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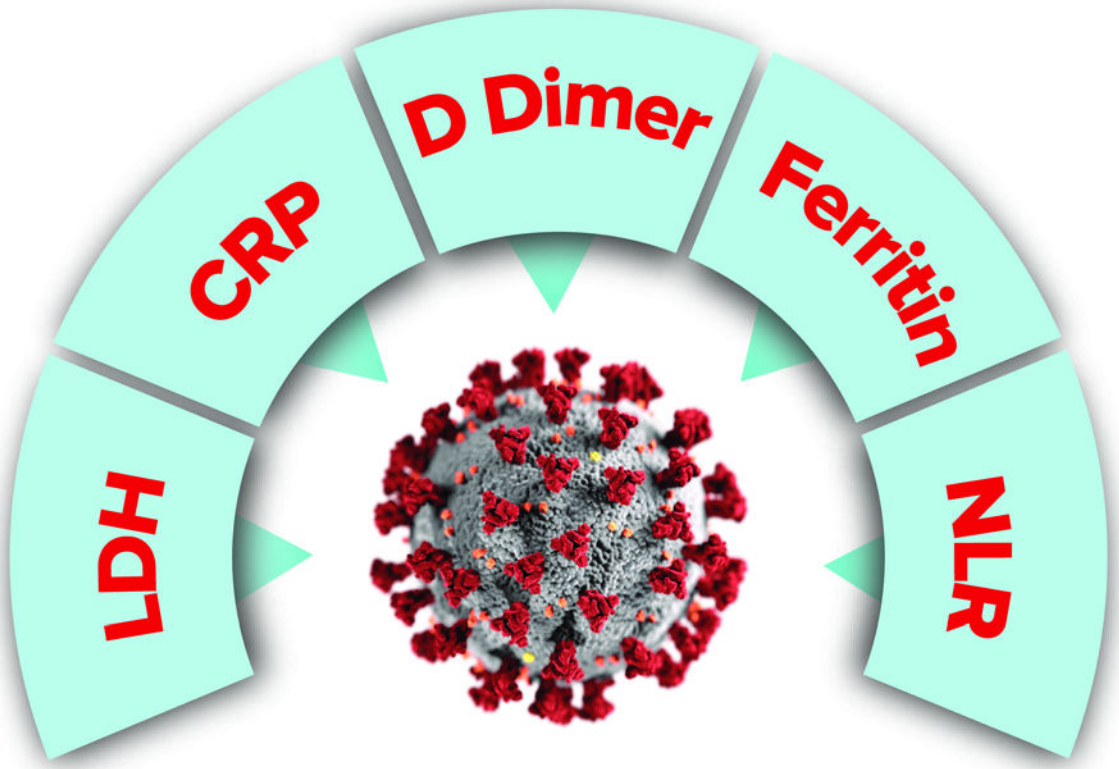

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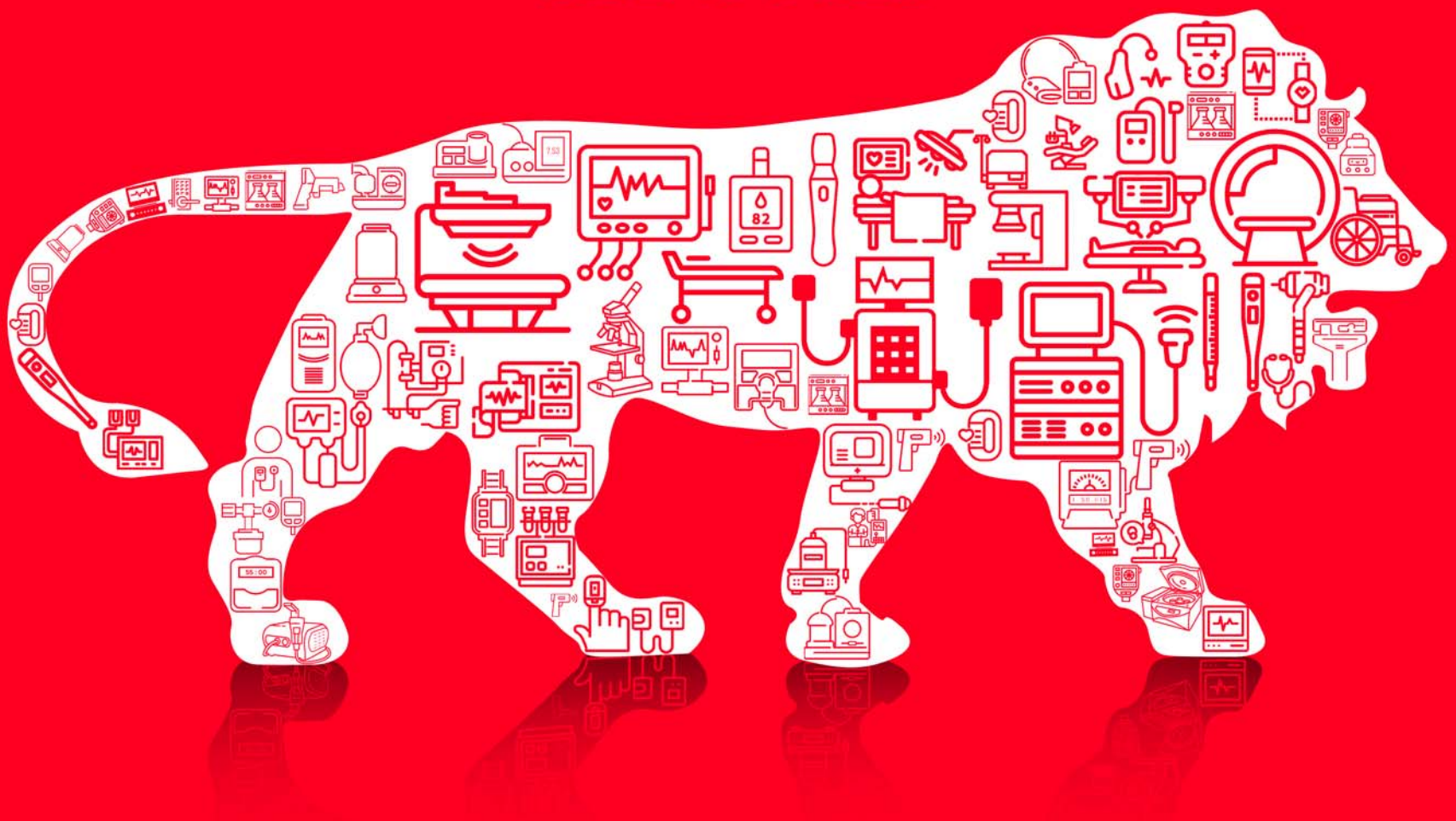

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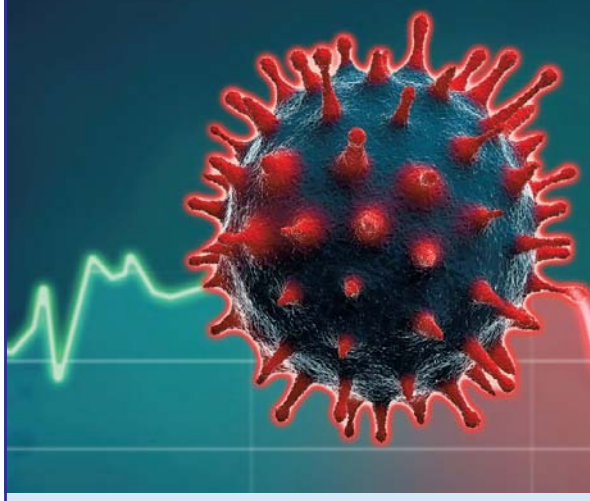

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Wanted: A PLI scheme for doctors, nurses?

Last year, 736 doctors lost their lives due to COVID-19, says Dr Jayesh Lele, secretary general, IMA. This year's second wave has already claimed 126 doctors. At one point, 49 of these doctors were from one state alone: Bihar.

Besides COVID-19, doctors and nurses are also perishing in fires breaking out in ICUs. Often caused by malfunctioning or overheated ventilators, medical personnel are particularly vulnerable as their PPE catch fire while they try to save their colleagues and patients. We are also hearing of young doctors driven to suicide, anguished by the lives they could not save due to lack of oxygen and medicines. Exhausted doctors, nurses are taking to social media to literally beg patients with mild COVID-19 symptoms to not insist on blocking a hospital bed/oxygenator when all they need is home quarantine.

To fight any war, we need soldiers and ammunition. Looks like we are running short on both counts in the war against COVID-19.

But while more manufacturing units could be offered the Production Linked Incentive (PLI) scheme to make more medicines, vaccines, ventilators etc, doctors and nurses cannot be assembled and rolled off a production line.

In fact, the government's PLI scheme for medical devices and medical device parks will hopefully ease the shortage of medical equipment *(see cover story in May edition: Making med-devices for Bharat and the world)*

Worse, doctors are already warning us to be prepared for the third surge, projected in June-July this year. This only means more doctors and nurses, at least 20 per cent trained for ICU duty, will be needed.

Which is why Prime Minister Modi's moves on May 3 to boost the availability of medical personnel to fight COVID-19 are very welcome and in line with most of the suggestions of healthcare associations.

But here too more could have been done. For example, Dr Ravi Wankhedkar, Chairman, IMA Covid Registry terms the decision to postpone the PG NEET exam for at least four more months as "retrograde" as it will keep the more than 1 lakh MBBS doctors who keep appearing for PG NEET year after year, out of the healthcare delivery system, adding to the burden of "serving junior doctors who are already physically and mentally fatigued."

It is unfortunate that we still hear of patients' relatives attacking medical staff, as recently happened at Apollo Hospital's Sarita Vihar, Delhi facility. No doubt the demise of their family member due to the unavailability of an ICU bed is tragic but taking the lives or injuring doctors and nurses puts more patients at risk.

Unfortunately, it is not just patients and relatives who take medical staff for granted. For instance, the health department of the Government of India and various states should maintain an official record of healthcare workers affected and died due to COVID-19 with their vaccination status. As per IMA, this is not being hence the association has stepped in to collect this data. IMA has also created a COVID Martyrs Fund, from which Rs 1.6 crore has already been disbursed to families of deceased doctors.

Unfortunately, doctors and nurses cannot be assembled and rolled off a production line

Keeping in mind that monetary incentives cannot be the sole motivation for healthcare professionals who are after all risking their lives when they take up COVID-19 duties, what could be considered a fair incentive?

A notification from the Himachal Pradesh government dated May 3, announced incentives ranging from Rs 3000 per month for fourth and fifth-year MBBS students, contractual doctors, and junior and senior residents; to Rs 1500 per month for nursing students, contractual lab staff and GNM third-year students.

Dr Wankhedkar calls this a "cruel joke by the Himachal Pradesh government", reminding us that it works out to just Rs 100- Rs 50 per day.

The Supreme Court had to intervene before the May 3 decision from the PMO. The apex court's April 30 response to a PIL asked for details on medical oxygen supplies, medicines and procuring vaccines for all.

It also asked the government how many families of medical personnel who died of COVID-19 were still awaiting clearance of their insurance claims under the *Pradhan Mantri Garib Kalyan* Package which had been extended to around 22 lakh healthcare professionals.

The apex court also drew attention to how healthcare professionals who got infected in the line of duty were often left to fend for themselves without beds, oxygen or medicines for themselves or their family members.

The SC's response also mentioned that the central government should examine and ensure that in addition to the schemes it had framed, other facilities such as the availability of food, resting facilities between work, transportation, non-deduction of leave etc should be provided to healthcare professionals on COVID-19 duty.

It is these facilities that will motivate healthcare professionals, more than the monetary incentives, but it is sad that the Supreme Court had to step in before we realised that we cannot fight COVID-19 without doctors, nurses, lab technicians, etc. After all, as Dr Devi Shetty put it, beds and ventilators don't treat patients, it's doctors and nurses who treat and save lives.

VIVEKA ROYCHOWDHURY *Editor*
viveka.r@expressindia.com
viveka.roy3@gmail.com

OPINION

How disease surveillance can change the healthcare situation in India

Dr Vikram Venkateswaran, a doctor turned technologist, and Founder of Healthcare India, believes that we should take full advantage of the advances already made by institutes like the Integrated Disease Surveillance Programme and private entities like the Virology Institute in Manipal to take healthcare in India from being reactive to proactive

In November 2020, the nodal office of the Integrated Disease Surveillance Programme (IDSP) was alerted about suspected cases of Mumps in a local village of Punjab. Mumps is a viral infection and is caused by Mumps Virus which is a Paramyxovirus, with an incubation period of 15-20 days. It affects mostly children and not surprisingly the observation came from the local village school which had 21 students.

The local health workers along with the epidemiologists visited the school and immediately isolated

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the infected children. They gave symptomatic relief to the affected children which were nine in number and spent the week educating and managing the health conditions of the local residents to ensure that the epidemic does not spread. The efforts of this team were successful as the cases subsided and the infection managed.

This is a good case of the success of the IDSP that has been running in India since 1997. Recently it has been expanded to 23 states and all UTs.

What is disease surveillance?

Disease surveillance is a system that uses digital technologies to collect data from multiple sources in real-time or near real-time and can help indicate the potential of a disease outbreak in certain locations, thereby enabling the government to take steps to control the situation. The idea is to take action right at the beginning at the local level to ensure that it does not spread regionally or nationally putting the entire healthcare machinery at strain.

Many Western countries have been doing so already, where they rely on hospital and lab reporting, digital monitoring and social media data to prevent and manage outbreaks. For instance, the US was able to identify cases of Ebola around nine days before the World Health Organisation declared the Ebola epidemic using a software that mines social media. This software, part of an infectious disease surveillance system, was able to pick up instances of a "mystery haemorrhagic fever" from among the various entries listed on government websites, local news sites, and social networks, correlating it with Ebola.

This is not different from the case in Punjab above which was identified mostly because of the reporting on local health workers who were visiting the school in Punjab as part of their weekly reporting on the local disease patterns.

How can it help India?

The key to managing India's healthcare situation is proactive intervention and prevention. While managing a population with our size is not going to be easy following traditional intervention will not help either as we really don't have the infrastructure to handle the caseloads. Coronavirus pandemic is showing us how difficult it is for our ecosystem to handle pandemics.

With the rise of internet connectivity and digital media in India, it is no surprise that both state and local authorities are looking at leveraging that data to detect outbreaks and intervene in advance.

We can also look at the social media feed from users who indicated their ailments – directly (by looking at the feed that saw people discussing their illness or indicating that they were unwell on social media) or indirectly (by analysing the number of people searching websites like Google, looking to investigate their symptoms and seek cure).

A similar mobile application called 'Flu Near You' was being used in the US to record flu cases during the season. Some of these might have inaccurate reporting by the users but it still gives the healthcare system a sense of what is happening in the various districts in the country.

Disease surveillance in COVID-19

COVID-19 has aptly demonstrated the use of disease surveillance for the reporting and managing of the pandemic. While the global nature of the pandemic makes it one of the worst outbreaks since the Spanish

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Flu, daily reporting of the numbers and tracking of data from the various state and local hospitals has helped the ecosystem define a plan to tackle the situation. While data has been shared with the Ministry of Health and Family Welfare for the tracking of the coronavirus, very few instances of sharing of such data have been permitted in the past. The idea is to identify 15-16 disease conditions that impact India the most and data on those conditions to be shared with the national program for better tracking and management.

