A structured process to identify unmet needs for Medical Device Innovation in Minimal Access Surgery, Neurology & Neurosurgery

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Abstract- **According to published estimates, 75% of medical devices and diagnostics in India are imported of which, most are priced at global price points. These devices are neither designed nor priced for the Indian population. As India works toward increasing healthcare access, reducing costs of healthcare and indigenous innovation suitable for the Indian ecosystems will play a big role. It is of vital importance to develop solutions specific to the Indian patient and compatible with the complex healthcare ecosystem. The BioDesign Process for Medical technology innovation was developed by Stanford University. The process extends from conducting observations in the clinical setting, to unearthing needs, developing a concept and thereafter provides a framework to eventually reach the stage of commercialization. We have used an adapted version of this process to identify unmet clinical needs in Minimal Invasive Surgery, Neurology and Neurosurgery 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 4 tertiary care centres and 6 rural centres, both primary and secondary, in South India. On completion, we arrived at close to a 100 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 of 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, neurology, neurosurgery unmet need, minimally invasive surgery, laparoscopy, 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 Minimal Access Surgery 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 Minimal Access Surgery (MIS) 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-MIS 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 reviews 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 100 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 in each therapy area.

The Top needs in Minimally Invasive surgery are:

1. An effective and definitive way to avoid infections at the post-op site in patients who have undergone open or laparoscopic surgical procedures in a tertiary healthcare setting.
2. A safer way to clear diseased tissue (soft tissue and bony tissue) in the sinuses to prevent major orbital complications such as nasolacrimal duct injury, retroorbital hematoma, optic nerve injury and one case of extraocular muscle injury.
3. An effective way to prevent the onset of port site hernia post abdominal laparoscopic surgery to prevent abdominal obstruction and other complications
4. A safer way to create an intestinal anastomosis in laparoscopic or open abdominal procedures to prevent anastomotic leak leading to complications such as septic shock, re-exploration surgery, and mortality
5. A simple, accurate, reliable non-invasive way to measure and monitor hepatic venous pressure in patients with chronic liver disease with cirrhosis and hepatocellular carcinoma for prognostication of patients in a tertiary care center.
6. An accurate way to identify and continuously monitor the location of the ureter in any laparoscopic abdominal or pelvic procedure to avoid injury leading to further complications and morbidity.
7. An accurate, affordable way to detect vascular structures (arterial and venous) peri-operatively (insertion of trocars and/or intra-operatively) in laparoscopic surgery to avoid laceration of said vascular structures during any laparoscopic abdominal or pelvic procedure to avoid injury leading to complications related to blood loss, conversion to laparotomy and possible mortality.
8. A safer and more accessible way to identify, skeletonize and avoid injury during dissection to the nerves (especially facial & recurrent laryngeal nerves) during head and neck surgery to avoid intra-operative damage and further complications.
9. A safer and more effective way to manage actively bleeding esophageal varices (compared to endoscopic banding and endoscopic injection sclerotherapy) to prevent complications such as strictures, ulcers, perforations, and re-bleeding.
10. A safer way to allow safe and complete dissection within the abdominal cavity without damaging the bowel such that complications such as peritonitis, sepsis, conversion to open surgery and mortality are avoided.

The Top 10 Needs in Neurology and Neurosurgery are:

1. A way to reduce the incidence of Ventilator Associated Pneumonia (VAP) in long-term intubated patients at THCs to prevent prolonged stay at hospital or death
2. An affordable, safer and continuous way to monitor ICP in patients at THCs to prevent the high risk of infection, permanent brain damage and seizures.
3. An affordable (as compared to surgery) and effective (no side-effects due to medications) way to manage Parkinson's disease in patients at THCs to prevent severe morbidity.
4. An effective way to prevent the onset of pressure ulcers in patients bedridden for >72 hours in any setting (hospital or home)
5. An affordable and continuous way (compared to MRI, CT [monitoring] Calcium channel blockers and triple-H therapy [preventing vasospasm]) to manage (monitor) cerebral arterial perfusion in patients with subarachnoid hemorrhage at THCs to prevent Delayed Cerebral Vasospasm and Delayed Ischemic Neurological Deficits (DIND)
6. A long-term and definitive (compared to antiepileptic drugs and corticosteroids) way to treat epilepsy (Hypoxic Ischemic Encephalitis sequelae, Lennox Gastaut Syndrome and Rasmussen

Encephalitis) in children at Tertiary care centers to prevent hemispheric atrophy, severe cognitive decline, and severe generalized morbidity

7. A way to improve post decompressive craniectomy prognosis in patients with moderate to severe TBI (intracranial hematomas) at THCs to prevent persistent vegetative state or death
8. A better way to treat impaired cognitive function, memory loss, disorientation and aphasia in patients with Alzheimer's Disease (AD)
9. An effective and reliable method to allow for visualisation and complete clearance of brain tumors in patients at tertiary care centres to avoid recurrences
10. A quantifiable, portable and affordable way to assess swallowing function in post-stroke patients at Tertiary Healthcare Centres to avoid the high risk of aspiration pneumonitis / Pneumonia.

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. There are some key reasons why healthcare startups in India are rarely able to achieve scale with their innovations. This first is that despite innovation in healthcare booming across the country, most concepts are adapted from Western medicine or built by engineers without the involvement of a healthcare professional. This disconnect is telling once the product has hit the market. The clinical insights and know how of current management practices helps in increasing adoption and acceptance. The skewed doctor-patient ratio makes it difficult for clinicians to both practice and be involved in innovation. [5]. In this study, clinicians were involved right from the observation phase to the filtering phase. Medicine is highly complicated and probabilistic and is changing at a rapid pace [6]. The second reason is the slow and arduous development cycle. 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 on helps one define a broad timeline and set realistic expectations. The regulatory system as well is complicated and cumbersome [7]. The complicated healthcare ecosystem includes doctors, paramedics, administrators, regulatory bodies, government bodies, associations, patients, clinical research bodies and many more [8]. For a solution to be successful, all these stakeholders need to be aligned. It's important to take all stakeholders in consideration through the product cycle, from start to finish. In this study, we attempted to include the insights and opinions of various stakeholders throughout the entire process.

Conclusions

This adapted unmet need discovery process is specific to India has been used with great success with a number of products having been developed in the last four years. India imports 75% of medical devices which are priced at global price points, which puts them out of reach for most patients [2]. Indigenous affordable innovation is the way forward in India but the right gaps need uncovered and subsequently addressed to really see improved health outcomes.

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