Title: Use of a Structured Process to Identify Compelling Unmet Medical Technology needs in Emergency Medicine and Critical Care in India

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Abstract

Background: Indigenous medical innovation, addressing specific unmet clinical needs, can bridge numerous gaps in India. The Stanford BioDesign Process is a practical, proven process to identify compelling needs for health technology innovation. **Objective:** To identify, validate and prioritise a comprehensive list of specific unmet medical technology needs in Critical Care and Emergency Medicine. **Methods:** A 10-week clinical immersion was carried out by a multidisciplinary team in 22 primary, secondary and tertiary centres across six states in India. Using the Stanford BioDesign Process observations and problems were documented and converted in to need statements. A modified BioDesign filtering process was applied to validate, score and prioritise the unmet needs which included disease-specific filters, technology-specific filters and market-specific filters. **Results:** 72 observations were recorded. 156 need statements were then passed through the multi-level filtering process. Each need was scored, and the top ten needs were then used to create need specification documents. **Conclusion:** Unmet need research like ours can help catalyse need-specific innovation in Emergency Care and Critical Care. This research is now being disseminated to create market-ready products that can bridge these gaps and improve health outcomes in India.

Introduction

India despite being among the fastest growing economies in the world continues to struggle with healthcare. The country contributes to 18% of global deaths and 20% disability-adjusted life-years (DALYs) with the unenviable position of being saddled between old world communicable diseases and the new world non-communicable disease. Epidemiology aside, there is a significant gap in access to high-quality medical care with political, social and economic factors leading to health inequalities.[1]

Despite these difficulties, Healthcare in India is a rapidly growing segment with a $3 billion healthcare market. [2] However, healthcare costs have been rising steadily, and with advances in medical technology, the gap to access continues to grow.[2] India continues to reel under the pressures of high imports with 75% of medical devices imported in to the country.[3] Medical device innovation in India has also suffered on this front due to the shortage of clinicians as innovators, the complex health system and stakeholders, prolonged and expensive development cycle and difficulties in commercialisation. [4] A large number of innovative solutions have failed due to the hostile environment. The lack of prior and thorough understanding of the unmet medical need, stakeholder mindset, regulatory hurdles and technical complexity leads to product failure as per studies. To overcome this barrier, we conducted this research study to identify and validate compelling unmet medical device needs across multiple geographies and all tiers of healthcare in Critical Care and Emergency Medicine in India.

The authors received formal training in the Biodesign Process which was developed by Stanford University. This process identifies unmet clinical needs considering various factors which would be important in developing a market-ready medical solution. The authors used BioDesign to develop over 12 medical technologies in India. In this study, we used an India-specific BioDesign process to identifying unmet clinical needs in the field of Emergency Medicine and Critical Care at 22 primary, secondary and tertiary centres across six states in India. In this manuscript, we present the process and the results of this unmet need research project. [5]

Methodology

The BioDesign Process consists of 3 phases: Identify, Invent and Implement. Of these 3, this research was focussed only on the first. The identify phase is, first and foremost, the search for unmet health needs with a high criticality. A multidisciplinary team of clinicians, engineers, designers and scientists directly observe the full cycle of care from diagnosis and treatment to recovery and document observations, explore problems and possible opportunities.[5]

The Observation Stage:

The multidisciplinary team comprised of a clinician, a mechanical engineer and a product designer with a combined total of close to 20 years of work experience. This team underwent a rigorous clinical immersion over a period of 10 weeks. The first eight weeks were spent conducting a clinical immersion in the Emergency Care Department and Critical Care Department in a large volume tertiary care centre in Bangalore, India. Following which, the team spent two weeks immersed in 21 centres across Uttar Pradesh, Madhya Pradesh, Telangana, Andhra Pradesh and Maharashtra. This peripheral immersion was conducted to unearth new unmet needs, understand the referral network and validate the needs documented during the eight-week tertiary care immersion. These included four primary health centres, six community health centres, five district hospitals, four medical colleges and two multispecialty private hospitals. An observation docket documented all observations with distinct tangible negative outcome in detail including history, examination, investigations, management, outcome, cost, follow-up and clinician insights. Using the insights of senior clinicians we went ahead with identifying the problem(s) and the unmet need(s) for each observation. We created comprehensive need statements basis the negative outcome, the site of healthcare delivery and the stakeholder in question.

The Filtering Stage:

The BioDesign process does involve a filtering process. However, in this study a modified filtering process was used. Each need statement was then passed through a series of filters as defined below:

Level 1 Filter: Redundant, pharmaceutical related or process related eliminated

Level 2 Filter: This level of filtering focused on the severity of the clinical condition (in the perception of observers and clinicians) as well as the epidemiology of the disease and the frequency of the negative outcome. We validated these findings with a comprehensive literature review of incidence and prevalence data. A scoring system of 1 – 3 – 5 was used through the process.

