

“Advances & opportunities for healthcare innovations in India: Recent ENT inventions for affordable healthcare: An innovators perspective”

Dr. Jagdish Chaturvedi

Abstract

The healthcare ecosystem in India for Medical Technologies is still in its infancy and currently sustains itself by accepting technologies that were developed in the west for a more mature healthcare ecosystem. Due to this technologies that are developed in the west are force fitted into our ecosystem and hence have limited penetration in our market because of varying stakeholder understanding and business models that suit our healthcare system.

Some recent ENT technologies such as the sinus irrigation and balloon sinuplasty system, cochlear implants, facial nerve monitors, image guided surgery and robotic surgery technologies struggle to penetrate the Indian market and serve the population who need these solutions due to a western go-to-market approach and reimbursement strategy that does not suit our healthcare system.

There is therefore a valid need to develop technologies that are tailor made for our Indian healthcare ecosystem such that larger target populations are benefitted. The speaker shares some case studies of ENT inventions as an inventor that has been developed specifically for the Indian market and discusses challenges in developing such technologies in India. There are ways to learn such processes today by exploring the Stanford India Biodesign fellowship program and the Affordable Innovation for MedTech (AIM) entrepreneurship program.

The Biodesign innovation process is a structured process to develop new medical technologies. It has been developed to help both amateur and experienced innovators to reduce their risk of failure. This process was developed in Stanford University's Program called Biodesign and serves as the foundation to the text book Biodesign: The Process of Innovating Medical Technologies.

The Biodesign process is designed to analyze unmet validated clinical needs and uses a structured filtering process to find the most compelling and impactful needs those are worth solving. Keeping in mind factors such as stakeholder's involved, business models, regulatory pathway and reimbursement strategy, creative solutions for the top unmet need are created by multidisciplinary teams. This process is different from what most organizations follow which is to develop a technology and find a right problem to solve using the technology in the healthcare system.

Keywords

Biodesign, Medical device technology, innovation, Indian healthcare ecosystem

Full text, with all subsections and illustrations

Presentation outline:

- Speakers contribution & experience in the field
- Overview of healthcare innovations ecosystem in India
- Recent advances in ENT medical devices and why they haven't succeeded to benefit a larger target population in India
- Advances & Challenges while inventing affordable ENT inventions: innovators experiences
- Key takeaways

Speaker profile:

Dr. Jagdish Chaturvedi, Director Clinical Innovations and Partnerships, InnAccel.

An ENT surgeon, a Stanford-India Biodesign Fellow 2012 and an MBA in Entrepreneurship and hospital management (NIBM).

Core expertise lies in the process of identifying and analyzing unmet clinical needs for quick development of low-cost and high quality medical devices, and teaching/ training the Biodesign process.

Designed and executed the Stanford India Biodesign internship program in 2012 and is currently spearheading the Affordable Indian Medtech (AIM) fellowship program at InnAccel. Has provided consulting services for unmet need analysis for both large and small MedTech companies in India since 2012.

Dr. Chaturvedi has developed 13 medical technologies (Intellectual Property/Patents) and 1 teaching methodology. 5 of which have been licensed to Indian companies, 4 have developed start up companies and 1 has developed into a Phd research project.

Current innovative ecosystem in India:

India ranks 66 out of 142 countries
Switzerland-1
UK-3
USA-5
China-7
Singapore-8
Israel-14
Germany-15
Korea-18
Yemen-142

Healthcare ecosystem in India:

- Indian Med Tech industry low on innovation:
 - Only 1% of sales invested in R&D (vis-à-vis 11% in the west)
 - 65% of Indian manufacturers focused on low end medical disposables
 - Very few Class III devices
 - Trained Talent nonexistent
 - Med Tech ecosystem in infancy
- Limited money for high-risk ideas – small venture capital
- Regulatory and IP changes good but slow
- Limited facilities for product testing, validation and accreditation

Factors driving medtech growth in India:

- ✦ Changing Demographics
 - Rapid growth in elderly population (60+) from 107 mn today to 175 mn in 2025—a 64% increase
 - High growth in Chronic NCDs such as Cardiovascular, Diabetes, COPD, orthopedics etc. which account for the majority of MedTech usage in developed countries
 - Sustained income growth resulting in an even faster growth in healthcare spending, as discretionary income rises
- ✦ Growth in Healthcare spending and Insurance
 - Public spending on healthcare to increase by 300% in 12th 5-yr Plan and reach 1.87% of GDP by 2017
 - Strong focus on National Rural Health Mission (\$75 billion allocation) to drive uptake of affordable technologies and delivery
 - Increase in Health Insurance coverage from 15 % today to 50 % by 2025 driven by Govt. schemes such as RSBY and Aarogyasri.
- ✦ Growth in Healthcare delivery
 - Hospital beds to grow from 1.05 mn in 2012 to 1.75 mn by 2025, driven by incentives for no-frills hospitals in Tier 2/3 towns, and 100% FDI in private hospital chains

