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EDITOR'S NOTE

Diagnosis, the first step of healing

The Indian Express launched *Express Pharma* in December 1994, about 25 years ago. This was followed by *Express Healthcare* in January 2000. And in 2019, we bring to you, *Express Diagnostics*. A monthly publication covering the full gamut of the diagnostics sector. News and news makers, policies and practice, established players as well as start ups.

Why diagnostics? 'If we can make the correct diagnosis, the healing can begin. If we can't, both our personal health and our economy are doomed.' This quote from Andrew Weil sums up the crucial role of diagnostics services in our health as well as our nation's future.

India's diagnostic market is expected to grow at a CAGR of 20.4 per cent over the decade 2012-22. According to estimates put out by the Ministry of Commerce and Industry on the India Brand Equity Foundation (IBEF) website, the growth is estimated to be from $12 billion in 2015 to $32 billion in 2022 from a modest $5 billion in 2012. The market is split between imaging and pathology based services, with 30 per cent and 70 per cent share respectively.

The logic is that as India ages and incomes rise, citizens will increase their health spends. Lifestyle-related conditions like obesity and diabetes require frequent and regular tracking of health parameters over the patient's life time. These go much beyond the annual health check ups. In an era of evidence-driven medicine, doctors now increasingly rely on diagnostics to validate and even guide their treatment protocols.

Government funding too has fuelled the growth of the diagnostics market. Schemes under the National Health Mission provide funding to states to provide free diagnostic services. The initiative got funding of Rs 759 crores for 29 states/UTs in 2017-18. Pegged as the world's largest government funded healthcare scheme, *Ayushman Bharat*, launched on September 23, 2018 will also drive growth in diagnostics.

But the government could do a lot more. For instance, newborn screening is not yet mandatory in India. Early detection of common metabolic and genetic disorders will lead to early treatment. This could drastically reduce the disease burden related to more than 50 diseases conditions like congenital hypothyroidism, sickle cell disease, phenylketonuria, fatty acid metabolism disorder etc.

Unfortunately, these alluring growth figures are a double edged sword. Aggressive CAGRs combined with lax monitoring have attracted the wrong kind of entrepreneurs. This edition's cover story analyses one aspect of the dark underbelly of India's diagnostics sector. Unlicensed pathology labs, with fake pathologists churning out fake reports could have tragic consequences for patients.

Misdiagnosis and wrong treatment due to fake reports are an additional burden on patients as well as the country. And in the long term, these bad apples will ruin the reputation of licensed path labs

Misdiagnosis and wrong treatment due to fake reports are an additional burden on patients as well as the country. And in the long term, these bad apples will ruin the reputation of licensed path labs. Do see the cover story for more details (***Illegal path labs: India's open secret***)

Less than five per cent of laboratories in India are authorised by the National Accreditation Board for Testing & Calibration Laboratories (NABL). Even larger chains do not have all their labs NABL certified but at least they have some internal processes in place to bench mark all their labs. The bottleneck is that we lack sufficient trained pathologists to man the expanding chains of diagnostics labs.

While the government is cracking down on unethical practices and illegal labs, the arm of the law will always lag the criminal mind. Health authorities have formulated and enacted laws like the Clinical Establishment (Registration and Regulation) Act of 2010 which govern such path labs. Unfortunately, implementation and enforcement at the state level is weak.

Expectations from patients too are growing and doctor distrust could soon spill over into this segment as well. As most of the diagnostics market consists of service providers in the unorganised space, there is wide variation in the price of tests. Credibility and reproducibility of test results too are a major problem. Accreditation of diagnostics labs is one answer but adds to the costs of the tests.

Lastly, as Martin H. Fischer cautions, diagnosis is not the end, but the beginning of practice. The diagnostics sector will need to drive and partner the next steps in the healthcare delivery chain.

For instance, personalised medicine in cancer hinges on cutting-edge diagnostics. At the other end, public health challenges like population-wide screening for communicable diseases like TB could be tackled with low cost screening tests.

Next-gen diagnostics will see participants as diverse as tech giants with wearables. Wristbands which monitor multiple health parameters, from pulse to blood glucose monitors, are no longer science fiction.

Be it incorporating the digital dimension or becoming miniature as point-of-care test kits, *Express Diagnostics* will reflect this evolution. Come, join us on this odyssey of discovery!

VIVEKA ROYCHOWDHURY *Editor*
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Transasia Bio-Medicals to setup manufacturing facility in Sikkim

Spread over two acres, the facility will produce 6000+ instruments monthly

Transasia Bio-Medicals, an Indian in-vitro diagnostics company, announced a Rs 50-crore investment in the expansion of its manufacturing facility in Sikkim. The largest of its India manufacturing plants, Sikkim is the fourth one after Mumbai, Daman and Baddi. Also, the first ever diagnostics manufacturing facility in North-east, the expanded facility will significantly enhance Transasia's capacity to cater to the growing Indian and overseas market demands. Spread over two acres, the state-of-the-art facility can produce 6000+ instruments monthly including the complete range of semi-automated analysers.

Announcing the new facility, Suresh Vazirani, Chairman and Managing Director, Transasia Bio-Medicals said, "Sikkim is fast becoming a major hub for healthcare manufacturing with 14 major players already there. Transasia's new facility will further reinforce this besides providing employment to local youth who otherwise would need to move out of the state for such quality opportunities. With this addition of capacity, we are well placed to deliver to the demand arising from continued growth posted by the company both in Indian and overseas markets."

Limited access to quality medical infrastructure, including skilled manpower and technologies have been the pain points of over 70 per cent of Indians who live in smaller towns and rural areas. Transasia addresses this through its competitive pricing, which makes diagnostics affordable besides having a sales and service network present nationwide.

EDx News Bureau

Malaria diagnostics market size worth $900 m by 2026

The market in Europe and Asia Pacific is anticipated to experience exponentially elevated demand as these areas have elevated malaria incidence

The global malaria diagnostics market is estimated to grow at a CAGR above 5.9 per cent over the forecast time frame 2019 to 2026 and reach the market value around $ 900 million by 2026.

An increased incidence of tropical illness in endemic nations, new diagnostic methods are developed and increased investments are anticipated to boost market growth by regional governments and private sector investors. Malaria is one of life's most common threateners, often caused by altering climate, low economic growth, poor health infrastructure and an absence of access for sophisticated therapy in tropical and subtropical areas.

There are also anticipations to fuel market growth in the near future, with an increasing amount of governments' projects and market participants investing. Major businesses are conducting numerous malarial elimination programmes to decrease the incidence of the disease. For example, the Malaria Initiative of Novartis was directed at enabling the elimination and control of malaria. In cooperation with different institutions, 750 million individuals in 60 nations have been supplied with non-profit therapy. This means the development of new technology and market penetration support are expected to be facilitated. The WHO reports that in 2012 there were approximately 203 million global reports of malaria. Malaria caused around 627,000 fatalities worldwide the same year. To curb the spread of malaria governments in developing and undeveloped countries in particular, there is no stone left unturned. This encourages advanced malaria diagnosis. There are also incentives for individuals residing in distant areas to provide them at a pocket-friendly or nominal price.

The market in Europe and Asia Pacific is anticipated to experience exponentially elevated demand as these areas have elevated malaria incidence. Moreover, the government's efforts to increase awareness of the illnesses, their therapy and prevention should provide a important boost to the industry in malaria diagnosis. In Asia Pacific and in the rest of the world, this situation is most common across emerging nations. For example, the Government of India has invested heavily in awareness-raising of malaria prevention and cure. The nation also has increasing spending on healthcare. This market is confronted with difficulties in accelerating diagnostic test adoption and use of malaria diagnosis.

(Source: Globe Newswire)

WHO updates global diagnostic tests to address health challenges

This year's list has expanded to include more non-communicable and communicable diseases

The first List of Essential Diagnostics was published in 2018, concentrating on a limited number of priority diseases – HIV, malaria, tuberculosis, and hepatitis. This year's list has expanded to include more non-communicable and communicable diseases.

Given how critical it is to secure an early cancer diagnosis (70 per cent of cancer deaths occur in low- and middle-income countries largely because most patients are diagnosed too late), WHO added 12 tests to the diagnostics list to detect a wide range of solid tumours such as colorectal,

liver, cervical, prostate, breast and germ cell cancers, as well as leukaemia and lymphomas. To support appropriate cancer diagnosis, a new section covering anatomical pathology testing was added; this service must be made available in specialised laboratories.

The list focusses on additional infectious diseases prevalent in low- and middle-income countries such as cholera, and neglected diseases like leishmaniasis, schistosomiasis, dengue and Zika. In addition, a new section for influenza testing was added for community health settings where no laboratories are available.

The list was also expanded to include additional general tests which address a range of different diseases and conditions, such as iron tests (for anaemia) and tests to diagnose thyroid malfunction and sickle cell (an inherited form of anaemia very widely present in Sub-Saharan Africa).

Another notable update is a new section specific to tests intended for screening of blood donations. This is part of a WHO-wide strategy to make blood transfusions safer.

"The List of Essential Diagnostics was introduced in 2018 to guide the supply of tests and improve treatment outcomes. As countries move towards universal health coverage and medicines become more available, it will be crucial to have the right diagnostic tools to ensure appropriate treatment," said Mariângela Simão, WHO Assistant Director-General for Medicines and Health Products.

(Source: WHO)

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- In e-mail communications, avoid large document attachments (above 1MB) as far as possible.
- Articles may be edited for brevity, style, relevance.
- Do specify name, designation, company name, department and e-mail address for feedback, in the article.
- We encourage authors to send a short profile of professional achievements and a recent photograph, preferably in colour, high resolution with a good contrast.

Email your contribution to:
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Editor, *Express Diagnostics*

Aster to enter diagnostics business in India

The company plans to start Aster Labs in Karnataka and Kerala in first phase and then extend to other states by FY21

Aster DM Healthcare announced, it is entering into diagnostic services segment in India and plans to have two operational labs by the second quarter of the current fiscal in the first phase.

The company plans to start Aster Labs in Karnataka and Kerala in the first phase and then extend to other states by FY21, where it already has a presence through its hospitals. The company will also look at strategic acquisitions to expand this business. Aster DM Healthcare said in a statement.

The company's focus is on bringing quality healthcare closer to the people. It has been doing this through its hospitals, clinics, labs and pharmacies in Gulf Cooperation Council (GCC) countries.

Azad Moopen, Founder, Chairman and MD, Aster DM Healthcare said, "We would like to look into these areas also in India which has become a major market for us with 12 operational hospitals. With this in mind, we are now expanding the range of services with Aster Labs to help meet some of the service gaps in the local healthcare market."

"Instead of the traditional 'Just Screening' only model, the company shall also be focussing on 'Preventive Healthcare' extending the service to the homes of its customers through proper logistic arrangements, added Moopen.

PTI

INTERVIEW

Fostering innovation in medical diagnostics

Donning several hats with ease, **Dr Renu Swarup**, Secretary, Department of Biotechnology, Ministry of Science and Technology, Chairperson of BIRAC and a scientist in an exclusive conversation with **Prathiba Raju** spoke about how BIRAC's guidance has created a great impact in improving R&D and indigenous start-up culture in the arena of medical diagnostics. She also speaks about the vibrant start-up ecosystem created and its strong industry academia linkage

Since its inception, how has BIRAC been supporting the biotechnology industry, diagnostics and pharma in particular?
The main purpose with which Biotechnology Industry Research Assistance Council (BIRAC) was set up seven years back was to support the biotechnology industry, as it shows in the name. Our focus was to try and see how we can support the startups and create a strong and vibrant innovation ecosystem. The main areas which we focus on our partnerships with the industry is primarily connecting the academia with the industry. There was a missing link, our first and foremost action was to connect it and make it into a platform. Our second major focus was to build capacities and of course, the third and most important is how do we make our Indian industry globally competitive. Now with BIRAC, the researchers get the support right from incubating their idea, development of the diagnostic tool and learning how to get through the regulatory processes. From paper to product in each stage, BIRAC helps them to bring all the stakeholders of innovation in one platform. So, BIRAC has successfully been able to work through all these and also look at bringing in strategic partnership – both national and international.

DR RENU SWARUP
Secretary, Department of Biotechnology,
Ministry of Science and Technology, Chairperson, BIRAC

Can you elaborate on BIRAC's work in the diagnostic sector?
Nearly 60 per cent of our support is in the biopharma sector and within that also, more than 50 per cent of it goes to medical devices and diagnostics sector. Firstly, the medical diagnostics segment obviously has a shorter gestation period and the complexity of the regulations – not in terms of the actual policies, but in terms of the time it takes, is less. It's not as capital intensive as the vaccine development area. When we look at it from the BIRAC perspective, we promote a lot of inter-disciplinary research and we have been approached by a lot of biomedical engineering groups, engineering groups and IITs. Medical devices is a sector where we have actually seen a lot of engineering students, the competitive groups working with the biologists and taking forward many innovative projects in anti-microbial resistance, cancer and vector-borne disease. BIRAC's assessment in terms of what is required in the market has helped such young engineers. So, we have really been able to support a lot of them. In 2017, the Department of Biotechnology (DBT) got the government's approval to start the biopharma mission. Under this mission, we look at the product development vertical in which medical devices segment plays a significant role. We have supported more than 1000 startups through direct funding and via incubation support. We have nearly 500 other beneficiaries who come in through academic institutes, smaller companies, SMEs, etc. If you look at the products, about 50 per cent of them are in the market and nearly 75 per cent of them are in the area of medical devices and biopharma.

> We have supported more than 1000 startups through direct funding and mostly via incubation support

In medical diagnostics, there is a lot of R&D which needs to be done but we don't concentrate much on it. After BIRAC and lot of push from the IIT students, how has it turned the phase?
DBT's primary goal is to fund the research to academic institutes. We do support a lot of research in medical diagnostic BIRAC came forward to create the fund to be able to help the startups and the industry. So, a lot of academic research is moving out now from the laboratories to the startups and to the industry. Today, a lot of new diagnostic devices are coming out-- be it for infectious diseases or for screening of various cancers. It is not just because of funding , but connecting the academia, industry and the startups as well. Also, incubation centres play an important role. For instance, IKP Knowledge Park, which runs medtech and biotech incubator IKP-EDEN, research park at IIT Kanpur are all focussing on medical device prototyping, validation, and research and development.

They facilitate a lot of translation of the research, help startups to understand what those gaps are and take it forward.

