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Will NITI Aayog's Bill bring cheer to all?

India's medical device sector could be poised for a long overdue transformation if NITI Aayog's draft Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019, reportedly doing the rounds of various ministries, is accepted.

But is India's medical device sector ready to be regulated on par with their global counterparts? Many of whom have years, if not decades, of data from clinical trials and post marketing research backing them? Are domestic manufacturers and importers ready for penalties to the tune of Rs 1 crore and/or imprisonment, if their devices are proved to be unsafe or if they do not protect patient data?

And do we have the required regulatory manpower, with the relevant technical skills, to implement the proposed bill? Or will it remain a toothless tiger?

After years of being treated like the younger sibling of the pharma sector, India's medical device manufacturers seem close to getting their wishes granted. Primarily for a dedicated medical device regulator as well as separate legislation.

Let's hope that they get their house in order and gear up for the closer scrutiny that this will entail, once all parts of the proposed mechanism are in place.

There are cautionary tales from other segments of the healthcare sector. Many clinical research organisations had to shut down during the transition to tougher norms. Similarly, many MSME pharma companies are struggling with spiraling input and regulatory costs, combined with increasing price controls on the final medicines. Will Made In India medical device manufacturers, so crucial to the success of schemes like Ayushman Bharat as well as the health of the general population, have the resilience to ride out the rough weather ahead?

All that's clear for now is that 2020 will be a do-or-die year for India's medical device sector. The process which started in 2006, now seems close to major milestones. Ironically, these were written into the original draft but are only now coming to pass!

India's Medical Device Regulation Act was first drafted in 2006. Policy makers recognised that 'an entirely different system and method of regulation from the current national and international practices that are being applied for the regulation of drugs and cosmetics is required'. The preliminary remarks in the 2006 draft noted that this was because 'a diverse range and multitude of medical devices are in use, which are manufactured using a wide variety of technologies'.

In spite of this statement, it has taken more than a decade for medical device regulation to come out of the shadow of the Drugs and Cosmetics Act, 1940 (D&C Act).

The highlight of NITI Aayog's proposal is that the medical devices sector needs a separate legislation and regulators. In contrast, according to the Ministry of Health and Family Welfare's October 18 notification, from December 1, all medical devices would be regulated under sub-section (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (D&C Act) and the Medical Devices Rules, 2017. The health ministry's notification gives the industry 30 days to forward suggestions /comments/objections.

Do we have the required regulatory manpower, with the relevant technical skills, to implement the proposed bill? Or will it remain a toothless tiger?

Medical device companies have reiterated their stand that they are not against regulation per se. Rather, they welcome regulatory oversight as a way to ensure good quality at affordable prices. Regulation would also protect the reputation of the sector, weeding out products of poor quality and shady manufacturers. However, they have pointed out that while staff of the CDSCO are competent to regulate medicines, they lack the technical expertise to evaluate medical devices. They allege that this lack of experience was evident during the recent cases of faulty implants.

There now appears to be a fairly wide acceptance among policy makers that drugs/medicines are very different from medical devices like stents, implants and imaging equipment. Thus, it is logical that different parameters would need to be applied. The issue is that creating a separate regulatory framework and mechanism, is a process of evolution.

The NITI Aayog's proposal will soon be released for public comments but it seems to have many of the components of the health ministry's October 18 notification. With the big difference that it would be monitored separately.

Medical device companies are also hoping that the NITI Aayog's draft Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019, reduces the list of medical devices on the notified list.

In spite of strident opposition from industry stakeholders, the health ministry has expanded the list of notified medical devices over the past year. Currently 23 medical devices are on this list, ranging from syringes and stents to condoms.

Four more devices will be added from January 1 (nebulisers, blood pressure monitoring devices, glucometers, and digital thermometers). Four months later, from April 1, 2020, seven more categories will be added: all implantable medical devices equipment, defibrillators, dialysis machines and bone marrow cell separators as well as four categories of imaging equipment (CT scans, MRIs, PETs, and X-rays).

The good news is that while the NITI Aayog's Bill awaits consensus, other parts of the regulatory system are being out into place. On October 3, a CDSCO notice announced that four labs had been registered by the CDSCO as medical devices testing labs. Each lab is restricted to certain categories of medical devices which it can test or evaluate. The CDSCO has indicated that more applicants are being evaluated.

Thus, both importers and domestic manufacturers of medical devices are pinning a lot of hopes on the NITI Aayog's proposed bill. While it might not be perfect, at least it will be a start in the right direction.

VIVEKA ROYCHOWDHURY *Editor*
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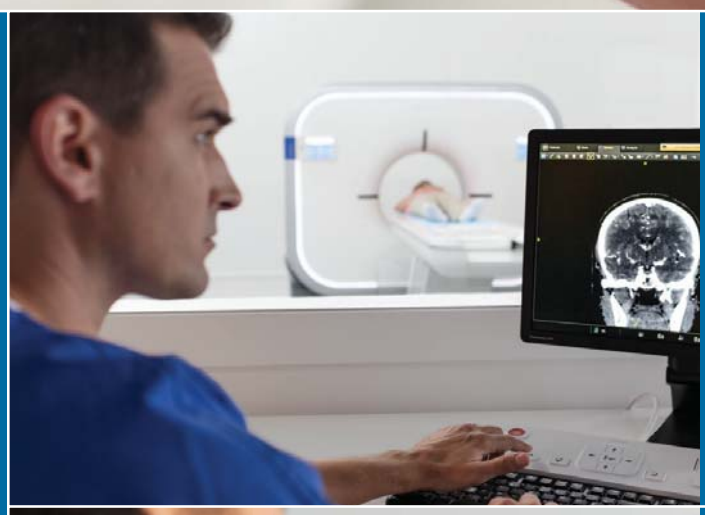

Canon Medical system organises a two day workshop on complex PCIs

Canon / Erbis had invited **Dr Kenya Nasu**, Director, Department of Cardiovascular Medicine, Toyohashi Heart Center, Japan to share his knowledge and expertise with Indian interventional cardiologists

With the rising incidence of CVDs in India, the cardiology community is set to witness a paradigm shift in treatment mechanisms, technologies, complexities of cases etc., that will enable the community to expand the canvas of research. Cases such as chronic total occlusion, resistant lesions, calcification, bifurcation, and multi-vessel disease will be on a rise. And so a constant update and innovation in surgical treatment sciences, technologies that will allow experts to better their approach to complex lesions will become a growing need. In keeping with this, recently, Canon Medical System conducted workshops on Complex PCIs at Mumbai's Thunga Hospital and Apollo Hospital. The workshop focussed on discussing complex cardiac interventions, technological innovations and areas still needing improvement.

Canon / Erbis had invited Dr Kenya Nasu, Director, Department of Cardiovascular Medicine, Toyohashi Heart Center, Japan to share his knowledge and expertise with Indian interventional cardiologist. Dr Nasu has been proficient in dealing with chronic total occlusions and other complex lesions. In these workshops, Dr Nasu explained some interesting approaches that interventional cardiologist can take in order to treat complex lesions.

Canon's vision behind this initiative is to develop a knowledge sharing platform for experts in the field of cardiac sciences to meet and discuss advancements and complexities associated with PCIs. Strategically this initiative will also help the company establish a strong presence in the cardiology business segment. (Read more: Canon Medical System's to go market strategy).

The two day workshop began on September 24, 2019 at Thunga Hospital, Mumbai with an inauguration meeting where Dr Nasu; N Sotomatsu, Executive Director, Erbis Engineering; Tomoko Kamijima, Senior Manager, Global Strategic Marketing, Canon Medical Systems; MS Menon, Projects Director, S Kumaran, Business Head – Cardiology Solutions, Erbis Engineering; Dr Satish Shetty, CMD, Thunga Hospitals; Rajesh Shetty, CFO, Thunga Hospital and Umesh Shetty – CEO, Thunga Hospital explaining the vision and purpose of the workshops.

Dr Satish Shetty, CMD, Thunga Hospital said that he was extremely delighted to be part of such a knowledgeable workshop at his hospital. At Thunga, they strive to provide the best quality care to patient and this association with Canon is a step in this direction, he acknowledged.

Dr Nasu addressed the audience saying, “I am here to share my knowledge and experience in complex PCIs and to help improve cardiac care in India.” Menon spoke on the vision for conducting the first workshop at Thunga Hospital. “We have a relationship with Thunga Hospital for more than 10 years. We choose this cath lab for our workshop

because of the highest quality standards that this hospital follows. This hospital has an eye for detail, when it comes to hygiene standards and we feel this is the right place to begin our initiative," he mentioned.

N Sotomatsu, Executive Director, EBRIS ENGG said, "We want to create more opportunities for collaborations between Japan and India and this workshop is a step towards it."

The day one workshop began with two complex PCIs conducted by a team of interventional cardiologists Dr Harminder Singh, Interventional Cardiologist, Medways Cardiac Clinic; Dr Surinder Hansra, Interventional Cardiologist and Fellow of European Society of Cardiology and Dr Ryan D'souza, Fellow, Invasive Cardiology, University Hospital, Bern, Switzerland. The first case was of a 65 year old man having three vessel blockages and the second patient was in his late 50s having two blockages but with a heart function rate of only 25 per cent. According to the doctors, the second case was more complex and Dr Nasu's intervention was really crucial to this procedure.

Dr Singh mentioned, "Japan has a very large geriatric population and so the doctors there are exposed to many complex cases. Dr Nasu's insights in the cases we worked together were really valuable. Moreover, we got to work on some really high-end image-guided machine that provided us superior quality imaging to manoeuvre around the clogged arteries. The knowledge acquired during the session on complex PCIs with information on the latest developments in hardware and instruments that are used in these procedures can now be passed on to our other colleagues. We can now create a community of well-informed cardio-vascular experts. With all this knowledge we can be sure of increasing the success rate of very complex PCI as well. "

Dr D'souza chipped in saying. "Dr Nasu updated us on an interesting technique called Plasma-mediated ablation (PMA)that makes use of high energy laser pulses to ionise molecules within the first few femtoseconds of the pulse. According to Dr Nasu, this process leads to a submicrometer-sized bubble of plasma that can ablate tissue with negligible heat transfer and collateral damage to neighbouring tissue. The use of PMA provides a unique means to study regrowth of the damaged axon as well as recovery of physiological behaviour. This also indicates that several types of neurons can regenerate rapidly following a single cut in the axon. This technique is being research further in Japan. Dr Nasu's insights are greatly appreciated."

Similarly, Dr Hansra also appreciated the wisdom shared by Dr Nasu and said that we should have more such workshops and knowledge sharing opportunities to improve our healthcare delivery system in India.

On the second day, the workshop was conducted at Apollo Hospitals, Navi Mumbai. Dr Nasu also shared his expertise during a couple of procedures done at Apollo's cath lab. Dr Sanjeev Kumar Kalakekar, Cardiologist, Apollo Hospitals, Navi Mumbai talked about the reasons behind the high incidence of heart diseases among Indians and the importance of PCI to deal with it. He said, "In India awareness on CVDs is growing in urban areas. However, awareness levels are low in rural areas when compared to urban population." Dr Kalakekar also mentioned that India is the diabetes capital and Indians are genetically prone to heart diseases where there are patients in the age group of 25-30 as well. Cost of procedures is a major concern, but govt schemes are now helping people."

Additionally Dr Kalakekar

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Canon's vision behind this initiative is to develop a knowledge sharing platform for experts in the field of cardiac sciences to meet and discuss advancements and complexities associated with PCIs

said, one should follow newer innovations, doctors should welcome ideas that reduce risk of radiation to patients. This also helps doctors to ensure accuracy.

Moreover, Dr Nasu also gave a presentation that explained Canon's cath lab system and the practices in Japan. He explained that the system is designed to provide high quality images by using a high dynamic range system. The cath lab also has after image correction system and a radiation dose monitor. (See box: Angiography system by Canon)

Giving a comparison of the healthcare system in Japan and India, Dr Nasu said that primary care is very important when it comes to management of CVDs in a country like India. In Japan, patients with Myocardial infarction (MI) get immediate care even at a primary health centre in a rural village. Whereas in India, especially in the rural areas, people do not get the necessary care for such illnesses. The insurance system in India is also very different when compared to Japan, therefore, it becomes a little difficult to provide specialised cardiac care in villages. Also, cases of myocardial infraction in Japan is far lesser than India.

He further spoke about the approach that India should take in order to curb the rising incidence of CVDs. He mentioned that a primary preventive care approach is a must. Management of diabetes, hypertension is also very crucial.

While talking about the technology and technique utilised during these procedures, Dr Nasu informed that PMA is a highly innovative mechanism to treat chronic total occlusions. It has a high success rate, with high precision and reduces procedure time as well. It also ensures low radiation dose as well.

Speaking about the technology, N Sotomatsu informed that Canon's cath lab system has a X-Ray radiation dose tracking system that can identify and indicate to the doctor the exact amount of radiation a patient is exposed to during the procedure. This is done in real time and the information is also communicated on a monitor as well as audio in order to ensure that patients aren't exposed to extra radiation. He also informed on the carbon footprint aspect and power (electricity) requirement of the system. “Our system saves around 15-17 per cent of energy without compromising on the image quality and system performance. We believe in developing products that are eco-friendly and reduce carbon footprint.”

At the end, Dr Nasu said that innovation is very important, it will help to maximise the impact of treatment and we are looking forward for better strategies for patient care.

CANON MEDICAL SYSTEM'S TO GO MARKET STRATEGY (N SOTOMATSU, EXECUTIVE DIRECTOR, EBRIS ENGG)

What opportunities do you see for Canon Medical system in the Indian cardiology business segment?
Healthcare is a very prime sector these days. There are immense investment opportunities floating and as a business strategy we would like to leverage them in order to build a strong business in India. In the cardiology pace, we see immense opportunities for cath lab offerings. There are many new hospitals coming up and even those seeking expansions.

What is your focus and vision when you develop your strategy to increase market share, especially when then market is already crowded with many cath lab solution providers?
We know that we already have immense competition. But our focus is not to increase market share only. We focus on increasing our presence and develop a community of loyal customers. We believe in creating a niche for our company that is built on strong relationships, sustainable innovations and reliable products.

How many installations have you done so far?
We have completed more than 50+ installations across India and we have some more in the pipe line.

What is your idea about customer satisfaction?
Well, when we think of customer satisfaction we think of providing solutions that will help hospitals to provide the best care to their patients and in a way that is cost-effective and sustainable to their respective organisations. That is why we offer two kinds of cath labs- floor mounted and ceiling suspended, depending on the room space the hospital has. Our system occupies 15 per cent less space as compared to our competitors. We believe in developing products for life.

GS1 India to host 36th edition of Global GS1 healthcare conference in New Delhi

With a focus on patient safety, the conference themes include track and trace for access to safe medicines

The Global GS1 healthcare conference will bring together Indian and international regulators, hospitals, drug and device manufacturers, private government bodies across the world to deliberate upon supply chain and operational efficiency issues, which can lower costs for healthcare providers and enhance patient safety in India.

