VOL.14 NO 11 PAGES 60

EXPRESS HEALTHCARE

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Dr Sanjay Sarin
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INDIA'S FOREMOST HEALTHCARE MAGAZINE

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Our fight against COVID-19 is far from over:
Dr Sanjay Sarin
Head, FIND India

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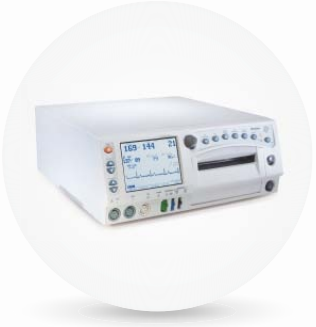

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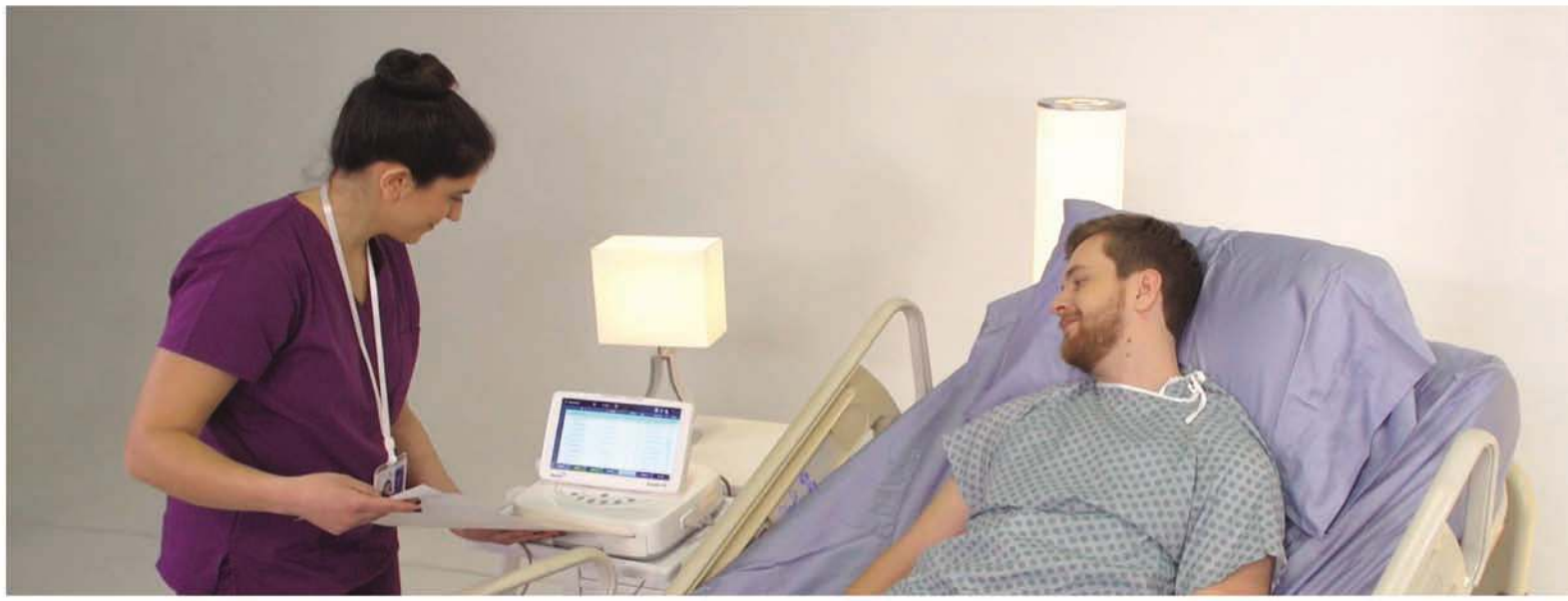

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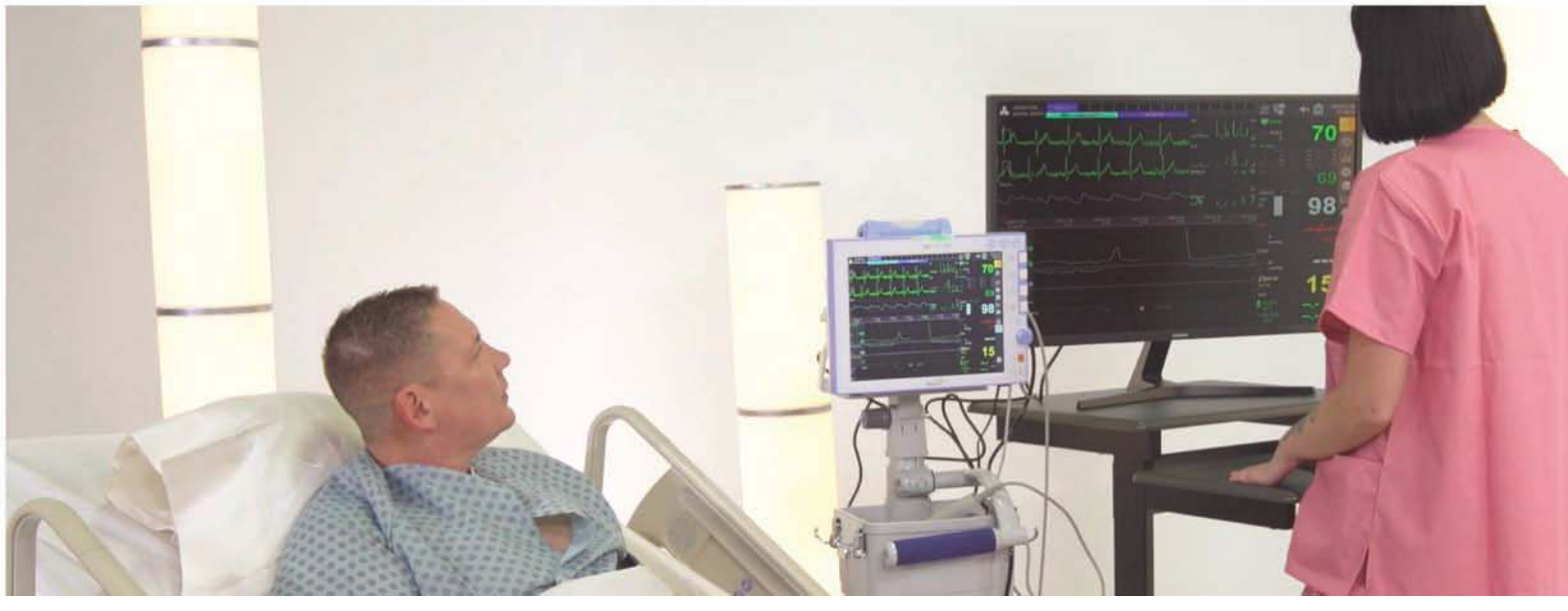

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INSACOG revs up to take on Omicron

Two years after the SARS-CoV-2 virus took global centrestage, just when we thought we had it under control, comes news of another variant that seems to have more tricks up its corona than its predecessors.

With the world in pandemic mode, decision-making seems to happen in fast-forward mode. Just two days after authorities from southern Africa first reported the variant to WHO, the UN agency designated it as the fifth variant of concern (VOC) on November 26, 2021.

Interestingly, on November 30, health officials from the Netherlands reported that the newly named Omicron variant turned up in two test samples taken on November 19 and 23, predating the southern Africa samples by a week. Thus, we have to assume that Omicron is already present in India and it is only a matter of time that it shows up in tests.

An important aspect that might prove crucial in containment strategies is that current SARS-CoV-2 PCR diagnostic kits continue to detect this variant even though it has multiple mutations in some key areas. The WHO's November 26 release mentioned that several labs indicated that for one widely used PCR test, one of the three target genes is not detected (called S gene dropout or S gene target failure) and went on to suggest that this test can therefore be used a marker for this variant, pending sequencing confirmation.

The Omicron variant is so far causing "very low hospitalisation" though patients experience "extreme fatigue even with mild disease" as per early reports from southern Africa's health officials. However, in its November 28, 2021 update, the WHO cautioned that initial reported infections were among university students—younger individuals who tend to have more mild disease—and so understanding the level of severity of the Omicron variant will take days to several weeks.

The WHO's statement that 'the overall risk related to Omicron is considered very high' underlines the 'preliminary evidence on Omicron suggesting, in contrast to previous VOCs, both potential immune escape and higher transmissibility that could lead to further surges with severe consequences.'

With concerns that reinfections may be higher, India's focus on expanding COVID-19 vaccine coverage must include an aggressive ramp up of testing, and more importantly, whole genome sequencing of a higher percentage of positive samples.

Mindful of the criticism that when the Delta variant was on a rampage, India did not test enough or share sequencing data with global agencies like GISAID fast enough, there are reports that more than a dozen labs will be added to the existing 38 labs of the Health Ministry's Indian SARS-CoV-2 Genomics Consortium (INSACOG).

If the past two years was about putting in place the bullets (vaccines, medicines, convalescent plasma etc) to fire at the enemy, this time it is about strengthening the radar to detect the stealthy intruder, getting past attempts at camouflage and subterfuge.

Having the best whole genome sequencing infrastructure is but the first step; maxing its potential will take nation-wide coordination

So,India's year old initiative to 'study and monitor genome sequencing and virus variation of circulating strains of COVID-19 in India,' INSACOG now becomes an even more vital part of our anti-COVID arsenal.

The good news is that the pandemic has cut down our overall response timelines. Union Health Secretary Rajesh Bhushan's first advisory letter to the states on the new variant was on November 25, a day before WHO declared it as a VOC.

These daily advisories now have to translate into effective implementation at the state and district levels. As INSACOG gears up for this latest stress test, having the best infrastructure is but the first step; maxing its potential will take nationwide coordination.

But with Prime Minister Modi himself alluding to this vital gap, speaking about the need to 'increase the sequencing efforts and make it more broad-based' in his November 27 briefing on Omicron, one hopes that INSAGOG will see a better response this time around.

As of November 30, 2021, of the 70471 genomes characterised by INSACOG, Maharashtra accounts for 27.4 per cent, Kerala 9.9 per cent followed by Delhi at 8.2 per cent. However, geographically vast states like Uttar Pradesh contributed 1.5 per cent to INSACOG, a clear indication that more work needs to be done on the ground to work out the kinks in supply chain and logistics etc.

PM Modi's nudge was followed on November 30 by Dr Balram Bhargava, Secretary (Health Research) and DG ICMR, informing state health officials that the Omicron variant doesn't escape RT-PCR and rapid antigen tests (RAT) and advising them to ramp up testing for prompt and early identification of any cases.

Manufacturers of RT-PCR kits like Thermo Fisher and MyLab have assured us that their RT-PCR and RAT test kits can still detect Omicron, even with key mutations in the S-gene / spike protein. Similarly, even though it will take at least two weeks for conclusive evidence, vaccine makers claim that their shots still work, or that they are already working on new vaccines to cope with new variants. This time, the search is on for variant-neutral vaccines and test kits that will at least theoretically offer broader and longer protection.

The fact is, Omicron will not be the last COVID-19 variant, even if fears about its increased transmissibility and immune escape leading to increased mortality prove to be unfounded. Omicron could fizzle out in a month or upstage Delta.

But the gift of this pandemic should be, and I am sure will be, a resilient public health system, which is really the only long-standing defence that we have to build and be part of. Each adversity comes with its own lessons. It is up to us to learn them well.

VIVEKA ROYCHOWDHURY *Editor*
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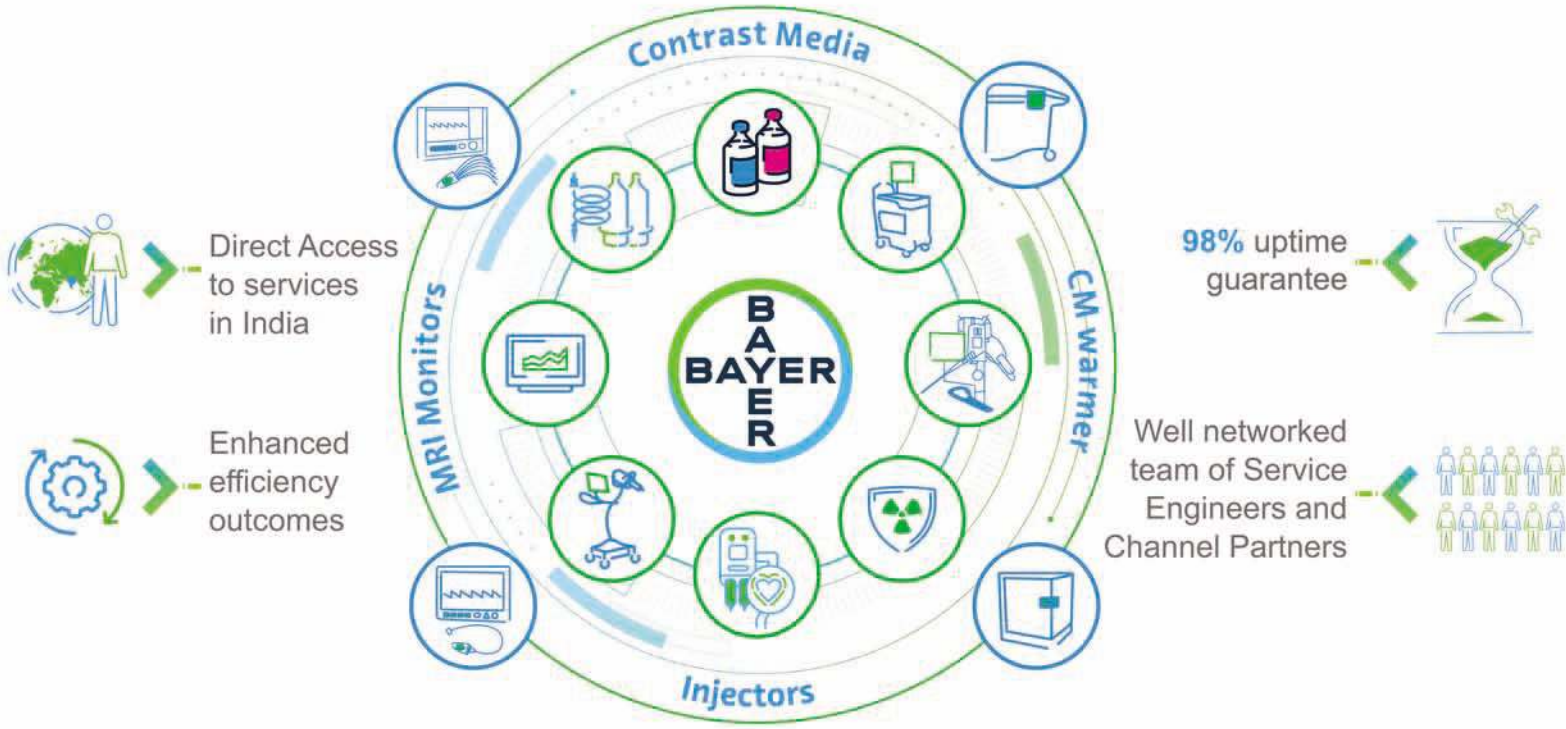

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INTERVIEW

Our fight against COVID-19 is far from over

Dr Sanjay Sarin, Head, FIND India cautions **Viveka Roychowdhury** that we need to intensify efforts to realise mass testing for test-trace-isolate implementation and sequencing-based surveillance – so that viral evolution does not jeopardise progress. As FIND is co-leading the Diagnostics Pillar of the Access to COVID-19 Tools (ACT) Accelerator, he outlines FIND India's work to ensure equitable access to reliable diagnosis, strengthen India's COVID-19 diagnostic capacity as well expand primary care testing in support of universal health coverage to combat diseases like TB, that disproportionately affect vulnerable populations in the country

Diagnostics is the first step in the treatment journey not just during a pandemic but also for NCDs, and infectious diseases like malaria, dengue etc. But resource scare countries like India do not have the funding to process affordable access to quality diagnostics testing equipment. How does FIND play a role in bridging this gap?

Indeed, testing is the first and best line of defence against any infectious disease including COVID-19. Yet, about 50 per cent of the world's population does not have access to safe and quality diagnostics as per the recently launched 'The Lancet Commission on diagnostics'. Low- and middle-income countries like India have limited resources to rapidly scale up and implement testing. And this is where FIND, the global alliance for diagnostics, comes into the picture. We ensure equitable access to reliable diagnosis by connecting communities, funders, decision makers, healthcare providers and developers to spur innovation and make testing an integral part of sustainable, resilient health systems.

We are working to save 1 million lives and save $1 billion in healthcare costs to patients and health systems. How are we doing that? As co-convenors of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a World Health Organisation (WHO) Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

In the last one year, FIND has strengthened India's COVID-19 diagnostic capacity by provisioning high-throughput COVID-19 testing machines, automated nucleic acid extractors and ancillary equipment for public sector laboratories across the country. These items have helped in improving testing throughput and reducing turnaround times. This coupled with independent evaluations of COVID-19 tests; and training India's public sector laboratory network has enabled FIND to continue bridging the gap between implementers, funders and communities, thereby maximising impact - from innovation to implementation.

As infectious diseases agents mutate, diagnostic test kits need to evolve as well. What is FIND's research on this front as far as COVID-19 goes?

The tests evaluated by FIND for COVID-19 are relatively broad, the efficacy of which is not being impacted by the mutants / variants of concern. But we continue to monitor the situation closely, as new variants emerge. In fact, this is one of the reasons why FIND has been advocating and supporting capacity building for sequencing - so that we can track the evolution of the virus and accordingly modify the testing strategies to mitigate their impact.

Diagnostic test kits are evolving beyond invasive, lab-based test kits to point of care (POC) kits. What kind of R&D is FIND funding in COVID and beyond?

There is a critical need to decentralise testing, especially in countries with a large population like India. The development of rapid, POC molecular diagnostic tests that have sensitivity and specificity comparable to the current gold standard techniques can significantly aid testing expansion. Such POC devices can generate information on both - viral presence and host response (e.g., antibodies), especially in non-laboratory settings with rapid turnaround times. The deployment of testing solutions out of centralised laboratories, for instance, at the primary care level, could be a key step for the rapid detection and identification of COVID-19 and prevention of transmission to the community.

FIND has been conducting independent evaluations of molecular tests and immunoassays, in collaboration with WHO and multiple partners, to assist in-country decision making. FIND is also supporting both research and development as well as local manufacturing efforts for point of care molecular and rapid tests, in multiple countries.

Where does FIND get its funding? And how does it decide which projects it will fund? What are the funding methodologies?

FIND is funded by multiple donors across the globe through multilateral mechanisms, country governments as well as private foundations and corporate partners. FIND has a Scientific Advisory Committee consisting of global experts on infectious diseases which guides the

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selection of projects supported and implemented by FIND. FIND also identifies projects in consultation with in-country and other global stakeholders to ensure that the funds are deployed towards supporting the top priorities and in-country challenges.

Crystal ball gazing into 2022, what are the predictions for the COVID-19 scenario and therefore what are the focus areas for FIND?

Our fight against COVID-19 is far from over and requires intensified efforts to realise mass testing for test-trace-isolate implementation and sequencing-based surveillance – so that viral evolution does not jeopardise progress. In 2022 and beyond, the pandemic is likely to evolve as there are significant swathes of unvaccinated population across the world, thereby allowing the virus an opportunity to evolve and potentially continue to infect.

Going forward, we seek to harness the momentum around testing for COVID-19, leveraging emerging digital innovations, and building on our organisational experience to continue supporting development and evaluation of new tests as well as working with countries on strengthening their response to outbreaks and pandemics.

In support of universal health coverage (UHC), our goal is to expand primary care testing to combat diseases that disproportionately affect vulnerable populations. Reducing the diagnostic gaps in TB, hepatitis, antenatal screening for both infectious and non-communicable diseases (NCDs), fever, pneumonia and neglected tropical diseases (NTDs) will save lives and livelihoods, save health systems money, and contribute to global and national disease elimination targets.

Alongside our efforts to serve diseases and populations, we are working to strengthen the diagnostic ecosystem. This includes advancing sequencing efforts to improve surveillance and diagnosis, fostering an integrated biobank network to facilitate diagnostic development and implementation across diseases, and diagnostic network design to optimise national lab networks' testing capacities. To enable accountability from all parties, we aim to cement the essential place of diagnostic testing within health systems through political commitments at the highest levels.

> It is critical to invest in building resilient health systems, develop patient centric strategies to mitigate the impact of COVID-19 on disease like TB, HIV and malaria including leveraging the significant investments in diagnostics and care infrastructure as part of response to COVID- 19 for the overall well-being of the population and protection from future pandemics

COVID-19 has distracted public health officials and diverted resources from other diseases like TB, malaria, polio, leprosy etc besides NCDs etc. In which areas do you see us playing catch up in 2022 and beyond? Any priority areas you can flag off?

The unprecedented COVID-19 pandemic has severely impacted health services for several other infectious diseases including TB. Recent data from nine high burden TB countries (representing 60 per cent of the global TB burden) shows a decline in TB detection ranging from 16-41 per cent. This drop has brought the overall number of people diagnosed and treated for TB in these countries to 2008 levels, a setback of 12 years. It is estimated that India witnessed ~ 60 per cent decline in TB notifications, during the lockdown period in 2020 as per the data available on government's Nikshay platform. Such a scenario may have led to significant morbidity and mortality as well as increase in the risk of TB transmission, within affected households.