BIRAC also has a number of collaborations with UK-based NESTA, Wellcome Trust to name a few. Can you tell us more on this?
The underlined philosophy of BIRAC is that we carry out all our activities through well-defined and well-identified strategic partnerships that we take on-- be it national or international. Our models of partnership are different but the whole principle behind the partnership is partners that we choose add strength to whatever we are doing within our activities-- be it connecting with larger networks, where our startups can get access to larger market, investors or co-funding partners where they bring in their funds and help us to look at co-funding opportunities. In terms of larger partnerships viz country-to-country, there would be larger network of researchers, startups, mentors who would engage with themselves. Our partnership with Wellcome trust-the DBT-WT Indian Alliances is an excellent initiative to promote capacities in biomedical research. Our largest co-funding partnership is with the Gates Foundation. We have the project management unit which is funded by them and the WellcomeTrust and DBT is the main government partner in that which is responsible for running a large number of Grand Challenges India programme. Apart from it, we have the Grand Challenges Exploration. Recently, we did one on the Idea Challenge, Data Challenge and Reinvent the Toilet programme – the main focus of these programmes was on maternal and child health. Another programme on AMR was a four-country challenge – Brazil, South Africa, Africa and India. Currently, we are also developing a partnership with Grand Challenges Canada.

How is the partnership with Canada different from Brazil, Africa and South Africa?
Grand Challenges Canada is a funding body, which encourages innovative market place. It looks at innovations which come from across the world. DBT has an MoU with them and with this partnership, we are enabling our innovators to compete in Grand Challenge Canada -- a global innovations platform.

OUR FOCUS IS TO CREATE A CONDUCIVE ENVIRONMENT FOR RESEARCH, BRING IN SUITABLE INFRASTRUCTURE FACILITIES SO THE MEDICAL DIAGNOSTICS FIELD COMES OUT WITH INNOVATIVE PRODUCTS

The biotechnology sector is growing exponentially. The target is to reach $100 billion by 2025. Where does India stand in this and how is BIRAC going to accelerate this?
We had put out an action plan in 2016 when the government brought out the Start Up India Action Plan and this number of $100 billion by 2025 was in our 2015 strategy that was announced in December. Our main target is to scale up the number of startups. Thus, we had then said that we will have 2000 startups by 2020. While we directly support 1000, but the ecosystem itself has a large number in it (around 1700-1800), we do say that anything that happens within the biotech sector, somewhere the enabling factor has come from DBT and BIRAC. We have created incubation facilities, mentor groups and more importantly, we have brought investors on the front who can recognise and appreciate the biotech innovations. According to a report, we were somewhere around $45 billion at the bioeconomy as a whole. Going by those numbers, $100 billion seems a doable figure by 2025, and we will have a large number of initiatives that we have proposed — like facilitating new product development, building capacities and more importantly, focussing on building the infrastructure, and a lot is happening for biopharma through the National Biopharma Mission.

Elaborate on the National Biopharma Mission?
The National Biopharma Mission specifically focusses on the development of new vaccines, bio-therapeutics, diagnostics and medical devices to address the rising burden of diseases in the country. They are into new product development, creating the shared infrastructure facilities and building capacities. Each vertical has its own different challenges. The main objective in product vertical is to identify priorities and decide the importance in terms of disease burden and develop indigenous product. Next task is to quickly get the product to the market, easing the regulatory policies and also, ensuring the product made are not just globally competitive, but also cost-effective and affordable for our own national needs is the target of the mission. For example we are looking into the factors in the new vaccine development viz dengue, pneumococcal vaccine, influenza. We are now trying to see how we can facilitate the TB vaccines

How will BIRAC compliment the medical diagnostics in future?
As for medical devices, we are looking at testing facilities, validation and prototyping of any of the medical devices. So, there are a large number of requirements, which come in through the lead assessment and we are supporting them. Our focus is to create a conducive environment for research, bring in suitable infrastructure facilities so the medical diagnostics field comes out with indigenous and innovative products.

How do you see the future of startups in India?
The startup culture is here to stay. Our policies that we are putting in for enabling the startup ecosystem will only grow. It will only compliment and identify what is missing and add value to that by bringing new policies. Our challenge today is looking at the scalability and sustainability of the ecosystem, and we are trying to address that currently.

Each of these components – the Launching Entrepreneurial Driven Affordable Products (LEAP) fund, which provides capital assistance to startups with new and meritorious ideas, innovations and technologies, Accelerating Entrepreneurs or ACE fund which is to foster R&D and innovation in biotechnology domains, including areas such as healthcare, pharma, medical devices, agriculture, sanitation, product commercialisation unit, the bilateral co-operations that we have built for connecting ecosystems -- these are all enablers in that direction. We also need to understand that there are huge challenges in the sustainability of these start ups. The biggest challenge is that a start up has to make sure that whatever idea they are taking forward, there is a market need for that particular idea. Many a times, there is no proper need assessment. BIRAC and government plays an important role in that. When we get into investing in them at their ignition grant stage, we do a thorough diligence to see whether their idea has a market potential. If there is no market potential, they don't get funded. The reasons is that it is a highly-competitive funding process but it's also to ensure that those who get funded have a correct path that they follow. So, they need to be connected with technical and business mentors to take it forward. Even after selecting an idea which has got a market potential, it can still fail because it's all about science. Entrepreneurs' journey is complex and with biotechnology, it becomes more complex. More than 20 per cent of our start-ups have good success stories.

The startup ecosystem will glow and we will continue to strengthen it.

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INTERVIEW

Our growth will focus on both testing capabilities as well as network growth and access

Emphasing on a customer-oriented approach as a key strategy for business growth, **Dr Sanjay Arora**, MD & CEO, Suburban Diagnostics, has set forward with his expansion plans for the company. The company is looking for synergies that will allow complimentary testing capabilities to consolidate. In an exclusive interview with **Raelene Kambli**, he shares his idealogy for a successful business enterprise

What is the current scale of your business in Maharashtra and the neighboring states?
Suburban Diagnostics is a comprehensive diagnostics service provider since 1994 (25 years and counting) with NABL and CAP accredited labs. Our network is spread over 150 customer touch points across Mumbai, Pune, Nagpur and Goa. We service over 4000 patients/ customers a day and perform over 14000 medical tests daily. Our central lab in Mumbai is spread across 8000 sq feet. Suburban Diagnostics offers a comprehensive menu of preventive health check-ups, pathology, radiology and cardiology tests along with several other value-added services.

What has been your success mantra? What were the challenges you faced in this journey?
At Suburban Diagnostics, our three-pronged approach focusses on the best team, utilising best technology and providing best customer experience. While the best team and best technology ensures quality and accuracy, customer centricity ensures a caring experience. This embodies our philosophy of precision and care.
Adding value is something we believe in everything that we do. “A good surgeon is one who knows when not to operate.” Similarly, a good diagnostic service provider must add value by doing what is necessary and avoiding what is not. We don’t just look at the sample, but the patient or customer behind it. “Does it make sense, does it correlate” are questions we ask ourselves with each and every test. “Impacting medical outcome” is the purpose of our existence since we know that 70 per cent of medical decisions depend on diagnostic testing. We do this by “putting a face to every test”, allowing our doctors to become more accessible and bringing in that sense of transparency with our customers.
Like in any service industry, we are people dependent. Delivering a standardised customer experience and quality standards across the network keeps us on our toes. We have a strong QA, operations, training, audit and business process departments that work tirelessly in overcoming these challenges. An engaged workforce is key to delivering a ‘wow’ customer experience. We have to ensure our internal team feels a sense of 'wow' at work, only then will they deliver a ‘wow’ experience to our customers. The HR team continually works on building better employee engagement programmes in ensuring this.

DR SANJAY ARORA
MD & CEO, Suburban Diagnostics

> “Our mission is “To be the most admired diagnostic company in the world”

Dr Arora, how much significance do you give to patient satisfaction as a key strategy for business growth?
The opportunity with our customers was not to make the patient feel like a patient but to make them feel like a customer. When you go to a restaurant it's out of choice but not out of compulsion. In healthcare, patients do not come because they want to; they come because they have to. The opportunity here was that when there is a need, the patient should not come over as they have to, but because they want to. They need to know that they are at the right place which they can trust. Patient's want to feel comfortable and this was the approach we wanted to take across the brand.

Suburban Diagnostics, as a brand, is driven by patient satisfaction. Every customer feedback that the brand receives is also marked to me. I take every feedback personally and I want my team to believe that unless we don't feel how a customer feels, then we have failed in our role of a healthcare provider. Bottom line for me and my entire team is to find a way to add value to someone's life every day.
One of the biggest tasks is how to keep our customers engaged and how we use technology to reach out to our customers. We create user groups of various diseases/ health conditions within our customer base and reach out to them proactively, specifically targeting their individual needs.

Today patients come to us only when they fall ill and if a doctor has recommended some tests but we want to change this habit of the patient so that they can come to us to remain healthy.
At Suburban Diagnostics, we advocate proactive healthcare, inspire people to live healthy and deliver a wow experience with precision and

AT SUBURBAN DIAGNOSTICS, OUR THREE-PRONGED APPROACH FOCUSSES ON THE BEST TEAM, UTILISING BEST TECHNOLOGY AND PROVIDING BEST CUSTOMER EXPERIENCE

care.Our mission is "To be the most admired diagnostic company in the world."

What do you do to ensure patient satisfaction and experience at Suburban?
Healthcare is all about establishing a relationship with the patient. I share my own experiences (of interacting with customers) with our team, which allows them understand the values we stand for and learn from the mistakes I have made. Standardisation plays a critical role in ensuring quality. To ensure experiences are fairly uniform, there must be a strong focus on training. Our training head has been with us for more than 20 years working in different functions of the organization and has a 360 degree view. She ensures that the values the brand stands for are imbibed by the team right from the induction process. One other way of ensuring patient satisfaction is being a good listener. We value our customer's feedback and take action on it. A monthly NPS score is monitored across the organisation and all feedback is taken to analyse the gaps in our processes. A corrective action (CA) and a preventive action (PA) plan is made along with case studies; these are shared across the organisation allowing the team to learn from each other. The best way for us to improve is to listen and work on the feedback our customers share with us. We also have regular audits of our centres and build a customer satisfaction score. Based on this, we have the Josh award which is an intra-organisation, inter-centre competition every quarter based on service delivery parameters.

What will be the way forward for Suburban diagnostics? What are your growth plans for the coming times?
Healthcare is becoming increasingly transactional. At Suburban Diagnostics, we want to remain anchored to delivery medical value and everything else is an outcome of this.

Our growth will focus on both testing capabilities as well as network growth and access. In both areas, technology will play a critical role.
While we remain western India focussed, we are always looking for synergies that will allow complimentary testing capabilities to consolidate.

Our aim is to reduce the healthcare burden in our community, our society, our country by focusing on those disease areas where we as a diagnostic company can collaborate with our clinical partners in unburdening healthcare. We should diagnose more at OPD so that the IPD burden goes down. We should detect early where we can prevent or reverse disease progression.
Healthcare is getting more personalised; molecular diagnostics and genomics will play a big role in how healthcare protocols and practices will be decided. Medicines that work on one individual may not necessarily work for another and if one is able to personalise the diagnostics, the therapeutics and the outcome, it's a win-win for everybody. With the tremendous advancements in technology, what is specialised today will become routine tomorrow. We will continue to invest in these newer technologies allowing us to be more relevant in the future.

Self-sufficiency in terms of sourcing talent plays a crucial role in Suburban's dominance in the segment. Hence, the organisation has setup its own paramedical training institute - Suburban College of Paramedical Education (SCOPE), under the aegis of S M Arora (Chairman, Suburban Diagnostics) who recently received a Ph.D. in paramedical education, at the age of 80. Suburban believes that SCOPE, where currently 300+ paramedical students are enrolled, will play a pivotal role in its further growth focused on penetrating diagnostics deeper, and exploring rural markets of India.

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ILLEGAL PATH LABS

INDIA'S OPEN SECRET

The government needs a comprehensive regulatory framework and a strong intent to fight the mushrooming of fake path labs in the country which often endanger people's lives with sub-standard services and bogus reports

By **PRATHIBA RAJU**

Diagnosis, the first and the most important step of treatment for any patient, can, unfortunately, go wrong many a times, as it happened with 33-year-old Amit Sharma. It could have even cost him his life. His blood report that was misdiagnosed for chronic myelogenous leukaemia (CML) as acute lymphoid leukaemia, but fortunately doctors conducted a re-analysis and Sharma was given appropriate treatment and he recovered soon.

Misdiagnosis is not uncommon, and not everybody is as lucky as Sharma. Many end up becoming victims due to fake lab reports. Delhi Police busted a fake lab run by two brothers one of whom was a courier boy. They had managed to give out 30,000 fake lab reports which included tests of haematology, immunology, BCR-ABL quantitative, hepatitis profile, cytopathology, urine examination and thyroid hormone assay.

As per a Harvard study by Professor Ashish Jha, over 5.2 million medical error cases have been accounted for in India annually. The study also noted that most of these medical errors are triggered due to lack of skills and proper training. Since 70 per cent of the treatment outcome is dependent on the initial diagnosis, these fly-by-night operators are often the first point responsible for misdiagnosis and inappropriate treatment.

Industry experts inform that diagnostics services are the most significant part of the healthcare segment, which has been growing in India over the past couple of years at a rate of 15-20 per cent and is at nearly Rs 40,000 crore as of 2016. Among them, radiology accounted for 20 per cent and pathology accounted for nearly 80 per cent, but this market is dominated by unorganised players.

Need for strict regulation

Seven years ago, spending nearly six months interviewing clinicians and fellow diagnosticians to understand the pain points of the industry, Zoya Brar, Founder CEO, Core Diagnostics said, "Even then, it was clear to me that the chasm between those who were providing reliable results, and everyone else, was extremely wide. Today, not much has changed. Good news, though, is that we are talking about it more transparently. Unfortunately, the sheer number of diagnostic labs outnumber certified pathologists in the country. As a direct result of this skill gap, most laboratories are functioning illegally and their results are often suspicious. Another data point is that less than five per cent of the laboratories are authorised by the National Accreditation Board for Testing & Calibration Laboratories (NABL). Self-regulation works well in the domain of pricing, but when it comes to quality, lack of a mandatory and enforced system has brought us to the point we are at today."

