

Design Approaches for Medical Technology Innovation and Implementation in Low-and Middle- Income Countries (LMICs)

A thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

By

Neelarnab Dutta

(IITG Roll no: 196105102, PMRF ID: 1900541)

Under the supervision of

Dr. Debayan Dhar

Associate Professor

Department of Design, IIT Guwahati



Department of Design,
Indian Institute of Technology Guwahati
Guwahati, Assam-781039, India

2024



Department of Design
Indian Institute of Technology Guwahati
Guwahati, Assam-781039, India

Declaration

I hereby declare that the work contained in this thesis entitled “Design approaches for medical technology innovation and implementation in low-and middle-income countries (LMICs)” is my work and done under the guidance of Dr. Debayan Dhar, Associate Professor at the Department of Design, Indian Institute of Technology Guwahati, Assam, India. To the best of my knowledge, it contains no materials previously published or written by another person or substantial properties of the material which has been accepted for the award of any other degree or diploma at the Indian Institute of Technology Guwahati or any other educational institution, except where due acknowledgment is made in the thesis. Any contribution made to this research by others, with whom I have worked at the Indian Institute of Technology Guwahati or elsewhere is explicitly acknowledged in the thesis. I declare that the intellectual content of this thesis represents my work and words. I have adequately cited and referred to the original work where others’ ideas, work, and words have been included. I also declare that I have adhered to all principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any idea/ data/ fact/ source in my submission.

Place: IIT Guwahati

Neelarnab Dutta

Date: 01.07.2024

IIT Guwahati Roll Number: 196105102

Prime Ministers Research Fellow ID: 1900541



Department of Design
Indian Institute of Technology Guwahati
Guwahati, Assam-781039, India

Certificate

This is to certify that the work contained in this thesis titled “Design approaches for medical technology innovation and implementation in low-and middle-income countries (LMICs)” submitted by Mr. Neelarnab Dutta to the Indian Institute of Technology Guwahati for the award of the degree of Doctor of Philosophy has been carried out under my supervision. This work has not been submitted elsewhere for the award of any other degree or diploma.

Place: IIT Guwahati

Date: 01.07.2024

Dr. Debayan Dhar
Associate Professor
Department of Design
Indian Institute of Technology Guwahati
Guwahati, Assam-781039, India

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Abstract

This thesis delves into the intricate landscape of medical technology innovation within Low- and Middle-Income Countries (LMICs), with India as a focal point. The overarching objective is to develop tailored design and innovation processes to enhance the effectiveness of medical technology innovation in resource-constrained settings. The initial scoping review identifies critical challenges, such as regulatory complexities, funding constraints, cultural disparities, and inadequate infrastructure, which hinder the successful implementation of medical technology innovations in LMICs. Despite existing literature acknowledging these challenges, there is a lack of a consolidated understanding of how these factors influence the design and innovation activities in LMICs.

The first research study critically assesses four well-established design and innovation processes—User-Centered Design (UCD), Human-Centered Design (HCD), Design Thinking (DT), and the Stanford Biodesign process—in the context of medical technology innovation. Through literature review, thematic coding, and comparative analysis, it identifies process supports crucial for successful medical technology innovation. The findings contribute to the development of a modified framework, "Healthcare Centered Design (HCD)," enhancing UCD for medical technology innovation projects. Research study 2 comprehensively explores factors influencing medical technology innovation in LMICs, utilizing theoretical lenses from Social Innovation Theory, Stakeholder Theory, Resource-Based View, and PESTEL analysis. The study identifies key challenges and barriers to Medical technology innovation through a systematic literature review and case studies with medical technology company leaders, proposing a redefined conceptual model for medical technology innovation management in LMICs. The third research study critically evaluated the LMIC-specific challenges that can be addressed within a design and innovation process. Through semi-structured interviews and comprehensive analyses, it proposes six essential LMIC-specific design and innovation process characteristics, offering valuable guidelines for evaluating existing processes for medical technology innovation in LMICs. Later, the study critically evaluates the Stanford Biodesign Process's applicability in LMICs based on these identified characteristics. Research Study 4 addresses the limitations of the conventional Biodesign process in LMICs by enhancing its phases for context-specific healthcare design. The study synthesizes three toolsets, integrates them into the Biodesign process, and conducts workshops to evaluate the effectiveness of the modified process, ultimately proposing a new toolkit. Study 5 validates the efficacy of the

modified Biodesign process in a case study focused on wound management and cervical cancer in India. The workflow toolkit aids in addressing context-specific challenges, showcasing the process's utility in generating solutions for real-life healthcare problems in LMICs. Further, an extended research study proposes an innovative solution to address the shortage of skilled professionals in Indian healthcare settings by integrating an offline AI bot within medical devices for semi-autonomous healthcare delivery. It identifies a lack of usability heuristics for Conversational User Interfaces (CUIs) in complex system-physical interaction scenarios and develops 16 new heuristics through extensive usability testing, contributing significantly to the field of human computer interaction (HCI).

In summary, this comprehensive thesis bridges existing gaps in understanding and addressing the challenges of medical technology innovation in LMICs. The proposed frameworks, processes, and toolsets provide a robust foundation for future research, fostering sustainable and context-specific healthcare solutions in diverse LMIC settings, with a special emphasis on India.

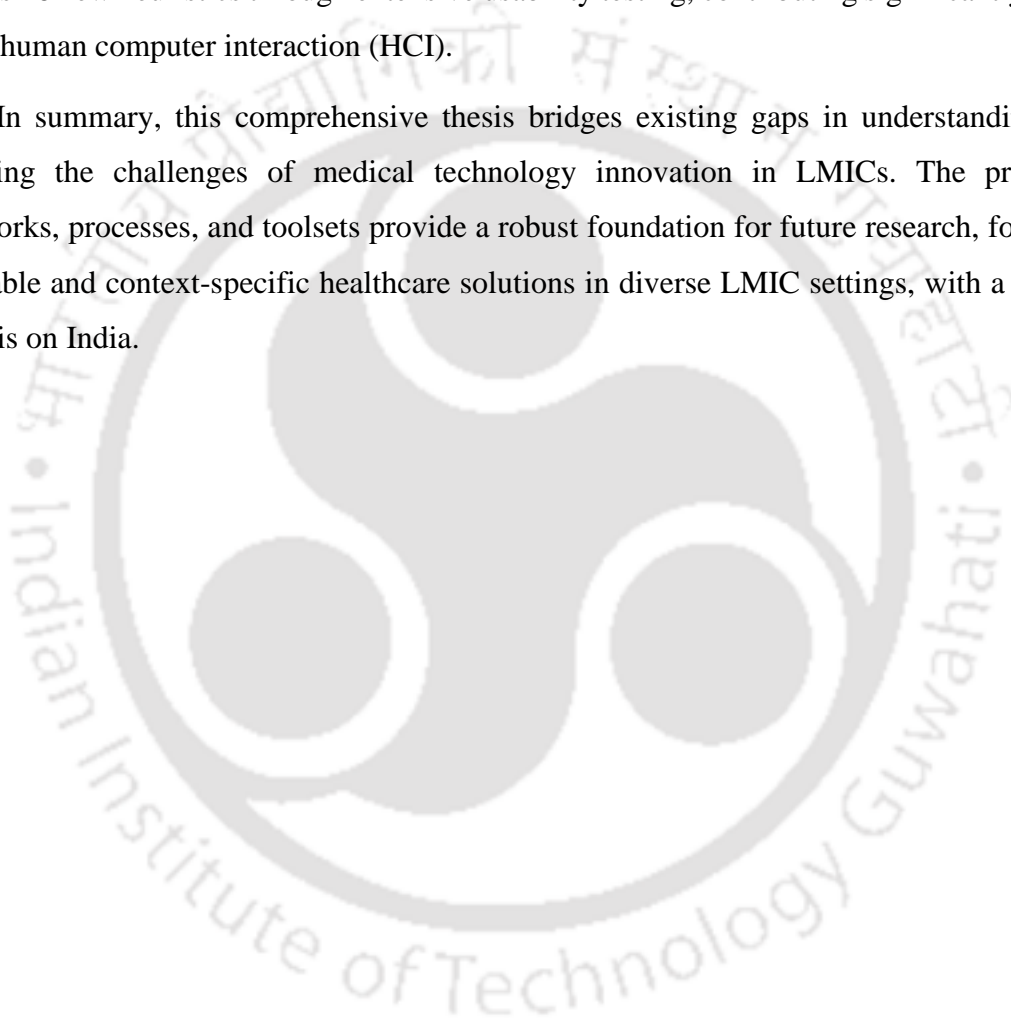


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List of Abbreviations

Abbreviations	Definitions
LMIC	Low- and Middle-Income Country
IP	Intellectual Property
AI	Artificial Intelligence
CUI	Conversational User Interface
HCD	Healthcare Centered Design
VIA	Visual Inspection with Acetic Acid
UX	User Experience
UI	User Interface
PCB	Printed Circuit Board
CAD	Computer Aided Design
NPWT	Negative Pressure Wound Therapy
3D	Three Dimensional
WHO	World Health Organization
PMD	Priority Medical Device
DALY	Disability-Adjusted Life Years
FGM	Female Genital Mutilation
STD	Sexually Transmitted Disease
HIV	Human Immunodeficiency Viruses
EBF	Exclusive Breastfeeding
PHC	Primary Health Center
MDR	Medical Device Rules
CDSCO	Central Drug Standard Control Organization
NRA	National Regulatory Authority
ISO	International Organization for Standardization
DCGI	Drug Controller General of India
IEC	Institutional Ethics' Committee
IERB	Institutional Ethical Review Board
CTRI	Clinical Trials Registry of India
CE	Conformité Européenne
FDA	Food and Drug Administration
TIM	Technology Innovation Model
RBV	Resource-Based View
PESTEL	Political, Economic, Social, Technological, Environment and Legal
OPD	Outpatient Department
UCD	User Centered Design
ACD	Activity Centered Design
GCD	Goal Centered Design
AD	Aortic Dissection
HTA	Medical technology Assessment

DT	Design Thinking
HCD	Human Centered Design
IMT	Innovation Management Techniques
CEO	Chief Executive Officer
CTO	Chief Technical Officer
SME	Small and Medium Enterprises
AIIMS	All India Institute of Medical Sciences
CT	Computed Tomography
CHC	Community Health Center
TRIZ	Theory of Inventive Problem Solving
PMA	Pre-Medical Approval
USP	Unique Selling Point
SC	Sub-Center
POC	Proof of Concept
GUI	Graphical User Interface
LCD	Liquid Crystal Display
IOT	Internet of Things
TCP	Transmission Control Protocol
SSH	Secure Shell
AC	Alternating Current
DC	Direct Current
PCT	Patent Cooperation Treaty
IRB	Institutional Review Board
PI	Principal Investigator
NLP	Natural Language Processing
ASR	Automated Speech Recognition
TTS	Text-To-Speech
SUI	Speech User Interface
VUI	Voice User Interface
HCI	Human Computer Interaction
NLU	Natural Language Understanding
NLG	Natural Language Generation
GPIO	General Purpose Input / Output
ECG	Electrocardiogram
MRI	Magnetic Resonance Imaging
BP	Blood Pressure
LEAP	Livelihood Empowerment Against Poverty Programme
BIRAC	Biotechnology Industry Research Assistance Council
MedTech	Medical Technology

Definitions of Terms

- i. **Medical technology innovation:** The term defines innovations from both the areas of medical biotechnology and biomedical technology (Moore Jr & Maitland, 2014; Yock et al., 2010).
- ii. **Design and innovation process:** The term defines a process that is used for both design or/and innovation goals. Such a process incorporates methods to systematically address need/requirements towards solution development by incorporating strategic design activities and innovation requirements (Gray, 2022; Daalhuizen & Cash, 2021; Yock, et al., 2010).
- iii. **Technology innovation model:** The term defines conceptual/theoretical graphical model how specific technology innovation happens, how various factors like science, engineering, social, political etc., impact various activities of innovation management (Stone, 2012; Khilji, Mroczkowski, & Bernstein, 2006).
- iv. **Workflow toolkit:** A set of tools that outlines all the methods and tasks of a process in a visual format like flow diagrams or flowcharts etc., to allow user to establish a comprehensive learning and understanding of the process and tool usage towards specific objective (Upadhyay, n.d.; Pascale & Ben-Tzion, n.d.).
- v. **Conversational user interfaces (CUIs):** User interfaces that allow natural human like speech interaction with user and two-way exchange of information for system operation (Langevin, 2021).

Chapter 1. Introduction and Research Background

Abstract

The chapter introduces the intricate landscape of medical technology innovation within Low- and Middle-Income Countries (LMICs), focusing on India. It emphasizes the complexity, expense, and risks faced by entrepreneurs due to systemic, cultural, and regulatory obstacles. Despite existing literature highlighting challenges, a consolidated understanding of their impact on the design process in medical technology innovation is lacking. The scoping review uncovers key challenges in LMICs, ranging from inadequate infrastructure to regulatory uncertainties, shaping the unique landscape of healthcare innovation in India. Existing literature on innovation management models and design processes lacks consideration for LMIC-specific factors. The chapter identifies three critical research gaps and formulates research questions, aiming to bridge these gaps and contribute a comprehensive framework tailored for LMICs. The research plan outlines a multi-phase approach to address these gaps, providing a roadmap for understanding, defining, and developing a novel medical technology innovation framework for resource-constrained settings.

1.1 Overview of Medical Technology Innovation Context

Innovations in the domain of medical biotechnology and biomedical technology strive to support health and well-being by inventing solutions towards diagnosis, prevention, treatment and management of disease state and clinical conditions (Yock, et al., 2010). Though the above terms are often used interchangeably, medical biotechnology mainly deals with research and innovation related to DNA, tissue culture, pharmaceuticals etc. which can be used for the diagnosis, prevention, treatment and management of diseases (Barh & Azevedo, 2017). Examples of medical biotechnology innovations are flu antibiotics, Covid 19 vaccines, pregnancy-detecting biomarkers, insulin etc. On the other hand, biomedical technology involves the use of engineering and technology knowledge, and understanding of anatomy, pathophysiology, clinical presentation and outcome of the disease state to invent tools, methods, strategies and devices for providing health care (Yock, et al., 2010). Examples of biomedical technology innovation include artificial limbs, imaging systems to detect cancer, wound-healing medical devices etc. In this thesis, the term "medical technology innovation" is utilized to delineate need-driven innovations from the realms of both medical biotechnology and biomedical technology (Moore Jr & Maitland, 2014; Yock, et al., 2010). For instance, a

pregnancy detection kit serves as a design outcome with a focus on user-centeredness (such as user convenience and hygiene), integrating contributions from both biomedical engineering perspectives (regarding structure, functionality, and material properties) and medical biotechnology (specifically, pregnancy-detecting biomarkers).

Medical technology innovation is the process of developing and implementing new technologies and processes to improve healthcare delivery, diagnosis, treatment, and patient outcomes. It involves addressing intricate disease states, biological mechanisms, and pathophysiology, all while adhering to established clinical protocols and adapting to evolving pathophysiological insights and technological advancements. Additionally, innovation in medical technology demands rigorous validation for patient safety and efficacy, considering the critical nature of clinical interventions and regulatory clearance.

The medical technology innovation process often takes a long time for product development and implementation, accompanied by uncertainties and changes in R&D and business-related objectives. This forces medical technology entrepreneurs to take various time-sensitive strategic decisions, like early-stage capital raising, collaboration, deciding on manufacturing partners, design, and regulations, to avoid innovation and firm-level failure (Atanu, Thim, Gopalakrishnan, Peter, & Vijay, 2021; Kenneth, Enrico, & Eric, 2014). Thus, effective management and coordination between activities of R&D and those of business is a major requirement for successful medical technology innovation (Ireland & Hine, 2007; Khilji, Mroczkowski, & Bernstein, 2006; Pisano, 2006). For Medical technology innovation, overcoming barriers to market entry and addressing indigenization challenges is a need and requires meticulous planning, significant investments, competitive analysis, safeguarding intellectual property, and a holistic approach that encompasses appropriate strategy development for research and development, production, funding, business strategy, as well as sales and marketing. Essentially, medical technology innovation is about navigating the complexities of healthcare issues, integrating advanced solutions seamlessly into the existing healthcare system, and addressing the challenges of commercialization to ultimately benefit both patients and healthcare providers.

1.2 Medical Technology Innovation from the Low- and Middle-Income Countries' Lens: A Focus on India

Indian healthcare industry is unique in the world. On one hand, India has world class health-centers providing best in class facilities, and on the other hand, there is a section of population

that struggles to meet basic healthcare needs. About 70% of India's population live in rural areas, where, despite of various efforts, hospitals lack basic equipment and facilities (Sehgal, 2010). Currently, the MedTech industry in India imports 75% of devices and is looking to move towards self-sufficiency (Sehgal, 2010; D'Souza, et al., 2018). Dependency on the imported medical products, lack of access, high cost further aggravates the problems of necessary health care delivery. Most of the imported products are neither priced nor designed for the Indian population (D'Souza, et al., 2018). Here lies the importance of indigenous innovation and start up ecosystem within the country.

Medical technology innovation and successful commercial implementation in Low- and middle-income countries (LMICs) like India, are often more complex, expensive, time-consuming and risky than in a resource-rich setting (Leonard, de Kock, & Bam, 2020; WHO, 2010; Agarwal, Brem, & Grottke, Towards a higher socio-economic impact through shared understanding of product requirements in emerging markets: The case of the Indian healthcare innovations, 2018). Jagtap and Larsson's study (2014) confirms such differences, revealing differences in design process requirements and strategies for Base of the Pyramid (BOP) and Top of the Pyramid (TOP) markets. Several Indian entrepreneurs in the past experienced and reported the difficulty of Medical technology innovation and indigenization in India. Kiran Mazumdar-Shaw (2017), reported several systemic, cultural and regulatory obstacles to medical technology innovation in India. There are highly complex regulatory compliance regime, low risk appetite of entrepreneurs, stagnant country's R&D spending, poor access to capital funding, shortfall of scientific talent and low patent filing (Mazumdar-Shaw, 2018). Researchers like Szymon Jaroslowski et al (2013) reported major challenges of product innovation in India due to reasons like lack of guidance on product specifications from national regulatory agency, lack of institutionalized healthcare payers and lack of transparency and formalized medical technology assessment in coverage decision making etc. (Jarosławski & Saberwal, 2013). Though such reporting exists in literature, our initial scoping review of literature revealed a lack of consolidated information about all such factors and their influence in the innovation journeys.

Design processes and innovation journeys are closely related in the realm of product or service development. Design processes are integral to innovation journeys as they provide the systematic framework for generating, refining, and implementing innovative ideas (Gray, 2022; Daalhuizen & Cash, 2021). There exist various popular design and innovation processes like User centered design, Human centered Design, Design Thinking Process, Biodesign process, to

systematically address health care design project requirements (Chatpun, Liawrungrueang, Prukpattranon, & Wongsiri, 2022; Zaufenberger, Stampfer, Mader, Gold, & Donsa, 2022; Schwartz-Lasfargues, et al., 2022). However, these processes and their associated activities primarily reflect an idealized industrial approach to product design and innovation, and does not contain necessary instrumentation to address LMIC specific challenges and barriers. Moreover, a very few studies revealed addressing LMIC specific factors via modifying or developing new process (Chachra, et al., 2018; Arun-Kumar, Sridhar, Chaturvedi, & Deshpande, 2017). Further, what remains conspicuously absent in the existing literature is an investigation into the extent to which Low- and Middle-Income Country (LMIC)-specific factors influence these design and innovation activities and processes. So, there lies the research motivation to explore how the various LMIC-specific factors impact the innovation management activities and how we can make these processes work successfully in such contexts.

To gain a comprehensive understanding of the factors that influence medical technology innovation, our study delved deeply into the specifics. We focused on the context of the Indian healthcare system and examined various case studies of medical technology innovation in India. This choice was motivated by several key factors: 1) India falls within the LMIC category, as indicated by a 2020-21 World Bank report (Data for India, Lower middle income, 2021); 2) India is recognized as an emerging global biotech hub and a significant contributor to biopharmaceutical advancements (Uppal, Chakrabarti, Chirmule, Rathore, & Atouf, 2021); and 3) India is fostering the growth of over 4237 biotech startups, experiencing a remarkable 25% growth rate between 2019-2021 (Suresh & Chandan, 2021). The anticipated research outcomes aim to unveil valuable insights into the essential requirements for successful medical technology innovation in LMICs, offering guidance on how to achieve them through a thoughtful design and innovation process.

Further, we kickstart the research by conducting an initial review of the literature to pinpoint genuine research gaps and unanswered research questions.

1.3 Background Study

The preliminary background investigation focused on comprehending the context of medical technology innovation, considering diverse implementation challenges encountered by Low and Middle-income countries such as India. To obtain a comprehensive view of the subject, an initial exploratory scoping review was conducted across various topic areas to pinpoint

research gaps. The following summarizes the key findings.

1.3.1 How the medical technology innovation context of LMICs different to developed nations?

The successful implementation and adoption of health innovations are necessary for most low- and middle-income countries (LMIC) to provide equitable access to quality healthcare (Leonard, de Kock, & Bam, 2020). The World Health Organization (WHO) (2010), in its report on the Priority Medical Device (PMD) project, emphasizes the relevance of prioritizing country-specific regional healthcare requirements in the choice of medical devices. The report provides an approach for prioritizing medical devices based on current and future health demands. It concludes that many devices manufactured for developed nations are ill-suited for LMICs due to various unique challenges and barriers (WHO, 2010). In the report, WHO identifies barriers to choosing appropriate medical devices, such as lack of information, fascination with technology, deference to personal preferences, lack of a single nomenclature, ill marketing practices, counterfeiting, and deficiencies in clinical guidelines. Barriers to the use of medical devices include donations, inappropriate design, limited management, lack of training, and maintenance problems. On the other hand, the only reported barrier to medical device innovation is a lack of funding to bear the various costs associated with the innovation process. Furthermore, barriers to the appropriate uptake of innovation are reported as resistance, reluctance, rejection, inappropriate design, and the high cost of innovative devices (WHO, 2010).

Among many challenges of healthcare delivery in LMICs, cultural differences between the patient and provider can affect access to care and quality of care provided (Office of Minority Health, 2002; Tucker, Marsiske, Rice, Nielson, & Herman, 2011). Lack of cultural awareness and insensitivity can negatively impact quality of care (Seibert, Stridh-Igo, & Zimmerman, 2002). In a clinical intervention process practitioners and patients may not have the same treatment goals and priorities (Women., 2011). Samuel Kimani et al (2020) has reported socio-cultural taboo of Kenyan Somali women as one of the barriers to sexual healthcare in resource constraint settings. The study shows demand for culturally sensitive female genital mutilation/cutting (FGM/C) procedure among Kenyan Somali women and assurance of procedural confidentiality and privacy (Kimani, Kabiru, & Muteshi, 2020). Findings of Stephanie Craig (2012) shows recommendation for culturally appropriate medical technology from tribes of Oregon, Washington and Idaho, to prevent Sexually Transmitted disease (STD)/HIV (S & D., 2012). Again, Christiana Nsiah-Asamoah (2020) reported

misconceptions and cultural practice related to exclusive breastfeeding (EBF) among mothers and grandmothers of two rural districts in Ghana that act as barrier to health training provided by the health workers (Nsiah-Asamoah, Doku, & Agblorti, 2020). According to the study, mothers from the two districts of Ghana perceived that despite grandmothers not exclusively breastfeeding (EBF), their children thrived. Misconceptions included beliefs that breastmilk is inadequate and formula-fed babies gain weight faster. Cultural practices like the early introduction of solids, local recipes persisted in Ghana. The above studies show why, in LMICs, when developing healthcare guidelines, clinical procedures, as well as medical technology, one needs to consider socio-cultural acceptability. Furthermore, a novel medical technology can introduce its own set of procedural and healthcare implementation guidelines.

Past literature revealed that in most LMICs, indigenization and local manufacturing of medical technology suffer due to: healthcare system-related challenges; inadequate healthcare and regulatory policies; and an underdeveloped R&D ecosystem (Abrol, Sundararaman, Madhavan, & Joseph, 2016; Jarosławski S. S., 2013; World Health Organization, 2011). Similarly, despite successful R&D, very few novel medical technology solutions reach large-scale production in the developing world due to a lack of strategies for scaling up innovation and diffusion (Malkin & Oldenburg Beer, 2013). Thus, innovative firms of LMICs often have to consider changes in strategies and time-sensitive decision-making to cope with evolving innovation ecosystem and public needs (World Health Organization, 2011; Leonard, de Kock, & Bam, 2020; Kenneth, Enrico, & Eric, 2014; Atanu, Thim, Gopalakrishnan, Peter, & Vijay, 2021). For example- organizations need to quickly adapt to changes in health policies, regulatory norms, healthcare burdens etc.

In conclusion, achieving equitable healthcare in low- and middle-income countries requires overcoming barriers to innovation, addressing cultural nuances, and adapting strategies to evolving healthcare landscapes for effective implementation and sustained impact.

1.3.2 Indian medical technology innovation context and some reported issues

Under the Indian Constitution, health is a state subject. Therefore, each state has its own healthcare delivery system in which both public and private (for-profit as well as non-profit) actors operate. While states are responsible for the functioning of their respective healthcare systems, certain responsibilities also fall on the federal (Central) government. These responsibilities include aspects of policy-making, planning, guiding, assisting, evaluating, and coordinating the work of various provincial health authorities, as well as providing funding to

implement national programs. Each regional/zonal set-up covers 3–5 districts and operates under the authority delegated by the State Directorate of Health Services. The district-level structure of health services serves as a middle-level management organization, acting as a link between the State and regional structure on one side and the peripheral-level structures such as Primary Healthcare (PHC) and Sub-Centre on the other. Figure 1.1 reveal the hierarchical structure of Public healthcare system from the state of Assam, India.

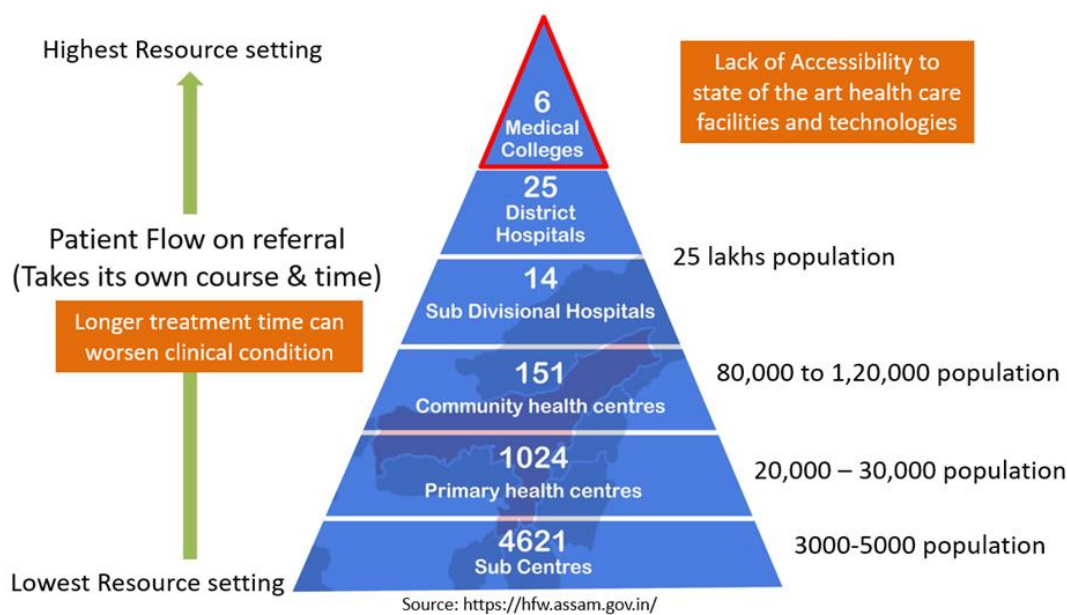


Figure 1-1: Public healthcare system in the state of Assam, India (Source: <https://hfw.assam.gov.in/>)

The hierarchical structure of the Public Healthcare system in India is characterized by a limited number of tertiary-care hospitals at the top tier, followed by district, community, and primary care centers (Selvaraj, Bhan, & Mahal, 2022). Across this hierarchy, there is an unequal distribution of resources and infrastructures within the healthcare systems. Figure 1.2 shows a evidence of a ‘Jugaad’ (a Quick-Fix solution) way of managing broken Limb in an Emergency Department of a Hospital in India, due to lack of appropriate resources and facilities. India's healthcare landscape grapples with challenges, particularly in rural areas where inadequate infrastructure persists. Majority of healthcare service cost is out of pocket expenditures, which most population cannot afford. There is also a huge import dependency to meet country's healthcare requirements (D'Souza, et al., 2018; SK & A., 2017). The MedTech industry's shift towards self-sufficiency is crucial for overcoming import dependency and improving access to affordable healthcare, addressing the critical needs of a significant portion of the population.



Figure 1-2: A 'Jugaad' (a Quick-Fix solution) way of managing broken Limb - evidence of poor infrastructure and resources within India (Source: Author captured)

Further, there exist native cultural differences within India and has been acknowledged by many countries as a result of cross-cultural immigration and living. Cultural diversity is defined in literature as “the differences between people based on a shared ideology and valued set of beliefs, norms, customs, and meanings evidenced in a way of life” (American Nurses Association, 1986). There are evidences of several culturally inappropriate medical practices in India, which are often not reported in literature. Figure 1.3 shows a real picture of pelvic examination procedure in a Community Health centers from Haryana, India, which is highly embarrassing for Indian women. A reason behind such culturally inappropriateness may be because of cross-cultural misfit of procedure, in appropriate design of medical technology. A WHO report on medical devices highlighted that most devices present in developing countries have been designed for use in developed countries. Consequently, when these medical devices are implemented in India they are either unaffordable or a misfit for such a socio-culturally diverse healthcare system (WHO, 2010).

Currently practiced pelvic examination for visual inspection (for VIA, VILI, VIAM, Pap Smear and HPV DNA test) of Cervix is painful, skill dependent and time taking. Also it is highly embarrassing for Indian women and it is one of the major reasons for poor patient follow up and show up in rural level screening campaigns.

Source: image taken during Clinical immersion at CRHSP Ballabgarh



Figure 1-3: Evidence of cultural insensitive clinical intervention in India (Source: Author captured)

In summary, India's healthcare system faces challenges of unequal resource distribution, rural infrastructure gaps, high out-of-pocket expenses, and cultural mismatches. Achieving self-sufficiency in the MedTech industry is crucial for accessible and culturally sensitive healthcare.

Medical technology regulatory hurdles: Evidences from India

Historically, the Indian medical device industry faced regulatory neglect until 2005, lacking specific regulations. From 2005 to 2017, the use of the Drug and Cosmetics (D&C) Act, 1940, for medical device regulation led to inappropriate compliance frameworks. Consequences included ignorance, variable quality, and predatory pricing. The absence of standards for import, manufacture, and distribution caused uncertainty, hindering innovators and entrepreneurs due to confusion and misinterpretation of regulatory processes (Kale, 2013; Harmon & Kale, 2015). India introduced its Medical Device Rules-2017 (MDR-2017) in response to the growing MedTech industry. The Central Drug Standard Control Organization (CDSCO) is the key regulatory authority responsible for enforcing MDR-2017, effective since January 1, 2018. The rules classify medical devices into four risk-based classes (class A (low risk), class B (low moderate risk), class C (moderate high risk) and class D (high risk)). However, despite the introduction of these rules, certain shortcomings have emerged. Various orders, notices, and guidelines, including those on central medical device testing laboratories, online registration, and draft guidance documents, have been issued for improvement. The notification lacks specificity, prompting additional publications for clarification and enhancement. Issues include gaps in classification, essential safety principles, and performance

guidelines for medical devices, indicating a need for ongoing refinement in the regulatory framework (Sharma & Chandra, 2020; Ministry of Health & Family Welfare, MEDICAL DEVICES RULES, 2017, 2017; Ministry of Health & Family Welfare, Medical Device & Diagnostics, 2019-23).

On top, recent scrutiny by the Drug Controller General of India (DCGI) and Institutional Ethics' Committees (IEC) has increased vigilance on clinical trials and regulations in India. The government has implemented measures for closer regulation of clinical studies, emphasizing the importance of understanding the process for clinical validation and testing of medical devices. Indirect clinical validation occurs in the early stages of device design, while actual clinical validation begins during beta prototype development. Before conducting clinical trials, approval from Institutional Ethical Review Board (IERB) or Institutional Ethics Committee (IEC) and registration with the Clinical Trials Registry of India (CTRI) are essential. Approval from DCGI is required for listed devices under MDR-2017. However, if device is not listed, for higher risk device classes the process of getting regulatory approval is not well defined and leads to additional complexity (Chaturvedi, *Inventing Medical Devices: A Perspective from India*, 2015).

In summary, literature has revealed that medical device regulations and clinical validation norms are still evolving in the Indian context. In some cases, manufacturers opt for European CE marking or US FDA approval if a new device does not fall under the list of notified devices in MDR-2017. This alternative can be time-consuming, expensive, and even more stringent.

1.3.3 Past conceptual understanding of medical technology innovation management

Successful medical technology innovation demands proactive strategic decision-making, effective management, and seamless coordination between R&D and business activities (Atanu, Thim, Gopalakrishnan, Peter, & Vijay, 2021; Kenneth, Enrico, & Eric, 2014; Pisano, 2006). Here comes the role of Technology and innovation management (TIM) models, Innovation management techniques (IMT) in demystifying influencing factors, various required activities and managing innovation by means of knowledge management (Khilji, Mroczkowski and Bernstein, 2006; Hidalgo and Albors, 2008).

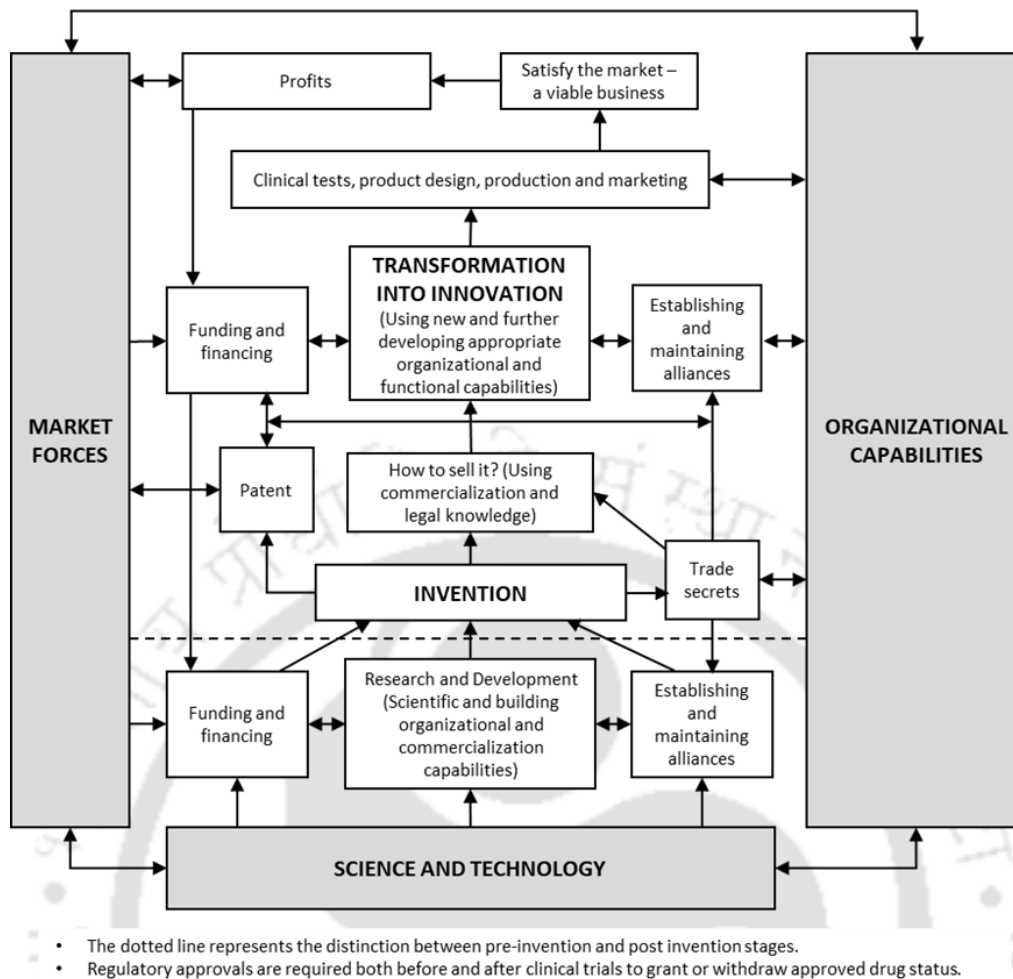


Figure 1-4: Biotech innovation management model by Khilji et al. (2006)

Innovation theories solely based on either the technology push or the market pull approach have their limitations: in addressing multifactorial healthcare requirements; and managing intense project activities of medical technology innovation. For medical technology, past research suggested an integrated approach to innovation management which considers balancing both activities of R&D and business, for firm-level success (Khilji, Mroczkowski, & Bernstein, 2006). Unlike traditional linear and unitary staged innovation processes, the integrated TIM model "Biotech Innovation Management Model" by Khilji et al. (2006), revealed complex relationships and connections among various inter- and intra-organizational activities at various stages of innovation management (See Figure 1.4). The integrated TIM model (Figure 1.4) integrates various innovation management activities under three main source factors: market dynamics, organizational capabilities, and scientific and technological knowledge, which promote medical technology innovation and influence organizational market competitiveness. Key activities considered within the TIM were research and development, funding and financing, establishing and maintaining alliances, intellectual

property (IP) management, product development, clinical testing and other activities that satisfy business needs.

The integrated TIM model by Khilji et. al. (2006) is of interest for the current research as it is a basis for innovation management across various medical technology areas, with over 240 research citations. The model defines the entrepreneurial roadmap of medical technology innovation and the influence of various factors on firm-level activities of innovation management. Follow-up research shows several scholarly contributions and topic-level expansions of the original parameters and activities of the model. Within the decade long TIM related research, several studies strengthen the idea of an integrated approach of harmonizing R&D and business-related goals and activities for the success of medical technology companies (Alegre, Chiva, & Lapiedra, 2009; Ireland & Hine, 2007; Siontorou & Batzias, 2010). The idea of incorporating market-orientated strategies for R&D effectiveness, successful market reach and commercialization of innovation is also being emphasized in several key studies (Luca, Verona, & Vicari, 2010; Tawate, Gupta, & Jain, 2019). A majority of studies valued the importance of inter-organizational alliances, and university-industry collaboration as an effective way to address MedTech R&D complexities and diverse skill requirements throughout various stages of product development (Bagchi-Sen, Smith, & Hall, 2004; Braun, Mueller, Adelhelm, & Vladova, 2011; Chang, 2006; Kenneth, Enrico, & Eric, 2014; Siontorou & Batzias, 2010; Wilfried & Marcus, 2013). Similarly, there exist studies discussing firm-level strategies for funding and finance, R&D, Knowledge management, Organizational and commercialization capacity building, Patent protection, clinical testing, production, marketing and business model planning (Alegre, Sengupta, & Lapiedra, 2013; Asim & Sorooshian, 2019; COREA, 2015; Heinonen & Sandberg, 2008; Li, Wang, & Zhao, 2018; Son & Zo, 2021). Most of these studies verify the integrity of the integrated TIM model by Khilji et. al. (2006) showing parallel, interacting and interdependent activities and source factors of medical technology innovation.

In summary, successful medical technology innovation requires an integrated approach that harmonizes R&D and business activities, as emphasized by the widely cited and validated "Biotech Innovation Management Model by Khilji et. al. (2006)."

1.3.4 Why the past medical technology innovation model is a no match for LMIC context?

The integrated TIM model of medical technology innovation proposed by Khilji (2006) is based on case studies from high-resource settings and focuses on only three central

components: R&D, financing, and alliances. The model proposed by Khilji et al. (2006) does not define the order and importance of other processes such as production, clinical testing, and regulatory clearance (Khilji, Mroczkowski, & Bernstein, 2006). Therefore, the model is an oversimplified representation of the medical technology innovation process and requires additional clarity. Moreover, Medical technology innovation for a resource-constraint setting like that of LMICs not only demands a solution from the perspective of clinical efficacy but also needs to address country-specific challenges, stakeholder requirements, and other influencing factors for greater acceptance and grass root level penetration (Beenkens & Stolk, 2010; WHO, 2010). There exists evidence of such dependencies in the literature. For instance, in most LMICs, indigenization and local manufacturing of medical technology suffer due to: healthcare system-related challenges; inadequate healthcare and regulatory policies; and an underdeveloped R&D ecosystem (World Health Organization, 2011; Jarosławski S. S., 2013; Abrol, Sundararaman, Madhavan, & Joseph, 2016). Similarly, the cultural and healthcare beliefs in low and middle-income countries (LMICs) differ from Western processes, and neglecting this factor can result in poor acceptance of innovation (Beenkens & Stolk, 2010; Kimani, Kabiru, & Muteshi, 2020; S & D., 2012; Nsiah-Asamoah, Doku, & Agblorti, 2020). The past technology innovation model did not adequately define these dependencies.

The past TIM for medical technology innovation represents an industrialized and organizational viewpoint of medical technology innovation management which is not sufficient to manage innovations in LMICs. There is a need to incorporate multiple theoretical lenses to investigate factors influencing medical technology innovation in LMICs.

1.3.5 Theoretical lenses required for analyzing LMIC-specific issues of medical technology innovation

Design thinking for successful innovation depends on three factors: desirability, feasibility, and viability (Magistretti, Dell'Era, Verganti, & Bianchi, 2021). Desirability represents the extent to which a solution meets the needs and expectations of users, stakeholders, or society. Feasibility refers to whether a solution can be implemented within the constraints of resources and finances. Viability is linked to the potential success and sustainability of a solution, considering market demand, affordability, legal, and political environments. Theories such as Social Innovation Theory, Stakeholder Theory, the Resource-Based View, and the PESTEL framework comprehensively explain all the requirements of these three factors. For medical technology innovation, considering such theoretical viewpoints can help generate a wide range of insights into the challenges of medical technology innovation and adoption in LMICs.

Social innovation theory focuses on defining innovations based on social needs and issues such as poverty, inequality, and cultural barriers (Oeij, van der Torre, Vaas, & Dhondt, 2019; Portales, 2019). It takes a bottom-up approach where societal needs drive innovation instead of the market. This perspective is particularly relevant in the LMIC context, where there are significant socio-economic and cultural challenges in innovation adoption (Beenkens & Stolk, 2010; WHO, 2010). Social innovation theory can help identify innovation issues by in-depth understanding of complex social issues and relationships in the implementation of innovative solutions.

Stakeholder theory emphasizes that organizations should consider the interests and values of all stakeholders, not just profits (Freeman, 2004). Close collaboration with stakeholders can resolve conflicting goals and enhance a firm's reputation and long-term sustainability (Jurgens, Berthon, Papania, & Shabbir, 2010). In healthcare, all stakeholders, like patients, healthcare providers, suppliers, investors, regulators etc. have specific interests in the operations and outcomes of a medical technology innovation firm. In LMICs, medical technology innovation firms should address the challenges faced by various stakeholders in adopting novel technologies. Identifying LMIC-specific barriers by considering multiple stakeholder perspectives can be beneficial.

The resource-based view (RBV) considers organizations as bundles of resources, and strategic management of such resources to improve firm-level capabilities and market competitiveness (Barney, Wright, & Ketchen, 2001). Resources include infrastructure, facilities, financial resources, human resources and intangible organizational knowledge. RBV theory can be used as a strategic lens to understand, within LMICs how organizational resources and capabilities influence the management of medical technology innovation. These include capabilities of healthcare institutions, innovation-driving firms, vendors, manufacturers and other shareholding organizations that are part of a medical technology innovation process.

PESTEL framework allows the identification of external factors from the political, economic, sociocultural, technological, environmental and legal perspectives which can impact organizational operations and business activities (Mayaka & Prasad, 2012). The framework helps organizations identify opportunities or threats against which they can make the strategic decision to adapt or make changes. Considering PESTEL's perspective in identifying and categorizing LMIC-specific challenges and barriers to medical technology innovation can be

helpful from a practical business management perspective.

In summary, integrating social innovation, stakeholder theory, resource-based view, and the PESTEL framework may offer a comprehensive lens to address the multifaceted challenges in medical technology innovation and adoption within LMICs.

1.3.6 Existing systematic processes to medical technology design and innovation

Systematic processes have been well accepted in the design community as practice, field, craft, framework, philosophy, and discipline in delineating the overall design and innovation activities in an optimal way. In the healthcare design domain, the ‘Biodesign process’ also known as ‘Stanford Biodesign process’ is pioneer and widely used in industry and academia for Medical technology design and innovation.

Stanford Biodesign process

Stanford Biodesign Process						
PHASES	IDENTIFY		INVENT		IMPLEMENT	
STAGES	1. NEED FINDING	2. NEEDS SCREENING	3. CONCEPT GENERATION	4. CONCEPT SCREENING	5. STRATEGY DEVELOPMENT	6. BUSINESS PLANNING
ACTIVITIES	1.1 Strategic Focus	2.1 Disease State Fundamentals	3.1 Ideation	4.1 Intellectual Property Basics	5.1 IP Strategy	6.1 Operating Plan & Financial Model
	1.2 Needs Exploration	2.2 Existing Solutions	3.2 Initial Concept Selection	4.2 Regulatory Basics	5.2 R&D Strategy	6.2 Strategy Integration & Communication
	1.3 Need Statement Development	2.3 Stakeholder Analysis		4.3 Reimbursement Basics	5.3 Clinical Strategy	6.3 Funding Approaches
		2.4 Market Analysis		4.4 Business Models	5.4 Regulatory Strategy	6.4 Alternative Pathways
		2.5 Needs Selection		4.5 Concept Exploration & Testing	5.5 Quality Management	
				4.6 Final Concept Selection	5.6 Reimbursement Strategy	
					5.7 Marketing & Stakeholder Strategy	
					5.8 Sales & Distribution Strategy	
					5.9 Competitive Advantage & Business strategy	

Figure 1-5: Stanford Biodesign Process-Phases, stages, and activities, Source: (Yock, et al., 2010)

The Stanford Biodesign process, presents a well-established systematic approach to innovate

healthcare systems and medical technologies. The process diverges from traditional medical technology innovation by prioritizing a pragmatic, need-driven approach rooted in clinical observations, design thinking principles, and strategic planning for successful implementation (Yock, et al., 2010). The Biodesign Process was initially developed by Stanford University in 2001, later adopted globally to train designers, engineers, doctors, researchers etc. in medical technology innovation and entrepreneurship. The process comprises three phases (consisting of six stages), each encompassing a series of activities, as illustrated in Figure 1.5. Here is a brief description of the three phases.

(a) Identify phase

In the "Identify" phase, a diverse team (engineers, product designers, business graduates, clinicians) selects a clinical area (e.g., cardiology, general surgery) for 6-8 weeks of observations in hospital settings, including OPDs, procedure rooms, and labs. They impartially observe healthcare interactions, processes, and outcomes. After documenting their findings, the team categorizes crucial needs, starting with unmet ones. These needs undergo screening based on factors like disease understanding, existing solutions, stakeholder agreement, and market potential. Ultimately, the team compiles a structured "needs criteria" document, outlining essential and desired elements for developing a solution.

(b) Invent phase

In the "Invent" phase, the team conducts collaborative brainstorming to generate a wide range of ideas for solving the identified need or problem. They draw upon their diverse expertise and perspectives to foster creativity. The initial need criteria, outlined in the need specification document, guide this ideation process. Following ideation, concepts are developed and evaluated based on factors like intellectual property potential, regulatory feasibility, reimbursement possibilities, and business viability. The phase then focuses on developing prototypes and engaging stakeholders in concept validation, ensuring that potential solutions are thoroughly assessed and refined.

(c) Implement phase

During the "Implement" phase, the team focuses on strategic planning to bring the selected concepts to commercial fruition. This includes assessing intellectual property protection, strategizing research and development efforts, planning preclinical and clinical testing, and ensuring regulatory compliance. Additionally, the phase encompasses securing funds, operational planning, financial strategy development, and crafting marketing, sales, and

distribution plans. The ultimate objective is to ensure a sustainable implementation of the solution to customers/users.

1.3.7 Other processes used for medical technology design and innovation

Among various widely known product design processes the User Centered Design (UCD) approach has been more comprehensive, widely accepted and practiced in for Product and Interaction design. The process has been widely adopted in both industry and academia including in medical technology design projects.

User-centered design process (UCD)

The evolution of the User-Centered Design approach has been shaped by numerous methods, research endeavors, and theoretical foundations that can be traced back to the 1980s and 1990s. Within the design research community and among practitioners, a persistent drive exists to continually explore, adapt, and scrutinize the UCD framework across diverse design domains, even extending into fields like healthcare. Regardless of how one defines, modify or extend UCD framework, the central philosophy remains the same i.e., users at the center of various design decisions and activities.

The core UCD process can be generally categorized into three primary phases: The Design Research phase, the Design phase, and the Design Evaluation phase, as outlined in reference (Williams, 2009; Still & Crane, 2017). The three primary phases of the UCD process are visually depicted in Figure 1.6 and described below:

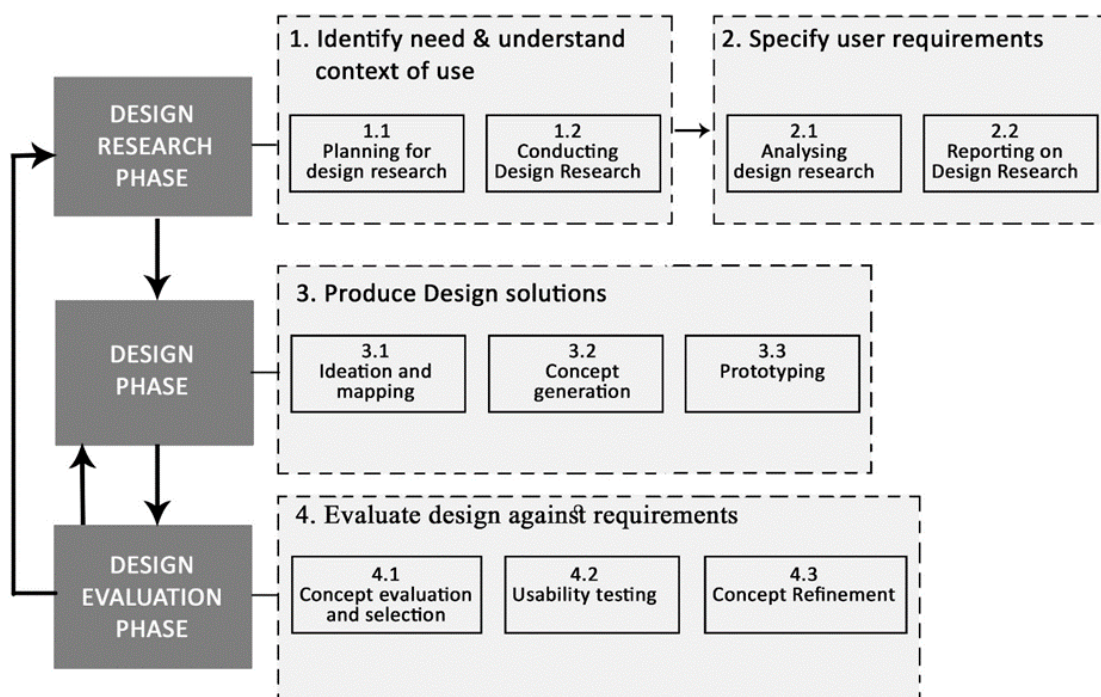


Figure 1-6: User Centered Design Process, Source: (Dutta & Dhar, 2021)

(a) Design research phase:

The design research phase aims to understand user needs, contextualize usage, and define requirements. It involves planning, conducting, analyzing, and reporting research activities. Planning entails identifying users and stakeholders, aligning with objectives, and deciding research methods. Conducting research involves methods like interviews, shadowing, and literature review to gather information. Analysis includes debriefing with the team, summarizing insights, data mapping, and identifying trends. Reporting includes delivering requirement specifications, written reports, presentations, personas, process flows, and usability test plans. This phase ensures a comprehensive understanding of user needs and forms the basis for the subsequent design process.

(b) Design phase:

The design phase involves activities related to ideation, conceptualization, and concept realization, aimed at addressing the requirements identified in the design research phase. While UCD literature often does not elaborate on how practitioners should tactically integrate research findings into the design process, over the years, researchers have developed various ideation and mapping tools and techniques that support this phase of the UCD process. Key deliverables in this phase include ideas, concepts, wireframes, process flows, and low-fidelity prototypes.

(c) Design evaluation phase:

In the UCD philosophy, evaluating the design typically centers on usability testing. Usability evaluation encompasses the measurement of User Experience by collecting, analyzing, and presenting usability metrics for various concepts and prototypes generated in the design phase. Besides formal usability testing, other design evaluation techniques involve expert reviews and concept evaluation matrices. Key deliverables for this phase include a usability test plan and a usability test report.

Human-centered design

Human-centered design is a problem-solving approach that prioritizes the inclusion of real people in the development process, aiming to create products and services that are finely tuned to the needs and preferences of the target audience. By keeping users' desires, pain points, and

preferences at the forefront throughout every stage of development, this process fosters the creation of more intuitive and accessible products, potentially leading to higher profits as customers are more invested in the solutions provided.

The human-centered design process (see Figure 1.7), as outlined by Harvard Business School Online Design Thinking and Innovation Course, consists of four phases: Clarify, Ideate, Develop, and Implement (Landry, 2020).

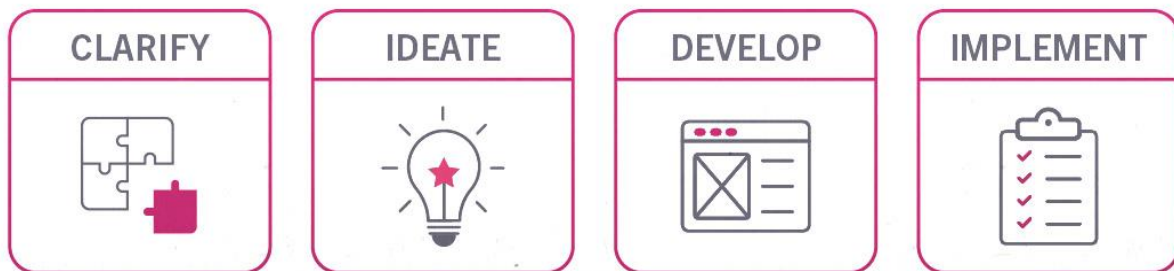


Figure 1-7: Human-centered design process (Source: <https://online.hbs.edu/PublishingImages/blog/posts/HBSO-StagesDesignThinking.png>)

(a) *Clarify:*

In this initial phase, the focus is on gathering data and observing customers to clearly understand the problem at hand and potential solutions. Empathy is crucial, and user research helps identify explicit and latent pain points, with the latter requiring deeper exploration to uncover transformative innovations.

(b) *Ideate:*

Building on the insights gained in the Clarify phase, the Ideate stage involves applying various design thinking tools to generate a multitude of ideas. Overcoming cognitive fixedness is essential to promoting creativity, ensuring that multiple perspectives are considered before settling on a potential solution.

(c) *Develop:*

The Develop phase involves combining and critiquing the generated ideas to create a range of possible solutions. This step emphasizes the importance of desirability, feasibility, and viability when evaluating concepts. Prototyping is introduced to quickly test ideas, reduce costs, save time, and enhance the final product's quality.

