Vaidya Pariksha scheme; the assumption was that the patients would have got these tests done from private laboratories in absence of availability of these tests at the government health facilities.

3.6.3 Patient satisfaction

During the primary survey, 120 patients were interviewed across various types of facilities – PHCs, CHCs, AHs and DHs. Following are the key findings from patient satisfaction survey:

i. 98% of patients knew that tests are available free-of-cost at the health facility they were visiting. Sources of this information were other patients, doctors at the government health facilities and health workers. Many patients said that it was general knowledge that all services at the government health facilities are free of cost. None of the interviewed patients got to know about free tests from radio/TV/newspaper.

ii. None of the patients visited the health facility only for getting tests done. All of them visited the health facility to consult with the doctor who then prescribed laboratory tests to them.

iii. 99% of patients got their tests done in the same visit.

iv. None of the patients were charged for any tests done by the service provider/at the in-house laboratory.

v. Procedure of sampling was smooth for 99% of patients. Sample of 95% of patients was taken in one prick.

vi. In 95% of cases, tests prescribed by doctors at the government health facility were available within the facility. A few ANC women had got TSH test done from private laboratories. In one PHC, ANC women had got VDRL test and blood grouping test done from the CHC.

vii. The report collection day and time was explained to almost all (96%) the patients.

viii. The waiting area was comfortable for 99% of patients.

ix. Average waiting time for giving sample for service provider's tests was 5–15 minutes and for in-house tests was 10–25 minutes.

x. Average waiting time for report collection was 5–10 minutes for service provider's reports and 5–15 minutes for in-house reports.

xi. The reports from private provider were mostly received after 1–2 days of sampling. A few ANC women at surveyed AHs and DHs were given reports for TSH after 3 days. Reports for in-house tests were given on the same day or next day.

xii. Patients were asked to rate (good/average/bad) the following:
- Overall experience
- Availability of tests
- Waiting time (for testing and report collection)
- Behaviour of staff
- Cleanliness of the testing/waiting area
- Cleanliness of the toilet (if used)

98% of patients gave good rating to overall experience, availability of tests and behaviour of staff; 95% patients gave good rating to waiting time and cleanliness of the testing/waiting area; and 90% gave good rating to cleanliness of the toilet.

According to majority of patients who had got themselves tested at the government health facilities before, their overall experience with laboratory services was same this time. For few patients, the experience was better this time. The most common reason cited for this was lesser waiting time followed by good behaviour of staff.

3.7 Laboratories of the service provider

As mentioned before, the service provider has set up 104 laboratories across the state for providing services under the NTR Vaidya Pariksha scheme. Seven of these laboratories

existed at time of launch of the scheme and were taken over by the service provider and turned into mother laboratories. The remaining 97 laboratories were newly set up.

Setting up of 97 new laboratories enabled standardisation of infrastructure and processes across these laboratories. The laboratories were planned in such a way that all designated tests of the NTR Vaidya Pariksha could be made available from the commencement of operations in these laboratories. At the same time, the large scale of purchase of equipment and reagents for all laboratories enabled service provider to negotiate good rates with the equipment and reagent vendors. On the other hand, seven mother laboratories which were existing and taken over by the service provider faced challenges in terms of availability of equipment for the requisite tests, alignment of existing software with the new centralised software developed for the NTR Vaidya Pariksha scheme, differences in work process flow etc.

3.7.1 Franchisee model

The 97 new laboratories were set up through a franchisee model. The service provider had identified local entrepreneurs in the state and partnered with them for setting up and running laboratories under the NTR Vaidya Pariksha scheme. The new laboratories (97) were set up in partnership with 65 franchisees. Each franchisee was allotted 1–3 laboratories.

The service provider mobilised its 200 employees from other states and stationed them for 45 days in Andhra Pradesh for recruiting and training staff and for hand-holding franchisees in setting up and running the laboratories. Out of these 200 trainers, 70 were laboratory technicians; the service provider trained these technicians in its head office in Chennai before sending them to Andhra Pradesh. The engagement of franchisees and a systematic approach towards their training and hand-holding paved the way for a speedy (in 60 days) rollout of services under the NTR Vaidya Pariksha scheme across the state. The local knowledge of franchisees and their motivation for revenue-sharing expedited the initiation of services. The franchisees were closely monitored by the district and state-level teams of the service provider.

In this partnership model, the revenue is shared between the service provider and franchisees on per-patient basis. The cost incurred at the franchisee laboratories is also shared – initial cost for equipment purchase; software; and recruitment and training of phlebotomists and laboratory staff was borne by the service provider. The operational costs borne by the service provider include ongoing IT support; periodic trainings; EQAS; certifications and accreditations; human resources for ongoing monitoring at district and state level; and transportation of samples from franchisee laboratories to the mother laboratories. The capital cost of setting up infrastructure in the laboratories was borne by the franchisees. The operational costs for reagents and consumables for tests and IQC; salaries of phlebotomists, ILD staff and laboratory technicians; cost of transportation from government health facilities to its laboratories; and rent for the laboratories are borne by the franchisees. The franchisees purchase reagents and consumables from the service provider to maintain uniformity and quality.

The service provider makes payments to the franchisees as and when it receives payments from the state government. According to the service provider, whenever there was delay in release of payments from the state government, the partnership of service provider with the franchisees got strained because their payments also got delayed.

There are certain shortcomings in subcontracting of the laboratories. An additional layer of independent franchisees reduces accountability and transparency and increases chances of malpractice by franchisees to earn more profits. The service provider loses control over several aspects of operations and becomes dependent on personal interests and motivation of franchisees. Also, to earn more profits, the franchisee could offer kickbacks and compromise on quality such as giving out reports without conducting the tests. In the past, the franchisees were penalised or disengaged by the service provider when it was found that they were not conducting tests of samples received in the laboratories, or they were not sending phlebotomists regularly to the government health facilities, or there was laxity in transportation time of samples and dispatch of samples to the mother laboratories. The service provider came across these challenges more so with franchisees who had engaged only for profits; other franchisees who took ownership of the cause functioned well.

In the two survey districts – Krishna and Visakhapatnam, seven and eight laboratories have been setup respectively. The number of government health facilities catered by each of the laboratories in the two districts is mentioned in table 35 and 36.

Table 35: Number of facilities catered by each laboratory in Visakhapatnam district

Laboratory name	DH	AH	CHC	PHC
Anakapalle		1	5	35
Araku			1	8
Bheemunipatnam			1	5
Chintapalle			1	11
Munchigud			1	5
Narasipatnam		1	3	17
Paderu			1	6
Visakhapatnam mother laboratory	Only advanced tests from Visakhapatnam and other districts			

Source: Service provider's data

Table 36: Number of facilities catered by each laboratory in Krishna district

Laboratory name	DH	AH	CHC	PHC
Nandigama	-	-	2	11
Machaillipatnam	1		2	11
Tiruvuru	-	-	1	6
Nuziveedu		1	1	11
Avanigadda	-	-	1	12
Gudivada		1	2	23
Vijayawada mother laboratory	Few advanced tests, such as peripheral smear from AHs and DH of Krishna district.		3	13

Source: Service provider's data

3.7.2 Equipment

All laboratories of the service provider have appropriate and adequate equipment for all routine and few advanced tests. L3 laboratories are equipped with haematology analyser (3-part), biochemistry analyser (semi-automated in majority of laboratories) and urine analyser; L2 laboratories have haematology analyser (3-part, and 5-part in few laboratories), semi/fully automated biochemistry analyser or both, PT analyser, urine analyser, electrolyte analyser and HbA1C nycocard reader; and L1 laboratories are equipped with haematology analyser (3-part, and 5-part in few laboratories), semi/fully automated biochemistry analyser or both, PT analyser, urine analyser, electrolyte analyser and HbA1c nycocard reader. Few L1 laboratories have HPLC for HbA1c, electrophoresis machine for haemoglobin electrophoresis, histopathology equipment and requisite set-up for manual testing for urine and blood cultures and drug sensitivity. Table 37 below gives a snapshot of various equipment available at different kinds of laboratories:

Table 37: Equipment at service provider's laboratories

Type of laboratory	Equipment
L3 laboratories (cater to PHCs and CHCs)	Haematology analyser (3-part) and biochemistry analyser (semi-automated in majority of laboratories) and urine analyser
L2 laboratories (cater to PHCs, CHCs, AHs and DHs)	Haematology analyser (3-part, and 5-part in few laboratories), semi/fully automated biochemistry analyser or both, PT analyser, urine analyser, electrolyte analyser and HbA1C nycocard reader

Type of laboratory	Equipment
L1/mother laboratories (cater to PHCs, CHCs, AHs and DHs)	**All laboratories:** Haematology analyser (3-part, and in few laboratories 5-part), semi/fully automated biochemistry analyser or both, PT analyser, urine analyser, electrolyte analyser and HbA1C nycocard reader. **Few laboratories:** HPLC for HbA1c, electrophoresis machine for haemoglobin electrophoresis, set-up for manual testing for urine and blood cultures and histopathology equipment.

Source: Service provider's data

According to information provided by the service provider regarding status of equipment in the two surveyed districts, two out of seven laboratories in Krishna and five out of eight laboratories in Visakhapatnam only had semi-automated analyser for biochemistry tests and did not have fully automated analyser. Back-up of biochemistry analyser (one semi-automated, one fully automated) was present in two L2 laboratories and one L1 laboratory in each of the two districts. Back-up of haematology analyser was present in only one L2 laboratory in Krishna district. The service provider has made provision for back-up of analysers only in a few laboratories. In absence of back-up, tests cannot be conducted in those laboratories.

Primary survey of six laboratories found similar positioning of equipment in each of the three kinds of laboratories. Only one L1 laboratory did not have neubauer chamber for manual cell count. All equipment was found to be in good condition. Daily cleaning was carried out for all equipment. The laboratories maintained manual records for equipment calibration. Haematology analyser, biochemistry analyser, urine analyser and electrolyte analyser were annually calibrated. However, centrifuge, pipettes, PT analyser, nycocard reader and culture hood were not calibrated. Equipment maintenance plan was not found in any of the surveyed laboratories. According to laboratory technicians, breakdown of equipment happened once or twice in a month and was mostly resolved on the same day. Records of equipment breakdown were not maintained at the time of survey. The service provider started recording equipment downtime only from May 2017. The records for the two study districts showed a total downtime of 27 days across all laboratories. According to the service provider, during equipment breakdown, samples for routine tests were sent to the nearest laboratory of the service provider. However, TSH test was outsourced to another laboratory during breakdown of the immunoassay equipment as the other mother laboratory having the same equipment was in a different district and sending the samples there would lead to high turnaround time attracting penalties for the service provider.

Haematology analyser, fully automated biochemistry analyser, immunoassay analyser, HPLC machine and haemoglobin electrophoresis machine were interfaced with the laboratory information system. Machines which had not been interfaced were semi-automated biochemistry analyser, PT analyser, urine analyser, electrolyte analyser and HbA1C nycocard reader. The results of tests conducted on equipment which were not interfaced were recorded manually and later typed and saved electronically. This increases the chances of pre- and post-analytical errors.

Urine and blood cultures were performed using manual methods in L1 laboratories; the automated system for blood culture though has much higher sensitivity and faster turnaround time.

Power back-up was present in all the surveyed laboratories.

3.7.3 Reagents and consumables

An inventory management system was in place at all laboratories. All laboratories placed orders for reagents and consumables to mother laboratories which further placed the orders to service provider's head office in Chennai. The head office purchased the reagents and consumables from fixed vendors. The orders for reagents were placed monthly from each of the laboratories. The reagents were received at the laboratories in 10 days from the time of ordering. An inventory of 45 days was kept in stock in the laboratories. There were few instances of stock-out mainly during high season of dengue and when camps were organised. Stock-outs happened for dengue kits, RPR kits and syringes. During stock-outs, stocks of other nearby laboratories of service provider were checked. In case of unavailability of extra stock in those laboratories, emergency orders were placed or in rare cases, the laboratories purchased locally. An effort should be made to move to quality assured/WHO prequalified reagents and diagnostics in the future.

In the surveyed laboratories, closed system reagents were used (for better testing quality); reagents and consumables were found to be of good quality, in adequate stock and were stored at requisite temperatures. However, blood culture bottles used were of suboptimal quality. Paediatric culture bottles were not available. The service provider did not purchase media for urine culture; it was instead prepared in mother laboratories. The prepared media was not amenable for transportation to L2 laboratories and therefore plating could not be done immediately after receiving the samples. The samples had to be transported to the mother laboratories for testing, leading to loss in integrity of samples.

According to state officials, the service provider used open system reagents in the initial stages of the rollout, the reagents were substandard and some of the reagents were found to be denatured at the time of inspection by the government monitoring officers.

3.7.4 Human resources

According to the information provided by the service provider, each district had a pathologist, 12 out of 13 districts had a biochemist (MD/PhD) and 4 out of 13 districts had a microbiologist (MD/PhD). These diagnosticians were stationed at L1 laboratories or district reporting centres. The total number of laboratory technicians in the 104 laboratories were 393 – 196 senior laboratory technicians (more than 3 years of work experience) and 197 junior laboratory technicians.

Among the surveyed laboratories, one L1 laboratory was headed by a pathologist (MD) and the other by a microbiologist (PhD). In the latter L1 laboratory, peripheral smears and cytology were reported by the pathologist at district reporting centre and biopsies were reported by pathologist at the Chennai laboratory.

The number of laboratory technicians was found to be adequate in all laboratories. The experience of the technicians varied from 1–5 years at the time of interviews. All tests except microscopy for histopathology, cytology, peripheral blood smear and fluid smear were conducted by laboratory technicians with no supervision by diagnosticians. The quality

control (IQC and EQAS) was also managed by the laboratory technicians. Quality assurance quality team managers sometimes assisted the laboratory technicians in troubleshooting for testing errors and equipment repair. During interviews with the laboratory technicians, it was found that most of them were adequately informed about conducting tests, running controls, maintenance of records and to some extent troubleshooting. However, the laboratory technicians were neither sufficiently equipped, nor supervised for identifying and managing erroneous results; they continued testing even when there were erroneous results due to technical problems in equipment, testing methodology etc. The laboratory technicians were also not trained adequately on corrective and preventive actions required for managing out-of-range internal and external quality control results.

Administrative staff in the laboratories was well-informed about management of the laboratories.

The service provider has instituted a dedicated central quality team which manages quality control, inspection of laboratories and NABL accreditation etc. The team lacked adequate expertise in managing corrective and preventive actions for out-of-range test results, IQC and EQAS. The team did not supervise the quality control and quality of processes, and did not conduct on-job training of laboratory technicians. There was lack of initiative in the central quality team for doing root-cause analysis of erroneous test results in the laboratories. Also, test-wise standard operating procedures had not been prepared by the team for training of laboratory technicians. The team visited the laboratories occasionally for inspection. During their visits, they did not impart any structured training to the laboratory staff.

3.7.5 Training

At the time of rollout, the service provider had conducted induction trainings for 916 phlebotomists and 237 laboratory technicians. The training was imparted by a team of 70 laboratory technicians who were mobilized from service provider's laboratories in other states. These technicians also assisted in recruitment of all the technical staff. The technicians who joined later were trained by quality assurance quality team managers.

Training for ISO certification was conducted for administrative and managerial staff, quality assurance quality team managers and select senior laboratory technicians.

Out of the 104 laboratories of the service provider, diagnosticians are stationed only in seven mother laboratories. Rest of the 97 laboratories function solely on the expertise of laboratory technicians. Therefore, robust training and competency assessment of technicians is key in delivering quality services under the NTR Vaidya Pariksha scheme. At the time of survey, the service provider had not instituted a training structure and curriculum for its laboratory technicians, phlebotomists and other staff. The standard operating procedures for training and training manuals were not in place. There was no dedicated team of master trainers. Training was ad-hoc and was conducted by quality assurance quality team managers only at the time of induction. The competency of quality assurance quality team managers as trainers was questionable as they did not receive periodic trainings themselves under the supervision of diagnosticians and did not undergo periodic competency assessments. The laboratory technicians also did not receive any refresher trainings and did not undergo any competency assessments. The trainings by equipment vendors were also conducted for only one type of equipment.

3.7.6 Records

At the time of survey, manual records were maintained for equipment calibration, critical test results, preventive and corrective actions, sample rejection and for samples which were sent to mother laboratories or outsourced to other laboratories. Records were not maintained for equipment downtime and repeat orders from clinicians. Records were found to be incomplete or inadequate for critical test results and preventive and corrective actions.

3.7.7 Quality assurance

The service provider has been continually working towards improving quality of its services. All 104 laboratories were certified under ISO 9001 and BIS within 10 months of rollout. All the 104 laboratories participated in EQAS and established IQC for select tests – out of 42 tests provided by the service provider under the NTR Vaidya Pariksha scheme, IQC is carried out for 25 tests and EQAS for 31 tests (table 38). IQC is not done for any of the advanced tests and rapid kit tests; and EQAS is not done for clinical pathology tests and rapid kit tests (table 40).

The service provider established IQC within 1 month of setting up of the respective laboratories and started participating in EQAS after 4 months of rollout of the scheme (table 39). The state government penalised the service provider for delay in initiation of EQAS.

Table 38: Number of tests for which IQC and EQAS are carried out in the laboratories of service provider

Total number of tests provided by the service provider	42
Number of tests for which service provider established IQC	25
Number of tests for which service provider participated in EQAS	31

Source: Service provider's data

Table 39: Time of initiation of EQAS in service provider's laboratories for each category of tests

Institute	Department	Month of Start
CMC	Biochemistry	May 2016
RML	Biochemistry, haematology and immunology	September 2016
AIIMS	Haematology	September 2016
RML	Histopathology and cytology	March 2017
RML	Microbiology and serology	March 2017
CMC	Haemostasis (PT)	June 2017

Source: Service provider's data

Table 40: List of tests for which IQC and/or EQAS was not performed

IQC and EQAS not done	IQC not done	EQAS not done
Fluid examination	Peripheral blood smear	Serum LDH
Semen analysis	Blood culture	
Troponin I	Urine culture	
Troponin T	Histopathology	
Coombs Test - direct	Cytology	
Coombs Test - indirect	Bone marrow aspiration	
Prothrombin time test and INR	Rapid plasma reagin (RPR)	
Urine complete analysis		
Dengue rapid test		
Rapid plasma reagin (RPR)		
Anti streptolysin O		
Rheumatoid factor		
Serum CRP		
Stool for ova and cyst		

Source: Service provider's data

EQAS was carried out once in 2 months for cultures, histopathology and cytology. EQAS for cultures was done in the outsourced laboratories also. EQAS was not done for histopathology and cytology in the outsourced laboratory in Visakhapatnam.