ZOYA BRAR
Founder CEO, Core Diagnostics

> In order to bring uniformity in the healthcare delivery system, the much-needed move to unearth illegal path labs functioning without valid licensing will act as an entry barrier and help the shift from unorganised to organised side. Audits or checks under the act will hopefully ensure that these labs are maintaining standards, procedures and quality, thus maintaining a basic minimum level of quality in labs in India

Mentioning that there are around 1000 NABL-accredited labs in India, which is a very small proportion of the total path labs in India, Nilaya Varma, Partner and Leader, Markets Enablement, KPMG India, said, "Even larger chains do not have all their labs accredited by NABL. Many rely on their internal processes and systems to monitor quality and ensure customers get reliable results. The real menace are the labs which have a poor quality control system and are in no position to give assurance on the reliability of test to their customers. Only having a pathologist associated with a lab will not necessarily provide reliable results."

Shedding light on the challenge of shortage of pathologists in India, Varma said, "We need to review what would constitute 'illegal path labs' and what role should pathologists play for different category of tests that may require a different level of involvement from them. Accordingly, there could be a case to consider different types of licenses for path labs. For example, if a lab is doing only bio-chemistry tests using automated equipment and undertakes proper care to ensure the quality and reliability of tests, it may be issued a license only for these limited tests."

Brig Dr Arvind Lal, CMD, Dr Lal Path Labs, touching upon this issue recently in an interview with Express Healthcare, informed that there are over 1,00,000 pathology labs in India but a majority of them are mere testing shops. Only 1,038 out of 1,00,000 labs are accredited by NABL, with hardly any government-sector lab being accredited. "I am happy to share with you that 32 of our labs are NABL accredited and another four are in the pipeline. You can see that there are very few quality labs in India. Ideally, like in developed countries, all labs should be accredited by the national body. In India, the first step should be to have strict regulation on the running of a lab as enshrined in the Clinical Establishment Act. This specifies clearly who can run a lab and the other basic requirements for running a lab. In most cases in India, labs are run by individuals who are not pathologists.

Voicing the consumer part and setting things into perspective, Professor Bejon Kumar Misra, Founder, Patient Safety and Access Initiative of India Foundation who had moved a Public Interest Litigation (PIL), sought directions to the government to formulate a 'robust policy' in the interest of patients for regulating the functioning and opening of pathological laboratories in the National Capital Territory (NCT) of Delhi and to constitute appropriate authority for regular checking of such laboratories. The PIL also called for strict implementation of the Clinical Establishment (Registration and Regulation) Act of 2010 in Delhi as many illegal pathological laboratories were killing people by providing incorrect test reports.

Clinical Establishment Act 2010 – can't be overlooked

Implementing a few measures in the right direction is the need of the hour. Varma informed that Clinical Establishment Act places more focus on minimum infrastructure and staffing that clinics and labs should have. While this would help in improving the standards of labs, additional efforts would be required to bring focus on the quality of test results. Further, he pointed out that the act has not been

adopted by many states and the implementation needs to be strengthened further.

Reiterating the same, Misra, said, "Encouraging existence of only accredited path labs in the country is important— irrespective of whether it is commercially viable or not. Health is a state subject; states have a responsibility towards protecting the health of the poorest of the poor. We cannot and should not allow mushrooming of path labs managed by unqualified professionals and non-calibrated testing equipment. The state governments need to engage them professionally and encourage them with business in the interest of the poor. It has to be part of the Public Health Delivery System (PHDS) supported by the Government and managed by qualified pathologists. Citizens' health is paramount and we can never compromise on patient safety and quality."

"We do not have a law as of the date on regulating the diagnostic centres and that is why we lack the data. We do not know how many labs are functioning in our country- they could run into millions. The Government of India enacted The Clinical Establishment Act in the year 2010 but none of the states have enforced it because of the strong opposition from the private sector healthcare providers, including medical practitioners. Even organisations like Indian Medical Association (IMA) are against the law because it will regulate the illegal activities and not allow unqualified and unaccredited labs to exist. We must immediately implement the Clinical Establishment Act of 2010. The government has failed to deliver in the interest of patients," Misra added.

Stating that there is a need for the government to create policies to incentivise high quality, Brar said, "While there is a relevance of penalising those who don't follow the law, there is a place for encouraging those who do. Both levers need to be deployed by the government in

NILAYA VARMA
Partner and Leader, Markets Enablement, KPMG India

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PROFESSOR BEJON KUMAR MISRA
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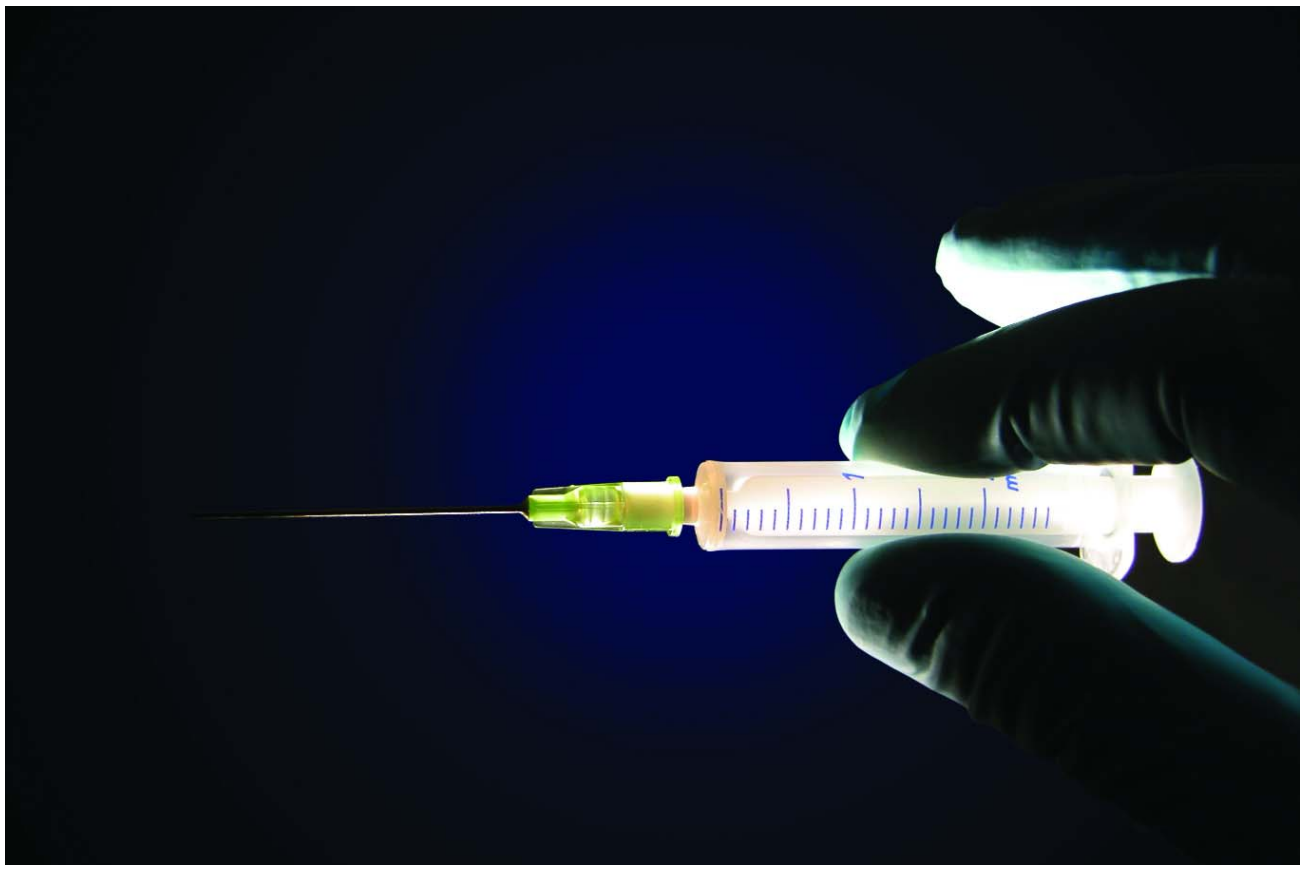
equal measure. Though the government has recently issued a public notice on minimum standards for diagnostics laboratories as well as implemented the Clinical Establishment Act, there is very little being done to create the former lever. And I believe this needs to be changed. The Clinical Establishments Act of 2010 seeks to regulate clinical establishments.

In order to bring uniformity in the healthcare delivery system, the much-needed move to unearth illegal path labs functioning without valid licensing will act as an entry barrier and help the shift from unorganised to organised side. Audits or checks under the act will hopefully ensure that these labs are maintaining standards, procedures and quality, thus maintaining a basic minimum level of quality in labs in India. As far as CORE is concerned, we view ourselves as not only building a company but reshaping an industry. Reshaping an industry is never a sprint— it is a marathon. And in the re-sculpted healthcare industry I envision that diagnostics will be at the centre-stage."

She added that diagnostics makes up for only three per cent of the healthcare expense, it impacts 70 per cent of the cost downstream, and 100 per cent of the outcome. So, setting up a high-end testing facility not only bridges this important lacuna, but also places the apt responsibility and accountability on diagnostics as a segment.

"The improvement of clinical outcome and reduction of downstream cost is simply a corollary. It is bound to happen. Education will have to be an important component of not just our offering, but it must pervade our mindset because the end-goal is to re-build the ecosystem. We believe that the entire ecosystem of healthcare - from the patient to physician to payer to diagnosticians - needs to understand this," Brar emphasised.

According to high-end diagnostics players, the government must help create a regulatory environment that ensures that organisations get incentivised to focus on providing the right quality. There should also be a severe penalty for those that are not following the principles laid down in the Clinical Establishments Act. Finally, those that are in a position to influence the ecosystem, should shoulder the responsibility of creating awareness and education on the need for high quality and the impact of allowing such illegal labs to survive.



Patients first

Reiterating that all pathological laboratories and diagnostic centres must get accredited by NABL, which is under Quality Council of India, all the states must immediately bring a law to assure quality and safety to the patients, Misra said, "As I am on the board of QCI, we are preparing on a war footing to train and qualify professionals to become assessors as we need them in thousands to get the labs accredited. I am also talking to the industry associations to encourage self-assessment and voluntary certification through a third-party assessment to allow patients to differentiate between the safe and quality-driven path labs/diagnostic centres and the fly-by-night operators. There is an urgent need for states to look into this issue as they are responsible to provide safety and quality to the patients."

Asking the government to wake-up to the priorities, Misra said, "I had to take a legal approach as they were refusing to either listen or appreciate our expectations as patients. I had to start from Delhi as I live here and it became easier to manage the hearings and interventions. Delhi is also a reflection of our country. So, why go far, when my neighbourhood itself needs to get the accessibility to safe, quality and affordable healthcare. It is critical and life-threatening to curb all illegal path labs. Unfortunately, we do not have any data— as I said earlier, it might run into thousands in Delhi NCR. A strong law is required to mandate only accredited laboratories, diagnostic centres to exist, with an immediate ban on path labs managed by unqualified pathologists and even diagnostic centres. Till then we must encourage self-assessed labs/ diagnostic centres to be made public based on a self-declaration and open to third-party audits by registered patient organisations or accredited state government assessors. As I have been made to understand, the Delhi Government is taking steps to notify their own rules or law but does not agree to Clinical Establishment Act due to political conflict as health is a state subject. We are yet to hear from the government officially before the Members of the Delhi High Court as they have been directing to explain the reason for the delayed implementation of the law and action against illegal pathologists. As an eye-wash, Delhi government did conduct some raids and closed some of the illegal units but they seem to have come up again due to lack of effective and efficient law enforcement mechanism," he said.

Going forward, Misra informed that a robust registry of all accredited pathological and diagnostic centres should be made public on a portal and accessible 24x7 via toll-free helpline. As patients or as a medical practitioner, one must know about the nearest diagnostic centre with the name, photograph and the degree of the qualified staff as per the requirement of the law for registration.

As voices like Misra's are repeatedly calling for tougher government regulation of medical laboratories and while few high-end players are willing to walk the talk with the government, a joint effort is needed to save consumers like Sharma who are clogged between quality service and hyped prices.

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Thyrocare's Mumbai Lab thrives on automation

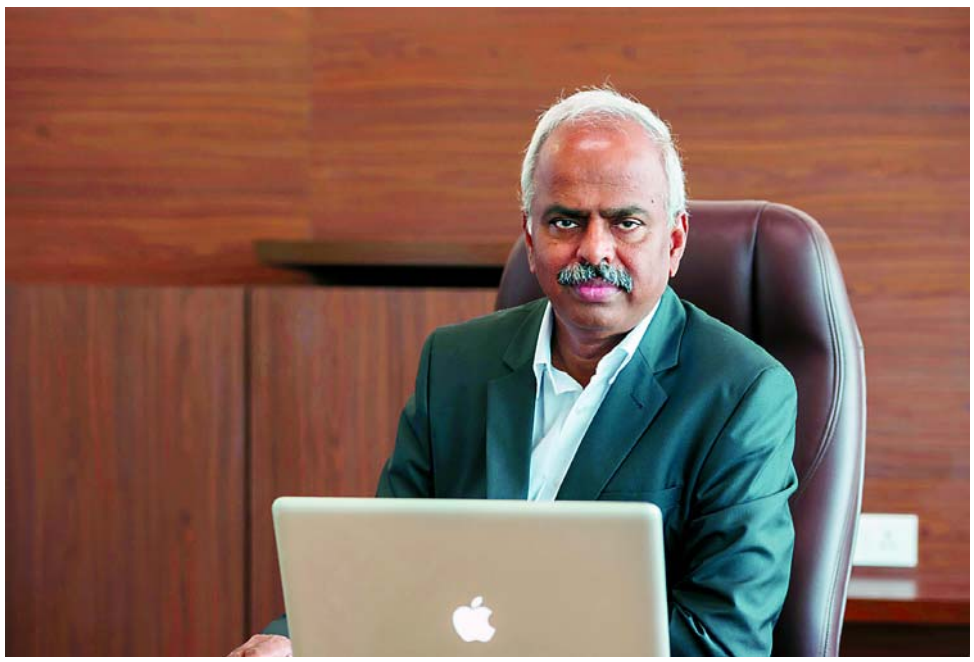
The company's biggest lab has so far striked a right balance between quality and quantity and is a result of smart, systematic and efficient work flows. But will it be able to sustain its efficiencies in the long run?

By Raelene Kambli

How do we evaluate the success of a particular diagnostic lab?

By the number of test samples processed at the lab? Or, by the turnover that the lab generates? Or by quality indicators (preanalytical, analytical, and post-analytical), accreditation? Reduced operation cost? Customer satisfaction or any other parameter?

