Maharashtra Diagnostics Services in Public Health Sector—A Case Study

Introduction[1]

The Free Diagnostics Services Initiative was announced three years ago, as another initiative under the National Health Mission. Soon after the announcement, guidelines for these were prepared and issued by the NHSRC.

The backdrop to these guidelines was the commitment in the National Health Policy 2017, (then in a draft stage) to ensure free drugs and diagnostics in all public health facilities. This was seen as essential to improving quality of care and as financial protection against the rising out of pocket expenditure on health care. Nominally public healthcare facilities were already providing drugs and diagnostics for free in many states. In practice when user fees were introduced in the nineties as part of the then health sector reforms, the provision of free drugs and diagnostics reduced. This was particularly true of Maharashtra where user fees collected were in part deposited in state treasury – and not even kept for local use. It was logical under such reforms out-prescribe the drugs which were to be bought in local commercial pharmacies, or in a commercially run pharmacy situated within the hospital premises. Under such reforms diagnostics became the major source of revenue for the hospital development committees (or Rogi Kalyan Samitis). Though those below the poverty line were to be exempted, such exemption was exercised in a very limited manner. Just like pharmacies mushroomed around public medical establishments in an earlier decade, private diagnostics establishments mushroomed in the last decade. In this same period, due to advances in technology and changes in the standards of care, and even the culture of healthcare, diagnostics came to occupy a much greater proportion of costs and efforts in the provision of healthcare.

In Maharashtra, at the time of the launch of the scheme, all public health facilities above and including the PHC already had a systems of diagnostics in place. This included the rural hospitals, the sub-divisional hospitals, the civil hospitals and district hospitals and the medical college hospitals. Under NHM the list of those exempted had increased and now included, in addition to the BPL, senior citizens and all pregnant women and children. More important the exercise of such exemption was also more liberal. However there were problems. The availability of diagnostics in PHCs could be very limited and uncertain. Quality assurance was not in place. There were frequent break-downs and a high down-time of equipment. And many diagnostics requiring higher technical capacity or capital investment was not available. As a result there were a considerable number of informal arrangements-often with deleterious conflicts of interests between local private diagnostic establishments

[1] A four person study team, comprising of Prof T. Sundararaman, Ms. Soniya Mishra (PhD student), and Dr Fareen Choudhary & Mr. Sagar Sinha (MPH students), made visits to Thane and Nashik districts in the week of 23rd April 2018, for the purpose of understanding the state's progress and challenges it is facing in its efforts to provide universal access to affordable diagnostics through its public health system.
The methodology used were the collaborative enquiry and the case study. The visiting team interacted with health administrators in the district, and administrators and health care providers in the district hospital, the rural hospital and in PHCs. The team also interacted with the agency that had been contracted provision of a significant part of the diagnostics. Visits to the laboratories and a discussion with the laboratory staff and physicians over the record and data maintained there was a major source of information.

and the providers in the health care facility. The Free Diagnostic Services Initiative was therefore a welcome step to address these problems.

Contours of the Scheme

In March 2017, NHM Maharashtra signed an MOU with HLL Lifecare Limited, a GoI owned corporation based in Kerala for the provision of laboratory pathology diagnostics for the entire state. The contract was for a five year period. Simultaneously similar efforts were made for radiology, and CT scans—but these did not take off due to legal contestations- and the matter is in the courts.

The contract was designed such that at each level, tests which had higher volume and lower technical capacity requirements were done in-house while others were out-sourced.

HLL, the Diagnostics Services Agency (DSA or simply the agency) organized the delivery of services on the lines of what is known as the hub and spoke model. To manage this project they have set up an agency called Mahahind Laboratories. The main features of this could be described as follows:

1. The list of tests that would be done at each of the three levels – PHC, CHC (RH/SDH< 50 beds) and District Hospital/Tertiary care center are specified:
    a. At the PHC there is a list of 25 tests of which three are haematological (platelets, complete blood count and prothrombin time), another 19 are blood biochemistry (renal function-3, liver function-7, lipid profile-4, electrolytes-3 and enzymes-2). There are also two minor urine tests and one stool test for ova and cysts (see Appendix 1).
    b. At the next level (RH/SDH) there are 32 tests of which the biochemistry tests are the same as in the PHC. There are 4 additional haematological tests and 5 additional serological tests (see Appendix 2).
    c. In the district hospital there are 52 tests- and almost none of the biochemistry tests on this list are part of the PHC and CHC list. This includes a number of rare immune tests for diseases associated with congenital infections and hepatitis and HIV sub-groups. It also includes 7 tumor markers, and bone marrow examination and cell counts, biochemistry and microbial cultures of all body fluids, semen examination and tissue pathology. Surprisingly it brings back stool examination and sputum for AFB (see Appendix 3).

2. The turn-around time (TAT) between collection (taken as 2 pm of the date of collection) and reporting the test is also specified (see Appendix 4).

3. Samples are collected in the hospitals and PHCs between 8 am and about 1 pm by a phlebotomist who is appointed, trained and deployed by the agency. Between 12.30 noon and about 2.00 pm these samples are collected from the facility (or a nearby collection point) by a runner and transported to the nearest laboratory. In the district hospital alone, samples are also collected in the afternoon between 4 and 6 pm. These have to be picked up around 6.30 pm.

4. While many samples would be analysed in this nearest laboratory (which can be termed L3), some of the samples are transported to the larger district laboratory- L2. But even over here- all tests are not done. Some select immunological tests, and all culture and microbial work is further transported overnight to a central laboratory

situated at Khargar, a Mumbai suburb (L1). Pathology samples-tissue diagnosis-are sent to Thyrocare a private firm. How Thyrocare operationalizes its work has not been part of this study.

5. Once the sample is received in a laboratory, the time of receipt is recorded, the samples are loaded and within a specific time the reports become available. Where possible- and this is for most tests- the reports are ready by the same evening.

6. These reports are then kept in digital form, till the biochemist, pathologist or microbiologist takes a look, approves, and signs off on them.

7. Once the approval is in place, the reports are uploaded on website and sent on email to the providers/facilities, where the providers can access it. In addition where contact cannot be established, hard copies are mailed to the providers so as to reach them on the day after.

8. For critical cases, samples can be collected at any time by requiring the phlebotomist to come on call- and transporting and testing the sample preferentially.

9. Payment to the agency are made monthly based on number of samples, (not the number of tests). These prices are fixed as follows:
    i. DH level: Rs 199 per sample
    ii. RH (<30 bed) & SDH(<100 bed): Rs 139.30 per sample
    iii. PHC: Rs 79.60 per sample
    iv. Special tests: Rs 796 per sample

10. But there is an agreement to pay for a minimum assured volume of 22,000 samples per day across the state. 30% payment is withheld, to be released post scrutiny. Scrutiny involves monthly report and certification from the Civil Surgeon. The TAT is a critical parameter of payment. If more than 10% of samples exceed the given TAT a penalty can be levied.

11. There is an External Quality Assurance System in place. 1% of tests are to be sent to an external laboratory daily and cross-checked for accuracy. This laboratory has to be chosen by the government and should be NABL accredited. Reagents are to be checked quarterly, by a government technician/medical college representative. The laboratories are also to get NABL accreditation within a two year time frame.

