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CHARTER OF ST JOHN’S MEDICAL JOURNAL

Vision
Economically marginalized communities empowered to be in charge of their Health.

Mission
Provide information about affordable and appropriate health care techniques and technologies to leaders working with marginalized communities.

Strategy
An annual journal which will provide educational material to forward the mission.

Contents
Original articles
Review articles
Brief reports / Case reports
Interesting clinical / Social illustrations
Information pamphlets
Book reviews

This journal is to help people meet most of their common health needs for and by themselves. But it does not have all the answers. In case of serious illness or if you are uncertain about how to handle a health problem, get advice from a health worker or doctor whenever possible. We thank the Hesperian foundation for permission to use ideas and literature from their resource material. The book “Where There is No Doctor” is a useful companion to this issue.
Profile of MedTech Divisions that have contributed in the development of this issue

**COEO Labs** : A MedTech startup company based in India, which develops innovative medical devices with focus on Emergency, Trauma and Critical Care. They are working on multiple projects including a system to help prevent Ventilator Associated Pneumonia (VAP) in ICU patients.

*Nachiket Deval (Co-Founder)* : Nachiket is a mechanical engineer and product designer from National Institute of Design. He has experience working with companies like Honeywell, Godrej, Boyce and Seasyst Engineering. His expertise includes aesthetics, user interaction and functional design. He has an AIM fellowship in emergency medicine.

*Nitesh K Jangir (Co-Founder)* : Nitesh is an electronics engineer with a focus on embedded system design. He has experience in defense R&D, industrial automation, and consumer electronics. He was part of the Stanford India Biodesign Program.

*Dr. Vimal Kishore* : Vimal is an Emergency Medicine Physician with St. John's Medical College Hospital. He was one among three clinical fellows in the 6 month Affordable innovation for Medtech enterpreuner program conducted by Innaccel in January 2015. This team further went on to start a company called COEO labs and is working on a device that reduces the incidence of ventilator associated pneumonitis.

**Satva MedTech** : This company is focused on creating affordable MedTech solutions to reduce maternal and child mortality in India. Launch product currently under development is a cost-effective and accurate fetal heart monitoring system

*Vibhav Joshi (Acting CEO)* : Vaibhav holds a bachelor’s in Electrical and Electronics engineering and Masters of Science in Biological Sciences. He has participated in events like New Venture Creation and HULT international BPlan competition.

*Sumedh Kaulgud (Hardware Development)* : Sumedh has a bachelor’s in Electrical and Electronics engineering with specialization in wireless system communication. He has participated in Goombah Ventures competition.

*Saurabh (Sr), Saurabh (Jr) and Arun (Co-founders)* : Currently finishing their Bachelor in Electrical and Electronics Engineering at BITS Goa.
InnAccel is India’s first MedTech accelerator. We focus on building an innovation ecosystem, anchored by state-of-the-art accelerators, and a network of national and global partners, to enable affordable MedTech innovation by startups. We aim to be the global leader in enabling Affordable MedTech Innovation for India and other emerging markets.

Siraj Dhanani (Founder/CEO) : Siraj is a successful entrepreneur, investor, and healthcare professional. Siraj’s in-depth experience includes pharmaceutical marketing (BMS, NJ) and healthcare investment banking (UBS, NYC).

A. Vijayarajan (Founder/CTO) : A medical technology veteran with over 30 years of experience. He was head of Product Development at GE Medical Systems, Chief Executive, Health Sciences (Wipro) and Vice President (Hewlett Packard).

Dr. Jagdish Chaturvedi (Director of Clinical Innovation) : Jagdish is a practicing ENT surgeon. He is a Stanford-India Biodesign fellow and holds an MBA degree in Entrepreneurship and Hospital Management. He has co-invented, developed and commercialized multiple affordable medical devices.

Dinesh Dikshit (CFO) : Dinesh is a chartered accountant with 20 years of experience in Strategic Financial Planning, Budgeting & MIS, Fund Sourcing & Management, Accounts & Auditing, and Taxation and Project financing.

Ramakrishna Pappu (Business Analyst) : Ramakrishna is a bachelor in science, Economics and Finance from New York University, Stern School of Business. Further he has an AIM Entrepreneurship fellowship in the Emergency Medicine. He has experience in conducting medical device innovation workshops.

Pooja Kadambi (System Design Engineer) : Pooja has a bachelors in Biomedical Engineering and Masters in Computer Engineering from University of Cincinnati. She has completed her Clinical Research Fellowship in Emergency Medicine. She has a varied experience in different MedTech domains.

Andrew Logan : Andrew is a graduate human biologist from Stanford university. He is an Idex intern placed with Innaccel since July 2014. He has been working on the internal projects under Innaccel during his internship.
Message from Director, St John’s National Academy of Health Sciences

The theme of St. John’s Medical Journal (Current issue) is Innovating for Affordable Healthcare. It has two complementary facets, namely Innovation and Affordable Healthcare.

Innovation is a critical tool that has assisted mankind to get free of the survival game, and go onto self actualize, that is to realize one’s complete potential in all the faculties. In the domain of health, self actualization is about going beyond personal issues and serving fellow beings. Self actualization is direct and obvious in the area of health. Hence application of innovation process in this area has a vast scope. The process can be applied in individual care/prevention and further expanded to impact health of populations. All these finally shift the quality of lives of individuals, societies and the world in the wider sense.

When the word affordable healthcare is mentioned, by default we think in terms of healthcare for the poor and marginalized. A more inclusive perspective would be to provide affordable healthcare to all, the poor as well the rich. When the poor get healthcare at low cost they start contributing more efficiently to the society. When the people who can afford high cost of healthcare can access the same at a lower cost, then they can be requested to contribute for welfare services to serve the poor. This may go a long way in equalizing economic and power equations in the society. In my opinion, innovating for healthcare, though it appears very clinical and scientific, has a major societal connotation.

St. John’s National Academy of Health Sciences has always stood for equity in healthcare. This issue of St. John’s Medical Journal intends to explore the innovation facet of equitable healthcare. I wish to place on record the Academy’s appreciation and gratitude to Dr. Ramesh and the editorial team in bringing out yet another issue of St. John’s Medical Journal on an important theme. May the God almighty bless this innovative endeavor.

Rev. Dr. Paul Parathazham
Director
St. John’s National Academy of Health Sciences
Message from Dean, St John’s Medical College

The mandate of St. John’s Medical Journal is to publish articles relevant to affordable healthcare. The target readership is people working for healthcare missions and allied organizations. The journal is an activity aligned to provide healthcare to medically underserved communities, which is the vision of St. John’s National Academy of Health Sciences. Theme of this issue is “Innovation for affordable healthcare”. The solution to any challenge in healthcare lies in innovation. Innovation may take the form of a new device, a different way of performing the process, altering the perspective or finding a new context. Each section of the journal addresses these issues in a easily understandable, concise and lucid manner.

The contents of the issue may be used as a resource to train people working for healthcare systems to innovate in providing affordable and universally accessible medical care. I hope leaders and key people in the healthcare systems of the missions and other health related organizations get benefited from this issue.

Dr Srinivasan K
Dean
St. John’s Medical College
Editorial

Innovating for Affordable Healthcare for All

Healthcare costs are increasing exponentially with time. Even primary healthcare provided by corporate healthcare systems cannot be afforded by upper middle class in India. A powerful nexus between market driven pharmaceuticals, monopoly based biomedical equipment manufacturers and insecure physicians are ensuring that the costs stay high. There is an urgent need to break this unhealthy nexus so that healthcare becomes affordable for all.

Innovation is one of the ways to break this nexus. Whenever mankind has liberated itself or found new pathways, there has been innovation at its core. There are four types of innovations. Product innovation, what we offer the world. A low cost hearing screening device to screen for hearing impairment in the community is an example of product innovation. Process innovation, how we create and deliver that offering. Community volunteers taking on the role of audiologists to screen for hearing impairment using this low cost device is an example of process innovation. Position innovation, where we target that offering and the story we tell about it. Use of this device in marginalized populations in resource limited settings is position innovation. Paradigm innovation, how we frame what we do. Setting up a healthcare system in resource limited setting using the frontline workers as first tier and occasional visits by specialist volunteers to provide the next level of care for hearing rehabilitation is an example of paradigm innovation. These categories of inventions are different facets of “knowledge creation”. Prudent application of these inventions can bring about tangible shifts in the quality of lives of individuals in the community.

Communities have to critically examine the barriers for accessing affordable healthcare for all. Each person from the community has to be trained to innovate (fortunately innovation is a natural god given talent). This will cause a revolution where communities will find solutions by themselves using any of the above mentioned methods of innovation.

This issue of St. John’s Medical Journal is devoted to educate healthcare personal in the process of innovation. Each section of the journal outlines the process of creating new knowledge using the various innovation processes described. There is a section on how to conduct a training session on innovations. This can be adapted to conduct meaningful sessions for frontline workers. I place on record, immense gratitude for Dr Jagdish Chaturvedi, Director (Clinical innovations), InnAccel who has guest edited all the articles for easy readability by lay persons.

I seek the blessings of the almighty, that this issue will ignite the spark of creativity and intelligence in the collective consciousness of marginalized communities to take charge of their health.

Ramesh A
Editor
Lead article

**MedTech Innovation using InnAccel Structured Process**
**Challenges and Opportunities**

*Andrew Logan*

**Introduction**
Approximately 75% of the medical devices and diagnostics used in India are imported from developed nations. This increases the cost of care. Also in certain contexts, they are maladapted to fit India’s unique healthcare provider, purchasing, and reimbursement framework. There is an urgent need to develop technologies specifically designed to suit the Indian healthcare system. A study was conducted at InnAccel to examine the effectiveness of applying a structured process for MedTech innovation in pediatrics and neonatology. InnAccel is India’s first MedTech accelerator organization. The focus of InnAccel is on building an innovation ecosystem, anchored by state-of-the-art accelerators, and a network of national and global partners, to enable affordable MedTech innovation by startups.