The pandemic has demonstrated the need to strengthen our existing health system, one that allows us to break disease silos and administer patient-centred care. It is critical to invest in building resilient health systems, develop patient centric strategies to mitigate the impact of COVID-19 on disease like TB, HIV and malaria including leveraging the significant investments in diagnostics and care infrastructure as part of response to COVID- 19 for the overall well-being of the population and protection from future pandemics.

What kind of partnerships does FIND look for with public health agencies and other organisations for COVID-19?

Partnerships are the core of our operating model. Our unique position, bridging the public and private sectors, allows us to bring a diverse set of stakeholders together to resolve technical, financial, and logistical barriers to diagnostic innovation in low-resource settings.

Our many partners include public, government donors, philanthropic organisations, industry, academic and research institutions, international public health organisations (including non-governmental organisations and foundations), health ministries and disease control programmes.

All our activities are based on scientifically validated or independently reviewed data and objective standards. Our work with private sector partners (including all entities that are privately owned or are developing or commercialising products or services for commercial purposes) is guided by our Private Sector Partners Policy, in compliance with our Code of Conduct and Statement of Recognition of Independence for private sector partners. These documents describe the principles to which our organisation always adheres to, in terms of governance, workforce environment, collaborations, research, and financial stewardship.

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The value of incremental innovation: A closer look

Dr Sanchayan Roy, Senior Consultant-Internal Medicine and Critical Care, National Heart Institute, New Delhi highlights the importance of incremental innovation and its role in post-pandemic era

Throughout human history, innovation in healthcare has been the mainstay of progress as it has provided numerable advantages for patients and created new opportunities. From diagnosis to mitigation and treatment, it was innovation that brought hope to millions of people battling the coronavirus. Over the last century, the pharmaceutical industry has been responsible for supplying thousands of new drugs, based on several smaller incremental innovations. As we battle a pandemic, it is imperative to look at solutions that will help us in making quality healthcare accessible.

For India to move forward on this path, the country will have to encourage the development of drugs that meet the needs of patients by providing the right incentives for incremental pharmaceutical innovations.

Incremental innovation is defined as the process of expanding therapeutic classes by improving molecular structures that enhance safety and efficacy, increases the number of available dosing options, bring ease of administration, and ensure patients comply with dosing schedules. Over the years, classes of drugs have expanded to provide physicians with the tools they require to treat diverse patient groups.

Incremental innovation is defined as the process of expanding therapeutic classes by improving molecular structures that enhance safety and efficacy, increases the number of available dosing options, bring ease of administration, and ensure patients comply with dosing schedules

The benefits of incremental innovation: A patient-centric approach

Besides providing doctors with a plethora of therapeutic options, incremental innovation has provided us with the existence of multiple similar molecular agents that provide a backup in situations where if a drug in a specific class is found to have certain side effects and is thus replaced by a newer and improved version of the drug. In such a scenario, it is essential to ensure that patients dependent on a particular class of drugs do not lose access to much-needed medication. There have been innumerable cases where in the past, the originator drug was removed from the market and has been replaced with better and more effective drugs. In fact, the World Health Organization's (WHO) Essential Drug List 2019 has several critical follow-on drugs including anti-bacterial, cancer and HIV/AIDS drugs due to their improved safety compared with the first-in-class drugs.

When medicines need to be consumed multiple times a day, the adherence to the treatment process becomes low. Incrementally innovated once-a-day drugs have bridged this gap significantly. Take for instance, we now have a medicine for patients with chronic heart failure that can be taken once a day opposed to the original one that was supposed to be consumed twice a day. Moreover, as per a study by All India Institute of Medical Sciences, 50 to 80 per cent people with hypertension and 24 percent people with cardiac diseases fail to follow proper medication prescribed by the doctor. The report is worrisome for India as uncontrolled hypertension is the most common cause for sudden heart attack in the country and cardiovascular diseases account for 17.7 million deaths worldwide. India accounts for over a fifth of these deaths.

Let us understand with an example how incremental innovation improves patient compliance. Tablets for bipolar disorder, epilepsy and prevention of migraine are usually in 500 and 1000 mg formats. This makes the tablet size large. Consequently, this makes it difficult for patients to swallow the tablet. However, due to incremental innovation we now have smaller tablets that facilitate ease of swallowing, helping patients with adherence to medication. In fact, liquid form of some of these medicines required for bipolar disorder and migraine are also available that provides dosing convenience for elderly patients.

Rethinking incremental innovation for the post-pandemic era

To realise the benefits of incremental innovation, India will need to foster strong collaboration between the government, pharmaceutical industry, and academia to work on a policy framework that supports innovation. There is a misconception that incremental innovations are a result of trivial modifications of existing inventions and that they do not require any effort to develop. However, studies confirm that incremental innovation involves investment of time and money. India invests mere 0.9 per cent of its GDP towards overall research and development which is inadequate for incremental innovations to reach the country.

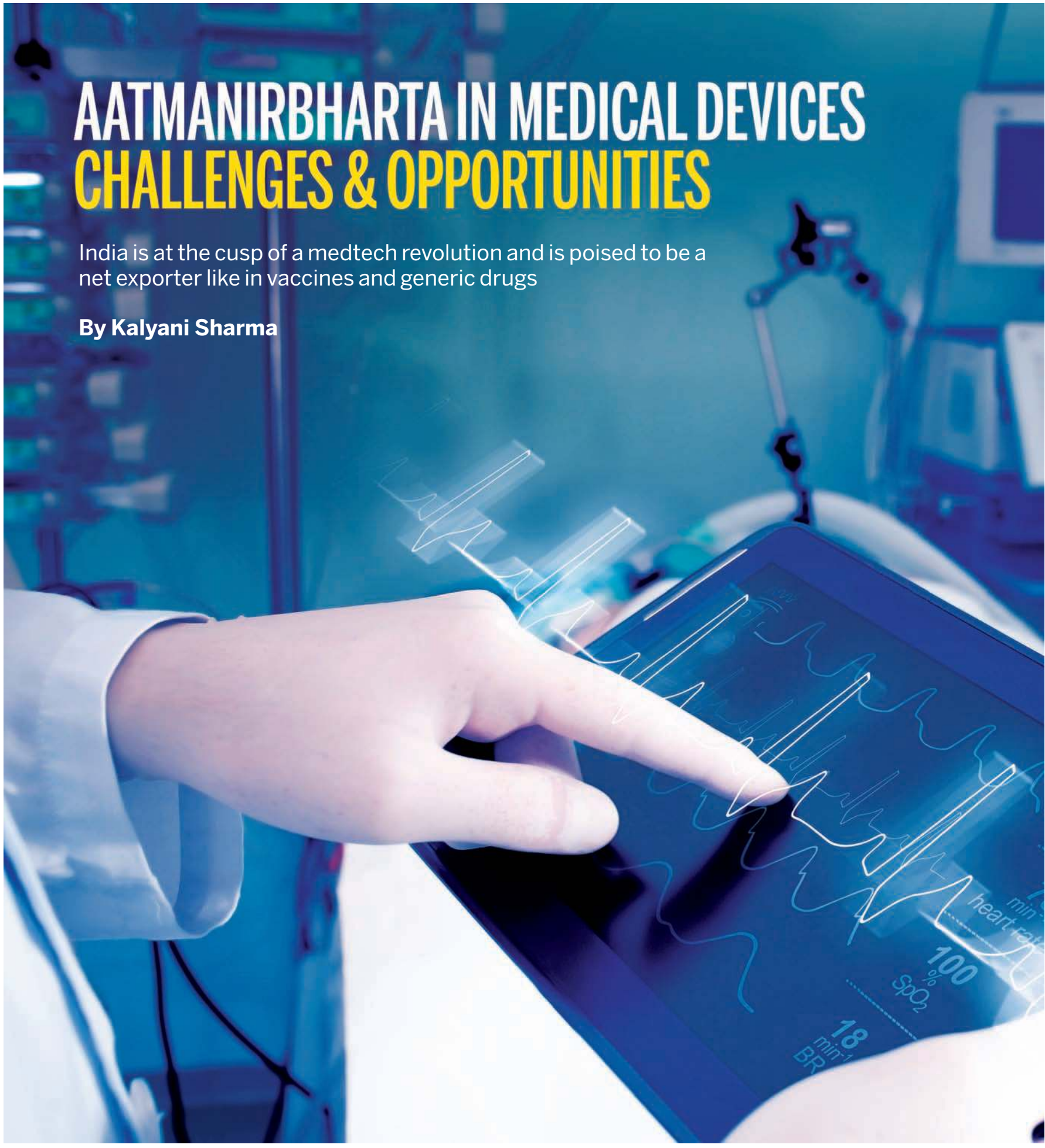
For post pandemic times, India needs to safeguard advanced treatment options for its patients, especially as NCDs continue to remain a threat. As we prepare ourselves for the post-COVID world, we must look at addressing the gaps in healthcare infrastructure that we are currently fighting.

As the disease profiles in the country continue to become more complex, there is a need to continuously innovate so that medicines are aligned with changing healthcare dynamics and patient needs. This will not only optimise patient outcomes but more importantly, give them a better quality of life.

AATMANIRBHARTA IN MEDICAL DEVICES
CHALLENGES & OPPORTUNITIES

India is at the cusp of a medtech revolution and is poised to be a net exporter like in vaccines and generic drugs

By Kalyani Sharma



Medical devices play a role not only in screening, diagnosing and treating patients but also in restoring patients to normal lives and in regularly monitoring health indicators to prevent diseases. With technological advancements, the role of medical devices is now expanding to improve quality of care across each stage of the healthcare continuum. The healthcare industry in general has witnessed various revolutionary changes in the healthcare sector like elevated use of technology adoption. The medtech sector in India, which at the beginning of the pandemic had a bigger responsibility and faced with multiple challenges like fast-track availability, manufacturing and access of the product majorly due to dependence on other supply chains and disruption of supply and demand system. The challenges are still not over but opportunities created in the form of call for 'Aatmanirbhar' or self-reliance' during the pandemic is the brighter side.

Sharing his views on medtech sector and COVID-19, Dr Sudhir P. Srivastava, MD and Founder, SS Innovations said, "The COVID-19 challenge showed us the truth about Indian dependence on imports for medical devices. Through the government of India's flagship "Make in India" initiative, Indian medical devices industry is on the path of self-reliance or Aatmanirbharta and currently, the Indian manufacturers are working hard to meet the surged demand for healthcare equipment. At present, the med-tech industry is highly dependent on import channels, and to reduce this dependency med-tech sector needs to focus on complete self-reliance. We have to be Aatmanirbhar from acquiring raw materials to producing the end product and delivering it at the required destination. We have just started and it will take us some time to reach that level of self-reliance."

Talking about India's import dependence, Ankit Anand, Vice-President, Software Engineering Cloud Solution, Sleepiz India says, "A country cannot be called self-dependent if it has to depend on another geography for the healthcare of its own people. As demonstrated through the COVID 19 pandemic, having an indigenously developed vaccine has helped us achieving a feat that would have otherwise been impossible, had we depended on imports. However, for medical devices and many healthcare technologies, we are heavily import-dependent with around 80 per cent of our medical devices being imported."

Dr Kirti Chadha, Chief Scientific Officer, Metropolis Healthcare said, "The COVID-19 pandemic has naturally shaken the foundations of India's healthcare system as it has scrutinised even the most advanced healthcare systems around the world. Amid mounting bumps in the road, India's healthcare system was able to withstand the pandemic. India's various efforts in the manufacturing of medical equipment, disposables, drugs, and, most recently, vaccines have established India as a leading nation. India not only managed to meet domestic needs, but also rose to the challenge and helped other countries."

Talking about the role of medical devices, Dr S. Narayani, Zonal Director, Fortis Hospitals Mumbai said, "Medical technologies for years together have enabled early and accurate diagnosis of health problems, facilitating timely intervention and improved outcomes. Be it innovative products that replace, repair and sustain failing body functions or telemedicine and connected devices that allow remote monitoring of patient's conditions in ICUs, OTs etc. The role of medtech became even more important during the pandemic when medtech married digital to address need gaps in healthcare."

Market scenario

The Government of India has recognised medical devices as a sunrise sector under the 'Make in India' campaign promoting domestic manufacturing and reducing the dependency on imports. The government schemes focusing on and balancing out ease of doing business and self-reliance will play a crucial role for its further growth.

As per IBEF, India is the 4th largest market of medical devices in Asia and counted amongst the top 20 markets in the world. In 2020, the total market was estimated to be US$5.2 billion and is projected to reach US$50 billion by 2025. However, most demand for medical devices in the country is currently met through imports, comprising ~80 per cent of the total sales. This high import dependency offers an attractive proposition for domestic manufacturers. At present, the Indian companies are largely involved in manufacturing low-end products for local as well as international consumption."

Dibakar Bhattacharya, Head-Government Affairs, Medtronic added, "The Indian medical device market is heavily dependent on imports-almost 80 per cent of the domestic requirement is imported. For high-tech medical devices, this dependency is almost 100 per cent. While India houses 14 per cent of the world's population, it only represents 1-2 per cent of the total medical device global revenue share of leading MNCs. Therefore, on one hand, is the industry's heavy import dependence, and on the other, a relatively small current local market size that is not attractive for global players to invest in large-scale manufacturing. There are several reasons for these drawbacks, such as the lack of adequate infrastructure and supply chain networks and high costs associated with setting up and financing. Additionally, limited domestic R&D capability and an underdeveloped ancillary manufacturing ecosystem are barriers for large-scale medtech manufacturing investment vis-a-vis competing economies."

Highlighting the current scenario of the sector, Gaurav Agarwal, Managing Director, IITPL - Innovation Imaging Technologies

said, "The current landscape is that India imports nearly 80per cent of its consumption of medical devices and is almost 90 per cent import-dependent in medical electronics. The Indian medical device market is $11 billion and, is expected to grow at 35 per cent to become a 50 billion market by 2025, making India one of the fastest-growing medical devices markets in the world."

"Identify areas/therapies/technologies, that have the highest import dependence and prioritise them using national disease burden. For example, cardiovascular disease is the number 1 cause of death in India. Build enabling policies like PLI, export incentives, R&D support, and incentives and support Indian medtech-preneurs innovate. The innovation ecosystem can be kick-started by building clusters of bio incubators at institutions of academic excellence in collaboration with industry supported by grants from the Ministry of Science. This model is responsible for Israel and China's leading medtech innovation", he added.

Talking about the market scenario, Runam Mehta, CEO, HealthCube said, "The current market size of the medical devices industry in India is estimated to be nearly $11 billion but India imports nearly 80per cent of its medical devices. For the country to become Aatma Nirbhar in its truest sense, we need to turn it into a global medical device manufacturing hub. This can be achieved with favorable fiscal policies, Nurturing talent, stronger R&D infrastructure, and building in-house technology. From setting up manufacturing plants to sourcing raw materials, there is a need to build the whole ecosystem locally. Public-private partnerships, strong funding mechanisms, simplification of land allotment, and registration processes are essential. However, the strategy has to be built around innovation."

With the large number of engineering graduates India produces each year from top institutions, India has the potential to become a global hub for R&D for medical devices. Several companies have started setting up their R&D centres in India employing large numbers of engineers and associates. Recognising and incentivising this within the framework of Aatmanirbharta is key

Meenakshi Nevatia
Vice President and MD, Stryker India

On one hand, is the industry's heavy import dependence, and on the other, a relatively small current local market size that is not attractive for global players to invest in large-scale manufacturing. There are several reasons for these drawbacks, such as the lack of adequate infrastructure and supply chain networks and high costs associated with setting up and financing. Additionally, limited domestic R&D capability and an underdeveloped ancillary manufacturing ecosystem are barriers for large-scale medtech manufacturing investment vis-a-vis competing economies

Dibakar Bhattacharya,
Head-Government Affairs, Medtronic

Dr Ravinder Deep Singh Sethi, Chief Operating Officer, Oncquest Laboratories said, "The medtech industry is highly import dependent on other countries for raw materials and now is the right time to challenge this arrangement, as companies are looking for alternative manufacturing hubs. India could be their preferred choice, provided we are able to offer a great environment. A conducive business climate with simplified land and labour laws, better infrastructure and logistics, and single window clearances can enable India to develop a full-bodied manufacturing network. Though it's a challenging business, it can be a great opportunity to attract foreign capital, latest technology, create jobs and boost our exports. Skill and scale should be the primary focus to be both quality and cost competitive and serve a global customer base."

Ease of doing business & making India globally competitive in the medtech sector

The Government of India's strategies and policies for business continuity and sectoral revival are already in place. The schemes and regulations allowing 100 per cent FDI aiming at global investors to choose India as their preferred destination for investments are driving the sector. This is also important as there is increased demand for technologically advanced, high-quality, low-cost medical devices that are accessible to the Indian population. These factors are also attracting international companies to set up production facilities in India. However, there are still some unexplored challenges and areas that needs attention.

Talking about the need of the hour in this direction, Dr Srivastava said, "As many countries are looking into investing in offshore manufacturing units, India could be their preferred location because of the availability of trained manpower. Added to that, if we provide a promising business environment with simplified labour and land laws, better infrastructure and logistical support, along with single-window clearances on permissions and tenders, then it will be beneficial. Foreign capital will bring in the latest technology, create new job opportunities and boost exports. The medtech sector will grow considerably and, will also move towards self-reliance by getting at par with other global suppliers."

Sharing his views on the same, Dr Veeraal Gandhi, Chairman and Managing Director, Voxtur Bio said, "The key challenges for the industry are dearth of infrastructure and logistics services, inadequate supply chain services and high cost of finance. The government has always been supporting the industry by simplifying regulations and paperwork. The introduction of the production linked incentive scheme (PLI) encouraging domestic manufacturing of medical devices has enhanced growth prospects immensely. The industry needs continued financial assistance and policy support from the government. An enabling eco-system must be created so that the companies can leverage emerging collaborative growth opportunities."

Highlighting the challenges, Nimith Agrawal, Founder, DoctCo added, "The medtech industry struggles with low penetration. The demand primarily comes from metro cities as there is low penetration in tier 2,3 cities and rural areas due to lack of awareness, avail-

ability, and affordability. Hospitals in non-metro cities opt for cheaper products compared to high-end products owing to costs and affordability issues. Moreover, the per capita spend on this sector is significantly lower. Public healthcare infrastructure receives inadequate investments making it inefficient and creating a lack of medical devices and equipment. Consequently, the medtech sector gets affected as distribution becomes challenging."

Soumya Sunder Dash, CEO and Co-founder, Sleepiz AG added, "Where there are challenges, there are opportunities. I would say opportunity is the other side of a challenge. And in India, there is no dearth of either. You just have to be perceptive and perseverant enough to drive your dream and believe that dreams do come true!"

Talking about the opportunities in this direction, Meenakshi Nevatia, Vice President and MD, Stryker India said, "About 80-85 per cent of the medical devices are currently imported. While it is important for the government to provide incentives to stimulate local manufacturing to reduce import dependency in the medium to long term, the very high duties (basic customs duties plus 5per cent health cess) is resulting in viability challenges for the industry to continue providing technologies at affordable prices and ensuring access to latest technology. Finding a balance here is key."

Medical devices regulations: Areas that still need attention

The medical devices regulation is the key parameter in India's medtech sector journey of excelling in meeting the global standards. However, the majority of industry still believes that there still is a scope of improvement.

Sharing his views on medical device regulations, Dr Srivastava added, "The Government of India has brought in many new policies and measures to encourage domestic manufacturers. But the regulations of the medical device are still not very streamlined and need a lot of clarity in how it should function. Currently, sixteen medical devices are regulated under MDR (Medical Devices Regulation), 8 others are regulated as drugs and 13 additional devices are going to be added to the MDR over 2021. The major concern for the industry is about the pace at which medical device regulation works. Although it's a great move to regulate all medical devices we have to make sure that the registration process is simplified. As the delays (such as delays on part of the CDSCO in granting import and manufacturing licenses before the end of the 30/42-month

exemption period) will lead to financial loss and deficit in the supply chain endangering the health of patients."

"The Indian medical devices industry is now becoming increasingly conducive to setting up manufacturing facilities. In the year 2017, the Government of India introduced The Medical Device Rules (MDR), 2017 and revamped the regulatory framework to make it competitive to the international norms. All these regulatory measures have reduced the time and effort needed to start the production. The permission of 100per cent automatic FDI in the medical devices sector and establishment of MedTech Zonesis further boosting domestic manufacturing. That being said, the pace of reforms is quite slow and the need for reform is pressing. For instance, no more than 29 devices have been brought under the purview of MDR whereas there are more than 1700 categories of medical devices in the world market", added Mehta.

Stressing on the challenges, Agarwal says, "There are many challenges as far as Indian medtech regulations are concerned, which result in creating obstacles in indigenous medical device manufacturing in India including unfavorable duty structure, Inadequate domestic demand for certain segments/product categories, complexity and lack of transparency in regulation, lack of comprehensive laws and lax enforcement mechanisms for IP protection, absence of indigenous 'quality certification' authority and unavailability of proper ecosystem support (suppliers, raw material, etc.) for medical device manufacturing."

Dr Gandhi suggested, "Because of the MDR 2017, the medical devices sector has excelled in meeting the global standards. A comprehensive regulatory framework taking into account both the medical devices and manufacturing processes will further enhance the global acceptability of the medical devices manufactured in India."