This helps not only the hospitals and the authorities but also others in the healthcare ecosystem like pharma companies to manage their supply chains and for medical devices to ensure the availability of equipment.

Weather data

We can take the disease surveillance system one step ahead by integrating weather data into it. Weather plays a big role in the spread of infectious diseases and also in aggravating certain conditions like asthma. Countries like Germany, Japan and UK have already started incorporating weather data into their disease surveillance programmes. Germany tracks ultraviolet radiation from the sun in its forecasts. It also tracks pollen a known cause of allergies and other factors in its advisory for the local regions.

In my book Own Your Health, I discuss how Japan has managed to integrate weather data into its disease surveillance programme. Japan undertook health-weather forecasting by including Ultra Violet (UV) forecasting, adjusted to skin type as part of its surveillance mechanism in 2008. The country has been divided into 39 regions based on significant differences in terms of lifestyles, clothing, and sensibilities of residents. This is just another example of why an integrated programme is critical for tracking health.

The NHS in the UK tracks cold weather conditions and warns trust hospitals on not only infections but also on cases of trauma. The city of Chicago has been tracking food poisoning as part of its move to track foodborne diseases. The system uses Twitter to identify epicentres of such outbreaks.

What India needs next

Fortunately, India already has an Integrated Disease Surveillance Programme as discussed at the beginning of the article. Most of the work done by this programme never makes news as the outbreaks are contained. The main move will be to bolster that programme leveraging digital. Today, the lead time from getting data from the local authorities – Primary Health Centers, Community Health Centers to district hospitals is long. The P Forms and N Forms that are filled and scanned take time.

There is a move to digitise the programme using the mobile application but it is taking longer than expected. The launch of the India Stack and the integration with it should accelerate the growth of the IDSP.

Leveraging digital and social media data is a critical step. While the data from the hospitals and healthcare centres are genuine case records and resemble structured data, integrating with unstructured data coming from digital and social media sources would give us the complete picture. Finally, adding weather data to it will complete the picture. Weather plays an active role in determining our health and adding that into the mix will complete the picture.

We have a unique opportunity in India to build a healthcare surveillance/ disease surveillance system unlike anyone else. We should take full advantage of the advances already made by institutes like the IDSP and the private entities like the Virology Institute in Manipal to take healthcare in India from being reactive to proactive. It can bring together various stakeholders like healthcare professionals (who on their own don't tend to use digital media for creating awareness on diseases), patients (who need authentic medical information online), and healthcare providers (like hospitals and clinics who can share disease information) to comprehensively tackle disease and its symptoms. The beginning has already been made, but it's time to make it a more mature system for wellness and preventive care.

COVID-19 has aptly demonstrated the use of disease surveillance for the reporting and managing of the pandemic. Daily reporting of the numbers and tracking of data from the various state and local hospitals has helped the ecosystem define a plan to tackle the situation

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INTERVIEW

At Terumo, we consider India to be a very important market for us

Shishir Agarwal, MD, Terumo India, as part of the 100-year-old Japanese Terumo Corporation, that serves to advance access of high-quality medical devices to patients and medical practitioners in India, firmly believes that Terumo India can be a very strong and reliable partner for India's developing healthcare ecosystem. He details Terumo's game plan for India to **Viveka Roychowdhury**

What are the trends in the medical devices industry, globally and in India?
I see three dominant trends shaping the global medical devices industry that is applicable to India as well.

Firstly, governments around the world are actively trying to reduce the overall cost of healthcare, for patients as well as healthcare systems. This correspondingly puts pressure on companies to optimise costs and enhance the efficiency of their operations.

The second major trend is the impact of technology. The traditional value chain as we know it is getting transformed by integrating artificial intelligence, predictive technology, and more to provide a service layer over products and provide customers a more integrated solution.

Thirdly, and perhaps most importantly, the healthcare ecosystem is progressively becoming more patient-centric. While it may not be so apparent yet, there is a pronounced shift from treatment and cure to prevention. I think this augurs well for the entire healthcare ecosystem.

> Culturally, the Japanese are known to invest and build for the long term. This focus on building for the long-term coupled with the great significance we place on values such as trust, care and respect, makes Japanese companies highly dependable partners for the long term

What does the Japanese value system, cultural framework and work ethics mean for Indian healthcare? How does this benefit the patient and caregiver population in India?
Japanese companies generally are quite well-known for their thriving high tech innovation ecosystem. This continues to be an area of strength in our being able to bring best-in-class technology to innovate for patients. But more importantly, culturally, the Japanese are known to invest and build for the long term. There are so many Japanese companies, including ours, that are over a hundred years old. This focus on building for the long-term coupled with the great significance we place on values such as trust, care and respect, makes Japanese companies highly dependable partners for the long term.

I therefore firmly believe that we can be a very strong and reliable partner for India's developing healthcare ecosystem.

At Terumo, we consider India to be a very important market for us. It has great potential for growth with a huge underserved population. The Indian Government is committed to investing in developing the healthcare ecosystem in the country. There is also growing awareness and appreciation for high-quality products. We at Terumo India look forward to enhancing affordable patient care in India through our high-quality products and solutions.

What is Terumo's game plan for India, in terms of target CAGR for the next few years? How has the pandemic impacted these growth plans?
Although 2020 presented many challenges, we have been able to respond to the market context with resilience and have emerged stronger as an organisation. After the sudden dip in the market during Q1 last year, we've had a sharp rebound in our performance, recovering faster than the market.

We expect to have a few important additions to our portfolio this year and will continue to invest in our digitalisation journey as we look to further scale up commercial models and stay focused on supporting doctors and patients in making procedures safer and effective.

viveka.r@expressindia.com
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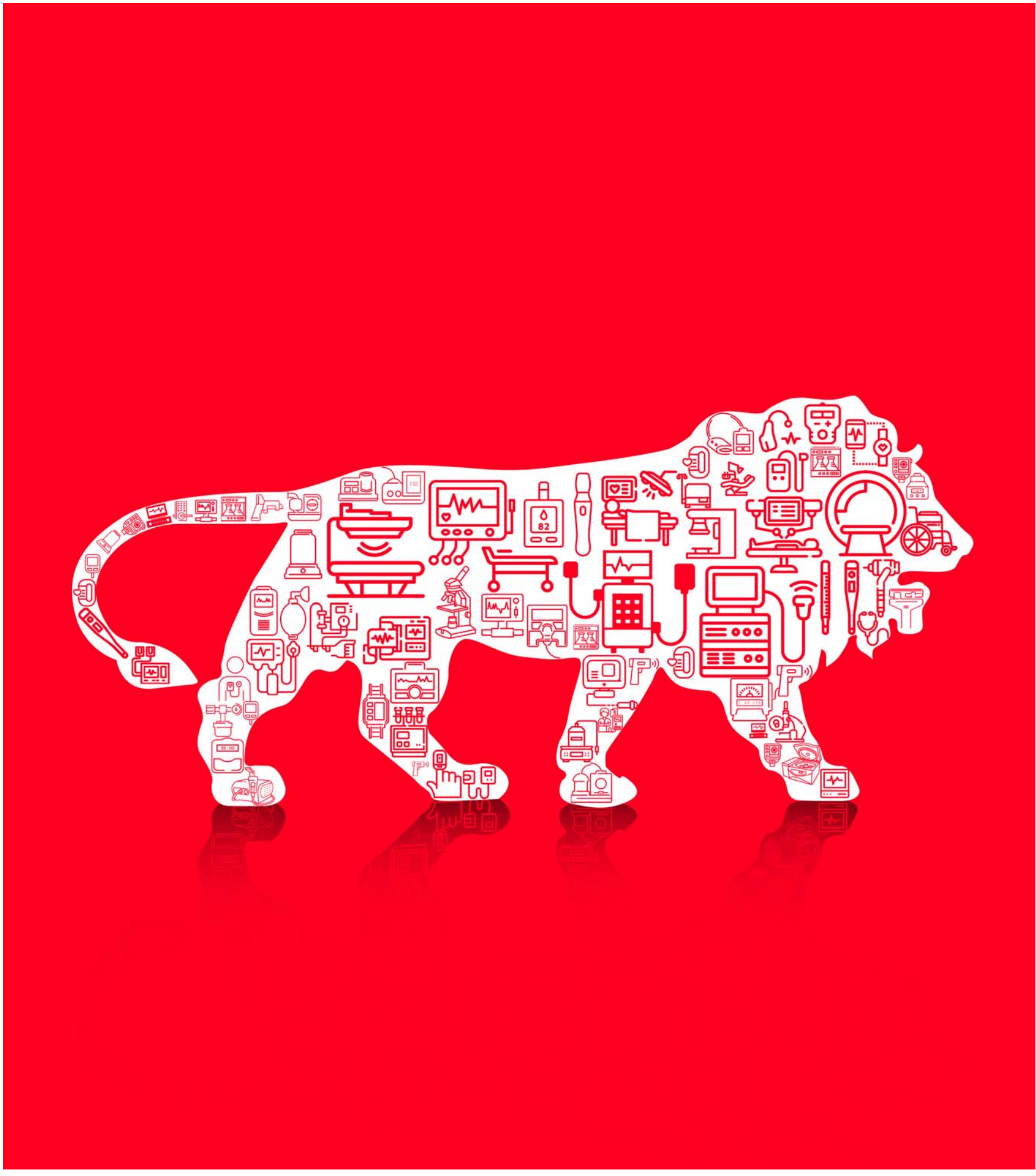


MAKING MED DEVICES FOR BHARAT AND THE WORLD

Atmanirbharta in life-saving medical devices was the proclaimed goal when policymakers launched a Production Linked Incentive (PLI) scheme, supplemented by the creation of medical device parks. Industry and states responded with enthusiasm to the sector's 'Make in India' moment but a year down the line, remain disappointed with the implementation. Just 14 of the 28 applications made under the PLI scheme have been approved till March this year. 16 states applied to develop medical device parks but there is no news yet of any fresh approvals. Industry experts suggest ways to speed up the initiative

By Viveka Roychowdhury

A few days before the national lockdown of last year, on March 21, 2020, the Union Cabinet gave details of two approved schemes aimed at spurring local manufacturing of medical devices.

Hailed as part of Prime Minister Modi's flagship Make in India/*AtmaNirbhar Bharat* campaign, the first scheme sanctioned Rs 400 crore for the setting up of four medical device parks, with common infrastructure facilities.

The second policy extended the Production Linked Incentive (PLI) Scheme to the local medical devices sector, setting aside Rs 3,420 crore for this venture. The two schemes will run over the next five years i.e. from 2020-21 to 2024-25.

India depends on imports to the tune of 85 per cent of the total domestic demand of medical devices and thus there is no argument that being self-reliant in this most crucial sector is vital from a health security perspective.

If anything, the COVID-19 pandemic has underlined our dependence on other nations for a range of medical supplies from medicines to oxygen concentrators and the like.

Vital stats of India's medical device sector

The growth potential of the medical devices sector is the highest among all sectors in India's healthcare market, with the country ranking as the fourth largest market for medical devices in Asia.

As per Invest India, India's national investment facilitation agency, the current market size of the medical device industry in India is estimated to be $11 billion, with a projected CAGR of 14.8 per cent and is expected to reach $11.86 billion in 2021-22 and $ 65 billion by 2024 and $50 billion by 2025.

With 100 per cent FDI allowed under the automatic route for both brownfield and greenfield medical device setups, the sector has reportedly seen strong FDI inflows which reflect the confidence of

Over the next three to four years, we have a planned investments of Rs 100 crore for setting up the manufacturing of medical devices

Dr Shravan Subramanyam
MD, Wipro GE Healthcare

There is a need to increase the PLI incentive to at least 15 per cent for five years to help local manufacturers become global players

Suresh Vazirani
Founder Chairman,
Transasia –Erba International Group of Companies

We need to make India great again, not only by attracting overseas MNCs but supporting the Indian Champions who are the only fall back option in every crisis including COVID

Rajiv Nath
Forum Coordinator, Association of Indian Medical Device Industry and MD, Hindustan Syringes and Medical Devices

The large players will create the currents which will assist the small players in their flight and the small players will bring the frugality and innovation which will benefit the large players and push the ecosystem forward

Pavan Choudary
Chairman & Director General, Medical Technology Association of India and MD, Vygon India

global players in the Indian market.

As per the Invest India site, since April 2000, the sector has seen $2.1 billion in FDI, of which $600 million was received in the last five years. Singapore, the US, Europe, and Japan are key investors and the sectors that attracted the most FDI are equipment and instruments, and second, consumables and implants.

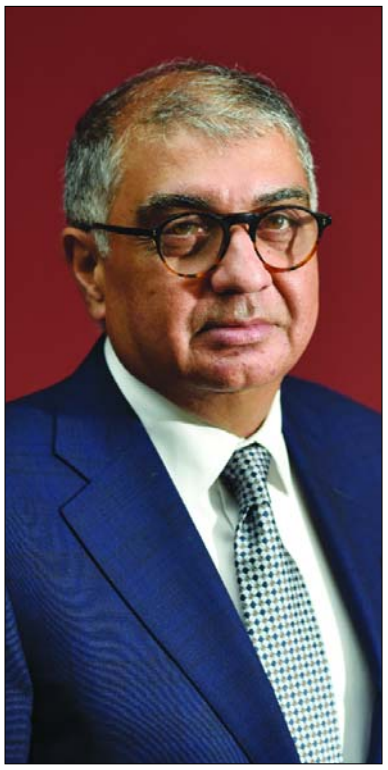
Around 65 per cent of the medical device manufacturers in India are mostly domestic players operating in the consumables segment and catering to local consumption with limited exports. As per Invest India, large MNCs dominate the high technology end of the medical devices market with extensive service networks.

There are 750–800 domestic medical devices manufacturers in India, with an average investment of $2.3–2.7 million and an average turnover of $6.2-6.9 million.

There are six medical devices manufacturing "clusters" in the country, including Andhra Pradesh, Telangana, Tamil Nadu, and Kerala who got in-principle approval for new medical devices parks in 2019. *(See box: Investment opportunities in India's medical devices segment)*

Ensure optimal utilisation of existing parks before setting up the new medical device parks across the four states. Then existing parks could serve as models for the inception of new medtech parks of the future

Pavan Mocherla
India Chair,
Asia Pacific Medical Technology Association and MD, India and South Asia, BD



If the PLI scheme is extended to the nutraceutical industry, it will stimulate the needed investment to grow in size and scale. This will help make India one of the best manufacturing hubs in naturals and botanicals

Sanjaya Mariwala
Founder President, Association of Herbal and Nutraceuticals Manufacturers of India and Executive CMD, OmniActive Health Technologies

Investments in the manufacturing of high-tech medical devices will happen when global companies start seeing volume-linked cost advantages in making the shift. Over time, with stable, practical and long-term policies we will see the efforts bear fruits

Shishir Agarwal
MD,
Terumo India

Status check

One year down the line, what is the progress on these two schemes?

According to Achal Chawla, Tax Partner, EY India and Divya Bhushan, Director, Tax, EY India, the Government of India has received 28 applications under the PLI scheme, of which, 14 applications have been approved till March 2021.

Likewise, the Government has received 16 applications from different states, showing an interest in the development of medical device parks.

Market buzz has it that the states are getting antsy that there is still no word on which applications have been accepted.

While there is unanimous support for the schemes, there is also disappointment that the implementation has lagged. Thus there are many suggestions that a lot more can, and must, be done for so vital a sector. Especially as the COVID-19 pandemic shows no signs of disappearing and will keep rearing its head in waves, most likely over the next few years.