Industry captains, decision makers, policy makers from across the global healthcare sector, Miguel A Lopera, President and CEO, GS1 Global Office, Belgium, Andreas M Walter, General Manager, European Medicines Verification Organisation (EMVO), Belgium, Jay Crowley, VP, USDM - Former US FDA Senior Advisor, along with Indian regulatory authorities will be present to participate at the conference.

With a focus on patient safety, the conference themes include track and trace for access to safe medicines. Hospitals working towards a better quality of care and increased efficiency, and Unique Device Identification (UDI).

> Experts will share best practices for how to strengthen collaboration between the stakeholders involved in patient care

Serving as a foundational source of information, the event brings together healthcare stakeholders, implementation partners and policymakers from around the globe to share their experiences related to healthcare and patient welfare, supported by GS1 standards.

Progress to address the worldwide challenge of providing better care, with greater efficiency, for every patient has led to increasing requirements and activities in the fields of pharmaceutical traceability, supply chain, hospital management and UDI regulation.

During the event, panel sessions will allow delegates to experience GS1 standards in action and to have discussions with their colleagues. Experts will share best practices for how to strengthen collaboration between the stakeholders involved in patient care. Moreover, to facilitate networking and knowledge sharing, the organisers have organised site visits.

Globally, pharma companies are using open and technology-independent standards on drugs at different packaging levels that permit easy identification and monitoring of supplies during movement in healthcare supply-chains. Automatic identification system (barcode) has a very wide range of applications, including point-of-care scanning to match product data to patient data, verification of patient identity, identifying implants uniquely, recording implant serial numbers in central registries, tracking and tracing of individual instruments for stock control and supplies management, and tracking assets throughout a network of facilities.

Globally there are stringent regulations covering pharmaceuticals which include, The US Drug Quality and Security Act (DQSA), EU Falsified Medicines Directive, National Health Policy in Argentina, National Health Surveillance Agency.

(ANVISA) in Brazil, Korea Food and Drug Administration (KFDA) and (Ministry of Health and Welfare Notification, 2011 – 58), The Saudi Arabia Food and Drug Authority.

In India, GS1 standards using barcodes have been mandated by the Directorate General of Foreign Trade (DGFT) for pharmaceuticals for exports since 2011 and hence the engagement with related Government bodies and Drug Controllers at Central and State levels has been active to sensitise them on global compliance requirements and best practices in the healthcare sector which can address the above challenges through adoption of global standards. In India, there exists a need to adopt global best practices and standards to enhance patient safety, upscale its healthcare systems and deliver affordable healthcare.

The 36th Global GS1 Healthcare Conference from November 5-7, 2019 at Le Meridien New Delhi would see a continuation of these deliberations around traceability in pharmaceuticals.

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RFEIT MEDICAL DEVICES

India's laws to administer medical devices are cryptic, giving enough room for counterfeit products to outwit regulations and corrupt the economy. Experts reveal ways by which India can succeed in its battle against counterfeits medical products

By Raelene Kambli

Attention healthcare providers!

Did you know that globally around 8-10 per cent of all medical devices are of fake origin?

Did you know that it is important for manufacturers to have a Unique Device Identification (UDI) to ensure traceability of their products?

And did you know that is important for healthcare providers to to check the identification and clinical examinations of medical products while procuring them?

Sadly, ill awareness about counterfeit products amongst healthcare providers is one of the chief reasons for such products to circumvent regulations and corrupt the economy.

The impact of counterfeit medical devices harm patient rights, damage brand equity and cause losses to original equipment manufacturers. According to Aarthi Sivanandh(Partner) and Bhargavi Ravi (Associate) of J Sagar Associates, globally approximately 8 per cent of all medical devices are counterfeit and only 20 per cent of countries in the world have established regulations to counter their spread. Most commonly counterfeit devices include surgical devices such as clip cartridges, mesh, plates and screws.

Dr Milind Antani, Lead - Pharma & Healthcare, Medical Device & Med-Tech Practice, Social Sector Practice, Nishith Desai Associates informs, "Counterfeit medical devices are not only a threat to public health but also reduce the level of public trust in the healthcare system. Usually, medical devices are required to undergo comprehensive clinical investigations to establish their safety before they can be marketed to the general public. For counterfeit medical devices, no such tests are carried out. Prevalence of counterfeit medical devices in the market also makes it tougher for manufacturers of generic devices to establish their presence in the market as patients are not as comfortable purchasing medical devices manufactured by less

Prevalence of counterfeit medical devices in the market makes it tougher for manufacturers of generic devices to establish their presence in the market

Dr Milind Antani
Lead - Pharma & Healthcare, Medical Device & Med-Tech Practice, Social Sector Practice, Nishith Desai Associates

Controlled print stations/ unique serial numbers ensure that counterfeits are not introduced at the re-labelling stage. This can also prove to be a deterrent for potential diversion

Charu Seghal
Head-Strategy and Operations consulting, Deloitte India

Traceability is one of the most effective tools for anti-counterfeiting. Use of digital technologies over and above the physical solutions takes the anti-counterfeiting features one step further, addressing and curbing supply chain issues

Nakul Pasricha
President Authentication Solutions Providers Association

Aarthi Sivanandh(Partner)
J Sagar Associates

Bhargavi Ravi (Associate)
J Sagar Associates

Litigation should aim to champion the rights of patients and public health. Protection of public health requires a wider approach than a mere IP-based approach

prominent companies.

Nakul Pasricha, President Authentication Solutions Providers Association, adds, "The use of non-compliant and counterfeit medical technology devices can seriously injure patients' health and significantly endanger a medical equipment company's reputation and business. Firstly, one cannot appraise its quality and safety for the user, since the equipment has never been examined or assessed by the authorised parties in the Ministry of Health. For instance, the dental industry is susceptible to many fake products, ranging from X-ray machines, turbines, drills, and even fake braces. The infection from a fake lead wiring can even endanger the patients' life. Counterfeit needles could be non-sterile and their use can put the user at risk of infections.Secondly, counterfeit medical equipment could provide the user with a false diagnosis of the patient's condition. For example, a blood glucose meter could fail to display the true values for a diabetic patient and a pregnancy test may not be accurate. Finally, the use of counterfeit medical devices harms the device's original registration holder, who invested a great deal of resources to prove the preparation's safety and efficacy and to register it with the Ministry of Health. Fake and substandard equipment can totally defeat the purpose and intent of medical treatment."

Charu Sehgal, Head-Strategy and Operations consulting, Deloitte India, states some of the economic threats associated with fake devices:

- A clinical threat in the form of a health risk to the patient that could result in injury, permanent disability, or even death. Such devices could also negatively impact the clinician's reputation
- An economic threat, as counterfeit devices capture a part of OEM's market, and this in turn affects the original manufacturers as well as vendors down the value chain
- Increased cost of production due to investments in preventive security measures (such as holograms and barcodes) and awareness campaigns within the medical community
- Creation of negative perception, as the presence of counterfeit devices can make hospitals and patients lose confidence in the original brand
- Fees to deal with legal suits in case of counterfeiting instances could pose a heavy burden

International problem

World over, industry experts, governments and regulators face a huge challenge in tackling this menace. Shares Sehgal, " It has become harder to detect counterfeit devices, as the look and feel of the packaging/labelling, as well as the product, are absolutely identical to the original. Additionally, there is low awareness about the presence of counterfeits in the medical community and

among purchase departments of hospitals. Also, there is limited training on how to spot counterfeit products. The presence of externalities also create challenges towards mitigating counterfeits. At times, there is inability to distinguish whether sub-par performance is due to the device being a counterfeit product or because of other issues such as poor clinical facilities or environmental factors (for example, some devices witness poorer performance in tropical climates)."

NUMBER OF SIGNS THAT A DEVICE COULD BE COUNTERFEIT, SMUGGLED OR FALSELY PRESENTED

- The accessories and devices are sold without packaging.
- The accessories and devices are sold in street businesses, stalls, kiosks, convenience stores and grocery stores rather than in pharmacies and pharmacy chains.
- In case of small units of medical equipment purchased within a large package - the expiry date on the main package does not correspond with the expiry dates on the individual packages.
- Spelling errors in English and in Hebrew.
- Lack of expiry date, lot number and name of manufacturer.

KEY FACTORS LEADING TO THE PROLIFERATION OF COUNTERFEIT MEDICAL DEVICES

(a) governments' unwillingness to recognise the existence or gravity of the problem;
(b) inadequate legal framework and insufficient sanctions;
(c) weak administrative measures, not focussed on fighting counterfeit medical products;
d. ineffective control of manufacturing, importation and distribution of medical products;
(e) ineffective collaboration among authorities and institutions involved in regulation, control, investigation and prosecution;
(f) ineffective national and international collaboration and exchange of information between the public and private sectors;
(g) inadequate access to health services and reliable pharmaceutical supply channels; (h) illiteracy and poverty;
(i) inadequate social protection systems;
(j) national drug policies that prioritise economic over public health aspects of medicine manufacturing;
(k) fragmented distribution channels;
(l) extraterritorial trade zones;
(m) unregulated Internet trade;
(n) unregulated third-party manufacturing.

The Indian problem

According to analysts at the global level, India is viewed with ambivalence on its war against counterfeits. On the pharma front, India is already accused of being a leading source for counterfeit drugs. As per the April 2019 report of the Office of the United States' Trade Representative, China and India are reportedly the leading sources of counterfeit medicines distributed globally. While it may not be possible to determine an exact figure, the study suggested that up to 20 per cent of drugs sold in the Indian market are counterfeit and could represent a serious threat to patient health and safety. A similar sentiment runs in the surgical and medical devices segment too.

However, domestic manufacturers from India despise this accusation.

An AIMED source had written to *Express Healthcare* stating that the India does not suffer much from the counterfeit medical devices problem. "We have negligible complaints from our Members on Counterfeit Medical Devices as that was earlier a bigger problem in Pharmaceutical Industry but we do get complaints of Licensed Manufacturers of Orthopedic Implants having to compete unfairly with unlicensed lower priced products which may be look alike non branded implants but may not be having the required grade of stainless steel etc. In fast moving disposables products like syringes etc., access to technology / high cost of packaging acts as a detriment to most counterfeits in India. But, we do face problem of counterfeiting from China e.g. for our disposable syringes in Sudan and Morocco which were excellent copies of our Dispo Van Brand and we had to complain to their regulators. In the long run, regulating all medical devices under a separate medical device specific law to address patient safety concerns on quality and counterfeits etc., is the solution", said the AIMED source.

"Such a damning international reputation not only affects credibility of legitimate players in India's drugs and medical devices sphere but also taints the desirability of India as a trading partner and as a potential investment destination. This will be particularly detrimental to India's legitimate generic industry. Therefore, on every front - ethical, consumer, health and safety, industry, and global reputation – it is the duty of the State, and of every player in the field, to create and implement the highest standards of quality control and checks to weed out the menace of counterfeit medical products", assert Sivanandh and Ravi of J Sagar Associates.

They further list down some factors that exacerbate the counterfeit drug problem in India:

1. Multiplicity of regulators – While the Central Drugs Standards Control Organisation (CDSCO) is the organisation placed in-charge of medical devices under the Drugs and Cosmetics Act and Rules, there are other regulators who also control medical devices – the Department of Pharmaceuticals (Ministry of Chemicals and Fertilisers), Customs Department (to punish illegal imports), authorities under the Essential Commodities Act, 1955 (under the Drugs (Price Control) Order, 2013). This leads to diffused power.

2. Poor enforcement – multiplicity of regulators adds to India's per-existing problem of inefficient enforcement of regulations.

3. Low cost of labour and relatively low cost of production make it easy to create counterfeit devices

4. Unchecked online sale of medicines and medical devices facilitate the spread of these counterfeits – easy access to online platforms and one needs to check as online retail pharma grows, the extent of quality checks that are in place before accepting stock for sale

5. India provides the cheapest data connection in the world – affordable and reasonably efficient data make it easy to create and access websites and complete transactions online. To the non-discerning customer this could be dangerous.

6. Illiteracy, poverty and lack of awareness among the people – Poverty instigates people to spend less even on life-saving medical devices. Illiteracy and lack of awareness often results in people being unable to differentiate between genuine products and counterfeits.

Further on, medical device sector in India for a long time has been import-dominated. And because most products do not have a UDI, keeping track of the devices and instruments becomes extremely difficult, inform experts.

Learnings from EU MDR

Having said that, EU's new Medical Device Regulation (EU MDR) which will come into effect in May 2020 is said to bring hope to those who have been combating against counterfeit medical devices for a long time. According to the new EU MDR, Unique Device Identification (UDI) will be enforced to help track devices throughout the economic operator supply chain and will be added to all labels. The EU MDR has, among other measures, introduced stricter ex-ante control for high risk devices, expanded the coverage of medical devices to include some aesthetic devices and has revised its classification systems to introduce an "implant card" to be carried by patients who have an implanted medical device. It has enhanced post-market surveillance and promised greater inter-agency cooperation.

Well this move is critical to all medical device manufactur-

ers globally, as Europe is an important market both from a trade and regulatory point of view. The new regulation will positively impact operations from one end of the supply chain to the other, from manufacturing to distribution. With the implementation of the new EU MDR, there will be an increase in demand for more information related to clinical data, technical documentation, and labelling by regulators. This will make it mandatory for manufacturers to have meticulous clinical evidence for their products.

As per industry analysts, this move ensures traceability of devices as well as sensitises patients, brands and policymakers to create awareness around solutions. This new regulation also opens avenues for regulators in India to learn new strategies and legal frameworks.

India's efforts to regulate medical devices

While India, already has a Medical Device regulation that covers 23 broad categories of devices, yet the existing law covers only a small portion of entire spectrum. Sehgal informs, "With the introduction of Medical Device Rules 2017, all companies interested in importing, manufacturing, and selling medical devices in India have to adhere to regulatory framework laid down by the rules, which are harmonised with the Global Harmonisation Task Force framework (GHTF)."

Early this year, the Central Government, in consultation with the Drugs Technical Advisory Board, published a Gazette Notification notifying eight additional categories of medical devices under the regulatory framework. This will be effected from April 1, 2020. The following medical devices (intended for human use) would be considered "drugs" under the DCA, namely: (a) all implantable medical devices; (b) CT scan equipment; (c) MRI equipment; (d) defibrillators; (e) dialysis machine; (f) PET equipment; (g) X-Ray machine; and (h) bone marrow cell separator.

Moreover, the Ministry also notified that all implantable medical devices, CT etc., should register their devices on the CDSCO's e-governance SUGAM portal (a single window interface for stakeholders to access the online services).