1. Epidemiology

   The frequency of problem as per clinician (number of cases per month)

   - < 5 patients per month=1
   - 6-12 patients per month =3
   - >13 patients per month =5

   The frequency of problem as per observers (number of cases seen per month during the clinical immersion)

   - < 2 patients per month=1
   - 2-5 patients per month =3
   - >5 patients per month =5

2. Criticality

- Short lasting, reversible: Not resulting in death, disability, hospitalization, or socioeconomic stress = 1
- Resulting in death, hospitalization >3 days, disability/ handicap (> 6 months), large financial burden to the patient/family = 5
- Needs in between 1 and 5 = 3.

Observed Epidemiology and criticality score: 3 (Frequency of clinician) + Frequency of observer + 3 (Criticality score)

3. Target patient population in a given year: We used India specific data where available. However, in many cases due to the shortage of validated health statistics, certain assumptions had to be made using a combination of data from India and global epidemiological data.

    - <100,000 patients/year = 1
    - 100,000 – 500,000 patients/year = 3
    - >500,000 patients/year =5

    Secondary research-based epidemiology and criticality score: Target patient population * Criticality score

    Filter 2 score: Subjective epidemiology and criticality score + secondary research based epidemiology and criticality score

Level 3 Filter: This filter evaluated the technical complexity of the solutions available, the regulatory landscape and the buyer environment.

1. The Number of predicates: This was made based on the solutions which currently exist as per guidelines and those used in the Indian clinical setting. We considered the prevailing practice as well as global gold standards.

    - High number of predicates i.e. >5 = 1
    - Medium number of predicates i.e. 1 to 5= 3
    - No predicates = 5

2. Technical complexity of predicates: This filter considered the technology behind the solution as well as the expertise needed to implement it in current clinical practice. A medium complexity solution is rated the highest, followed by low complexity and lastly by a highly complex solution.

    - High =1
    - Medium =5
    - Low =3

3. Regulatory and clinical trial complexity: This filter took into consideration probable regulatory hurdles and clinical trials one would have to conduct for a particular solution. It was a judgment call based on the current predicates in the system and the classification of devices as per the Global Harmonisation Task Force classification (Class A - Low Risk, Class B - Low to Moderate Risk, Class C - Moderate to High Risk, Class D - High Risk)

    - High (Class D) =1
    - Medium (Class C) =3
    - Low (Class A & B) =5

4. Buyer environment: This filter took into consideration the eventual buyer of a particular medical solution. This, in turn, depended on which level in the healthcare system the particular condition was treated based on the peripheral immersion which helped understand, more thoroughly, the referral system in India.
    - High (Tertiary Care Centre) = 5
    - Medium (Secondary Centre) = 3
    - Low (Individual/Primary centre) = 1

Filter 3 score= Number of predicates score + Regulatory and clinical trial complexity score + Buyer environment score

Final Score= Filter 2 score + (Filter 3)/4

Each filter was validated using secondary research with literature reviews. When faced with difficulties in data availability, we held roundtable meetings with clinicians and senior specialists to attain approximates needed for the filtering process.

Results

We documented 72 observations during the clinical immersion period. On analysis of the problem and need it led to the creation of 156 unique need statements.

Level 1 of filtering eliminated the redundant, pharmaceutical related or process-related needs leaving us with 86 need statements.

These 86 need statements were then passed through Level 2 and Level 3 of the filtering process and scored accordingly. Ten needs remained at the end of the filtering process and were as follows:

1. A safe and continuous method to monitor changes in intracranial pressure with patients with intracranial tension in the Intensive Care Unit (ICU) to allow for prognostication in a tertiary care setting.
2. An accurate, accessible method to conduct a toxicology screen for specific high-risk classes of toxic substances with inherent toxicity consumed to complement history and examination and allow for prognostication and immediate management to avoid mortality in a tertiary emergency healthcare setting.
3. A more effective way to emergently manage burn wounds in patients with burns to avoid infection and fluid loss and allow for repeated inspection and avoid sepsis, shock and mortality in a tertiary healthcare setting.
4. An affordable and faster way to detect antimicrobial resistance in sepsis to allow earlier initiation of appropriate antibiotics to prevent the onset of septic shock in a tertiary healthcare setting.
5. An accurate way to detect minute abnormalities in the brain that are missed on CT and MRI by a radiologist to accurately manage a patient in a tertiary care setting.
6. An effective way to prevent aspiration pneumonitis in Intubated patients in a tertiary care setting.
7. A safer way to replenish fluids in patients with hypovolemic shock when a peripheral IV line is insufficient to avoid procedure related central line complications in a tertiary care setting.
8. An effective and safe way to tap a pleural effusion to avoid pneumothorax in patients in a tertiary healthcare setting.