(d) *Implement:*

The final phase focuses on bringing the innovation to market successfully. Communication of

the innovation's value to both internal and external stakeholders is crucial for adoption and sustained growth. Reflection on organizational culture and group dynamics is necessary to ensure ongoing innovation in line with user-focused solutions.

The iterative nature of human-centered design is emphasized, highlighting the need to adapt continuously to evolving customer wants and needs. Keeping humans at the center of the development process is presented as a key strategy for ensuring ongoing innovation and achieving long-term product-market fit.

Design thinking Process

Design thinking is a problem-solving approach that emphasizes empathy for the end-users, encourages creativity, and integrates iterative prototyping and testing. The process is commonly employed within the design community for projects in healthcare design, social innovation, user experience design, and similar fields. The process typically consists of several stages, each contributing to the overall development of innovative solutions. These stages are often iterative and non-linear, allowing for flexibility and adaptation as insights emerge. The widely accepted design thinking process generally comprises five key stages: Empathize, Define, Ideate, Prototype, and Test (Dam, n.d.). Figure 1.8 illustrates the five stages of Design thinking process.

Design Thinking



Figure 1-8: Design Thinking Process. (source: intercation-design.org)

(a) Empathize

The first stage of the design thinking process involves understanding needs and perspectives of the end-users. Designers engage in activities such as conducting interviews, surveys, and observations to immerse themselves in the users' experiences. They seek to understand users' emotions, needs, and challenges by putting themselves in users' shoes. Empathy-building

exercises, like creating user personas and empathy maps, help in synthesizing qualitative data and forming a deeper understanding of users' perspectives. The goal is to develop a deep understanding of users' emotions and needs, fostering a human-centered approach to problem-solving.

(b) Define

In the Define stage, designers analyze information collected during the Empathize stage to distill the core problems and challenges. This step involves synthesizing data to create a clear and concise problem statement, also known as the "point of view." This statement guides the design team's focus and sets the stage for generating innovative solutions. It helps ensure that the subsequent stages are directed towards addressing identified problems in a meaningful way. Group discussions and collaborative sessions are essential to distill the information and define the core challenges that need to be addressed.

(c) Ideate

Ideation is a creative phase where design teams generate a wide range of possible solutions to address defined problem. The emphasis is on divergent thinking, encouraging the exploration of various ideas without judgment. Ideation involves brainstorming sessions and creative workshops where diverse ideas are generated. Designers use techniques such as mind mapping, brainstorming, and SCAMPER (Substitute, Combine, Adapt, Modify, Put to another use, Eliminate, Reverse) to encourage divergent thinking. The goal is to produce a multitude of ideas without judgment. Post-it notes, sketches, and other visual aids are commonly used to document and visualize these ideas.

(d) Prototype

In the Prototype stage, designers transform selected ideas from the Ideate stage into tangible representations. These representations, or prototypes, can take various forms depending on the nature of the problem and the available resources. Designers create low-fidelity prototypes using materials like paper, cardboard, or digital tools. These prototypes are meant to be quick and easy to modify. The emphasis is on creating a physical or digital manifestation of ideas that can be tested and refined based on user feedback. Rapid prototyping and iterative refinement are key activities in this stage.

(e) Test

The final stage involves testing prototypes with end-users to gather feedback and insights. This

stage is crucial for refining and improving proposed solutions. The Testing stage involves activities such as usability testing, user interviews, and feedback collection. Designers observe how users interact with prototypes and gather insights on usability, desirability, and effectiveness. Iterative testing allows designers to refine and improve the prototypes based on real user experiences. This stage often involves a feedback loop with users, encouraging a collaborative approach to refining and validating solutions.

Further, literature also revealed specific processes like *Activity Centered Design*, *Goal-Directed Design*, *agile methods* which are used for designing user interactions, software for medical devices or systems.

Activity-Centered Design is an approach that focuses on understanding and designing for specific activities or tasks that users engage in. It emphasizes observing and analyzing how users perform tasks to inform the design process. This process aims to create user interfaces or systems that align closely with the users' actual activities, improving usability and overall user experience (Kaptelinin, Kuutti, & Bannon, 1995).

Goal-Directed Design is a design philosophy that places user's goals and objectives at the forefront of the design process. Instead of solely focusing on features or functionalities, designers using this approach prioritize understanding what users want to achieve. By aligning design decisions with user goals, the resulting products or interfaces are more likely to be effective and satisfying for the users (Abidin, Junaedi, & Sardi, 2018).

Agile methods refer to a set of iterative and flexible software development processes. These processes prioritize collaboration, adaptability, and customer feedback throughout the development process. Agile processes typically involve breaking down the project into small, manageable units called iterations, with regular reassessment and adaptation of plans based on feedback. This iterative and incremental approach allows for a more responsive and dynamic development process, accommodating changes and improvements as the project progresses. Common agile processes include Scrum, Kanban, and Extreme Programming (XP) (Johner, 2015).

In summary, the literature has unveiled diverse design and innovation processes relevant to medical technology innovation in LMICs (Chatpun, Liawrungrueang, Prukpattranon, & Wongsiri, 2022; Zaufenberger, Stampfer, Mader, Gold, & Donsa, 2022; Schwartz-Lasfargues, et al., 2022). Most previous case studies have predominantly showcased systematic adherence to the standard stages and activities of these design processes for

addressing clinical problems in LMICs. However, there is a lack of research exploring how specific factors unique to LMICs influence conventional design and innovation process's activities, potentially requiring alterations to the methodology. Out of all the design and innovation processes Stanford Biodesign process has been found to be more widely used for medical technology innovation. However, few case studies on the Biodesign Process reveal that it doesn't align well with the context of developing countries like India (Chachra, et al., 2018; Arun-Kumar, Sridhar, Chaturvedi, & Deshpande, 2017). In those studies, authors have modified the initial Identify phase, but the disclosed process modification do not propose generalized process improvements or modifications to address LMIC-specific contextual requirements. In conclusion, while established design and innovation processes like the Stanford Biodesign process, User-centered Design, Human-centered design and Design thinking provide structured processes for medical technology design and innovation, there is a need to explore their adaptability to diverse contexts, especially in LMICs, to ensure effective implementation.

1.4 Insights from Background Study: Research Gaps and Questions

1.4.1 Research gap 1

The scoping review revealed that the medical technology innovation context in low- and middle-income countries (LMICs) differs from that in developed nations. Distinct challenges, such as inadequate infrastructure, regulatory constraints, and cultural differences, affect access and care quality (Abrol, Sundararaman, Madhavan, & Joseph, 2016; Jarosławski S. S., 2013; World Health Organization, 2011). Other reported barriers include information gaps, inappropriate design, and insufficient regulatory norms (WHO, 2010). Despite literature acknowledgments, a consolidated report on how these specific challenges impact medical technology innovation in LMICs is lacking.

Further, the prior integrated TIM model for managing medical technology innovation was primarily built upon case studies from developed countries and does not align well with the context of low- and middle-income nations (Khilji, Mroczkowski, & Bernstein, 2006). The model represents an oversimplified industrial approach to medical technology design and innovation. It lacks clarity on context-specific factors and their impact on innovation activities. This highlights the need for exploring the following key research questions.

Research Questions:

“What factors influence medical technology innovation in LMIC settings, and how do these

factors impact the management of innovation activities at the firm level?”

1.4.2 Research gap 2

The initial exploration of design and innovation processes for medical technology innovation revealed various systematic processes such as Biodesign process, User-centered design (UCD), Human-centered design (HCD), Design thinking process (DT) etc., employed in a variety of medical technology design and innovation projects (Chatpun, Liawrungrueang, Prukpattranon, & Wongsiri, 2022; Zaufenberger, Stampfer, Mader, Gold, & Donsa, 2022; Schwartz-Lasfargues, et al., 2022; Dharmawan, et al., 2020). However, the review did not provide insights into how these diverse design and innovation processes, each with its unique framework and approach, perform in meeting the process requirements of medical technology innovation. Do these processes encompass all the necessary support needed for a medical technology innovation process? Here were the related research questions:

Research questions:

“How does the design and innovation process for medical technology differ from that of generic products, and what specific requirements must a systematic process fulfill to support medical technology design and innovation effectively?”

1.4.3 Research Gap 3

A review of literature highlighted the worldwide recognition of the Stanford Biodesign process for medical technology innovation. Yet, previous reports had indicated that the Biodesign process may not seamlessly fit within the context of LMICs (Chachra, et al., 2018; Arun-Kumar, Sridhar, Chaturvedi, & Deshpande, 2017). In response to this, past researchers had made specific modifications to the process to address distinct clinical challenges in LMICs. However, it is important to note that these modifications are highly context-specific and primarily focus on the initial phase of identifying needs. They do not propose any broad process enhancements or alterations to the overall process. Regrettably, prior studies have not adequately established a research foundation for identifying LMIC-specific considerations in the design of medical technology. They have not effectively demonstrated how the conventional Biodesign process falls short in addressing these specific considerations. These gaps in the literature raise the following research questions:

Research Questions:

“What are the specific medical technology design and innovation process considerations for Low- and Middle-Income Countries (LMICs), and what limitations does the

conventional Biodesign process encounter? How can the conventional Biodesign process be modified to create a new workflow toolkit that adequately integrates LMIC-specific considerations?"

1.5 Aim and Objectives

Research Aim

The proposed research work aimed to identify low- and middle-income country (LMIC)-specific design and innovation requirements, and formulate a new workflow toolkit and methodologies for successful medical technology innovation in LMIC settings like India.

Objectives

(a) Objective 1: To identify medical technology innovation challenges and barriers in LMICs like India, analyze how they impact firm-level innovation management activities and define a theoretical working model.

The scope of the objective 1 research is descriptive in nature contributing to design epistemology, i.e. we will be identifying key factors, associated challenges and barriers and revealing how they impact firm level innovation management activities via diagrams and evident based explanations.

(b) Objective 2: To identify specific process support required for Medical technology innovation process and compare scope of popular design and innovation processes in addressing medical technology innovation-related activities.

The scope of the objective 2 research is both descriptive (contributing to design epistemology) and prescriptive (contributing to design praxeology). As initial part of the study will be descriptive i.e., we will be identifying process support requirements for medical technology innovation. Next, we will compare the popular design and innovation process to check how the meet those requirements and prescribe necessary improvement required to popular design processes like UCD process.

(c) Objective 3: To define LMIC-specific Medical technology design and innovation process considerations and identify specific limitations of the existing Biodesign process.

The scope of the objective 3 is mainly descriptive (contributing to design epistemology) where we will be identifying LMIC specific design and innovation process considerations and evaluate the conventional Biodesign process where it stands in meeting those LMIC specific

process considerations.

(d) Objective 4: To define a medical technology design and innovation workflow toolkit and methodologies for LMICs like India and evaluate the same using appropriate methodology.

The scope of the objective 4 research is mainly prescriptive (contribution to design praxeology) where based on identified LMIC-specific shortfalls of Biodesign process a design of additional toolsets and processes will be synthesized to fill the required support gaps. Further, the modified process will be evaluated via appropriate methodology.

(e) Objective 5: To explore the applicability of the new Workflow toolkit in healthcare delivery for resource constraint setting by considering specific disease burden of LMICs like India.

The scope of the objective 5 is to demonstrate how to use the modified biodesign process for clinical problem solving via a case study by considering specific clinical context.

1.6 Research Plan

Figure 1.9 depicts the comprehensive research plan, accompanied by concise details regarding the methodology for each individual objective of the study.

1.6.1 Brief Research plan for Objective 1

The scope of Objective 1's research was descriptive, contributing to the design epistemology. We identified key factors, associated challenges, and barriers, and revealed how these elements impacted firm-level innovation management activities through diagrams and evidence-based explanations.

The research objective for Objective 1 was to use a multi-phase approach to identify medical technology innovation challenges and barriers in low- and middle-income countries (LMICs). The methodology comprised several interconnected phases: first, a systematic literature review was conducted to extract reported issues; next, multiple case studies were undertaken through semi-structured interviews to collect data and generate transcripts. Subsequently, thematic analysis was employed to extract factors, challenges, and barriers from the collected data. Following this, the interview data was analyzed to identify firm-level innovation activities. Finally, the research analyzed how the various identified challenges and barriers impacted firm-level innovation activities and synthesized a theoretical TIM model that offers insights into the dynamics of medical technology innovation in LMICs. Actual research execution and findings have been discussed in Chapter 2 of this thesis.

1.6.2 Brief research plan for Objective 2

The scope of Objective 2's research was both descriptive (contributing to design epistemology) and prescriptive (contributing to design praxeology). The initial part of the study was descriptive; we identified process support requirements for medical technology innovation. Next, we compared popular design and innovation processes to see how they met those requirements and prescribed necessary improvements to popular design processes like the User-Centered Design (UCD) process.

To achieve this objective, the research study followed a multi-faceted methodology. First, a comprehensive literature review of case studies on medical technology design was conducted to identify the distinctive characteristics that set medical technology design apart from generic product design. Subsequently, the research synthesized these findings to identify the process supports required for medical technology innovation projects. Finally, the research study compared the stages and activities of popular design and innovation processes to check their fitment for medical technology innovation. Actual research execution and findings were discussed in Chapter 3 of the thesis.

1.6.3 Brief research plan for Objective 3

The scope of Objective 3 was primarily descriptive, contributing to design epistemology, where we identified LMIC-specific design and innovation process considerations and evaluated the conventional Biodesign process in terms of how well it met those LMIC-specific considerations.

To achieve this goal, our methodology involved a multi-pronged approach. First, an in-depth analysis of previously identified LMIC-specific challenges and barriers was conducted to understand how they could be effectively addressed within the innovation process. Additionally, semi-structured interviews were conducted with Stanford-India Biodesign alumni to collect data on their innovation journeys, generate transcripts, and perform thematic coding to gain insights into the unique requirements for medical technology innovation in the LMIC context. Subsequently, this information was synthesized to establish the specific process requirements for medical technology innovation in LMICs. Finally, the shortcomings of the conventional Biodesign process were analyzed and recommended necessary improvements to better cater to the unique challenges present in LMICs. Actual research execution and findings have been discussed in Chapter 4 of this thesis.

1.6.4 Brief research plan for Objective 4

The scope of Objective 4 research was primarily prescriptive, contributing to design praxeology. Based on the identified LMIC-specific shortfalls of the Biodesign process, additional toolsets and processes were designed to fill the required support gaps. Furthermore, the modified process was evaluated using an appropriate methodology.

To achieve this, the research involved a multi-phase approach. The initial phases involved analyzing the workflow of stages and activities in the conventional Biodesign process and identifying new tool and activity requirements to align with the unique context of LMICs. Following this, two workshops were conducted to train design students; the first group utilized the conventional Biodesign process for specific clinical contexts, while the second group used the newly developed workflow toolkit for the same contexts. Data was collected from these workshops, including identified problems, population and desired outcomes, need statements, need selection processes, need criteria, ideas and concepts, concept selection processes, and implementation strategies related to research and development, intellectual property, regulatory compliance, clinical trials, and more. Finally, expert validation of the toolkit was carried out by evaluating the findings from the two workshops and obtaining feedback from experts, whose insights informed further iterations of the tool's design. Actual research execution and findings were discussed in Chapter 5 of this thesis.

1.6.5 Brief research plan for Objective 5

The objective 5 of this research plan was to demonstrate the applicability of the new Workflow toolkit in medical technology innovation for resource-constrained settings, considering the specific disease burden of LMICs. The methodology involved selecting specific clinical areas, implementing the modified Biodesign process to demonstrate how to utilize various tools and perform activities, and reporting stage-wise project progress and important research findings as we adapted the Workflow toolkit to the unique challenges of healthcare delivery in LMICs. Actual research execution and findings have been discussed in Chapter 6 of this thesis.

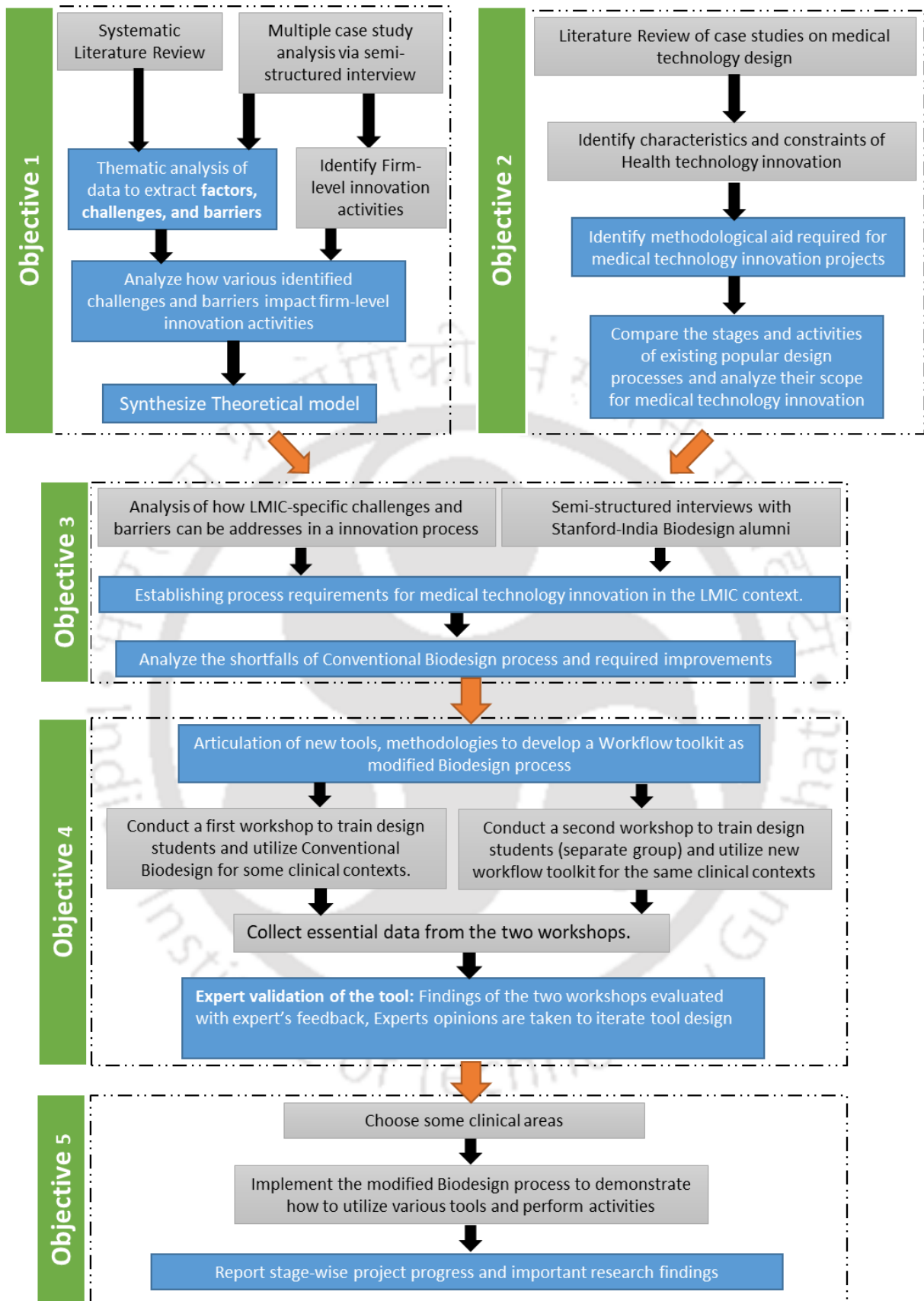


Figure 1-9: Overall Research plan (Source: author generated)

1.7 Structure of the thesis

Table 1-A shows the structure of the overall thesis and objective wise breakdown of chapters.

Table 1-A: Structure of the thesis

Research questions investigated	Objectives	Thesis Chapters
Introduction, Background, Research gaps, Research questions		Chapter 1 Introduction and Research Background
RQ 1: What factors influence medical technology innovation in LMIC settings, and how do these factors impact the management of innovation activities at the firm level?	Objective 1: To identify medical technology innovation challenges and barriers in LMICs like India, analyze how they impact firm-level innovation management activities and define a theoretical working model.	Chapter 2 Factors Influencing Medical Technology Innovation in LMICs
RQ 2: How does the design and innovation process for medical technology differ from that of generic products and what specific requirements must a systematic process fulfil to support medical technology design and innovation effectively	Objective 2: To identify specific process supports required for Medical technology innovation process and compare scope of popular design and innovation processes in addressing medical technology innovation-related activities.	Chapter 3 Scope of Existing Design and Innovation Processes for Medical Technology Innovation
RQ 3: What are the specific medical technology design and innovation process considerations for Low- and Middle-Income Countries (LMICs), and what limitations does the conventional Biodesign process encounter?	Objective 3: To define LMIC-specific Medical technology design and innovation considerations and identify specific limitations of the existing Biodesign process.	Chapter 4 Identifying LMIC-specific Design and Innovation Process Characteristics for Medical Technology innovation
RQ 4: How can the conventional Biodesign process be modified to create a new workflow toolkit that adequately integrates LMIC-specific considerations?	Objective 4: To define a medical technology design and innovation workflow toolkit and processes for LMICs like India and evaluate the same using appropriate methodology.	Chapter 5 Development and Evaluation of New Workflow Toolkit for LMIC inclusive Medical Technology Design and Innovation: a Modified Biodesign Process
	Objective 5: To explore the applicability of the new Workflow toolkit in healthcare delivery for resource constraint setting by considering specific disease burden of LMICs like India.	Chapter 6 Developing Clinical Solutions for the Resource-Constrained Healthcare Context of India: A Case Study on Utilizing the Modified Biodesign Process
Chapters 2 through 6 of this thesis delve into the primary research inquiries and goals. A significant discovery was that challenges such as the scarcity of skilled personnel in lower-tier healthcare facilities in LMICs extend beyond conventional design strategies and necessitate technological interventions for the efficient implementation of healthcare solutions. Subsequent investigations center on the utilization of AI-driven Conversational User		Chapter 7 Addressing the Scarcity of Skilled Personnel in Resource-Limited Healthcare Settings Through

Research questions investigated	Objectives	Thesis Chapters
Interfaces (CUIs) to address the dearth of proficient healthcare workers in LMICs.		the Scope of AI Chatbot Technology
Thesis Conclusion		Chapter 8 Key Contributions and Thesis conclusion

1.7.1 Summary of Chapters:

Chapter 1: Introduction and Research Background

Chapter 1 lays the groundwork for a thorough examination of medical technology innovation within the unique context of LMICs. The chapter begins by providing an overview of the significance of medical technology innovation and outlines the motivations behind the research. A comprehensive background study follows, exploring the medical technology innovation landscape in LMICs and the challenges faced, with a specific focus on the Indian healthcare context. The chapter also reviews past integrated TIM model of medical technology innovation management, highlighting their inadequacy for LMICs and introducing the theoretical lenses required for analysis. It addresses existing systematic design processes and their challenges in LMICs. The chapter concludes by summarizing key insights, identifying research gaps, defining research objectives, presenting the research plan, and outlining the thesis structure, offering readers a roadmap for the subsequent chapters.

Chapter 2: Factors Influencing Medical Technology Innovation in LMICs

Chapter 2 delves into the complexities of medical technology innovation within Low- and Middle-Income Countries (LMICs). The chapter begins with an introduction and background setting the stage for the research. It then outlines the comprehensive methodology, involving a systematic literature review, semi-structured interviews, and a critical analysis of the findings. The results section highlights the identified challenges and barriers to medical technology innovation and examines firm-level activities associated with innovation management, elucidating how these challenges impact these activities. The discussion section redefines the conceptual model of medical technology innovation management, while exploring the theoretical and practical implications.

Chapter 3: Scope of Existing Design and Innovation Processes for Medical Technology Innovation

Chapter 3 delves into the investigation of healthcare design processes, beginning with an introductory overview and a background context. The methodology for this research is extensively outlined, comprising a literature review of existing healthcare design processes, an

examination of challenges and constraints in medical technology innovation, identification of specific design requirements for healthcare projects, and a comparative analysis of existing design processes. The results and discussion section provides insights into the effectiveness of these processes, with a particular focus on the adaptation of user-centered design principles for healthcare projects.

Chapter 4: Identifying LMIC-specific Design and Innovation Process Characteristics for Medical Technology innovation

Chapter 4 delves into the crucial task of identifying LMIC-specific design process requirements for medical technology innovation, while also assessing the limitations of the popular Stanford Biodesign Process. The chapter commences with an introduction and background, outlining the significance of this research. The methodology is elaborated upon, involving semi-structured interviews with MedTech start-ups, thematic coding to extract LMIC-specific design process requirements, and a critical analysis of the Stanford Biodesign Process's shortcomings. Subsequently, the results section presents the challenges specific to LMIC-related medical technology design, the identified LMIC-specific design process requirements, and the shortcomings of the conventional Biodesign Process in the LMIC context. The chapter then engages in a comprehensive discussion of the findings, culminating in a conclusion that consolidates the key insights gained throughout the chapter.

Chapter 5: Development and Evaluation of New Workflow Toolkit for LMIC inclusive Medical Technology Design and Innovation: A Modified Biodesign Process

Chapter 5 presents a comprehensive exploration of the development and assessment of an innovative Workflow toolkit and processes designed to enhance the inclusivity of Medical Technology design in Low- and Middle-Income Countries (LMICs) like India, while applying a modified Biodesign Process. The chapter initiates with an introduction highlighting the significance of analog and workflow tools, breaking down the Stanford Biodesign Process, and outlining the limitations observed in the conventional Biodesign process. The methodology section elucidates the synthesis of the new Toolsets and processes, followed by an evaluation of the modified Biodesign process. The results section discusses the necessary adjustments required for the conventional Biodesign process, introduces the new toolkit, and presents the outcomes of toolkit evaluation. A thorough discussion and a concluding section summarize the chapter's key findings and implications.

Chapter 6: Developing Clinical Solutions for the Resource-Constrained Healthcare Context of India: A Case Study on Utilizing the Modified Biodesign Process

In Chapter 6, the author presents a comprehensive case study on utilizing the Modified Biodesign Process to develop clinical solutions for the resource-constrained healthcare context of India. The chapter begins with a brief introduction to the case studies, highlighting the importance of clinical immersion and initial background research. The utilization of the Modified Identify Phase is explained in detail, including the analysis of data from clinical immersion, need statement development, need scoping, need screening, and need criteria generation. The Modified Invent Phase is also discussed, covering concept feature generation, clinical solution synthesis, and concept selection. The chapter further explores the Modified Implementation Phase, addressing R&D, manufacturing strategy, IP strategy, and clinical validation strategy.

Chapter 7: Addressing the Scarcity of Skilled Personnel in Resource-Limited Healthcare Settings Through the Scope of AI Chatbot Technology

The chapter 7, uncovers that issues like shortage of skilled professional cannot be fully addressed by design process utilization alone rather technological intervention is required. The study explores the potential of AI Chatbot technology to address the scarcity of skilled personnel in resource-limited healthcare settings. The chapter provide an overview of the scope of this technology and delves into the concept of Conversational AI and Conversational User Interfaces (CUIs) in the context of healthcare. It examines the complex integrated system-physical interactions associated with CUI-based healthcare delivery and discusses methods to evaluate their usability. In that context, the chapter further outlines the research gaps, aims, and objectives, leading into a detailed methodology section covering the development of Conversational AI integrated medical devices, usability testing, analysis of existing heuristics, and the synthesis of new heuristics. Results and discussions follow, encompassing usability issues, existing heuristics, and the implications of new heuristics for CUI design and evaluation, along with their broader applicability.

Chapter 8: Key Contributions and Thesis conclusion

In the final chapter, the author consolidates the critical research findings, emphasizing the thesis's unique contributions and broader implications. The chapter offers valuable recommendations based on the study's outcomes and acknowledges its limitations while suggesting potential areas for future research, ensuring a comprehensive conclusion to the

thesis.

1.8 Conclusion

In conclusion, addressing the complexities of medical technology innovation in Low- and Middle-Income Countries (LMICs) requires a nuanced understanding of unique challenges. By identifying challenges, proposing a new theoretical model, and developing a tailored workflow toolkit, it aims to enhance the success of innovation endeavors in resource-constrained healthcare settings.



Chapter 2. Factors Influencing Medical Technology Innovation in LMICs

Abstract

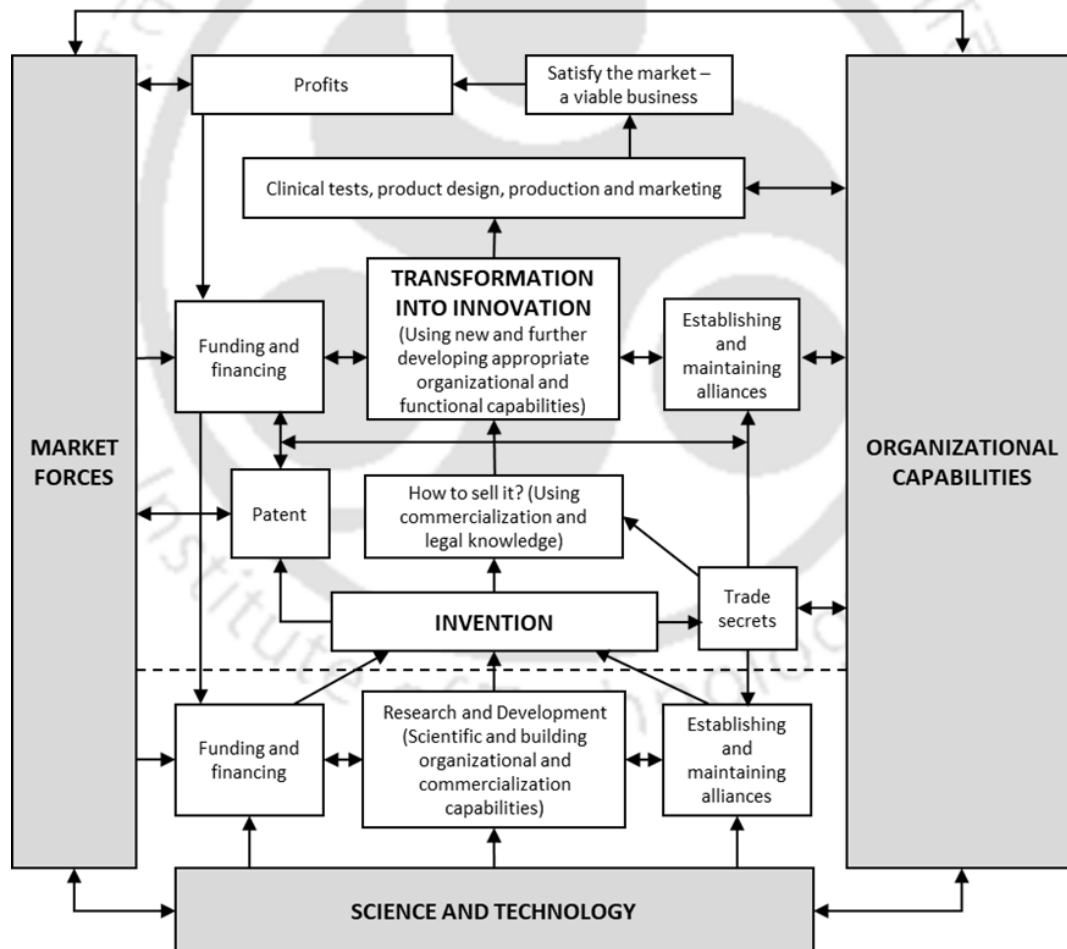
The existing TIM model of medical technology innovation management is poor-fit for low- and middle-income countries (LMICs) as it overlooks their unique challenges and constraints. The purpose of this study is to investigate key governing factors and underlying issues of Medical technology innovation in LMICs and how they impact firm-level activities of innovation management. A two-fold qualitative research methodology comprised of a literature review and multiple case study analyses via semi-structured interviews was adopted for data collection. A thematic coding approach and multiple theoretical perspectives were considered for data analysis and drawing conclusions. The study identified 23 challenges and barriers to medical technology innovation, categorized under six factors: *healthcare context and system; organizational capabilities; innovation ecosystem; demographic burdens and characteristics; market forces; and science and technology*. It was found that compared to high-income countries (HICs), in LMICs issues associated with *country-specific healthcare context and system, innovation ecosystem and demographic burdens and characteristics* influence innovation management activities and make medical technology innovation more challenging. The study contributes to the technology innovation model (TIM) research by demystifying new factors and proposing a comprehensive TIM model for understanding the roadmap of medical technology innovation and the influence of various factors on innovation management activities.

2.1 Introduction and Background

Medical technology innovations are complex and have longer product development life spans until the product is available in the market, spanning 12-15 years (Baker, 2003; Khilji, Mroczkowski, & Assudani, 2012). Unlike consumer products, novel medical technologies require validation for patient safety, solution efficacy, and quality assurance before getting regulatory clearance for market entry (Dutta & Dhar, 2021). In most low- and middle-income countries (LMICs), the complexity of medical technology innovation is greater than that of high-income countries (HICs) due to influence of diverse regional factors (Agarwal, Brem, & Grottke, Towards a higher socio-economic impact through shared understanding of product requirements in emerging markets: The case of the Indian healthcare innovations, 2018). For

Instance, in LMICs the absence of facilities for product testing and the lack of supporting institutions hinder the systematic inspection and quality assurance of new innovations, resulting in subpar product quality (Abrol, Sundararaman, Madhavan, & Joseph, 2016).

Successful implementation of medical technology innovations demands prior strategies to deal with market entry barriers like capturing new market share, disrupting existing clinical practice, providing a competitive edge, and intellectual property protection. These challenges extend the scope of organizational innovation management activities beyond scientific research and development (Dutta & Dhar, 2021). In this context, technology and innovation management (TIM) models and innovation management techniques (IMT) support demystifying influencing factors, identifying required activities, and managing innovation through knowledge management (Khilji, Mroczkowski, & Bernstein, 2006; Hidalgo & Albers, 2008).



- The dotted line represents the distinction between pre-invention and post invention stages.
- Regulatory approvals are required both before and after clinical trials to grant or withdraw approved drug status.

Figure 2-1: Biotech innovation management model by Khilji et. al. (2006)

The existing TIM for medical technology innovation integrated various innovation management activities into three fundamental drivers: market dynamics, organizational strengths, and scientific and technological expertise, as shown in Figure 2.1 (Khilji, Mroczkowski, & Bernstein, 2006). The model unveiled intricate interconnections and relationships within a range of inter- and intra-organizational activities throughout the different phases of innovation management (Khilji, Mroczkowski, & Bernstein, 2006). The model is a basis for innovation management research across various medical technology areas and defines the entrepreneurial roadmap of medical technology innovation. Follow-up research shows several scholarly contributions and topic-level expansions of original parameters and activities of the model (Ireland & Hine, 2007; Alegre, Chiva, & Lapiedra, 2009; Wilfried & Marcus, 2013; Verma & Ravichandran, 2020).

However, the past TIM is a poor representation of medical technology innovation management in LMICs as it fails to include essential factors specific to LMICs. For example, past studies reported how the cultural and healthcare belief system in LMICs are different from HICs setting. Samuel Kimani et al (2020), in their study have reported socio-cultural taboo of Kenyan Somali women as one of the barriers to sexual healthcare in LMICs (Kimani, Kabiru, & Muteshi, 2020). The study shows demand for culturally sensitive surgical procedure among Kenyan Somali women and assurance of procedural confidentiality and privacy. Again, as reported, in most LMICs, indigenization and local manufacturing of medical technology suffer due to: healthcare system-related challenges; inadequate healthcare and regulatory policies; and an underdeveloped R&D ecosystem (World Health Organization, 2011; Jarosławski S. S., 2013; Abrol et al., 2016). The past TIM failed to explain several of such dependencies.

Past TIM-related research shows a lack of understanding and inclusion of LMIC-specific issues that impact organizational activities of innovation management. Khilji's (2006) conceptual model of medical technology innovation, which is drawn from case studies in high-resource settings and is an oversimplified representation of the medical technology innovation process and don not explains influence of several reported factors specific to LMICs.

Thus, there is a need to understand LMIC-specific challenges and barriers and how they impact medical technology firms' complex network of inter-organizational and intra-organizational activities. Very few consolidated reports on challenges of medical technology innovations specific to the LMIC context exist in the literature. While some reports from

LMICs, such as India, Kenya, Uganda, Ghana, Bangladesh, and Srilanka, have brought up specific concerns related to medical technology innovation, such as regulation, manufacturing, or adoption, these reports are mostly limited in scope. For example, Saidi (2016) in his study assesses the impacts of the absence of adequate medical device regulation in South Africa. Similarly, Park et al. (2022) identified various factors associated with accessing and utilization of healthcare services by slum residents in LMICs like India, Bangladesh, Nepal, Peru, Kenya, Ethiopia, Malawi, etc. The majority of the consolidated reports from the past were grounded in Indian context. For instance, Jarosławski and Saberwal (2013), in their study considered case studies from India and identified five barriers to *medical device development* which were mainly related to government negligence in terms of policymaking, practice, regulations and guidelines (Jarosławski S. S., 2013). Another study by Rane and Kirkire (2016) identified 11 India-centric barriers to *efficacious medical product development*, which can be categorized as organizational barriers or ill practices, government's regulation and policy-related shortcomings (Rane & Kirkire, 2016). A literature-based analysis from Sahu and Panja (2017) identified few generic barriers primarily related to the government's *negligence related to practices and policies* (Sahu & Panja, 2017). The work of Leonard, de Kock, and Bam (2020) was based on a conceptual health innovation system framework which considers three entities: *functions, components and the context* of a health innovation system and proposed seven components as *barriers to medical technology innovation adoption* (Leonard, de Kock, & Bam, 2020). It was observed that most past research agendas were limited to challenges and barriers related to innovation effectiveness, efficacious product development, and successful innovation implementation. Similarly, Aranda Jan, C.B., et al (2016) identified 56 contextual factors across nine categories in their study, establishing a taxonomical framework for healthcare design considerations in LMICs . However, these 56 factors do not encompass challenges associated with the innovation aspect, which extend beyond design to include activities such as business scoping, technology research and development, innovation scoping, intellectual property management, clinical efficacy and product safety validation, regulatory approval, innovation scale-up, and production, and commercial implementation and product diffusion.

Given the information on the complexity of medical technology innovation in the context of LMICs and the research gap, our objective was to investigate the challenges and barriers associated with medical biotech innovation in LMICs and how do these challenges and barriers affect the firm level innovation management activities? For instance, from the pool of

identified challenges and barriers, we would establish which all impact clinical trial related activities. The study concludes by describing the significance of these factors and proposing a more comprehensive TIM that fits LMIC-specific contexts. The nature of the study is exploratory, and we chose India as the context of the study, as India being a part of the LMIC category is an emerging economy and a major promoter of biomedical and biotech startups to meet the healthcare needs of its own and that of the world (Uppal, Chakrabarti, Chirmule, Rathore, & Atouf, 2021; Suresh & Chandan, 2021). In examining the intricacies of innovation management at the firm level, our analysis integrates diverse theoretical perspectives, including Social Innovation Theory, Stakeholder Theory, the Resource-Based View (RBV), and PESTEL analysis, to comprehensively identify and scrutinize the influencing factors (Oeij, van der Torre, Vaas, & Dhondt, 2019; Portales, 2019; Freeman, 2004; Jurgens, Berthon, Papania, & Shabbir, 2010; Barney, Wright, & Ketchen, 2001; Mayaka & Prasad, 2012). Social Innovation Theory offers insights into how firms can develop solutions that address unmet social needs or challenges, highlighting the importance of societal impact in innovation. Stakeholder Theory is utilized to understand the expectations and influences of various stakeholders on innovation processes, emphasizing the necessity of aligning innovation with stakeholder needs for success. The Resource-Based View (RBV) provides a lens to assess how resources and capabilities can have impact on innovation, stressing the critical role of internal assets in developing and sustaining innovation. Lastly, PESTEL analysis guides the examination of external macro-environmental factors (Political, Economic, Social, Technological, Environmental, and Legal) that affect innovation implementation, underlining the importance of external context in shaping innovation strategies. Together, these theories facilitate a comprehensive analysis of innovation management, ensuring that the desirability, feasibility, and viability of innovative solutions are thoroughly evaluated in relation to user needs, available resources, and market and environmental conditions.

2.2 Methodology

As the study set out with an exploratory aim, its methodologies evolved alongside the emerging findings. The retrospective overview of the study's methodology unfolds as follows (see Figure 2.2):

- i. We commenced with a systematic literature review to gather data concerning challenges and barriers to medical technology innovation.
- ii. Thematic analysis of the collected literature data was conducted by experts to

identify key factors and underlying challenges and barriers to medical technology innovation. At this stage, challenges and barriers were extracted based on data analysis using the theoretical perspectives of social innovation theory, stakeholder theory, resource-based view, and the PESTEL framework.

- iii. The results of the thematic coding revealed 5 key factors and a set of 22 LMIC-specific challenges and barriers from the perspective of the theoretical frameworks we considered. We also obtained insights into how the identified challenges and barriers impact various firm-level activities such as IP management, manufacturing, regulatory processes, etc. However, we recognized the need for a better understanding of the overall activities or milestones in the process of medical technology innovation and how the identified challenges and barriers actually affect those activities or milestones.

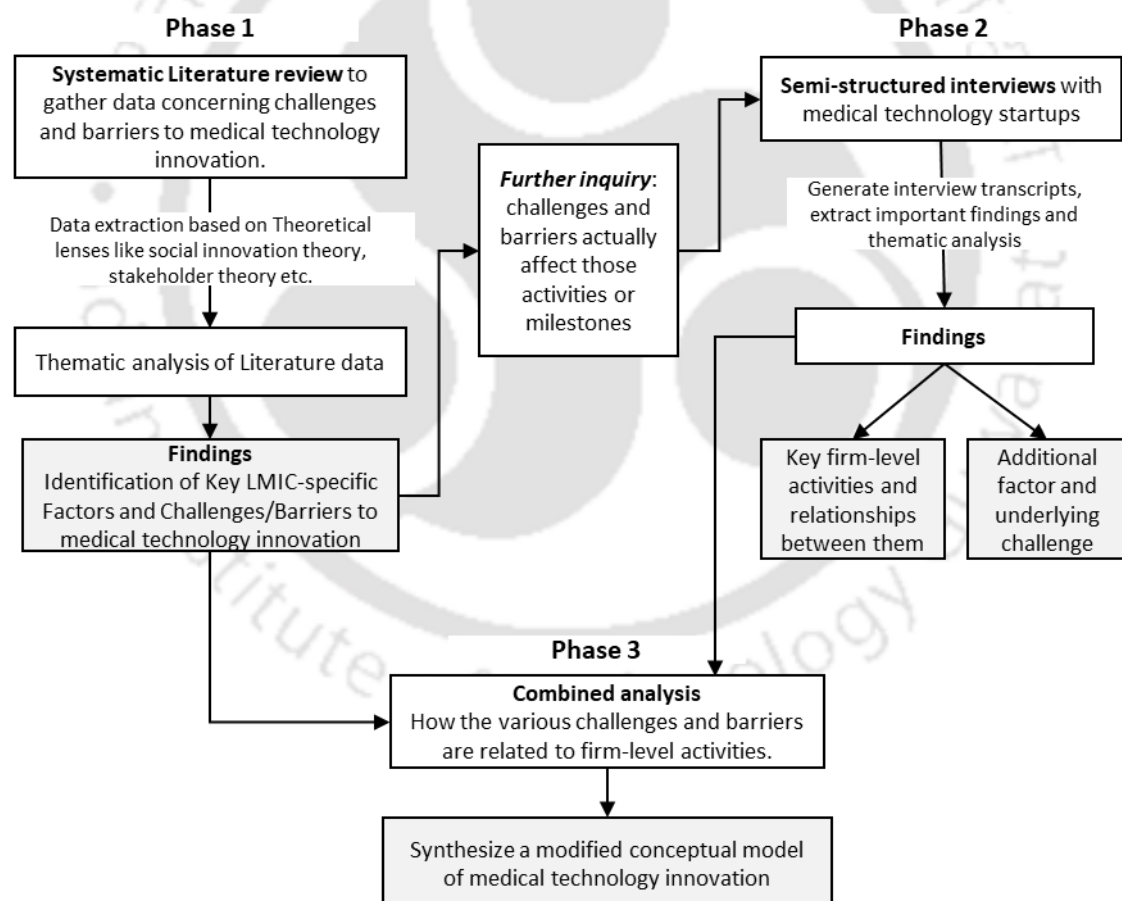


Figure 2-2: Methodology used for the study (author generated)

- iv. The follow-up process involved conducting semi-structured interviews with medical technology startups to identify how the various challenges and barriers previously identified impact firm-level activities.

- v. The analysis of interview transcription data resulted in the following key findings:
 - i. Key firm-level activities and their sequencing and relationships with each other.
 - ii. Thematic analysis of the interview transcripts corroborated several challenges and barriers identified through literature data analysis. Furthermore, we identified an additional factor and underlying challenge that we had previously missed in the literature data analysis.
 - iii. The interview data revealed how the various challenges and barriers are related to firm-level activities.
- vi. Additionally, based on the interview findings, we gained clarity on some of the findings from the literature data regarding how various challenges and barriers impact firm-level activities. Previously, at the time of literature findings, this clarity was lacking due to a lack of understanding of key firm-level activities or medical technology innovation milestones and their sequencing and relationships.
- vii. Later, based on the established relationships between the factors and firm-level activities from both literature and interview data, we proposed a modified conceptual model of medical technology innovation.

Here are details about the Systematic literature review, semi-structured interview and Combined data analysis procedure.

2.2.1 Systematic literature review procedure (Phase 1)

For the systematic literature review, two well-established processes for article selection were integrated: one proposed by Arksey & O'Malley (2005), known for its transparency in search strategies, and the other by Tranfield et al. (2003), chosen for its streamlined breakdown of the systematic literature review process (Arksey & O'Malley, 2005; Tranfield, Denyer, & Smart, 2003).

Data collection

The data collection stage followed the approach suggested by Arksey and O'Malley (2005) and consisted of five stages (Figure 2.3). It started with the identification of appropriate keyword combinations using Boolean operators, as illustrated in Table 2-A. Among the search databases

like SCOPUS, PubMed, Web of Science, IEEE, and Google Scholar, for our initial search inquiry SCOPUS database was found to be one of the most comprehensive databases for this topic after initial exploration across various databases. Other databases such as PubMed, Web of Science, IEEE, and Google Scholar were used in a limited capacity after a set of initial searches, either due to the majority of articles being outside our scope or the appearance of the same articles already found in SCOPUS. While the search query included the keyword 'India', it was noted that the search results extended beyond articles exclusively focused on 'India'. Instead, they encompassed a variety of publications, including those from WHO and other LMICs such as Kenya, Uganda, Ghana, Peru, Bangladesh, Sri Lanka, and South Africa, where the term 'India' was referenced. These diverse sources provided valuable insights into challenges specific to LMICs. For instance, one of the search results highlighted a WHO report addressing the issue of mismatched innovation requirements when HICs dispose of unused medical products in LMIC settings as donations (WHO, 2010). Additionally, there were articles discussing issues like corruption in the healthcare sector in Uganda, which hinders access to orthopedic care and medical devices (Bouchard, Kohler, Orbinski, & Howard, 2012).

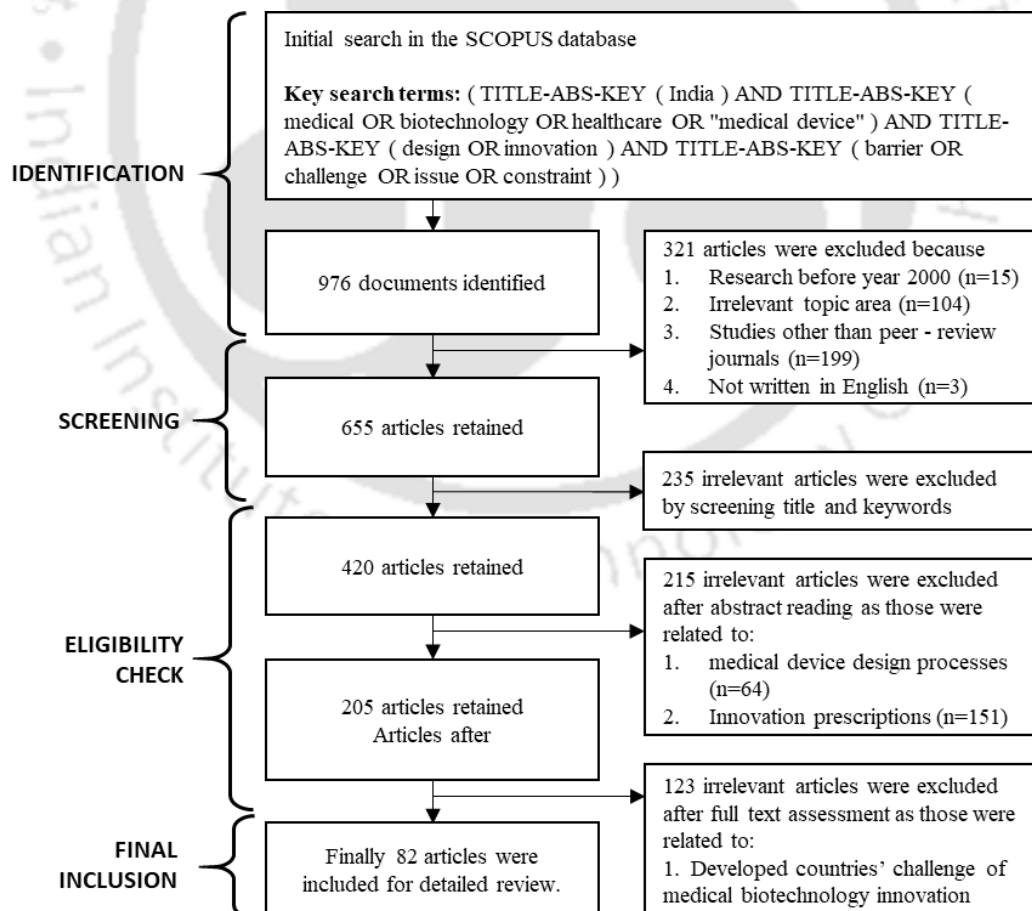


Figure 2-3: Flowchart of article selection process (author generated)

Initially, 976 documents were identified through the broad search. To facilitate the initial screening, a set of inclusion-exclusion criteria was developed, as depicted in Table 2-B, leading to the exclusion of 321 irrelevant articles. Subsequently, the remaining 655 articles were subjected to further screening, and their titles and keywords were evaluated for relevance to the subject area, resulting in the exclusion of 235 irrelevant articles. Following these initial screening steps, as illustrated in Figure 2.3, 420 journal articles were retained for eligibility checks. Based on the abstracts, 64 articles related to medical device design processes and 151 articles related to innovation prescriptions were excluded. These exclusions were made as they primarily focused on case studies of medical device design or provided solely design/innovation guidelines, lacking content that described the challenges or barriers of medical technology innovation. The remaining 205 articles were primarily addressing challenges or barriers to medical technology innovation and entrepreneurship. Upon conducting a thorough full-text assessment of these articles, it was identified that 123 of them pertained to challenges of medical technology innovation in developed nations. Consequently, these articles were excluded from the final review. Finally, 82 articles that reported challenges or barriers to medical technology innovation from the perspectives of India and other LMICs were included.

Table 2-A: Key search terms to guide the search

Search Terms
(India) AND (medical OR biotechnology OR healthcare OR “medical device”) AND (design OR innovation) AND (barrier OR challenge OR issue OR constraint)

Table 2-B: Inclusion and exclusion criteria

Criterion	Inclusion	Exclusion
Time period	2001 to 2022	Studies outside these dates
Study focus	Articles related to innovation challenges from the subject areas of Medicine, Social Sciences, Business Management and Accounting, Engineering, Pharmacology, toxicology and pharmaceuticals, Nursing, Decision Sciences, Economics, Econometrics and Finance, Multidisciplinary, Health professions, and Psychology.	Articles related to Computer Science, Biochemistry, Genetics and Molecular Biology, Environmental Science, Immunology and Microbiology, Agricultural and Biological sciences, Energy, Material Science, Neuroscience, Arts and Humanities, Mathematics, Chemical Engineering, Physics and Astronomy, Dentistry, Earth and planetary sciences, Veterinary and chemistry
Type of articles	Published in Peer-reviewed journals (Document type: Articles, Source type: Journals)	Dissertation, Conference proceedings, or editorials

Language

English

Non-English

Data analysis

The analysis of the data revealed that 82 articles belong to 66 peer-reviewed journals (see Figure 2.4) and broadly define 12 topic areas (see Figure 2.5).



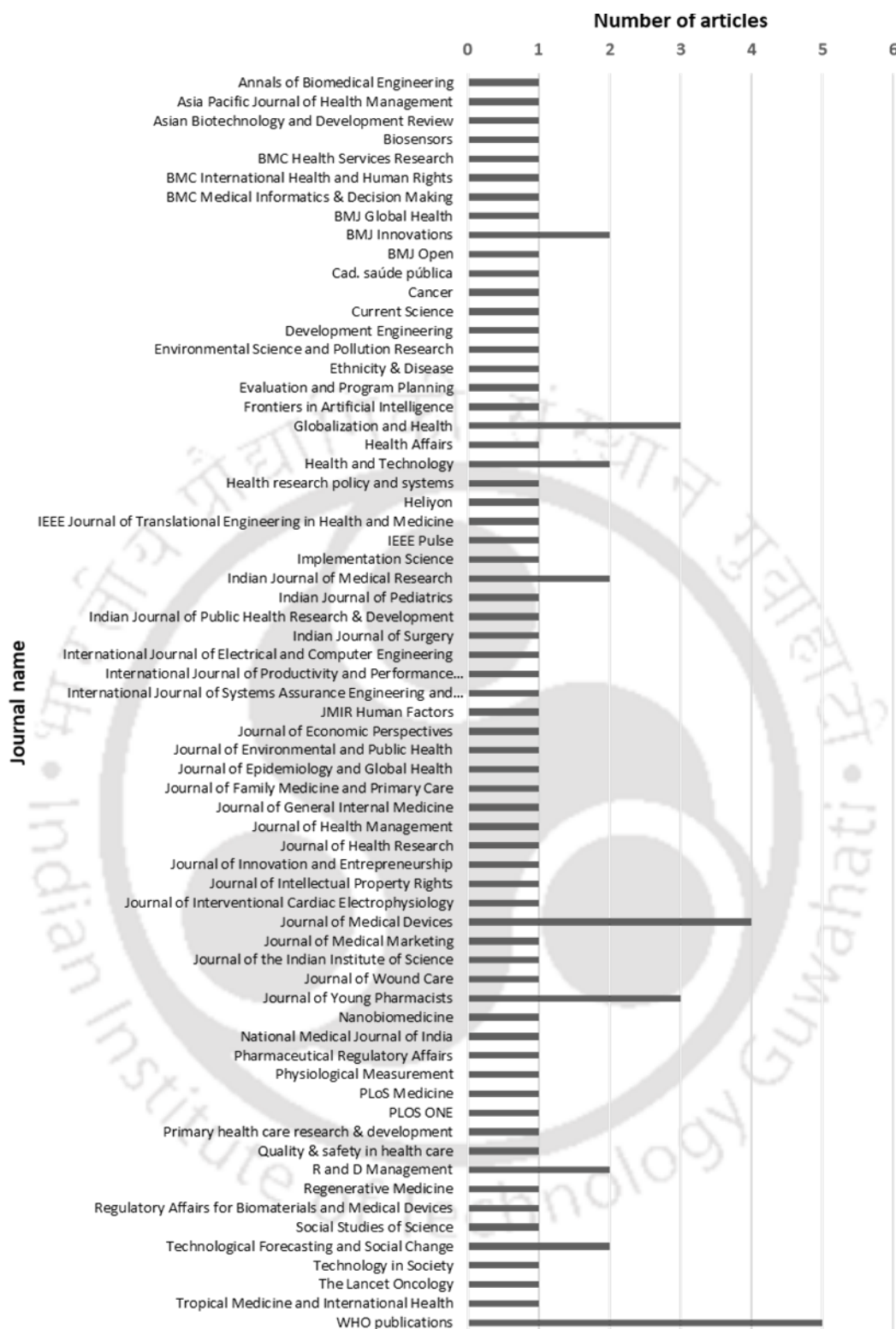


Figure 2-4: Journals and number of selected articles (author generated)

The identified topics were: 1) Clinical problems, healthcare management and challenges, 2) Case studies of innovation management, 3) Innovation acceptance, adoption and accessibility, 4) Innovation ecosystem, challenges and barriers, 5) Innovation implementation

and diffusion, 6) Innovation management strategy and activities, 7) IP Management, 8) LMIC related problems, challenges, 9) Regulatory, safety and quality management, 10) Socio-cultural and economic factors, 11) Specific technology or intervention and 12) Translational research and innovation.