Situation is changing: India's decade of innovation is 2010-2020:

“The country must develop an innovation ecosystem to stimulate innovations. Innovators must be challenged to produce solutions to our society needs. And innovative solutions with potential must be nurtured and rapidly applied.”
– Prime Minister Manmohan Singh

Doctors who are successful Innovators:

Dr. Thomas Forgarty- Forgarty Balloon catheter:150 inventions and counting
Dr. Paul Yock- Rapid Exchange™ balloon angioplasty system
Dr. Josh Makeover- Accelarent- Balloon Sinuplasty
Dr. Rodney Perkins- Ear Lens, Sound ID, Resound hearing aids, Laserscope, Novacept, Plumnox, Cohesion
Dr. Balram Bhargava- Indigenous Platinum Iridium coronary stentMechanical chest compression device

An overview of some recent ENT Inventions:

- *Accelarent Balloon Sinuplasty system* –Large population in India who need Sinuplasty but a very few get access to the Balloon Sinuplasty solution.
Reasons: Original Business model is based on market penetration through insurance company coverage's. In India >70% population pays out of pocket.
- *Cochlear Implantations*- Many children who are indicated for cochlear implantation cannot afford the huge cost of the implant and associated expenses.
Reasons: The companies manufacturing these devices work on a high cost of developing the implants and will make sustainable business only on recovering these costs by increasing the selling price. The Business model is based on a physicianinfluencing the sale. In India the payer profile is largely unaffordable.
- *Facial Nerve Monitors and image guided techniques*- These are implemented in the west as a mandate by the FDA for hospitals who are performing large number of parotid surgeries and where the need to do revisions are high. This is an effort by the regulatory authority or hospital to ensure these intragenic consequences are limited.
Reasons: In India there is no such regulatory authority reinforcing this and very few hospitals are concerned about this clinical outcome. The model is not based on clinician being the buyer, but rather it's the hospital administration on the regulatory authority who makes the decision.
- *Da Vinci's Robotic surgery*- Is available in very few centers in India and is just beginning its application in the field of ENT. However this is a very expensive capital equipment that needs a whole new system of surgery with a whole new sets of instrumentations and technology. Because it is a huge shift from what is existing, it is difficult to adopt and also difficult to train in the technique.
Reasons: only large centers in India who get high volumes of surgeries that can be performed using this system will consider the huge expenses associated with buying, maintaining and training surgeons for robotic surgery.

There is a need for affordable innovations in ENT

There is a need for affordable, high quality solutions that are designed for the Indian healthcare system keeping in mind Indian stakeholders and business models. As an inventor I have attempted to try this in our ecosystem and have come across some challenges that are worth discussing.

Low cost portable tri-purpose ENT multiscope recorder





As evident from the images every product goes through a lot of iterations before it fits into the healthcare ecosystem. As shown above, the initial products were designed for ENT surgeons to use and as it became clearer that the problem was more in the rural areas and a health care worker would be the most likely user, the design and features of the device changed to suit healthcare workers. Now there is a low cost solution that the healthcare worker can use to screen ENT diseases and send the patients to clinicians at their clinical centers for a review. This will ensure that ENT clinician's will see more cases that need definitive treatment.

Low cost Nasal foreign body extractor



Again is a problem that is more evident in the rural area and is a product designed for better removal by primary care physicians who can treat the patient and then refer the patient to the ENT for further follow-up and management of any complications. This model ensures that general practitioner's can now address a population of cases that they were losing to referrals and ENT surgeons can get only selected cases of complicated removals that require the use of general anesthesia.

Low cost Epistaxis controlling device



This solution is addressing the needs of patients who have recurrent epistaxis and have no interim solution till they see the doctor. This device is designed to be an over-the-counter product that will be the equivalent of a band aid for epistaxis to do primary control before definitive care. The buyer is the patient and the usage is as simple as using a band-aid.

Stanford India Biodesign Program

There are a few opportunities available in our country that can teach a structured process for innovation of medical technologies so as to ensure the inventions are tailor made to Indian problems and not force fitted from western technologies.



Stanford University, CA



AIIMS, New Delhi



IIT Delhi



The SIB runs an annual fellowship program, which trains a multidisciplinary team on the Biodesign process by having them train at Stanford University on the Biodesign process and implement it in India at AIIMS hospital in New Delhi and IIT Delhi.

Shown below is an outline of the Biodesign process



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The Biodesign process is designed to analyze unmet validated clinical needs and uses a structured filtering process to find the most compelling and impactful needs those are worth solving. Keeping in mind factors such as stakeholder's involved, business models, regulatory pathway and reimbursement strategy, creative solutions for the top unmet need are created by multidisciplinary teams. This process is different from what most organizations follow which is to develop a technology and find a right problem to solve using the technology in the healthcare system.