12. The number of tests performed are updated on a dashboard available at www.mahahindlabs.com

Implementation of Outsourced Diagnostics and its Challenges

These are still early times for this contractual arrangement- and as can be expected there are many problems with implementation.

Turn-Around- Time (TAT): One of the immediate problems is with the turn-around-time(TAT). In Diagnostic Service Agency's (DSA's) perception it is adhering to prescribed TATs for most tests. But that is not the perception of the clinical care providers. One reason

is that TAT is being measured only for samples collected by agency – whereas many samples fail to be collected on time for a variety of reasons. More importantly, it appears that the TAT reported in the L2 laboratory that we visited began from the time it received the sample to when it gave the result—which are not the terms of the MOU. This interpretation would make TAT a very poor indicator. Providers and even managers are therefore asking a '*collection to laboratory*' time report in addition to TAT at the laboratory for understanding the real picture.

Pathology tests have a one week TAT but—the physicians inform us—that it could take even three weeks for the report. So too with microbiology test, which are—according to one physician—usually received too late for any clinical action.

TAT also depends on which is the location of the nearest Laboratory – L3, L2 and L1. There are only five L3 labs for such a large district as Nashik and one of them was non-functional (Peth) (see Figure 1).

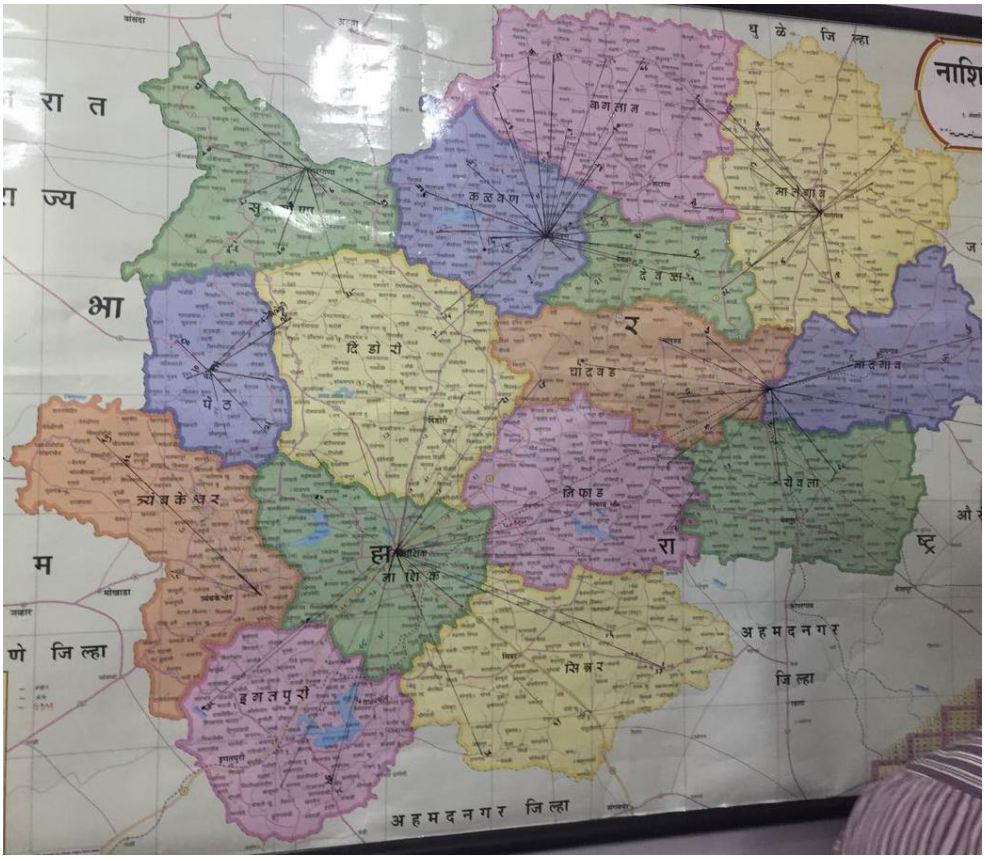


Figure 1 Map of Nashik District showing the 5 L3 Labs

There is one L2 lab and this is Nashik town which is over 200 km from the other end of the district. One advantage of the hub and spoke is that if one L3 hub becomes non-functional as had happened at Peth, then the spokes easily re-align with the next nearest hub- so that services are not disrupted. But the TAT would change.

Collection of Sample: There are problems at the collection site. At the PHC the central problem is the regularity of the phlebotomist. In one PHC visited the phlebotomist had taken leave for 14 days to study for an examination. During that period all sample collection from the PHC stopped and there were no efforts at alternatives. No alarms either. The PHC had a

regular lab technician but neither the public provider nor the DSA thought that she could do the sample collection for a few days. This lack of coordination between DSA and the public providers in sample collection should be one of the easier problems to solve.

At the DH and SDH the samples of in-patients have to be collected from the ward. Often due to last mile issues the ward samples could get missed. Which would mean that the sample would get collected only the next day. But this delay would render the sample useless or unreliable for the diagnostic test. Sometimes, like with cerebro-spinal fluid, it is very difficult to collect another sample. The OP space given to phlebotomists is minimal and lacks privacy- but is functionally adequate. In Nashik DH there are 3 phlebotomists, two for the out-patient load, working in two shifts and one for in-patients. In Thane there are only two phlebotomists.

The recruitment and deployment of phlebotomists are in turn outsourced by sub-contract of HLL to another to another agency.

Problems in Transport: The standard procedures for transfer of samples and its implementation needs urgent review. The current SOP calls for all samples to be put into zip-lock packs and sealed; and then put into another plastic container under a layer of sponge and the whole of this is to be placed in a transport bag with frozen gel packs along the four sides and 2 at the bottom. This is expected to maintain a 2 to 7 degrees C. What was witnessed was thermocol boxes with frozen ice-gel lining, but not all the other layers. It was not clear as to how long this packing could maintain desired temperatures. At the district laboratory in a month close to 160 blood samples are rejected because of haemolysis or clotting (April in Nashik district). These are samples from the collection point to L2 laboratory.

For microbial cultures, where the samples are being transported across the state, the loss of sample quality would be even more. These microbial samples come from all over the state in such packing, through professional couriers who travel on overnight regular passenger buses to Mumbai with the samples in the luggage hold. The evidence to support sample transport SOPs for different tests needs to be examined.

Quality Assurance: There are many gaps in the QA system. The EQAS Laboratory is chosen by HLL and not by the government (at least as perceived at the district level). The laboratory so chosen is an NABL accredited laboratory (Thyrocare), but it also has a sub-contract with HLL within the same project. This sub-contract is for all tissue pathology reporting. Another limitation is that the 1% sample for cross-check is chosen by the laboratory itself, and not a random pick by the external agency as is the norm. Further when the results are received back from EQAS its interpretation is uncertain- and was certainly beyond the skills of the technicians the study team or government monitoring team interacted with. Finally when a negative quality report is occasionally received, no one is quite sure about the corrective action required in that case. Anecdotally many physicians report significant variations in lab reports of the same person, whose sample has been sent more than once. Such narratives could be biased, but the systems to prove and disprove such contestations are not in place.