Sivanandh and Ravi of J Sagar Associates inform about some penalties under the Indian MDR for those not meeting the standards:

1. For the manufacture, distribution and sale of unlicensed or adulterated medical products (where such adulterated medical products are not likely to cause death or grievous hurt) – imprisonment of 3-5 years and a minimum fine of Rs 1 lakh or three times the value of the confiscated drugs, whichever is higher.

2. For the manufacture, distribution and sale of spurious

medical products (where such spurious medical products are not likely to cause death or grievous hurt) – imprisonment of seven years to life and a minimum fine of Rs 3 lakh or three times the value of the confiscated drugs, whichever is higher

3. For the manufacture, distribution and sale of spurious or adulterated medical products which are likely to cause death or grievous hurt – imprisonment of 10 years to life and a minimum fine of Rs 10 lakhs or three times the value of the confiscated drugs, whichever is higher

4. For all other manufacturing, distribution or sale in contravention of the DCA, DCR and MDR – imprisonment of one-two years and fine of not less than Rs 20,000.

5. For the import of any prohibited medical products, including those which are misbranded, adulterated or spurious – penalties under Customs Act, 1962 will apply.

Anti-diversion law needed

Now, with counterfeit medical products also comes another problem- illicit diversion of medical products. Sehgal explains, "Illicit diversion refers to the process of goods being redirected from the intended region of sale to a different country or destination. This could be done to take advantage of price differential or for other reasons. Illicit diversion is also referred to as the secondary market, parallel trade, gray market, and third-party importation. Anti-counterfeiting measures also act as an effective deterrent to diversion. Often, counterfeits get introduced into the supply chain at the local distribution hubs. Controlled print stations/ unique serial numbers ensure that counterfeits are not introduced at the re-labelling stage. This can also prove to be a deterrent for potential diversion."

Hence, it is vital that any anti-counterfeiting mechanisms also take anti-diversionary steps. Experts reveal that the Indian law is currently not very clear on this point and does not have explicit provisions concerning anti-diversion.

But this can be resolved if manufacturers adopt innovative packaging solutions, UDI, barcoding and more.

Key tools to tackle counterfeits

Ensuring that the medical devices at the point of use is the right one ultimately increases the awareness amongst end users. Therefore, it becomes a pressing need for manufacturers to take ardent steps to improve track and trace mechanisms as well as secure packaging and supply chain.

Pasricha urges manufacturers to focus on solution such as holograms, barcoding, UDI and more to thwart fake products.

Secured Packaging – Medical devices usually have three levels of packaging-the primary packaging (usually a pouch), which then goes into a secondary packaging of a product box and finally packaged into a shipper where there will be multiple products stored in one package. To avoid counterfeiting, manufacturers can apply deterrents to each of these items of packaging. Solutions such as hologram, UV identification code, 2-D barcode with unique numbering/serialisation or hidden text printed using security or magnetic ink can be used. These are not intended as end-user checks but as deterrents to the counterfeiter. A trained personnel can quickly establish if the product is authentic and can take things further by referencing the unique numbers used in the security marking via an authentication site, making it easy to identify fakes that might have sneaked in.

Secure Supply Chain – Traceability is one of the most effective tools for anti-counterfeiting. Use of digital technologies over and above the physical solutions takes the anti-counterfeiting features one step further, addressing and curbing supply chain issues. A unique serial number or reference number (URN) is a randomised number printed onto the product's packaging and as it is unique, it can be used to define exactly who manufactured the item, where it was manufactured and the country or state of origin. This type of serialisation at the item level is vital in the fight against counterfeiting and has proved to be very effective in many cases. Web-based labeling and data management solutions can support one in delivering secure printing for mass serialisation to protect the product and the consumer. Serialisation not only gives one the ability to authenticate the product as genuine, but also offers the ability to track product's movement throughout the supply chain, improve efficiency and most importantly, protect the end user. Things can be taken up another level by linking logistics systems with the serialisation data, providing a smart active method system that would look for activities and trends based on knowing which serial numbers were assigned to what product, to be sold in which territory. For example, if a shipment of product with serial numbers assigned to the China market were scanned at a customer site in South America, this would be captured as a diverted product and flagged up to the manufacturer/supplier accordingly to engage and investigate. It is therefore a combination of both passive and active methods that ensure true safety of items and consumers.

Sivanandh and Ravi also mention that some packaging players are working to create innovative hi-tech solutions. For instance, TruTag Technologies has developed programmable micro tags which can be embedded into packaging or into the device itself. Made of high-quality pure silica (SiO2) these micro tags can carry large quantities of information which can be used to determine authenticity and traceability.

Need for a clear manifesto against counterfeiting

India's regulatory framework seem exhaustive and penalties appear to be strict but experts inform that the real challenge lies in its enforcement. Says, Sivanandh, "The challenges ranges from detection of counterfeit medical devices to being able to prosecute those responsible for such counterfeits. Given the complexity of the pharma and medical devices supply chain, this poses a real challenge to State machinery. It will be necessary, above all, to ensure inter-agency communication and cooperation."

To take proactive measures, in March 2019 regulators raided a wholesale market in Varanasi and Delhi's Bhagirath Palace - which is one of Asia's biggest wholesale markets. The raids also included a residence-cum-office in Shahdara. The raid in Varanasi was carried out by FDA with the support of a major medical device company. Over 6,000 units of counterfeit medical devices such as surgical products were found during these raids. On duty officer, Bhagwan, IO, district investigation unit disclosed, "This is one of the biggest raids to bust counterfeit products in recent times."

Another raid in July 2019 was conducted in Agra which uncovered counterfeit skincare products. However, little is known about the trails these

offenders will face.

Experts say that surprise checks and inspections of licensed manufacturers (to ensure quality standards) and suspected unlicensed or counterfeit manufacturers and distributors is vital to ensure compliance with laws. But unless it is made manifestly clear that the government considers counterfeiting a serious punishable offense and manufacturers cannot act with impunity, the problem will continue to exist. Nevertheless, India can certainly learn from or even join the WHO and interpol's operation called the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) that began in 2008. The mission initially began to prune counterfeit medicines by the Permanent Forum on International Pharmaceutical Crime (PFIPC), IMPACT and Interpol initiated Pangea. It was the first international activity targeting illegal advertising, sale, and supply of medicines over the internet. Today, Operation Pangea, an annual operation, has over 123 participant countries. According to Interpol's website, in 2018 along, Operation Pangea seized 10 million units of counterfeit medical products worth over $14 million. About 859 people were arrested and 3,671 websites were taken off the Internet.

Further, experts emphasise that the industry and healthcare providers must know that counterfeiting is not the same as intellectual property right violations. Explain Sivanandh and Ravi, "Counterfeiting of medical products does not always entail the violation of intellectual property rights (a medical device that does not have the claimed properties or is substandard would also be counterfeit/misbranded/adulterated/spurious). The IP approach identifies the rights holder as the main victim of counterfeiters and litigation is focussed on protecting his rights. For counterfeit medical products, the real victim is the patient and litigation should aim to champion the rights of patients and public health. Protection of public health requires a wider approach than a mere IP-based approach."

They remind us of the Theranos scandal where a poor idea, fake claims and bad conceptualisation was never shot down. It got regulatory approvals and the company conducted clinical trials on real terminally-ill patients in partnership with pharma giants in the most regulated legal system in the world –USA. Putting several patients' lives at stake. It took around a decade from regulators to detect the fraud. That alone explains the complexity of the problem world over. With India having cryptic laws for medical devices, it will be tough to clamp down the proliferation of counterfeit medical devices. Nonetheless, today we see immense technological transformations in healthcare that can certainly fix the problem.

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INTERVIEW

It is our social responsibility to contribute towards a healthy and progressive India

SBI Life's aim is to help individuals realise and unlock their full potential thus leading to poverty alleviation and economic development of the country. **Manjula K**, EVP, Chief of HR and Management Services, SBI Life in an interaction with **Sanjiv Das** reveals more on how SBI Life is trying to build a strong and sustainable community

What is SBI Life's focus for the healthcare sector?

India enjoys a large demographic dividend which by 2050 will allow us to have a far larger workforce than both the US and Europe combined. Most of this workforce will be required by the organised sector and will be supplied from the middle class.

To make the most of this time-bound opportunity a lot depends on whether or not we are able to help our employable population reach their full potential both in terms of skill training and health.

As things stand, India has one-third of the world's stunted children making malnutrition the biggest deterrent in our growth story.

As a responsible corporate, SBI Life believes that it is our social responsibility to contribute towards a healthy and progressive India.

While the Government of India (GoI) has implemented some of the large scale programmes such as National Health Protection Scheme, Ayushman Bharat and Integrated Child Development Scheme (ICDS) to tackle the grave issue of malnutrition, SBI Life believes in augmenting these government initiatives to bring about a holistic

development of the communities we operate in.

This approach helps us to align our focus on strengthening government's existing and promising projects and avoid unnecessary duplication of national efforts.

Ultimately, our aim is to help individuals realise and unlock their full potential thus leading to poverty alleviation and economic development of the country.

Tell us about the healthcare CSR initiatives undertaken by SBI Life?

Under healthcare, primarily, SBI Life is complementing GoI's ICDS programme through our intervention in villages of Madhya Pradesh (MP) and Rajasthan. The focus here is on maternal and child health during the first 1000-days.

We selected MP and Rajasthan as data indicated alarming levels of malnutrition especially among women and children. So far, we have adopted more than 145 villages in these regions covering a population of about 400,000 individuals.

Secondarily, other areas that we are working towards is tackling the increasing burden of treatment cost of cancer among the economically weaker section of the society. We provide medical aid to leprosy affected people, therapeutic support to differently-abled children, medical aid to visually impaired people and have also successfully conducted platelet donation drives.

Which states and who all are going to benefit from this initiative? Did SBI Life tie-up with the state governments?

SBI Life's CSR interventions are currently spread across 15 states and we place a lot of emphasis on the regions that we choose for our interventions. MP and Rajasthan, for instance, were chosen after referring to government's reports like the National Family Health Survey-Four and Millennium Development Goals report (MDG 2014-15) that put Dhar district in MP and Baran in Rajasthan among the worst-performing districts on maternal and child nutrition. So we decided to extensively work in these regions.

We have started seeing the positive impact of our work and are happy to see a lot of enthusiasm and high participation rate among our beneficiaries. This gives us a confidence that our approach is right and encourages us to replicate our interventions to other relevant regions as well.

For these successes and many more in future, we thank our NGO partners who are integral to our on-ground implementation and grassroot collaborations. Our on-ground partners ensure a meaningful liaising with the government bodies depending on the need and nature of the project. For instance, in MP and Rajasthan, our NGO partner has signed MoUs with the state governments. This ensures implementation of relevant projects in making a significant impact at the national level.

While we do carry out our

CSR work in direct collaboration with our NGO partners, we also wish to work in collaboration with the government through Public Private Partnership (PPP) mode in the future, depending upon the need and nature of the project.

In our view, PPP is an effective tool for bringing private sector efficiencies in timely delivery of quality public services. We wish to leverage this mode to achieve best results and benefit for the communities where we operate in.

What will this CSR initiative entail in terms of healthcare provision?

Through our interventions, we ensure support to pregnant and lactating mothers in each step of their pregnancy lifecycle till their child turns two. Once we map a village in terms of age, gender, marital status etc., we then regularly engage with current and prospective mothers through an Accredited Social Health Activist (ASHA) and community sessions. Our NGO partner 'Action Against Hunger' reaches out to the pregnant women through ASHA/ Auxiliary Nurse Midwife (ANM)/ Anganwadi Workers (AWWs).

As a first step, we encourage the pregnant women to get a hospital-based pregnancy test for confirmation. She is then counselled to register her pregnancy at the hospital accompanied by our NGO partner's Community Mobilizer (CM) or an ASHA/AWW. Once a woman is registered, she receives a Mother and Child Health (MCH) card.

Pregnancy is a very crucial time and access to right information and facilities is the key to ensure safe birth and healthy maternal and child health. This is why we do not leave any stones unturned to ensure health and safety of mother and her child.

We engage with her intensively through monthly basis during which she is counselled on nutrition and healthcare. We work closely with her to ensure that she completes at least four Antenatal Care (ANC) check-ups.

Then we ensure regular monitoring for risks such as anaemia, blood pressure, blood sugar and other possible vulnerabilities. She is guided to conduct the ANCs either during Village Health Nutrition Day (VHND) or through a nearby health facility. In every step, she receives full support and guidance from an ASHA or AWW.

Her consumption of Iron Folic Acid (IFA), calcium and deworming is also monitored and she is connected to the appropriate resource for a regular supply. The woman is referred to the AWC for Take Home Ration (THR) which is then followed up through an AWW. At the same time, through home visits, group sessions and community activities, she receives counselling on the importance of nutrition during pregnancy.

As she enters her seventh month into pregnancy, a session on birth preparedness is conducted with her using the Birth Preparedness and Complication Readiness kit (BPCR kit). Through regular visits and sessions, it is ensured that she knows where the nearest health facility is and what transport is available to her for an institutional delivery.

The ASHA supported by NGO CMs helps the woman to regularly visit the health facility for regular check-ups and necessary vaccinations. During her visit to the hospitals, she is counselled on the importance of initiating breastfeeding and the importance of giving the new born her body warmth.

Upon returning home after the delivery, a Post-natal Care (PNC) visit at the health facility is facilitated for the woman with the support of an ASHA/AWW. ASHA worker alongside NGO CMs also conducts home-based visits for the new born and the mother and provides counselling on recognising danger signs and consuming IFA tablets. She is also counselled on family planning, importance of taking ample rest at home, breastfeeding and following a nutritious diet for a healthy recovery. We work with her and guide her on good child feeding practices such as exclusive breastfeeding for the first six months and complementary feeding post that. We further work with the mother on diet diversity, good sanitation and hygiene practices, immunisation and various services available through the Anganwadis till the child turns two. This ensures that the child crosses the critical window (conception to the child turning two) with good health, thereby reducing the chances of malnutrition and enabling them to grow, learn and prosper.

> SBI Life believes in augmenting government initiatives to bring about a holistic development of the communities we operate in. This approach helps us to align our focus on strengthening government's existing and promising projects and avoid unnecessary duplication of national efforts

What process do you follow when it comes to the implementation and monitoring of CSR activities?

We believe that on-going engagement of the key stakeholders and sustenance of the project is solely dependent on well-planned implementation and thorough monitoring.

The three mantras that we follow are: pre-project research, project review in regular intervals with surprise visits and post-implementation follow-up.

The pre-project research mainly involves a baseline study. At this stage we facilitate an open and transparent dialogue with the community, government officials and NGO partners to understand the key challenges faced by the people. It is this consensus from all the key stakeholders and our beneficiaries that helps us execute socially relevant interventions and ensures project sustainability in the long run.

Once we have identified the key issues and probable interventions we conduct a regular project review and surprise visits. This helps us to effectively monitor project progress and challenges, if any. We work tirelessly with our NGO partners to ensure that desired results are achieved for the beneficiaries.