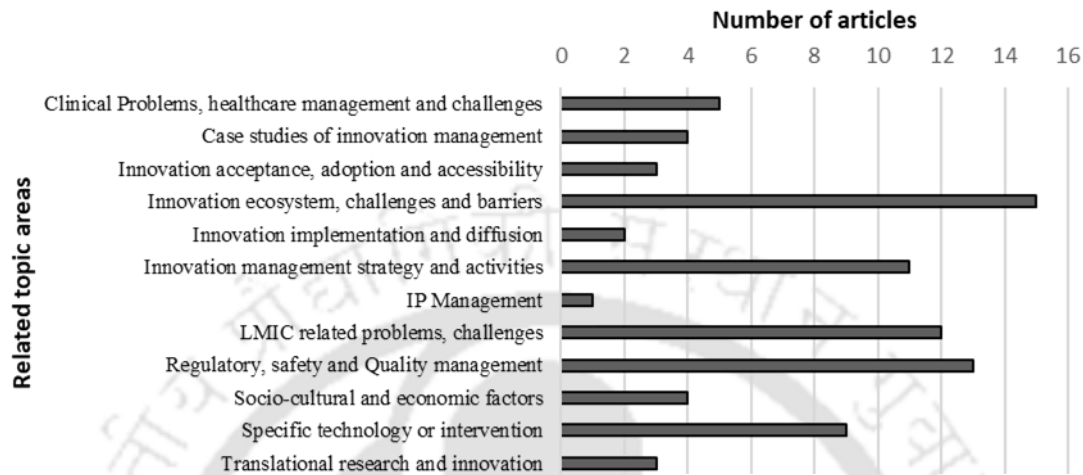


Figure 2-5: Subject area covered by the 82 articles (author generated)

Coding of constructs

The study employed thematic coding to identify challenges and barriers to medical technology innovation in Low and Middle-Income Countries (LMICs) based on a literature review (Gibbs, 2012). Multiple viewpoints were considered, including social innovation theory, stakeholder theory, resource-based view, and PESTEL framework to identify and define the key themes. The coding process comprised three phases: open coding, axial coding, and selective coding. Three qualitative research experts, having more than eight years of experience in thematic coding, followed an in-depth coding process involving the identification of LMIC-specific issues, highlighting important findings, and synthesizing themes to define them. This initial process is called open coding. After merging, rephrasing, and eliminating duplicate codes, a final list of open codes was compiled. Subsequently, the axial coding process categorized these open codes into distinct challenges and barriers specific to medical technology innovation. Finally, the selective coding process grouped the axial codes into key factors. The results have been presented in Table 2-E of the study. Figure 2.6 represents the thematic coding procedure.

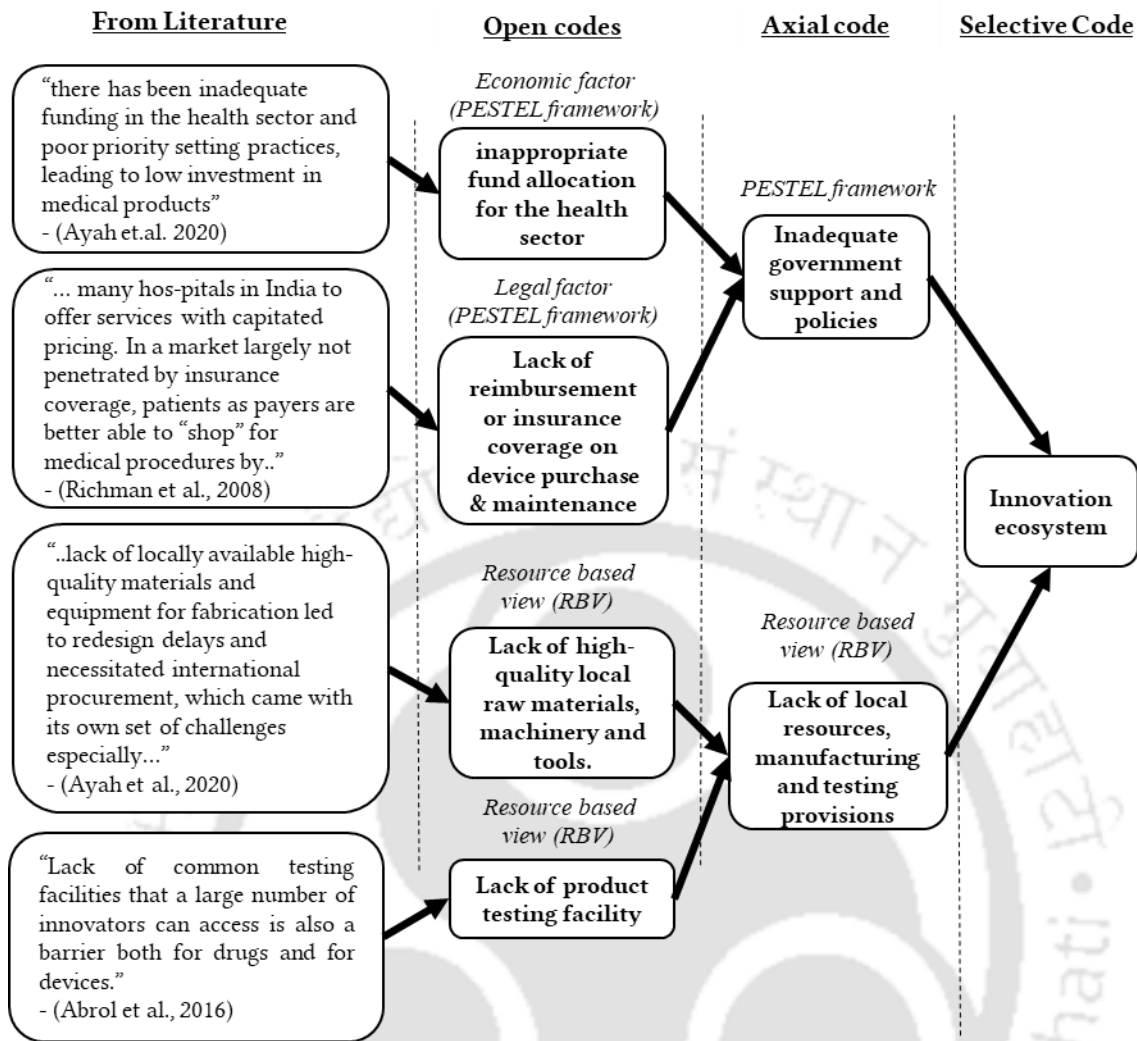


Figure 2-6: An illustration of the thematic coding process (author generated)

2.2.2 Semi-structured interview procedure (Phase 2)

In addition to generated codes, we found literature data showing the impact of identified challenges on various business aspects. However, we needed a comprehensive understanding, thus opted for semi-structured interviews with medical tech startups in phase 2. In the second phase, multiple exploratory case study analyses were conducted through semi-structured interviews to gain insights into the intricate process of medical technology innovation and the corresponding intra- and inter-organizational challenges. This approach allowed for the collection of rich data and provided the opportunity for theoretical generalization (Yin, 2013).

Sampling and recruitment

The initial phase of the research involved the selection of 15 Indian medical technology companies. These companies were primarily startups that had been operating commercially for a period ranging from 4 to 10 years and had a wide range of clinical and product profiles. The

selection process utilized purposive and expert sampling methods, considering the qualifications of key personnel, the performance of the firms, and their capabilities, all of which were assessed through comprehensive background research (Dolores & Tongco, 2007). The main objective of this selection was to investigate the variations in how these companies manage innovation and the challenges they face during their innovation journeys (Eisenhardt, 1989). To facilitate this investigation, a set of interview questions was developed (refer to Table 2-C), which underwent validation through face validation and three initial pilot interviews before being used for the actual interviews.

Table 2-C: Sample interview questions

Interview Questions
<ul style="list-style-type: none"> • May I know about your venture or product? • Where do you want to position/avail your product? • Tell me about the journey and various activities you have gone through from the very beginning till date. • How would you like to break down the journey into specific milestones or important objectives in the whole process? • How was your experience in achieving each of these milestones or objectives? You can share positives as well as any challenges or issues faced in achieving these milestones • Further follow-up questions based on answers by interviews

Data Collection and Analysis

Semi-structured interviews were conducted aimed at gaining a comprehensive understanding of the innovation journeys, various innovation management activities, and challenges faced by the firms. Each interview consisted of a predetermined set of questions outlined in Table 2-C, and additional follow-up questions were asked for deeper exploration. All interviews were recorded in audio and video format and transcribed. Data collections and analysis happened in parallel. Each successive interview was planned following the completion of the prior interview's data analysis. For parallel interview data analysis, three previously recruited qualitative research experts analyzed the transcripts after each interview to identify variations in information related to firm-level activities and associated challenges.

Data analysis of the interview transcripts happened in two ways. In the first stage, the interview transcripts were examined for information about firm-level activities for medical technology innovation management. In the second stage, a detailed review and analysis were carried out to identify reported issues and barriers to innovation management and how they impact firm level activities. For that important quotes from interview data were extracted. To consolidate the findings, a thematic coding process was again used to extract key themes from interview data (Gibbs, 2012). Tables were used to extract quotes and assign them relevant open codes. The Open coding process involved detailed reading of the interviewee's quotes to

comprehend the meaning and define the individual challenges and barriers. Similar to phase 1, multiple theoretical viewpoints were considered to identify open codes. Later all such open codes were further compared with the literature-based open codes to analyze how they corroborate or extend in scope.

To ensure diversity and depth in the data, new interviews were scheduled over a span of three months. The interview process ceased when theoretical saturation was reached, meaning that in terms of findings we were getting consistent and repeated themes (factors and challenges) and repeated information about how the various challenges impact firm level activities. In total, nine in-depth interviews were conducted with founders and co-founders of different firms between March 2022 and May 2022. At that time, we realized no new insights could enhance the reliability and variety of the data. All interviews were recorded in both audio and video formats and subsequently transcribed, resulting in a total of 7 hours and 19 minutes of audio files and 146 pages of transcription data. Considering this study's phenomenological approach, the final sample size of nine interviewees from seven organizations was deemed sufficient (Kvale, 1996). Table 2-D provides information about the seven biotech firms, details of the nine interviewees' work profiles, and other interview-related particulars. To maintain confidentiality, pseudonyms were used to disguise the real names of the selected firms.

Table 2-D: Details of the organizations and interviewees

Company Pseudonym	Product/company profile	Interviewees' work profile	Duration and transcript pages
MaternalCo, India	<ul style="list-style-type: none"> Innovated miniature cardiocography (Class II) devices. ISO 13485-certified company Sales products in India 	Founder	00:41:54 13 pages
FractureCo, India	<ul style="list-style-type: none"> Innovated breathable orthopedic immobilizers (Class I) for different human body parts. Product received regulatory approval. Sales of product in India and USA 	Founder & CEO	00:51:54 17 pages
BedsoreCo, India	<ul style="list-style-type: none"> Innovated an automatic patient repositioning mattress (Class II) for patients suffering from bed sores. Product has undergone clinical validation 	Founder & CEO	00:30:21 11 pages
PreeclampsiaCo, India	<ul style="list-style-type: none"> Innovated screening test kit (Class I) for detecting preeclampsia from a urine sample Product has undergone clinical validation 	Co-founder & director	00:57:03 23 pages
		Co-founder & director	00:57:30 17 pages
NeonatalCo, India	<ul style="list-style-type: none"> Innovated medical devices (Class II) for neonatal hearing screening ISO 13485-certified company Sales products in India 	Founder & CEO	01:07:02 18 pages
IncontinenceCo, India	<ul style="list-style-type: none"> Innovated medical devices (Class II) for faecal and urinal management. 	Co-Founder & CEO	00:30:33 11 pages

Company Pseudonym	Product/company profile	Interviewees' work profile	Duration and transcript pages
	<ul style="list-style-type: none"> Four approved FDA-approved devices to date Sales of products in India, Europe and USA 	Co-Founder & CTO	00:42:41 14 pages
BiocareCo, India	<ul style="list-style-type: none"> Have been involved in various innovation projects as a medical device R&D service provider Have wide expertise and understanding of biotech innovation and commercialization process 	Co-founder	00:59:54 22 pages

Further a combined analysis of Interview and Literature review data was carried out for deeper insights on how various firm level activities get influence from the identified challenges and factors.

2.2.3 Phase 3: Combined analysis of literature findings and interview data

In Phase 3, the authors and the three previously recruited coders combined the results from the literature review and semi-structured interviews to develop a consolidated list of challenges and barriers to biotech innovation for LMICs.



Figure 2-7: Thematic coding using the card sorting method (author generated)

Card sorting technique was utilized to merge and map codes generated from Phase 1 and Phase 2, as shown in Figure 2.7 (Conrad & Tucker, 2019). Moreover, the interview data

on innovation journeys was analyzed to examine the interconnectivity and dependence among various firm-level activities. Both the interview and literature review data were critically analyzed to map the influences of key factors and identify challenges and barriers on various firm-level innovation management activities. The established relationships and influences were further verified from the interviewees through phone calls. Based on the overall findings, a more comprehensive TIM was proposed to explain all aspects of medical technology innovation in LMICs.

2.3 Results

2.3.1 Identified Challenges and Barriers to medical technology innovation

The open coding process combinedly for the literature review and interview data, results in a comprehensive list of 96 distinct open codes. To illustrate, consider this excerpt from the literature review:

"In rural areas, discussing self-breast examination or undergoing mammography is hindered by cultural barriers. Additionally, the cost associated with mammography deters many rural women from getting screened, resulting in a growing cancer burden in these regions."

One of the open codes generated from the perspective of Social-innovation theory was '*cultural sensitivity*,' which pertains to sociocultural factors that impede the adoption of innovation. Similarly, another open code was derived from the viewpoint of both Social-innovation theory and the PESTEL framework, and it was labeled as '*cost-sensitive nature of the healthcare system*.' This code highlights how economic factors can act as external influences affecting the adoption of innovation.

Upon further examination and categorization of these open codes from the two data sources, a total of 23 key challenges and barriers (referred to as axial codes) related to medical technology innovation were identified. The thematic coding of the interview transcripts affirmed most challenges extracted in literature analysis process, while also uncovering a previously overlooked generic factor (related to both LMICs and HICs) and its associated challenge. In conclusion, based on the findings from literature and interview data analysis, the identified challenges (axial codes) were categorized under six distinct factors (selective codes), with five of these factors being specific to Low and Middle-Income Countries (LMICs).

Table 2-E provides an overview of these five LMIC-specific factors: Healthcare context

and system, Organizational capabilities, Innovation ecosystem, Demographic burdens and characteristics, Market Forces, along with the corresponding challenges and barriers associated with medical technology innovation, and the underlying open codes.

Table 2-E: LMIC-specific factors and issues of medical technology innovation

Selective codes (Key factors)	Axial codes (challenges and barriers)	Open codes	Source data (refer to section 4.3)
Healthcare context and system	Non-uniform healthcare system and practices	<ul style="list-style-type: none"> Non-uniform healthcare resources and facility Non-uniform healthcare skills and practice 	Literature review data
	Inadequate healthcare resources, staff, infrastructure, and services.	<ul style="list-style-type: none"> Limited healthcare workforce poor healthcare and technical expertise lack of necessary laboratory resources, equipment and consumables Poor infrastructure for healthcare, maintenance and repair 	Both the literature review and interview data
	Poor healthcare management of health institutions	<ul style="list-style-type: none"> Poor operational practices of health institutions Reluctance to adopt new technology 	Literature review data
	Inferior healthcare quality and practice	<ul style="list-style-type: none"> Poor healthcare service Poor healthcare coverage 	Literature review data
	Inefficient procurement and vendor payment processes of health institutions	<ul style="list-style-type: none"> Lack of accountability and inefficient vendor payment system Inefficient operation management activities of health institutions Slow and Complex procurement process and tender bidding system 	Both the literature review and interview data
Organizational capabilities	Limited risk capacity and innovation appetite.	<ul style="list-style-type: none"> Unpredictable innovation and commercialization roadblocks Innovation ecosystem sensitive to external shock and crisis situations. 	Interview data
		<ul style="list-style-type: none"> Low-risk appetite of innovation firms Tendency for lower-risk class innovation rather than clinical need 	Both the literature review and interview data
	Innovation misfit and misplacement	<ul style="list-style-type: none"> Poor need and social impact assessment Diverse contextual requirements beyond just clinical need Innovation misfit for local conditions and existing healthcare setup poor consideration of diverse stakeholders' requirements poor implementation of innovation innovation misfit to extreme and diverse environmental conditions 	Both the literature review and interview data
	Inadequate innovation strategy and execution	<ul style="list-style-type: none"> Poor technology feasibility analysis Poor financial management Poor human resource and organizational capability management 	Interview data
<ul style="list-style-type: none"> Poor R&D and manufacturing planning 		Both the	

Selective codes (Key factors)	Axial codes (challenges and barriers)	Open codes	Source data (refer to section 4.3)
		<ul style="list-style-type: none"> Poor quality management in manufacturing Poor planning for product marketing, distribution and after-sales service Poor knowledge and strategy for innovation diffusion Poor strategy for innovation scaleup Poor management of resources and funding Poor initial research for need assessment Poor design approach Lack of training and manual for new innovation Poor cost estimation of innovation Lack of balancing R&D and business activities of innovation Miscalculation of execution time and effort Poor team-building strategy 	literature review and interview data
	Poor stakeholder collaboration and synergy	<ul style="list-style-type: none"> poor community networking and support lack of drive and inter- and intra-organizational collaboration Poor synergy among the team and various stakeholders 	Both the literature review and interview data
	Poor Medical innovation knowledge and capability	<ul style="list-style-type: none"> Lack of knowledge in Biotech innovation management and commercialization poor understanding of the market and economy of innovation poor R&D and business development capability 	Both the literature review and interview data
	Lack of innovation culture	<ul style="list-style-type: none"> poor vision and motivation for innovation impact Lack of spirit, organizational culture for innovation 	Literature review data
Innovation ecosystem	Inadequate government support and policies	<ul style="list-style-type: none"> inappropriate fund allocation for the health sector poor attention, priority setting and policy-making of government Inadequate government initiatives to promote knowledge and information on innovation Lack of adverse reporting and post-market surveillance to prevent counterfeit and poor technologies lack of bureaucratic transparency about healthcare reforms Lack of reimbursement or insurance coverage on device purchase and maintenance No formalized medical technology assessment Lack of awareness programs and poor dissemination of innovation 	Both the literature review and interview data
	Lack of experts, educational schemes and infrastructure for technology translation.	<ul style="list-style-type: none"> Lack of medical device innovation talent for organizational hire 	Interview data
		<ul style="list-style-type: none"> Scarcity of professional experience in medical technology innovation Lack of Experts and experienced professionals in medical technology manufacturing Inadequate professional education in 	Both the literature review and interview data

Selective codes (Key factors)	Axial codes (challenges and barriers)	Open codes	Source data (refer to section 4.3)
		technology translation <ul style="list-style-type: none"> Inadequate institutional ecosystem and infrastructure for technology translation 	
	Inadequate and evolving regulatory and IP frameworks	<ul style="list-style-type: none"> Mismatch between clinical demand and regulations Inadequate, Evolving, less comprehensive regulatory framework Poor IP regulations Inadequate and Evolving national safety and quality standards regulatory body accustomed to licensing novel, creative solution Slow regulatory approval and patent grant process Lack of innovation testing protocols and guidelines No scope for harmonization with international regulations 	Interview data Both the literature review and interview data
	Inadequate funding and investment support for innovation	<ul style="list-style-type: none"> Limited monetary resources to support new technology innovation 	Both the literature review and interview data
	Lack of local resources, manufacturing and testing provisions	<ul style="list-style-type: none"> Lack of appropriate local manufacturing and assembly facilities Lack of high-quality local raw materials, machinery and tools. Lack of locally available parts and components Lack of product testing facility 	Both the literature review and interview data
Demographic burdens and characteristics	Disease diversity, unequal healthcare coverage.	<ul style="list-style-type: none"> Poor healthcare coverage due to large sized population Variation in disease profile and economic burden across geography 	Both the literature review and interview data
	Varied socioeconomics and cost sensitivity	<ul style="list-style-type: none"> Low financial strength of small and mid-sized enterprises Cost-sensitive nature of the healthcare system Diverse socio-economic status 	Both the literature review and interview data
	Socio-Cultural diversity and barriers	<ul style="list-style-type: none"> poor socioeconomic status cultural sensitivity Caste and Gender-related racism Non-scientific healthcare beliefs and practices illiteracy and poor healthcare knowledge and awareness Socio-demographic diversity and linguistic barriers Socio-economic and cultural diversity 	Literature review data
	Widespread prevalence of ill practices	<ul style="list-style-type: none"> Multi-layered stakeholder and commission involvement in product sales Risk of fraud in contract manufacturing Existence of Counterfeit products Corruption within the healthcare system Bad politics in innovation adoption Poor product security 	Interview data Both the literature review and interview data

Selective codes (Key factors)	Axial codes (challenges and barriers)	Open codes	Source data (refer to section 4.3)
Market Forces	Competitive and fragmented market	<ul style="list-style-type: none"> • Non-uniform market forces 	Interview data
		<ul style="list-style-type: none"> • High market competition and fragmented smaller market create hurdles for new innovation • Brand loyalty and favoritism • Large Cap manufacturers dominate market access and technology licensing • Poor incentive and profit margins with new innovation 	Both the literature review and interview data
	Market entry barriers for new innovation	<ul style="list-style-type: none"> • Novel devices bring additional effort to institutional adoption 	Literature review data

Additionally, the thematic coding process revealed a generic factor: *Science and technology*, that also influence medical technology innovation management. A comprehensive summary of these challenges and barriers, is presented in the discussion section the study. More details about thematic coding of literature review and interview data are available at Appendices A.4 and A.5. Table 2-F, highlighted a summary of how various theoretical lenses were used in the thematic coding process.

Table 2-F: Associated theories corresponding to identified themes

Selective codes (Key factors)	Axial codes (challenges and barriers)	Associated theories
Healthcare context and system	Non-uniform healthcare system and practices	Resource based view (RBV)
	Inadequate healthcare resources, staff, infrastructure, and services.	Resource based view (RBV)
	Poor healthcare management of health institutions	Resource based view (RBV)
	Inferior healthcare quality and practice	Resource based view (RBV)
	Inefficient procurement and vendor payment processes of health institutions	PESTEL framework
Organizational capabilities	Limited risk capacity and innovation appetite.	PESTEL framework
	Innovation misfit and misplacement	Social innovation theory
	Inadequate innovation strategy and execution	PESTEL framework
	Poor stakeholder collaboration and synergy	Stakeholder theory
	Poor Medical innovation knowledge and capability	PESTEL framework
Innovation ecosystem	Lack of innovation culture	PESTEL framework
	Inadequate government support and policies	PESTEL framework
	Lack of experts, educational schemes and infrastructure for technology translation.	Resource based view (RBV)
	Inadequate and evolving regulatory and IP frameworks	PESTEL framework
	Inadequate funding and investment support for innovation	Resource based view (RBV)
Demographic burdens and characteristics	Lack of local resources, manufacturing and testing provisions	Resource based view (RBV)
	Disease diversity, unequal healthcare coverage.	Social innovation theory
	Varied socioeconomics and cost sensitivity	Social innovation theory
	Socio-Cultural diversity and barriers	Social innovation theory
Market Forces	Widespread prevalence of ill practices	PESTEL framework
	Competitive and fragmented market	PESTEL framework
	Market entry barriers for new innovation	PESTEL framework

Figure 2.8, displayed below, illustrates the distribution of open codes in relation to their data sources. It illustrated that most of the open codes obtained from the interview data and literature review data corroborated. Specifically, 73 out of 98 open codes were derived from both the literature review and interview data. Among the remaining 25 open codes, 16 exclusively relied on the literature review, while 9 were solely derived from the interviews.

Open code frequency

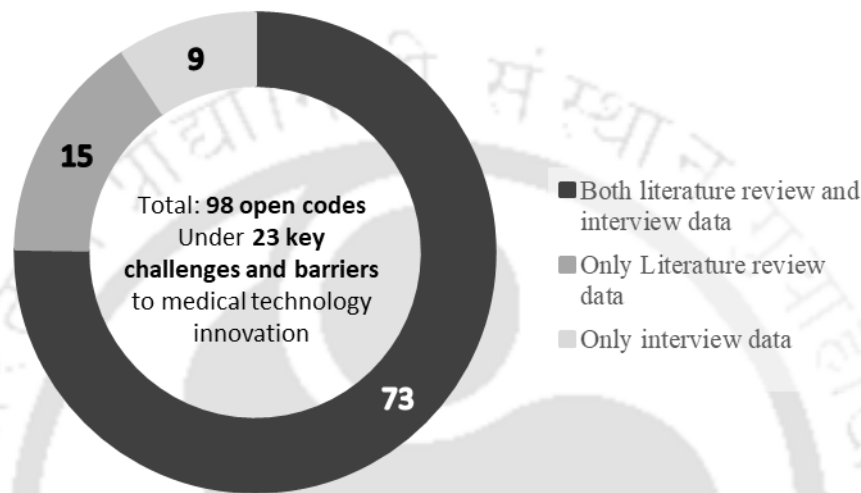


Figure 2-8: Frequency distribution of consolidated open codes with respect to source of data (author generated)

At the end of the thematic coding process, we identified 5 key factors (excluding the generic factor) specific to LMICs and 22 underlying challenges and barriers (excluding the generic challenges) to medical technology innovation. Apart from the codes generated, we also identified to some extent literature data on how the challenges we identified affect different activities of companies, like how they manage intellectual property, make products, and deal with regulations. But we also realized we need a clearer picture of all the key steps involved in developing medical technology and how these challenges affect each such major step. For that the interview data collected in phase 2 of the study helped us. Here are details about further findings from the interview data

2.3.2 Identified firm-level activities of medical technology innovation management

The analysis of interview data yielded significant insights. Firstly, it delineated the core firm-level activities, their interconnection, and sequencing. A range of firm-level innovation management activities was identified by carefully analyzing the interview data. Key variations in activities among firms were found to be related to their R&D requirements, regulatory requirements (such as Class I, II, III), and the type of clinical intervention they focused on, i.e.,

diagnostic, preventive, or treatment-related. It was observed through data analysis that these various organizational activities could be categorized into two main categories: R&D and project management activities, and business management activities. Detailed information about the different types of firm-level innovation management activities, including example sub-activities, is provided in Table 2-G.

Table 2-G: Key firm level activities

Key Firm Level activities	
<i>R&D and project management activities</i>	<i>Business management activities</i>
• Initial need and business scoping	• Mission and business strategy planning
• Technology research and development	• Operation and performance management
• Innovation scoping and Intellectual property (IP) management	• Finance and account management
• Clinical efficacy and product safety validation	• Human resource and technical capability management
• Regulatory approval-related activities	• Store and purchase management
• Innovation Scale-up and production	
• Commercial Implementation and Product diffusion	

Additionally, the interview data elucidated the inter-dependencies and influences among the organizational activities, as demonstrated in Figure 2.9. Additionally, critical analysis of the literature review data also enables us to understand the order and relationship between various innovation management activities. For example, a quote from one of the interviewees:

“Changes could happen when you are moving from one scale of manufacturing to another scale. So, you are moving from let’s say making 10, 15 devices to making 1000 or 10000 devices... that’s when changes happen to the product because your whole manufacturing process is going to change, the assembly process is going to change...”

illustrated the iterative path between the activities of the innovation Scale-up and production stage and the technology research and development stage. All such, findings were also re-verified from the interviewees.

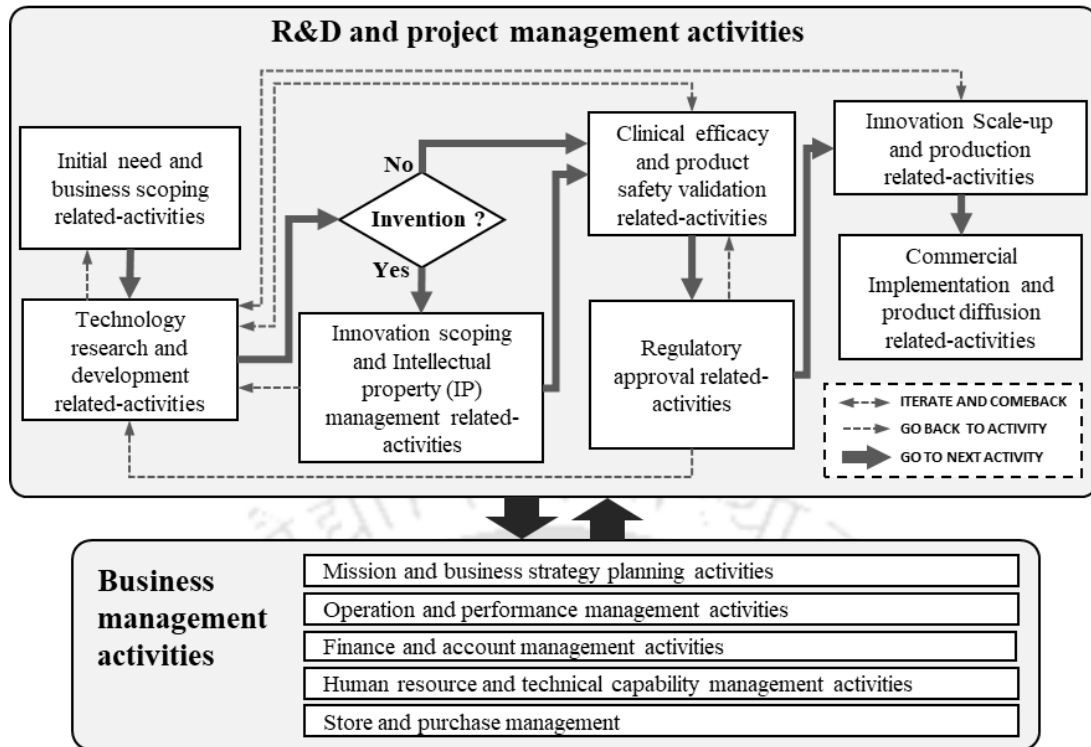


Figure 2-9: Inter-dependencies among firm-level activities of medical technology innovation (author generated)

Lastly, the interview data elucidated the interconnectedness between the identified challenges and barriers and the firm-level activities they impact. Moreover, the interview findings provided clarity on certain aspects of the literature data concerning how different challenges and barriers influence firm-level activities. Previously, during the literature review, this clarity was absent due to a limited understanding of key firm-level activities or the sequencing and relationships of medical technology innovation milestones. So further we did a combined analysis of literature and interview findings to establish these details.

2.3.3 How the identified factors influence firm-level medical technology innovation activities?

One of the key objectives of the study was to map the influence of factors, challenges and barriers of medical technology innovation with associated activities. Previously, the extraction of key factors, challenges, and barriers was conducted based on multiple theoretical perspectives, such as the resource-based view (e.g., challenges in innovation adaptation due to non-uniform healthcare systems and practices), social innovation theory (e.g., misfit and misplacement of innovation), stakeholder theory (e.g., poor collaboration and synergy among stakeholders), and other external factors including political, economic, social, technological, environmental, and legal aspects (e.g., challenges in innovation implementation due to inadequate and evolving regulatory frameworks).

If we carefully observe, most of the identified challenges in this study can be categorized into specific levels of analysis, such as barriers to innovation adaptation, barriers to innovation use, and barriers to implementation. Many past studies have already reported on such types of analysis. However, the key research gap identified was the lack of granularity in understanding how innovators or MedTech entrepreneurs at the firm level encounter these challenges in their innovation management activities. Therefore, in this study, we conducted our analysis on how specific firm-level activities like 'Initial need and business scoping', 'Clinical efficacy and product safety validation', etc. are affected by the identified challenges and barriers.

Most of the companies selected for the interview process have their products in the market. During the interviews, participants discussed their journeys, elucidating ideal processes, wrong decisions, issues faced, how they overcame those, and also provided suggestions. Follow-up questions were asked, apart from the key structured questions, to delve deeper into such topic areas. All such inputs from the interviews are later considered (themes, quotes) for critical analysis to derive the influence of factors on firm-level activities and how a firm's strategic planning activities are linked with R&D and project management activities. The study used quotes from interviewees and findings from literature reviews to understand how the specific challenges and barriers in LMICs influence innovation management at the firm level. For example, based on an interviewee's response:

"Finding a contract manufacturer in India is still a challenge. Of course, you always, if you have the money and the means you can always go out and work with companies that are in the west or even in south-east Asia." and

"A challenge in the design or the implementation part was basically sourcing components because most of the things that we are actually looking at are not readily available in India and we have to figure it out from different countries outside like China and sourcing it from there."

it was interpreted that the lack of local raw materials, components, and manufacturing and testing facilities impacts technology development and innovation scale-up and production-related activities. Similarly, an extracted note from the literature review data:

"Intellectual property protection is a concern in many low-income countries that may not have well-established patent regulations or enforcement capabilities"

revealed that inadequate, and evolving regulatory and IP frameworks impact innovation

scoping and intellectual property (IP) management activities. Table 2-H below outlines the process of analyzing interview quotes to identify key factors and challenges, and their potential impact on firm-level innovation management activities.

Table 2-H: Analysis of interview quotes to identify impact on firm level activities

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p>IncontinenceCo, India: <i>“Not too many people especially in a country like India seek treatment for those kinds of conditions nor a lot of treatments are provided in such areas. So, chose US and European market as our main customer base and decided to go ahead with US FDA and related safety standard. And we realized that at a very early stage of initial need identification which shaped our business today”</i></p>	<p>Healthcare Context and Ecosystem</p> <ul style="list-style-type: none"> • Inadequate healthcare workforce, resources, infrastructure and poor services. • Poor quality of care and healthcare practice 	<ul style="list-style-type: none"> • Initial need and business scoping • Clinical efficacy and product safety validation • Regulatory approval • Commercial Implementation and product diffusion • Mission and business strategy planning
<p>IncontinenceCo, India: <i>“The challenge would be access to a clinical environment that’s where most of the innovators really face the real challenge of how to identify a need. As an organization you need to strategically establish some collaboration with hospitals or health institutes, government is better. Because a clinician onboard can assist you in development as well as in clinical validation and further commercialization of your product”</i></p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> • Poor strategy-making and ineffective execution of various activities of innovation • Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> • Initial need and business scoping • Technology research and development • Clinical efficacy and product safety validation • Regulatory approval • Commercial Implementation and product diffusion related-activities • Mission and business strategy planning activities
<p>IncontinenceCo, India: <i>“Prototyping short batch manufacturing especially if you doing a class 2 or class 3 device which has to be done in a certain environment, has to be sterilized, and has to be made in a certain kind of material is still a challenge.”</i> <i>“Finding a contract manufacturer in India is still a challenge. Of course, you always, if you have the money and the means you can always go out and work with companies that are in the west or even in south-east Asia. But there are other issues like language barrier, chances of getting your idea theft, which can impact your business”</i></p>	<p>Innovation ecosystem</p> <ul style="list-style-type: none"> • Lack of local raw materials, components, and manufacturing and testing facilities • Lack of experts, educational schemes and infrastructure for technology translation. <p>Demographic Attitudes and Characteristics</p> <ul style="list-style-type: none"> • Widespread prevalence of ill practices 	<ul style="list-style-type: none"> • Technology research and development • Innovation Scale-up and production • Commercial Implementation and product diffusion • Mission and business strategy planning activities • Innovation Scale-up and production • Commercial Implementation and product diffusion • Mission and business strategy planning activities

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p>IncontinenceCo, India: “Sometimes you have to change the product to meet regulatory requirements, let’s say FDA does not or the Indian regulatory agency do not have anything just to take example...US have different regulations for using PVC as a material in your product, India has different regulations and Europe has different regulations, so you may be able to sell your product with PVC tubing and PVC component in your product in India, but you may not be able to change in the US or in Europe. And That’s when you need to make a product change for successful commercial implementation in one or two locations.”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate and evolving regulatory and IP frameworks 	<ul style="list-style-type: none"> Clinical efficacy and product safety validation Regulatory approval Commercial Implementation and product diffusion Mission and business strategy planning activities
<p>IncontinenceCo, India: “if you are not in a clinical setting just getting a clinical trial going is not really straightforward and it takes a lot of pain to get clinical trials going on. There exist negligence of healthcare provider and lack of skilled healthcare workforce”</p>	<p>Healthcare Context and Ecosystem</p> <ul style="list-style-type: none"> Inadequate healthcare workforce, resources, infrastructure and poor services. Poor healthcare management of health institutions 	<ul style="list-style-type: none"> Clinical efficacy and product safety validation
<p>IncontinenceCo, India: “It is still not a notified device in India. ..So we took a slightly more proven pathway.. even back then when .. the regulatory framework is not available in India, we still went ahead and got FDA approval first before selling our first product anywhere, whether its US or in India. As a business strategy, we got our FDA approval first and we got CE approval also, we were very thorough with our regulatory strategy ”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate and evolving regulatory and IP frameworks 	<ul style="list-style-type: none"> Regulatory approval Commercial Implementation and product diffusion Mission and business strategy planning
<p>IncontinenceCo, India: “Yes, you can sell technically because there was no framework available in India, we could have sold but would doctors accept it, is going to be a challenge ultimately making commercial implementation difficult. That question is going to come whether you have FDA, CE? so thought let’s be on the safe side. Otherwise there is lot of competition in our country, specially from big players like GE healthcare, Siemens etc. and there is lot of entry barriers for company like us who can’t provide service and incentives like them. So you need to strategize well in advance since early need finding and what technology you will be developing”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate and evolving regulatory and IP frameworks <p>Market Forces</p> <ul style="list-style-type: none"> Competitive and fragmented market Market entry barriers for new innovation 	<ul style="list-style-type: none"> Regulatory approval Commercial Implementation and product diffusion Regulatory approval Commercial Implementation and product diffusion Mission and business strategy planning Initial need and business scoping Technology research and development
<p>IncontinenceCo, India: “There is not a lot of talents, medical device talents in India. So, we have to hire lot of people fresh from straight out of college and they know nothing about medical devices and we have to train them, because finding trained talent is almost next to impossible. Otherwise, it will impact your product R&D activities”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> Technology research and development

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p>IncontinenceCo, India: “There is no reimbursement strategy in India. So, people have to spent from their own pocket to get such therapeutic service. Again, not many have insurance coverage. So, all these will fire you back.i.e. you as a company only need to make devices at low cost.. otherwise, your services will not be asked by patients. So, a novel innovation having high cost of development is always a failure in our country. Even companies don’t have that risk capacity so often go with generic and class 1 devices and innovations ”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate governance, policy-making and support 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion Mission and business strategy planning
	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Low risk capacity and appetite of innovation drivers 	<ul style="list-style-type: none"> Technology research and development Mission and business strategy planning
	<p>Demographic Attitudes and Characteristics</p> <ul style="list-style-type: none"> Cost sensitivity and diverse socio-economic status 	<ul style="list-style-type: none"> Technology research and development Commercial Implementation and product diffusion Mission and business strategy planning
<p>BedsoreCo, India: “but the fact is repositioning the patient, on a timely basis, for every 2-hour duration, which is recommended, is kind of impossible in a country like country like ours or in a very resource constraint setting. So we designed our product to address that, which automatically reposition the patient based on set time.”</p>	<p>Healthcare Context and Ecosystem</p> <ul style="list-style-type: none"> Inadequate healthcare workforce, resources, infrastructure and poor services 	<ul style="list-style-type: none"> Technology research and development
<p>BedsoreCo, India: “one challenge would be, like, how would you bring out a solution which can actually solve the problems of different stakeholders? Because once you solve the problem of bit shows, it's not just solving the problem of one stakeholder, there are multiple stakeholders involved. So as a organization we initially failed to collaborate and identify need of both clinician and hospital’s store and purchase section. We should have consulted both from beginning ”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor strategy-making and ineffective execution of various activities of innovation management Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> Technology research and development
<p>BedsoreCo, India: “A challenge in the design or the implementation part was basically sourcing components because most of the things that we are actually looking at are not readily available in India and we have to figure it out from different countries outside like China and sourcing it from there.”</p>	<p>Innovation ecosystem</p> <ul style="list-style-type: none"> Lack of local raw materials, components, and manufacturing and testing facilities 	<ul style="list-style-type: none"> Technology research and development Innovation Scale-up and production
<p>BedsoreCo, India: “other challenge is the hiring process, which, if I would say or the team building process because you don't have the bandwidth of hiring experienced people in such a grant, funded situation. There is lack of funding sources and every year many startups apply for those available. And chances of getting a grant and investment is really low as competition is high”</p>	<p>Innovation ecosystem</p> <ul style="list-style-type: none"> Lack of adequate funding and investment sources to support innovation 	<ul style="list-style-type: none"> Technology research and development Innovation Scale-up and production
<p>BedsoreCo, India: “so, getting validation requires some sort of a relationship established with the hospitals or the clinics or the user stakeholder groups. So, building that</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> Technology research and development

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<i>relationship for a validation process is something kind of challenging and is strategic from the beginning”.</i>		<ul style="list-style-type: none"> • Clinical efficacy and product safety validation
BedsoreCo, India: “ <i>Second thing is we were actually focused more or less on the product development as engineers and we did not give that much time to understand what is the next steps in terms of clinical trials and regulatory. So, we faced difficulty in balancing our business development activities due to lack of dedicated person to look after those. So, business strategy development in parallel is really important, what I realized.</i> ”	Organizational Capabilities <ul style="list-style-type: none"> • Poor strategy-making and ineffective execution of various activities of innovation management 	<ul style="list-style-type: none"> • Mission and business strategy planning
BedsoreCo, India: “ <i>A thing is, uh, the people in your team have to actually align with your vision, so people come from different backgrounds and they sticking to one culture is kind of difficult. So, I faced those challenges as well. I won't say it's negative. But it's just that it takes time for the team to understand what actually we are working on and what could be the impact and for them to align with the vision of what the company actually wants to build. So that takes a real amount of time.</i> ”	Organizational Capabilities <ul style="list-style-type: none"> • Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> • Technology research and development
MaternalCo, India: “ <i>We were trying to use ultrasound technology, which in itself was a big challenge in terms of procurement from local Indian manufacturers. Uh, we did approach one of the defence labs based out of Delhi, and we got some samples, but the quality was inadequate. So, for final product development we had to look outside India for the components.</i> ”	Innovation ecosystem <ul style="list-style-type: none"> • Lack of local raw materials, components, and manufacturing and testing facilities 	<ul style="list-style-type: none"> • Technology research and development • Innovation Scale-up and production
MaternalCo, India: “ <i>We spent almost about three years whole and sole just building product, titrating, validating in a clinical setting. It took us almost 7 years to reach clinical trial. We were almost financially drained till that time. Due to covid-19, again we could not receive external investments. Medical device commercialization that is of higher safety classes are not easy for everyone due to inherent complexities and long developmental timeline. We did not realize these when we started.</i> ”	Science and Technology <ul style="list-style-type: none"> • Complexities inherent to clinical problems, biology and solutions • Longer development and commercialization timeline 	<ul style="list-style-type: none"> • Mission and business strategy planning activities
MaternalCo, India: “ <i>we had issues early on with sensor design; then we fixed that. ... we had challenges in terms of how the displays design, how is it accessed? We had issues with wireless communication. We did not have right team to understand and solve the issue. So, our R&D took quite long time. We also looked at IITs, tried to collaborate but..had a poor experience, they also did not have that sort of expertise. Finding talent in India is a challenge”</i>	Organizational Capabilities <ul style="list-style-type: none"> • Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> • Technology research and development
	Innovation Ecosystem <ul style="list-style-type: none"> • Lack of experts, educational schemes and infrastructure for technology translation 	<ul style="list-style-type: none"> • Technology research and development

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p>MaternalCo, India: “So building a product that's just. One aspect to an entrepreneur 's journey. Building a successful company means that one has to decouple himself or herself from. Success is dependent on one product alone. It you know irrespective of that product being successful or not, the company needs to be successful.”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor strategy-making and ineffective execution of various activities of innovation management 	<ul style="list-style-type: none"> Mission and business strategy planning
<p>MaternalCo, India: “I didn't know at the beginning when I started out, and I've almost everyone knows it, for the most part, is unlike most of the products, medical device space is a very. Uh, time-consuming space. It needs an immense amount of. Effort and dedication to stick it out for. At least you know 4 to 6 years to see any outcome in the first place.”</p>	<p>Science and Technology</p> <ul style="list-style-type: none"> Complexities inherent to clinical problems, biology and solutions Longer development and commercialization timeline 	<ul style="list-style-type: none"> Mission and business strategy planning activities
<p>MaternalCo, India: “the Indian system we recently we updated the CDSCO guidance document in 2017-2018, so that's fairly new in the grand scheme of things. Before that we didn't really have. That so we I would say we as an industry are just familiarizing ourselves with those standards and with the new configuration, at least from a regulatory standpoint, for medical devices it is all. It is even more important for startups. Simply because there is no established protocol across the industry. Uh, simply because. As a department itself, they have established protocols for known products, but for new products I would say the department itself is still learning”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate and evolving regulatory and IP frameworks 	<ul style="list-style-type: none"> Regulatory approval Commercial Implementation and product diffusion
<p>MaternalCo, India: “More often than not, we end up being very poor estimators of project execution timelines, especially in health care, given that there's so many players that we need to deal with before it even reaches the market, and then some more after it starts selling. This impacted our initial roadmap and timeline to reach market”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor strategy-making and ineffective execution of various activities of innovation management Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion
<p>PreeclampsiaCo, India: “the engineers in my team site every little thing is a problem. But that's how it is like the ground reality is government hospital. So initially we collected a junk of problems and needs which are not problems in reality.”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> Initial need and business scoping
<p>PreeclampsiaCo, India “designers get very carried away, you know. No, no, they get very carried away with their own design. Sort of. You start designing like form factors, ergonomics, all of that stuff. And when some of these processes takes like months. What as a CEO my concern was how to reach market early and come with something like a minimal viable product. Well</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Poor strategy-making and ineffective execution of various activities of innovation management 	<ul style="list-style-type: none"> Technology research and development Commercial Implementation and product diffusion Mission and business strategy planning

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<i>we can always add new features in version 2 of the product”</i>		
PreeclampsiaCo, India <i>“we had a road map and everything, but you have to be prepared for sort of. Seeing what the commercial road blocks are going to be and you have to adapt and start solving them, 'cause those will not come in a linear manner to you. There's only sporadic they're going to be very sort of unique to each case that you deal with. So yeah, you you can plan for some of these implementations. But it's not gonna be a straight path for any of these commercial success”</i>	Organizational Capabilities <ul style="list-style-type: none"> Poor strategy-making and ineffective execution of various activities of innovation management Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> Mission and business strategy planning activities
PreeclampsiaCo, India <i>“in India because of the way sort of purchasing is structured, reluctance of hospitals to get involved or take on the financial risk early on. You have like multiple layers in between like distributors, sort of purchasing agents, all sorts of things. The difference is how do you price it and how do you make it attractive for the end user is very different in India versus the global markets”</i>	Demographic Attitudes and Characteristics <ul style="list-style-type: none"> Cost sensitivity and diverse socio-economic status 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion
	Healthcare Context and Ecosystem <ul style="list-style-type: none"> Inefficient procurement and vendor payment processes of health institutions 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion
NeonatalCo, India: <i>“These babies are not screened on time just because. There are not particular equipments or suitable equipments which can be used in resource constrained setting. However, in Tertiary care hospitals there are provision to detect this early. So we identified this problem during our clinical immersion and chose to work on it”</i>	Healthcare Context and Ecosystem <ul style="list-style-type: none"> Non-uniform healthcare system and practices Inadequate healthcare workforce, resources, infrastructure and poor services. 	<ul style="list-style-type: none"> Initial need and business scoping
NeonatalCo, India: <i>“so the many times what happens is that engineers designers, these people were making the products, but they're not very well aware of market reality. They do not have access to the clinical scenario, only based on secondary information from internet they make products. So their product at the end does not meet the requirements of clinicians. So hospital collaboration is necessary and a teamwork is must having clinician onboard.”</i>	Organizational Capabilities <ul style="list-style-type: none"> Lack of collaboration and stakeholder synergy Poor knowledge and capability for Biotech innovation 	<ul style="list-style-type: none"> Initial need and business scoping
NeonatalCo, India: <i>“Making a device here in India in itself is a is a is a very challenging job like. I don't know how many people would understand that and how many companies are there who are making these devices here in India. You will find many of these vendors who will be making one component or something which like a ball or a syringe a very very basic. So, due to underdeveloped ecosystem, lack of manufacturing facility small firms are incapable of developing something great or complex like ultrasound devices .”</i>	Innovation Ecosystem <ul style="list-style-type: none"> Lack of experts, educational schemes and infrastructure for technology translation Lack of local raw materials, components, and manufacturing and testing facilities 	<ul style="list-style-type: none"> Technology research and development

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p>NeonatalCo, India: “<i>physicians obviously would go for something which is like coming from the US or US FDA. Approved or see approved. OK, if you say that I am not notified and I don't require any kind of certification, they might not get convinced. They they might actually say that, uh? They might just say that Oh no, no we want to. We have a preference for FDA or CE approved product</i>”</p>	<p>Innovation Ecosystem</p> <ul style="list-style-type: none"> Inadequate and evolving regulatory and IP frameworks 	<ul style="list-style-type: none"> Regulatory approval Commercial Implementation and product diffusion
<p>NeonatalCo, India: “<i>our system is not designed for. For medical device innovation. You know who has the patience to really come? Do this for 10 years and then only get the outcome. You're getting my point, right? Like how? How many? How many parents, how many? Uhm, people would agree to you that, OK, I'm going to take the next 15 years or 10 years to really make something and then sell it in the market and then really make it big</i>”</p>	<p>Science and Technology</p> <ul style="list-style-type: none"> Complexities inherent to clinical problems, biology and solutions Longer development and commercialization timeline 	<ul style="list-style-type: none"> Mission and business strategy planning activities
	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Low risk capacity and appetite of innovation drivers 	<ul style="list-style-type: none"> Mission and business strategy planning activities
<p>FractureCo, India: “<i>like making silicone parts is not so easy, particularly in India like even getting the raw material is a difficult job. So somehow we got those few samples from the different companies and we try to make a smaller version of the prototype where we tested the cons.</i>”</p>	<p>Innovation ecosystem</p> <p>Lack of local raw materials, components, and manufacturing and testing facilities</p>	<ul style="list-style-type: none"> Technology research and development Innovation Scale-up and production
<p>FractureCo, India: “<i>When you are already into the research and development phase and you don't get enough fund to. To give the salary to the people to give the money to or like a payments to your customer like vendors. Then your whole process will be delayed and it will lose the excitement in the team and people will not able to execute in time. This way your patent protection, clinical trial, production etc. all activities will suffer</i>”</p>	<p>Innovation ecosystem</p> <ul style="list-style-type: none"> Lack of adequate funding and investment sources to support innovation 	<ul style="list-style-type: none"> Technology research and development Innovation scoping and Intellectual property (IP) management Clinical efficacy and product safety validation Regulatory approval Innovation Scale-up and production
<p>FractureCo, India: “<i>The reason alignment is very much important. So rather than focusing on just a skill set that you need, you also need to focus on the reason, because chances are very high that like everything will go North and South. And does not follow your plan in such situation. Like short term expectation will not retain the employee or the founder or the co-founder or the team member. But if you have a common vision which is having alignment, it will take you a few extra miles</i>”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> Mission and business strategy planning activities
<p>FractureCo, India: “<i>We have a different kind of the insurance here. which is giving very very low reimbursement to the hospitals and doctors. And</i></p>	<p>Innovation Ecosystem</p>	<ul style="list-style-type: none"> Commercial Implementation and product diffusion

Interviewed organization and Quotes	Identified key influencing factors and challenges	Analysed potentially impacted firm-level activities
<p><i>another is the private sector where there are two different kind of the insurance when he is the insurance that covers the daycare. Daycare means, like all the OPD, OPD and the single day trip. And another insurance which is more common in EU India is? For just accidental insurance, which is like any accident or admission which is required, then that insurance will be reimbursed and they have a cap limit starting from 2 Lac rupees to 10 Lac rupees. OK, so they do not cover any kind of prescription, prescriptive devices etc. so for innovators like us we need consider if patient is going to pay the bills if our service charge is high. Currently 70% in India is out of pocket expenditure”</i></p>	<ul style="list-style-type: none"> Inadequate governance, policy-making and support <p>Demographic Attitudes and Characteristics</p> <ul style="list-style-type: none"> Cost sensitivity and diverse socio-economic status 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion
<p>FractureCo, India: “So in India, even if you make 10 times better product, if you don't compete in terms of the price, chances are. Well, yes, or it's more difficult to establish. In the market. Nobody wants to pay more in India. That is kind of a golden rule”</p>	<p>Demographic Attitudes and Characteristics</p> <ul style="list-style-type: none"> Cost sensitivity and diverse socio-economic status 	<ul style="list-style-type: none"> Commercial Implementation and product diffusion
<p>FractureCo, India: “when you are designing or developing some innovative product which is having some IP involved, you can outsource the maximum process which is non-proprietary and you keep the. All the proprietary items in your in-house manufacturing. This way you can protect your IP which is otherwise challenging in contract manufacturing.”</p>	<p>Demographic Attitudes and Characteristics</p> <ul style="list-style-type: none"> Widespread prevalence of ill practices 	<ul style="list-style-type: none"> Innovation Scale-up and production Commercial Implementation and product diffusion
<p>BiocareCo, India: “We tried to collaborate with someone in. Ideally with no names here. Yeah, but it didn't go through as expected. Maybe tried, uh. A lot. To contact some facilities across the country. But I think, uh, more support in that direction would have helped us to collaborate faster and do our experiment first. It's not easy according to be interesting. One, if you keep writing mail, they. Have their own agendas.”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> Technology research and development
<p>BiocareCo, India: “Difficult to find a collaborator itself in my second project, although. I had a collaborator. Uh, the PhD students that were working on this project had their own timelines. And that that delays the whole prototyping. So, if you can find something which is which can be done by you in your lap in your home.”</p>	<p>Organizational Capabilities</p> <ul style="list-style-type: none"> Lack of collaboration and stakeholder synergy 	<ul style="list-style-type: none"> Technology research and development

Likewise in Table 2-H, several such relationships were identified and mapped from the two-source data (see Figure 2.10 - 2.17). Below are key findings on how the LMIC-specific factors influence the firm-level innovation activities:

Influence on R&D and project management activities

Activities related to the ‘initial need and business scoping’ stage encompass stakeholder inquiries, detailed understanding of clinical scenarios and practices, problem identification, analysis of clinical requirements, and identification of business opportunities. The interview and literature review data revealed that all six factors play a role in shaping these activities (see Figure 2.10). For example, a ‘competitive and fragmented market’ (related to market forces) drives the development of new value propositions and business scoping. Conversely, a ‘lack of collaboration and stakeholder synergy’ (related to organizational capabilities) hinders initial field research and clinical access to problems. Similarly, the ‘non-uniform healthcare system and practices’ (related to healthcare context and ecosystem) influence the need assessment beyond clinical problems. The ‘lack of adequate funding and investment sources to support innovation’ (related to the innovation ecosystem) affects early decision-making in selecting or rejecting specific need areas. Additionally, ‘socio-cultural barriers and ignorance’ (related to demographic attitudes and characteristics) influence firms’ decision-making in need assessment beyond clinical requirements. Moreover, the ‘complexities inherent to clinical problems, biology, and solutions’ (related to science and technology) impact the final selection of needs and business scoping activities.