The medtech industry is highly import dependent on other countries for raw materials and now is the right time to challenge this arrangement, as companies are looking for alternative manufacturing hubs. India could be their preferred choice, provided we are able to offer a great environment. A conducive business climate with simplified land and labour laws, better infrastructure and logistics, and single window clearances can enable India to develop a full-bodied manufacturing network

Dr Ravinder Deep Singh Sethi
Chief Operating Officer, Oncquest Laboratories

The introduction of the production linked incentive scheme (PLI) encouraging domestic manufacturing of medical devices has enhanced growth prospects immensely. The industry needs continued financial assistance and policy support from the government. An enabling eco-system must be created so that the companies can leverage emerging collaborative growth opportunities

Dr Veeraal Gandhi
Chairman and Managing Director, Voxtur Bio

Talking about the need of the hour in this direction, Dr Chinmaya P Chigateri, Director & CEO, Healthminds Consulting added, "A set of robust regulations for the pharma sector helped India to become one of the world's leaders in generic drugs via a regime of price controls, process patents and industrial promotion policies. The need of the hour is to create a similar, independent framework for medical devices and software to reduce the dependence on imported medical technology and create an opportunity for Indian companies to thrive."

Entering the post-pandemic phase and need of the hour

In order to realise the growth spectrum, the medtech sector needs to further improve infrastructure and logistics networks and to enhance the supply chain ecosystem. Moreover, there's a need for effective collaboration across value chains for facilitating innovation and introducing new products that expand the sector to its potential of USD 50 billion by 2025.

Stressing on the need of bringing strong emphasis on R&D and innovation, Nevatia added, "With the large number of engineering graduates India produces each year from top institutions, India has the potential to become a global hub for R&D for medical devices. Several companies have started setting up their R&D centres in India employing large numbers of engineers and associates. Recognising and incentivising this within the framework of Aatmanirbharta is key. Also, there is a great opportunity for collaboration and partnerships with Indian institutions - a strong funding mechanism becomes imperative which can be achieved through capital subsidies and tax incentivisation."

Talking on the similar lines, Bhattacharya said, "India produces one of the largest numbers of STEM graduates in the world. This means the availability of an excellent talent pool for investing in global-scale R&D activities. For the R&D sector particularly, India provides significant ease-of-doing-business factors and those can be further strengthened by bringing in national-level policy and incentives for investors. India also has an extremely vibrant start-up ecosystem that can be tapped for introducing market appropriate medtech innovations. A structured partnership program among academia, start-up ecosystems, and global medtech players can help bring sustainable and affordable innovations across the healthcare system."

Rajneesh Bhandari, Founder NeuroEquilibrium added, "Reversing the trend of adopting medical technology from developed countries, India is becoming a hotbed of health tech and medtech innovation. Instead of reverse-engineering western products, now Indian innovators are going global with unique and path-breaking medtech products and solutions. There are over 3000 healthtech/medtech startups in India, many of which are looking to build global products and services. As a result, India has reached an inflection point, and we will see more innovative startups come up and find global markets."

A creation of flexible supply chain and focus on their management is the need of hour for better patient outcome and positive business outcomes.

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INTERVIEW

The spirit of Aatmanirbhar Bharat has spawned medical devices and med-tech companies in India

Anish Bafna, CEO & MD, Healthium Medtech in an interaction with **Kalyani Sharma** talks about his company's plans for the Indian market and highlights the opportunities and challenges in medtech sector in India

Tell us about the Healthium Medtech journey so far and company's future plans

Healthium Medtech Limited, is a global medtech company focused on products used in surgical, post-surgical and chronic care. Our vision is to deliver "Access to precision medtech for every patient, globally."

As of fiscal 2021, some key aspects are

◆ We are the largest independent medical devices company and the 2nd largest company overall, in the surgical consumables market in India

◆ The largest non-captive surgical needles manufacturer, in overall volume sales globally

◆ Third largest company overall in the urology collection devices market in the U.K., by market share.

◆ 1 in 5 surgeries conducted globally, uses a Healthium product as of 31st March, 2021.

◆ We have extensive market access and export our range of products to over 80 countries

and our sales network reaches 90 per cent of all districts in India which have secondary healthcare facilities encompassing 40,000 surgeons across 18,000 hospitals across India as of 31st March, 2021.

◆ Our comprehensive and Innovative product portfolio across 4 focus areas: Advanced Surgery, Wound care, Urology and Arthroscopy encompasses 52000 SKUs across different products.

◆ As of July 31, 2021, we have 64 patents in the US, Europe and India including pending applications pending post CareNow acquisition.

◆ With eight integrated, scaled manufacturing facilities, we have a strong focus on quality, and several of our facilities have different global accreditations and registrations, including with US FDA, C.E, TGA and ISO.

◆ In particular, we were the first Indian Class III medical device company to receive US FDA registration for one of our manufacturing facilities.

◆ Further, we are the only company in India with a CE-certified surgical needles manufacturing facility as of March 31, 2021.

◆ Our manufacturing facilities employ technology that we have largely developed in-house to ensure high quality and to allow for extensive customisation of our products to meet our customers' diverse needs.

◆ We have over time executed a number of acquisitions, and have demonstrated that we can successfully integrate and grow the acquired businesses. The acquisition of Quality Needles, CliniSupplies, VitalCare, AbGel and CareNow has enabled us to add a slew of products to our portfolio and further deepen our customer relationships.

We aim to grow by deepening and expanding our geographical presence by increasing our footprint of hospitals and expanding our customer base, expanding our product portfolio with high-quality, innovative products, and drive accelerated growth by leveraging market access.

The medical devices industry is an integral part of the healthcare ecosystem and has been recognised for its role in managing the pandemic by creating scale and affordable solutions within a short period

Can you highlight the role of the medical devices sector in India in achieving the 'Availability, Accessibility, Affordability and Acceptability (4As)' of universal healthcare?

According to Frost & Sullivan Report, surgical procedures in India are highly underpenetrated at ~2,000 surgeries per 100,000 people, compared to other emerging market peers at 4,500 surgeries per 100,000 people. Frost & Sullivan estimates the surgical procedures to grow at a CAGR of 9.83 per cent (2021-2025) and reach 27.23 million procedures by 2025.

The growth of economy has strengthened the growing middle-income population in the tier-2 and tier-3 cities which are key contributors in demand for healthcare services in the country. However certain trends, as per Frost & Sullivan report have shown the role of medical devices in moving towards achieving the 4As of universal healthcare:

◆ **Growing disease prevalence:** India's high population growth rate and increasing prevalence of chronic lifestyle diseases has led to an increase in the need for surgical interventions to reduce the complications associated with such ailments.

◆ **Improving access to care:** The healthcare service industry is growing at a fast pace which has driven an increase in surgical procedures from 1,500 to 2,000 per 100,000 people (2015-19), however this lags other emerging markets at 4,500 surgeries per 100,000 people. This gap has resulted in significantly lower medical device per capita spends versus peer emerging markets.

◆ **Emergence of smaller hospitals:** Smaller private hospitals with surgical focus in tier-2 and tier-3 cities have increased access to surgical interventions for the rural population, driving increase in market penetration and overall growth in surgical procedures. These hospitals offer a strong value proposition of lower cost and convenience for the local population.

◆ **Increase in insurance penetration:** In 2019-2020 around 36.5 per cent of the population in India was covered by health insurance, which is expected to increase to 55 per cent by 2025. Public schemes such as Ayushman Bharat and other state government schemes have further accelerated the utilisation of health resources driving growth in volume of surgeries conducted.

◆ **High GDP growth driving rising income:** India is one of the world's fastest growing economies. India's GDP at current prices is US$ 2.7 trillion in 2020 and is estimated to grow at a CAGR (2020-25) of 8.3 per cent. The growth of economy has strengthened the growing middle-income population in the tier-2 and tier-3 cities which are key contributors in demand for healthcare services in the country. Tier-2 cities such as Surat, Patna, Jaipur and Indore have recorded an economic growth rate of over 40 per cent making them an attractive destination for healthcare investments.

Healthium has also made efforts towards the 4As. We have created wider access with our sales teams covering 90 per cent of all the districts with secondary healthcare facilities, and the sales force covering over 40,000 surgeons across 18,000 hospitals, as of March 31, 2021. We have created several patented products for bettering patient care. We believe we have a significant opportunity in our markets and focus areas given our differentiated value proposition of providing high-quality, innovative products at a compelling value. Our business strategy is aimed at exploiting this opportunity by

◆ Deepening and expanding our geographical presence and market access to expand our customer base

◆ Expanding our product portfolio to deepen our customer relationships.

◆ Focusing on operational excellence to continue to deliver superior value to our customers.

We believe that our well-established corporate product brands, and relationships with hospitals, surgeons and distributors create competitive advantages for our business. This enables us to develop a broader customer base and deepen our customer relationships, which in turn enables us to drive uptake for our new products.

The medical device industry has witnessed considerable growth over the years and continues to display significant potential, however there are still several gaps that need to be filled. Can you throw some light on these gaps?

The medical devices industry is an integral part of the healthcare ecosystem and has been recognised for its role in managing the pandemic by creating scale and affordable solutions within a short period. However, the industry is highly import-dependent with high

quality and affordable medical devices for patients, which remains a gap. We will continue to invest in R&D as we aim to make products that address the needs of patients and healthcare professionals.

The Indian government is working on a range of initiatives to develop healthcare infrastructure, reduce the access gap (example Ayushman Bharat Yojana) and improve the management of chronic diseases. The reduction in out-of-pocket healthcare expenditure as a percentage of current healthcare expenditure for India from 71.7 per cent in 2000 to 62.7 per cent in 2018 displays the impact of government initiatives in improving access to affordable care. COVID-19 has spurred the state and central governments to enhance domestic manufacturing and healthcare infrastructure to ensure self-sustenance and adequate coverage.

What is the need of the hour as far as ease of doing business & making India globally competitive in the medtech sector is concerned? How crucial will be the role of Aatmanirbhar Bharat in this?

The Government of India has recognised medical devices as a sunrise sector under the 'Make in India' campaign promoting domestic manufacturing and reducing the dependency on imports. Consumables and disposables form the largest export category, accounting for 47 per cent of exports as per the Engineering Export Promotion Council of India. Promoting local manufacturing of high-end medical devices in scale and quality will attract investments in the sector. The spirit of Aatmanirbhar Bharat has spawned medical devices and med-tech companies in India, which have emerged as global leaders, pioneers and innovators.

Penetration of surgical procedures in India has grown from 1,500 per 100,000 people to 2,000 per 100,000 people between 2015 and 2019. The gap between India and other emerging countries has been narrowing over the last few years as the Indian government has undertaken various initiatives to increase access to healthcare across India. Certain state policies will drive investments in the medtech sector like the Andhra Pradesh Medtech Zone (APMTZ). The development of more such zones will house capital intensive scientific facilities and laboratories.

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INTERVIEW

A separate code for medical devices will better address the unique needs of the medtech sector

Abby Pratt, Senior Vice President, Global Strategy & Analysis, AdvaMed in an interaction with ***Express Healthcare*** explains about code for medical devices sector and its crucial role

Why is separate code is required for Medtech sector?
A separate code for medical devices will better address the unique needs of the medtech sector. The AdvaMed code aims to bridge the gap and drive cognizance on the unique requirements of the medtech sector with respect to training and clinical research. Medical devices vastly are distinct from pharmaceuticals in terms of their design, manufacturing, innovation life cycle and deployment in a clinical setting. Given the knowledgebase, skills and training required of healthcare professionals to operate, deploy or utilise certain medical devices, manufacturers of medical devices will need to engage doctors differently as compared to their counterparts in the pharmaceutical industry. Therefore, a distinct code for medical device manufacturers around ethical conduct with healthcare providers and physicians is critical.

How is the new code going to help the medtech industry in the interaction with the healthcare professionals?
Medical device companies, globally and in India are dedicated to advancing medical science; developing high quality, innovative medical technology; and improving patient care. The new code will act as an essential guide for all companies as they strive to achieve their business objectives while ensuring patient safety and integrity in all their actions. We urge all med-tech companies – including small, medium, and large size firms and all the representatives on the forefront of these businesses to proactively adopt the code. The code will not only standardise interactions with healthcare professions during the course of their business but also help maintain a healthy medtech innovation ecosystem for the benefit of the industry as whole. Code adoption strengthens the industry's relationships with physicians and other health care providers by focusing interactions on developing innovative and cutting-edge technology and patient care, thereby helping to ensure the independence of health care professionals' medical and clinical judgment.

While the COVID-19 pandemic is far from over, the global disruption it has caused will drive many healthcare organisations to rethink their business model

How has AdvaMed conceptualised and developed the methodology for the code of ethics for India?
AdvaMed stood up a task force in October 2019 to draft an India Code of Ethics based on the U.S. Code but tailored to business and market realities in India in response to the AdvaMed India Executive Committee's recommendation to develop a code of ethics to promote greater consistency across the industry for ethical interactions with healthcare professionals in India. That task force, comprised of mainly India based ethics and compliance lawyers, completed the draft code in June 2020. Following successful completion of legal review by outside counsel from both India and the U.S., the Code underwent rigorous member committee review

and recommendation processes, resulting in the Code's unanimous approval by the AdvaMed Board of Directors in September 2021.

How is AdvaMed working in the medtech industry and the government for greater adoption of the code of ethics in India?
AdvaMed and its members are committed to work with the Indian government, including the Department of Pharmaceuticals, and bring their expertise and knowledge for strengthening medtech sector in the country. The code is a valuable example for the India Government to consider as they contemplate developing their own code for the sector. For India, the code takes into account the unique requirements of the country – both at the professional and cultural level. AdvaMed has also worked to educate its members on and achieve industry commitment to the code with promotional materials, training webinars and certification workshops.

What are the key lessons learned during the pandemic?
While the COVID-19 pandemic is far from over, the global disruption it has caused will drive many healthcare organisations to rethink their business model. The COVID-19 pandemic placed extraordinary pressure on global healthcare systems and medical supply-chains, causing enormous disruptions and shortages. Companies and healthcare professionals alike were forced to make rapid procurement and distribution decisions. The pandemic highlighted the critical role of ethical business practices and effective compliance programs in ensuring that decisions are made in the best interests of patients.

Post-pandemic scenario of the sector
COVID-19 has presented a humanitarian crisis like no other. Indeed, the speed and depth of disruption due to the pandemic is creating unprecedented challenges for societies and economies across the world. This is especially clear on the frontlines of healthcare delivery. As infections spread around the world, health systems have redirected substantial resources to COVID-19 response efforts. Consequently, there is a great need for guidance to ensure ethical conduct of research, decision making in clinical care, and public health policymaking at every level of the global COVID-19 response.

In India, AdvaMed aims to demonstrate medtech's commitment to ethical business practices and effective compliance with wide-spread adoption of the India code of ethics.

MedTech, leading the path to a growing economy

Himanshu Baid, Managing Director, Polymed talks about medtech sector market landscape in India and possible opportunities for further growth

The country's healthcare sector has grown rapidly over the last 5 years, with a Compound Annual Growth Rate (CAGR) of approximately 22 per cent since 2016. Healthcare has become one of the largest sectors of the Indian economy, in terms of both revenue and employment.

The medtech industry is highly import dependent on other countries for raw materials and now is the right time to challenge this arrangement, as companies are looking for alternative manufacturing hubs. India can be their preferred choice. The Prime Minister's call for Atmanirbhar Bharat, is a step in the right direction for our domestic manufacturing sector. A self-reliant India would mean the country reducing its dependence on imports by focusing on 'Make in India'. Atmanirbhar Bharat can help us regain the lost ground of industrialisation. A business climate with simplified land and labor laws, better infrastructure and logistics, and single window clearances can enable India to develop a robust manufacturing ecosystem. This will also help attract foreign capital, latest technology, create employment and boost our exports. Skill and Scale should be the primary focus to achieve both quality and cost competitiveness. There exists a huge scope for India in medtech sector, not only to be self-reliant but also capture a considerable share of the global supply chain.

To overcome the challenges, there is a need for sustained financial as well as policy support from the government. The government has also announced production-linked incentives (PLI) for domestic manufacturing, which is slated to provide financing to the tune of US$425 million. An additional US$52 million infrastructure financing in medical parks is expected to boost domestic production in the Indian medical device industry.

A business climate with simplified land and labor laws, better infrastructure and logistics, and single window clearances can enable India to develop a robust manufacturing ecosystem

The Government has also adopted a 'Manufacturing Ecosystem Cluster Development' approach. Medical device parks are being developed around five device manufacturing clusters in the country. State Governments are committed to setting up dedicated industrial parks for enabling efficient domestic manufacturing at lower costs. These parks will provide all the essential infrastructure, allowing companies to adopt 'Plug and Play' model. As a consequence, Industry estimates suggest that the cost of production will be reduced by 15-20 per cent with this model. Further, companies will have easy access to in-house standard manufacturing/testing facilities as well as consolidated raw material procurement. They will be able to use the common facilities and pay for them on a per-unit manufactured basis. Crucially, this mechanism will ensure that all necessary approvals are in place before hand, thereby reducing the time taken to begin commercial production.

On the policy front, the Indian Government has announced favorable policies for encouraging Foreign Direct Investment (FDI). In fact, India's FDI regime has been liberalised extensively. Currently, FDI is permitted up to 100 per cent under the automatic route (i.e., the nonresident investor or Indian company does not require approval from the Government of India for the investment) in the hospital sector and manufacturing of medical devices. India has emerged as one of the fastest-growing economies over the last two decades, receiving large FDI inflows.

While the adoption of home healthcare solutions in India is currently at a relatively nascent stage, it has tremendous potential for growth in the future on account of the rising elderly population in the country, increase in the incidence of chronic diseases, enhanced demand for constant personalised care as well as the emergence of nuclear family structures in urban areas.

The country's relative cost competitiveness and availability of skilled labor are also making India an increasingly favored destination for Medical Value Travel. In the medical devices and equipment segment, expansion of diagnostic and pathology centres as well as miniaturised diagnostics have high potential for growth.

A comprehensive health diplomacy which can leverage Indian strengths and match it to Indian requirements at the international level requires an ability to synthesise the various activities already being undertaken by different branches of Government. A "purpose-driven" and integrated approach to this critical area is required.

In the years to come, demographic and epidemiological trends are likely to boost the demand for healthcare as well as influence the nature of health services demanded. Through a futuristic and dynamic approach, and creating an efficient ecosystem for domestic manufacturing, India can emerge as a trusted partner for the world for medical devices.

Medtech industry in India: A future of possibilities

Koji Wada, Managing Director, Fujifilm India highlights the lessons learnt from the pandemic in medtech sector and possible opportunities

The healthcare industry globally was severely hit due to the COVID-19 pandemic. The speed and depth of disruption due to the pandemic created bizarre challenges and unparalleled threats for everybody across the world. The medical industry has been at the forefront of battling the COVID-19 pandemic since the first outbreak by ensuring the supply of PPEs, oxygen concentrators and ventilators, testing kits, etc. Due to this increased demand for products and the rapid pace of R&D, the industry faced a major supply challenge. However, the pandemic showcased India's ability to produce and become "aatmanirbhar" in the healthcare sector.

From setting up emergency COVID-19 centres within weeks to producing vaccines, India was able to fulfil all its needs and further assist other countries in their fight against the virus. The pandemic has proved that if the public and private sectors collaborate and work together for the growth of the healthcare sector, India could ensure quality and affordable medical service and help for all. This also led the government to initiate things and accelerate innovations on a mass level.

With public-private partnership and participation, capital, tax subsidies in medical devices parks and other advanced medical technologies that support through the diagnosis to treatment journey of a patient, the day is not far when we can onset the path of helping the nation become self-reliance through technological advancements leveraged in med-tech industry.

With public-private partnership and participation, capital, tax subsidies in medical devices parks and other advanced medical technologies that support through the diagnosis to treatment journey of a patient, the day is not far when we can onset the path of helping the nation become self-reliance through technological advancements leveraged in med-tech industry

Thanks to the digitisation, the med-tech industry has now developed the potential to tackle their most pressing challenges. They have become more effective in their ways and made the processes effectively simpler, and even time efficient. For patients too, it is now possible to get diagnosed without paying visit to a doctor. Thanks to online consultations owing to med-tech developments, virtual diagnosis is now a reality in India. And on top of that, it is hassle free for medical practitioners also. The digitisation has led to vast adoption of cloud in India by business and professions of all kinds and sizes for storing data. Cloud adoption has also accelerated the pace at developments in med-tech industry. It is now very efficient to store hefty data without a miss and hassle with cloud. According to BCC research, the global healthcare cloud computing market is expected to hit $35 billion by 20221. Hence, showcasing how pertinent the technological advancement in the med-tech industry has become to go through thorough diagnosis and treatment.

The pandemic has increased the use and adoption of technology across all sectors, including the medical supply chain. The Indian healthcare sector was the backbone of India during the challenging times of the first and second waves of the pandemic by providing several tech-enabled solutions. There are some technology trends like big data, blockchain, drone deliveries, cloud computing, artificial intelligence, robotics and IoT (internet of things) that have completely transformed the medical supply chain and drastically shaped the med-tech sector in India

The med-tech and medical device startups are creating a buzz with their presence along with businesses that are investing and manufacturing COVID-19 supplies. Some new-age technologies such as 3D printing, artificial intelligence, smart sensors and robotics have contributed to the revolution of the medtech sector. The Indian medtech industry may witness an extensive revolution with a collaborative and dynamic approach, delivering superior quality products and world-class manufacturing facilities. With Government's support in policies and subsidies, India can become a global healthcare destination.