Monitoring: Government officers in the district who are monitoring the programme have poor knowledge or no knowledge of the quality assurance or transport of sample protocols. The government officers have information on the number of tests performed- but not on the

tests that are positive- or other information by which they can take a view on likely quality of tests.

HLL collects vast amounts of data, but there is a significant gap in how they use this data to improve performance. Dashboard data is not used to prepare any kind of epidemiological report, nor is the number of positive tests recorded anywhere. A cursory look across the pattern of test orders placed by different PHCs and CHCs shows inexplicable variations. The only kind of reports generated daily, and which the HLL team are conversant with, are the daily sales reports which gives the sum earned on each day in each district.

Payment Issues: In PHCs in Nashik district, in the week of April 2nd to April 7th, the total number of samples sent for testing was 2600 and the average number of 'tests per sample' was 2.04. At the RH/SDH level the ratio of tests per sample was 2.24 and the number of samples received was 2059. At the DH and tertiary level, there was a ratio of 1.65 tests per sample with a total of 874 samples. The cash earnings in this week from the district health system was 6.67 lakhs in one week in one district. This is clearly too low a sum to pay for such an operation.

Looking closer and analysing the cash flow on one day 21st April we find that the total earnings was Rs 1.59 lakhs. But of this only Rs 29,034 came from the district facilities. (There were 81 samples from PHC (unit rate Rs 79.6), 44+31 from RH/SDH (unit rate Rs 139.30) and 42+19 from RRH/DH (unit rate Rs 199). This together comes to Rs 29,034 on that day). But then on the same day the DSA has conducted 164 special tests, each of which are priced at Rs 796 per sample. This gives a total earnings of Rs. 1,30,544. Of the total daily earnings of Rs 1.59 lakhs, 82% is from the special tests done for the super-speciality levels of care. There are 6 tests on this special tests list- 1. PCR; 2. Antibiotic sensitivity; 3.cancer and tumor markers; 4. electrophoresis, 5. Ig G, IgM and IgE, and 6. HPLC variants.

There are also other findings regarding payments. One management respondent informed us that the 30% of the payment has not been paid for last three months, due to lack of adherence to MOU provisions.

In-House Testing and its Relationship with the Outsourcing Arrangement

Nashik district hospital provides ambulatory (OPD) care for approximately 700 patients per day and IPD care for nearly 500 patients. The outsourced tests account for only about 60-80 samples total (OPD+IPD per day) of which 25 are outpatients and about 35 are in patients. In the preceding week, 203 samples were taken by the diagnostic service agency and on them 344 tests or about 800 samples and 1300 tests per month. In contrast in March 2018, in-house testing was for 24988 tests. If we combine the 4851 tests of TLC, DLC, BC and Platelets as a single CBC test, the numbers tested still come to about 11,000 tests – more than 9 times the other tests.

The break-up of these would be Hb: 3807; CBC 4851; ESR: 602; MP: 30 and blood biochemistry of blood sugar, urea, creatinine and LFT as 6218 and 19 lipid profile. This also included 647 tests for WIDAL (of which 70 were positive) and VDRL 316. Also urine microscopy in 715 and cytology of 1682 and pregnancy testing for 309. The hospital lab had the capacity for a number of immunological tests (including for HBsAg) and body fluid cytology, which are now not being done.

The hospital has a fully functional CT scan machine, ultrasound machine and X-ray machines. These are all in house. The functionality of the CT and ultrasonography is excellent. There was in March a total of 1373 tests done of which 518 were obstetric cases, 798 were abdomen or pulmonary and 57 were others. On one day there are about 13 CT scans taken of which 8 are of the head. In a month there would be about 300 CTs- which would be optimal utilization. There are clear records of exemption of user fees and about 40% were exempted.

Clearly despite all the attention it draws, it is still the in-house testing on which the clinical performance and outcome depends.

How well is the in-house diagnostics functioning?

The first and most surprising finding is that all in-house diagnostics are priced—though at rates considerably lower than those in the market. Moreover, exemptions from payment could account for as much as 40 to 60% of all patients. Reasons for exemption were BPL status, senior citizens, pregnancy and young children and those under the RNTCP programme. But others would have to pay, and—since payment is per test—it could add up to significant levels.

Performance in terms of turn-around time seems good, though there is no practice of calculating this. However there are equipment break-downs which can take months to repair-making essential tests such as blood biochemistry unavailable for a long time.

Equipment maintenance is outsourced to another agency, Faber Sindoori. There is considerable dissatisfaction with its services, though it is not always clear as to who is to blame. Although they have a toll-free number that is available, and equipment is better maintained at DH level, the scenario changes at more peripheral levels. The X-Ray machine has been defunct at the RH Nashik, for over 1.5 years. The auto-analyser at Nashik DH has not been functional for two months due to what was reported as software issues. There is lack of clarity on who is responsible for such a long down-time.

There are no quality assurance features for in-house laboratory tests.

Many of the tests that are part of the outsourcing arrangement- especially micro-biology, pathology and immunology and tumour markers were never established as in-house tests. Among in-house tests that shifted to outsourcing, HBsAg is the main one.

This is the same pattern in the 30 bed rural hospital in Nashik district that was visited. This facility has four full time doctors and sees about 90 out-patients daily. It has both a HLL phlebotomist (earning Rs 7000 per month) and an in-house Lab Tech (earning Rs 45000 per month). It has an X ray machine (100 mA) not functional for last 18 months due to lack of technician. Both X rays and USG are outsourced by a local arrangement to a private local agency- and X-rays are charged Rs 50 per film and USG Rs 500 to 700. For pregnant women, the hospital reimburses the private agency for the first USG, but the patient has to pay for the second and third ultrasound.

The agency sample collection is 32-35 per day. In-house, twice the amount is done. In house tests include Hb: 21%, CBC: 13.5% , Blood Sugar and urea: 7.2%, Blood Group: 6.19% MP:

18.52%, WIDAL: 3.19% (45% positive), Also available are VDRL, urine tests and stool tests.

Equipment maintenance was a problem here as well, with the auto clave being non-functional.

A similar pattern is seen in the Bhiwandi SDH. There is a computerised X-Ray machine but its films are expensive film and therefore only used for MLC cases. For the rest, the doctor visits the X ray room, sees the image on monitor and reports. There are two ECG machines of which one is functional. For both ECG and X ray the costs are about Rs 50 per test. Though there is no radiologist, an order has been placed for a new CT scan and USG. Radiologist has been a budget request to NHM. In laboratory in house tests, Blood Sugar tests are performed, but testing for MP is not available.

At the PHC visited, about 20% of out-patients and 25% of in-patients have samples taken per day. There are only 4 or 5 in-patients in the 10 beds there. Most of the in-house test samples are done by the RNTCP lab tech since the phlebotomist was missing and the government lab technician post is not filled. The OPD has nearly 30-40 patients per day but the diagnostics average only 3 samples per week- 31 tests in total- mainly CBC. More rarely, blood lipids tests are ordered. TAT is reported by providers as 2 to 3 days- but the agency states that reports are sent out via email the same evening. There are gaps in looking for these reports.