Most experts say that majority of successful laboratories have two common traits; they are effective and efficient. Successful laboratories accomplish their tasks faster than others, by way of systematic management of sample processing, quality efficiencies, optimal utilisation of resources and ofcourse add immense value to the diagnostics business. Moreover, they strike a right balance between quality and quantity and this indeed, is a result of smart work, continued commitment, and good leadership. Thyrocare Laboratories' diagnostic lab situated in Turbhe, Navi Mumbai is an apt example of the right amalgamation of smart work, high quality efficiencies and systematic workflows that ensures reduced turn-around-time, customer satisfaction, non-conformities and complaints as well as this laboratory contributes maximum to the overall business of the company. It is one of the biggest laboratory that the company has apart from its nine regional and rural market labs. And since Thyrocare works on a high volume business model focussing on centralised collection centre, this lab plays a crucial role in their business function. It is also said to be the first reference laboratory in India which barcoded samples at point of collection in 25,000 points.



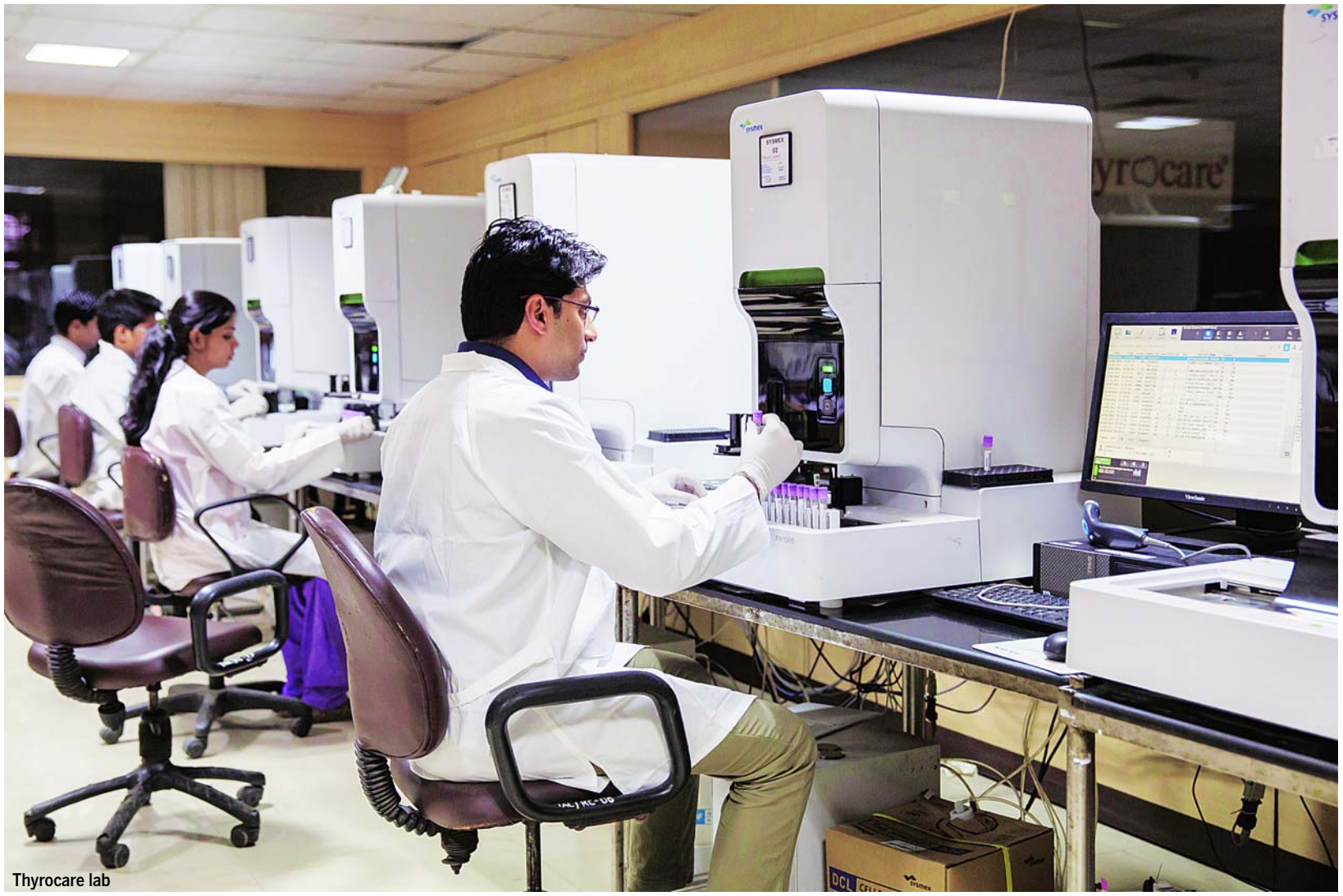
Dr A Velumani, Ceo and Founder, Thyrocare Laboratories

As per Dr A Velumani, Ceo and Founder, Thyrocare Laboratories, the success of this lab and his business truly rests on the core values that his organisation and his team comprises. These values aimed at providing highest customer satisfaction, play a significant role in defining all clinical and non-clinical functions within the organisation and the lab.

The automation advantage

Being one of the first automated lab in the country, this laboratory has a 93 metre-long track (Aptio by Siemens Healthineers) for sample processing that processes around 65,000 samples in a day with 90 per cent of procedures and

Aptio track



Thyrocare lab

99 per cent of automatable being automated. It includes pre-analytical, analytical, post analytical components which supports an IT-driven front end for franchisee operations, quality control, inventory controls, analyser controls and also total testing cycle or turn-around-time (TAT) controls. Moreover, even the vial opening, vial closing, dispatching to right department, to right technology, to right analyser and then validating the results till all results are released and archived – in a right location in right cold room, all is automated.

Thyrocare was one among the first labs to make a bi-directional interfacing, where the server and analyser are communicating both ways seamlessly. That ensures that the franchisee sitting in Madurai or Ludhiana can give instructions to the analysers for their patients needs and once the testing is done and results are released, printouts can be remotely taken. They have a huge IT department that remotely supports this system in order to monitor and enhance the process.

Thereupon, what are the key features of this system that enables around 65,000 blood samples processed in a day? How does the system ensure accuracy and robustness?

According to Dr Velumani, these 65,000 samples correspond to 3,50,000 investigations that are done using 15 different technologies and 100 plus auto-analysers that are needed by 3000 plus franchisees from various part of the countries, which is tested in 8 different locations. "A lot of IT controls are there which makes a sample to reach to the right location, to the right technology and to the right analyser. An investment of Rs 20 crore has been gone into devising the multi-layered control system which allows a man to think very little. An idiot proof system that is purely dictated only by barcodes – ensures that almost nil, data entry errors, pre-analytical errors, analytical and post analytical, results down loading, billing and credit systems," he informs.

THYROCARE WAS ONE AMONG THE FIRST LABS TO MAKE A BI-DIRECTIONAL INTERFACING, WHERE THE SERVER AND ANALYSER ARE COMMUNICATING BOTH WAYS SEAMLESSLY

What about QC/QA?

Quality checks and more

Once you install an automated system in lab, one cannot be complacent. Even an automated system needs quality checks and so Thyrocare has come up with a SOP for the same on a daily basis. The lab processes maximum blood samples only in the night. During the day, the lab undergoes quality checks and maintenance in order to perpetuate efficiency in the process.

The quality checks are done every four hours or at least thrice a day.

According to Thyrocare, the company religiously complies with the NABL and CAP norms. Dr Velumani invests around Rs 6 crores per annum in QC which is 1.5 per cent of their total turnover. Therefore to maintain accuracy and quality of output, they have a system in place. "Accuracy aspect is decided not by Total Laboratory Automation but by individual analyser automations, maintenance and calibrations. Enough measures are there to avoid, intra assay, inter assay, intra analyser, inter analyser consistencies, which are supported by internal quality controls and external QC participation," he says.

Moreover, to maintain quality of the tests done at the lab, Dr Velumani informs that they have an unique barcoding system that ensures error free results. "We understood in 1996 itself after doing first 10,000 samples that 90 per cent of errors are due to — not using a right quality of tube (results in rejections), using glass tubes (results in breakage and loss of specimen) and also un-uniform size that makes transportation costly and cumbersome. So, before rolling out the first franchisee, which has all components, with barcodes grouped for that patient, that are required to do blood collection. Depending on packages asked the colour of tube, barcode, kit guides for an error free sample collection. We were the first reference laboratory in India (may be even today only laboratory) which barcoded the samples at point of collection in 25,000 points in this country," he says proudly.

Apart from all of these, the lab also has an efficient waste management system that automatedly separates hazardous waste and the others, and also collects material which can be sent for recycling process to the Brihanmumbai Municipal Corporation (BMC). According to the lab staff, this system and process of waste management costs them less than a rupee making this system highly efficient, cost effective and advantageous to the extent that it helps them maintain their the social footprint as well.

Now, having SOPs for quality checks, automated barcoding and a good waste management system for error free results is certainly commendable, but what happens when automation fails?

CORE VALUES AND USP

Quality: As the company's business line deals in mid-value tests, quality becomes a significant core value. The company believes that high quality diagnostic testing is the foremost way to earn customer trust. Being cost disruptive is just a technique to attract more customers, but the actual sustainability lies in maintaining the quality of services they provide.

Automation: This becomes a great enabler of efficiency, accuracy and quality. According to the Dr A Velumani, Founder and CEO, Thyrocare laboratories, automation contributes for reliability of systems, reproducibility and accuracy of results, productivity of man power and efficiency of analysers which inturn assures fullest utility of men, machines and materials there by enhancing the profitability after allowing a scalability.

Analyser in multiple: This reduces the risk of process derailment and ensure continuity of sampling process.

Unbaised by any vendors: At this lab, you will find high-end eqipument by multiple vendors. This is done with an intention to assemble advanced equipment that suits the requirement of the lab, without be baised to any one vendor.

Investing in technology: Digital and medical technology becomes crucial to the entire functioning of Thyrocare laboratories. Around 80-85 per cent of all record keeping is done digitally. "Fortunate for us, Internet came into existence in India when we started Thyrocare, and we got into it straight. Also, an end-to-end IT solution was needed and we had an IT department as big as our laboratory department in the first five years of our business," says Dr Velumani. Further, Thyrocare also has a comprehensive data system called Charbi that controls, monitors and executes all the business processes within the organisation. "Charbi– was a website I purchased in 1999, to have a brand for 'Lipid profile' because then there were 20 lipid profiles for each thyroid profile in the market. But I understood without wasting time, that lipid profile is not providing meaningful information to common man and it is likely scare them without a reason. This domain was unused for four years and then I advised our IT to use it for our Intranet. What we started casually in 2003 to day is handling 90 per cent of our business responsibilities. It has modules for accounts, Personnel, HR, Training, CRM, Purchase, Inventory, Franchisee management like that it is fully integrated in-house IT platform that allowed us to retain our philosophy, culture and allowed us seamlessly to plan, control, monitor and execute all our business needs, globally," he notifies.

Training and development: By bringing in automation, the company has not reduced the number of employees, but have upgraded their skills to perform other roles and responsibilities. Although, automation plays a significant role at this lab, manpower is utilised to do quality checks and more. Every month each staff member undergoes training sessions at various levels.

So, let's understand how this laboratory functions based on these core values.

Automation failure and crisis management

Automation failure can cause a derailment in the entire functioning of the lab services, damage customer service and experience and even impact the balance sheet. Thyrocare also deals with such crisis. Dr Velumani informed that they experience automation failure at least twice in a month. While initially, automation failure caused them a loss of around 25 per cent of revenue, they decided to bring in the old system where each clinical human resource has a specific task to follow. It is organised, efficient and well-executed to make up for the time that automation fails. Around 100 staff members are deployed in this process.

While, thyrocare has managed to create an idiot proof system, a diagnostic business model based on a centralised collection system can have some slip-ups and logistics issues. And since, this lab pulls the maximum weight of all the blood samples processed at Thyrocare, how does Dr Velumani manage to organise logistics in an efficient way?

"This is a puzzle piece for the entire industry. People think air cargo is very costly. Of course it is costly. A consignment of 10 kgs costs Rs 5000. We derive pleasure of volumes in logistics also. We made sure using such standardised vials, kits and components in such a way, that 5000 vials can travel in a cool pack that weighs 10 kgs for a cool Rs 2 per sample. We receive our consignment from 25 different major airports in this way. Rs 10,000 per destination is a Rs 8 crore annual budget which is 2 per cent of our total revenues. We also cover 200 kms around each airport where the specimen comes by road or train to the nearest airport," Dr Velumani replies.

While Dr Velumani has managed to maintain and efficiently run his automated lab, it is important to note that this entire automated process demands for a huge investment. "The total automation on floor works out to be approximately Rs 100 crores of investments and 99 per cent of them are imported. Thus, it is a huge investment for a laboratory. Also an MNC charges 10 per cent of the hardware cost as maintenance and hence we incur an annual basis of around 7 or 8 crores of maintenance charges. Again as I said, automation does not give revenues. It is not expected to justify its cost. Without that one cannot just run anything more than 25,000 tests a day. It is a necessity to a large extent but it is also a luxury for the brand to have it on its floor. I am happy that I have one-of-its-kind in India, on my floor and will continue to invest more on them," Dr Velumani expounds on the logic behind the investment in automation.

Going forward

In future, Thyrocare plans to expand its TB unit at this lab. The company will also be investing in pre-natal analyses as it sees huge market opportunities. While Dr Velumani informed that he does not have plans to invest in another automated lab elsewhere in India at present, he will continue to invest in maintaining and adding value to this Mumbai lab. The only concern could be the overload on this central lab. It currently undertakes more than 50 per cent of the overall blood samples processed by Thyrocare. Will this lab continue to successfully endure the volume of work it undertakes? And will it sustain its efficiencies in the long run?

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Soaring high

Metropolis Healthcare took a long time to go down the IPO despite being one of the early initiators of corporate diagnostic chains in India. But, with a proven track record of consistent performance, the success of its IPO is expected to spur the diagnostic major towards greater heights

Sanjiv Das

IPOs are a growing trend, clearly evidenced by the fact that 2018 witnessed 90 IPO launches worth $3.9 billion, according to a report. 2019 too saw a continuation of this trend with 14 IPOs in just the first quarter of the year, according to a report in E&Y.

The diagnostic sector too has got on this bandwagon and several leading players in this segment has opted for this route to further their growth trajectory. A recent entrant was Mumbai-based Metropolis Healthcare. On April 15, 2019, the scrip got listed at Rs 960 on the Bombay Stock Exchange, a 9.09 per cent premium over issue price of Rs 880 per share.

