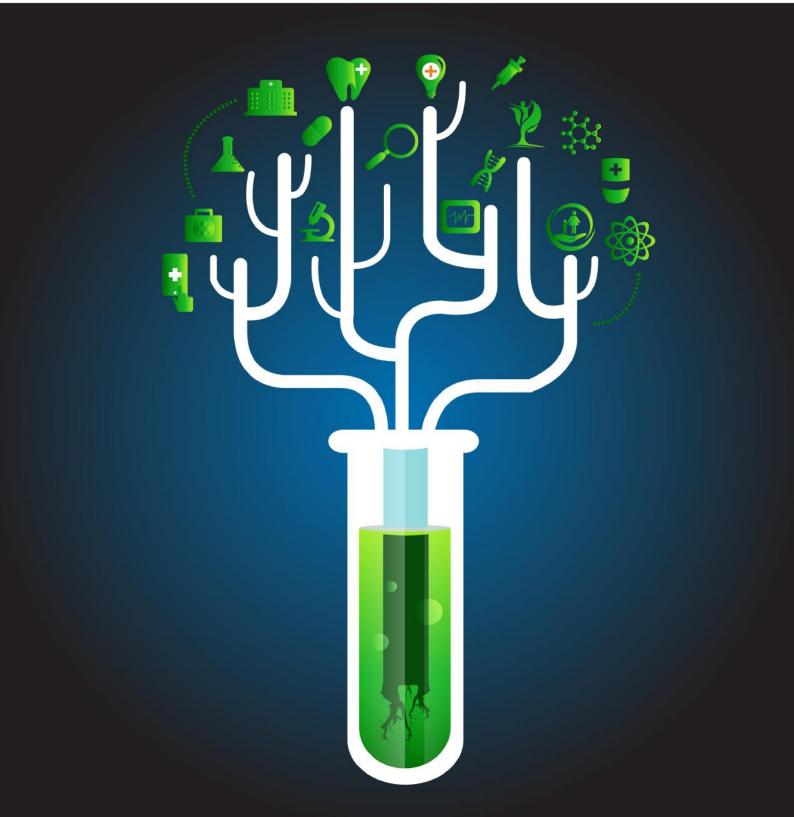
# nnoHEALTH

India's First Magazine of Healthcare Innovations

Issue Price: INR 100/-Quarterly Magazine







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#### Way Forward.....

Healthcare delivery is a challenge in every country may it be India or USA where health budget consumes 17.2 % GDP, yet the community is not satisfied & many improvements are being considered in healthcare delivery by using Information Technology (IT), insurance and cost cutting. It is a different story in India where the community is competing for limited resources as only 1.3 % GDP is spent on health. The outcome required is qualitative healthcare delivery at optimum cost. There is nothing like affordable cost since it depends from person to person income.

Information technology has played a vital role in the innovation of healthcare systems. It is normal corollary to innovate and use technology to reduce disease burden by improving health outcome by use of IT, m-health, e-health through effective Hospital Information System (HIS), Telemedicine & Electronic Health Record (EHR). Frugal innovations in Indian healthcare have attracted global attention. IT has been used innovatively in real time to reduce operating cost by Iris Hospital Kolkata, India. Use of various devices like Tablet, Palm held computing have been integrated at all levels to improve Iris hospital operations to control nosocomial infection, medication management, inventory management and decentralized billing system to reduce cost and improve efficiency. Other such e-health innovations are tracking future patient load by Arvind eye hospital, diagnosis and treatment by use of telemedicine, e Mamta project in Gujarat to reduce infant and maternal mortality rate by tracking pregnancy, providing ambulance for emergency patients by Emergency Management Research Institute and many more. India has declared this decade for innovation and has established National Innovation Council, National Health Innovation Council and National Innovation Foundation with budgetary support to incubate new innovative ideas.

The use of technology forces healthcare

professionals to perform efficiently and reduce the scope of error. Lean experts say that every process in hospital has 70 -90% waste, reducing it will increase value for which the patient is ready to pay. No patient is willing to pay for waiting in hospital, nosocomial infection and medication error. Lean is a tool for innovation and both are two sides of the same coin. A collection of reliable real-time data, its analysis and collation can reveal real problem and find solution easily. Innovation is of four types e.g. Product innovation, Process innovation, Marketing innovation and Organizational innovation. Technology is used for streamlining processes and development of new technology is based on health care providers and patients need. Innovation in healthcare is ultimately in product, process and structure. Innovation is to be market driven and the quest for new technology to improve operation, transparency, accountability & reduction of waste would ultimately benefit healthcare providers and patients by reducing cost.

There are new challenges emerging in healthcare like ransomware and cybersecurity. Our endeavor is to make professionals aware of latest tools, techniques and challenges through magazine, webinars, conference, innovators' club and soon to be launched training programs by global experts and exchange of ideas. The European Union is already part of our initiatives.



Editor in Chief and MD, InnovatioCuris

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#### **Lessons from the Villages of Nagaland**

**Sachin Gaur** is Director operations at InnovatioCuris. He is interested in topics of mHealth and Cyber Security. Have deep expertise in digital marketing, mobile application development in domains like health and education. Have multiple patents granted.

ast November 2016, I got an opportunity to walk in the remote villages of Nagaland. The journey was organized by Prof Anil Gupta from IIM Ahmedabad, India. Prof Anil has been doing Shodh Yatra¹ for last 19 years (a walk of approximately 150 kms to 200 kms to scout grass root innovators and cross-pollinate ideas). The hindi meaning of 'Shodh' is to research and 'Yatra' is journey. As, we in IC are constantly looking for inspiration and innovations, being part of the Shodh Yatra was an excellent opportunity to meet some innovators and see the country with a different point of view. A point of view which believes in the grassroot innovations, celebrating them and spreading them.

Essentially speaking the Yatra takes you through many small villages and in each village you repeat 4-5 activities. Celebrating the elders of the village and document the traditional learnings by asking questions. Organizing Idea and Bio Diversity competitions among young children and students. Also, engaging the village community and sharing innovations from other parts of the villages. One of the ways to put the experience of Shodh Yatra is in Prof Gupta's word: "During the Yatra we can learn from four teachers: the teacher in nature, teachers

within, teachers among peers and the teacher among common people"

We met people who were 100 plus years old and villages of Nagaland were rich in biodiversity and very clean. All, my stereotypes were broken about remote and inaccessible parts of the country in a good way. The superiority of traditional knowledge in terms of knowing the medicinal use of plants by the communities was amazing. If such a task is taken up by communities to document traditional knowledge countrywide and further look at it through scientific methods. It can open up new avenues for the marginalized communities in terms of commercialization of traditional plants and medicine and also preserving the oral and tacit knowledge of the communities.

Most of us who live in cities have become distant from nature and the understanding of it. Such visits not just give you new eyes to look at what nature can offer us, but also the sense of community from the villagers, who are so giving in their nature. Some of them are constantly innovating and we need structures and methods to spread the good work.



Figure: Left to Right: Entrance of Village Holongba, Village Elderly and Student Biodiversity Competition



#### **How InnovatioCuris was Named?**

**Anushka Singh** an eighth grade student at Delhi Public School, Gurgaon is an avid reader. She follows all contemporary literature starting from Famous Five to Harry Potter but has developed a keen liking to Greek mythology. This interest has led to writing more about this subject. She is proving to be a budding author and her bibliophilic nature has won her the title of book worm amongst her friends. She is showing her creative interests in her paintings and short stories.

t was my privilege when I was asked to name the new company to deal "Healthcare Innovation" as a couple of names planned by founders were already registered. It was a great learning and opportunity for me. I've always had a liking for Greek and Roman mythology which has connect with health sector. When others seemed bored to hear the tales of mighty demigods like Perseus and Hercules, I was always interested and loved to hear their tales. This is why every time I stepped outside, I found myself looking at the staff of Hermes, the god of travellers beside every medical institute, hospitals and ambulances. I was extremely confused because what does the god of travellers has to do with a hospital? I quickly realized that the staff was not meant to be one of Hermes, but of Asceplus, the god of MEDICINE. You see, the staff of Hermes has wings and two snakes wrapped around it, while Asceplus' staff has a single snake with no wings in sight. As this symbol began to appear everywhere, I was greatly frustrated, as Hermes was better known as the god of THIEVES. It was almost symbolic, as many doctors these days suggest a million unwanted tests, a few surgeries and foot long prescription, mounting up to

a giantish fee, for something which might just turn out to be a common cold. So as soon as I got the chance to name a company, I jumped at it and dove immediately into the archives of mythology inside my head. Immediate choices were Apollo, god of healing. But the name was already taken, and so was Artemis, who was Apollo's twin sister, goddess of the hunt. (But in this context, the fact that she was the goddess of childbirth seems more important). I thought of Asceplus, the previously mentioned god of medicine but finally decided on simply translating the words 'innovation and healthcare' to Latin to form the words 'InnovatioCuris' which was immediately accepted and instantly registered. The symbol was also something I had an opinion, and you can see that as it has the staff of Asceplus in it, with a single snake and no wings. It looks very innovative as well, which was its main function. It attracts the attention of the onlooker and makes you wonder about its origin. And well, that's the way I ended up naming a company 'InnovatioCuris'. And hey, now you know what it means too! At least you wouldn't put up Hermes' staff next to your pharmacy now I hope...?



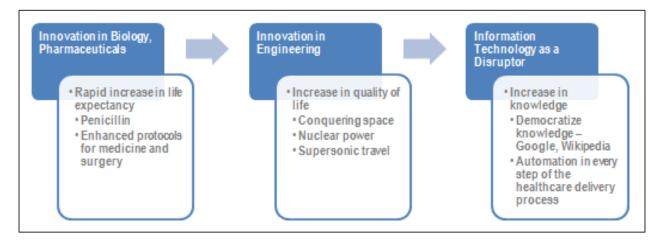
#### Innovation – The Current Frontier

**Sandipan Gangopadhyay** is President and COO at GalaxE.Solutions, Inc. He has spent over two decades in high-profile roles in both Pharmaceutical and Information Technology companies around the globe, including designing and implementing innovative bulk drug manufacturing processes based on gravity feed, inventing fault tolerant operating systems and setting up one of India's first private Software Technology Parks. He is a member of the Indian Institute of Chemical Engineers, and is certified in the Governance of Enterprise IT. He brings his passion for innovation and truly revolutionary technology helping people live healthy and forever.

In creating new antibiotics. In the automobile. In nuclear power. Just think about the pace of innovation in the past 100 years; with individuals

born into a horse and buggy era living to see a man walk on the moon, through the clouds. That pace of advancement is only increasing in the world of information technology – into the cloud.

#### **Does IT Drive the Most Innovation Today?**



Indeed, it is truly revolutionary. Never mind 100 years. How about the past Ten? Five? Two? The Internet, social networks, complex solutions for managing healthcare have been revolutionary. Innovation, especially in the IT space, is key to bringing economic growth, enhanced lifestyles, education and overall improvements in human growth, health and advancements. And, perhaps nowhere is that more important or challenging than in the healthcare space.

Just consider the goal, demands and what ultimately is at stake. First, costs are mounting. Increasing governmental regulations play a large part in that dynamic but there are others considerations as well: litigation; insurance; and expensive research

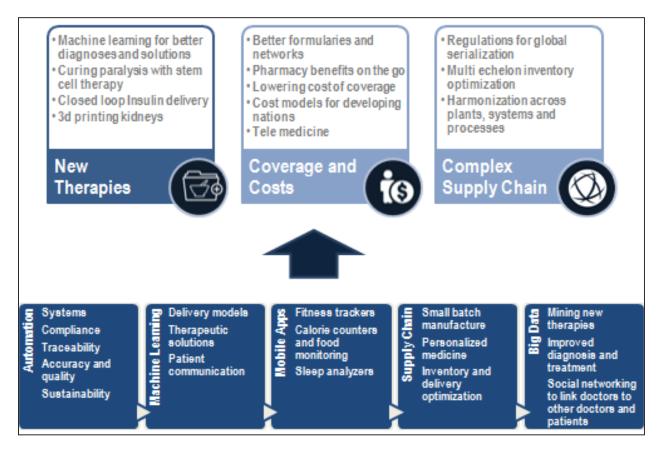
into new medicines. Then, there is the very long, very complex delivery chain involved – from doctors to insurance companies to PBMs (Pharmacy Benefit Management) – with everyone taking their cut – and new regulations pushing for every item to be serialized in every step of the way - that ultimately has to deliver the right medicine to the right person at the right time. The task has never been more daunting.

To be sure, technical innovation is managing the health of our nation and that of the world. So, how do you get desired physical outcome without breaking the bank? It requires a unified, orchestration of innovation in the business transaction processes. The best deals are applied; the best contractor

applies; the best network – pharmacy network, prescriber network – apply. The best formularies are used; the best service providers are rewarded; more service providers are incentivized to become

better. And, orchestration of such innovation needs to happen with delivery methodologies for new drugs; how they are invented; how they are commercialized in the marketplace.

#### **How Can IT Innovations Drive Better Health?**



Ultimately, all of these areas and considerations must be scrutinized and analyzed, in particular through new IT automation, in order to decipher the correct solutions that then must be well-coordinated and properly managed. Every situation

is different. There are no templated answers. Only areas to be contemplated and acted upon to enable the best medicines, healthcare benefits and final outcomes for individuals and those who serve them.



# Multi-Disciplinary and Focusing on Societal Problems is The Way To Go!

**Prof Prabhat Ranjan** heads TIFAC as its Executive Director. TIFAC is set up as a Technology Think Tank and is an autonomous body of Dept of Science and Technology, Govt of India. Recently Prime Minister of India launched Technology Vision 2035 prepared by TIFAC under his leadership. He obtained his PhD from University of California, Berkeley and did college education from IIT Kharagpur and Delhi University. He has received many awards for his contribution to Science and Technology.

This interview covers the approach taken by Prof Prabhat Ranjan (advisor of InnoHEALTH magazine) for solving societal problems, especially in healthcare.

# Tell us About your Motivation to Innovate in the Medical Domain?

did PhD in nuclear fusion, then immediately came back to India in 1986 within a week of finishing my studies. My purpose was to serve nation and society rather than to chase publications. So, I changed my field from astrophysics to nuclear fusion a week before I was joining for my PhD studies.

Nuclear Fusion as you know is a field where building a reactor requires multidisciplinary skills. I was responsible for bringing two Indian reactors to the International standards. My venture into disabilities happened by chance. When I joined Dhirubhai Institute of Communication Technology, we had an approach that all students should work on design projects linked with real problems of society. I had two students Ramya and Pallavi, who were focused on a project on disabilities. They went to visit blind people association in Ahmedabad for scouting problems.

When they went to Hyderabad for vacation, they came across news of a girl who had Cerebral Palsy. The girl had passed 10th standard in spite of the medical condition and the story made it to the newspapers. They travelled to Chennai to meet the girl. Students came back and narrated the story of this girl, Bhawana to me. She could either change the television channel or volume and not both at the same time. I said, "Let's give her a better system." That was the task we took upon. Gross movement

of hand was used to operate the television set. Up down movement of hand to change the channel and left right movement of hand to change the volume. That's how I got into the medical technology space. Our initial work started with this student project, where we tried to develop a system, which could allow persons with restricted finger movement (incapable of pressing remote control button) operate TV by using hand gestures to change volume and channel. After developing a prototype, we added the capability to not only operate TV but also other devices such as light, fan, air-conditioner, computer etc as per the need of user.

This device, which we named as "CePal" won us HP Innovate first award in 2009 and National Trust funded it for further development. With further improvements and user trials, we finally developed two versions of this to meet different needs called "Mini-CePal" and "RF-CePal", which was given to various users as per the requirement of the National Trust.

# What is the Cost of this Technology and some Technical Details?

The cost of this technology would be in millions in the US but the same technology in India is priced at just INR 4000.

# (i) CePal: Hand Gesture based Environment Control Unit (ECU)



Figure 1: Mini-CePal : Single Piece Device - Needs to be Pointed Towards the Equipment

Mini-CePal: This device is made in one piece and mounted on hand/wrist. It monitors hand gesture of the user and sends an Infra-red command through an IR LED mounted at front of box. While it has the capability to operate four different types of equipment, it has been found most suitable to operate a computer for those who do not have fine finger movement to press keyboard buttons or

button based remote control. 50 of these devices have been distributed by National Trust to various user agencies.

RF-CePal: This system consists of two parts:

- (1) A fixed base station (as shown in figure 2),
- (2) Hand device (as shown in figure 3)



Figure 2: Base Station with one of the Flexi-Tube LED Shown. Up to Four Such LEDs can be Connected



Figure 3: Final Version of the Hand Device with Four LED Indicators

Hand device monitors the hand movement using accelerometer in two directions: Up/Down and Left/Right. It also detects taps by the user. All this is transmitted to base-station by wireless

communication using Zigbee protocol. This system supports up to four equipments. One can change the equipment being operated by tapping the hand two times within a defined interval. It also has 4 LEDs to indicate, which mode became operational. A fifth mode "sleep mode", is also defined, when the device ignores hand movements.

Base station acts as a gateway between hand device and equipment to be controlled. It receives commands from the hand device using wireless communication. It interprets this information and prepares the control commands to be sent to equipment to be controlled. It has IR LEDs mounted on flexi-tubes, which can point in the direction of equipment. Through this, it is able to control the equipment as per the intention of user. This also has four LED, which lights up to match with the LEDs on hand device to indicate the equipment being controlled.

Detailed technical description of this device is given in reference.<sup>1</sup>

#### (ii) Systems Based on Brain-Computer Interface

In many cases of severe disability, the user is not able to move any body part and some are not able to speak as well. For such cases, we have used the latest development in the Brain-Computer Interface (BCI) technology to provide capabilities to the user to be able to use a computer and to control Environment (TV, Light, Fan etc) based on brainwave and head movement monitoring.

We have taken advantage of the development of neuro-headsets for playing computer games, where brainwaves (EEG waves) of the user are monitored using these headsets to improve their gaming experience. With games market being very large, these devices have become much cheaper

and easier to use. This is making it possible to take advantage of this development to help persons with disability at a much lower cost and for wider use.

We have been using Emotiv Epoc headset,<sup>2,3</sup> which collects EEG waves from 14 different location on the skull as well as tracks head movement using a gyrosensor. All this data is wirelessly transmitted to a computer, which can process this further. Depending on the user's ability and need, we can recognize the facial expressions, emotions and train the system for recognizing certain conscious thoughts. This can be combined with the information from gyro-sensor to provide a means to communicate in those cases where users do not have any leg/hand movement or voice. Many users with spinal cord injury, Muscular Dystrophy and other issues can immediately take advantage of this.

Brain-CePal: In addition to being able to communicate through a computer, we also developed a system by which user can control the environment around them. This is based on our earlier work of RF-CePal and we modified the system to make it operable through computer and control environment around them through neuro-headset. Depending on user's need, this can be completely done through user thoughts although as of now we have not come across any user needing this capability.

# Any Particular Insight for the Readers or the Industry Peers on How to Foster Innovation in Health Sector?

The health sector is no longer a sector, which can be confined to the boundary of one field. Today, 3D printing can make a major difference in the health sector but medical professionals are not aware of its full potential. Similarly, they need to work with engineering experts who may be of great support in achieving newer kind of medical technology. The

<sup>&</sup>lt;sup>1</sup>Juhi Ranjan, Hiren Shah, Sanika Joshi, Brijesh Chokhra and Prabhat Ranjan, RF-CePal: "A Universal Remote Control based on MEMS accelerometer", Sixth IEEE Conference on Wireless Communication and Sensor Networks (WCSN-2010) at Indian Institute of Information Technology, Allahabad, December 2010.