Inter-laboratory comparisons were also carried out for few tests periodically. In IQC, daily one-level instead of two-level controls were put. Out of range IQC was calculated based on more than two standard deviation (SD) from the reference range prescribed in the reagents' guideline inserts. Westgard rules were not considered to establish deviations. Also, tests were conducted even when IQC was out of range and corrective actions (if taken) failed.

The laboratory technicians were trained on preparation of controls as well as on corrective actions but required more effective training and supervision on managing corrective actions for out of range IQC results. The records of corrective actions were maintained manually, however, the records were found to be incomplete and in few cases inaccurate. IQC data was uploaded and then validated remotely by diagnosticians of the service provider. The validation was not real-time and therefore the technicians continued testing despite out-of-range IQC.

Standard operating procedures were not in place except those for running the equipment. The quality of pre-analytical, analytical and post-analytical processes carried out by the laboratory technicians was not monitored by district or central quality team. Internal and external audits of the laboratories were not conducted. The Pathologists of the central quality team had inspected the laboratories once or twice in 18 month period of scheme implementation.

3.7.8 NABL accreditation

As a contractual responsibility, the service provider is mandated to get all its laboratories accredited under NABL within 3 years of signing of the Agreement. The 3-year period given to the service provider for accreditation is too long as the contract period is over by the time NABL accreditation is done. The contract therefore ends up purchasing only less than desirable quality of services, for almost the entire duration of the contract period. At the time of survey, the service provider was in the process of getting all seven mother laboratories NABL accredited. However, 16 tests, mainly advanced tests have not been included in the scope of accreditation. Tests which have not been included in the scope are listed in table 41 below.

Table 41: Tests not included in the scope of upcoming NABL accreditation of seven mother laboratories

S.no.	Name of the test
1	Blood culture
2	Urine culture
3	Histopathology
4	Cytology
5	Fluid examination
6	Prothrombin time
7	Semen analysis
8	Serum calcium
9	Troponin T
10	Troponin I
11	CRP
12	ASLO
13	RA Factor
14	Total eosinophilic count
15	Coombs test direct
16	Coombs test indirect

Source: Service provider's data

Also, tests such as blood culture and urine culture which were outsourced to private laboratories in some districts were not NABL accredited.

3.8 Quality of test results

3.8.1 Validation of test results

The state government had enforced an effective work allocation for validation of test results by respective diagnosticians. All test results were validated by qualified pathologists/biochemists/microbiologists. Haematology and clinical pathology results were validated by pathologists; biochemistry and immunoassay test results by biochemists; and serology and microbiology test results by microbiologists. Each diagnostician validated between 100-1400 tests per day depending on case load of that day.

The diagnosticians remotely validated results of tests conducted by laboratory technicians. The normal results were auto-approved. However, no inbuilt algorithms were in place for auto-approval of results. The laboratory software had a provision for adding diagnostician's comments and for ordering re-run or re-check of samples which then reflected in the laboratory information system of the respective laboratories. For example, the software enabled the diagnostician to order preparation of blood smear in case of low platelet count and order for dilution of sample in case of abnormally high value of serum creatinine. The laboratory technician then performed the requisite procedure as ordered by the diagnostician.

Precision testing was not carried out to check accuracy of results of tests conducted by laboratory technicians who worked without any direct supervision of senior technicians or diagnosticians.

3.8.2 Erroneous results

In the initial stages of rollout, there were several complaints from clinicians about inaccuracy of test results. The service provider took some steps to address this issue – for example, open system reagents were substituted with superior quality closed system reagents, calibration errors were corrected etc. At the same time, many complaints from clinicians about accuracy of test results went unaddressed due to the assumptions of service provider that the results given out could not be inaccurate considering that equipment were calibrated annually, IQC and EQAS were done on a regular basis and good quality reagents were used. However, the service provider overlooked the fact that there could be many other causes of erroneous results which were not considered.

During the survey, it was found that in majority of cases, root-cause analysis was not carried out by the service provider's quality team for various aspects of inaccuracies in test results such as erroneous results, out-of-reference range results, repeat testing requested by clinicians and out-of-range IQC and EQAS.

The laboratory technicians continued testing even in the event of repeated erroneous results for tests of several patients; arising because of technical problems in equipment, testing methodology etc. The erroneous test reports were also given to the patients. The doctors complained to the service provider when results for specific tests were given as too high or too low for all patients for a prolonged period, or as normal for patients with clinical signs. However, in most cases, doctors continued prescribing those tests as they were mandated

to use services of the service provider only. For example, in one of the surveyed laboratories, prothrombin time test results were uniformly high for many days; and no root cause analysis had been done and erroneous reports were given to the patients. In another case, the biochemistry analyser was giving false high results for all serum bilirubin tests; and the technicians continued testing on a faulty equipment which got repaired only after a few days.

Inaccuracies resulting due to loss of sample integrity had also not been corrected. Prolonged sample transportation time of 3–12 hours to the mother laboratories and inadequate cold chain to support the long pre-analytical time led to inconsistent results for tests like urine culture and fluid examination. Also, absence of certain gold standard pre-analytical processes such as preparation of blood smear at the time of sample collection instead of the existing practice of preparation of smear at the testing laboratory (which involves delay of 5–14 hours from the time of sample collection), compromised the quality of reporting of platelet count test and peripheral blood smear examination. Also, lack of relevant clinical history and specimen description in the requisition forms for cytology and histopathology specimens compromised the quality of reporting.

Errors arising out of manual labelling of secondary tubes and manual entry of results were not taken into consideration by the service provider. Also, since the pipettes were not calibrated, pipetting errors could have occurred while conducting tests on semi-automated equipment.

Some of the tests were carried out using relatively inferior technology. For example, HbA1c was done using nycocard reader for several months; it was later replaced by HPLC on request of the state government. Blood culture bottles used were of inferior quality with lesser sensitivity. Blood culture test was done using manual method instead of the automated method which is faster and more sensitive. Also, tests for RA factor, CRP and ASLO were performed on biochemistry analyser instead of turbidometer.

Reagents of few tests have very short shelf lives and those need to be monitored. For example, for assessing reagent stability for prothrombin time test daily, a daily control of normal reference range blood sample is required to be put. This was not in practice at time of the survey and the quality team was also unaware about this requirement.

As mentioned earlier, it was found during the survey that the tests were conducted even when IQC was out of range and corrective actions (if taken) failed. In many cases the corrective actions taken were faulty. For example, in a surveyed laboratory, the internal control was out-of-range. The control was re-run and it came within range this time and it was assumed that the equipment was ready to conduct tests since the internal control was now within the range. It was not considered that two different results of the same control reagent could also indicate an error in precision of the equipment.

3.8.3 Repeat testing

Doctors ordered for repeat testing when the test results of service provider were found to be inaccurate or did not correlate with the clinical picture. Tests were either repeated at the service provider's laboratory or cross-checked in the in-house laboratory/private laboratory or patients were referred to a higher facility. Discrepancies were found several times between test results of service provider and private laboratory/in-house laboratory and this

confused the clinicians even more for arriving at diagnoses. In several cases of doubtful reports though, doctors did not prescribe repeat testing and started treatment according to the patients' clinical picture.

In the surveyed PHCs, 3–10% of service provider's tests were repeated. The most common tests which were repeated were platelet count and serum bilirubin. In majority of CHCs, 2–5% tests were repeated. In 2 surveyed CHCs, the percentages were 5–10% and 15–20% respectively. In another CHC, there was no repeat testing any more. Also, few doctors carried out inter-laboratory comparison of service provider's tests with the in-house laboratory on a regular basis to validate service provider's test results. The most common tests which were repeated were haemoglobin and urine examination.

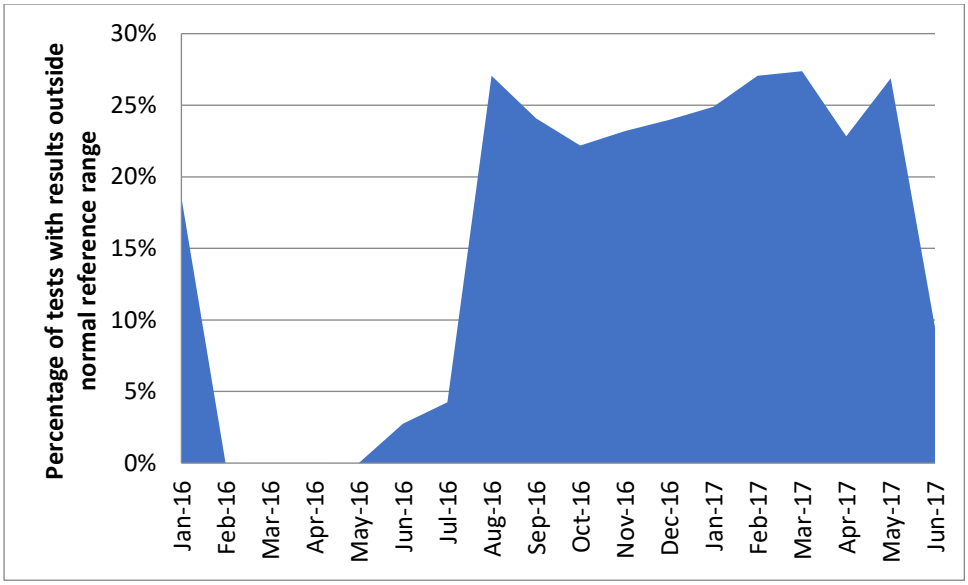
In one AH, 5–10% of service provider's tests were repeated and discrepancies were found between the two test results. 30–40% cases of TSH were repeated at private laboratories. In the other AH, very few tests were repeated. In one DH, less than 10% tests were repeated. Many patients were not willing to get repeat tests from private laboratories because the tests were not free there. For an instance, some patients visited the DH only for thyroid function screening and if report was found to be erroneous, they did not want to spend money on repeat tests at private laboratories. In the other DH, 2–3% of tests were repeated.

The clinicians in the government health facilities communicated orders for repeat testing to the phlebotomists. The communication was verbal for re-testing of the same sample. However, in case of re-sampling, a new requisition form was filled by the clinicians. Record of repeat testing was not maintained at the laboratories of the service provider. In one laboratory, an estimate of repeat orders was provided by its laboratory technicians – from DH: serum electrolytes were repeated in 5-10% cases, prothrombin time in 2–3% and HbA1c in 0.1% cases (mainly tests with very high HbA1c results were repeated); from PHCs – platelet count and serum bilirubin were repeated 5–6 times in a month; and from CHCs – serum bilirubin, blood urea and serum creatinine were repeated 5–10 times in a month. The repeat tests were billed as new cases only if a fresh requisition form was filled by the ordering clinician.

3.8.4 Out-of-reference range tests

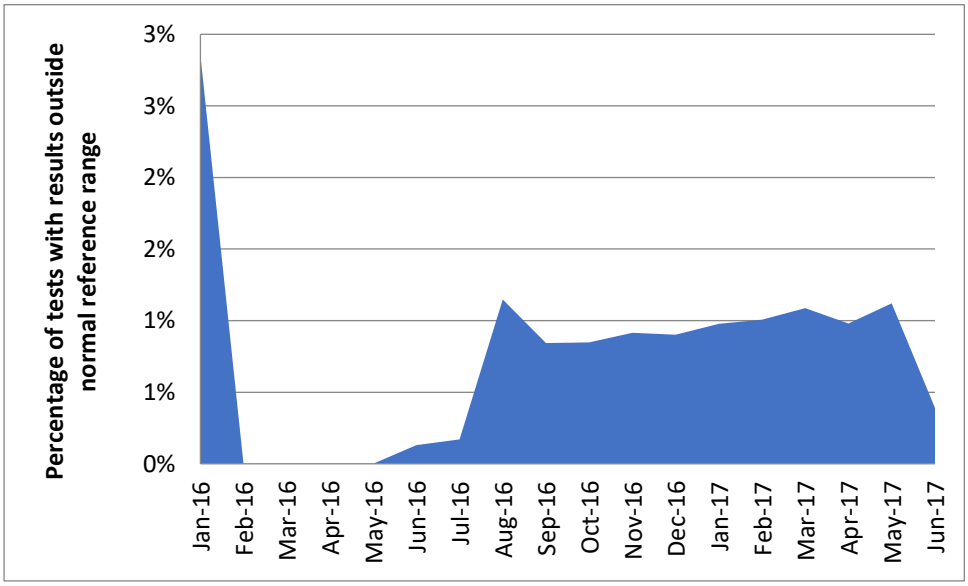
It was found on analysis of secondary data of out-of-reference range test results that the results of all kinds of tests were found to be within normal reference range for all patients for several months (February to July 2016) (figure 22 and 23). Also, the percentage of abnormal results (out-of-reference range) among IPD patients tested was found to be extremely low throughout the period of January 2016–June 2017 (0–1.3%) (figure 23). From July to August 2016, the percentage of out-of-reference range test results increased from 4% to 28% among outpatients and from 0.2% to 1.3% among inpatients (figure 22 and 23). In June 2017, a sudden steep fall in percentage of abnormal test results was again observed for both OPD and IPD patients (figure 22 and 23).

Figure 22: Percentage of tests with results outside normal reference range among outpatients



Source: Service provider's data

Figure 23: Percentage of tests with results outside normal reference range among inpatients



Source: Service provider's data

3.8.5 Sample rejection rates

Sample rejection rates were found to be abnormally low at service provider's laboratories and varied from 0% to 0.63%. Also, it was unclear if the samples were screened rigorously for loss of integrity before these were tested. The records of sample rejection were maintained manually and the rejection rates were not monitored.

3.8.6 Rating of quality and availability of tests

During the survey, 32 doctors at the government health facilities were asked to rate the quality and availability of tests provided through the NTR Vaidya Pariksha scheme and in-house laboratory on a scale of 1–5 (5 being the highest and 1 being the lowest).

Half of the doctors at PHCs and CHCs (50%) rated quality of tests under the NTR Vaidya Pariksha between 4–5. In AHs and DHs, majority of doctors (61%) rated the quality between 3–4. The relatively lower rating in AHs and DHs, compared to PHCs and CHCs could be explained by poor quality of results of advanced tests which are available only at AHs and DHs. For in-house laboratories, majority of doctors across different types of facilities rated the quality between 4–5 (77% in PHCs and CHCs; and 69% in AHs and DHs) (table 42). It was observed that doctors across the surveyed facilities were more satisfied with quality of in-house laboratory services compared to the services under the NTR Vaidya Pariksha scheme.

The availability of tests was assessed in terms of variety of tests, actual availability of these tests and turnaround time of tests. Maximum number of doctors at PHCs and CHCs (45%) rated the availability of tests under NTR Vaidya Pariksha scheme at 3. One of the reasons cited for lower rating was that very few tests had been made available through the NTR Vaidya Pariksha scheme, especially at PHCs. In AHs and DHs, doctors were mostly satisfied with the basket of tests and availability of designated tests under NTR Vaidya Pariksha scheme; but the turnaround time was a concern. Availability was rated at four and five by majority of doctors (41% each). The availability of in-house laboratories was rated at three by maximum number of doctors at PHCs and CHCs (45%). These doctors were dissatisfied with the small number of tests assigned to in-house laboratories at PHCs. In AHs and DHs, maximum number of doctors (57%) rated availability of in-house laboratory tests at 4 (table 42).

The relatively lesser satisfaction with quality of services under the NTR Vaidya Pariksha scheme compared to those at in-house laboratories could be explained by resistance among doctors to prescribe tests to the service provider instead of private laboratories which usually incentivise doctors for prescribing tests.

Table 42: Rating by doctors at government health facilities for services under the NTR Vaidya Pariksha scheme and at in-house laboratories

Rating	Percentage of doctors who gave rating (for services under the NTR Vaidya Pariksha scheme)		Percentage of doctors who gave rating (for services at in-house laboratory)	
	PHC/CHC	AH/DH	PHC/CHC	AH/DH
Number of doctors who rated the services	14	18	13	16
Quality				
4–5	50%	33%	77%	69%
3–4	43%	61%	15%	6%
2	7%	6%	8%	
1	0%	0%	0%	19%
Availability				
5	27%	41%	18%	36%
4	36%	41%	18%	57%
3	45%	12%	45%	0%
2	9%	6%	9%	24%
1			9%	7%

3.9 Monitoring of services

3.9.1 Monitoring by the state government

The state government set up stringent monitoring mechanisms for monitoring rollout of services under the NTR Vaidya Pariksha scheme. Following are the key monitoring structures set-up/leveraged by the state government:

i. A dashboard, available in the public domain was created by the service provider on request of the state government in the initial stages of the rollout. The dashboard contains real-time facility-wise data of the total number of patients tested and tests done. In addition, state-wide data of total number of each type of test conducted and percentage of tests complying with stipulated the turnaround time are also indicated. All data is represented in two kinds of timeframe – to-date and of that day.

ii. The state program implementation unit (SPIU) was engaged in the initial 1 year of rollout of the scheme to closely monitor the implementation. The monitoring team at SPIU included a diagnostician too. The SPIU monitored the dashboard data daily for facility-wise total number of patients tested and total number of tests conducted as well as state-wide turnaround time. Besides dashboard data, the service provider furnished more detailed data on turnaround time of individual tests on a weekly basis and EQAS results every month in a CD. This data was used for releasing payments. The data was examined by the SPIU team for any deviations. Penalties were levied on the service provider accordingly. The SPIU team also participated in all meetings of state officials with the service provider.

iii. The state government leveraged the drug control administration (DCA) for inspection of laboratories of the service provider. The inspections started in May 2016, 4 months after rollout of the scheme. Each laboratory was inspected once in 3–4 months by the drug inspectors. The drug inspectors checked: a) equipment: availability and usage status of equipment, calibration certificates of the equipment; b) laboratory staff: availability of laboratory staff and their qualification certificates; c) list of facilities catered by the laboratory and list of tests provided by the laboratory to these facilities; d) reagents and consumables: quality, inventory, purchase bills; the quantity of reagents and consumables in purchase bills was tallied with number of tests conducted in that period; e) other processes of the laboratory were examined and records, log books, certificates of laboratory registration, biomedical waste management, pollution clearance were also checked; f) the drug inspectors also checked log in and log out times in the main computer where reports were entered and matched these with the time of report generation on the patients' reports; g) in few instances, they also called patients on the phone numbers provided in the records for verifying if those were real patients and whether they received their test reports.