In-house there is blood sugar done as part of NCD screening, and sputum samples are sent for TB, and BSE for malaria.

The clinicians would have liked tests for fever, tests like WIDAL, dengue and RDK for Malaria, but these are not available on either list. Even RDK which is part of the in-house list is not available. Dengue and Hepatitis tests are occasionally available whenever kits become available.

The list of outsourced tests at the PHC includes tests for diabetes, renal function, liver function and lipidemia. But there are absolutely no drugs provided at the PHC level to manage any of these conditions—not even the most basic of anti-hypertensive.

The list of tests performed by the DSA at the PHC level are limited. To overcome this there is a rule that providers at lower level care facilities are at liberty to request tests on the lists of higher facilities, when they require it. However, this information is not common knowledge among PHC / RH doctors and almost none ask for these tests.

The good news is that there is no user fees for diagnostics at the PHC- whether outsourced or in-house. It is also worth noting that this was the only one of over 12 facilities visited where the free diagnostics scheme was announced.

Assessment of Strengths

The most welcome feature of this Free Diagnostic Services Initiative (FDSI) (at this stage of the roll out of the scheme) is the way it has underlined the state's commitment to making access to free diagnostics happen. This initiative has also brought attention to the challenges of the organization of diagnostic services. Whereas considerable services were available earlier, what is new is the attention being given now on a) whether diagnostics are

regularly and reliably available, b) the turn around time, and c) whether it has quality assurance in-built into it.

There are many tests which are becoming available for the first time. The introduction of Histopathology is a clear value addition: in Nashik district hospital nearly 30-40 tests are requested monthly of which about 6 are PAP smears, 13 are for HPE 2, 15 are for HPE 4, and 10 are cancer related. About 16 microbial cultures were ordered the previous month. It is difficult to imagine all this happening without this scheme.

The commitment to free diagnostics is also important. By making costly diagnostics free of charge, the government has underlined a policy direction where financial protection through subsidy for public services becomes part of its mandate and approach.

The Challenges

One of the central questions of assessment is whether the FDSI has improved the quality of care in terms of clinical effectiveness. While it may be interesting to note whether FDSI has led to increased footfalls in the public hospitals and enhanced public hospital credibility, it is trivializing the importance of this scheme, to reduce it to a public relations exercise. Do clinicians feel better equipped to provide appropriate care? Are patients who access public healthcare now having better outcomes? Is there a reduction in use of unnecessary antibiotics? Are patients having to wait for lesser time and face lesser inconvenience in getting tests done? Is there a decrease in out of pocket expenditure for the patient? Is there a reduction in costs of care to the system? Are we getting more value for money? These are some of the key questions that we need to address.

This study has not undertaken to measure clinical outcomes or technical efficiency. This study focusses on processes and outputs, that would be indicative of our progress towards increasing access, outcomes and efficiency.

There are two challenges in ensuring better clinical outcomes. First, there must be a match between the tests required, the tests requisitioned, and the tests available. The second is the match between the availability of diagnostics, the availability of drugs, standard protocols, and the willingness and skills of doctors to provide a better range of services and quality of care. A lot of earlier cases being referred up to a higher level for want of diagnostics, must now be resolved there. But this requires not only the supporting systems, but the primary care provider's readiness to do so.

For example in the PHC visited, the most frequently requested test is the CBC- which has limited value in decision making. Fever is a common complaint and tests for WIDAL and dengue and malaria would make a difference. These are not part of the outsourcing list of diagnostics and even among in-house tests, only malaria tests are available, and that too with interruptions. WIDAL, which is absolutely essential for managing fever, is not available—and not part of the outsourcing plan at all. There is a wide range of drugs available for infectious disease but we see very few samples sent for urine or stool tests and no blood/serum tests available for infectious diseases.

On the other hand blood biochemistry tests are available at the PHC. This includes tests for renal function, diabetes, liver function and lipid profile. These are infrequently prescribed. Perhaps this is because PHCs do not undertake to treat them at this level. There is a major NCD screening programme that detects hypertension and diabetes—but then the patients are

referred up—with no feedback whatsoever and no intention to treat. There are no drugs for hypertension, diabetes or lipid lowering agents available in the PHCs visited. The testing thus becomes more an obligation to keep the contract going than the fulfilment of a healthcare need. Considerable orders for tests like blood uric acid, calcium, electrolytes from different PHCs strengthens the perception that the pattern of ordering tests may have little to do with healthcare needs.

At the district hospital one physician tells us that he had admitted a patient with hepatic encephalopathy. All the blood biochemistry that is required to manage the patient on a day to day basis were not available. These were part of in-house services and due to the auto-analyser break-down the tests were not being done. Moreover even when these tests are available, these have to be paid for on an out-of-pocket basis and though unit costs are low, since they have to be done repeatedly, the payments may be significant. A few outsourced tests with less relevance were also ordered but even these come too late to be of help. Again there are many tests on the district list, for which treatment is not currently offered in this DH. And there are other healthcare needs where diagnostics are needed, but the tests are not on the list. Thus a hiatus develops between the drive to keep the scheme going and the need for diagnostics to improve quality of care. Adding to this is another barrier in the form of a lack of confidence in reliability and timeliness of test reports. This is particularly so for micro-biology but spills over the all tests. 'At the end of the day', the physician tells us, 'I am still relying almost exclusively on my clinical judgement'.

The second big weakness is the failure to conceive of in-house diagnostics and outsourced diagnostics as a continuum. This is in part a design failure since the scheme guidelines highlights only the outsourcing part. Thus a curious paradox develops. High-cost, complex elective tests are available for free, whereas much simpler basic tests needed more urgently and with greater frequency are priced and lead to OOPE. There is nothing at all in the national guidelines on strengthening the delivery of in-house tests. There are no quality assurance approaches being attempted, or even being suggested for in-house tests under the FDSI, though the government NQAS does mention it. The bio-equipment maintenance contract which covers equipment used in in-house testing, is not working very well. Outsourcing has brought in technical leadership and management skills for the high-tech tests, but there is no equivalent for the in-house tests, making it difficult to manage. And most importantly, there are human resource gaps that need to be addressed.

Human Resources for in-house laboratory services are a major challenge faced by the District, Rural and primary health center. In Thane district hospital, with more than 1000 patients, there are 4 Lab Technicians, working for 8 hours each. Similarly in the sub-district hospital (Bhiwandi) there are only 2 lab technicians and there is no in-house lab technician in Rural Hospital Thane.

The outsourced diagnostic services agency addresses this problem by concentrating its lab-technicians in its hubs. In the district hub they have 8 lab-techs working with advanced automated equipment that can handle significant volumes. One or two lab techs absent on a given day would not interrupt service provision. In the periphery the DSA have replaced laboratory technicians and assistants with a newly created entity called the phlebotomists. For the most part they are qualified laboratory technicians, trained further in house but their work is limited to drawing and despatching samples. Their monthly remuneration is in the range of Rs 5000 to Rs 8000 – and they have a very high turn-over. Their employment is further sub-

contracted to employment agencies. This is in contrast to the remuneration of Rs 35000 or so that a regular government employed lab technician would start with.

