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Research Article

A structured process to identify unmet needs for Medical Device Innovation in Obstetrics and Gynaecology

Rohan D'Souza[1], Abu Saquib Tauheed[1], Ravi Jangir[1], Parul Chachra[1], Rishabh Sirdesai[1], Darien Rodrigues[1], Adithi Sarovar[1], and Jagdish Chaturvedi[1*]

[1]InnAccel Technologies, Bangalore, India

***Corresponding author**: Jagdish Chaturvedi, ENT Consultant, Apollo Hospitals, Bangalore; Director, Clinical Innovations, InnAccel Acceleration Services, Bangalore, India, E-mail: jagdishc@innaccel.com

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Abstract

According to estimates, 75% of medical devices and diagnostics in India are imported and most are priced at global price points. These devices are neither priced nor designed for the Indian population. India is working toward increasing healthcare access. In this process, reducing costs of healthcare and innovation will play a huge role. However, it is of vital importance to develop solutions specific to the Indian patient and compatible with the complex healthcare ecosystem. The process of Medical technology innovation called the BioDesign process was initially developed by Stanford University. This ranged from observations in the clinical setting, to unearthing needs, developing a concept and thereafter a framework to eventually reach the stage of commercialization. We have used an adapted version of this process to identify unmet clinical needs in Obstetrics and Gynaecology in India. The Stanford Biodesign process was devised for mature healthcare systems and hence has been adapted to suit India sensibilities. The clinical immersion spanned across 10 weeks and involved 2 tertiary care centres and 6 rural centres, both primary and secondary, in South India. On completion, we arrived at 74 unmet clinical needs with significant negative outcomes. These needs went through a rigorous four round filtering process to arrive at the top 10 needs. These filters ranged from epidemiology and criticality and disease to competitive landscape and technical complexity. In this article, we present our need identification process as well as our top 10 medical device specific needs.

Keywords: medical devices, obstetrics, gynaecology, biodesign

Background

India, a country with 1.3 billion people, has a healthcare care system with multiple well established fallacies [1]. The lack of adequate medical professionals, the urban-rural divide and the creaking infrastructure makes for significant challenges. These challenges are more so in Critical care and Emergency Medicine in a country where ICU beds are few and far between and trained emergency personnel are lacking [1]. However, these challenges when turned on their head present great opportunities for healthcare entrepreneurs. Currently the MedTech industry in India imports 75% of devices and is looking to move toward self-sufficiency [2]. Herein lies the importance of indigenous innovation.

These voids may seem obvious but can be perilously misleading. Lack of complete and holistic understanding of the need, disease, stakeholders, users and regulatory hurdles has led to the early demise of many an entrepreneurial journey [3]. The Stanford Biodesign process is designed to analyse unmet validated clinical needs and uses a structured filtering process to find the most compelling and impactful needs worth solving. Keeping in mind factors such as business models, technical complexity, regulatory pathway and reimbursement strategies, creative solutions for the top unmet need are created by multidisciplinary teams [4].

Objective

In this study, through partnering with clinicians, we have identified the most pressing unmet needs in the field of Obstetrics and Gynaecology in India that could potentially be addressed through innovative medical devices. The dataset could be harnessed by entrepreneurs, considering to delve into medical technology space, and individuals (or foundations) planning to invest in healthcare.

Methodology

As followed in Stanford Biodesign, the team gathered to conduct our study was multidisciplinary. This was in essence to minimize innate bias at an individual level and augment perceptivity when put in any given clinical situation [4]. This assortment of professionals included a clinician, an electronics engineer, mechanical engineers, product designers and a PhD holder. The mentors were subject matter experts who provided guidance and mentorship to the team through their years of industry experience.

The 'identify' phase of the BioDesign process centred on important unmet health needs. The key element of this phase is the direct observation of the full cycle of care from diagnosis and treatment to recovery. The 8 week clinical immersion was conducted in Obstetrics and gynaecology in a tertiary care centre in Bangalore. The Fellows observed what's done and how it affects the provider, the patient, and the system, while asking questions that challenge the status quo [4]. This was followed by a peripheral immersion at 10 primary, secondary and tertiary health care centres in India. The clinical needs found in the tertiary care hospital were validated in other large centres. The 'Identification' exercise was conducted at secondary and primary centres through observation and clinician interviews.

During this first-hand observation period, needs were collected without any bias and judgement. Thereafter, the needs were filtered through a structured process. Quantifiable measures were applied to prioritize the needs. In total, four filters were applied. The first filter consisted of eliminating redundant needs, and needs related to pharmaceutical, IT (Information Technology) or non-ENT spaces. This was done to exclude needs that were irrelevant or that would have no product-based solutions. The second filter was based on identifying predicate devices or existing devices addressing similar problems for each need, literature review and frequency of occurrence of each need based on two factors- the clinician's multiple years of experience in the field and the observers' experience during the immersion period. The third filter was based upon the criticality of the need and understanding the technological feasibility of innovation for a particular need. The fourth filter was included scoring every need in terms of intellectual property (IP) landscape, and through clinical feedback from multiple clinicians from various hospitals. Each need was scored and filtered based on an unbiased numerical scoring system.

Results

At the completion of 2 months of clinical immersion over 74 unmet clinical needs with significant negative outcomes were collected from 96 detailed observations.