As of April 26, 2019, Metropolis Healthcare had a market capitalisation of Rs 4,746.15 crore *(Source: BSE)* at a closing price of Rs 945.85 per equity share. The IPO valuation was around Rs 4,415 crore (Rs 880 per equity share).

Prior to the IPO, the company posted an attractive financial profile where revenue from operations grew from Rs 4,754.69 million to Rs 6,435.67 million, representing a CAGR of 16.3 per cent; adjusted EBITDA grew from Rs 1,297.96 million to Rs 1,773.83 million, representing a CAGR of 16.9 per cent; profit for the year grew from Rs 819.55 million to Rs 1,097.47 million, representing a CAGR of 15.7 per cent. During the nine months period ended December 31, 2018, the company posted a revenue from operations, adjusted EBITDA and profit for the period were Rs 5,593.06 million, Rs 1,457.38 million and Rs 887.71 million, respectively.

In FY 2019, the company posted consolidated revenue growth of 18.1 per cent, registering an increase in revenue per patient (5.4 per cent) and revenue per test (8.5 per cent). EBIDTA before CSR and one-time share based and other expenses were at Rs 2073 million in FY19. It posted a PAT before CSR and one time share based and other expenses at Rs 1308 million. Earnings per share was reported at Rs 24.06.

Thus, the company made a decent market debut.

Why did the Metropolis IPO succeed?

Well, Metropolis Healthcare, a professionally-managed and promoter-led company, is a leader in this segment with presence across 19 states in India in the Western and Southern region. The company has also developed a highly differentiated and focussed growth strategy of dividing the key target cities in which it operates.

It has also been able to establish itself as the most promising brand and bagging accreditation from College of American Pathologists (CAP) Laboratory Accreditation Program for its Global Reference Laboratory. As of December 31, 2018, 25 of its clinical laboratories hold one of CAP, Kenya Accreditation Service, International Laboratory Accreditation Cooperation, Asia Pacific Laboratory Accreditation Cooperation or National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation. Apart

from this, a majority of the company's clinical laboratory machines used in operations are approved by the US FDA and/or CE.

These factors have built the brand's credibility in the minds of consumers, which in turn has led to investors' trust in the company's growth prospects.

Ameera Shah, Managing Director of Metropolis, explains, "The listing post IPO at a premium is a testimony to our competitive strengths and attractive financial profile. Being one of the leading diagnostics companies in India, we are well positioned to leverage the expected industry growth. We have a widespread operational network, young patient touch point network and asset-light growth of service network. Besides this, we have a strong and established brand known for its quality, good customer service and robust information technology structure."

So, what's next in its growth trajectory?

From here on, Metropolis Healthcare has a clear vision to further its growth. Shah disclosed their vision saying, "Our company expects that listing of the equity shares will enhance our visibility and brand image and provide liquidity to our shareholders."

According to her, the IPO will be instrumental in achieving the key goals of the company in future while charting the right path in this direction. Some of the key focus areas in this direction will be:

- Continuing to focus on organic growth initiatives to expand their reach
- Providing quality tests and services
- Focussing on the expansion of their service networks
- Increasing market share in their individual patients business segment
- Pursuing new avenues of growth
- Focussing on consolidation opportunities in a largely unorganised sector
- However, since the market continues to be volatile, the company also foresees certain risk factors.

Conquering the roadblocks

Many companies pursue IPOs as a means to increase the amount of available financing to the company and possibly generate billions for the owners in the process. But with it comes a lot of risks. Metropolis took certain initiatives to prevent the associated risk factors before going in for the IPO.

Informs Ameera Shah, "The diagnostics market is a highly-competitive and fragmented industry with standalone centres having approximately 47 per cent market share, 37 per cent for hospital-based diagnostic centres and remaining 16 per cent for organised diagnostic players. Low entry barriers, low capital expenditure requirements and minimum regulatory supervision makes it easier for new competitors."

Other risk factors are limitation of trained human resource availability; vulnerability to technological advancements, challenge in entering new geographies, capability to launch new tests, pricing pressures, capability to optimise operational expenditures and lack of a comprehensive and stringent government regulatory framework. Thus, the road to progress is not without its hurdles. So, how would this diagnostic player overcome them?

Ameera Shah,
Managing Director, Metropolis

The next phase of growth

Metropolis is giving a special focus on organic growth initiatives to expand its reach. As mentioned earlier, the company has differentiated and focussed growth strategy of dividing the key target cities. It has identified five 'Focus Cities', for the financial year 2019. These are Mumbai, Bengaluru, Chennai, Surat and Pune.

According to Shah, "We have a significant presence and operational experience in these five focus cities, and derived 58.78 per cent and 62.75 per cent of our revenue from operations from these cities for the nine months ended December 31, 2018 and financial year 2018, respectively. We intend to deepen our penetration by increasing the number of Third Party PSCs, enhancing our laboratory capacity and test menu by adding latest machines and technology, expanding business derived from individual patients, employing focussed sales and marketing teams to generate walk-ins through targeted marketing strategies and use of the customer relationship management (CRM) marketing tool, doctor engagement through medical awareness initiatives and meetings with medical practitioners; and increased focus on home collection service and wellness offerings. We intend to evaluate the list of focus cities on a yearly basis to ensure that our resources are deployed in line with our growth strategy."

Shah mentioned about 'Seeding Cities', which are expected to have strong growth potential. The 'Seeding Cities' are Rajkot, Nashik, Nagpur, Kochi, Raipur, National Capital Region (NCR), Kolkata and Guwahati.

'Seeding Cities' constituted 18.77 per cent and 19.14 per cent of Metropolis' revenue from operations for the nine months ended December 31, 2018 and financial year 2018, respectively. Given the expected increase in demand for diagnostic services in the 'Seeding Cities', the company expects them to be the core focus of medium to long-term growth. The company plans to expand its network in those cities by increasing the number of patient touch points, expanding test offerings and employing targeted marketing strategies to grow its business.

According to Shah, there are plans to convert some of these Seeding Cities into Focus Cities, in a phased manner, after these cities meet internal benchmarks.

Metropolis, also has an eye on key cities, which can have the potential to become 'Seeding Cities' in the medium term. The other 'Key Cities' constituted 22.45 per cent and 18.11 per cent of the company's revenue from operations for the nine months ended December 31, 2018 and financial year 2018.

Shah says, "We intend to use the asset-light model for expanding our service network in other Key Cities, with primary focus on growth of our ARC network to service institutional customers."

Metropolis believes that quality and reliability of tests and services are critical to its success. The company's vision is to help doctors treat their patients better and in order to do so, it has upgraded the technology for better quality, efficiency and reliability; consistent value addition to tests being offered; and has been promoting disease and disorder specific profiles, to allow doctors to receive comprehensive view of the patient's disease status.

Further, the company to provide user friendly services has initiated the value-added services such as house calls, e-services, longer operating hours for patient touch points and call centres, and home delivery of test reports. With an intention to improve value-added services in order to

METROPOLIS FACTSHEET

- The laboratory network grew to 119 from 106 in FY 2018
- Service network comprises 1,631 patient touch points (out of which 28 are located outside India) in Kenya, Ghana, Sri Lanka, Mauritius, Uganda and Tanzania
- Entered into agreements with third parties for collection and processing of specimens in Nepal, Nigeria, the UAE and Oman
- Outside India, has laboratory operations in Ghana, Kenya, Zambia, Mauritius and Sri Lanka
- There are agreements with third parties for collection and processing of specimens in Nepal, Nigeria, the UAE and Oman
- As of December 31, 2018, the company has an operational network of 10 clinical laboratories, 26 patient touch points and seven ARCs, outside India.
- As of December 31, 2018, the laboratory network consisted of four RRLs, located in Kenya, Zambia, Ghana and Sri Lanka; one satellite laboratory in Ghana; and five express laboratories, out of which four are located in Kenya and one is located in Sri Lanka

make them more attractive for existing as well as prospective customers the company is actively involved in campaigns focussed on creating awareness of particular conditions such as cancer, lifestyle diseases, monsoon diseases, and the importance of periodic testing.

Paths to progress

Thus, there are plans galore for further progress but what are the strategies that Metropolis intends to adopt to leverage the opportunities for growth? Let us examine.

Third party PSCs: Metropolis is utilising the third party patient service centre (PSC) model for expanding the geographical reach of its service network, due to its high scalability and limited capital expenditure involved. The third party PSCs include associate patient service centres (APSCs) and standalone independent laboratories converted into Metropolis-branded patient service centres (D-APSCs).

In recent years, the company has successfully used the Third Party PSC model to grow business and the total number of APSCs and D-APSCs have grown from 41 as of March 31, 2016 to 408 as of December 31, 2018. These models enable the company to see a growth in revenue by providing management and branding to Third Party PSCs, while benefiting from the extension of its network and brand presence in key geographies.

Shah says, "We also intend to grow our owned PSCs in 'Focus' and 'Seeding Cities.' We expect that a wider geographic reach will expand our customer base as well as improve our profitability by allowing us to better leverage our infrastructure. We will also continue to seek strategic partnerships with key third-party patient service centres in India, Africa and the Middle East to expand our geographic reach."

She further mentions, "Across our Focus Cities, we derived 47.8 per cent of our revenue from operations from individual patients in the financial year 2018 as compared to 41.9 per cent of our revenue from operations in the financial year 2016, representing a CAGR of 20.72 per cent. During the nine months period ended December 31, 2018, we derived 51.34 per cent of our revenue from operations from individual patients."

There are plans to pursue scientific upselling of tests where it will help the company to increase the scope of test menu. Shah mentions, "We are also focussed on growing our portfolio of tests, with special focus on specialised tests which have less competition and higher margins due to advanced technology, skilled manpower and complex processes involved."

High standards of corporate governance: The corporate governance framework is based on an effective independent board, separation of the board's supervisory role from the executive management team and constitution of the board committees, as required under law. The board has been constituted in compliance with the Companies Act and the SEBI Listing Regulations and in accordance with best practices in corporate governance. Currently, the Board has six Directors consisting of three independent directors, two executive directors, including one woman director and one non-executive director.

Partnering with government: While the company has a good foothold in the private healthcare space, it has also partnered with the government to tap the public health sector.

The company also participates in select public-private partnership tenders. The company's contract with National AIDS Control Organization (NACO) has helped it become one of the providers of HIV-1-Viral load tests. There are similar opportunities for PPP tenders in the African markets and the company intends to participate in these tenders on a selective basis.

Investing in research: Metropolis wants to have an increased focus on contract research, laboratory testing for clinical research processes with contract research organisations and pharma manufacturers.

Shah mentions, "Our experience in conducting approximately 473 clinical research assignments, as of December 31, 2018, for contract research organisations and pharma manufacturers is expected to benefit us in obtaining additional clinical research assignments in the future."

Global expansion: As part of the company's expansion plans, Metropolis in the past recent years ventured into the global market. Apart from setting up a laboratory in Mauritius under the LIH model, there are agreements with third parties for collection and processing of specimens in Nepal, Nigeria, the UAE and Oman. As of December 31, 2018, it has a service network of 26 patient touch points and seven ARCs, outside India. The specimens that the company receives from these countries are imported in compliance with the Indian Council of Medical Research guidelines for the import of test specimens.

According to Shah, "We will also continue to seek strategic partnerships with key third-party patient service centres in India, Africa and the Middle East to expand our geographic reach. Our key approach will be profitable growth."

Ensuring value for customers: Metropolis wants to constantly enhance value for their shareholders through differentiated strategies, tried and tested execution and high standards of corporate governance.

According to Shah, B2C part of the business gives operating leverage and B2B business provides profitability. More than 40 per cent of the business coming from specialised tests.

She mentioned, "Our experience in diagnostic and related healthcare testing and services has allowed us to selectively combine diagnostic tests into diverse profiles to assist patients seeking to monitor their health and to prevent or treat diseases and other health conditions. These packages are a combination of a variety of early detection and diagnostic tests to screen selected diseases and disorders with primary focus on life style diseases. Based on age, sex, clinical history, parental history and affordability, there are options of several packages. Besides pathology tests, the packages also include non-pathology tests such as ECG, X-ray, ultra-sound and stress test. The reports issued by us include basic medical advice and are presented in a reader-friendly format."

The way forward

Thus, through differentiated strategies, the company is striving to outperform industry pace of growth, which it has already demonstrated it in first nine months of FY19. Despite investments, the company's average EBITDA was at around 27 per cent.

But, at the same time, the company will have to gear up to face increased competition as the sector continues to grow. Hence, it will be pivotal to stay relevant in the market by striking a balance between profitability and responsibility to outdo the challenges and adopt sustainable approaches to initiate, achieve, and foresee profitable growth for the future. The company needs to think big on expanding its customer base and venture into new regions, to sustain its success in the long run.