There are some lessons that we learnt from the pandemic

It is essential for India to invest in its healthcare infrastructure especially in the med-tech sector to meet the growing population. The government needs to allocate funds in the budget so that there's a bright future for this sunrise sector. India is in dire need to reactivate the telemedicine revolution not only in the major cities but also in remote areas.

Telemedicine proved to bridge the healthcare gap in India and became a very useful tool during the COVID-19 pandemic. During the two waves of the COVID-19 Pandemic, the Healthcare providers substantially used the telemedicine systems to reduce doctor-patient contact and helped in breaking the chain of transmission of infections. We need to further develop this digital infrastructure to be prepared for any such future situations. India has proven its capabilities on the global front, and with the right lessons learnt from the pandemic, the country will further establish its mark in the medtech industry globally.

Increased demand of quality and affordable healthcare equipment after COVID outbreak

Mehernosh Daruwalla, Founder & Managing Director, Lotus Surgicals talks about post-pandmeic scenario of medtech sector in India

The novel coronavirus pandemic sparked multiple intertwined healthcare crisis that revealed deep underlying gaps in the healthcare system. A sudden boost in demand and supply chain bottlenecks even compelled India to find new solutions and embrace the wave of self-dependency. These factors have exerted immense pressure on Indian healthcare providers to innovate and develop a competitive edge throughout their business operations. With the authorities managing to control the crisis, the industry needs to focus on the next big challenge in the form of providing good quality and economical healthcare solutions in the post-pandemic world.

The impact of COVID-19 on Indian healthcare

India's robust response against the pandemic has been with stealth, pace and scale, resulting in a quick economic bounce back from the earlier grim situation. A proactive action plan to cope with the pandemic involved setting up of dedicated COVID-19 hospitals, isolation centres and technology-powered resource mapping. Private players were also crucial, which accounted for 60 per cent of total inpatient care in COVID times. Though the risk of virus resurgence is real, a more prompt system is already in place to tackle the situation.

Overall, the quick response, innovation, good manufacturing push and changing consumer psychology toward healthcare have posed a potential opportunity for the industry. The rising healthcare awareness and services demand is developing a classic demand-supply curve with demand winning. Hence, the healthcare fraternity needs to bridge this emerging supply gap with good quality and affordable healthcare solutions throughout the Indian subcontinent.

Tackling the need for quality & affordable healthcare equipment

In the post-COVID-19 era, the public expenditure in the health sector has significantly increased. It has made healthcare one of the most important yet expensive things of modern times. Development finance for health requires a shift in support towards more focused investments. Hence, to make healthcare available and affordable to all we need to foster an environment favourable for manufacturing and significant R&D. Setting up more plants to increase scale for domestic consumption as well as exports is crucial.

India's high import dependency for critical KPIs is one of the major challenges that need to be solved. Better and more functional acquisition and supply of raw materials also need to be established.

While building capacity and developing new treatments is critical, we need to also pay attention to the routine requirements of the healthcare world. Increasing healthcare demand means a multiplier effect on routine healthcare products demands. Finding the right cost competitiveness is also very crucial in today's globally knitted healthcare market. Speciality equipment, medical devices and Pharma etc. are bound to receive a massive push for which the country should prepare early.

The growth of the Indian medical devices market in recent times

In the last decade, the medical devices and healthcare sector has grown tremendously. Due to the huge imbalance between demand and supply of medical devices, there is a vast opportunity to manufacture devices in India. With the support of healthcare workers and the government, many domestic companies are taking initiatives in building a strong foundation for the Indian healthcare system.

India, amongst 20 markets for medical devices, stood at US$ 11 billion in 2020 and is expected to reach US$ 65 billion in 2024. Indian government is playing a huge role in strengthening the healthcare industry through various initiatives by emphasising research and development (R&D) and 100 per cent FDI for medical devices to boost the market. From April 2000 to March 2021, FDI inflow in the medical and surgical appliances sector stood at US$ 2.19 billion.

In India, since the public health sector is less funded, the arena of healthcare is extremely capitalised. Due to this nature of a free economy in the healthcare sector, with extremely high demand, the prices of private healthcare in India continues to boom at an unprecedented rate. Also, we haven't met with complete scientific technology as to reach there, it requires loads of finance, due to which medical device manufacturing in India is still comparatively costly. But if we look back two three decades ago, Indian medical devices lacked transformation way too much in every terms. But with growing technology and consistent help of government Indian Pharma has stands world's 3rd largest by overall volume and world's largest as provider of generic medicines globally, with 20 per cent and 3.5 per cent share of total global pharmaceutical exports by volume and value respectively to more than 200 countries and territories in 2021.

The same success can be replicated by Indian entrepreneurs if given suitable help from the government. China has complete hands-on over import of medical devices, but, since the outbreak of COVID-19 the world has lost trust from China. This can be used as opportunity as we can make medical devices with all the resources available. Government is also doing their best to make things better.

For reference, in a recent project, the Government of Andhra Pradesh is establishing the Andhra Pradesh MedTech Zone (APMTZ), which will house all capital-intensive scientific facilities, laboratories, etc., and will be leased to manufacturers in Vishakhapatnam. This initiative will help decrease the cost of good-quality products. In the future, Indian companies are expected to make various alternatives for multinational products with the help of technology and study, ensure quality & cost and make healthcare easy and affordable in the changing world.

The rising healthcare awareness and services demand is developing a classic demand-supply curve with demand winning. Hence, the healthcare fraternity needs to bridge this emerging supply gap with good quality and affordable healthcare solutions throughout the Indian sub-continent

Aatmanirbharta in medical devices: Current scenario and need of the hour

Ashok Patel, CEO and Founder, Max Ventilator explains talks about self-reliance in medtech sector in India

Even as experts continue to debate and speculate over the eventuality of a third COVID wave, its intensity and probable new symptoms and new strains, the need to attain self-reliance will remain a watchword of India's health governance. And fostering and development of an indigenous world-class medical device industry will be an integral part of that self-reliance drive. What is the current status of the industry and what can be done more in terms of policy and other ways to steer it into a direction and path of self-reliance?

The prevailing medical devices landscape

The fourth largest market for medical devices in Asia, as of 2021, India is an $ 11 billion market. With a projected CAGR of 37 per cent in the coming future, the industry is expected to reach a market size of $ 50 billion by 2025.1 Currently, there are nearly 750-800 domestic manufacturers in India, with an average investment of $ 2.3-2.7 million and an average turnover of $ 6.2-6.9 million.2 At the same time, there are over 6000 start-ups. Some of the key states that serve as medical device manufacturing hubs include Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, Telangana and Tamil Nadu. Yet, India imports nearly 80 per cent of its medical devices. For its part, the government has ensured that a favourable policy climate exists for investment from outside. With 100 per cent FDI being allowed under the automatic route for both greenfield and brownfield establishments, until June 2021, the country has notched up investments worth $ 2.23 billion. Notably, between financial year 2019 and 2020, the investment had almost doubled Y-o-Y to over $ 301 million.3 At the same time, the US, Germany, China, Brazil and Iran have been key importers of Indian medical devices.

Where the industry falls short: domestic manufacturers catching up, yet patchy

Notwithstanding the impressive numbers, besides the fact that the country is dependent on nearly 80 per cent of its needs on imports, its domestic manufacturers are mainly focused on relatively low-end products such as consumables, surgical, cardiac stents and implants and general medical devices. The high-end technology products are mainly dominated by foreign players either through investments or the export route. In fact, electronics and equipment constitute a sizeable 56 per cent of the country's medical devices imports. However, COVID-19 has definitely given an impetus to a flourishing diagnostics and imaging sector with over 2500 labs now conducting advanced molecular tests such as RT-PCR tests. In addition, domestic manufacturers are also coming up with upgraded implants and prosthetics technologies, technologically-advanced life support systems such as ventilators, automated external defibrillators (AEDs) and oxygen concentrators besides an array of modern automated and precision surgical tools and systems for different conditions. Yet, these recent developments are few and far between on a national level.

Regulations afoot to push the industry for quality and competitiveness

For its part, the government has in recent years attempted to streamline the regulatory framework for the industry with a series of rules and guidelines. The Medical Devices Rules 2017 had prescribed for a four-fold risk-based classification system covering all medical devices and equipment. Then the Medical Devices (Amendment) Rules 2020 has provided for a separate regulatory framework for medical devices divorced from drugs while also mandating companies to compulsorily register on a government-designated portal and acquire license for operations. Stipulating ISO 13485 as a pre-condition for registration would ensure that domestic manufacturers can compete in the world market and would be treated on equal terms with leading global companies.

Governments' initiatives on medical device parks and PLIs

Along with regulatory initiatives, the central government and states have also attempted to give an impetus to domestic manufacturing by way of setting up of clusters and medical device parks within the country as also through production linked incentives (PLIs). Already, state governments of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh have given "in-principle" approval to develop medical devices parks. So, while Gautam Budh Nagar, Noida, is expected to have Northern India's first medical tools and system manufacturing park by 2022, the Punjab government has also announced a medical device park at Rajpura.4 Furthermore, the government has also announced a PLI scheme for making medical devices in four segments that includes devices for cancer care, radiology and imaging, anaesthetics and cardio-respiratory devices and all implants including implantable electronic devices. The scheme is to extend incentive at the rate of 5 per cent of incremental sales to eligible applicants.

What more can be done

So, while these have been commendable steps, there is a lot more that needs to be done to enable the emergence and indeed flourishing of an international quality and globally competitive domestic medical device industry.

- Motivate buyers (hospitals) to buy genuine Make in India medtech devices. Offer rebate on purchase and provisions for higher depreciation Indian medical device purchase.
- Additional incentive for R&D expenses to be invested to the current scheme, requires fulfillment of complex procedure of defining the manufacturing industry. Bank can be made responsible to recognise award and the status of R&D house. Using this can endorse the existence of R&D activities. Local industry association can endorse the existence
- Educational Institution can get associated with medical device industries by adding subjects on medical devices daily studies. Full time involve-

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ment of students with industrial activities in R&D. The current allocation of time is very much insufficient (current allocation by most of the University is One semester, half/one day per week)
◆ Support from local education institutions for educating industry and their representatives in to exposure to new technologies, process of device certification, applicability of product standards, interpretation of product standards, implementation of requirements of product standards, guidelines for testing.
◆ BIS and OCI to allow easy access to all the required standards
◆ ERTL, E2DC, DRDO, provide guidance in finding applicable standards for particular medical device as and when requested by industry.
◆ Simple process of filing patents, registration of designs, copy rights (... within... Indian territory)
◆ Concessional Inclusion from labor laws, factory act, employment law for R&D employees and man power. So that industry can grow at faster pace.
◆ Allow medical device industry to execute legal contract for minimum service duration.
◆ Faster and shorter reverts for legal actions, structural roles and punishments for Protection of IP rights and theft of intellectual property.
◆ Product imported under CKD or knockdown condition that is reassembled and re-label in India should be discouraged. So, with these steps, the Indian medical device sector can not only truly become self-reliant but also go a long way in contributing to quality healthcare for Indians in India!

1. *https://www.investindia.gov.in/sector/medical-devices*
2. https://www.investindia.gov.in/sector/medical-devices
3. https://www.ibef.org/industry/medical-devices.aspx
4. https://www.ibef.org/industry/medical-devices.aspx

Medical devices-Initiatives, challenges and road ahead for India

Dr Vinod Kumar SV, Dean In-charge & Professor, IIHMR University highlights various initiatives in medtech sector in India and throws light on the challenges and opportnitites

As per the World Health Organization, medical devices include the whole range of instruments, machines, implants, appliances, and even software, reagents or any such material which is intended for being used for a medical purpose. It is believed that there are an estimated 2 million different types of devices grouped into more than 7000 generic groups.

At an estimated USD 11 Bn, India ranks fourth in Asia and is one of the top twenty global medical device markets. COVID-19 pandemic has highlighted the need for adequate availability of medical devices like never before. The pandemic times have shown us how the emergency services could become incapacitated due to lack of medical devices and how the manufacturers and suppliers were strained by unprecedented demand for specific life saving devices and equipment. As we stand at the crossroads of an expanding market of medical devices laden with opportunities, there is also the challenge of ensuring quality and accountability through adequate regulations. According to the Indian Brand Equity Foundation (IBEF) report, the Indian Medical devices market has the potential to grow at a CAGR of 35.4 per cent to reach USD 50 Bn by 2025.

Government has taken many steps to promote the growth in this sector. The medical device industry has been recognised as a sunrise sector under the make in India campaign by the government. The union ministry has also launched the scheme to promote establishment of medical devices parks under the Atmanirbhar Bharat Abhiyaan. The world class infrastructure facilities at these device parks would enable easy access to standard testing and resources. One of the first such parks, 'MedSpark' has been established by Kerala at Thiruvananthapuram in

2020. In April 2021, the Ministry of Health and Family Welfare, Government of India has notified that Medical Devices would qualify as drugs, under the section 3 of Drugs and Cosmetics Act 1940. In 2021, the Quality Council of India (QCI) launched Indian Certification of Medical Devices (ICMED) Plus Scheme, with an aim to link the components of quality management system with product specific quality validation by witness testing of the items in line with the set specifications and standards. This is perhaps the only scheme in the world having an integrated approach to quality management systems, product certification standards and regulatory requirements.

Adding more rigour to the regulations, the government implemented the Medical Devices Rule 2017 which came into effect from 01 January 2018. The regulations classify the medical devices into four categories Class A (low Risk), B (low to moderate risk), C (Moderate to High risk) and D (High Risk). These regulations lay down the procedure for licensing the Import, manufacturing for sale, distribution and sale, stock, exhibiting or offering for sale. Central Drug Standard Control Organisation (CDSCO) though its Central Licensing Authority and State Licensing Authority has the responsibility of regulating these aspects. Through a further amendment in February 2020 to the Medical Devices Rules, a large number of medical devices now need to be registered with CDSCO. Thus, the largely unregulated medical devices sector has been brought under regulatory control through these initiatives of the government.

India is thus at a juncture of expanding global opportunities which could be transformative for the country's medical devices and technology industry. The government has taken several initiatives to encourage and support the medical device industry and has also tried to ascertain that medical device are brought under the regulatory control. However, to ensure that we utilise the potential to the fullest, it will be crucial to ensure that a smooth working model is developed to ensure integration of manufacturing, testing, quality control and regulatory frameworks.

> As we stand at the crossroads of an expanding market of medical devices laden with opportunities, there is also the challenge of ensuring quality and accountability through adequate regulations

INTERVIEW

Digital shift in the medical space

Sean Narayanan, CEO, Apexon in an interaction with ***Express Healthcare*** talks about a shift in healthcare industry from traditional processes to digital solutions

How have hospitals, emergency medical services firms etc. shifted their focus from traditional or manual processes to digital solutions?
During the COVID-19 pandemic, we have seen an increase in the adoption of digital solutions in the healthcare sector and these changes are here to stay in the post-pandemic world. Providers and hospitals are embracing new technologies like AI, ML and Robotic Automation.

Some of the solutions using these technologies include automation in physician credential validation, authorisation (with insurance companies), eligibility validation, and actionable intelligence solutions to improve physician productivity. Apexon has implemented over 100 bots for automation and has invested in Blockchain solutions in healthcare processes.

What are the benefits the healthcare sector has been seeing with the adoption of digital solutions?
With the ease of retrieving patient data, digital technology has helped maintain a single repository of a patient's medical history that can be accessed and reviewed for better and quicker care. It has made healthcare an improved and efficient experience for patients.

Patients, physicians, and payers are adopting patient engagement platforms as a core element in managing and optimising patient experience. These platforms with chat solutions provide access to appointments, medical records, case management, accessibility to insurance cards, virtual doctor appointments, 24/7 nurse support lines and claims and payment support. The pandemic has accelerated the adoption of these digital solutions.

Virtual doctor visits have become prevalent, thereby cutting down time and making access to healthcare easier. Digital patient engagement platforms have improved healthcare distribution and access, as well as communication and collaboration between patients and providers

With the help of Apexon's digital solution for clinical trials, we are helping pharmaceutical companies speed up processes to bring drugs to the approval stage. COVID-19 vaccine development and approval was the fastest in history, with digital transformation technology being a key enabler in accelerating that timeline.

In today's scenario, has the patient experience improved with technology?
Virtual doctor visits have become prevalent, thereby cutting down time and making access to healthcare easier. Digital patient engagement platforms have improved healthcare distribution and access, as well as communication and collaboration between patients and providers.

These platforms provide the consistency and reliability that manual processes cannot match. Solutions like app-based scheduling have significantly reduced or even eliminated long patient wait times, improving the quality of experience. Health exchange APIs are making data exchange more efficient, leading to better care coordination among providers, and enabling easier access to patient health records.

What are the challenges faced with digital transformation in healthcare? Especially with cyber-attacks on patient data being the biggest threat.
Data management and cybersecurity have always been a challenge across all industries. Healthcare providers have systems that manage enormous amounts of sensitive electronic medical records, combined with practice management and financial systems that add to its complexity.

There is rightly an increased focus on security, and we feel that patient data today is still more secure than it used to be. Healthcare organisations are making significant investments in protecting their digital assets, including patient records.

What is the role of digital solutions in sustainable healthcare practices?
Digital transformation through telehealth reduces costs and saves communities from avoidable pollution with virtual consultations and by reducing travel. Electronic Health Records have reduced paper dependency to a large extent. Digital solutions have led to institutions achieving efficiencies in their supply chain, safe management of chemicals and pharmaceuticals, and minimisation of waste.

INTERVIEW

Blockchain will redefine the way how healthcare is administered, accessed, and paid for

Pradeep Goel, Chief Executive Officer, Solve.Care in an interaction with **Kalyani Sharma** highlights the role of blockchain technology in transforming the healthcare ecosystem

Walk us through the journey of Solve.Care?
Solve.Care was established in 2017 to solve the fragmented healthcare system that is rife with inefficiency, too much coordination, and bureaucracy; to remove frictions across clinical care coordination, administration, and payments. The root cause for these issues is the way data is managed and controlled by the various stakeholders (healthcare facilities, insurance, governments, doctors, patients etc.) in healthcare. Because of the lack of trust among stakeholders, data is stored in centralised siloed systems, and to access that data requires permissions from the various stakeholders.

Solve.Care's journey started with the acquisition of UKRSOFT, an IT service company. We began utilizing the experience of the team for extensive research, development, deployment, and maintenance of enterprise solutions for companies. Since then, we have grown by leaps and bounds. Leveraging blockchain technology, Solve.Care has developed a full-stack decentralised healthcare platform to host an entire ecosystem journey where different interoperable (health) Care Networks are built and operated to serve the many different needs of healthcare while removing barriers and frictions inherent in the industry.

Since then, Solve.Care has built Care Networks for partners and clients such as Arizona Care Network, Boehringer Ingelheim, Uber health, Lyft, Aon plc, and many more. The Global Telehealth Exchange (GTHE) is a Care Network on the Solve.Care Platform that connects patients and doctors across national borders and was recently launched in India. HealthLink Technologies is the official distributor for GTHE in India. GTHE is currently available in 27 countries, where patients across 12 countries can book appointments with doctors in India to have teleconsultations with them.

With the growing scale of technology adoption in Indian healthcare, what should be the need of the hour as far as data protection is concerned?
The usage of new digital technology in healthcare is undoubtedly accelerating. As a result of the pandemic, telemedicine has become increasingly mainstream. With these advancements, it has become more important than ever to share/store medical records in a safe and secured manner. In the face of the COVID pandemic, the healthcare system faced serious challenges, even in developed countries. This has prompted the healthcare industry to reconsider its existing approach.

Healthcare systems are currently centralised, resulting in a slower and less efficient delivery of services. Everything is centralised, including consent management, data management, and adherence to numerous administrative and clinical protocols. This is the silo mentality I was referring to earlier.

In addition to the inefficiency of centralised systems, the data stored there is never fully secure. The history of data breaches of even the most secure centralised systems is well documented. Just earlier this year, the Health Service Executive (HSE) of

Ireland suffered a major ransomware cyberattack which caused all of its IT systems nationwide to be shut down.

But there is a solution to this. By employing blockchain technology, we can decentralise all sensitive medical data and put it in the control of the actual owner, i.e., the patient. This provides unparalleled data security protecting both patients and the other healthcare stakeholders. For example, patients give their permission to share their medical data with the doctors they want to visit and they can rescind consent at any time.

This is the way how data is managed on the Solve.Care Platform and all Care Networks, including GTHE. All data is decentralised and stored in individual patient nodes. All private information is further encrypted and only the data owner has access to it, with total control as to with whom the data is shared.

Do you think block chain technology in healthcare could be the real game changer in transforming Indian healthcare? (with scale of patient data increasing)
Blockchain is based on the principles of transparency, security, immutability, decentralisation, scalability, privacy, and automation in data ownership and digital consents. With these characteristics, it will redefine the way how healthcare is administered, accessed, and paid for. It will become the de-facto standard in the management of healthcare. Blockchain technology enables medical professionals to have frictionless access to the necessary patient data and take more time to focus on their patients and deliver quality care. There is also medical insurance to consider. A lot of cost and time is spent in admin, in verifying data to see if a patient is covered for a specific procedure, in adjudication, and in the processing and payment of claims. By employing smart contracts in blockchain, all these can be automated to remove the frictions, without the worry of fraudulent claims.