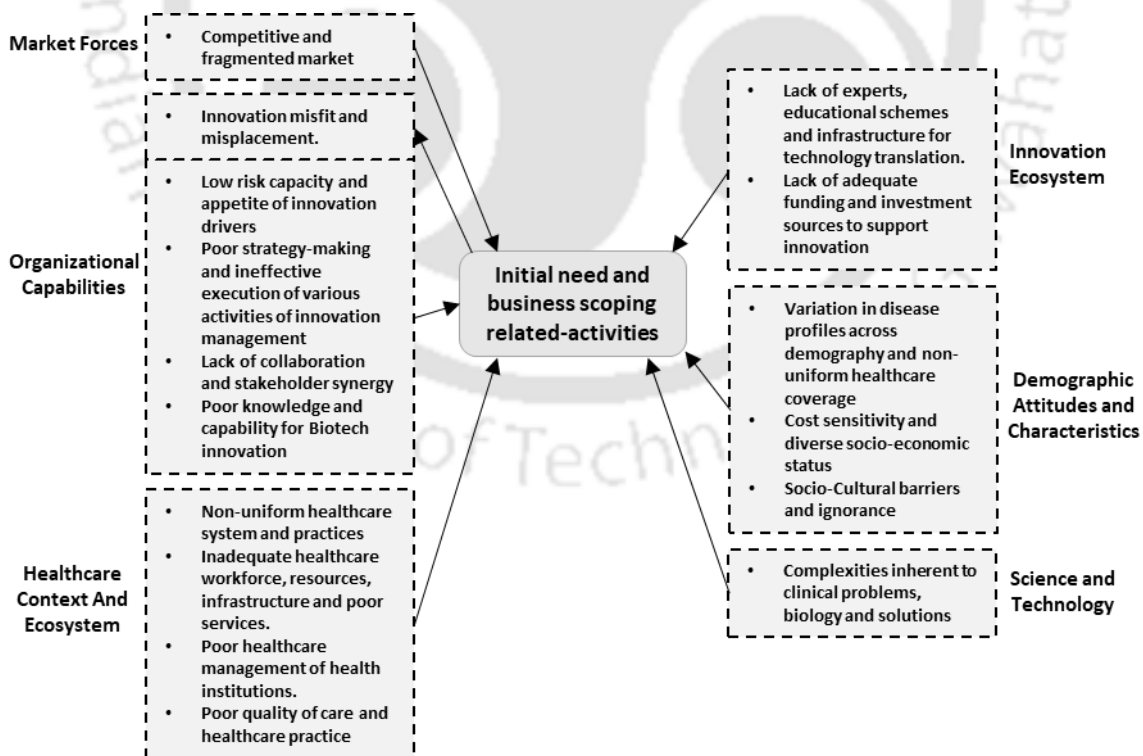


Figure 2-10 Influence of factors on ‘initial need and business scoping’ activities (author generated)

At the firm level, activities pertaining to ‘Technology research and development’—such

as generating product specifications and concepts, developing proof of concepts, conducting research and development, and evaluation—are also influenced by all six factors (see Figure 2.11). For instance, a competitive and fragmented market (related to market forces) influences firms' decision-making in creating new value propositions during technology development. Limited knowledge and capability for biotech innovation (related to organizational capabilities) impede firms' ability to develop technology and extend the R&D timeline. Insufficient healthcare workforce, resources, infrastructure, and subpar services (related to healthcare context and ecosystem) influence decision-making in design and product feature selection for technology developed for resource-constrained settings. Similarly, the absence of experts, educational schemes, and infrastructure for technology translation (related to the innovation ecosystem) constrains firms' capacity to develop technology efficiently. Cost sensitivity and diverse socio-economic statuses impose constraints on the overall design of a product to ensure affordability. Furthermore, the complexities inherent in clinical problems, biology, and solutions directly affect the time and cost investment in new technology development.

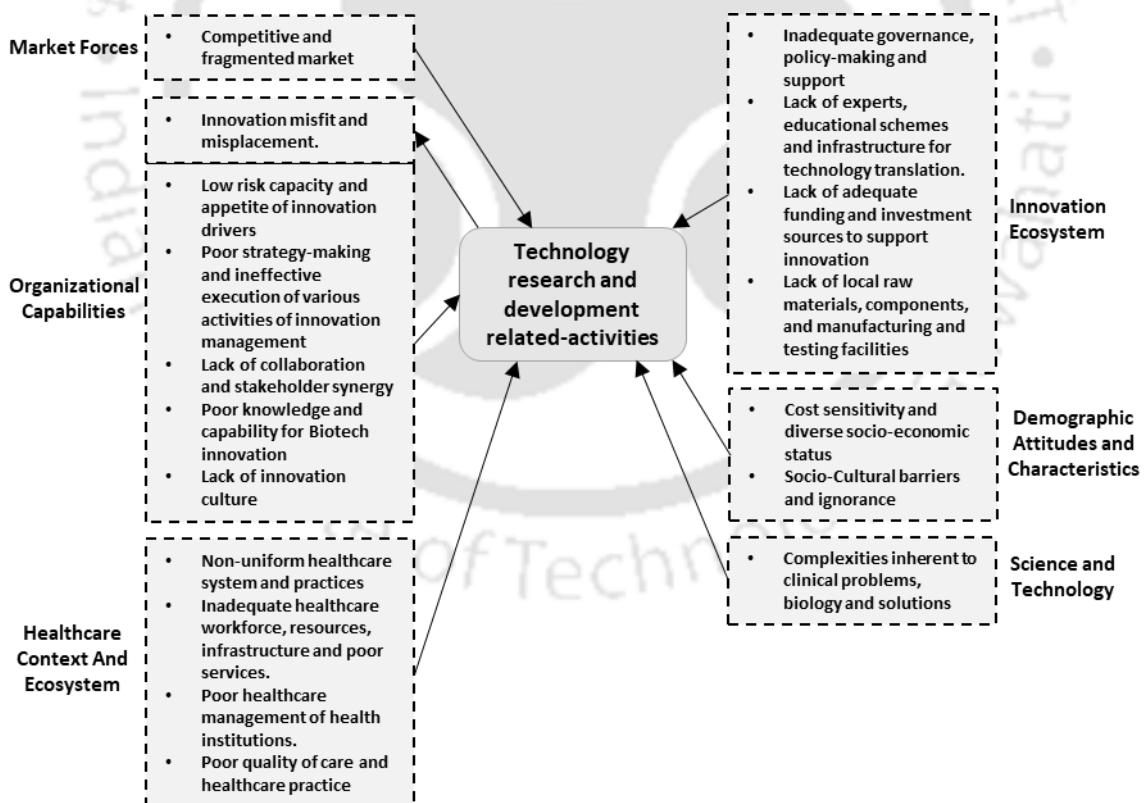


Figure 2-11 Influence of factors on 'technology research and development' activities (author generated)

The activities of "Innovation Scoping and Intellectual Property (IP) Management" include the scoping of innovation, patentability and freedom-to-operate analyses, and patent

filing, among others. Our data analysis revealed that factors such as "Market Forces," "Organizational Capabilities," "Innovation Ecosystem," "Demographic Attitudes and Characteristics," and "Science and Technology" influence these activities (see Figure 2.12). For example, competitive and fragmented markets, related to market forces, drive IP protection and management activities to attain exclusive commercial rights. Additionally, a lack of innovation culture, associated with organizational capabilities, negatively impacts innovation scoping and a firm's ability to protect its IPs. Similarly, inadequate and evolving IP frameworks, linked to the innovation ecosystem, introduce procedural complexities and higher costs in IP filing. The widespread prevalence of ill practices, such as IP theft and infringement, related to demographic attitudes and characteristics, can add complexity to a firm's IP management roadmap. Furthermore, complexities inherent to clinical problems, biology, and solutions, associated with science and technology, affect the patentability of new medical technologies.

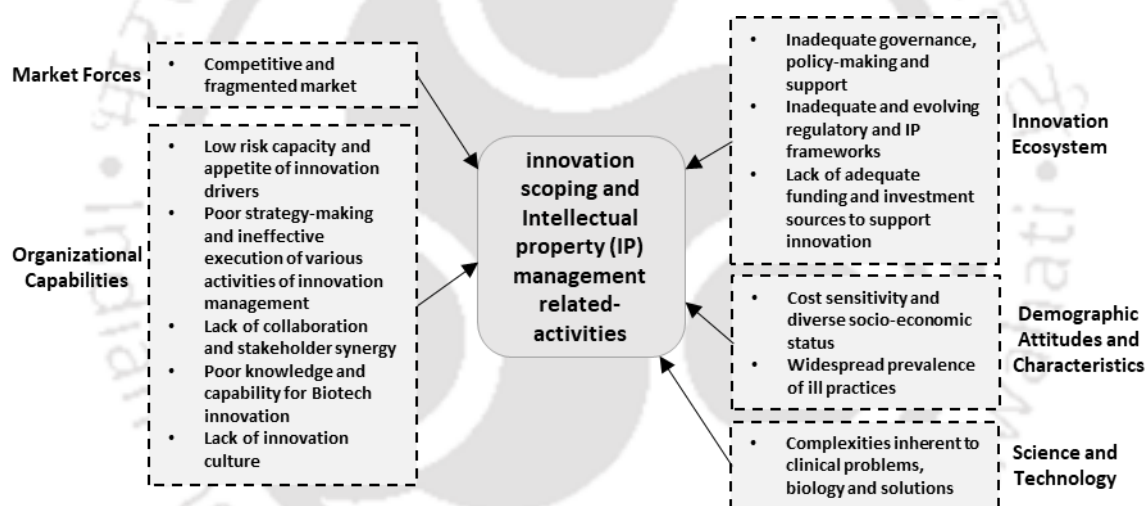


Figure 2-12 Influence of factors on 'Innovation scoping and Intellectual property (IP) management' activities (author generated)

Clinical efficacy and product safety validation encompass activities such as product safety testing, obtaining Institutional Review Board (IRB) ethical approval, institutional collaboration, and planning clinical study protocols. Our data analysis revealed that all six identified factors impact these activities (see Figure 2.13). For instance, clinical efficacy and product safety validation pose significant market entry barriers for new medical technologies, which is related to market forces. Organizational capabilities, such as collaborating with healthcare facilities and engaging stakeholders during clinical trials, are essential. Additionally, inadequate healthcare workforce, resources, infrastructure, and poor services, associated with the healthcare context and ecosystem, impact firms' clinical trial planning, increase associated

costs, and delay the overall clinical trial timeline. The lack of adequate funding and investment sources, related to the innovation ecosystem, also negatively impacts activities such as human resource recruitment, and the purchase of equipment and disposables. Furthermore, socio-cultural barriers and ignorance, associated with demographic attitudes and characteristics, hinder patient recruitment for clinical trial participation. Finally, complexities inherent to clinical problems, biology, and solutions, related to science and technology, affect the overall clinical trial procedure in terms of safety issues, infrastructure, and skill requirements.

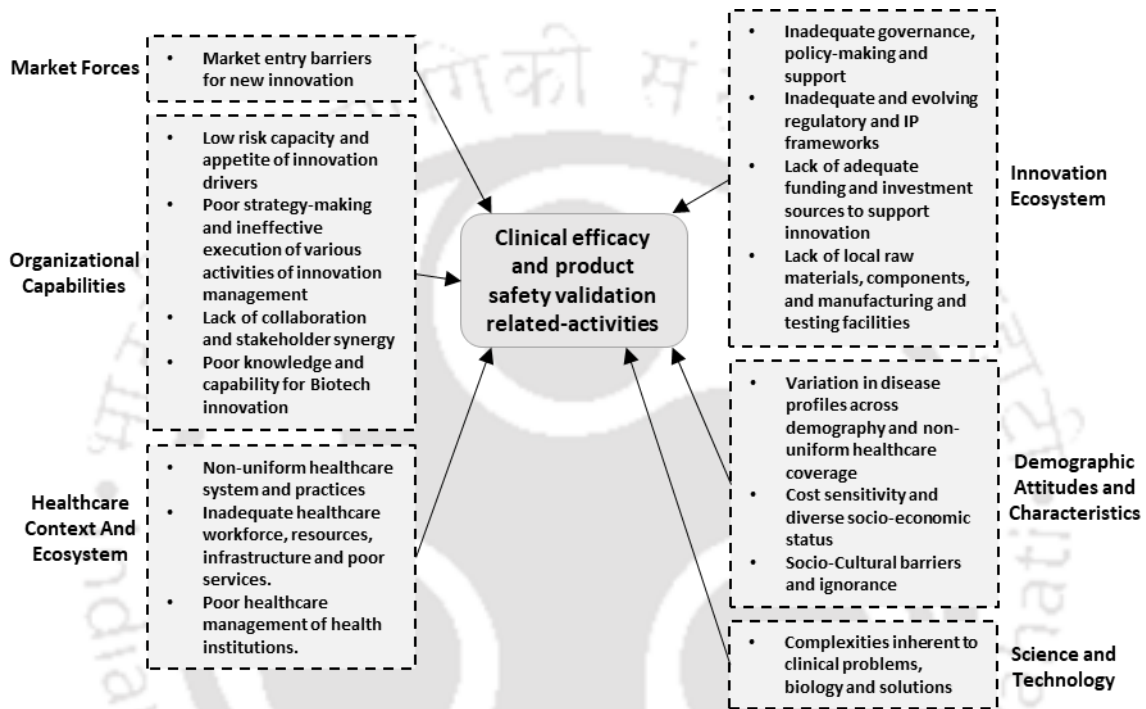


Figure 2-13 Influence of factors on Clinical efficacy and product safety validation activities (author generated)

Regulatory approval of novel medical technology involves choosing the appropriate regulatory body and roadmap, navigating clearance procedures, implementing a quality management system, and preparing technical and design files, among other tasks. All six identified factors influence these activities in various ways (see Figure 2.14). For instance, from the perspective of both market competition and market entry barriers (related to Market Forces), the implementation of medical technology demands regulatory approval if there are associated safety concerns with its use. Low risk capacity and a limited appetite for innovation (related to Organizational Capabilities) lead to a preference for lower-risk innovations to ease regulatory processes, which can affect innovation scoping and impact. Non-uniform healthcare systems and practices, along with poor standards of care (related to Healthcare Context and Ecosystem), mean that healthcare product markets in low- and middle-income countries (LMICs) are poorly regulated and monitored, impacting firms' decisions on the regulatory

approval process. Similarly, an inadequate and evolving regulatory framework (related to Innovation Ecosystem) in LMICs often compels innovators to seek approval from US FDA or European CE, which leads to greater complexity, higher costs, and delays in obtaining regulatory clearance. Limited financial capacity of firms and diverse socioeconomic constraints (related to Demographic Attitudes and Characteristics) impact resource allocation and innovation prioritization, thus influencing the firm's regulatory approval roadmap. Additionally, complexities inherent to clinical problems, biology, and solutions (related to Science and Technology) determine the device class in terms of safety level, which in turn impacts the overall regulatory approval procedure.

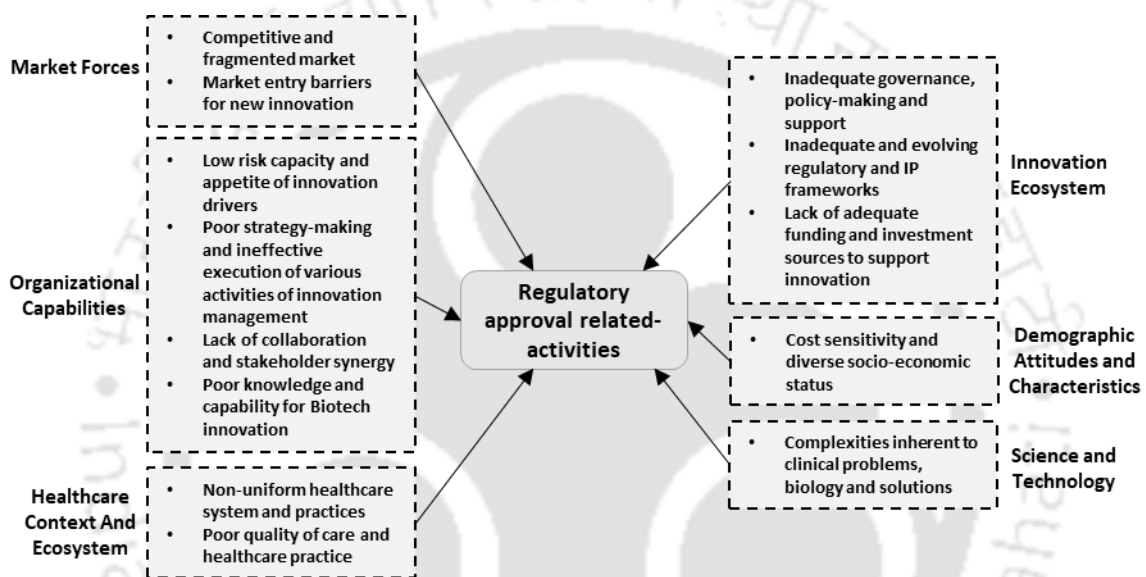


Figure 2-14 Influence of factors on Regulatory approval related activities (author generated)

Innovation scale-up and production-related activities involve product design for manufacturing (DFM), choosing between contract manufacturing or in-house production, and planning for packaging and assembly, among other tasks. Analysis of interview and literature review data reveals the influence of factors like Market Forces, Organizational Capabilities, Innovation Ecosystem, Demographic Attitudes and Characteristics, and Science and Technology on these activities (see Figure 2.15). For example, market competition and addressable market size (related to Market Forces) determine production volume and batch size. A lack of collaboration with appropriate personnel, vendors, institutes, and a lack of interpersonal or inter-organizational synergy (related to Organizational Capabilities) negatively impact the innovation scale-up process. Additionally, the lack of local raw materials, components, and manufacturing facilities often makes innovation firms dependent on imports and foreign vendors, which brings further coordination and execution issues. The widespread

prevalence of ill practices such as the theft of designs by contract manufacturers and unprofessionalism (related to Demographic Attitudes and Characteristics) also negatively impacts innovation scale-up and production-related activities. Furthermore, design complexities inherent to the clinical problem, biology, and solution (related to Science and Technology) also influence DFM, mold design, material selection, and manufacturing processes involved in innovation scale-up.

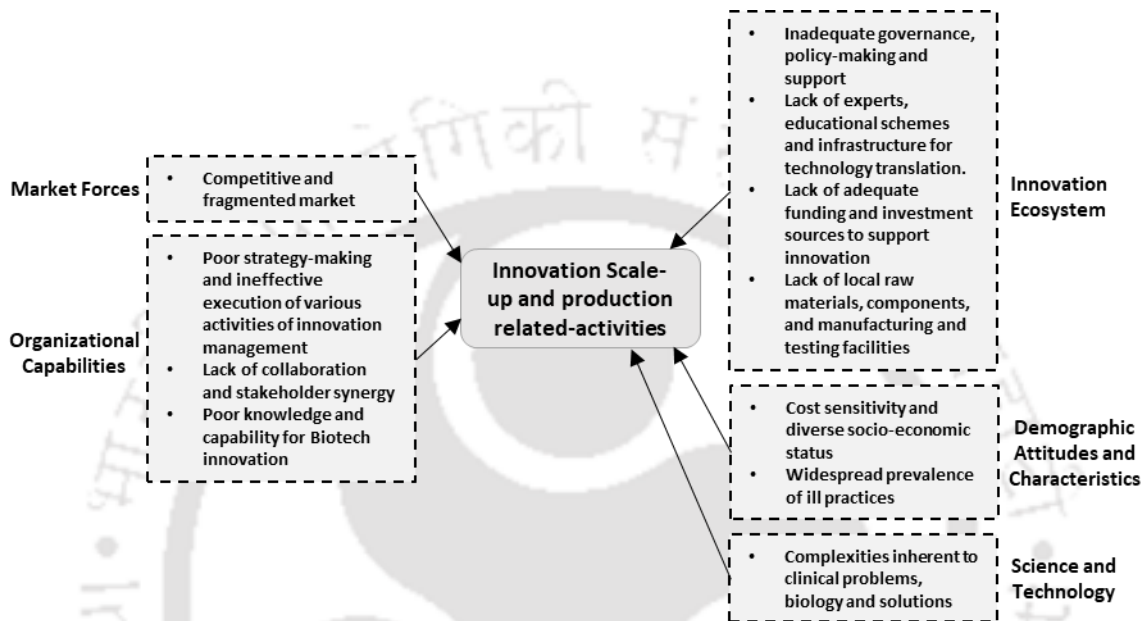


Figure 2-15 Influence of factors on Innovation Scale-up and production related activities (author generated)

Commercial Implementation and Product Diffusion involve activities such as developing sales and marketing strategies, identifying and networking with distribution channels, applying for tenders, preparing for direct sales, and conducting product promotion campaigns. It was found that all six factors influence such activities (see Figure 2.16). For example, market entry barriers (related to Market Forces) such as new training requirements and incompatibility with existing infrastructure pose hindrances to the institutional adoption of new innovations. Poor strategy-making and ineffective execution of commercial implementation activities (related to Organizational Capabilities) may affect the timely reach and diffusion of innovation. Additionally, poor quality of care and non-standard healthcare practices (related to Healthcare Context and Ecosystem) create obstacles to the commercial adoption of innovation. A lack of adequate funding and investment sources (related to the Innovation Ecosystem) impacts a firm's investment capacity for marketing and product promotion campaigns. Furthermore, socio-cultural taboos, non-scientific belief systems, and ignorance (related to Demographic Attitudes and Characteristics) also act as barriers to

commercial implementation and innovation diffusion. Moreover, technological complexities associated with new innovations can require extensive training and infrastructure setup, which can prolong the commercial adoption of the innovation.

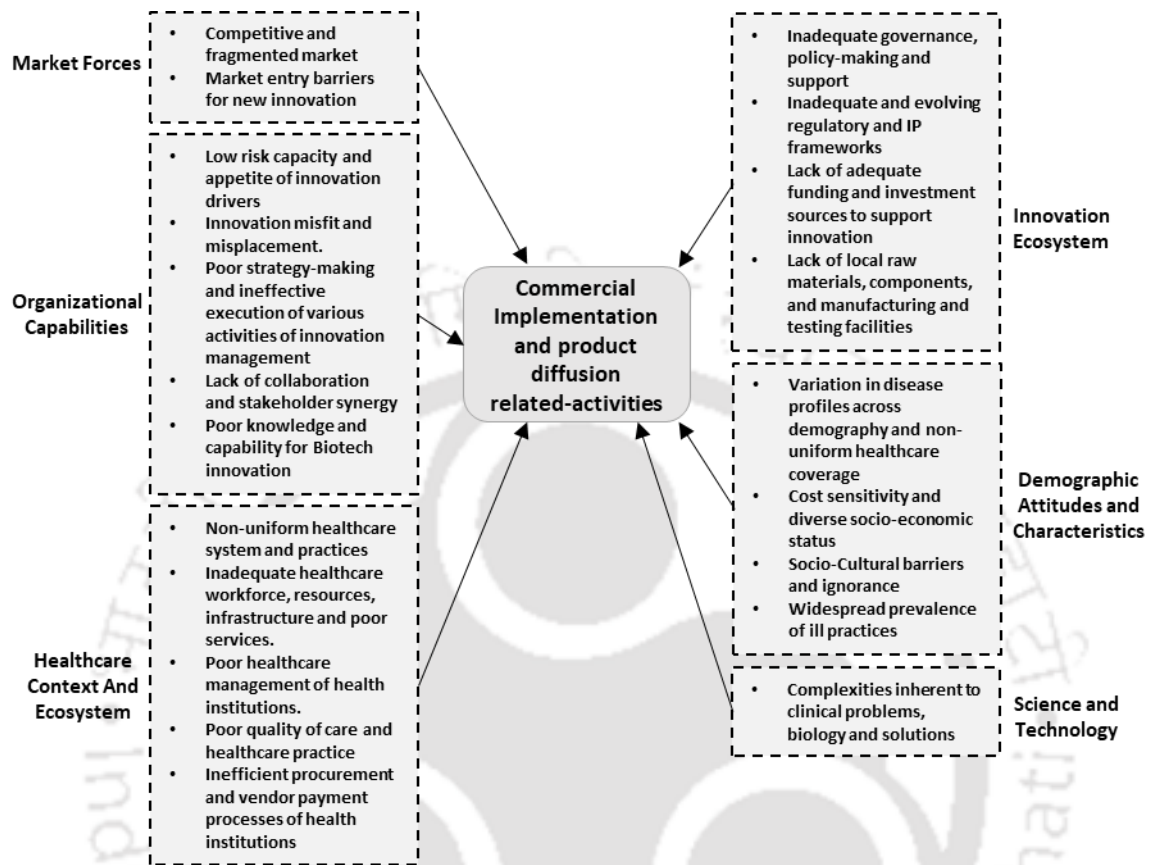


Figure 2-16 Influence of factors on Commercial Implementation and Product diffusion related activities (author generated)

Influence on Business management activities

Apart from the various firm-level R&D and project management activities, equally balancing business management activities such as "Mission and Business Strategy Planning" is also vital for successful innovation implementation. These activities include planning execution strategies, planning for strategic collaboration and alliances, arranging funds and investments, conducting business analysis and growth planning, product portfolio planning, and sales, marketing, and distribution planning. All six identified factors affect these activities (see Figure 2.17). For example, a competitive and fragmented market (related to Market Forces) drives firms to create unique mission and business strategies to maintain a leading role in the market. On the other hand, poor strategy-making and ineffective execution of various innovation activities (related to Organizational Capability) negatively affect an organization's mission and business goals. The prevalence of inefficient procurement and vendor payment processes in

health institutions (related to Healthcare Context and Ecosystem) influences firms to adopt alternative sales strategies, such as availing of a subscription model for product/service sales or direct sales, to manage constant business growth. Similarly, firms need to devise strategies to address challenges in an underdeveloped ecosystem, such as lack of funding, inadequate regulatory guidelines, and raw material unavailability. Additionally, firms must develop cautious strategies to overcome challenges stemming from Demographic Attitudes and Characteristics, such as cost sensitivity and socio-cultural barriers, to enable the successful implementation of innovation. Furthermore, issues related to the technological complexity of a solution (related to Science and Technology), which may pose additional challenges like the risk of damage or contamination of products, require strategic decision-making in storage, shipment, and distribution.

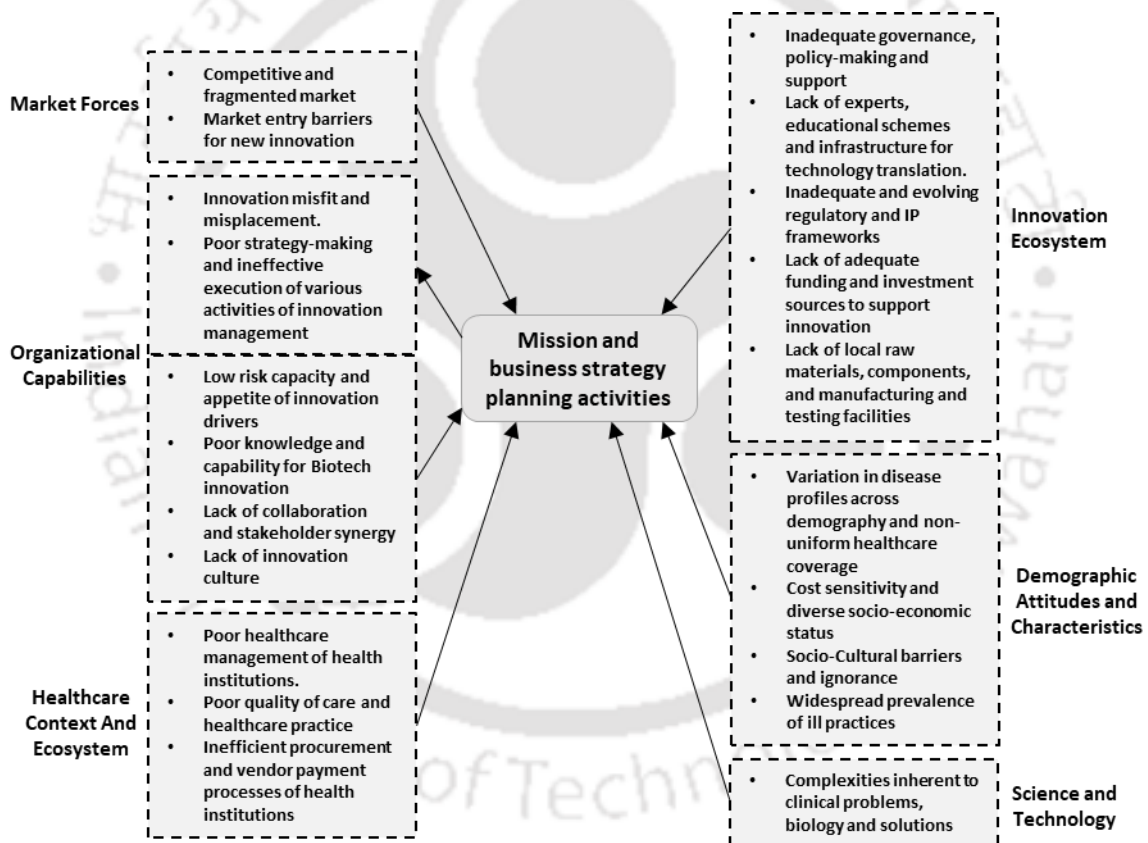


Figure 2-17 Influence of factors on firm's mission and business strategy planning activities (author generated)

2.4 Discussion

Previous research has shown that many medical technology companies grapple with the dilemma of effectively managing and harmonizing their organizational growth and innovation efforts, particularly in low- and middle-income countries (LMIC) (Khilji, Mroczkowski, & Assudani, 2012). This challenge is, in part, attributed to a lack of understanding regarding the

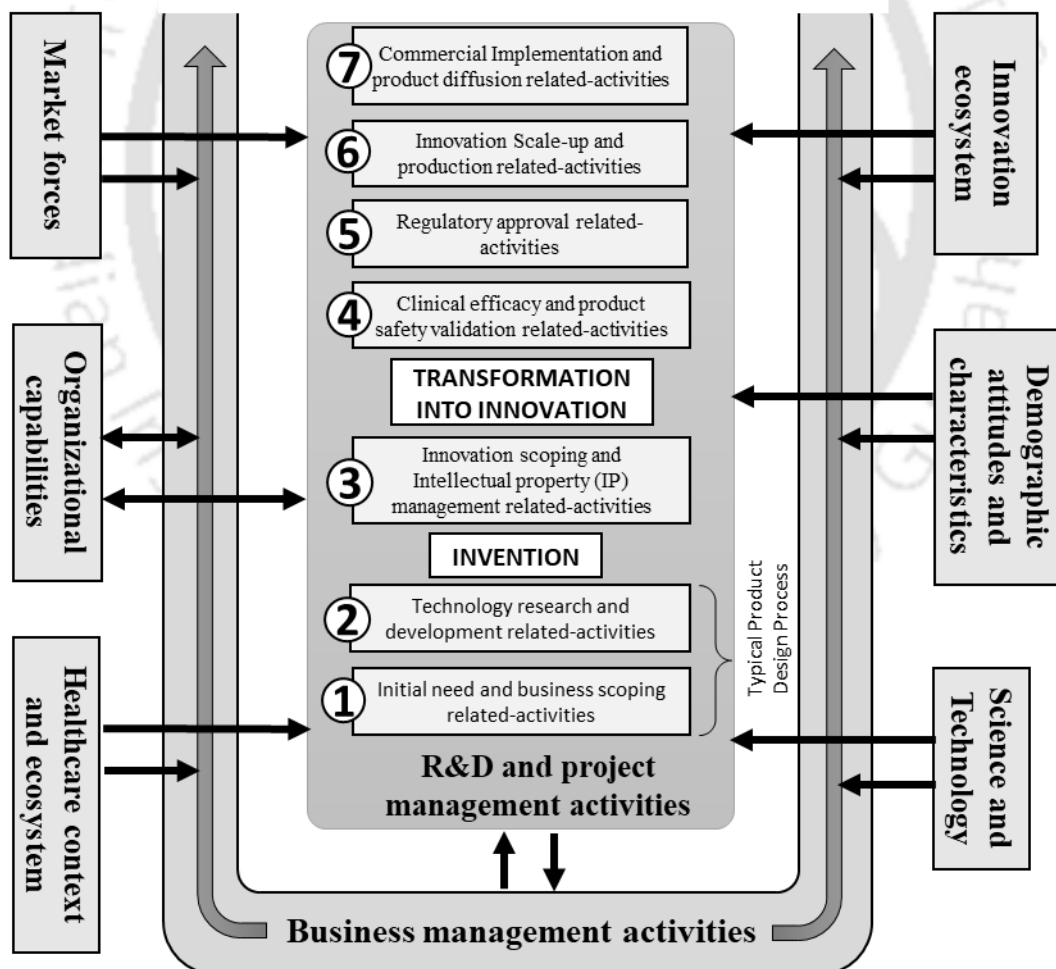
pivotal factors, issues, and how they impact different aspects of a company's operations.

This study employs various theoretical perspectives to examine data collected from both existing literature and real-world case studies in the medical technology industry. It identified six factors and the underlying issues related to innovation in this sector. The study subsequently summarizes how these challenges and factors affect the innovation activities of medical technology companies at the execution level, as presented in the study's results section.

These findings provide the essential prerequisites and foundation for the development of a more comprehensive integrated TIM model of managing medical technological innovation.

2.4.1 Redefining TIM model of medical technology innovation management

Based on data analysis and findings, a more comprehensive conceptual model of medical technology innovation management is realized (see Figures 2.18 and 2.19).



→ Influence of/on activities Or Influence of/on analysis and decision-making

Figure 2-18 Redefined conceptual model of medical technology innovation management (Simplified version-author generated)

Figure 3.18 presents a simplified version of the conceptual model. It illustrates the seven firm-level R&D and project management activities associated with medical technology innovation, alongside the parallel business management activities, and the influence of six identified factors on these firm-level activities. These factors are: Healthcare Context and System; Organizational Capabilities; Innovation Ecosystem; Demographic Burdens and Characteristics; Market Forces; and Science and Technology.



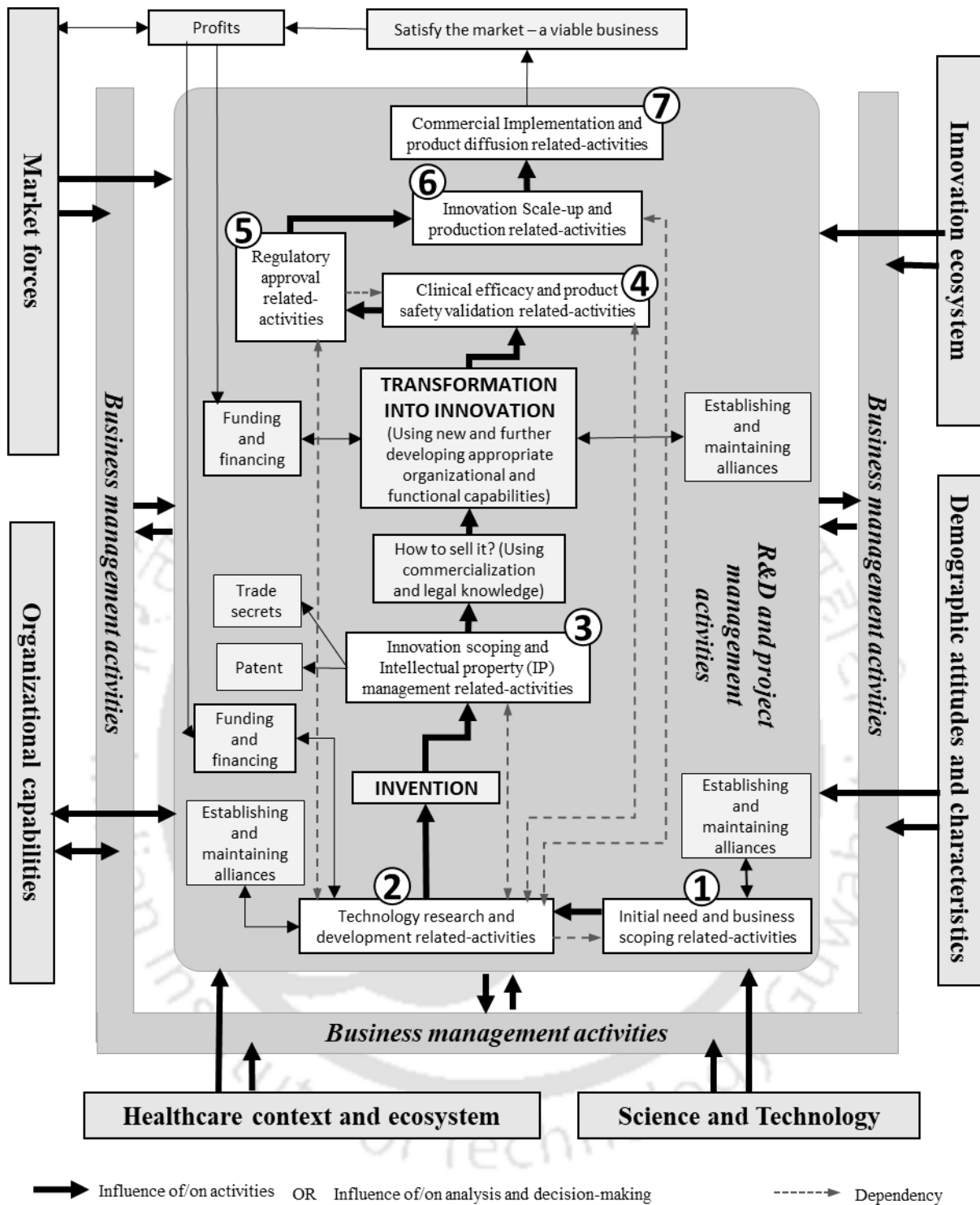


Figure 2-19 Redefined conceptual model of medical technology innovation management (Detailed version - author generated)

Figure 2.19, on the other hand, represents a detailed version of the model, showcasing the medical technology innovation roadmap by revealing key activities and influencing factors. This conceptual model illustrates the core seven R&D and project management activities, alongside their connections to mission and business strategy planning activities. It highlights

the intricate nature of medical technology innovation by revealing the interconnections and dependencies among these firm-level activities and the underlying factors.

The model summarizes the findings of the current study and illustrates the complex nature of medical technology innovation and the influence of various factors. The model identifies 'healthcare context and ecosystem' as one of the source factors impacting firm-level activities. The study outlines several key issues within LMICs' healthcare context and ecosystems that significantly impact medical technology innovation management. Non-uniform healthcare systems, marked by an unequal distribution of resources and expertise, make the uniform adoption of innovation difficult (Selvaraj, Bhan, & Mahal, 2022). These systems often suffer from inadequate healthcare resources, such as limited equipment and skilled personnel, which challenge the development and integration of new technologies (Abbas, Smiath, Poluta, & Velazquez-Berumen, 2017; Marks, Thomas, Bakhet, & Fitzgerald, 2019). Poor management practices in health institutions, including suboptimal priority setting and budget allocations, further hinder the effective adoption of innovative solutions (Ayah R, 2020; Beenkens & Stolk, 2010; Abrol, Sundararaman, Madhavan, & Joseph, 2016). Moreover, inefficient procurement and vendor payment processes, alongside resistance to new technologies, stifle innovation encouragement and adoption (Carpenet, Brischoux, & Alain Faure, 2011; Malkin & Oldenburg Beer, 2013). These systemic inefficiencies ultimately lead to inferior healthcare quality and limited innovation accessibility, creating a challenging environment for medical technology advancement in LMICs.

Similarly, the model highlights another source factor, 'organizational capabilities,' influencing medical technology innovation. The study identifies several organizational challenges affecting innovation management in LMICs. Limited risk capacity and innovation appetite mean that high costs and lengthy development timelines often deter smaller firms, leading them to opt for lower-risk innovations (Dixit, Srivastava, Sahu, & Selvamurthy, 2018; Joshi, et al., 2021). There's also a prevalent issue of innovation misfit, where technologies developed in other contexts fail to align with local needs and conditions, thus limiting their adoption (Gupta & Thomke, 2018; Leonard, de Kock, & Bam, 2020). Inadequate innovation strategies further hinder effective management due to poor planning, execution, and after-sales support (Rane & Kirkire, 2016). Furthermore, poor stakeholder collaboration and a lack of inter-professional networking impede innovation diffusion (Leonard, de Kock, & Bam, 2020; Harris, 2006). Organizations frequently lack essential knowledge on biotech commercialization, regulatory requirements, and market dynamics, contributing to innovation

failures (Alagumalai, 2019). Lastly, a general absence of an innovation culture within organizations, characterized by a lack of vision and an imbalance between the scientific and business aspects of projects, also negatively impacts the innovation process in LMICs (Walters, Thomas, Brown, & Lewis, 2001).

The model also represents 'innovation ecosystem' as another key driver of medical technology innovation. The study identifies critical challenges within the innovation ecosystem that impact innovation management in LMICs. Key issues include inadequate government support, where limited policies and poor post-market surveillance lead to the prevalence of inferior products and restrict technology adoption (Jadhav, Chunkhare, & Jadhav, 2017; Harmon & Kale, 2015). Additionally, the scarcity of experienced professionals and under-developed infrastructure limits effective R&D and technology translation (Dixit, Sahu, Srivastava, & Selvamurthy, 2019). Regulatory and intellectual property frameworks are often incomplete and evolving, complicating commercial implementation and international compliance (Ayah R, 2020; Abbas, Smiath, Poluta, & Velazquez-Berumen, 2017). Funding limitations further constrain R&D and commercialization efforts (Dixit, Srivastava, Sahu, & Selvamurthy, 2018; Piaggio, et al., 2021). Moreover, the absence of local manufacturing resources and testing facilities hampers quality assurance and increases dependency on imports, raising costs and affecting product competitiveness (Ayah R, 2020). These ecosystem inadequacies collectively delay the adoption and diffusion of innovative technologies in LMICs.

Furthermore, the model considers 'demographic attitudes and characteristics' as another influencing factor of medical technology innovation. Demographic factors significantly affect innovation management in LMICs. Large country sizes, diverse diseases, multilingual populations, and socio-demographic variations such as age, literacy, and gender disparities complicate uniform healthcare coverage and innovation adaptation (Dhawan, et al., 2015). Socio-economic challenges, including low incomes and cost-sensitivity, impede healthcare access and stifle technology development among smaller enterprises (Ginsburg, et al., 2020). Moreover, socio-cultural diversity introduces barriers such as stigma, taboo, and privacy concerns, which hinder innovation diffusion (Beenkens & Stolk, 2010; Kaur, Kaur, & Kaur, 2018). Widespread corruption, poor product security, and sub-standard technologies further undermine innovation effectiveness and market access (Abbas, Smiath, Poluta, & Velazquez-Berumen, 2017; Bouchard, Kohler, Orbinski, & Howard, 2012). These demographic and socio-economic burdens create a complex environment for managing and

implementing healthcare innovations in LMICs.

Moreover, another factor the model considers as a source of medical technology innovation is 'Market forces'. Market forces present significant challenges for innovation management in LMICs, where the adoption of innovations is often influenced by favoritism and brand loyalty rather than competitive tender processes. The market is fragmented, entry barriers are high, and there is heavy reliance on imports and dominant biotech firms, making it difficult for new innovations to penetrate (Jarosławski & Saberwal, 2013). Additionally, the financial returns on novel medical technologies are low due to high developmental costs, competitive pricing, and poor funding (Bano, Gupta, & Shekhar, 2020). Similarly, institutional evaluation, fitment, and training complexities with novel healthcare solutions delay incorporation (Malkin & Oldenburg Beer, 2013). These market dynamics result in a challenging environment for introducing and scaling new medical technologies in LMICs.

Lastly, the model highlights a generic factor impacting medical technology innovation: the inherent complexity of science and technology in medical fields. This complexity arises from the involved clinical problems and biology, making medical technology innovations more challenging than in other sectors (Sabet Sarvestani, Coulentianos, & Sienko, 2021). In LMICs, these complexities lead to high R&D costs, prolonged development timelines, ethical and safety concerns, extensive clinical trials, and regulatory challenges, all of which significantly affect organizational innovation management activities.

Other than the source factors and key firm level activities, the conceptual model also demonstrates that aspects such as funding, investment, alliances, and collaborations have an influence on various stages of medical technology R&D and project management activities, including technology development, IP protection, product scale-up, and so forth.

2.4.2 Theoretical implications

The study revealed that the HICs' blueprint of medical technology innovation management is a poor fit for LMICs as the past conceptual model did not consider several essential factors and their dependencies on medical technology innovation. The findings of the study revealed three additional factors that lead to the complexity of medical technology innovation management in LMICs compared to past TIM specific research. It was found that, in addition to Khilji (2006)'s reported source factors, science and technology, organizational capabilities and market forces (refer to Figure 2.1), medical technology innovation, and strategic decision-making also get affected by country-specific healthcare context and system, innovation

ecosystem and demographic burdens and characteristics. The model revealed a non-linear innovation journey map and demystify the integrated approach of balancing R&D and business activities for medical technology innovation management. It shows how the identified factors influence firms' mission and business strategy planning and operation activities, which indirectly affect all the R&D and project management activities. The proposed conceptual model shows that, unlike consumer product innovation, the R&D and the commercialization-related activities of medical technology innovation can't be separated for isolated execution. Rather activities need an integrated approach of execution by realizing inter-dependencies of various firm-level activities. For instance, using dashed arrows the model shows the dependency of appropriate technology research and development on activities related to IP protection, regulatory approval, product clinical efficacy and safety validation, and innovation scaleup production.

Further, the model provides a theoretical reference for design researchers in identifying requirements for developing design methods, tools and guidelines for successful medical technology innovation and implementation in LMIC context. For instance, researchers can utilize the six foundational factors as matrices or filters to assess prevailing healthcare design procedures and tools, gauging their appropriateness for LMIC contexts while also pinpointing areas for enhancement. Understanding the six factors and their underlying connection to the innovation process will equip design researchers with a deeper understanding of the methodological support needed. Such insights may pave the way for refining existing design processes, encompassing activities like problem analysis, needs assessment, concept evaluation, and strategy formulation for implementation.

2.4.3 Practical implications

The study demystifies the medical technology innovation process, stages, activities, and influencing factors. The resultant knowledge integration will positively impact strategic decision-making in the innovation process. As depicted in Figure 2.19, the model revealed the importance of inter-organizational and professional alliances and synergy as an effective way to address the complex R&D and diverse skill requirements in medical technology innovation projects (Harris, 2006). Due to inadequate funding support, medical technology firms operating in LMICs should strive to arrange and manage funds from early inception and throughout the innovation journey to carry out various R&D and business activities hassle-free (Jaroslowski & Saberwal, 2014). The newly introduced source factors and their influences convey that successful innovation adoption requires consideration of the healthcare context,

innovation ecosystem, and societal issues (Harris, 2006). Although IP protections like patent filing, design registration, etc. enhance organizational market competitiveness in terms of capability, for LMICs, such strategies should be adapted consciously, keeping in mind the inadequate IP enforcement capabilities and financial liability associated with IP filing and maintenance (Malkin & Oldenburg Beer, 2013). Again, regulatory, safety, and quality requirements should be considered in the early business scoping and technology development phase, to plan product portfolios and innovation road maps based on the firm's risk appetite and capacity (Harris, 2006). In LMICs, inadequate and slow regulatory frameworks can increase costs and delay innovations' market reach (Ayah R, 2020). Similarly, issues pertaining to technology development and manufacturing need to be considered strategically considering the firm's capacity, public policies, and available resources and infrastructures (Malkin & Oldenburg Beer, 2013). Overall, an understanding of the proposed model along with the underlying challenges and barriers will provide a comprehensive entrepreneurial roadmap for medical technology innovation in LMICs.

2.5 Limitations and Future Scope

While the research study aims to address critical gaps in medical technology innovation in low- and middle-income countries (LMICs), the generalizability of the findings may be limited by the focus on specific regions, such as India. Further validation through broader empirical testing in diverse LMIC settings is essential to confirm the generalizability and effectiveness of the proposed framework. In terms of methodology, incorporating longitudinal studies and real-time monitoring of medical technology innovation projects in LMICs could provide a more nuanced understanding of the long-term impact and sustainability of the proposed theoretical model.

The research study lays a strong foundation for future exploration and expansion of knowledge in medical technology innovation for LMICs. Future research endeavors can build upon these foundations to develop systematic processes and tools to aid designers, innovators, and entrepreneurs in the innovation process. Some areas of research, such as navigating innovation projects within poor regulatory and government policies and the underdeveloped innovation ecosystem of LMICs, require further exploration.

2.6 Conclusion

The study investigated how medical technology innovation management in LMICs is different compared to HICs. It revealed six key factors covering 23 challenges and barriers to medical

technology innovation. The study further reported how various factors impact firm-level medical technology innovation activities and articulates a comprehensive conceptual model. It was found that compared to HICs, medical technology innovation in LMICs is more challenging due to the influence of additional factors which are country-specific healthcare context and system, innovation ecosystem, and demographic burdens and characteristics. The findings will add to technology innovation management research and help medical technology entrepreneurs with strategic decision-making.



Chapter 3. Scope of Existing Design and Innovation Processes for Medical Technology Innovation

Abstract

Innovating medical technology presents a unique set of design, development, and implementation challenges, distinct from those encountered by typical product designers. The literature highlights the use of diverse design and innovation processes such as User centered design (UCD), Human-centered design (HCD), Design thinking (DT), and the Biodesign process in medical device projects. However, the extent to which these processes effectively facilitate medical technology innovation remains relatively uncharted. The purpose of this study is to explore the distinctions between design and innovation context of medical technology and generic products. The study identified the key process support requirements for medical technology innovation, and compare different design and innovation processes for applicability in medical technology innovation. The study methodology comprises three key phases. First, a literature review of 53 case studies on medical technology innovation projects was conducted. Second, it focused on understanding medical technology innovation requirements through thematic coding analysis. The study identified four key characteristics of medical technology innovation context: *Multifactorial nature of healthcare issues, Complexity of disease states, bio-mechanisms, and pathophysiology, Critical importance of clinical interventions in terms of biocompatibility and patient interaction, Challenges related to entry barriers and the localization of solutions for market entry.* Finally, the study compared established design and innovation processes in medical technology innovation and recommended enhancements.

3.1 Introduction and Background

Design processes offer structured methods for acquiring crucial procedural insights related to any design undertaking (Daalhuizen, Person, & Gattol, 2014). A design process serves as a structured model of a design task, serving as a cognitive tool to assist designers in attaining their design objectives (Daalhuizen J. , 2014).

In the context of medical technology innovation, the literature has brought to light a multitude of instances where design and innovation processes have been applied to foster the advancement of medical technology and innovation. Several well-recognized design and

innovation processes, including User-Centered Design (UCD), Human-centered Design (HCD), Design Thinking Process and Stanford Biodesign process, have gained extensive acceptance across the industry and academia for driving innovation in medical technology projects. For instance, Christel et al. (2022) conducted a case study that demonstrated how the User-centered design (UCD) process enabled successful design and innovation of a connected sensor system for detecting colorectal anastomotic leakage in a complex hospital environment (Schwartz-Lasfargues, et al., 2022). In another report, Dharmawan et al. (2020) utilized the Stanford Biodesign process to innovate an in-vivo surgical lighting device for Head and Neck surgery (Dharmawan, et al., 2020). Similarly, there are reported case studies where Design Thinking process was employed to design and innovate medical apps like for detecting Diabetic Foot Syndrome and Pressure Ulcers, as well as medical devices like a wireless endoscope for carpal tunnel release (Chatpun, Liawrungrueang, Prukpattranon, & Wongsiri, 2022; Zaufenberger, Stampfer, Mader, Gold, & Donsa, 2022). Furthermore, there are literature reports on the application of specific design processes, such as the design of implantable orthopedic medical devices, an open innovation-inspired approach for robotic rehabilitation systems (Aitchison, Hukins, Parry, Shepherd, & Trotman, 2009; Formicola, Ragni, Borboni, & Amici, 2022; Medina, Kremer, & Wysk, 2013).

Existing literature has brought to light the utilization of different design and innovation processes, in the context of medical technology innovation, showing their role in shaping the outcome of medical technology innovation projects. Despite a general understanding of how such processes are carried out for medical technology design and innovation, little is actually known about the process support that medical technology design and innovation demand within a systematic process. Furthermore, the existing literature lacks exploration into systematically comparing these diverse design and innovation processes to evaluate their effectiveness when applied to projects in medical technology innovation. There is a need to delve deeper into understanding what sets medical technology design and innovation apart from traditional product design and innovation, recognizing the unique challenges and considerations it presents.

Hence, within the scope of this study, we are actively pursuing answers to these critical questions. By conducting this research, we aim to shed light on how process support required for medical technology innovation projects distinguishes itself from conventional product

innovation projects.

3.2 Methodology

The study methodology involved conducting a literature review of case studies on medical technology innovation projects to extract key findings related to medical technology design and innovation context. It then focused on understanding the characteristics and constraints of medical technology innovation and identifying process support needed for the innovation journey. Further, the study conducted a comparative analysis of established design and innovation processes for medical technology innovation, leading to the identification of possible process improvements. Figure 3.1 illustrates the study methodology visually.

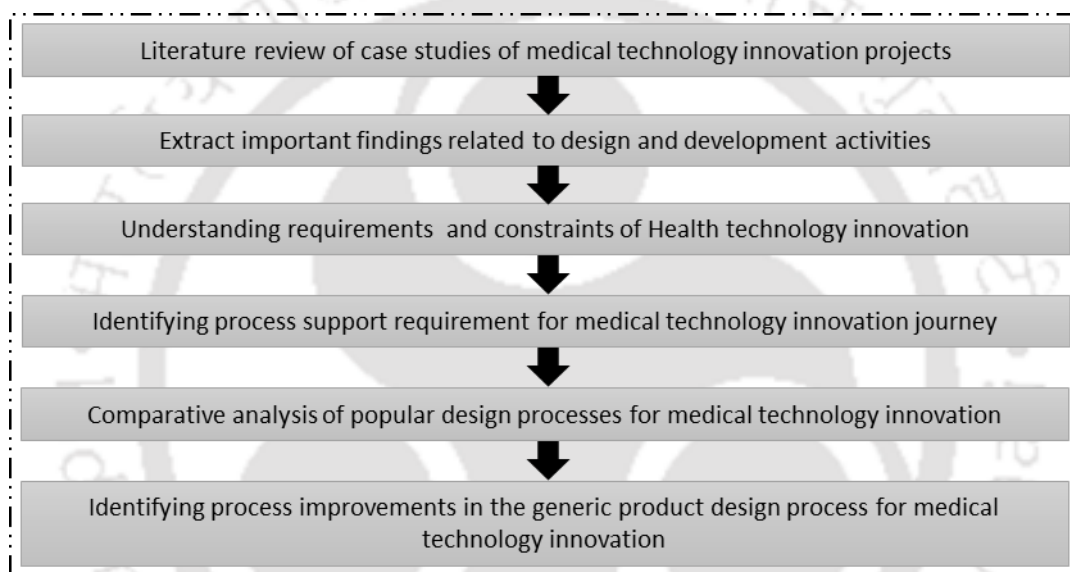


Figure 3-1: Study methodology (author generated)

3.2.1 Literature review

Data collection

An informative, rather than all-encompassing, non-systematic literature review was planned. For the identification of case studies on medical device innovation, the SCOPUS database was selected. Table 3-A shows the key search terms and usage of Boolean operators to initiate the search.