**Methodology**
A structured process was used to address unmet clinical need analysis where multidisciplinary teams underwent clinical immersions, identified pressing needs, validated understanding with experts, brainstormed new treatments, and then prototyped solutions as shown in Figure 1.

In the first phase, a multi-disciplinary team performed clinical observations at a hospital in a strategic focus area for six to eight weeks. The team shadowed clinicians and closely monitored the care provided. The team was instructed to note inefficiencies and poor health outcomes. Then, the team performed extensive research on their observations and developed in-depth understanding of their needs. Next, the team filtered these needs based on factors such as incidence of negative outcome, criticality, market size, and personal interest. Once a top need was identified, the team brainstormed all of the possible ways in which the problem can be solved. These brainstorming sessions was to generate a large volume of high-quality ideas. Finally, the team prototyped the most
promising ideas and validated their work with clinicians. If the need and solution still seemed promising at this point, a start-up was planned to bring this product to market.

Figure 1: A Structured Process in MedTech Innovation

Criteria to selection a Strategic Focus Area

India accounts for 20% of child mortality in the world. 5.3 lakh under 5 children die per year in the lowest income quintile compared to 1.78 lakh children who die per year in the highest income quintile. There are vast differences between the states of India. The under 5-mortality rate in Kerala is 14 deaths per 1000 live births, whereas Madhya Pradesh has 92 deaths per 1000 live births. These factors made us to perform an unmet clinical need analysis in the field of pediatrics and neonatology.

Team Composition

Six clinical immersions were conducted in a tertiary care hospital. During these immersion, we had two biomechanical engineers spend 6 weeks shadowing clinicians in the pediatrics department. The overall goal of this immersion was to identify clinical needs that could be further developed by an indigenous medical technology start-up.
Results

On completion of two months of clinical immersion, 71 detailed observations were made. From these 52 unmet clinical needs with significant negative outcomes were derived. The team members identified disease state fundamentals, existing treatment options, treatment gaps, market size, business competitors, regulatory requirements, potential business models, and reimbursement strategies. The teams then took all the need statements collected during the period of the clinical immersion and applied four rounds of filters in consultation with clinicians, patients, and administrators to arrive at the top needs as shown in Figure 2.

![Figure 2: A Graphical Representation of the Key Steps in the Filtering Process](image)

Finally, personal interest and motivation play a key role in determining the needs to be pursued further as depicted in Figure 3.

<table>
<thead>
<tr>
<th>Need</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A fast, reliable way for clinicians to measure bilirubin levels in order to provide timely and optimal phototherapy treatment</td>
</tr>
<tr>
<td>2</td>
<td>A way to assess the maximum amount of positive pressure tolerable by an individual neonate’s lungs in order to provide effective ventilation and prevent the occurrence of pneumothorax</td>
</tr>
<tr>
<td>3</td>
<td>A reliable way to immediately detect pneumothorax in the NICU in order to provide timely, lifesaving treatment</td>
</tr>
<tr>
<td>4</td>
<td>An easier way to safely deliver nutrition and antibiotics to hospitalized neonates in order to prevent vein damage, cyanosis, and infection</td>
</tr>
<tr>
<td>5</td>
<td>A more effective way to provide suction in ambulances or clinics without electricity or a main suction line in order to decrease the risk of infection and asphyxia.</td>
</tr>
</tbody>
</table>

![Figure 3: Some of the Top Needs Identified Following a Structured MedTech Innovation Process](image)
Discussion

This article discusses a structured process adapted for the Indian healthcare system to identify and solve critical unmet needs. The strength of this method was the ability to identify multiple unmet needs by clinical immersion in a short time. The main barrier while employing this technique was inability to engage a dedicated physician as part of our team. This led to a whole host of problems. The lack of a dedicated physician led to decreased understanding of clinical and disease state fundamentals. A clinician serves as a knowledge base in immersions, helping non-clinical fellows understand basic anatomy and pathophysiology. In these immersions, we were forced to split our time between observations and extensive research. The next barrier was inherent skeptical attitude about engineers and salesmen in the healthcare system. Many of the clinicians and nurses we encountered were concerned that we were monitoring their performance and might report misdeeds to their superiors. A clinician can help bridge this gap and explain our intentions while observing. Finally, without a doctor present, it was difficult to know which procedures are the most critical.

This study demonstrates the importance of a stable pre-planned multidisciplinary team for effective clinical immersions. An astute, motivated physician assists in explaining the clinical details to the non-clinical members. This process is augmented by Biomedical engineers and Biodesigners who can look at the situation with a fresh perspective which the doctors may get adapted due to constantly working in the same setting. Also for a MedTech product to be successful, it needs to fit seamlessly into the clinical workflow. After working for many hours in a clinical environment, engineers may learn specific details like, a nurse may only have only one hand available while performing a specific procedure or that devices aimed towards children require specific considerations. Having the whole team in the clinical space allows to connect with the user (ex. nurse, doctor, administrator) and the patient. In our experiences, these connections can motivate team members to continue developing products in situations where others would have given up. Having all the team members in the clinical environment gives them a better understanding of all stakeholders involved in implementing a novel device. Thomas Fogarty, an internationally recognized surgeon, inventor, and entrepreneur noted, “Innovators tend to go out and ask doctors what they want rather than observe what they
need. When you talk to physicians, as well as others involved in the delivery of care, you’ve got to learn the difference between what they say, what they want, what they’ll pay for and what they actually do.”

MedTech innovation is a unique process that requires interdisciplinary collaboration. For this process to be successful it requires commitment and dedication from all members. After initial difficulties in our immersion, we spent weeks getting to know the clinicians in our unit and continually attempted to recruit them to join our team. Once we had developed a rapport with doctors and nurses, the process went much more smoothly. While we were able to adjust mid-immersion, we highly recommend that each immersion have a complete multidisciplinary team with doctors, engineers, designers, and analysts to harness the power of creative collaboration.

**Conclusion**

The structured process of InnAccel to develop a new biomedical product is highly effective in defining the strategic focus area. The challenges faced were limited involvement by the clinicians in the early stages and suspicious outlook about engineers in the medical landscape.

**References**


Review Article

Igniting MedTech in India
Public-Academic-Private Partnership Model
Siraj Dhanani, Ramakrishna Pappu, Andrew Logan

Introduction

Medical technology, that is devices, diagnostics, equipment and assistive tools, is an important and fast-growing segment of healthcare globally as shown in Figure 1. MedTech today encompasses all aspects of medical care and can range from low-end consumables such as sutures, syringes and needles, to high-end robotic surgery platforms costing over INR 10 crores each. Globally, medical technology comprises 5 - 7% of the total healthcare expenditure, but is estimated to have a much higher impact on healthcare than this proportion suggests.

Figure 1: A comparison of historical and predicted MedTech spending in the US, BRC, and India
Today, India comprises a small portion of the global MedTech market, with 2013 sales estimated at $6 billion (less than 2% of global sales of over $300 billion).\(^1\) However, the Indian market is rapidly expanding, and is expected to cross $40 billion in annual sales by 2025 (accounting for 8 - 10% of the global market in 2025). The MedTech market in BRIC (Brazil, Russia, India, China) countries is expected to touch $200 billion, almost equal to the US market in 2025, but at a much lower per capita spend.\(^2\) What does this immense growth in the emerging markets mean for the global medical technology industry?

Emerging MedTech markets have very different characteristics than the developed markets in terms of healthcare systems and financing. These markets are characterized by limited health insurance coverage, extreme price-sensitivity in the self-pay population, resource-constrained public healthcare systems, and low and variable skill levels in healthcare professionals. These differences have a big impact on medical technology availability and utilization in these markets as depicted in Figure 2.

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**Figure 2: A pie chart representing expenditures from different sections of the Indian healthcare market**
The average Indian today spends less than $5 annually on medical technology, compared to about $400 by the average American. India’s explosive growth in the MedTech market will lead to a corresponding rise in per capita MedTech spends, however, even in 2025, the per capita MedTech spend in India will be about $30 or less than 5% of the estimated per capita spend in the US ($660) in that year. BRIC countries, as a bloc, will report a per capita MedTech spend of about $60 annually or less than 10% of the US per capita spend.

Similarly, the healthcare ecosystem in India is very different from developed world ecosystems. India has a serious shortage of skilled healthcare professionals across all levels (relative to global standards), and the skill levels of these professionals are also lower (and with massive variations within the system) than in developed markets. Similarly, there are significant resource constraints in the physical healthcare system, and in the general infrastructure. All of these differences impact the way devices and diagnostics are used in these markets. This results in sub-optimal availability, access, and utilization of medical technology that has been developed primarily for developed markets and imported into India and other emerging markets.

Interestingly, about 70% of the Indian MedTech market, even today, comprises imported products. In fact, Indian producers supply low-end consumables, and commodity equipment (for labs and hospitals), but have rarely entered high value segments in the MedTech space (surgical tools/systems, implants, in-office procedures, patient aids, etc.). As a result, most products imported into India are effectively utilized only in the Tier 1, “global” markets in India, and face serious shortcomings when deployed in ‘Bharat’, or the 90% of India in the low and mid-income segments. Thus, there is a big and growing need for appropriate and affordable medical technology for these markets. Technology that is aligned with the needs, affordability, and resources available in these markets; and calls for a radically different approach to MedTech innovation. We call this innovation, “affordable innovation,” though it addresses much more than just the affordability of payers in these markets, it is innovation that is truly aligned to the needs of this market.
Perspective on Global Medical Technology Innovation

Globally, small private companies that have been funded through venture capital and research grants have led medical technology innovation. It is estimated that of the 10,000 unique product categories in MedTech, small private companies have developed two-thirds. Larger public companies have a very active licensing and company acquisition strategy to get access to these innovations and leverage their sales and marketing expertise to bring them to market.