The application of blockchain technology for healthcare provides an opportunity to revolutionize healthcare in India. Even now wanting to book an appointment with a specialist, can sometimes have a month's wait time. However, with Global Telehealth Exchange, patients can now have a consultation with a doctor or specialist across 12 countries, in just 15 minutes. The technology is a great step in removing barriers to accessing timely healthcare.

Your views on the recent nationwide rollout of the digital Health ID. What could be the possible challenges in its implementation and need of the hour in this direction?
It is a great move with an important feature of the programme being to create a comprehensive repository through a healthcare professionals' registry (HPR) and a healthcare facilities registry (HFR). The idea to create a programme for easy and timely access to medical data should always be lauded.

However, there remains the concern of the security of the data. As with any centralised system, there will always be a risk of a security breach. I already gave the example of the Irish experience. Healthcare services were shut down and paralysed throughout the whole country.

Please highlight the future plans of the company? Any new partnership or collaboration in the pipeline?
GTHE is rapidly expanding around the world. In addition to patients in India, patients from Bangladesh, Bahrain, Brazil, Kenya, Kuwait, Nepal, Nigeria, Oman, Pakistan, Saudi Arabia, Sri Lanka, and UAE can also access Indian registered doctors through GTHE for consultations. We have a global rollout plan as we intend to make GTHE available in every single country throughout the world. We recently announced our intention to work together with ARPI (American Research and Policy Institute), an academic research and policy organization, to address shortcomings in the Medicaid market in the US. We have also recently partnered with Alivecor to connect KardiaMobile users with doctors on GTHE for consultations about their ECG readings. We are also working on many partnerships, with the main intention of further improving our value proposition of blockchain solutions for the betterment of healthcare and ultimately the patient.

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India's digital health mission is the need of the hour but privacy concerns can't be ignored!

Advocate Satya Muley, Founder, Satya Muley & Co talks about digital health mission and role of data privacy

National Digital Health Mission (NDHM), which was announced on August 15, 2020, proposes to create 'Womb to Tomb' digital health profiling of Indians. To put it simply, health records of a person such as illnesses, medical prescriptions, reports, and clinical tests will be digitised and stored under one digital health identification.

NDHM aims to develop the backbone necessary to support the integrated digital health infrastructure of the country. It is expected to bridge the existing gap among various stakeholders of the healthcare ecosystem through digital highways.

No doubt it is a first step towards strengthening India's health system and making it more robust to attain constitutional goals of Indians. But, as per current legal framework— the Government is prohibited from collecting health data of individuals. Such information can only be accessed with the direction of a court of law. Here comes the catch.

For NDHM to be implemented— data collection, storage and processing guidelines, legislation has become an essential precondition. When the law is still unclear regarding data privacy— meaning that the digitisation, storage, and processing of sensitive health data of Indians by the NDHM would lead to more questions than answers. Will the provisions of NDHM conflict with the elements of Right to Privacy?

Right to Privacy is sacrosanct

Personal data is now being monetised and weaponised! All this can be attributed to lack of pertinent statues and poor implementation of the existing ones.

Even after the landmark judgment in Justice K. S. Puttaswamy, where the Supreme Court of India recognised the Right to Privacy as a Fundamental Right stemming from Article 21 of the Constitution of India which talks about the Right to Life and Liberty, not much has changed.

Although it seems that we have not progressed much and most likely have fallen into a rut. The Supreme Court in this 2017 judgment also gave express directions to the Government of India to enact a comprehensive privacy law.

The Government of India very promptly appointed a Committee of Experts on a Data Protection Framework for India which was chaired by Justice B. N Srikrishna, which submitted its report during July 2018. The draft Personal Data Protection Bill was placed in Parliament during December 2019 which the Union Cabinet quickly cleared and referred it to a Joint Parliamentary Committee. Since then, there has not been much movement on the subject.

Immense possibilities and instances continue till date of rampant collection, misuse of personal and sensitive information for marketing, surveillance, and other unauthorised purposes without the consent or even the knowledge of the individual.

But..what amounts to personal data?

As per the Personal Data Protection draft bill, all information related with an individual which is regarding their personal choices, movements, reproductive choices, sexual orientation, choice of partners, food habits, financial data from which an individual may be identified or is identifiable, either directly or indirectly is personal data.

Personal data gets further classified as non-sensitive and sensitive data. Sensitive data is related to intimate matters where there is a higher expectation of privacy such as sexual orientation, passwords, biometric data, genetic data, political beliefs, caste, religion, or financial status. It is a startling fact that as of today India does not have a legislation which expressly protects such personal sensitive data and there is absence of guidelines for processing and storage of such sensitive data.

Consent and fair usage of data in the health care sector

When the majority of Indian health care is in private hands how will the stakeholders deal with aspects such as consent of the patient. Consent must be explicit, informed, and meaningful. For vulnerable groups such as children, uneducated and senior citizens, the consent process must be much more robust.

The patients must be provided with autonomy, self-determination, transparency about their data for them to have full control over their data and attach accountability to the data storage authority. This means the patient must have the right to access, confirm and correct their personal data, the right to object to the data processing if desired, must also have a right to be forgotten. These principles are included in the draft Personal Data Protection Bill, and it remains to be seen whether such principles will be part of the final piece of legislation.

It is true that the Indian health sector is plagued with poor service delivery and shortage of trained health workforce. In rural areas the situation is much grimmer. The first instance of care is sought through informal private health clinics. In such a scenario the NDHM's aim appears to be steep.

Fiduciary relationship and obligations

Implementation of NDHM will mean that the individuals will depend upon the health care operators to protect their personal sensitive data while the health care operators shall have to balance it with their own interests remaining within the legal provisions. Therefore, due to such dependence the health care service provider processing the sensitive data shall have to be under the obligation to deal fairly with such data and use it for authorised purpose only. The health care sector operators including the Government is envisaged to be treated as Fiduciaries as per the proposed legislation.

The fiduciaries will be mandatorily required to process the data fairly, reasonably. Taking of blanket and implicit consent from the individuals will have to be done away with.

Global scenario and challenges

NDHM is a welcome initiative, provided it is rolled out with proper supporting legislation, governing guidelines regarding the data collection, processing, and privacy.

Unless this is done, NDHM will find it difficult to face stiff hurdles like judicial scrutiny of its key policies, public and political opposition. Putting the requisite safeguard mechanisms in place may also lead to the NDHM project and in turn health care becoming more expensive in India. Such digitalisation has led to health care becoming expensive in western countries. We have also seen that digitalisation of health care sector in developed countries has assisted in tackling pandemics, endemics and implementing national disease control campaigns in a better way. Data is also a fundamental requirement to support research & development.

A lot of preparatory work and strategic planning is due before India embarks upon transforming the health care sector. Without a proper Data Privacy Law, the NDHM will end up becoming a non-starter. Leapfrogging by the National Government over the Data Privacy Law bill is a bad idea not just for the ambitious NDHM, but also risks jeopardising the optimism surrounding the expected Data Privacy Law.

Finally, it is claimed that implementation of NDHM is expected to significantly improve the efficiency, effectiveness, and transparency of health service delivery overall, which is welcome. The NDHM will also do well if ground level health infrastructure is also focused upon, mainly in rural India.

Securing medtech through cyber education

Roy Zur, CEO, ThriveDX SaaS highlights the role of cyber education in securing medtech sector

When a healthcare system is attacked, it is not merely on the computers of the hospital but on the patients and the people who take care of them, hence it is more disastrous and threatening.

On October 30th 2021, the healthcare systems at New-Foundland province of Canada were behaving abnormally. They were unable to process the medical appointments and the schedules of the surgery. There was chaos all around in the hospitals and the healthcare system practically came to a halt. An investigation found that a cyber attack on the healthcare systems led to its collapse. Some say that the cyber attack on the healthcare systems could be the worst in the country's history, but it also has repercussions on national security.

Medicine and technology are two different fields, different worlds, but are converging to meet the needs of people in this fast-digitalising world. While this brings convenience and ease, the thieves on the internet are up to creating the nuisance

Is this fear true? indeed it is...

Medicine and technology are two different fields, different worlds, but are converging to meet the needs of people in this fast-digitalising world. While this brings convenience and ease, the thieves on the internet are up to creating the nuisance.

According to a document by World Economic Forum, between June 2020 to October 2021,

"Over 10 million records have been stolen, of every type, including social security numbers, patient medical records, financial data, HIV test results and private details of medical donors. On average, 155,000 records are breached during an attack on the sector, and the number can be far higher, with some incidents reporting the breach of over 3 million records."

https://www.weforum.org/agenda/2021/11/healthcare-cybersecurity/

But, when a healthcare system is attacked, it is not merely on the computers of the hospital but on the patients and the people who take care of them, hence it is more disastrous and threatening.

Digital and connected devices in hospitals

Just as in any other industry, hospitals too have become hi-tech with advanced devices and robotics that can communicate over the internet. With lab machines and reports to doctor's appointments, prescriptions and delivery of medicines at home, digitalisation has covered the entire gamut of healthcare services. Machines like CT scans, MRIs, X-rays are all digital and are interconnected with the hospital management system for smooth flow of patient information.

While it provides quicker services, they are prone to cyberattacks and the motive behind cyberattacks on healthcare companies is clear- it is to fetch very valuable identity and health data of the patient from databases of healthcare service providers like hospitals, clinics, pharmacies, health insurance companies, and other healthcare providers.

Healthcare during pandemic

Pandemic forced adoption of technology in all industries including healthcare. Tele-medicine gained prominence with online consultation, prescription, ordering medicines and payments on the patient portal. But this also made the patient portal an easy target for cyber attackers.

According to a report by Check Point Research, there was a 45% rise in cyber crimes in the healthcare sector around the world and 37% in India, with a total of 2915 incidents in a month during the pandemic which made it one of the most targeted sectors. According to Global Risks Report, 2021, cybersecurity failure is ranked 4th as a part of present danger among the top risks in the next 10 years.

Vulnerability of healthcare system

Experts believe that hackers find telemedicine as an easy target because there is a transfer of data between networks and personal devices and the integration of new technologies with existing ones without having a unified security strategy.

Further, healthcare institutions invest less in security systems. As per statistics, hospitals in India allocate not more than 5% of their budget for cyber security, keeping them vulnerable to cyberattacks.

What can be done?

To mitigate the risks of cyber threats, a multi-pronged strategy needs to be put in place. Efforts are needed from all stakeholders of the industry.

At the policy level, the government should push the Personal Data Protection Act to provide specifics regarding personal data storage and usage. This should apply to medical devices too. At present, all medical devices in India are regulated as "drugs" as per the 'Medical Device Amendment Rules 2020'. While these rules require the devices to be registered with the Drugs Controller General of India, they do not speak about patient data security or privacy within the devices.

At the manufacturer level, it must be a practice that the devices should have the latest data security and protection software together with frequent up-gradation and continuous training to the hospital staff.

Healthcare institutions must ensure that they have a robust cybersecurity architecture that covers the entire hospital management system together with all radiology and diagnostic devices. They should frequently organise cybersecurity audits to check for any vulnerabilities and loopholes and should immediately plug them. They should also regularly conduct workshops on 'healthy cyber practices' to be followed by all staff members including doctors and management.

On a broader level, the government should also push to introduce a basic cybersecurity curriculum in healthcare education which will give the aspiring medical practitioners first-hand knowledge about computers and cybersecurity, so that doctors, nurses and lab technicians do not violate the cybersecurity guidelines and can become the primary responder to an attack.

RPM brings in revolutionary changes in Indian healthcare landscape

Sanjeev Dahiwadkar, Founder & CEO, Cognota Healthcare highlights the advantages of remote patient monitoring and its crucial role in the revolution of Indian healthcare system

Virtual healthcare is on a rise within the healthcare ecosystem in recent years. But the COVID pandemic has accelerated this trend. Amid strict social distancing measures, Remote Patient Monitoring (RPM) emerged as a necessity than an option. Faster adoption of RPM through various telehealth systems, wearable devices, and much-sophisticated IoT-powered software solutions is already underway across the globe. Therefore, RPM solutions sit at the very core of digital healthcare.

For emerging economies like India and many African nations, the adoption of RPM solutions holds more significance than developed economies. Because the availability of healthcare professionals in these geographies is scarce. According to the World Health Statistics report 2017, around 40 per cent of countries have less than one physician per 1,000 people and less than 18 hospital beds per 10,000 people. In emerging economies like India, the ratio is far worse. Every allopathic doctor in India provides healthcare to at least 1,511 people, much higher than the World Health Organization's norm of one doctor for every 1,000 people. The shortage of trained nurses is even worse with a nurse-to-population ratio of 1:670 against the WHO norm of 1:300. Therefore, digital health through virtual care is the best option going forward.

India is already making rapid strides

Given the cost-effectiveness, the potential of wider reach, and scarcity of healthcare professionals, RPM has the ability to revolutionising the healthcare ecosystem in India. And this transformation is already underway. For instance, India's National Health Policy, 2017 envisions a digital health ecosystem and recognises the integral role of eHealth, mHealth, IoT, wearables, cloud computing among others in the delivery of health services. In March 2020, the Ministry of Health & Family Welfare (MoHFW) of India issued telemedicine practice guidelines, a step forward in the adoption of telehealth on a wider scale. As per the government data, India's National Telemedicine Service – eSanjeevani had crossed the milestone by completing 3 million consultations by end of March, 2021. Currently, more than 35,000 patients are using this innovative digital platform on daily basis across 30 states. The rapid adoption of the teleconsultation platform is transforming the healthcare delivery mechanism by reaching the far-flung areas of the country. Hearteningly, not only public sector healthcare providers but also private hospitals, medtech players, and other such companies operating in the space are also utilising these AI, & ML-powered teleconsultation platforms to treat patients remotely.

As per the Union Budget, 2021, India's public expenditure on healthcare stood at 1.2 per cent as a percentage of the GDP. In a country of 130 million people, technology can only enable both public and private agencies to provide quality healthcare at such public investment figures. Moreover, medical inflation is one of the highest in India. Against this backdrop, tertiary care hospitals in both the public and private sectors are also using many advanced RPM solutions. IoT-powered software applications are successfully embedded within hardware devices to automatically collect health metrics like heart rate, blood pressure, temperature, and more such critical data points from patients without any physical interventions from ICUs. Such data, which is shown on a dashboard on a real-time basis, help doctors to make life-saving interventions.

Similarly, several wearable devices powered through IoT are making inroads into the Indian healthcare ecosystem for monitoring glucose, blood pressure, oxygen saturation, weight and BMI, fitness logging, temperature, heart rate, and dementia surveillance among others.

Patient participation increases through RPM

In India and other developing countries, proactive health screening is not as widely practiced as in developed nations. As per data, preventive healthcare accounts for around three per cent of the total retail consumption. This indicates that very less percentage of Indian population spend on annual health check-ups. Even those who are sick with major illnesses, rely on medication and monthly or quarterly visits to the doctors. If key readings change in between, unless it is life threatening, mostly patients would not know. For example, blood pressure rising slightly but regularly would not be noticed until patient is being checked up at follow-up visits. With RPM, such key readings are now monitored proactively and change patterns can trigger early intervention from doctors saving complexities that may come due to ignoring such health anomalies. Therefore, RPM is increasing health awareness among the population and prompting preventing healthcare through early diagnosis; thus, saving time, money and life of patients.

Burgeoning market size

The future holds a lot of promise for the RPM market across the world and especially in India. As the per capita income grows, India is witnessing a lot of lifestyle changes. In turn, many chronic diseases related to lifestyle changes are also creeping in. Apart from being the diabetic capital of the world, the country is also seeing a lot of heart-related ailments in recent years. In all these diseases, remote monitoring of patients is vital for timely treatment. Moreover, the demographic dividend in terms of more youth population is likely to wane in the next two decades in India. A more ageing population will translate more RPM interventions where health conditions can be monitored from the comforts of home. Therefore, the use of more wearable devices, RMP software solutions, and teleconsultation platforms is expected to increase.

According to global market research firm Fortune Business Insights, the global telemedicine market was pegged at $41.63 billion in 2019 and around $80 billion in the pandemic year of 2020. The market research firm predicts the global market size for telemedicine to touch $396 billion by 2027. A significant share of this market size will be contributed from RPM-related service offerings. As per market intelligence firm Mordor Intelligence, India's RPM market is likely to see a CAGR of 6.4 per cent during the 2020 to 2025 period. As the per capita income of Indian citizens rises with rising GDP growth in the coming years, the country will see more adoption of RPM services. And this definitely brings good news for both service providers and patients.

Mining data with machine learning and AI for Healthcare

Sina Bari, Director, Medical AI, iMerit Technology explains about data mining and highlights role of technologies like machine learning and artificial intelligence

The healthcare industry generates vast amounts of data through record keeping, imaging, laboratory analysis, and compliance. While, traditionally, data was stored in hard copy, digital record keeping of critical data is now the norm. The utilisation of data from electronic health records (EHRs) is, therefore, increasing significantly. This healthcare 'big data' is vital to support a wide range of functions such as clinical decisions, infectious disease outbreak, and preventative health.

According to the US Department of Health and Human Services, the progress of the value-based healthcare delivery system, a provider payment model based on patient outcomes has run almost parallel to the implementation rate of EHRs/electronic medical records (EMRs). Insights firm Research and Markets estimates that the EHR market will reach $33 billion by 2025.

Data mining in healthcare

Data mining is the process of extracting, organising, and finding patterns in large datasets. Various sectors such as manufacturing, telecom, the automotive industry and others effectively use data mining. For example, in the retail sector, data mining is used to analyse customer response and in the financial sector, it helps predict economic trends.

In healthcare, data mining holds immense potential due to the exponential growth of EHRs, benefiting the entire healthcare ecosystem. For example, data mining can help the industry in customer relationship management, patient care and cost reduction as well as in fraud detection. It enables transforming big data into useful information for decision purposes.

With the adoption of EHRs, the volume and complexity of extracting data points and insights is becoming increasingly challenging. Researchers are thus exploring how artificial intelligence (AI) and machine learning (ML) can aid in drawing out useful information.

A study by research and advisory company Emerj suggests that most AI use cases and emerging applications for medical data mining appear to fall into three categories:

◆ **Predictive analytics:** Use of ML to determine possible patient outcomes, such as the likelihood of a worsening or improving condition, or chances of inheriting an illness in an individual's family.

◆ **Diagnostic analytics:** Advanced analytics that examine data or content to determine why a health outcome happened, as defined by Gartner.

◆ **Prescriptive analytics:** Developing ML algorithms to perform comprehensive analyses of data to improve patient management (handling of cases, coordinating tasks like ordering tests, etc.).

An effective AI- and ML-backed data mining system provides a framework to transform data into useful insights, empowering data-driven decision making. These smart techniques and tools not only benefit healthcare providers, but also assist patients and the overall healthcare ecosystem in functioning efficiently.

Mining health data for AI/ML applications

For AI- and ML-led applications, data from the healthcare ecosystem is a goldmine of information and insights, which can be analysed to deliver smart decision making and solve complex individual and societal health challenges. This data encompasses not only clinical data but also data from the ecosystem.

◆ **Administrative and claims data:** Comes from federal, state and local government agencies as well as healthcare providers and insurers. Examples: hospital discharge summaries, payment records of patients, insurers.

◆ **Clinical data:** Encompasses data generated in a clinical setting, controlled by a clinician. Examples: clinical trials data, EHRs.

◆ **Genomic data:** Includes different characteristics, ranging from DNA sequences to individual variants. Such data is very sensitive and must be used under carefully controlled conditions.

◆ **Patient generated data:** Includes health-related data created and recorded by or from patients through Internet of Things (IoT) devices and social media listening, typically outside of the clinical setting to address a health concern. This data type is becoming increasingly prevalent through the creation of mobile health applications and wearable health devices.

◆ **Surveillance data:** Encompasses systematic collection, analysis and interpretation of health-related data essential to planning, implementation and evaluation of public health practices. Examples: registry data, vitals data, survey data, etc.

India story

The NITI Aayog think tank, in its 2018 report, identified healthcare as a top priority in the list of domains that need an AI push. The report also projected AI application in healthcare to overcome barriers within the ecosystem, particularly in rural areas lacking healthcare facilities. In such scenarios, AI-driven clinical evaluation, treatment, early identification of potential epidemics and pandemics, and imaging diagnostics are made easier and more convenient. However, making data available for different aspects such as groups, individuals and geographies is still inadequate for feeding AI and ML models.

To tackle data scarcity, healthcare leaders and the government, in collaboration with healthcare providers, are working towards the adoption of technologies like AI and ML. Administrative bodies are enabling hospitals and healthcare facilities to invest in technologies for building a strong and effective healthcare ecosystem.

AI and ML technologies and data mining need to come together to enable intelligent analysis and decision making. For the healthcare ecosystem, it is important to understand the different uses of technology stacks, processes, and algorithmic architectures depending on the end-goals and resources available. In addition, clinicians must join with technologists to provide their subject matter expertise in shaping this data. When used capably, data mining can turn raw data into valuable insights, leading to operational and strategic efficiency.