<sup>&</sup>lt;sup>2</sup>Emotiv Epoc Neuroheadset : http://www.emotiv.com/store/hardware/epoc-bci/epoc-neuroheadset/. <sup>3</sup>Neurosky headset : http://www.neurosky.com/.

medical education in India should allow students to take more courses outside the medical domain in order to enhance their capabilities to do multidisciplinary work.

# How can Other Scientists Who are Outside Medical Field Contribute to the Health Sector?

Yes, there are discussions going on as to how we can attract scientists from various other domains. If we focus on problems faced by society rather chasing the incentives of publications, we can dissolve these silos easily. Multi-disciplinary work is not easy, one needs to move out of their field's boundary, learn new things and work with others.

#### Is There Anything that you Would Want to

# Inform the Readers, Who are Interested in Future Innovations in Health Care?

On February 10, 2015, we had a discussion on future of brain where we looked at how human brain and computer (Artificial Intelligence) can combine together to perform various tasks and we are planning one more discussion in February 2017, which will focus on future of human species and how certain technology areas which are called exponential technologies may impact the future. So, I would like you and others to participate as we finalise the date. The discussion will revolve around the topics of Robotics and the impact on jobs. The purpose of the medical field is to improve the quality of a person's life as well as the fundamental changes taking place around us. We expect that development of these devices would make a major difference in the life of persons with disability.





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#### **How Genetic Testing can Innovate Healthcare Delivery**

**Dr. V.L Ramprasad** holds a Master's Degree and Ph.D. from BITS, Pilani. He has worked as Scientist (Molecular Genetics) at Vision Research Foundation, Sankara Nethralaya and was handling Affymetrix and Illumina technologies at Spinco Biotech. He also worked as Principal Scientist at SciGenom Labs. He has 17 peer-reviewed publications to his credit.

Though in a nascent stage, precision medicine is evolving at a fast pace. There are many labs set across the country and world which offer genetic testing at an affordable fee. Moving from a traditional medical model of treating pathologies to an individualized predictive and preventive model of personalized medicine promises to reduce the healthcare cost on an overburdened and overwhelmed system. The increasing number of catalogs of causative and risk genes will provide a foundation for Personalized Medicine and pharmacogenomics. The advent of NGS has helped in bringing down the cost of genome sequencing to less than \$1000. However, there are many other new technologies on development that will make the sequencing even faster and more economical.

he current medical model focuses on the detection and treatment of pathologies. Treating disorders, especially on advanced states, is very expensive for patients and society in general. The Human Genome Project not only provided the essential reference map for the human genome but also stimulated the development of technology and analytic tools to process massive quantities of genomic data. Thus, accelerated the early detection of disorders and the identification of pharmacogenetic markers to customize treatments. Furthermore, the Human Genome Project has significantly contributed to the discovery of numerous genetic markers, several human diseasespecific genomes, including cancers. Because of increased discovery rate of clinically relevant biomarkers, the relevant application of conventional molecular diagnostic methods like low- and/or medium-throughput sanger sequencing is restricted as they cannot screen such a huge number of genetic markers with a limited tumor/disease specific material. The advent of next-generation sequencing (NGS) technologies has not only reduced sequencing cost by orders of magnitude, but also significantly increased the throughput with just a few or single cell. One such new development

in pre-natal genetic testing is "pre-implantation genetic screening".

#### **Pre-Implantation Genetic Screening**

Chromosome segregation during female meiosis is particularly error prone in humans. These chromosomal abnormalities also called as Aneuploidy, worsen with advancing age. Many of recent studies have demonstrated that aneuploidy rates in the oocytes of women over 40 are over 75%, whereas approximately a quarter of oocytes from women in their early 30s are chromosomally abnormal.<sup>1</sup> A majority of human embryos produced from such oocytes using in vitro fertilization (IVF) techniques are aneuploid and has been shown that they fail to implant in the uterus, although a minority do succeed in forming a pregnancy only to later miscarry.2 Hence, reliable identification of euploid (healthy) embryos is inevitable, but the main obstacle to testing human embryos for aneuploidy is the extremely limited amount of tissue available for analysis. Thus, most methods currently available for the genetic analysis of pre-implantation embryos may not be suitable

<sup>&</sup>lt;sup>1</sup>Fragouli E, Alfarawati S, Goodall NN, Sánchez-García JF, Colls P, Wells D. The cytogenetics of polar bodies: insights into female meiosis and the diagnosis of aneuploidy. Mol Hum Reprod, 2011;17:286–95.

<sup>2</sup>Scott RT, Ferry K, Su J, Tao X, Scott K, Treff NR. Comprehensive chromosome screening is highly predictive of the reproductive potential of human embryos: a prospective, blinded, nonselection study.Fertil Steril,2012;97:870-5.

and suffer from shortcomings which limit their clinical applicability. A few chromosome screening methods applicable to single cells biopsied from pre-implantation embryos are available, but the high cost of testing has restricted their usage.<sup>3</sup> New advancements in NGS technology provided an excellent alternative tool for the identification of chromosomal abnormalities using a few or single cell.

#### **Next Generation Sequencing (NGS)**

Next-generation sequencing popularly referred to as 'high-throughput sequencing'. The advent of next-generation sequencing (NGS) technologies in the context of pre-natal genetic testing provides highly accurate, low-cost diagnosis of aneuploidy in cells from human pre-implantation embryos and is rapid enough to allow testing without embryo cryopreservation. Many reports indicated NGS improves IVF success rates. Thus, NGS becomes a reliable aneuploidy screening method and has the potential to revolutionize pre-implantation genetic screening (PGS).<sup>4</sup>

Furthermore, NGS becomes an integral part of precision medicine as it provides a viable alternative for characterizing genomic aberrations in tumors/ other human disease for predictive and prognostic purposes with its massively parallel sequencing capability. This specific advantage of NGS technology enables testing of multiple genes/clinically relevant biomarkers per tumor as the standard-of-care,

which may not be feasible with low- and mediumthroughput traditional techniques such as Sanger sequencing, pyrosequencing, allele-specific polymerase chain reaction (PCR).<sup>5,6,7</sup>

The predominantly used NGS technologies are from:

- Illumina (HiSeq 2500/4000/X Ten etc.)
- Roche Applied Science/454 Life Sciences
- Life Technologies (Ion Torrent/Proton)
- Pacific Biosciences (Sequel)

The application of NGS technology in genetic testing is enormously increasing because it requires a single input of relatively low-quantity DNA or RNA for the screening of multiple markers, in contrast to traditional sequencing technologies, which need cumulatively larger quantities of input nucleic acid. NGS can provide simultaneous screening of a variety of genomic aberrations such as singlenucleotide variants (SNVs), multiple-nucleotide variants (MNVs), small and large insertions and deletions, and copy number variation (CNVs) of the genes. However, the benefits offered by these NGS technologies come with several challenges that must be adequately addressed before they can be transformed from research tools to routine clinical practices. Integrating NGS into a clinical diagnostic setting requires thorough validation with respect to consistent performance and accuracy, as per the stringent regulations and guidelines established by the regulatory agencies governing the clinical laboratories.8

<sup>&</sup>lt;sup>3</sup>Fragouli E, Alfarawati S, Daphnis DD, Goodall NN, Mania A, Griffiths T, Gordon A, Wells D. Cytogenetic analysis of human blastocysts with the use of FISH, CGH and aCGH: scientific data and technical evaluation. Hum Reprod 2011;26:480–90.

<sup>&</sup>lt;sup>4</sup>Hong KH, Taylor DM, Forman E, Tao X, Treff NR. Development of a novel next-gen sequencing (NGS) methodology for accurate characterization of genome-wide mitochondrial heteroplasmy in human embryos. Fertil Steril 2012;98:S58–9. <sup>5</sup>Roychowdhury S, Chinnaiyan AM. Translating genomics for precision cancer medicine. Annu Rev Genomics Hum Genet. 2014; 15():395-415.

<sup>&</sup>lt;sup>6</sup>Previati M, Manfrini M, Galasso M, Zerbinati C, Palatini J, Gasparini P, Volinia S. Next generation analysis of breast cancer genomes for precision medicine. Cancer Lett. 2013 Oct 1; 339(1):1-7.

<sup>&</sup>lt;sup>7</sup>Roper N, Stensland KD, Hendricks R, Galsky MD. The landscape of precision cancer medicine clinical trials in the United States. Cancer Treat Rev. 2015 May; 41(5):385-90.

<sup>&</sup>lt;sup>8</sup>Jennings L, Van Deerlin VM, Gulley ML, College of American Pathologists Molecular Pathology Resource Committee. Recommended principles and practices for validating clinical molecular pathology tests. Arch Pathol Lab Med. 2009 May; 133(5):743-55.

#### **Genetic Testing is Now More Accessible**

More than a thousand genetic tests are available today and the number is still increasing. Genetic test panels give patients an insight into diseases which they may have inherited and give them an understanding of what preventive measures need to be taken. The results help understand the chances of a person liable to get inflicted by a genetic disorder and passing it on to someone else and vice versa. An expert in genetics is the best person to seek advice from, for those wanting to take a genetic test as such tests include risks and have their limitations as well. There are many labs set across the country and world which offer genetic testing at an affordable fee. Though many test labs have been established and it has been made more accessible, it continues to remain an expensive affair for the middle and lower middle sections of society in India.

#### **Precision Medicine**

Precision medicine or 'specific treatment' helps researchers and doctors to understand the exact treatment they need to offer to the patients. The advent of precision medicine is moving us closer to more precise, predictable and powerful health care that is customized for the individual patient. The approach of personalized therapy involves having a deep understanding of the unpredictability in a person's genes, his/her environment and lifestyle. A complete bespoke treatment with appropriate decisions customized to a person's medical condition. The therapies adopted range from imaging to molecular diagnostics and analytics/software and will be in accordance with the

person's genetic analysis. As mentioned previously, NGS becomes an integral part of precision medicine because of its high throughput and multiplexing capabilities which enables to analyze many clinically relevant markers across many samples.

#### The Future

Though it's a nascent stage, precision medicine is evolving at a fast pace. Moving from a traditional medical model of treating pathologies to an individualized predictive and preventive model of personalized medicine promises to reduce the healthcare cost on an overburdened and overwhelmed system. The increasing number of catalogs of causative and risk genes will provide a foundation for Personalized Medicine and pharmacogenomics. The advent of NGS has helped in bringing down the cost of genome sequencing to less than \$1000. However, there are many other new technologies on development that will make the sequencing even faster and more economical, such as Oxford Nanopore technologies (GridION™ System based on nanopore-based sensing). The future perspective of this advanced technology may reduce the cost of screening diseases specific gene panel to \$100 within a time-frame of an hour. Research is proving that the therapies which are intended for one type of cancer could, in the future, be used to treat other types of cancers, on the premise of changes occurring in a person's DNA. Discovery of mutations via sequencing and optional treatments are some of the findings through the process of sequencing and these may offer much hope towards better customized treatments for individuals.



#### Innovations in Healthcare Delivery – Opportunities and Challenges

**Dr. Srivats Bharadwaj** is Founder, CEO and Chairman, Vatsalya – Centre for Oral Health. He is specialist Dentist of international repute with over 19 years of extensive experience. He has several prestigious nominations to his credit including being the council head for International Association for Disabilities and Oral Health, clinical director of Special Olympics International (USA).

About 72.6 percent of the rural population in India do not have access to basic oral health. Unfortunately, in our prevalent war against diabetes, cardiac issues, HIV/AIDS, et al, we ignore the seemingly less-important battles – like oral health, for instance – that can actually strengthen our chances of success. Enhancing access to affordable dental care is important in its own right, but is unlikely to be a sufficient strategy for reducing the burden of disease. The innovation that India needs today is an integration of public health solutions for oral diseases with those for chronic diseases and with the national public health programmes.

When we think of innovation in healthcare, most of us tend to look for the 'Eureka' moments. The wonder drug that can cure cancer, the surgical procedure that can revive a brain-dead patient, the hi-tech diagnostic tool that can predict cardiac adversities. But these innovations — no matter how spectacular - are of little value without the right healthcare delivery processes.

A very interesting article that appeared in the November 2013 issue of Harvard Business Review looked at how some Indian hospitals are able to provide world-class healthcare at as much as 95 percent lower costs than those at US hospitals. The answers, the authors argue, don't always lie in grand designs, but in smart delivery systems.

#### Addressing the Issue

In a recent interview, US-based surgeon and bestselling author Atul Gawande called India's public health system one of the "most complex things" in the world. And that's true, given the sheer magnitude of the burden of infectious diseases as well as non-communicable diseases that the country has to tackle.

Unfortunately, in our prevalent war against diabetes, cardiac issues, HIV/AIDS, et al, we ignore the seemingly less-important battles — like oral health, for instance — that can actually strengthen our chances of success. According to the WHO, the

risk factors for oral diseases include an unhealthy diet, tobacco use and harmful alcohol use. These risk factors are the same for the major chronic diseases — cardiovascular ailments, cancer, respiratory diseases and diabetes.

Studies have shown that periodontal diseases (also known as gum diseases) pose a risk to general health, especially for patients with other chronic diseases. Among patients with diabetes, periodontal disease can accelerate the chances of pancreatic failure, stroke, myocardial infarction and renal failure.

Similarly, maternal periodontal disease during pregnancy is sometimes associated with increased risk of pre-term delivery and low birth weight. Yet only 50 percent of pregnant women with a dental problem visit a dentist during their pregnancy. Despite studies affirming that most dental care procedures are safe during pregnancy, myths of perceived risks still prevail even within the medical fraternity.

#### **Integrative Approach**

The innovation that India needs today is an integration of public health solutions for oral diseases with those for chronic diseases and with the national public health programmes. Say a patient is seeking treatment for HIV, it's significant to examine his oral health condition too. Research has shown that inadequate oral healthcare can

undermine the success of HIV treatment regimens.

World Health Assembly in 2005 included Oral Health with other non-communicable diseases for health promotion and disease prevention strategies. However, most of our policymakers as well as medical practitioners are still in the dark about the burden of oral diseases in the country and their impact on our overall health and wellbeing. Although there has been no nation-wide study to determine the burden of oral health conditions in India, individual studies indicate that the average prevalence of dental caries is 40-45 percent in all age-groups; periodontal diseases is 90 percent; malocclusion is 30 percent.

In 2000, the US Surgeon General identified oral disease as a "silent epidemic", wherein a significant amount of money is spent on expensive, invasive treatments that could have been either avoided with simple preventive measures or at least treated at a lower cost and lower risk if identified earlier.

#### **Reality Check**

The biggest challenge in implementing an integrative approach vis-a-vis oral health and other diseases is the dismal dentist: population ratio (1:8,000 in urban areas and 1:50,000 in rural areas). About 72.6 percent of the rural population, says the data from Dental Council of India, do not have access to basic oral health.

Enhancing access to affordable dental care is important in its own right, but is unlikely to be a sufficient strategy for reducing the burden of disease, states a white paper on Oral Health commissioned by the National Interprofessional Initiative (Oral Health: An Essential Component of Primary Care). Sometimes, we just need to go back to the basics. Prevention is still better than cure. Primary care providers, such as general physicians, nurses and midwives, need to be trained to expand the disease prevention workforce. Children, pregnant women, diabetes and other patients who visit the hospital regularly are ideal candidates for preventive healthcare.

There are several examples of promising healthcare delivery innovations. The challenge is to ensure that they are successfully and widely adopted. And this calls for a change in the attitudes of medical practices, healthcare organisations and policymakers. We need to move away from the traditional doctor-centric healthcare setup and make it patient-centric. Thanks to the advances in information technology, it's now possible to deliver medical care to patients at a time and place of their convenience. Telemedicine makes the remote delivery of healthcare over the phone a reality, while electronic health records facilitate easier access to expert medical opinions.

Innovations in diagnostic technology, pharmaceuticals, surgical procedures and medical devices are undoubtedly important. But what's more important is inventive methods to deliver these services in a timely, safe and effective manner to patients. Obviously, this can't happen overnight. But as Bill Gates so succinctly put it, "We overestimate what we can accomplish in two years, but we underestimate what we can accomplish in 10."



## Operational Innovations and its Impact on Healthcare Delivery in India

**Arvind Sivaramakrishnan** is Chief Information Officer, Apollo Hospitals Enterprise Limited. He is currently responsible for the IT strategy and implementation across the Apollo Hospitals group. He has previously worked as the Director of Clinical Applications at Healthcare Practice of Computer Sciences Corporation, Michigan USA.

The surge to bring out the potential of Indian healthcare market needs to aim at finding suitable solutions to increase precision treatments, extending reach of healthcare delivery beyond urban cities, and to reduce considerable healthcare delivery cost. It is true that the Indian IT sector is expanding with more and more mobile phones and Internet cafes connecting people from even the most remote places in the country. This trend can be leveraged for reducing complex workforce and overheads in Indian healthcare operations. Telemedicine as an option can bridge distances while inducing minimal infrastructural cost.

As per estimates, the telemedicine market is made up of at least 800 million Indians. While lack of accessibility, infrastructure, and quality healthcare services have impaired healthcare delivery in rural areas, it is heartening to know that with the support from the government, India as a country is warming up to the concept of convergence of healthcare and technology, and how it will bring about optimized and precise results. Indian healthcare is today taking the centre stage with its growing potential to merge tools of Information Technology to deliver better healthcare services in our country.

However, India as a country can no longer afford slow transformation in healthcare. We need a dynamic change in ways of how healthcare can be better delivered to all. CRISIL projects the healthcare delivery market to grow at a CAGR of 12 percent and attain a reach 6.8 trillion by the year 2020, which implies that there is a vast scope for penetration and innovation in the current Indian healthcare condition.

The surge to bring out the potential of Indian healthcare market needs to aim at finding suitable solutions to increase precision treatments, extending reach of healthcare delivery beyond urban cities, and to reduce considerable healthcare delivery cost.

The most approving route to reduce healthcare costs is to invest more on process innovation than product innovation. Healthcare providers

innovating their business processes, not only reduce cost but also enhance efficiency and quality of healthcare delivery. With growing interest from the government to bring in more PPPs it is rather a good time for Indian healthcare players to horizontally and vertically innovate their separate healthcare activities.

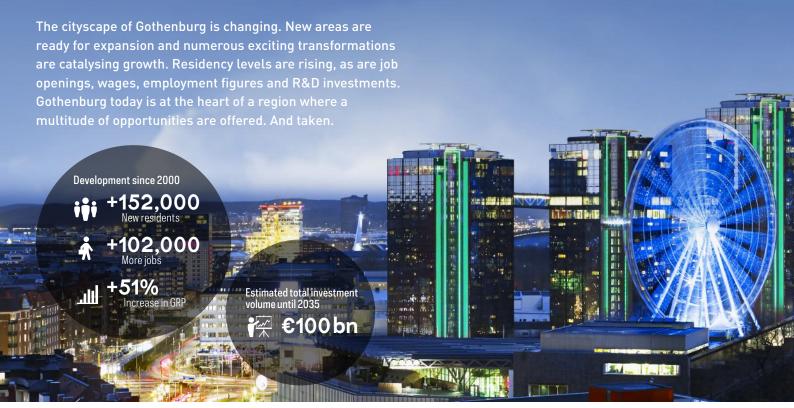
It is true that the Indian IT sector is expanding with more and more mobile phones and internet cafes connecting people from even the most remote places in the country. This trend can be leveraged for reducing complex workforce and overheads in Indian healthcare operations. Telemedicine as an option can bridge distances while inducing minimal infrastructural cost.