This trend is particularly evident in the United States. The five years from 2007-2012 saw over 1,000 acquisitions of small private companies by global MedTech players. The industry is supported by a vibrant venture capital industry, which invests billions of dollars in startups that have identified an unmet need and are developing innovative products to meet the identified need. Technology incubators at universities, or private medical technology accelerators support many such startups. It is estimated that over a 1,000 such medical technology incubators and accelerators support companies each year.

Israel has also developed a thriving medical technology industry over the last 20 years. This was achieved by a comprehensive government program to drive innovation and research by setting up 24 technology incubators to support startups in this space. These incubators were placed under private management and substantial early stage funding was made available for startups at these incubators through liberal grant funding, and technology venture capital funds. Today, Israel has a thriving MedTech sector, with over a 1,000 companies developing innovative products for the US and Western markets. Now, Singapore is replicating the Israeli model through it’s A*STAR program to create a research-led MedTech industry.

Technology incubation, supported by research grants, and ample high-risk venture capital for early-stage, research-led companies, has been the model that has successfully created these global hubs of MedTech innovation. This model can be effectively deployed in India to create the world’s first ecosystem for affordable MedTech innovation in 5 - 7 years, and tap the emerging global opportunity in affordable medical technology.
Structural Gaps in India’s MedTech Innovation Ecosystem

InnAccel, conducted a 9-month long study to understand the gaps in the Indian MedTech innovation ecosystem, and determine how these gaps can be effectively filled.\textsuperscript{4} We conducted 50 interviews, including 20 interviews with MedTech entrepreneurs, investors, academicians, clinicians, government officials, and venture capital industry professionals. We collected information on the need for a technology incubation ecosystem focused on MedTech, and the specific elements that such an ecosystem should provide. We also evaluated the possible models under which such an ecosystem could be made available on a sustainable basis to entrepreneurs and the role of government and private sector in creating this ecosystem.

All respondents indicated an urgent need for a functioning ecosystem to support MedTech innovation. This need was particularly expressed by entrepreneurs, all of whom were finding it difficult to innovate in this space. The interviews identified the key elements that are missing today, that need to be provided for innovators to enter this field and successfully develop products that meet Indian, and emerging market needs. These include:

- Physical infrastructure (office space, labs and research/prototyping facilities)
- Access to clinicians, and the clinical environment
- Access to engineering, prototyping, and product development expertise
- Access to high-risk capital for product engineering and development
- Overall business management, mentoring and strategic input

The study indicated that a functioning ecosystem, that provides these elements to startups, is necessary to kick start this industry in India and attract entrepreneurs to this sector. It should be noted that MedTech innovation takes longer than IT and digital startups (which comprises over 90\% of all startup activity today), and requires 2 - 3 years to develop a regulatory-compliant, well-engineered product that is ready for commercialization. Entrepreneurs need significant high-risk capital (INR 1 - 5 crores) to fund development for this period, and get the company ready for commercialization and the next stage of funding, which is typically Series A Capital (INR 10 - 25 crores) from established venture capital funds for commercialization and further growth.
Creating World’s First Ecosystem for Affordable MedTech Innovation

Based on our study, it is clear that a multi-pronged approach is required to create a functioning ecosystem to support affordable MedTech innovation. This ecosystem can be created through a unique Public - Academic - Private Partnership model, where government, universities, and private players work together to leverage their differentiated strengths. Specifically, we identify four key steps that can be taken in a time-bound manner to create this ecosystem.

**Step 1: Set up world-class medical technology incubators in India**

Invite proposals from academic - private consortia to partner on setting up dedicated MedTech incubators with state-of-the-art labs, product engineering and prototyping infrastructure, and office space for 20 startups at each incubator. The government should fund setup and operating expenses for these incubators, the academic partners (e.g. IITs) should provide the facility (and access to specialized equipment), while the private partner would invest the people and expertise to run the incubators. Startups would be incubated over a 2-3 year period focused on product engineering, development, and clinical validation. The government could consider tapping into the CSR funds of companies (PSUs and private sector) for funding these incubators.

Target: 5 dedicated medical technology incubators functional in 3 years, creating a capacity to support 100 startups at a time

**Step 2: Set up grant funding mechanism for early stage MedTech research in high-priority areas**

Create a dedicated mechanism to fund idea-stage research (pre-proof of concept) in priority areas of medical technology. This fund should be for individuals and small companies, and should be adequate to support 12-18 months of early stage research. It is critical that the approval and funding process be tight (8-10 weeks from initial application to funding) to ensure quick movement, as these projects can form the pipeline of companies to be supported by the incubators. The Department of Biotechnology (DBT) has an early-stage grant funding program (BIG) that today supports both biotech and medtech research. This program can be expanded or a dedicated program for MedTech research can be setup.
Target: 100 grants (up to INR 50 lakhs each) awarded in 5 years for research in technologies and products that meet high-priority healthcare needs

**Step 3: Support the creation of dedicated seed-stage venture capital fund(s) for MedTech innovation**

MedTech startups in India face a big funding gap during the technology and product development phase. This funding, called seed funding (typically INR 1 – 5 crores), is critical for startups to develop well-engineered products for Indian needs, and to get them to the next round of funding (Series A - typically INR 10 - 25 crores) and product launch. The government can incentivize the creation of such venture capital funds by matching private capital with government investment (i.e. if a MedTech seed-stage fund raises INR 100 crores from private investors, the government would match the private investment with another INR 100 crores, giving the VC INR 200 crores to invest in MedTech startups). Reducing the cost of setup and registration can also incentivize such venture capital funds, and providing tax breaks to investors who invest in such funds.

Target: Raise dedicated seed-stage funds of INR 500 crores in 3 years to be invested in MedTech startups, mobilizing private investment of INR 250 crores

**Step 4: Provide tax breaks for indigenous MedTech manufacturers, and provide preferential market access in public health procurement:**

Medical technology, being a critical and life-saving industry sector, should be considered for a 10-year tax holiday for Indian companies, on both domestic sales and exports. This will spur growth in this sector, similar to the effect STPI had on the IT sector. Given the negligible share of Indian companies in the Indian MedTech market today, it is unlikely that a tax break on this sector is likely to result in significant revenue loss. Consider providing preferential access to Indian startups in procurement for the public healthcare system. This could also include setting aside a small percent of the medical technology procurement budget for indigenous innovation or products designed and developed by Indian startups specifically for the Indian market.

Target: Bring tax benefits to the MedTech sector, and public sector procurement incentives for this sector in 2 years
Summary

The Indian healthcare system suffers from a significant gap in appropriate medical technology that is aligned to our healthcare system, affordability issues, and resource constraints. This gap is actually a generational opportunity to create completely new products that meet the needs of this market and tap an emerging MedTech market of over $200 billion in developing countries. This opportunity can be addressed by creating a well-functioning technology incubation ecosystem in India that allows entrepreneurs to innovate for specific, local, healthcare needs. Such an ecosystem has been created in Israel and other innovation hotspots, and India can take learning’s from these successful attempts, to create the world’s first affordable Medtech innovation ecosystem.

This ecosystem can be created by an innovative Public-Academic-Private Partnership model, which leverages the differentiated competencies of these different stakeholders. We estimate that such an ecosystem can be created with total deployment of INR 750 crores over 5 years, spread across private and government funding. This can allow India to gain a dominant position in affordable MedTech innovation, and profitably tap a market opportunity of over $200 billion by 2025. Even more importantly, this will provide appropriate products for the vast majority of our population, drastically reduce avoidable mortality and morbidity, and significantly improve healthcare for the underserved consumers in India and other developing countries.

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Educational article

Product Engineering Development Platform
A Compass to Navigate MedTech Landscape

Vijayarajan A, Pooja Kadambi.

Introduction

The key to MedTech entrepreneurship is to develop a product that addresses a clear unmet clinical need. Identifying and understanding an unmet need requires diligence; comprehensive clinical, technical, and market understanding. To address this need an appropriate solution concept must be formulated. The concept must take into account different parameters like regulatory considerations, intellectual property, business models and technical feasibility. The conceptualization process will culminate with the selection of the “strongest” solution concept. Transforming the chosen concept into a functional prototype and finally a usable product is the endpoint. Medical Device development has become increasingly complex with the constant influx of newer technologies and stricter regulatory and safety requirements. The final step in the developmental process is ensuring that the product meets all the necessary clinical, safety and user needs.

Most companies would like to have the approval of an independent regulatory body like the EU (CE certification), USA (FDA approval) which are recognized and accepted by multiple countries globally. There are also country specific regulatory requirements that must be fulfilled as in Canada, Japan, China and Australia. Currently India does not regulate or register most medical products but the end users/buyers typically demand some regulatory and safety certification. The successful commercialization of a MedTech product requires careful planning, coordinated cross-disciplinary efforts and a well understood consistent and rigorous process.

