THE FILTERING PARAMETERS

The AIM (Affordable Inventions in Medical Technology) Fellowship Program

The Affordable Inventions in Medical Technology (AIM) Fellowship conducted by The Lemelson Foundation and InnAccel is focused on the creation and publication of a robust database of validated clinical needs within the Indian healthcare system based on hours of clinical immersion and extensive secondary research. In essence, it is meant to provide entrepreneurs, engineers, designers and others inclined toward healthcare innovation, with a solid foundation to build on as they create solutions to bridge key gaps and address specific unmet needs.

The Methodology: Following the Stanford BioDesign Process

The core essence of the BioDesign Process is the clinical immersion of multidisciplinary teams, to investigate and validate unmet clinical needs, identify gaps and opportunities in the need area, ideate and systematically select a lead concept to address the need, and determine its feasibility through prototyping and proof of concept testing. It consists of 3 phases Identify, Invent and Implement. Of these 3, this Fellowship was focussed only on the first.

The identify phase is, first and foremost, the search for important unmet health needs. By directly observing the full cycle of care from diagnosis and treatment to recovery and billing, we explore problems and opportunities and ask pointed questions that challenge the status quo. During this first-hand observation period, it's ideal to collect hundreds of needs, without judging or prioritizing. This is followed by filtering the list with rigorous objectivity. This intense and iterative process involves exploring epidemiology, criticality, technical complexity, competitor analysis and regulatory obstacles. Ultimately we narrowed down to 10 needs in each therapy area, which if solved would have a major impact on health and wellness.

This document details the 3 levels of filtering used during the AIM Fellowship to prioritise the top unmet needs

THE FILTERING PROCESS: 3 STAGES OF FILTERING

Level 1: The level 1 filter eliminated those needs which are redundant, pharmaceutical related or process related.

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

Epidemiology

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

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

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)

Target patient population in a given year: We used data wherever available for India. However, in many cases due to the dearth 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: The third level of filtering evaluated the technical complexity of the solutions available, the regulatory landscape and the buyer environment.

Number of predicates: This was made based on the solutions which currently exist as per guidelines and those being used in the Indian clinical setting. Both at prevailing practice as well as gold standards were considered.

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

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

Regulatory and clinical trial complexity: This filter was based on the 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

Buyer environment: This filter was based on the eventual buyer of a particular medical solution. This in turn depended on which level in the healthcare system the particular condition was treated. The peripheral immersion helped understand, more thoroughly, the referral system in India which defined this filter.

- 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