But for whatever reasons even this deployment of phlebotomist is inadequate. Though Nashik DH has three, Thane DH had only a single one for such load, and so also with the SDH visited. In the rural hospital it is a staff nurse who helps by drawing samples since neither lab assistant nor the agency's phlebotomist is in place.

Contract Management:

One of the rationales for outsourcing is that since contracts are explicit on outcomes and quality and payment is output based, it would be better than in-house input financed arrangements. But this requires a good contract management. We summarize below key features of the contract- and the extent to which the outputs were realised. As can be seen some of the gaps are due to poor or inappropriate terms of the contract, others due to monitoring weakness and yet others due to design flaws.

A REVIEW OF THE MoU FOR LABORATORY SERVICES

Expected	Observed	Remarks
Samples from PHC, to be collected only once between 8am and 12pm	Samples collected between 1:30 pm and 2:30 pm	Lack of clarity about final time of sample collection- it is the MOU wording that needs to change.
Samples collected from DH/GH/MH/WH and SDH two times (between 8 am and 1:30 pm, and 4pm and 6:30 pm)	Samples collected only once by runner boy from SDH. Only in case of urgent requests is an on-call request made for presence of phlebotomist and runner boy Even from DH the samples seem to collected only once.	Same as above. The MOU should say at the end of the collection time in the laboratory- which is about 1.30 and 6.30 in the DH
Maximum distance between sample collection centre at PHC and Lab testing the sample to be not more than 45 km	Some samples are sent only to Kharghar in case of special tests. Not all PHCs are so covered.	The MOU needs to specify the laboratories as of three types- L1, L2 and L3 for different tests- and have time and distance criteria for each.
Empanelment/contracting of laboratory other than HLL Lifecare Ltd must be done in exceptional circumstances, with prior permission of State Health Society.	Empanelment of tests at DH level to various other laboratory firms, including Thyrocare for all tissue diagnostics	There is no problem with further outsourcing – but are these open to QA. More important Thyrocare is the QA agency- a clear conflict.
Service provider to follow SOPs for blood collection, transport, storage and tests, approved by State Authority/State Health Society	Use of only icebox, but lack of knowledge about use of icepack for transport of samples. Guidelines are more for transport of samples between floors at a facility.	Lacunae in SOP guidelines for transport—fails to account for the tremendous distances these samples must travel across the state in order to reach the district central lab, or the Kharghar Hub.
TAT for PHC/RH/SDH (<50 beds) starts at 2:00 PM	TAT calculation at HLL labs begins only when the sample reaches the district laboratory.	Discrepancy between TAT claims.

Hard copies of report must be submitted to assigned nodal officer of institution within 24 hours of declaration of test result on web portal	Hard Copies of report take over 2 days to reach institutions. Web portal does not reveal test status, only total number of tests performed	
All critical results to be reported within 3 hours of dispatch of sample using IT facility	No doctor at any level was observed to have viewed reports on their email. No record shown of emails being delivered/received. Some critical tests take longer than 3 hours to reach facility (especially in case of Kharghar)	Restrictive rule (3 hours). Lack of technological proficiency among doctors to view reports on email. Also a lack of change management.
Check of 1% sample per day for quality assurance	1% sample chosen by HLL to be performed by agency chosen by HLL-in this instance Thyrocare. Thyrocare is also one of the laboratories to which HLL outsources tests.	Potential conflict of interest. Lack of understanding of results post cross-check. At most, this practice is used to verify equipment calibration, and not quality of tests.
Minimum Assured Volume of 22000 samples per working day	Several days on which OPD is closed, for example on weekends etc., no samples are collected- but yet payment is made on basis of MAV	A minimum assured volume on a monthly basis would account for the losses incurred on days when no samples are collected
Service provider shall make alternative arrangements for reporting all of the cases at the approved rates in case there is breakdown, which extends for more than 72 hours (3 days) of the sample collection. If the breakdown in the services extends beyond 15 days the contract may be cancelled.	In a PHC, the HLL phlebotomist was absent for 14 days—the position remained unfilled for that period. No HLL samples were collected for that fortnight of absence. In-house lab technician did not take over the case-load	

Design Challenges of the Hub-and-Spoke

The clinical challenge: One of the fundamental challenges of the hub and spoke design is that it fails to appreciate the logic of clinical decision making. In all pathology and microbial reporting it is important for the pathologist and microbiologist to have an adequate clinical information of the patient, to make a meaningful interpretation. Quite often, even this is not enough and a conversation is required. But the current model does not factor this event. If the hub where the reporting is done is within the district such a contact would be easier to establish. But currently samples travel with no clinical notes and with no possibility of establishing a conversation.

Again the transport of live micro-organisms require much more rigorous conditions. Normally the plating has to be done within one or two hours. Would the microbes be viable after 6 hours, let alone the 24 hours that it seems to be taking? Would it be viable after ice-packing even for a couple of hours? Initial consultations with experts tell us that it is unlikely.

These insights must caution us against a premature celebration that finally pathology and microbiology services have become available. The big problem that the hub and spoke hopes

to solve is that of lack of trained microbiologists and pathologists at the district level. But if problems of transport and the requirement of clinical decision making compromise the quality of reporting we would be back to square one. Perhaps further innovation would help-but it would then add to the costs.

The economics challenge: If one challenge is from a fundamental question of clinical science, the other is a fundamental question of economics. If the basis of the tender is a per sample quote, then cost efficiency and therefore profitability is a function of increasing turn over with the most optimal mix of tests per 100 samples as required for lowering the costs of production of the services. The requirements of profitability will therefore seldom match the requirements of clinical care. We see evidence of this in the pattern of tests ordered. Why would a few PHCs order over 250 serum calcium and serum uric acid tests in month, when most order less than 10 in a month? Many of the tests ordered in high numbers have no corresponding care in the PHC level. These need to be studied further. Further it emerges that a significant portion of the expenditure is going into high value diagnostics of limited use, whereas more essential diagnostics continue to have limited access. On the positive side, the payment per sample imposes a strong drive to ensure that more services are made available. If we have to make it free of profitability, and even independent of the number of samples tested, then would we be able to drive greater provisioning of services?

The agency representatives are full of conflict of interest narratives where public providers are seen to be finding fault with the outsourcing system since it is interfering with commission/kick back linked local informal (or sometimes formal) outsourcing arrangements. Often the government doctor has a private practice—and in such a context the conflict is even more visible. The government doctors are on the other hand quite critical of the outsourcing arrangement, not only due to service gaps described earlier, but also because of alleged practices like making multiple samples out of one test and so forth. An analysis of tests ordered across PHCs and RH of Nashik shows confusing trends, that has no obvious epidemiological explanation.

Once incentives are introduced into the system they always have unpredictable consequences. That by itself is no reason against such an effort.

Curiously the anticipated problem of irrational and excessive use of diagnostics is not being seen. The number of tests per sample is low because of the design-but even the proportion of patients who are sampled/tested is low.