The usage of predictive data analytics can help in bringing about speed in diagnosis of patient conditions thereby ensuring that the right treatment protocol is initiated as quickly as possible. This translates to an overall increase in the operational efficiency of the health system.

On the other hand, connectivity issues, interrupted power, lack of trained people to manage the centres, and the preconceived notions of the prospective users -- doctors and paramedical staff -- come in the way of successful implementation. With combined effort of health institutions and with the government implementing various schemes to reduce medical cost, one could not deny that Indian healthcare scenario is going through a revolution,

the results of which will be reaped within a span of next 10 years. We as individuals need to accept and adopt the constant changes brought in through Information Technology in our health practices and make sure that India becomes the most preferred health destination of the world in the upcoming years.

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#### Regulations, Laws and Ethics in Healthcare Delivery in India

**Dr. Kamal Mahawar** is Consultant General and Bariatric Surgeon with Sunderland Royal Hospital in the United Kingdom. He is also an Associate Clinical Lecturer with Newcastle University and editor of renowned scientific journals. His recent book 'The Ethical Doctor' published by Harper Collins India examines some of the serious issues affecting Indian healthcare.

Any detailed analysis of the current state of Indian healthcare can be confusing. The decades of under-investment and lack of systematic planning has resulted in widespread chaos, degeneration of values, skewed distribution of resources, and a sense of helplessness on the part of both the state and the population. It is sadly true that doctors have systematically attempted to benefit from the failure of the policy and the regulation rather than seeking to correct it and their leaders have been busy protecting their own positions and interests rather than that of the patients they are meant to serve. Though the situation seems impossible, there is still hope. A series of determined initiatives can fix the problem.

ndian society is going through a catharsis. In an increasingly interactive but ever more disintegrated world, Indians are finally finding both the confidence and the desire to transform their own society. A country of 1.3 billion people is no longer prepared to accept being an "also ran". In this process of churning, undeniably, there will be much pain but from this one hopes, will emerge an India - confident, strong, and sure.

There is a lot wrong with contemporary Indian society – it's thinking, it's structure, it's systems but we still have a chance. Each one of us alive today will not be here in say just less than 100 years time. Almost every single house in the country will become inhabitable in not too distant a future, and our cities will almost completely have to be rebuilt. We just need to ensure that the "new" that replaces the "old" is robust and before you know India would be transformed. I sincerely believe that with appropriate corrective action, we can resurrect almost every aspect of the Indian society – yes it's thinking, the structures, and even the systems.

This corrective action, however, will only become possible if we come out of our current situation where failure has led to arrogance rather than introspection. We will have to start by admitting freely and openly what is wrong with our society and then engage in a collective discourse to fix it. We need to raise both the level and the intellectual quality of our public discussion and move forward

slowly - a step at a time - but decisively.

Any detailed analysis of the current state of Indian healthcare can be confusing. The decades of under-investment and lack of systematic planning has resulted in widespread chaos, degeneration of values, skewed distribution of resources, and a sense of helplessness on the part of both the state and the population. The task at hand is enormous.

#### **Human Resources**

Healthcare industry is heavily dependent upon human resources. You can't look after patient without doctors, nurses, technicians, etc. and yet little thinking has gone into ensuring an adequate work-force for the future that we can retain to work in the country. The current situation is that we are creating doctors and nurses but without the adequate hospitals and clinics for them to work in. The government keeps saying doctors and nurses don't want to work in rural India but without understanding that doctors and nurses need adequate facilities, diagnostics, and other supporting services to deliver healthcare. Doctors and nurses need decent houses, schools for their children and facilities for a productive and entertaining social life. Given the fact that this is unlikely to change anytime soon in rural India, we will need to provide incentives for people to work in the villages – the same sort of thing that can force a doctor or a nurse to go and work in a small town in

Saudi Arabia can also take them to a village in their own country. Our planners simply need to wake up to this reality. If a doctor or a nurse sees that he'll save for four years by working for a year in a village, he is likely to drag himself there and also ensure he works hard to keep his patients and employers happy. The current situation where nobody wants the job in the first place does not leave the government with any levers when those in it don't perform or simply don't turn up! Adequate salary and tax incentives can go a long way in helping retain our homegrown talent and will ultimately pay back for itself by ensuring a healthier society. Health, after all it used to be said, is wealth.

#### The Role of the Government

In modern societies, we have left it to the governments to set the appropriate structures upon which we can all build our individual lives. If the structure is robust, our lives can indeed be very fulfilling but if it is not, the whole system can degenerate into chaos. The policy has failed Indian healthcare at every step and exploited by the very people entrusted to protect and develop it. Doctors continue to be educated and trained in a system that rarely keeps pace with the changing needs of the patients and the scientific developments. Underfunded medical colleges continue to treat the impoverished in shabbiest of the conditions and produce little in the name of research and scientific output. They struggle to recruit world-class faculty while those who take up these jobs find they can neither deliver world-class care nor engage in academics or research because of the lack of funding and bureaucratic controls. Our corporates happily donate millions of dollars to foreign institutes as they have well-established mechanisms for publicity that our institutions have failed to establish. And while our educational institutions and hospitals are crumbling due to lack of resources, our temples are one of the wealthiest in the world. There is much for us all to reflect over in the contemporary Indian society.

#### The Profession

At the same time, it cannot be denied that healthcare is fundamentally the doctors' responsibility in any society. If any of the other stakeholders' are falling short, it is up to us to make noise and ensure we can

deliver quality healthcare to the people. However, Indian healthcare is remarkably short in this area too. A large number of doctors, let down by the system, have become so cynical that greed and self-aggrandisement have taken over empathy and ethics. The profession has got infested with one corrupt practice after the other and the doctors have simply chosen to look the other way. Yet, they complained bitterly when medical services were brought under the purview of the consumer courts. I agree that involving courts was not the right thing to do but what options did the doctors leave for the patients when the regulator, the Medical Council of India (comprising entirely of doctors), does not have an effective patient complaint cell or even a register of all qualified doctors. It is true that the desire of the medical profession in India to protect each other is much stronger than their will to protect patients. And while the rot was setting in, the so-called leaders of the profession were building their own hospitals and nursing home. Isn't it amazing that not a single leader from the profession has spoken against the widespread lack of healthcare provision in the country for the poor or the ethical abyss that the profession has sunk into? It is sadly true that doctors have systematically attempted to benefit from the failure of the policy and the regulation rather than seeking to correct it and their leaders have been busy protecting their own positions and interests rather than that of the patients they are meant to serve. If you don't believe me, just think how many of hundreds of medical societies in the country come out with anything useful for the people. Where is the desire to develop the local evidence base to guide local care? Where are the local guidelines for common clinical conditions that can be used by doctors and nurses working in remote towns and villages? Despite this, hundreds of conferences are organised annually at considerable expense and much fanfare where the emphasis is on reciprocating lectures and chairmanship rather than any real scientific data sharing. There will no doubt be islands of excellence in this vast sea of greed and corruption but I hope I have been able to give you a general idea of the state of the affairs. Many of these problems are not simply confined to India either.

#### **The Private Sector**

The private sector rose to fill in the vacuum left

by the state and it is a fact that without private healthcare, large sections of our communities will have nowhere to go. But once again, the private sector has been allowed to mushroom without any attempt to match demand to supply. This has led to a situation where they are killing and pulling each other down into a moral quagmire with over competition in urban areas while vast sections of rural parts of the country are left un-served. Private nursing homes, diagnostic facilities, and hospitals are functioning without a regulatory overseeing mechanism and poor patients have no alternative, as the state hospitals are not fit for human treatment.

Though the situation seems impossible, there is still hope. A series of determined initiatives can fix the problem. We need reform across the board. We need to reform our state primary health care provisions, our medical colleges and how we fund them, medical education and postgraduate training, continued medical education, regulation of the profession and the hospitals, mechanisms for patients to voice complaints, planning to distribute provisions evenly, and systems for accountability from all. And even if we did all this, there will be yet more left to do.

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# Stabilizing the World: An Innovation to Help Fight a Health Condition of Epidemic Proportions

**Babu Padmanabhan** is Managing Director & Chief Knowledge Officer, Steerlife and Founder & Promoter, Steer Group. He has led to the development of intelligent compounding technology that has redefined pharmaceutical manufacturing. The fractional lobed processor (FLP) invented by him provides critical break-through.



**Prashanth Thankachan** is Ph.D. Researcher at St Johns Research Institute. He is a physiologist by training, with research interest in the field of micronutrients, in particular iron. He uses novel stable isotopic techniques to assess invivo micronutrient bioavailability, nutrient-nutrient interactions and physiological adaptations to changing micronutrient status.

Prevention of iron deficiency anemia needs two-pronged strategy — a primary strategy would be to increase the bioavailability of native iron in the diet and a secondary strategy would be to increase the density of iron in the diet through fortification. It is anticipated that delivery of iron in a soluble form along with ascorbic acid will increase the bioavailability of iron and also provide the additional amount of iron needed for prevention of iron deficiency anemia. A self-dissolving effervescent tablet in water turning it into a fizzy drink with flavoring could be the answer we are looking for.

A nemia, or anaemia, is usually defined as a decrease in the amount of hemoglobin or in the number of circulating red blood cells (RBCs). It can also be defined as a lowered ability of the blood to carry oxygen. Anemia is the most common disorder of the blood affecting about a quarter of the population, globally.

Anemia occurs either due to nutritional deficiency of iron (low dietary intake of iron), blood loss from the body (parasitic infestations), decreased red blood cell production, or due to increased red blood cell breakdown (thalassemia and a number of neoplasms of the bone marrow). Nutritional deficiency of iron is a prime contributor to the high prevalence of iron deficiency anemia seen among populations. Nearly two billion people suffer from anemia, most of which is due to iron deficiency anemia, largely affecting young children and pregnant women due to their increased requirements of iron.<sup>1</sup> In developing nations like India the numbers are alarming. Every second

pregnant woman and about 40% of preschool children are estimated to be anaemic.<sup>2</sup>

The body loses 1-2mg iron daily, this lost iron has to be replaced into the body to remain in iron balance and is obtained on a daily basis from the food consumed. If the diet fails to provide the required iron into the body (either due to low iron in the diet or due to poor bioavailability [absorption of the nutrient into the body] of the iron from the diet), then a state of iron deficiency develops, that if uncorrected, progresses into iron deficiency anemia.

A vegetarian or a vegan diet may be limiting in its iron density and has poor bioavailability due to the presence of iron absorption inhibitors (phytates, tannins, phosphates, calcium). The presence of intestinal parasitic infestations adds to the burden by increasing iron losses.

Prevention of iron deficiency anemia is therefore, a

<sup>1</sup>WHO Micronutrient Deficiencies — http://www.who.int/nutrition/topics/ida/en/ and WHO Global Database on Anaemia, Worldwide prevalence of anaemia, 1993–2005World Health Organization, 1993 - 2005 (http://apps.who.int/iris/bitstream/10665/43894/1/9789241596657\_eng.pdf).

<sup>2</sup>WHO Micronutrient Deficiencies — http://www.who.int/nutrition/topics/ida/en/.

two-pronged strategy — a primary strategy would be to increase the bioavailability of native iron in the diet and a secondary strategy would be to increase the density of iron in the diet through fortification.

It is well known that ascorbic acid can increase the bioavailability of iron. For ascorbic acid to be effective in improving iron absorption, a molar ratio of 2:1 to 4:1 of ascorbic acid to iron is needed. Ascorbic acid has to be also provided in a 'cold' medium since it is heat labile.

For minimal sensory effects, a ferric salt is more suitable for fortification. An organic conjugate of ferric iron is ideal; this has very low sensory effects, but solubility in water needs to be considered. Based on the comparative data of different iron compounds (Table 1 listed below), it was seen that ferrous bisglycinate is a fortificant of choice. It is easily soluble in water, has low negative sensory properties, causes less GI irritation, has similar bioavailability as compared to standard formulations, has a shelf life stability in years, is approved by the World Health Organization for use in milk, juices, and soft drinks and has been used as a fortificant of choice in Latin America.

The formulation proposed is in a self-dissolving effervescent tablet in water. The plan is to have children and women drink a fizzy drink (from the tablet), which contains ascorbic acid and iron and an effervescent couple (comprising of an acid and base). The drink should be sweet and flavored in

different ways. One tablet will contain an iron salt, ascorbic acid, sucralose, potassium bicarbonate, citric acid and flavor.

It is anticipated that delivery of iron in a soluble form along with ascorbic acid will increase the bioavailability of iron and also provide the additional amount of iron needed for prevention of iron deficiency anemia. The dosage form is anticipated to provide iron in a palatable form as the carbonated drink along with the flavour and sucralose as sweetener would mask the metallic taste associated with iron ingestion.

The efficacy of this formulation would be evaluated in a double-blinded randomized controlled trial with two arms: placebo, and intervention (Ascorbic Acid + iron salt) using a sample of 75 children per group, aged 6-10, boys and girls. Improvement in haemoglobin will be measured as the end point. The clinical trial is scheduled to commence shortly in India.

The potential impact that this innovative, fortified effervescent solution can have is simply astounding. It can improve the overall quality of life and productivity levels of over 2 billion people who need daily support, over 56 million pregnant women, every year and of over 293 million pre-school age children.<sup>3</sup> The solution can reduce maternal mortality, reduce mortality in children under the age of 5 and increase the number of healthy births.

Table 1: Key characteristics of iron compounds commonly used for food fortification purpose: solubility, bioavailability and cost.<sup>4</sup>

Compound	Iron content (%)	Relative bioavailabilitya <sup>a</sup>	Relative cost <sup>b</sup> (per mg iron)
Water soluble			
Ferrous sulfate. 7H20	20	100	1.0
Ferrous sulfate, dried	33	100	1.0
Ferrous gluconate	12	89	6.7
Ferrous lactate	19	67	7.5
Ferrous bisglycinate	20	>100°	17.6
Ferric ammonium citrate	17	51	4.4
Sodium iron EDTA	13	>100°	16.7
Poorly water soluble, soluble in dilute acid			
Ferrous fumarate	33	100	2.2
Ferrous succinate	33	92	9.7
Ferric saccharate	10	74	8.1
Water insoluble, poorly soluble in dilute acid			
Ferric orthophosphate	29	25-32	4.0
Ferric pyrophosphate	25	21-74	4.7
Elemental iron	-	-	-
H-reduced	96	13-148 <sup>d</sup>	0.5
Atomized	96	(24)	0.4
CO-reduced	97	12-32	<1.0
Electrolytic	97	75	0.8
Carbonyl	99	5-20	2.2
Encapsulated forms			
Ferrous sulfate	16	100	10.8
Ferrous fumarate	16	100	17.4

EDTA, ethylenediamineteraacetate; H-reduced, hydrogen reduced; CO-reduced, carbon monoxide reduced.

a Relative to hydrated ferrous sulfate (FeSO4.7H2O), in adult humans. Values in parenthesis are derived from studies in rats.

b Relative to dried ferrous sulfate. Per mg of iron, the cost of hydrated and dry ferrous sulfate is similar.

c Absorption is two-three times better than that from ferrous sulfate if the phytate content of food vehicle is high.

 $d\ \ \textit{The high value refers to a very small particle size which has only been used in experimental studies.}$ 

<sup>&</sup>lt;sup>4</sup>Guidelines on food fortification with micronutrients, Edited by Lindsay Allen, Bruno de Benoist, Omar Dary and Richard Hurrell, http://apps.who.int/iris/bitstream/10665/43412/1/9241594012\_eng.pdf.

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#### **Fostering Healthcare Innovations in India**

Muthu Singaram is Founder, VibaZone Private Limited (Canada, India and Malaysia). He is parallel entrepreneur having been involved in several start-ups over last 20 years and his passion is in Entrepreneurial Development, Mentoring, Management of Emerging Technologies and Innovation.



**Prathistha Jain** is Director, VibaZone Private Limited (India). She is an aspiring Entrepreneur having been involved with start-ups and her passion is in Entrepreneurial Development and Innovation. She is also an image consultant and a regular cospeaker at Entrepreneurship conferences.

Healthcare innovation should be sustainability beyond anything else. Sustainability can be weak or strong. It is weak only when technology is the focus. There will come a time when the technology would be outgrown, thus, it is important that a strong sustainability model should be the focus as it would consider multiple parameters to ensure sustainability. Healthcare innovation should focus on frugal innovation and recombinant innovation.

#### What is Healthcare Innovation First?

ealthcare innovation should focus on innovative information technologies, devices, workflow processes, care models or business models. Many companies focus on devices as the returns on these are more tangible. However, it is equally important to focus on the other areas mentioned too.

# Technology for Healthcare vs. Healthcare Technology

It is important to understand the difference between the two. Technology for healthcare would be things like mobile phones which can be used for better health and interventions that reduce malnutrition, improve sanitation, and increase safety on roads. Healthcare technology would be specifically designed to prevent, diagnose, or treat an illness, from the highly specific focused on a disease to the more widely applicable monitoring devices.

# Why is Innovation in Healthcare So Critical and Yet Hard?

Innovation is critical because of the need, potential and impact of affordable healthcare technologies

on a society like India. Given India's low healthcare spending, is it possible to use technology efficiently and effectively to tackle India's healthcare challenges? Besides the core technology aspects, we need to examine the nature and pathways of healthcare R&D and innovations in India, proposed evidence-based policy measures to overcome the bottlenecks and barriers, and to enable positive and healthy growth of the med-tech industry, eventually leading to strengthening the public health care system and the public health conditions of the country.

In the 12th 5-year plan for India the following was cited in the chapter on health. "Health should be viewed as not merely the absence of disease but as a state of complete physical, mental and social well-being. The determinants of good health are: access to various types of health services and an individual's lifestyle choices, personal, family and social relationships. The focus is on the strategy to deliver preventive, curative and public health services. Other sectors that impact good health, such as clean drinking water and sanitation are dealt under other headers. These are essentials in health care hence the chapter should cover and handle these areas carefully." Innovation should also focus on basic needs like clean water and hygiene besides

affordable healthcare technology, along with advanced communications as these will be able to reduce disease burden and improve healthcare.

The healthcare system suffers from the following weaknesses:

- 1. Availability of health care services from the public and private sectors taken together are both qualitatively and quantitatively inadequate. We are short of medical personnel and hence we should focus on increasing the number of people by bringing in methodologies which require minimal training to up-skill an individual to use medical equipments and carry out processes.
- 2. The quality of healthcare services varies considerably in both the public and private sector depending on various factors. As we do not have proper regulation, it is difficult to measure the standard of care and effectiveness of healthcare delivery.
- 3. Affordability of health care is a serious problem for a vast majority of the population, especially in tertiary care. As many cannot afford the services and most families end up selling their assets to treat the family members, in some cases, treating the bread winners themselves. Also, drugs for chronic conditions are expensive and require regular monitoring and management.
- 4. Physical Reach / Accessibility of a healthcare facility which is having an outpatient department (OPD) for common ailments, and an inpatient department (IPD) for hospitalization.

The problems outlined above are likely to worsen in future with increasing disease burden and limited health systems capacity. Over the next several years, the cost of health care would go up unless proper regulations and new models are created in India to provide health care.

The Indian medical devices industry is a very small part of the total manufacturing industry, accounting for only 0.2 percent of all certified facilities. Following points are worth noting in this context.