Multiple sources infused with product development expertise provide global industry best practices and standards to follow in medical device development. Examples include:

- Stanford Bio-Design Process1
- Design Control Guidance by FDA\textsuperscript{2}
- Various guidance documents from Global Harmonization Task Force \textsuperscript{3}
- ISO standards for medical devices like 13485 and 14971 \textsuperscript{4}
- IEC standards like 60601 and 62304 for electro-mechanical systems \textsuperscript{5}

MedTech entrepreneurs need a guide to navigate the often daunting and complex process of developing a regulatory compliant, commercially ready product from their initial solution concepts. This article will discuss the stages and processes that outline a recommended method to MedTech entrepreneurs developing healthcare products. Figure 1 shows the evolution of an innovative idea to become a finished product.

Figure 1: Main Steps in Creating a Medical Device
Unmet Need

The WHO states that 4 million newborn babies die each year. This is a problem. The unmet need here would be for a way to prevent or reduce the number of newborn deaths each year. However being able to say that a mother’s lack of knowledge of newborn warming care is the primary cause of certain number of neonatal deaths due to hypothermia is a more specific and addressable issue. A method (program or tool) to teach pregnant women how to maintain the warm chain for newborns in order to reduce the incidence of mortality from environmentally induced hypothermia could be one of the solutions. Thus it is evident that there is a significant difference between a “problem” and an “unmet need” and a “solution”. By addressing real needs many problems can be solved or indeed prevented. Firsthand knowledge of the problem provides a better understanding of the underlying need. A method to gather a lot of potential needs is through direct observation in a clinical setting. An event or action that contributes to a negative health outcome for the patient qualifies as a valid clinical observation in the context of needs identification. Requests from doctors, government agencies and complaints about existing solutions are other sources of potentially strong unmet clinical needs. Table 1 shows the different filters applied to identify the top needs and get to the root cause of negative health outcomes.

<table>
<thead>
<tr>
<th>First Level of Filter</th>
<th>Elimination</th>
<th>No elimination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redundant or very similar needs (will be eliminated)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Pharmaceutical needs (will be eliminated)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>IT related needs (will be eliminated)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Non Focus area needs (will be eliminated)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Second Level of Filter</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Frequency of observation by Observer</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Frequency of observation based on VOC</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Criticality of need by observer</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Criticality of need based on VOC</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Third Level of Filter</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Epidemiology: Incidence/Prevalence</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Market size estimate</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Fourth Level of Filter</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Predicate competition scenario</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Technical complexity of predicate</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Regulatory/Clínical trial complexity</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Buyer Environment</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 1: Needs Filtering and Scoring System
Criticality can then be determined based on the frequency of the issue and the severity of the consequence of that issue occurring. For example, Ebola has a high rate of fatality, but in India the frequency is negligible, hence this would be a less critical need than Dengue fever which has a lower fatality probability per case relative to Ebola but a much higher frequency of morbidity and mortality in India.

Concept Generation
Brainstorming solutions after the need is fully understood is the first step in innovation. Approaching this exercise with an open mind and without locking on a solution early on is essential. Sketching, creating mind maps, post-it notes idea board and so on are all ways to document and generate ideas. It is important for everyone to have a voice and to work towards consensus. A hands-on organic approach has been shown to spark creativity and innovation. You cannot generate ideas and information beyond what you know. This is why literature surveys, generating an intellectual property (IP) database and competitor product analysis, combined with sound technical knowledge and cross-collaboration across different fields of expertise helps generate and select sound concepts.

Selecting a Concept
At the end of the concept generation there will be many different solution ideas. It is necessary to filter our unsuitable ideas and select the top concept/s. This filtering process is done through both qualitative and quantitative methods. Rating concepts are based on how well they address the needs as well as based on their strengths and weaknesses with respect to Intellectual Property, regulatory, reimbursement and technical profiles. Tools like the PUGH matrix, expert opinion and surveys can aid in further narrowing down ideas. Once the approach and solution concept has been agreed upon, the selected concept/s are fully defined and proceed to the product development phase.

Product Development
“Make the product” is easier said than done. The process of engineering and designing a product is grueling, iterative and often complex. Figure 2 shows the execution of various steps that go into planning and implementation.
Figure 2: Different Processes in Planning and Development

While the above figure depicts a linear non-overlapping process, product development in any field, especially medical devices is a collaborative, interlinked and iterative process. Figure 3 shows the medical product development “web” that represents a product’s lifecycle that is seamless and endless. A few key processes within the product development framework warrant further explanation. Product requirements, Design and Engineering, Validation of the solution product and Regulatory Submission will be discussed in detail below.

Figure 3: Product Development Web (www.fda.gov)
**Product Requirements / Input**

Outlining the specifications for a product in the form of requirements is the start of product development after concept creation and ideation. The PRD or product requirement document serves as the ultimate guide for engineers and designers. It is created to capture all the needs of the products in a measurable and comprehensive manner.

This goes beyond basic and essential functional requirements and seeks to capture every aspect of product. Figure 4 represents the different categories of requirements.

![Figure 4: Different categories of product specifications](image)

Thinking of many factors early on during development avoids costly mistakes and extra iterations later on. For example a device that is to be used in an operating room will not be acceptable if it is difficult to unpack while wearing surgical gloves to preserve the sterile environment. Thus the packaging should be clearly defined for the end user or patient.

Company ABC developed a surgical device. Many of the specifications were based on requirements of surgeons who were right-hand dominant. These needs were not
appropriate for left-handed surgeons and in fact made it more difficult for them to use. Thus a significant number of their target users would be unable to use the device. This demonstrates that the source and method of gathering data is important. Figure 5 represents the different sources that can be used. Each category has importance and its own pool of needs. Safety requirements are critical to protect user and patient alike. Medical devices should not compound or generate new problems when used.

![Diagram of sources for design inputs]

**Figure 5: Sources of Design Inputs**

**Safety Requirements**

Emergency off buttons, color coded input/outputs, insulation and waterproofing and clear instructions and warnings are all examples of requirements directly linked to safety. ISO 13485 and ISO 14971 mandates a risk identification and management plan for any medical device. Thus factoring risk (hazard severity multiplied by occurrence frequency) is considered mandatory. Risk Management deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment. The components for risk management include: identifying, analyzing, evaluating, controlling and monitoring risk. Figure 6 shows the different hazards that the typical use of a medical device may expose a patient or user to. The objective of risk management is to reduce risk to an acceptable level while maintaining the functionality. The ALARP (As low as reasonably possible) standard is often used to define and move
forward with acceptable levels of risk. Risk management activities should begin as early as possible in the design and development life cycle. The activities to prevent, mitigate and manage risk are planned to ensure that the risk control measures are appropriately applied and that the product is safe to use.

**Medical Device Hazards**

![Medical Device Hazards Diagram]

**Figure 6: The different types and categories of hazards**

**Usability Requirements**

Usability requirements are to make users like the product and to ensure safe and appropriate use of the product. User interface layout, dimensions of grip, instructions for use, orientation and order of buttons, assembly geometry are some of the factors that must be designed to enhance user experience.

Human factor (HF) design comes into play to help understand, avoid and mitigate risk along with ensuring usability of a product. There are three components that one needs to consider for this type of design: the target user, the user interface and the environment of use. By defining such requirements early (as outlined when discussing the PRD) one can ensure that the product safety and usability is inherently present. HF is an important
safety consideration for verification testing during engineering and development. Figure 7 represents its role along with the inputs and outputs of HF driven design.

![Diagram of Human Factor Inputs and Outcomes](image)

**Figure 7: Human factor design- Inputs and Outputs**

**Design and Engineering**

The product requirements (specifications) serve as the design inputs while the prototype along with its subsystems and documentation and final product form the design output. For example in a primarily mechanical system the evolution from an idea to a product will typically be as seen in Figure 8.

![Diagram of Engineering development of a product](image)

**Figure 8: Engineering development of a product**
This stage utilizes core engineering technologies and capabilities across different domains as required by the product. Mechanical, Electrical, Computer and Biomedical engineering are some of the most commonly required skills. Specialization in optics, signal processing, ergonomics and micro-fabrication may be required for certain projects. It is important to have knowledge about existing and generated intellectual property (IP). The value of a patent will impact the commercialization of the product. Equally important for a new company is establishing the right to operate their product without infringing legally on another company’s property. Imperfect Design is a major contribution to unsafe devices. The pathway to successful device development is cyclical and iterative as ideas are prototyped, tested, improved, re-tested, optimized and finalized. Verification of Design Outputs (intermediate) and Design Review are the error correcting mechanisms that are essential for the efficiency and effectiveness of the process which leads to the desired product. The main steps in developing a medical product along with some important design and engineering documents usually reviewed are shown in the flow chart, Figure 9. There are multiple versions of each prototype created at system and subsystem levels. Once specifications are sufficiently met, risk is controlled and the product has been tested (by component and integrated) in the lab it is deemed suitable for clinical use.

![Flow Chart](image_url)

**Figure 9: Information flow of Medical Device Development**
Validation

Once the product has been developed and put together it must go through three forms of external validation namely clinical, safety and usability.

The goal of clinical evaluation is to assess and certify that the device is both clinically safe and maintains acceptable performance standards. This evaluation is performed through the assessment and analysis of clinical study data relevant to a medical device. Thoroughness and objectivity are important when designing and executing studies post approval from an ethics board.

For safety testing, the previously identified standards are checked against the device. Planning for safety validation should begin early in the design process; establishing the scope of validation and the validation methods and acceptance criteria. If this is not taken into account early in the process, the timeline and budget for the project both will be stretched. Many of these tests (like sterilization, EMI/EMC, drop test etc.) require an unbiased outside agencies to conduct the tests and certify the product as having passed. Validation may expose deficiencies in the original assumptions concerning user needs and intended uses.

Usability was discussed when describing human factor considerations. Focus groups, observed one-on-one interactions, clinical feedback and training are all ways to gather usability data. Testing how a user interacts with the device in a simulated or actual clinical environment will allow for a better understanding of user errors, misunderstanding of instructions, inability to set up or use the product and so on.