It was found that in the initial stages of rollout, the quality of processes such as cold chain, labelling etc. was suboptimal and quality and storage of reagents was sub-standard. The laboratories did not maintain records of sample pick-up time, sample receipt time etc. In some cases, purchase bills of reagents and consumables did not tally with the number of tests shown as conducted by the laboratory. Power back-up was not available in few laboratories. The service provider gradually strengthened its processes and started using better quality reagents. Power back-up was also provided in laboratories.

Clearly, the DCA played an important role in identifying teething issues in the early stages of rollout and helping the state government in streamlining these issues and bolstering operations under the NTR Vaidya Pariksha scheme. Nevertheless, going forward, it would not be prudent if DCA continues to monitor the franchisee laboratories on behalf of the

franchiser (primary contractor) on a regular basis. It would be more useful if it plays the role of providing additional layer oversight to service provider's ongoing monitoring.

iv. District health officials (DMHO and DCHS) made monthly visits to the government health facilities to inspect all services including the NTR Vaidya Pariksha scheme. For this scheme, they checked availability of sampling services, report dispatch services, maintenance of records, biomedical waste management and qualifications and training of phlebotomists. Many of these visits were surprise visits. Some officials preferred making these surprise visits at the beginning or end of the working hours to check the availability of staff at those times. DCHS and DMHO collected monthly data from the government health facilities on total number of patients tested and total number of tests conducted under the NTR Vaidya Pariksha scheme and submitted this data to the state officials. Along with this, they also took feedback, though patchy and informal from the doctors on various aspects of service provider's services, such as quality and turnaround time.

The state government had recently appointed nodal officers for each district to supervise all public private partnership schemes. For the NTR Vaidya Pariksha scheme, the nodal officers are required to inspect health facilities as well as laboratories of the service provider.

v. State-level review meetings were conducted monthly and were chaired by the Health Minister and Principal Secretary, Department of Health and Family Welfare. All schemes and programmes were discussed in these meetings. District health officials, DCA and SPIU provided feedback on the progress of the NTR Vaidya Pariksha scheme. During the initial stages of rollout, the concerns raised about the scheme were – discrepancies in test results, delayed turnaround time, poor cold chain, equipment calibration not carried out in service provider's laboratories, EQAS not initiated etc. The service provider was also invited to these meetings for presenting progress on the scheme as well as actions taken on concerns raised in the previous meetings.

vi. The district collector conducted review meetings with district health officials and administrators and doctors of the government health facilities once in 2 months to discuss the progress of various programmes. In few meetings, the District in-charge of service provider was also called to address concerns regarding the NTR Vaidya Pariksha scheme.

These monitoring interventions of the state government were instrumental in improving the access and quality of services provided by the service provider under the NTR Vaidya Pariksha scheme.

Penalties were levied on the service provider for not meeting certain contractual clauses such as turnaround time and EQAS. At the same time, the state government worked closely and synergistically with the service provider for ironing out the teething issues. The state government also enabled a participative instead of imposing approach with the service provider in making decisions related to implementation of the scheme. For example, the government worked out the feasibility of adding few expensive advanced tests to the list in

consultation with the service provider. The state government also provided adequate autonomy to the service provider in its day-to-day operations.

It was found that in 50% of surveyed CHCs, one AH and both DHs, the administrators sought feedback from the clinicians on quality and availability of tests provided by the service provider. The feedback was however taken occasionally and was informal and verbal. Very few administrators escalated the concerns of doctors to the district officials. Few administrators also escalated concerns to the service provider.

Some gaps were noticed in communication between district officials and the government health facility staff on availability of services under the NTR Vaidya Pariksha scheme. For instance, according to a district officer, sickle cell test (haemoglobin electrophoresis) was provided at a tribal AH. However, doctors at the AH denied availability of the test.

Data validation is a vital part of any public private partnership programme. It was noted during the survey that the in-house laboratory technician sought data from the phlebotomist of the service provider on a daily basis on number of patients registered for testing under the NTR Vaidya Pariksha scheme on that day. This data was uploaded by the pharmacist or data entry operator on the government portal. It was observed that the data was rarely validated at any level at the government health facility. In one DH, the medical superintendent occasionally signed the register in which service provider's data was recorded. However, this was not cross-checked with any record. In another DH, the medical superintendent occasionally checked the validity of patients registered by the service provider for testing by matching patients' names on filled requisition forms with the OPD register of the hospital. There was also no mechanism in place for validation of reports received at the health facility from service provider's laboratory.

The data on number of patients registered for testing and number of tests ordered at each government health facility was uploaded on dashboard on a real-time basis in the laboratories of service provider. The data got updated as patient (sample) registration was carried out at these laboratories. This data was sometimes tallied with the data provided by the government health facilities by SPIU. Also, the SPIU kept a close watch on dashboard data and flagged extremely low or high numbers of patients tested at a particular government health facility.

At the time of survey, there was no mechanism in place for checking whether tests of registered patients were conducted or not. As mentioned before, in the initial months (February–June 2016), it was found that 100% test results were within normal reference range. This is very odd, given the profile of patients visiting the government health facilities, especially DHs and AHs. Also, 95–100% dengue tests were positive in this period.

The service provider was later directed by the state government to archive print-outs of test reports directly from the equipment, possibly as a checking mechanism for whether tests were actually conducted.

For grievance redressal, complaint boxes were available at the government health facilities, but were not used. The doctors and administrators at the health facilities informally handled patients' complaints.

3.9.2 Monitoring by the service provider

The service provider has instituted mechanisms for monitoring services under the NTR Vaidya Pariksha scheme. The monitoring team of the service provider comprises of state-level and district-level teams. The state-level team consists of five members – general manager – operations, head – total quality management, head – quality assurance and two PhD doctors. Each district team consists of 12 members – one district operations manager, four quality assurance quality team managers, four operations executives, one IT manager, one inventory manager and one accountant.

The quality assurance quality team managers are senior laboratory technicians with 4–5 years of experience. These managers are responsible for supervising quality assurance in laboratories, troubleshooting for analytical processes, training of laboratory technicians, addressing concerns of clinicians about accuracy of test results, checking maintenance of records in the laboratories, ensuring adherence to biomedical waste management etc.

The operations executives manage an average of two laboratories each. They are responsible for managing availability of phlebotomists, ILD staff and laboratory technicians, supervising phlebotomists for maintaining records (requisition forms, batch sheets, registration and report dispatch registers), monitoring logistics of sample transportation and report dispatch and addressing complaints from doctors on logistics issues, such as the turnaround time.

The district team connects over a conference call daily to update the district operations manager on the daily operations and challenges. The central team is in turn updated by the district operations managers daily. These updates are used as a monitoring tool as well as for troubleshooting.

In each district, there is a team of 2–3 diagnosticians who carry out test results' validation, reporting and monitoring of IQC. The central quality team carries out inspection of the laboratories.

During the survey, it was found that in one AH and two DHs, district teams of the service provider met the medical superintendent to take feedback on their services once in 2–3 months, and doctors once in 5–6 months. In the other AH, the service provider's representative met the doctors every month. In the surveyed PHCs and CHCs, the doctors were aware of the availability of service provider's representative; however, these representatives had visited the doctors rarely or never. In few CHCs, the representatives made frequent visits to the doctors. In most of the facilities, the service provider's representatives requested doctors to prescribe tests to more patients.

The doctors had provided feedback to the district team or to the phlebotomists stationed in the facilities. Various concerns raised were inaccuracy of test results (haemoglobin, platelet count, serum creatinine, dengue test and urine examination), high turnaround time of reports running into 2–3 days for routine tests and more so for advanced tests, delays in receiving reports in the morning, delays in reports of emergency samples (5–6 hours), non-communication of critical results to the health facility, delays in sample pick-up and transportation of samples, unavailability of certain tests for a period of time (serum bilirubin, serum creatinine), addition of more tests (TFT, ESR), insufficient cold chain; quicker sample dispatch of sick newborn care unit (SNCU) samples, unavailability of phlebotomists,

untrained phlebotomists, insufficient waste bags and low salaries of phlebotomists of the service provider. Corrective actions were taken by the service provider for few aspects at few facilities. These included inaccuracies of test results, high turnaround time, delays in reports of emergency samples and unavailability of certain tests for a period. However, for other concerns, no corrective actions were taken at any of the facilities.

In the survey, it was found that some doctors were not updated about the availability of tests at their respective facilities. For an instance, at one AH, in the initial stages, blood culture was not available on many days and turnaround time was around 15 days. One of the clinicians stopped prescribing this test at that time and did not resume prescribing even after the test was readily available and the turnaround time had reduced. The reason cited by the clinician was that he had not been updated by the service provider about availability of the test.

The service provider had set up a call centre on request of the state government for grievance redressal. According to the service provider, it received few calls from clinicians and patients from the government health facilities in the first two months, after which no calls were received. However, the phone number was not found to be displayed in any of the surveyed facilities.

3.10 Adherence to clauses in the Agreement

The service provider has complied with most of the clauses in the Agreement. Following are a few gaps in implementation of the Agreement clauses:

i. In the list of designated tests, the service provider has not made provision for serum calcium test.

ii. The phlebotomists of service provider do not conduct all tests assigned to in-house laboratory in health facilities where position of in-house laboratory technician is vacant.

iii. Blood culture test is not conducted on automated blood culture system.

iv. The service provider has not got its laboratories audited by a third party NABL accredited laboratory.

v. The service provider has not declared the list of empanelled laboratories to the state government.

vi. The service provider has not prepared and submitted standard operating procedures on sample transportation, storage and testing processes to the state government, has not declared human resources and equipment at each laboratory, has not shared detailed logistics plan and has not maintained proper records of critical test results and informed doctors about the same.

vii. The service provider has not submitted reports to the state government on unavailability of sampling services at the government health facilities.

3.11 Payments to the service provider

Payments to the service provider were made in accordance with the clauses mentioned in the Agreement signed between the two parties. The service provider was required to submit invoices on weekly basis with details of turnaround time of all tests conducted during that period and data of EQAS at month end for EQAS results of that month. The authorisation of payments was done by SPIU, followed by the commissioner, Department of Health and Family Welfare and finally by the principal secretary, Department of Health and Family Welfare. The electronic disbursement of payments by the state government to the service provider is a good practice.

A weekly payment cycle is recommended in the Agreement. There was a challenge in making weekly payments though, as the penalties were levied on a monthly basis in accordance with the Agreement. The payment cycle was found to be of 40 days in most cases with longest duration of 120 days. The service provider submitted invoices on a weekly basis to the state government. In the initial months, the payments were released in 60-65 days. Some of the factors leading to delay in payments were – penalties levied on a monthly basis (as mentioned in the Agreement), clarifications sought by the government about deviations in services, and changes in authorising officers. Penalties were levied for delayed turnaround time and EQAS not performed or EQAS out-of-range for more than 2% of tests. The penalties were started in June 2016 for EQAS and in July 2016 for the turnaround time, deductions were done based on penal clauses. Also, full payments were made most of the time. Sometimes, parts of payments were withheld by the state government if ambiguities were found in the services of the service provider. In few instances, the service provider had questioned the penalties levied by the government.

For first 3 months of the services, the state government had not made payments to the service provider for patients who were not tested but charged in lieu of minimum assured volume, because complete rollout of services took place at the end of the third month only.

As stipulated in the Agreement, the state government did not charge any fee or rent for the space provided to the service provider inside the government health facilities for sample collection. The service provider had so far not asked the government for payments on count of operational costs, damages for mishaps etc.

3.12 Budget allocation

The central government contributed to 60% and the state government 40% of the budget for the NTR Vaidya Pariksha scheme. In 2015–16, the budget allocated was INR 75 crore, in 2016–17 INR 105.75 crore and in 2017–18 INR 105.75 crore. The expenditure in 2015–16 was INR 12.47 crore and in 2016–17 INR 101.75 crore (table 43).

For the in-house laboratory services, 100% of the cost was borne by the state government.

Table 43: Allocation and expenditure of budget under the NTR Vaidya Pariksha scheme

Year	Budget Allocation (crore in INR)	Expenditure (crore in INR)
2015–16 (January–March)	75.00	12.47
2016–17	105.75	101.75
2017–18	105.75	

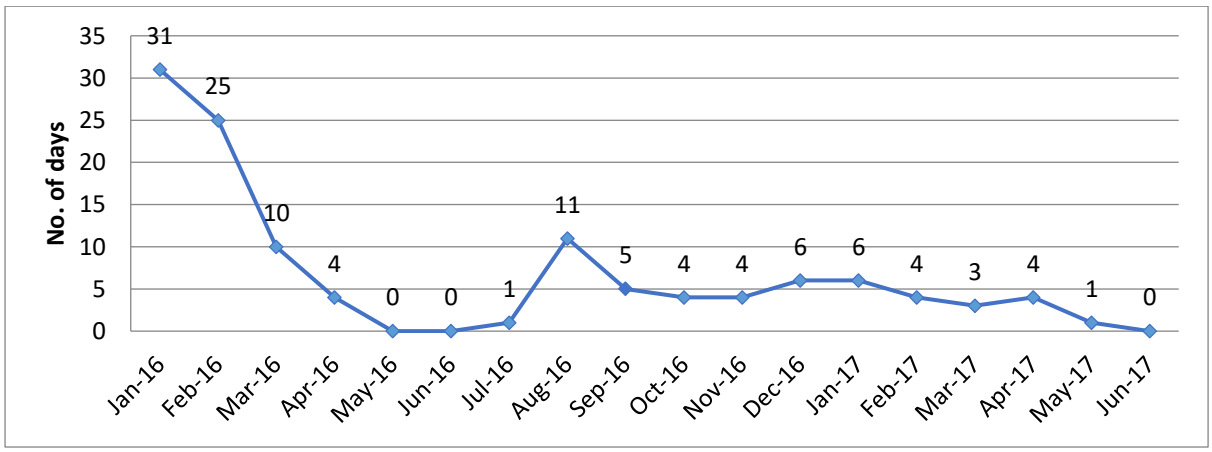
Source: State government's data

3.13 Cost – efficiency of the scheme

3.13.1 Minimum assured volume

A daily minimum assured volume of 12 000 patients was committed to the service provider by the state in the signed Agreement. In the first 2 months, the daily minimum assured volume was not achieved for almost 100% of days as the scheme was rolled out only in DHs and AHs in the first month and partially in CHCs and PHCs in the second month. The total number of days when minimum assured volume was not achieved were 119 from January 2016 till June 2017 and 63 from March 2016 (when rollout was almost complete) till June 2017. The number of days on which minimum assured volume was not achieved decreased steadily to 0–1 day in May–July 2016 and showed a sharp rise in August 2016. This corroborates with the steep increase in uptake of services by the doctors at the government health facilities in May–July 2016 and drastic fall in July–August 2016. The numbers again decreased steadily to 0–1 in May–June 2017 with increase in patient load (figure 24). Also, in the first month, the service provider included Sundays in the daily minimum assured volume criteria; and this was disapproved by the state government. The state government did not pay the service provider for minimum assured volume for first 3 months of the rollout as the complete rollout was achieved only after 3 months. Assurance of minimum volume as mentioned in the Agreement reflects poor contracting – the Agreement should have stated – 50% of assured volume in the first month, 75% in second month and 95% in third month.

Figure 24: Monthly trends in number of days when minimum assured volume was not achieved



Source: Service provider's data

From March 2016 onwards, majority of the days on which minimum assured volume was not achieved were Saturdays (table 44).

Table 44: Number of days when minimum assured volume was not reached from March 2016 to June 2017

Total	63 days
Mondays	4
Tuesdays	7
Wednesdays	5
Thursdays	8
Fridays	11
Saturdays	28

Source: Service provider's data

The monthly cumulative number of patients for which minimum assured volume was not achieved ranged from 0 to 274 065. If the minimum assured volume was not counted on a daily basis but on a monthly basis (daily minimum assured volume x number of working days in a month), then the total patients tested in a month actually exceeded the monthly minimum assured volume by 5%–88% for various months. (January and February were not included because of incomplete rollout) (table 45).

Table 45: Monthly minimum assured volume (12000 x n number of working days in a month)

Month	Monthly minimum assured volume	Number of patients tested	Percentage of patients tested above minimum assured volume
January 2016	312 000	39 299	-87%
February 2016	300 000	179 371	-40%
March 2016	324 000	342 490	6%
April 2016	312 000	394 017	26%
May 2016	300 000	497 700	66%
June 2016	312 000	539 938	73%
July 2016	312 000	587 751	88%
August 2016	324 000	339 791	5%
September 2016	312 000	367 375	18%
October 2016	312 000	388 732	25%
November 2016	312 000	356 133	14%
December 2016	324 000	350 875	8%

Month	Monthly minimum assured volume	Number of patients tested	Percentage of patients tested above minimum assured volume
January 2017	312 000	326 088	5%
February 2017	288 000	329 686	14%
March 2017	324 000	364 649	13%
April 2017	300 000	340 916	14%
May 2017	324 000	413 681	28%
June 2017	312 000	422 937	36%

Source: Service provider's data

The cost incurred-to-date for patients who were not tested but billed by the service provider in lieu of minimum assured volume ranged from 0 to 8.2% in various months over and above the cost for patients tested (January and February not included) (table 46).