- 1. Indian Government's National health policy aims to increase and upgrade healthcare facilities.
- 2. The government acknowledges the need for foreign/ private involvement in medical technology.
- 3. The duties on medical equipment have been reduced over a period.
- 4. Most critical medical devices do not require import duties.
- 5. Make in India Policy to boost this sector. Need for Indigenous Technology is well felt in the

sector due to following factors.

- Huge growing market supplies predominantly by imports
- ♦ High healthcare delivery costs
- ♦ Growth of indigenous technology essential for strengthening the Indian industry
- Public supported R&D is hugely required
- ♦ Development of materials and devices is a major challenge.

#### **Other Challenges**

It is worth noting that currently there is no act for Biotechnology Regulatory and the one which was drafted has lapsed in the parliament that covered primarily biotechnology and not medical technology. A specific medical device bill (currently it is covered under Drugs and Cosmetics Act) and Indian's own certification (like FDA in US, CE in Europe) is important; passing a bill in this area will make a huge difference to the market needs.

Infrastructure gaps remain substantial and are exacerbated by under utilisation of existing resources. Healthcare infrastructure is poor, compared to urban areas. Underutilization of infrastructure further compounds the problem of meagre infrastructure.

Current World Bank data shows India spends only 4.7 % of its GDP on healthcare. This has only grown 0.7 % in over 20 years. We have 0.7: 1000 ratio for physicians, 1.7:1000 ratio for nurses and midwives and 0.7:1000 ratio for hospital beds.

Leading economics spend up to 10 % of the GDP on healthcare and have two or three times as many medical personals and beds.

The healthcare sector is currently multi-layered and complex, which makes it difficult to unlock its true potential and provide quality services. It extends to information gathering, interactions across roles, and the potential for control over wider ranges.

# How can Co-Working Spaces, Incubators and Accelerators in India Help Innovation?

Given the severe challenges of cost, availability of health care personal and weak delivery system - the rise of co-working spaces, incubators and

accelerators in India can play a role in helping innovative projects to bring medical care to the masses at a reasonable cost. These innovations will also create business and impact the employment generated by these start-ups. Unlike e-commerce and aggregated models based start-ups, healthcare start-ups require specialised skill sets, larger funding and entail longer gestation period.

All three can play a different role, let us look at each of their roles.

#### **Co-Working Space**

Co-working spaces have easy access in most cities and are affordable so start-ups which are technology light like application, business models and systems can surface in these places. Most of these places have a reasonable amount of networking events with minimal support and can help start-ups get going.

#### **Incubators**

These are generally publicly funded and housed in colleges and research centers. Here technology development can happen as these facilities have some equipment and that can be used by start-ups to build their products. The start-ups would get expert advice and assistance from faculty and staff.

#### **Accelerators**

Accelerators are usually managed by organizations which are looking for good technology to be applied to their existing products and customer line. They are crucial because they would give a start-up a channel for distribution and manufacturing as these companies would already have successfully entered markets earlier and would have a good market reach to support the new technology.

#### **Opportunities in the Healthcare Innovation**

The Indian healthcare sector is diversifying and opportunities are emerging in every segment, be it providers, payers or medical technology. New players are building their entry strategy and domestic players are exploring new care models to stay ahead.

#### **Innovation and Entrepreneurship**

Healthcare as a driver for Innovation and Entrepreneurship can create innovative products and generate manpower in the healthcare sector. With the advent of alternate and innovative healthcare models, such as wellness centres, diabetes clinic, day care centres, diagnostic chains, among others, the entrepreneurial spirit in the sector has heightened.

#### **Medical Research & Technology**

Medical technology is a broad field where innovation plays a crucial role in sustaining health. From "small" innovations like adhesive bandages and ankle braces, to larger, more complex technologies like MRI machines, artificial organs, and robotic prosthetic limbs, technology has undoubtedly made an incredible impact on medicine. Medical scientists and physicians are constantly conducting research and testing new procedures to help prevent, diagnose, and cure diseases as well as developing new drugs and medicines that can lessen symptoms or treat ailments.

#### **Growing Demand**

Rising income levels, ageing population, growing health awareness and changing attitude towards preventive healthcare is expected to boost healthcare services demand in future. Growing elderly population, changing disease patterns, rise in medical tourism, better awareness of wellness, preventive care and diagnosis has led to an increase in demand for healthcare services.

#### **Private and Public Partnership**

Private providers have shown a keen interest in partnering with the government on various kinds of projects, including primary health centres, emergency and trauma units, radiology and dialysis centres in public hospitals, as well as health insurance schemes.

#### **Policy Support**

NITI Aayog has allocated USD 55 billion under the

12th Five-Year Plan to the Ministry of Health and Family Welfare, which is about three times the actual expenditure under the 11th Five-Year Plan The share of healthcare in total plan allocation is set to rise to 2.5 percent of GDP in the 12th Plan from 0.9 per cent in the 11th Plan. The 12th plan focuses on providing universal healthcare, strengthening healthcare infrastructure, promoting R&D and enacting strong regulations for the healthcare sector. Establishing a system of Universal Health Coverage (UHC) in the country that means each individual would have assured access to a defined essential range of medicines and treatment at an affordable price, which should be entirely free for a large percentage of the population.

### **Way Forward**

Healthcare innovation should be sustainability beyond anything else. Sustainability can be weak or strong. It is weak only when technology is the focus. There will come a time when the technology would be outgrown, thus, it is important that a strong sustainability model should be the focus as it would consider multiple parameters to ensure sustainability.

Healthcare innovation should focus on frugal innovation and recombinant innovation.

#### **Frugal Innovation**

Frugal innovation is the process of reducing the complexity and cost of a product and its production. Designing products for such countries may also call for an increase in durability and when selling the products, reliance on unconventional distribution channels. When trying to sell to so-called "overlooked consumers", firms hope volume will offset razor-thin profit margins. Globalization and rising incomes in developing countries may also drive frugal innovation. Such services and products need not be of inferior quality but must be provided cheaply. Some great Indian examples are the Jaipur foot, oral dehydration salt and many more.

#### **Recombinant Innovation**

Innovators rarely come up with new ideas; instead, they convert old ideas into new ones, adapting them from one context to another. Henry Ford adapted his automobile assembly-line technologies from meat packing plant assembly lines. The Reebok "pump" was an athletic-shoe air bladder borrowed from intravenous bag technology. Even abstruse and highly specialized technologies like polymerase chain reaction have their roots in the existing practices of other genres.

#### Conclusion

Healthcare innovation should be focused on future needs and not today's needs. Market needs are changing at a rapid rate with India's rapid growth and modernisation. Technology will keep changing hence it is not suitable to depend on it alone. The key to healthcare innovation is simplicity based on strong sustainability combining technology, accessibility, affordability, quality and availability.



# Safety Standards: Making India's Healthcare Sector Safer and Future Ready!

Jibu Mathew is Business Head of UL's Life and Health Business Unit for South Asia and emerging markets. He has varied experience in IT consulting, regulatory advisory and market access strategy in Medical Electronics, Healthcare and High-tech industry for more than a decade. He is also an Industry representative in Bureau of Indian Standards [BIS] Committee on Medical and Hospital Standards.

Safety is omnipresent and intrinsic to the entire healthcare delivery spectrum and the entire medical fraternity must move towards industry equilibrium. Medical devices are crucially linked to the growing demands of the healthcare chain which need a strong regulatory framework. This also means sourcing the right kind of equipment and devices from the right vendors and checking them for regulatory approval stamps from established certifying bodies.

# Introduction: India's Beleaguered Healthcare Changing Disease Burden in India Infrastructure

istorically, healthcare set-ups were always admired for their commitment and expertise to provide their patient with a new lease of life! From a simple fever to complex surgeries and medical miracles, people from different parts of the world have traveled to India to benefit from the quality services and a comparative cost advantage. India may be a global tourism hub, with a growth rate expected to touch an astounding \$8 billion by 2020.1 However, access to safe and quality healthcare eludes a vast majority of the population.<sup>2</sup> Adding further woe is the dismal expenditure for the sector. Consider this:

- India has one bed for every 1,050 patients as compared to the US, which has one bed for every 350 patients.
- India's ratio of 0.7 doctors and 1.5 nurses per 1,000 people is much lower than the WHO average of 2.5 doctors and nurses per 1,000 people.
- To combat this poor doctor-patient ratio, India needs to add 1.54 million doctors and 2.4 million nurses to match the global average.3

Over the past few years, there has been a palpable transition from infectious to non-communicable diseases (NCD) in the country, owing to change in dietary patterns, economic growth and greater life expectancy. While NCDs remove the threat of immediate mortality, they call for an urgent need to ramp up healthcare technology and innovation to prevent adverse outcomes. For instance, WHO's health profile for India (2014) points out that 53 percent of deaths in the country are on account of non-communicable diseases (NCD), with diabetes and cardiovascular diseases taking the lead.4 One in four Indians risks dying from an NCD before they reach the age of 70, the report states. Further, diabetes is engulfing the nation at an alarming rate - 65.1 million people are suffering from the disease in the country, compared to 50.8 million in 2010. By 2030, 100 million people are expected to be diabetic.5

### India – The Healthcare Technology Paradox

To combat the paucity of traditional health

¹http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/indian-medical-tourism-industryto-touch-8-billion-by-2020-grant-thornton/articleshow/49615898.cms.

<sup>&</sup>lt;sup>2</sup>https://www.infosys.com/consulting/insights/Documents/indian-medical-device-industry.pdf.

<sup>3</sup>https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015health-care-outlook-india.pdf.

<sup>4</sup>http://www.who.int/nmh/countries/ind en.pdf?ua=1.

<sup>&</sup>lt;sup>5</sup>http://globalhealthaging.org/2015/07/24/india-is-diabetes-capital-of-the-world/.

infrastructure, e-health, m-health and home healthcare services brought about pioneering changes in healthcare delivery for the rural and inaccessible area.<sup>6</sup> With increasing corporatization and FDI inflows in private healthcare, state of the art treatment is becoming increasingly available to metros, tier 1 and tier 2 cities.<sup>7</sup>

This brings to the front an important aspect of healthcare delivery – the use of medical devices, ranging from humble objects like gloves and syringes to complex tools like implants, ventilators and scanning technologies. The medical device sector reveals a deep-seated, but interesting paradox in India's healthcare system – while the country boasts of being the manufacturing capital of the world for pharmaceuticals, 75% of the medical devices are imported from countries like China, with nearly 30% coming from the United States alone.<sup>8</sup> Most of these devices rampantly used are either substandard, un-calibrated and continue to compromise patient safety!

These revelations imply that it takes just one faulty/substandard medical device to play havoc in our lives. When we approach our healthcare provider, we blatantly overlook what goes on behind the scene - have we ever noticed what kind of medical equipment or invasive devices are being used to cure our ailment? Is it safe and hygienic and absolutely necessary for use? Does it have a regulatory stamp of approval? Is it calibrated correctly? The steep costs of importing these devices are ultimately passed on to the consumer, making access to safe and quality healthcare unaffordable.

#### Medical Devices Market - Current Scenario

Despite its significant growth, the medical devices industry in India is still at a very nascent stage. In terms of market size, the total medical device consumption in the country at present is to the tune of \$ 5.8 billion. When corresponded with the 1.2 billion plus population, the penetration of medical devices into healthcare sector is very minimal, especially in comparison to similar economies, such as China, Korea or Japan.

However, the medical devices sector in India is specifically focused on two aspects - penetration and affordability. Keeping this in view, there is a lot of innovation, in pockets, that is contributing to the growth of this sector. This is specifically in noncommunicable diseases space, where screening devices for point of care testing are being created for e.g. cardiovascular diseases, diabetes etc. The medical device industry in India is currently dominated by MNCs that manufacture and import products. There are also small and medium businesses, mainly dealing with disposables and implants and medical electronics. The third segment is that of the startup community.

# Challenges in the Med Tech Industry: Inadequate and Antiquated Regulations

Despite the promising emergence of multiple startups in the med tech industry that are targeting the domestic segment, India's regulations for medical devices are largely inadequate and antiquated. What's more, the entire sector is loosely governed with lack of strong regulations controlling the production, import or distribution of medical equipments and devices, encouraging the inflow of substandard devices entering the Indian market and harming the consumers. While the government's support through 'Make in India' campaign to help India reach the \$50 billion devices market by 2025 has laid the platform for the growth of the med-tech sector in India, it also puts a thrust on ensuring that they follow global best practices in manufacturing them. From performance testing and usability to non-clinical testing, the devices need to pass standards tests for evaluation before medical professionals can actually use them, which call for the role of third-party testing labs to test devices and products for a minimum quality level.

Currently, the medical devices industry is faced with an ambiguous regulatory framework, wherein medical devices are treated as drugs under the Drugs and Cosmetics Act. As a result, the distinctive identity for medical devices has been absent for long. Earlier this year, a newborn and a three-month-old were severely burned after a short

<sup>&</sup>lt;sup>6</sup>http://www.grameenfoundation.org/press-releases/nationwide-launch-mobile-health-program-rural-india-signals-new-era-mhealth-emerging.

<sup>&</sup>lt;sup>7</sup>http://www.ibef.org/industry/healthcare-india.aspx.

<sup>8</sup>https://www.infosys.com/consulting/insights/Documents/indian-medical-device-industry.pdf.

circuit sparked a blaze in a hospital nursery in Meerut.<sup>9</sup> Over the last few years, the country has been marred by such incidents, raising serious concerns about overall safety in hospitals and the safety and quality standards of medical equipments in particular in India. Sample this... Of the 700 device makers in India and more than 2000 devices sold locally, ranging from a pair of humble reading glasses and gloves to critical MRI machines and implants, only a dismal 22 of them are presently under any direct regulatory supervision by the Drug Controller General of India's office. India has become a dumping ground for many used and refurbished medical devices which are not calibrated to work in Indian conditions.<sup>10</sup>

# Safety Compliance, Standardisation & Third Party Certification is the Key!

India is slowly witnessing gradual change over the last 12-18 months, with a regulatory framework currently developed by the Ministry of Health & Family Welfare and CDSCO (Central Drugs Standard Control Organization). While this landmark move is definitely a welcome step to overhaul the regulatory system in the country, experts still feel that there are significant concerns to be addressed in the draft Medical Devices Rules 2016.<sup>11</sup>

Experts believe that following the highest safety standards is the only way to achieve accurate and consistent medical care outcomes. Standards fuel innovation rather than acting as a barrier (as commonly thought), by ensuring a framework / boundaries under which devices can operate. "Can you imagine the impact if there were no standards on the performance requirement of a pacemaker"? Even though India is at the cusp of a quality revolution of sorts, we still have some catching up to do in terms of the conformity assessment framework. In a growingly complex, competitive economic landscape, the need to align people, processes and technology is stronger than ever. In order to compete globally, India needs to develop a

culture of product safety and standards.

Safety is omnipresent and intrinsic to the entire healthcare delivery spectrum and the entire medical fraternity must move towards industry equilibrium. Medical devices are crucially linked to the growing demands of the healthcare chain which need a strong regulatory framework. This also means sourcing the right kind of equipment and devices from the right vendors and checking them for regulatory approval stamps from established certifying bodies. From safety, performance testing and usability to non- clinical testing, any medical device requires to be compliant to standards tests for evaluation before medical professionals can actually use them, which call for the role of third party conformity assessment bodies, testing labs to test devices and products to ensure safety and quality is maintained. What India needs is a set of gold standards in the medical devices industry while strengthening the basic device testing infrastructure.

# Conclusion – Standards Not a Market Barrier, But a Quality Enhancer

For the country to be in the highest pinnacle of world standards, quality cannot be compromised. Whether it is creating a safe environment for us to live, or dream big with Smart Cities and Make in India Campaigns, our country is marching towards ambitious plans of becoming a hub for global arbitration, reviving the manufacturing sector and strengthening services sector, to name a few. For any of these to become a success, the key is the need to adopt national and international standards while creating a framework for regulations and compliance. However, India has historically struggled to develop a holistic system of standards and regulatory framework. With plenty of legislations in place to drive quality, the challenge has always been enforcement and until such time non-compliant devices continues to creep into the Healthcare delivery system, keeping end users guessing when the next patient safety disaster will happen.

<sup>9</sup>http://timesofindia.indiatimes.com/city/meerut/Fire-in-nursing-homes-incubator-one-infant-dead/articleshow/48794392.cms.

<sup>&</sup>lt;sup>10</sup>http://timesofindia.indiatimes.com/india/First-worlds-discarded-medical-devices-flood-Indian-markets/articleshow/46696235.cms.

<sup>&</sup>lt;sup>11</sup>https://in.news.yahoo.com/indian-medical-device-industry-seeks-governments-attention-upcoming-102342865. html.



#### **GST** and Indian Healthcare

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GST long awaited game changer is now about to become a reality for Indian economy. Talking about the world's second largest population and huge health care market, the GST is going to make or mar the industry. With positive move of One Indian One Tax, the rates and procedure is going to ultimately decide the result of GST.

## **Introduction to Indian Taxation System**

The Indian Taxation system is one of its own types in the world with numerous taxes and complex compliance system. And perhaps very few in the country actually understand the complete taxation system. While the entity has to collect and pay huge amount of taxes, what is more difficult is the compliance system of the country. The continuous efforts of various government for years has been to make the system simple and industry friendly has ultimately resulted in implementation of GST.

### **GST History**

It all started with establishment of empowered committee headed by Asim Dasgupta in the year 2000 by the Vajpayee Government. The UPA1 and UPA2 government took it forward and finally after a very long time in 2016 again NDA government is going to implement the same.

## **General Expectation from GST**

While manufacturers are quite optimistic about the new tax law, commoners are not sure how it is going to impact their lives as yet. The expectation form GST is to simplify and streamline the tax structure in India.

The industry in general feels that this is a milestone for Indian economic development and will provide a huge fillip to manufacturing. This step is also expected to accelerate prime minister's 'Make in India' initiative and lower prices for the consumers. The immediate impact of GST may also increase the cost of finished products in some sectors, however

in the long term this would prove beneficial to the industry and consumers, and augur well for our overall economic development.

### **Indian Healthcare Industry**

The emerging economy of India is one of the largest producers of generics, and also experiencing a boom in medical tourism which generates additional returns for the healthcare industry. Globally India's pharmaceutical industry currently is ranking in the top 5 in terms of volume and top 15 in terms of value. To provide the required healthcare facility to the growing population of the country, the government has raised the FDI cap for Brownfield Pharmaceutical investments to 74% in June. Eventually, 100% FDI is allowed in Greenfield Pharmaceutical investments and beyond 74% under government approval in Brownfield Pharmaceutical investments. This step is expected to develop more qualified personnel and provide state-of-the-art facilities and technologies to patients.

Though the rates of GST are recently notified and item wise list is pending, it is expected to have a positive effect on the pharmaceutical sector in an overall sense. The GST is expected to simplify the tax structure, since eight different taxes are levied at state, central and municipal level in the pharmaceutical industry at the moment. GST, by consolidating all these into one tax would increase the ease of doing business, as well as mitigate the cascading effects of multiple taxes applied on one product. Apart from this, GST will also result in operational efficiency by streamlining the supply chain which can alone add 2% to India's pharmaceutical market size.

The pharmaceutical companies need to move to a hub-and-spoke model with primary and secondary hubs across states, besides overhauling the process of the companies used to select their warehousing network with cities like Chandigarh, Lucknow, Guwahati, and Nagpur emerging as primary hubs in addition to the metros.