What's good ...

Almost all association chiefs echo Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD) who says that these (two schemes) are very welcome Make in India enabling initiatives and the first motivation of its kind.

Pavan Choudary, Chairman & Director General, Medical Technology Association of India (MTaI) and MD, Vygon India states that the PLI scheme is "undoubtedly a step in the right direction which has been taken through adequate consultation with the industry within the bundle of constraints which were there around the generic PLI scheme system." He points out that it has already achieved partial success, and a few thousand crores of investments are expected to come in, thanks to the scheme.

Pavan Mocherla, Asia Pacific Medical Technology Association's (APACMed) India Chair, and MD, India, South Asia, BD, believes that the "recently introduced PLI scheme for medical devices is highly commendable as it serves as an attractive incentive for medical devices to be manufactured locally, both for domestic use as well as for

exports. The scheme also reinforces the government's commitment to strengthen India's manufacturing capabilities which in turn, helps to attract foreign investments in a broad range of medical device product segments ranging from capital equipment, implantable devices, diagnostics, and consumables."

At an individual company level, Dr Shravan Subramanyam, MD, Wipro GE Healthcare explains what his company found attractive about the PLI scheme saying, "The production link incentive is an excellent opportunity for enabling 'self-reliance' for India, in a critical industry (during these pandemic times) – medical devices. As a country, we still import a large portion of the medical equipment ... and with PLI, private/local companies will be enticed to increase their supply chain footprint in India... first to increase our localisation potential, and eventually to unleash our capabilities for the world. To be a part of such a pivotal moment in the evolution of India's Healthcare ecosystem... any company would be honoured to receive the PLI nod from the Department of Pharmaceuticals, Government of India."

Wipro GE did get the nod to participate in the PLI scheme and Dr Subramanyam says that over the next three to four years, they have planned investments of approximately Rs 100 crores for setting up the manufacturing of medical devices. He sees the PLI scheme as a combination of import substitution and a higher growth rate propelled by lower cost leading to additional revenues.

As the dependency shifts to Wipro GE Healthcare's local manufacturing hub over the next few years, he anticipates that the need for importing these target products will naturally decrease. Thus making India more self-reliant for these devices.

He also points out that the various schemes brought in by the Government do play a part in making the devices competitive by a few percentage points. He ties it in with how the company is "constantly looking for innovation in 'super-value' products. What that entails – is a relentless search for products and features that are designed for India... made for India-use and even priced in an affordable range, for the multitude of India-hospital needs, spread across the different tiered cities."

Giving the perspective from the IVD sector, Suresh Vazirani, Founder Chairman, Transasia–Erba International Group of Companies says that the PLI scheme "is a good start and will incentivise domestic manufacturers to engage in high-value production. It can make Indian manufacturers globally competitive, attract investment in the areas of core competency and cutting-edge technology; ensure efficiencies; create economies of scale; enhance exports and make India an integral part of the global supply chain."

Shishir Agarwal, MD, Terumo India, a Japanese company, also terms it a "welcome step to make healthcare more affordable and accessible to patients in India."

Hinting that we will not see results overnight, he predicts, "Initially, it is likely to create more activity in the mid to low technology, high volume category (of) manufacturing. Investments in the manufacturing of high-tech medical devices will happen when global companies start seeing volume-linked cost advantages in making the shift. Over time, with stable, practical and long-term policies we will see the efforts bear fruits."

... and what's not

MNCs and domestic companies do differ but also agree on the improvements needed to make the PLI and med-tech cluster schemes better.

Choudary of MTaI feels that the PLI scheme can be improved further by seeing if the medical device and equipment universe can be covered more comprehensively especially with respect to those products which can be import substituted in the short term in three ways.

Firstly, identifying how the small and medium scale companies can enter the ring because more than 90 per cent of the companies in this sector belong to the SME space.

Secondly, giving more time to MNCs who may be interested to apply for the scheme, as such decisions in global companies easily take a year to get ex-com and Board approvals after the business case development.

Mocherla also echoes this, suggesting that to ensure the scheme is widely adopted, it is worth considering that the duration for submission of applications is extended to two to three years instead of the current timeline of two to three months, as MNCs typically have long planning cycles when it comes to making investment decisions on where to base their production plants.

Third on Choudary's list is to bring convergence between the benefits offered by this scheme and other moves which the government is making, like the medical device parks.

Nath of AiMeD has a separate wish list for the government to nurture domestic companies to create Indian MNCs, by extending the PLI scheme to all medical electronics; drugs/vaccine delivery devices/technologies, and thirdly, all implants.

Nath makes the important point that the investment needs to cover all investments, including land, building and plant, machinery and utilities as with medical devices, buildings and utilities are designed around a process, for example, clean rooms, power backups, ETP, air conditioning etc.

Vazirani of Transasia points out that the largest share of the PLI scheme rests with the automobile sector. He wishes that the government would have outlaid a larger amount for the medtech and IVD sector as well.

As per Vazirani, "The (PLI) scheme will be completely successful when we become the manufacturing hub for the world. And in order to participate in global and regional value chains, import tariffs will have to be correspondingly calibrated. Last and most important, a scheme of such magnitude cannot be monitored by routine mechanisms. It will require a comprehensive, technically evolved approach with appropriate growth strategies, to develop a global ecosystem."

Strategy for medtech parks

Speaking about medtech parks, Vazirani emphasises that "their success will be critical for the sector's future. However, most of the medtech parks provide no other support other than the land. This has to change. Medtech parks should consider themselves as an integral part of the eco-system and should handhold the industrial units to help them get all necessary Government approvals in a short time."

The general consensus is that strengthening existing infrastructure needs to be prioritised rather than starting from scratch, which could jumpstart the process and save precious time.

Mocherla hails the government's initiative of promoting medtech parks in India to boost infrastructural capacity as a "huge stride towards developing a robust manufacturing ecosystem for medical devices in India. These parks would not only significantly reduce costs of manufacturing but also improve accessibility and affordability of medical devices for the Indian population, thus improving the overall quality of healthcare delivery."

But he also points out, "it is prudent to ensure optimal utilisation of the existing parks before setting up the new medical device parks across the four states. To better support and scale up these existing clusters such as those in Haryana, Maharashtra, and Trivandrum, it would help if we develop ancillary industries and provide common warehousing, 3D printing, testing, and sterilisation facilities. These existing parks could then serve as models for the inception of new medtech parks of the future."

Making India great again

Nath of AiMeD too makes the same point that existing clusters need to be strengthened. He gives examples of how this can be done by encouraging the development of low-cost plastic disposables in Gujarat and Delhi NCR, surgical textiles based in Coimbatore, orthopaedic implants in Gujarat, Maharashtra and Delhi NCR, IOL in Tamil Nadu and Gujarat.

Similarly, medical electronics could be strengthened in Maharashtra, Karnataka and Tamil Naidu by providing laboratories, research linkages with local universities, common R&D and tool room facilities, sterilisation facilities, regulatory support, consultancy and training services, permanent exhibition/showrooms, conference sharing and start-up facilitating centres etc.

Additionally, Nath suggests that medtech parks can be created with common product categories with common technologies so that they are specialised, interdependent cooperative clusters around key common raw material/component suppliers.

For example, he cites that AMTZ at Vishakhapatnam in Andhra Pradesh was envisaged to be focused on medical electronics with mother units of X-Ray tubes (to attract X-Ray manufacturers), magnetic coils (to attract manufacturing of CT scans and MRI equipment) and EMC testing to aiding manufacturing of large medical electronic equipment.

Similarly, Nath/AiMeD recommends that Nagpur's MIHAN SEZ in Maharashtra and Karnal in Haryana should focus on orthopaedic implants and surgical instruments by inviting and supporting a stainless steel alloy manufacturer instead of the industry being dependent on expensive imports from Sweden etc. It

should also have a strategically located logistics hub for medical equipment online traders and for national distributors considering its central distance to all parts of India.

For Chennai, AiMeD's recommendation is to develop a medical park focused on instruments like medical electronics and IVD. Whereas Trivandrum, Kerala's medical park should focus on latex and rubber technology with a commonly shared zero discharge effluent treatment centre.

Moving up the map of India, Nath suggests that UP's Noida should focus on small consumer electronics and mid-sized electronics along with IVD reagents in collaboration with NIB.

Hyderabad, Telangana should focus on medical electrical equipment and implants needing clinical research studies while Karnataka's medical park should focus on embedded and standalone software, AI and IoT app-based products.

The rationale for AiMeD's suggestions is that the focus of an existing or created cluster needs to be on shared backward integrated resources to provide economies of scale and interdependent expertise of core skills and technologies that are complementary but not disruptive competition to existing clusters. Projects that encourage import substitution need to be encouraged and prioritised considering the volume and range of medical devices that continue to be imported.

Nath mentions that AiMeD had recommended this model to the Government of Andhra Pradesh and Chief Minister Chandra Babu Naidu for the state's AMTZ which is now considered a model medical park.

He mentions that the other locations coming up in a planned manner are possibly at Hyderabad and possibly at Nagpur, Bangalore, Gujarat, Haryana, Tamil Nadu and Kerala, Noida and Baddi whose state governments have been in contact with AiMeD and indicated interest.

Nath is of the opinion that "we need to make India great again, not only by attracting overseas MNCs but supporting the Indian champions who are the only fallback option in every crisis including COVID, vis a vis overseas MNC owned company who historically wish to profit from our market but are shy of risking investments in creating factories."

So, while he is thankful to the Department of Pharmaceuticals (DOP) for announcing this Scheme in March and giving further details, AiMeD's request that as in the case of MeitY's PLI Scheme, DOP should consider a special provision to recognise the role of domestic companies (owned by Indians) who "have valiantly fought competition and risked investments within the adverse 12 per cent to 15 per cent disability factor and not only survived but tried to grow."

According to Nath, the growth of the local medical device sector has been stunted due to lack of adequate infrastructure, supply chain and logistics; high cost of finance; inadequate availability and cost of quality power; limited design capabilities; and finally, low focus on R&D and skill development.

Interestingly, Nath specifies that AiMeD doesn't seek direct subsidy for their members / investors. Instead, they seek a revenue support model and CAPEX reduction assistance by way of a coordinating role of state/ centre/medical device park developer and most important, supporting policies that don't cost (and will bring more revenue to Government) by making manufacturing in India gain a competitive advantage over imports. Otherwise, he warns that "these parks will remain as greenfield parks and not create humming factories that generate employment."

AMTZ: A model medtech zone

Choudary of MTaI as well as others single out the Andhra Pradesh Medtech Zone (AMTZ) as an example of a medical device park that is already doing very well. He urges that the other parks should also be developed around either the defence manufacturing corridors which are re-energising thanks to the impetus the government is providing there or the already existing manufacturing/ancillary hubs.

Furthermore, MTaI's view is that all the PLI schemes should be seen holistically and whenever synergies are possible these should be maximised to alter the manufacturing profile of the country. Larger PLI schemes that have significant synergy with medtech should be kept in mind and driven together interdepartmentally. The large

INVESTMENT OPPORTUNITIES IN INDIA'S MEDICAL DEVICES SEGMENT

Projects/promoters: 7
Opportunity: $264.94 million
Private projects: 4
Government projects: 3
Major investors listed: 3M, Abbott, Baxter, Boston Scientific, B Braun

MEDICAL EQUIPMENT MANUFACTURING PROJECTS

Promoter Type	Status of project	Location	Total Project Cost
Private sector	Under implementation, tender awarded	West Sikkim Last updated: August 2020	$135 million
State government	At idea stage	Kerala	$67.5 million
State PSU/State Nodal Agency	Under development	Sultanpur Medical Devices Park, Telangana Last updated: August 2020	$33.75 million
Private sector	DPR/Feasibility Study in Progress	Palghar Medical Factory Upgradation Project, Maharashtra Last updated: August 2020	$27 million
Joint venture	DPR/Feasibility Study in Progress	Atal Nagar Health ATMS Project, Chhattisgarh Last updated on: February 1, 2021	$0.68 million
Private sector	Project completed	Hospital oxygen manufacturing plant Last updated on: August 9, 2020	$0.81 million
Private sector	Idea stage	Instant Diagnostics Devices Manufacturing Unit [Pune, Maharashtra] Last Updated on: August 9, 2020	$0.2 million

(Source: Invest India)

players will create the currents which will assist the small players in their flight and the small players will bring the frugality and innovation which will benefit the large players and push the ecosystem forward, is Choudhary's reasoning.

PLI for IVD sector

However, Vazirani is disappointed that currently, the PLI scheme offers incentives of just three to five per cent for the IVD industry. "Such low incentive is too small to make India a global player. There is a need to increase the PLI incentive to at least 15 per cent for five years to help local manufacturers become global players," is his take.

He points out that the current COVID-19 pandemic has shown that diagnostics is an essential part of preventive healthcare in every country. He does concede that the domestic diagnostic industry is still at a nascent stage, estimated at $9 billion (around Rs 675 billion) and is expected to grow at a CAGR of approximately 15 per cent over the next five years.

"Make in India and the goal for an Atma Nirbhar Bharat can provide the required fillip to achieve this growth. To add to that, the pandemic has further provided the necessary impetus to scale-up domestic production," is Vazirani's analysis.

He alludes to the fact that the Government of India is beginning to recognise the importance of diagnostics in preventing and treatment of diseases, pointing to the allocation of Rs 64,000 crores in the budget for FY 2021-22, with a focus on preventive healthcare. He feels this should aid in boosting local manufacturing of diagnostic equipment and test kits in India.

In fact, the med-tech park model has already benefited Transasia Bio-Medicals with a partnership with AMTZ for various launches like the mobile COVID-19 test lab to help faster and safer testing across India, called Infectious Disease Diagnostic Lab (iLAB), made at Transasia's Vizag manufacturing facility at AMTZ.

Thanks to the facilities and expertise from AMTZ and DBT, I-LAB was conceived and developed at a lightning speed and manufactured and assembled in a record time of eight days.

I-LAB was conceived by the government to ensure testing facilities in lakhs of villages that do not have any COVID testing labs. I-LAB functions like a typical pathology lab with sample collection, diagnostics, and reporting. The entire process of collection, testing and issuing of reports is governed by the guidelines issued by ICMR.

But though it was a great initiative, Vazirani rues the fact that the GoI did not decide to provide an I-LAB to every district of India to cater to the needs of all the villages in each district. If this was done, he feels it would have greatly helped contain the recent spread of COVID-19 in thousands of villages.

Good policy, slow implementation?

The consensus is that while there is nothing wrong with the PLI and med-tech cluster schemes, policymakers need to speed up the implementation. And tweak it as per the requirements of this sector.

In fact more sectors are clamouring to be part of the PLI and cluster scheme.

Sanjaya Mariwala, Founder President of the Association of Herbal and Nutraceuticals Manufacturers of India (AHNM) and Executive CMD, OmniActive Health Technologies makes a case for the nutraceutical sector, pointing out that if the PLI scheme is extended to the nutraceutical industry, it will stimulate the needed investment to grow in size and scale. This will help make India one of the best manufacturing hubs in naturals and botanicals.

As Mariwala points out, nutraceutical manufacturing is a complex process and heavily dependent on raw material availability. Proximity to the farms is very critical for both research as well as manufacturing. While this is an advantage for India, not enough investors are considering this sector due to a fear of technology, lack of willingness to involve themselves in agriculture and supply chains, disinclination to invest in marketing new concepts, and lack of standard guidelines/ policies for manufacturing and quality control. The medical device sector is relatively one of the more recent additions to the PLI scheme and while the work done has been commendable, the pandemic makes the rollout of the PLI and med-tech park scheme more crucial than other sectors.