INTERVIEW

There is dire need to repeal the more than 100 discriminatory laws against persons affected by leprosy

With an alarming 57 per cent of world's total reported cases of leprosy coming from India, **Dr Ashok Agarwal** - Country Director, NLR India, in an interaction with **Viveka Roychowdhury**, reviews the evolution of the country's strategies to detect and treat leprosy and proposes some further public policy interventions needed as part of the India roadmap for zero leprosy by 2030

What are the strategy and goals of India's National Leprosy Eradication Programme (NLEP)?
In India, the National Leprosy Eradication Programme or NLEP was launched in 1983. India achieved the global target of elimination of leprosy as a public health problem at the national level in December 2005. Still, about 57 per cent of world's total reported cases of leprosy comes from India.

NLEP is a Centrally Sponsored Scheme under the umbrella of National Health Mission (NHM). The primary goal of the Programme is to detect the cases of leprosy at an early stage and to provide complete treatment free of cost, in order to prevent the occurrence of disabilities in the persons affected and stop the transmission of disease at the community level. The Programme also aims to spread awareness about the disease and reduce stigma attached with the disease.

NLEP strategies:

◆ Active case detection & regular surveillance (ACD&RS): Operational guidelines introduced in July 2020 (blocks categorised as high and low priority, provision for incentive to front line workers for case detection)

◆ Treatment of all cases with MDT

◆ Disability prevention and medical rehabilitation (DPMR): Distribution of Self Care kits and MCR footwear; Re-constructive Surgeries (RCS)

◆ Community awareness and behavioural change communication to reduce stigma and stop discrimination -Sparsh Leprosy Awareness Campaign (SLAC): this campaign is organised yearly around the World Leprosy Day/India Leprosy Day (around January 30)

◆ Focused Leprosy Campaign (FLC): active case search where a new case with G2D is detected; this search targets 300 surrounding households in urban areas or the entire village in rural areas

◆ Special plan for hard-to-reach areas: provision of leprosy services through community participation

◆ ASHA-based surveillance for leprosy suspects (ABSULS) in low priority blocks of districts

◆ Post-exposure prophylaxis with single-dose rifampicin (SDR-PEP) to contacts of index cases

◆ Epidemiological investigation of occurrence of G2D in patients detected with visible deformities

◆ Capacity building of Human Resources (HR)

◆ Implementation of online reporting system with patient tracking mechanism (Nikusht) for improved monitoring and supervision

◆ Leprosy screening through health related programmes for children (Rashtriya Bal Swasthya Karykram-RBSK), adolescents (Rashtriya Kishor Swasthya Karykram- RKSK) and adult population (above 30 years of age) under Ayushman Bharat

What are factors that may help achieve and maintain the elimination of leprosy?
Framing and adoption of elimination strategies had helped in achieving the elimination and also to maintain it. Some of these key strategies are as follows:

a) Making MDT available free of charge to all leprosy patients. The large scale detecting and treating of all cases with MDT and thereby reducing the disease burden to a very low level had helped in clearing backlog and new cases of leprosy under treatment, thus reducing the pool of infection within communities.

b) Integral element of the elimination strategy is the expansion of geographical coverage of leprosy services by integrating them into the general health services to improve access to treatment as well as by conducting Leprosy Elimination Campaigns specifically focussing on hard to reach areas, remote, difficult areas and suburban pockets with poor health infrastructure etc.

c) Active case detection and regular surveillance (ACD&RS) launched in July 2020. All states are to select the priority villages/ urban locations where house to house survey is to be conducted every six months; the new cases detected to be put on MDT and the contacts given LPEP. Besides the frontline workers like ASHA, active participation of communities and volunteers is required to make this programme successful. All states have started working on this programme.

d) Strengthening the implementation of the leprosy post exposure prophylaxis programme across the country; this was launched as a national programme by government in October 2021

How has the detection and treatment of leprosy evolved over the past decades?

In India, the national leprosy eradication programme (NLEP) was launched in 1983 with the introduction of multidrug therapy (MDT) for treatment of leprosy in 1982, and thus strategies under national leprosy control programme (NLCP) got changed.

Key strategies of NLEP includes early case detection with particular focus on MB cases and children, early diagnosis and treatment with MDT, involvement of community health volunteers i.e., ASHA in early case detection and strengthening disability prevention services. As India achieved elimination of leprosy i.e., goal of NLEP in 2005, eventually the programme got integrated in general health care services due to decreasing number of new leprosy cases, with reduction in prevalence rate of 57.8 per 10,000 in 1983 to less than 1 per 10,000 by end of 2005; even further down to 0.67 per 10,000 as in March 2018.

In 2015, an innovative strategy i.e., leprosy case detection campaigns (LCDC) was launched under NLEP for implementation in high endemic districts, that resulted in detection of 34,000 new cases in 2016 from these districts which accounted for 25 per cent of annual new cases. A three- pronged approach i.e., LCDC in high endemic districts; focussed leprosy awareness campaigns using ASHA and multi-purpose health workers in "hot spots" where new cases with grade 2 disability (persons with visible disabilities) are detected and areas specific plans for case detection in hard to reach areas was included in NLEP for implementation to address challenges of early detection and treatment of new cases.

In 2017, the SPARSH leprosy awareness campaign (SLAC) was launched to generate mass awareness on leprosy for voluntary self-reporting in facilities for early diagnosis and treatment, and thereby address issues of stigma and discrimination in the community. During SPARSH campaigns, nationwide, gram sabha (village committees) organise anti-leprosy day i.e. January 30 with involvement of panchayat raj institutions (PRI), village health sanitation nutrition committees (VHSNC) and persons affected by leprosy. The awareness campaign is implemented for a fortnight at village, block and district levels.

Emphasis is given to leprosy screening which is included in Rashtriya Bal Swasthya Karyakram (RBSK), an important initiative aiming at early identification and early intervention for children from birth to 18 years and Rashtriya Kishore Swasthya Karyakram (RKSK) that was launched in 2014 aiming to address health needs of adolescents i.e. from 10 to 19 years, referral of suspect cases followed by confirmation of diagnosis, treatment, population (who are 30 years and above) based screening under Ayushman Bharat National Health Protection Scheme (NHPS), a flagship central scheme launched in 2018 to provide free access of health care to people with low income. Screening for leprosy is also introduced under National Urban Health Mission (NUHM) to cover population residing in slum areas and peri urban areas.

In July 2020, to strengthen the active case detection and regular surveillance for leprosy, the central leprosy division (CLD) had issued an operational guideline on "Active case detection and regular surveillance for leprosy" under NLEP and several sensitisation meetings on the guidelines were held for the state nodal officers. This has replaced the periodic LCDC programme.

On the treatment front, Multi-drug therapy (MDT) was introduced in 1983 under NLEP; depending on the type of leprosy the medicines are to be taken for 6 or 12 months.

For reduction in annual new case rate through early case detection, screening of contacts and preventive treatment with single dose rifampicin (SDR), the Government of India under NLEP launched the LPEP-SDR nationally in October 2018.

What can be the public policy interventions to combat the stigma around leprosy and the impact on livelihoods etc?

The Government of India converted the national leprosy control programme (NLCP) that was launched in 1955 into national leprosy eradication programme (NLEP) in 1983 by introducing MDT as treatment of leprosy and since then there has been remarkable reduction in number of new cases and decrease in prevalence rate (PR) per 10,000 population across the country.

The fact that leprosy is a curable disease with MDT treatment has an effect on reduction of stigma in the community, as the number of suspect cases getting diagnosed and treated has increased over the decades. With the introduction of ASHA based surveillance for leprosy suspects (ABSULS) in NLEP, the early case detection rate has increased through increase in referral rate by ASHA, and confirmation of leprosy followed by MDT treatment at health centre.

Since the main impediment for early case detection is lack of knowledge about leprosy in general public, SPARSH leprosy awareness campaign was launched in 2017 for involvement of several stakeholders such as panchayat raj institute (PRI), civil societies and persons affected at village level etc. to raise mass awareness on leprosy.

The fact that leprosy is a curable disease with MDT treatment has an effect on reduction of stigma in the community, as the number of suspect cases getting diagnosed and treated has increased over the decades. With the introduction of ASHA based surveillance for leprosy suspects (ABSULS) in NLEP, the early case detection rate has increased through increase in referral rate by ASHA, and confirmation of leprosy followed by MDT treatment at health centre

Proposed public policy interventions:

◆ *Repeal /amendment of existing discriminatory laws:*

◆ Besides the strategies such as early case detection, diagnosis and treatment with MDT, ABSULS, SPARSH and Leprosy Post Exposure Prophylaxis (LPEP) using SDR-PEP for early case detection among contacts of leprosy case etc., there is dire need to repeal the several (more than 100) discriminatory laws against persons affected by leprosy which are still existing in the country. This requires high level of advocacy with policy makers and human rights commission in partnership with relevant stakeholders and affected community. ILEP agencies are leading on advocacy matters for bringing forth the required changes in laws.

◆ *Using customised IEC/BCC interventions:* To effectively communicate to the targeted audience, there is need to develop locally relevant/customised IEC materials and methods to raise awareness and change perception of leprosy. A community baseline survey could be conducted to assess the existing myths and misconceptions on leprosy, which could add value to the drafting of such IEC strategies.

◆ *Capacity building of persons affected:* Building capacity of persons affected by leprosy by making them aware of their rights /entitlements, supporting them to form groups (self- care group and/or self- help groups), linking them with relevant welfare schemes, and integrating them into disability development, vocational training and livelihood schemes would lead to their empowerment in terms of economic, social and political that are indicators of

stigma reduction.

◆ *Involvement of persons affected:* The meaningful involvement and participation of persons affected in activities or forum will make a difference towards stigma reduction and issue-based planning and implementation of strategies and programme.

How must the strategy be tweaked to address this issue, in the light of the published study from NLR?

As per the published paper dated March 2, 2021 of NLR titled "New NLR study predicts 90 per cent leprosy reduction through preventive treatment of 40 million people in 22 years: -to interrupt leprosy transmission and reduce annual new cases significantly, contact tracing and preventive treatment needs to be implemented in all leprosy-endemic countries"; through coordination of resources and efforts among stakeholders, prevention treatment of 40 million people with leprosy is achievable.

In India the LPEP/ SDR-PEP has been implemented since 2018 across all states and districts that involves contact tracing, screening and provision of single dose rifampicin to contacts at most at risk. Different states and districts are implementing LPEP at varying pace and intensity. The status of implementation including the challenges may be assessed; accordingly appropriate actions may be taken to strengthen the programme.

The drug regime for leprosy treatment has moved from single to multi-drug treatments and now preventive/prophylactic treatments are also available. How affordable and accessible are these regimes?

The standard treatment of leprosy has been MDT since its introduction in 1983 under NLEP, which comprises of 2 drug regimens for pauci-bacillary (PB) leprosy and 3 drug regimens for multi-bacillary (MB) leprosy, given to leprosy patients for a duration of 6 months for PB and 12 months for MB leprosy cases.

However, WHO has recommended for changing the 2-drug regimen for PB leprosy to 3 drug regimens as per guidelines issued in 2018. The MDT is supplied by Novartis Foundation through WHO and thus is given free of cost at all government health facilities and also through private hospitals and institutes as provided by the Government of India based on demand request.

For the preventive therapy using single dose rifampicin, the procurement of drug is decentralised at district level and under LPEP, the SDR is administered to contacts by health worker/ASHA during household visits for contact tracing and screening, and thus is provided free of cost. It is made accessible to all eligible contacts as screened by health worker/ ASHA, though the scale and quality of implementation in terms of contact tracing and supply of rifampicin are the major challenges under LPEP of NLEP.

What has been the impact of NLR's work in India with policymakers etc to detect and treat leprosy?

NLR India has been working in India for more than 20 years; providing technical assistance to the government for implementing different components of the national leprosy eradication programme. Our team of around 70 works across 129 districts of seven states namely Delhi, Rajasthan, Jharkhand, Bihar, Uttar Pradesh, Uttarakhand and West Bengal covering around 24 per cent of India population; which witnessed around 23 per cent of the leprosy new cases of the country in 2019-20. We regularly interact with the government officials of the central leprosy division, the state and district leprosy offices; discuss strategies; and help in mentoring and monitoring the government staff providing leprosy services.

NLR India has brought the SDR PEP to India; we along with government tested the feasibility of implementing the programme in the country; encouraged by the results, government decided to implement it as a national programme. We are in discussion with the government for strengthening its implementation by all the states and UTs.

We have been instrumental in development of the urban leprosy programme and home based self-care programme in West Bengal which is gradually finding wider recognition; our primary health center (PHC) based self-care model in few districts of Jharkhand is now being scaled-up statewide by the government. In Aurangabad district of Bihar, since 2016, we are implementing community based rehabilitation of the persons with disabilities; this is again a unique project. In 2021, we started a call center in Jaipur as a pilot project to strengthen the follow-up and delivery of leprosy curative and preventive services.

NLR India is also serving as the national coordinator for ILEP (International Federation of Anti-Leprosy Associations). ILEP along with WHO will soon be working on the India roadmap for zero leprosy by 2030.

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INTERVIEW

The COVID-19 pandemic has created a paradigm shift in the POC testing scenario in India

Mylab has acquired a majority stake in POC system developer Sanskritech. **Rahul Patil**, CEO, Mylab Discovery Solutions in an interaction with **Kalyani Sharma** talks about this acquisition and highlights the status of POC market in India

Myab has acquired a majority stake POC system developer Sanskritech. Can you throw some light on this acquisition. What is the main vision behind this investment?

During the second wave, we saw overburdening of our testing systems and it became evident that decentralised testing would significantly improve access and turnaround times. This acquisition will enable us to further strengthen our efforts to make Point of Care (POC) testing available everywhere in India including any remote village.

With the vision of making diagnostics accessible to all, Mylab acquired a majority stake in Sanskritech – the developer of Swayam, which is a POC system with over 70 test parameters and telemedicine facility. We will establish these POC testing systems at doctor offices, nursing homes, community health centres, airports, etc. through lab partners to enable patients to get test results faster, at a lower cost and without the need to wait for hours. We plan to establish more than 1,000 POC systems in the next two years and start deployment of these systems with lab partners this year.

The volume of point-of-care (PoC) testing has risen during the COVID-19 pandemic. Can you share your views on the acceptance of point-of-care testing in India?

Recently 'The Lancet Commission on Diagnostics report' mentioned that globally, nearly half of the population does not have access to essential diagnostics for many common diseases such as diabetes, hypertension, HIV, and tuberculosis. POC diagnostics, which are often characterised by being independent of laboratory infrastructure and being highly affordable, can greatly improve the accessibility of diagnostics.

> The awareness about the benefits of POC diagnostics is increasing. There is a growing recognition that POC diagnostics can help in the reduction of burden on healthcare system as they are designed to have applications in the clinical settings as well as in remote places

The COVID-19 pandemic has created a paradigm shift in the POC testing scenario in India. Over time, POC testing has gained significant attention for rapid diagnosis and monitoring of various life-threatening or infectious diseases. Because POC testing is easy-to-use, and can be performed at any place, offers results within minutes, it will be an attractive approach to achieve a massive expansion in testing.

Solutions for India have to be pragmatic given our large population and POCT allows us to make diagnostics accessible within the resources that we have. I believe POCT will bring mainstream in the coming years and with AI-driven interpretation, it will break barriers that had been existing for quite a time.

The PoC testing is fast and comparatively more efficient but still at a niche stage in India. Can you give us a comprehensive analysis on PoC testing in India and other countries?

India is a resource-limited country in terms of healthcare, thus, POC diagnostics promise benefits and helps in improving the healthcare status of the vast population. Despite the global advancements in laboratory-based clinical diagnostics technologies, developing countries cannot always afford high-end, automated, and expensive instruments. These instruments need regular maintenance by skilled professionals, which adds up to the overall cost of diagnosis. This has resulted in limited access of advanced medical technologies to clinicians and patients. Moreover, with the existing resource gap in our country, which is huge, it is challenging to deliver healthcare facilities in rural areas.

The awareness about the benefits of POC diagnostics is increasing. There is a growing recognition that POC diagnostics can help in the reduction of burden on healthcare system as they are designed to have applications in the clinical settings as well as in remote places. POC diagnostic devices used for monitoring Glucose, ECG, blood pressure, etc. have tremendously aided the clinical and personalised healthcare. Technological advancements have led to the development of several innovative POC diagnostic devices for different applications. Recent advancements in the field of biosensing technology, microfluidics, and paper-based diagnostics will improve the quality and efficiency of diagnostics. Scientists and entrepreneurs have made a huge impact on the development of next-generation POC diagnostic devices, which are based on the latest technologies such as AI, IoT, etc. These technological advances can make diagnostic tools affordable and accessible in India.

Some companies are developing POC tests and machines, but most are importing them from China and other countries. Mylab has a dedicated center of excellence for POC testing and we have also partnered with

Hemex Health in the US to develop POC for diagnosis of a large number of infectious and vector borne diseases.

India needs robust point of care interventions for tackling future infectious diseases. What is the need of the hour as far as strengthening of the POC market in India is concerned?

Development of indigenous rapid point of care tests with better sensitivity and specificity

◆ Software and algorithms for interpretation of test results without the need for expert technician

◆ The ability to manufacture PoC diagnostic tests at scale, respond to rapid rises in demand like pandemics, and keep the cost of manufacturing low are crucial

◆ Use of technologies such as AI and Machine Learning to make POCT cheaper, faster, and easier to check for quality control.

◆ POC diagnostics need to be integrated within health system and need to be more personalised data-centric

◆ Connected POC diagnostic devices to ensure flow of data from devices to national health grid

> Over time, POC testing has gained significant attention for rapid diagnosis and monitoring of various life-threatening or infectious diseases. Because POC testing is easy-to-use, and can be performed at any place, offers results within minutes, it will be an attractive approach to achieve a massive expansion in testing

How do you see the growth of the PoC testing market in India in the next five years?

The PoCT market in India will witness significant growth owing to the increasing prevalence of chronic diseases which need long-term care and frequent monitoring, and rapidly growing demand of cost-effective and innovative POC diagnostic products. Moreover, the shift towards decentralised diagnostics, and improved access to point-of-care devices through online platforms are some of the other key factors that are likely to drive the long-term growth of the point-of-care diagnostics market in the near future. While the research firms estimate POC to grow at 12 per cent CAGR over next few years, our own estimate is much higher and we believe this market should grow near to 18 per cent y-o-y.

Please tell us about Mylab's future plans. Any new product/ acquisition/ partnership in the pipeline?

Developing new point-of-care tests-We plan to make point-of-care testing available everywhere in India including a remote village. We have in our pipeline more than 40 tests which will be now available for Point of care detection.

◆ **POC devices:** We have tied up with Cleveland-clinic funded Hemex Technologies in US for the POC devices and also developing in-house solutions that can help fuel growth of our POCT testing kits

◆ **AI algorithms: We** are working to develop future products which will bring diagnostics to the palm and smartphones of the customers. These technologies will use artificial intelligence and biological techniques for simplified diagnostics.

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Bionet ST Segment analysis and maps

ST segment map is a graphic tool that displays the deviation of ST in spatial direction. The BionetCardio7 ECG machine includes this function

Myocardial ischemic problems occur when the coronary arteries do not supply enough blood to the myocardial tissue meeting the demands for oxygen. Unchecked Ischemia can progress to injury and infarction, and in severe cases, the anaerobic myocardia cells may die and never recover.

An ECG can show different characteristics depending on the degree of myocardial ischemia progression. First, myocardial ischemia shows ST segment depression and symmetric T inversion. ST segment elevation appears in the subsequent myocardial injury. Eventually, when the myocardial infarction is reached, pathologic Q wave and QS type are shown.

The cases of myocardial ischemia and infarction, which are directly related to life, it can be checked and confirmed by the ST segment value, and the location and direction of the potential life-threatening complication can be determined by the vector direction in which each electric current flows in the ECG.

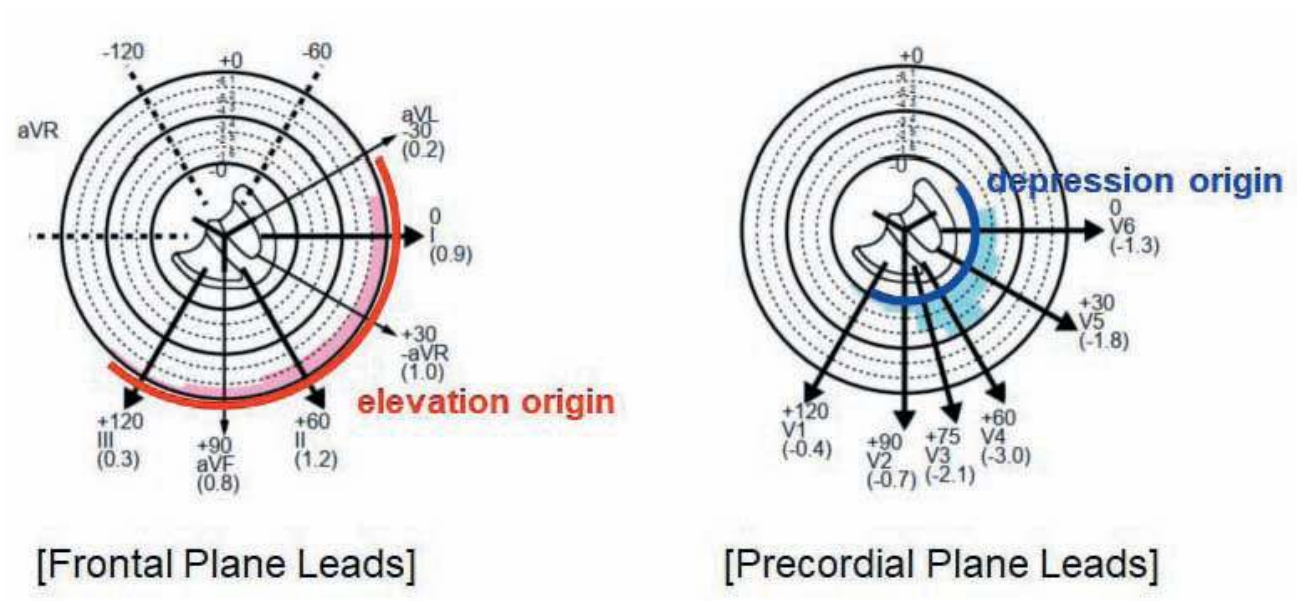


Figure 1. Bionet ST segment Map shows two planes for each section of the heart and displays the ST segment elevation or depression level in each lead-related spatial orientation

Figure 2. Classic bar graph showing ST segment deviations

What are ST segment maps?