GST implementation will also envisage a seamless flow of tax credit, account for improvement in overall compliance and is also expected to create a level-playing field for pharmaceutical companies in India. A big advantage for companies will be the reduction in transaction costs with the discontinuance of Central Sales Tax (CST). GST is expected to bring down the manufacturing cost and even a 2% reduction in production or distribution cost is believed to add over 20% to profits. GST, if its rate is below the current total tax rate, will eventually help consumers by making healthcare and drugs more affordable which already is a big goal for the Indian Government.

Although, the new tax legislation is believed to bring down the manufacturing cost, it cannot be said with certainty as to how the ultimate consumer will be benefited through this as most of the medicines are available at the MRP which is inclusive of the taxes, how is the end consumer going to benefit from that? It will be ultimately the industry's call whether to share their profit margin with their customers or not.

India's healthcare industry is worried that the implementation of the goods and services tax (GST) may lead to higher taxes that could erode its profits, even as it hopes that the new regime will help streamline the supply chain. GST will help companies rationalize their supply chain. However, if the overall tax cost goes up above 12% there won't be any savings as such.

GST, once implemented, would put various sectors under the purview of service tax. The list of exempted services presently includes healthcare sector and it is expected to continue after the GST regime at least for initial period until basic cost of healthcare sector becomes affordable to the common man of the country. It is believed that levying service tax on healthcare services and facilities will be a retrograde step and will certainly push back the agenda to provide best in class healthcare.

Overall, the effects of GST implementation on the healthcare and pharmaceutical sector are still uncertain. However, industry experts believe that GST will set industry players and consumers in a win-win situation. In case the tax rate is set at an efficient level, the healthcare industry will benefit as GST certainly reduces complexities and removes many hurdles to the industry's growth. The industry is on a path of promising growth and increased productivity.



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# Bringing Diverse Set of Stakeholders Makes the Market Ready for R&D!

**Eva Makienko**, the Director of the Centre of Excellence in Health Promotion and Rehabilitation, introduces the studies conducted and applied solutions developed at the Centre located in Estonia, Europe.

The IC magazine team interacted with the Centre of Excellence in Health Promotion and Rehabilitation in Estonia. Below are some excerpts from the interaction.

# Can You Share a Bit About the Objective of Your Centre?

The mission of the Centre of Excellence in Health Promotion and Rehabilitation, located in Estonia, Europe, is preserving and restoring the working capacity of the working-age population through research and development in the fields of curative mud treatment as well as mobility and operational capacity.

# **International Cooperation**

The Centre of Excellence in Health Promotion and Rehabilitation was founded in Estonia, in 2011 on the basis of Tallinn University Haapsalu College. Its formation was supported by the regional preconditions of development in the fields of mobility and operational capacity (Haapsalu Neurological Rehabilitation Centre. University Haapsalu College) and curative mud treatment (curative mud mining, traditions of mud treatment, spas in Estonia), which had the potential for international export. The partners of the Centre include organisations from the public and private sectors as well as universities (e.g. Tallinn University, University of Tartu, Tartu University Hospital, Haapsalu Neurological Rehabilitation Centre, Estonian Spa Association, spas, the municipality of Haapsalu).

Haapsalu Neurological Rehabilitation Centre (founded in 1958), a partner of the Centre of Excellence, offers high-level modern and evidence-based rehabilitation services that is founded on teamwork and participates in health studies. Altogether the hospital has a staff of 130 (doctors, nurses, physiotherapists, occupational therapists,

speech therapists, psychologists, and social workers).

In the field of mobility and operational capacity the Centre develops cooperation with rehabilitation specialists from Europe and all over the world (cooperation partners thus far include for example Shriners Hospitals for Children Greenville South Carolina USA, Karolinska Institutet, Uppsala Universitet, Lunds Universitet, Sahlgrenska Academy at the Göteborg University Sweden, University of Nijmegen Holland).

In the field of curative mud treatment, international cooperation has been developed with, for example, the Baltic and North Sea Rehabilitation Association (Prof. Aivars Vetra from Riga University, Prof. Cristoph Gutenbrunneri from Hannover University); Prof. Elena Ilieva from Plovdiv University, General Secretary of the European Society of Physical and Rehabilitation Medicine; European Society of Physical and Rehabilitation Medicine, the leader of the Balneology group Prof. Pedro Cantista from Portugal; Prof. Jose Maria Carbajo (Instituto Nacional de Investigation of Madrid).

In addition, the Centre of Excellence in Health Promotion and Rehabilitation participates in international cooperation through its networks of partners connected to the Centre's focus areas (such as the clusters Connected Health, SportEst, etc).

# Laboratories of the Centre of Excellence in Health Promotion and Rehabilitation

The Centre's research and development activities are conducted in its four laboratories: Mud Product

Development, Health Promotion and Product Design Laboratories that are located in the same building with Tallinn University Haapsalu College and the Medical Rehabilitation Laboratory, equipped with excellent European-level high-technology equipment, in Haapsalu Neurological Rehabilitation Centre.

The Centre's research and development in the field of curative mud treatment and the field of mobility and operational capacity are conducted mainly in the aforementioned four laboratories. In the period of 2012-2015 the Centre conducted 14 studies, based on which useful, applied product conceptions and solutions are created to further improve health products and services.

# Research in the Field of Curative Mud Treatment, Useful Solutions

In 2012-2015 the Centre's curative mud experts took samples from all of the five official mud deposits in Estonia and analysed them with an XRF device. The proportion of mineral and organic matter in the samples was determined. Altogether the database contains the data from the analyses of 145 samples, which have been thermogravimetrically analysed and whose content of organics, minerals and carbonates has been determined. In addition, 24 main chemical elements (Si, Al, K, Ca, Mg, Fe, Mn, Zr, Ti, Ba, Th, Nb, Sr, V), potentially toxic heavy metals (Pb, Ni, Zn, Cu, Cr, Cd) and non-metals (P, S, Br, Cl) have been determined.

As a result of the Centre's organic and biochemical studies in the field of curative mud treatment, it has been ascertained that Estonian curative mud contains biologically active substances that cause its therapeutic effect and that Estonian curative mud does not contain substances harmful to the human body. The research results of the Centre in the field of curative mud treatment are an output for further product development and further application in medicine, pharmaceutical and cosmetic industry, etc.

From April 2013 to September 2014 over 150 industrial workers of Lääne County with work-related shoulder and arm overstrain were tested during the study "Assessing the curative effect of Haapsalu curative mud in the treatment of work-related musculoskeletal overload diseases and/or

syndromes of working age population in developing new curative mud products/services". The effects of general and local mud treatment as well as heat therapy were studied. In 10 procedures, patients with light to moderate musculoskeletal pain experienced a statistically significant improvement in blood circulation, proved by Laser Doppler. In addition, they experienced decrease in muscle strain, measured by a myotonometer. On the basis of the clinical studies conducted by the Centre of Excellence in Health Promotion and Rehabilitation, it can be said that balneological treatment, including mud treatment, is effective in the complex of early treatment of workers with overload pain.

These results show that spa treatment, including mud treatment, is suitable for working age patients with joint and muscle pain. In cooperation with occupational health specialists "Guide for mud treatment, heat therapy and hydrotherapy for work-related shoulder and arm overload syndrome" was completed.

In the second quarter of 2014 similar studies were conducted to explore the effect of Estonian lake mud on the analysis group with an early overload syndrome, with the aim of preventing the development of overload disorder. According to the study, treatment schemes combined with general procedures were more effective for alleviating back and wrist pains. Treatment schemes that contained mud worked best for the elbow, and treatment schemes with mineral water or local heat therapy proved most effective for the shoulder. Neck pain reacted well to all combinations of heat therapy. In summary, spa treatment was effective as a combined treatment as well as local heat therapy.

From December 2012 to April 2014 a study of the quality of life following a six-day spa treatment was conducted in four Estonian spas with the aim of analysing the effects of a six-day spa treatment on the quality of life of patients with osteoarthritis of the knee at the end of their treatment and up to six months following the treatment. All the patients with the osteoarthritis of the knee whose health permitted the use of integrated treatment and who wished to participate, became study subjects in the order of their arrival. Altogether 374 people participated in the study. Treatment results between different mud treatment packages were assessed, based on the changes in clinical

indicators. No statistically real difference can be seen between the mud treatment packages; thus, both mud treatment packages are suitable and there is no clear preference. In case of the mud treatment package that used a combination of mineral water and mud baths, the treatment effect could be observed later than in the case of using only curative mud, but the effects lasted longer.

Based on the studies of the Centre of Excellence in Health Promotion and Rehabilitation, we can claim that biologically active substances found in Estonian curative mud form an important foundation of the therapeutic effect in such cases as musculoskeletal overload diseases or syndromes.

Also, Estonian curative mud is suitable for product development in pharmacy and cosmetics. In cooperation with a pharmaceutical plant, the Centre has developed a massage cream that contains humid substances from the curative mud of Haapsalu. In the Centre's Health Promotion Laboratory, we have tested both the curative mud massage cream as well as a mixture of mud and disintegrator-ground peat for vacuum massage, to introduce a new spa service.

In the field of curative mud treatment the Centre of Excellence in Health Promotion and Rehabilitation holds the patent "Therapeutic mud mixture and a method for its manufacture" (patent application number P201500002, letters patent number EE 05778 B1) and the patent "Electrical mud therapy device for limbs" (patent application number P201400009, letter patent number EE 05772 B1) - this is a patent for a mud therapy device for hands. The Centre's Mud Products Development Laboratory has developed a solution that enables the transport of Estonian curative mud in a dried and disintegrator-ground form.

# Can You Elaborate About the Research That is Taking Place at the Centre and its Facilities?

The Centre's equipment, which contains a gait robot for children and adults, a robot-tilt table, an arm robot, a whole-body isokinetic dynamometer and stress test devices, is unique throughout Europe and enables the implementation of the Centre's rehabilitation projects, and better planning of services and treatment results.

In 2012-2015 the following studies, which mainly supported entrepreneurship in rehabilitation, were conducted in the Rehabilitation Laboratory:

- The effectiveness of early rehabilitation (up to 1.5 years after the trauma) in achieving independence in patients with spinal cord injuries
- Rehabilitation, directing to active participation in the labour market and avoiding late complications in patients who have sustained spinal cord injuries over 1.5 years ago
- Improving the mobility and operational capacity of a stroke patient and a patient with traumatic brain injury
- Improving early rehabilitation and developmental treatment of children with neurological damage by introducing innovative treatment methodologies
- A health promotion study of school children aged 6 18 in early diagnostics of mobility and operational capacity (preventative action in the formation of working-age population)
- A study of the effects and applicability of vibroacoustic therapy in the rehabilitation of brain and spinal cord injuries

In addition, studies of posture problems and osteoporosis have been conducted in the Centre's health laboratory.

The results of the studies conducted in the laboratories of mobility and operational capacity support new, innovative treatment methods in rehabilitation and developing assisting equipment that supports independent living through improving mobility and operational capacity and integrating disabled people into the labour market. The results of the studies are directed mainly at supporting the health promotion and preventative development activities of the Centre.

The vibroacoustic bed is an example of the applied solutions in the field of mobility and operational capacity. The bed, which is based on vibroacoustic therapy (VAT), was developed by a team of specialists of the Centre's laboratories. The device for vibroacoustic therapy (VAT) or vibroacoustic bed, designed by the experts of the Centre's Design Laboratory, has been confirmed as an industrial design solution (Community design Register, no 003004332-0001); in addition, software for the bed

has been created.

The VAT device has an innovative ergonomic design, making it comfortable for the user as well as the person conducting the procedure. It is mobile, easily maintained, and aesthetically compatible with different environments. Potential end-users of the device include producers of medical and wellness products. The vibroacoustic bed is produced in Estonia under a licence agreement by the enterprise SMARTdo OÜ. The bed was presented at

the International VIBRAC Conference in Finland in October 2016.¹

In order to conduct research and development and implement useful solutions in curative mud treatment, mobility and operational capacity, the Centre of Excellence in Health Promotion and Rehabilitation is interested in international cooperation with entrepreneurs as well as universities.



Priit Aigro, a representative of SMARTdo, and Ivar Vinkel, an expert of the Centre of Excellence, introducing the VAT-bed. Photo: Piret Räni



## Health Promotion within WHO Healthy Cities in the Baltic Sea Region

**Johanna Reiman** is M.Sc. (Agriculture), M.Sc. (Economics), and has 28 years working experience in health and wellbeing. She has organized tons of international conferences and seminars, promoted multi-stakeholder programmes and projects and promoted ideas to innovations.

There are challenges in taking health as a core of the planning process in the cities. Lack of clear responsibilities in part of the municipalities, weak leadership for health, and missing procedures are only a few examples. This results in insufficient budget allocations. Economic challenges continuously overweigh health in decision—making, even if choosing correct actions could bring considerable savings. It is essential that the municipality or region knows the health situation in the respected area and has the resources and skills to analyse impacts of major policies from the health perspective. Political will and legal backing are also important in bringing cross-sectoral health promotion into practice.

ealth promotion work needs innovations on the local level. Healthy Cities is a programme which encourages cities and municipalities for cross-sectoral work. Health and wellbeing should be put high on the agenda of the cities. Structures are needed to ensure the sustainability of the work. This means that all city functions must take health promotion into account. Education, transport, urban planning, culture and youth services should take residents' health to their plans. It is advisable to build a cross-sectoral health and wellbeing board which follows the plans and activities. Healthy Cities is about involving all sectors.

Healthy Cities work in phases and the themes vary. Phase VI (2014-2018) themes are linked to European Health 2020 strategy. Thus, the topics are 1) improving health for all and reducing health inequities; and 2) improving leadership and participatory governance for health.

All in all, the health promotion work is connected to urban health. Urbanization is a trend all over the world. People move to cities as there are most of the jobs. Cities also have a wide variety of culture and possibilities for various types of housing. City life may – despite its benefits - bring aspects which are harmful to life. Loneliness, sedative lifestyle, pollution and lack of social belonging are serious problems which affect people's lives. Cities should find innovative solutions to the challenges their people face over the life course.

### **European Health Challenges**

Europe is facing big changes which affect the health of the population. Societies are ageing rapidly. Unemployment is a problem of young people and affects also persons in middle age and older. Migration changes the services needed. Urbanization means that planning becomes more challenging for cities. Ensuring the wellbeing of the population requires an open mind and readiness for cooperation. Municipalities have to start to combat the challenged together with companies and non-governmental organisations. World Health Organization is willing to help cities plan their work for the health of the residents. In Healthy Cities programme open local innovations are shared among the network members.

Western lifestyle is a threat to the society. The health data show that non-communicable diseases (NCDs) cause the biggest disease burden in all European countries. Illnesses such as diabetes, cancer, and cardiovascular diseases account for an ever larger share of fatal illnesses. This challenge is being faced by other parts of the world also.

In the Baltic Sea Region countries, non-communicable diseases cause about 80 % of deaths. These diseases are preventable and can be avoided by the modification of unhealthy lifestyles, e.g. healthy habits. Diets containing more vegetables, adequate physical activity and

the avoidance of smoking should all be adopted. The national governments recognize this necessity in their health programmes and strategies. How they are implemented depends on the capacity of the municipalities, their politicians, public health administrators and methods of working. Healthy Cities programme states that unifying the efforts of different sectors and making health promotion not only effective otherwise but also cost-effective.

### WHO Healthy Cities – How Did it Start?

For decades, United Nations organisations have traditionally worked with ministries and nations. Healthy Cities began as a World Health Organization project in 1987. It has over the years become a movement with very committed cities. The network has an annual business and technical conference and also runs several sub-networks. The WHO Healthy Cities programme has promoted cross-sectoral well-being effort as well as comprehensive and systematic policies and planning for health. The Healthy Cities movement is present in more than 30 European countries and over 1400 cities and regions.

Baltic Region Healthy Cities Association has served as a World Health Organization Collaboration Centre for Healthy Cities and Urban Health in the Baltic Region since 2002. The Association assists cities in implementing Healthy Cities' goals and to build capacity for health and well-being. Furthermore, the Association is involved in health promotion projects, many of which concentrate on promoting cross-sectoral planning for health. The members of Baltic Region Healthy Cities Association include the City of Turku, University of Turku, Åbo Akademi University and the Social Insurance Institute of Finland. Baltic Region Healthy Cities Association - based in Turku, Finland - aims at increasing the awareness of local governments in adopting health as a central part of the decision-making process in municipalities.

Health inequities mean that differences in societies grow. In Europe, many people are doing well and live healthy and long lives. However, there are people whose health conditions are bad and they may be outside the society with no education. Despite several years of efforts to combat the inequities,

the divide is only growing.

#### **Coordinated Action is Needed**

Social and welfare costs remain to account for a very large share of both national and local budgets in all countries surrounding the Baltic Sea. Promotion of health and well-being requires coordinated action from all sectors of the society at national, regional and local level. It has been confirmed that investment in health promotion is cost-effective and that the best results are obtained if all sectors work together, taking into account the effects of policies on well-being. This means that, for example, education, economic and cultural sectors can strongly promote health. Also, traffic and environmental departments should enhance human well-being.

There are challenges in taking health as a core of the planning process in the cities. Lack of clear responsibilities in part of the municipalities, weak leadership for health, and missing procedures are only a few examples. This results in insufficient budget allocations. Economic challenges continuously overweigh health in decisionmaking, even if choosing correct actions could bring considerable savings. It is essential that the municipality or region knows the health situation in the respected area and has the resources and skills to analyse impacts of major policies from the health perspective. Political will and legal backing are also important in bringing cross-sectoral health promotion into practice.

Baltic Region Healthy Cities Association has accomplished numerous local health promotion projects. Recent themes in the projects include promoting volunteering of elderly people and thus making them participate in the society and find meaningful daily activities (www.letusbeactive. eu). Promoting children's healthy habits is a theme of a project where the other partners are University of Turku, University of Tallinn Rakvere College and City of Jurmala in Latvia. One theme where the Association has been active is health literacy. It has been found that many Europeans lack understanding of health information. Health and welfare experts should pay special attention to understandable health information and ensure that

guidance given is understood.

The World Health Organization definition of health says that "Health is a state of complete physical,

mental and social well-being and not merely the absence of disease or infirmity." The challenge remains around the Baltic Sea and the rest of Europe to ensure health for all.

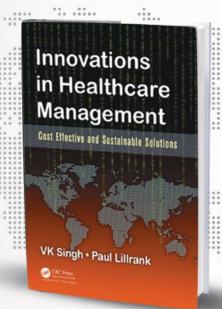
# INNOVATIONS IN HEALTHCARE MANAGMENT

Cost-Effective and Sustainable Solutions authored by **Dr. V.K Singh** & **Paul Lillrank**, 2015 published by CRC Press, Taylor & Francis group, USA.

Book is available as eBook, eBook rental, Kindle version and print form with publisher.

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The review was Published by ICT Post, read here: http://bit.ly/2fUQP1V





### Digital Healthcare in India on the Verge of its Eureka Moment

**Nipun** is the Co-founder and Director of Curofy, where he leads the medical team, handles investor & media relations and oversees overall business strategy. He is a graduate from IIT Delhi. He entered the healthcare industry in college, when he started a medical tourism company and after working for few months in the sector, he saw the bigger problem of inefficient digital health communication, which led to Curofy. He is passionate about making digital health communication easier and more organised and likes to interact with various healthcare stakeholders.