Table 3-A: Key search terms to guide the search

Search Terms
“medical device” AND “innovation” AND “Case study” OR “Report”

Table 3-B: Inclusion - exclusion criteria

Criterion	Inclusion	Exclusion
Time period	2001 to 2022	Studies outside these dates
Subject area	Medicine, Engineering	All other areas
Document type	Article	All other documents
Source type	Journal	All other source
Language	English	Non-English

A total of 338 related documents were yielded by the initial search. Following this, the initial documents were subjected to additional screening using a predefined set of inclusion and exclusion criteria outlined in Table 3-B, leading to the selection of 135 journal articles. The resultant articles were further scrutinized based on their titles, leading to the exclusion of 45 additional articles from the pool. Finally, after an abstract and full-text assessment of the remaining 90 articles, 53 articles reporting case studies related to medical device innovation were included for the study.

Data analysis

Analysis of data revealed that majority (66.7%) of the 53 articles discuss the subject area of medicine and engineering, while remaining (33.3%) are from subject areas like Nursing, Immunology, Material science, Computer science, Business management, Pharmacology, Chemical engineering and Biochemistry. Figure 3.2 illustrate the subject area defined by the 53 selected journal articles.

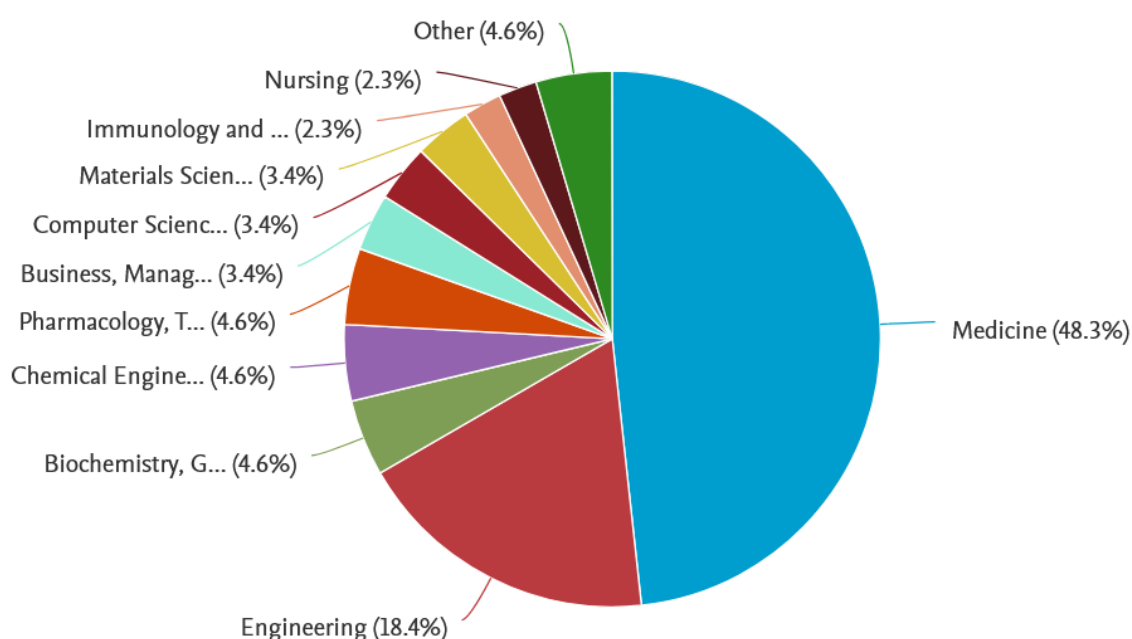


Figure 3-2: Subject areas defined by the final selected 53 articles (author generated)

3.2.2 Understanding characteristics and constraints of medical technology innovation

The study aimed to gain a deeper understanding of medical technology innovation, exploring its unique aspects in comparison to generic product design and innovation. To achieve this, a systematic process of thematic coding and analysis was employed (Gibbs, 2012). Three thematic coding experts participated in the process: a faculty and two research scholars, each with over five years of experience in thematic coding. Initially, essential text passages or paragraphs related to the requirements of medical technology innovation were extracted from the selected articles. These extracted texts were then categorized into individual themes and labeled with short descriptors, a technique known as open coding. Subsequently, all the generated open codes were examined to uncover relationships among them and was organized into specific innovation process tasks, referred to as axial codes. Lastly, the axial codes were further grouped into higher-level themes to delineate the characteristics and constraints of the design and innovation process in medical technology.

3.2.3 Identifying process supports requirements for medical technology innovation

Later, through a comprehensive examination of the medical technology innovation-related activities outlined in the case studies, coupled with a thorough consideration of the nature and constraints inherent in the medical technology innovation process, a set of process supports requirements were identified to facilitate and ensure the effective and successful execution of medical technology innovation initiatives. The analysis involved a focus group discussion followed by brainstorming to generate ideas on the process support requirements for medical technology design and innovation. The focus group consisted of four designer-cum-research scholars and a faculty member with prior experience in academic research and the brainstorming method. The objective was to pinpoint process supports requirements that can serve as essential guidelines in the development and evaluation of medical technology design and innovation processes, providing a structured framework for the development and implementation of cutting-edge medical technologies.

3.2.4 Comparative effective analysis of existing medical technology design and innovation processes and further recommendation

Furthermore, the study conducted a comparative assessment of various well-established design processes employed in medical technology innovation projects, including User-Centered Design, Design Thinking Principles, Human-Centered Design, and Stanford Biodesign

Process. This assessment was made in relation to the identified process supports for successful medical technology innovation. The primary aim of this analysis was to pinpoint deficiencies in the various innovation processes within healthcare and recommend necessary adjustments to enhance their effectiveness.

3.3 Results and Discussion

3.3.1 Nature of medical technology innovation process

The thematic analysis of case studies and reports on innovation in medical devices unveiled four distinct attributes of the medical technology innovation process as selective codes. These attributes include the "Multifactorial nature of healthcare issues," the "Complexity of disease states, bio-mechanisms, and pathophysiology," the "Critical importance of clinical interventions in terms of biocompatibility and patient interaction," and the "Challenges related to entry barriers and the localization of solutions for market entry." In comparison to conventional product innovation, medical technology innovation and integration encompass these unique characteristics and constraints. These discoveries emerged from the examination of numerous case studies and literature sources.

Table 3-C below highlights the findings of the thematic coding process.

Table 3-C: Results of the thematic coding process

Selective codes	Axial codes	Open codes	Literature sources
Multifactorial nature of healthcare issues	Clinical problem	<ul style="list-style-type: none"> • Cardiovascular Disorders • Pain • Orthopaedic issues • Neurological emergencies • malnutrition • Endocrine Disorders 	(Bonfanti, 2020) (N.G. Patel, 2020) (F. Nativel, 2019) (Thaete K, 2019) (Abraham MB, 2016)
	Socio-economic factors	<ul style="list-style-type: none"> • Poverty • Low affordability • Cost effective design • economic viability • Economic challenges of using innovation • economic burdens of disease • socio-political and environmental context 	(Domapielle, 2023) (C, et al., 2022) (Eggington, 2019) (F. Nativel, 2019) (Matthew Prime, 2018) (Chambers, 2013)
	Demographic factors and poor policies	<ul style="list-style-type: none"> • Geographic inaccessibility • Poor government initiatives • paucity of institutionalized health care payers • absence of national evidence-based guidelines • poor Government priorities 	(Domapielle, 2023) (Jarosławski S. S., 2013) (Chambers, 2013)

Selective codes	Axial codes	Open codes	Literature sources
	Healthcare infrastructure issues	<ul style="list-style-type: none"> no logistics of implementation maladaptation of medical device maladapted to low-resource settings unequal geographical distribution 	(Thaete K, 2019) (Chaturvedi J, 2015) (Jarosławski S. S., 2013) (Mahal, 2006)
	Healthcare system issues	<ul style="list-style-type: none"> complex healthcare ecosystem Procurement influence by physicians and sales representatives poor healthcare management inefficiency in public facilities unethical practices in private diagnostic facilities inefficient use of medical devices in public facilities 	(Chaturvedi J, 2015) (Hudson P Silva, 2011) (Mahal, 2006)
Complexity of disease states, bio-mechanisms, and pathophysiology	Understanding biomechanism, anatomy	<ul style="list-style-type: none"> Mimic biological process anatomical features of the patient understanding of the patient-specific haemodynamic features modify anatomy or physiological processes 	(Sateesh, Guha, Dutta, Sengupta, & Rao, 2022) (Bonfanti, 2020) (Polisena J, 2014)
	Understanding Pathophysiological changes	<ul style="list-style-type: none"> Fuels antimicrobial resistance Prevent Bacterial colonization insights on disease progression slow or stop disease progression 	(Nicholas G. Fischer, 2022) (Bonfanti, 2020) (Smith, 2015)
	Considering Clinical protocols and standard practices	<ul style="list-style-type: none"> Standard of care antibiotic usage Infection prevention strategies change daily practice of healthcare professionals 	(Nicholas G. Fischer, 2022) (Alan G Fraser, 2020)
	Identifying Technological usage and constraints	<ul style="list-style-type: none"> scientific principle driving solution synthesis Technically challenging engineering parameters, customization, and standardization state-of-the-art technology Engineering experiment 	(Sateesh, Guha, Dutta, Sengupta, & Rao, 2022) (C, et al., 2022) (Ramírez-Rios, et al., 2021)
Critical importance of clinical interventions in terms of biocompatibility and patient interaction	Product safety testing	<ul style="list-style-type: none"> safe introduction of implants safety benchmarks improve the safety of medical devices risk of harm to patients 	(N.G. Patel, 2020) (Matthew Prime, 2018) (Polisena J, 2014)
	Clinical validation	<ul style="list-style-type: none"> Product efficacy testing Solution analysis Bench top testing pre-clinical and clinical assessment Reporting clinical evidence high-risk device design of clinical studies animal testing as preclinical assessment Institutional Review boards study 	(Sateesh, Guha, Dutta, Sengupta, & Rao, 2022) (incarone, et al., 2021) (Alan G Fraser, 2020) (Viceconti M, 2017) (Abraham MB, 2016)
	Quality control	<ul style="list-style-type: none"> Changing standards Efficient Quality Management ISO 13485 ISO 25539 Part 1 	(Song, et al., 2022) (Kheir O, 2021)

Selective codes	Axial codes	Open codes	Literature sources
	Regulatory compliances	<ul style="list-style-type: none"> • Changing regulatory norms • regulatory approval of medical devices • post-market surveillance • approval of medical devices • regulatory changes and reform • Medical Device Post-Market Surveillance • FDA 510(k) clearance process • comply with a regulatory standard 	(Song, et al., 2022) (Alan G Fraser, 2020) (Wenbo Liu, 2017) (Adam W. Beck, 2017) (Zippel, 2017) (Jan B. Pietzsch, 2013) (Chambers, 2013)
	Medical technology Risk assessment	<ul style="list-style-type: none"> • assess the robustness of the model • Early medical technology assessment • post market device evaluation • clinical and economic evaluation of Medical devices • Medical technology Assessment (HTA) 	(Federici, 2021) (Adam W. Beck, 2017) (Zippel, 2017) (Tarricone, 2011) (Antonio Migliore, 2009)
Challenges related to entry barriers and the localization of solutions for market entry	IP management & technology licensing	<ul style="list-style-type: none"> • Comprehensive measures for IP protection • Medical device patents 	(Song, et al., 2022) (O' Cearbhaill, 2019)
	R&D management	<ul style="list-style-type: none"> • interdisciplinary resources for product development • interdisciplinary thinking and problem-solving 	(Alagumalai, 2019)
	Manufacturing planning	<ul style="list-style-type: none"> • biomaterial usage • modify the design • Manufacturer evaluations • device development process • assessment of the new device design • Manufacturing support 	(Matthew S. Waninger, 2013) (Chambers, 2013)
	Competitive analysis and new value proposition	<ul style="list-style-type: none"> • Assessment of clinical and market needs • Medical device value analysis • value creation and value capturing mechanisms • Value Driven Innovation 	(Song, et al., 2022) (Heidi Krantz, 2017) (Stephan Winterhalter, 2017) (de Ana, 2013)
	Fund arrangement	<ul style="list-style-type: none"> • cost of the research and development of medical devices • financial imbalances • Financial support 	(incarone, et al., 2021) (Chambers, 2013)
	Business planning	<ul style="list-style-type: none"> • Reimbursement strategy • Tenders for the Procurement • Public Procurement • net monetary benefit • incremental cost-effectiveness ratio • Business Models • market access • successful implementation of an innovation 	(F. Nativel, 2019) (Messori A, 2019) (Stephan Winterhalter, 2017) (Chambers, 2013)

Below are the details about the four identified attributes of Medical technology innovation process:

Multifactorial nature of healthcare problems

The healthcare problem is a multifaceted issue that goes well beyond the clinical aspects. It involves a web of intricate factors, including socioeconomic conditions, demographics, and the state of healthcare infrastructure. Often, these underlying interdependencies remain hidden from plain view. As illustrated in Figure 3.3, the process of identifying healthcare issues and conducting a thorough requirement analysis necessitates a deep and immersive involvement in the clinical landscape at various tiers of the healthcare system.

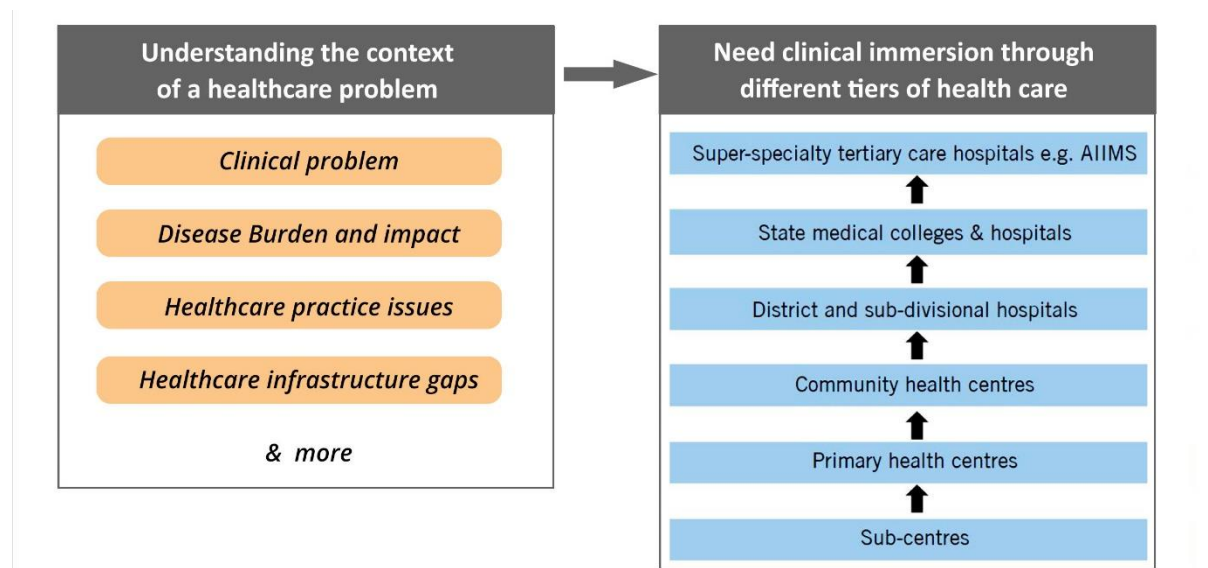


Figure 3-3: Multifactorial nature of healthcare problems (Source: author generated)

This level of involvement is vital for gaining a comprehensive understanding of the existing gaps in clinical services and opportunities for improvement. It also allows for a nuanced exploration of issues related to disease management, the specific requirements of various healthcare stakeholders, infrastructural challenges, the pain points experienced by patients, barriers rooted in socioeconomic disparities, and the systemic challenges that affect the delivery of healthcare services.

Complex nature of disease states, bio-mechanisms and pathophysiology

Developing a solution to address a clinical issue is a complex undertaking that requires a deep understanding of several crucial components. These components encompass a profound knowledge of the various disease conditions involved, a sophisticated comprehension of the underlying biological mechanisms at play, a comprehensive understanding of the pathophysiological processes, and a familiarity with the intricate network of clinical practices that govern healthcare. This intricate web of knowledge can be particularly challenging for

individuals lacking a clinical background, as illustrated in Figure 3.4, which highlights the complexity of these elements.

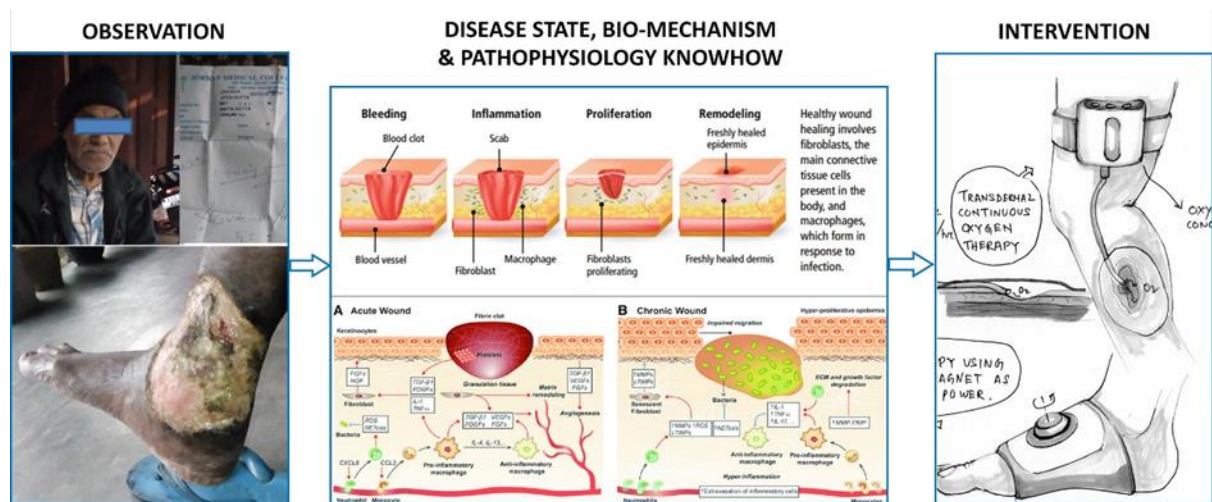


Figure 3-4: Complex nature of disease states, bio-mechanisms and pathophysiology (source: Author generated)

Furthermore, when it comes to fostering innovation in the field of medical technology, it's essential to acknowledge that progress must occur within the framework of established clinical protocols. Simultaneously, it must consider the available treatment options and adapt to our evolving understanding of pathophysiology. This innovative process must also navigate the ever-changing landscape of technology and the unique challenges presented by healthcare delivery. Balancing these elements and constraints is crucial to ensure that medical technology solutions are not only effective but also seamlessly integrated into the existing healthcare system, ultimately benefiting both patients and healthcare providers.

Critical nature of clinical intervention in terms of biocompatibility and patient interaction

Implementing innovative medical technology necessitates rigorous validation for patient safety and solution efficacy due to the critical nature of healthcare issues. Depending on the device's classification and patient interaction level, the technology's design and development must encompass strategies like comprehensive product safety testing, stringent quality control, essential clinical validation, and regulatory clearance. Figure 3.5 provides an overview of the diverse requirements for ensuring healthcare technology's readiness for the market. This involves a meticulous evaluation of potential risks, maintaining high manufacturing standards, confirming the technology's clinical benefits, and obtaining the necessary regulatory approvals. These steps are essential in navigating the complex process of bringing advanced healthcare solutions to the market, given the life-and-death implications often associated with healthcare problems

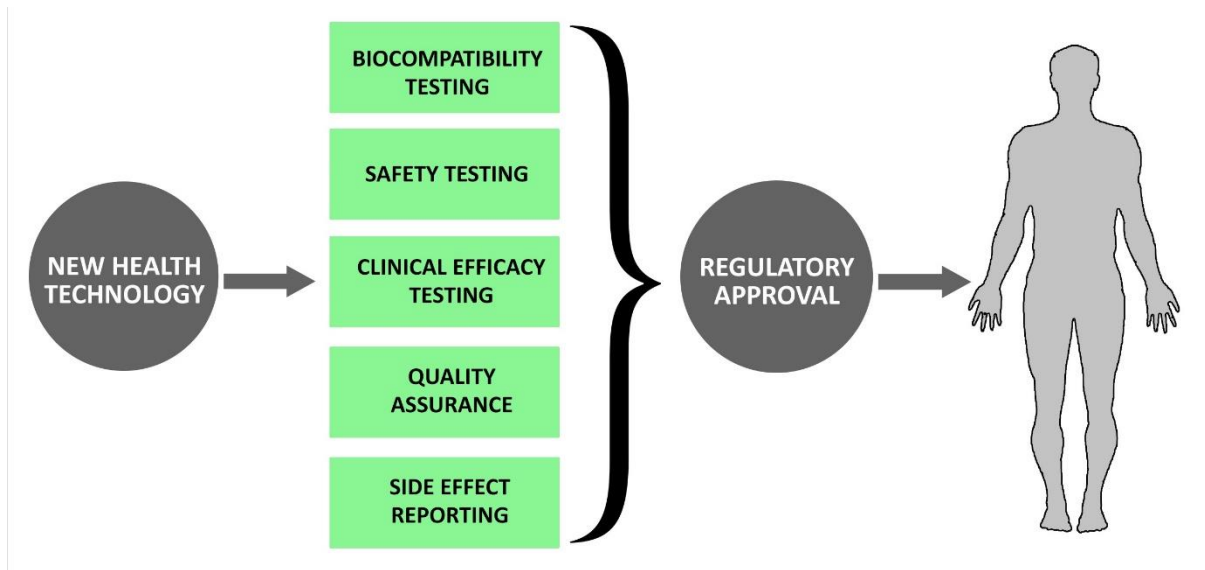


Figure 3-5: Critical nature of clinical intervention in terms of biocompatibility and patient interaction (Source: Author generated)

Entry barriers and indigenization issues to bring a solution into market

Achieving success in the implementation of medical technology demands careful consideration of strategies for commercialization, significant investments of time and financial resources during the design and development stages. Nevertheless, several formidable obstacles must be addressed when introducing new medical technology, such as securing a foothold in a fresh market segment, revolutionizing current clinical practices, establishing a competitive edge, and safeguarding intellectual property rights. These challenges necessitate meticulous pre-planning during the design and development phase. To ensure the triumphant commercialization of groundbreaking medical technology, a comprehensive approach is essential, encompassing effective management of intellectual property, rigorous competitive analysis, a compelling value proposition, meticulous research and development planning, strategic production planning, astute technology licensing, securing adequate funding, crafting a robust business strategy, and meticulous planning for sales, marketing, and distribution (Pisano, 2006; Ireland & Hine, 2007; Khilji, Mroczkowski, & Assudani, 2012).

3.3.2 Identified process supports requirements for medical technology innovation

Following thorough analyses conducted through focus group discussions on various design and innovation activities gleaned from past case studies, and taking into account the identified characteristics and constraints linked with medical technology innovation, we have brainstormed and identified a comprehensive set of detailed process supports essential for successful innovation in medical technology (Refer Table 3-D). These are as follows:

Table 3-D: Identified process supports requirements for medical technology design and innovation

Characteristics and constraints of medical technology innovation	Required process supports
<i>Multifactorial nature of healthcare problems</i>	To strategize for: <ul style="list-style-type: none"> • conducting field research to explore various clinical and healthcare implementation challenges • unmet clinical gap identification, analysis and selection • deriving user and stakeholder requirements
<i>Complex nature of disease state, bio-mechanisms and pathophysiology</i>	To strategize for: <ul style="list-style-type: none"> • assimilating clinical contexts (i.e. underlying biomechanism, pathophysiology etc.) while synthesizing solutions • mapping requirements and synthesizing design solutions • appropriate concept selection
<i>Critical nature of clinical intervention in terms of biocompatibility and patient interaction</i>	To strategize for: <ul style="list-style-type: none"> • product safety testing • quality control • clinical validation • regulatory clearance
<i>Entry barriers and indigenization issues to bring a solution into market.</i>	To strategize for successful medical technology implementation by: <ul style="list-style-type: none"> • overcoming entry barriers • overcoming commercialization challenges

Required process supports for ‘Multifactorial nature of healthcare problems’

(a) *To strategize for conducting field research to explore various clinical and healthcare implementation challenges:*

A process should facilitate in-depth research to understand the multifaceted healthcare problems. This include understanding the interconnections between clinical problem, socio-economic factors, demographic factors and poor policies, healthcare infrastructure issues and healthcare system issues.

(b) *To strategize for unmet clinical gap identification, analysis and selection:*

It should enable identification of deficiencies and unmet requirements in clinical practice by enabling data collection, multidimensional factor analysis and prioritization based on their significance and achievability.

(c) *To strategize for deriving user and stakeholder requirements:*

It should enable capturing end-users (e.g., patients, healthcare providers) and stakeholders (e.g., hospitals, regulatory bodies) requirements. For example, requirements can be patient or

provider pain points, regulatory requirements or can be hospital's business goals.

Required process supports for 'Complex nature of disease state, bio-mechanisms, and pathophysiology'

(a) To strategize for assimilating clinical contexts (i.e. underlying biomechanism, pathophysiology etc.) while synthesizing solutions:

A process should facilitate clinical problem solving. Such a process should allow integration of understanding of the disease state, etiology, clinical presentation, clinical course, underlying biomechanism, pathophysiological changes, while synthesizing solutions. Such process may enable collaboration with healthcare professionals and input uptake from real clinical scenarios.

(b) To strategize for mapping requirements and synthesizing design solutions:

It should facilitate mapping of complex healthcare requirements to potential design solutions. Such a process should allow solution analysis to identify critical design parameters.

(c) To strategize for appropriate concept selection:

It should facilitate performing multidimensional filtering and prioritization to evaluate and select the most promising design concepts.

Required process supports for 'Critical nature of clinical intervention in terms of biocompatibility and patient interaction'

(a) To strategize for product safety testing:

A process should guide strategy development to plan and ensure product safety and biocompatibility. Such a process should consider relevant Safety standards and regulations.

(b) To strategize for quality control:

It should guide strategy development to plan and implement quality control measures throughout the design and manufacturing process to maintain consistency and reliability. Such a process should consider relevant Quality standards and regulations.

(c) To strategize for clinical validation:

It should guide strategy development to plan and conduct clinical trials and testing of medical technology with a focus on patient interaction and safety. Such a process should consider collaboration with medical institutions and ethics committees.

(d) To strategize for regulatory clearance:

A process should facilitate establishment of regulatory strategies to navigate the approval process. Such a process should ensure compliance with local and international regulations, such as FDA in the United States or CE marking in Europe.

Required process supports for ‘Entry barriers and indigenization issues’

(a) To strategize for overcoming entry barriers

A process should facilitate forecasting and strategizing against possible market entry challenges that may impact product positioning and diffusion. Such a process should allow exploring competitive landscape, Intellectual property landscape, new value proposition, Cost to market estimation etc.

(b) To strategize for overcoming commercialization challenges:

It should facilitate forecasting and strategizing against possible commercial failure, so that necessary steps can be considered at an earlier stage in the design process. These include navigating through complex processes of manufacturing, Quality management, Regulatory compliances, business and reimbursement strategies.

3.3.3 Results of comparison

A comparative analysis of state of art design and innovation processes like User centered design (UCD) process, Human Centered Design (HCD) process, Design Thinking (DT) Process and Stanford Biodesign process, with respect to the identified process supports leads to following findings.

- i. The UCD process comprises of four stages: "Understand" involves empathizing with the user's experience, "Specify" focuses on identifying user needs, "Design" entails creating solutions through various design methods, and "Evaluate" assesses the design's alignment with user needs through testing and feedback. The most important problem to solve is determined by user needs and feedback, and the UCD process is iterative, allowing designers to revisit earlier stages to refine designs based on user input.
- ii. The HCD process extends UCD approach by considering all stakeholders or human needs, capabilities, and behavior in the design of a product. Otherwise the process scope is similar to UCD.
- iii. The DT process extends both UCD and HCD philosophy to problem solving by

integrating technical feasibility and business requirement of design, with needs of people. The DT process is a user-centric problem-solving approach with five core stages. It begins with “Empathize”, involving extensive user research to understand user needs and emotions. Next is “Define”, where a problem statement is crafted based on user research findings. “Ideate” follows, focusing on brainstorming and generating various design solutions for the identified problem. “Prototype” is the stage where rough drafts are created to illustrate the design's functionality. Finally, “Test” involves sharing and gathering user feedback on the prototypes. Design Thinking is iterative, allowing for repetition and adjustment of steps based on user feedback, making it a flexible process.

- iv. The Stanford Biodesign process like DT process, brings into account technical feasibility and business goals while addressing needs of people. Though both have similarities, the stages of Biodesign process are more defined for addressing clinical problem and patient-provider requirements by incorporating specific requirements of medical technology design and successful implementation. The Biodesign process mainly has 3 stages. “Identify” phase involve understanding clinical problem, requirements of patient and providers in a systematic way. Structured Need statements and need criteria are formulated after comprehensive data collection and analysis. The “Invent” phase involve team brainstorming ideas towards solution synthesis, prototyping and evaluating solutions based on specific pre-defined filters and experts’ feedback. Finally in the ‘Implementation’ phase various requirements for solution implementation are addressed like patent protection, clinical validation, regulatory route planning etc.

Table 3-E discusses these distinctions in detail, based on the requirements for process support previously outlined.

Table 3-E: Comparison of various design and innovation process w.r.t. identified process supports requirements

Required process supports	Stanford Biodesign process	Design Thinking Process	UCD process, HCD process
<p>To strategize for:</p> <ul style="list-style-type: none"> conducting field research to explore various clinical and healthcare implementation challenges. 	<p>The process incorporates methods for conducting field research and data collection. Various contextual enquiry methods like observation, interview, focus group enquiry etc. are part of it.</p>	<p>The process incorporates methods for conducting field research and data collection. Various contextual enquiry methods like observation, interview, focus group enquiry etc. are part of it.</p>	<p>The process incorporates methods for conducting field research and data collection. Various contextual enquiry methods like observation, interview, focus group enquiry etc. are part of it.</p>

Required process supports	Stanford Biodesign process	Design Thinking Process	UCD process, HCD process
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>unmet clinical gap identification, analysis and selection.</i> 	<p>The process is tuned for clinical gap identification which considers identification of clinical aspects like disease aetiology, clinical presentation, altered biomechanism, pathophysiological changes etc. Need selection process consider factors related to clinical problem, need of people, feasibility and business goal.</p>	<p>The process defines structured methods to analysis field research and user research data, identify and select design problem. Need selection process consider need of people, feasibility and business goal.</p>	<p>The process defines generic methods to analysis field research and user research data, identify and select design problem. Need selection process consider need of user and other stakeholders.</p>
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>deriving user and stakeholder requirements.</i> 	<p>The process facilitates structured method to define design requirements. Design requirements consider clinical problem, need of people, feasibility and business goal.</p>	<p>The process defines generic approach to define design requirements. Design requirements consider need of people, feasibility and business goal.</p>	<p>The process defines generic approach to define design requirements. Design requirements consider need of people.</p>
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>assimilating clinical contexts (i.e. underlying biomechanism, pathophysiology etc.) while synthesizing solutions</i> 	<p>No specific method that guides assimilating context specific information while solution synthesis. The process defines use of generic methods like brainstorming for solution synthesis.</p>	<p>No specific method that guides assimilating context specific information while solution synthesis. The process defines use of generic methods like brainstorming for solution synthesis.</p>	<p>No specific method that guides assimilating context specific information while solution synthesis. The process defines use of generic methods like brainstorming for solution synthesis.</p>
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>mapping requirements and synthesizing design solutions</i> 	<p>The process defines use of generic methods like, mind mapping for mapping requirements in solutions.</p>	<p>The process defines use of generic methods like mind mapping for mapping requirements in solutions.</p>	<p>The process defines use of generic methods like mind mapping for mapping requirements in solutions.</p>
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>appropriate concept selection</i> 	<p>The process suggests specific pre-calibrated filters for concept selection. Evaluation process demonstrates dependencies of implementation phase requirements in concept evaluation process. Final concept selection involves product prototyping, testing and taking patient-provider's feedback.</p>	<p>No pre-calibrated filters for concept evaluation. Concept evaluation involve use of generic tool like Pugh's matrix. with user defined evaluation filters. Final concept selection involves product prototyping, testing and taking stakeholder's feedback.</p>	<p>No pre-calibrated filters for concept evaluation. Concept evaluation involve use of generic tool like Pugh's matrix. with user defined evaluation filters. Final concept selection involves product prototyping, testing and taking stakeholder's feedback.</p>
<p>To strategize for:</p> <ul style="list-style-type: none"> • <i>product safety testing</i> 	<p>The process includes product safety testing and required strategy development aspects.</p>	<p>No aspects included in the process</p>	<p>No aspects included in the process</p>

Required process supports	Stanford Biodesign process	Design Thinking Process	UCD process, HCD process
To strategize for: <ul style="list-style-type: none"> quality control 	The process includes Quality management and required strategy development aspects.	No aspects included in the process	No aspects included in the process
To strategize for: <ul style="list-style-type: none"> clinical validation 	The process includes clinical validation and required strategy development aspects.	No aspects included in the process	No aspects included in the process
To strategize for: <ul style="list-style-type: none"> regulatory clearance 	The process includes regulatory requirements and required strategy development aspects.	No aspects included in the process	No aspects included in the process
To strategize for successful medical technology implementation by: <ul style="list-style-type: none"> overcoming entry barriers 	The process discusses strategies related to intellectual property (IP) management, R&D management, Marketing, sales and distribution management etc.	No aspects included in the process	No aspects included in the process
To strategize for successful medical technology implementation by: <ul style="list-style-type: none"> overcoming commercialization challenges 	The process discusses strategies related to manufacturing, operation and finance, Funding, business planning and reimbursement.	No aspects included in the process	No aspects included in the process

3.3.4 Identifying process improvements for medical technology innovation

Medical technology design and innovation brings its own course of design, development and implementation challenges, which is often alien to most mainstream product designers. Many times, designers often lack knowledge about the characteristics and constraints associated with medical technology innovation and implementation. Key reasons being lack of awareness and access to a clinical scenario, lack of institutional collaborations and stakeholder access, complex nature of clinical problem, complex roadmap of solution realization etc.

The comparison made in this study demonstrate that though the UCD, HCD and the Design Thinking process offer broad frameworks for conducting user and stakeholder research, identifying needs, comprehending usage contexts, and specifying user requirements when dealing with specific business objectives or problem statements, however, for medical technology design and innovation, designers must gain in-depth knowledge of disease states, pathophysiology, treatment options, stakeholder requirements, healthcare delivery challenges, and more before embarking on the need identification and selection phase. While prior literature has discussed the utilization of these methods in designing medical technology, the comparative analysis presented in Table 3-E indicates that the general process support offered

by UCD, HCD, and the Design Thinking process is inadequate and requires further refinement to meet the demands of medical technology innovation.

The comparison further revealed that, the requirement analysis and design phases of all the four design processes share similarities in their underlying activities. However, in case of the Biodesign process, Concept evaluation activity involve use of specific pre-calibrated filters like intellectual property opportunities, regulatory compliance, business potential, technical feasibility, team feasibility, and stakeholder feedback for concept filtering. This process fine tuning is hardly considered in generic process like UCD, HCD and DT.

Furthermore, the Biodesign process ensures that medical technology implementation aligns with demands related to design validation for patient safety, clinical efficacy, and strategic planning for successful market penetration and commercial sustainability. Though these aspects are vital for Medical Technology design and innovation process, those are completely missing in the generic processes.

Modifying UCD process for medical technology innovation

The following presents an example of theoretical synthesis of study findings and explores how one can adapt the popular UCD approach to better align with healthcare design and innovation projects.

For User-Centered Designers, attempting medical technology innovation without a solid understanding of the Medical technology design and innovation requirements presents a formidable challenge. The comparative analysis of current study assists in comprehending such process gaps within the conventional UCD approach. Figure 3.6 illustrates a modified UCD framework, referred to as "Healthcare Centered Design (HCD)," which seamlessly integrates additional activities and phases to consider requirements of medical technology innovation. As depicted in Figure 3.6, the proposed theoretical HCD framework extends the 'Design research' activities of conventional UCD process by incorporating additional methods, for investigating healthcare delivery context, need filtration and design requirement generation. These changes will also have an impact on the 'Design' phase, as the solution synthesis process becomes more objective, addressing specific criteria and needs. Next, for the 'Design Evaluation' phase, distinct concept selection filters specific to medical technology innovation are proposed to incorporate, in addition to prototype testing and usability studies. Further, a completely novel phase, "Design Implementation," is introduced to ensure the validation of solutions and planning and strategy development for successful implementation. Similar to the Biodesign

process, this theoretical framework showcases several optimizations to address the requirements and constraints inherent in medical technology design and innovation.

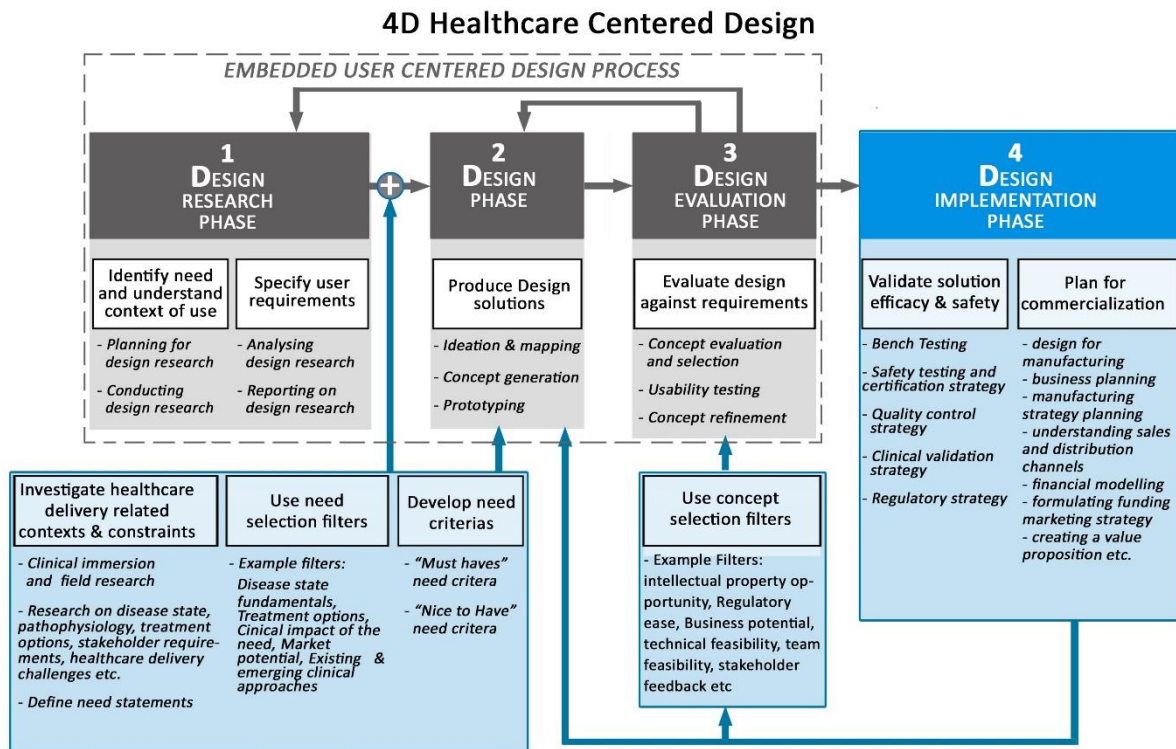


Figure 3-6: Proposed Healthcare Centered Design (HCD) process (author generated)

3.4 Conclusion

This chapter has explored the importance of design and innovation processes with a particular focus on medical technology innovation. The literature demonstrates the successful application of established design and innovation processes such as User-centered Design, Human-centered design, Design thinking, and the Stanford Biodesign process in driving innovation in medical technology. These processes have proven instrumental in addressing complex challenges and generating innovative solutions, as evidenced by numerous case studies. However, despite our existing understanding of how systematic processes function, there remains a significant gap in comprehending the specific process needs and conducting comparative analyses of different design and innovation processes when applied to medical technology projects. This study sought to address these crucial questions, aiming to uncover the unique requirements of medical technology design and innovation projects compared to traditional product design and innovation, thereby contributing to the advancement of this vital field.

The research methodology used in this study was comprehensive and structured, designed to advance our understanding of medical technology innovation. It began with a

rigorous literature review that identified and filtered 53 relevant case studies related to medical device innovation. The subsequent phases of the research delved deeper into the characteristics and constraints of medical technology innovation, ultimately revealing the unique requirements of medical technology innovation and process supports essential for facilitating successful medical technology innovation initiatives.

A comparative analysis of established design and innovation processes highlighted specific deficiencies of existing generic design and innovation processes in addressing the complexities of medical technology innovation. To bridge this gap, the study proposed a modified User-Centered Design framework called "Healthcare Centered Design (HCD)" which integrates additional activities and phases to address the unique needs of medical technology innovation projects. The development of the "Healthcare Centered Design (HCD)" framework presented in this study provides a promising path forward. By embracing this new framework, designers can ensure the consideration of critical factors in medical technology innovation that User-Centered Design may overlook, ultimately enhancing the success of User-Centered Designers in medical technology innovation projects. Future work could involve experimental validations of the HCD process in developing healthcare solutions with practicing designers, contributing significantly to the field of medical technology innovation, especially for industrial designers trained in the UCD approach.

Chapter 4. Identifying LMIC-specific Design and Innovation Process Characteristics for Medical Technology innovation

Abstract

The conventional framework for innovating medical technology in developed nations does not align well with the needs of Low- and Middle-income countries (LMICs), as evidenced by past studies. This mismatch can be attributed to differences in healthcare systems, sociocultural sensitivities, and the underdeveloped innovation ecosystem in LMICs. Consequently, the Stanford Biodesign process, which adopts an industrialized approach to medical technology design and development, has been found lacking in addressing the specific requirements of LMICs. However, past research reports have not thoroughly laid the groundwork to establish the limitations of the conventional Biodesign process for LMICs. To address this gap, our study employed a two-phase research methodology. During the first phase, we performed a thorough examination of the challenges and barriers specific to LMICs (as discussed in Chapter 3) to determine which of these issues can be tackled within the design and innovation process. In the second phase, we conducted semi-structured interviews with Biodesign fellowship alumni startups in India to gain insights into the challenges faced and the solutions adopted within the different stages of the Biodesign process throughout their journeys in medical technology design and innovation. By triangulating the findings from both phases, we identified a set of critical design process characteristics that are essential for creating healthcare solutions to meet the unique demands of LMICs. Furthermore, by building upon the process supports requirements for medical technology innovation processes outlined in Chapter 2 and incorporating the design process characteristics revealed in our ongoing research, our study illuminates the shortcomings of the widely adopted Stanford Biodesign process, explaining why and how it falls short in the context of LMICs. This research significantly contributes to the field of design epistemology by exploring how to effectively design medical technologies for LMIC settings.

4.1 Introduction and Background

The development and localization of medical devices for low- and middle-income countries (LMICs) holds paramount importance for various reasons. These include addressing

indigenous healthcare demands and diseases, decreasing reliance on imports and healthcare expenses, as well as nurturing domestic manufacturing and the expansion of local economic sectors (WHO, 2010). Yet, the path of medical technology advancement is marked by intricacy, arising from complex clinical issues, strict efficacy and safety demands, rigorous regulations, high expenses, and a long path to commercial success (Dutta & Dhar, 2021).

PHASES	IDENTIFY		INVENT		IMPLEMENT	
	1. NEED FINDING	2. NEEDS SCREENING	3. CONCEPT GENERATION	4. CONCEPT SCREENING	5. STRATEGY DEVELOPMENT	6. BUSINESS PLANNING
ACTIVITIES	1.1 Strategic Focus 1.2 Needs Exploration 1.3 Need Statement Development	2.1 Disease State Fundamentals 2.2 Existing Solutions 2.3 Stakeholder Analysis 2.4 Market Analysis 2.5 Needs Selection	3.1 Ideation 3.2 Initial Concept Selection	4.1 Intellectual Property Basics 4.2 Regulatory Basics 4.3 Reimbursement Basics 4.4 Business Models 4.5 Concept Exploration & Testing 4.6 Final Concept Selection	5.1 IP Strategy 5.2 R&D Strategy 5.3 Clinical Strategy 5.4 Regulatory Strategy 5.5 Quality Management 5.6 Reimbursement Strategy 5.7 Marketing & Stakeholder Strategy 5.8 Sales & Distribution Strategy 5.9 Competitive Advantage & Business strategy	6.1 Operating Plan & Financial Model 6.2 Strategy Integration & Communication 6.3 Funding Approaches 6.4 Alternative Pathways

Figure 4-1: Stanford Biodesign Process-Phases, stages, and activities (source: (Yock, et al., 2010))

Employing a methodical strategy for designing and innovating medical technologies is vital to navigate the intricate challenges linked with medical technology innovation. Systematic processes offer clear paths, aiding strategic planning and diverse activity management for successful implementation (Gray, 2022; Daalhuizen & Cash, 2021). The renowned "Biodesign Process," also known as the "Stanford Biodesign process," (see Figure 4.1) is a prominent medical technology design and innovation process that effectively addresses clinical requirements and fosters successful medical technology innovation through its multifaceted approach. Distinguished among prior design and innovation processes, it offers a structured roadmap rooted in design thinking principles, catering to healthcare entrepreneurship and

adeptly guiding medical technology innovation (Yock, et al., 2010). In many LMICs, there are governmental initiatives designed to introduce and educate talented students, innovators, researchers, and academics to the Biodesign process. The primary aim of these programs is to inspire and provide guidance for MedTech entrepreneurship, ultimately fostering the development of local medical technology within the region (Wall, et al., 2017).

Application challenges of Biodesign process in LMICs

In managing medical technology innovation, LMICs face unique challenges that are deeply influenced by a range of systemic, organizational, and demographic factors detailed in Chapter 2. Key obstacles include uneven healthcare coverage and resource allocation, skill shortages, and regulatory uncertainties, all of which complicate the adoption and integration of new technologies. Additionally, R&D in LMICs is constrained by limited funding, inadequate local manufacturing capabilities, and a dependency on imports which escalate costs and complicate technology transfer (refer to Chapter 2 pages 98-100, for a detailed discussion on these factors). Socio-cultural dynamics also play a critical role, introducing barriers such as stigma, privacy concerns, and diverse healthcare needs that affect the diffusion of medical technologies. For a comprehensive overview of these challenges and their impact on innovation management within LMICs, see the detailed analysis in 'Results' and 'Discussion' section of Chapter 2.

The existing framework of the Biodesign process follows an industrialized approach and does not adequately account for such country-specific influencing factors. Previous studies had recognized limitations when adapting the Biodesign process for LMICs and made modifications to adapt it to local needs. For example, a 2015 study by J. Chaturvedi et al. reported that LMICs like India have distinct clinical requirements compared to developed economies due to factors such as low affordability, a complex healthcare ecosystem, non-standard medical practices due to resource limitations, the absence of mandatory medical technology assessments, insufficient insurance coverage, and a lack of reimbursement provisions, all of which hinder the implementation of expensive medical procedures. Consequently, in that study the process of data collection and need identification within the Biodesign process was tweaked to meet the requirements of countries like India (Chaturvedi, Logan, Narayan, & Kuttappa, 2015). Similar adaptations were reported in follow-up studies in areas like otorhinolaryngology, emergency medicine, and nephrology (Arun-Kumar, Sridhar, Chaturvedi, & Deshpande, 2017; Chachra, et al., 2018; Chaturvedi & Srinivas, MedTech Innovation using a structured Biodesign process Barriers and Opportunities, 2021).

While prior research acknowledges the challenges faced in medical technology design and innovation within low- and middle-income countries (LMICs) and suggests some modifications to the conventional Biodesign process, they lacked the groundwork that established the necessary process modification that could effectively tackle country-specific factors affecting Medical technology design and development. Additionally, previous studies often overlook presenting data how LMIC-specific challenges influences a medical technology innovation journey. Recognizing previous research gaps, this study aims to investigate multiple case studies of medical technology design and innovation in LMICs. The objective is to identify specific innovation process requirements for integrating LMIC-specific factors into the medical technology innovation process, which may have been overlooked by the existing Biodesign process. Our study concentrates on the Indian MedTech context as India qualifies as an LMIC and is a significant player in the global MedTech and biopharmaceutical research market (Data for India, Lower middle income, 2021).

4.2 Methodology

The study aimed to investigate the roadmaps and challenges of medical technology innovation faced by startups in LMICs, with a focus on identifying deficiencies in the current Biodesign innovation process.

4.2.1 Phase 1: LMIC-specific challenge analysis for design and innovation

The initial phase of our research involved an examination of the specific challenges and obstacles related to medical technology innovation in LMICs that were previously discussed in Chapter 3. Our goal was to determine which of these challenges could be addressed through design methods and activities. We enlisted a team of three design researchers and one faculty with prior experience in developing and using design processes, to analyze the 23 axial codes identified in Table 3-E of Chapter 3. Challenges that were deemed beyond the scope of a design and innovation process were excluded. This evaluation serves as the initial groundwork for comprehending the set of LMIC-specific challenges that a design and innovation process should be capable of addressing (Refer to section 4.3.1 for the results of the analysis).

4.2.2 Phase 2: Semi-structured interviews with Indian Biodesign fellowship alumni startups

In Phase 2, Semi-structured interviews were conducted with Biodesign Fellowship Alumni Startups from India to explore medical technology innovation journeys, and various LMIC-specific challenges faced with respect to the three phases of the Biodesign process.

Sampling

The study engaged nine persons from seven Indian Biodesign Fellowship Alumni Startups for interview purposes, each with 4-10 years of operation and a range of clinical and product offerings. The final sample size was determined by halting interviews when information repetition became apparent among the participants. The selection process employed purposive and expert sampling methods, considering the qualifications, performance, and capabilities of key personnel (Dolores & Tongco, 2007). All the interviewees were experts in the Biodesign process. They received extensive field exposure and training in the product design process, encompassing design thinking and manufacturing aspects, for over a two-year period. Moreover, as founders and CEOs, they had complete exposure to all aspects of the product lifecycle. The objective was to analyze the challenges encountered and solutions adopted by these firms throughout the three phases of the Biodesign process in their innovation journeys (Eisenhardt, 1989).

Data collection

The primary objective of the interviews was to collect information and comprehend how different Biodesign Fellowship Alumni implement the Stanford Biodesign Process in their innovation journeys. The focus was on evaluating the extent to which the process facilitated their real innovation endeavors. Additionally, the interviews sought to uncover any barriers or implementation challenges faced by the alumni when applying the process in the Indian context. Lastly, the interviews aimed to assess the clarity of the implementation roadmap for their products. A set of interview questions (see Table 4-A) were developed and validated further through pilot interviews and experts' feedback. These interviews also encompassed follow-up inquiries beyond those of Table 4-A. All these interviews were conducted online and meticulously documented in audio and video recordings, and subsequently transcribed. The interviews continued until a point of theoretical saturation was reached, ensuring comprehensive data collection. Table 4-B presents details on seven biotech firms, job profiles of nine interviewees, and relevant firm information.

Table 4-A: Sample interview questions

Sample interview questions
<ul style="list-style-type: none"> • Tell me about the medical device you're developing for commercialization. • Did you follow a specific design and innovation process like Stanford Biodesign in your product development? • How did you choose the specific need area for your medical device? • Can you summarize the key design and implementation milestones of your project?

- Were there any significant barriers or external factors that impacted your development journey?
- How does the Biodesign process you learned at AIIMS compare to your real-world experience?
- Was the implementation roadmap clear to you at the end of the Proof of Concept development?
- Further follow-up questions. (Probing questions: Can you elaborate? or can you give specific detail?).

Table 4-B: Startups and interviewee profiles

Sl no	MedTech Startups	Interviewee designation
1	Curious Labs Private Limited	Founder & CEO (Biodesign process expert)
2	Brun Health Private Limited	Founder (Biodesign process expert)
3	Innoweave Biocare Pvt Ltd	Director (Biodesign process expert)
4	Innoweave Biocare Pvt Ltd	Co-Founder (Biodesign process expert)
5	JC OrthoHeal Private Limited	CEO (Biodesign process expert)
6	Consure Medical	Co-founder, CTO (Biodesign process expert)
7	Consure Medical	Co-Founder & CEO (Biodesign process expert)
8	Sohum Innovation Lab	Founder & CEO (Biodesign process expert)
9	Cohesive Design Labs	Founder & Design director (Biodesign process expert)

Data analysis

To analyze the data from a design perspective, we involved a team of three design researchers and one faculty member with prior experience in developing and using design processes. Further analysis of interview transcripts involved extracting data related to barriers and challenges faced by startups at various stages of the Biodesign process and the solutions adopted. A cross-check with previously identified challenges specific to LMICs (from Chapter 3) was conducted to identify similarities and variations. Finally, we categorized the issues that can be addressed through process modification or the addition of new methods.

4.2.3 Identify critical LMIC-specific design and innovation process characteristics

Through the combination of findings from both phase 1 and 2 of the study, we pinpointed a set of pivotal design and innovation process attributes that are crucial for developing healthcare solutions that can effectively address the distinct needs of low- and middle-income countries. This was done on the basis of mapping the various challenges and evaluating the core characteristic of the desired solution.

4.2.4 Analyzing Stanford Biodesign process in the context of LMICs

The primary objective of this study was to illuminate the limitations of specific stages and activities within the widely employed Stanford Biodesign process, particularly in the context of applications in Low- and Middle-Income Countries (LMICs). To achieve this, a two-stage evaluation method was employed. In the first stage, we assessed the adequacy of the Biodesign process in meeting the requirements of medical technology innovation, as outlined in Chapter 2. In the second stage, an evaluation was conducted on the three phases, stages, and activities

of the Biodesign process against the characteristics specific to LMICs' design and innovation processes.

By comparing the results obtained from both stages, we drew conclusions about the overall limitations of the conventional Biodesign process in the context of LMIC-specific applications. This systematic approach not only highlighted existing challenges but also facilitated the identification of potential areas for improvement within the conventional Biodesign process. All findings were validated with the interviewees at a later stage, through telephonic discussions

4.3 Results

4.3.1 Medical technology innovation challenges that are addressable in a design and innovation process

Table 4-C below listed the 23 LMIC-specific challenges and barriers identified in chapter 3.