Table 46: Cost incurred by the government for patients not tested but billed by the service provider in lieu of minimum assured volume (monthly basis)

Month	Cost for patients not tested but billed in lieu of minimum assured volume (INR)	Cost for patients tested (INR)	Percentage of total cost over and above the cost for patients tested (cost for patients not tested/cost of patients tested)
January 2016	6 440 5275	9 235 265	697.4%
February 2016	28 988 660	42 152 185	68.8%
March 2016	5 153 785	80 485 150	6.4%
April 2016	3 735 090	92 593 995	4.0%
May 2016	0	116 959 500	0.0%
June 2016	0	126 885 430	0.0%
July 2016	147 110	138 121 485	0.1%
August 2016	5 788 520	79 850 885	7.2%
September 2016	4 021 790	86 333 125	4.7%
October 2016	3 063 930	91 352 020	3.4%
November 2016	976 190	83 691 255	1.2%
December 2016	2 247 305	82 455 625	2.7%

Month	Cost for patients not tested but billed in lieu of minimum assured volume (INR)	Cost for patients tested (INR)	Percentage of total cost over and above the cost for patients tested (cost for patients not tested/cost of patients tested)
January 2017	6 263 455	76 630 680	8.2%
February 2017	2 609 440	77 476 210	3.4%
March 2017	3 017 400	85 692 515	3.5%
April 2017	3 565 890	80 115 260	4.5%
May 2017	182 125	97 215 035	0.2%
June 2017	0	99 390 195	0.0%

Source: Service provider's data

Similarly, analysis was done for a yearly minimum assured volume arrangement (daily minimum assured volume x number of working days in a year). Three time periods were considered for calculating the percentage of patients tested over and above the yearly minimum assured volume: a) January 2016 to June 2017: this encompassed the total period of services provided till date (June 30, 2017). However, the rollout was not complete till March 2016 and therefore the number of patients tested was very less compared to the daily minimum assured volumes till March 2016; b) March 2016–June 2017: complete rollout had taken place and the daily minimum assured volume became valid; c) August 2016–June 2017: the state government made an effort for rationalisation of services under the NTR Vaidya Pariksha scheme in July 2016 and, therefore, this period was also studied.

The total volume of patients during these three periods exceeded the minimum assured volume by 17%, 27% and 16%, respectively.

Extra cost incurred by the state government in these three periods in lieu of minimum assured volume was 8.7%, 2.7% and 3.4%, respectively over and above the cost for tested patients (table 47).

Table 47: Total cost incurred by the government for patients not tested but billed by the service provider in lieu of minimum assured volume

Time period	Percentage of patients tested above minimum assured volume	Cost to the government for patients not tested but billed to the government in lieu of daily minimum assured volume not achieved on select days (INR)	Percentage of total cost to the government over and above the cost for patients tested (cost of patients not tested/cost of patients tested)
January 2016–June 2017	17%	134 165 965	8.7%
March 2016–June 2017	27%	40 772 030	2.7%
August 2016–June 2017	16%	31 736 045	3.4%

Source: Service provider's data

If the minimum assured volume was based on a monthly/yearly instead of daily basis, the government could have saved the money paid to the service provider for patients who were not tested but billed in lieu of daily minimum assured volume. It is, therefore, suggested that the minimum assured volume should be committed on a monthly/yearly basis which will encompass the daily and seasonal variation respectively and at the same time provide the bidder a minimum assured figure to work out the costing.

3.13.2 Comparative analysis with CGHS

Cost-per-patient and cost-per-test (CGHS) models were compared and cost to the government for outsourcing the laboratory services based on these two models was calculated. For calculating cost-per-test for the NTR Vaidya Pariksha scheme, the individual tests were multiplied with the CGHS rates for those tests. In any CGHS model, the rates offered by the service provider to the government have been calculated on basis of cost to the service provider for testing only. The CGHS rates typically do not incorporate the huge cost of logistics which are part of the current hub and spoke model under the NTR Vaidya Pariksha scheme. In the hub and spoke model recommended by Ministry of Health and Family Wefare, the service provider is responsible not only for testing but also for transportation of samples from all government health facilities to its testing laboratories incurring a huge cost on logistics (transportation, cold chain, salaries of delivery personnel). If the cost of logistics is incorporated in the CGHS model, then the comparison between the two costing models would be more valid.

Similar to analysis of minimum assured volume, for analysis of cost efficiency also, three periods were considered: a) January 2016–June 2017: this encompassed the total period of services provided till date (June 30, 2017). However, the rollout was not complete till March 2016 and, therefore, the number of patients tested was very less compared to the daily minimum assured volumes. The government would have had to pay huge cost to the service provider in lieu of minimum assured volume. However, the state government had not yet

paid the service provider for these 3 months; b) March 2016–June 2017: complete rollout had taken place. The cost for minimum assured volume became valid; c) August 2016–June 2017: the state government made an effort towards rationalisation of services under the NTR Vaidya Pariksha scheme in July 2016 and, therefore, this period was also studied. When the period after rationalisation of services was considered, the per-patient model was 2.3% cheaper than the CGHS model (with logistics cost added to the CGHS cost). When the logistics cost was removed, the per-patient model was 2.2% more expensive. For the other two periods, the per-patient model was more expensive with and without cost of logistics incorporated (7.7% and 12%, respectively in the January 2016–June 2017 period and 3.4% and 7.5%, respectively in the March 2016–June 2017 period) (table 48).

Table 48: Percentage difference in costs to the government for per-patient model vs. per-test CGHS model {(total cost of per patient – total cost of CGHS)/cost of per-patient}

Peculiar features of the period	Study period	With logistics cost added to CGHS model	With logistics cost not added to CGHS model
Rationalisation of services by the state government under the NTR Vaidya Pariksha scheme	August 2016–June 2017	-2.3%	2.2%
Complete rollout in March, 2016; cost for minimum assured volume became valid	March 2016–June 2017	3.4%	7.5%
Patient load very less in January and February 2016 because of ongoing roll out; cost for minimum assured volume not valid but included here.	January 2016–June 2017	7.7%	12.0%

Source: Service provider's and CGHS data

Interplay of several factors enhanced the cost efficiency of the per-patient model compared to the per-test model of CGHS. These were:

i. Rationalisation (reduction) of percentage of patients tested (out of total number of patients) in PHCs and CHCs.

ii. Increased patient-to-test ratios in PHCs, CHCs, AHs and DHs.

iii. Increased proportions of tests in the upper quartile of cost (INR 121 in CGHS rate) and reduced proportions of tests in the lower quartile (INR 58 in CGHS rate).

It was observed that rationalization of services in July 2016 led to a marked improvement in cost efficiency of the scheme compared to the previous few months (table 49). The factors contributing to the substantial increase in cost efficiency from July to August 2016 were: a) marked fall in percentage of patients tested (out of the total number of patients) in PHCs and

CHCs. The percentage fell from 14.4% to 7.5% in PHCs and from 15.3% to 9.4% in CHCs; b) increase in overall patient-to-test ratio from 2.9 to 3.2. The increase was marginally more in PHCs and CHCs compared to DHs and AHs; c) decrease in the proportion of tests which were cheaper. The decrease in the proportion of cheaper tests could be attributed to the marked reduction in prescription of the cheaper basic tests at PHCs and CHCs as an outcome of reduction in number of patients tested in these facilities (and not due to an increase in more expensive tests in DHs and AHs).

Similar correlations were observed in the next few months. The cost efficiency again started reducing from March–June 2017, when total number of patients tested as well as the percentage of patients tested (out of total number of patients) increased more so in PHCs and CHCs, while the patient-to-test ratio reduced and the proportion of tests in the upper quartile of cost also reduced (table 49).

Table 49: Comparison of two cost models – cost per patient and cost per test

Comparison of 2 costing models - Cost-per-patient and Cost-per-test and correlation with Patient-to-test-ratio, Test type and Patient load. (Difference in costing calculated as Total Cost to the Government in a per patient model-Total Cost to the Government in a per test model/ Total Cost to the Government in a per patient model)																		
	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17
Percentage difference in cost to the Government for per-patient and per test model (cost incurred in lieu of minimum assured volume added in per-patient cost)	82%	36%	9%	22%	22%	17%	12%	-5%	-14%	-16%	-7%	4%	7%	4%	9%	14%	16%	13%
Patient to test ratio	4.3	3.6	3.4	2.9	2.8	2.9	2.9	3.2	3.3	3.2	3.1	3.0	3.1	3.1	3.0	2.9	2.7	2.7
Percentage of patients tested (out of total patient load)	1%	5%	10%	11%	14%	13%	14%	8%	9%	9%	9%	9%	9%	9%	10%	10%	11%	12%
Percentage of tests in upper quartile of cost (Rs 121 and above)	7.0	5.0	4.7	4.3	4.1	4.5	5.0	6.9	7.7	8.2	7.0	6.1	5.9	5.5	5.3	5.4	5.5	6.1
Percentage of tests in lower quartile of cost (Rs 58 and below)	38.1	50.7	54.9	56.7	57.1	57.0	57.2	53.1	53.0	52.9	53.0	53.0	52.6	53.7	54.1	54.3	54.4	53.7
Total patients tested	39299	179371	342490	394017	497700	539938	587751	339791	367375	388732	356133	350875	326088	329686	364649	340916	413681	422937

3.14 Information, education and communication (IEC) for the scheme

The government worked jointly with the service provider and launched massive campaigns for creating awareness about the NTR Vaidya Pariksha scheme among the populations. Many channels are being used to create awareness about the scheme. These include:

i. Posters, pamphlets, banners and inserts.

ii. ANMs and ASHAs were sensitised about the scheme in their regular review meetings and now they disseminate information at sub-centre and village level respectively.

iii. Local newspapers and TV.

iv. Under 104 services, only haemoglobin and random blood sugar tests are done. For other tests, patients are asked to go to CHC/PHC and hence awareness about the scheme is generated.

v. Medical officers talk about the scheme at Mandal meetings with people's representatives.

vi. Under Janma Bhoomi – Mavooru programme, when Gram Sabha, the government officials and public meet once in 6 months, awareness is generated about various government schemes.

vii. Doctors talk about the scheme to their patients.

The cost of IEC (posters, banners, pamphlets etc.) was borne by the service provider. In the initial stages, the name of the service provider was mentioned on all IEC material as well as on requisition forms. This was removed later. During the survey, it was found that there was a widespread sentiment among the staff at the government facilities that name of the service provider should not be mentioned on the scheme-related communication. They felt that this leads to confusion among people that tests are being solely provided by the service provider and not jointly with the government.

It was observed that there were separate displays (posters, banners etc.) for tests available in in-house laboratories and through the service provider. These displays were not even at same locations within the health facility. This could lead to confusion among patients regarding which all tests are available at health facilities. The displays for services under the NTR Vaidya Pariksha scheme were seen at several prominent places at health facilities including the entrance, OPD area and sampling area.

OPD timings were mostly displayed in facilities but laboratory timings were not displayed.

3.15 In-house laboratories

3.15.1 Availability of tests

The in-house laboratories were functional in all surveyed facilities. The tests carried out at each surveyed facility varied according to the availability of laboratory technicians and equipment, and supply of reagents.

The in-house laboratories in surveyed PHCs and CHCs were closed on Sundays and public holidays. In both AHs and one DH, the laboratory technicians were on call on Sundays and public holidays for conducting emergency tests. In the other DH, the laboratory was functional round-the-clock on all days.

The state government had mandated a list of 10 tests to be conducted at in-house laboratories of PHCs; 12 for CHCs and 15 for AHs and DHs (table 1). It was found during the survey that in the five (out of eight) PHCs where in-house laboratory technician was available, tests for haemoglobin, blood group, random blood sugar, HIV and malaria (rapid/smear) were being conducted. Other tests were conducted only in few of those five PHCs – HBsAg in three PHCs, Widal in three PHCs, urine for albumin sugar in three PHCs, Urine pregnancy test in two PHCs, sputum for AFB in two PHCs and BT/CT in one PHC. In the remaining three surveyed PHCs, where position of in-house laboratory technician was vacant, it was noted that the service provider's phlebotomist did not conduct all tests designated for in-house laboratories. Random blood sugar was conducted by the phlebotomist in all three PHCs; whereas haemoglobin and urine albumin/sugar were conducted only in one PHC, and HBsAg and urine pregnancy test in the other PHC. In one PHC, peripheral smear for malaria was prepared by phlebotomist of the service provider and was sent to CHC or district malaria laboratory for examination.

In PHCs, where designated tests were unavailable, patients and ANC women were referred to the nearest government facility. It was found that patients had to travel long distances at times for basic tests such as haemoglobin and blood sugar; ANC women travelled to CHCs for RPR and blood group test.

In all the eight surveyed CHCs, tests for haemoglobin, blood group, peripheral smear for malaria, HIV, HBsAg, blood sugar, urine albumin/sugar and sputum for AFB were available. Other tests were carried out only in few CHCs – BT/CT in three CHCs, Widal in six CHCs, urine for pregnancy test in seven CHCs, ESR in three CHCs, serum bilirubin (total) in three CHCs, blood urea and serum creatinine in one CHC, and urine bile salts and pigments in one CHC.

In one surveyed AH, tests for haemoglobin, blood group, BT/CT, peripheral smear for malaria, blood sugar, urine albumin/sugar, urine pregnancy test, HBsAg, HIV, RPR, widal and sputum for AFB were done. In the other AH, tests for haemoglobin, blood group, peripheral smear for malaria, HIV, HBsAg, widal and Urine routine examination were available.

In one surveyed DH, tests for haemoglobin, blood group, blood sugar, HIV, HBsAg, peripheral smear for malaria, urine pregnancy test, widal, BT/CT and urine albumin/sugar were done. In the other DH, tests for haemoglobin, TLC, DLC, CBC, ESR, blood group, BT/CT, peripheral smear for malaria, RPR, widal, HIV, HBsAg, CRP, ASO, RA factor, blood

sugar, blood urea, serum creatinine, serum bilirubin (total), serum bilirubin (direct), stool examination, urine examination, semen analysis, urine pregnancy test and sputum for AFB were conducted.

There were no tests which were available only on specific days at the in-house laboratories. It was found that in one CHC, maximum number of blood sugar tests were done on Mondays and Saturdays for the geriatric patients. Also on PMSMA day, the ANC case load was very high across facilities leading to a higher test load at the in-house laboratories.

3.15.2 Infrastructure

3.15.2.1 Equipment

During the primary survey, an assessment was done for presence and functional status of the equipment at the in-house laboratories of all surveyed facilities. In all eight surveyed PHCs, glucometer, haemoglobinometer and microscope were present in a functional state except one PHC where the haemoglobinometer was dysfunctional. In five out of eight PHCs, centrifuge was available but used occasionally. Calorimeter was also available in five out of eight PHCs but was used rarely and was dysfunctional in one of the five PHCs.

In all eight CHCs, haemoglobinometer, microscope and centrifuge were present in a functional state. Glucometer was not available in one CHC. Calorimeter was available in six out eight CHCs; and was dysfunctional in one of these CHCs. In four CHCs, semi-automated biochemistry analyser was available but not in use except in one CHC where it was used occasionally for conducting blood sugar test. In three CHCs, the analyser was installed few months ago but was lying unused as reagents had not been supplied for any test except blood sugar. Also, in few CHCs, tests such as widal and blood group were not conducted because the kits were not supplied.

In both AHs and DHs, glucometer, haemoglobinometer, microscope and centrifuge were available and functional. In one AH, semi-automated biochemistry analyser was available and was in use. In one DH, semi-automated biochemistry analyser and haematology analyser were available and in use. In the other DH, haematology analyser was lying unused. The SNCU laboratory in this DH had semi-automated biochemistry analyser which was in use for paediatric patients.

There was no equipment maintenance plan in any of the laboratories, except in few facilities where daily cleaning of equipment was done.

There were instances of breakdown of equipment in the surveyed facilities. In one PHC, equipment was not working for the past 1.5 years and it had been communicated to the DMHO. In some of the other facilities, equipment breakdown happened 2–4 times a year. One CHC reported that haemoglobin and ESR pipettes were damaged after every 6 months and were replaced. In one DH, calorimeter was beyond repair and was replaced. The duration of breakdown varied in different facilities – ranging from half day, 3–4 days, 1 week, 1 month to 1.5 years.

3.15.2.2 Human resources

During the survey, it was found that in five out of eight surveyed PHCs, one senior in-house laboratory technician was posted. In one of these PHCs, the technician was from RNTCP. In

the remaining three PHCs, the positions were vacant for as long as one and a half years. In CHCs, two laboratory technicians were present in all CHCs – one general technician and one from ICTC. In one CHC, there were three laboratory technicians – one general technician, one from RNTCP and one from ICTC. In one AH, there was only one laboratory assistant and one laboratory technician of blood bank doubling up as laboratory technician for main in-house laboratory. In the other AH, there were two laboratory technicians. In one DH, six laboratory technicians and three laboratory assistants were posted – three senior technicians worked in the main laboratory, one technician in neonatal care unit laboratory, one technician in blood bank and two technicians in ICTC.
The in-house laboratory technicians took 1–2 leaves per month. In one CHC, the technician took 3–4 leaves in a month.

3.15.2.3 General Infrastructure

All facilities had a waiting area which was clean. The waiting area in PHCs and CHCs was common for the laboratory and OPD. Two out of eight surveyed PHCs and three out of eight surveyed CHCs did not have adequate space for patients waiting in the queue. Five out of eight PHCs, five out of eight CHCs and one out of two DHs did not have adequate seating in the waiting area.

The laboratory floors were in good condition in most of the facilities, except in one PHC and three CHCs. Most of the in-house laboratories had adequate access to light except one PHC and one CHC. In one CHC, there was no water supply in the laboratory.

All health facilities had functional toilets which were clean except in three PHCs and two CHCs. It was noted that toilets and facilities in general were much cleaner where the cleaning services had been outsourced.

In one PHC, four CHCs, one AH and both DHs, there was backup for power supply. In four PHCs and four CHCs, there was no consistent power supply for the equipment. The power cuts lasted 2–3 hours in summers. Three out of eight PHCs did not have sufficient power points in the laboratories. Among the surveyed facilities, separate sinks for washing and staining were found in laboratories of only one CHC, both AHs and both DHs.