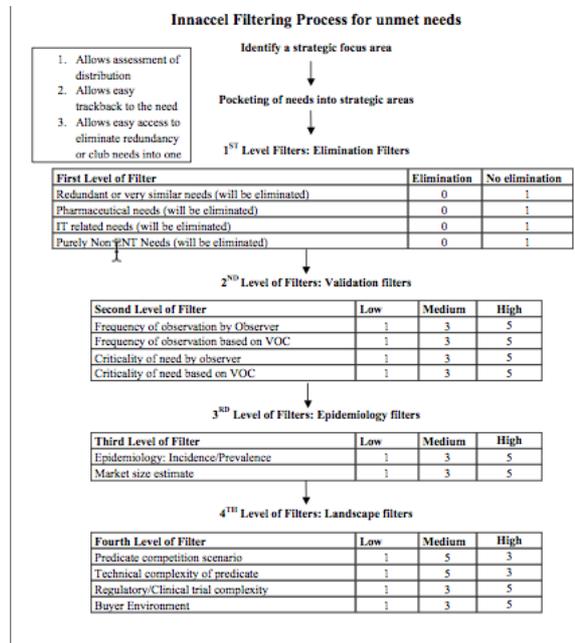
The AIM Entrepreneurship program:

This program follows a more Indo-specific Biodesign process started by a Medtech accelerator based out of Bangalore called InnAccel. The following are some of the Indo- Specific alterations made to the Biodesign process.

Increasing clinical involvement: In the modified Biodesign process we are involving clinician clinicians who have been trained to apply the Biodesign process without discontinuing their clinical commitments and having them remain integral to the hospital they are employed in. This makes it easier for clinicians to be involved in the process and interact with engineers and designers from the team.

Collecting better data: In the process of making clinical observations the teams are now trained to create an Observation Docket which includes collection of lengthy & detailed clinical observations with 8 key parameters such as frequency of the problem, criticality of the problem, cost to the patient, incidence/prevalence of the problem in literature, patient pathway, treatment gap, need statement and problem statement.

Stakeholder analysis: In order to understand the stakeholders better, structured voice of customer studies were included in the form of Voice of Customer (VOC) validation and these were incorporated in the filtering process. This became a part of a pre calibrated filtering criteria (15 criteria/ 4 levels) which is designed to find high impact unmet clinical needs.



In addition a detailed market assessment, stakeholder & business model analysis is carried out with senior experts in order to help incorporate these into concepts while selecting the most appropriate solution for the problem.

Advances in capital raising: Increasing access of innovators to private funding in the form of VC funding through medtech accelerators is a new model to raise capital and receive management expertise along with access to resources such as prototyping labs, expert mentorship and clinical access. This allows quick cash flow into the start up company and allows for better management of usage of the capital.

Current opportunities to learn and apply the Biodesign process:

- Stanford India Biodesign fellowship and Internship program
- InnAccel's Affordable Innovations in MedTech Entrepreneurship program

Key Take-away's:

- Biodesign process is an efficient process used to innovate medical technologies
- The healthcare ecosystem in India is not a perfect fit for western technologies
- Key challenges are to identify a problem and devise a solution that can fit into our ecosystem
- There is now an increase in opportunities for learning and implementing the Biodesign process

References

Biodesign: The Process of Innovating Medical Technologies.
 Author's personal experiences from following the Biodesign process at SIB and for the AIM entrepreneurship program

Author's biography (200 words)

Dr. Jagdish Chaturvedi, Director, Clinical Innovation and partnerships at InnAccel, Bangalore is an ENT surgeon by training (St. John's Medical College, Bangalore), a medical device innovations expert (Stanford India Biodesign fellow 2012) and an MBA in entrepreneurship and hospital management (National Institute of Business Management). Apart from being an actively practicing ENT surgeon (currently with Apollo Hospitals, Bangalore), Dr. Chaturvedi has been involved in inventing numerous low cost medical devices since the past few years. His first invention involved conceptualizing and developing a low cost portable tri-purpose multiscope ENT recorder while partnering with a design firm in Bangalore (ICARUS). Further in the space of ENT, Dr. Chaturvedi has co-invented Nasoplast, an epistaxis controlling device and NoXeno - an easy to use nasal foreign body extractor.

In addition, through the Stanford India Biodesign Fellowship program 2012 and while structuring and executing the Stanford India Biodesign Internship program 2013, Dr. Chaturvedi has co-invented 10 other low cost medical devices in other fields (gastroenterology, pulmonology and community medicine) within a short span of 3 years. 5 out of these have been successfully licensed out to MedTech industries (Both large and small) for further development and commercialization.

Dr. Jagdish Chaturvedi continues to contribute to the affordable healthcare space by supporting his colleagues in similar inventions and is currently an integral part of an indigenous MedTech accelerator based out of Bangalore called InnAccel which is creating opportunities to support entrepreneurs and start up companies working in the affordable healthcare innovations ecosystem in India.

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