We close the loop by conducting a thorough post-implementation follow-up in the end. This step not only helps us to identify if we have met our project objectives but also guides us in building a concrete strategy for the future.

The basic thing to understand here is that since every project is unique, companies need to customise their monitoring tools and templates to effectively monitor the project.

Now these are just the basic building blocks that we follow towards creating an impactful, long-term and sustainable project. But we do continue to research for newer methods catering to unique requirements of individual projects supported by us.

How is SBI Life going to benefit from the healthcare CSR initiatives in the long run?

In today's world, no business can prosper without creating a shared value for its shareholders, customers, employees and society at large. Good news is that more and more companies have understood and accepted this fact.

Among many other socially responsible corporates, SBI Life too understands the value of building a strong and sustainable community. This understanding is reflected in our business philosophy – 'Protection of Life'.

One way to achieve 'Protection of Life' of the communities where we operate in is by empowering them to access affordable and quality healthcare. Under healthcare, our focus is on increasing health performance and not just providing services to the people. This means we place positive health outcome and enhanced healthcare delivery as our key evaluation indicators in discussing success and positive outcome.

The end benefit for the company is to create meaningful and active engagement within the communities we operate in and contribute towards their holistic development.

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INTERVIEW

AMR is a concrete threat to our future health

Niclas Jacobson, Deputy Director- General and Head of the Division for EU and International Affairs (Ministry of Health and Social Affairs) discusses the Swedish-Indian partnership in the healthcare sector so far, future collaboration prospects and the need for all countries unite on the AMR issue with **Tarannum Rana**

Sweden has provided India assistance on multiple healthcare platforms – from providing medical technology to disease eradication. What has been Sweden's strategy to tap India's healthcare market?
Our strategy has been to get different collaboration partners in the healthcare sector, and we started on that 10 years ago with an MoU between our respective ministries. Since then, a lot of things have happened. Under this MoU, we have a joint working group which I am co-chairing with my Indian colleague from the Ministry of Health. We meet at least once a year to go through this MoU, to see where is it working, where are the hiccups and how should we develop it further. Recently we have added ageing as an issue for mutual collaboration.

Under this MoU, we also have working national authorities like Sweden's National Board of Public Health Agency or the Medical Products Agency. These authorities have their own MoUs with their Indian counterparts to exchange knowledge and find common ground for collaboration. This is the working method. We also try to involve the private sector in some way. We have different Swedish companies coming in our delegations which can meet their Indian counterparts and find where

their products can fit in the Indian Health System. More recently, not only have we tried to develop our partnership in sectors like research, public healthcare sector and private sector, but we have also expanded it more over the country. In February, for instance, our minister went to Jodhpur, Rajasthan, and there we tried to establish a collaboration with AIIMS Jodhpur. It is important for us to know the state of healthcare in India outside tier-one cities.

Of all the 12 areas which were mentioned in the MoU signed by India and Sweden in 2009, which is given top priority by Sweden?
One top priority for the Swedish Healthcare agencies is Anti Microbial Resistance (AMR) – this issue requires urgent attention. Even though India and Sweden come from different realities, AMR is very much a real problem threatening healthcare. Both countries have everything to gain from collaborating (on AMR). We can learn from each other and combat this situation as soon as possible.

Coming back to the MoU, all the areas encompassed in it are important but certain parameters have changed over time. Some of the areas which we would like to get restarted are midwifery and women health. Moreover, when this memorandum was signed, India was still a recipient of our development aid, but now the equation has changed- both the countries are more like equal partners now. Though there is no more development aid, Sweden we can impart knowledge and innovation which can bolster India's healthcare plans.

What does Sweden expect from India in terms of the MoU?
We expect a complete commitment to this collaboration, which I can happily state, we have received from India till now. A collaboration requires the partners to commit on equal footing and participate equally. I see this happening in this (India and Sweden's) partnership and I hope to see this equation unchanged in the future. When we started-out with development aid, I feared that when these resources dry out, the partnering interest will die out as well, but that didn't happen. Interestingly, from the last couple of years, the Indian side has increased its participation- India has now more resources, and has become a worthy partner. In fact, lately, I haven't spoken to anyone who doesn't want to

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Top 10 hospital marketing strategies

Roma Agarwal, Independent Healthcare Consultant recommends measures to build a successful brand, right from attracting customers and providing service to building a relationship with the brand and converting them into loyal customers

IN A hospital service industry, every employee works with the principal goal of providing service to its customers. The consumers here are the patients coming for primary consultation or seeking other support services, be it radiology, diagnostics or pathological investigations.

Hospital marketing strategies are different from other product marketing strategies where, in the latter, one can experiment with the content and market it only through monologue channels. When the most important aspect that matters from a business perspective (in private or corporate organisations) is profit or loss, there needs to be a discussion on what strategies were implemented, what the central plan was, right from the start.

In marketing, each sub-department works taking one step at a time, creating the proposition, getting approvals, working on the content and then beginning with field work. Right from attracting the customer, bringing them in, providing the service, building their relationship with the brand till the final step of converting them into your brand promoters, all of it, each step here should not be just a responsibility but it has to showcase your skills, requiring development through strategic planning.

Following are ten strategies which make for the soul in successful hospital marketing:

Positioning your brand

Marketing goes with the definition of 'identifying and meeting human and social needs.'

The catch here is to simply think. Think of ways your hospital will be different from the rest outside your fence, ways to reason why your potential customer should get converted to a loyal one, and ways to present the above-mentioned points distinguishing yourself from the rest. The areas could be your associated consultants, use of state-of-the-art technology, or your service standards. Positioning your brand with the advantages can be done with basic position maps. This marketing strategy will communicate points of similarities and differences with your competitors.

Analysing the market needs

Researching your market has been the first step, the core of marketing strategies. Here research is your grip into the specific details of what your customer reach is, who your customers are and what exactly they need. When you have your research done, then the conversation will be about the last specific mentioned here. 'Need'. Just like an obvious truth, there is a distinction in people's understanding of the difference between what the customer 'wants' and what it 'needs'. While the former is something which they are aware of, the latter is the untapped market potential which you'll have access to, only with your research paper in hand. In a healthcare industry, one can create demand for a service just by analysing the market's need and increasing its awareness.

Winning the activity branding game

When the need has been found and you're ready with the proposition to your business plan, the next step will be its execution, the final presentation to the public. In hospitals, this is essentially required when marketing activities are planned.

For a healthcare service provider, for example, the need could be any lifestyle disorder widespread in your market niche, and the 'value' here will come with the understanding of such prevalence in the public. Here the hospital brand enters, with educating the public through their marketing activities in branding and promotions, that such prevalence requires an intervention and that 'we' are here with its solution. Because many marketing activities fail with few footfalls, not because the 'need' was lacking, but because your customer did not understand it. The plan is to be creatively simple.

Document customer's value

The competition is huge and your consumer has several options to select from. What the marketer needs to work on is to make them understand why they need to 'spend' on 'your' brand. This requires customer value research where they understand what the brand values. Marketing campaigns based on social causes, events, celebrating awareness, etc. come under the umbrella of communicating important messages which the society understands, respects and ideals in, through these health campaigns. For example, hospitals can come up with a special women's health package for breast-cancer awareness, or an ortho campaign for 'parents', targeting specific market segments.

Stressing on internal marketing

internal marketing is where you involve all your staff, from the ground level right up to the topmost hierarchical position.

You have a large workforce working with you day and night; these people represent what your brand stands for and that understanding must be clear. This is not only restricted to the human resources but involves marketing personnel as well. Why? Because healthcare is consumer centred. The patients here have a choice. This is where the marketer comes into the picture with the integration of these values through campaigns to align all employees to represent your brand value. When you have a campaign and all your staff (customer care associates, nursing staff, medical officers, consultants and everyone else) is (a) aware of it (b) understands the 'need' that is represented in your branding and promotional activities and most importantly (c) is aligned with the value the brand reflects and the message it promotes , then wait for the results.

Benefit strategy

Your customer is your patient in the out-patient department who has come for a doctor's consultation or a regular health check-up. They can also be an in-patient admission. Now, your customer will opt for your service only if they find the benefit to it. Marketing is not about your company's sales, but it is solely about how your customers think they are benefited.

Here, the strategy follows the age-old formula of value, benefit and cost. The formula states that 'value' is equal to 'benefit' upon 'cost'. This implies that the customers will pay for your service only if they perceive the 'value' to be greater than 1, that is when

they understand that the benefit, they are receiving is greater than the price they are paying for.

Website development

Healthcare is a growing industry where its consumers are up to date with all health-related information available online. Be it about an epidemic, a genetic disease or a new technological advancement in the field, for medical or surgical management, the awareness is the elephant in the room.

In a digitally advancing scenario, you need to establish your online presence as well. Your hospital's website ought to contain all information, from tie-ups to helpline numbers, online assistance 24*7, query redressal, feedbacks, testimonials, consultant's information, their availability, milestones achieved, every other information which your customer should be aware of and updated regularly.

Directing communications through various channels

Hospital's marketing strategies should focus on not only getting new customers, but also constantly retaining existing ones. The next stage to a loyal customer is a brand promoter. This will happen only if the customers get the service that they desire, more than what was expected. Analysing feedbacks and channelling other communications is important for brand loyalty. Your communications channels could be monologue (advertisements, promotions etc.) or dialogue channels (e-mails, call-centres etc).

Hospitals can work on channelising inputs and feedbacks from these sources, converting leads and thus working on the strengths as well as correcting flaws in the journey to increasing customer loyalty.

Monitoring brand equity

Even with huge footfalls, some marketing campaigns fail, because of their below average turnovers. This can be attributed to a gap left somewhere in the strategic planning. To be consistent it is required to regularly audit and maintain your brand equity. This will help you grow, building relationship with your customers, increase demand and help you target customer segments in emerging markets.

The ocean strategy

With new hospitals springing up with their upbeat promotions and huge investments, your hospital needs to retain the existing position. When we discuss new market entries, there is usually a red one, where your competitor is entering an already potentially stable market with cut-throat competition. To retain the stance here, your organisation can always explore the 'blue', i.e. entering headstrong into a complete uncharted and untapped potential market with strategies ready to sail in the ocean (the blue ocean strategy).

When the market plays with the primary colours, the strategies in marketing will help you press them to grow in your niche market segment.

AMR is a concrete threat...

Continued from Page 25

collaborate with India.

What opportunities do you see for this collaboration to expand? Which areas will it focus on ?

I think that there will soon be a focus shift on technology-Artificial Intelligence being on the forefront. Also, areas like ageing will gain attention. Right now, India is very young in terms of population, but after some years, elderly care will become a poignant point of focus in healthcare which will need different kinds of services than what is largely needed now. We are also looking forward to take this collaboration outside the big cities and focus on towns and villages. India is a large country, both geographically and population-wise, and with it comes its own set of challenges and opportunities. We can work on them together.

Data analytics is another area we can work on. Back in Sweden, we work with patient data in a very structured way and we have been able to tackle various medical emergencies in a better way using this data. For example, we recorded stroke cases across hospitals in Sweden, learnt which hospital and which procedure has proved more successful and strategise emergency-care accordingly. That has helped us reduce the mortality rate in stroke cases. Quality data can be used very efficiently and this system can be implemented in India as well.

How is India doing in terms of AMR surveillance? How can Sweden help India in this respect?

I am no expert on how exactly is India faring in terms of AMR, but I do know that India is devoting much attention to this issue – they have developed their own national plan against AMR. Also, Sweden- WHO's Centre for AMR Surveillance has collaborated with CDSCO in India along with Safdarjung Hospital, New Delhi and with AIIMS, Jodhpur. This collaboration aims to understand the reality of AMR in India, apply lessons that we learned in Sweden to combat this issue and make AMR surveillance in India as effective as possible. In Sweden, we have managed to get from high usage and prescription of antibiotic drugs to very low compared to international standards. We have also been able to spread awareness in our society on AMR not only in the healthcare sector but also in the veterinary sector since this problem is prevalent across all living species. It is important that all affected sectors work towards this. Sweden has acquired significant knowledge on the issue which can help India manage AMR surveillance satisfactorily.

What is 'Alliance of Champions'?

'Alliance of Champions' is a group of countries that, on the initiative of Sweden and United Kingdom, came into being in 2015 with the aim to control AMR, if not eradicate it completely.

A country may not necessarily be a part of the Alliance to benefit from its findings/activities. In fact, we would like to spread awareness on AMR as much as is possible. Any country that is committed to AMR surveillance has the Alliance' support. The same stands for India. We are currently in touch with the Indian government on the possibility of them joining the 'Alliance of Champions' as well. The member list includes China, Russia, the US, and we would like for India to join soon.

How can India benefit from joining the 'Alliance of Champions'?

The nature of collaboration of the 'Alliance of Champions' works on mutual commitment. It doesn't require for a member to donate money or sign any papers. It only requires a moral commitment to work against AMR and pull your country's attention to this issue. This group meets regularly and also attends the World Health Assembly in Geneva. We were also able to raise the issue AMR during the General Assembly in New York, to much benefit to the cause. If India joins, it will be joining an empowered group that is completely dedicated to the AMR issue. AMR is a concrete threat to our future health and we need to act now.

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INTERVIEW

Onco.com envisions to become a one-stop platform for all cancer related needs for patients and their caregivers

Rashie Jain, CEO and Co-Founder, Onco.com discusses the company's vision and expansion plans in an exclusive interview with **Sanjiv Das**

How is Onco.com's Online Cancer Patient Assistance Pathway helping cancer patients? What type of services are being offered by Onco.com?

Our platform is one of the first online service in the world to provide customised cancer treatment advice and helping patients with the right information they need to navigate their journey through cancer. Through this platform, any patient or caregiver can avail free preliminary treatment guidance by first providing basic information like the type of cancer, organ affected, stage of the disease, patient's general condition and treatment done to-date. We then provide them with diagnostic and treatment assistance, as per international protocols, based on a proprietary knowledge database created by our team of oncologists.

Onco.com has a network of more than 1500 oncologists from India and the US as well as 500+ treatment centres (speciality hospitals, infusion centres) and diagnostic labs from across India. We prioritise the needs of both early and advanced-stage cancer patients, by empowering them with an unbiased opinion from our panel of oncologists. While recently diagnosed patients can get help on suggested treatment routes, those who are undergoing therapy, or are on the verge of signing up for a procedure, can also evaluate their options with us. Today, we serve patients from 18 countries including India, Africa, the Middle East and South Asia.

Our platform offers two consultation services - a preliminary opinion that is free of cost, and a Tumour Board opinion, which provides a chargeable, detailed report by a multi-disciplinary panel of oncologists.

We also help connect patients with hospitals and diagnostic centres for relevant tests. Most dear to our hearts is our care management service where a care manager helps support a patient and the family throughout the diagnosis, treatment and post-cancer process.