Regulatory Submission

The most well-known regulatory bodies globally are the USA Food and Drug Association (FDA) and the European Union certification (CE) entity whose compliance is recognized globally. Most countries (like India) deem those standards as sufficient for sale and use of a medical product. Canada, China, Japan and Australia also have their own medical device regulatory bodies and standards. Regulatory bodies typically work under one guiding principle; that the product performance and safety standards are appropriate for what the product is claiming to achieve. The submitted product is then considered ready for commercial production and clinical use. The FDA and CE both have their own
classification system and special rules and exemptions outlined for each class of device. The existence of a similar approved predicate device in the market, small modifications to one’s own approved product and a situation where there is a dire need for a product all affect the regulatory pathway of a product. Regulatory approval is not guaranteed in any situation, however by using proper protocols it becomes more likely. Figure 10 represents the medical device classification system used by the FDA (CE uses a similar system with some sub-classes). Figure 11 outline the regulatory pathways for FDA approval and CE marking/certification respectively.

![Diagram of Medical Device Classification System](image)

**Figure 10: Classification and Distribution of Devices**

<table>
<thead>
<tr>
<th>CE MARKING IN FIVE STEPS</th>
<th>Steps for FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decide which Directives are applicable to your product</td>
<td>If your product has a predicate file s 510K application</td>
</tr>
<tr>
<td>Ensure your product is compliant with the applicable Directives by testing and apply the relevant conformity assessment procedures</td>
<td>If your product has no existing predicate follow PMA Clinical Trial pathway</td>
</tr>
<tr>
<td>Compile and retain a technical file, which satisfies the requirements of the Directives</td>
<td>Class III life-sustaining devices will always have PMA pathway</td>
</tr>
<tr>
<td>Write and sign the Declaration of Conformity and keep the original with the technical file</td>
<td>Submit Design History File to the FDA for review and approval</td>
</tr>
<tr>
<td>Apply CE marking to the equipment in accordance with the requirements of the Directive</td>
<td>Review process could involve changes and request for additional data</td>
</tr>
<tr>
<td>CE marking is self-declared. CE Certification can be obtained once Notified Body verifies that product meets the required “Essential Principles” standards</td>
<td>Approval is required for sale in the USA and has a mark/stamp for the product</td>
</tr>
</tbody>
</table>

**Figure 11: FDA and CE Pathways**
Design Transfer / Launch
The culmination of the medical device innovation process is getting the product into the hands of the customer/user. This involves design transfer for manufacture along with a quality control (QC) plan.

The aim of design transfer is to achieve a manufactured product through set processes that are replicable, scalable, precise, accurate (with tolerances) and with quality controls in place. Packaging, transportation and storage are all factored into the design transfer process. Installation of the product, training and servicing are often required for medical products and need to be covered in a separate servicing process during design transfer. This is especially true for specialized and complex electro-mechanical systems.

Design transfer is not a single event but takes place throughout the design process. However the freezing and formalization of the transfer happens prior to pilot production. Once the product is in use, further validation is done through post-market studies over a few months to ensure that there are no major issues with the product. Post-market studies are also useful in gathering customer feedback to identify any changes and features that need to be implemented in future products.

InnAccel PED Framework
For entrepreneurs to be able to follow the above methodology for his/her MedTech product development InnAccel has built a documented process-based platform. The PED process utilizes a stage-gate design. It has multiple stages and includes deliverable milestones that any project must accomplish in order to succeed. This platform will serve as the guiding framework for MedTech product development.

It will be particularly useful for first time medical device developers and young entrepreneurs in the healthcare space. Figure 12 represents the different phases, milestones, deliverables and product development flow. Some of the key terms used in the framework are defined below.
**Figure 12: Stage Gate Development Framework**

- **Stages** - The project life span is divided into time segments called stages. The end of a stage is marked by milestones that can be reviewed by the Board / Management. This review serves as a node to decide whether to continue with, perform a course correction or put an end to the project.

- **Procedures** - Represent distinct divisions between the types of work. A stage may have more than one procedure. In terms of time segments, the procedures may overlap as many can/should be done in parallel. Some procedures like risk management go across stages.

- **Milestones** - Significant success or completion points, several of which may occur within a stage. Typically there will be one major deliverable milestone at the end of each stage that will be reviewed and evaluated.

- **Activities** - Each stage/procedure is completed by doing a set of tasks and. They can include research, documentation, designing, engineering, reviews, and
verification. While all activities are necessary for the development process, some may result in critical milestone work products.

- **Work Products** - Completion of an Activity or set of activities will deliver work products also referred to as project or product deliverables. All work products are reviewed and/or verified.

- **SOP** - Standard operating processes are the steps/instructions that must be followed to complete procedure or activity. These may have to be tailored for particular projects.

- **Checklists** - These serve as an expanded translation for the SOP with additional resources and examples listed.

- **Templates** - Fillable forms, excel sheets and documents that are used to capture information for the project according to the appropriate SOP

All these components are provided to companies in order to carry out their product development activities effectively. The PED will also be useful for management to be able to evaluate the progress of the product development team and provide timely guidance and resources.

As ideas are prototyped, tested, reviewed, improved, re-tested, optimized and finalized. There will be changes to many of the deliverables and a repeat of many activities. To evaluate the project through targeted reviews, a list of deliverables have been outlined in this platform. These test reports, requirement documents, plans, prototypes will serve as the basis for evaluating progress and making important management and R&D decisions. Figure 10 above outlines these decision nodes in green.

At the end of each stage a key question is asked - “Is the project/product ready to move on to the next stage?”

- If yes then proceed forward and update the project plan/timeline as appropriate.

- If the answer is no, then there are two options
  - Should we terminate the project? (typically stage 1 and 2 only)
  - What aspects need to be re-evaluated?
The boundaries between the various milestones, indeed between the different components of the PED are fuzzy and fluid in nature. It is important however to define the framework in order to keep track of the varied progress of a product and be able to budget, time and plan things accordingly.

**Conclusion**

The three goals of good medical device engineering are: a safe product, an effective and reliably performing product and a manufactured product that can be precisely and accurately replicated. Engineering products with safety and usability built into the design will create inherent utility for the user, developer and business. Imperfect design leads to product malfunction which may cause harm; leading to product warnings, recalls, and lawsuits.

Understanding the nuances, documentation and the protocols of medical product development is often complicated; thus having experienced mentors and a structured guide can facilitate this process. The role of design controls through the product development process and built in safety design is to help identify problems early, apply corrections and reallocate resources appropriately. ¹⁰

This article outlines the basic steps any medical device developer will have to take for product development. Regulatory bodies, investors, granting agencies, management and partners all require some level of transparency, communication and planning. By adhering to high standards and a disciplined process from the beginning consistency is maintained across the project and troubleshooting along with conflict resolution becomes minimal. There is a definite intrinsic value to having a traceable, documented design and development process. A properly documented process validates not only the final product but allows us to evaluate and improve upon the process itself. Having checks and balances in place will save resources (time, money and effort) in the long run and aid in effect product, project and business management.

**References**


Designing and Delivering a Training Program on Medical Device Innovations
Jagdish Chaturvedi.

Introduction

This article provides guidelines to design and deliver various forms of training programs for medical device inventions across diverse settings and participants. The author is a clinician and a trained Biodesign expert. He has conducted workshops of different designs: Short course (1 - 4 days), fellowship program (6 - 8 months), Internship program (3 months) over the last 2 years. He has trained over 500 participants from multidisciplinary backgrounds. These training sessions have collectively generated an unmet needs database of over 500 clinical needs, over 100 early prototypes, two start up companies and two technology licenses (Indian manufacturing company).

Figure 1: Dr. J. Chaturvedi (second from the left) with Dr. Paul Yock, Director of Stanford Biodesign

Types of Training programs –

Broadly there are two main approaches for training participants in the process of medical device inventions - workshops and fellowship/internship programs.

The workshops are intended to give an overview of the medical device innovation process and allow the participant to briefly experience the process of inventing a medical device in a simulated environment. These generally last for 1 - 4 days. These are academic in orientation and the expectations for an outcome that is something substantial in the form of a product or a start-up company is minimal. The recommended number of
participants for a workshop is 30 - 50. Fellowships or internships on the other hand are more detailed in their structure and allow participants to experience the process in greater detail in a real life setting. These typically spread over 6 months. The chances for a product or a company to evolve from such an effort is much higher. The recommended number of participants in a team for a fellowship or internship is 3 - 4.

Setting Expectations

It is critical to set the right expectations prior to initiating any type of training program.

Asking the participants their expectations - A recommended way to achieve this is by conducting a short interactive session with the participants right at the start of the program asking them their reason for participation. This allows the audience to contribute right from the beginning and gives them an opportunity to express what they would like to get out of the program. This is the best time to clarify what is realistically possible from the program and the scope of what is possible needs to be clearly defined.

Giving a quick overview - It is also a recommended practice to give an overview of the training program to the participants right after setting the expectations and laying out the benefits or advantages to the participant.

Offering to leave the program if not keen to try something new - After carrying out the above, participants must be allowed the option to leave the training program if they expected something else or are not interested to participate even after understanding the scope and overview of the workshop. Many might think of this to be radical step and it may effect the program severly if many participants leave the program. However, this step will go a long way in making the workshop more effective and productive for everyone. There have been instances where a few unmotivated participants have created a negative environment that hinders the productivity of teams and their outcomes. It is better to start the program with those who are ready to try something new.