ST segment map is a graphic tool that displays the deviation of ST in spatial direction. The BionetCardio7 ECG machine includes this function. ST segment Map is shown in two forms. One shows the vertical section of the heart, the other shows the horizontal section. The vertical section of the heart describes the limb leads and changes in the inferior wall area (ECG in leads II, III, and aVF) and the high lateral wall of the left ventricle (ECG in leads I and aVL) of the heart [Figure 1. – Precordial Plane Leads]. In the case of the horizontal section, the chest leads are displayed indicating changes in the anterior wall (ECG in leads V1 – V4) and the anterolateral wall of the left ventricle (ECG in leads V5 – V6) [Figure 1. – Precordial Plane Leads]

Each map contains a total of 6 circles including 3 dark lined circles in mm unit and each lead directions with ST measuring values. aVR is expressed as -aVR. For ST segment elevation, the ST segment value is expressed as a positive number and is indicated from the outermost circle to the inner side. For ST segment depression, the ST segment value is a negative

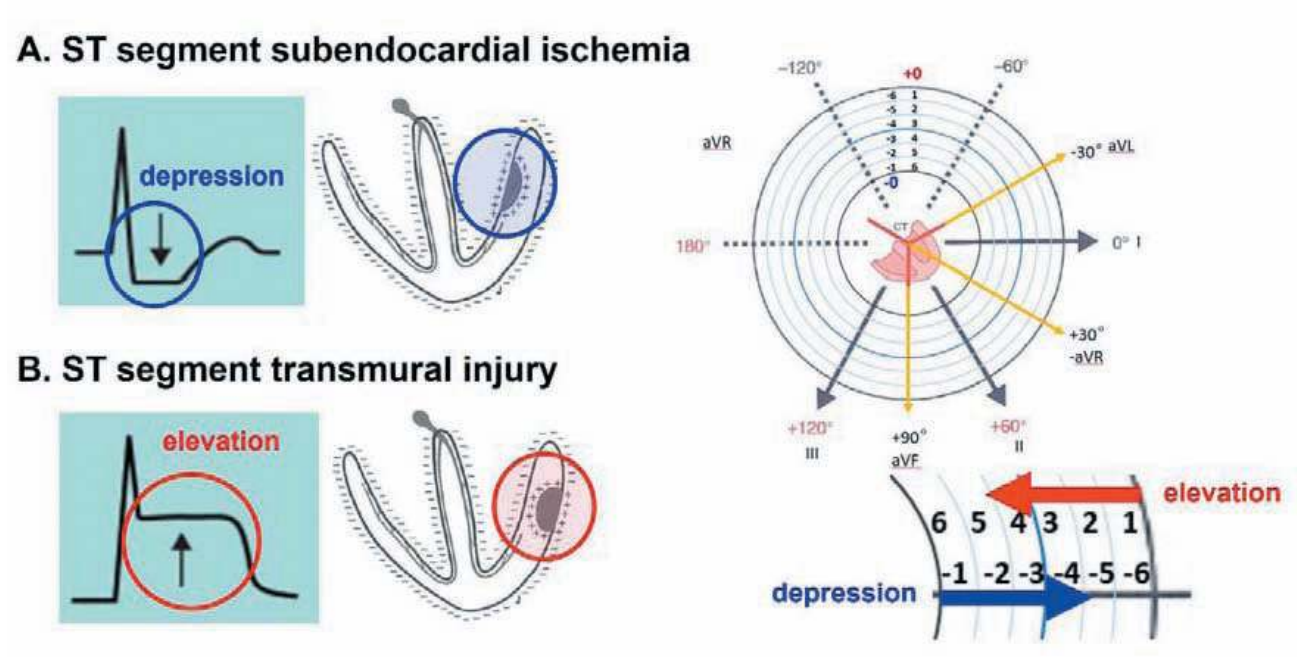
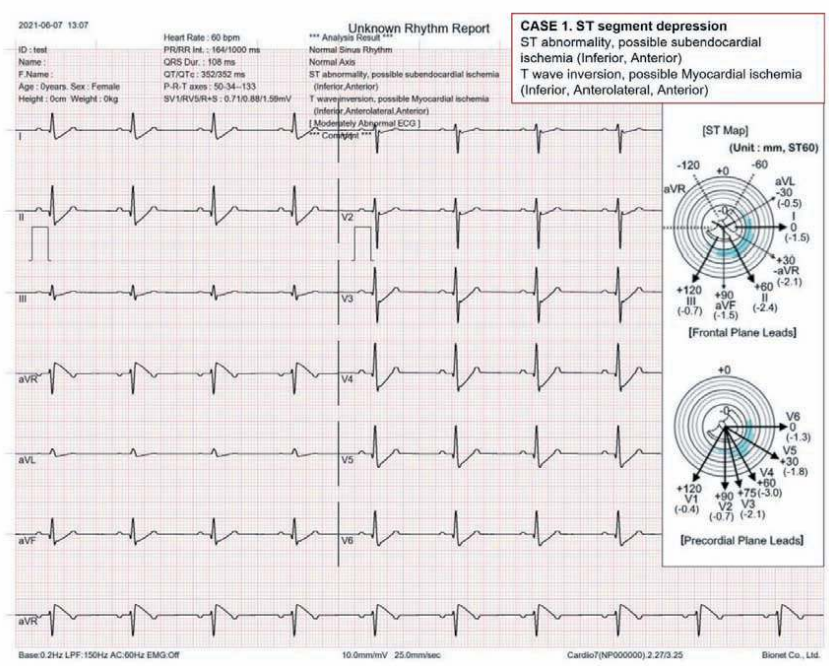
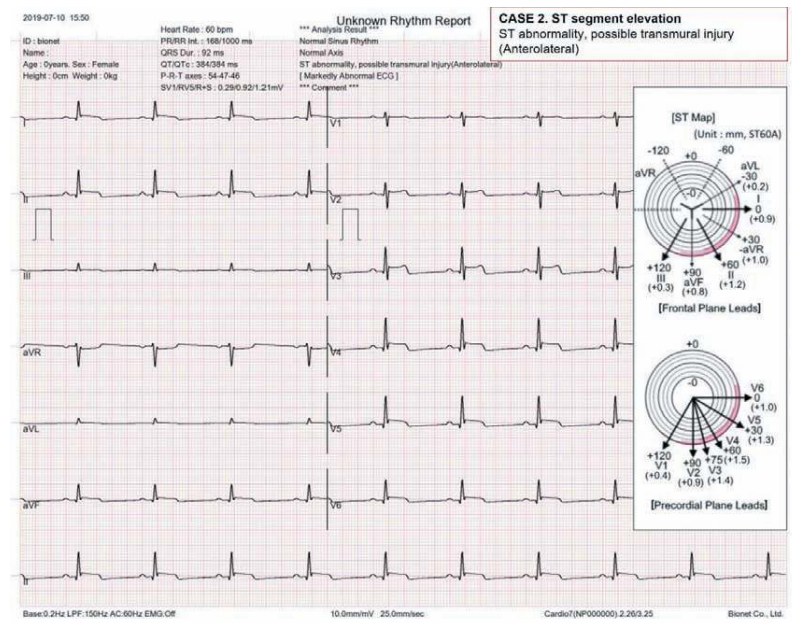


Figure 3. By setting the clinical location and the origin of the ST segment Map to the same location, you can easily observe which problem the patient has between subendocardial and transmural.

SAMPLE CASES



Case 1



Case 2

**The reports were achieved through the simulator settings*

number, displayed from the innermost circle to the outside [Figure 1].

What is advantageous?

The classic way of representing ST segments was in the form of a bar graph. Bar graphs can show the level of ST segment deviation, but the spatial orientation cannot be shown [Figure 2].

The Bionet ST segment Map allows an easy and intuitive understanding of ST segment deviation as well as spatial orientation. Unlike other suppliers that display negative values on the opposite side, Bionet ST segment Map sets two separate origins for each clinical location of subendocardial ischemia and transmural injury. The starting origin and the displayed direction help the clinic intuitively and quickly determine whether there is subendocardial ischemia or transmural injury [Figure 3].

The ST segment Map can assist medical staff in monitoring ST segment more frequently, quickly, and accurately, which can enhance medical treatment for cases of myocardial ischemia.

Related patents

Ecg Data Display Method For Detection Of Myocardial Ischemia (kor 10-2020-0052056, Eur 21168200.0, Usa 17/224,086)

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- We encourage authors to send a short profile of professional achievements and a recent photograph, preferably in colour, high resolution with a good contrast.

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LOGIQ P10 XDclear - Redefining ultrasound imaging for flexibility & clarity of diagnosis

Dr P.M Venkata Sai, Senior Consultant, Head of Radiology & Imaging Sciences, SRMC, Chennai; **Dr TLN Praveen**, President-Society of Fetal Medicine, Medical Director, Abhishek; **Dr Chander Lulla**, Consultant Sonologist and Fetal Medicine Specialist, Ria Clinic, Mumbai and **Dr Raj Subai**, Radiologist Owner, Sakthi Scans, Madurai shed light on various parameters of LOGIQ P10 XDclear

Dr P.M Venkata Sai

Dr TLN Praveen

Dr Chander Lulla

Dr Raj Subai

Lifestyle diseases have been on a steady increase over the last decade. A combination of sedentary living, unhealthy eating habits, stress and anxiety has majorly contributed to them. While hypertension, diabetes and cardiac ailments are very obvious, there's another set of illnesses that are slow to identify and diagnose, often lurking unseen and hidden till they blow out of proportion, becoming obvious with visible signs and symptoms.

Obesity – a progressive condition - is a worrying lifestyle problem, giving rise to cardiac ailments, causing stroke, toxicity and liver damage over a period of time. Recent case histories of many patients visiting doctors for various ailments show an increased BMI, a worrying sign. One corollary of obesity is Non-alcoholic Fatty Liver disease; a silent condition, yet critical to diagnose and manage early on to stop its progressive decline. Fatty liver often progresses to NASH or Non-alcoholic Steatohepatitis in 25-30% of patients. Among this group, 25-30% further go on to have fibrosis, with 2% among them ending up with cirrhosis and hepatocellular carcinoma. This silent progression of the disease often happens without the patient's knowledge, but is easily treatable and reversible when caught on time. While traditional imaging techniques done earlier, identified fatty liver by the visual bright imagery that showed up on scans when compared to kidneys, the method wasn't foolproof with many cases also incorrectly diagnosed. Ultrasonography has made several massive strides in demystifying and bringing clarity to imaging techniques with non-invasive methods, helping radiologists make quick decisions with precision and purpose. The new LOGIQ P10 XDclear ultrasound system is one such machine that provides a robust set of advanced features. It is now easier to diagnose deep tissue diseases and perform a wide range of examinations on organs, including that of liver, cardiac, OBG, vascular, breast, thyroid, musculoskeletal, urologic, and paediatric studies. The proof of the machine's efficacy lies in the hands of sonologists and imaging technicians, and this is what they have explored in their practice.

Sheer Wave Elastography

Dr P.M Venkata Sai: The P10 has a 2D resolution which I'm very happy about. Its most unique feature lies in the exceptional clarity while doing the abdominal ultrasound, especially in non-cirrhotic fatty liver disease. With the sheer wave elastography of liver tissue, I can assess tissue microscopy which can also be recorded in a chart format. The machine is so intuitive, that it even warns me about any incorrect measurements I might have taken.

Dr TNL Praveen: For radiologists, Elastography, Sheer wave Technology and Ultrasound Contrast are the three most useful and critical tools. They not only reduce our work by half, but bring clarity to imaging, help us record and compare disease progress, preempt future changes and help us make purposeful medical decisions. For example, while a lesion itself is obvious, its stiffness is greatly understood by the combination of sheer wave elastography and contrast. The P10 has these in convex, linear and endo-cavity transducers.

UGAP- Ultrasonography Guided Attenuation Parameter

Dr Chander Lulla: In the old imaging setup, liver deterioration would be decided by color and Graded 1, 2, 3 based on physical changes and parameters, a very subjective decision. Grade 1 was the hardest to diagnose. Fibrosis of liver needed a liver biopsy or blood test, and the latter could have plenty of false positives. Acute stages often showed up positive, but chronic stage disease could display normal values. This meant diagnosis was often unreliable and needed more attempts at tests. In the 1990s liver biopsy was the gold standard to diagnose fibrosis, the advent of elastography in 2010 changed all that. Today we rarely do liver biopsy and rely mainly on ultrasonography which tells us the minutest changes in fibrosis and liver cirrhosis. With the new UGAP, we can actually estimate the degree of steatosis or fat percentage in liver and preempt future changes.

Dr P.M Venkata Sai: Besides the steatosis and fibrose scan done by gastroenterologists today, predicting fat build up in the liver is very critical and this is where UGAP is of immense help. As a part of my regular checkup, I've been able to assess for fatty liver, calculate BMot Flow and check liver vasculature whether uniform or heterogenous; easily and seamlessly which otherwise took considerable time and numerous sittings earlier.

Micro Vascular Imaging

Dr P.M Venkata Sai: The liver vasculature imaging with this machine, picks out minute aberrations and changes. Micro vascular imaging focuses on smaller vessels and this is especially useful for tumour characterisation and detection of specific cancers. Thyroid assessment, assessing the nodule, composition and scoring of thyroid glands are all easier and more precise.

Dr Raja Subai: I'd like to mention how lean and flexible this machine is, and the large monitor that gives absolute focus and clarity. Little details in blood vessels, subtle lesions can be picked up easily. Measurements of lesions, vessels and organs are accurate and can be recorded and saved for future use. Renal vessels are visible. The liner probe has a larger footprint advantage in peripheral vascular doppler. Micro vascular flow pickup is another good feature that traces malignancy; secondary deposits in nodes and new changes.

Dr TNL Praveen: To summarise, the Logic P Series and particularly XD Clear platform has a wonderful architecture. The heart of the machine is very agile; better resolution images, better spatial resolution, and depth perception are the gamechangers for us radiologists. As someone in this space since many decades, I appreciate machines which help me in imaging in my obstetrics and gynaecology work. This machine fulfils all my requirements in foetal medicine and care.

AG InstaLume from Agappe Diagnostics

Niranjan Umesh Kamath, Chief Commercial Officer, Agappe Diagnostics talks talks about company's AG InstaLume kit which is the fastest confirmatory COVID-19, RNA extraction free test kit on RT-Lamp Platform, with more than 98.7 per cent sensitivity & 100 per cent specificity

As a matter of fact, India is handling the COVID-19 vaccination drive efficiently from day one & we script unique history. We have attained victory of Indian science & collective spirit of 130 crore Indians. Congratulations India on crossing 115 crore vaccinations. Let's offer our bouquet of gratitude to our doctors, nurses & all healthcare professionals who worked hard to achieve this pinnacle.

Currently entire nation is reopening gradually to resume back to normalcy. We must also notice that the pandemic is not yet eradicated completely and remember that COVID19 may outbreak into 3rd wave anytime if we don't continue the precautions as recommended by the government of India. This pause in infection spreading may be due to vaccination and majority of the individuals infected during the second wave. But this immunity induced by vaccine or infection has a limit of 6 months or so and incidence of 3rd wave is still possible if we are careless.

The technology of RT LAMP platform has been fine-tuned in a way that RNA extraction step can be completely skipped, thus saving much time. This is made possible only with the AGAPPE DIAGNOSTICS high end technology incorporated - RNA extraction free buffer

Precaution

We think that COVID-19 pandemic is over as the test positivity is reducing gradually. Still, we need to continue testing to block the incidence of further waves of pandemic as daily test positivity is increasing in Europe, Russia and China. As international travel is open, in no time infection will be transferred to various geographies. Only option we still have is to continue screening quickly without affecting the people's routine. Preventive measures are to be continued until the virus is eradicated either by heard immunity or with an effective drug or the virus lose its virulence in some evolutionary process.

Currently the test duration to perform RT PCR (Gold Standard test) test is 24hrs and at airports it is about 8 hrs. Fortunately, laboratory that uses RT- LAMP technology produce faster repots in less than 4 hrs. At airports the results are produced in less than 3 hrs which is still much quicker that RT PCR technology. Still there is a huge delay and difficulties faced by the international travelers and the flight operating companies. Huge delay may affect the flight operator's business ending up in huge loss.

This is the scenario in hospitals when results are delayed. Surgeries getting delayed due to COVID-19 test report put patients' life at risk.

Fine technology

Agappe Diagnostics Ltd offers AG InstaLume kit, which is the perfect solution where report is expected in 35 minutes, in ultrafast mode for confirmatory COVID-19 RNA extraction free test kit. Here, the technology of RT LAMP platform has been fine-tuned in a way that RNA extraction step can be completely skipped, thus saving much time. This is made possible only with the AGAPPE DIAGNOSTICS high end technology incorporated - RNA extraction free buffer. As usual, Nasal swab can be collected and mixed directly in RNA extraction free buffer and tested directly with AG INSTA LAMP kit. The reaction vial can be loaded in MISPA LUME – Real time LAMP Analyzer and results will be generated in 30 mins. Thus, sample to report turnaround time is reduced to 35 minutes with high accuracy from the moment of your sample collection. This RT LAMP technology and RNA extraction Free buffer are tested and approved by ICMR, and duly licensed from CDSCO, Govt of India.

Application

The application of this tests is principally in for Airports, Religious places, Marriage/ functions receptions, Hospitals for patients, bye-standers as well as any other functions where there is greater number of gatherings are expected.

AGAPPE takes pride in joining hands with SPICE HEALTH a division of Spicejet Airways in setting up a Rapid Molecular Diagnostics testing for passengers going to UAE countries at Varanasi & Amritsar international airports. Coimbatore international airport also employs the Agappe Rapid Molecular Diagnostics kits from Agappe for testing the UAE passengers.

Thus, to reduce the delay is above said crossroads where quick reports are expected, Agappe has come up with RNA extraction free Direct COVID 19 LAMP test kit where the sample to report duration is only 35 minutes. Now patients and travelers don't have to wait for a report in long queues for hours as they will get the report in minutes. Doctors and flight operators don't have to be stressed up to handle the complications due to the delayed reports.

Cost of a 16-station equipment is only one fourth or one fifth of an RTPCR machine and it is very simple to operate. Untrained technicians also will be able to perform tests with one step technology with more than 98.7 per cent sensitivity & 100 per cent specificity.

RTLAMP platform is very selective & highly specific for such Molecule biology tests and this can be extended to other infections parameters like Dengue, Malaria, TB etc in coming months.

Indian medtech industry: Lion in a cage

Jatin Mahajan, Managing Director, J Mitra & Co shares his views on medtech industry in India and highlights the challenges & opportunities

The medical devices market in India stood at Rs. 77,539 crores in 2020 and is expected to grow at a CAGR of 35.4 per cent from 2020 to 2025 (IBEF report).

Diagnostics account for around 70 per cent of all therapeutical decisions, and it is the first line of defense against all diseases and ailments. But India has the lowest per capita spend of around USD 3 (INR 200) on medical devices and an import dependency of 75-80 per cent.

Healthcare is the largest service sector of the Indian economy, and yet providing access to quality healthcare for the 1.3 billion-plus population is a considerable challenge. Moreover, we house 16 per cent of the world's population and 21 per cent of the world's disease burden. Therefore, Aatmanirbhar Bharat (or self-reliant India) in medtech is not a choice but an unavoidable necessity. The corona pandemic has aptly proved that mass disruptions can happen anytime, and Aatmanirbhar is necessary for existence and survival.

Multinational corporations cater to the high-end segment comprising the diagnostics imaging segment. On the other hand, domestic players operate primarily in the consumables segment. Numbering about 800, these domestic players account for around 65 per cent of India's total medical devices manufacturers.

The government has taken steps for the growth and proliferation of the sector in the country. It recognised the medical devices segment as a sunrise sector under the "Make in India" campaign in 2014. Accordingly, India has initiated schemes to strengthen the segment – which includes boosting research and development and augmenting manufacturing through the 100 per cent FDI route.

The Government's intentions seem good, but the on-ground realities and concrete actions depict a somewhat different story – the intents are taking a very long time in translating into concrete time-bound actions. Under the aegis of AiMED, we have made numerous representations to the government highlighting the various issues and concerns.