Recently you have received an accolade from the American Society of Clinical Oncology (ASCO). What was the recognition for?

Online Cancer Patient Assistance Pathway (OCPAP™), built by our team was honoured at the American Society of Clinical Oncology (ASCO) Breakthrough: A Global Summit for Oncology Innovators conference, for its innovative and cutting-edge technology offering tailored treatment guidance for cancer patients. The ASCO Summit brought together the very latest in oncology practice, scientific discovery and technological advances to transform the future of cancer care.

What changes do you foresee in terms of funding for cancer care in India?

The cancer care sector in India is growing at 15 per cent annually owing to increase in incidence, new technologies coming in the market and growing insurance penetration.

Moreover, according to recent statistics, there are three million cancer patients in India, with 1.5 million new patients being diagnosed every year. This number is slated to touch two million by 2022. Although the burden of cancer in developing countries is less than their developed counterparts, the proportion of cancer-related deaths is 70 per cent in these countries. As per the Global Survey of Clinical Oncology Workforce 2018, for every 10,000 cancer patients, there are only one to five trained oncologists in developing countries like India, while there are 50 to 100 in developed countries. Likewise, the new patients-per-oncologist ratio ranges between 700 to 10,000 in developing countries compared to 70 to 200 in developed nations. These numbers, as well as our own analyses make us believe that funding will remain open and grow bigger in the healthcare segment, especially in cancer care.

> Our current focus is to build a convenient and navigable platform that provides quick access and essential information for a patient's needs

You have recently completed a $7 million series A funding by Accel, Chiratae Venture and Dream Incubator. How will you utilise these funds and how will it change your business progress?

Onco.com envisions to become a one-stop platform for all cancer related needs for patients and their caregivers. We want to expand our customer base and scale up our operations globally.

How many patients are you currently catering to in India and abroad?

Currently, over 30,000 patients from 18 countries including India, the US, and nations in Africa, Middle East and South Asia, actively use the platform. Onco.com will utilise the funds to further strengthen the team, scale operations and expand customer outreach in India and beyond.

What will be your business strategies and investment plans for the next five years?

In the next five years, we will expand our outreach to international patients not just in developing countries but also in the EU and the US where a service such as Onco Tumour Board can help provide comprehensive online guidance ahead of the treatment. We are growing in double digits every month and we continue to keep the same growth momentum so that more patients and their families can use Onco's services and get started on their treatment with confidence. We would also like to explore financing especially for patients from underprivileged backgrounds as cancer treatment is expensive and a lot of people drop out because of lack of funds.

How many doctors have registered with Onco.com so far?

Currently, Onco.com has a network of more than 1500 oncologists from India and the US.

What type of technological innovations would you foster to support cancer cure in future?

Our current focus is to build a convenient and navigable platform that provides quick access and essential information for a patient's needs. Our platform powered by predictive analytics and a smart medical database at the back end allows us to offer preliminary opinion to cancer patients today. In the future, we will keep on building this technology to offer more comprehensive and personalised guidance to cancer patients on their treatment options and diagnostic tests they can avail.

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INTERVIEW

Our hand model consists of bones, muscles and skin measured from a real person's hand

Our work gives an insight into how robotics could, in the future, create hands that function similarly to real biological hands, informs **Jernej Barbic**, Associate Professor, Computer Science, USC Viterbi School of Engineering in an exclusive interview with **Akanki Sharma**

> While many researchers have built hand anatomy models earlier, our work models the hand anatomy in motion. The geometric positions and shapes of our bones, muscles and skin are correct not just in one pose, but across multiple poses representing the hand's range of motion

How important is the role of prosthetics in the medical field? How has it evolved through these years in India and across the world?
Prosthetics make it possible to replace lost or damaged human limbs, and are thus significant in our society. Most robotic hands today do not attempt to directly mimic real human hand anatomy; instead, they create human hands as robotics devices with rigid parts actuated by servo motors at the joints. However, in real hands, there is a complex interplay between soft tissues (hand muscles, tendons) and bones. Due to this, the real human hand is much more versatile than the robotic hands of today. Our work gives insight into how robotics could, in the future, create hands that function similarly to real biological hands.

What led you to develop this model? What are its key functions and features? Also, elaborate on how it is the most realistic computational model of the human hand in motion.
I have been working in the research areas of computer graphics, simulation and animation for nearly 20 years. I always wanted to

model hands as they are an important part of the human body, and therefore, their simulation has many applications. Over the years, I developed many techniques for computational modelling of elastic objects and started applying them to the human body, both the hard tissues (bones) and soft tissues (muscles, fat). At some point, I realised that we can combine the techniques into high-quality models for animation and simulation of the human hand.

Our hand model consists of bones, muscles and skin that were measured from a real person's hand. What differentiates our model from other models is that we acquired our model in multiple hand poses, and not just in one pose. This made it possible to build a computer model for how precisely each bone of the human hand translates and rotates around its parent bone. Similarly, we can build a data-driven model for how the muscles and tendons in the human hand actuate as the hand is articulated. While many researchers have built hand anatomy models earlier, our work models the hand anatomy in motion. The geometric positions and shapes of our bones, muscles and skin are correct not just in one pose, but across multiple poses representing the hand's range of motion.

One future avenue for our work is to study how the bone and muscle kinematic models change across multiple subjects, by MRI-scanning a large number of subjects. This may make it possible to build generic computational models across an entire population

Little is understood about the complexity of the hand's underlying anatomy due to which animating human hands has long been considered one of the most challenging problems in computer graphics. How do you address this issue?

We acquired the internal hand anatomy in multiple poses using an MRI scanner. We performed a separate MRI scan in each pose and then extracted the internal hand anatomy (bones, muscles, fat) in each pose. From this data, we built a computational model for how the bones translate and rotate relative to each other, in three dimensions, inside the human hand. Given a brand new hand motion, we first used the model to translate and rotate all the bones. Thereafter, we ran soft-tissue finite element simulation to compute the motion of the fat and skin, which gave us the final realistic hand appearance. We can simulate any motion of our subject in this way, even if it is quite different from the captured poses. We repeated this procedure for two subjects: one male and one female. The biggest challenge that we addressed in our work was to keep the human hand still in a fixed pose in the MRI scanner. We resolved this by building a tight-fitting rubber mould, one per pose. Each mould is a perfect negative image of the hand in a specific pose. We manufactured it using techniques from the special effects industry in Hollywood. Prior to MRI scanning, the subject inserts his/her hand into this mould which keeps the hand still during scanning. This innovation made it possible to create high-resolution scans of the hand in multiple poses.

What capacity does it hold for medical education in India? Are you in touch with any of the medical colleges or do you plan to do so ?

We can create virtual reality three-dimensional animations of how the bones move inside a human hand as one is articulating it. Sensors track the real hand and detect its motion, including the motion of the fingers, in real-time. We can then display a real-time version of the hand in virtual reality and showcase the skin and the soft tissue (fat) transparently. Therefore, a person will be able to see his/her 'real' hand and its internal anatomy in motion similar to, say, undergoing a continuous X-ray of a hand; but without any radiation dangers. We are in touch with the medical school at our university (University of Southern California, in Los Angeles) about the medical education activities.

What benefits can it provide in the fields of robotics, virtual reality and graphic designing?

For virtual reality and computer graphics, it provides highly realistic hands that look like real hands not just in one pose, but across the entire range of motion of the hand. For robotics, it gives an insight into how real biological hands work as they are actuated, and as such make it easier for robotics to replicate this functionality in the future.

What was the cost incurred in creating it, and in what way will researchers take it to the next level?

The cost of creating our two hand models was approximately $10,000. One future avenue for our work is to study how the bone and muscle kinematic models change across multiple subjects, by MRI-scanning a large number of subjects. This may make it possible to build generic computational models across an entire population. Given a new subject, we may then be able to diagnose how different this specific subject is from the general population. We may also be able to identify any defects in the function of the subject's hand, perhaps simply from a video of the subject's hand in motion.

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INTERVIEW

Our niche infomercial campaigns like the one we have been doing with Naaptol have been proving very useful in reaching out to consumers and patients residing in tier III to tier VI cities

Omron Healthcare India, in its vision to increase market share within the preventive healthcare segment aims to boost its turn over to Rs 140 crore in FY 19. In an interaction with **Raelene Kambli**, **Rohit Saini**, General Manager – Sales and Marketing, Omron Healthcare India shares their strategy for growth and explains how the company stands by its global vision of zero strokes and zero asthma attacks

Omron has been in the preventive healthcare space since 2010. What has been the key takeaway from a business perspective? How do you the see the industry growing?
Preventive healthcare space was in a very nascent stage when Omron Healthcare started operations in India. The awareness around management of diseases like hypertension, asthma was very limited. Within the last decade, the awareness has gone up but the rise in the levels of mindfulness and importance about preventive healthcare in order to manage these kinds of ailments has not been really significant.

We have been trying to contribute and bridge the gap via our niche above and below the line communication and engagement initiatives. Side by side, we have been putting in efforts to enhance our reach through novel concepts like pick-up centres (for customer satisfaction) and experience centres (for product experience) which are one of its kind initiatives in the industry.

As per Invest India, the industry is set to grow substantially as the cases for lifestyle and respiratory diseases like hypertension, asthma and obesity are on the rise. As per varied government reports, the healthcare industry is set to

reach $372 billion by 2022 and is growing by a healthy CAGR of 22.9 per cent (2015-2020).

What was OMRON's turnover and growth rate in 2018-19? Also, what is the target for FY 2019-20?
Omron Healthcare India clocked in a turnover of Rs121 crore in FY 18 and is aiming for Rs140 crore in FY 19.

What is OMRON's current market share in the Indian healthcare sector?
In the preventive healthcare space, Omron has a market share of 58 per cent for BP monitors and 23 per cent for nebulisers. We are the market leaders in both categories.

Any expansion plans for 2020?
We are prepping up to strengthen our ongoing communication pipelines to focus on consumer awareness about preventive healthcare via a 360-degree approach and are optimistic that it will gain more steam by 2020. This will go hand in hand with our expansion endeavours to reach out to more consumers and increase our market share in both the primary categories - BP monitors and nebulisers. We stand by our global vision of zero strokes and zero asthma attacks through constant awareness building around the utility of home monitoring devices amongst the Indian consumers.

Tell us about Omron's presence in tier 1 and 2 cities?
Omron has a wide expanse across metros and tier 1 cities with direct distribution network of more than 100 channel partners. There is also a very substantial indirect coverage through our authorised dealer network. Our niche infomercial campaigns like the one we have been doing with Naaptol have been proving very useful in reaching out to consumers and patients residing in tier III to tier VI cities.

What has been Omron's channel strategy to tap market presence?
Our primary strategy relies on giving a strong focus to retail channel and synergise it with various sell-out and awareness-based activities to enhance category and product visibility. A targeted approach to tap digital consumers, enhancing e-commerce sales and exploring collaboration with the doctors through Omron Academy have been showing great results in fostering the need for home blood pressure measurement amongst the hypertensive patients.

Tell us about the number of channel partners currently and future plans for the channel network.
Our channel network as of now stands at more than 100 direct distribution points supported by a sturdy number of more than 150 authorised dealers. The channel expansion is a continuous endeavour and we shall continue to reach out to more and more consumers through our network.

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INTERVIEW

CareCover creates a unique low-cost insurance product

Nivesh Khandelwal, Founder and CEO, CareCover tells **Viveka Roychowdhury** on how his company identified and addressed the gaps in currently available health insurance plans

What are the gaps in the currently available health insurance plans?
The gaps in the currently available health insurance plans span across non coverage of pre-existing diseases and many medical treatments, a cap on room charges and type of room. Comprehensive health insurance is usually expensive and beyond the reach of the common man.

How do the requirements of Indian population differ from across the world when it comes to health insurance plans?
According to the World Health Organisation (WHO), India ranks 184 th out of 191 countries in terms of percent-of-GDP spending on health. A study shows that less than 5 per cent of India has private insurance. 65 per cent of the people who are insured are under-insured and hence 70 per cent of India's healthcare expenditure is paid for from savings.

The challenge in India is that due to a lack of data, health insurance requirements of the Indian population have not been assessed accurately by anyone. Health insurance companies in India work with very high-level data and hence create general plans without taking into consideration specific requirements.

What are the circumstances that make people put off taking health insurance and how has CareCover has addressed them?
The key reasons why people delay/don't buy health insurance are the lack of affordability of high premiums and complex nature of health insurance policies. Non-payment of dues is the third reason as most people are scared of the insurance companies in India since they think that the claim upon the untimely demise or a sudden medical expense may not be paid for in times of a financial need.

Fourthly, there is also ignorance or lack of knowledge. People in India tend to pay huge medical bills from their own pockets or suffer when the person they were dependent on passes away simply because they were oblivious to the benefits and safeguards a life or health insurance policy promises to a person or group of persons.

The fifth reason is the myth that health insurance is costly with high premiums. People are still reluctant to buy insurance in India since they tend to go by word-of-mouth analysis of people who give wrong information about policies and quote blatant prices which are not even correct.

Many salaried people tend to rely on their employee benefits and think that they can claim expenses from their employers in terms of an accident or any other mishap. They do not feel the need for health insurance and have a chalta hai attitude till a crisis strikes.

Many people do not realise the importance of insurance until they need it. People take life insurance in their mid-30s or mid-40s and health insurance only if they feel that they might end up in the hospital for some unforeseeable circumstance. They do not see the value.

CareCover addresses the first two problems by creating a unique low-cost insurance product with easy to understand policy parameters.

> We are currently partners with more than 1500 single, multi and super-speciality hospitals across 10 cities

When was CareCover operational? You are also CEO and Founder of LetsMD, tell us how the two companies serve patients?
CareCover was started in September 2019. CareCover is a pre-approved medical payment plan which allows a consumer to pay their medical bills in 0 per cent EMIs at any of our partner hospitals. The card can be used to finance any treatment that is not covered under health insurance. The enrolled members having valid activated cards can simply call at our toll-free helpline number for basic details like name of the seeking treatment, hospital name, estimated amount required for treatment along with a letter from the hospital verifying the patient name and bill estimation.

LetsMD is a health care market place and a health finance facilitating company, which endeavours to reduce woes of patients who are either taking or intending to take hospital care and treatment and run short of cash. The services of LetsMD are changing the healthcare landscape and ecosystem in India.

CareCover claims to have cut short the time to get cover as well as the documentation. What are the company's safeguards against fraudulent claims etc?
The CareCover card is only valid at partner hospitals which are very carefully curated based on a proprietary merchant score we have created using feedback from more than 35000 patients we have helped over the last three years. Secondly, we have a proprietary algorithm that assesses the credit and hospitalisation risk of each borrower to ensure minimal fraud.

How large and spread out is CareCover's network of hospitals and what is the target to increase the number of hospitals under the scheme?