The ethical challenge: A third and more fundamental question is of ethics. The terms of the provision of these services has been to de-skill the laboratory assistant and technician into phlebotomists and degrade terms of employment both in terms of wages and job-security of technical staff at every level. This also has adverse consequences for the nature and status of the primary and secondary health care teams.

Design Challenges of the In-House Service:

If the hub-and-spoke has its fundamental challenges, so do the in-house services.

Management Capacity*:* The first and most important of these is the lack of management capacity. The organization of laboratory services is an increasingly specialised area-requiring knowledge of equipment, re-agents, standards of care, clinical judgement and much

more. The structure of the government organization does not readily provide the space to recruit and nurture such capacity. Currently if an equipment goes out of order there is no clarity on whom to turn to – who will know what is to be done. One cannot expect the necessary skills to be available in the district, much less within the hospital. This is one of the big positives that the hub and spoke outsourcing approach brings with it. Even on procurement and quality assurance one needs such accumulation or concentration of management skills.

Lack of Output Based Financing: The second challenge is output basing. There is no one who is measuring and maximising outputs and cost-efficiencies. There is no laboratory management information system that can review the performance of different laboratories in the district. Again this is a function of management capacity- but more related to more efficient organization of services and HR management. Thus, an auto-analyser installed in a PHC is not only more difficult to maintain, it will never get adequate samples for a load. It should be doing some samples in-house and sending others to the higher centers, and getting digitised reports back in time. Outcome basing as a concept has just not arrived.

Quality Assurances: The third gap is in quality assurance. This is just beginning to happen under the National Quality Assurance Scheme- but hitherto it has not been a concern. In the districts visited laboratory quality for in-house tests has not yet arrived.

Barriers to Innovation: And the other major gap is innovation. There is no incentive to any innovation in either the delivery of services or the choice of technologies. It is not only the mind-sets, but the cumbersome rules of the government that come in the way. Imagine the problems of getting someone to play the role of the runner.

Learnings and Recommendations

Outsourcing and hub-and-spoke models solve certain problems but create others. As the study shows it may increase expenditure and even volume of diagnostics, but not necessarily health outcomes. Much of the expenditure on the outsourced DSA goes to very few tests of very limited impact on outcomes. Further while much of the discussion is on ownership it does appear that it is not ownership but the organization and management of services that holds the key. Both private and public players face similar barriers and need similar strategies to overcome.

We make the following recommendations. These are tentative and need further discussion. They draw upon a fund of good practices and learnings from other states as well as from the learnings of this study.

1. Revise in parallel the essential diagnostics list, the essential drugs list and the standard treatment protocol for PHCs and for RH/SDH. For this purpose the standard treatment guidelines need not be elaborate. Just enough to inform both the essential drugs and diagnostics list. The last such list made for Maharashtra by the state department of public health would be adequate.
2. Create a separate essential diagnostics list for super-speciality hospitals and tertiary care centers. The DH list should be limited to care provided at the DH.
3. Improve implementation of the MoU with the DSA on the following areas:
    a. The number of days of absence of the phlebotomist across the district must be reported. However sample collection should not be interrupted. The local lab tech or nurse to fill in for phlebotomist whenever the latter is absent. State

may take a liberal view on how DSA would compensate for such absence and use of government staff.

b. Issue guidelines to the doctors and nurses on when different diagnostics are relevant and when they are not. Certain tests like serum uric acid must have sufficient justification to be ordered.
c. Introduce some change management and hand-holding measures to enable clinical providers to access patient reports on the same evening where relevant, and to make use of these reports in an optimal manner.
d. TAT must be calculated from collection time to reporting time and not just lab processing time. At all times the collection to lab time, and from receiving in lab to reporting time must be noted separately for each sample and be available for review. Based on the above, plan for establishing more L3 labs where needed.
e. The DSA should clarify which tests are being done in L1, which in L2 and which in L3 labs, which are outsourced to empanelled labs and to whom. If there is any change it should be notified.
f. The quality assurance reference laboratory should be recruited by transparent process by the state government and not by HLL and should not have any sub-contract from HLL.

4. Improve design of MoU on the following aspects:
    a. Create a revised SOP for pathological and microbiological tests with professional help and introduce it into the MoU. This may alter costs. The current SOPs may be grossly inadequate for reliable reporting.
    b. Create revised SOPs for specimen transport, taking qualified help and using evidence, and then build this into MoU.
    c. Minimum Assured Number of Samples should be on a monthly threshold- and not a daily threshold. This would make unnecessary payments for Sundays and closed working days redundant.
5. Improve In-House Provision of Diagnostics on the following aspects:
    a. Create a management team at the state level. This team at state level would need a qualified pathologist, microbiologist, radiologist, biochemist and a number of senior bio-medical engineers. At least some of them would be full time.
    b. Create a district diagnostics management team (DDMT) at the district level chaired by a specialist (biochemist, pathologist, microbiologist or radiologist) and preferably coordinated by a bio-medical engineer. The team should include all the regular and contractual laboratory and radiology staff providing diagnostic services. They could have the DDMT chair as reporting authority (at least in part)- who would also be responsible for monthly salary release and for annual performance review.
    c. Build up a strong Laboratory Management Information System that can report on the outputs of each laboratory- PHC, RH/SDH, DH- by each test for each month. This will help the DDMT constantly review and improve performance of the individual laboratories.
    d. Ensure all in-house laboratories are quality certified under the NQAS within the next two years and the DDMT is in charge of driving this forward.
6. In the long term, consider the MOU contract with the HLL as a change management strategy rather than a permanent approach. Eventually it may have to revert to government management. The rationale for such an anticipation is primarily on the economic viability and sustainability of the outsourced model. Presently it seems that

the entire district diagnostics is being subsidised by the ordering of a limited number of high value super-speciality diagnostic tests. Further this phlebotomist approach is known to work well in the private sector, but is unlikely to sustain within government. The demand for minimum wages and better terms of employment are likely to follow. Desirability of this is also a question. There are many other examples of gaming the system and reducing costs which are also not going to sustain. However there has been positive change due to this MoU with HLL, and one can argue that in Maharashtra's context without such an arrangement, this expanded range of free diagnostics would not have arrived. But what could be the alternative. Learning from other examples- one could consider the following.

a. A sub-set of RH/SDHs have their laboratory developed as an L3 laboratory. These would receive some samples from the PHC (be the hub for the PHC) and do some tests in-house and also send some samples to the L2 laboratory (be the spoke for the L2 laboratory). The Lab techs at the PHC would do most tests themselves—but where an auto-analyzer is needed, instead of managing this in-house they would send the sample to the L3 laboratory.
b. All district hospitals and a sub-set of SDH in very large districts would develop a L2 laboratory in-house. It would be the hub for some of the tests from the PHC and RH and SDHs coming directly to them because they cannot be done at the L3 labs. It would do many tests in-house, but it would also send out samples to L1 laboratory where it cannot do the tests.
c. There would be a L1 laboratory in every cluster of districts, but which could also be the L2 lab for that home district.