Majority of CHCs, one AH and one DH followed the biomedical waste management guidelines, though only partially (used coloured dustbins and needle destroyer). Majority of PHCs did not adhere to these guidelines. In one PHC, it was noted that the biomedical waste was picked up only once a week.

3.15.3 Reagents and consumables

The stock of reagents and consumables was maintained by the in-house laboratory technicians. The technicians raised indent to the pharmacists who further sent the orders electronically to the central drug store. In one of the PHCs without an in-house laboratory technician, service provider's phlebotomist maintained the stock. In most facilities, the orders were placed quarterly. The orders were delivered by the central drug store to the health facility within 2–7 days of placing the orders. Cold chain was maintained during transportation of supply from the central drug store to the health facility. One DH reported that occasionally the transit time from central warehouse to the central drug store was long and the health facility was not permitted to purchase the reagents locally during that period even if there was a stock-out at the health facility.

None of the facilities had an inventory management system in place. Stock-outs were quite common at the health facilities. Shortage of reagents was found especially for tests of blood sugar. The government had recently stopped the supply of sugar reagent for calorimeter/biochemistry analyser and as a result, the facilities depended exclusively on more expensive glucometer method for which also, a huge shortage of strips was observed at most facilities. A PHC reported that there was no supply of sugar strips for the past 7–8 months. Also, the new format of online ordering did not reflect sugar reagent in its list. Urine strips and kits for urine pregnancy test were out of stock for one year in few PHCs. Widal and RPR kits were also unavailable at a PHC. In one PHC, Anti-D sera for Rh typing in Blood grouping were unavailable and the laboratory technician used a wrong reagent (anti AB sera) instead. In two PHCs, sampling tubes and urine pots were out-of-stock. CHCs reported shortage of kits for HBsAg, blood group, widal and urine for pregnancy test for duration of 2 months to 1 year. Shortage of sampling tubes and syringes was also noted in a CHC. In all facilities, sugar tubes were unavailable and samples for blood sugar were collected in EDTA tubes (meant for collecting haematology samples). In many CHCs, new semi-automated biochemistry analysers were lying unused and patients had to go to private laboratories for emergency tests.

Some of the reagents which were unavailable at the central drug store were purchased locally. Few PHCs purchased RBS strips every quarter. CHCs purchased RBS strips, sugar reagent, ESR tubes, haemoglobin solution, widal kits and occasionally malaria kits. One CHC purchased kits for widal test, urine pregnancy test and blood group test every 2 months. Another CHC had been purchasing kits for HBsAg, blood group and widal tests for almost a year. In one DH, the reagents were borrowed from the nearest government health facility at times. In the other DH, local purchase had reduced drastically because most of the tests were now sent to the service provider. There was no standardised mechanism for ensuring quality in local purchase. An effort should be made to move to quality assured/WHO prequalified reagents and diagnostics in the future. Brand names, expiry date and good shops/laboratories were a few criteria that were considered during local procurement.

According to laboratory technicians, they never received expired reagents from the central drug store. Most of the surveyed facilities had adequate storage space for reagents and consumables and they were stored at requisite temperatures. Cold storage was inadequate in some facilities – in one PHC, the reagents were stored in a thermocol box for cold storage; and in one CHC, HIV kits were kept at room temperature instead of the refrigerator. The temperature charting of non-freezer area of refrigerators where reagents were stored was not done at most of the facilities.

In two PHCs, few kits were about to expire. Also, in one CHC, widal kit was found to be expired but in use. In one DH, dengue - IgM kit and throat swab media for H1N1 were found to be expired and lying unused. In the other DH, many RPR kits expiring in the next month were found.

3.15.4 Sample collection

The timings for registration and sample collection at the in-house laboratories were 9:00–14:00 in most PHCs. In few PHCs, emergency sample collection was done till 16:00. In six out of eight CHCs the timings were 9:00–16:00 pm; in remaining two CHCs and both AHs 9:00–14:00; in one DH 8:00–13:00 and till 14:00 for inpatients, and in second DH, timings

were 9:00–12:30. In CHCs and AHs, most patients requiring emergency tests after 15:00 went to private laboratories. In few facilities, sampling and testing was carried out after 15:00 for emergency cases. In one DH, the laboratory technicians were on call after 15:00 for emergency tests such as haemoglobin, BT/CT, blood sugar and urine for pregnancy tests. In the other DH, technicians were available in the laboratories round-the-clock on shift duties. In one AH, the staff nurse conducted tests for emergency cases after the in-house laboratory closed at 14:00. Only haemoglobin, blood group, HIV and HBsAg were done by the nurse and other tests were sent to the service provider. In one CHC, the in-house laboratory technician would be on call for conducting emergency tests for women in labour. In another CHC, the staff nurse carried out only blood sugar test for emergency patients.

Except in one DH, the sampling stations were situated inside the in-house laboratories where registration of patients for sampling was also carried out. In one DH, sampling for blood group and HIV tests was carried out separately in the blood bank instead of the main laboratory. The registration of patients was carried out at the time of sampling at the sampling station itself. The registration was manual. In few facilities, a unique laboratory number was generated for all patients and was noted on the OPD slip to be presented at the time of report collection. In one DH, separate unique laboratory numbers were generated for different samples of the same patient; these samples were collected/deposited at different counters such as general haematology and biochemistry, ICTC, malaria etc., and a different laboratory number was generated at every counter. It was observed that in some cases, the laboratory number written by the laboratory technician on the OPD slip was not legible. In other facilities, new unique laboratory number was not generated and the OPD number was used as the unique laboratory number; the patient collected the report by presenting the OPD number.

Sampling methodology was observed wherever possible and was found to be mostly correct. In one PHC, anti-D sera for Rh typing in blood grouping was unavailable and the laboratory technician used anti-AB sera for Rh typing. In one CHC, it was observed that the samples for blood sugar tests were lying in syringes inverted in tubes for 2–3 hours before testing. The quality of blood smear prepared by the laboratory technician was found to be poor in one DH**.** In many facilities, sampling tubes were re-used after washing.

Labelling of tubes was manual. In many facilities, for labelling the sample, a small piece of paper with OPD number, patient's name and test details was inserted in the upper half of the sample tube. In some facilities, labelling was not done as the testing was done on the spot. In some facilities, OPD slip was retained by the laboratory at the time of sampling for writing the reports on these slips. It was observed that the secondary tubes used for testing were not labelled and were identified based on the order of the samples. This could lead to errors in identification of samples.

According to the in-house laboratory technicians, sample rejection rate (haemolysed/ clotted/insufficient sample) was minimal.

3.15.5 Test Reports

The in-house test reports were mostly validated by the government laboratory technicians. In one CHC, the medical officer validated HIV test reports. None of the facilities had pathologists/microbiologists/biochemists available for reporting/validating test results. In one DH, a pathologist was available but he was posted at the emergency department.

The turnaround time – time from sample collection to report dispatch to the patients varied for different tests. For haemoglobin, blood sugar, HIV, HBsAg, urine pregnancy test, BT/CT, urine albumin/sugar, tests were conducted immediately after sample collection and test reports were dispatched within 10 minutes to half an hour of sample collection. For other tests such as ESR, widal, blood urea etc., test reports were given within 1–4 hours. Test reports for sputum for AFB and peripheral smear for malaria were given on the next day. In one DH, reports for all tests except haemoglobin, BT/CT and urine routine examination were given on the next day.

According to the laboratory technicians, there were no delays in reports for in-house tests except in few instances. The timings for report dispatch in most PHCs, two CHCs, both AHs and DHs were 9:00–14:00. In six out of eight CHCs, the timings were 9:00–16:00. Reports for emergency samples were released on priority.

Manual reports were provided to patients – tests results were noted down on OPD slips of patients by the laboratory technicians. In few facilities, reports were written down on a small plain piece of paper. It was observed that on several reports, the date of test order/report was not mentioned. In many cases, the test name/test result value was not legible. In one CHC, report for sputum for AFB was given out on a separate form. In one DH, CBC reports were printed from the haematology analyser and were provided to the patients. Manual records of test reports were maintained in registers by the laboratory technicians.

Except one DH, the reports were dispatched at the sampling stations situated inside the in-house laboratory. The average waiting time for patients in the queue for report collection was 5–20 minutes.

3.15.6 Quality assurance

Currently there are suboptimal quality assurance mechanisms in place for in-house laboratories (except few for tests done under RNTCP, ICTC and malaria control programme) even at the level of district hospitals.

Protocols for quality assurance – internal and external were not found at any of the surveyed in-house laboratories. In laboratories of few PHCs and CHCs, standard operating procedures for RNTCP, ICTC and malaria control programme were displayed on the walls. EQAS was done for RNTCP in three CHCs. In few CHCs and DHs, standards were used when new kits were opened. It was observed that there was no supply of reagents for quality control in a district hospital and request for same had been sent to the state government.

3.15.7 Quality of test results

The in-house laboratories are solely managed by laboratory technicians who also validate the test results of routine tests. There is no supervision over these technicians. Several types of errors were found at various levels of functioning of the laboratory such as use of wrong anticoagulant in sampling, use of anti AB serum for Rh type testing etc.

In all surveyed facilities except in one AH, doctors found test results of in-house laboratory superior to those of the service provider. Doctors trusted test results of in-house laboratory and ordered repeat testing from in-house laboratory for some of the patients who were tested at private laboratories or through the service provider. In one CHC, the doctor did not trust Widal and Malaria test reports of private laboratories and repeated testing in in-house laboratory in 5–10% cases.

At the same time, doctors also found some discrepancies in in-house laboratory test results and ordered repeat testing from the in-house laboratory itself. In majority of PHCs and CHCs, results were found inaccurate for 0–5% of tests and repeat testing was ordered for some of these cases. In one CHC the tests were repeated for 5–10% of tests and in another CHC for 30% of tests, in one DH for 1–2% of tests and in one AH and one DH, no results were found to be inaccurate. In the other AH, repeat tests were not ordered despite the inaccuracies in test results.

In one DH, the doctors ordered repeat testing for haemoglobin, serum bilirubin and HBsAg. In one AH, doctors were not confident about test results of peripheral smear for malaria, blood sugar and widal. In one CHC, repeat tests were ordered for haemoglobin, urine routine examination, serum bilirubin and urine for pregnancy test and in few other PHCs and CHCs, for haemoglobin and blood sugar.

For test results from private laboratories, the doctors usually ordered repeat testing in 5–10% of cases.

3.15.8 Biomedical maintenance programme

The state government has outsourced the biomedical maintenance programme (BMMP) to a private party. Based on information from doctors at the surveyed health facilities, yearly calibration of laboratory equipment was not done by BMMP team. The facilities upload the functional/repaired/not repaired status of equipment daily on a government portal. During equipment breakdown in in-house laboratories at the surveyed facilities, the pharmacist or staff nurse and in few facilities, medical officer or a nodal officer called the helpline number of BMMP. The BMMP team in most cases inspected the equipment within 24–48 hours. In one AH, the repair was done within 4–5 days. In a DH, the BMMP team stationed one engineer round-the-clock. The repair of small equipment with minor problems was done within 2–5 days. However, for some equipment where parts had to be replaced, it took longer or was not done. In one PHC, it was found that the BMMP team did not repair the equipment for many months and the facility constantly escalated the issue to the district health official. In one CHC, the equipment was not repaired for 1 month.

3.15.9 Grievance redressal

In most facilities, there were no mechanisms in place for collecting feedback for in-house laboratory services from patients, doctors and other staff of government health facilities. A few facilities had complaint boxes for patients which were not used. In one DH, the quality manager took some feedback. In a CHC, programme supervisors took feedback from the patients about RNTCP services.

3.15.10 Privacy of patients

During visits at several government health facilities, laboratory technicians were found to be announcing loudly in front of everyone in the queue whenever there was any TB or HIV patient in the room. There is a need for sensitising the staff about respecting patients' privacy.

3.16 Central drug store

The central drug store in district Krishna caters to 150 government health facilities (teaching hospitals, DHs, AHs, CHCs and PHCs) in the district.

The central drug store has adequate human resources. Details are as follows:

Deputy executive engineer – 1

Pharmacist – 1

Data entry operator (outsourced) – 1

Packers/Transportation helpers (outsourced) – 4

Cleaners (outsourced) – 3

Infrastructure at the central drug store was mostly adequate. The stock was stored on two floors. There was no elevator though for transferring the supplies to and from the second floor of the store. Therefore, most supplies were lying on the ground floor which was overcrowded and may result in damages and mix-ups; this is also not in line with the good distribution practices (GDP) standards. The heavy containers were stored at the bottom. Some of the containers were found to be lying directly on the floor because of unavailability of enough pallets. Mechanical equipment for loading and unloading the boxes was present. There were no fans in the main store.

There were two kinds of cold storage used for reagents – 25–30℃ for rapid kits for HBsAg and HIV and urine strips; and 2–8℃ for HBsAg (ELISA), RPR and blood group kits. Temperature charting was not done for walk-in-cooler. There was round-the-clock power back up. There were two fire extinguishers; however, no mock drills had been conducted.

Procurement for equipment and reagents is done by the medical wing of APMSIDC. The corporation floats tenders and procures from various suppliers based on tendering. Central drug store of each district receives annual supply based on utilisation in the last year.

When the stock is received by the drug store, the pharmacist receives, verifies and enters the stock in the E-Aushadhi software. The stock goes into freezing mode and cannot be issued until the quality analysis is completed by the head office. After completion of quality analysis, the stock moves into active mode and can be issued to the health facilities.

All health facilities raise indent online using E-Aushadhi software on a quarterly basis. The central drug store prepares an issue list for respective health facilities' budget which is split quarter-wise. The budget is automatically checked by the software and issue voucher is printed. In case the requirement of health facility for reagents and consumables increases compared to last year and it needs more stock, the health facility sends a request to the head office of APMSIDC. The shortage of budget in a particular year occurs due to provision of budget based on previous year's usage leading to shortages of reagents in the health facility. In case budgetary allocation for reagents and consumables needs to be increased, the respective state official can add the budget.

The central drug store delivers orders at the health facility within 15 days of order placement by the facility. If there is a shortage of reagents/kits in the drug store of a district, the stock is drawn from drug store of another district. Cool boxes with ice packs are used to transport reagents from the drug store to the health facilities.

There are occasional shortages in the drug store because of lack of supply from the head office which happens due to delays in tendering or delay in supply from manufacturers.

The physical inventory for adequacy of stock is carried out by the drug store staff on a monthly basis. A check on expiry of stock is also done through E-Aushadhi software. Minimum stock was maintained at the surveyed drug store. The drug store only received rapid test kits including HBsAg, HIV, urine strips, RPR, urine pregnancy and blood sugar strips. It was found that supply of RPR kits to the drug store was much lesser after introduction of the NTR Vaidya Pariksha scheme. First expired first out system of inventory management is followed at the drug store. The minimum duration of expiry for the stock issued to the health facilities is 3 months.

For quality control, random samples of reagents/kits are sent to the head office for testing at the recognised laboratories. The drug store had not received any complaints from health facilities about quality of reagents and consumables.

4. Key recommendations

The state government has accomplished its objective of providing free and accessible laboratory services to patients visiting government health facilities to a large extent through the NTR Vaidya Pariksha scheme. The scheme has reached a certain level of maturity in terms of geographical reach, volume of services provided and in its management. However, there are certain aspects of the scheme where there is scope for improvement, and some issues that require immediate attention for strengthening functioning of the scheme. A few recommendations have been made in the following sections for the state government for further improvement of the scheme, and for the MoHFW for guiding potential rollout of the Free Diagnostics Scheme in other states.

4.1 Recommendations for the state government

4.1.1 Scope of services and service utilization

i. It is suggested that the government develops a clear strategy and institute monitoring mechanisms to avoid unwarranted fluctuations in utilisation of services by doctors. Utilisation of individual/single tests should be monitored closely by the state government as well as by the service provider. To enable adequate utilisation of services among doctors, the service provider should improve upon certain aspects of its services (especially related to advanced tests), build confidence among doctors/district officials about quality of its services, and take periodic feedback from them.

ii. To increase uptake of highly underutilised advanced tests like Blood culture, urine culture, histopathology, cytology, fluid examination (in DHs and AHs) and prothrombin time and serum amylase (in CHCs), the service provider should improve the accuracy and the turnaround time of these tests; run FNAC clinics inside the hospitals; and sensitise the doctors about availability and reliability of these tests. In addition, the service provider should take periodic feedback from the doctors regarding their satisfaction with test outcomes; processes etc. and complete the loop by taking corrective actions.

iii To build the confidence of doctors in its services, it is suggested that the service provider showcases its technical and operational strengths to the doctors through periodic one-on-one interactions and CMEs. Incorporating a clear and detailed interpretation of test results for tests like TSH in the reports will further augment doctors' confidence regarding accuracy of results and help them arrive at an accurate clinical diagnosis.

iv. It is suggested that the doctors prescribing the tests write detailed clinical history and specimen details especially for advanced tests like histopathology and cytology for improving accuracy of results for these tests. A copy of case summary sheet or OPD sheet of the patient could be sent to the laboratory with the specimens of histopathology, cytology and fluid. Standard templates for clinical history could be created for ease of use and legibility.

v. The district health officials, who are an important link between the staff at the government health facilities and the service provider, should also be periodically updated about the systems and processes used by the service provider. This will help in building their confidence in the service provider's services.

vi. A regular and structured inter-laboratory comparison of in-house laboratories and service provider's laboratories should be instituted for relevant tests to allay any quality-related concerns of the doctors. These comparisons would also enable identification of discrepancies in test outcomes of the two laboratories.

vii. Adequate oversight is required for tests which are being done in-house and through the service provider at individual facilities. Although it may appear prudent to use services of the service provider, it is important not to lose the focus on cost-efficiency of in-house laboratory services and maintain the capacity of public health facilities to provide services in the long run.