We are currently partners with more than 1500 single, multi and super-speciality hospitals across 10 cities. The goal is to partner with 5000 healthcare service providers in the top 20 cities in India.The target to achieve the above mentioned goal is within next 12 months which stands for Nov 2020.

Which companies, services are competitors to CareCover and what is its USP?
CareCover is a first in class product and we do not have any direct competitors.

Our USP is that we combine EMIs and insurance to create a very unique low-cost cover for the consumers which is priced 50 per cent-70 per cent cheaper than traditional health insurance

Our USPs are that we cover all surgeries, offer 0 per cent interest EMIs till 18 months, cover all the pre existing illnesses. We also promote Goal-Based investments. Extra interest is paid to the savings account holder at Let's MD. Our card would cost them 1/3rd the cost of medical insurance. Its hassle-free because there is minimal documentation, fast turnaround time once documents received and there is no need to visit the branch. Origination is entirely digital.

What are the different packages available? Which has seen the most traction?
We finance all surgeries. We do not have packages with hospitals.

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INTERVIEW

We aim to work with 9000-10,000 hospitals by end of 2020

HealthNine, an IT firm, interconnects healthcare stakeholders to enable real-time exchange of data and transactions. **Ritesh Kajaria**, CEO, HealthNine Technologies explains how its system works as a centralised health information exchange for all healthcare entities, the need for such a solution in the Indian market, their growth plans and more, in an interview with **Lakshmipriya Nair**

How is private healthcare financing in India transforming? What are its key drivers?
Private healthcare financing in India is quite restricted, albeit there have been several Indian and foreign players who have entered the market to provide such financing. The reality today is that most individuals make direct payments at the point of services, which are usually not covered under any financial protection scheme. The highest percentage of out-of-pocket health expenditure is made towards medicines (52 per cent) which is usually not covered under any private healthcare financing scheme. Even if 30 per cent of the total health expenditure is incurred by the public sector, the rest of the 70 per cent is usually borne directly by customers, where private insurance playing a smaller role only via hospitalisations.

Appropriate healthcare financing is a means to ensure adequate funds for health care with provision for equitable access to all population. This also reduces financial barriers among citizens to utilise health services. This segment is likely to be driven in the future through two factors: First, new private insurance products will expand business through deepening their offerings compared to widening the risk covered. Second, the concentration for private players will remain on urban middle and upper middle classes who have the capability to pay with an interest towards good health for themselves and their families. This is likely to scale up the insurance segment further, with growth in hospital usage and protection against growing hospitalisation expenses.

What are the major challenges in the sector? Are the processes in place? If not, how can they be better enforced?
The current healthcare industry is associated with an opaqueness when it comes to the workings behind the scene. There is also a perceived lack of connect between hospitals and patients. The aim of all parties has always been to be patient-first and patient centric, however usually the processes in place usually slow the entire system down, which then percolates down to patients and their bills and claims settlements.

A PwC report points out that there is a strong need for increasing transparency and improving the connect between hospitals and patients, thus dispelling the negative perception of the industry. With the aim of balancing the need for being patient-centric and being efficient in the way hospitals and insurance companies communicate, there is a need for a gap solution provider that effectively takes care of all information seamlessly.

What benefits do you bring to the current paradigm? How will it impact the sector and the patients?
Healthnine Technologies is a health-tech startup that is

working towards building a seamless and real-time transmission of information between hospitals and insurance companies. Currently 15 per cent of all claims are fraudulent claims which means that a large part of the insurance industry is invested towards recovery and fraud management. With our AI and ML enabled network, our intention is to work as a linchpin between hospitals and insurance organisations that spots frauds and minimises errors related to manual data entry. Healthnine's network automate claims settlements and build an information exchange with comprehensive information on all parties that reduces the manual communication and labour currently required during claims settlement. This will be a respite for the 25 per cent claims that usually take more than a month to be settled. This means that Healthnine will practically automate the entire claims settlement market in India, with patients, hospitals and insurance firms having to finish up the task in a fraction of time compared to what it currently requires.

How many hospitals have you partnered with currently? Which are the geographical locations that you are focussed on? Why?
We are currently running several pilots with insurance companies for them to understand how seamlessly the Healthnine technology embeds itself into the existing system, without having to overhaul the current processes. We are also working with 1,500 hospitals in our network, with an aim to work with 9000-10,000 hospitals by end of 2020. Our current focal areas are cities like Mumbai, Bangalore, Pune and Delhi where we will initiate services in a phased manner.

How do you plan to roll out your services? What is your growth strategy for the next three years?
Since the essence of Healthnine Technologies lie in easing lives of patients, we intend to percolate down to tier-II, tier-III and other regions of the country to ensure more and more patients, hospitals and insurance companies can benefit from the reduction of manual effort and automation of claims settlement. Our long term goal is to also expand our network to other health players like imaging labs, pharmacies, etc. to electronically exchange claim information within a community and across the country in real-time. This reduces the burden on patients to lug around their files and information without the risk of misplacing it or not having all information at one place.

What is your competitive advantage?
Thanks to the array of software suites that we use, the Healthnine offering transforms the current manual process into a completely seamless workflow for patients and members if they use the Healthnine portal or mobile app. We understand the significance of privacy and safety of data, which is why our network has additional levels of security like, end-to-end encryption and compliance with HIPAA to ensure data privacy. The technology behind the platform allows a single window login for all insurance and TPA access.

We have seamlessly integrated the entire workflow, from insurance intimation to final billing settlement, along with being a comprehensive repository of medical data and data analytics for patients that is completely secure and private. With Healthnine coming on-board as a partner for insurance companies and hospitals, this claims settlement process will become simpler, with the requirement of lesser resources to do the same job that was done manually earlier. With our system, the risk of fraud and errors also drop down to the negligible.

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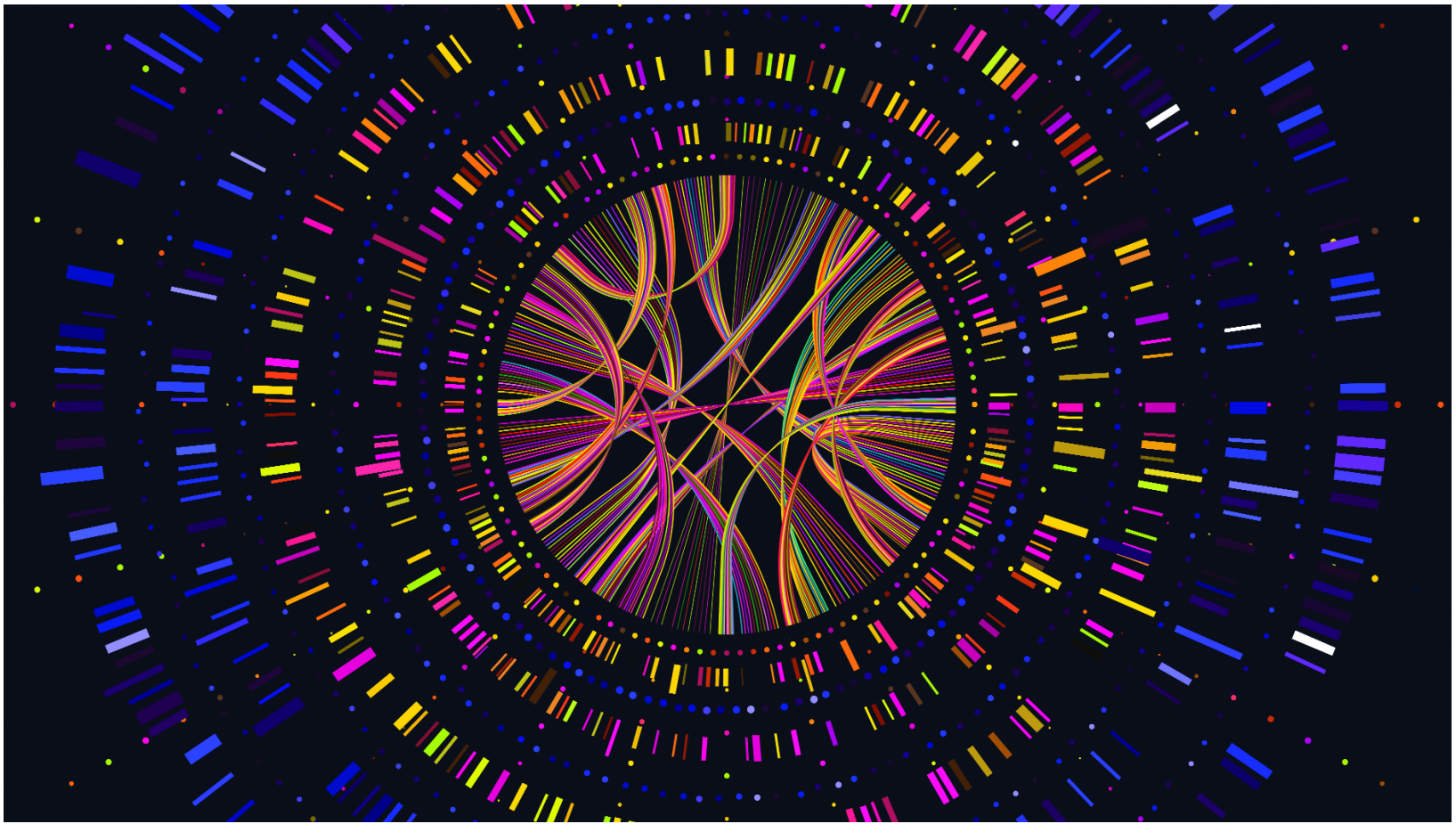
Big data and predictive analytics: Disrupting Indian healthcare space

Nirmalya Gupta, MD and **Dhrubabrata Ghosh**, Director, Protiviti Member Firm for India highlight how adoption of these disruptive technologies in healthcare will help in critical decision making as well as improve patient management and treatment outcomes



THE DATA management landscape in therapeutic research within the healthcare delivery in India is set to undergo radical changes in the near future. Whilst it is still at a nascent stage, some developments have already been initiated and the pace is set for acceleration very soon. Major hospitals, healthcare providers, pharma giants and R&D centres are utilising big data and predictive analytics in their critical decision making. Clinical developments, real-time alerting, telemedicine, 3D printing and use of real time data in clinical trials are some of the changes that are happening within the industry. Many healthcare providers are using electronic health records to develop databases for interoperability and future use. A premier healthcare provider in India has already embarked upon the journey of utilising artificial intelligence (AI) capabilities in patient - management, clinical prescriptions suggestions and patient health predictions. Another major provider is currently in partnership with Microsoft to create an AI-focussed network for cardio related diseases. With the development of these AI tools and real world data, the provider will be able to gauge risk of heart diseases in patients at an early stage in hope of preventing or reversing these life-threatening conditions. Some of the healthcare providers have started using IBM Watson Health for disease identification and drug prescription.

The use of data and other disruptive technologies are still at a relatively nascent stage in the Indian healthcare industry as mentioned above. However, active participation of the major players and cohesive partnerships with the global IT leaders definitely hold great prospects for the future of the healthcare industry. At the current pace of development, substantial increase in the investments and support from government,we are very hopeful that use of data and technology in therapeutic research within the industry will hugely evolve over the next three to five years.

Data analytics to show maximum growth in following key areas:

- **Clinical development:** R&D centres and pharma clients are analysing Big Data for new drug or investigational products testing to reduce the cost of trials and running simulations. Use of data driven predictive models and statistical tools is improving the clinical trial success.
- **Prevention of drug abuse:** Developed countries are using Big Data to tackle the problem of overdose or misuse of opioids. Data scientists are working with health insurance service providers to develop predictive models where individuals are analysed on the risks that they are carrying based on a universe of critical healthcare-related risk factors.
- **Improved staffing:** Hospitals are hiring data scientists to crunch admission and time data using 'time series analysis' techniques and building predictive models for charge ability and admission for nurses, doctors and paediatrics.
- **Drug management:** Healthcare providers, along with the government, are connecting their inventories with the prescribed drugs at a real time basis to monitor drug usage and

shortfall. This helps them in effectively managing the stock across multiple locations.

◗ **Real-time alerting**: Healthcare providers are utilising the capabilities of clinical decision support software and AI focussed networks to analyse patient health records and real-time medical data to provide insights to the practitioners to take critical decisions.

◗ **Prospective cure of cancer:** Medical researchers are using the data on patient treatment plans, recovery rates and symptoms of cancer patients to predict treatments that have the highest rate of success in real life scenario. This is still in a developing stage. However, the Cancer Moonshot Programme in the US is a definite indicator of what the future that lies ahead of us.

◗ **Telemedicine:** This term has been present in the market for over 40 years. However, with the current technology and IoT, it has been able to come into full bloom. The primary consultations, initial diagnosis, remote patient monitoring and real-time consultations are the current benefits of Telemedicine technology.

◗ **Lifestyle analytics**: The proposed system will provide healthcare solutions, based on various models to analyse the lifestyle of individuals and provide useful insights to prevent medical accidents and emergencies and increase the accuracy towards patient treatment.

◗ **Outbreak analytics**: In case of outbreaks such as dengue, H1N1, Zika and other diseases, it becomes imperative to identify the origin of the disease for the effective management of the same. Analysing huge amount of client and demographic data and connecting multiple data points to perform link analysis holds the key.

In the past few years, life sciences companies have made massive investments in commercial analytics.

In 2020, brand leaders will continue to invest in infrastructure to achieve truly prescriptive analytics. For many teams, rapid experimentation is the critical capability needed to translate insights into action.

Promising areas

◗ Extensive use of AI in life sciences and healthcare industry

◗ Neuro-linguistic programming tools and capabilities for effective patient management and medical value creation

◗ Block chain capabilities with wearable technologies and telemedicine for secured data pooling and analytics

◗ Genomic analytics for more cost-effective and efficient gene sequencing

◗ 3D printing for prosthetics and tissue engineering

Bottlenecks

There are a number of challenges in AI or similar technologies across the industry. Companies are struggling with issues pertaining to data quality, availability, storage, access, integration, privacy, security, retention, and management, complexity of the AI and block chain tools and limited talents in these areas. Specific challenges could be further articulated as below:

◗ **Electronic Health Records (EHR)**: High costs, functionality and security are the major concerns while implementing the EHR based system.

◗ **Real-time alerting:** Lack of infrastructure and regulatory compliances across the countries are the roadblocks faced for implementing Real-Time Alert System.

◗ **Telemedicine:** High-costs and acceptance from society are the major hurdles in implementation of telemedicine.

The global scenario

The healthcare sector is booming at a faster rate globally. According to an International Data Corporation (IDC) report sponsored by Seagate Technology, it is found that Big Data is projected to grow faster in healthcare over other sectors like manufacturing, financial services or media. It is estimated that the healthcare data will experience a compound annual growth rate (CAGR) of 36 per cent through to 2025. Effective use of Big Data could add $300 million per year to the healthcare industry.