Productisation is the new age equivalent of globalization. It promises to ease the daily struggles and lead us to a world of prosperity and unparalleled consumer first consumer driven services. Though ages behind in the digital race, healthcare in the country and the world is slowly but surely on the move. With big players like Apple, Samsung, Nike all into solving the healthcare puzzle, innovators are taking digital health seriously. The Facebooks of the world has taught us that the entire marketing can locked within the realms of a few buttons. And an ROI driven data backed healthcare industry of the future needs to follow suit.

he world today is going through a transformation. The extent can even be compared to globalisation when the entire world inherited the concept of global citizens. And the so-called lesserdeveloped countries got a taste of what is to be a part of a developed world. Pessimists may call it the advent of neo capitalism but most of us are realists. And even after the accounting for the negatives, it did more good than evil. It opened the world to the exchange of ideas and knowledge. Today we are going through another phase called Productisation; a transformation that believes in outdoing all inefficiencies and building products to ease our daily struggles. Yes, we are still at a stage where we can call them baby steps, yet one cannot ignore is palpable presence.

The world is changing. And in a big way. The digital product revolution, in a way has revolutionised the way we go about our daily business. We don't catch up with our friends in a coffee shop, we Whatsapp them. We don't stand on a walkway waiting for the next cab to arrive, we book an Uber. We don't shop in at a mall, we get it from amazon. You name an aspect of life and productisation has left its mark one way or the other. Beyond the realms of individual life, industries are being defined by their adoption of technology. The Ubers, Amazons, the Airbnbs of the world have truly disrupted industries and have made lives of the people infinitely better. It is a better world we live in today. The promise is immense.

Healthcare however has been lagging behind for long now. They have not yet embraced the fast paced change the world is going through today. It almost feels paradoxical to think that the talks of a grand digital revolution often forget to mention the most important aspect of life itself, healthcare. I have always believed healthcare is and will always be the yardstick of development and hence true innovation in a country. And with the ethnic, geographical, linguistic diversity in India, it will take a lot more to turn it around. Good news! The transformation is well underway.

It would be wrong to tag the healthcare industry as tech laggards. The reality is quite the opposite. Their Internet adventures can be dated back to 1996. 24X7 rep visit was an initiative that was aimed at reduction of sales force with one size fits all branded website. However, that failed. Sites like WebMD does indicate that the intent was always there, but the doctors, the focal point of the healthcare ecosystem never went digital. And hence the entire industry was branded as a late adopter.

Where does the problem lie? Well on the surface we can put the blame on the industry that has an acute aversion towards technology. We can also blame the doctors for being among the tech laggards. But if nothing works out, we can always blame the government for the lacklustre infrastructure. However, the problem is even more deep-rooted and basic. Let's take the doctor's perspective first

since they are focal point of the industry. The doctor to patient ratio is 1700:1. In remote villages it is as acute as 60,000:1. Hence luxury products take a backseat. There is a continuous need easing their life. For making him/ more efficient. And it is the very primal need that needs to be fixed to make the entire industry tick. And, Yes the healthcare industry also needs a digital makeover. Though they have the resources to sustain conventional efforts, digital will undoubtedly help their influence percolate to the nooks and corners of the country. It also opens up a new medium for them to engage with their end users and increase the efficiency of its workforce by manifolds.

#### Where Do We Stand Today?

Well pretty much at the crossroads. From digital healthcare giants like DXY, M3Inc to relative newbies like Figure 1 (Figure 1 is a company name), Doximity, ZocDoc, HealthTap to tech giants like Google, Apple, Microsoft are all solving specific parts of the puzzle. With the start up wave gushing into India, start-ups like Practo, 1mg, Lybrate, Curofy, Portea are solving problems specific to our country. Today almost all the stakeholders are willing to give digital a try. This is evident from their Facebook campaigns; pilots we have been receiving from almost all major brands. We can safely say that the e-commerce and the social media bug have certainly bit the healthcare industry. But here in lies the susceptibility of the situation. The industry is now impending towards digital. But they are merely strolling. Its companies like us that need to get them going. Get them running. The advantages are obvious. Yet these initial days are crucial. Because only the success of these initial phases can determine how quickly the healthcare industry is coming online.

It is also heartening to see doctors slowly but surely embracing the online world. Facebook, LinkedIn, Figure 1, Curofy - all have played a pivotal role in it.

With numbers soaring to all time high the onus is on companies like us to make their time worthwhile. That's the first and perhaps the most important challenge. If that is overcome, everything else will follow a chain reaction.

With doctors slowly but surely waking up and taking notice of digital platforms, it only makes sense for the entire healthcare industry to move digital as well. And the possibilities are immense. Digital makes the inaccessible accessible. Let's take Facebook for example. It's not a social network, it is the social network. It has not only redefined the way we interact today, but also we think about various products. Yes, it is a marketing platform like no other. It has absorbed the entire marketing world in 10-12 buttons. All the marketing in the world fits in with in the realms of these few buttons. Hence the question remains whether the entire healthcare industry and its marketing fall under the realms of these few buttons?

The answer is a resounding yes. From market research to brand recall to brand building to e-detailing, every function can be moulded in the form of buttons. Think scientific content or detailing and you get read more. As I said the possibilities are infinite. With mushrooming of niche networks like Doximity, Sermo, Curofy and Figure 1, and doctors taking a liking towards it, the time is right for the healthcare giants to embrace the digital makeover. Healthcare industry needs to take a ROI driven approach to penetrate deep in the markets. And with regulations taking its toll, going digital will go a long way in reducing the burden on these companies. And who knows it might turn out to be the ultimate marketing avenue for them. Today digital marketing is merely an extension to orthodox methods and makes up for 1-5% of their marketing budget. With time this will increase. The digital healthcare in India is on the verge of its eureka moment. If we play our cards right, this is surely possible.



# **Evolution of Glucose Monitoring: From Glucose Monitors to the Ambulatory Glucose**

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**Gopika Krishnan**, B Pharm, MSc, and Academic Head at Jothydev's Diabetes Research Centre, Trivandrum, Kerala, India

Glucose Monitoring has been around as a valuable tool since many years. However in spite of many advances, there have been important shortcomings of the current tools we have. The HbA1c is a highly validated and researched tool however, it only provides an 90 day retrospective average of a patients glucose and gives no major in-depth analysis of their glucose profile. One can use the self-monitoring tools and lab test to obtain their glucose profile but testing strip costs and finger stick blood pricks and pain limits their usability in patients. It is widely known that continuous glucose monitoring systems (CGMS) provide the best data for analysis, but its duration is too short or too cumbersome and costly for use in routine practice. In this regards the new tool, FreeStyle Libre Pro and its software reports that provide the Ambulatory Glucose Profile (AGP) is easy to use, and provides the complete glucose profile of a patient so that a doctor can make informed treatment decisions. It is an exciting time for Diabetes, with many new innovations in the pipeline that can ease the hurdles associated with proper monitoring.

#### Introduction

onitoring glucose values at specified time intervals, based on need is a prerequisite to ensure success atany stage or type of diabetes. There is sufficient evidence to support the fact that increased frequency of blood glucose monitoring, significantly improves glycemic control, which invariably translates to a reduction in the micro and macrovascular complications of diabetes.

Though glucometers became popular way back in 1980s, this technology has not been widely accepted in India so far; the major limitation being the cost involved in the procurement of glucometer and strips and the concerns on inaccuracy of glucometer compared to laboratory values. Even among those who are willing and affordable to follow self-monitoring of blood glucose instructions, forgetfulness and laziness prevents them from regular monitoring. Ambulatory glucose profile (AGP) with flash monitoring systems is an innovation to overcome the hurdle.

The term, "AGP" dates back to 1987 when the data

from glucometers obtained over a period of 14 days were collapsed into a graphical depiction. Though the concept failed initially, AGP from self-monitored blood glucose (SMBG) data later evolved into techniques for measuring amplitude and frequency of change in the glycemic levels. Currently, the term AGP is popular for the collated 14 day graphical pattern generated from the revolutionary Abbott FreeStyle flash glucose monitoring system.

# History and Evolution of Home Blood Glucose Meters

The history of glucose monitoring can be traced to mediaeval times where attempts were made to identify various diseases by examining urine samples. Stanley Benedict devised an improved copper reagent for urine sugar in 1908 and this became, with modifications, the mainstay of urine monitoring of diabetes for over 50 years.<sup>1</sup>

Continued research at the Miles-Ames Laboratory was destined to be a key element in the history of blood glucose meters. The quest for a more convenient and specific method culminated in a 'dip

and read' urine reagent strip, Clinistix, in 1957.<sup>2</sup> In 1965, an Ames research team under Ernie Adams went on to develop the first blood glucose test strip, the Dextrostix, a paper reagent strip which used the glucose oxidase/peroxidase reaction.<sup>3</sup> Around the same time, the German company Boehringer Mannheim developed a competitive blood glucose strip, the Chemstrip bG. Limitations of these strips became the triggering factor to develop an automatic, electronic glucose test strip reader to improve precision and give more quantitative blood glucose results.<sup>4</sup>

This paved way forthe development of Ames Reflectance Meter (ARM; Figure 1) by Anton H.Clemens to produce quantitative blood glucose results with Dextrostix in the late 1960s, and the first model became available in 1970.<sup>5,6</sup> He used reflected light from the surface of the solid strip, which was captured by a photoelectric cell to produce a signal equivalent to blood glucose. The first reported patient to use blood glucose meter was Richard Bernstein, who suffered from type 1 diabetes and had episodes of hypoglycaemia resulting in hospitalisation.



Figure 1: Ames Reflectance Glucometer

A major advancement came with the introduction of the Lifescan (Johnson & Johnson) OneTouch II in 1992, a reflectance blood glucose system that eliminated the need to time accurately the application of blood to the test strip and its removal prior to the measurement of the colour.<sup>7</sup> The number of smaller, handheld glucometers

continued to increase and Bayer, Abbott and Roche purchased pioneer companies Ames, MediSense and Boehringer Mannheim, respectively, between 1995 and 1998.

Blood glucose monitoring was regarded as an integral part of intensive diabetes treatment and management after completion of both major

<sup>&</sup>lt;sup>2</sup>Free AH, Adams EC, Kercher ML, Free HM, Cook MH. Simple specific test for urine glucose. Clin Chem. 1957;3(3):163-168.

<sup>&</sup>lt;sup>3</sup>Kohn J. A rapid method of estimating blood-glucose ranges. Lancet. 1957;273(6986):119-121.

<sup>&</sup>lt;sup>4</sup>Cheeley RD, Joyce SM. A clinical comparison of the performance of four blood glucose reagent strips. Am J Emerg Med. 1990;8(1):11-15.

<sup>&</sup>lt;sup>5</sup>Cheah JS, Wong AF. A rapid and simple blood sugar determination using the Ames reflectance meter and Dextrostix system: a preliminary report. Singapore Med J. 197;15(1):51-52.

<sup>&</sup>lt;sup>6</sup>Mazzaferri EL, Skillman TG, Lanese RR, Keller MP. Use of test strips with colour meter to measure blood-glucose. Lancet. 1970;1(7642):331-333.

<sup>&</sup>lt;sup>7</sup>Strowig SM, Raskin P. Improved glycemic control in intensively treated type 1 diabetic patients using blood glucose meters with storage capability and computer-assisted analyses. Diabetes Care. 1998;21(10):1694-1698.

diabetes studies, the UK Prospective Diabetes Study (UKPDS)<sup>8</sup> and the Diabetes Control and Complications Trial (DCCT)<sup>9</sup> and American Diabetes Association (ADA) lowered the target variation to 5% between meters and the laboratory method leading to acceptance of SMBG as an integral part of self-management of patients with diabetes.<sup>10,11</sup>

Different types of glucometers are currently available in the Indian market. Newer models are more advanced in technology, providing better features yet come in lighter weight, smaller size and at more affordable prices.

There are three principle enzymatic reactions utilised by current glucometers: glucose oxidase, glucose dehydrogenase, and hexokinase. More complex meters have features to aid in identifying trends and to graph reports for more comprehensive data tracking, particularly for patients who test several times a day.

### **Use in Type 1 Diabetes & Type 2 Diabetes**

Since the introduction of glucose meters in the 1980s, SMBG has become the cornerstone of management in type 1 diabetes. Home blood glucose monitoring is associated with improved glycemic control in patients with type 1 diabetes. A database study of almost 27,000 children and adolescents with type 1 diabetes showed that, after adjustment for multiple confounders, increased daily frequency of SMBG was significantly associated with lower glycated haemoglobin (HbA1c) levels (20.2% per additional

test per day, levelling off at five tests per day) and with fewer acute complications. <sup>14</sup> Evidence suggest that a strict glycemic control reduces the risk of microvascular and macrovascular complications and in the UKPDS Study, each 1% reduction in HbA1c was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in risk for any end point or death related to diabetes. <sup>8</sup>

Home blood glucose monitoring is recommended in type 2 diabetes patients to gather information on the fluctuating blood glucose levels at several time points and to adjust the therapeutic regimen accordingly. Though to a limited extend, it also helps the patient to adjust the diet and exercise pattern in day to day life. SMBG have been proven useful in recognizing hyperglycemic and hypoglycemic episodes and helps the physician to individualise the treatment targets for patients who have frequent hypoglycemic episodes, diabetes which is brittle etc. Further, home blood glucose monitoring empowers the patient to be more conscious of his blood sugar fluctuations and its relation to timing of meals and snacks and physical activity. 15 The Indian consensus guideline on blood glucose monitoring recommends SMBG protocols to be individualised to address each individual's specific educational, behavioural, and clinical requirements and provider requirements to aid therapeutic decision making.<sup>16</sup>

Diabetes Tele Management System (DTMS®) is a system in which home blood glucose monitoring is combined with a decision support system provided by a multidisciplinary team of doctors,

<sup>8</sup>UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). The Lancet. 1998;352(9131):837-853.

<sup>9</sup>The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med. 1993;329(14):977-986.

<sup>10</sup>American Diabetes Association: clinical practice recommendations 1996. Diabetes Care. 1996;19 Suppl 1:S1–118.

<sup>11</sup>Clarke SF, Foster JR. A history of blood glucose meters and their role in self-monitoring of diabetes mellitus. Br J Biomed Sci. 2012;69(2):83-93.

<sup>12</sup>Tonyushkina K, Nichols JH. Glucose Meters: A Review of Technical Challenges to Obtaining Accurate Results. J Diabetes Sci Technol Online. 2009;3(4):971-980.

<sup>13</sup>Evans JMM, Newton RW, Ruta DA, MacDonald TM, Stevenson RJ, Morris AD. Frequency of blood glucose monitoring in relation to glycemic control: observational study with diabetes database. BMJ. 1999;319(7202):83-86.

<sup>14</sup>Ziegler R, Heidtmann B, Hilgard D, et al. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. Pediatr Diabetes. 2011;12(1):11-17.

<sup>15</sup>Benjamin EM. Self-Monitoring of Blood Glucose: The Basics. Clin Diabetes. 2002;20(1):45-47.

<sup>16</sup>Kesavadev J, Sadikot S, Wangnoo S, et al. Consensus guidelines for glycemic monitoring in type 1/type 2 & GDM. Diabetes Metab Syndr. 2014;8(3):187-195.

diabetes educators, dieticians, nurses, pharmacists, psychologist etc. based on a patient customised software. Our studies have shown the benefit of SMBG not only in type 1 diabetes but also in type 2 diabetes on various therapies including patients only on oral medications in maintaining customised glycemic targets and in modifying diet, exercise and drug dosages.<sup>17</sup>

### **Accuracy of Glucometers**

Glucometers find widespread use in hospitals, outpatient clinics, emergency rooms, ambulatory medical care and home self-monitoring. The universal availability and use of glucometers mandate certain level of confidence in the accuracy of glucometers. However, accuracy of test results can be affected by varied factors including environmental effects, patient condition, medication, and other metabolic factors. The accuracy of glucometers may be considered as technical and clinical. Technical accuracy refers to the analytical result agreement of a glucometer to a comparative laboratory method. Clinical accuracy compares the medical decisions based on the test results.<sup>12</sup>

A study evaluating the clinical significance of glucometer precision found that the analytical variability of a glucometer though only 5%, the clinical insulin doses varied in 8–23% of cases, depending on the glucose concentration when compared against dosage based on the laboratory result. A glucose meter total variability of 10% led to different insulin dosage in 16–45% of cases, and >10–15% led to a two-fold or greater discrepancy in insulin dosage. The study concluded that a glucose meter total precision of <1–2% was required to ensure similar insulin dosage compared to the laboratory methods >95% of the time. However, none of the current glucose meters available on

the market are capable of providing this level of precision.<sup>18</sup>

The ADA recommends glucometers to possess accuracy within  $\pm 15\%$  of the laboratory method at all concentrations, with a future performance goal of  $\pm 5\%$  agreement at all glucose concentration. However, there is no single standard to assess the accuracy of glucometers so far.

Evidence suggest that 91-97% of blood glucose errors is due to poor skill of the users like mechanical stress applied to the strips, failure to clean the site for testing, dirty meters, and sample issues like specimen clots, bubbles, and failure to apply an adequate amount of blood to the test.<sup>20</sup> ,<sup>21</sup> Calibration errors are also common for those meters which require calibration.

# **History & Evolution of Continuous Glucose Monitoring**

In the recent years, with advancements in technology, continuous glucose sensing has evolved as a useful tool to address insufficient glycemic management and to redefine the concept of SMBG in diabetes management. Continuous glucose monitoring (CGM) emerged as a research tool initially and later as an investigation to modify treatment to normalise glycemic excursions. Evolution of CGM can be traced back to the mid-1970s followed by the development of sensor technology and implantable glucose sensors in early 1980s. The first commercial CGM system known as CGMS Gold (CA, USA) came to market following the US Food and Drug Administration (FDA) approval in 1999. Several CGMS are presently on the market. They can broadly be divided into systems providing retrospective or real time information on glucose patterns.

<sup>&</sup>lt;sup>17</sup>Kesavadev J, Shankar A, Pillai PBS, Krishnan G, Jothydev S. Cost-effective use of telemedicine and self-monitoring of blood glucose via Diabetes Tele Management System (DTMS) to achieve target glycosylated hemoglobin values without serious symptomatic hypoglycemia in 1,000 subjects with type 2 diabetes mellitus--a retrospective study. Diabetes Technol Ther. 2012;14(9):772-776.

<sup>&</sup>lt;sup>18</sup>Boyd JC, Bruns DE. Quality specifications for glucose meters: assessment by simulation modeling of errors in insulin dose. Clin Chem. 2001;47(2):209-214.

<sup>&</sup>lt;sup>19</sup>American Diabetes Association. Self-monitoring of blood glucose. Diabetes Care. 1994;17(1):81-86.

<sup>&</sup>lt;sup>20</sup>Kristensen GBB, Nerhus K, Thue G, Sandberg S. Standardized evaluation of instruments for self-monitoring of blood glucose by patients and a technologist. Clin Chem. 2004;50(6):1068-1071.

<sup>&</sup>lt;sup>21</sup>Skeie S, Thue G, Nerhus K, Sandberg S. Instruments for self-monitoring of blood glucose: comparisons of testing quality achieved by patients and a technician. Clin Chem. 2002;48(7):994-1003.