4.1.2 Operations

i. It is suggested that the phlebotomists are stationed at AHs and DHs on all days and round-the-clock. In case of absenteeism, the phlebotomist could be called from a CHC where two phlebotomists are posted instead of moving a phlebotomist from a PHC where there is only one phlebotomist. In case, sending a substitute is not feasible, the government laboratory technicians could draw the samples. However, the service provider should station a new phlebotomist in case the phlebotomist is unavailable for more than 10 percent of working days. Absence of sampling services should be reported to the district health officials in a monthly report.

ii. More flexibility in deployment of service provider's staff is required. For instance, more phlebotomists may be provided at PHCs and CHCs on PMSMA days when the patient load is high. Similarly, during high season and epidemics, the service provider should increase the workforce of ILD staff for more frequent sample pick-up from health facilities. The service provider should also arrange for extra laboratory technicians at its laboratories to manage the extra test load during such times (this is a common practice in private laboratories). This will ensure that turnaround time and quality of testing are not compromised despite high test load. At the same time, the service provider should not be required to station extra phlebotomists at health facilities exclusively for conducting tests in in-house laboratories.

iii. Service provider's phlebotomists require more training on sampling of small children and infants, as it needs more expertise than in case of sampling of adults.

iv. The service provider should consult the health facilities and the state government to decide sample dispatch time at individual health facilities to ensure that no patients are denied services because sample dispatch has already happened. At the same time, it would be important to ensure that sample transportation time is not compromised.

v. The service provider needs to ensure that the consumables are available in adequate quantity at all facilities so that sampling services are not compromised.

vi. The biomedical waste management at sampling stations of service provider in the government health facilities should be improved and monitored – non-functional needle destroyers should be replaced; colour-coded dustbins and bags should be made available at PHCs and CHCs; and it should be ensured that the phlebotomists wear complete personal protective gear.

vii. It is recommended that cold chain for sample storage be strengthened at all steps – storage of samples at the government health facilities prior to dispatch; transportation from health facilities to primary receiving laboratories; and transportation from L2 to mother laboratories. It is suggested that refrigerators should be made available with power back-up for storing the samples awaiting dispatch (which could be up to 5 hours after the time of sample collection). To ensure adequate cold chain during transportation of samples to the testing laboratories (transportation time could be up to 10 hours), cool boxes equipped with temperature monitoring device and containing sufficient quantity of ice packs at requisite temperature should be made available. For monitoring cold chain at the government health facilities, the service provider should train the phlebotomists and conduct surprise visits at the government health facilities to ensure that the samples are refrigerated.

viii. It is important to work around the long pre-analytical time in case of advanced tests, samples for which are transported to the mother laboratories. It is suggested that in case of fluid examination, cell count and biochemistry should be done in the primary receiving laboratory (L2) and smear for cytological examination sent to the mother laboratory. Similarly, in case of peripheral blood smear, the first smear should be prepared at the time of sampling and second at the time of receipt of sample at L2 laboratory instead of when the samples reach the mother laboratory. These stained smears should be sent to the mother laboratory or district reporting centre for reporting. For urine cultures, urine samples should be plated in L2 laboratories and the plate instead of urine sample should be transported to the mother laboratory for reporting.

ix. It is recommended that the service provider makes the blood culture test (currently done in 5 districts) available in all 13 districts, as the test is mostly used for critical patients.

x. It is suggested that printing stations are made available by the service provider at AHs and DHs to enable printing of reports within the hospital, as and when the reports are ready. It would be useful if the government provides a closed room for installing printing station at these facilities which could also be used for phlebotomy.

xi. It would be important to integrate the national programme on NCDs (NPCDCS) with the NTR Vaidya Pariksha scheme. Any potential duplication of laboratory services through the service provider selected for implementing NPCDCS should be avoided.

4.1.3 Turnaround time

i. It is recommended that the current definition of turnaround time is revised. For an accurate analysis of the turnaround time for laboratory services, the starting point needs to be time of sample collection at the government health facility. It is, therefore, suggested that pre-analytical time (time from collection of sample to initiation of testing) is incorporated in the existing definition of the turnaround time and closely monitored.

ii. For assessing efficiency of processes at different stages of the sample cycle in terms of turnaround time, it is suggested that the state government should monitor pre-analytical, analytical and post-analytical the turnaround times separately. It would also be useful to further divide these parameters into specific components and monitor each component separately to identify areas requiring strengthening. The pre-analytical time could be divided as: a) transportation time from the government health facility to primary testing laboratory; b) transportation time from L2 to mother laboratory for advanced tests. Similarly, analytical turnaround time could be divided as: a) time for testing; b) time from testing to report validation. Also, time of receipt of printed reports at the government health facilities should be defined, recorded and closely monitored for each type of facility by the service provider as well as by the government. The suggestive values for each component of the turnaround time are given in Annexure I.

iii. Till the time, the new definition of turnaround time is adopted; the turnaround time prescribed in the Agreement should be revisited for certain tests. For example, for serum CRP, prescribed turnaround time in the Agreement is 2 days. However, the test is widely used for monitoring of septicaemia in newborns and therefore test results should be made available in the shortest possible time (within 2 hours).

iv. The test results which fall in critical range should be automatically recorded and sent through automated messaging system to the concerned doctors within 30 minutes of validation of the reports. The turnaround time for automated messaging of test results in critical range should be closely monitored by the state government.

v. It is suggested that the state government works with the service provider to urgently bring down the turnaround time for advanced tests such as fluid examination, cultures, TSH etc., and for emergency tests such as troponins.

vi. It is recommended that the state government keeps a close watch on the turnaround time for each kind of test at each type of facility (PHCs, CHCs, AHs, DHs) and for OPD/IPD/emergency and critical tests. The state government should also ensure that the service provider carries out a root cause analysis for delays in test results for each kind of test and for individual government health facilities and provides monthly reports on gaps identified and actions taken to plug those gaps.

vii. Monitoring of the turnaround time will require a robust IT system, which tracks the sample status almost instantaneously. This IT system should be integrated between

health facilities, local laboratories and mother laboratories; and each case is closed only after generation of the report and its final receipt by the patient.

4.1.4 Quality assurance

i. It is recommended that the service provider makes focused and concerted efforts for building capacity across various categories of staff, as most of the laboratories are functioning without direct supervision of a diagnostician. Following are some specific recommendations for capacity building:

   a. The service provider should put in place a training structure and curriculum and dedicate at least one qualified resource (MD/PhD Biochemistry) to design and implement the trainings. The trainings should to be based on:
      - Test-wise standard operating procedures which outline testing methodologies and key performance/quality requirements.
      - All kinds of error-prone areas of the laboratory processes (pre-analytical, analytical and post-analytical) along with corrective and preventive actions for these.
      - Errors which have already happened in the past and corrective actions taken (if any) to share learning and to avoid similar errors by others.

   b. After induction training, laboratory technicians should receive refresher training every quarter which should be imparted by a diagnostician in the laboratories where the technicians are posted. The duration of each training should be conducted for 2 days. Besides the quarterly training by diagnosticians, the laboratory technicians should also receive training from quality assurance quality team managers every month. For phlebotomists and ILD staff, refresher training should be conducted on a six-monthly basis. The duration of each training should be 1 full day. Since quality assurance quality team managers are trainers in the training cascade and are involved in supervision of quality and troubleshooting in laboratories, they should receive rigorous quarterly training from a diagnostician at the mother laboratory. The duration of each training should be 2 full days.

   c. Induction trainings and refresher trainings should be followed by competency assessment of the staff. Those failing the competency assessment should be further trained before they re-join work.

   d. It is also important to build capacity of diagnosticians and assess quality of their work and supervision of laboratories by them. It is suggested that the diagnosticians should receive yearly training.

ii. It is suggested that the algorithms are defined and incorporated in the auto-approval systems to assess validity of normal test results by matching the normal test results with results of other relevant tests of that patient, IQC results of that day for those tests etc. Also, precision testing (testing of same sample repeatedly) should be incorporated to keep a check on accuracy of processes used by laboratory technicians. The work of laboratory technicians should also be supervised periodically.

iii. It is recommended that the service provider gives clear instructions to the laboratory technicians not to conduct tests on erroneous equipment or when results are erroneous due to unknown causes. Till the equipment is rectified or the root cause analysis is carried out for other technical faults, the samples for those tests should be sent to the nearby laboratories of the service provider. In case re-routing of samples is not possible, the service provider should stop accepting samples for those tests and inform the health facilities about unavailability of those tests for the specified period. Once the tests become available, the facilities should again be informed. Also, diagnosticians of the service provider who validate the test results should be made responsible for monitoring erroneous results and their requisite and timely correction. At the same time, the in-charge of the government health facilities should ensure that all events of erroneous results are recorded at health facilities and the report is sent to the state government.

iv. It is suggested that the criteria for sample rejection are defined in the MIS of the service provider and laboratory technicians are trained on identification of criteria for sample rejection. Also, each event of sample rejection should be recorded electronically and monitored by service provider's central quality team for sample rejection rates of individual laboratories. The laboratories should also record the source of rejected samples – facility type, OPD/IPD etc. At the same time, the service provider should train its phlebotomists for minimising sample rejection.

v. The service provider should engage its quality team at all levels – head of quality, district managers, diagnosticians and quality assurance quality team managers for close monitoring of significant deviations in test result values for each test and for individual facilities (separately for outpatients and inpatients) and carry out a root cause analysis on the same day with help from the doctor of that government health facility and the testing laboratory. It is suggested that the government also keeps a close watch on test result values for any significant deviations. Analytical monitoring reports should be assessed by the state government every month.

vi. It is suggested that request for repeat orders (testing of the same sample or re-sampling) is not communicated verbally to the service provider but a repeat order form is filled by the phlebotomist in case of re-sampling, and by the laboratory technician in case of re-testing of the same sample. For identification of repeat samples, the phlebotomist could put a sticker on the requisition forms as well as on the sample containers. The records of repeat orders by doctors should be maintained electronically at the service provider's laboratories and monitored for tests which are repeated most frequently. This would enable the laboratories to identify and correct the errors which are causing discrepancies in the test results.

vii. Specific suggestions regarding quality control – IQC and EQAS are as follows:

    a. The quality control – IQC and EQAS should be established for all 42 designated tests (currently, IQC is done for 25 tests and EQAS for 31 tests). For rapid tests, traceability of kits should be ensured. For cytology, histopathology, and peripheral smear examination, it would be useful if the service provider's diagnosticians

participate in an inter-diagnostician comparison. Inter-laboratory proficiency could be carried out for tests like prothrombin time, fluid cell count etc.

b. For IQC, daily 2-level instead of 1-level controls should be put and both levels should be put one after another. Westgard rules must be followed to establish deviations in IQC.

c. When IQC is out of range, the laboratory technicians should refrain from testing on that equipment till the requisite corrective action has been taken and validated by the diagnostician.

d. Quality assurance quality team managers, diagnosticians and central quality team should take greater responsibility for monitoring out-of-range IQC and EQAS and corrective and preventive actions taken.

e. The service provider should maintain electronic records of out-of-range IQC and EQAS. The corrective and preventive actions for out-of-range IQC and EQAS need to be defined in MIS and records of these actions should be maintained.

f. Monthly reports should be shared with the government on percentage of IQC and EQAS which were out-of-range and percentage of IQC and EQAS for which requisite corrective and preventive actions were taken.

g. The service provider should build capacity of its quality team and laboratory technicians for identification of out-of-range IQC and EQAS and for its management through appropriate corrective and preventive actions. The training curriculum needs to incorporate training on corrective and preventive actions.

h. The service provider needs to engage more resources in its central quality team. An ongoing association with agencies such as CMC Vellore, National Institute of Biologicals, AIIMS etc., is recommended for improving quality control systems of the service provider.

i. An independent body should review the appropriateness of corrective and preventive actions for quality control, erroneous results etc.

viii. Since all laboratories under the scheme are required to become NABL accredited and be fully NABL accredited for all tests within 3 years of commencement of the scheme, it is suggested that the service provider should immediately initiate the accreditation process of all the laboratories, as the process of accreditation takes time. The service provider should submit an action plan to the state government for achieving NABL accreditation. The scope of NABL accreditation needs to be expanded to all tests (currently the service provider plans to exclude 16 tests from NABL accreditation; most of which are advanced tests such as histopathology and cytology and few are critical tests such as cultures and troponins). Also, the service provider should outsource tests to only those private laboratories which are accredited for those tests.

ix. The service provider should get all its laboratories audited by a third party NABL accredited laboratory. Also, the diagnosticians of each district should conduct half-yearly internal audits of the laboratories of their respective districts (currently done once in 15–18 months). The highlights of internal and external audits should be shared with the state government. The central quality team of the service provider should oversee all audits.

x. The service provider should use superior technology for few tests. For example, tests for RA Factor, CRP and ASO should be conducted on a turbidometer instead of semi-automated biochemistry analyser. Also, in laboratories with sample load of more than 30, biochemistry tests should be performed on fully automated biochemistry analysers instead of semi-automated biochemistry analysers; this will significantly reduce pre-analytical errors of re-labelling as well as analytical and post-analytical errors.

xi. It is suggested that the equipment for which test results are recorded manually like urine analyser, electrolyte analyser and coagulation analyser are also bi-directionally interfaced like other equipment. Interfacing should be monitored by the state government.

xii. The pipettes should be calibrated every 6 months to avoid pipetting errors. Also, centrifuges, coagulation analysers and nycocard readers should be calibrated annually. The equipment maintenance plan should be prepared and followed. It is suggested that calibration of equipment is closely monitored by the state government.

xiii. There is a scope for improvement in the process of sample sharing between service provider's phlebotomists and in-house laboratory technicians. The sample should not be transferred from one tube to another as it leads to over-concentration of the anticoagulant. Instead, the sample should be divided into two tubes from the sampling syringe itself. Also, the in-house laboratory technicians should not simply borrow some quantity of sample from service provider's tube at the time of testing but put the sample in a separate tube which could be saved for later if repeat testing is required. A standard operating procedures document stipulating all these details should be formulated and circulated among the staff.

4.1.5 Supervision and monitoring

i. A dedicated resource needs to be appointed by each facility to oversee services under the NTR Vaidya Pariksha scheme. This resource (nodal officer) should carry out validation of patient data for the scheme; supervise availability and quality of services; and handle grievances related to the services under the scheme.

ii. It is recommended that the administrators at health facilities and district health officials take up a larger role in monitoring of services at the health facility level. They should assess monthly analytical reports on availability and utilisation of service provider's services at individual government health facilities; and quality assurance at service provider's laboratories. The district officials should provide

feedback to the state officials based on an in-depth and closer monitoring of the services and its uptake. All information from the health facilities and laboratories should be validated before it is presented.

iii. The dashboard should be strengthened to include:

a. The percentage of patients tested (out of total number of patients), as this is a better indicator of utilisation of laboratory services at each facility than total number of patients tested. For this, data should be provided on total number of patients (outpatients and inpatients) at individual facilities by the state government to the service provider.

b. A facility-level drill down and separate analyses for PHCs, CHCs, AHs, DHs and OPD/IPD for existing indicators like total number of patients tested, total number of tests conducted, types of tests conducted and turnaround time. Monthly trends of all these parameters should be studied for monitoring utilisation of services. The state government should also monitor facility-wise and doctor-wise utilisation of each kind of test.

c. Monthly figures in addition to the currently available real-time and to-date figures.

d. Weekly and monthly MIS data analytics and reports (in the form of statistical reports, charts and data summary visuals) for better monitoring and supervision.

iv. It is suggested that MIS data be combined with periodic surveys/ inspection reports of the government health facilities and service provider's laboratories to enable the state government to maintain a more vigilant supervision of the scheme.

v. It is also suggested that reports from analytics of laboratory services be integrated with data on medicines prescribed, pharmacy usage and other relevant parameters. This will not only enable closer monitoring of the scheme, but also help in tracking morbidity conditions, appropriateness of medicines prescribed, supplies needed in a facility and other decision support information for the state officials. This will also enable effective reimbursement (payment) administration. To achieve this, integration of IT systems between the service provider and the public health system at all levels will be required. The state can build technical capacity for such analytics, interpretation of reports and taking corrective measures.

vi. It is imperative to use a single patient identity (registration number) for patients availing laboratory services to maintain uniformity in identification of new and repeat patients. This would enable capturing of repeat orders by clinicians in case of inaccuracies in test results and follow-ups. This would also help in analysing the population morbidity (disease patterns and trends). Options of using Aadhaar data with thumb impression identification of patients or using ID issued under the health insurance scheme can be explored.

vii. To ensure that patients using laboratory services furnish their unique ID, it is suggested that a message in local language be displayed prominently in the health facility and printed on the acknowledgement slip given to patients for report collection.

viii. It is suggested that patients' profile – BPL/APL, tribal, ANC, gender, age group etc., be captured to facilitate analysis of uptake of services among these segments of population.

ix. Data of patients availing laboratory services should to be captured electronically at the point of sample collection for seamless flow and data integration. Also, the time of sample collection should be recorded to track the pre-analytical turnaround time. The records of all patients availing laboratory services both at the in-house laboratory and through service provider need to be captured electronically in one single integrated MIS at the government health facility itself. The state government is in the process of implementing EHR. Once implemented, EHR application could be leveraged for the same.

x. It is recommended that data validation be strengthened at the health facility level. Following are some specific suggestions regarding the same:

a. Validation is required for number of patients prescribed tests, number of tests prescribed and percentage of patients for which printed reports are provided by the service provider for all prescribed tests.

b. The designated nodal officer at the health facility under supervision of the administrator should be given the responsibility for data validation. The nodal officer should check whether the requisition forms were filled by the doctors, any tests have been removed from the prescribed list of tests on the forms and the number of samples matches the tests prescribed on the requisition forms. The nodal officer should put his/her signature on the sample dispatch register maintained by the phlebotomist(s) at the health facility. The nodal officer should also check whether all printed reports have reached the health facility by matching the printed reports received with the report receipt register maintained by the phlebotomist(s) at the health facility.

c. Once the MIS/EHR is in place, data recorded by phlebotomists of the service provider in the MIS of the government health facilities should be validated as mentioned in point B. It would be useful if the software has a feature to reflect completion of the process of validation. Receipt of printed reports should also be validated in patient's EHR.