Microsoft has also taken an initiative to accelerate healthcare innovation through artificial intelligence and cloud computing. Microsoft is working with the market pioneers to develop innovative tools for healthcare, biotech and life science. They have further announced a number of solutions, projects and AI accelerators that contributes towards intelligent healthcare such as Microsoft genomics, Microsoft azure security, and AI networks, Microsoft 365 huddle solution templates, Project Empower MD and Project Inner Eye. Many healthcare providers, medical research societies, Biotech companies and pharmaceutical organisations are working side by side with Microsoft to take the full advantage of Big Data and these emerging technologies.

Apple also sees healthcare and wellness as core part of its wearable ecosystem and is partnering up with many healthcare providers, pharma companies and insurance organisations to provide better health solutions to the general public.

IBM Watson Health is providing solutions in the areas of cardiology, oncology, medical research and pharmacy etc. With a base of over 13,000 partners and clients, IBM Watson is creating meaningful change in health.

Healthcare is witnessing a new wave of transformation globally. Increasing competition, investment and disruptive technologies will further evolve the general public healthcare and medical research. Healthcare data analytics will help the market contributors and government to make better informed decisions ultimately benefiting the society.

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INTERVIEW

We are looking to make India a hub for the Cios Fit

With a view to leverage digital technologies and manufacture equipment and devices that suit Indian needs, Siemens Healthineers has recently set up a manufacturing unit collocated with its Bangalore R&D centre. **Gerd Hoefner**, Managing Director and President, Siemens Healthcare shares the company's vision behind this move with **Usha Sharma**

What are the various medical equipment business segments that Siemens Healthineers operates in India and what is the market share?
We operate in three segments— imaging, advanced therapies and diagnostics, and are market leaders in each of them. In diagnostic imaging, our portfolio spans across computed tomography, magnetic resonance, molecular imaging, X-ray products, ultrasound, and imaging IT. In advanced therapies our portfolio consists of angiography systems, mobile C-arms, hybrid operating rooms, and imaging for radiation oncology. In the diagnostics, we offer solutions for clinical chemistry, immunoassay, hemostasis, hematology, blood gas, urinalysis, molecular virology, liquid biopsy, automation, and IT.

What opportunities do you see in the coming years and how are you going to capitalise them?
We see a large opportunity for digitalisation of healthcare. We also believe that healthcare will become more precise, enabling the right treatment at the right time for every patient. Improving patient experience will be important. We believe patients are becoming informed consumers. Once accurately diagnosed, what matters to patients is preferred treatment outcomes that will ultimately lead to a higher quality of life.

Recently, the company inaugurated its manufacturing facility in India, what will this unit focus on?
The Bangalore factory will produce mobile Cios Fit, a unique C-arm radiology system designed for India and emerging markets and it will also manufacture the computed tomography systems from the Somatom go. Platform.

Give us details on the investment done in establishing this manufacturing unit, size and capacity of the unit?
We have invested Rs 20 crore in the new manufacturing facility. This unit already has around 70 employees, and the workforce will be extended in three phases by the fiscal year 2025. Operations have already started in this new ISO13485 (2016) certified state-of-the-art facility, which is spread across 5,000 square meters and can fulfill the strong demand from India and emerging markets.

What is the objective behind setting up manufacturing facility close to your research and development center?
As Siemens Healthineers is harnessing the power of digitalisation in healthcare, the collocation of the manufacturing with our R&D centre will helps us in leveraging synergies and enable us to deliver value to customers faster. Over the years, the R&D centre at Bengaluru has grown into a digital hub for the company accounting for over half of all the software engineering talent within Siemens Healthineers. The centre generates solutions spanning all our business segments.

Give us a brief update on Cios Fit, a mobile C-arm and its relevance in the Indian healthcare market. Are these products available in the global healthcare market too?
Cios Fit, is a multidisciplinary mobile C-arm created to address the tough demands of India. It will address high patient loads and the need to perform multiple procedures. It offers best in class image quality clear images on a touchscreen monitor; it is simple to use and has fewer moving parts for higher reliability. Cios Fit's powerful imaging technology produces crystal clear images of anatomical structures, implants, screws, and devices, which will enable surgeons in India to maintain consistency for accurate treatment and improved patient experience. We are looking to make India a hub for the Cios Fit. After we meet the local demand, we could look at exporting the imaging devices from the India facility to countries like Africa and China.

The company is also focusing on creating 'Avatar' a technology based on augmented reality (AR), how will this improve imaging mechanisms?
The whole gamut of mixed reality solutions that include augmented and virtual reality has a great potential to add value to health care providers in multiple scenarios such as training the hospital staff, aiding surgeons in real time, and guiding customer support engineers.

Give us the brief update about the company's PPP model and how are you expanding it further?
Siemens Healthineers believes in India's growth story and will invest wherever we see a positive business case.

u.sharma@expressindia.com

CASE STUDY – Dr Nanjappa K. M. from Cauvery Uroderm Centre, Kalyan shares his experience using Cios Fit, a mobile C-arm. Particularly for the Indian market, you say that Siemens Healthineers has a robust research and development plans in the artificial intelligence, cyber security, and digital technology area, please elaborate on the same. Siemens Healthineers is a pioneer in AI development for over 20 years, and we have over 500 patent families related to machine learning. We also have over 45 AI-based offerings. We conduct around 500 AI experiments per day on Sherlock - our 20 PetaFlop supercomputer using our unique data lake of curated images, reports, and clinical data.

Impact of GST under NPPA orders

Surbhi Premi, Joint Director, Lakshmikumaran & Sridharan advises the healthcare sector to carefully analyse NPPA orders to fix their margins and opines that hospitals should strategise their operations to ensure that the input GST does not hit their pricing

Though healthcare services have been exempted from GST, hospitals witnessing the impact of GST under the price notifications ('orders') issued by the National Pharmaceutical Pricing Authority ('NPPA'), the drug price regulator in India to fix pricing of drugs/formulations and implants under the provisions of the Drugs (Prices Control) Order ('DPCO').

There are variety of orders issued by the NPPA. Some of them fix the retail price of drugs/formulations and implants. There are orders prescribing the ceiling price. There are even orders that prescribe limit on trade margin along with the ceiling price. The terms retail price, ceiling price and trade margin involve their own nuances. Most of the orders provide that no additional charge, whatsoever, over and above the specified limit shall be charged from the consumer/patient except applicable GST, if any, paid or payable. Therefore, from the prima facie reading of the orders, one may form a view that the GST is payable extra and hence, it should not impact the pricing and the margins of the hospitals.

These orders should be carefully analysed to understand whether these orders are applicable only on the trading transaction or service transactions also. Further, whether the supplier can collect GST on the supply of medicines and implants over and above the MRP etc. under these orders.

First, let us have a look at the practices followed by the hospitals for OPD and IPD patients to understand the impact of GST on their operations.

In case of OPD patients, drugs are supplied separately for a charge along with applicable GST whereas the healthcare services are treated as GST exempt services.

In case of IPD patients, during medical treatment, the patients are administered different drugs, consumables, implants, etc. as per medical requirement along with other medical procedure like investigation under pathology and radiology etc. The IPD patients get admitted to the hospital with an objective to get ailment treated and in the course of such treatment, doctors may prescribe certain medicines/ drugs to the patients. What the consumer seeks, therefore, is the treatment of his ailment by the expert doctors and paramedics, which involves administration of medicines, drugs etc., as advised by the doctors as part and parcel of such treatment. However, it has always been a bone of contention between the tax department and the assessee whether the medicines, drugs, stents, valves, implants and other consumables provided to patients during medical treatment is composite supply of healthcare service or supply of goods. Similar issues have arisen in foreign jurisprudence also.

In the case of Nuffield Health, [2013] UKFTT 291, it was held by the foreign court that it is not the patient who determines the nature or quantity of the drugs he is provided with, even if this is separately itemised on an invoice. In the absence of any significant element of choice in relation to the volume or nature of drugs provided, the economic reality is that that provision is not dissociable from all the other elements that Nuffield provides as part of a single supply of medical and hospital care. Similarly, in the case of the prostheses any element of patient choice is subject to the overall clinical judgment as to the identification of the patient's needs and the appropriate appliance. The court further stated that if the provision of drugs or prostheses were separate supplies of goods, it would follow that the provision of other goods used, such as needles, drips, tubes etc. as itemised on an invoice should also be treated as separate supplies which would be wholly artificial split of leading to a potential distortion of the functioning of the VAT system. In the case of General Healthcare, [2016] UKUT 315 (TCC), UK Upper Tax Tribunal also held that supply of drugs and prostheses during the course of treatment shall qualify to be supply of health care services.

The Punjab and Haryana High Court in the case of Fortis Healthcare (2015 VIL 73 P&H) examined the exigibility of medicines, drugs, stents, valves, implants and other consumables and incidentals provided to patients during a medical procedure/treatment to value added tax as 'sale of goods'. On the question whether a package for treatment (such as knee replacement surgery) would be given different treatment for the reason that it involves placing of stents, implants etc., the court observed that the fact that a hospital may charge money for individual stents etc., whether as part of a package or separately is entirely irrelevant. A contract of medical service cannot be said to be a contract for sale of a stent, or valve or of medicines to be used in a medical/surgical procedure, which could be brought within

the purview of value added tax. The essential element of such a contract is the procedure of knee replacement, hip replacement, angioplasty, which as an intrinsic and integral part involves placing an implant whether in the knee, hip or a heart etc. The only choice available to the patient is the nature of the implant, namely, its quality but such a procedure is admittedly, a medical procedure and a service that cannot be completed without an implant/drugs and medicines as an integral part of the procedure. Hence, it was held by the court that the contracts of medical service could not be said to be contracts for sale of medicines/drugs, stents, implants etc. as the dominant intention in these contracts is to avail the medical treatment services.

Recently, similar view has been taken by the Kerala AAR in the case of Starcare Hospital Kozhikode (2019-VIL-134-AAR) wherein it was held that supply of medicines, consumables, surgical items etc. for providing healthcare services to in-patients for diagnosis or treatment, constitute a 'Composite Supply' of healthcare services and hence, exempt from GST. The same is in line with earlier AARs in the matter of KIMS Healthcare Management (2018-VIL-246-AAR) and Erankulam Medical Centre (2018-VIL-179-AAR).

Therefore, in case of IPD patients, since no GST is paid/payable on the composite supply of healthcare services, a question may arise as to whether the input GST on their procurements shall form part of their cost and therefore, the part of overall ceiling price/retail price? Whether the GST needs to be recouped from the prescribed trade margins?

In furtherance of above, for instance, in case a drug costs Rs 20,000+GST, the ceiling price is Rs 22,000 and the rate of GST is 12 per cent or more, the amount recovered by the hospital would be even lower than its procurement cost as shown in the table below.

With a view to avoid hit of GST on the trade margins, are hospitals entitled to treat the service portion of their supply as supply of healthcare services and the supply of drugs/formulations and implants as separate supply of goods to pay and collect GST above the ceiling price, as per the above orders? Hospitals should carefully analyse these orders to fix their margins. Further, the hospitals may need to strategise their operations so that the input GST does not hit their pricing.

NPPA Order	Standard	Separate supply of implants	Supply of implants as composite supply of Healthcare services
1	2	3	4
Cost	Actual	20,000+2,400 (GST@12% creditable)	20,000+2,400 (GST@12% non-creditable)
Margin	8%	1,600	1,792
GST	As applicable (over and above ceiling price)	12%	Nil (composite supply of Healthcare- exempt)
Ceiling Price	22,000		
Price to patient		21,600+2,592 (GST@12%) 24,192	24,192 (GST nil) 22,000
Margin of Hospital		1,600	-400

INTERVIEW

'All our products are fairly priced and competitive to market rates and in no way, compromise on quality'

Mayank Lakhani, MD, La-med Healthcare in an exclusive interaction disscusses with **Express Healthcare** the future of the medical device industry in India and how National Medical Device Policy will help domestic players

Low cost is always linked to low quality. As a medical device manufacturer, how do you counter this perception? How affordable are your medical devices?
We can co-relate your question with our motive which is 'quality is never an accident'. It is always the result of the best intention, a sincere effort, intelligent direction and skilful execution. Low price doesn't always mean low quality, but it could entail a challenge to the other existing high-end products. All our products are fairly priced and competitive to market rates and in no way, compromise on quality. On the contrary, we pride ourselves on the high-standards we follow internally to ensure each product is top-notch. Our products sold through tenders are even further discounted to meet social regulations. There are sufficient players in the market so prices cannot be fixed arbitrarily.

How do you see India's drug-pricing regulator, National Pharmaceutical Pricing Authority's (NPPA) move on price control on a few medical devices? With increasing price constraints, will regulatory requirements viz accreditation be an additional burden on local manufacturers?
We think this move is great. Not only does this ensure a level playing field for all medical-device manufacturers, customers also benefit from a cap in prices as they don't end up spending so much on their medical expenses. As a manufacturer, we will happily comply with all regulatory requirements of the government as long as they are reasonable and for the good of all parties involved.

Do you think the National Medical Device Policy will help domestic players? Reasons?
Yes. Absolutely. The National Medical Device Policy will help domestic players accomplish timely development of medical devices in India, make quality Indian products at par with their international counterparts and also put in place a system of checks and balances that will prevent third-rate medical products from hitting the market.

How do you see the future of the medical devices sector panning out in the country in the next five years?
India's medical-devices industry is set for significant growth in the next five years. It is currently valued at approximately $6 billion and has expanded at a significant growth rate over the past few years. Having said that, the industry is still at a nascent stage with sub optimal penetration and usage of medical devices. India comprises only 1.7 per cent of the world market as our industry is still import dependent. There are 750–800 domestic medical devices producers in India with an average speculation of $2.3–2.7 mn and a turnover of $6.2–6.9 mn. Around 65 per cent of the makers are mostly domestic players operating in the consumables segment and catering to local consumption with limited exports. The medical device market size is expected to reach $50 bn by 2025. The orthopaedic prosthetics and patient aids segments will be the two fastest-growing verticals by 2020, projected to grow at a CAGR of 9.6 per cent and 8.8 per cent, respectively. (Source: skpg.com)

You have been in the medical devices market since 2007. What are some innovative products you offer and how do you stand out in such a competitive, crowded medical devices market?
Our company has a strong innovation-led team which focusses on both bettering our existing products as well as introducing new products as per the market feedback. In the critical care division, we have innovative products like CVC kit with NF1, three-way stop cock with NF1 and NF2. Also, our product link CT with check valve is among the most important products used for the MRI scan of patients. Six sigma process controls and TQM measures have been built into our processes rather than being externally implemented. The company's products are CE marked with DNV Norway and are registered in more than 55 countries across the world. We've gained the status of a trusted quality manufacturer of medical devices across major government hospitals and institutions pan India and across the world.