A typical CGM system consists of a glucose oxidase-based, electrochemical sensor inserted through the skin using a needle introducer, a transmitter that is fixed onto the sensor and a receiver that picks up the interstitial fluid signal. The oxidation of interstitial glucose by the sensor generates an electrical current. The electrical current data are filtered and cleared from background noise by the transmitter and sent to the receiver, which provides an approximation of the blood glucose level. The glucose data can be obtained at every 5 minutes intervals.<sup>22</sup>

The sensor measures the interstitial fluid (IF) glucose where a lag of average 15 minutes is associated with the sensor glucose levels when compared to blood glucose levels due to the physiologic delay in transferring glucose between the blood and IF space (approximately 2–8 min), the transit time of IF glucose through the sensor membrane (1–2 min) and signal filtering (3–12 min). Due to this reason, CGM readings cannot be considered 100% accurate.<sup>23</sup>

The glucose sensor must be calibrated against corresponding blood glucose meter levels to ensure the continuous accuracy of sensor data. Such calibrations transform the sensor signals into matching capillary glucose levels and assumes that the plasma to IF glucose gradient remains relatively constant.<sup>24</sup> Recalibration at fixed intervals is required to overcome signal drift issue.<sup>25</sup> Calibration should

take place when blood glucose levels are relatively stable when the rate of change in sensor glucose values should be less than ±0.5 mg/dl/min.<sup>26,27</sup> Different CGM sensors available in the market include iPro2 Professional CGM, Guardian Real Time CGM system, Dexcom G4 Platinum etc.

## **Accuracy of CGM Sensors**

Though sensor accuracy have improved over the years, the accuracy of sensors available for use in patients show varied results across clinical trials. In a comparison between Dexcom G4 sensor and Enlite sensor (guardian real-time system), the mean absolute relative difference (MARD) in blood glucose for the Dexcom G4 was significantly lower (13.9%) than for the Enlite sensor (17.8%) (P<0.0001).<sup>28</sup> In yet another study, comparing the Navigator, G4 Platinum and Enlite, there was marked differences in both accuracy and precision and Navigator and G4 found to outperform the Enlite.<sup>29</sup> In a head to head comparison between DexcomG4 Platinum and Medtronic Paradigm Veo Enlite system at a clinical research centre (CRC) and in daily life conditions, overall MARD value standard deviation measured at the CRC was 13.6 (11.0)% for G4 Platinum and 16.6 (13.5)% for Veo Enlite system (P<0.0002). The overall MARD assessed at home was 12.2 (12.0)% for G4 Platinum and 19.9 (20.5)% for Veo Enlite system (P<0.0001).30 Interestingly both sensors showed lower accuracy in the hypoglycemic range which underscores the importance of supplementing CGM

<sup>&</sup>lt;sup>22</sup>Cengiz E, Sherr JL, Weinzimer SA, Tamborlane WV. New-generation diabetes management: Glucose sensor-augmented insulin pump therapy. Expert Rev Med Devices. 2011;8(4):449-458.

<sup>&</sup>lt;sup>23</sup>Cengiz E, Tamborlane WV. A Tale of Two Compartments: Interstitial Versus Blood Glucose Monitoring. Diabetes Technol Ther. 2009;11(S1):S11-S16.

<sup>&</sup>lt;sup>24</sup>Rebrin K, Steil GM. Can interstitial glucose assessment replace blood glucose measurements? Diabetes Technol Ther. 2000;2(3):461-472.

<sup>&</sup>lt;sup>25</sup>Koschinsky T, Heinemann L. Sensors for glucose monitoring: technical and clinical aspects. Diabetes Metab Res Rev. 2001;17(2):113-123.

<sup>&</sup>lt;sup>26</sup>Aye T, Block J, Buckingham B. Toward closing the loop: an update on insulin pumps and continuous glucose monitoring systems. Endocrinol Metab Clin North Am. 2010;39(3):609-624.

<sup>&</sup>lt;sup>27</sup>Wolpert HA. The nuts and bolts of achieving end points with real-time continuous glucose monitoring. Diabetes Care. 2008;31 Suppl 2:S146-S149.

<sup>&</sup>lt;sup>28</sup>Matuleviciene V, Joseph JI, Andelin M, et al. A clinical trial of the accuracy and treatment experience of the Dexcom G4 sensor (Dexcom G4 system) and Enlite sensor (guardian REAL-time system) tested simultaneously in ambulatory patients with type 1 diabetes. Diabetes Technol Ther. 2014;16(11):759-767.

<sup>&</sup>lt;sup>29</sup>Damiano ER, McKeon K, El-Khatib FH, Zheng H, Nathan DM, Russell SJ. A comparative effectiveness analysis of three continuous glucose monitors: the Navigator, G4 Platinum, and Enlite. J Diabetes Sci Technol. 2014;8(4):699-708.

<sup>&</sup>lt;sup>30</sup>Kropff J, Bruttomesso D, Doll W, et al. Accuracy of two continuous glucose monitoring systems: a head-to-head comparison under clinical research centre and daily life conditions. Diabetes Obes Metab. 2015;17(4):343-349.

with SMBG.<sup>31</sup> Hence, CGM readings cannot be fully relied upon for therapeutic decision making.

A recent published article discussing the accuracy of the factory calibrated sensor showed that the overall MARD of the sensor was 11.4% when compared to capillary BG values

# **History & Evolution of Ambulatory Glucose Profile**

Beyond the traditional metrics, glycemic variability has been identified as a predictor of hypoglycaemia and is implicated in the pathogenesis of vascular diabetes complications. Assessment of glycemic variability is thus important, but exact quantification requires frequently sampled glucose measurements. In order to optimise diabetes treatment, there is a need for more advanced, userfriendly monitoring methods. For the meaningful measurement of inter-day glycemic variability, a CGM data for a longer period is required. This will help clinicians and patients easily visualise glycemic patterns to make therapeutic decisions.

New introduction to the field of sensor technology in this regard, is the ambulatory glucose profile (AGP) where the glucose data over a period of 14 days is collated to form a graph as if they occurred in a single 24-hour period. It has been observed that the glycemic glycemic pattern over the first 4 days of CGM cannot ideally predict the subsequent days and it is only over 7 days that the pattern tends to stabilize. The 14 days of glucose data help predict the glucose pattern over the next 30 days with 90–95% certainty, making it easier to visualise glycemic patterns. Thus, AGP combines inputs from multiple days of CGM data and collates them into a single 24-hour period, making glycemic patterns more recognizable.

The history of AGP dates back to 1987, where Mazze et al.<sup>32</sup> used specifically modified reflectance meters containing memory chips which enabled them to store 440 individual blood glucose values

with corresponding time and date. These data were organised into 14 day periods and collapsed into a graphical depiction which came to be known as AGP. The AGP was introduced as a solution to two major problems related to the use of reflectance meters. It was observed that 75% of the patients who practiced SMBG reported values which were significantly different from the actual values. Secondly, physicians had to heavily depend on logbooks to search for glycemic patterns and the efficiency of this subjective method was seriously questioned. Though the introduction of computer partially solved this problem with the help of software and graphics, substantial errors in the entry of data into the system was a major limiting factor. Thus, AGP was a novel step which systematically presented SMBG data and reflected features beyond glycemic control including amplitude and frequency of changes in the glycemic level.

However, this technology was wrought by several limitations including that AGP being a day time profile and not a continuous monitoring system. It did not consider variables including diet, exercise, timing of medications etc. Moreover, frequent and sustained SMBG was required for the construction of AGP.<sup>32</sup>

Interest on AGP rekindled when an expert panel of diabetes specialists met in Florida, to discuss the utility of CGM in clinical practice and research applications where they were introduced to a universal software report, the AGP, created by Mazze et al. and further developed by the International Diabetes Centre (IDC),<sup>33</sup> Minneapolis, MN, and asked to provide feedback on its content and functionality, both as a research tool and in clinical settings. The panel observed that standardizing glucose reporting and analysis, with tools such as AGP, may be one step toward optimizing clinical decision making in diabetes.

#### **Ambulatory Glucose Profile in India**

Abbott launched the FreeStyle Libre Pro Flash

<sup>&</sup>lt;sup>31</sup>Nakamura K, Balo A. The Accuracy and Efficacy of the Dexcom G4 Platinum Continuous Glucose Monitoring System. J Diabetes Sci Technol. 2015 Mar 23.

<sup>&</sup>lt;sup>32</sup>Mazze RS, Lucido D, Langer O, Hartmann K, Rodbard D. Ambulatory Glucose Profile: Representation of Verified Self-Monitored Blood Glucose Data. Diabetes Care. 1987;10(1):111-117.

<sup>&</sup>lt;sup>33</sup>Mazze RS, Strock E, Wesley D, et al. Characterizing glucose exposure for individuals with normal glucose tolerance using continuous glucose monitoring and ambulatory glucose profile analysis. Diabetes Technol Ther. 2008;10(3):149-159.

Glucose Monitoring System in India, first time ever in the world in March 2015. It consists of a small, round sensor, which is applied on the back of the patient's upper arm. It requires no patient interaction or glucose meter calibration and is performed up to a period of 14 days.

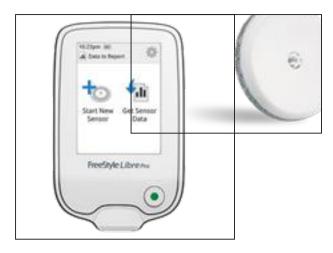


Figure 2: Libre Pro Reader and Sensor

The sensor continuously measures glucose in interstitial fluid through a small (5mm long, 0.4mm wide) filament which is inserted just under the skin and records glucose levels every 15 minutes, capturing up to 1340 glucose results over 14 days. After 14 days, a FreeStyle Libre Pro reader device is used to scan the sensor and download the glucose results that are stored in the sensor in 5 seconds. The personal system, FreeStyle Libre Flash Glucose Monitoring (not yet available in India), was launched in European markets in October 2014. Holding the reader within 1.5 inches of the sensor obtains the real-time value and past eight hours of glucose information along with a trend arrow on a line graph, just like traditional CGM.

The scanning process works through many layers of clothing, allowing for excellent discretion and flexibility. It also provides the option to add tags to each scan, such as carbs, insulin, exercise, and customizable options.



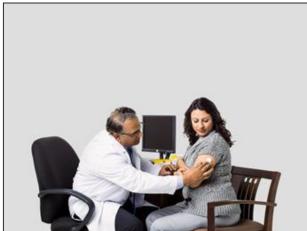




Figure 3: Flash Glucose Monitoring. Sensor Gets Applied to Back of Arm of Patient and Doctor uses the Reader to Get Glucose Data to Obtain the AGP Profile

The AGP sensor which works using wired enzyme technology comes factory calibrated precluding the need for glucometer calibrations and with a MARD 11.4 % Flash glucose monitoring (Figure 2). In a study, which looked into the feasibility of using this modified version of the sensor found in the Freestyle Libre Pro CGM for 14 days, sensors using wired enzyme technology showed excellent in vivo stability, with no significant sensitivity loss over the 14 day wear period.<sup>34</sup>

The AGP graph consists of five curves: 25th and 75th percentile curves also known as the inter quartile

range (IQR), median curve and 10th and 90th percentile curves. The IQR shows the daily, nightly and postprandial span of 50% of glucose values and the shape of the median curve can provide insight into intraday glucose variability. Glucose variability is said to exist when glucose values are widely spread i.e., when the IQR and 10th and 90th percentile curves cover a large area. AGP help assess target, identify degree of variability and risk of hypoglycaemia. AGP results were found to be an effective basis for education, helping achieve better understanding of glycemic variability and increasing involvement in diabetes self-management. 35,36

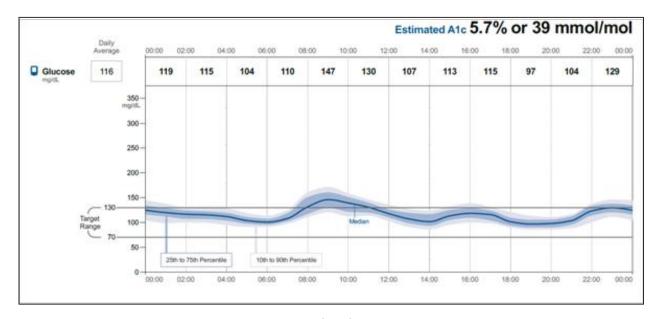


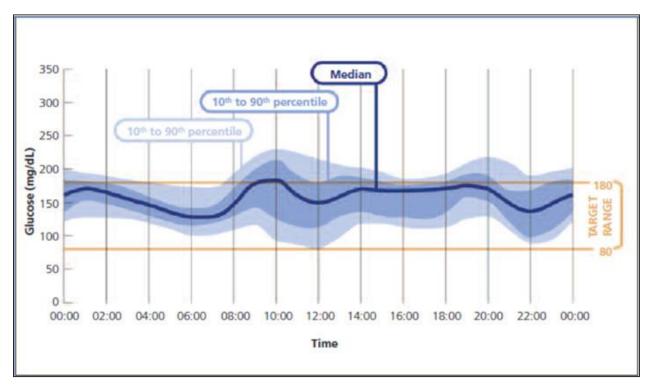
Figure 4: Ambulatory Glucose Profile of a Patient: the 14 day CGM Data is Collapsed to Look Like a Model 24-h Graph

Ambulatory Glucose Profile (AGP) report of 14 days of Continuous Glucose Monitoring (CGM) data, displayed by time to show the spread of glucose values within each time interval. The dark blue line is the median curve (50th percentile) and shows the median glucose value for each time point. The blue shaded area represents the interquartile range (IQR). The outlier values (lowest and highest 10%) are represented by the light blue shaded area.

<sup>&</sup>lt;sup>34</sup>Hoss U, Budiman ES, Liu H, Christiansen MP. Continuous glucose monitoring in the subcutaneous tissue over a 14-day sensor wear period. J Diabetes Sci Technol. 2013;7(5):1210-1219.

<sup>&</sup>lt;sup>35</sup>Matthaei, S. Assessing the value of ambulatory glucose profile (AGP) in clinical practice. Br J Diabetes Vasc Dis 2014;4:148-152.

<sup>&</sup>lt;sup>36</sup>Matthaei S, DeAlaiz RA, Bosi E, et al. Consensus recommendations for the use of Ambulatory Glucose Profile in clinical practice. Br J Diabetes Vasc Dis. 2014;4:153-157.



#### **Zoomed Image of Figure 4**

FreeStyle Libre Pro Flash glucose monitoring system is considered a revolutionary product as it does not require expertise for sensor insertion precludes glucometer calibration and displays glucose values. In contrast, conventional CGM systems involve sophisticated devices, demand expertise, can be used only up to a maximum of one week and are much more expensive.

#### **Conclusion**

The benefits of home blood glucose monitoring in the prevention of long term complications of diabetes are well proven. This benefit is observed only in those individuals in whom therapeutic and lifestyle changes are incorporated based on monitored parameters. For such changes to be made, either the patient should be highly educated

and motivated or should receive directions from experts at frequent intervals.

Considering the fact that home blood glucose monitoring is a cost effective modality in preventing the expensive complications of diabetes, this procedure should be recommended by health care professionals in all eligible patients irrespective of the medications.

In the history of diabetes, AGP with FreeStyle Libre Pro is the first device to provide glucose values without the need for additional pricking the fingers. As the system measures glucose from the interstitial fluid, the values may not exactly reflect the blood glucose readings, this revolutionary technology could be the first one to replace conventional glucose meters and existing continuous glucose monitoring systems.

# Pulse



## **Healthcare Innovations for the Month of September - December**

**Dr. Avantika Batish** is working as Director Strategy and Healthcare at International Health Emergency Learning and Preparedness. Also, guest faculty for MBA HR and MBA Healthcare Management at various B-Schools and is a soft skills trainer.

#### **Indian Healthcare Innovations**

# BabyChakra Launches "MOMLINE"

#### Naiyya Saggi, CEO & Co-Founder

BabyChakra, India's most trusted parenting platform will also be launching "MomLine" on their Android app as well as on other points of community engagement. The "MomLine" will ensure that mothers who want to donate breast milk can directly connect with mothers in desperate need of breast milk for their little ones. This is a first-of-its-type initiative globally. The team at BabyChakra is passionate about healthier, happier moms and babies.

### **Mars Plus**

### **Founder: Nilesh Vyas**

What if the doctor you choose to see is able to view all your medical history and past treatments? What if your lab orders and prescriptions are available at your fingertips and you can compare costs before taking them? What if every test and x-ray you take, magically appear on your Doctor's mobile? What if you don't have to retake a test just because you went to another Doctor?

Mars Plus has come up with the mission of providing an integrated platform for end-to-end healthcare management connecting patients, doctors, hospitals and ancillary healthcare networks such as the labs, pharmacy etc. It has a cloud-based, mobile-first approach to make healthcare accessible anytime, anywhere, from any device. The company plans to have a pan-India presence by 2017.

### **Arogya**

#### Founder: K.P Singh

With the changing lifestyle, medicines have become one of the necessities of every individual. But costly medicines have made many people devoid of proper healthcare. Understanding the vast gap in selling price and cost price of medicines due to a large margin of retailers and wholesalers, Arogya was started in association with the Red Cross Society in Indore. The company with 13 branches currently in Indore sells medicines at a discount of 20% to 75% on MRP.

# HemoCue, in Association with Embassy of Sweden Launches World's First Real-Time Anaemia Monitoring System

Early and accurate diagnosis can play a key role in improving treatment outcomes in anaemia. Employing detection methods that are fast, accurate and reliable promises to be a significant step forward in meeting the challenge anaemia poses. Keeping this in mind HemoCue, the global leader in pointof-care diagnostics recently launched HemoCue HealthTrender Anemia, the new-age anaemia screening and monitoring system in New Delhi. HemoCue HealthTrender Anemia is an innovative device that when integrated with community health programs, especially in rural areas can help address the issues of delayed and incorrect diagnosis. The real time data that it helps generate and analyze can be instrumental for decision makers to create policies around anaemia management. Numbers reveal that the physical and cognitive losses due to iron deficiency have a significant effect on the Gross Domestic Product – in some developing countries

up to as much as four percent.

The Government of India is relentlessly involved in carrying out programs to fight anaemia. Many of the programs are executed by village clinics, healthcare centers and NGOs in rural areas under harsh conditions with limited access to electricity, pure water combined with a poor infrastructure. Under these conditions it becomes virtually impossible to collect data, review, act or evaluate the programs in a timely and effective way; something that has been requested for a long time but never adequately solved.

HemoCue HealthTrender Anemia is a cloud-based solution that can help overcome these challenges as it offers immediate insight using real-time data captured from the HemoCue Hb201+ analyzer in the field.

# 'SAVE MOM', a Maternity Healthcare Startup!

#### **Founders: Senthil Kumar and Divya Krishnan**

The venture has developed a wearable digital health echo system for pregnant women. The endeavour has recently received funding of rupees 30 lacs from Sudip Bandyopadhyay, Group Chairman, Inditrade Capital and Rahul Singh, Founder & CEO – The BeerCafe. Save Mom is a B2B start-up that offers smart wearable for pregnant woman. Boasting aesthetic bead-like design, the wearable device monitors sleep cycles, heartbeat, basal metabolic rate, and glucose rate. It also has a reminder for taking medicine, and calculates the body's requirement of iron. The smart wearable operates on a cloud-enabled monitoring system and has 10 months of battery life.