The level 1 filter eliminated redundant, pharmaceutical or process related needs. The observation docket now had 56 needs based on the information collected both during the clinical immersion process, the validation interviews and focus group meetings with clinicians.

The level 2 filter whittled the list of needs down to 35. This level of filtering focused on the severity of clinical need (in the perception of observers and clinicians), the epidemiology of the disease and frequency of the negative outcome. This data was then validated by a comprehensive literature review of incidence and prevalence data.

The third level of filtering evaluated the technical complexity of the problem and regulatory landscape. This was made based on the solutions, which currently existed as per guidelines. We looked at both prevailing practice as well as gold standards.

Lastly, the fourth level of filter was applied, which focussed on the business aspect of the needs. The buyer environment and competitive landscape were determined and rated to finally determine the top 10 needs.

The top needs found in Obstetrics and Gynaecology field were:

1. An accurate and low skill way to detect fetal distress in women who are not in labour, at home to avoid Intra-Uterine fetal death (IUFD)
2. An accessible and low skill way to monitor asymptomatic uterine fibroids in fertile women at Primary centres to prevent infertility and surgical risks associated with hysterectomy
3. An effective way to prevent seizures in pre-eclampsic/eclampsic women at secondary care centres and above to prevent high risk of brain damage and/or magnesium toxicity
4. A safe, low skill and uterus sparing procedure way to manage uterine fibroids in women at secondary care hospitals and above to prevent risks of hysterectomy
5. A safe way to manage tubal rupture in ectopic pregnancy at secondary care hospitals and above to preserve normal fertilisation pathway
6. An effective way to manage post-partum haemorrhage in women at primary healthcare centres and above to avoid hypovolemic shock and high risk of maternal death
7. An affordable way to reduce the incidence of neonatal sepsis at primary healthcare centres and above to avoid neonatal death
8. An accurate and low skill way to detect cervical cancer in women at primary healthcare centres to reduce the incidence of late stage cervical cancer
9. An affordable and effective way to prevent surgical site Infections in open abdominal/pelvic surgeries in community health centres and district hospitals to avoid re-suturing of incision and risk of sepsis
10. An accessible and affordable way to manage placental abruptions when blood is unavailable at District Hospitals and above to prevent hypovolemic shock and fetal asphyxia

Discussion

A study by IBM stated that 90% of Indian start-ups fail [3]. This number is particular said to be due to the lack of innovation [3]. This process describes the structured way in which the AIM Fellowship team used an adapted version of the Stanford BioDesign process for Medical innovation to assess the top needs in India in Obstetrics and gynaecology. The key reasons why healthcare start-ups fail in India is down broadly to 4 key reasons.

Innovation silos

Innovation in healthcare is taking place on a huge scale, especially in universities and incubators across the country. Unfortunately, most innovation concepts adapted from Western medicine or is a solution built by technical

experts without a healthcare professional. This tends to disconnect once the product has hit the market. The clinician's insights into the clinical problem as well as the current management practices goes a long way in iterating the solution and in turn increase adoption by his/her peers. This is why involving clinicians at every stage of the development process is essential, not only to create a better solution but also to facilitate clinical trials and improve adoption. The biggest problem in India is skewed doctor-patient ratio that makes it exceptionally difficult for clinicians to both practice and be involved in innovation. [5]. In our study, clinicians were involved right from observation to filtering.

Disconnect between the problem and solution

In spite of solutions working in theory as per the studies, adoption and acceptance by healthcare practitioners is often found to be low. This is due to the fact that medicine is highly complicated and probabilistic, and, in many cases, the underlying problem is not addressed by the solution in question or is out of financial reach of end users [6]. Furthermore, solutions which 'replace' clinicians are never accepted well. Understanding the underlying need from healthcare professionals, as was done here, goes a long way toward building a solution which is relevant.

Slow and ardous development cycle

The regulatory system, both in India and abroad, is complicated and cumbersome [7]. Unlike software, where one can release a beta version as soon as possible and iterate based on feedback, in Medical Technology a person's life is often at stake. However, resources are exhaustible and has led to the demise of many a start-up. Determining the technical complexity of possible solutions early one helps one define a broad timeline and set realistic expectations. It is also important to budget accordingly rather than to be caught unawares and fall in to the abyss!

Complicated ecosystem

The healthcare ecosystem consists of doctors, paramedical professionals, healthcare administrators, regulatory bodies, government bodies, associations, patients, clinical trial bodies and many more [8]. All these stakeholders in need to be aligned for a solution to be successful since each one is dependent on the other. This is further complicated by the tiered structure of healthcare; primary, secondary and tertiary. The stakeholder analysis grid makes for a complicated exercise. It's important to keep all the stakeholders in consideration throughout the product cycle, from start to finish. In our study, we have attempted to include the voices of various stakeholders through the entire process

Conclusions

This process which has been adapted for India has been used to great success and a number of products have been developed addressing critical clinical needs in the last three years. This process assesses every need in a holistic a manner by comprehensively considering various variables. India is said to import close to 75% of medical devices and most are priced at global price points, thus putting it out of reach for many patients [2]. In light of these struggles, innovation is truly the way forward to bridge the gaps in the Indian healthcare system, but the right gaps need to be addressed and more importantly implemented.

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