9. An accurate and accessible way to detect coronary events in patients that present with a Non-ST segment elevation MI and atypical symptom to avoid misdiagnosis in a secondary healthcare setting.
10. A safer way to manage vascular injuries in a patient with trauma to avoid delay in treatment and vascular insufficiency related complications downstream to the injury site in a tertiary health care setting without a vascular surgeon.

Discussion

Emergency Care in India is similar to the U.S.A model, that is "scoop and run".[6] Despite its reactive nature, the therapy area has developed and continues to evolve its systems to match its socioeconomic needs. Historically, the first attempted move at establishing Critical Care in India was by Farokh E Udwadia who established coronary care units in the early to mid-1970s. Soon after what was the said to be the first attempt at establishing Emergency Medicine services was when The Association for Trauma Care in India in 1985 connected 15 ambulances to a central wireless dispatch centre in Mumbai. [6,7] This has changed significantly over the last couple of years as technology has progressed in leaps and bounds. Emergency Medicine Services and Critical Care services in India remain fragmented, and the country's health system continues to struggle in both these therapy areas. 23% of all trauma cases in India are said to be transportation-related, and 1,374 accidents and 400 deaths take place every single day in the country.[8] The 77% of trauma cases other than road traffic accidents are due to other causes such as falls, drowning, agriculture-related, burns, etc.[9] 42,800 of every 1 million Indians die every year from sudden cardiac arrest, and the country also boasts the highest snakebite mortality in the world, with the World Health Organization estimating it at 30,000 every year.[10, 11] Although the number of specialists and the number of specialised courses are increasing with every passing year, gaps still exist in the system, especially in technology. Identifying the exact underlying gap which exists across various centres in India is a difficult task especially when it comes to medical device innovation.

A key part of this is the diversity across India. India has 146,036 sub-centres, 23,458 primary health centres, and 4,276 community health centres and over 500 NABH accredited multispecialty hospitals. Although the number is low, there are said to be 150,000 ICU beds across the country. [6] Based on our research across numerous states and districts, we found that every state in India is like an independent entity in itself when it comes to healthcare. The epidemiology of diseases changes, at times, quite drastically as one moves from state to state as well as from district to district. These differences extended to other aspects as well including funding patterns, human and other resources and prioritisation. As we followed the referral chain in some districts, we found the referral system to be very robust but outdated. India's healthcare system is a pyramid model wherein cases are seen at primary centres then secondary and lastly apex and tertiary centres. Primary and secondary centres from what we observed rarely take on what they are not equipped to handle. These referral processes are decades, and with minimal upgradation of facilities, patients prefer the private set up. One aspect of this is the lack of access to technology and resources in lower centres. It is often two-fold, in some centres, the technology was missing altogether, and in others, despite the availability, it remained unused. This means that Tertiary care centres are grossly overburdened. District hospitals and medical colleges are completely overburdened for various reasons. Patients (rural and urban regardless of education) prefer the district hospitals and medical colleges as they are sure it is a one-stop shop for their ailments, unlike the lower centres where they may get referred. The health knowledge has also improved, and the general public prefers to avoid the primary and secondary centres. The flow to higher centres makes them incredibly overburdened. This coupled with a high rate of migration between states as patients flock to large centres from other states to receive treatment.

As per an IBM study, over 90% of startups fail, and a lack of understanding of the stakeholders and the unmet is part of the top 10 reasons given in the report. [12] In essence, is what we are trying to help innovators overcome with this database of unmet clinical needs. In our study, besides the unmet clinical gap that exists, we took into consideration parameters which can help negotiate obstacles and de-risk the path as much as possible.

The limitation of this study is that we only covered 22 centres and six states across the country. We tried to get representation across primary, secondary and tertiary centres across North, South and Central India. Although this research can help innovators, it is by no means a sure shot formula for success given the volatile nature of clinical practice and the Indian Healthcare Ecosystem.

Conclusion

There is a moral and social obligation for achieving health equity in India. The recent trends of economic growth and technological advances in the country have not been matched by an improvement in access to healthcare across all geographies and all strata of society. Leveraging technology to bridge various healthcare gaps is cited time and again as the way forward. However, we continue to rely on imports for medical devices. The need of the hour is to focus on indigenous innovation targeting specific unmet needs followed by the aggressive implementation to achieve the health outcomes outlined in the Sustainable Development Goals. [13] This database is one of four that are being created to stimulate specific unmet need based medical innovation. Thus far, we have collaborated with some premier engineering institutions across the country and run multiple hackathons to convert these unmet needs to prototypes and eventually, we hope, market-ready products that will improve the health metrics across the nation.

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