Table 4-C: 23 LMIC-specific Challenges of Medical Technology Innovation (refer Chapter 3)

LMIC-specific challenges of medical technology innovation
1. Non-uniform healthcare system and practices
2. Inadequate healthcare resources, staff, infrastructure, and services
3. Poor healthcare management of health institutions
4. Inferior healthcare quality and practice
5. Inefficient procurement and vendor payment processes of health institutions
6. Limited risk capacity and innovation appetite.
7. Innovation misfit and misplacement
8. Inadequate innovation strategy and execution
9. Poor stakeholder collaboration and synergy
10. Poor Medical innovation knowledge and capability
11. Lack of innovation culture
12. Inadequate government support and policies
13. Lack of experts, educational schemes and infrastructure for technology translation.
14. Inadequate and evolving regulatory and IP frameworks
15. Inadequate funding and investment support for innovation
16. Lack of local resources, manufacturing and testing provisions
17. Disease diversity, unequal healthcare coverage.
18. Varied socioeconomics and cost sensitivity
19. Socio-Cultural diversity and barriers
20. Widespread prevalence of ill practices
21. Competitive and fragmented market
22. Market entry barriers for new innovation
23. Complexities inherent to clinical problems, biology and solutions

Table 4-D demonstrates the results of the analysis aimed at identifying challenges and barriers to medical technology innovation that can be addressed within a design and innovation process and how they can be addressed. Three main categories were identified:

- i. challenges that cannot be addressed in a design and innovation process,

- ii. challenges that are partially addressable, and
- iii. challenges that are completely addressable.

Among the 23 challenges, four were identified as primarily beyond the scope of addressing through a design and innovation process. These challenges include: *Inefficient procurement and vendor payment processes of health institutions, Limited risk capacity and innovation appetite, Lack of innovation culture and Widespread prevalence of ill practices.*

Five out of the 23 challenges were identified as partially addressable within a design and innovation process. These challenges include: Poor healthcare management of health institutions, Inferior healthcare quality and practice, Poor stakeholder collaboration and synergy, Poor Medical innovation knowledge and capability, and Complexities inherent to clinical problems, biology and solutions.

The remaining 14 challenges out of the 23 can be effectively addressed within a design and innovation process.

Table 4-D: Possible ways how challenges and barriers can be addressed in design and innovation process

Challenges and barriers of medical technology innovation	Possible way to address in a design and innovation process
1. <i>Non-uniform healthcare system and practices</i>	A design and innovation process can aid in identify healthcare service disparities and address during inventing solution and implementation.
2. <i>Inadequate healthcare resources, staff, infrastructure, and services</i>	A design and innovation process can aid in forecasting usability issues of new design due to infrastructure and resource limitations and address them during inventing solution and implementation.
3. <i>Poor healthcare management of health institutions</i>	This problem is partly causal and partly human related to human negligence. The causal aspect can be addressed in a design and innovation process by identifying reasons for poor healthcare management and address them during inventing solution and implementation.
4. <i>Inferior healthcare quality and practice</i>	This problem is partly causal and partly related to human negligence. The causal aspect can be addressed in a design and innovation process by identifying reasons for poor healthcare quality and practice and address them during inventing solution and implementation.
5. <i>Inefficient procurement and vendor payment processes of health institutions</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process only can aid by providing strategy development method, to overcome such barriers
6. <i>Limited risk capacity and innovation appetite.</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process only can aid by providing strategy development method, to overcome such barriers
7. <i>Innovation misfit and misplacement</i>	A design and innovation process can aid in identify all various implementation requirements, opportunities and address during inventing solution and implementation

Challenges and barriers of medical technology innovation	Possible way to address in a design and innovation process
8. <i>Inadequate innovation strategy and execution</i>	A design and innovation process can facilitate methods to develop strategies for the execution of required activities of medical technology innovation
9. <i>Poor stakeholder collaboration and synergy</i>	This problem is partly addressable if collaboration is required for design decision making, knowledge share and co-design. A design and innovation process can facilitate tools and processes that require collaboration.
10. <i>Poor Medical innovation knowledge and capability</i>	This problem is partly addressable A design and innovation process can facilitate systematic process, tools and processes to execute a medical technology innovation project.
11. <i>Lack of innovation culture</i>	This problem is mostly beyond the scope of addressing using a design and innovation process.
12. <i>Inadequate government support and policies</i>	A design and innovation process can identify issues related to healthcare policies, government initiatives and address during inventing solution and implementation.
13. <i>Lack of experts, educational schemes and infrastructure for technology translation.</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
14. <i>Inadequate and evolving regulatory and IP frameworks</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
15. <i>Inadequate funding and investment support for innovation</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
16. <i>Lack of local resources, manufacturing and testing provisions</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
17. <i>Disease diversity, unequal healthcare coverage.</i>	A design and innovation process can identify such issues and address during inventing solution and implementation.
18. <i>Varied socioeconomics and cost sensitivity</i>	A design and innovation process can aid in identify such issues related to socio-economics and affordability and address during inventing solution and implementation.
19. <i>Socio-Cultural diversity and barriers</i>	A design and innovation process can aid in identify such issues related to socio-cultural barriers and address during inventing solution and implementation.
20. <i>Widespread prevalence of ill practices</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process can aid in identify such issues and address during inventing solution and implementation.
21. <i>Competitive and fragmented market</i>	A design and innovation process only can aid by providing strategy development method, to overcome such barriers.
22. <i>Market entry barriers for new innovation</i>	A design and innovation process only can aid by providing strategy development method, to overcome such barriers
23. <i>Complexities inherent to clinical problems, biology and solutions</i>	This problem is partly addressable A design and innovation process can aid with tools for better understanding clinical problems underlying biology and inventing creative clinical solutions

4.3.2 Navigating challenges in medical technology innovation: perspectives from Indian Biodesign fellowship alumni

The interview transcripts unveiled numerous challenges encountered by the Indian Biodesign alumni during the innovation of their clinical solutions. As part of our study, we systematically mapped these identified challenges and corresponding preventive measures to the stages and activities of the Biodesign process for further analysis. Table 4-E provides a summary of the findings and our analysis, indicating all various issues that could have addressed within a design and innovation process through strategic or systematic measures. Previous reference of LMIC-specific innovation challenges and barriers were also considered to define some of the issues.

Table 4-E: Analysis of reported challenges of medical technology innovation by Indian Biodesign fellows

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
IDENTIFY phase	“that’s where most of the innovators really face the real challenge of how to identify a need.”	Poor need assessment. No guidelines on what problem to look for	Not reported	Yes. Probably by providing some sort of template and example of problems
	“I designed initially keeping in mind that this is for developing countries or emerging economies where these devices are not available or they need to import the devices. However, there is a constraint of too much Noise in the environment or like the health care providers’ places are too much crowded. Uhm, many of those things which needs to be solved like they can’t be solved”	Diverse Healthcare implementation issues apart from only clinical aspect. Biodesign process does not systematically cater implementation problems during need finding.	Not reported	Yes. By identifying all sort of systemic implementation problems while developing need statements.
	“Not too many people especially in a country like India seek treatment for those kinds of conditions nor a lot of treatments are provided in such areas”	Poor healthcare services or healthcare service gaps. Problem identification in Biodesign process is restricted to	Not reported	Yes. A method to analyze state of art healthcare solutions and map their availability in healthcare settings to identify service gaps.

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
		clinical immersion and observation. It can't observe things that does not exist in a system		
---- More ----				
INVENT phase	“one challenge would be key. Uh, like, how would you bring out a solution which can actually solve the problems of different stakeholders? Because once you solve the problem, it's not just solving the problem of one stakeholder, there are multiple stakeholders involved. So one initial challenge we faced was this though we had different concepts with us.”	No involvement of stakeholder in the design process. The Biodesign process currently does not defy a participatory design approach	“We wanted to come out with a solution which could actually solve the major stakeholders problem”	Yes, Participatory design approach can be employed by including real patient, hospital authority, clinician at the time of solution synthesis.
	“we wanted a urine sample to be transported from KM hospital to IIT Bombay. OK, and that takes around forty 30-40 minutes. In my research, I did not know that proteins in the urine can get destroyed in that time frame. That impact our solution”	Poor understanding of Biology impacted the solution. The Biodesign process currently employed a generic brainstorming session to problem solving which is nothing but just a collaborative ideation technique.	“Making sure that you're going. To take the sample without destroying that. Protein we have to do the research. We had to tell them that we will. Actually freeze it. Or we will use the ice pack.”	Yes, some techniques enhancing creativity in clinical problem solving can be useful. Also systematic considerations of all dependencies of the invention need to be made.
	“but the fact is repositioning the patient, on a timely basis, for every 2-hour duration, which is recommended, is kind of impossible in a country like ours or in a very resource constraint setting”	Invention did not consider implementation issues. Currently Invent phase of Biodesign process does not	Not reported	Yes. By identifying all sort of systemic implementation problems while ideating solutions

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
		systematically address implementation issues of a solution.		
---- More ----				
IMPLEMENT phase	“Prototyping short batch manufacturing especially if you doing a class 2 or class 3 device which has to be done in a certain environment, has to be sterilized, and has to be made in a certain kind of material is still a challenge.”	Lack of local resources, manufacturing and testing provisions. Though Biodesign process discusses manufacturing strategies in general, it does not provide any tool to forecast implementation issues and identify solutions	“Of course, you always, if you have the money and the means you can always go out and work with companies that are in the west or even in south-east Asia.”	Somewhat addressable, A problem prediction and strategy development methodology can help
	“Sometimes the change would happen because you learn something new in the clinical setting that could happen at the stage of clinical trial, and you would be lucky to find all of that at the stage of bench-top testing and make those changes.”	Long chain of dependency in medical technology design. The Biodesign process though described as iterative, does not disclose such dependencies	“Design changes occur all the times, we changed the design even today”	Yes. A problem prediction and strategy development methodology can help. Such issues can address that by incorporating these dependencies at an early stage in the design process
	“Sometimes you have to change the product to meet regulatory requirements, ... just to take example...US have different regulations using PVC as a material in your product, India has different regulations, Europe has different regulations, so you may be able to sell your product with PVC tubing..PVC component in your product in India, you may not be	Lack of regulatory harmonization. The Biodesign process does cover only standard US FDA, CE regulations.	“And That’s when you need to make a product change.”	Somewhat addressable, A problem prediction and strategy development methodology can help. while inventing or R&D Regulatory concerns could be analyzed and strategically addressed

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
	able to sell in US or in Europe.			
	“It is still not a notified device in India.”	Inadequate and evolving regulatory and IP frameworks. The Biodesign process does cover only standard US FDA, CE regulations.	“..So we took a slightly more proven pathway.. even back then when .. the regulatory framework is not available in India, we still went ahead and got FDA approval first before selling our first product anywhere”	Yes, A problem prediction and strategy development methodology can help. Also, while identifying need, Inventing solutions regulatory roadmap could have been explored
	“other challenge is the hiring process, which, if I would say or the team building process because you because you don't have the bandwidth of hiring experienced people in in such a grant funded situation.”	Lack of Funding strategy. Though Biodesign process discusses funding related strategy making it does not provide actionable tool to forecast probable issues and strategy development.	“team building is always still a challenge, which still we are trying”	Yes, A problem prediction and strategy development methodology can help.
	“we had issues early on with sensor design, then we fixed that. We built the electronics. Uh, you know, went on with the user into. Phase we had challenges in terms of how the displays design, how is it accessed? We had issues with wireless communication. when we integrate it all into the same package, the biggest challenge we had was. That we couldn't separate out the feedback loop from the acoustic system from the audio from the speaker to the ultrasound sensors that	Poor R&D management. Though Biodesign process discusses R&D related strategy making it does not provide actionable tool to forecast probable issues and strategy development	“we went across trying to fix this through different processes. Mechanical design, better dampening processes, electronics design and algorithm design. But none of the procedures ended up being effective enough to give us what we want, at least with respect to”	Somewhat addressable, A problem prediction and strategy development methodology can help.

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
	were supposed to sense to fetal heartbeat.”			
	“Other than that, the implementation part was not at all clear. Everything was learned on to go even now we were actually learning it like how should we actually go forward in terms of conducting the trials or regulatory or stuff like. It's not evident anywhere that you have to follow these 10 steps to go there.”	Poor understanding of implementation roadmap. The implementation stages and activities of Biodesign process although informative, provide no actionable tool to strategize objectives, predict time line etc.	Not reported	Somewhat addressable, A common strategy development methodology and timeline prediction approach can help.
	When you are already into the research and development phase and you don't get enough fund to. To give the salary to the people to give the money to or like a payment to your customer like vendors. Then your whole process will be delayed and it will lose the excitement in the team and people will not able to execute in time.	Lack of Funding strategy. Though Biodesign process discusses funding related strategy making it does not provide actionable tool to forecast probable issues and strategy development	“Get the funding on time is important”	Yes, A problem prediction and strategy development methodology can help.
	“More often than not, we end up being very poor estimators of. Project execution timelines, especially in health care, given that there's so many players that we need to deal with before it even reaches the market, and then some more after it starts selling”	Poor understanding of implementation roadmap. The implementation stages and activities of Biodesign process although informative, provide no actionable tool to strategize objectives,	“So you want to take on projects where, let's say, you have decided that you want to allot a 3 year timeline. I would say if you have, you need to plan to reach the market in 30 to 40% of the time that you have allotted for the overall project”	Somewhat addressable, A common strategy development methodology and timeline prediction approach can help.

Phases of Biodesign Process	Examples of reported issues	The problem from Biodesign process perspective	Reported solution or preventive measure	Is the solution addressable by a design and innovation process
		predict time line etc.		
	“We are working on. And you know. Uh, we were trying to use ultrasound technology, which in itself was a big challenge in terms of procurement from local Indian manufacturers.”	Lack of local resources, manufacturing and testing provisions. Though Biodesign process discusses manufacturing strategies in general, it does not provide any tool to forecast implementation issues and identify solutions	“we did approach one of the defense labs based out of Delhi and we got some samples but the quality was inadequate.”	Somewhat addressable, A problem prediction and strategy development methodology can help.
	“That’s a challenge in India especially, and that’s a challenge everywhere but more so in India ... that if you are not in a clinical setting just getting a clinical trial going is not really straightforward forward and it takes lot of pain to get clinical trials going on.”	Poor stakeholder collaboration and synergy. Though Biodesign process discusses clinical trial strategies in general, it does not provide any tool to forecast implementation issues and identify solutions	“surrounded with very motivated and skilled mentors and clinicians who are forthcoming and helping us with our clinical trials.”	Yes, A problem prediction and strategy development methodology can help. While clinical strategy making such problems could
	---- More ----			

4.3.3 Identified LMIC-specific design and innovation process characteristics

By triangulating the findings of the two phases of the study, the research study further categorizes the addressable challenges and outlines potential design actions aimed at developing six essential characteristics of a design and innovation process tailored for LMIC context. These characteristics encompass, *Addressing clinical problem, Addressing disparities in healthcare systems, Overcoming socio-cultural barriers, Navigating underdeveloped innovation ecosystems, Managing organizational innovation challenges and Tackling market entry challenges*. Table 4-F illustrates these six categories along with their respective

addressable challenges and possible design and innovation strategies for mitigation.

Table 4-F: LMIC-specific design and innovation process characteristics

LMIC-specific design and innovation process characteristics	Addressable challenges and barriers of medical technology innovation	Possible way to address in a design and innovation process
Addressing clinical problem	<i>Complexities inherent to clinical problems, biology and solutions</i>	This problem is partly addressable A design and innovation process can aid with tools for better understanding clinical problems underlying biology and inventing effective clinical solutions
Addressing disparities in healthcare systems	<i>Non-uniform healthcare system and practices</i>	A design and innovation process can aid in identify healthcare service disparities and address during inventing solution and implementation.
	<i>Inadequate healthcare resources, staff, infrastructure, and services</i>	A design and innovation process can aid in forecasting usability issues of new design due to infrastructure and resource limitations and address them during inventing solution and implementation.
	<i>Poor healthcare management of health institutions</i>	This problem is partly causal and partly human related to human negligence. The causal aspect can be addressed in a design and innovation process by identifying reasons for poor healthcare management and address them during inventing solution and implementation.
	<i>Inferior healthcare quality and practice</i>	This problem is partly causal and partly human related to human negligence. The causal aspect can be addressed in a design and innovation process by identifying reasons for poor healthcare quality and practice and address them during inventing solution and implementation.
	<i>Disease diversity, unequal healthcare coverage.</i>	A design and innovation process can identify such issues and address during inventing solution and implementation.
	<i>Innovation misfit and misplacement</i>	A design and innovation process can aid in identify all various implementation requirements, opportunities and address during inventing solution and implementation
Overcoming socio-cultural barriers	<i>Varied socioeconomics and cost sensitivity</i>	A design and innovation process can aid in identify such issues related to socio-economics and affordability and address during inventing solution and implementation.
	<i>Socio-Cultural diversity and barriers</i>	A design and innovation process can aid in identify such issues related to socio-cultural barriers and address during inventing solution and implementation.
	<i>Widespread prevalence of ill practices</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process can aid in identify such issues and address during inventing solution and implementation.
Navigating underdeveloped innovation ecosystems	<i>Inadequate government support and policies</i>	A design and innovation process can identify issues related to healthcare policies, government initiatives and address during inventing solution and implementation.
	<i>Lack of experts, educational schemes and infrastructure for technology translation.</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
	<i>Inadequate and evolving regulatory and IP frameworks</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers

LMIC-specific design and innovation process characteristics	Addressable challenges and barriers of medical technology innovation	Possible way to address in a design and innovation process
	<i>Inadequate funding and investment support for innovation</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
	<i>Lack of local resources, manufacturing and testing provisions</i>	A design and innovation process can identify such issues and address during inventing solution and implementation. A design and innovation process also can aid by providing strategy development method, to overcome such barriers
Managing organizational design challenges	<i>Limited risk capacity and innovation appetite.</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process only can aid by providing strategy development method, to overcome such barriers
	<i>Inadequate innovation strategy and execution</i>	A design and innovation process can facilitate methods to develop strategies for the execution of required activities of medical technology innovation
	<i>Poor stakeholder collaboration and synergy</i>	This problem is partly addressable if collaboration is required for design decision making, knowledge share and co-design. A design and innovation process can facilitate tools and processes that require collaboration.
	<i>Poor Medical innovation knowledge and capability</i>	This problem is partly addressable A design and innovation process can facilitate systematic process, tools and processes to execute a medical technology innovation project.
	<i>Lack of innovation culture</i>	This problem is mostly beyond the scope of addressing using a design and innovation process.
Tackling market entry challenges	<i>Inefficient procurement and vendor payment processes of health institutions</i>	This problem is mostly beyond the scope of addressing using a design and innovation process. A design and innovation process only can aid by providing strategy development method, to overcome such barriers
	<i>Competitive and fragmented market</i>	A design and innovation process only can aid by providing strategy development method, to overcome such barriers.
	<i>Market entry barriers for new innovation</i>	A design and innovation process only can aid by providing strategy development method, to overcome such barriers

Listed below a brief summary of the six characteristics of medical technology design and innovation process (see Figure 4.3).



Figure 4-2: LMIC-specific design and innovation process characteristics (source: author generated)

Addressing clinical problem

The design and innovation process should aid in addressing the complexities inherent to clinical problems, biology, and their solutions by providing a structured framework and innovative tools that facilitate a deeper understanding of clinical issues rooted in biology and the development of creative and effective clinical solutions. This process can enable healthcare professionals and researchers to navigate intricate medical challenges, identify novel processes, and ultimately improve patient care and outcomes.

Addressing disparities in healthcare systems

The process of designing and innovating medical technology should enable systematic addressing of challenges related to healthcare access, workforce shortages, and infrastructure deficiencies. By considering various healthcare management issues, the design and innovation process should facilitate the synthesis of solutions to improve health outcomes and promote greater equity in healthcare access.

Overcoming socio-cultural barriers

The process of design and innovation should enable identifying and resolving socio-cultural obstacles to healthcare accessibility. Those engaged in the implementation journey must also

consider affordability and availability, considering a wide range of socioeconomic backgrounds and cultural norms, while striving to bridge gaps in language and tradition. This promotes inclusivity and fosters positive societal transformation.

Navigating underdeveloped innovation ecosystems

The design and innovation process should enable thoughtful deliberation and strategic decision-making to address challenges stemming from an underdeveloped innovation ecosystem, including lacking regulatory and safety standards, limited innovation funding, scarcity of local resources and facilities, and absence of device insurance coverage. Those involved in the design and innovation process should actively tackle governance, resource, and infrastructure deficiencies while navigating evolving regulations and securing funding for sustainable innovation implementation.

Managing organizational innovation challenges

The process of fostering design and innovation should consider various organizational elements that influence the successful project execution, including team expertise, resource availability, financial limitations, time constraints, and more. Individuals involved in the design implementation journey should assess their willingness to take risks, strengthen catalysts for innovation success, fine-tune execution plans, encourage teamwork, and nurture a culture that values design and innovation within their respective organizations.

Tackling market entry challenges

The successful commercialization of new innovation necessitates a thorough assessment of diverse market entry obstacles within the design and innovation process, requiring thoughtful deliberation and strategic decision-making. Those involved should strategically tackle challenges such as market competition, entry barriers, and procurement inefficiencies. This approach is vital to create new value propositions, achieve successful market entry, and foster collaboration with important stakeholders.

4.3.4 Identified Shortcomings of the Conventional Biodesign Process in LMIC Contexts

The conventional Biodesign process, developed at Stanford University, primarily aims to address clinical issues by identifying unmet needs. However, our study identified several shortcomings when applying this process in low- and middle-income countries (LMICs), where unique local challenges such as socio-cultural barriers and healthcare system disparities exist.

Evaluation of Biodesign Process:

We analyzed the process based on two perspectives:

- i. Based on ‘*Process support provided for medical technology design and innovation*’ (refer Table 2-E of Chapter 2).
- ii. Based on ‘*Identified characteristics of a medical technology design and innovation process specific to LMICs*’ (refer to Table 4-F and Figure 4.2).

Table 4-G presents the results of the evaluation based on the process supports requirements identified in Chapter 2 (refer Table 2E). It was found that the methods discussed in the conventional Biodesign process for clinical solution synthesis are overly generic (brainstorming sessions) and are not adequate for fostering the necessary creativity to solve problems in the field of Biological science. Similarly, there is no systematic approach suggested for mapping various requirements when creating solutions. Moreover, the conventional Biodesign process does not offer any systematic methods or tools for strategy development in the management of activities like R&D, IP, clinical validation, regulatory clearance, etc.

Table 4-G: Shortfalls of the Biodesign process from the perspective of process supports provided

Required process supports (previously identified in Chapter 2)	What conventional Stanford Biodesign process offer?	Identified shortfalls of the Biodesign process from the perspective of process supports provided
<i>To strategize for:</i> <ul style="list-style-type: none"> • <i>conducting field research to explore various clinical and healthcare implementation challenges.</i> 	The process incorporates methods for conducting field research and data collection. Various contextual enquiry methods like observation, interview, focus group enquiry etc. are part of it.	None
<i>To strategize for:</i> <ul style="list-style-type: none"> • <i>unmet clinical gap identification, analysis and selection.</i> 	The process is tuned for clinical gap identification which considers identification of clinical aspects like disease aetiology, clinical presentation, altered biomechanism, pathophysiological changes etc. Need selection process consider factors related to clinical problem, need of people, feasibility and business goal.	None
<i>To strategize for:</i> <ul style="list-style-type: none"> • <i>deriving user and stakeholder requirements.</i> 	The process facilitates structured method to define design requirements. Design requirements consider clinical problem, need of people, feasibility and business goal.	None

Required process supports (previously identified in Chapter 2)	What conventional Stanford Biodesign process offer?	Identified shortfalls of the Biodesign process from the perspective of process supports provided
To strategize for: <ul style="list-style-type: none"> capturing clinical contexts (i.e. underlying biomechanism, pathophysiology etc.) while synthesizing solutions 	The process defines use of generic methods like brainstorming for clinical solution synthesis	No systematic method provided to foster creativity for clinical solution synthesis.
To strategize for: <ul style="list-style-type: none"> mapping requirements and synthesizing design solutions 	The process defines use of generic methods like, mind mapping for mapping requirements in solutions.	No systematic approach suggested for mapping requirements into design solutions
To strategize for: <ul style="list-style-type: none"> appropriate concept selection 	The process suggests specific pre-calibrated filters for concept selection. Evaluation process demonstrates dependencies of implementation phase requirements in concept evaluation process. Final concept selection involves product prototyping, testing and taking patient-provider's feedback.	None
To strategize for: <ul style="list-style-type: none"> product safety testing 	The process discussed broadly product safety testing and required strategy development aspects.	No systematic method or tool for strategy development suggested
To strategize for: <ul style="list-style-type: none"> quality control 	The process discussed broadly Quality control and required strategy development aspects.	No systematic method or tool for strategy development suggested
To strategize for: <ul style="list-style-type: none"> clinical validation 	The process discussed broadly clinical validation and required strategy development aspects.	No systematic method or tool for strategy development suggested
To strategize for: <ul style="list-style-type: none"> regulatory clearance 	The process discussed broadly regulatory clearance and required strategy development aspects.	No specific method or tool for strategy development suggested
To strategize for successful medical technology implementation by: <ul style="list-style-type: none"> overcoming entry barriers 	The process discusses strategies related to intellectual property (IP) management, R&D management, Marketing, sales and distribution management etc.	No systematic method or tool for strategy development suggested
To strategize for successful medical technology implementation by: <ul style="list-style-type: none"> overcoming commercialization challenges 	The process discusses strategies related to manufacturing, operation and finance, Funding, business planning and reimbursement.	None

Again, Table 4-H presents the results of the evaluation based on identified characteristic of medical technology design and innovation process specific to LMICs (refer to Table 4-F and Figure 4.2).

Table 4-H: Identified shortfalls of Biodesign innovation process

LMIC-specific design process characteristics	What conventional Stanford Biodesign process offer?	Identified shortfalls of the Biodesign process from the perspective of LMIC-specific characteristics of medical technology design nad innovation process
<i>Addressing Clinical problem</i>	<ul style="list-style-type: none"> The 'IDENTIFY' phase of Biodesign process introduces necessary methods to identify clinical problem, population effected and desired outcome. It further offers a template for need statement development, pre-calibrated filters for need filtering and a template for need criteria generation. The 'INVENT' phase of Biodesign process introduces generic brainstorming technique to synthesize solution for clinical problems. It further offers pre-calibrated filters to screen concepts. The 'IMPLEMENT' phase broadly inform about various strategy development activities and Business planning activities. 	<ul style="list-style-type: none"> No systematic method provided to foster creativity for clinical solution synthesis. No systematic approach suggested for mapping requirements into design solutions No systematic method or tool for strategy development suggested
<i>Addressing Disparities in Healthcare Systems Overcoming Socio-Cultural Barriers</i>	<ul style="list-style-type: none"> The 'IDENTIFY' phase of Biodesign process does not provide process supports in identifying issues like healthcare system disparities and socio-cultural barriers. Current need statement and need criteria development templates, and need selection filters do not consider such issues to address. The 'INVENT' phase of Biodesign process does not provide process supports to address issues like healthcare system disparities and socio-cultural barriers while synthesizing solutions. Current concept screening process do not consider such issues as filters. The 'IMPLEMENT' phase of Biodesign process does not consider implementations barriers like healthcare system disparities and socio-cultural barriers while strategy development. 	None of the phases like 'IDENTIFY', 'INVENT' and 'IMPLEMENT' facilitate process supports to address such issues.
<i>Navigating Underdeveloped Innovation Ecosystems Managing Organizational Innovation Challenges Tackling Market Entry Challenges</i>	<ul style="list-style-type: none"> The 'IDENTIFY' phase of Biodesign process does not consider assessing challenges of Underdeveloped Innovation Ecosystems, organizational challenges and market entry barriers upfront prior to identifying a Need. The conventional Biodesign process is a need driven approach rather than market driven. The 'INVENT' phase of Biodesign process does not provide process supports to address issues like Underdeveloped Innovation Ecosystems, organizational challenges and market entry barriers while synthesizing solutions. Current concept screening process do not consider such issues as filters. The 'IMPLEMENT' phase of Biodesign process does not consider implementations barriers Underdeveloped Innovation Ecosystems, organizational challenges and market entry barriers while strategy development. 	None of the phases like 'IDENTIFY', 'INVENT' and 'IMPLEMENT' facilitate process supports to address such issues.

Combined Summary from Tables 4-F and 4-G: Phase-specific Limitations.

(a) Limitations of 'IDENTIFY' phase of Biodesign process in the context of LMICs

The Biodesign process, as conceived by Stanford University, primarily focuses on addressing clinical problems by identifying unmet needs and need criteria from a clinical perspective. However, in LMICs, healthcare challenges often involve unique local implementation issues and socio-cultural barriers, in addition to clinical needs. The Stanford Biodesign process overlooks addressing these implementation challenges within its framework.

The 'IDENTIFY' phase of the Biodesign process is instrumental in establishing the foundation for the innovation journey. It introduces essential methods for identifying clinical problems, the population affected, and desired outcomes, providing a structured approach to problem definition. It further offers valuable resources such as templates for need statement development, pre-calibrated filters for need filtering, and templates for need criteria generation, streamlining the process of defining needs. However, a notable limitation in this phase is the absence of necessary support for identifying systemic issues like healthcare system disparities and socio-cultural barriers. Current need statement and need criteria development templates and filters do not consider these crucial aspects. Moreover, the phase lacks a focus on assessing challenges related to underdeveloped innovation ecosystems, organizational obstacles, and market entry barriers upfront, as the Biodesign process primarily follows a need-driven approach rather than being market-driven.

(b) Limitations of 'INVENT' phase of Biodesign process in the context of LMICs

The 'INVENT' phase of the Biodesign process is focused on generating innovative solutions for identified clinical problems. The idea generation phase in the Invent phase is too generic and lacks specific process supports to foster creativity for solving complex clinical problems, which are deeply rooted in Biological science. It introduces generic brainstorming techniques for idea generation and provides pre-calibrated filters for screening concepts. Further, the phase has limitations. Similar to the 'IDENTIFY' phase, it does not provide process supports for addressing issues like healthcare system disparities, socio-cultural barriers, underdeveloped innovation ecosystems, organizational challenges, and market entry barriers during the synthesis of solutions. The concept screening process also does not adequately consider these critical factors as filters, potentially leading to solutions that are not well-suited for the diverse healthcare landscape. To enhance this phase, it is essential to incorporate processes and filters that consider these issues during the concept generation and screening process, ensuring that

solutions are comprehensive and effective.

(c) Limitations of 'IMPLEMENT' phase of Biodesign process in the context of LMICs

The Implementation phase of the Biodesign process though informative, hardly provides any systematic tool or approach for strategy making. Some of the considerations like reimbursement, Post-market surveillance are still not applicable to LMICs due to evolving nature of regulatory and healthcare policies.

The 'IMPLEMENT' phase of the Biodesign process is a critical stage in bringing innovation to reality. It provides guidance on various strategy development and business planning activities, equipping innovators with the tools needed to translate ideas into practical solutions. However, there is a significant limitation in this phase, as it does not consider critical implementation barriers such as healthcare system disparities and socio-cultural barriers when developing strategies. This oversight can lead to difficulties in effectively deploying innovative solutions in diverse healthcare settings. Furthermore, the phase does not adequately address challenges related to underdeveloped innovation ecosystems, organizational obstacles, and market entry barriers during strategy development, potentially hindering the successful implementation of innovations. The Biodesign process would benefit from a more comprehensive consideration of these real-world challenges in the 'IMPLEMENT' phase to enhance the likelihood of successful implementation.

4.4 Discussion

While design and innovation space in the medical technology field has been thriving in high-income countries, the landscape in LMICs is considerably different due to unique challenges. In this study, we delve into a multiple case study analysis using semi-structured interviews that shed light on critical factors influencing medical technology innovation management in LMIC settings. The study explored diverse startup profiles dealing with various clinical problems to capture the broad spectrum of challenges faced in medical technology design and innovation within these settings. By identifying these key challenges, the study highlights why the conventional Biodesign process may not be suitable for LMIC contexts. To foster meaningful and sustainable medical technology innovation in LMICs, a more contextually aware and adaptable approach was realized. The research contribution lies in its articulation of factors affecting the design processes (design epistemology), which are critical for adapting to the specific needs and constraints of LMICs (Cross, 2006).

Theoretical and practical implications

One of the prominent findings of the study is the need to address disparities in healthcare systems within LMICs such as uneven infrastructure, access, and quality. The study found that startups focusing on innovative medical technologies must not only create effective solutions but also ensure their adaptability and reach within the healthcare system. Again, socio-cultural factors significantly influence the adoption of medical technologies in LMICs. Deep-rooted cultural beliefs, traditions, and perceptions about healthcare can either facilitate or hinder the acceptance of new medical technologies. Startups operating in LMICs need to navigate these socio-cultural barriers through culturally sensitive design and marketing strategies. The research highlights the challenges of operating within underdeveloped innovation ecosystems in LMICs. Limited access to research and development resources, skilled talent, and funding opportunities can impede the growth and sustainability of medical technology startups. Consideration of local innovation ecosystems and partnership options while designing is crucial for overcoming these hurdles. Moreover, managing design and innovation within healthcare startups in LMICs is not just about product development but also involves overcoming organizational challenges. These challenges can include issues related to talent retention, capability development, and creating a culture of design and innovation within the organization. Successful management of these internal dynamics is essential for sustained innovation. Further, entering and navigating the markets in LMICs can be daunting due to regulatory complexities, price sensitivity, and competition. Understanding the nuances of market entry and building right strategies are essential in overcoming these challenges.

4.5 Conclusion

In conclusion, our study highlights a substantial misalignment between the conventional framework of medical technology design and innovation, such as the Stanford Biodesign process, and the specific needs of LMICs. By thoroughly investigating the challenges inherent to LMICs and interviewing Biodesign fellowship alumni startups in India, we identified critical design and innovation process characteristics essential for addressing the unique demands of these regions. Our research study illuminates the limitations of the widely adopted Stanford Biodesign process in the context of LMICs, emphasizing the necessity of a tailored approach.

Chapter 5. Development and Evaluation of New Workflow Toolkit for LMIC inclusive Medical Technology Design and Innovation: a Modified Biodesign Process

Abstract

The Biodesign process, originally developed by Stanford University for Medical technology design and innovation, consists of three phases: 'Identify,' 'Invent,' and 'Implement.' In Low- and Middle-Income Countries (LMICs), it falls short in each phase due to its focus on clinical issues, neglecting local implementation issues and socio-cultural barriers, and lacking systematic processes to address healthcare system disparities. This study examined the limitations of the conventional Biodesign process and introduces a modified Biodesign process comprising a new set of tools and processes within it, to address the unique challenges of LMICs. The study provides necessary details about how the new tools can be used by designers and innovators with adequate instructions. Two workshops with separate design student groups were conducted to evaluate the modified process against the Conventional Biodesign approach. The findings revealed that the modified toolkit significantly improved problem identification, need statement generation, concept development, strategy formulation, and selection processes, while introducing new criteria and filters that enhanced LMIC-specific relevance. This research study makes a valuable contribution to 'Design praxeology' by introducing new methods and procedures for medical technology design and innovation, empowering designers to create impactful and sustainable healthcare solutions for LMICs.

5.1 Introduction and Background

Previous findings indicate that designing and developing medical technology in LMICs is hindered by various challenges, such as inconsistent healthcare practices, underdeveloped innovation ecosystems, and socioeconomic and cultural barriers to effective implementation etc. The Biodesign process, as originally conceived by Stanford University, represents a valuable framework for addressing clinical problems by identifying unmet needs from a clinical perspective. However, when applied to Low- and Middle-Income Countries (LMICs), it becomes evident that this approach has limitations in addressing the unique challenges faced in these regions. Here are brief details about the Conventional Biodesign process workflow activities and identified shortfalls.

5.1.1 Stanford Biodesign Process workflow breakdown

An important component of Biodesign process is focused attention on needs finding and characterization, which differs from the traditional “tech-push” model in medical technology innovation. Here are the details about workflow activities of the three phases of Biodesign process.

Conventional processes and activities of ‘Identify’ phase:

Figure 5.1 shows the stages and activities of ‘IDENTIFY’ phase of Biodesign Process.

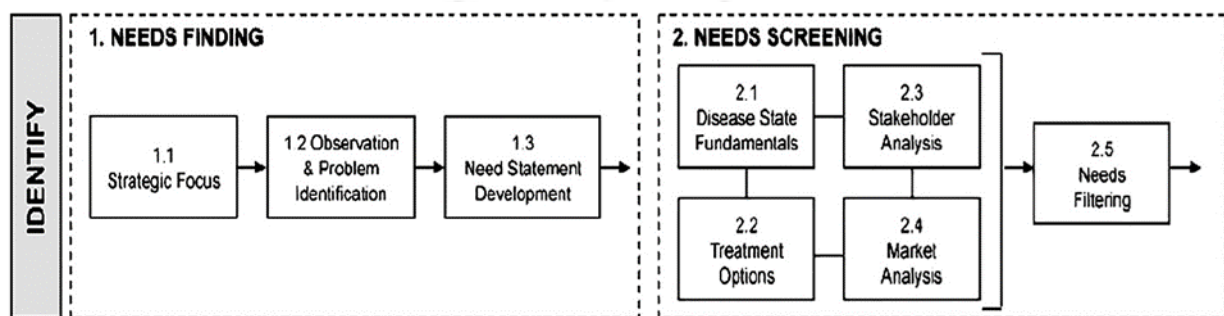


Figure 5-1: Identify phase's activities of Stanford Biodesign process, source: (Yock, et al., 2010)

- i. The ‘Identify’ phase starts with choosing a strategic clinical focus area based on innovators personal inventory, opportunity areas and other external factors. For instance, a team of innovators can choose strategic focus area as ‘Neurology’ based on expertise or personal passion or future opportunity. Figure 5.2 illustrates the process of choosing clinical focus area in general.

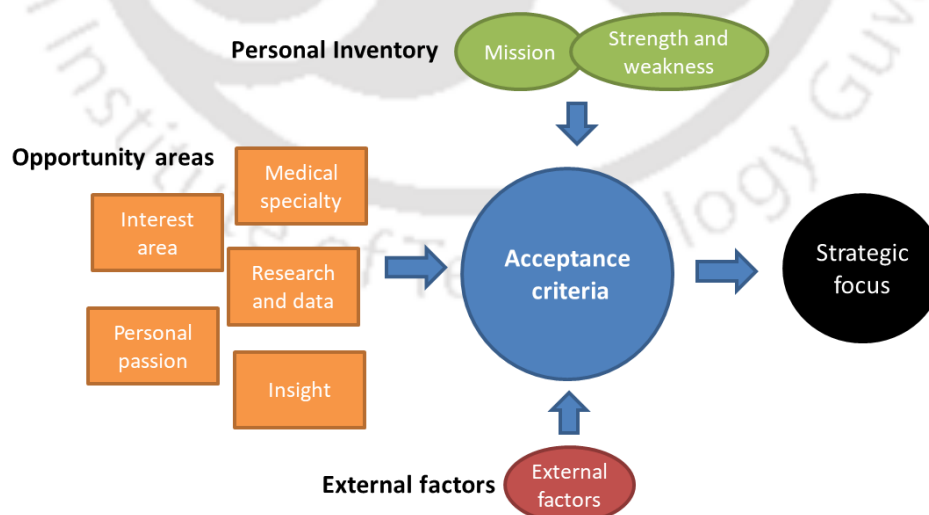


Figure 5-2: Choosing a strategic clinical focus area, source: (Yock, et al., 2010)

- ii. The ‘Identify’ phase places a strong emphasis on the identification and characterization of clinical requirements before moving forward with the development of a solution.

Innovators deeply immerse themselves in clinical settings at various healthcare facilities to pinpoint issues related to specific disease conditions, treatment and preventive measures, healthcare delivery problems, and patient challenges, among other concerns. Figure 5.3 illustrates how clinical immersion needs to be conducted in a healthcare setting to identify clinical problems.

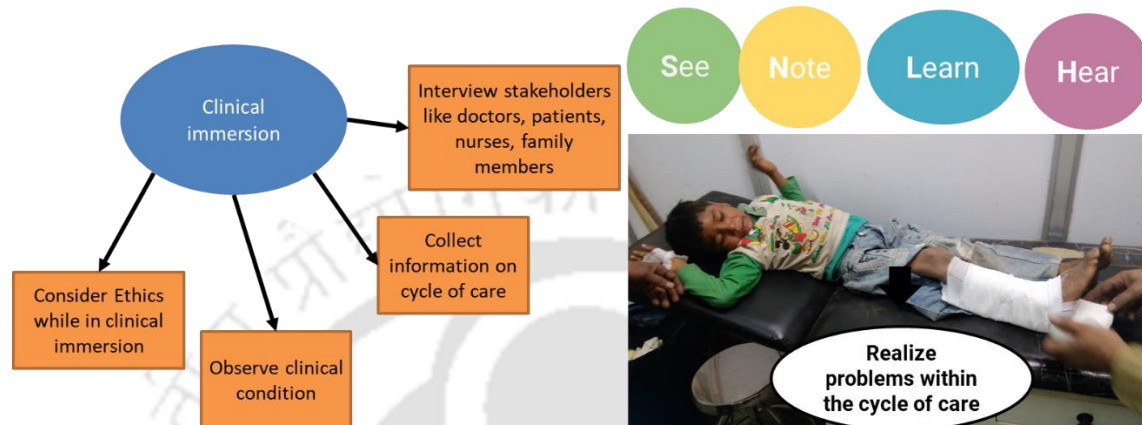


Figure 5-3: Need Exploration- observation and problem identification, Source: (Yock, et al., 2010) and partly author generated

- iii. Subsequently, a collection of need statements is formulated, encompassing the identified clinical challenges, the specific target population, and the measurable outcomes of potential solutions. Table 5-A demonstrate the template for need statement development with examples and examples of possible clinical outcome.

Table 5-A: Need statement development, Source: (Yock, et al., 2010)

Need statement template:	
“A way to address (problem) in (population) that (outcome)”	
Examples:	
<ul style="list-style-type: none"> • A way to treat bifurcation lesions in the left main coronary artery to reduce the recurrence rate • A way to close sternotomy without risk of sternal wire breaking 	
Desired Outcomes	As measured by
• Improved clinical outcome	Treatment success rate
• Increased patient safety	Rate of adverse events
• Reduce cost	Total cost of care
• Improve physician’s/facility’s productivity	Time and resource required
• Improve physician’s ease of use	Reduce complexity and simplify
• Improve patient convenience	Frequency and occurrence of treatment, change in treatment venue
• Accelerated patient recovery	Length of Hospital stay

- iv. Following this, a process of need selection is conducted to identify the most feasible needs. During the Need screening process various factors are considered such as the clinical impact of the requirement, understanding of pathophysiology, evaluation of

existing and emerging clinical processes, and an initial assessment of market potential, among other considerations. Table 5-B disclose the various filters used for need statement screening.

Table 5-B: Need selection filters, source: (Yock, et al., 2010)

Round 1 screening: Gut check screening					
Team interest	Yes =1	No= 0			
Need type	Mixed /incremental =1	Blue sky =0			
Round 2 screening: Moderate research					
Number of affected patients	Large =3	Moderate = 2	Small =1		
Understanding of disease state and problem area	Clear =3	Reasonable =2	Limited =1		
Treatment landscape	No avail. Solution=3	Few but gap exist =2	Crowded =1		
Patient impact	Lifesaving =5	Eliminate serious complications =4	Eliminate undesirable outcome =3	Improve patient wellbeing=2	No major impact =1
Positive Feedback from advisors	Yes =1	No=0			
Round 3 screening: In-Depth research and expert validation					
Market size	>INR 50 crore =3	>10 crore & <50 crore = 2	<INR 10 crore =1		
Expert opinion	High preference =3	Mid preference =2	No preference =1		
Provider value (cost, time, skill)	Change 2 or more =3	Changes at least 1=2	No change =1		
Round 4: Final screening					
Competitive landscape	Intense =1	Moderate =2	Low=3		
Industry/partner opinion	Yes=0.5	No=0			
Government agencies	Yes=0.5	No=0			

- v. Finally, a set of criteria is established for the chosen needs, typically consisting of 3 to 6 "essential" criteria and a similar number of "desirable" criteria. Clinicians play a pivotal role in this stage due to their ability to grasp pathophysiology and clinical

interventions. Figure 5.4 demonstrates an example of need criteria generation.

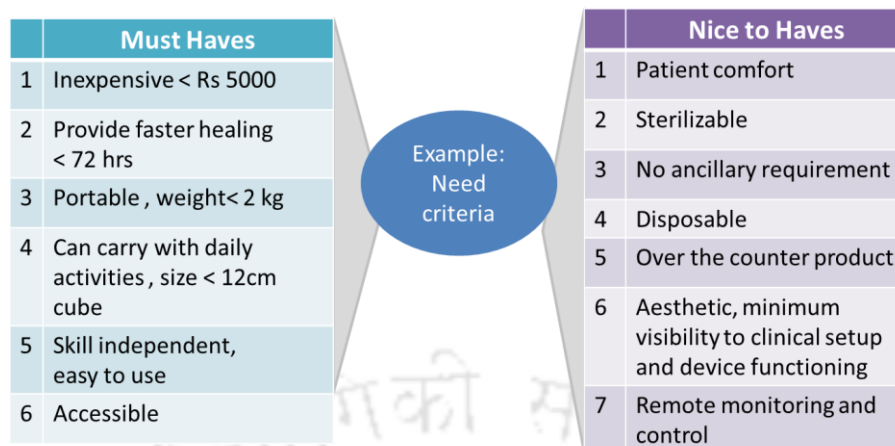


Figure 5-4: Generating need criteria (source: author generated)

Conventional processes and activities of 'Invent' phase:

Following the need criteria generation, the next set of activities are related to product invention.

Figure 5.5 shows the stages and activities of 'INVENT' phase of Biodesign Process.

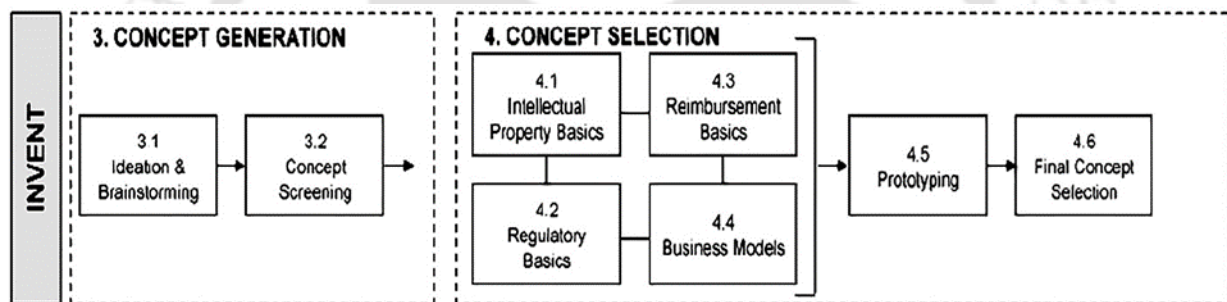


Figure 5-5: Invent phase's activities of Stanford Biodesign process, source: (Yock, et al., 2010)

- i. The 'Invent' phase is centered on a design-thinking approach to come up with ideas. It involves multiple team-based brainstorming sessions with experts from engineering, design, and medicine backgrounds.
- ii. The team generates various potential solutions for each identified need from the "Identify" phase. A key player in this phase is the designer, who bridges the ideas and thought processes of the team with technology and clinical practices to bring concepts to life. Figure 5.6, illustrates the process of idea and concept generation.

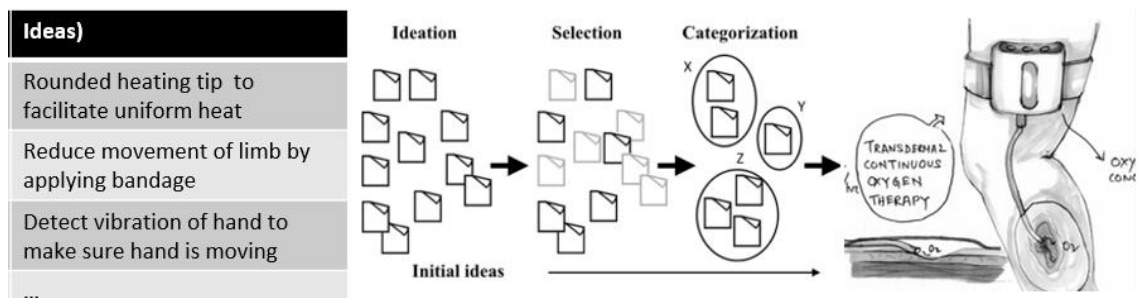


Figure 5-6: from ideas to concept generation (source: author generated)

- iii. Following this, a second screening process is employed with the aim of refining the concepts. This screening involves considering factors like intellectual property (IP) scope, the likely regulatory pathway, potential for reimbursement, technical feasibility, and the viability of the business model necessary to deliver the solution to patients. Table 5-C demonstrates an example of concept selection process.

Table 5-C: Concept screening process, source: (Yock, et al., 2010)

	IP	Regulatory	Reimbursement	Business models
Concept 1	3	2	1	2
Concept 2	2	3	2	2
Concept 3	1	1	1	1
Concept 4	2	1	2	2

- iv. Subsequently, in-depth prototyping of the most promising concepts is conducted to assess their usability. User feedback and expert opinions are crucial in the final selection of concepts. It's important to note that the "Invent" phase in the Biodesign process is not a linear progression. It often undergoes multiple iterations to arrive at the optimal solution for successful implementation.

Conventional processes and activities of 'Implement' phase:

Following the selection of final concept, the conventional Biodesign process further support in the development of strategies for further requirements like device R&D, IP management, Clinical validation and Regulatory clearance etc. Figure 5.7 shows the stages and activities of 'IMPLEMENT' phase of the Biodesign process.

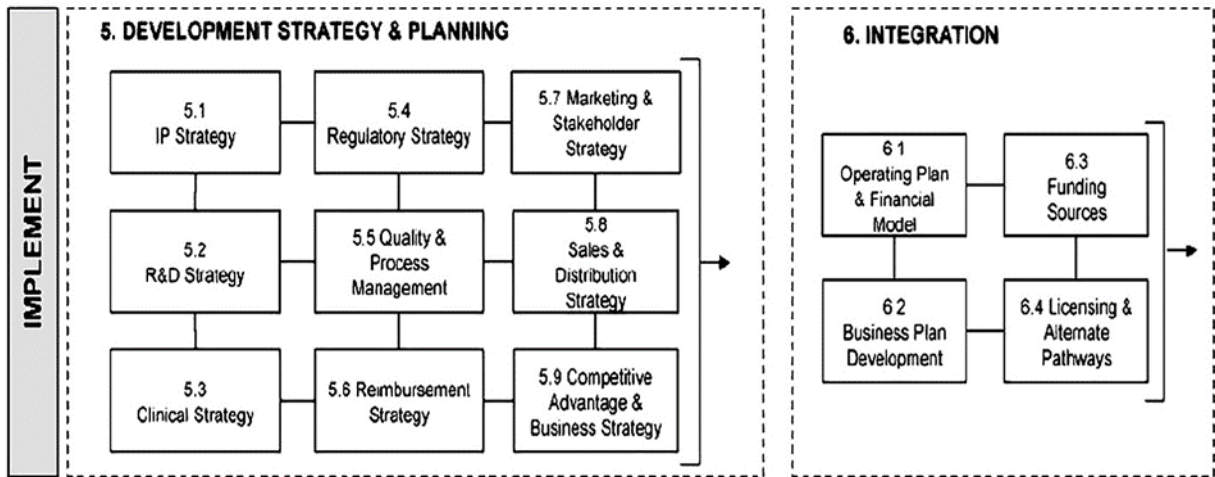


Figure 5-7: Implement phase's activities of Stanford Biodesign process, source: (Yock, et al., 2010)

- i. In the implementation phase, the top 1 or 2 concepts that have been chosen after a rigorous selection process undergo further investigation for the purpose of commercialization and development. This phase ensures the long-term viability and successful implementation of the solution to address the unmet need. A comprehensive analysis of each concept is conducted, encompassing aspects such as understanding the intellectual property landscape, planning for a viable reimbursement pathway, assessing engineering feasibility, and determining the necessary resources for continued research and development. During this stage, the designer takes necessary steps to optimize the design and may occasionally revisit activities from the Invent phase if required.
- ii. A detailed plan for device testing is formulated, which includes pre-clinical and clinical trials. The subsequent activities involve assessing product safety through an authorized facility, collaborating with healthcare professionals and institutions for clinical efficacy studies, and planning for regulatory clearances and certifications. If needed, further adjustments are made to the design to meet clinical or regulatory requirements.
- iii. Once the design is approved for implementation, additional activities essential for commercialization are carried out. These include designing for manufacturing, creating a business plan, strategizing manufacturing processes, piloting production, determining sales and distribution channels, financial modeling, securing funding, developing a marketing strategy, and crafting a compelling value proposition, among other tasks.

5.1.2 Identified shortfalls of conventional Biodesign process:

The previous study in Chapter 4, discusses the major shortfalls of Stanford Biodesign process

in the context of Low - and middle -income countries' (LMICs) requirements (refer Chapter 4, section 4.3.4, page nos. 138-139). Here is the objective assessment on the limitation of the three phases of the Biodesign process.

'IDENTIFY' Phase:

(a) Limitation:

The 'IDENTIFY' phase of the Biodesign process primarily focuses on clinical problems and neglects unique local implementation issues and socio-cultural barriers in LMICs. It lacks necessary support for identifying systemic issues like healthcare system disparities and socio-cultural barriers

(b) Assessment:

This limitation makes the process less effective in addressing holistic healthcare challenges in LMICs. To enhance this phase, there is a need for processes and templates that consider not only clinical needs but also local context and implementation challenges to ensure a more comprehensive problem definition.

'INVENT' Phase:

(a) Limitation:

The 'INVENT' phase provides generic idea generation techniques and concept screening methods, which may not be suitable for solving complex clinical problems deeply rooted in Biological science in LMICs. It lacks specific process supports for addressing local issues like healthcare system disparities, socio-cultural barriers, and innovation ecosystem constraints during solution synthesis.

(b) Assessment:

This limitation hampers the ability to develop contextually relevant and effective solutions for LMICs. To improve this phase, incorporating processes and filters that consider local challenges during idea generation and concept screening is crucial to ensure innovative solutions align with the diverse healthcare landscape.

'IMPLEMENT' Phase:

(a) Limitation:

The 'IMPLEMENT' phase of the Biodesign process lacks a systematic approach for addressing

the strategy development needs specific to LMICs. It does not adequately consider healthcare system disparities, socio-cultural barriers, and local challenges during strategy development, such as underdeveloped innovation ecosystems and market entry barriers.

(b) Assessment:

This limitation can hinder the successful implementation of innovations in LMICs. To enhance this phase, it is essential to integrate tools and processes that consider real-world challenges and local context, making the implementation strategies more robust and adaptable to the unique healthcare landscape in LMICs.

In conclusion, the Conventional Biodesign process requires significant adaptation to be effective in Low- and Middle-Income Countries. This adaptation should encompass a more comprehensive understanding of the local context, including socio-cultural barriers and unique implementation challenges. Moreover, specific tools and processes should be developed to address the intricacies of medical technology innovation in LMICs, considering the ever-evolving healthcare landscape in these regions. The subsequent sections of this chapter discuss in details about the development and evaluation of a new workflow toolkit, designed as a modified Biodesign process that is more instrumental in addressing the identified shortfalls.

5.2 Methodology

5.2.1 Synthesis of new Toolsets and processes

The initial task involved ideation for addressing the procedural and LMIC-specific limitation of conventional Biodesign process. This was systemically carried out via team brainstorming, against each identified gap to find solution in the form of new tool and strategy or modification of existing methods of conventional Biodesign process. We mainly ideated for improve the data collection strategies, data analysis activities and methods of ideation, evaluation matrices and strategy development processes. Details about the final set of ideas is provided in Table 5-D.