Being honest about time of involvement - It is always good to say how long the training program will last for and how long sessions will take. Many times, participants hurry up their involvement in sessions when they feel the training has crossed their time expectations and this drops the energy and focus of participants. It is advised that the
participants are adequately prepared at the earliest opportunity if there is going to be a delay or realistically how long is a particular session likely to take.

Creating structure and schedule

1. For workshops

Prerequisites - For a medical device innovations workshop, the following are the list of things that are usually required for a 1 - 3 days event.

[5 White Boards with Marker Pens (Green, Blue and Black with each board), One LCD projector and laptop, foam, Lego Sets (3-4), pins, paper, glue, post-it notes, cardboard paper, thermacoal, scissors, blades, thread, wires, candles, matchsticks, clay, pencils, wooden planks, wooden sticks and anything that you feel is available for quick prototyping. Each team needs to have one laptop throughout the workshop.]

Typical Structure - The following are key areas that need to be covered in a medical device innovations workshop, preferably in the order suggested below. Participants are divided into teams of 3 - 4 members from multidisciplinary backgrounds if possible (Doctor, engineer, designer, business expert)

- Identifying needs (through clinical observations, clinician discussions, watching clinical videos or selecting from needs database)
- Selection of a compelling unmet clinical need
- Developing criterias that will set the guidelines for potential solutions
- Generating ideas and developing solutions
- Prototyping on the selected concept solution

2. For Fellowship / Internship

Prerequisites - For a medical device innovations fellowships or internships, the following are necessary

- Selection of a team of 3-4 members - Doctor, engineer, designer, business expert who are motivated develop a product that can be brought to the market with a commitment of 3-5 years
- Access for the team to spend 6-8 weeks in a hospital for clinical observations
Access for the team to a well equipped prototyping and design lab

Typical Structure - The following are key areas that need to be covered in a medical device innovations fellowship or internship

- Identifying needs over 6 - 8 weeks (through clinical observations, clinician discussions, watching clinical videos or needs database)
- Selection of a compelling unmet clinical need via a structured and scientific filtering process
- Developing criteria’s that will set the guidelines for potential solutions
- Generating ideas and developing solutions
- Prototyping on the selected concept solution to a proof of concept stage
- Filing of intellectual property
- Understanding business models, stakeholders and competitive landscape

Important Do’s and Don’ts during the training sessions –

Do’s:

1. Keep the sessions short (30-45 minutes)
2. Target for one or two learning objectives from each session
3. Keep the sessions interactive
4. Allow 15 minutes for questions and answers after each session
5. Give as many real life examples as possible
6. Include group activities or games that enhance creativity and team work
7. Make participants work in teams as much as possible
8. Keep 60 percent of the focus on observations and needs identification

Don’ts

1. Don’t try to cover the topics comprehensively in one session. Choose what to exclude based on audience (Ex. If it is a session on needs statement creation, then try to achieve formation of a need statement and criteria selection as the focus. Avoid talking about scoping of needs and other deeper information if that is going to lead to confusion. You can stage that to another session at another day)
2. Don’t deliver a lecture, instead make it as hands on as possible
3. Don’t criticize any suggestion or input, there are no right answers, just recommendations.

4. Don’t delay prototyping to the end. Have participants make things as soon as possible.

**Ensuring outcomes**

The only secret to ensuring the desired outcome is by inculcating interest, tenacity, and drive within the participants. Therefore the training program must highlight all possible benefits and incentives from participating in such a program. Also, any misunderstandings must be clarified. The outcomes will surely follow.

Listed below are some benefits of learning the process of medical device inventions:

- Development of a new skill
- Ability to invent independently
- Filing of intellectual property (publication)
- Valuable experience for fellowships/courses/jobs abroad
- Ability to impact large populations by improving healthcare
- Huge long-term or upfront revenues
- Increasing job opportunities for Indian employees

In addition to creating willingness, guiding teams to set realistic goals also helps in ensuring delivery of outcomes. Below are some key milestones, with their timelines, that are realistic to set with the participants.

For workshops:

- At the end of the workshop teams should have a looks-like prototype made out of paper/foam/materials provided during the sessions along with a short slide deck that has information on their team, area of focus, needs identification process, needs filtering process, top need and one or two concepts for the solution.
- At 2 weeks after the workshop the teams must have had the needs validated by revisiting the hospital and should have created a detailed need specification document for the top need.
- At 6 weeks after the workshop a refined looks-like prototype or a proof of concept can be expected.
For fellowships: At the end of the fellowship, teams should have

- A comprehensive observation docket for every observation (at least 50-75)
- Well defined problem statements and need statements (at least 50)
- A filtering pathway for arrival on top 3 needs (at least 4 levels of filtering)
- Voice of customer data for the top 25 needs (on criticality magnitude and existing solutions)
- Need specification documents with needs criteria for top 3 needs
- Looks-like prototype for top 3 needs
- Atleast 2 team members willing to form a start up company
- Provisional IP must be filed for the concepts
  - After 3 months of the fellowship the teams should have incorporated a start up company and developed a proof of concept for their selected need.
  - After 6 months the teams should have a product development engineering plan and should have raised seed capital.

Follow up

For workshops it is advised that a single follow up is carried out 2 weeks after the workshop to assess progress. For fellowship teams that form into companies, a weekly review by the senior mentorship team is recommended.

Key insights

Indicators for errors in needs identification: The following are pointers for the teams to revisit their need and look at their process for anything that they may have missed or wrongly assumed.

1. Need is obvious but no effective solution in market or process in place to address the need: For example, the need is “a faster way to call an ambulance after a road traffic accident in order to reduce delay in management”. Here it is an obvious need that ambulances need to reach the patient at the earliest however this is not being addressed effectively today. Therefore it is important to understand if there are any factors that exist which stop the implementation of an effective solution such as policy decisions, political involvement, too many people involved in bringing about a change, solution dependent on the assumption that patients or people may behave in a particular manner etc. It is
recommended that the need be pursued once there are no critical questions left unanswered.

2. Solution embedded in the need: For example “A faster way to insert a needle inside the vein in order to prevent shock”. Here inserting a needle into the vein is a concept solution. For brainstorming and concept generation, a non-solution imbedded statement is necessary or else taking the above example, the team will only brainstorm on different ways of inserting the needle into the vein. If the need statement had been “a faster way to restore falling blood pressure in patients with shock” then instilling fluids from an IV line still remains a concept and allows the team to think of other things such as postural solutions or pressure bandages or hydration patches etc. This makes the concept generation more comprehensive.

3. Top need appears unimportant to clinicians when discussed with them For example, the top need is “a way to prevent a reddish brown rash after application of adhesive bandage in order to reduce discomfort”. Here, if this is the top need after evaluating 100 needs then something has been miscalculated since this need even though high in volume of cases may not be a very critical or compelling need to solve. In these cases the teams would have taken the prevalence data of the number of people get a bandage rather than the number who develop a rash due to a bandage. This could have falsely increased the filtering scores and erroneously brought the need to the top.

**Indicators for team effort**

If a multidisciplinary team of 3 - 4 members have had no disputes or arguments and claim a very smooth and comfortable journey during a 3-6 month timeframe then the process that they are following and their mindset needs to be re-evaluated. Such a profile often indicates that the team is not trying hard or one member is dominating and the rest are agreeing. For a good concept to emerge, there must be logical and scientific opposition during brainstorming such that the solutions are crystalized and made more realistic. This often leads to mild disputes and rifts between team members. The teams must work effectively despite these disputes. Teams that convert these rifts to misunderstandings and personalize these with egoistic harm and damage to self esteem often end in the breaking of such a team and hence not suitable as a team for an entrepreneurial venture.
Selecting a Strategic Focus Area

VAP (ventilator associated pneumonia) is one of the major and deadly hospital acquired infection. The Institute for Healthcare Improvement (IHI) states that VAP kills more patients every year than any other hospital-acquired infection (HAI), and 46% of those diagnosed with the condition die.\textsuperscript{1} Ventilator associated pneumonia is a bacterial lung infection that affects patients who are ventilated for more than 48 hrs.

Understanding Disease State Fundamentals

VAP that occurs within 48 hours after tracheal intubation is usually termed as early onset, often resulting from aspiration.\textsuperscript{2} VAP occurring after this period is late onset. Early onset VAP is often due to antibiotic sensitive bacteria (e.g. oxacillin-sensitive Staphylococcus aureus, Hemophilious influenza and Streptococcus pneumoniae), whereas late onset VAP is frequently caused by antibiotic resistant pathogens (e.g. oxacillin-resistant Staphylococcus aureus, Pseudomonas aeruginosa, acinetobacter species and enterobacter species).\textsuperscript{3,4,5} The pathogenesis of VAP usually requires that two important processes take place

1. Bacterial colonisation of the aero-digestive tract.
2. Aspiration of contaminated secretions into the lower airway\textsuperscript{6}

Therefore, the strategies to prevent VAP usually focus on reducing bacterial colonization in the aero-digestive tract, decreasing the incidence of aspiration or both. The presence of invasive medical devices is an important contributor to the pathogenesis and development of VAP.\textsuperscript{7} Many patients have nasogastric tubes that predispose them to gastric reflux and increase the potential for aspiration. Endotracheal tubes facilitate bacterial colonization of the tracheo-bronchial tree and lower airway aspiration of contaminated secretions through mucosal injury, pooling of contaminated secretions
above the endotracheal tube cuff and elimination of the cough reflex.\textsuperscript{6} The ventilator circuit and the respiratory-therapy equipment may also contribute to the pathogenesis of VAP if they become contaminated with bacteria, which usually originate in the patient’s secretions.\textsuperscript{6, 8} The United States’ Center for Disease Control recommends the following guidelines for the prevention of ventilator-associated pneumonia\textsuperscript{9}:

\textit{a. General strategies}

- Conduct active surveillance for VAP
- Adhere to hand hygiene guidelines published by the Centers for Disease Control and Prevention or the World Health Organization.
- Use non-invasive ventilation whenever possible.
- Minimize the duration of ventilation.
- Perform daily assessments of readiness to wean and use weaning protocols.
- Educate healthcare personnel who care for patients undergoing ventilation about VAP.