d. In addition to daily validation, the nodal officer along with the administrator should also match the monthly figures on the dashboard (total number of patients tested and total number of tests conducted) with the data available at the health facility in the sample dispatch-cum-report receipt register.

e. The health facilities should be careful that data of service provider's tests does not spill into that of in-house tests leading to over-projection of number of in-house tests.

xi. To enable the assessment of tests patterns of doctors, it is suggested that doctors' data is defined in the MIS of service provider and captured against each patient in the MIS. A unique ID will be required for proper identification of the doctor. Also, the name and unique ID of the prescribing doctor will be required on the requisition form for tests. To this end, the state government should provide database of doctors to the service provider which includes name, specialty, phone number and employee code/Aadhaar number (unique identifier). The state government should also make it mandatory for doctors to put a seal on the requisition forms; the seal should contain name and unique ID.

xii. The number of patients prescribed tests, number of each type of tests prescribed and patient-to-test ratio could be monitored for each doctor monthly. An intra-specialty comparison could be done for more effective assessment of the prescription patterns. Once EHR is implemented, the percentage of patients who were prescribed tests by each doctor (out of the total patients who consulted that doctor) could be tracked.

xiii. Periodic and random prescription audits are recommended to keep over-prescription of tests in check. It would be useful to make unit heads accountable for rational prescriptions in their respective departments in hospitals. This would also enable direct supervision of junior doctors.

xiv. It is suggested that the state government introduces evidence-based prescription practices to determine the upper limit to the number of tests prescribed or combination of tests in groups. The prescription patterns should be monitored closely in terms of single test prescriptions, types of tests ordered, number of patients who were prescribed tests etc. The government can develop standard treatment guidelines (if not available) coupled with laboratory test prescription guidelines/test panels to ensure standardization and develop evidence based medicine (EBM) protocols specially at lower levels of the health system. Once MIS is in place for prescription of laboratory tests and pharmacy, these guidelines would be useful for standardizing care.

xv. A circular may be sent to all the government facilities and doctors that they should refrain from prescribing tests to the private laboratories for those tests that are available at the facilities under the NTR Vaidya Pariksha scheme. It would also be helpful to display information in the health facilities that if any patients are asked to get their tests done from private laboratories, they can drop a complaint in the complaint box. The state government may consider not allowing any private laboratories within 5 km radius of the government health facilities.

xvi. It is suggested that the government monitors the availability of doctors at the government health facilities. Also, the service provider should report to the

government daily about facilities with zero samples or a very low percentage of patients prescribed tests and the reasons for the low utilisation of services there.

xvii. It is recommended that all decisions related to provision of services under the NTR Vaidya Pariksha scheme, for example conducting screening camps should be taken after approval from the state government.

xviii. It is recommended that the service provider, not DCA be the first-level monitoring agency for the franchisees and should be accountable for their performance. DCA should be the regulatory authority as an additional layer of oversight for independently monitoring the laboratories. The service provider should prepare and implement a schedule of periodic internal and external audits of all its laboratories, using robust protocols.

xix. It is suggested that an expert committee consisting of government pathologists/ biochemists/microbiologists/other reputed experts and relevant stakeholders is constituted to monitor the technical aspects of service provider's laboratories periodically. Surprise visits at the service provider's laboratories will help in spot checks on quality of reagents being used, type of laboratory technicians working in the laboratory, absenteeism of staff, work process flow, compliance with biomedical waste management guidelines etc. If required, the government could use independent professionals/professional bodies for this monitoring.

xx. It is recommended that the service provider gives access to the state government to view real-time laboratory information system of all its laboratories. A dedicated resource assigned by the government can randomly check in the system whether the tests were actually conducted at the service provider's laboratories and the test reports are genuine.

xxi. All government health facilities should maintain attendance register/biometric attendance (at facilities which have this provision) for service providers' phlebotomists. The records should be regularly checked by the administrators as well as district health officials. The service provider should inform the health facilities about absence or late arrival of the phlebotomist(s). The service provider could also track availability of its phlebotomists if phone numbers of the government health facilities are made available to the service provider.

xxii. It is recommended that the state government formulates protocols for monitoring of service provider, conducting patient satisfaction surveys, making payments to the service provider, conducting annual review of performance of service provider etc.

xxiii. It is suggested that the government continues to conduct periodic security audit of the service provider's IT systems for data security and confidentiality.

xxiv. It is recommended that to increase uptake of services of the call centre set up by the service provider, phone number of call centre is displayed clearly at

prominent places in the health facilities as well as on the test reports. The facility administrator should be made responsible for adequate uptake of call centre services. The service provider should record all feedback/complaints and action taken in its MIS and provide a monthly report to the state government.

xxv. Periodic patient satisfaction surveys should be conducted for assessing patients' experiences with services under the NTR Vaidya Pariksha scheme. In these surveys, it would also be important to investigate if any fee was paid by patients for getting tests done at the government health facilities.

4.1.6 Contract management

The recommendations below have emerged from a detailed analysis of the Agreement between the state government and the service provider. Some of the recommendations could be adopted right away by the state government and others could be used at the time of re-negotiation of the Agreement/re-tendering.

i. The primary responsibilities of the contractor (signing authority) vis-à-vis franchised laboratories (sub-contractors) including quality control, supervision, penalties to the franchisees and accountability of the service provider in regular monitoring of franchisees and for meeting performance requirements and quality of services rendered by them needs continuous monitoring. It should also be mentioned that in case of any deficiency or poor quality of services by the sub-contractors, the primary contractor will be held responsible and be liable for all penalties.

ii. It is recommended that the Agreement includes detailed description of certain crucial aspects of the scheme such as mutual roles/responsibilities and obligations of the government and service provider, project governance mechanism, supervision and monitoring mechanism, use of IT in monitoring and data analytics (morbidity tracking), contract management including payment procedures, and operational aspects of key processes including but not limited to sample collection, sample transportation including quality of storage and cold chain, sample processing etc.

iii. It is suggested that the critical aspects of the PPP structure, that is, detailed description of outputs and standards including performance indicators and penalties in case of shortfall in performance at various stages are defined. The penalty framework and events of default should be more elaborated in line with standard concession Agreements already available. It is recommended to add few more KPIs (for penalty) and monitoring indicators. A suggestive list of KPIs and monitoring indicators has been developed by WHO evaluation team (Annexure I) for consideration.

iv. The scope of breakdown of services should encompass unavailability of accurate testing and unavailability of any designated tests, besides unavailability of sampling services.

v. Currently the penalty on quality control only includes EQAS not-performed. It is suggested that inability to perform IQC should also be incorporated in the penalty clause. Along with this, appropriate preventive and corrective actions for IQC and EQAS should also be monitored.

vi. The tests for Sodium, Potassium and Chloride; and Troponin I and Troponin T are respectively clubbed together in the Agreement and should be mentioned separately. Till the changes are made in the Agreement, service provider should disaggregate these tests for data analytics, instead of counting them as a single test.

vii. The Agreement should specify the number of days in a month for which the service provider needs to station phlebotomists at each type of facility.

viii. It is suggested that the cost per sample in the Agreement is changed to cost per patient.

ix. Considering that the penalty clauses are monthly, the payment cycle should be made monthly instead of weekly in the Agreement.

x. The service provider's services could be utilised for conducting screening camps and the cost for these camps could be fixed by the state government in the Agreement based on number and types of tests to be conducted through these camps.

xi. For the period till NABL accreditation is accomplished, the Agreement should clearly specify the technology of equipment to be used for each kind of test, quality of reagents to be used for testing and internal control, mechanisms of IQC and EQAS, agencies for EQAS, cold chain monitoring and transportation of samples. Minimum qualifications and training structure for the service provider's staff should also be outlined.

xii. The penalty clause on unavailability of sampling services should be revised. Penalty should be levied on the service provider if its sampling services or any designated tests are unavailable at the government health facilities for more than a total of three working days in a month, instead of penalising unavailability of sampling services only for more than three days at a stretch. This leaves room for unavailability of services for short but frequent intervals.

xiii. It is suggested that the turnaround time is defined as per the best industry practices and should incorporate pre-analytical turnaround time (to indicate time taken from sample collection to report availability).

xiv. The Agreement should have provision to address the possibility of service provider charging fee from patients for its services/giving adverse incentives to healthcare professionals or other officials.

xv. It is suggested that the methodology for calculation of minimum assured volume is revised. Instead of assigning absolute diagnostic load at each type of facility as minimum assured volume; it should be calculated as a percentage of patient load at

health facilities. Based on the level of care provided at different types of health facilities and data from few states, the minimum assured volume of diagnostic load could be kept at 8% of total patient load for DHs and AHs and 5% for CHCs and PHCs. Also, the minimum volume should be assured on monthly/yearly basis rather than daily-basis in interest of cost-efficiency of the scheme.

xvi. It is suggested that the turnaround time for critical results (within 3 hours of dispatch) is corrected in the Agreement.

xvii. Grievance handling mechanism should be clearly defined in the Agreement.

xviii. It is suggested that at the time of renewal of Agreement/re-tendering, the state government assesses tests that could be reassigned to the in-house laboratories; especially tests which are high-volume and low-cost like TLC, DLC and rapid tests (e.g. RPR and dengue rapid test). Considering that CBC, TLC and DLC constituted 15–25% of total tests prescribed to the service provider, the government could consider procuring haematology analysers for all types of facilities and manage these most commonly done tests at its in-house laboratories. These analysers are user-friendly and do not require high level of expertise for testing as the procedure does not involve elaborate pre-analytical and analytical processing. It would also be important to maintain the supply of reagents/kits for tests for which in-house capacity exists (e.g. RPR and dengue rapid test) rather than redirecting the tests to the service provider because of lack of reagents.

4.1.7 Adherence to Agreement clauses

The service provider has complied with most of the clauses in the Agreement. There are a few clauses which have not been implemented so far:

i. The phlebotomists of service provider conduct all tests assigned to in-house laboratory in health facilities where position of in-house laboratory technician is vacant.

ii. The service provider declares the list of empanelled laboratories to the state government.

iii. The service provider prepares and submits standard operating procedures on sample transportation, storage and testing processes to the state government, declares human resources and equipment at each laboratory, shares detailed logistics plan, and maintains complete records of critical test results and inform doctors about the same.

iv. The service provider submits reports to the state government on unavailability of sampling services at the government health facilities.

v. The service provider gets ‘all’ its laboratories audited by a third party NABL accredited laboratory.

vi. Blood culture test is conducted on an automated blood culture system.

vii. The service provider makes provision for serum calcium test (not been made available so far).

4.1.8 Payment administration

i. It is suggested that the payment cycle be made monthly, as currently invoices are submitted by the service provider on a weekly basis whereas penalty clauses of turnaround time and EQAS are applicable on monthly basis.

ii. It is suggested that the state government seeks clarifications from the service provider on ambiguous points before authorising any deductions to avoid delays in payments.

iii. The state government should ensure capacity building of the officials responsible for authorising payments.

4.1.9 IEC

i. It is recommended that only name of the scheme is mentioned on the NTR Vaidya Pariksha scheme-related communication and citing service provider's name can cause confusion among patients.

ii. It is suggested that a combined list of tests (provided in-house and through the service provider) is displayed for clarity of patients about the tests available at the government health facilities.

iii. It would be useful to have clear display of laboratory timings at the health facilities, in addition to OPD timings.

4.1.10 In-house laboratories

i. It is recommended that upgradation of infrastructure; and provision of power back-up and cold storage is done in the in-house laboratories.

ii. It is suggested that the supply of reagents (especially for blood sugar test) to in-house laboratories is maintained.

iii. The sample tubes/containers should be disposable and not re-used.

iv. Monthly instead of quarterly assessment of inventory should be done for availability of buffer stock and its expiry.

v. Capacity building of the in-house laboratory technicians is suggested through quarterly trainings, competency assessment and use of standard operating procedures in the laboratories. In addition, the administrator/another doctor at the facility should be trained on basic concepts of laboratory and should be made responsible for supervising the functioning of the laboratory for processes, reagents and consumables, inventory management, equipment etc. Also, periodic supervision of in-house laboratories should be carried out by diagnosticians through visits to the laboratories and assessment of data on test results, quality control etc.

vi. The in-house laboratories could adopt few best practices of the service provider, including registration, labelling, sampling and report dispatch. The reports should be given to the patients in a printed form instead of writing on the OPD slip or a piece of paper.

vii. It is recommended that the state government provides reagents for quality control and institutes a quality assurance team which sets up and monitors internal and external quality controls, standard operating procedures etc.

viii. An equipment maintenance plan should to be put in place. Regular calibrations and routine maintenance will enable more effective utilisation of the equipment.

ix. It would be useful if the state government can institute requisite measures to ensure uniformity and quality in local procurement of reagents and consumables.

x. The timings for laboratory services should to be displayed clearly at the health facilities.

xi. The government staff should to be sensitised about respecting patients' privacy.

xii. The government could consider an outsourcing model for housekeeping services at all types of health facilities; as the laboratories, toilets and facilities in general were found to be much cleaner where these services have been outsourced.

4.2 Recommendations for Ministry of Health and Family Welfare for potential implementation of Free Diagnostics Scheme in other states

4.2.1 Key enablers for successful implementation of the NTR Vaidya Pariksha scheme for potential adoption by other states

It is recommended that the following enablers which facilitated successful implementation of the NTR Vaidya Pariksha scheme in Andhra Pradesh are adopted by other states:

i. High political and administrative commitment; leadership; and adequate budgetary allocations by the state government.

ii. Rapid rollout of services with a phased approach.

iii. Availability of all designated tests at all facilities.

iv. Delivery of services through newly set-up laboratories, which enabled operational efficiency in the services as well as cost efficiency for the service provider.

v. Concerted and intensive efforts by the state government for overcoming initial resistance of doctors to prescribe tests to the service provider under the new scheme.

vi. Timely payments to the service provider and levying of penalties when required.

vii. Establishment of a robust monitoring framework by the state government since beginning of rollout of the scheme.

viii. Continual improvement in quality of services by the service provider through IQC, EQAS and NABL accreditation (on the anvil).

ix. Clear delineation by the state government of the tests that would be done in-house and those that would be outsourced at the outset.

x. Intensive IEC campaigns by the state government to increase awareness about the scheme among the populations.

xi. The state government's synergistic (not imposing) way of working with the service provider and service provider's compliance with suggestions from the state government for improvement of its services.

4.2.2 Agreement between the state government and service provider

Some key observations and recommendations from a detailed analysis of the Agreement between the state government and service provider for the NTR Vaidya Pariksha scheme have been mentioned in section 4.1.6. These could be used by the Ministry of Health and Family Welfare to inform similar programmes in other states.

4.2.3 Cost efficiency

i. It is suggested that the states consider strengthening in-house laboratories at PHCs for low-end and rapid tests, and utilise the budget optimally in purchasing advanced tests at CHCs and above from the service provider. Also, the states could build their in-house capacity at all levels of facilities by procuring equipment for tests which are high volume and require minimal expertise. This would strengthen the capacity of public health system in providing basic health services in the long run. Advanced tests from the service provider would help in improving efficient purchase of services (tests) under the capitation mode. Moreover, it will add value to the patients seeking services at PHC level and enhance their satisfaction with less OOPE when travelling to higher centres for tests.

ii. It is suggested that a detailed financial analysis or value-for-money (VFM) analysis/cost-benefit analysis of the NTR Vaidya Pariksha scheme is done by the

Ministry of Health and Family Welfare to understand if it would be more efficient to purchase higher level tests from CHC level and upwards rather than low-end tests at the PHC level, through capitation mode; whether per capita rate could be different for various levels of facilities; and which of the two – per capita or per test model is more cost effective.

It is also recommended to carry out a comparative analysis of cost of running in-house laboratories with the cost of NTR Vaidya Pariksha scheme for cost efficiency in terms of utilisation of services of each type. This learning could enable other states to prepare a robust financial model for planning its services.

iii. States are advised to carry out an in-depth assessment of tests required at various levels of facilities to be incorporated in the Agreement to avoid extra costs incurred. The feasibility of adding tests on discretion of the government after the rollout as suggested in the Agreement is questionable as it did not work out in the NTR Vaidya Pariksha scheme without additional cost incurred to the government.

iv. It is suggested that a few tests are added in the current list of Free Diagnostics Scheme guidelines as listed in Annexure II. These additional tests would help in improving efficient purchase of services (tests) under the capitation mode and further improve the healthcare delivery services at each level with great benefits to the catchment populations.

v. It is suggested that instead of outsourcing all facilities for the entire list of tests, the states consider to group the government health facilities into 2–3 categories based on existing in-house capacity (staff, equipment etc.) and access of the facility. Some facilities might not require outsourcing at all and in others, all tests might need to be outsourced. In the remaining, a mixed approach could be followed and tests selectively outsourced based on the in-house capacity and access of the individual facility.

vi. It is suggested that the minimum assured volume should be applicable only after the complete rollout of the services in the defined geography.

4.2.4 Operational efficiency

Other states could avoid teething problems which compromise quality of services in the initial stages of the rollout by taking requisite measures before the services are rolled out. These measures are outlined below:

i. The service provider should be given 90–120 days for initiation of the rollout of services. The services should be rolled out in a phased manner. The laboratories should start full-fledged services in 1% of facilities in each district for 2 weeks before they extend their services to rest of the facilities. In parallel, the service provider should do a dry-run for 2 weeks at all government health facilities. This would give enough time to the service provider to set up robust processes to deliver quality services as well as to ensure effective access through requisite turnaround time right at the outset. Also, if quality and availability of services is good in the beginning, it is

likely to gain popularity among doctors at the government health facilities which in turn would foster adequate utilisation of services at the health facilities.

ii. In the preparatory phase of the rollout, the following measures would enable a smooth implementation:

   a. Laboratories should be inspected by the service provider and the state government before they become operational. The equipment, quality of reagents, qualification and experience of laboratory technicians, infrastructure for cold chain, standard operating procedures, laboratory information system used in the laboratories etc., should be assessed. Quality control systems should be instituted in the preparatory phase.

   b. The training structure and curriculum for laboratory technicians should be in place and presented to the government.

   c. Requisite infrastructure, tracking systems and details of processes to be tracked should be in place for monitoring as per monitoring indicators so that requisite monitoring could be initiated as soon as the services become operational.

   d. States should build capacity for monitoring of the scheme at all levels including facility level.

   e. Procurement and adequate testing of equipment, ice boxes, needle destroyers, and reagents should be complete and results of testing should have been assessed.

   f. Doctors should be sensitised about introduction of services of a private provider right at the outset.

iii. The monitoring indicators should be used from the beginning of rollout. The states should to closely monitor all aspects of services including availability of sampling services and tests at the government health facilities, cold chain, transportation, quality assurance at laboratories, including processing of samples, testing, quality control, validation of results and training of staff of service provider.

iv. The service provider should commence inspections of its laboratories and sampling areas at the government health facilities and these should be in turn supervised by the government through periodic inspections. Test patterns audits should be enforced right from the beginning of implementation of the scheme.