Articulation of tools

Furthermore, a new set of tools and methods has been developed in the form of visual templates and actionable tasks to address the unique design requirements of LMICs, based on the various ideas generated. These tools were seamlessly integrated into the conventional three-stages of Biodesign process: Identify, Invent, and Implement, to ensure easy adoption by the Biodesign community. The modified Biodesign process portrays the previously identified LMIC-specific

characteristics of design and innovation process and addresses limitations of the conventional Biodesign process. The toolkit comprises three toolsets (Toolset 1, Toolset 2, and Toolset 3) and supporting processes, tailored to address LMIC-specific process needs. Toolset 1 helps identify healthcare service gaps, clinical issues, and implementation problems, generating LMIC-focused need statements and design criteria. Toolset 2 aids in ideation and evaluating design concepts using LMIC-aligned filters and matrices. Toolset 3 facilitates analysis and strategy development for anticipating and addressing challenges across R&D, IP, regulatory, clinical trials, and quality management activities. Finally, a workshop toolkit was developed, which includes both the new toolsets and the conventional Biodesign activities, to efficiently train designers and integrate healthcare design and innovation requirements specific to LMICs.

5.2.2 Evaluating the modified Biodesign process

For the evaluation of the modified Biodesign process, a comparative effectiveness research approach was planned. This approach allowed comparing the effectiveness of newly introduced activities—data collection, data analysis, ideation, screening, and strategy development—with the conventional activities of the Biodesign process.

Workshops to compare the new workflow toolkit and conventional Biodesign process

Two workshops were conducted, with a five-week interval between them, to compare the performance of a newly developed toolkit with the conventional Biodesign process for medical technology design and innovation. The study involved recruiting two separate groups (Group A and B) of design students for the workshops (Cross, Christiaans, & Dorst, Design Expertise Amongst Student Designers, 1994). These students had backgrounds in design and technology but lacked prior experience in medical technology design and innovation. Figure 5.8 represents the evaluation methodology.

Selection procedure

Initially, we considered creating a pool of capable design students through purposive sampling. The students were selected based on their cumulative grade points, understanding of the product design subject area, and prior experience in design projects. This initial pool consisted of design students from the B.Des (3rd and 4th Semester) program and the M.Des (Electronic Product Design) program at the Indian Institute of Technology Guwahati. In terms of experience and design knowledge, the students' knowledge, skills, and academic performances were comparable, as all of them had prior knowledge of the product design process, design thinking, and skill sets. Each of these students had completed a major project in product design

and prototyping and had obtained above 70% in the project. Moreover, the selected students had a mean Cumulative Performance Index of 7.51 with a standard deviation of 0.63.

Finally, two groups were formed based on random selection of candidates from the pool, attempting to maintain equality in the male-to-female ratio and an equivalent ratio of B.Des to M.Des students. In Group A, a total of 26 design students were selected (Average CPI: 7.625, SD: 0.63, 12 females, 14 males), and in Group B, 22 design students were selected (Average CPI: 7.375, SD: 0.616, 10 females, 12 males.)

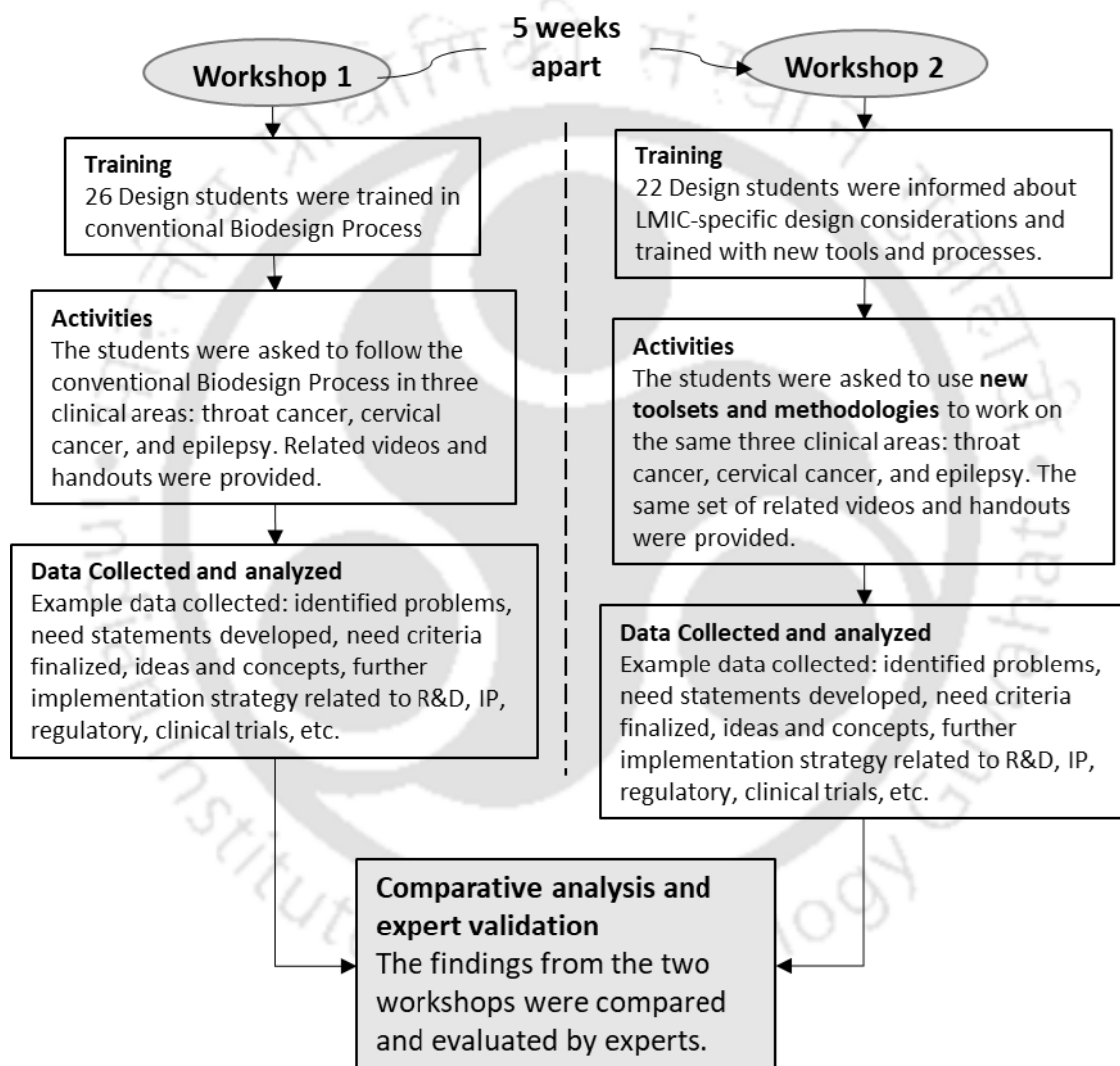


Figure 5-8: Methodology to evaluate the modified Biodesign process (source: author generated)

Workshop 1, which was held on March 18th and 19th, 2023, involved the 26 students (Group A) who received initial training in the conventional Biodesign process. They were tasked with addressing clinical areas such as Cervical cancer, Throat cancer, and Epilepsy, for medical technology design and innovation. In contrast, Workshop 2 took place on April 22nd

and 23rd, 2023, approximately 5 weeks later, and included the 22 separate design students (Group B) who were introduced to new toolsets and processes for tackling the same clinical problems. In both workshops, the design students were given handouts and videos with secondary data to guide their research. This controlled approach was found to have a minimal impact on the performance of the tools and the study's overall objectives. Both workshops collected physical and digital records of identified problems, need statements, idea generation, and implementation strategies. Figure 5.9 and 5.10 shows events from the workshops like training sessions, student activity sessions etc.

Events from **Workshop 1** (March 18th and 19th, 2023)

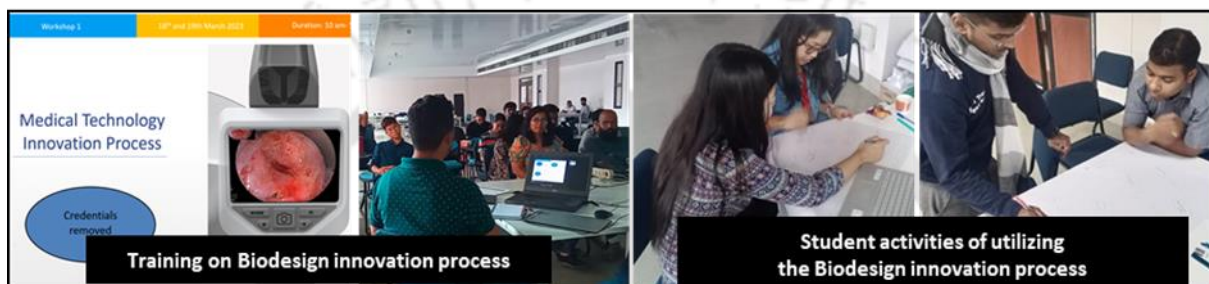


Figure 5-9: Events from Workshop 1 (March 18th and 19th, 2023)

Events from **Workshop 2** (April 22nd and 23rd, 2023)



Figure 5-10: Events from Workshop 2 (April 22nd and 23rd, 2023)

Expert analysis of Workshops' results

After the workshops, 11 Biodesign Fellowship alumni, having MedTech commercialization experience, analyzed and compare the two workshops results, focusing on the nature of identified problems, need statements, need criteria, generated ideas, concept selection, and implementation strategies. All the raw data generated from the two workshops (Excel sheets, sketches, diagrams, write-ups) was reorganized by the author into Excel sheets containing different tabs for various tasks. Two such Excel sheets were created to combine student tasks: one for Workshop 1 and another for Workshop 2. The experts were individually provided with these two datasets generated by the authors. They were not informed about the Biodesign

process modifications in the two datasets to avoid bias in the evaluation. We used a mixed-method approach in the evaluation process. To evaluate the nature of identified problems, ideas, and filters used, etc. the experts were asked to provide their comments by comparing similar tabs (each tab for one task, e.g., identified problems) in the two excel sheets. They were provided with separate Excel sheets to comment on the two datasets and give a comparative assessment. In addition to the qualitative assessment, experts used MS Excel-based matrices for the comparative analysis. A relevant scoring scale between 1 to 5 (5 being most relevant and 1 being least relevant) was used by the eleven Biodesign fellows for scoring the final need statements and concepts.

5.3 Results

5.3.1 Required modifications to the conventional Biodesign process

Table 5-D provides details about the final ideas generated to address various limitations of the conventional Biodesign process.

Table 5-D: Ideating tool and method requirement for addressing current limitations of the Biodesign process

Phases of Biodesign process	Identified Limitations	Generated Ideas for improvement	Tool name convention used in the subsequent section
IDENTIFY	The Biodesign process primarily focuses on clinical problems and may not address broader healthcare challenges, including local implementation issues and socio-cultural barriers in LMICs. This phase lacks necessary support for identifying systemic issues like healthcare system disparities, socio-cultural barriers. Similarly, being Need driven approach the process does not consider market factors like underdeveloped innovation ecosystems, organizational obstacles, and market entry barriers, before identifying problem.	Visual Mapping of available healthcare solutions across healthcare facilities and patient flow to identify service gaps	Tool 1-Part A: Healthcare Service Gaps Identification
		A improved way of data collection from field study to extract both clinical and various healthcare implementation issues and barriers	Tool 1-Part B: Problem Identification During Clinical Immersion
		Visual mapping of clinical procedure and infrastructure usage to identify various associated clinical and implementation problems	Tool 1-Part C: Analyzing Healthcare Interaction and Implementation Gaps
	The existing templates for need statement development do not consider these crucial aspects, potentially leading to incomplete problem definitions.	A new template for need statement development and scoping, that incorporate both clinical and implementation requirements.	Tool 1 –Part D Need Statement Development and Scoping
The current need selection filters do not consider crucial LMIC specific constraints like healthcare system	New need screening filters that incorporate LMIC specific constraints.	Tool 1-part E: Need screening	

	disparities, socio-cultural barriers while screening Need statements.		
	The Need criteria generation process mainly focused on solving clinical problem, with no systematic approach to identify various requirements. The process lacks consideration of successful healthcare implementation along with clinical requirements.	A systematic need criteria generation process that incorporate both clinical and implementation requirements	Tool 1-Part F: Need Criteria generation
INVENT	This phase does not provide process supports for addressing issues like healthcare system disparities, socio-cultural barriers, underdeveloped innovation ecosystems, organizational challenges, and market entry barriers during the synthesis of solutions.	A systematic approach of ideation that allow mapping of clinical and implementation requirements in designing concepts.	Tool 2 - part A 'Concept Feature Generation'
	The 'INVENT' phase provides generic brainstorming techniques for idea generation, which may not be suitable for addressing complex clinical problems rooted in biological science.	A co-design approach of concept design that allow multidisciplinary information sharing and activity involvement.	Tool 2 - part Clinical and technical solution Synthesis
	The concept screening process may not adequately consider critical factors like healthcare disparities and socio-cultural barriers, potentially leading to solutions that are not well-suited for diverse healthcare landscapes.	New concept screening filters that incorporate LMIC-specific requirements	Tool 2 - Part C: Concept selection process
IMPLEMENT	The 'IMPLEMENT' phase lacks systematic tools or processes for strategy development, which is crucial in bringing innovations to reality. This phase does not consider critical implementation barriers, such as healthcare system disparities and socio-cultural barriers, when developing strategies.	A common strategy development tool that allow forecasting possible technical and implementation challenges and ideating possible solutions against the challenges.	Tool 3: Strategy development for implementation

5.3.2 New Toolkit explained

Based on various ideas revealed in Table 5-D, a new set of toolsets and processes was developed as part of the modified Biodesign process. Figure 5.11 shows the proposed modified Biodesign process along with the incorporated modifications. Apart from the conventional activities of the Biodesign process, the new toolset 1 introduces two additional activities for the 'Need finding' stage. These are 'Exploring varying nature of problems, barriers and gaps', and the new approach of 'Need statement development and scoping'. Again, new toolset 1 introduces five additional activities for 'Need Screening' stage. These are the activities related to 'Healthcare system analysis', 'Socio-cultural analysis' and 'Policy and funding Analysis', and the new 'Need selection' and 'Need criteria generation' procedure. Similarly, the new toolset 2, introduces two new activities for the 'Concept generation' stage. These are the activities of 'Concept feature Generation' and 'Clinical solution synthesis'. Again, the new

toolset 2 introduces four additional activities for the ‘Concept screening’ stage. These are the activities to understand ‘Healthcare system compatibility’, ‘Socio-cultural compatibility’ and ‘Innovation ecosystem support’ for the solutions and the new ‘Final concept selection’ procedure. Further, the new toolset 3, introduces a ‘Common strategy development process’ under the ‘Strategy development ‘ stage of ‘Implement’ Phase.

Modified Biodesign innovation process

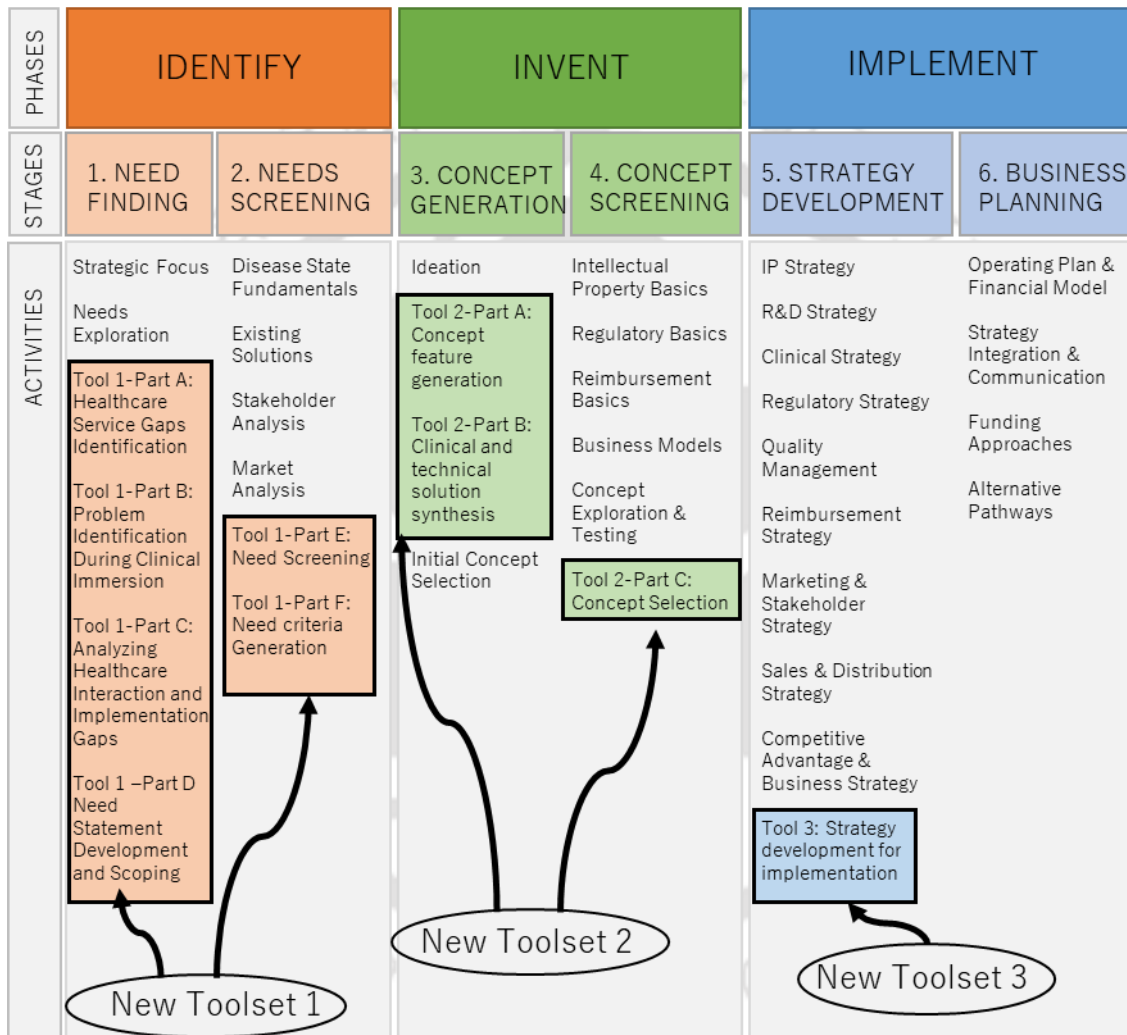


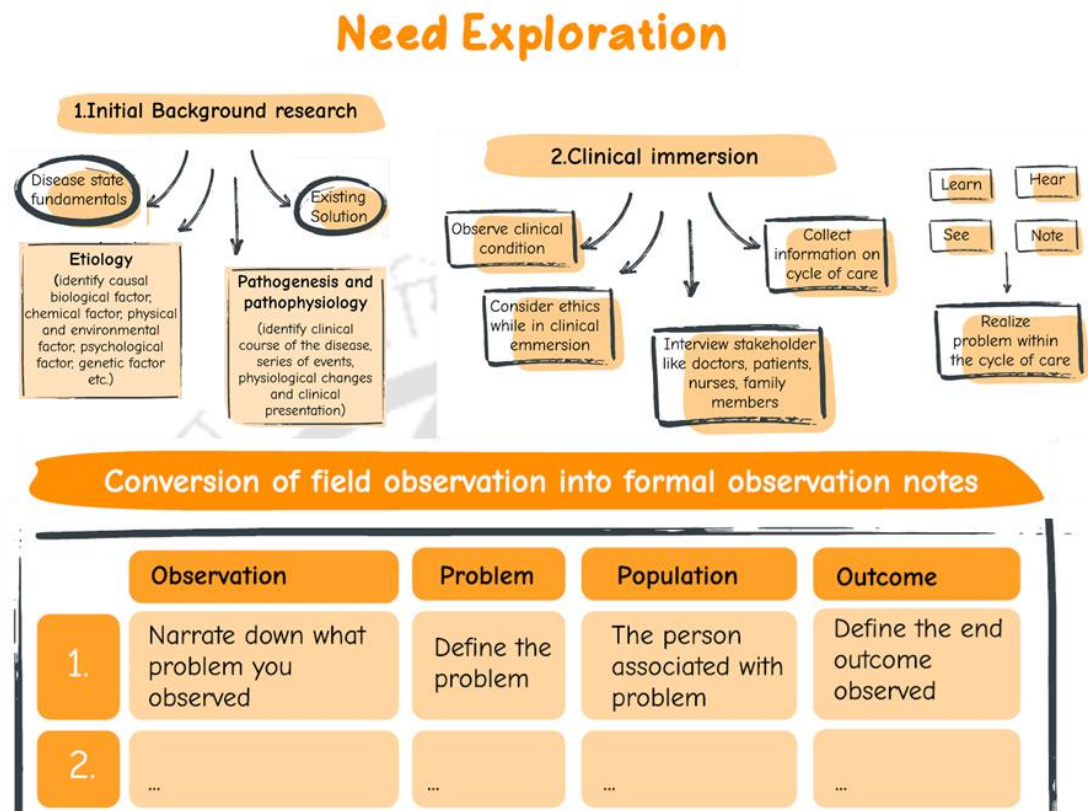
Figure 5-11: Modified Biodesign process (source: author generated)

Following are the details about the newly developed toolset.

Modified ‘Identify’ phase and new tools

The Biodesign process begins with the ‘IDENTIFY’ phase, focusing on a specific clinical area (e.g., cardiology, neurology) and involves initial research and clinical immersion. The conventional activities in this phase include identifying unmet clinical needs by understanding

problems, affected populations, and outcome requirements, using methods such as interviews and observations (see Figure 5.12). To meet the specific requirements of LMICs, this phase involved the following modifications.



Consider ethics while in clinical immersion

Interview stakeholder like doctors, patients, nurses, family members

Etiology
(Identify causal biological factor, chemical factor, physical and environmental factor, psychological factor, genetic factor etc.)

Pathogenesis and pathophysiology
(Identify clinical course of the disease, series of events, physiological changes and clinical presentation)

Conversion of field observation into formal observation notes

Figure 5-12: clinical immersion and taking formal observation notes (source: author generated)

(a) *Tool 1-Part A: Healthcare Service Gaps Identification*

In LMICs, the public healthcare system covers the majority but suffers from hierarchy and non-uniformity due to limited resources. Designers must comprehend clinical challenges linked to healthcare service gaps across various settings. The conventional Biodesign process lacks a systematic method for identifying and analyzing healthcare service gaps related to clinical conditions.

The new tool 1 - part A and advantage: The study presents a systematic approach to collect and map data for identifying healthcare service gaps, as depicted in Figures 5.13 and 5.14. Figure 5.13's left side allows detailed analysis and mapping of clinical conditions, causal factors (etiology), physiological/pathological changes (pathophysiology), and disease progression (pathogenesis). The central part maps available healthcare interventions (prevention, diagnostics, management, and treatment) according to disease stages (pathogenesis). On the right side, the tool maps service availability across healthcare facilities,

revealing gaps. This procedure identifies missing healthcare interventions and their reasons. Figure 5.14 illustrates the process of identifying healthcare service gaps for Bacterial Meningitis in the context of Indian healthcare settings.

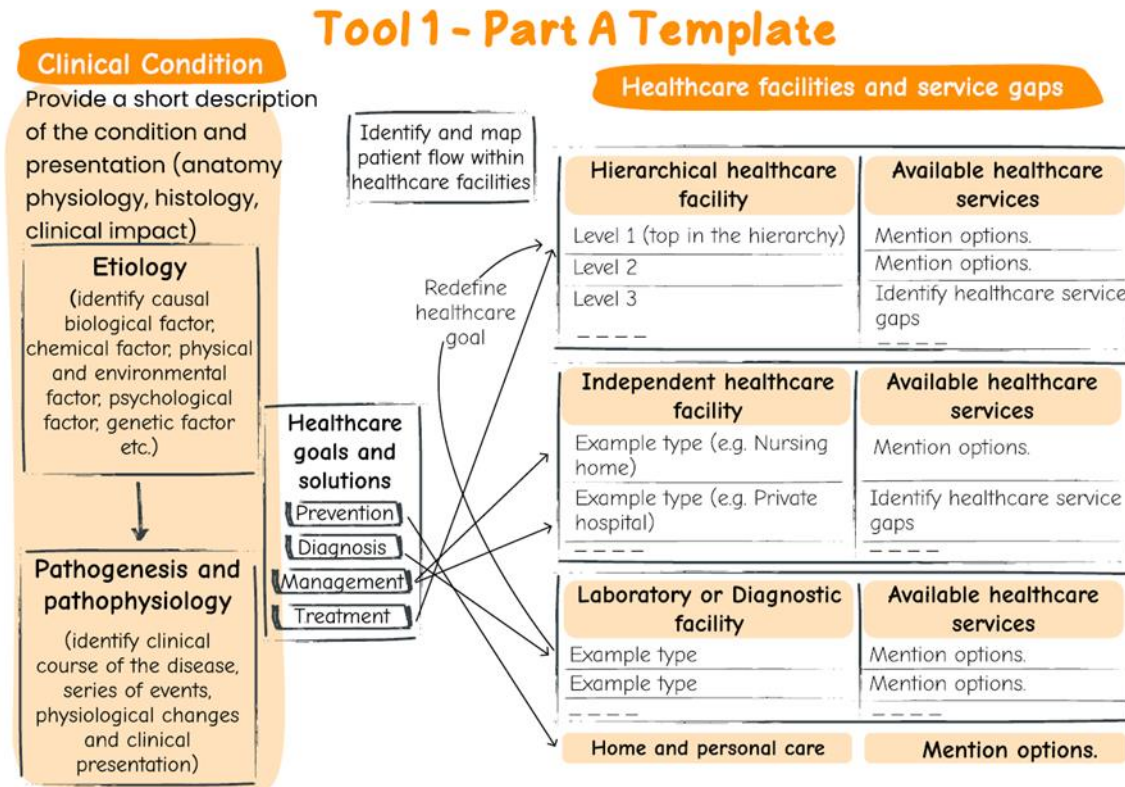


Figure 5-13: Tool for identifying healthcare service gaps (source: author generated)

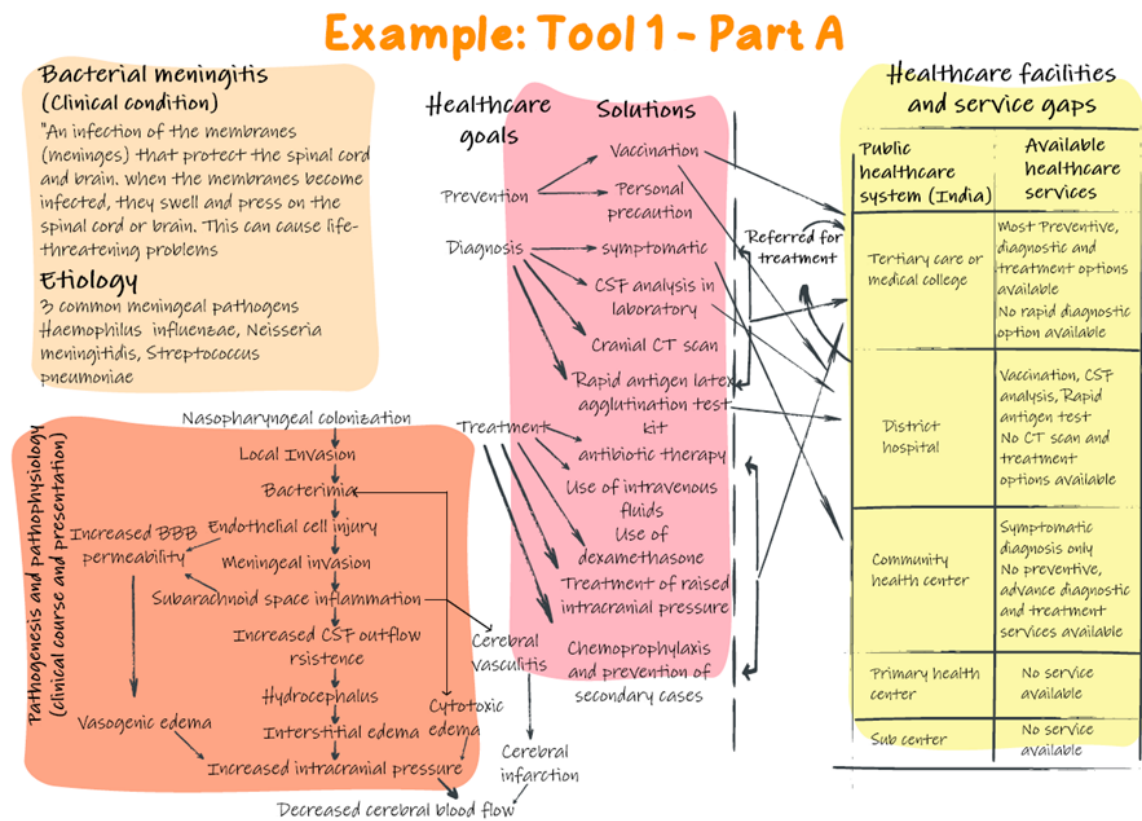


Figure 5-14: Example of identifying healthcare service gaps (source: author generated)

Tool 1-part A usage guideline:

- i. Starts with defining and mapping the Clinical condition on the left side of the page. This include from top to bottom (follow the template shown in Figure 5.13):
 - a. a short description of clinical presentation of the disease, anatomy, physiological changes, disease histology and clinical impact
 - b. a short description of disease etiology that include identification of various causal factors that may encompass biological, chemical, physical and environmental, genetic or psychological factors.
 - c. mapping of pathogenesis and pathophysiology of the disease state i.e. mapping the clinical course of the disease, series of events, pathological changes, risk factors and various clinical presentations.
- ii. The next task is to identify existing healthcare clinical goal of stakeholders (patient, clinician, healthcare facility) in relation to clinical course of the disease and

presentation. For example, clinical goals for a disease like cervical cancer can be Prevention, Screening and Diagnosis, Treatment or Management. On a paper, we can map the clinical goals on the right side of the clinical course of a disease state as shown in Figure 5.13. After that, the follow up task is to understand available solution/options for clinical goals and map them against each clinical goal. For example: For the clinical goal of prevention of cervical cancer available solutions are vaccination and personal hygiene.

- iii. The Third task is to identify all Public and private healthcare facilities of the country and map them in hierarchy in tabular format. Tables should include information about type of healthcare facility and available healthcare services in relation to the disease state we are exploring. The final task is to identify healthcare service gaps at various healthcare facilities i.e. identifying the absence of specific healthcare solutions/options. For instance, on performing this procedure for a clinical condition like Bacterial meningitis, we can identify that Cranial CT scan for the diagnosis of the disease is not available in Indian Community Healthcare centers (CHCs)

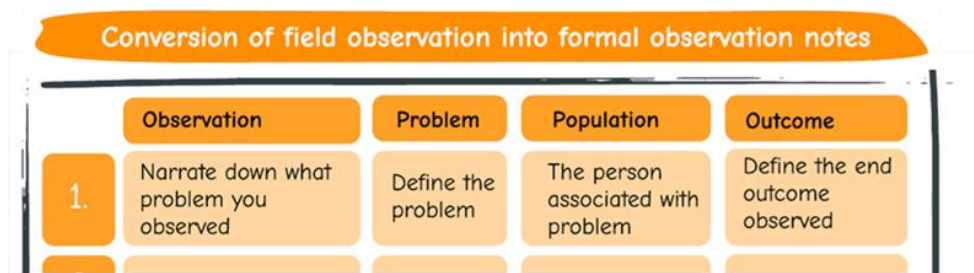
(b) Tool 1-Part B: Problem Identification During Clinical Immersion

In LMICs, clinical challenges are interlinked with implementation issues. Addressing both simultaneously during clinical immersion is crucial for effective solutions. Identifying all LMIC-specific problems during clinical immersion can be challenging for novice designers due to factors such as limited awareness, clinical access, research curiosity, and time constraints. The conventional Biodesign process does not explicitly define these types of issues.

The new tool 1 – part B and advantage:

The study introduces a set of problem types as observation lenses to guide designers during clinical immersion (see Figure 5.15). These lenses provide clear definitions, examples of desired outcomes, and measurement criteria. This simplifies field observations, helping designers identify various implementation and clinical problems. Figure 5.15 illustrates how multi-perspective observation lenses can unveil multiple issues from a single clinical observation.

Tool 1- Part B



Observation from clinical immersion

A village lady, aged 37, did not visit DOT center regularly for Tuberculosis treatment. She was reported with Drug resistance to TB medication due to treatment lapse As per her reporting, she stays far away from the DOT center and have 3 kids at home to take care. Her visit to DOT center is time consuming and it effect her work life.

Problems

1. Treatment lapse in TB,
2. Long duration of TB treatment/
3. Poor healthcare accessibility,
4. Effect work life .

Desired Outcomes

1. Timely medication,
2. Effective TB treatment,
3. Improve accessibility,
4. Low opportunity cost

Problems	Example desired outcome	As measured by	
Absence of healthcare solution	Non invasive way to diagnose	Sensitivity and specificity	Healthcare Problems
Gap and issue with current apparatus, instrument,	Improved clinical outcome	Treatment success rate	
Patient pain points	Improved patient convenience	Frequency and occurrence of required treatment, change in treatment venue	
Provider pain points	Improve physician/facility productivity	Time and resource required	
Procedural Issue	Less complicated procedures	Ease of use	
Complications with outcome	No side effect	Occurrence of clinical complication	
Environmental issue	Procedure operable in extreme weather conditions	Operational effectiveness	Implementation Problem
Socio-cultural issue	Culturally respectful procedure	Degree of privacy maintained	
Healthcare facility and management issues	Task shifting of devices due to limited skilled professional	Ease of use, help and guidance	
Healthcare service gap	Diagnose cancer in Primary health center	Operational effectiveness	

Figure 5-15: Observation and nature of healthcare problems (source: author generated)

Tool 1 – part B usage guideline:

This tool defines the approach of taking observations and identifying problems while performing clinical immersion during initial need identification phase.

- Before going to field study prepare table templates for formal observation note, on a piece of paper, as shown in Figure 5.15. This table template should have separate vertical columns to capture information about specific observations, type of problem and problem itself, population/stakeholder impacted and desired outcome.
- Built a strong understanding of healthcare related problem types, and examples of desired outcomes before field study as shown in template in Figure 5.15. During field study use the paper template prepared in step 1 to capture findings.

- a. Note down observations in passive narration defining patient's age, gender related information, clinical presentation of a disease or condition, observed healthcare service, patient - clinician interactions, patient – facility interaction, procedural information, challenges and issues faced.
- b. Taking reference from the problem types provided in Figure 5.15, identify and record various problems observed during field study.
- c. Identify and record the stakeholder getting effected i.e. problem faced by clinician, patient or other healthcare service guy within thin the cycle of healthcare service.
- d. Consult the population affected and identify and record desired outcome and how can measure the improvement.

(c) Tool 1-Part C: Analyzing Healthcare Interaction and Implementation Gaps

Documenting procedural details, challenges, and pain points is crucial during clinical immersion to gain insights into healthcare practices and identify usability issues. The current tabular method recommended in the Biodesign process is inadequate for recording real-time procedural details, lacking visual memory for events, issues, and complications.

The new tool 1 - part C and advantage: Figure 5.16, illustrates a systematic approach for mapping procedural and interaction data gathered from field observations. It comprises four key activities as shown in Figure 5.16 (left to right):

- i. Understanding clinical conditions.
- ii. Identifying healthcare solutions related to disease pathogenesis.
- iii. Observing and comprehending specific procedures in diverse healthcare settings, and recording processes and system/stakeholder interactions as visual maps.
- iv. The final task involves pinpointing issues such as socio-cultural factors, patient concerns, complications, and procedural challenges within the visual maps.

Tool 1- Part C

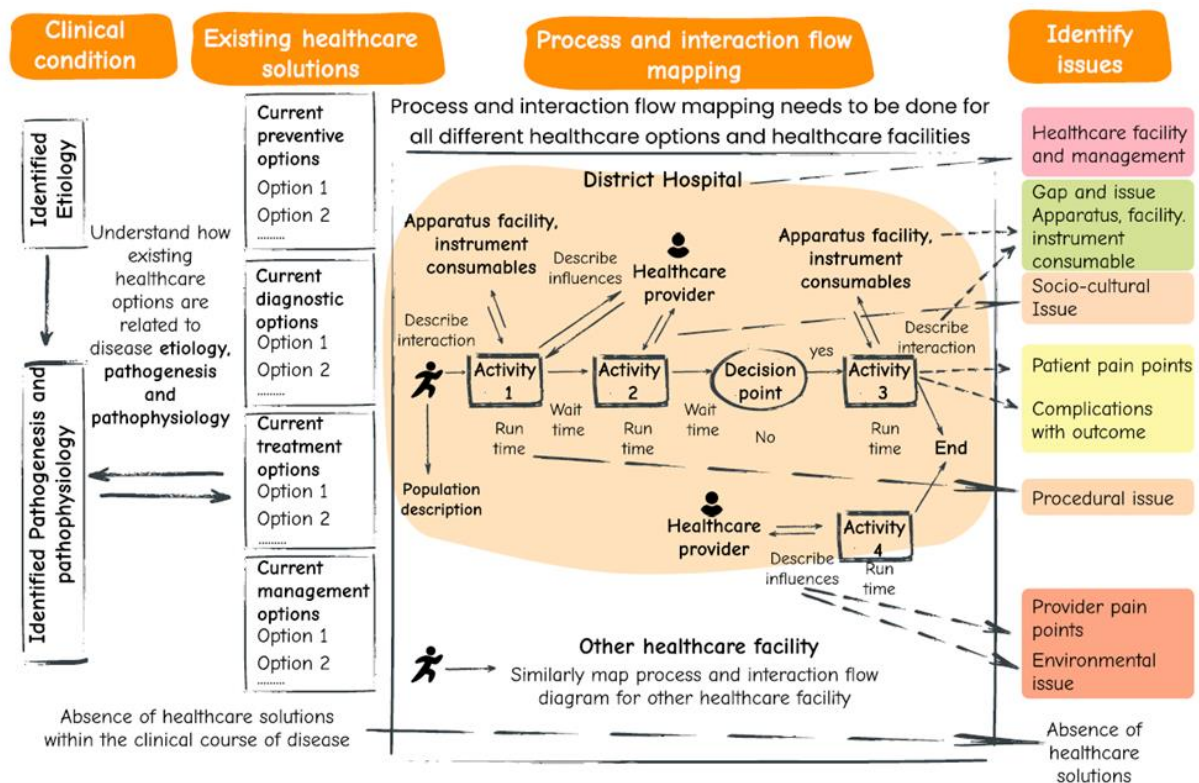


Figure 5-16: Identifying healthcare implementation gaps (source: author generated)

Tool 1 – part C usage guideline:

The following set of activities aimed to create visual map of clinical procedure and specific interaction of patient, clinician and healthcare facility to identify problems.

- i. It starts with tracking the patients' or clinicians' journey inside a procedure. Both patient and provider perspective are ok to start with. As a mapping task, all various activities performed by patient or clinician needs to be mapped sequentially from start to the end of a procedure as shown in Figure 5.16. Rectangular shape can be used for defining various activities. While mapping the activities various decision points needs to be identified and represented using Rhombus shape. Different activity paths from the decision points need to be mapped separately till activity endings. Various stakeholder interactions like patient interaction with Clinician or other personal needs to be mapped by defining double sided arrow and the nature of interaction between them. Similarly, stakeholder interactions with specific facilities, devices, infrastructure needs to be mapped using double sided arrow and defining kind of interactions. Once defining structural mapping of activities, decision points, and various interactions the subsequent

task is to define Run time and Wait time of each activity and interactions within the procedure. This can be defined using clock symbol and specifying approximate time association.

- ii. Next, identify or back trace clinical presentation of the disease state, etiology, associated healthcare goal for which we analyzed specific healthcare service or procedure. This step can be seen as a specific instance of data generated previously using Tool 1-Part A for understanding clinical condition. However, during clinical immersion sometimes we may come across procedures without gaining in-depth knowledge about disease state, pathogenesis, etiology etc. So back tracing such details and mapping while analyzing procedure would help in understanding/reasoning the procedural steps better. Back tracing can be done later after taking field observation. For example, for the clinical condition of Bacterial Meningitis (see example from Figure 5.14), we can observe procedure for reducing intracranial pressure and later connect the information about Procedural goal, and clinical need.
- iii. Step 1 and step 2, though are interconnected may happen at different temporal space. This is an iterative process. So, if necessary, add additional information to the process and interaction flow diagram based on back tracing and further realization of procedure and issues.
- iv. The final task is to trace and map all various issues realized within the procedure from observed activities or interactions. Example of issues can be issues of apparatus, instrument or facility, socio cultural issue, Patient pain points, outcome complications, procedural issue, provider issue, environmental issues etc.

(d) Tool 1 –Part D Need Statement Development and Scoping

In the "identify" phase, a crucial goal is to develop a clear and precise need statement that outlines the innovation objectives. The Biodesign process's need statement template focuses solely on clinical issues, the affected population, and desired outcomes. The original template is: "A way to address (problem) in (population) that (outcome)" (Yock, et al., 2010). However, it lacks consideration for addressing both clinical and implementation problems in LMICs. Furthermore, it lacks a methodology for scoping appropriate need statements.

The new tool 1 – part D and advantage: Tool 1-Part D presents a revised need statement template that enables designers to address both clinical and implementation issues while incorporating desired outcome characteristics (Figure 5.17). The tool also guides designers in

scoping need statements more effectively by considering the disease's pathophysiology and clinical course, resulting in multiple need statements derived from a single clinical problem or observation. This approach enhances precision in addressing healthcare challenges.

Tool 1- Part D

Need Statement development

A (desired outcome characteristics of healthcare and implementation problem) way to (address clinical condition) in (population) that (allow desired healthcare outcome)"

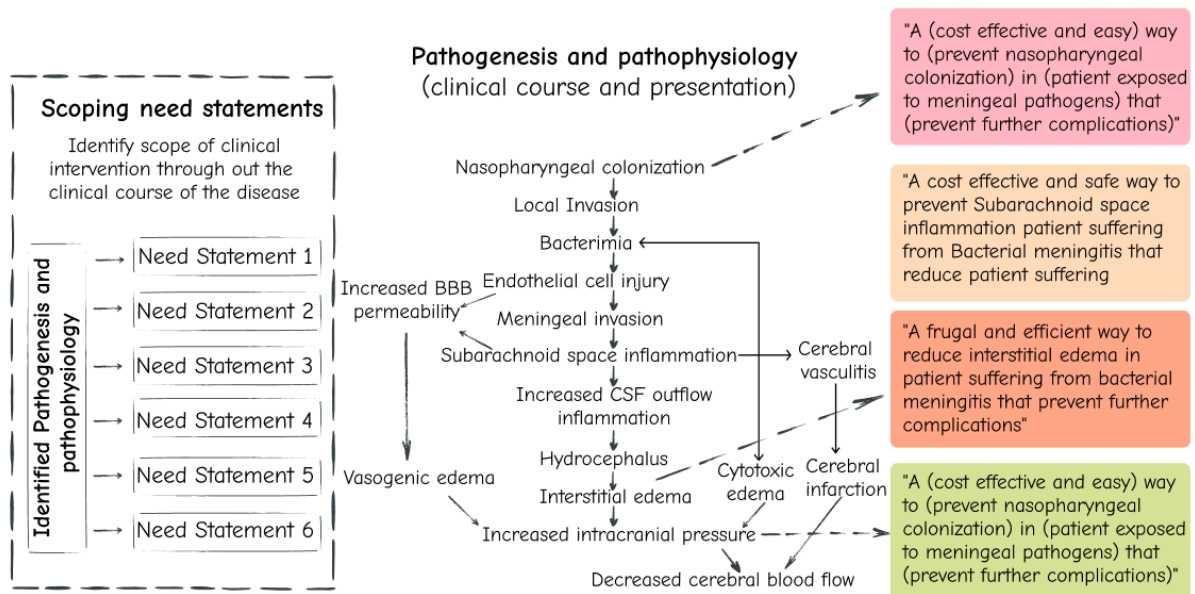


Figure 5-17: Need statement development and need scoping (source: author generated)

Tool 1 – part D usage guideline:

- i. Starts with defining initial need statement. Use previously identified information like healthcare service gaps, healthcare problems, population effected and desired outcome and measure to define need statements. Use the template provided in Figure 5.17 as an example template to bring together all such information. A typical need statement should include:
 - a. a clinical condition or disease state or healthcare problem
 - b. population affected
 - c. desired healthcare outcome
 - d. desired solution characteristic of healthcare and implementation problem
- ii. Refine and scope the need statements based on previously identified disease pathogenesis and pathophysiology. On a piece of paper draw the clinical course of

disease progression with the associated information of altered biomechanism, clinical presentation, risk factors. Next, redefine the initial need statements to target specific stage of disease progression or clinical presentation. Make sure the resultant need statements read logically correct and are not too narrow for solution synthesis. Consult clinician if required consultation on the development of final need statements.

(e) Tool 1-part E: Need screening

Selecting the right need or problem for further design and development tasks involves assessing all need statements with the appropriate criteria and filters. The need selection metrics proposed by the Biodesign process are crucial but insufficient for addressing the unique factors of medical technology design in LMICs.

The new tool 1 – part E and advantage: Four new filters were realized, including parameter values, to address healthcare implementation needs in LMICs. These filters, illustrated in Figure 5.18, encompass: 1) Fitment to non-uniform healthcare systems, 2) Fit to resource constraint setting, 3) Fit to society and culture, and 4) Fit to policies and funding options. To enhance the need screening process, it is recommended to incorporate these filters alongside the initial ones proposed by the Stanford Biodesign process.

Tool 1- Part E

LMIC specific Need filtering				
1.	Fitment to non-uniform healthcare system	Fit to entire hierarchy = 3	Fit to few = 2	Fit to specific healthcare setting= 1
2.	Fit to resource constraint setting	Fit to existing infrastructure and workforce = 3	Fit to either existing infrastructure or workforce = 2	No Fit=1
3.	Fit to society and culture	Socio cultural values addressed = 2	Socio-cultural values not addresses = 1	
4.	Fit to policies, funding options	Fit to WHO goals or government health planning = 3	Fit to Market demand =2	Fit to stakeholder requirement =1

Figure 5-18: LMIC specific metrics for need screening (source: author generated)

Tool 1 – part E usage guideline:

Following process defines the need filtering and selection process. Use tables/Excel sheets for the need selection process. Within a table, the first (left most) column should define various need statements, the last column (right most) should define Total score against each need

statement and in-between columns should capture the evaluated scores against various filters/matrices. The threshold score for selecting a need statement for further round of filtering is subjective i.e. depends on evaluators judgement and comparative analysis. The process involved three round need filtering. Rounds 1 and 2 employed need screening filters as recommended by the traditional Biodesign process, whereas Round 3 applied the newly established need screening filters outlined by Tool 1-E in the revised Biodesign process.

- i. The first-round usage the filters/matrices ‘Team interest (yes=1, no=0)’ and ‘Need type (mixed/incremental=1, blue sky=0)’ to quickly get rid of initial set of non-workable need statements.
- ii. In the second round use filters/ matrices ‘Estimated market size (Large=3, Medium=2, Small=1)’, ‘patient impact (Large=3, Medium=2, Small=1)’, ‘Number of affected patients (Large=3, Medium=2, Small=1)’, Understanding of Disease state (High =3, Medium=2, Low=1)’, ‘Treatment landscape (no solution=3, some=2, crowded=1)’, ‘Provider values- low cost, less time, low skill requirement (All three improve=3, Two improve=2, One improve=1)
- iii. The third and final round of filtering usage the filters/matrices defined in Figure 5.18 to perform a final check on LMIC-specific consideration. Use the Matrices/ filters ‘Fitment to non-uniform healthcare system (Fit to entire hierarchy =3, Fit to few = 2, Fit to specific healthcare setting=1)’, Fitment to resource constraint setting (Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1), Fit to society and culture (Socio-cultural values addressed= 2, Socio-cultural values not address = 1), Fit to policies, funding options (Fit to WHO goals or government health planning = 3, Fit to Market demand =2, Fit to stakeholder requirement =1)

Table 5-E, 5-F and 5-G illustrates an example of the need filtration process.

Table 5-E Round 1 Need filtering process

Need statements	Team interest yes=1, no=0	Need type mixed/ incremental=1 blue sky=0	Total
Need statement 1	0	0	0
Need statement 2	1	1	2
Need statement 3	1	1	2

Need statements	Team interest <i>yes=1, no=0</i>	Need type <i>mixed/ incremental=1 blue sky=0</i>	Total
Need statement 4	1	1	2

Table 5-F Round 2 Need filtering process

Need statements	Estimated market size	patient impact	Number of affected patients	Understanding of Disease state	Treatment landscape	Provider value (cost, time, skill)	Total
	<i>Large=3, Medium=2, Small=1</i>	<i>Large=3, Medium=2, Small=1</i>	<i>Large=3, Medium=2, Small=1</i>	<i>High =3, Medium=2, Low=1</i>	<i>no solution=3, some=2, crowded=1</i>	<i>Three changes=3, Two changes=2, One changes=1</i>	
Need statement 2	2	3	2	3	2	1	14
Need statement 3	3	3	2	3	2	3	16
Need statement 4	2	1	1	2	2	1	9

Table 5-G Round 3 Need filtering process

Need statements	Fitment to non-uniform healthcare system	Fitment to resource constraint setting	Fit to society and culture	Fit to policies, funding options	Total
	<i>Fit to entire hierarchy =3, Fit to few = 2, Fit to specific healthcare setting=1</i>	<i>Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1</i>	<i>Socio-cultural values addressed= 2, Socio-cultural values not address = 1</i>	<i>Fit to WHO goals or government health planning = 3, Fit to Market demand =2, Fit to stakeholder requirement =1</i>	
Need statement 2	2	2	2	2	8
Need statement 3	3	3	2	3	11

(f) Tool 1-Part F: Need Criteria generation

After selection of final need statements, the next step is to create need criteria for each statement. This involves finalizing product features, value propositions, usability requirements, and engineering parameters. The need criteria generation process in the Biodesign process lacks a methodological approach for addressing both clinical and implementation needs.

Furthermore, there should be a clear description of product specifications and constraints.

The new tool and advantage:

Figure 5.19, illustrates Tool 1-Part F, which presents a systematic approach for establishing need criteria. This tool divides the criteria into two primary categories: "must-have", encompassing essential Clinical and Implementation requirements, and "nice to have", comprising additional requirements. The ultimate goal is to satisfy all outcome characteristics outlined in the need statements. These criteria are then further organized into functional specifications or constraints, each accompanied by suitable values or descriptions. This method effectively prioritizes clinical and implementation needs, promoting a well-rounded approach to medical technology design and innovation.

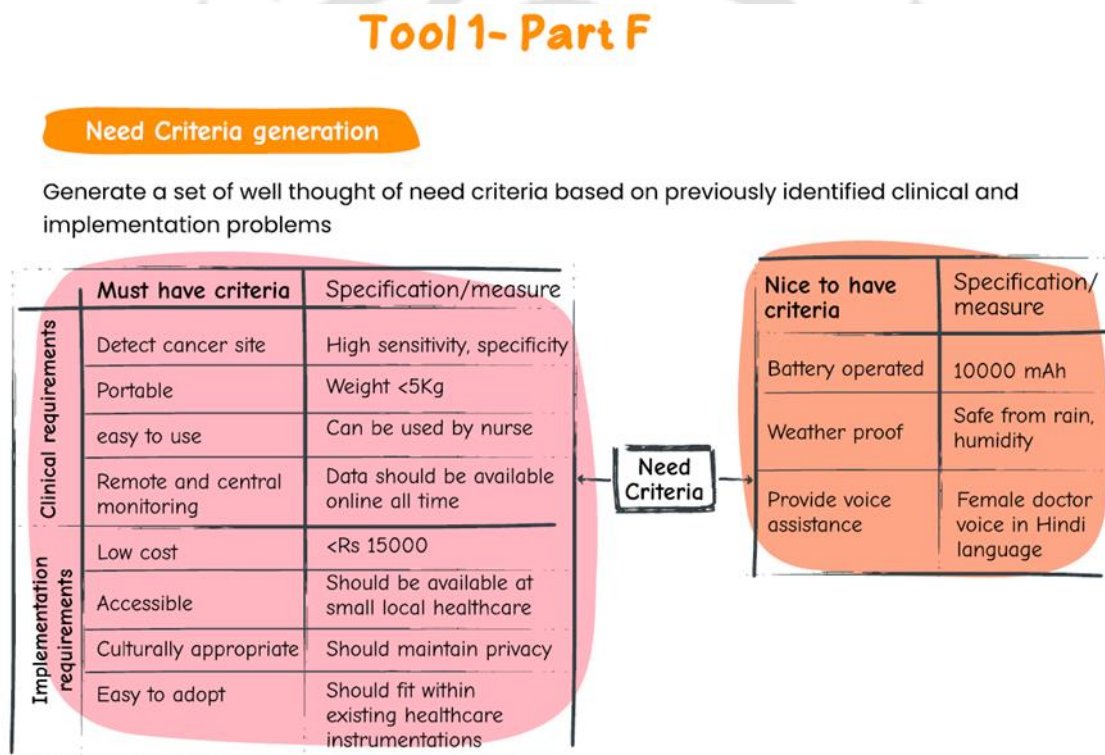


Figure 5-19: Need criteria generation (Source: Author generated)

Tool 1 – part F usage guideline:

Need criteria development process starts with the development of need statement where we include desired solution characteristic of healthcare and implementation problem. here is the systematic approach of need criteria generation

- i. Starts with the development of Must have need criteria (design requirements) by creating a table as shown in Figure 5.19 (left side). Create a table where the first two

columns define the ‘must-have’ characteristics of the solution and associated ‘specifications’. Horizontally, the table should represent these need criteria from two different requirement perspective. One from the perspective of clinical requirements that address core clinical problem, and the other from the perspective of implementation requirements, which capture solution characteristics that can eliminate implementation risks or issues. A well-defined need statement will allow easy understanding of clinical and implementation challenges. Defines the specifications as either values or constraints.

- ii. The next task is to define the nice to have criteria a similar table as shown in Figure 5.19. Create a table where first column defines the ‘nice-to-have’ criteria and the second column defines the corresponding specification. Define nice to have criteria from the perspective of technological usage, additional stakeholder comfort, practical usage requirement etc.

Modified ‘Invent’ phase and Tools 2-A to 2-C

The 'INVENT' phase in the Biodesign process aims to create innovative solutions for clinical problems. However, it lacks specific methods for fostering creativity, particularly for complex clinical issues rooted in biology. It primarily employs generic brainstorming techniques and pre-calibrated filters for concept screening. It doesn't address critical factors like healthcare disparities, socio-cultural barriers, and market entry obstacles while developing and screening solutions. Here are the modifications suggested using Toolset 2.

(a) Tool 2 - part A & B: Ideation and concept generation process

Once the need criteria are formulated, the next step is to ideate and generate concepts that align with the specified requirements and address the identified needs. The Biodesign process outlines a rather conventional approach to medical technology ideation, primarily centered on team brainstorming involving experts from various fields like engineering, research, and clinical backgrounds. While it emphasizes ideation through collaboration, it lacks a methodological approach to idea generation, which is crucial for novices tackling biological problems where the underlying science might be unfamiliar. The presence of clinicians or biotechnology researchers is helpful, but a lack of creative problem-solving approach limits the effectiveness of basic brainstorming in bridging the gap between engineering and biological science knowledge for solving human health issues.