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SUCCESS STRATEGIES

- Weighted average for return on net worth for FY16 to FY18 was 27.41 per cent on consolidated basis and 29.11 per cent on standalone basis.
- Had an attractive RoCE given their asset-light model - High ROCE of 64 per cent in FY18. Asset light: ~ 90 per cent of incremental individual patients touchpoints added in last two years were third-party.
- Metropolis' young network and Individual patients transition will be a key driver of its revenue growth and margin expansion.
- 20.7 per cent individual patients revenue CAGR in Focus Cities
- Young network: 75 per cent of the existing Individual patients touch points added during FY2016-18
- Average realisation of Rs 402/test and Rs 835/patient
- Consistent EBITDA margin of ~28 per cent over the last three years
- Higher test volumes is the key contributor to the company's growth
- High proportion of specialised & semi-specialised tests leading to higher revenue per test / patient
- Higher test volume and test mix change through upselling and offering customised packages are the key drivers of growth
- The company has an established track record of successful acquisition and integration, bringing in industry practices, maintaining quality controls and standards, standardised machines and SOPs

INTERVIEW

India needs to include he4 tests as a part of routine check-ups to prevent ovarian cancer mortality

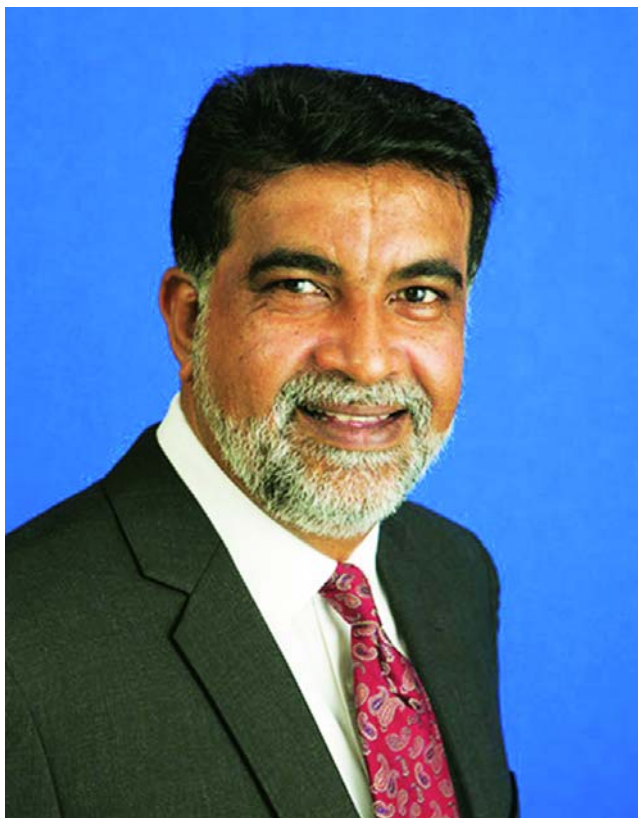
Dr Jaganathan Sickan, Senior Associate Medical Director, Diagnostics, Abbott stresses on the need for early detection of ovarian cancer by making biomarker tests like HE4 tests a part of routine check ups. Excerpts from an email interview with **Viveka Roychowdhury**

What is the threat posed by ovarian cancer in India?
Despite being the third most common form of cancer in women, ovarian cancer is the most malignant as it causes 55 per cent of cancer-related deaths in women. In India, the incidence of ovarian cancer in women ranges between 0.9 to 8.4 per 100,000 and is seen commonly above the age of 35 and more frequently between 55-65 1. Across multiple studies conducted in different regions of India, reproductive factors such as delayed childbirth and declining parity level have been strongly associated with risk of breast and ovarian cancer.[2]

India has the second highest mortality for ovarian cancer in the world.[3] A study analysing data on 865,000 women with ovarian cancer diagnosed in 61 countries showed that India had the lowest calculated survival rate of 15.6 per cent.[4]

Globally, the incidence of ovarian cancer is expected to increase. Global Cancer Observatory, Globocan predicts that by 2035, there will be a worldwide increase of 55 per cent in incidence and an increase in deaths of 67 per cent due to ovarian cancer.[5]

What are the three critical things all women should know about ovarian cancer?



DR JAGANATHAN SICKAN
Senior Associate Medical Director, Diagnostics, Abbott

There are no symptoms for ovarian cancer:[6] Women must get tested regularly to ensure either early detection or ruling out the presence of cancer. 75-80 per cent of ovarian cancers are diagnosed at stage 3 and 4, where the survival rate is only 10 per cent. When the disease is diagnosed and treated before the cancer has spread outside the ovary, the survival rate increases to 93 per cent.[7]

It's more dangerous than breast and cervical cancer: Ovarian cancer kills more than 50 per cent of diagnosed patients, as most of them are diagnosed late.

Shun the shame: Alongside medical interventions, what would help is if women talk about diagnosis and surgery openly. Most women are not comfortable discussing reproductive system changes that surgery entails, and therefore shy away from even doing the critical tests to ascertain risk.

How has detection and screening evolved over the years? How can proactive screening and risk stratification be used to facilitate early detection? Which groups of women should be screened?
The ROMA (Risk of Ovarian Malignancy Algorithm) is an FDA-approved, clinically-validated risk-stratification tool, with differentiated scoring for pre- and post-menopausal women. Up to 96 per cent of ovarian cancers can be screened by the combination of HE4 and CA125 markers. This allows physicians to deploy the ROMA tool widely for risk stratification and routine screening across adult women of all ages.

For nearly three decades, CA125 has been used as a biomarker for monitoring the course of ovarian cancer. HE4 is a novel gynaecological tumour marker that shows better sensitivity and specificity in differentiating between malignant and benign pelvic masses.

Today, the process of screening is focussed primarily on an ultrasound test. Once a pelvic mass is observed, the gynaecologist takes steps to confirm whether the mass is benign or malignant. The chances of a mass being observed increase as the cancer advances, but what we really need is a robust way to detect the probability of ovarian cancer earlier. ROMA-based risk stratification tool provides us an opportunity to do exactly that.

By taking a routine blood sample, using a combination of HE4 and CA125 biomarkers and taking the age of the patient into consideration, we can compute their ROMA score, which tells us how likely it is that she has ovarian cancer. If the ROMA score is high, the physician can confirm a diagnosis through a microscopic examination of ovarian tissue. By contrast, if the ROMA score is low, it helps a physician definitively rule out ovarian cancer with greater assurance.

Are there any gaps and on-ground realities to overcome in diagnosis of ovarian cancer?

Up to 75 per cent of ovarian cancer patients will have a recurrence, and the use of HE4 in combination with CA125 to monitor recurrence is well-established. However, what is relatively less known and implemented is the potential of using the same test to screen all women during routine check-ups, to have a higher chance of detecting first-time ovarian cancer at an early stage. Abbott developed the world's first tool to stratify ovarian cancer risk, and we are spreading awareness among clinical practitioners and patients of the power of routine screening.

As with any positive change, we will need to maintain momentum. Gynaecologists may prefer an ultrasound to a blood test given ingrained practices. We can simply add routine HE4 screening to this habit, to ensure higher accuracy of risk detection through both methods.

What could be the initiatives to bridge the gaps?

There are two elements to consider when making screening more accessible. First, we need to prioritise the use of resources to screen those who are most at risk of ovarian cancer. To name a few risk factors, women above the age of 50, women with two or more relatives who have had ovarian cancer, women diagnosed with breast cancer under the age of 50, women with delayed childbirth and those who have a family history of multiple cancers should all undergo regular screening. Second, health systems need to ensure that screening is included in the routine check-ups and screening packages that both private and public sector hospitals offer.

Early diagnosis through screening is key to reducing mortality due to cancer. How expensive is the diagnosis of ovarian cancer?

The cost to patient can vary from one hospital to another. It is important to identify cancer early so there are more treatment options and better possible outcomes for the patient — so there is value in investing resources in screening to ensure early diagnosis.

Are there public funds to organise screenings for ovarian cancer? How have other countries with the same resource crunch and socio-economic realities coped with these challenges?

While it is intuitive to approach cancer screening with a top-down solution, bottom-up solutions can also be effective. Patients play a critical role in coming forward to consult a healthcare practitioner when they observe unusual changes in their condition and asking for an appropriate test to rule out the risk of cancer. Mass awareness initiatives in the Philippines, for example, have involved the majority of medical practitioners, and have thus reached a wide patient base. Both doctors and patients understand the threat cancer poses and diagnostic methods, which makes early stage detection more likely. Of course, there are many other considerations in coping with resource crunches, but awareness forms a critical part of the answer.

How has the stigma attached to cancer in general and ovarian cancer in particular, impacted detection, diagnosis and treatment?

Gender-related cancers continue to be associated with shame and stigma in India. The impact on detection and diagnosis is significant – patients may delay visiting their doctor or shy away discussing unusual changes. Moreover, they may not get all the information and support they need to know their risk, take action if required and fight cancer successfully.

Stigma for women-specific cancers could be because of the implications it has for reproductive health and even accepted standards of beauty. Support groups can play a vital role in destigmatising the cancer and helping patients come to terms with their diagnosis. We should not ignore this human aspect of diagnosis and treatment, and much remains to be done on the ground.[8]

What have been the most successful ways to increase awareness and acceptance of ovarian cancer in India? Do celebrity role models like Manisha Koirala really work long term?

Sustained campaigns by Indian Cancer Society and National Institute of Cancer Prevention and Research for breast cancer have helped reduce the stigma and oncologists have reported greater awareness and discussion about lumps among women patients. Since women go to gynaecologists frequently for routine check-ups, we can expect similar success in perception and behaviour change from long-term campaigns that target ovarian cancer. The key is sustained action, in order to overcome ingrained beliefs and break taboos.

Besides social issues, is India's healthcare infrastructure geared to detect and treat ovarian cancer across all socio-economic groups? Are women in the rural areas, the urban poor served by the healthcare ecosystem?

Access to diagnosis, treatment and specialists is critical to improve ovarian cancer survival rates. 80 per cent of all districts in India do not have comprehensive cancer centres, and penetration of radiotherapy equipment is also low.[9] There is a shortage of gynaecologic oncologists in India.[10] Evidence shows that surgery and treatment by gynaecologic oncologists in specialised centres is beneficial to patients.[11] However, the proportion of women receiving such care varies widely across the country. The mortality to incidence ratio for women-specific cancers is worse in India compared to global peers. This can partly be attributed to low access to treatment for cancer in general.

Are there any learnings from global best practices in screening and ovarian cancer detection that can be applied in India?

Both globally and in India, we are seeing increasing adoption of the use of HE4 tests when a mass is detected in a scan. We need to accelerate the use of HE4 tests by including them in routine screenings for women. For example, Germany has the highest rate of testing before diagnosis, with 34 per cent of women with one or more family members affected by ovarian cancer being tested.[12]

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INTERVIEW

‘We envision to provide newborn hearing screening to every child’

Unlike developed countries newborn hearing screening is not mandatory. By the time hearing impairment is detected, it becomes too late to take any corrective steps. Pointing out the required measures needed to be taken by the government, **Nitin Sisodia**, Founder & CEO, Sohum Innovation Lab, speaks about his company’s efforts in this direction in an interview with **Usha Sharma**

NITIN SISODIA
Founder & CEO, Sohum Innovation lab

Globally, how many babies are born with hearing impairment and how severe is it in India?
800,000 hearing impaired babies are born every year all over the world, of which 100,000 are in India and 90 per cent are in developing countries. Besides India, 40 low income and 53 low middle-income countries do not have an affordable solution for early screening of hearing impairment. Universal newborn hearing screening has thus been endorsed in many developed countries, but still not widely adopted in India due to high infrastructural and operational costs and requirement of skilled workers. Sohum BERA technology tackles these issues with reduced costs, increased accuracy, simplicity of use and accessibility to remote areas with its telemedicine portal. Sohum provides early screening, that leads to timely treatment and rehabilitation, as well as savings in healthcare expenses to the system.

What are the causes, are there any associated genetic factors ?
The possible factors which lead to hearing loss in newborns are both genetic and non- genetic. The non-genetic factors are rubella infection in mothers, low APGAR score, low birth weight, ventilation, jaundice (hyperbillrubinemia), bacterial meningitis, family history & administration of toxic drugs. Marriages in the same family and presence of hearing loss in the family also affect hearing of a child.

In developed countries universal newborn hearing screening is a norm, tell us about the Indian context?
In India and similar developing countries, newborn hearing screening is not mandatory and not available. Only in few tertiary hospitals, the protocol of screening high risk newborns is followed. Most of the urban poor and rural population doesn’t have access to newborn hearing screening. It is mainly because of expensive equipment and disposables, unavailability of experts to conduct the test and ineffective care cycle. Sohum has created an affordable technology which can be used by healthcare workers with no requirement of expert and it is enabled with telemedicine modality to ensure aftercare.

How essential is early diagnosis to ensure and effective care cycle?
Early diagnosis can save the speech and mental development of the child. A child who is diagnosed early and provided hearing aid or cochlear implant with rehabilitation in the first six months of age will be able to speak and learn just like a normal child. Early screening and diagnostics will enable the children with hearing loss to be a part of mainstream education and livelihood opportunities.

Can hearing impairment be reversed, if it diagnosed at a right time?
Hearing impairment can be conductive, sensioneural or mixed hearing loss. Different types of hearing loss require different interventions. Fitting a hearing aid, cochleae implant with rehabilitation or a surgical intervention can improve the condition. Hearing impairment can be corrected with an intervention and its impact on the growth of the child can be minimised.

What efforts and measures government is taking to avoid these problems?
Government has several national level programmes and schemes to prevent and provide intervention for the affected population. There is

a National Programme for Prevention and Control of Deafness (NPPCD) & Cochlear implant program (ADIP Scheme) from Ministry of Social Justice and Empowerment. These programmes are creating awareness, enabling health setups with infrastructure, and providing free hearing aids and cochlear implants to patients in need. The programmes will be more effective if Newborn Hearing Screening gets implemented at scale and babies can reach these programme initiatives at an early stage. We envision to provide newborn hearing screening to every child born no matter where he or she is born.

Tell us about Sohum hearing screening device? And how has it been designed?

In most advanced healthcare systems, universal newborn hearing screening is mandatory at the time of birth. In a resource constrained setting, such as India, hearing impairment goes undiagnosed till the child is about four years. By then, it is too late for the care cycle to be effective. This leads to speech loss, impaired communication skills, mental illness and unemployment. Sohum provides early screening, that leads to timely treatment and rehabilitation, as well as savings in healthcare expenses to the system.

Sohum is a gold standard Brainstem Evoked Response Audiometry (BERA) technology to conduct Newborn Hearing Screening with high sensitivity and specificity. The compact, battery operated device can perform in noisy clinical settings (no requirement of noise proof room), require minimal disposables (low per test cost), can be used by semi- skilled healthcare worker and gives automated results (no requirement of specialist), and is telemedicine enabled (ensures every baby tested positive, receives aftercare). Sohum provides early hearing screening, that leads to timely treatment and rehabilitation to save the child from speech loss and disability.

What support did you get it from SIB, DBT? Was it under the 'Make in India campaign'?

I did my fellowship from Stanford India Biodesign programme in 2010, an initiative of Department of Biotechnology (DBT) and collaboration of AIIMS, IIT D and Stanford, the programme focuses on the process of finding unmet clinical needs in healthcare system and solving them. And since then I could find several unmet clinical needs in the Indian healthcare system and could solve few of them, reducing the burden of disease and generating livelihood. Our initiative 'Sohum' for Newborn Hearing Screening is a need found during the programme. The project focused on designing a novel technology which works in resource poor setting (developing country scenario) and a sustainable implementation model which incentivise all stakeholders.

DBT has shown immense far sightedness initiating this programme, nurturing Indian talent to solve Indian and global healthcare needs. Make in India, local innovation, creating healthcare startups and companies was at the core of the SIB programme. The intention of DBT to solve developing countries healthcare needs with Indian talent and intellect is really commendable. Dr APJ Kalam said once “Do we realise that self-respect comes with self-reliance”. The thought is very relevant in today’s Indian context and that is what SIB- DBT is trying to achieve.

What is your marketing plan for India?