Tell us about your company's latest product offerings which will help you retain your leadership position in the domestic as well as the international market?
The company believes in providing premium quality medical devices to its customers which in turn, helps us retain our leadership position in the domestic as well as international market. In the last few years, we've offered some great innovations to our targeted market such as needle-free connectors, Ventilator Circuit with Combo Kit, PTCA Kit, Anti UV Extension Line, etc. Moreover, the company has plans to introduce many innovative products with the underlining principle of safety and simplicity to facilitate better patient care through innovation in line with our philosophy of conscious care.

Practical Applications of AI in Radiology

Vijayananda J, Fellow Architect, Philips Research, Philips Innovation Campus, Bengaluru and **Suyog Gaidhani**, Senior Manager, HealthSuite Digital Platform, Philips Innovation Campus, Bengaluru elucidate on automation through AI which will make radiologists job easier providing more time for critical cases or complex ones which require deeper attention

Healthcare systems are under constant pressure to deliver high quality and efficient care to growing populations, but at the same time the financial and human resources to deliver that care are increasingly being stretched. Broadly, hospitals today are confronted with the following challenges:

- How to provide the best quality of diagnosis and treatment to patients
- How to guarantee patient satisfaction at the lowest possible cost
- How to implement the most efficient operational workflow
- How to ensure the hospital staff is engaged to deliver their best

Against the background of these challenges, healthcare is undergoing a rapid digitisation and the radiology department is at the forefront of it. Over the past decade, there has been an exponential growth of computational power, while the cost of data storage has dropped dramatically. As a result, the amount and granularity of stored digital imaging and the associated clinical data has increased tremendously. However, only a fraction of this data is being used to improve the quality and efficiency of care since the growth rate and diversity of the data has far outpaced our ability to analyse it.

The opportunities for AI in radiology lies in its potential to help translate these large amounts of data into actionable insights. These insights can empower radiologists, hospital administrators and patients to achieve better health outcomes at lower cost. AI can improve the operational performance and efficiency of radiology workflows while delivering high quality and integrated clinical decision-making.

Let's take AI from the perspective of a radiologist. Due to heavy workloads, radiologists today need to interpret images quickly, potentially reducing the diagnostic accuracy. It is apparent that when radiologists are rushed to report on their assigned cases, their error rate rises. Automation through AI can help in making the radiologists job easier allowing more time to be spent on the most critical cases or complex ones that need deeper attention.

Traditionally, radiologists have been used to base their entire findings on the imaging associated with the assigned case. However, given the increasing complexity of diseases, availability of more patient data can certainly lead to better diagnosis. For example, if the radiologist is looking at the CT of a patient with a complaint of abdominal pain and if the fact that the patient is also HIV-positive is presented to the radiologist, it can trigger a check of the lungs, as well. AI can help in pinpointing locations of clinical interest and fetching all relevant contextual information from various sources like laboratory, pathology and EMRs for a more comprehensive diagnosis.

On the operational workflow front, hospitals and imaging centres today are plagued by lack of predictability in scheduling patients due to patients not turning up, emergency cases being prioritised, procedures taking more time than expected due to motion artefacts etc. This can lead to increased waiting time for the patients and cause further anxiety and discomfort. AI algorithms can ease this pain considerably by predicting with a high accuracy the waiting time for a scheduled patient based on historical data and patient behavioural patterns. With this information, patients can be informed upfront about delays helping in lessening their time in the hospital. At the same time, healthcare providers can better utilise their equipment and improve staff satisfaction levels.

Radiology technicians spend considerable time in configuring the scan parameters based on the patient demographics and the type of the scan. For e.g. If a 'fat' patient is scheduled for an MRI scan, then the Field of View has to be adjusted to take care that the scan covers entire region of interest. The scan sequence (for e.g. Survey, T1, T2, FLAIR etc.) has to be planned for specific anatomies. AI can help make this entire process efficient by predicting what scan parameters are likely to be modified along with the potential new values and automatically configuring the values of these scan parameters, given the demographics of the patient and type of scan.

In summary, AI will surely transform radiology in the years to come and while much focus is being placed on the development of breakthrough AI models, it is just as important to focus on their integration into the radiology workflow. This would range from ensuring a seamless blend the results from AI with the human decision-making process to implementing an effective feedback loop for continuous improvement of the overall solution. Another aspect to be considered is the explain-ability of the AI model that can help a radiologist to determine on what basis it has arrived at its prediction. Without paying attention to these challenges in radiology integration, adoption of AI may suffer from inhibitors and create cognitive biases that could limit its adoption and success. Conversely, a precise approach around workflow integration that addresses these challenges could facilitate and accelerate the adoption of AI in radiology.

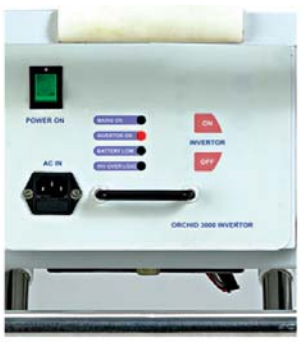
nice Neotech range of products to protect neonatals

COMMAND and CONTROL

The microprocessor controller features a display that is easy to read at any angle during transport. Servo control skin and air modes helps maintain the temperature. Visual indication for battery power status, power sources and system alarm status are designed to keep the care given in command.

FLEXIBLE POWER SOURCE

Inverter is an air (or) ground transport, power is the last



thing you should worry about. The orchid 3000 from nice neotech operates on AC or DC power using AC when available (or) switching to its internal battery when necessary for extended length transports. The system can be configured with a second linear battery.

ACCESS MADE EASY

Access to the infant is quick and easy through the front access door and the head door (or) side access doors. The head door folds down and the mattress retracts out from the hood to provide access for emergency procedures.

FRONT DOOR

Total view and access with frontal access panel and three entry ports.

INTEGRAL HUMIDIFIER

Humidity is extremely important especially for babies less than 26 weeks in gestational age. An integral humidity pad helps minimise the infants evaporative heat loss by providing 50-70 per cent humidity in the patient hood for up to hours.

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- Auxiliary tray, shelf for other additional equipment as pulse oximeter, respirator with blender, infusion pump, oxygen analyser.
- Double wall standard
- Double wall hood to decrease radiant heat loss

RETRACTABLE BED SIDE DOOR

For respiration tubing and others. Way in for monitor leads and tubes with no occlusion.

Standard Accessories

- Observation lamp, IV pole, skin temperature probe

Accessories (Optional)

- O2 cylinder, slow suction
- O2 driven venturi slow, Suction with humidified oxygen

INTEGRATED EXAMINATION LIGHT

An integrated examination light provides evenly distributed illuminations to the mattress, assisting you in accurate patient assessment during transport.

THE RIGHT SIZE AND WEIGHT

This makes transport easy. The nice Neotech Orchid 3000 transport incubator is designed to fit into smaller spaces. System weight has also been reduced to enhance mobility and easy access in and out of emergency transport vehicle.

IRIS PORT (Optional)

An iris port and six tubing ports offer ventilator tubing support and entry possibilities for sensors while keeping the temperature stable.

COLLAPSIBLE STAND

With shock absorbers stainless steel stand with collapsible for ambulance and in hospital transport purposes. Four shock absorbers system to allow resistance to peripherals as respirators, Infusion pumps and monitors. Fixed type trolley (optional), also it absorbs shocks and vibrations during transport.

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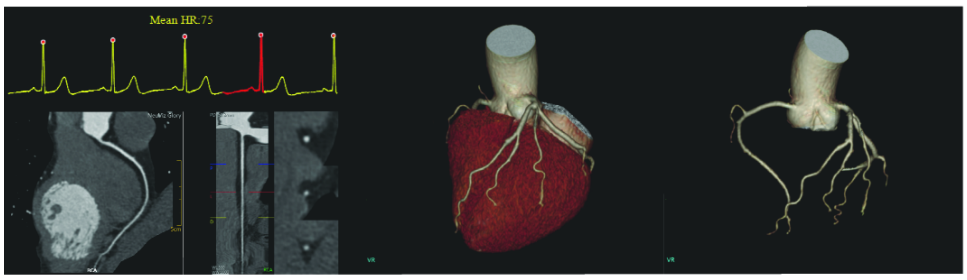
Anupam Agarwal, Director, Consort Overseas

NeuViz Glory CT
1-Beat Scan

kV	mA	Pitch	Rotation time	Scan time	Effective Dose
100	420	1.5	0.259s	0.59s	1.0mSV

Clinical manifestation: Chest distress
Female, BMI: 21kg/m2, Heart rate: 75bpm, One beat cardiac examination.
Diagnostic result: Mixed coronary atherosclerotic plaque in LAD.



Featuring:
One-beat cardiac scanning

THE NEUVIZ Glory is the ultra-high-end Al based CT product with a full range of technological innovations. It not only provides high-resolution images of any part of the body, but also makes patient care easier and better,

Features, such as one-beat cardiac scanning, wide spectral scanning coverage, with a unique low dose design and advanced Al technology providing healthcare providers with an efficient workflow and a more comfortable patient experience,

The NeuViz Glory can perform one-beat cardiac scanning, capturing high quality images of the heart in just one beat. A professional servo motor and direct drive bearings enable 0.259s rotation time and a series of artifact correction functions realise 25ms temporal resolution. Combined with an 8cm detector, the NeuViz Glory greatly reduces the radiation dose, increasing the work efficiency and safety of hospitals.

Clinical manifestation: chest distress female, BMI: 21kg/m2, heart rate: 75bpm, one beat cardiac examination. Diagnostic result: Mixed coronary atherosclerotic plaque in LAD.

- Unique 60kV scanning
- Spectral imaging
- Advanced Al technology

Meeting dynamic needs of patient

N Manogaran, Vice President-Sales, BPL Medical Technologies, emphasises on the importance of Automated External Defibrillators in India as it can be deployed in public places which could help save many lives

Patient Monitors

Patient monitor market in India is growing as always due to the increase in number of beds. Five parameter monitoring has become standard and market demands more additional parameters like IBP, ETCO2 etc. Larger screen size and touch options are few more user needs.

Pre-configured monitor market continues to hold higher share compared to modular monitors. Critical parameters like AGM, BIS will be growth drivers for premium monitor segment.

Industry observed growth in neonatal monitors as the importance for neonatal care is on the rise.

Like any other industry, connectivity features with patient monitors have become need of the day. WIFI, HL7 and remote monitoring are user demanding features. Most monitor brands today offer multiple connectivity solutions. Remote monitoring options can change the dynamics as it can lead to better patient care.

Defibrillator

User choice of the product is based on reliability and proven brand, being an emergency and life saving device. Ease of use, readiness to offer additional monitoring parameters are some other preferred features. Biphasic DF segment is growing over monophasic DF recent years.

Defibrillator with AED and pacer is generally a highly preferred configuration. Parameters like SPO2 and ETCO2 are also opted by some as built-in monitor with DF.

AED – Automated External Defibrillators market segment is still under performing. Market like India should demand high number of AED's as life saver in public places like malls, apartment complexes, railway stations etc. AED segment is yet to get higher demand and growth of this segment in recent past is not significant.

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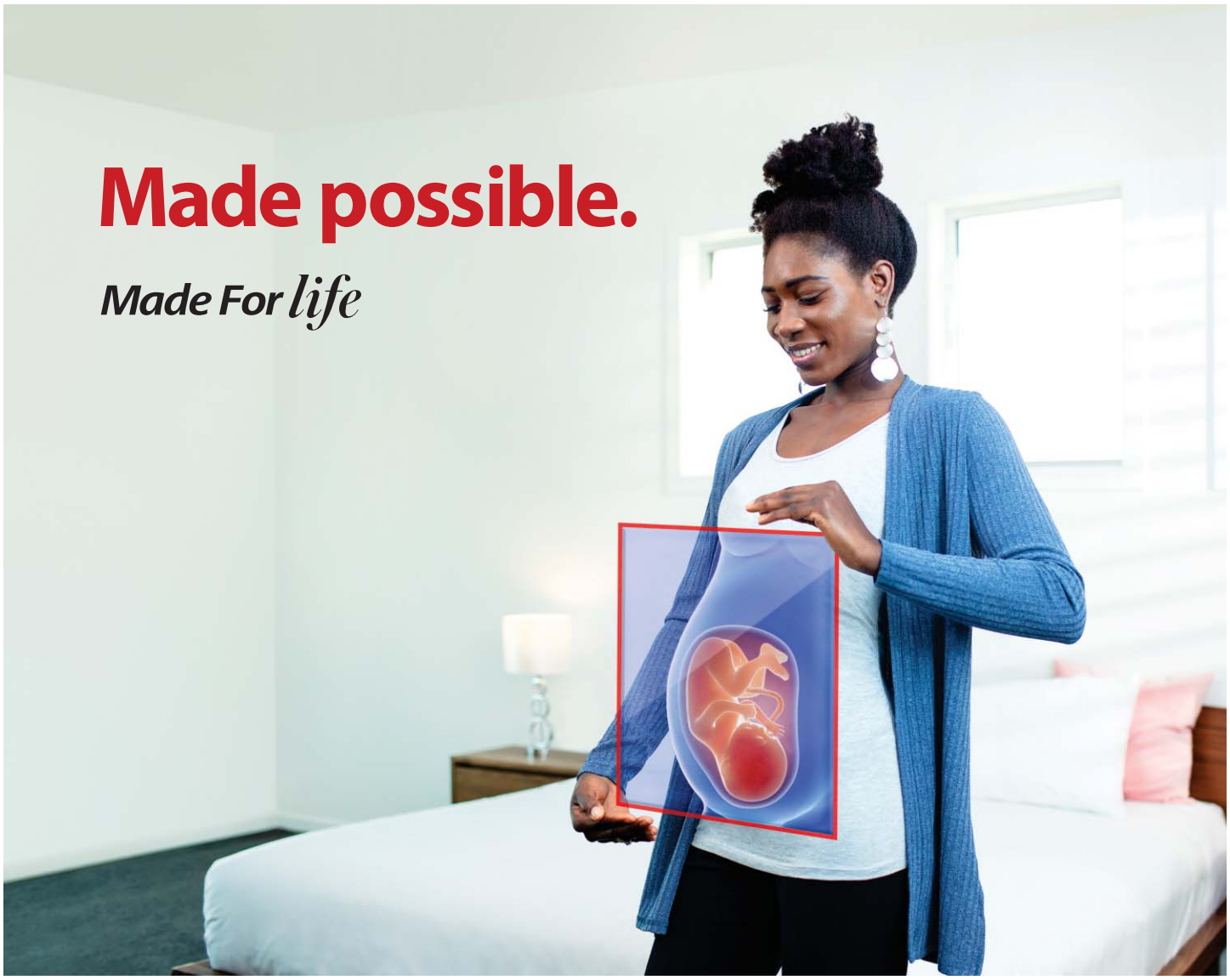

Working together to understand your needs and challenges drives valuable outcomes that positively impact you and your patients future.

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*Model supports all critical parameters like **IBP, ETCO2, Anaesthesia Gas Monitoring, BIS & Cardiac Output.***

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