In such an arrangement, the lab tech is not de-skilled. If the lab-tech of a PHC is absent, with the help of the other nurses and doctors the PHC can still send its samples. The only problem would be a longer TAT time. Similarly if an L3 lab becomes non-functional, the PHCs in that area, and that facility itself, can re-align its hub and spoke relationship to the next nearest functional L3 or L2 laboratory.

Financing for these laboratories, including HR costs could be routed through the DDMT—and one can consider blended payments and incentives to contractual as well as regular staff.

If such a vision is accepted, the contract with HLL need not be cancelled. It can be re-worked as a change management contract that should deliver such an outcome. Being a public sector agency, that should be acceptable to all parties.

APPENDIX I

OUTSOURCED DIAGNOSTIC TESTS FOR THE PHC LEVEL

Hematology and Clinical Pathology	
1	Platelet count
2	Complete Blood Count
3	Prothrombin Time Test and INR
Biochemistry	
4	Blood Urea
5	Serum Creatinine
6	Serum Bilirubin (T)
7	Serum Bilirubin (D)
8	SGOT
9	SGPT
10	Serum Alkaline Phosphatase
11	Serum Total Protein
12	Serum Albumin
13	Total Cholesterol
14	Serum Triglycerides
15	Serum VLDL
16	Serum HDL
17	Serum Amylase
18	Serum Calcium
19	Serum Sodium
20	Serum LDH
21	Serum Uric Acid
22	Serum Potassium
23	Urine Routine
24	Urine Microscopy
25	Stool for Routine Microscopy & Ova & Cyst

APPENDIX II
OUTSOURCED DIAGNOSTICS OF THE CHC LEVEL
(IN MAHARASHTRA- RH & SDH <50 BEDS)

Hematology	
1	Complete Blood Count
2	Peripheral Blood Smear
3	Total Eosinophil Count
4	Coombs Test (Direct)
5	Coombs Test (Indirect)
6	Malaria Parasite (Slide)
7	Prothrombin Time Test and INR
Biochemistry	
8	Blood Urea
9	Serum Creatinine
10	Serum Bilirubin (T)
11	Serum Bilirubin (D)
12	SGOT
13	SGPT
14	Serum Alkaline Phosphatase
15	Serum Total Protein
16	Serum Albumin
17	Total Cholesterol
18	Serum Triglycerides
19	Serum VLDL
20	Serum HDL
21	Serum Amylase
22	Serum Calcium
23	Serum Sodium
24	Serum LDH
25	Serum Uric Acid
26	Serum Potassium
27	Serum Chloride
Serology	
28	Rh Factor
29	Anti-Streptolysin O (ASLO)
30	HBs Ag
31	Serum CRP
32	TSH, T3, T4

APPENDIX III
OUTSOURCED DIAGNOSTICS OF THE DISTRICT HOSPITAL LEVEL
INCLUDES SDH>50 BEDS, AND TERTIARY HOSPITALS

Biochemistry & Immunoassay	
1	Total Protein
2	Serum Albumin
3	Serum Calcium & Phosphorus
4	Serum LDH
5	Serum Uric Acid
6	HbA1C by HPLC
7	Ionic Calcium
8	CPK T
9	CPK MB
10	Rheumatoid Factor (RA)
11	Anti Streptolysin O (ASLO)
12	Electrophoresis
13	HPLC (variants)
14	PCR
15	IgG, IgM, IgE
Clinical Pathology	
16	Stool for Ova & Cyst
17	Fluid (CSF, Ascitic, plural) cell count and Biochemistry
18	Semen Analysis
Immunoassays	
19	Thyroid- TSH, T3, T4 (Total and Free)
20	Testosterone
21	Progesterone (P4)
22	Hydroprogesterone (17-OPH)
23	Prolactin
24	AMH
25	PSA total and Free
26	FSH
27	Estradiol
28	LH
Serology	
29	Rheumatoid Factor
30	Anti-Streptolysin O (ASLO)
31	HBs Ag rapid Test
32	Serum CRP
Microbiology	
33	Blood Culture
34	Grams' Staining
35	Cultures (anaerobic and aerobic)
36	Sputum for AFB
37	Antibiotic sensitivity tests
38	Cancer & Tumor Marker tests
Pathology	
39	Histopathology
40	Cytology
41	Bone Marrow Aspiration
42	ABG + Electrolyte
43	Serum Lactate
44	CSF Culture
45	Pap Smear
46	TORCH
SPECIAL TESTS	
1	PCR
2	Antibiotic Sensitivity Tests
3	Cancer and Tumor Marker Tests
4	Electrophoresis Tests
5	IgG, IgM, IgE
6	HPLC (variants)

APPENDIX IV

Recommended Turn Around Times for Tests at DH level

Biochemistry & Immunoassay		**TAT**
1	Total Protein	8 hrs
2	Serum Albumin	8 hrs
3	Serum Calcium & Phosphorus	
4	Serum LDH	4 hrs
5	Serum Uric Acid	2 days
6	HbA1C by HPLC	
7	Ionic Calcium	
8	CPK T	
9	CPK MB	
10	Rheumatoid Factor (RA)	2 days
11	Anti Streptolysin O (ASLO)	8 hrs
12	Electrophoresis	7 days
13	HPLC (variants)	
14	PCR	7 days
15	IgG, IgM, IgE	
Clinical Pathology		
16	Stool for Ova & Cyst	2 days
17	Fluid (CSF, Ascitic, plural) cell count and Biochemistry	8 hrs
18	Semen Analysis	2 days
Immunoassays		
19	Thyroid- TSH, T3, T4 (Total and Free)	2 days
20	Testosterone	
21	Progesterone (P4)	
22	Hydroprogesterone (17-OPH)	
23	Prolactin	
24	AMH	
25	PSA total and Free	
26	FSH	
27	Estradiol	
28	LH	
Serology		
29	Rheumatoid Factor	
30	Anti-Streptolysin O (ASLO)	8 hrs
31	HBs Ag rapid Test	1 hr
32	Serum CRP	2 days
Microbiology		
33	Blood Culture	5 days
34	Grams' Staining	
35	Cultures (anaerobic and aerobic)	
36	Sputum for AFB	
37	Antibiotic sensitivity tests	7 days
38	Cancer & Tumor Marker tests	7 days
Pathology		
39	Histopathology	7 days
40	Cytology	7 days
41	Bone Marrow Aspiration	
42	ABG + Electrolyte	
43	Serum Lactate	
44	CSF Culture	
45	Pap Smear	
46	TORCH	