In fact, one of the completed projects listed on the Invest India site is an oxygen manufacturing plant in a hospital. Another project is an instant diagnostics devices manufacturing unit in Pune, Maharashtra.

Thus no other sector saves lives, creates jobs and makes the country part of a global manufacturing ecosystem. Hopefully, med-tech and med device companies, as well as the state governments who hope to partner with them, will not have to wait much longer for their proposals to become a reality.

viveka.r@expressindia.com
viveka.roy3@gmail.com

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viveka.roy3@gmail.com
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INSIGHT

Boost manufacturing of medical devices to accomplish *'Atmanirbhar'* Bharat Mission

Achal Chawla, Tax Partner, EY India and **Divya Bhushan**, Director, Tax, EY India opine that the new scheme for medical devices and creation of medical device parks would certainly empower the creation of a comprehensive healthcare network that can provide capital intensive facilities required by devices manufacturers along with contemporary manufacturing units capable of playing a critical role in meeting the country's demand

The COVID pandemic has brought unprecedented attention to a nation's need for self-sufficiency in medical devices, supplies and echoed the vitality of being *'AtmaNirbhar.'*

Recognising the need of the times, in July 2020, the Government of India announced the following incentive schemes to reduce dependency on imports of medical devices, promote domestic manufacturing of medical devices, and help create a robust infrastructure:

- Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices, with incentive outlay of Rs 3,420 crores (PLI Scheme)
- Promotion of Medical Device Parks, with incentive outlay of Rs 400 crores

Under the PLI Scheme, incentives will be given to eligible players in specified segments i.e. cancer care/radiotherapy medical devices, radiology and imaging medical devices (both ionising and non-ionising radiation products) and nuclear imaging devices, anaesthetics and cardio-respiratory medical devices including catheters of cardiorespiratory category and renal care medical devices, all implants including implantable electronic devices like cochlear implants and pacemakers.

Achal Chawla, Tax Partner, EY India

In order to qualify for incentives under the scheme, applicants will have to fulfil the minimum threshold investment criteria of Rs180 crores, as also the minimum threshold of incremental sales (over the base year), ranging from Rs 120 crores to Rs 560 crores.

Once eligible, the incentive will be granted at the rate of five per cent, for a period of five years (FY 2021-22 to 2025-26).

PLI scheme is indeed reflective of Government's intention to promote an *'AtmaNirbhar'* Bharat as the country's current dependence on higher-end medical products such as cancer diagnostics, medical imaging tools, ultrasonic scans and PCR technologies is slated to go down post its implementation.

In addition to hopefully making India self-sufficient by meeting its demand for medical devices through locally produced supply, this ambitious initiative of the Government is also expected to put India on the global map as a key exporter of medical devices.

Presently, the Government of India has received 28 applications under the PLI scheme, of which, 14 applications have been approved till March 2021.

Supplementing the PLI scheme is the scheme for the Promotion of Medical Device Parks. The scheme will help strengthen the country's infrastructure base such as component testing centres, create a common warehouse and logistics base, and attract large investment in medical devices segments.

Under this scheme, Government announced its intention to establish four medical device parks of Rs 100 crores per park or 70 per cent (90 per cent in the case of North Eastern States) of the project cost of common infrastructure facilities, whichever is less.

By incentivising such medical parks, the government will create world-class standard testing and infrastructure facilities to drive domestic production smoothly. Additional common warehouse and logistics facilities which also help reduce transportation and warehouse cost.

Divya Bhushan, Director, Tax, EY India

Presently, the Government has received 16 applications from different states, showing an interest in the development of medical device parks.

Looking at success stories of such parks in the past, it would not be amiss to mention the Andhra Pradesh MedTech Zone which was approved by the Government in 2019. The Park produced ventilators, COVID diagnostic kits, N-95 masks and Personal Protective Equipment kits. Equipment – equipment, the importance of which cannot be overemphasised in present times.

The new scheme for medical devices and creation of medical device parks would certainly empower the creation of a comprehensive healthcare network that can provide the capital intensive facilities required by devices manufacturers along with contemporary manufacturing units capable of playing a critical role in meeting the country's demand, especially during the current crisis.

It would invigorate confidence further if the Government relaxed the threshold for minimum incremental sales of Rs 560 crores and investment of Rs 180 crores, as it will enable a greater outreach of the schemes if the window is reopened for fresh applications. Time is of the essence, so speedy implementation of the scheme is key. Any additional allocation of budget for setting up more parks could also help boost production in the near future.

One is optimistic in looking to a future where we are self-sufficient, as now, more than ever, COVID has re-emphasised the importance of a road map to self-sufficiency. The above schemes are indeed a step forward in this direction.

(Views expressed are personal)

INTERVIEW

In India, immunotherapy has emerged as a highly successful strategy to treat malignancies

In March 2020, APAC Biotech received the Indian patent for their cancer immunotherapy product APCEDEN, designed for cancer patients who have exhausted all conventional modalities of treatment. Backed by an advisory board of oncologists from India's leading hospitals, the CDSCO-approved treatment has reportedly proven success in giving these patients median life benefit along with significantly improving their quality of life. **Dr Bandana Sharan**, Director-Research, APAC Biotech, reviews the development of the therapy, its scope, and the infrastructure and staff support hospitals need to put in place to offer personalised cancer immunotherapy, in an interaction with **Viveka Roychowdhury**

How does personalised cancer immunotherapy work? What is the risk-benefit ratio compared with existing therapies?

Cancer is a devastating disease that takes the lives of hundreds of thousands of people every year. There are four main types of standard cancer treatments: surgery, radiation therapy, chemotherapy, and immunotherapy. Due to disease heterogeneity, standard treatments, such as chemotherapy or radiation, are effective in only a subset of the patient population. The development of tumours can have several different underlying genetic factors and may express dissimilar proteins in one patient versus another. This inherent unpredictability of cancer development lends itself to the growing need for precision and personalised medicine.

The role of chemotherapy to overall survival benefit is only approximately 4.3 per cent, due to the limited specificity of chemotherapy drugs. In spite of this, chemotherapy has been the standard of care in treating several types of cancers, and oftentimes it may be the only option treatment available that a patient receives. This low efficacy is not restricted to only chemotherapy, but also to other prevailing cancer treatments as well. It is very important, that several personal factors should be considered before selecting a cancer treatment as, the effectiveness of these treatments depends on many independent factors, such as the type of cancer, carcinoma stage, site of the cancer development, metastasis, and also patient associated factors such as age, immune and genetic predisposition and overall health.

> Limitations of the conventional mode of cancer treatment regimen have paved the way towards more specific, safe, effective and autologous mode of customised immunotherapy, which harnesses a patient's own immune system to fight cancer

Thus, these limitations of the conventional mode of cancer treatment regimen have paved the way towards more specific, safe, effective and autologous mode of customised immunotherapy, which harnesses a patient's own immune system to fight cancer. Immunotherapy treatments include monoclonal antibodies (mAbs), checkpoint inhibitors, cytokines, dendritic cell-based immunotherapy vaccines, and chimeric antigen receptor (CAR) T- cell therapies. The adoption of dendritic cell-based therapy vaccines (DCT) has steered the field of cancer treatment toward the concept of precision and personalised medicine (PPM), in which

therapy selection is tailored to each individual. At APAC Biotech through dendritic cell-based immunotherapy, we try to naturally mimic the immune system to fight cancer.

The benefits of this therapy include its proven safety and complete self-derived autologous mode of action to foster the host immune surveillance system that gets activated through mature dendritic cells primed with an array of tumour antigens (derived from the patient's own tumour tissue) that is infused back into the patient. The risk involves negligible side effects such as mild fever in a few of the reported cases as evident from our clinical trial and other studies performed on DC-based vaccines globally.

How does APCEDEN work? Can you share the results of clinical trials done on the product, in terms of median life benefit, quality of life, other markers?

Our product APCEDEN is an autologous monocyte (CD14+) derived Dendritic Cell (DC) based personalised Immunotherapy that activates the patient's immune system against specific cancer. It acts by stimulating the production of immune cells produced naturally in the body, that target and attack cancer cells. DC itself is an immune cell involved in the recognition, processing and presentation of foreign antigens to the T-cells in the effector arm of the immune system. Although dendritic cells are the most potent Antigen Presenting Cells (APCs), they are usually not present in adequate quantities to allow for an effective immune response in cancer patients. Dendritic cell therapy thus involves harvesting monocytes from the cancer patient and processing them in the laboratory to differentiate into mature antigen-presenting dendritic cells primed with patient-specific tumour antigens which are then infused back into the patient in order to allow massive participation of dendritic cells in optimally activating the immune system against specific cancer.

The results of our clinical trial suggest a significant survival benefit of 199 days for the APCEDEN therapy treatment group when compared with the control group (356 vs 157 days). The event-free survival time of APCEDEN therapy was 439 days in patients who demonstrated an objective response at first evaluation as per immune-related response criteria. APCEDEN demonstrated highly convincing survival benefits, enhanced quality of life in refractory cancer patients with stabilised cancer disease when compared with the control group.

What are the published research papers on this product?

APAC Biotech has six major publications in international peer-reviewed journals. Here is the link for the publications *https://www.apacbiotech.com/immunotherapyresearch*

What is the average cost of such therapies?

Immunotherapy products are sold for approximately $93,000 in the US and similar treatments in China costs around $30,000. APCEDEN developed by APAC, in comparison, costs approximately $10,000 (Rs 7.50 lakhs which includes the hospital charges).

What kinds of cancers can be treated with this product?

Theoretically, we can treat all solid tumours with APCEDEN, but as per DCGI approval, we can treat four indications: ovarian cancer, prostate cancer, colorectal cancer and non-small cell lung cancer (NSCLC).

How common is such therapy in India? How many patients use such treatments annually?

In India, immunotherapy has emerged to be a highly successful strategy for treating malignancies in the last decade. APAC Biotech is a pioneer in such advancement by being the only Indian company which has received a patent for their DCT technology, approval from Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India and manufacturing licence from Food and Drug Administration, Haryana State Government, thus contributing towards Indian economy and Make in India concept. APAC Biotech's Central Lab in Gurgaon is GMP (Good Manufacturing Practices) facility accredited by ICMR and DCGI. We advance in the understanding of the dynamic interaction between the immune system and cancer, and this has resulted in the development of a number of novel therapeutic strategies that harness several aspects of the immune system to treat cancer. About 50 patients are being treated annually through APCEDEN.

What infrastructure and staff support do hospitals need to put in place to offer personalised cancer immunotherapy? Are such services only present in urban areas?

The most crucial infrastructure required for the DCT is a blood bank for conducting leukaphareses, which most of the big hospitals possess. Our services are currently present in urban areas only.

How many hospitals are part of the company's current network? Are there plans to expand this network and if so, how will the 'manufacturing' scale up?

Currently, the company has eight hospitals in its network: Sir Ganga Ram Hospital, Apollo Hospital- Indraprastha (Delhi), Hyderabad, Medanta Mediciti- Gurugram, Fortis Hospital- Gurugram to name a few. They are also slowly expanding to cover more cities. The company is at the moment looking to raise funds to expand its network and to scale up its manufacturing capacity.

Currently, the company has eight hospitals in its network: Sir Ganga Ram Hospital, Apollo Hospital- Indraprastha (Delhi), Hyderabad, Medanta Mediciti- Gurugram, Fortis Hospital- Gurugram to name a few

Do such patients receive help to cover these expenses under any government schemes?

Yes, patients receive cover benefits for prostate cancer under the government scheme through ECGHS.

Does insurance cover such therapies?

Yes, there have been a few selective cases where some TPAs have covered the cost of DCT.

What has been the financial performance of the company over the past 12 years?

Up until 2017, before the government authorisation, the company was purely involved in research and processes to secure government approvals. The financial performance has not been substantial as no marketing team was deployed and it's the perseverance of the current research and development team in securing the authorisations from various hospitals. The company does plan to deploy a marketing and business development team post the investment.

What is the increase in the number of patients treated year-on-year?

The number of patients has increased year on year with nearly, 40 patients in the year 2018, 60 patients treated with DCT in 2019 and despite the COVID-19 crisis we have successfully treated 20 patients in 2020. In the month of January 2021, we have banked nearly 20 tumours.

What are the other products and services under development?

The latest facilities added towards our product enhancement include:

- **Keep My Tumour** that includes Cryopreserving Cancer patient's tumours alive which helps them to benefit from Advancing Cancer treatments and diagnostic technologies that will be developed in the future.
- **LTR-MEMVAXRALEUCEL:** The LTRM vaccine technology works by "tricking" the immune system into treating cancer as it would a viral infection through the reprogramming of powerful immune cells known as dendritic cells. The treatment is personalised (e.g. uses the patient's own tumour protein and own tumour mRNA amplified), and like any successful vaccine, is designed to be long-lasting and dramatically reduce the risk of future relapse. LTR-M will be tried on two very lethal cancer indications namely GBM (Glioblastoma multiforme) and PDAC (Pancreatic ductal adenocarcinoma) where median overall survival is close to 1-1.5 years only.

viveka.r@expressindia.com
viveka.roy3@gmail.com

INTERVIEW

The IVD market will be driven by technology, leading to the development of new devices that use high-end software

Thomas John, Managing Director, Agappe Diagnostics, shares details about the trends, opportunities and challenges in India's IVD diagnostics sector and divulges the company's strategies for growth, in an interview with **Lakshmipriya Nair**

What are some of the major developments in the IVD market in recent years? Give us an overview of the drivers and deterrents to the growth of the Indian IVD diagnostics market.
One of the major developments in recent years includes the advent of automated in vitro diagnostic tools that are efficient, accurate, and error-free in diagnosis. This has in turn led to a big boost in the manufacture of reagents, triggered by research and development initiatives in this area. All these developments have taken place because of the increase in the prevalence of cancer, autoimmune diseases, and inflammatory conditions. We are witnessing the emergence of point-of-care analysers, laboratory-based analysers, handheld personal in vitro diagnostics tools etc.

Agappe Diagnostics is the first Indian company to indigenously develop and commercially make available the three-part haematology analyser, that too during the peak of the COVID-19 pandemic. We are also the first Indian IVD company to launch IoT-based semi-automated clinical chemistry analysers. We are the first Indian company to develop the RT-lamp based COVID test kit, approved by ICMR and CDSCO sanction. These test kits have been accredited by NABL for use by laboratories.

In the coming days, the IVD market will be driven by technology, leading to the development of new devices that use high-end software. The focus will be on technology rather than products.

Molecular diagnostic tools will dominate the market, as much as molecular science is going to dominate the clinical field. Pre-analytics is also expected to be another main driver. Technology adoption is likely to be faster owing to the changes in end-use. One of the main deterrence is the nature of the IVD sector itself. It is price sensitive and often witnesses intense competition in the development of instruments and reagents. The second deterrent is multiple regulatory and standardisation mechanisms that stymie the application of new technology. Currently, there is a lack of clarity on these matters which is preventing Indian companies from making big investments.

Tell us about the shifts that this sphere is witnessing as a result of the COVID-19 pandemic. What are the major lessons learnt from this health crisis and its management?
A significant development brought by the COVID-19 pandemic is that all major players — Doctors, researchers, regulatory authorities, the diagnostics industry, health delivery systems — came together to fight the virus. As the pandemic goes through its course, it is important to take this initiative forward in tandem with the fight against the pandemic.