According to the Department of Pharmaceuticals, indigenous manufacturers have a disability of 12-15 per cent due to lack of sufficient infrastructure, logistical and supply chain issues, high cost of finance, power supply, limited design capabilities, low focus on R&D and skill development.

The current environment is choking the domestic segment and driving them to a slow death. Moreover, the PLI scheme does not consider the various disadvantages and constraints that the Indian device manufacturers face vis-à-vis the foreign manufacturers to the tune of 15 percent. The business balance tips in favor of "exported-to-India" products.

The Indian manufacturers invest heavily to create a robust manufacturing infrastructure that makes India self-reliant, creates job opportunities, and boosts India as a global manufacturing hub. On the other hand, foreign players profiteer from the available option in India without any commitment towards its overall economic growth. And yet, these Indian manufacturers get no benefits and encouragement for their initiatives and allegiance.

Healthcare is the largest service sector of the Indian economy, and yet providing access to quality healthcare for the 1.3 billion-plus population is a considerable challenge. Moreover, we house 16 per cent of the world's population and 21 per cent of the world's disease burden. Therefore, Aatmanirbhar Bharat (or self-reliant India) in MedTech is not a choice but an unavoidable necessity

India's stand related to COVID-19 procurement has been in contrast to its Make in India initiative. It has focussed on procuring from foreign companies and neglecting home-grown Indian companies with much better track records, creating a high-capacity, low-demand situation for Indian companies.

The medtech industry strongly urges the government to:

- Correct the duty structure on medtech devices
- Provide incentives for domestic production
- Improve the financial benefits for domestic manufacturers in the MSME category
- Implementing a Procurement policy that favors quality domestic products as against imported products
- Removing dependency on imported raw materials and creation of conducive business environments
- Adopt the rule-based classification of medical devices as per GHTF definition
- Implement legislative changes in favor of a comprehensive medical device regulations
- Create a conducive ecosystem for SME's focusing on medtech by establishing medical technology clusters with shared infrastructure and facilities
- Encourage greater collaboration between medical centers and technological institutions.
- Inclusion of medical technology education within the medical curriculum
- Insurance sector reforms to stimulate health insurance, thereby providing the financial incentives for medical technology innovation.
- Set up a venture investment fund to address the lack of early-stage venture capital

The Indian medtech industry has tremendous potential, not just for the domestic requirement but also for the international market. There is much that works to India's advantage. But, the Indian medtech industry is like a caged lion waiting for the right opportunities, incentives, and environment to showcase its true might.

Simplifying setting up of dental practices

Vivek Tiwari, Founder & CEO, Medikabazaar explains about his company's dedicated dental microsite which is designed for dentists and dental clinics with an aim to provide an entire gamut of dental solutions under one roof

As the pandemic caught hold of the world, dentists felt the effects of lockdowns, suspension of routine work, and restricted movement for patients and clinicians alike. During the first wave of the pandemic, routine dental services were restricted due to limited supply of personal protective equipment (PPE), to contribute in flattening the curve, and protect patients and dental personnel against infection.

The inevitable consequence of such conditions was a significant reduction in turnover, affecting cash flow and dental practitioners encountered financial strain. The pandemic caused two major implications on dental practitioners: the dental clinicians' earnings got affected and even patients were not too keen on seeking treatments.

Changes brought about by the pandemic

The pandemic-induced lockdowns meant that people placed their elective surgeries and dental treatments on the backburner; thus, drying up the inflow of people that needed regular in-facility interventions such as root canals and cosmetic treatments. Losses in revenue have been met with a sharp increase in costs for dental establishments since the beginning of the pandemic.

Patient unwillingness: As the economic effects of lockdowns started to reflect, along with fears of contracting COVID-19, patients also put dental treatments on the backburner due to financial constraints, choosing to only undertake treatment for serious conditions.

Time inconveniences for dentists in dealing with multiple vendors: A dental clinic includes many moving parts like high-tech equipment such as dental chairs, X-ray machines, innumerable consumables, disposables like masks, gloves, syringes and precision instruments like endo motors, handpieces etc. Usually, the same vendor will never have all product types at hand, thus pushing dentists to approach multiple vendors. Therefore, taking away precious time and energy that dentists could devote to treating patients.

Increasing trend of dentists buying online: Supply chains and the manufacturing ecosystem suffered due to lockdowns, as industries witnessed complete shutdowns. This in turn affected clinical procurement, which led dentists to move to buying medical supplies through online channels.

> From procuring authentic dental supplies and product discovery to price comparison between various brands, the platform offers of a plethora of features. It also facilitates the final delivery of the entire range of products needed to set up a dental clinic

Lengthy documentation for finance: Financial procedures that can easily be done in one visit, often require multiple visits. Lengthy finance approval processes make setting up a dental clinic more stressful.

How Medikabazaar dental helps

Medikabazaar, India's largest online portal for B2B medical supplies and equipment, offers the most comprehensive and largest catalogue for dental products. Our dedicated dental microsite is designed for dentists and dental clinics with an aim to provide an entire gamut of dental solutions under one roof. Under this initiative, Medikabazaar has put together a variety of offerings making the microsite a compelling value proposition vis-a-vis product range, crowns, financing options, and special offers and discounts.

Dentists can set up their whole dental clinic simply by visiting medikabazaar.com/dental where they can explore India's widest dental catalogue with over 20,000 products. The platform has further on-boarded all leading brands in the category and collaborated with Zoo Labo of Japan, which is one of the prominent names in world-class dental crowns and bridges.

From procuring authentic dental supplies and product discovery to price comparison between various brands, the platform offers of a plethora of features. It also facilitates the final delivery of the entire range of products needed to set up a dental clinic. Medikabazaar Dental has offerings tailored for all dental needs, be it for individual practitioners wanting to set up or upgrade their establishment, dental clinics aiming to buy products (on a one-time/recurring basis), or hospitals wanting to procure complete dental supplies.

Besides solving problems of having to deal with multiple vendors, Medikabazaar is also providing financing options to make setting up dental clinics easy and affordable, with the help of our smart and flexible payment offering Medikabazaar Freedom. Dental practitioners can also avail a flat discount on dental products for orders above Rs. 2,499 as part of the special online offer.

Elsevier and Gramin collaborate to help support remote management of maternal and infant health

Elsevier's AI-enabled ClinicalPath Primary Care India solution facilitates automated screenings at grassroot level

Elsevier, a global leader in information and analytics, today announced the availability of ClinicalPath Primary Care India - its clinical decision support solution across all Gramin centres in India.

The collaboration allows Gramin to conduct AI-based automated screenings, for multiple health conditions based on the latest Indian Standard Treatment Guidelines.

Beginning with antenatal care for expecting mothers in rural, remote areas, the initiative helps to improve access to care in remote areas and the quality of healthcare at the grassroots level.

ClinicalPath Primary Care India is a clinical decision support tool that merges multiple guidelines to facilitate personalised care advice and ease of screening to support frontline healthcare workers in providing effective care for maternal and infant health with sometimes complex conditions.

The solution recommends suggestions based on specific questions during patient screenings at the point- of-care. This results in earlier identification of high-risk cases for healthcare workers to initiate proactive patient management and optimising clinical impact.

The collaboration between Gramin and Elsevier can potentially support local communities and patients from remote areas in the following ways:

Early detection of high-risk situations: Notification of high risk cases from regular screenings, round the clock health helpline availability; regular screenings and follow ups for registered members if they sign these up.

Equity of service: Equity of care and advice for pregnant women in remote areas and metro cities.

Care accessibility: Either digitally through mobile phones or in-person at the centre

On-demand availability: No ASHAs required

About Elsevier: As a global leader in information and analytics, Elsevier helps researchers and healthcare professionals' advance science and improve health outcomes for the benefit of society. We do this by facilitating insights and critical decision-making for customers across the global research and health ecosystems.

The collaboration allows Gramin to conduct AI-based automated screenings, for multiple health conditions based on the latest Indian Standard Treatment Guidelines

In everything we publish, we uphold the highest standards of quality and integrity. We bring that same rigor to our information analytics solutions for researchers, health professionals, institutions, and funders.

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About Gramin

Gramin Health Care (GHC) is the first healthcare system that works exclusively towards providing and strengthening primary healthcare services to the last mile of Rural India. GHC has been creating healthcare ecosystems in underserved rural areas to ensure health services at a distance they can travel, at a cost they can afford and with a dignity they deserve. With a vision to revolutionise the health care delivery mechanism, GHC focuses on employment generation, bridge the gap between gender spaces and provide affordable, accessible and quality healthcare services to people in under-served communities.

Gramin Health Care was established in 2016 with a firm focus to bridge this gap in a holistic, self-sustaining and scalable manner. With institutionalised primary and preventive healthcare being our pillars, we target the issues of availability, affordability and accessibility in a unique multi-pronged approach. We have forged strategic trilateral alliances across the government, industries and communities which allow us greater reach, local connect and the ability to offer comprehensive solutions which include products of international standards at nominal cost.

Gramin Health Care has also been creating a Digital Revolution to improve access, enable end-to-end care and fix the continuum of Rural Healthcare in India.

Don't guess at Gauss

Bayer Radiology offers non-magnetic MRI patient monitors and infusion pumps manufactured by IRadimed which are well proven to improve MRI safety

The value of a non-magnetic infusion pump may not be readily apparent until an adverse event occurs. This can be a life changing situation for the patient, staff and the facility. Using devices beyond their Gauss threshold has the potential to cause injuries, MRI image distortion, inaccurate readings and equipment damage. Next time an acute patient needs an MRI ask yourself these questions:

◆ Are you confident that the devices you use in MRI are built from the ground up specifically for MRI?

◆ Are you confident that you and your staff understand your MRI rooms Gauss field map?

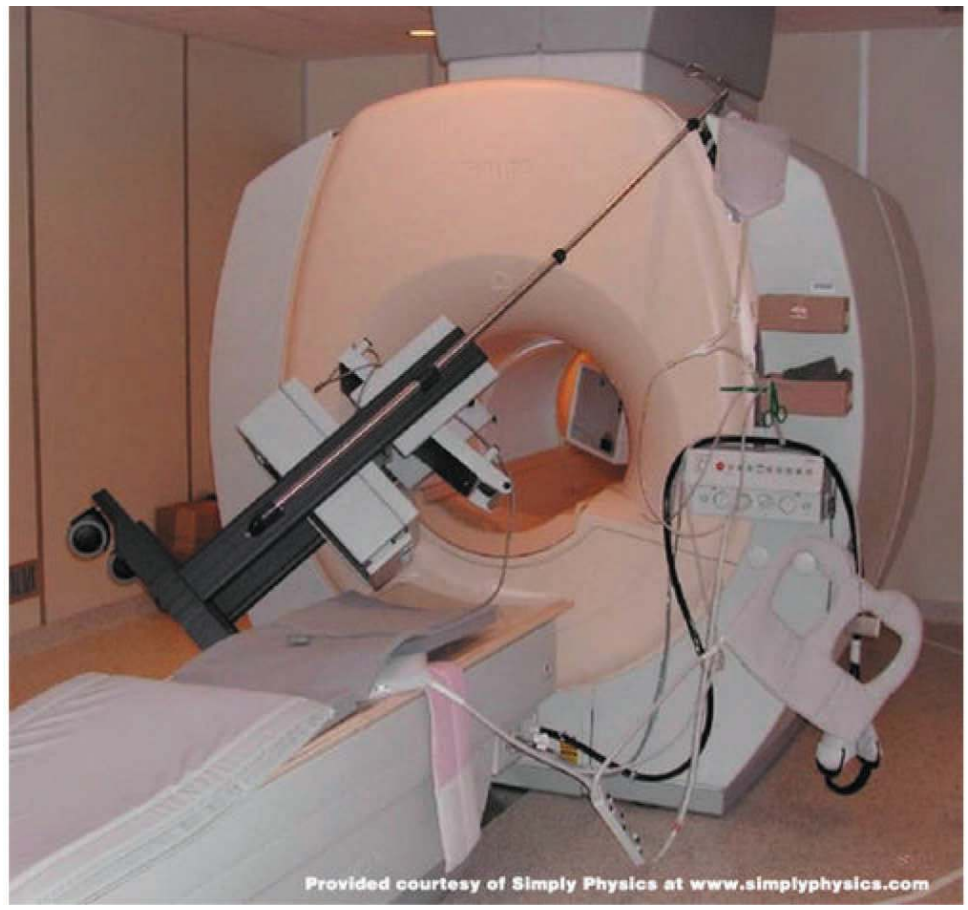
Bayer Radiology offers non-magnetic MRI patient monitors and infusion pumps manufactured by IRadimed which are well proven to improve MRI safety. Let's see how:

Projectile hazard reduction

Conventional patient care equipment and even MRI conditional equipment with a low Gauss rating can be a significant risk in the MRI for patients, staff, and MRI scanner. Most clinicians do not know the specific Gauss map in each MRI Magnet room that they practice in. Patient care devices such as Infusion Pumps and MRI Patient Monitors have been known to be attracted to the scanner damaging the equipment and causing harm to patient and staff. IRadimed is the only manufacture offering non-magnetic MRI patient monitors and infusion pumps.

Clinical accuracy assurance

Patient care devices such as vital sign monitors and infusion pumps utilise pump motors, valves and circuit boards which can alter the readings when exposed to a magnetic field. For example, electric motors used to measure capnography and infuse medications can be inadvertently sped up or slowed down when operated beyond their Gauss condition which can result in inaccurate measurements and failure. The Joint Commission warns that some "programmable infusion pumps may perform erratically" when in the presence of a magnetic field. Do clinicians know the Gauss conditions of their equipment and where that is in each of your MRI suites? IRadimed is the first and only IV pump and patient monitor company to develop non-magnetic motors giving you piece of mind that the displayed numbers are accurate.



MRI Magnet Room Gauss Example

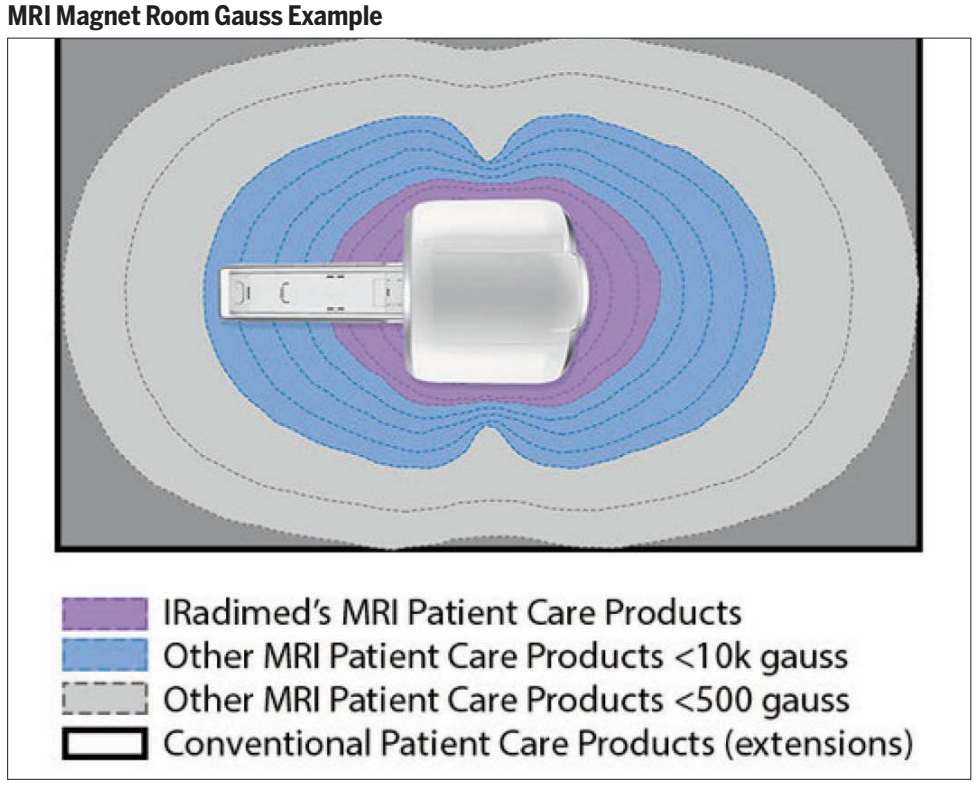


Image represents a 3 Tesla MRI system

MRI image quality assurance

The purpose of scanning a patient is to obtain an MRI diagnosis. Any device or activity that negatively alters the MRI image is unacceptable. MRI image artifact (noise and/or distortion on the image) can be present when patient care devices such as vital sign monitors, accessories or infusion pumps exceed their Gauss conditions. When one of these artifacts present themselves on the MRI image it extends the patient's time inside the scanner causing a delay of their diagnosis and the MRI schedule. The most common type of MRI image artifacts when patient care devices exceed their Gauss conditions are:

◆ Image Distortion can occur when certain materials are used that can "block" part of the visible MRI image. Just because certain plastics, rubber and metals used with an accessory are non-magnetic does not mean that they are radio-translucent and may cause significant inhomogeneity.

◆ Electronics can cause Radio Frequency Interference on MRI images when the device leaks a RF energy at a particular frequency causing a "zipper" on the image.

◆ When electronics surpass their Gauss condition random noise may be present on the image. The appearance of this type of electronic noise causes the MRI image to be grainy and potentially unusable.

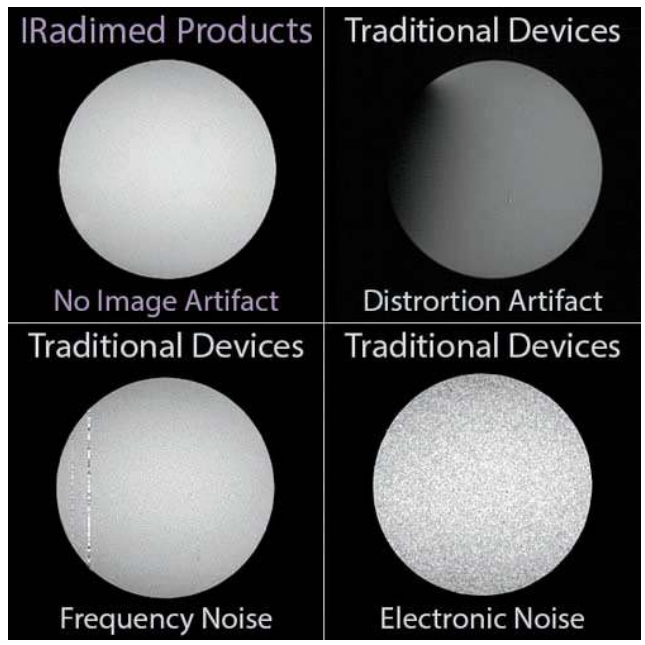
IRadimed products are designed to not cause MRI image artifacts. No other MRI manufacture offers a higher Gauss rating than IRadimed giving your patients and radiology staff 'MRI Image Assurance'.

MRI burn reduction

The Joint Commission, ECRI Institute and the FDA have published warnings regarding the potential for 1st, 2nd or 3rd degree burns during MRI procedures. When patient care devices such as MRI monitors are involved in patient thermal injuries it is usually due to the patient being in contact with a sensor or cable that was used beyond its condition for use. IRadimed MRI monitoring accessories and IV infusion lines are designed to drastically reduce the potential for thermal injuries. IRadimed eliminates the potential for conductive cable looping by utilizing fiber optics and integrating wireless with our specifically designed leadwires and electrodes.

Up-time reliability

The MRI environment is very harsh for complex medical devices like monitors and pumps. The magnetic field and high RF pulses can cause constant stress on the internal components of medical devices, especially the ferromagnetic components such as pumps, motors and valves. When one of these critical components exceeds its Gauss limitation the pump, motor and/ or valve the device could become inoperable during an MRI case. This failure can happen quickly or over a period of time if the ferromagnetic component gets magnetised. IRadimed is the first and only manufacture to utilize non-magnetic pumps and motors providing you and your staff piece of mind.



Improved clinical ergonomics

Each patient care device used inside an MRI suite has a specific Gauss limitation that the clinical staff must abide by. As a rule of thumb, the lower the Gauss rating, the further away from the MRI bore it must be positioned. This situation compounds when multiple devices with different Gauss limitations are needed to be used on the same MRI case. This Gauss limitation can create a procedure where the standard of care is deviated inside the MRI. For example, an Anesthesiologist will typically have a monitor and infusion pump / anesthesia machine located at the patient's bedside when practicing in every department except MRI. It is common to have the patient monitor attached to the gas anesthesia machine so the clinicians have all their equipment in the same place for easy correlation. This same example inside the MRI can have very different workflow ergonomics. A Syringe pump rated at 400 Gauss might be placed against the wall away from the patient and the monitor. IRadimed is the only supplier of MRI Patient care devices with high enough Gauss ratings to allow clinicians to have the same standard of care in the MRI that they throughout the hospital.

Each patient care device used inside an MRI suite has a specific Gauss limitation that the clinical staff must abide by. As a rule of thumb, the lower the Gauss rating, the further away from the MRI bore it must be positioned

For more information and resources about Bayer Radiology products and service offerings, connect with Bayer team on Medrad.service@ bayer.com

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Reference:
https://www.iradimed.com/en-us/mri-safety, accessed on 23rd Nov 2021.

Bayer join hands with innovators in MRI patient care - IRadimed

Non-Magnetic MRI Patient

FMD Smart MRI

Non-Magnetic MRI IV Infusion Pump

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