Annexure I: Key performance indicators and monitoring indicators

1. Key performance indicators

S. No.	KPI	Prescribed limit for penalty	Remarks
1	Percentage of samples (patients) for which turnaround time is within the prescribed limit	Total turnaround time to be achieved for 95% of samples (patients)	1. Total TAT* = pre-analytical + analytical + post analytical TAT (from time of sample collection till time of electronic report dispatch) 2. Sample is one patient with one time sampling. 3. Any test of the patient which exceeds prescribed turnaround time will be counted as exceeded turnaround time for the sample (patient).
			*a. Pre-analytical TAT for PHCs, CHCs (from government health facility to primary receiving laboratory): Tests received at the testing laboratory within 8 hours of sample collection.
			*b. Pre-analytical TAT for AHs, DHs (from government health facility to primary receiving laboratory): Tests received at the laboratory within 2 hours of sample collection.
			*c. Pre-analytical TAT for advanced tests transported from primary receiving laboratory (L2) to mother laboratory): Cultures, fluid cytology and TSH received at the L1 laboratory within 3 hours; histology, FNAC, pap smear, HbA1C and Hb electrophoresis received within 12 hours

S. No.	KPI	Prescribed limit for penalty	Remarks
			*d. Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab (refer to part 3 of Annexure I for time of testing for tests)
			*e. Analytical TAT (report validation): Tests validated within 1 hour of testing
			*f. Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 1 hour of report validation
			*Total TAT for PHCs/CHCs: a+d+e+f
			*Total TAT for DHs/AHs: b+d+e+f for routine tests and b+c+d+e+f for advanced tests transported to mother laboratories
			*Total TAT for critical test results for PHCs/CHCs: a+d+e + 30 minutes through automated messaging
			*Total TAT for critical test results for DHs/AHs: (b+d+e for routine tests and b+c+d+e for advanced tests transported to mother laboratories) + 30 minutes through automated messaging
2	Percentage of working days in a month when each type of test is available	Unavailability of tests not to exceed a total of more than three working days in a month	

S. No.	KPI	Prescribed limit for penalty	Remarks
3	Percentage of working days in a month when sampling services are available	Unavailability of sampling services not to exceed a total of more than three working days in a month	
4	Percentage of tests for which service provider participated in EQAS/inter-laboratory proficiency testing and IQC	Service provider to participate in EQAS/inter laboratory proficiency testing and IQC for 100% of tests	
5	Percentage of tests for which EQAS/ILPT and IQC for which appropriate corrective and preventive actions were taken	Appropriate corrective and preventive actions to be taken for 100% of EQAS/ILPT and IQC	Appropriateness of corrective and preventive actions to be validated by third party
6	Percentage of samples for which cold chain is adequate	Cold chain to be adequate for at least 95% of samples (patients)	a) One sample implies any one sample of a patient (hematology, Biochemistry, urine, fluid etc.) b) Temperature monitoring device to be used for charting the temperature
7	Percentage of QAQT mangers and laboratory technicians at testing laboratories who underwent induction training followed by quarterly refresher training and competency assessment by MD/PhD Biochemistry/Pathology	At least 95% of QAQT mangers and laboratory technicians at testing laboratories to undergo induction training followed by quarterly refresher training and competency assessment by MD/PhD Biochemistry/Pathology	

S. No.	KPI	Prescribed limit for penalty	Remarks
8	Percentage of laboratories accredited under NABL for all tests within three years of signing of contract	100% of laboratories to be accredited under NABL for all tests within: a) 3 years of signing of contract (for Andhra Pradesh) b) 2 years of signing the contract (for states which plan to roll out the Free Diagnostics Scheme)	

2. Monitoring indicators

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
1	Percentage of public health facilities serviced by the private provider	State	Quarterly	
2	Total number of patients tested	State, district, facility, OPD, IPD, women, children and tribal patients	Monthly	
3	Total number of tests conducted – test-wise	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
4	Patient to test ratio	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
5	Percentage of tests with 1,2,3…n number of tests prescribed	State, district and facility	Monthly	
6	Percentage of government health facilities with zero samples for more than 10% of working days	State, district and facility	Monthly	
7	Percentage and types of tests which are unavailable for a total of more than three working days in a month	State, district and facility	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
8	Average of frequency and duration of unavailability of sampling services at government health facilities	State, district and facility	Monthly	Services unavailable due to absence of sampling/sample pick-up staff, consumables for sampling not available etc.
9	Percentage of service provider's laboratories with NABL accreditation	State and district	Half-yearly	
10	Percentage of tests accredited under NABL	Laboratory and test-wise	Half-yearly	
11	Percentage of laboratories which underwent third party annual audits by NABL accredited laboratory	State, district and laboratory	Yearly	
12	Percentage of outsourced laboratories which are NABL accredited for the referred tests	State, district and laboratory	Yearly	
13	Percentage of laboratories which underwent yearly internal audit	State, district and laboratory	Yearly	
14	Sample rejection rate	State, district, facility, OPD, IPD and laboratory	Monthly	Sample hemolysed , sample clotted , insufficient sample, delay for prothrombin time and labeling error
15	Percentage of tests repeated on request of clinicians	State, district, facility, clinician, OPD, IPD and type of test	Monthly	Re-run/re-sampling requisition form to be filled by the laboratory. For patient identification for repeat testing, unique ID of patients (Aadhaar card/any other ID proof) can be used.
16	Percentage of tests with results outside the normal reference range (test-wise)	State, istrict, facility, linician, PD, IPD and type of test	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
17	EQAS, IQC, ILPT and traceability of kits			
a.	Percentage of tests for which a) EQAS b) IQC c) Inter lab proficiency testing d) Traceability of kits was done	State, district, laboratory and test-wise	Monthly	
b.	Percentage of tests for which a) SDI of EQAS was between 2 to 3 and >3 b) SDI of Inter lab proficiency testing was between 2 to 3 and >3 c) IQC Westgard rules (5+1) were violated d) Traceability of kits failed	State, district, laboratory and test-wise	Monthly	Records of borderline/unacceptable SDI scores for EQAS/ILPT, violated Westgard rules for IQC and failed traceability of kits along with corrective actions for both EQAS (borderline/unacceptable) and IQC (violated Westgard rules) to be maintained in electronic format.
c.	Percentage of out of range EQAS and IQC for which corrective actions were taken	State, district, laboratory and test-wise	Monthly	a) EQAS of >2 SDI b) SDI of inter lab proficiency testing was >2 c) IQC tests (for which westgard rules (5+1) were violated) d) Traceability of kits failed. Records to be maintained in electronic format.
d.	Percentage of corrective actions taken which were accurate	State, district, laboratory and test-wise	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
18	Percentage of tests validated by MD pathology/biochemistry/microbiology	State, district, laboratory and test-wise	Monthly	
19	Percentage of equipment calibrated annually	State, district, laboratory and test-wise	Yearly	
20	Percentage of equipment which are interfaced - equipment-wise	State, district and laboratory	Half-yearly	
21	Average a) frequency and b) duration of equipment downtime (equipment-wise)	State, district and laboratory	Monthly	
22	**Training**			
a)	Percentage of QAQT mangers and laboratory technicians at testing laboratories undergoing induction training followed by quarterly refresher training and competency assessment by MD/PhD biochemistry/pathology	State, district and laboratory	Half-yearly	
b)	Percentage of phlebotomists and ILDs undergoing induction training followed by quarterly refresher training by QAQT managers	State, district and laboratory	Half-yearly	
23	**Cold chain**			

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
a)	Percentage of samples received at the primary receiving/testing laboratory for which cold chain was inadequate	State, district, laboratory, separate for PHCs, CHCs, AHs and DHs	Monthly	1. One sample implies any one sample of a patient (hematology, biochemistry, urine, fluid etc.) 2. Temperature monitoring device to be used for charting the temperature
b)	Percentage of samples received by L1 laboratories from L2 laboratories for which cold chain was inadequate	State, district and laboratory	Monthly	Temperature monitoring device to be used for charting the temperature
24	**Quality of processes**			
a)	Percentage of urine cultures plated within 4 hours of sample collection	State, district and laboratory	Monthly	Plating to be done at the primary receiving laboratory
b)	Percentage of peripheral smears prepared at the time of sample collection	State, district and laboratory	Monthly	Two blood smears to be prepared – first by the phlebotomist at the time of sample collection and second at the primary receiving laboratory
c)	Percentage of fluids for which TLC and DLC was done, and stained smear was prepared within 4 hours of sample collection	State, district and laboratory	Monthly	TLC and DLC to be done at the primary receiving laboratory
d)	Percentage of blood culture samples tested on automated blood culture system	State, district and laboratory	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
25	Percentage of samples (patients) for which turnaround time is within the prescribed limit			1. Turnaround time: Time from sample collection to receipt of electronic report at the health facility. For critical test results: Time from sample collection to receipt of report at the health facility through automated messaging 2. Total TAT* = pre-analytical + analytical + post analytical TAT (from time of sample collection till time of electronic report dispatch) 3. Sample is one patient with one time sampling. 4. Any test of the patient which exceeds prescribed turnaround time will be counted as exceeded turnaround time for the sample (patient).
a)	Pre-analytical TAT for PHCs, CHCs (from government health facility to primary receiving laboratory): Tests received at the laboratory within 8 hours of sample collection.	State, district, facility, OPD, IPD and type of test	Monthly	
b)	Pre-analytical TAT for AHs, DHs (from government health facility to primary receiving laboratory): Tests received at the laboratory within 2 hours of sample collection.	State, district, Facility, OPD, IPD, and type of test	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
c)	Pre-analytical TAT for advanced tests transported from primary receiving laboratory (L2) to mother laboratory): Cultures, fluid cytology, TSH received at the L1 laboratory within 3 hours; histology, FNAC, pap smear, HbA1C, Hb electrophoresis received within 12 hours	State, district, facility, OPD, IPD and type of test	Monthly	
d)	Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab	State, district, facility, OPD, IPD and type of test	Monthly	Turnaround time for testing listed in part 3 of Annexure I
e)	Analytical TAT (report validation): Tests validated within 1 hour of testing	State, district, facility, OPD, IPD and type of test	Monthly	
f)	Post-analytical TAT: Percentage of test reports received at the facility (electronic) within 1 hour of report validation	State, district, facility, OPD, IPD and type of test	Monthly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
g)	Total TAT: For PHCs/CHCs: a+d+e+f For DHs/AHs: b+d+e+f for routine tests and b+c+d+e+f for advanced tests transported to mother laboratories	State, district, facility, OPD, IPD and type of test	Monthly	
h)	TAT for critical results: For PHCs/CHCs: a+d+e + 30 minutes through automated messaging For DHs/AHs: b+d+e for routine tests and b+c+d+e for advanced tests transported to mother laboratories + 30 minutes through automated messaging Percentage of test reports received through automated messaging at the government health facilities within stipulated TAT from time of sample collection	State, district, facility, OPD, IPD and type of test	Monthly	
26	**Report dispatch**			
a.	Percentage of printed reports received at PHCs and CHCs by 9:00 next working day of sample collection	State, district, facility, OPD, IPD and type of test	Monthly	
b.	Percentage of printed reports received at AHs, DHs within 1 hour of report validation	State, district, facility, OPD, IPD and type of test	Monthly	
27	**Grievance redressal**			

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
a.	Number of complaints from patients and health care staff at government health facilities and other government officials	State, district and facility	Monthly	
b.	Percentage of complaints (from patients/clinicians/for which corrective action taken within 7 days of receiving the complaints	State, district and facility	Monthly	
28	Percentage of patients satisfied with laboratory services, including any fee charged by the service provider for laboratory services	State, district and facility	Yearly	To be monitored by the government
29	Number of days for which minimum assured volume of patients was not achieved	State	Monthly	It is recommended that daily minimum assured volume guarantee be changed to yearly
30	**Payments**			
a.	Percentage of incomplete monthly payments to service provider	State	Yearly	
b.	Percentage of monthly payments to service provider delayed by more than one week	State	Yearly	
c.	Percentage of amount deducted from invoice payment as penalties	State	Monthly	

3. Proposed turnaround time for testing

Name of test	Testing time
A. Hematology	
TLC	2 hours
DLC	2 hours
Platelets	4 hours
Complete blood count/hemogram	4 hours
Peripheral blood smear	24 hours
Total eosinophil count	4 hours
Coombs test (direct)	4 hours
Coombs test (indirect)	4 hours
Prothrombin time	2 hours
B. Biochemistry	
Blood Urea	2 hours
S Creatinine	2 hours
S Bilirubin total	2 hours
S Bilirubin indirect and direct	2 hours
SGOT	2 hours
SGPT	2 hours
S Alkaline phosphatase	2 hours
S Total protein	2 hours
S Albumin	2 hours
S Calcium	2 hours
S Sodium	2 hours
S Potassium	2 hours
S Amylase	2 hours

Name of test	Testing time
S LDH	2 hours
S Uric acid	2 hours
S Total Cholesterol	2 hours
S Triglyceride	2 hours
S VLDL	2 hours
S HDL	2 hours
Troponin I/Troponin T	30 minutes
C. Immunoassays	
TSH	12 hours
D. Serology	
RPR rapid test	2 hours
Dengue rapid test	2 hours
Rheumatoid factor	4 hours
Anti Streptolysin O (ASLO)	4 hours
S CRP	2 hours
E. Microbiology	
Blood culture (bactec)	1st report 48 hours; 2nd report 5 days
Urine culture	48 hours
F. Histopathology	5 days
G. Bone marrow aspiration	3 days
H. Cytology including fluid cytology	24 hours
I. Clinical pathology	
Fluid examination (biochemistry, cell count)	2 hours
Urine complete	4 hours
Stool routine	4 hours

Annexure II: List of tests proposed to be added under Free Diagnostics Scheme

CHC	AH/DH
Peripheral smear, TSH, CRP, GTT, HbA1C, urine culture, rapid typhoid (IgM) test, pap smear, semen analysis, RA factor, ASO, electrolytes, calcium, uric acid, CPK MB, trop T and LDL	Anti-HCV, pus culture, ABG, bone biopsy, serum lipase, serum calcium, rapid typhoid (IgM) test, CSF ADA and FNAC clinic by a qualified Pathologist at least twice a week.

Annexure III

List of interviewees

A. Senior state officials

1. Dr Poonam Malakondaiah, Principal Secretary, Department of Health, Medical and Family Welfare
2. Dr Jitendar Sharma, Advisor for Health and Medical Technology
3. Mrs Sujata Sharma, Special Commissioner, Department of Health, Medical and Family Welfare
4. Mr I Samuel Anand Kumar, Former Special Commissioner, Department of Health, Medical and Family Welfare
5. Dr Durga Prasad, Commissioner, AP Vaidya Vidhan Parishad
6. Dr S. Aruna Kumari, Director, Public Health and Family Welfare
7. Dr Savitri, Joint Director and Nodal officer, NTR Vaidya Pariksha scheme
8. Dr Ravishankar, Director General, Drug Control Administration
9. Mr G Vasudeva Rao, State Programme Manager, National Health Mission

B. Senior management of Medall Healthcare Private Limited (service provider)

1. Mr Balasubramaniam R, President, Division 2
2. Mr Hari Kumar G, General Manager, Operations

C. Other people who were interviewed

State government

1. District health officers (DCHS and DMHO) of Krishna and Visakhapatnam districts
2. 35 doctors and administrators and quality managers at 20 government health facilities
3. Laboratory technicians at in-house laboratories of 20 government health facilities
4. Central drug store team

Service provider

1. District teams of Medall of Krishna and Visakhapatnam districts
2. Phlebotomists at 20 government health facilities
3. Laboratory technicians and Laboratory managers at six laboratories

Patients

120 patients at 20 government health facilities

References

1. Government of India, Ministry of Health and Family Welfare. 2015. National Health Mission: Free Diagnostics Service Initiative.

2. Government of India, Planning Commission. 2004. Report of the PPP Sub-Group on Social Sector. Public Private Partnership.

3. Government of India, Planning Commission. 2012. Guidelines: Institutional Mechanisms for Monitoring of PPP Projects.

4. Government of India. 2017. National Health Policy.

5. Ken Research. 2017. Market Research Report: India Diagnostic Laboratories. Market Outlook to 2021 Growing Prevalence of Diseases and Launch of Technologically Advanced Procedures to Drive Growth.

6. Dr Ramakrishnan 2012. Public Private Partnership (PPP) in Indian Health Care. SSRN: https://ssrn.com/abstract=2186897 or http://dx.doi.org/10.2139/ssrn.2186897.

7. Venkat Raman A and James Warner Björkman. 2009. Public-Private Partnerships in Health Care in India: Lessons for Developing Countries. Routledge.

8. World Health Organisation. 1999. WHO Guidelines on Collaborations and Partnerships with Commercial Enterprise.

9. World Health Organization. 2016. Impact evaluation of the Free Diagnostics Scheme by the governments of Rajasthan and Madhya Pradesh, including trends in out-of-pocket payments in healthcare.

10. World Health Organization. 2001. Making a Public-Private Partnership Work: An Insider's View. Bulletin of the World Health Organization. 79(8):795-796.