We are targeting all newborns in resource-poor settings, starting with India. In India, 26 million babies born every year, need to be screened for hearing impairment. We aim to focus on institutional births, which addresses 47 per cent of these births (12.2 million) through maternity homes, paediatric clinics, privately owned local and chain hospitals. With the support of government run programmes and local entrepreneurs we target non-institutional births (mostly rural). Currently, more than 50 Sohum devices are in use in Bangalore (Narayana Netralaya, Vani Vilas Maternal and Child care hospital), Bhopal (5 hospitals), Pune, Delhi (MAMC) & in the States of Tripura, Rajasthan & Himachal Pradesh. We have exported Sohum devices to Uganda and Tanzania in this year and looking to expand the Sohum programme in South- East Asia.

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INTERVIEW

Callhealth and Livehealth together will target 2000 towns and cities across India

Vivek Mahendra, Enterprise Architect and Chief Platform Officer, CallHealth, in a conversation with **Prabhat Prakash** discusses on Callhealth's plans of achieving scale with their partnership with Livehealth

How will this partnership help CallHealth and LiveHealth respectively? How will this collaboration help you achieve scale at a faster pace?

When we were doing our field test, we on-boarded a lot of big players in the market. The intent of the partnership was that the labs will have a well-established lab information management system and we could do a simpler plug-in and ensure the data moves seamlessly from sample on-boarding to the report inputs. However, we realised that while we put together HL7-based integration, the labs weren't ready for it. This is one of the biggest challenges that we are facing as we expand. Labs aren't ready with proper management system or they have used test codification systems and nomenclature that isn't globally accepted. Due to this, we had to undergo a four to six weeks of integration process. These labs have state-of- the-art facilities but their data wouldn't be interpretable by any open source system as they aren't using global information exchange standards (example: lOINC codes) as a means of exchange. We faced this challenge because we had partnered with different labs and these labs were in different phases of maturity (example: nascent state or state-of-the-art).

VIVEK MAHENDRA
Enterprise Architect and Chief Platform Officer, CallHealth

> We were looking at creating a docking station for the labs which would make it easier to do an integration

As per this partnership, we will aim to target about 2000 towns and cities across India. We were looking at creating a docking station for the labs which would make it easier to do an integration.

LiveHealth is a startup but they have been able to work with 2200 diagnostic labs across the country and they use a cloud-based lab information management system. They maintain a global dictionary of all lab nomenclature that exists, and we have created our own lab nomenclature too. This makes it easy for us to access these 2200 labs because the integration would be at a singular level (LiveHealth level) then we would be able to integrate with each of the corresponding labs under them using their platform. This would directly facilitate our expansion across the country.

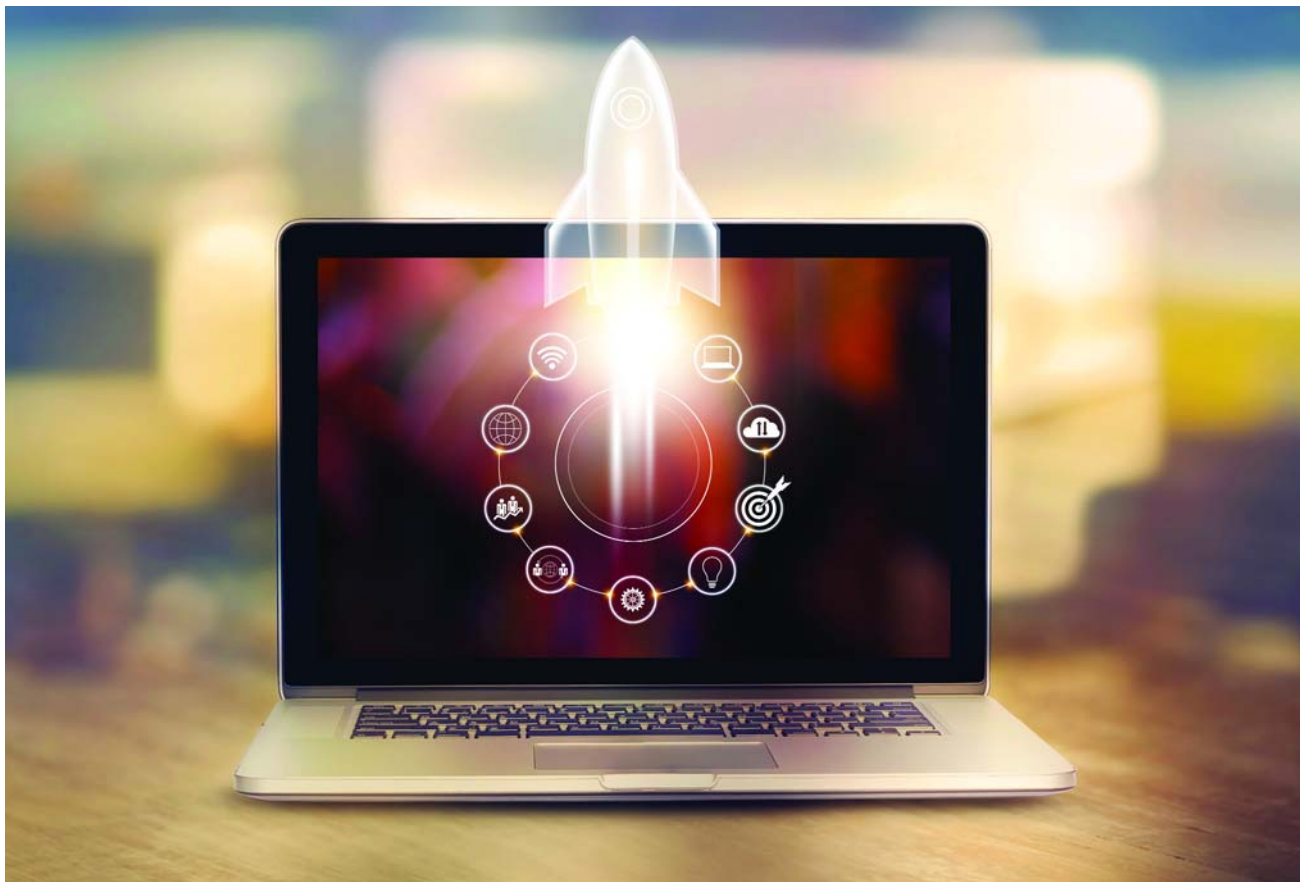
From a CallHealth perspective we have collaborated to create a unified nomenclature mapping. We will now have a singular mapping of each test code that gets serviced across these 2200 labs. This would help us in our integration as it would just be a single day process. All we have to do is, sign a

contract and tick off on our configurator the number of tests we have delivered as per our contract. The data collected from our labs will provide us with information to look for patterns aligned to demographics, disease types and risk factors. This partnership will help us scale at a faster pace as 2200 labs are already accessible to us.

How will your business strategy change with this partnership? Will there be a change in the current business model?
This will not change our strategy as it aligns with our goal. In the healthcare ecosystem, our platform is supposed to be a singular docking system that we interface with. This partnership will help us achieve our vision. There will be no changes in our business model with a partner on board. LiveHealth will get its revenues from the labs they are associated with. We are only ensuring that we maintain a uniformity with their global data dictionary and there is a stability to plug-in. The customers' journey flows through CallHealth.

How do you plan on achieving the target of 5500+ labs?
We already have access to labs associated with LiveHealth. We are already engaging directly with close to about 800 different lab partners. All these labs have their own collection centres which would help us achieve our target of 5500+ labs.

How will the logistics be managed with utmost accuracy? How will the delivery time be reduced in the urban as well as rural market?
All the labs that we are associated with are NABL labs. We are only going to engage with labs that are nationally accredited. The whole journey of a sample from a patient to the lab is a responsibility that we are taking through our professional health ecosystem partners. We have created our own IP, we call it a Thermo-K container which helps preserve samples in prime shape for about 8-10 hours. All the phlebotomists that are on board have been hired through a background check with their respective certifications. We keep track of the sample being collected with proper hygiene and procedure. The phlebotomists are equipped with a centrifuge machine as well. To control this at the field level, we have built through our application small audit trackers that will ensure time of both sample collection and sample deposition, keep track of the medical waste being disposed. There is also a photograph of the sample and the sample quantity at the time of collection. Proper vacutainers are used. Tracking is done on real time basis. These measures will help us manage our logistics with utmost accuracy. There is zero delay once the report is generated as the report can be accessed online.



WE HAVE CREATED OUR OWN IP, WE CALL IT A THERMO-K CONTAINER WHICH HELPS PRESERVE SAMPLES IN PRIME SHAPE FOR ABOUT 8-10 HOURS

What are the new innovative technologies that would be integrated in new labs? What measures will be taken to secure patient data?
We have established a health information exchange; this exchange is accessible using the HL7 protocols. This is globally accepted, we can just plug-in and we are good to go. We use AI and ML when the data is presented to the end user (patient, doctor). The report has information components besides the report itself. If there are a series of tests done and they show a trend this could help the doctor treat the patient better.

For patients, the report will be easy to understand. There is also a chatbot available for the report that is generated. The patient can also share their reports with other doctors for consultation through a secure mechanism. We are also using blockchain signatures to ensure the security and integrity of the report. For people who aren't tech savvy, they can contact our call centre for the report, and it would be sent to them. At the point of service if a patient wants to pay using cash rather than using a card, that option too is available.

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Siemens Healthineers next generation solutions for laboratory diagnostics launched

Atellica Solution can process more than 30 different sample container types, including paediatric and tube-top sample cups that can be aspirated from the primary tube

Siemens Healthineers introduces Atellica Solution for India, providing laboratory diagnostics professionals, control and simplicity; so they can spend more time driving better outcomes and less time on operations.

"The Atellica Solution is developed through extensive market research with laboratory professionals around the world. The result is a groundbreaking solution that provides simplified workflow, tighter control, and more time to focus on driving better clinical outcomes, helping address patients accurately." said Arpan Malhotra, Head of Diagnostics, Zone India, Siemens Healthineers.

Laboratories can gain independent control over every individual sample—from routine to STAT—to deliver rapid, high quality patient results to clinicians with the help of transport technology, together with a multi-camera vision system, intelligent sample routing, and automatic quality control (QC) and calibration. The Atellica Magline Transport is a key feature with patented bi-directional – magnetic transport technology that is 10 times faster than conventional sample conveyors, and provides innovative and unique sample management capabilities.

Laboratory operations are simplified through intelligent sample management offered by Atellica Solution. It can process more than 30 different sample container types, including paediatric and tube-top sample cups that can be aspirated from the primary tube. Laboratories can streamline inventory and deliver consistent patient results no matter where patients are tested, by using the same reagents and consumables across different analyser configurations.

LABORATORY OPERATIONS ARE SIMPLIFIED THROUGH INTELLIGENT SAMPLE MANAGEMENT OFFERED BY ATELLICA SOLUTION

The Atellica Solution is a flexible, scalable, automation-ready solution for immunoassay and clinical chemistry testing. It is a comprehensive solution, that integrates solutions for sample management, immunoassay and chemistry testing platforms. It also can operate as a stand-alone system or connect to Aptio Automation to provide a comprehensive, multidisciplinary testing solution that could include haemostasis, haematology, and plasma protein analysers.

Industry-leading productivity per square metre can be achieved with the immunoassay analyser that runs up to 440 tests per hour. Atellica S olution enables delivery of rapid, high precision results with the immunoassay analyser that features a patent-pending dual incubation ring design, temperature and humidity controls of the reaction environment, powerful magnets for relevant particle separation and robust washing protocols. Powering the Atellica Solution is a comprehensive menu of 170 assays, including 10-minute turnaround times for key cardiac, reproductive and thyroid tests, with 50 more assays in the pipeline.

It is most suitable for mid- and high-volume labs delivering unprecedented flexibility to adapt to changing testing needs and space constraints. The solution is scalable to combine up to 10 analytical components into more than 300 customisable configurations—including linear, L and U shapes.

The Atellica Solution is engineered for reliability, offering remote-access monitoring, self-recovery and many service innovations designed to maximise uptime. Siemens Healthineers aims to support healthcare providers worldwide, to meet their challenges and excel in their respective environments. With offerings such as the Atellica Solution, Siemens Healthineers helps lab professionals simplify their operations so they can focus on transforming care delivery for better clinical outcomes.

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Personalised approach towards precision medicine

Kent Lefner, Partner-Healthcare, Insurance and Life Sciences, Infosys and **Bhargava Hukunda**, Principal Consultant-Healthcare, Insurance and Life Sciences, Infosys elaborate on the need for new data solutions to unlock the full potential of precision medicine

A one-size-fits-all approach to medicine doesn't work for every patient because factors like genetics, environment and lifestyle can impact the effectiveness of the treatment.

The need for a personalised approach has given rise to precision medicine, which focusses on the individual, but not in the way one would think. Rather than designing treatments on a case-by-case basis, greater efficacy has been found by placing patients into subgroups based on characteristics that predict the effectiveness of a treatment.

Big-data thinking in medicine can help practitioners better understand the factors that influence the disease, the nuanced evolution of that disease, improve diagnostic accuracy and optimise treatment plans. Most hospital and physician groups are not yet ready to support this form of analytics.

The field of precision medicine holds tremendous promise, but there are challenges standing in the way of wider adoption. The first is the time it takes to analyse data about the population, create subgroups for whom a treatment plan can be applied and then evaluated, and then determine the probability of success. For each subgroup, data is being collected from thousands of patients, which is a massive undertaking. Our understanding of the human genome is still in its infancy and evolving every day. Progress has been made, but so much is still unknown. Getting it right will take time.

Another challenge is data sharing. It's often difficult to acquire the expansive data that exists between provider, payer, pharmaceutical and medical device companies to coalesce into one body of knowledge. The industry is changing. Change is happening, but it's slow and incremental. A regulatory framework will also be needed to address how data is shared between parties, as each link in the medical chain will want a say in the decision-making process.

Kent Lefner, Partner – Healthcare, Insurance and Life Sciences, Infosys

Bhargava Hukunda, Principal Consultant - Healthcare, Insurance and Life Sciences, Infosys

BIG-DATA THINKING IN MEDICINE CAN HELP PRACTITIONERS BETTER UNDERSTAND THE FACTORS THAT INFLUENCE THE DISEASE

Cost is another challenge. It's expensive to study human genomics, and not everybody is willing to spend the full extent of the money required to do that. Many payers, for example, still view genomics and precision medicine as too expensive and too experimental for them to apply significant funding against, creating a barrier to success.

A new, data-centered solution

Unlocking the full potential of precision medicine starts with finding better ways to collect, share and make decisions based on data. Current solutions aren't optimal in this area because data is siloed in the various healthcare segments.