COVID-19 has taught a lot of lessons. Firstly, it brought out the importance of molecular diagnostics in the precise diagnosis of diseases. It also showed up the big gap in the availability of reliable molecular

diagnostic tools to carry out confirmatory tests and the need for affordable diagnostics technology with faster turnaround of results. The absence of a strong local IVD manufacturing sector could be felt during the pandemic. Despite all these, our experience shows that the pandemic has witnessed the emergence of several indigenously developed technologies. Medical devices/IVD companies have incurred considerable expenditure in R&D for developing COVID-19 detection and prognosis kits and other consumables.

At Agappe, we have given emphasis on technology, investing over five per cent of our revenues in R&D. As mentioned earlier, we launched the three-part haematology analyser and the COVID-test kit. The IVD sector has an important role to play because the shift will be to pre-analytics and post-COVID prognosis, even as the co-morbidities become exposed in the post-pandemic phase. Preventive healthcare will also play a major role, requiring the Government to seriously rethink its strategies.

How has the government's thrust on Make in India and support for indigenous manufacturing of medical devices helped the IVD diagnostics sector? How is Agappe Diagnostics poised to benefit from these schemes and policies?

The Government of India's medical devices policy and the PLI scheme have been widely welcomed by the industry.

But one should understand that the Medical Devices policy pre-dates COVID-19 pandemic. Therefore, its outcome must be evaluated in the context of the pandemic and the lessons it has taught us. As mentioned earlier, the pandemic exposed the virtual non-existence of a local home-grown industry.

We strongly hold the view that the "Made in India" products must be competitive on quality as well as cost-effectiveness. The focus should be on technology solutions developed locally through strong R&D to meet our nation's needs. We also require an ecosystem to commercialise innovations and incremental innovations into reliable products. In this context, the Government policies need to be fine-tuned further so that investments in the IVD industry goes hand in hand with innovations and technology development.

We feel that both challenge and opportunity lie in recognition and rewarding of Innovations and incremental innovations of domestic Medical Devices/ IVD industries, particularly those companies that have invested time, energy and funds to make "Make in India" happen. To take this forward, we suggest that expenditure in R&D incurred by domestic/homegrown IVD companies be considered for reward and factored into the PLI scheme.

Secondly, the Government should announce a Preferential Purchase policy and Pricing policy. This will go a long way in assisting domestic/homegrown IVD manufacturers achieve the scales of revenue/sales to beget the benefits of the PLI scheme.

What are your recommendations to ensure the sustainability of the IVD sector in the long run to achieve true *Atmanirbharta?*

India has always laid emphasis on 'HealthCare for All'. Preventive health is one of the major components of this policy. Diagnostics plays an important role in preventive health since most of the diseases are diagnosed at the pre-hospitalisation stage. Over 15-20 per cent of the health care cost is accounted for by pre-hospitalisation or pre-surgery diagnosis. These tests are not covered by insurance. To ensure the sustainability of the IVD sector and truly achieve *Atmanirbharta*, pre-hospitalisation and pre-surgery diagnosis should be brought under the insurance coverage. If necessary, the government should bring in new legislation or move an amendment to the existing insurance laws to facilitate this. Such a change will go a long way in achieving preventive health and further the national goals of 'Healthcare For All'. Apart from the fact that it would ensure the sector's sustainability in terms of technology development and affordable products, it would address the healthcare issues of the rural population.

Tell us about Agappe's plans for the next three years. Any major investments and collaborations in the pipeline?

After launching the first semi automated specific protein system in India in the year 2011, today we control the protein estimation in India and the neighbouring market, making specific protein-based diagnosis and prognosis affordable to the masses. Our recent launch of Mispa Count X, the first Made-in-India, three-part haematology analyser is another milestone towards our commitment to *Aatmanirbhar Bharat* as envisaged by our government. Our aim is to become the number one IVD company in India by 2025.

What is the change that Agappe intends to bring about in India's diagnostics sector? How are you working towards it?

Agappe is always known as a true innovator in the IVD sector, bringing out revolutionary products. Our success mantras are Innovation, Quality and Affordability. We have industry-industry partnerships and industry-academia partnerships to enhance our product portfolio. We are planning to introduce compact and user-friendly systems in haematology, clinical chemistry, immunology and molecular diagnosis. Our aim is to bring in affordable solution in the IVD segment to address the masses in India and nearby developing countries.

lakshmipriya.nair@expressindia.com
laxmipriyanair@gmail.com

Diagnosis is better than disease

Rajesh Patel, CEO, IVD - India, Trivitron Healthcare elaborates on the crucial role played by diagnostic tests at every step of disease management – diagnosis, monitoring, screening and prognosis

There are rights to which we are entitled, simply by virtue of our humanity. Among all the rights to which we are entitled, health care may be the most intersectional and crucial. Universal health care is crucial to the ability of the most marginalized segments of any population to live lives of dignity. And for better healthcare, the need for detection and timely treatment has clearly emerged as the need of the hour. In healthcare, diagnosis helps improve patient care, contributes to protecting a patient's health and in some cases even helps limit healthcare spending.

For over half a century that has gone by, innovations in diagnostics transformed the practice of medicine. Advancements in technology have further enabled the development of new generations of diagnostic tests. These technologies have revolutionised healthcare, by guiding timely medical intervention.

Diagnostic tests play a crucial role at every step of disease management – diagnosis, monitoring, screening and prognosis.

Diagnosis

Diagnosis helps find out if a patient is suffering from a specific condition. A diagnostic test detects a possible condition or confirms the lack of one. Sometimes diseases need to be studied over and over for not just their nature but also their stage or degree of development. Diagnostic tests form the framework with which healthcare professionals are able to better assess the effectiveness of the chosen treatment in stopping the progression of the disease.

Monitoring

Some chronic diseases cannot be cured, but the chosen treatment, medications, hormones and lifestyle changes can go a long way in avoiding a worse situation in the future. Monitoring look for decrease or increase in the disease, which helps in multiple treatment options.

Screening

Some diseases like the modern COVID-19, while in the initial stages, may present minimum or no symptoms at all. This is where screening comes into play. Screening studies patients who do not yet present any symptoms for a particular illness, to find out if the illness has begun to develop quietly. These tests are sometimes applied to populations at community levels and are therefore affordable and easily accessible by all.

Prognosis

Prognosis is a little far-fetched, in that it helps assess the likelihood of developing a disease in the near or distant future, thereby assisting a patient to take necessary precautions much earlier than required of him. Genetic tests, for instance, analyse a patient's predisposition for developing a disease, allowing the patient and his doctor to be more attentive to discovering early signs and to take preventive measures.

Thus, diagnosis is integral to the process of detecting, treating, producing accurate results and curing illnesses. Diagnostic tests impact major healthcare decisions, though it also relies on an accurate interpretation of the test results, judgment and an expert bent of mind in prescribing the treatment.

Chest CT illuminates mortality risk in people with COPD

A greater amount of intermuscular fat was associated with higher mortality rates

Body composition information derived from routine chest CTs can provide important information on the overall health of people with chronic obstructive pulmonary disease (COPD), including their risk of all-cause mortality, according to a study published in *Radiology*.

COPD is a group of chronic, progressive lung diseases like emphysema and chronic bronchitis that affect about 30 million people in the US alone. It is frequently associated with obesity and sarcopenia, a loss of muscle mass and strength. Obesity is associated with lower mortality in patients with COPD. The longer survival rates of obese patients compared to leaner counterparts, a phenomenon known as the "obesity paradox," has been suggested in several chronic illnesses.

Chest CT is often used to characterise COPD, screen for lung cancer, or plan for surgical options. Beyond lung assessment, these exams offer an opportunity to assess obesity and sarcopenia through soft-tissue biomarkers.

"Chest CT scans have long focused on the lungs or heart. Few prior investigators have evaluated muscle quality, bone density, or degeneration of the spine as an index of overall health. These are readily available and quantifiable in these CT examinations," said study co-author and Radiology editor David A Bluemke from the University of Wisconsin School of Medicine and Public Health in Madison, Wisconsin.

For the new study, Dr Bluemke, along with Farhad Pishgar and Shadpour Demehri from Johns Hopkins School of Medicine, and colleagues used chest CT exams to study the associations between imaging-derived soft tissue markers and all-cause mortality in COPD.

The study group was made up of 2,994 participants drawn from the Multi-Ethnic Study of Atherosclerosis (MESA), a large trial investigating the roles of imaging-derived soft-tissue and bone markers for predicting outcomes relevant to cardiopulmonary diseases. Of the 265 patients in the study group with COPD, 49 (18 per cent) died over the follow-up period.

A greater amount of intermuscular fat was associated with higher mortality rates. Existing research has linked higher levels of intermuscular fat with diabetes and insulin resistance.

Higher subcutaneous adipose tissue, in contrast, was linked to lower risks of all-cause mortality.

The authors convincingly showed fat in the muscle was much more predictive of bad outcomes than a simple distribution of subcutaneous fat.

The findings point to a role for body composition assessment in people with COPD who undergo chest CT. Such assessments are readily obtainable in clinical practice.

In theory, CT-derived body composition assessments would provide an opportunity for earlier interventions in patients who face a higher risk of adverse health events.

Body composition assessments taken from chest CT also present an opportunity for artificial intelligence-derived algorithms that could quickly and automatically add risk assessment to the imaging report.

"I expect that more studies in the future will begin looking at all information on the CT, rather than just one organ at a time," Dr Bluemke said. "Clinicians will need thresholds when to intervene when fat or bone abnormalities become severe."

The study was just the latest to tap into imaging data from the MESA trial, a collaboration involving more than 6,000 men and women from six communities across the US.

Digital breast tomosynthesis reduces rate of interval cancers

A reduction in the interval cancer rate when using DBT might be attributed to improved detection of rapidly growing cancers with poorer prognosis, possibly contributing to lower breast cancer mortality

Screening with digital breast tomosynthesis (DBT) reduces the rate of interval breast cancers compared to screening with digital mammography, according to a study published in *Radiology*. The study adds to a growing body of evidence supporting DBT as a breast cancer screening tool with important advantages over mammography.

DBT works by capturing a series of X-ray images of the breast from different angles. Previous research has shown that it has a higher sensitivity for breast cancer detection than digital mammography.

The impact of these additional DBT-detected cancers is not fully understood. While they may constitute a screening benefit, they could also contribute to overdiagnosis, a term for the diagnosis of early-stage, slow-growing cancers that would not have caused harm to the patient in their lifetime.

The rate of interval cancers—cancers that arise between routine screenings—offers one way to better elucidate screening benefits. They are considered more aggressive than cancers detected during a screening exam.

"Interval cancers have, in general, a more aggressive biological profile than screen-detected cancers," said study lead author Kristin Johnson, radiology resident at Skåne University Hospital in Malmö, and Ph.D. student at Lund University, Sweden. "This means that the prognosis is less favorable for interval cancers compared to screen-detected cancers."

Interval cancer detection rate reporting is required in many screening programs as an indicator of effectiveness. A reduction in the interval cancer rate when using DBT might be attributed to improved detection of rapidly growing cancers with poorer prognosis, possibly contributing to lower breast cancer mortality.

For the new study, Dr Johnson and colleagues compared interval cancer rates in Sweden's population-based Malmö Breast Tomosynthesis Screening Trial with those from an age-matched control group of patients who underwent digital mammography at the same center.

The study group included almost 15,000 women who were screened with DBT and digital mammography between 2010 and 2015. Those women were matched with a control group of more than 26,000 women who had only digital mammography screening during the same time period.

The interval cancer rate in the patients screened with DBT and digital mammography was 1.6 per 1,000 screened, significantly lower than 2.8 per 1000 in the group screened with digital mammography only. The interval cancers in the trial generally had non-favorable characteristics.

The reduced interval cancer rate after screening with DBT could translate into screening benefits, according to Dr Johnson.

"One could speculate that some of the additional cancers detected in DBT screening would have been diagnosed as interval cancers if not detected by DBT," she said.

The results support the growing evidence of DBT as a screening modality with potential to replace digital mammography in future breast cancer screening. However, Dr Johnson cautioned that other trials have not shown significantly reduced interval cancer rates in DBT screening compared to digital mammography screening. And interval cancer rates, while important, are not the only measure when evaluating the potential benefits from DBT in screening.

"Other factors, such as cancer types detected and cost-benefit, have to be taken into account," Dr Johnson said.

Toward that end, the researchers are working on a cost-benefit analysis of the Malmö Breast Tomosynthesis Screening Trial. They are also analysing the trial for false positive recalls, those instances when patients are called back for additional screening for suspicious findings that end up being benign.

Digital tools as medical devices for transformation of healthcare services

Dr Paritosh Basu, Senior Professor, NMIMS School of Business Management elaborates on some potential applications of digital platforms and tools that can help implement India's National Digital Health Blueprint successfully

The COVID-19 virus has exposed the healthcare shortcomings of nations across the world, forcing us all to realise the magnitude of the chasm in our infrastructure for healthcare service delivery. All countries, irrespective of their levels of economic development, have been caught underprepared, and India is no exception to this stark reality.

Globally, countries have realised that preventive measures reduce burdens of hospitalisation, intensive care, and expensive treatments. The quicker the response time, the lesser would be the intensity of crises escalating with unmanageable dimensions. Universal altruism should be the mantra for ensuring collaboration among stakeholders within and across all nations and multilateral agencies.

For any healthcare infrastructure, the major building blocks are collection, safe storage and analytics of data related to citizens' health and medical conditions across societal strata, service providers, manufacturers of medicines and devices, results from their applications, and research. This should be supported by appropriate documentation following a prescribed set of guidelines. One would not come to a different conclusion even if the present pandemic is taken out of our calculations. Well-defined policy guidelines with an orchestrated plan for action is the clarion call of the day.

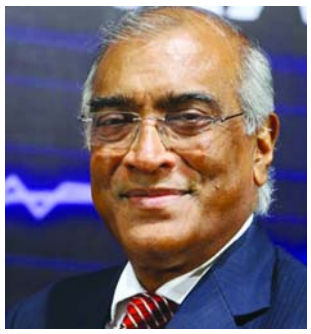
India's National Digital Health Blueprint

In July 2020, NITI Aayog shared India's National Digital Health Blueprint (NDHB) as a sequel to the National Health Policy, 2017 (NHP). This Policy laid down the key principles of "... citizen-centricity, quality of care, better access, universal health coverage, and inclusiveness", and Paragraph 5.4 of the NDHB further outlines "Methods & Instruments recommended by NDHB'. All these, inter alia, reveal the government's objectives and intent for applications of digital tools and platforms, for delivering healthcare services with a smile.

Here are some potential applications of digital platforms and tools that can help implement India's National Digital Health Blueprint successfully:

■ **Blockchain-based healthcare platform:** A blockchain technology-based platform can seamlessly record and help medical and health management right from expression of need to settlement of payments/availing of government grants. It can also update, stack and store citizens' identity, health data and documents in a retrievable digital library. The encryption of all inputs facilitates safety, privacy, security, immutability, auditability, and transparency, for patients as well as medical services providers. Authorised participants of this platform would have two separate keys for accessing and performing transactions from individual nodes of the 'Distributed Ledger Platform', which Blockchain is synonymously known as. Because of all these features, the information contents of the platform would be near impossible to be hacked, modified, erased, or exploited with ulterior motives.