APPENDIX V

IN HOUSE RATES FOR BASIC TESTS IN THE DISTRICT HOSPITAL

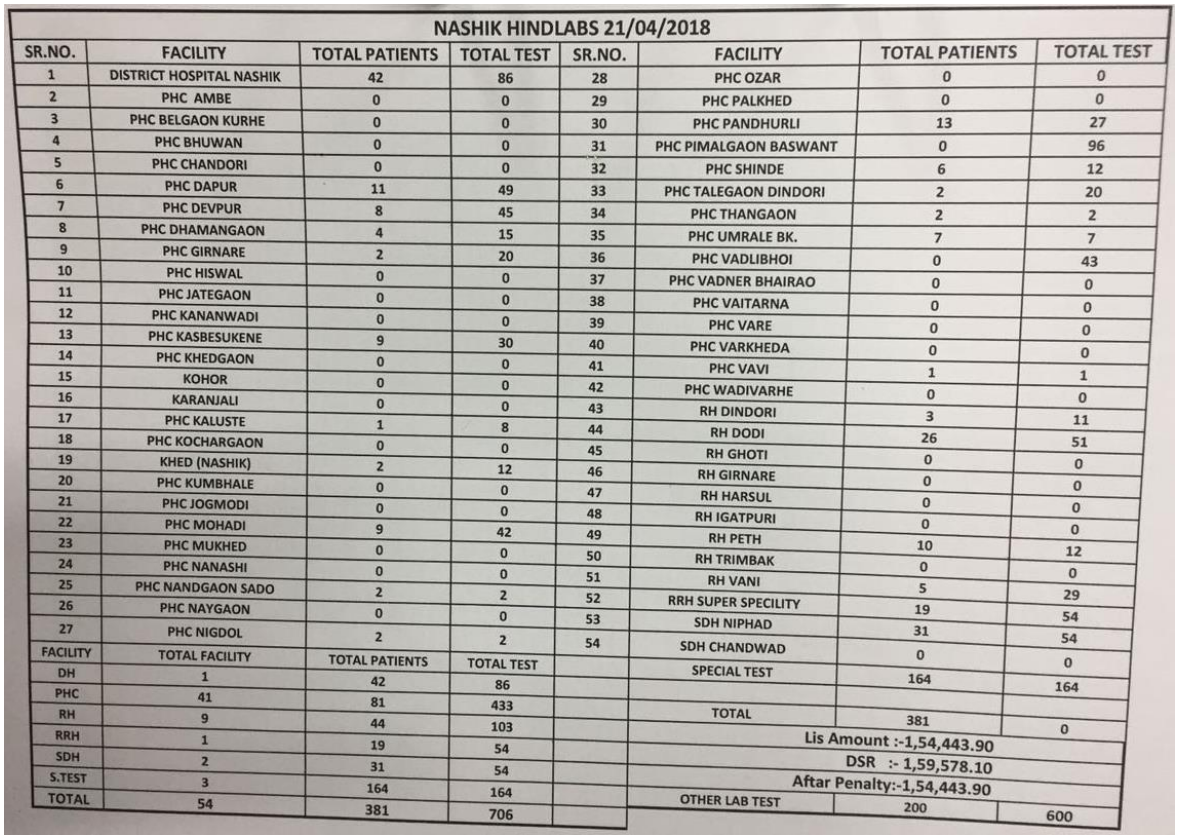
Test	Rate (Rs)
B.T.C.T	30
HB	20
CBC	35
Platelet	35
CBC+ESR	55
Haemogram	50
CBC+PLT	70
Eosinophil	35
MP	30
RFT	80
LFT	90
Blood Sugar F PP	50
Blood Sugar R	30
RA	30
WIDAL	30
ASO	30
VDRL	30
HBsAg	30
PUT	30
Urine (R&M)	75
Urine (ALB, Sugar)	80
STOOL (R+OCCULT)	35
STOOL (OCCULT)	25
Cholesterol	30
Triglycerides	40
HDL	30
SEMEN	100
Dengue Rapid	125
Dengue ELISA	150
Lepto Rapid	125
Lepto Elisa	150
Bilirubin	30
SGOT	30
SGPT	30
Total Protein	30
Stool for Cholera	20
CRP	30
CSF	90
Body Fluids	90
Chikungunya	Free
Malarial Antigen	Free
CBC	60
FNAC	70

APPENDIX VI

DISTRICT CASH FLOW FOR ONE DAY (HLL)

NASHIK HINDLABS 21/04/2018					
FACILITY	**Total Facility**	**Total Patients**	**Total Tests**	**Unit Rate (Rs)**	**Total Price (Rs)**
DH	1	42	86	199	8,358.00
PHC	41	81	433	79.6	6,447.60
RH	9	44	103	139.3	6,129.20
RRH	1	19	54	199	3,781.00
SDH	2	31	54	139.3	4,318.30
Special Tests	3	164	164	796	1,30,544.00
				TOTAL	**Rs 1,59,578.10**

Source: HLL Records



NASHIK HINDLABS 21/04/2018

SR.NO.	FACILITY	TOTAL PATIENTS	TOTAL TEST	SR.NO.	FACILITY	TOTAL PATIENTS	TOTAL TEST
1	DISTRICT HOSPITAL NASHIK	42	86	28	PHC OZAR	0	0
2	PHC AMBE	0	0	29	PHC PALKHED	0	0
3	PHC BELGAON KURHE	0	0	30	PHC PANDHURLI	13	27
4	PHC BHUWAN	0	0	31	PHC PIMALGAON BASWANT	0	96
5	PHC CHANDORI	0	0	32	PHC SHINDE	6	12
6	PHC DAPUR	11	49	33	PHC TALEGAON DINDORI	2	20
7	PHC DEVPUR	8	45	34	PHC THANGAON	2	2
8	PHC DHAMANGAON	4	15	35	PHC UMRALE BK.	7	7
9	PHC GIRNARE	2	20	36	PHC VADLIBHOI	0	43
10	PHC HISWAL	0	0	37	PHC VADNER BHAIRAO	0	0
11	PHC JATEGAON	0	0	38	PHC VAITARNA	0	0
12	PHC KANANWADI	0	0	39	PHC VARE	0	0
13	PHC KASBESUKENE	9	30	40	PHC VARKHEDA	0	0
14	PHC KHEDGAON	0	0	41	PHC VAVI	1	1
15	KOHOR	0	0	42	PHC WADIVARHE	0	0
16	KARANJALI	0	0	43	RH DINDORI	3	11
17	PHC KALUSTE	1	8	44	RH DODI	26	51
18	PHC KOCHARGAON	0	0	45	RH GHOTI	0	0
19	KHED (NASHIK)	2	12	46	RH GIRNARE	0	0
20	PHC KUMBHALE	0	0	47	RH HARSUL	0	0
21	PHC JOGMODI	0	0	48	RH IGATPURI	0	0
22	PHC MOHADI	9	42	49	RH PETH	10	12
23	PHC MUKHED	0	0	50	RH TRIMBAK	0	0
24	PHC NANASHI	0	0	51	RH VANI	5	29
25	PHC NANDGAON SADO	2	2	52	RRH SUPER SPECILITY	19	54
26	PHC NAYGAON	0	0	53	SDH NIPHAD	31	54
27	PHC NIGDOL	2	2	54	SDH CHANDWAD	0	0
FACILITY	TOTAL FACILITY	TOTAL PATIENTS	TOTAL TEST		SPECIAL TEST	164	164
DH	1	42	86				
PHC	41	81	433		TOTAL	381	0
RH	9	44	103		Lis Amount :-1,54,443.90		
RRH	1	19	54		DSR :- 1,59,578.10		
SDH	2	31	54		Aftar Penalty:-1,54,443.90		
S.TEST	3	164	164		OTHER LAB TEST	200	600
TOTAL	54	381	706				