\textit{b. Strategies to prevent aspiration}

- Maintain patients in a semi-recumbent position (30° - 45° elevation of the head of the bed) unless there are contraindications.
- Avoid gastric over distention.
- Avoid unplanned extubation and reintubation.
- Use a cuffed endotracheal tube with in-line or subglottic suctioning.
- Maintain an endotracheal cuff pressure of at least 20 cm H2O.

\textit{c. Strategies to reduce colonization of the aero digestive tract}

- Orotracheal intubation is preferable.
- Avoid histamine receptor 2 (H2)–blocking agents and proton pump inhibitors in patients who are not at high risk for developing a stress ulcer or gastritis.
- Perform regular oral care with an antiseptic solution.

\textit{d. Strategies to minimize contamination of equipment used to care for patients receiving mechanical ventilation}

- Use sterile water to rinse reusable respiratory equipment.
- Remove condensation from ventilatory circuits. Keep the ventilatory circuit closed during condensation removal.
- Change the ventilatory circuit only when visibly soiled or malfunctioning.
- Store and disinfect respiratory therapy equipment properly.

In spite of these detailed guidelines, the prevalence of VAP is still very high.

\textbf{Performing Systematic Gap Analysis}

While the international statistics are daunting, we also found VAP to be a particular problem in India. In order to learn more about the problem, we performed a systematic treatment gap analysis. This included research, interviews with care givers, visits to private and government hospitals with ICUs and ventilators in Tier 1 and Tier 2 cities in four different states (Karnataka, Maharashtra, Madhya Pradesh, Rajasthan), clinical immersion in an ICU (15 days), and medical conferences. We concluded that the following are the major reasons why protocols and guidelines for VAP prevention are not efficient in an Indian scenario

1. Diagnosis of VAP is still unclear and reporting of VAP is uncommon. This allows hospitals to neglect responsibility for extended morbidity and mortality.

2. Most patients and caregivers are not informed about ventilator associated pneumonia. They are typically told that the patient has contracted pneumonia or an illness.

3. The lack of skilled man power is a major issue in Indian healthcare settings. As per the ICU protocol, each patient in ICU should receive one-to-one nursing care. But, in reality, one nurse typically cares for of multiple patients. This can increase the chance of cross-infection.

4. Regular oral care and suction consumes hospital resources and increases costs.
5. Many nurses who staff the ICU are not trained for critical care and therefore are unaware of the dangers of VAP and the protocols for VAP reduction.

6. The best products available in market are inefficient at secretion management. From interviews we learned that best available technology for VAP reduction are CASS (continuous aspiration of subglotic secretion) tubes. These tubes removes 50 - 70% of subglottic secretions. However, CASS tubes are costly, require one-to-one nursing care, and still suffer from frequent mechanical failure. In addition, once a patient is intubated with a standard endotracheal tube, reintubation with a CASS tube is rarely recommended.

7. Diagnosis of VAP requires regular X-ray imaging, which is not done by most the hospitals.

8. Re-use of deposable medical device still exists, especially hospitals of Tier 2 cities. We repeatedly found endotracheal tubes and suction catheters being re-used in patients after minimal sterilisation.

9. Current suctioning often increases the chance for bacterial infection by spreading bacteria around the body. In particular, suctioning of the secretions near the cheeks is often done first. Then, the same suctioning tube is used for suctioning in nasopharyngeal area.

**VAPCARE**

We at Coeo labs are currently developing a product, VAPCARE, to prevent VAP in intubated patients. This product manages oral hygiene and secretions without human intervention through the following mechanisms:

1. Automatic management of secretion.
2. Automated mouthwash and lavage.
3. Automated clearing of blocked suction ports.
4. Intelligent suctioning system
5. Early alert to declining patient condition
References:


UNESCO has declared ‘Reducing Child and Maternal Mortality’ as a millennium development goal. India with an infant mortality rate (IMR) of 42 per 1000 has a long way to go to meet this target. In response to this global initiative, the Reproductive, Maternal, Newborn, Child & Health (RMNCH) space is heating up with a large number of companies and researchers developing innovations and interventions to improve clinical outcomes. However one niche area that has not received enough attention until now is labour management and antenatal monitoring of the mother and the fetus.

Sattva MedTech is a Bangalore-based antenatal diagnostics and interventions equipment company. We are a bunch of electronics engineers from BITS, Goa and are working on a fetal electrocardiogram-based fetal heart rate monitor. Constriction of the placenta and the high stress put on the fetus during labour can cause reduced blood supply to the fetal heart. This causes the fetus to compensate by increasing heart rate. This condition is called fetal distress. Fetal distress can lead to meconium leakage, aspiration, and can have long-term impact on fetal health. In severe cases, this condition leads to stillbirth. Fetal distress monitoring is standard practice, and the current standard is a Non-Stress Test (NST) followed by invasive intrauterine scalp electrode (FSE) or a 3D Doppler test.

The Non-Stress Test machine has a poor negative predictive value and is affordable only for medium or large-sized hospitals. The follow up invasive FSE or the 3D Doppler tests are rarely if at all conducted due to prohibitive costs. Indian Obstetrics specialists base their decision for a C-Section on patient history, NST numbers (when available) and clinical acumen. Rural or bottom of the pyramid homes, often do not have access to either obstetric specialists or diagnostic technology. Almost 70% of these deliveries are non-institutional and conducted by midwives. Ironically these are the conditions where fetal monitoring is most required. Absence of timely fetal monitoring leads to stillbirths and miscarriages.
Our team came together around the vision of making timely, accurate and definitive fetal distress diagnosis available to these patients and scenarios. I had the opportunity to visit several Public Health Care Centers in the Barpar District of Uttar Pradesh. The dilapidated state of the clinics was an eye opener for me! The stories of stillbirths, the anguish of the women who had lost their babies and the sight of one child born with cerebral palsy were gut wrenching. While brainstorming for ideas, we decided to focus on building a non-invasive smartphone integrated fetal monitoring device. The proposed device will be designed for deployment from specialty maternity clinics to frontline health workers like Auxiliary Nurses or Lady Health Volunteers as shown in Figure 1.

Figure 1: Model to illustrate Smart phone based Integrated device for Antenatal care in the community
Stories to inspire

Clinicians as Inventors: Not an Impossibility

Vimal Kishore

Medical education trains doctors to be reasonable, adapt to diverse situations, get the work done, and give out the best even with scarce resources. There lies a lot of innovation that goes unnoticed in the process of adapting. That small budding sapling of innovation gets crushed in want of its growth factors.

I always had a predilection towards innovation from my childhood and even when I was studying MBBS. I had friends from biomedical engineering and other technical branches taking medical inputs from me and this kept my inspiration to innovate alive. When I joined St. Johns Emergency Department as a resident, I had an opportunity to learn about the AIM (Affordable Innovation in Medicine) Entrepreneurship program and about innovation in medical technology. The introduction to innovation in medicine was fascinating. Ideas lying dormant in my brain sprouted new wings and I willingly joined the course. I learned the scientific process of innovation. Problem finding with the team members from different educational backgrounds reiterated the fact that as doctors we tend to ignore the subtle things that are pivotal for innovation. We tend to manage a particular situation without even giving a second thought about how it could be developed further for benefit of the patient. As a team we came up with great number of unmet needs in department of Emergency Medicine alone. It was astonishing to consider the number of needs that may generated if all departments used this method of identifying unmet needs.

Coming up with top needs is a real nightmare. It involved going through each and every need, evaluating its criticality, market size, predicate estimation and finally arriving at top needs. But each and every step gave me a glimpse of a new dimension in our regular medical work. Brainstorming was the next big thing. This is the time where you can actually be yourself, you can come out with your novel idea, no matter how weird your ideas sound. Juxtaposing all the ideas to form a plausible solution is crux of the brainstorming sessions. This is most effective when you have good teamwork and people
from diverse backgrounds. Contemplating ideas with product designers, electronics engineers and expertise in the medical technology to culminate into a feasible product was really enthralling.

Out of the two top needs, which included a device to prevent VAP (Ventilator associated Pneumonia) and a device to monitor and manage intracranial pressure, the VAP concept stole the show. At the zenith of the program, filing an intellectual patent as a co-inventor made me feel that there is always time to let your dormant ideas get ignited.

Furthermore, the development of the product, periodic feedback and spontaneous brainstorming sessions incarnating the idea into a more sophisticated product gave me immense contentment. I remember many a time, a jovial discussion would flare up into an exhaustive brainstorming session resulting in appending a new feature to the product. To add to this our product to tackle VAP got selected to the final round among 90 other devices at the department of Biotechnology, Government of India. This was very encouraging.

Innovation in medical devices opened my eyes as a clinician. I feel that medical device technology can unleash a whole new world of exciting possibilities for doctors who are ready to devote a very minimal part of their clinical practice towards innovation. In that way, inventions would be based on true needs and would cater to vast unmet health care problems of the overburdened Indian healthcare system.

The narration of my experiences, I hope will inspire clinicians to get themselves trained in the process of innovating. It is very important that we start creating affordable medical technologies in India. If every medical personal takes on leadership and starts making indigenous devices, in a short period of time India can become a leader in the area of biomedical innovations.