This platform operates with a digitally embedded 'Super Smart Contract' and event-specific smart Contracts', to be digitally signed by and between stakeholders with/without modification(s). The terms of such contracts typically ensure compliance with policies and SOPs



for achieving related legal provisions and objectives outlined in the NHP and NDHB. This process would forestall citizens' anxiety towards digital enslavement.

Such a platform can be designed with a pyramidical node structure, from individual citizens at the base, to local municipalities/panchayats, to district and state levels. It can be integrated with the similar platform of the federal government for interoperability. This design would help in achieving cooperative federalism, which is NDHB's fourth objective.

■ **Cognitive intelligence and data analytics:** The fifth objective of NDHB is to promote health data analytics and medical research. Applications of Artificial Intelligence (AI), Machine Learning (ML) and Big Data Analytics would help in achieving this objective. Digitalised core health data, various test reports, doctors' prescriptions, surgical history, etc., can all be retrieved directly from the digital library. Films for X-Rays, Sonography, CT Scans, etc., can also be analysed for predictive analysis and diagnosis.

Similar research-oriented data analyses can also be conducted for service providers, such as insurance providers, hospitals, doctors, paramedics, pathological and radiological laboratories; manufacturers of medicines, medical kits, equipment, devices, oxygen; and related logistical arrangements, etc.

The results from such studies would help in identifying trends in citizens' health conditions segmented by age groups, gender, comorbidities, geography, etc., and insightful inferences drawn about the efficacy of medical tests, treatment methodologies and drugs administered. The aforementioned blockchain platform can be seamlessly integrated to ensure the collection of data without any human intervention and maintaining only one version of the truth. After all these processes are performed, the following objectives of NDHB would, in all probability, become achieved realities:

- Enhancing the efficiency and effectiveness of governing healthcare services across all strata of society with speed and timeliness,
- Ensuring quality of healthcare, and
- Leveraging the legacy information systems already existing in the health sector.
- Integration of equipment and devices

■ **Integration of equipment and devices:** Digital transformation of diagnostic tests, teletreatment, robotic surgical procedures, and the like, would help in interconnecting and updating events and records online on a real-time basis. We have already witnessed the impact of APIs and Bluetooth in instances such as connecting smart stethoscopes enabling doctors to view ECGs on their smartphones. Tools such as Internet of Body (IoB), integrated into a patient's body, and Internet of things (IoTs), integrated into Sonographers, CT Scanners, Ventilators, etc., would help in transmitting signals directly to the attending doctors' computers. With such interventions, doctors would even be able to monitor patients' sleeping patterns.

■ **Software as a medical device:** The software used for all the above digital solutions would serve as a medical device for improved speed and quality service deliveries, and would help prompt accurate diagnoses and treatment-related decisions for saving precious lives. Edge computing software would help in reducing load and accelerate data processing. Software used for the 'AmazingTrio', viz., Blockchain, IoT and AI, would fast update Blockchain nodes using RPA and Bots. It is also advisable to introduce Central Bank Digital Currency for enabling blockchain platforms in the impromptu settlement of financial transactions.

■ **Digital Health Passport for international travelling:** The day is not far when international and domestic travellers would need to carry another passport to cross sovereign/state boundaries other than the one issued by immigration authorities. This Health Passport would be digitally issued and managed by the same Blockchain Platform.

India has taken on a colossal challenge in embarking on this long journey in the quest to ensure good health for all. Yet, none can conclude that it is not achievable. Our nation must derive benefits from its vibrant startup ecosystem and cerebral innovators, and there is an immediate need to coordinate the efforts of all stakeholders.

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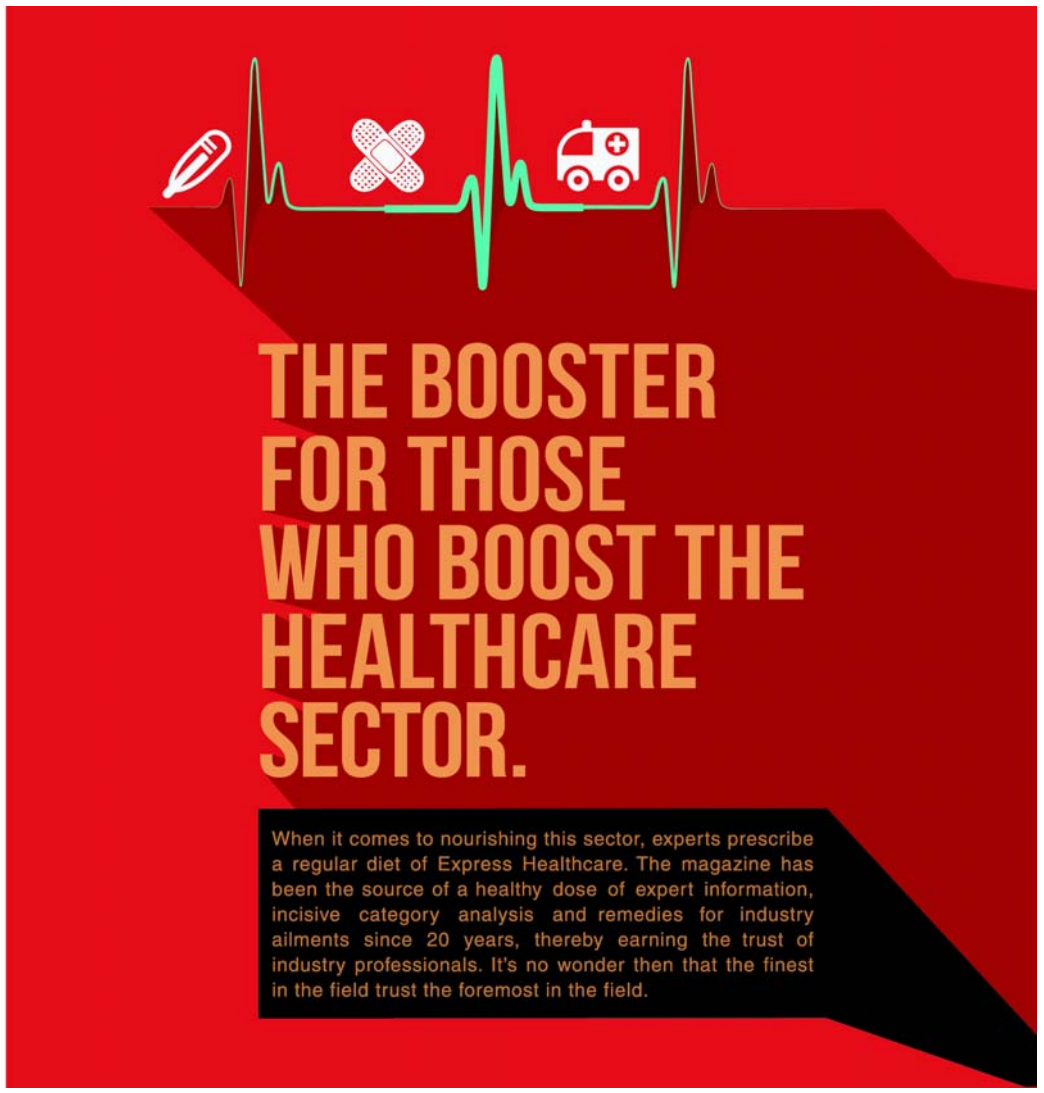


INTERVIEW

GE's Centricity High Acuity – Critical Care solution has helped with better patient outcomes in the ICU

Dr Sunil Kumar Garg is a Senior Consultant from the Institute of Critical Care Medicine and the Founder of Saiman Healthcare. Saiman Healthcare prides itself in bringing critical care to patient's homes at an affordable cost. Dr Garg recently adopted GE's Centricity High Acuity – Critical Care solutions. Here he tells us how remote monitoring devices are making a significant difference to the way critical care is shaping in India and how this is redefining the future of Indian healthcare

What made you start Saiman Healthcare?
After completing my MBBS and MD from Rajasthan in 2007, I did my higher training in Critical Care Medicine in Delhi. While working at a multi-speciality hospital there, I saw ahuge gap that needed to be filled. Although many speciality hospitals are providing intensive care around the capital, their skyrocketing prices would often drive the patients back home. While cost and limited beds were my concerns, I believe healing happens faster at home, where you are surrounded by your loved ones and positive vibes. That's why I decided to bring quality critical care to patients' homes. Today, we are operating in and around Delhi, we plan to scale up to tier 2 and tier 3 cities soon and slowly make 'ICU at home' a reality across India.

What made you adopt Centricity Solutions?
Critical patients require constant and continuous monitoring. With the doctor to patient ratio so inadequate, we were faced with various challenges in terms of providing timely care to our patients through other means. Our clinicians and staff were overworked and overwhelmed with patient data, prescriptions, management, and monitoring.

That's why we decided to leverage GE's Centricity Virtual Care solution. An easy-to-use and easy-to-train device, it provides the ICU staff with 24/7 support, eliminates the need for a dedicated virtual solution, and leverages existing integration.

How have your patients taken to this new form of treatment? Are they comfortable with the doctor not present physically?
What's better? The doctor present virtually or not present at all? One doctor cannot tend to every patient 24/7. That's the reason we adopted the centricity solution. Now the patients stay home and heal faster. GE's Centricity Virtual Care solution and its advanced

analytics prompt and trigger real-time clinical experts with video support. So, we are always there for our patients and this instils confidence in them, which probably helps in faster recovery.

How has this impacted your hospital's functioning?
It has helped us on two fronts. One, in terms of providing thebest possible care to our patients,and two, empowering our staff with the confidence to handle critical cases seamlessly. Where earlier we were struggling to track and monitor patient treatment and care through WhatsApp and legacy systems, today our nurses can provide diligent ICU care from their command centre, which manages all the patients' data single-handed.

How has patient treatment changed since adopting Centricity High Acuity?
This solution has helped with better patient outcomes in the ICU. From our earlier nurses to patient ratio of 3:1, today we have moved to 2:1. It's just a matter of time before remote patient care devices become a household name. With less severe cases showing up at hospitals, more beds can be allocated to needy and critical patients, accurate and timely care can be provided to patients at all times, making disease management more efficient and effective.

What metrics are you tracking to measure improvements in care delivery?
There has been tremendous improvement in the way intensive care is carried out today. We can constantly monitor our patients and maintain protocol standards even with a high volume of patients. The disease exposure threat to the clinicians has been minimized. Data management and archiving have become simple, which leaves the nursing staff with more time to take care of the patients and not focus on the administrative work.

For support, contact:
1800-102-7750, 1800-419-7750, 1800-425-7255 or 1800-425-8025 | gehealthcareservices@ge.com | TeamGEHealthcare@ge.com

GE's Centricity Virtual Care solution is an easy-to-use and easy-to-train device. It provides the ICU staff with 24/7 support, eliminates the need for a dedicated virtual solution, and leverages existing integration

INTERVIEW

Venue Go is able to show clinicians everything in one go from head to foot in the shortest time possible

Prof Dr N Ganapathy is the Chairman of Dhanvantri Hospitals situated in Erode, TN. He is specialised in Critical Care. He has led the hospital in the use of cutting-edge diagnostic and clinical tools for medical treatment and interventions. This has made treatments accessible to the rural and semi-urban populace while providing basic healthcare, with techniques that are on par with international standards. Below he tells us how the use of Venue Goby GE Healthcare, a Point of Care Ultrasound has made a significant difference to the way treatment outcomes are managed in his hospital

How are common workflow gaps addressed with the use of Ultrasound?
Working in a hospital in a small town like Erode can be very demanding given the large number of patients we see - both in-patient and across remote areas. Patient management is a time intensive process that needs the coming together of several different modalities and procedures. Having a varied set of diagnostic tools often means long waiting times to take major critical decisions. This impacts morbidity and mortality outcomes and can prove labour and cost intensive. Having the Point of Care Ultrasound machine has been a boon in reducing several of these diagnostic impediments - accuracy of procedures, efficacy of outcomes, progress of treatment and making a tangible and significant impact on the people we treat.

Since how long have you been using Ultrasound for Point of Care applications?
Point of Care Ultrasound is a very good tool being used in our hospital since 2000. For the last 20 years, it has made a big difference in the way diagnostic tools are accessed and used. In today's times ultrasound is no more the purview of a specialist but is quickly replacing a physician's stethoscope.

How is the Venue Go product making a difference in your clinical practice over the previous generation of Ultrasound?
Being a bedside portable machine, it is able to show us clinicians everything in one go from head to foot in the shortest time possible.

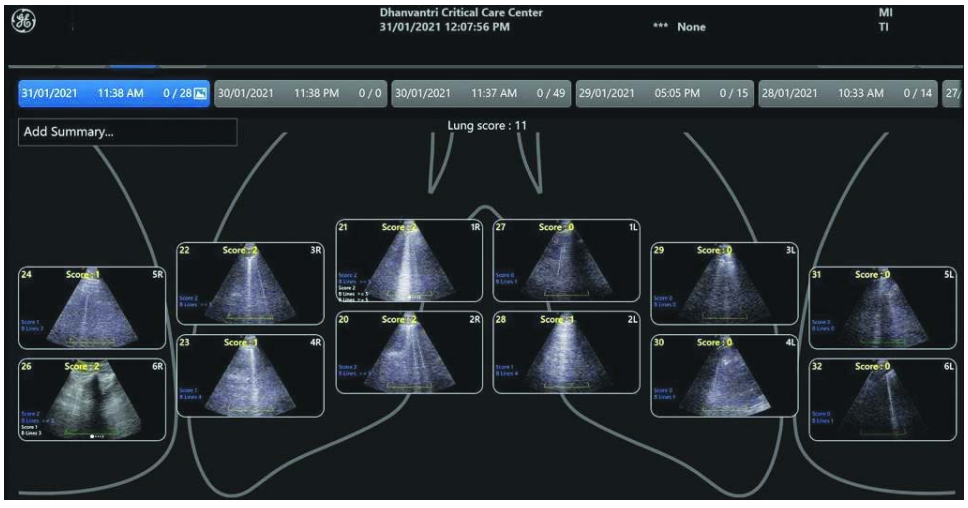
We've been carrying the stethoscope, ultrasound and so many tools with us everywhere. Now one intelligent, precise machine can do everything. Previously, a stethoscope was used to get heart rate, but now the POCUS probe can be placed directly on the heart to know

what is happening even at the tissue level. I wholeheartedly suggest this device to be made mandatory in the MBBS curriculum, internship and in final year medicine. Students should be focused and trained in point of care ultrasonography.

Senior staff nurses are already getting trained in this, so they know what to do and conduct early diagnosis using first level indicators. In normal circumstances, we get 8-10 cases at our hospital. Each case takes 60-90 minutes with this machine, for in-depth examination from head to foot including arteries, bones, soft and hard tissue. This machine saves time in emergencies and critical care cases.

How does lung sonography help in respiratory diseases such as current pandemic?
In case of COVID-19 and other respiratory diseases, reading lung scores is unimaginably good through this machine, and MRI doesn't need to be done. There are several papers published on this. With rampant cases of Pulmonary Fibrosis and Toxicology, this machine helps visualise improvement of the lung condition thereby impacting treatment. It shows improvement of oxygen saturation, tissue repairs and more.

Bronchoscopy and culture sensitivity which is normally done for lung problems takes time to assess, and we often begin treatment for such conditions before reports come in. With this ultrasound, we can see changes almost immediately, whether patient is deteriorating or improving. It helps pre-empt diagnosis and doesn't require shifting of patients during MRI, because everything happens at the bedside.