Platforms need to handle high volumes of data and produce actionable insights. By doing so, they can offer tremendous benefits to participants in the healthcare ecosystem.

Successful implementations haven't happened on a wider scale because of distractions and varying priorities. Most participants in the healthcare industry are focussed on issues surrounding chronic care management, higher patient efficacy, interactive enablement, competitiveness and competitive disruption response. Breaking through their list of priorities and convincing them to invest money in this kind of solution could prove challenging.

A second barrier to success is the willingness of the ecosystem to share the vastness of data. Creating that ecosystem won't be easy, but with the power of a member genome solution, the process becomes manageable

Who will invest in the future of precision medicine?

To adopt this type of system in a precision medicine context means starting with data. The sad reality is that, due to competition and lack of government regulations driving cooperative capabilities, an industry-wide data exchange does not exist within healthcare. However, this should not stop interested parties from taking steps to adopt solutions powered by AI and automation that can maximise their efforts in the field of precision medicine.

The first step is to identify the different dimensions of data that will be required and pulling together what's available to create a baseline. Creating a data baseline would allow an organisation to jumpstart any precision medicine initiatives because once that data is available, it can be input into a member genome framework that has all the architecture components and analytic algorithm libraries in place. Beforehand, it will be important for organisations to define the parameters of this pilot effort by looking at source systems, derived attributes and data transformation, as well as target visualisation and analytical model specs. A member genome solution should have a pre-fabricated set of gene blocks and data models across all dimensions of a health plan including member, customer, plan benefits, providers, lifestyle, behavioural and customer service.

A robust solution should include all three parameters of the Think, Build, Run paradigm. Beyond the platform itself, companies should think through their strategy and convert that strategy into action. The build components make that action a reality. The run components can operate the business on behalf of clients at more cost-effective levels than competitors.

INSIGHT

Efficient diagnostic management

Ishaan Khanna, CEO, Biobank & Diagnostics, Lifecell International, talks about ways to properly evaluate and screen the population for genetic disorders

The structure of India's healthcare system is multifaceted, consisting of various types of providers practising in different systems of medicine and facilities, and within different ownership structures. Congenital and hereditary genetic diseases today possess a significant health burden in India and contributes to third most common cause of mortality in newborns in India.

Factors contributing to this high prevalence include consanguineous marriages, high birth rate, improved diagnostic facilities, and a lack of expertise in genetic counselling. Prenatal testing is the best strategy for reducing the burden of genetic disorders and congenital disabilities that cause significant postnatal functional impairment. However, there are still many genetic disorders that occur in families without any history of an affected child or individual. For the most common genetic disorder like Down syndrome, beta-thalassaemia and neural tube defects, sufficient data has been published to establish the need for population-based screening for these disorders in India.

An approximate of 21,400 children with Down syndrome, 9000 with beta- thalassaemia and 5200 with sickle cell disease are born in India every year.

From introduction aneuploidy screening has continued to grow and evolved since its inception in the 1980s. Initially, conventional Down syndrome screening took place in the second trimester using alpha-fetoprotein (AFP) only and would eventually expand to include total or free Beta human chorionic gonadotropin (hCG), unconjugated estriol and dimeric inhibin A (DIA). By the late 1990s, an alternative screen in the first trimester using ultrasound (e.g. nuchal translucency, nasal bone) and biochemical markers, free Beta hCG and pregnancy-associated plasma protein A (PAPP-A) was introduced. More recently, AFP, Inhibin and placental growth factor (PlGF) have been incorporated into the first trimester screen.

First Trimester Penta test- a new developed biochemical screening test that incorporates 5 analytes [PAPP-A + free hCGß + AFP + uE3 + Inhibin-A] to predict the genetic risk as well as pre-eclampsia significantly improves the detection of abnormalities whilst simultaneously lowering the number of false alarms raised.

Recently, a new screening technology using cell-free fetal DNA from maternal circulation has been introduced. This screening is characterised by high detection rates of ~ 99 per cent with low false positive rates but has an associated failure rate of 1–5 per cent. The failure rate coupled with the significant cost of the screen has hampered universal adoption of cell-free fetal DNA technology. NIPT has also become a highly preferred technique by doctors who consider it to be a safer, faster, reliable, less tedious.

Traditional prenatal screening and diagnosis methods still dominate large part of the Indian market with Amniocentesis, and Chorionic Villi Sampling .However, both these techniques, being invasive pose some risk to the developing foetus — which is why many conceiving mothers do not prefer these methods. The diagnostic market which has been dominated by conventional cytogenetic technique like Karyotyping and FISH has also seen rapid evolution with introduction of chromosomal microarray analysis -a molecular cytogenetic technique to visualise chromosomes at a very high resolution and QF-PCR a rapid diagnostic tool for common aneuploidies. In prenatal samples, cytogenetic microarray is considered an option even in foetuses with normal USG evaluation.

This technique helps in primary prevention of numerous well-delineated sporadic microdeletion/duplication syndromes. CMA has made its place in all invasive prenatal diagnosis and is here to stay and replace traditional karyotyping.

The other common genetic disorders in Indian ethnicity are Beta-Thalassemia, Sickle Cell Anaemia, Spinal Muscular Atrophy and Haemophilia A. Today multiple private labs offer carrier screening to couples planning for pregnancies testing common genetic disorders. The carriers are usually healthy people, but when both parents are carriers of a mutation in the same gene, the risk of having an affected child is high.

Currently, there is no provision for evaluation and screening population for genetic disorders, and no national public health programme is functional for carrier or newborn screening for genetic disorders. Multidisciplinary approach including government, policy makers, regulatory committees, clinicians, genetic counsellors and by private labs can help long way in helping families chose the right test in right time for efficient diagnosis and management.

Genetics and cancer diagnosis

Genetic testing is becoming an essential prerequisite for early and accurate diagnosis of cancer. **Dr Dada Akolkar**, Director Research and Innovation, Datar Cancer Genetics gives an insight

Cancer is a genetic disease with more than 200 types of cancers known to manifest in humans. So far, the use of genetic testing in the diagnosis is limited to a few cancers such as colon cancer. There is no single test that can accurately diagnose each type of cancer. Complete evaluation of a patient includes a thorough clinical history, physical examination, and diagnostic testing. Diagnostic procedures for cancer include imaging/scanning, laboratory tests (including tests for tumor markers), surgery, tumour biopsy, endoscopic examination, and genetic testing.

Genes and cancer

Genetic tests have diverse purposes, including screening for and diagnosis of genetic disease, the identification of future health risks, prediction of drug responses and identifying targeted therapies to provide customised cancer care. Genetics plays a major role in identifying high-risk individuals for precision-based surveillance of cancer. Genes can affect whether a person is likely to develop cancer or not. About 5 per cent to 10 per cent of all cancers are known to be strongly related to inherited gene mutations. Gene mutations or changes in genes play an important role in the development of cancer. Mutations can cause a cell to make (or not make) proteins that affect how the cell grows and divides into new cells. Certain mutations are found commonly in certain cancer types. Finding these common mutations can confirm the diagnosis of cancer.

Effective diagnostic testing is necessary to confirm or eliminate the presence of cancer, monitor the disease process, and to plan for and evaluate the effectiveness of treatment. Genetic testing is increasingly becoming an essential prerequisite for early and accurate diagnosis of cancer. Early detection of cancer gives the patient the best chance of fighting and overcoming it.

Incorporating genetic tests in present-day diagnostics

The results of your genetic testing may help to:

- ◆ diagnose a disease and the severity
- ◆ find gene changes responsible for an already diagnosed disease;
- ◆ guide selection of medicines and other treatments;
- ◆ assess the success of and resistance to the treatment
- ◆ find gene changes that increase the risk of developing a disease
- ◆ find gene changes that could be passed on to children.

Following types of genetic tests play an important role in cancer diagnosis and management

Diagnostic testing is used to precisely identify the disease that is making a person ill. The results of a diagnostic test may help you make choices about how to treat or manage your health problems. Going forward diagnostic tests for cancer can become a part of the annual health-check plans for the earliest detection of cancers.

Screening test: This type of testing usually is offered to people who have a family history of a specific inherited disease or who belong to certain ethnic groups that have a higher risk of specific inherited diseases. Detection of specific mutations can help the person to pro-actively take preventive action, Angelina Jolie is one such example – she took the extreme step and underwent preventive bilateral

mastectomy as she had the BRCA1/2 Mutations and a strong family history of cancer.

Pharmacogenomic testing gives information about how certain medicines are processed by an individual's body. This type of testing can help your health care provider choose the medicines that work best with your genetic makeup. Some drugs do not help patients with certain genetic mutations. These mutations impact drug metabolism in an individual and affect its usefulness.

Genetic testing helps identify mutations that impact therapy. For example, cetuximab (Erbitux) and panitumumab (Vectibix) are drugs used to treat advanced colorectal cancer. However, patients with a mutation in the KRAS gene do not benefit from these drugs. Genetic testing can thus help therapy selection.

One of the most exciting advances in the treatment of lung cancer has come from an understanding of genetic changes in lung cancer cells. Whereas in the past lung cancer was broken down into perhaps five types on histopathological examination, it is now a known fact that no two lung cancers are the same. If there were 30 people in a room with lung cancer, they could have 30 different and unique types of the disease.

There are many mutations that are being studied by scientists looking at lung tumours. So far, driver mutations (mutations that drive the growth of the cancer cells) have been identified in approximately 60 per cent of lung adenocarcinomas and it's likely this the number will increase in time

Personalised treatments

The use of therapies based on individual genetic make-up, (medications that target particular genetic abnormalities in a tumour) has been coined as personalised medicine or precision oncology. What this means is that, rather than a conventional chemotherapy regimen of treating all cancer patients with a particular work-up, each individual receives the chemotherapy regimen as per genetic findings in the person and his tumour. In general, such treatments have fewer side effects than traditional chemotherapy and have an exceptionally better chance of therapy success. Many targeted therapies have been approved for people with lung cancer, E.g. Erlotinib for a specific EGFR mutation or Crizotinib for lung cancer with ALK4-EML gene rearrangement. There are many mechanisms by which patients may become resistant to treatments, and molecular analysis can detect such biomarkers enabling prompt modification of therapy. NCCN (National Comprehensive Cancer Network) clinical practice guidelines of 2019 for Lung cancer clearly state that 'testing of lung cancer specimens for molecular alterations are important for identification of potentially efficacious targeted therapies as well as avoidance of therapies unlikely to provide clinical benefit'.

Certain genetic tests now available, analyse the gene expression and help predict which patients are more likely to have a recurrence of their cancer after treatment or which patients may benefit most from treatments.

The guiding principle of personalised medicine and its progeny—precision medicine and precision oncology is that an understanding of the molecular drivers of an individual patient's tumour will lead to a better management strategy and outcome for that patient.

The ability to identify the molecular profile of a variety of cancers is an extremely rapidly developing area in genetics. Thus, by seeding genetic tests in the array of clinical patient scenarios, early and accurate diagnosis can be made.

The US Food and Drug Administration recently approved the treatment for adult and paediatric patients whose tumours are different but have a common genetic mutation. It has the ability to make sure that the right patients get the right treatment at the right time. This innovation in precision oncology drug development will help ensure more personalised and effective treatments for cancer patients.

There is increasing evidence to support the routine analysis of circulating tumour DNA in clinical decision-making for certain subgroups of patients with so-called hotspot mutations.

With continued refinement and technological progress, non-invasive molecular biomarkers including of circulating tumour DNA may be clinically useful at all stages of cancer management from diagnosis to disease progression.

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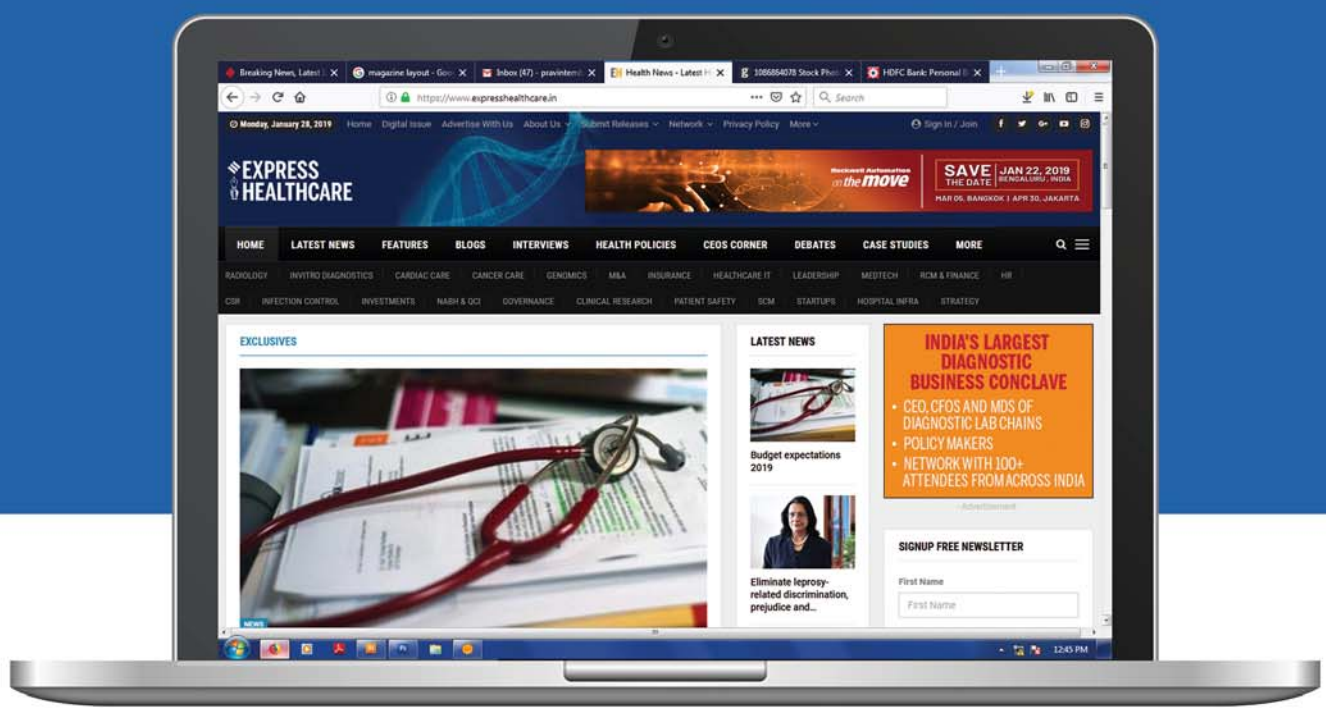

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