*The reasonable man adapts himself to the world; the unreasonable one persists in trying to adapt the world to himself. Therefore all the progress depends on the unreasonable man.*

- George Bernard Shaw -
Beyond healthcare

Integrating Innovation Units into Healthcare Systems

Ramesh A, Jagdish Chaturvedi.

The most appropriate location for an Innovation Unit for biomedical inventions is the healthcare system, where an unmet need originates. A healthcare system could be hospital or community based. Conventionally innovation units are located in engineering institutions. This article examines the process of integrating an innovation unit into a healthcare system. A step before integration of innovation units into healthcare systems is to define the intentions of this unit. An innovation centre should be able to perform the following activities.

1. Maintain a database of unmet clinical needs derived from challenging healthcare situations in the healthcare system. So there must be a system in place that ensures that all divisions in the healthcare system document their unmet needs, use filters and arrange them in the order of priority.

2. Facilitate departments to create a “Proof of concept” from the unmet needs. This will require ongoing training sessions of all the stakeholders.

3. Assist in filing for provisional patents for “Proof of concepts”. Legal expertise should be made available for this process.

4. Develop Memorandum of Understanding to create Public-Private-Academic partnership models. These models can choose to explore early stage licensing out of the IP to potential start up companies or small and medium sized MedTech companies for a nominal fee/royalty agreement. This can spin off technologies to entrepreneurs who want to form MedTech companies on valid critical needs and also serve as an early R&D effort for many established MedTech companies. Start-ups that form from these projects may be explored for acceleration/incubation through partnering incubators.

5. Raise funds for sustaining the centre and drive project development.
7. Assist in getting Institutional Ethics Clearance for efficacy and feasibility studies, perform clinical studies to validate new technologies, conduct clinical trials and “first in man” studies.

8. The centre must make efforts to create a database of clinical epidemiology, incidence and prevalence of diseases, market sizing for various healthcare domains.

After defining the functions of an innovation unit, the stages of forming and integrating such a unit are as follows.

**Stage 1 of Integration : Creating Awareness in the Healthcare Ecosystem**

Though the concept of innovation and invention is not new, the structured process of creating a new device needs to be explained to medical personal. A workshop involving medical students, faculty, paramedical staff and hospital managers is the first step to create awareness in a hospital based system. In a community based system, leaders of the community as well as frontline workers need to be involved.

**Stage 2 of Integration: Conduct Brainstorming of Representatives from all the divisions of the Healthcare system**

There should be joint meetings with all the departments to explain the purpose of this innovation unit. A structured brainstorming should be conducted and the ideas generated should be documented.

The inputs of the departments should be incorporated into the unit so that over a period of time the unit gets increasingly relevant to find solutions for problems faced while caring for patients.

Also a system for regular feedback from the divisions for on goingly refining the unit should be put in place.
**Stage 3 of Integration: Developing a Resource unit to foster Innovation**

A working committee can be constituted from participants of the workshop. The possible members and their job description can be as follows

1. **Convenor:** Functions as an innovation manager who co-ordinates the functions of the innovation unit. The innovation manager should preferably be a healthcare personal from the healthcare system. It would be preferable to appoint a senior faculty who is accountable to the organisation within which the unit is housed.

2. **Advisors:**
   - Academic advisor should be the dean of the institute
   - Engineering and product design advisors: Consultants from Innovation incubators or accelerators who will work for a consultation fee.
   - Legal advisor: A lawyer with experience in patent issues and intellectual property rights, who will provide the services for a consultation fee.
   - Community development advisor: Will provide opinion on community based feasibility studies as well as assist in creating social case studies while applying for funds from corporate houses.

3. **Research officer** to co-ordinate validation studies, cadaver studies, clinical studies and trials.

4. **Office assistant** for maintaining the centre, carrying out paper work, logistics, managing meetings, accounts

**Stage 4: Regular Audits to monitor the progress and quality of the unit**

A structured process should be put in place to regularly monitor the progress of the unit in terms of its ability to improve the quality of lives of people in communities.

Such an unit will help bridge the gap between clinicians who know what to solve and engineers/designers who know how to solve and bring the product to reality. This can help churn out numerous India specific medical technologies that can significantly impact our healthcare system by solving the issues faced by healthcare professionals and patients in India.
Information pamphlet

A Roadmap to Identify - Invent - Integrate a Medical device

Jagdish Chaturvedi.

Step 1: Idea to Proof of Concept (Identify)

Clinical observation

Identifying clinical need

Clinical experience

Generating Idea/Concept

Open sourcing or making the invention public

Filing IP provisional

Raising funding for proof of concept development 1-15 lakh INR

Applying for grant money or institutional support

Self-funding

External funding from investors/Incubators

Raising funding for proof of concept development 1-15 lakh INR

Applying for grant money or institutional support

Self-funding

Hiring an engineer and/or product designer as required or engineer and designer can be integral to the team

Developing Proof of concept

The technology may be licensed out to a larger company for limited up front fees (50 K - 2 Lakh INR) and royalty agreement (1-3%) or can be transferred to a start up company for shareholding/equity
Step 2: Proof of Concept to Regulatory Compliant Product (Invent)
Step 3: Regulatory Compliant Product to Commercialization (Integrate)
Book Review

Jugaad Innovation - A Frugal, Flexible and Inclusive way to grow.

Pooja Kadambi

The word Jugaad according to Wikipedia is “a colloquial Hindi-Urdu word that can mean an innovative fix or a simple work-around, used for solutions that bend rules, or a resource that can be used as such, or a person who can solve a complicated issue”. The definition itself sounds confusing and made-up; capturing the essence of Jugaad which is a way to make do with what exists to achieve what people wants. This International bestseller by Navi Radjou, Jaideep Prabhu and Simone Ahuja breaks down the driving principles of Jugaad and touts it as the modern way to facilitate innovation with limited resources. The recent India mission to Mars got global attention not just for the mission but for how little it cost. Innovation has always been valued in the world and frugal innovation has always been desired. Due to economic crises and globalization the same desire has become a necessity. By using examples across the board like Google, 3M, IBM, Akash Embrace, Zhongxing Medical and so on the authors have tried to target a vast demographic of readers and demonstrate universal application of their message.

An important message that gets buried in the book shows up early on page 24. “Jugaad isn’t relevant for all situations and contexts. In particular, jugaad shouldn’t replace the structured innovation to innovation; rather, jugaad should complement it.” MedTech innovation is a complex process with multiple stakeholders, regulations and requirements. The Jugaad principles are applicable; however it should not be used as a
way to cut corners or speed up a process at the risk of harming someone. Consumer products, apps, marketing models etc. typically do not have the same risks as medical devices where malfunction could lead to physical harm or death. Thus the need for structure, checks and balances is high for medical devices.

The six principles of Jugaad feature in the beginning of the book and each have a chapter dedicated to understanding them better. The book is structured like a series of case studies that build evidence in support of the driving principle. The principles are pretty self-explanatory and quite obvious. They can be applied to MedTech innovation but only to an extent.

1. Seek opportunity in adversity- In the affordable healthcare sector especially, this principle can be applied to identifying and addressing unmet needs. Who is affected by a problem? What is the root cause of the problem? What are the barriers to solving this problem? Posing all these questions in the face of observed issues that lead to poor patient outcomes will help entrepreneurs identify opportunities in the healthcare space.

2. Do more with less- This lesson applies to life not just business. Which company will not want to increase their margins and minimize expenses? MedTech product development can do this by implementing process and structure to minimize product iterations, compliance testing and by working on customized solutions rather than the “ironman suit” model of one product does it all. In order to do more with less there is more planning required and less of an ad-hoc “jugaad” approach during innovation. This book seems to use jugaad and creative thinking/problem solving interchangeably which is not always obvious. The distinction is an important one because too often jugaad is used as a medium for slipshod engineering and unreliable systems.

3. Think and act flexibly- This chapter cites “Rigid, Time-Consuming Product Development Processes” as a barrier to success and “Jugaad Innovators Don’t Plan- They Improvise” as the go-to model. Medtech regulations mandate a rigorous process and constant improvisation can lead to disastrous consequences for customers and the businesses alike. Flexibility within a planned framework and being able to reallocate resources to meet targets is the appropriate interpretation.
4. Keep it simple- Very often medical devices use complex technologies and have multiple safeguards in place which incorporates some amount of over engineering. Also the need for simplicity must be put into context. By keeping the end user in mind products can be designed to be simple at least on the outside. Google’s mammoth search engine is used as an example of simple use but complexity in design. The book’s statement “Make it simple not simplistic” is apt for MedTech products.

5. Include the margin- Targeting the marginalized/minority sections of society can be profitable as well as socially responsible. The use of technology to scale up personalized solutions even in remote areas is applicable to many telemedicine and home healthcare products. Some margins are growing and it makes sense to create products to meet their needs. The number of babies being born, the number of people over 65, the number of people with learning disorders and so on are all increasing rapidly. This all goes back to clearly identifying and defining a need.

6. Follow your heart- This all about following passion and intuition while combining it with empathy and inspiration. Working on an issue/problem one cares about always helps in keeping oneself motivated and positive. Healthcare is personal and users are typically a highly specialized group. Building relationships and factoring in the needs of users and/or patients is essential. Intuition comes from experience and expertise and cannot be the basis of decisions. Research, customer/user feedback, rigorous quality control and safe and usable design are the foundations of medical device development.

Overall I would give this book a 6 on10 as a guide for MedTech entrepreneurs because it has many lessons that are not applicable to the space. In fact the book itself whether intentionally or unintentionally reads like a jugaad compilation of many existing self-help, marketing, business strategy and success narrative books.