Lung Score

What is the future of Artificial Intelligence in Point of Care Ultrasound space?
Artificial intelligence is revolutionising medicine, giving us new precise perspectives to use our skills and treatments. Using the AI tools of Venue Go, i.e. Auto B-Lines and Auto IVC, helps in providing quick diagnosis, early treatment and getting patients back to their daily lives faster. This also helps in equipping students better for the long run.

Radiometer Medical India launches 24/7 Toll-Free Helpline Number for its customers

This helpline number was commissioned from April 15, 2021 to help improve customer service

Radiometer Medical India announced the launch of its 24/7 service helpline through single Toll-free number 1800-266-3837 for its customers in India which will commence from April 15, 2021. In the wake of the pandemic, ensuring timely and quality service to every customer gained a lot of impetus, making the need of timely support exceptional and more pronounced.

The launch of this 24/7 helpline service will give an extra boost to the Customer service efforts made by Radiometer Medical India so far. Having a 24/7 dedicated toll-free number will allow the customers to reach out to the Service Team whenever there is a need to troubleshoot. It will be handled by a team of proficient Service Engineers who will be equipped to diagnose the breakdown of the analysers and take necessary pre-emptive actions in allocating the resources in case the site needs to be visited. Backend integration of this helpline with LIVE Connect, the exclusive remote service solution offered by Radiometer Medical will allow Service Engineers to remotely monitor and access the analyser.

Speaking on this occasion, Radiometer Medical India, General Manager, Smit Dave was quoted as saying, "In critical care settings, time is LIFE. There is no technology in the world which cannot face a breakdown. By having a 24/7 customer support on Toll Free number, we expect to reduce the TAT during such breakdowns and thus stand shoulder to shoulder to our clients. We want to be available all the time. That is our purpose, our value proposition – Whatever comes next, we make sure life comes first."

Adding to that, Radiometer Medical, Vice President – Global Services & Customer Support, Anders Myhre was quoted as saying, "Delivering uninterrupted customer service and expertise have always been our focal point. The unprecedented COVID crisis has however made it quite challenging. Amidst the travel restrictions, it wasn't easy for the Service Engineers to be available at customer's site to attend breakdown calls, given that several installations are at remote locations in India. The launch of 24/7 toll-free helpline is our promise to support our customers round the clock. This helpline will further harness the existing capability of remote diagnosis of analysers through LIVE Connect, allowing our Service Engineers to remotely troubleshoot, ensuring speedy resolution, remote security updates, reduced downtime and improved productivity at customer's site." Diagnosing the analyser remotely will allow the service team in quick closure of cases of breakdown, sparing the Service Engineers time to resolve more cases every day.

Ana Magalhaes, Radiometer Medical, Director – Customer Experience & Training, stated, "With a dedicated helpline number, our team of Service Engineers will be just a phone call away from our customers. The 24/7 helpline will ensure customers have convenient, round-the-clock access to Radiometer leading to less downtime, if any. At the end of the day it is about ensuring a positive experience and an enhanced level of satisfaction to all our customers."

Radiometer Medical India aims to deliver unmatched customer service support to every customer at all corners of India with an effort to reduce complexity and increase automation.

About Radiometer Medical

Radiometer is a medical device company. At Radiometer, our mission is to help caregivers make diagnostic decisions that save lives. We help develop products and solutions that provide healthcare professionals with the critical information they need in acute care diagnostics. Our diverse community of colleagues share a common identity, mindset, and purpose to empower caregivers to make diagnostic decisions to improve patient care, because for us, answering what's next in health care starts with what comes first – life.

CASE STUDY

Remote solution improves cardiac care

GE's remote consult ECG solution comprises a cardiology information system that integrates, manages and streamlines the flow of cardiac information

Cardiac care challenges in North East India

To date, India clocks 2.1 million deaths every year - with rural residents overtaking the urban populace. 1 While thought to be more prone to infectious diseases, now the northeastern belt in India is facing health conditions arising from lifestyle disorders.

ECG machines, the critical diagnostic tool for heart ailments is available mostly in urban areas, but their penetration in rural setups - especially tier 2 and 3 cities - remains largely inadequate., with most experts operating almost exclusively in cities.

The need for a solution that could increase cardiac care penetration in this market, breakthrough the infrastructure challenges and harness better diagnostic interpretations prompted Dr Bikash Rai Das, Cardio Thoracic Surgeon and Chief Cardiologist at AccuRate Labs Guwahati reach out to GE Healthcare to address the problem.

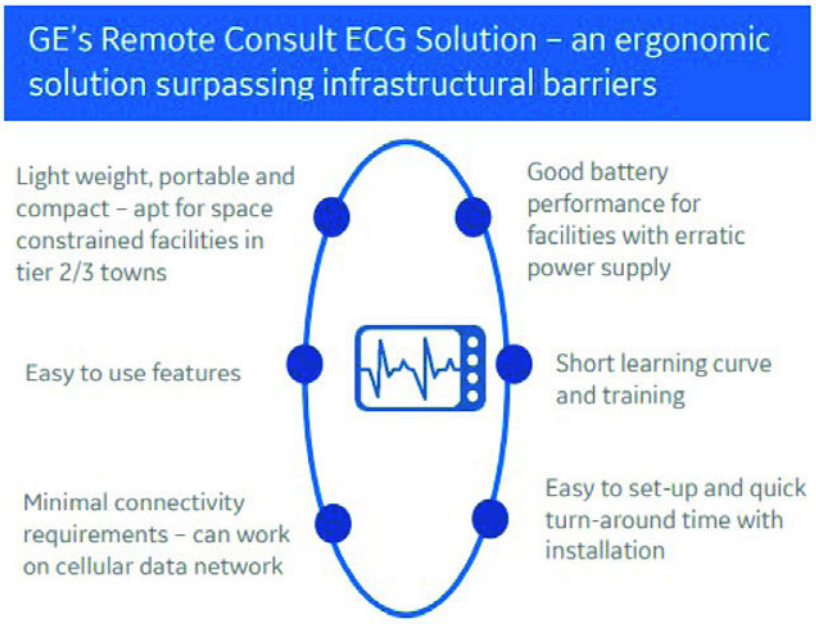
As a result, GE Healthcare's Remote Consult ECG Solution - a potable, compact solution with a central hub integrated with remote medical devices for the reporting and analysis of medical data - was developed in 2018.

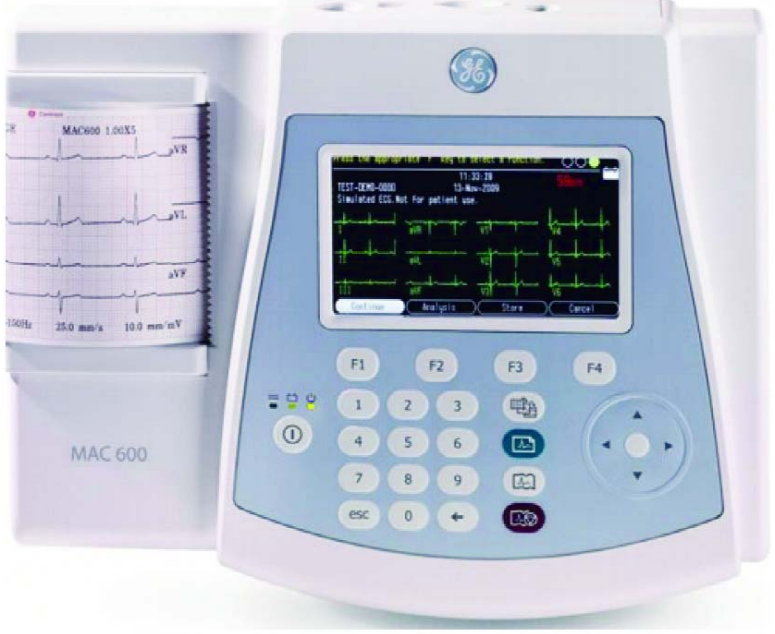
"When I saw patients losing their life due to lack of such basic facilities, I knew something has to be done. Saving lives by ensuring early detection was the only motivation when I decided to invest in this project," - Dr Das.

GE's remote consult ECG solution

Lightweight, compact, and requiring minimal connectivity with a quick turn-around-time, the solution comprises a cardiology information system that integrates, manages and streamlines the flow of cardiac information. The system connects data with diagnosis. Comprising a central hub with the AccuRate Lab as the centre of excellence, the solution acquires patient data from general physicians at nodal centers across remote parts of Assam, analyzing and interpreting the data for further diagnosis and treatment. Unlike the traditional ECG, the solution is robust, scalable and integrates with devices as varied as
Cardiac assessment system for Exercise Testing to Ambulatory ECG's, streamlining workflow and clinical benefits.

Built along the hub and spoke model, the ECG systems were installed at Guwahati's primary facility as well as various hospitals and clinics around the state. Nurses and technicians were trained to use the simple solution and interface with the central facility, while expert cardiologists reviewed the ECG graphs 24/7.





Feeling the beat of impact

Within 7-8 months, the solution was extended to more than 25 facilities in Assam, including some of the most remote parts of the region. The review of ECG reports by trained cardiologists 24/7, significantly improved quick medical interventions ensuring positive results. Tertiary care physicians who directly interacted with patients, received well-interpreted reports within 10 minutes of conducting ECG on patients. From 33 reports being generated per month across five centers, the lab currently generates more than 600 reports across 13 centers. An unexpected positive outcome of the solution has been the accidental discovery of underlying health conditions by specialists prior to elective surgeries, thereby reducing complications and morbidity. Infrastructure and setup costs have reduced. The solution has also shown capabilities of functioning in transit while patients are moved from ambulance to healthcare centers.

"Before the installation of Remote Consult ECG Solution, it would take a week to get the ECG data interpreted, now it takes 10 minutes, and seamless communication with physicians and cardiologists seated across remote areas of the state." - Bijit Rai Das, Chief IT Manager, Accurate Labs

There are very few practicing cardiologists in most remote locations in India. As per recent statistics, India has ~4,000 cardiologists, while 88,000 are needed to cater to the population. In few states and regions, the presence of cardiologist is negligible. Thus, sparsity in specialists has led to delayed representation of cases at tertiary care setups followed by high risk of mortality.

"Cardiac care has made progress in leaps and bounds in India...though access to quality and timely care is still a big roadblock especially in rural communities...where reliable equipment and expertise would be major challenges...hence people would delay seeking consultations and conducting investigations despite complaints and symptoms. I congratulate and thank Dr Bikash Rai Das and team for being the early adopter and mastering the Remote consult ECG technology well to save precious lives from the day one they started using the Remote Consult ECG solution." – Amit Mohan, Business Head - LCS & LCS Digital, GE Healthcare South Asia

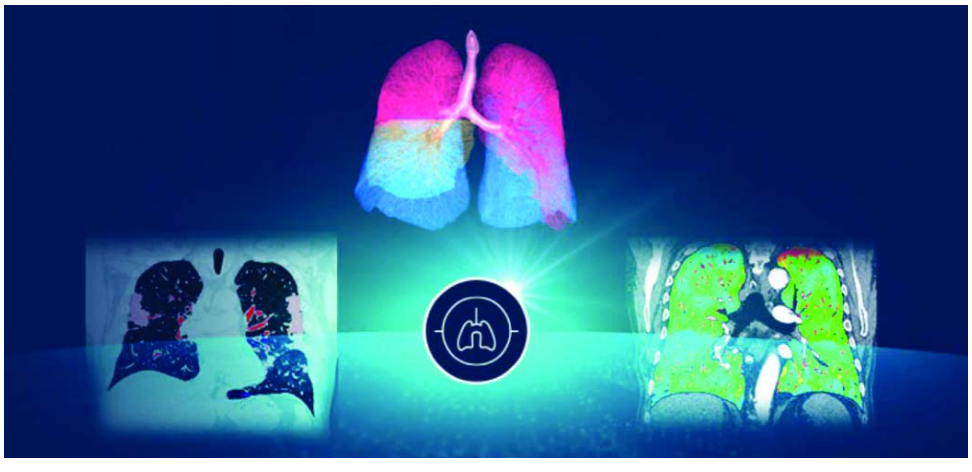
The work with AccuRate Labs on the Remote Consult ECG Solution is an exciting and encouraging demonstration of GE Healthcare's commitment to optimize medical solutions to make high-quality healthcare more accessible to all.

Thoracic VCAR: New age technology from GE

Among other benefits, it improves the lung segmentation and brings enhanced functionalities for parenchyma analysis to identify different ranges of HU variances within the segmented lung fields

Chest and lung scans make up 20 per cent of all computed tomography (CT) scans globally and currently, this number is much higher for India which is grappling with a highly infectious second wave of COVID-19 1

Chest and lung CT scans are often used to help assess deadly conditions like pneumonia, and viral respiratory infections showing imaging patterns including Ground Glass Opacity, which could be present in COVID-19 patients.2So it's vital that radiologists gather quick and accurate patient data to make treatment decisions.



GE Healthcare's Automated CT technology called Thoracic VCAR gives its users the ability to make quantitative measurements of the lungs to aid in the assessment of lung disease. The application blends automated lung and airway segmentation with basic review and advanced lung tissue analysis. Using Thoracic VCAR, users can generate a clear, concise report that communicates vital medical information to referring physicians and patients.

Recently released new version of Thoracic VCAR improves the lung segmentation and brings enhanced functionalities for parenchyma analysis to identify different ranges of HU variances within the segmented lung fields. It helps to characterize and quantify areas of low and high attenuation within the lungs and disease patterns such as Ground Glass Opacity or vascular dilatation which could be presented in pneumonia or COVID-19 patients.

To learn more about Thoracic VCAR , visit
https://www.gehealthcare.in/products/advanced-visualization/all-applications/thoracic-vcar

1. IMV 2019 CT Market Outlook Report.
2. Forum of International Respiratory Societies. The Global Impact of Respiratory Disease – Second Edition. Sheffield, European Respiratory Society, 2017.

Building a smart IoMT ecosystem with GE Healthcare's Mural Connect

A 'Made in India' initiative, Mural Connect is a hub that can be installed in an ICU or Operation Theatre and seamlessly connects to standard as well as life care solution devices

'Mural Connect' is an intelligent data hub developed in 2020 that can be connected to any kind of medical device. Developed as one of GE Healthcare's first future-ready smart products, it plugs into the company's vision of crafting next generation technology tools underlined by the IoMT (Internet of Medical Things). Mural Connect is a truly collaborative, cohesive product poised to transform healthcare treatment both for the patient and medical fraternity.

As a central smart hub, the Mural Connect device has boundless capabilities, facets of which will be released over time. It has the ability to interface through WiFi and Bluetooth with various medical devices located in ICU/OR helps in aggregating patient data, which can be accessed remotely or via the cloud. The possibilities of data aggregation are far-reaching; from connecting various patient parameters to continuous monitoring of the smallest data, from enabling clinical decision making to ensuring interventions in a timely manner. Mural Connect's stand as a true IoT for GEHealthcare is further strengthened by the device's ability to perform remote upgrades, requiring very minimal human intervention.

How the product works

A 'Made in India' initiative, Mural Connect is a hub that can be installed in an ICU or Operation Theatre and seamlessly connects to standard as well as life care solution devices such as Unity IV, Clarity box for anaesthesia. Conceptualized as an open source system, the hub integrates with medical apps built on top of it. At the bedside it integrates to the Ventilator, BP monitor, Heart Rate monitor. Remotely it is instantly patchable, with all interfaces brought into a single, upgradeable format to liberate data from machines securely. While the current purpose is digitization of hospitals, the next phase is management of pre-operative spaces.