# Cytecare Opens its First Chain of Facilities in India for Organ-site Cancer Care

# Dr. Ferzaan Engineer, Co-Founder & Chairman of Cytecare and Suresh Ramu, Co-Founder & CEO of Cytecare

Cancer treatment is evolving every day and newer techniques and treatment protocols are being developed to increase the probability of positive

outcomes. Medical research has revealed that no two cancer patients are identical and hence each person needs a customized treatment protocol. This revelation led to the emergence of Cytecare. Cytecare Hospitals has now forayed into providing dedicated cancer care with its first organ site focused 150-bed facility in Bengaluru. The six storied facility in Yelankha enroute to Bengaluru's Kempegowda International Airport is the flagship facility of the healthcare major's 4- 5 similar hubs which are planned across India. Their effort is to ensure continuity of care. The facility would expand across 4-5 major hospitals in the country via a huband-spoke model with sub-centres to strengthen the network for easy access to patients. Their primary attention is on the Indian patients and of course, international cases will also be attended to. Leading oncologists and medical professionals from the best centres in the country and globally have partnered in this mission. They will provide the much-needed advances not just in treatment but diagnostics and drugs. The hospital utilizes Digital Breast Tomosynthesis (DBT), a next-generation breast imaging digital technology. It is also the first hospital in Karnataka to have the Elekta Versa HD. Globally, the advanced linear accelerator is used in the delivery of stereotactic body radiotherapy (SBRT) and radiosurgery (SRS). The high precision Versa HD provides the industry's largest IGRT conebeam CT field-of-view and designed with patient safety in mind. The objective is to drive medical excellence, global best practices to deliver superior clinical outcomes.

# Diagnostic Start-up Healthians.com Raises US\$ 3 Million from Investors

# Deepak Sahni, Founder, Anuj Mittal, Co-Founder and Teruhide Sato, Founder and Managing Partner, BEENEXT

Healthians.com, a diagnostic and wellness start-up has raised \$3 million (around INR 20 crore) in Series A Round of funding led by BEENEXT along with Digital Garage, BEENOS and others. The company had raised its seed round last year in July from YouWecan ventures.

Healthians.com runs on a technology-led asset-light model. The operational model involves working in close partnership with lab owners to significantly increase lab capacity utilisation, upgrade to highquality infrastructure and implement a proprietary 52-point technology-led quality management system in order to ensure high-quality results. Their focus is on cost, quality and customer experience.

The platform has conducted over a million diagnostic tests and has served over 150,000 customers in the Delhi/NCR region. The company has its own team of over 200-plus phlebotomists in Delhi/NCR alone, making it the largest home collection service in the country. The future plans of the company include creating the largest umbrella brand in the country by adding over 200 labs and 3,000-plus phlebotomists to its existing network across 30 cities over the next 12-18 months. The business aims to grow swiftly to achieve a 5,00,000 monthly sample load by the end of 2017. The company aims to become India's largest diagnostic brand by 2019.

# Modasta Raises US\$ 1.5 Million from Mauritius-based HNIs

# Founders: Bikram Barman, Pankaj Pandey and Geethanjali

Digital healthcare content start-up Modasta Technologies Pvt. Ltd founded in 2015 has raised \$1.5 million from a group of Mauritius-based high net worth individuals (HNIs) in angel funding. These HNIs are senior technology and medical professionals.

The fund will be allocated for business growth, upgrading technology, talent acquisition and marketing outreach activities. Modasta offers multilingual health content curated by Indian doctors. As the first of its kind initiative in India, Modasta will service the length and breadth of the country with pertinent content on a plethora of subjects from lifestyle diseases, mental health, women's health, men's health, sexual health and paediatrics amongst others. The platform provides content in English, Hindi, Telugu and Tamil, in the form of articles, videos and audios contributed by doctors along with online group discussions in health forums. It plans to offer content in more languages and introduce online doctor consultation services called "telehealth".

# P.D. Hinduja Hospital & MRC Launches Firstof-its-Kind Wheelchair-friendly Transportation Service for Patients with Limited Mobility

#### **Gautam Khanna, CEO**

India is home to a large number of patients with limited mobility who often find it difficult to travel alone. Travelling is difficult for the specially-abled, senior citizens and patients undergoing orthopedic, and musculoskeletal surgical procedures, OPD procedures like dialysis, chemotherapy and stroke treatment. With an aim to provide a safe and hassle free transportation service for these patients, P.D. Hinduja Hospital & MRC will provide this innovative first-of-its-kind service across the city of Mumbai.

Hinduja hospital has become the first hospital in India to launch a special wheelchair-friendly patient transportation service for those with limited mobility. This service is enabled by specially designed vehicles provided by Ezy Mov to help patients travel independently for treatment.

The vehicle is equipped with the latest advanced hydraulic wheelchair lift. It also consists of safety features like a fire extinguisher, medical kit, a ratchet restraint system for holding the wheelchair in place, along with provisions for an extra seatbelt for the wheelchair occupant, seating for the attendant and electric points for charging.

### **Quadio Technologies**

#### **Neeraj Dotel, CEO**

The company has created its own device and an internet-based solution that allows it to conduct the test remotely, taking audiometry to people in smaller towns and villages where this facility is largely lacking. The company currently has seven such clinics in Gujarat and Maharashtra, in towns like Nadiad, Anand and Dhule and have about 100 patients coming in at each centre every month. Outreach programmes whenever done around these towns gets a footfall of up to 200 in a day.

#### Karma Healthcare

### Jagdeep Gambhir, CEO

The company was set up in 2014 where a team of doctors in Udaipur is connected to smaller centres across the state of Rajasthan. Karma provides access to primary healthcare providers, and in some cases, specialists like paediatricians or gynaecologists, and has consulted 38,000 patients so far. To ensure that people go to them — and not the local quack — Karma's services are priced marginally below theirs. Technology is an enabler, but the physical connect is equally important as observed by the team. They find that the centres that do the best are the ones that have really good nurses. It helps that the doctors are in the same state and are familiar with the local dialects, which helps put the patients at ease. In extreme cases, the patients can still travel to the doctor in person if need be.

#### Olito

#### Rajesh Kumar Singh, CEO

Another company that has big plans for this space is Olito, set up earlier this year in Pune by a group of former techies. The first steps are done by establishing an actual clinic in Pune, signing on 100 doctors, and creating a mobile app. The patients who come to their clinic here can use the app to contact the doctors for their follow-ups, the next step will be expanding to Ghaziabad and Lucknow. From these cities, the company will tap into pharmacists or paramedics in smaller towns around them, who can connect patients in their villages to the doctors in Pune through the app. These would be people the locals already trust and would make it easier for Olito to connect with them.

#### **Mobident**

#### Vivek Madappa, Co-Founder

Mobident is one of the growing number of startups based in Bangalore that are reversing the way traditional healthcare works. It works on the model wherein the dentist visits the patient's house instead of the patients coming to a clinic.

Lack of time (to go visit a doctor), awareness and accessibility are the main reasons cited for the success of this model with the aim to catch the problem early and true belief that "Prevention is better than cure".

The company's "portable dental clinic in a suitcase" comes with a portable chair too. Since majority of the population requires only basic protection and not serious treatment, this arrangement is enough for a home visit.

#### Chikitsak

#### Milind Naik, Co-Founder

Non-communicable diseases screening start-up Chikitsak and cervical cancer screening start-up Aindra have partnered with non-governmental organisations to take their kits across to the rural masses. In the process, they also create microentrepreneurs, who were previously unemployed or were getting low salaries.

Chikitsak uses a camera bag-like kit which consists of nine devices including an android tab, a printer and a simple coloured health chart to screen patients. The whole screening costs just INR 50 and measures around 17 basic health parameters including ECG, anaemia, blood pressure and BMI.

The start-up also helps its NGO health workers earn INR 11,000-12,500 a month. The rural masses do not have proper awareness. This model is an income generation option for rural women who are part of self-help groups. They earn a lot of respect and also help in detecting problems early.

# Indian Healthcare Sector Sees 88 Funding Deals Worth \$397 Million in 2016

Start-ups and investors alike see a huge opportunity in the demand and supply gap that exists in the Indian healthcare sector both as social cause and a business case. Therefore the investments are inevitable in healthcare. According to News Corp VCC Edge Healthcare Sector Funding insights, Indian healthcare sector has registered 88 funding deals amounting to \$ 397.41 million so far this year out of which healthcare start-ups cornered 73 deals amounting to \$ 113.45 million. This includes 54 angel/seed deals worth \$ 11.19 million, 23 venture capital funding deals worth \$ 155.83 million and 11 private equity deals amounting to \$ 230.39 million. Since 2012, the sector has witnessed 558 funding

deals to the tune of \$ 5,657 million. Start-ups in the healthcare space have received funding worth \$ 735 million from 336 deals since 2012.

So far this year, start-ups with consumer- centric digital modes of service delivery have raked in \$ 77.3 million. Biotechnology segment attracted the top private equity and venture capital deals so far in 2016 with Quadria Capital's investment of \$ 70.27 million in Concord Biotech Ltd. Other top private equity deals during the year were in the healthcare facilities and services space such as that of ADV Opportunities Fund I LP investing \$ 45 million in Dr Agarwal's Health Care and TPG Growth Equity III LP investing \$ 33 million in Cancer Treatment Services International Inc.

It has been noted that while start-ups with consumer-centric business models and digital modes of service delivery such as facilitating doctor appointments, efficient information management system and online pharmacies have been attracting investor interest, trends suggest that there will be money backing for the start-ups focusing on corporate tie-ups, medtech, virtual diagnostics & preventive care.

#### **Healthcare Innovations Abroad**

# RingMD: Using Data to Provide Affordable Healthcare to More People in Asia

RingMD is a health tech start-up trying to drive patient care transformation in Asia with a simple idea to match doctors and patients around the world regardless of location. Users sign up to the platform in order to facilitate consultations via video link. Conditions which do not require a physical examination can then be remotely diagnosed and treated.

Patients can also wear a device on their wrist which transmits their pulse, blood pressure and other vital signs to their doctor in real time. Doctors can use this data to help patients make more informed decisions about their health.

The site earns a fee from doctors who wish to charge for their services. Data collected — held confidentially — provides insights on attitudes towards healthcare and the illnesses that may be

ailing large populations. The effort of RingMD is to convince partners in the healthcare industry — governments, hospitals and other players such as insurance and pharmaceutical companies to adopt more data-driven thinking in the delivery of healthcare.

# Median Technologies Collaborated with Microsoft to Develop New Cancer Detection, Diagnosis & Monitoring Methods

# Fredrik Brag, Chief Executive Officer at Median Technologies

Precision Medicine is about to revolutionize how diagnostic and biological data is used to pinpoint and deliver care that is preventive, targeted and effective. Extracting biomarkers of disease from medical images is at the core of the Precision Medicine effort. Big Data computing and analytics will allow efficient processing and analysis of imaging biomarkers which is essential for early detection of cancer and monitoring of new targeted cancer treatments.

Median Technologies (ALMDT) is a leading medical imaging solutions and service provider for image interpretation and management in oncology. Median Technologies and Microsoft announced a joint global initiative in the rapidly growing Precision Medicine market to develop new cancer detection, diagnosis and monitoring methods using Big Data analytics.

As part of the initiative, Median Technologies will install its groundbreaking imaging biomarker phenotyping system (IBIOPSY) on the Microsoft Azure cloud computing platform. On Azure, IBIOPSY will provide capabilities for processing and analyzing medical images, extracting biomarkers of disease in real time for cancer diagnosis and treatment purposes. The collaboration will allow delivering these solutions into routine clinical practice on a global scale on the Azure cloud computing platform. Microsoft Innovation teams have collaborated on the IBIOPSY project to bring innovative technologies at the service of cancer research. By taking advantage of the powerful Microsoft Azure cloud platform, IBIOPSY will provide faster imaging and health data analysis and will accelerate the discovery and delivery of new biomarkers for cancer diagnosis and

treatment monitoring.

# Synaptive Medical and General Atlantic Announce Strategic Partnership

#### **Cameron Piron, President of Synaptive Medical**

General Atlantic, a global growth equity firm with over 35 years of experience investing in 250 growth companies and deep expertise in the healthcare and technology sectors, has made a strategic investment in Synaptive Medical, a leading medical device and technology company.

The healthcare industry is shifting toward an integrated delivery model that treats the whole patient from the diagnosis to surgery and beyond. Efficient medical imaging, combined with timely and effective care, is a critical driver of that change. Synaptive is developing novel imaging solutions that will help improve clinical outcomes for patients in partnership with the people and institutions that care for them. Synaptive, a Toronto based company develops integrated technologies to solve challenges both in and beyond the operating room through deep collaboration with surgeons and hospitals. The company's BrightMatter™ suite of products provide advanced visual and information tools that allow surgeons to focus on patient outcomes within a global healthcare industry. The company's surgical technology—which combines informatics, imaging, surgical planning, navigation and advanced optics—has been installed at top-ranked health care facilities across the United States, including recent installations at Emory University Hospital, the Gates Vascular Institute, Grady Health, Indiana University Health Methodist Hospital and Mount Sinai. Synaptive also pursues unique collaborations with its customers, such as its recent initiative with Henry Ford Health System to empower ONConnect, a virtual tumor board that aims to offer patients greater transparency in determining their brain tumour treatment options.

# CitiusTech Sets Up Healthcare Innovation Fund With SINE

Healthcare technology company CitiusTech has launched a Healthcare Innovation Fund in collaboration with SINE - IITs Society for Innovation

and Entrepreneurship fund to invest in innovative ventures in healthcare and healthtech. The fund was set up in 2015 wherein Citius wanted to do more than just put up some money as part of the mandatory CSR under the government policy. To start with, this is a five year commitment with an increasing annual contribution which could be extended at the end of the initial five year period. The final decision on what start-ups are selected rests with SINE, while CitiusTech executives would step in as mentors as and when needed. This fund also envisages the idea of enterprise start-ups to students on campus, who typically are more exposed to consumer facing businesses and don't often have perspective on entrepreneurship opportunities in the healthtech space or on the enterprise side, and this is a way to boost healthcare innovation on campus. So far the fund has invested in four companies which are CareNx, a remote monitoring tool to detect highrisk pregnancies earlier, Transpact, which makes a therapeutic product for children with cerebral palsy, Medprime Technologies, a medical devices start-up and InceptorTechnologies, a low-cost digital Braille reader.

# Insulin Cells Under Skin Could Save Diabetics From Jabs

Scientists have created artificial beta cells from human kidney cells that act as sugar sensors and insulin producers. The therapy involves a capsule of genetically engineered cells implanted under the skin that automatically releases insulin as required. Researchers at ETZ Zurich (Swiss Federal Institute of Technology) have used a cell line based on human kidney cells, HEK cells which have been enhanced with a voltage-dependent calcium channel and a gene for the production of insulin and GLP-1, a hormone involved in the regulation of the blood sugar level. When the blood sugar level exceeds a certain threshold, the potassium channels close. This flips the voltage distribution at the membrane, causing the calcium channels to open. As calcium flows in it triggers the HEK cells built-in signalling cascade, leading to the production and secretion of insulin or GLP-1. Diabetic mice when implanted with these artificial cells were found to have normal blood sugar levels for several weeks. In developing the artificial cells, experts had the help of a computer model which allows predictions to be made of cell behaviour, which can be experimentally verified.

#### **Interaction with Readers**

"It is really of very high quality in all respects. I think, it should be prescribed as a reference learning material for Healthcare professionals and management students."

#### Dr. S. Venkataramanaiah, Associate Professor, Indian Institute of Management, Lucknow, India

"Congratulations!

Amazing perseverance and continued efforts. Keep it up"

#### Keerti Pradhan, Professor, Chitkara University, Chandigarh, India

"It has, indeed, been a very progressive year for InnovatioCuris. The magazine InnoHealth has been a great help to people like me who are in the field. Some of the ideas expressed by the authors are pragmatic and simple to follow. We are actually implementing these ideas as strategy to deliver Telemedicine in the rural Rajasthan. I suggest that a section in the magazine be for practical innovative ideas being implemented in the rural world. Thank you for the huge initiative and effort."

#### Maj Gen Dr AK Singh (Retd), Jaipur, India

"I recently got a chance to read first issue of Innohealth and I must say it's well documented and contents well aligned. Please find my feedback below

As an expert on US healthcare I always compare healthcare delivery models in India and US. This magazine gives an excellent platform to present those ideas wherein the best practices from across the globe can be presented and later on implemented. Be it emphasizing the importance of adopting standards in Healthcare IT and that too by member of parliament Mr. Konda Vishweshwar Reddy who understands the importance of this adoption or be it Innovating with micro insurance to create community based health insurance scheme by Dr. Dinesh B Baliga. The magazine sticks to it's topic of Healthcare Innovation presenting examples and successfully implemented innovative ideas.

There are two major concerns when it come to healthcare model:

- 1. Delivery
- 2. Affordability

Both the above concerns are addressed in different write ups. I also liked the term "Indovation" which specifically jots down innovative solutions adopted in India.

My best wishes to authors in filling the gap between ideas and respective implementations."

**Gaurav Verma, Associate Manager, GalaxE Solutions, US** 

We will like to have your suggestions/feedback for the magazine. Please write to magazine@innovatiocuris.com mentioning the issue number.

#### **Guidelines to Authors**

#### **Guidelines for Contributors of InnoHEALTH**

InnoHEALTH magazine covers wide range of topics on Innovations in healthcare to reduce cost of healthcare delivery yet keeping the best quality of care. The magazine is published quarterly in the months of January, April, July and October every year in the print and digital form. The digital version would be sent to 25,000 health professionals worldwide as part of our community. The magazine is complimentary till we decide otherwise. We would publish articles to share an idea of innovation in devices, drugs, biotech, pharma, healthcare IT, Hospital design, management process and policy innovation. Mission is to share best global practices with each other to emulate.

We are looking following when evaluating an article:

- a) You don't have to be well known to be a contributor, but you must know a lot about the subject you're writing about. You need to prove to your readers that it is backed by references/adequate graphs/drawings etc.
- b) It has to be original write up and not published elsewhere and you would be answerable if somebody challenges your work for plagiarism. If you can explain the thought process so that the reader understands how to apply the innovation in a real situation. It should be replicable and scalable to make it more powerful.
- c) Article that are persuasive and pleasure to read.

#### **General Information**

We may not be able to publish all articles not because of quality but it does not fit theme of the magazine. You may be asked to do multiple rounds of revisions. We may rewrite your title on our advice to suit article contents and making it attractive for readers.

We would need a one-two line summary of the article, a two-line bio of the author and a high-resolution headshot of the author along with the article. Once, our team edits the article, it will be sent back to you for the final approval before it is published. The pictures if any in the article should also be separately emailed in high resolution.

We seek articles round the year. However, the issue in which they will be published might depend on the theme of the issue and the quarter in which they were sent to. The call for articles will be made to the contributors 3 months in advance with a one-month window to submit the articles.

You may write work done by your organisation but do not write as promotional piece. InnovatioCuris (IC) which bringing this magazine holds copyright on the articles, but authors continue to own the underlying ideas in their articles. Please illustrate your points with real-world examples. Please send your article to <a href="magazine@innovatiocuris.com">magazine@innovatiocuris.com</a>

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# IC INNOVATOR'S CLUB

# **About the Club**

The Club is created for Innovators and its mission is to support the growth of its members in their roles as Innovators mainly through education, local and global networking and strategic alliances and partnerships.

The objective of enhancing innovation among its members will be achieved through:

- Creating a nurturing and creative environment to share global ideas
- Special programs for identifying innovation needs in healthcare
- Providing access to international markets through business delegations and business matchmaking programs
- Expanding social resources through promoting social networking among members
- Updating members on healthcare/business issues through reports and interactive sessions with experts
- Various International Conferences & Seminars

# Who should join?

Any person who has interest in Innovation like start-ups, mentors, investors, IT, academicians, healthcare providers/ planners, device manufacturers, pharma sector, quality/lean experts and others.

# **How to Apply**

http://innovatiocuris.com/icinnovatorsclub/

The short-listing of members will be done through a rigorous process looking at their passion for innovation.

# **IC Innovator's Club Advisory Board**



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