As R Sureshkumar, CTO, LCS & Ultrasound, GE Healthcare, South Asia says, "Conceptualized to liberate data from field devices and make it useful, GEHealthcare's Mural Connect helps provide meaningful insights to customers. It helps clinicians make right choices from clinical and operational points of view. Firstly, the hub enables plugging in of additional digital LCS solutions. Secondly, it helps service generation team access plenty of unseen medical opportunities. Thirdly, this is a significant step in building an IoMT ecosystem for medical clinical platforms. The possibilities of impacts are endless - remote monitoring, consolidation of EMR records, dashboard of every hospital bed, understanding of complex data and following patient progress."

Virosil: A Swiss, eco-friendly, chlorine-free fumigant

Virosil is an eco-friendly formulation manufactured and marketed by Sanosil Biotech in technical collaboration with SANOSIL AG of Switzerland

SANOSIL BIOTECH, a Mumbai-based company which is the first company to pioneer the novel concept of eco-friendly fumigation in operation theatres in hospitals and healthcare industry with its product Virosil. Virosil completely replaces the use of carcinogenic proven formalin. The product, Virosil is based on Hydrogen Peroxide (H2O2) and Silver Ions. (nanotechnology). The combination of these two ingredients gives a broad spectrum synergistic activity on all kinds of viruses, bacteria, fungi, yeasts, molds, protozoa and algae. It is a clear, colourless, odourless, tasteless disinfectant which is non-carcinogenic, non-mutagenic, revolutionary and can be used where other chlorine based disinfectants have been feared.

An operation theatre can be made 100 per cent sterile within 60 minutes using Virosil as a fumigant. Healthcare workers will not face any irritation as our product is 100 per cent eco-friendly. This also results in faster turnaround time for OT's and prevention of hospital acquired infections.

Our formulation is presently being used in reputed hospitals and institutions in the healthcare industry as a very effective fumigant and disinfectant thereby providing an microbe free and a completely safe and sterile environment.

The added benefits of Virosil is that it does not give any foul odor, irritation to the eyes, requires no de-fumigation and is very safe and easy to handle as per our recommendations. Our formulation (Virosil) was being earlier marketed by Johnson & Johnson under the brand name Ecoshield.

The company also offers a customised disinfection audit on its *website: www.sanosilbiotech. com*

Contact
Sanosil Biotech,
Ist Floor, Warden House,
Sir PM Road, Fort,
Mumbai – 400 001, INDIA.
Tel: 022 – 43112700
Email:info@sanosilbiotech.com

Barco announces NEXXIS partnership with Sigma – Jones AV in India

Partnership to leverage Barco's leadership across Video-over-IP platform, Nexxis and surgical displays with a unique technology platform specifically designed for integration into digital OR

Barco announced its partnership with Sigma – Jones AV to deliver best-in-class digital experiences in healthcare for its next-gen operating room video integration solution Nexxis. Barco leverages Nexxis, its video-over-IP platform for digital integration in the operating room to deliver precise imagery, efficient workflow, and maximise flexibility across the increasingly complex Operating Room (OR) procedures globally.

As per a release, Jones AV is one of the most successful Barco Nexxis partners to have developed a tried and tested Nexxis platform. Featuring one of the largest install bases and some of the most complex and innovative solutions for fully integrated state-of-the-art operating theatres across Europe, Sigma AVIT is one of India's leading premium corporate AV system integrators and has a pan-Indian network of offices and engineers. The synergies in Sigma – Jones AV add value to hospitals by bringing the long-standing experience in operating theatre integration from Europe with an unparalleled service network and local experience.

Along with Sigma – Jones, Barco has tied up with five partners across the Asia-Pacific region, including Heytech in Thailand, GET Medical in Taiwan, MedEqual in Philippines, Cetech in Vietnam and Rutledge AV, A Diversified Company in Australia. With these partnerships, Barco aims to expand its presence in the surgical sector across the APAC region and deliver cutting-edge surgical displays to digital operating rooms thereby increasing awareness for the solutions available to facilitate better and efficient healthcare.

Elaborating on the collaboration, Rajiv Bhalla, Managing Director, Barco Electronics Systems said, "Barco's partnership with Sigma – Jones AV will guarantee that our market-leading technology is deployed in India in the best way possible. It will not only help in delivering cutting edge and future-proof OT integration solutions built on our Nexxis platform but also in giving clients the reassurance of great after-sales service and customer care for the long term. Sigma – Jones AV was the natural choice for Barco's India partnership as the company combines the experience and expertise of two industry stalwarts"

Every Nexxis component is designed and manufactured with special attention to the protection of the environment and the sustainable use of natural resources. The latest Nexxis components are smaller and use 50 pe cent less power. Nexxis is built on a future-proof and scalable architecture by using network technology and open standards. It also assures best-in-class HD and 4K image quality for mission-critical medical imaging applications.

"For us, it has been paramount to bring the right technology to the Indian market," said Raymond V Soans, Director – Sales and Marketing of Sigma – Jones AV, "Indian hospitals are experiencing a watershed moment and are leaping forward through the use of new technologies contributing to better patient safety, improved infection control, smarter working environments for staff and safer and more efficient operations."

"Quality is also key here," said Ingo Aicher, Director, Sigma – Jones AV, "no other area in the hospital is as mission-critical as the operating theatre. We have been partners with Barco, deploying the Nexxis platform in Europe, since early 2013 and it has never let us or any of our clients down."

The Sigma – Jones offices in Bangalore feature a fully equipped Nexxis 4K showroom operating theatre, showcasing the advantages of advanced 4K visualisation with near-zero latency, lossless true colour video over IP image distribution.

Besides showcasing the efficiency and patient safety improvements through the use of smart AV in integrated theatres, the showroom also features advanced connectivity between the OT and lecture theatres for better and advanced training of surgeons and superior imaging for congresses and research collaborations.

Medix Global announces winners of its Digital Health Innovation Challenge India

The winning team will be awarded a cash prize and three months of mentorship with Medix Global's team alongside potential investments and collaboration opportunities

Fitterfly, a digital health tech start-up, was announced as the winner of the inaugural edition of Digital Health Innovation Challenge India hosted by Medix Global, a global provider of innovative and digital health and medical management solutions.

The Navi Mumbai based startup offers personalised digital therapeutics programmes for diabetes, pregnancy, and PCOS and obesity to deliver health outcomes. With Covid-19 pushing remote monitoring and digital therapeutics to the forefront of medicine and India often referred to as the diabetes capital of the world, the startup is poised to help solve difficult problems through innovative solutions with a potential to impact a significant proportion of India's population.

Stamurai and Wellthy Therapeutics were selected as the first and second runner ups respectively. Stamurai offers speech therapy for stuttering and speech impairments through an automated solution via a mobile app. Wellthy Therapeutics designs clinically validated digital health interventions for chronic disease management through a cloud-based technology stack and analytical tools.

Speaking on the occasion, Sigal Atzmon, Founder & CEO, Medix Global said, "We congratulate the winners of the first edition of the Digital Health Innovation Challenge India. These are very challenging times and now, more than ever, we need to collaborate, innovate and find solutions that will ensure that people everywhere have access to quality healthcare services. Developing digital health solutions is the only way to do this at scale. The innovative business models and exciting ideas we witnessed today have tremendous potential to grow and even revolutionize how healthcare is consumed and delivered. With Medix's global expertise, we look forward to working with them closely in making quality healthcare services affordable and accessible for everyone."

The three startups were among the five finalists that made it to the last round from a diverse pool of over 110 applicants. The other startups that made it to the final round included Metamagics (GridSense) and State of Mind.ai. The three winning startups will also be eligible for further potential funding and strategic collaborations to help scale their ventures locally and outside of India. They will also receive three months of mentorship with Medix Global's expert team.

IIT Mandi researchers invent method to detect abnormal brain characteristics associated with Ischemic stroke

The IIT Mandi team's invention is based on the fact that intricate interactions between nerve cells (neurons) and blood vessels (vasculature), called the NeuroVascular Coupling (NVC) that regulates blood flow in the brain

Innovators at the Indian Institute of Technology Mandi have invented a method to simultaneously study the variations in nerve functions and brain blood flow associated with brain disorders such as Ischemic stroke. The invented method helps in locating and classifying damaged sites (lesions) in the brain, brought about, or leading to neurological diseases.

Results of this study led by Dr Shubhajit Roy Chowdhury, Associate Professor, School of Computing & Electrical Engineering, IIT Mandi, has been published in *IEEE Journal of Translational Engineering in Health and Medicine* and the team has been recently granted a US patent for the invention. Dr Roy Chowdhury has collaborated with Dr Abhijit Das, a neurologist from Institute of Neurosciences, Kolkata, and Dr Anirban Dutta, an Assistant Professor in Restorative Neurorehabilitation from the Department of Biomedical Engineering, University at Buffalo, US. The IIT Mandi team's invention is based on the fact that intricate interactions between nerve cells (neurons) and blood vessels (vasculature), called the NeuroVascular Coupling (NVC) that regulates blood flow in the brain. Diseases such as Ischemic stroke adversely affect the NVC. NeuroVascular Uncoupling results in such cases, wherein, the nerve impulses do not trigger the required blood flow. Timely detection of NVC is critical for the prevention, diagnosis, and treatment of such diseases.

"Our method uses a multimodal brain stimulation system to differentially stimulate different components of the neurovascular unit (NVU) and observes the resultant electrical nerve signals by EEG (electroencephalography) and blood flow by near Infrared spectroscopy (NIRS)," explained Dr Chowdhury.

In simpler terms, a benign electrical current is given to the brain through electrodes, and the responses of the brain in terms of nerve action and blood flow are simultaneously measured by Electroencephalography (EEG) and Near-infrared Spectroscopy (NIRS). While EEG and NIRS are already used independently, the prototype developed by IIT Mandi innovators combines them into a single point-of-care unit to get a more accurate picture of the NVC. The data thus obtained is fed into mathematical models to detect problems in NVC, which can point to neurological diseases. In addition to detecting these abnormalities, this method can pinpoint the location at which the uncoupling exists, thereby providing a better handle on the problem area.

"The simultaneous assessment of nerve function and brain blood circulation would allow urgent treatment decisions to be made quickly in cases of stroke and hypertension," said the lead researcher. The developed device can also help in identifying the progress of diseases such as Parkinson's and can in fact predict occurrence of these diseases even before presentation of symptoms.

IIT Madras, UK researchers develop paper-based sensor to detect AMR-triggering pollutants

This research has been funded by DST along with UK's Natural Environment Research Council and Engineering & Physical Sciences Research Council under Indo UK Water Quality Research Programme

Indian Institute of Technology (IIT) Madras and UK researchers have developed a paper-based sensor that can detect antimicrobial pollutants, which induce antimicrobial resistance in water bodies. This sensor works on a 'see and tell' mechanism that makes it logistically effective for wide implementation.

This research was first reported through a journal publication in *Nature Scientific Reports* and was acclaimed as one of the top 100 in chemistry.

This research was funded by Department of Science and Technology (DST), Government of India in bilateral collaboration with UK's Natural Environment Research Council and Engineering and Physical Sciences Research Council (EPSRC) under the 'Indo UK Water Quality Research Programme.'

In IIT Madras, this research was led by Prof S Pushpavanam, Institute Chair Professor, Department of Chemical Engineering, IIT Madras and Dr T Renganathan, Associate Professor, Department of Chemical Engineering, IIT Madras.

Elaborating on the unique aspects of this research, Prof Pushpavanam said, "Paper-based sensor offers an affordable platform for various point-of-care applications as they support fluid flow based on a wicking action and governed by capillary forces. This eliminates the requirement of a pump-to-flow liquids. We have come up with a novel method for the fabrication of paper- based devices using a commercial laser printer."

Speaking about the technical aspects of this sensor, Prof Pushpavanam added, "The way it works is that we use a porous substrate such as paper, which enables us to use standard software to print required designs on it. Once printed, the printer ink is deposited on the surface of the paper. When heated this penetrates the thickness of the paper and forms a hydrophobic barrier through which liquid cannot pass. This allows us to direct the flow of liquid in preferential directions through the areas which are not printed and are hydrophilic."

The practical applications of these sensors include:

- Environmental monitoring
- Food safety analysis
- Healthcare monitoring

Speaking about the current Indo-UK project, Dr Renganathan, Associate Professor, Department of Chemical Engineering, IIT Madras, said, "We have used these fabricated devices for the detection of antibiotics such as ciprofloxacin, biocides such as triclosan and heavy metals such as chromium, copper and lead. These devices can be used for antimicrobial resistance surveillance in water bodies."

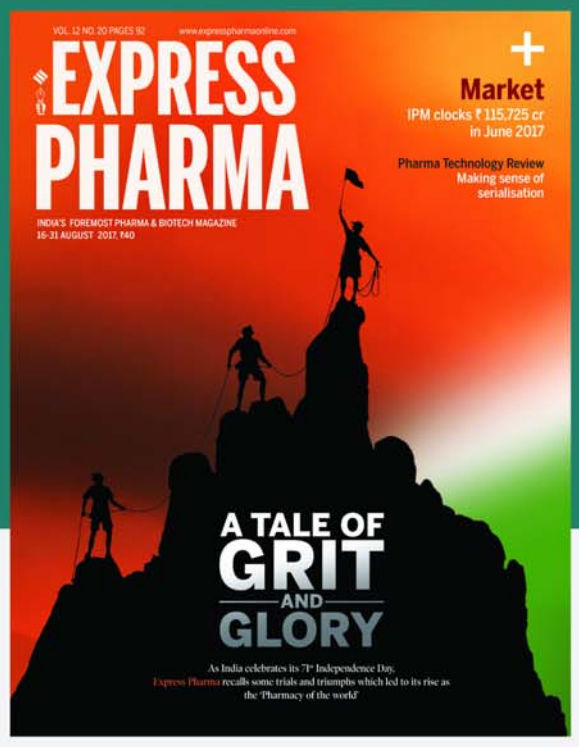
Highlighting how this sensor is unique compared to existing technology, Dr Renganathan added, "We use a normal laser printer without any modification and it offers high resolution and accuracy. The hydrophobic barriers are compatible against organic solvents and high temperature. The developed laser printed paper-based microfluidic sensor is a viable option for large scale manufacturing and enables routine monitoring of pollutants in both developed and resource constrained regions."

The novel strategy for low-cost fabrication of the robust Laser Printed-Microfluidic Paper-Based Analytical Sensors developed by IIT Madras will help to detect antimicrobials easily in the parts per million range. It will also help u nderstand the relationship between AMR and AMR-triggering pollutants and assist policymakers in framing solutions to tackle grand societal AMR challenge.

The novel strategy of combining adsorption based preconcentration using reagents that undergo a measurable colour change enabled parts per billion level detection of pollutants. The process utilises the easily available laser printer and hence offers tremendous potential for large scale sensor fabrication. It could enable community-driven microfluidics and facilitate mass surveillance.

THE FORMULA FOR THOSE WHO FORMULATE THE PHARMA SECTOR

Express Pharma has been the backbone of this sector since 20 years. It is what the experts look to when the entire industry looks to them. That is because the magazine contains a potent mix of innovative ideas, cutting-edge analyses and expert insights. It's no wonder then that the finest in the field trust the foremost in the field.



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