The new tool 2 – part A & B and advantage: The study introduces a two-step method for

idea generation and concept development: 1) Generating concept features and 2) Synthesizing clinical and technical solutions.

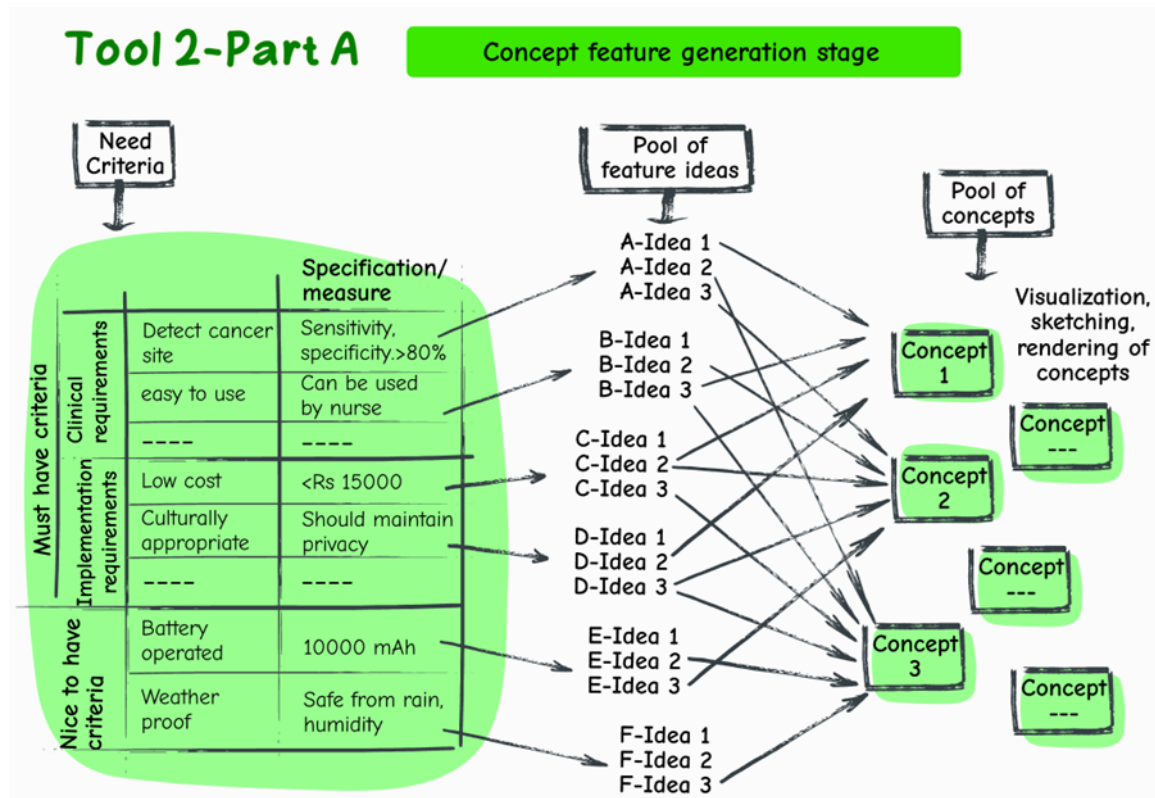


Figure 5-20: Concept feature generation process (source: author generated)

In the ‘**Concept Feature Generation**’ stage as described by Tool 2-Part A, the primary objective is to create separate idea pools for each need criterion categorized as ‘Must-haves’ and ‘nice-to-haves.’ Techniques like Team Brainstorming and Trigger Word can aid in generating preliminary solution ideas for each criterion, emphasizing a balanced focus on clinical and implementation requirements (see Figure 5.20). Subsequently, these ideas are merged from individual criteria to form a concept pool, aiming to develop concepts that encompass all essential criteria. Visualizations, concept sketching, and rendering play a valuable role in realizing these concepts effectively.

The ‘**Clinical and technical solution Synthesis**’ stage as described by Tool 2-Part B, involves a collaborative effort among clinicians, biotech researchers, engineers, and designers to address core biological problems (see Figure 5.21). Team building is a crucial element of the Biodesign process, especially at the start of any medical technology project. The process strongly advocates for a multidisciplinary team that includes clinicians, designers, and engineers. Collaboration and team dynamics play a significant role throughout the medical device innovation journey. Occasionally, the core team might need to expand by including

additional domain experts based on the evolving needs of the project. In Biodesign fellowship programs, forming such a team at the outset is standard practice. However, for an individual industrial designer employing the Biodesign process for medical device innovation, it is recommended to engage in extensive networking and collaboration to facilitate project development. It is typically advantageous to select and consult with a clinician early in the project. If necessary, scheduling meetings with clinicians well in advance can help address the logistical challenges of aligning with the busy timetables of medical professionals, ensuring a smooth and effective collaborative ideation process.

The process begins with clinical and biological experts conducting a comprehensive visual mapping of anatomy, etiology, pathophysiology, and pathogenesis (step1). This knowledge forms the basis for collaboration with designers and engineers, who integrate these biological mechanisms into physical and engineering processes. Scientific principles guide the generation of ideas (step2), which are then fine-tuned through iterative feedback from clinical and biological experts (step3). The refined concepts undergo evaluation by field experts to ensure practicality (step4), completing a structured and collaborative approach that spans from foundational understanding to real-world applicability. Throughout this process, previous feature conceptualizations and visual representations are adjusted to incorporate clinical solutions seamlessly. This stage promotes interdisciplinary collaboration to develop field-adaptable solutions for complex biological issues.

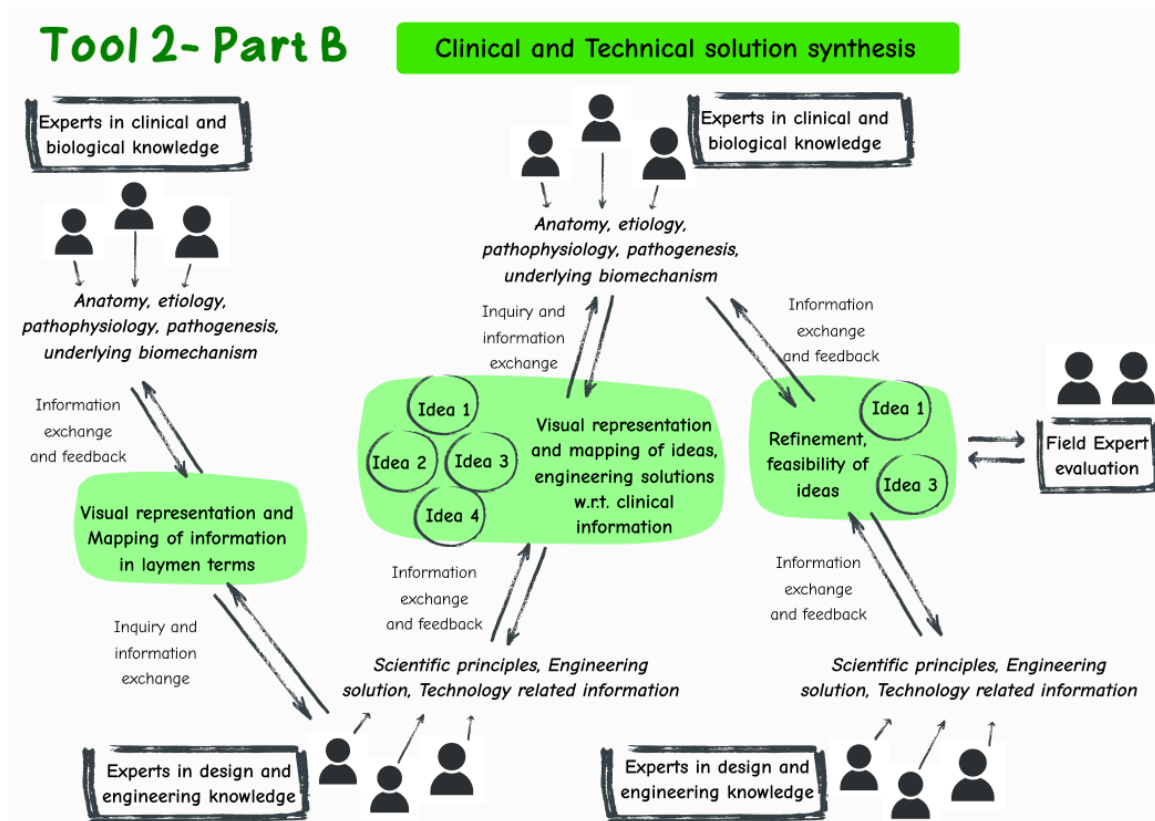


Figure 5-21: Clinical and technical solution synthesis process (source: author generated)

Tool 2 – part A & B usage guideline:

Concept feature generation using Tool 2-part A (refer Figure 5.20)

- i. Start with the task of re-arranging and writing ‘must-have’ and ‘nice -to-have’ need criteria in a new tabular format, as shown in Figure 5.20. The table should categorize the three types of requirements from top to bottom: clinical requirements, implementation requirements and the nice to have criteria.
- ii. Next generate a pool of ideas for each need criteria. Techniques like trigger word or Team brainstorming is ideal for generating such pool of ideas. Write down and map the ideas nest to the need criteria.
- iii. The final task is to combine an idea or two corresponding to each must-have criteria to arrive at distinct pool of concepts. Incorporation of ideas corresponding to nice-to-have criteria is optional. These concepts define all the features that enable them to address the identified need.

Clinical and technical solution Synthesis using Tool 2-Part B (refer Figure 5.21)

- i. Form a multidisciplinary team comprising clinicians, researchers, engineers, and

designers with expertise in various disciplines, such as mechanical, electronics, chemical, computer science, biotechnology, biochemistry, physics, and industrial design. Ensure clinicians are specifically from the relevant clinical domain.

- ii. Begin by engaging clinical and biological experts to provide a comprehensive visual description of the anatomy of the disease location or clinical condition, including the causative factors, underlying biomechanisms, pathophysiological changes, and the clinical course. These experts should also detail existing solutions, usage methods, clinical procedures, and the latest research in the solution space.
- iii. Have a team of engineers, designers, and researchers assimilate the intricate biological knowledge, with designers visually mapping relevant information from clinician and researcher descriptions. This visual map becomes the foundation for ideation in developing clinical solutions.
- iv. Once the team reaches a consensus on the visual mapping, generate ideas based on correlating biological mechanisms with physical and engineering processes. Engineers and basic science researchers should explain scientific principles and technological details to guide ideation against identified engineering or scientific terminologies. Utilize methods like TRIZ (Russian acronym) or TIPS (Theory of Inventive Problem Solving) if additional assistance is needed. Develop multiple concepts considering available technologies and various biological aspects of the problem.
- v. Illustrate or render the concepts, seeking input from the entire team for issues or options for further improvement. This phase is iterative; refine concepts based on iterative feedback from clinical and biological experts.
- vi. Create low-fidelity prototypes of the concepts and evaluate them in the field through patient interaction or with other field experts. Iterate through steps 3 to 4 if necessary, ensuring continuous refinement and improvement in the solution development process.

(b) Tool 2 - Part C: Concept selection process

Following concept generation, designers assess concepts using defined metrics to decide which ones should advance for further development and successful implementation. The concept selection matrices as suggested within the current Biodesign process fall short in adequately defining the requirements for LMICs.

The new tool 2 – part C and advantage: As shown in Figure 5.22, an additional set of seven

filters has been proposed to evaluate concepts for LMIC-specific requirements. These were: 1) Fitment to a non-uniform healthcare system, 2) Fitment to resource constraint setting, 3) Fitment to society and culture, 4) Funding and investment availability, 5) Product development support, 6) Manufacturing support and 7) regulatory hurdles. These seven filters are to be used alongside the original filters recommended by the Biodesign process during the concept selection process.

Tool 2- Part C

LMIC specific concept filtering				
1.	Fitment to non-uniform healthcare system	Fit to entire hierarchy= 3	Fit to few= 2	Fit to specific healthcare setting= 1
2.	Fitment to resource constraint setting	Fit to existing infrastructure and workforce= 3	Fit to either existing infrastructure or workforce= 2	No fit= 1
3.	Fitment to society and culture	Socio-cultural values addressed= 2	Socio-cultural values not addresses= 1	
4.	Funding and investment availability	High= 3	occasional= 2	Low= 1
5.	Product development support	Developmental knowledge and strong collaboration exist= 3	Either developmental knowledge or strong collaboration exist= 2	No knowledge and collaboration exist= 1
6.	Manufacturing support	All manufacturing and parts procurements can be done via vendor within country= 3	Partial dependency on foreign vendor for manufacturing or component procurement= 2	No knowledge and collaboration exist= 1
7.	Regulatory hurdles	Class 1 device or notified device	Non-notified device (but FDA 510K)= 2	Non-notified device (needs PMA)= 1

Figure 5-22: LMIC specific metrics for concept selection (source: author generated)

Tool 2 – part C usage guideline:

The following process outlines the concept filtering and selection procedure, employing tables or Excel sheets for clarity. In each table, the leftmost column should list the names of the concepts, the rightmost column should indicate the total score against concepts, and columns in between should record the evaluated scores against various filters/matrices. The threshold score for advancing a concept to the next filtering round is subjective, relying on evaluators' judgment and comparative analysis. The process entails two rounds of concept filtering.

- i. The first-round usage the filters/matrices as shown in Figure 5.22: Fitment to the non-uniform healthcare system (fit to the entire hierarchy=3, fit to a few=2, fit to a specific healthcare setting=1), fitment to resource-constrained settings (fit to existing

infrastructure and workforce=3, fit to either existing infrastructure or workforce=2, no fit=1), fitment to society and culture (addressing socio-cultural values=2, not addressing them=1), funding and investment availability (high=3, occasional=2, low=1), product development support (developmental knowledge and strong collaboration existed=3, either of them existed=2, no knowledge and collaboration were present=1), manufacturing support (all manufacturing and parts procurement could be done within the country=3, partial dependency on foreign vendors=2, complete dependency on foreign vendors=1), and regulatory hurdles (Class 1 devices or Notified devices=3, non-notified devices with FDA 510k=2, non-notified devices requiring PMA=1). One scoring the concepts against the matrices, aggregate the scores. The concepts that received similar high aggregate scores proceeded to the second round of filtering.

- ii. The second round usage filters/matrices: Efficacy (proven=3, somewhat=2, not proven=1), Patentability (yes=2, no=1), Freedom to operate (yes=2, no=1), Product type (disposal=5, reusable=4, implantable=3, capital equipment=2, service=1), Revenue model (fee per use=2, subscription=1), and Availability (over the counter=3, prescription=2, physician sell=1). After aggregating the final scores, 1 or 2 concepts with the highest scores are selected for further development and implementation.

Modified 'Implement' phase and Tool 3

Successful implementation of medical products requires a well-defined strategy and a series of actions, including concept/technology research and development, intellectual property protection, product safety testing, product quality management, clinical validation, and regulatory clearance. This is what makes the medical technology design and innovation process distinct from conventional product development. However, the conventional Biodesign process lacks necessary instrumentation to consider crucial implementation barriers, such as healthcare disparities, socio-cultural factors, underdeveloped innovation ecosystems, organizational challenges, and market entry obstacles, while strategy development. Here is the new strategy development approach using Tool 3.

(a) Tool 3: Strategy development for implementation

In the process of bringing medical technology to market, key milestones such as IP management, R&D, manufacturing, clinical validation, regulatory approval, quality control, marketing, and distribution demand a well-planned strategy to address technical and external

hurdles. While the existing Biodesign process outlines various strategic processes for addressing implementation phase objectives, specific concepts like reimbursement strategies and regulatory clearance pipelines are not directly applicable to LMIC settings. This phase demands substantial financial, resource, and time investments (spanning 3-7 years) compared to earlier stages. Establishing a clear roadmap for essential objectives in LMICs is challenging due to the nascent state of the innovation ecosystem and other implementation obstacles. Consequently, many medical technology designers from LMICs, including Biodesign fellowship alumni, grapple with challenges arising from the absence of comprehensive information on commercialization strategies and a lack of an effective approach within the Biodesign process to plan and navigate implementation-level hurdles.

Tool 3

Strategy making for R&D, IP, Quality management, Clinical trial, Regulatory approval activities

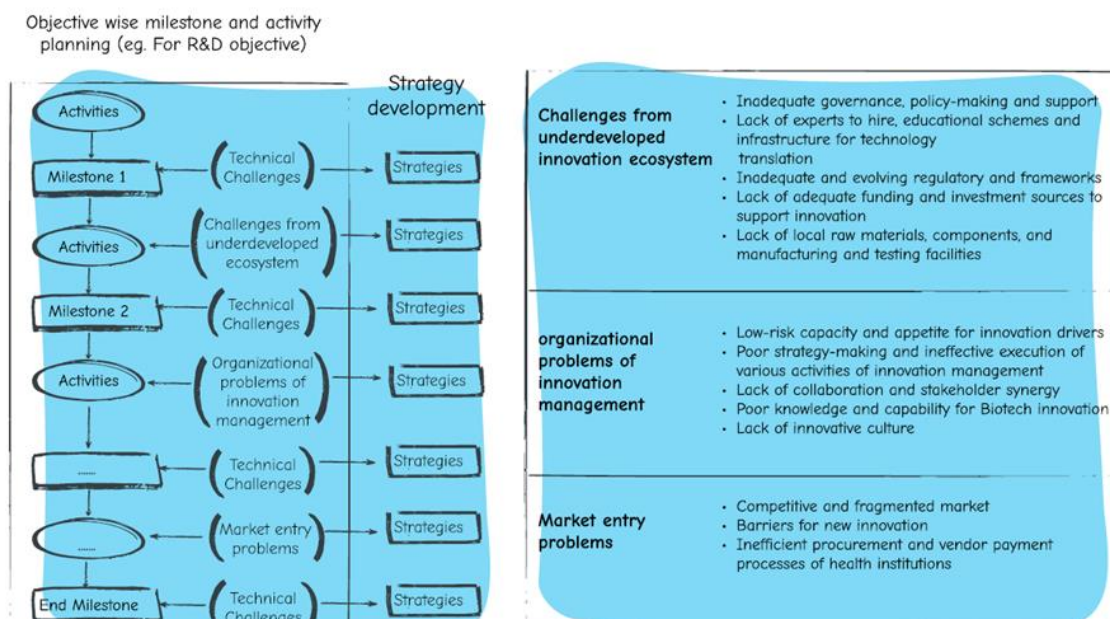


Figure 5-23: Common strategy development process (source: author generated)

The new tool 3 and advantage: Tool 3 (Figure 5.23), provides a standardized strategy development approach for the implementation phase's major objectives. It highlights three categories of challenges beyond technical ones: 1) Underdeveloped innovation ecosystem, 2) Organizational problems of innovation management, and 3) Market entry issues. For any objective (e.g., R&D), the process begins by defining milestones and their order of execution. Key technical and implementation challenges for each milestone are then identified, drawing on expert opinions and research. Subsequently, all necessary activities for these milestones are mapped, along with potential technical and implementation challenges. Once milestones,

activities, technical, and implementation challenges are mapped, experts help formulate strategies to address them. This approach is universally applicable to major implementation objectives. After applying this strategy development approach across objectives, outlining the strategic roadmap for medical technology's commercialization and execution timelines becomes possible (See Figure 24).

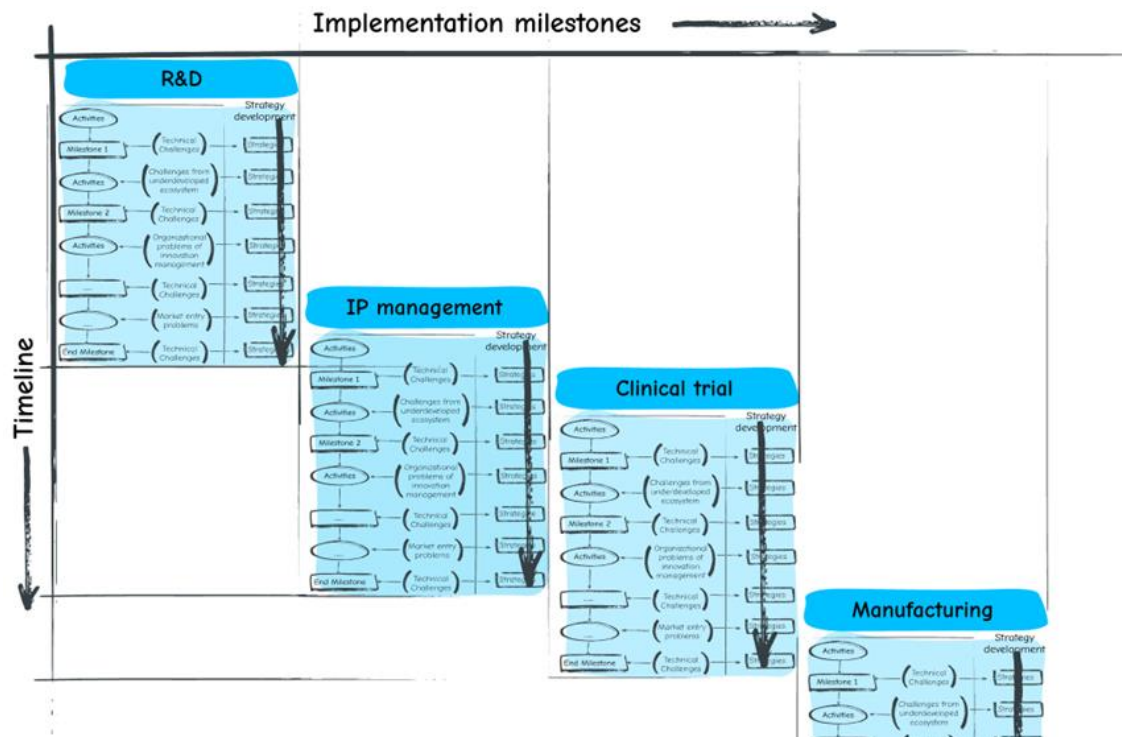


Figure 5-24: Project timeline prediction (source: author generated)

Tool 3 usage guideline:

The process requires subject matter expertise to comprehend potential challenges and barriers and propose viable strategies against potential threats. Collaboration with experts is highly advisable to bring necessary expertise before the development of a strategy. Strategy development goals can encompass various healthcare implementation objectives, such as R&D strategy development, regulatory strategy development, clinical strategy development, etc.

- i. Begin by identifying key milestones in the process. Document them sequentially on paper, leaving spaces between them for the inclusion of text. Consult the template in Figure 5.23, where milestones are represented within rectangular shapes on the left side.
- ii. Identify the necessary activities that will lead to achieving these milestones. Document them before the milestones. Establish the flow of activities and milestones, referring to the template in Figure 5.23, where activities are represented between milestones within

oval shapes on the left side.

- iii. Anticipate various technical and implementation challenges that could potentially act as barriers to achieving those milestones and activities. Refer to the template in Figure 5.23, where various technical and implementation challenges are outlined in the center next to the milestones and activities.
- iv. Propose various strategies that could be adopted to overcome these barriers and challenges. Refer to the template in Figure 5.23, where strategies are suggested against the forecasted challenges on the right side.

5.3.3 Results of toolkit evaluation

The modified Biodesign process has certain new toolsets compared to the conventional Biodesign process. However, in terms of outcomes from workshops 1 and 2, the deliverables were the same in both. These included: identified problems, need statements, need criteria, concepts, and implementation strategies.

The new tools within the modified Biodesign process are mostly analytical, informing designers about the factors to consider and how to consider them. However, they do not objectively control the outcomes. The outcomes remain subjective and provide creative freedom to designers. Depending on the designer's ability to analyze, understand specific contexts and factors, and how they weigh the filtering process, there exists subjectivity in the nature of the final workshop deliverables.

To illustrate this, the Tables 5-H and 5-I, below presents all problems identified and need statements developed from the two workshops, respectively.

Table 5-H: The pools of problems identified from Workshop 1 and 2

Identified Problem Statements	
Workshop 1 (conventional Biodesign Process)	Workshop 2 (Modified Biodesign Process)
<ul style="list-style-type: none"> • lack of awareness among the people to identify the problem and to give basic first aid • lack of clinics and diagnosis centre • expensive treatment process • the person has to close the hole every time they speak • Problem in using multiple tools and using them in narrow passages • Not always there is a suitable object to provide head support • Not everyone around the patient understands the importance of timing the seizure • Women are not ready to enrol in free screening programs and come to camps for screening 	<ul style="list-style-type: none"> • Absence of Health care centre in rural areas • Wastage of leftover acetic acid at the end of the day • Financial problem, • duration of overall procedure • pain during the examination • convincing the patient that the process is safe • Miscalculation of proportions" • Insufficient light, • sanitization of instruments" • Hygiene of surroundings • Difficulty in maintaining the patient records • Managing the patients in the health care centre

<ul style="list-style-type: none"> • The patients do not turn up for follow up after screening • If the symptoms of cancer (head, neck) are not detected in the early stage, complications may lead to death. • Handling all the instruments by the healthcare professionals during the biopsy procedure is difficult • Time spent on waiting for the result may delay the further treatment process • There might arise hygiene issues during regular closing and opening of the hole to speak • The patient suddenly started shaking and collapsed. It was as if he was getting electric shocks. The patient is unable to control his body, brain activity becomes abnormal. • The common person does not know how to help someone who has a seizure. • The seizures can occur anytime without warning. • Most women in rural areas are afraid of checkups as they have little or no awareness. The people in rural areas do not know about it and don't report it which leads to deaths. • The virus, HPV is a contributor. • Vocal cord cancer. Unable to breathe and speak properly. Condition worsening with time. • The fellow kids do not know how to handle the situation and unable to detect the occurrence of seizure. • most women do not go under annual health checkup for diagnosis of any problems • most women do not go under annual health checkup for diagnosis of any problems. Lesions may lead to cervical cancer. Vaccines are costly. No way to monitor or biopsy. Scared of the word "Cancer". Neglecting own health after looking after the family. • People are not aware of the cancer and most likely will not go for the screening. HPV can also lead to this cancer. • painful process. Inflexible instruments. Invasive technique. • Hole in the neck. Patient Needs to close the hole in the neck while speaking. • Unable to detect the reason for seizure. Unable to detect the reason for the malfunction of neurons. Cause of epilepsy remains unknown. • strain for patient as well as doc. • usage of acetic acid in cervix might cause change in PH. Also it might create an irritation or burning sensation. • lack of DIY device for visual inspection of cervix cancer. • difficulties in follow up of treated patients • difficulties in Door step medical checkups • Doc are still using the traditional way of mouth observation. 	<ul style="list-style-type: none"> • Preparation of chemical for visual inspection freshly every other day with distilled water • Lack of sleep for the patient due to anxiety of the treatment process • Afraid for the use of speculum while inspection • the cryotherapy is considered as over treatment. It is expected to have any undesired effect on the patient • Worries associated with the term 'cancer' makes the reluctant to go forward with the treatment • Reluctant to give consent for cryotherapy • Reluctant to come for screening due to ill information • There are bigger health issues for women that they are concern than a possibility of cancer in future which is bugging them now. • Vaccination against HPV virus not possible due to high cost of the Vaccine • Alternative screening methods are costly and un accessible • Trial and error nature of choosing speculum size may cause pain • Handheld devices like regular torches are used may be difficult to handle in middle of procedure • Procedures can seem to be very daunting • Procedure may sometimes cause pain • Patient does not return for follow up actions • Heavily reliant on healthcare provider's visual ability to distinguish the different lesions can be easy to miss • lots of waste generated like sheets being thrown away • Women not coming for regular and follow ups because they are afraid or ignorant of procedures • All records seem to be analogue and no digital means implemented for easy future access and for follow up actions • low cost and efficient Lighting apparatus for the inspection • "Measuring may not be accurate • Measuring apparatus may be defective" • Patient might feel pain on applying the solution on the cervix • "Unable to provide of room for test or conducting the screening procedure, • unable to provide the apparatus and materials required • defective products • lack of funds to get adequate apparatus required" • "Unskilled doctor/healthcare professional who apply the solution on the cervix • doctor Unable to detect the colour changes " • doctor Unable to detect the colour changes • The temperature and humidity effects on the prepared acetic acid solution, colour changes after applying on the cervix if not done in a controlled environment
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<ul style="list-style-type: none"> • touch sensitivity to find the neck cancer will changes doc to doc • Unergonomic, non-flexible and large medical equipment • user need to close the neck hole to talk to someone • difficulties in usage of medication when the user have seizure • difficulties in predict seizure • Problem breathing • Unable to detect the cause of seizure. • Unable to know the reason for breathing trouble • Doctors/ healthcare workers are unable to convince the women about the importance of getting treated for HPV • Women are not aware of the problems that might come because of the long-term HPV and fear of the unknown. • Patient able to speak only by placing a finger to close the hole in the neck • The device has straight metal parts which are not flexible and cause wound in the tissue of the throat. • Difficulty for patient to safe guard self in Seizure situation (Unconscious) and ask for help and treatment when he is alone • Difficulty for person with patient to ask for help and perform right practice with patient to help them out • Two tools required for the same track observation process." • During patient screening camps, tools may need to be reused and cleaned multiple times for the same purpose • Women may experience difficulty in talking about and expressing interest in getting checked for cervical cancer. • It can be difficult to encourage women to attend cervical cancer checkup camps. • Lack of awareness about epilepsy • Fear of social stigma in women about cancer • Cannot detect or indicate the event of epilepsy before hand • Repeated closing using finger may lead to potential infection. • A device can be designed to aid his process of speaking. • Covering it while performing his day-to-day activities like taking a bath, wearing clothes, etc. • The reason why many females in rural areas do not go for regular checkups is because they feel uncomfortable in such examinations. • Safety and privacy concerns • Unable to reliably detect and cure the cause of epileptic seizures • No real accurate non-invasive cost-effective method to predict the onset of epileptic seizures 	<ul style="list-style-type: none"> • "Women may be hesitant • misconceptions about the test and follow-up procedure • scared • Improper communication with the patients" • Inproper Information management of woman who come for screening if not done digitally • Unable to communicate properly and convince women for the test • Absence of method/ tool for quick home based screening • Preparation of fresh acetic acid solution every day for screening • Improper storage of consumables • Unavailability of proper light source for screening • Unavailability of appropriate size of the speculum • Lack of awareness about the disease and screening • Travel to healthcare centre for screening • Pain experienced during the insertion of speculum • Wait time in healthcare facility for diagnosis • Loss of wages during the time spent on diagnosis & treatment • Lack of willingness of the woman to go through the procedure • Lack of cooperation from the patient during the procedure • Over / under application of the acetic acid solution • Lack of proper visibility of cervix area to detect change in appearance of cervix • Occurrence of injury/ bleeding during the procedure • Frequent adjustment of light source to carry out the procedure • Inappropriate preparation of acetic acid solution (variation of concentrations) • Convincing the affected patients for the follow-up/ treatment • Delay in the treatment if the patient does not follow up • Unavailability of hygienic and conducive environment • Trust issues of the patient with the HP to permit for diagnosis • Lack of support from family for screening and diagnosis • Overcrowd in healthcare centre • Lack of hygiene in washroom/ examination room • Excess waste generation during/ after the procedure • Disposal of waste after each procedure & each day
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<ul style="list-style-type: none"> • Throat biopsies require a very invasive procedure involving a direct laryngoscope that leads to bruising and discomfort in patient post procedure. • Current treatments leave very visible holes in the neck for breathing and speaking requires the user to physically close it to speak • Vaccine related solutions are too costly • Unnecessary amount of treatment given in the assumption that patients will not return • Women are scared off due to lack of awareness of the disease and treatments available • Self-help during Seizures to prevent head injury • Improve Trust factor in Health care provider, Address other Health problems in women • Easily accessible tools for self-detection of such symptoms • How does one know if minor muscle twitching can be associated with early form of epilepsy detection? • Unseen internal damage post treatment • Lack of knowledge and screening centre for cervical cancer • Need proper lighting to detect any changes in the cervix for proper inspection • Difficulty talking and breathing at the same time. • Tools for biopsy may causes injury to the other parts in the mouth • Positioning the body of the patient quickly to avoid any injury to the patient • There is a possibility that the person might find difficulty to start breathing again after the seizure has stopped (stakeholder: patient) • the seizure attack was sudden and the fellow mates (children) did not know what to do • The attack was sudden (Stakeholder: those dealing with smart medical devices for giving alert about the attack) • "Use of a simple torch in place where good lighting is required for the inspection (Stakeholder: the providers) • lack of awareness among the women about the easy screening procedure which is why they are hesitant • Lack of smart devices that can monitor woman's health during menopause unhealthy lifestyle • Lifestyle, habits like smoking and drinking • awareness about self-screening • Always get the appropriate head support during the attack is difficult. • Awareness • Always such kind of trained person get around the patient is difficult so that the patient can go through the appropriate procedure. • Choke problem 	<ul style="list-style-type: none"> • Incomplete cleaning of apparatus due to lack of time during multiple procedure • Immediate treatment procedure after diagnosis as per the need • Speculum size identification issue • Medical waste generation • Improper size of speculum causes pain in patient • Quantity of acetic acid to be mixed can't be guessed and gets wasted since excess needs to be discarded by end of day. • Getting women to consent is difficult • Disposable gloves and sheets may not be economically viable for under developed countries • One person doing all the tasks • The acetic acid solution has to be prepared at the clinic every day freshly before the procedure is done. • The current apparatus is uncomfortable for the patient and sometime painful • There are other conditions which could lead to the doctor being unable to diagnose the pre-cancer condition • Unavailability of any other method for diagnosis
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<ul style="list-style-type: none"> • If the guy who had known to provide first aid was not present in that area, the boy would have harmed himself. • The organisers find it difficult to convince the people to attend the medical camp and find it equally difficult to convince them to undergo cryotherapy • loss of ability of speech after laryngectomy (need to close hole while speaking) and recovery period 	
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Table 5-1 The pools of Need Statements developed from Workshop 1 and 2

Developed Need Statements	
Workshop 1 (conventional Biodesign Process)	Workshop 2 (Modified Biodesign Process)
<ul style="list-style-type: none"> • a way to improve awareness among the people to identify the problem and give basic first aid for the people presents at the incident location • a way to improve the availability of diagnosis cancer for the women living in rural areas in the early stage by developing self-testing kit • a way to minimize the cost for the treatment process for the people with financial constraints by coming up with more affordable method • a way to close the hole every time they speak, for the person who underwent surgery so they can speak comfortably without closing the hole manually • a way to minimizing use of multiple tools in narrow passages for the doctors who examining by making a single tool to perform multiple functions • A way to provide head support to the patient affected by epileptic seizures • A way to record time during seizures when an epileptic patient suffers from seizures • A way to encourage women to undergo cervical cancer screening by providing home-based screening devices • A way to enable women affected with cervical cancer to continue with follow up • A way to detect the symptoms of neck/ throat cancer of throat cancer prone patients (smokers) by detecting the lumps or • A way to reduce the complexity of handling multiple instruments by the doctor during a biopsy by simplifying the instrument of use and procedure • A way to reduce the time delay to obtain the result of the biopsy for patients suffering from\ throat cancer by detecting the lesions or cancerous cells during the biopsy • A way to prevent infections in patient undergoing rehabilitation of throat cancer by enabling a hygienic way to open and close the hole while speaking 	<ul style="list-style-type: none"> • A quick and easy way to screen adenocarcinoma in women that helps them to save time. • A sterile and hygienic way to screen adenocarcinoma in women that ensures hygiene of patient and environment • An efficient way to prepare the consumables for screening adenocarcinoma in women that allows the staff a easy way of record keeping • “A (pain-free and informed) way to (examine cervices) in (rural low-income women of age 30 to 40) that allow (easy inspection of cervices)” • “A (treatment without undesired outcome and taboo free) way to (treat squamous intraepithelial lesion) in (rural low-income women of age 30 to 40) that allow (side effect free treatment for cervical lesions)” • “A (easier and low cost) way to (prepare 5% acetic acid) by (nurse) that allow (hassle free cervical examination for squamous intraepithelial lesion)” • An (effective and guaranteed pain-free) way to (open the cervix) in (Adult women of all age groups) that (makes the cervical scanning easy and pain-free.) • A (more reliable, digital and incentive providing) way to (make patients come for check-ups and follow ups) in (Adult women of all age groups) that (assists in maintaining patient information along with scheduling and following up on future check-ups). • A (more accurate and skill independent) way to (identify squamous or endocervical columnar differentiation lesions of cervical cancer) in (Adult women of all age groups) that (helps in preventing false positives and produces more trust amongst patients). • a Low cost and handy Lighting apparatus that allow easy detection of squamous differentiation after the application of acetic acid solution in the cervix in woman taking the screening test that help doctors for efficient inspection.

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| <ul style="list-style-type: none"> • A way to systematically give first aid to epileptic patient. • Something to give a warning of an approaching seizure. • A way to diagnose the population which are susceptible to get a seizure. • To perform the testing efficiently. • A way to address the handling of seizure patient by commoners that increases awareness of seizure. • A way to go under annual health check-up in women over 40 years of age that increases the chance to detect any early signs of cervical cancer, breast cancer etc. • A way to make vaccines for cervical cancer affordable in women ranging from 30-60 years of age that can create the culture of preventive care. • A way to monitor and do biopsy in women ranging from 30 to 60 years suffering from cervical cancer that can lead to better follow ups. • A way to make people aware of head and neck cancer in common population specially those who smoke and drink making them more aware of the disease so that they can take preventive measures and for early detection. • A way to make people go for annual screening of head and neck cancer specially in people who drink and smoke by making the process free and not time consuming. • A way to make biopsy of throat cancer non-invasive in people having sore throat, trouble swallowing, globus and hoarseness to make the process easy. • A way to address the hole in the neck in patient having undergone surgery for cancer of the vocal cord that can avoid the making of the hole. • A way to find the cause of epilepsy in patient so that with the help of technological advancement it will be easy to diagnose, prevent and cure. • A way to do cervix cancer diagnose that can be used by user itself. A way to avoid acetic acid in visual inspection of cervical cancer. An easier and cheap way to do pap smear test by the patient itself. • A way to follow up treated patients. A way to motivate patient to visit PHC to do both treatment/ follow up • A way to address the problem of breathing post seizure in patients such that the patient is able to breath normally post seizure. • A way to address the problem of being unable to detect the cause of seizure by doctors that enables doctors to find the causal agent of the seizure. • A way to address the problem of being unable to convince the women about the importance of getting treated for HPV by Doctors/Healthcare | <ul style="list-style-type: none"> • a painless and well-known way to apply acetic acid solution in the cervix while performing the procedure for the detection of squamous differentiation in Woman who is taking the screening test (age: 30-50) that allow the women confidently come for the screening • An efficient and familiar device to perform the detection of squamous differentiation in Woman who is taking the screening test (age: 30-50) that provide clear, accurate and understandable results for easy communication to the woman • A ready-to-use and low-waste generation way to overcome the time delay and reduce disposables in the preparation of consumables by healthcare professionals that allows an effective method for screening of squamous differentiation • A self-cleansing and customisable way to overcome the problems related to unhygienic and inappropriate-sized apparatus used by healthcare professionals that allow a sterile and efficient method for screening of squamous differentiation in middle-aged women • “A painless and rewarding way to screen squamous differentiation of cervical cancer in women above 30 yrs that allow correct speculum size identification” • “A cost-effective and efficient way to help diagnose cervical cancer by health care providers that allow correct vaginal size identification” • “A waste-free and skill-efficient way to help reduce waste during cervical cancer diagnosis by health care providers that allows minimisation of medical waste” • A painless and cost-effective way to diagnose cervical cancer in female population that leads to a cervical cancer free female population. • An accurate and easy way to diagnose precancerous state in patient exposed to HPV infection that allow detecting cancer even though there are other pre-existing conditions. • Research leading to fewer manual interruption and availability of pre-prepared acetic acid or similar solution to reduce the wastage of resources in hospitals that leads to improved management of resources. • A quick and easy way to screen cervical cancer in women that helps them to save time. • A sterile and hygienic way to screen cervical cancer in women that ensures hygiene of patient and environment • An efficient way to prepare the consumables for screening cervical cancer in women that allows the staff an easy way of record keeping • A (pain-free and informed) way to (examine cervices) in (rural low-income women of age 30 to 40) that allow (easy inspection of cervices) • A (treatment without undesired outcome and taboo free) way to (treat lesions) in (rural low- |
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<p>workers that women willingly come and get diagnosed and treated for HPV.</p> <ul style="list-style-type: none"> • A way to address the problem of lack of awareness in women about long term HPV and involve them willingly in diagnosis and treatment of the same. • A way to address the problem of speaking by placing finger on the hole caused because of surgery in neck cancer patients that prevents infection. • A way to address the problem of straight metal parts in the intubation device in design that the patient is not harmed when performing the procedure. • A way to auto detect seizure situation of seizure patient and auto connect to the ambulance nearby, Help nearby • A way to alert and inform person who is nearby to the seizure attack patient, to help him out of the situation. • A way to get self-checked for cervical cancer test by Indian rural women, so the risk of disease will reduce. • A way to remove social stigma and fear of cancer in middle aged women so that diagnosis of cervical cancer increases. • A way to detect the event of epilepsy beforehand in epilepsy patients so that they patient safety is not affected • A way to prevent infection in vocal cord surgery patients to aid in speaking and performing other day to day activities. • A way to provide a comfortable situation for rural women with possible cervical cancer so that more females get diagnosed in an early stage. • A way to reliably detect and cure the cause of epileptic seizures so that doctors can accurately identify the source of seizures and hence the patient can be permanently cured of their epilepsy. • An accurate, non-invasive and cost-effective way to predict the onset of epileptic seizures in patients so that patients are now better prepared against unpredictable seizures and carry on with their lives worry free. • A way to make throat biopsies requiring the very invasive procedure involving a direct laryngoscope that leads to bruising and discomfort in patients that leads to the conception of an injury free method or device for throat biopsy that causes minimal discomfort or bruising in patients post procedure. • A way to make current treatments that leave very visible holes in the neck for breathing and speaking in patients that leads to finding an alternative hole less solution or makes the process of speaking easier during life post operation. 	<p>income women of age 30 to 40) that allow (side effect free treatment for cervical lesions)</p> <ul style="list-style-type: none"> • A (easier and low cost) way to (prepare 5% acetic acid) by (nurse) that allow (hassle free cervical examination) • An (effective and guaranteed pain-free) way to (open the cervix) in (Adult women of all age groups) that (makes the cervical scanning easy and pain-free.) • A (more reliable, digital and incentive providing) way to (make patients come for check-ups and follow ups) in (Adult women of all age groups) that (assists in maintaining patient information along with scheduling and following up on future check-ups). • A (more accurate and skill independent) way to (identify the possible lesions or signs of cervical cancer) in (Adult women of all age groups) that (helps in preventing false positives and produces more trust amongst patients). • a Low cost and handy Lighting apparatus that allow easy detection of colour changes after the application of acetic acid solution in the cervix in woman taking the screening test that help doctors for efficient inspection • a painless and well-known way to apply acetic acid solution in the cervix while performing the procedure for the screening test in Woman who is taking the screening test (age: 30-50) that allow the women confidently come for the screening • An efficient and familiar device to perform the cervical cancer screening test in Woman who is taking the screening test (age: 30-50) that provide clear, accurate and understandable results for easy communication to the woman • A rapid and self-screening way to overcome the problem associated with taboo/ trust issues in the middle-aged women that is an effective home-based solution for cervical cancer • A ready-to-use and low-waste generation way to overcome the time delay and reduce disposables in the preparation of consumables by healthcare professionals that allows an effective method for screening of cervical cancer • A self-cleansing and customisable way to overcome the problems related to unhygienic and inappropriate-sized apparatus used by healthcare professionals that allow a sterile and efficient method for screening for cervical cancer in middle-aged women • A painless and rewarding way to screen cervical cancer in women above 30 yrs that allow correct speculum size identification • A cost-effective and efficient way to help diagnose cervical cancer by health care providers that allow correct vaginal size identification
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| <ul style="list-style-type: none"> • A way to make the very costly vaccine related solutions for patients that leads to obtaining a cost-effective variant of the HPV vaccine • A way to prevent head injury in patients during seizure that can be self-helped when no assistance is available. • A way to address other health issues besides cervical cancer among rural women to enhance the motivation to get checked up at various Health centres in the rural areas • A way to improve the trust factor in Health Care providers that can amplify and enhance the interaction between health workers and the women in rural areas. • A way to easily access self-help tools for chain smokers that can detect the symptoms at home periodically. • A way to detect if minor muscle twitching in people that can suggest the possibility of early-stage epileptic symptoms • A way to minimize un foreseen internal damage in patients that can occur during throat biopsy treatment. • A way to ease Screening of Cervical Cancer such that the cancer can be detected early • A way to make the speaking easier for people who have undergone laryngectomy surgery without much effort • A way to aid positioning of the epileptic patient such that no further injury happens • a way to help start breathing again in case of difficulty after the seizure has stopped in the patient that can be used by the people around him to help him • a way to use good lighting for the inspection of the patient that helps the doctors perform the inspection in proper light • a way to monitor woman's health during menopause by woman themselves that can alert the woman when they detect some change that requires consultation of a healthcare professional • a way to build awareness about self-screening in people that will help in early detection of throat cancer • A simpler way for the women to self-examine themselves for with the help of tool for cervical cancer. • Increasing the awareness around the patient about the cancer treatment and making a safer environment or encouraging themselves to get themselves treated. • A way to help people who had under gone Tracheal-Oesophageal Puncture to speak continuously for longer period of time. • A way to take tissue sample easily to test from throat cancer • A way to help people who are prone to seizure not harm themselves in case no other person | <ul style="list-style-type: none"> • A waste-free and skill-efficient way to help reduce waste during cervical cancer diagnosis by health care providers that allows minimisation of medical waste • Research leading to fewer manual interruption and availability of pre-prepared acetic acid or similar solution to reduce the wastage of resources in hospitals that leads to improve med management of resources. • A painless and cost-effective way to diagnose cervical cancer in female population that leads to a cervical cancer free female population. • An accurate and easy way to diagnose precancerous state in patient exposed to HPV infection that allow detecting cancer even though there are other pre-existing conditions. |
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surrounding them is aware of the first aid procedure <ul style="list-style-type: none"> • A way to make the process very transparent that those who feel reluctant to undergo the procedure feel secure enough to come forward 	
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At a quick glance, one can appreciate the quality of the need statements and problems identified in both Workshop 1 and Workshop 2 pools, but comparison was difficult. So, we realized that expert feedback is required on the nature of the problems identified, need statements developed, filters used, implementation strategies developed, etc. This comparison was worthwhile, as initially, we did not know how the new tools performed compared to the conventional Biodesign process, nor how the two workshop outcome data sets compared to each other.

Thus, 11 Biodesign fellowship alumni primarily conducted the evaluations in two main aspects: 1) They compared the nature of outcomes and processes from Workshop 1 (based on the Conventional Biodesign process) and Workshop 2 (utilizing new toolsets and methods) and provided descriptive feedback and comments. 2) They assigned scores to assess the relevance of final selected need statements and concepts from the two workshops, based on LMIC-specific requirement metrics. Two Excel sheets were prepared to organize student tasks from Workshop 1 and Workshop 2. These sheets, crafted by the authors, were distributed individually to the experts, who were kept unaware of the Biodesign process changes in the datasets to prevent evaluation bias. To analyze the nature of identified problems, ideas, and filters used, etc., experts were invited to review and comment by comparing corresponding tabs (each dedicated to a specific task, such as identified problems) in the two Excel sheets. Separate Excel files were provided to the experts for their assessments, enabling them to conduct a comparative review of the datasets. Detailed information follows.

Nature of the problems identified from the provided clinical data

Important findings by the experts include a greater diversity in the nature of problem statements and a higher number of problems identified per observation from Workshop 2. Comments from experts revealed that the problems identified in Workshop 2 encompass LMIC-specific considerations, cultural issues, healthcare infrastructure, and implementation challenges. Credit was given to the new approach of observation and problem identification. Table 5-J shows sample problems identified for the same clinical observation (sample video on cervical cancer) from the two workshops, along with experts' comments.

Table 5-J: Nature of the problems identified in the two Workshops

	Sample problems identified (screenshots from team Excel sheets)		Expert comments
Workshop 1	Observation	Problem	"I noticed in workshop 2, they seem to be much better at identifying problems compared to workshop 1. It's really beneficial to have this systematic and categorical approach."
	People are not aware about the cervical cancer and they do not get it checked until it reaches its fatal stages. Even if psi's conduct remote screening services for them, people hesitate to get checked and are afraid of being treated. The doctors use freshly made acetic acid with cotton swab in the cervical area and then inspect the cervix with good light to detect any signs of cervical cancer. So during the inspection the doctor would require extra set of help for the lighting and inspections for true detections	Lack of knowledge and screening centre for cervical cancer Need proper lighting to detect any changes in the cervix for proper inspection	
Workshop 2	Problem Type	Problem	"And what I found interesting is how they had prior information about the different types of problems. It really helped them provide a more insightful perspective."
	Absence of healthcare solution	Absence of method/ tool for quick home based screening	
	Gap and issue with current apparatus, instrument, consumables	Preparation of fresh acetic acid solution everyday for screening	
		Improper storage of consumables	
		Unavailability of proper light source for screening	
		Unavailability of appropriate size of the speculum	
	Patient pain points	Lack of awareness about the disease and screening	
		Travel to healthcare centre for screening	
		Pain experienced during the insertion of speculum	
		Wait time in healthcare facility for diagnosis	
	Provider pain points	Loss of wages during the time spent on diagnosis & treatment	
		Lack of willingness of the woman to go through the procedure	
	Procedural issue	Lack of cooperation from the patient during the procedure	
		Over / under application of the acetic acid solution	
		Lack of proper visibility of cervix area to detect change in appearance of cervix	
		Occurrence of injury/ bleeding during the procedure	
	Complications with outcome	Frequent adjustment of light source to carry out the procedure	
Inappropriate preparation of acetic acid solution (variation of concentration)			
Convincing the affected patients for the follow-up/ treatment			
	Delay in the treatment if the patient do not follow up		
Environmental issue	Unavailability of hygienic and conducive environment		
Socio-cultural issue	Trust issues of the patient with the HP to permit for diagnosis		
	Lack of support from family for screening and diagnosis		
Healthcare facility and management issues	Overcrowd in healthcare centre		
	Lack of hygiene in washroom/ examination room		
	Excess waste generation during/ after the procedure		
	Disposal of waste after each procedure & each day		
Healthcare service gap	Incomplete cleaning of apparatus due to lack of time during multiple procedures		
	Immediate treatment procedure after diagnosis as per the need		

Nature of Need statements

Table 5-K illustrates sample need statements from the two workshops and emphasizes the feedback received from experts. The Expert analysis revealed that the need statements from workshop 2 encompass additional requirements from individuals, society, and healthcare settings, in addition to clinical requirements, for successful implementation. Furthermore, the experts acknowledged the effectiveness of the need-scoping approach in directing attention towards addressing specific clinical stages or presentations of a disease, as well as specific events related to altered biomechanisms or pathophysiology. The additional feedback

highlighted the importance of incorporating considerations for the type of implementation challenges within the need statements accordingly.

Table 5-K: Nature of Need statements developed in the two workshops

	Sample 'need statements' (screenshots from team Excel sheets)	Expert comments							
Workshop 1	<table border="1"> <thead> <tr> <th>Problem, Population, Outcome</th> <th>Need statement: A way to (address problem (population) that (outcome)</th> </tr> </thead> <tbody> <tr> <td> problem: Lack of knowledge and screening centre for cervical cancer population: Female population in rural areas outcome: Make it easier for women the early detection of cervical cancer so that it can be treated timely. </td> <td>"A way to ease Screening of Cervical Cancer that the cancer can be detected early"</td> </tr> </tbody> </table>	Problem, Population, Outcome	Need statement: A way to (address problem (population) that (outcome)	problem: Lack of knowledge and screening centre for cervical cancer population: Female population in rural areas outcome: Make it easier for women the early detection of cervical cancer so that it can be treated timely.	"A way to ease Screening of Cervical Cancer that the cancer can be detected early"	<p>"I was really impressed with the scoping technique they used in Workshop 2. It's so valuable in creating tailored need statements for various clinical presentations of the disease from just one set of observations."</p> <p>"And what caught my attention was how in Workshop 2, they covered a broader spectrum of healthcare challenges. They delved into issues related to infrastructure and societal norms, which is crucial for a holistic perspective."</p>			
Problem, Population, Outcome	Need statement: A way to (address problem (population) that (outcome)								
problem: Lack of knowledge and screening centre for cervical cancer population: Female population in rural areas outcome: Make it easier for women the early detection of cervical cancer so that it can be treated timely.	"A way to ease Screening of Cervical Cancer that the cancer can be detected early"								
Workshop 2	<table border="1"> <thead> <tr> <th>Problems, Population, Outcome</th> <th>Need statement: "A (desired outcome characteristic of healthcare and implementation problem)/way to (address clinical condition) in (population) that (all desired healthcare outcome)"</th> </tr> </thead> <tbody> <tr> <td> healthcare problem: Absence of method/ tool for quick home based screening Desired outcome: Availability of home-based screening Implementation problem: Trust issues of the patient with the HP to permit for diagnosis Desired outcome: Self testing kits made available for screening population: Middle-aged woman </td> <td>"A rapid and self-screening way to overcome the problem associated with taboo/ trust issues in the middle-aged women that is an effective home-based solution for cervical cancer"</td> </tr> <tr> <td> healthcare problem: Time delay in preparation of consumables Desired outcome: Availability of ready-to-use doses of acetic acid and consumables Implementation problem: Excess waste generation during/ after the procedure Desired outcome: A low-waste procedure population: healthcare professional </td> <td>"A ready-to-use and low-waste generation way to overcome the time delay and reduce disposables in the preparation of consumables by healthcare professionals that allows an effective method for screening of cervical cancer"</td> </tr> <tr> <td> healthcare problem: Unavailability of appropriate size of the speculum Desired outcome: Customisable size of tool for diagnosis Implementation problem: Incomplete cleaning of apparatus due to lack of time Desired outcome: Procedure that is hygienic population: healthcare professionals or middle-aged women undergoing screening </td> <td>"A self-cleansing and customisable way to overcome the problems related to unhygienic and inappropriate sized apparatus used by healthcare professionals that allow a sterile and efficient method for screening for cervical cancer in middle-aged women "</td> </tr> </tbody> </table>	Problems, Population, Outcome	Need statement: "A (desired outcome characteristic of healthcare and implementation problem)/way to (address clinical condition) in (population) that (all desired healthcare outcome)"	healthcare problem: Absence of method/ tool for quick home based screening Desired outcome: Availability of home-based screening Implementation problem: Trust issues of the patient with the HP to permit for diagnosis Desired outcome: Self testing kits made available for screening population: Middle-aged woman	"A rapid and self-screening way to overcome the problem associated with taboo/ trust issues in the middle-aged women that is an effective home-based solution for cervical cancer"	healthcare problem: Time delay in preparation of consumables Desired outcome: Availability of ready-to-use doses of acetic acid and consumables Implementation problem: Excess waste generation during/ after the procedure Desired outcome: A low-waste procedure population: healthcare professional	"A ready-to-use and low-waste generation way to overcome the time delay and reduce disposables in the preparation of consumables by healthcare professionals that allows an effective method for screening of cervical cancer"	healthcare problem: Unavailability of appropriate size of the speculum Desired outcome: Customisable size of tool for diagnosis Implementation problem: Incomplete cleaning of apparatus due to lack of time Desired outcome: Procedure that is hygienic population: healthcare professionals or middle-aged women undergoing screening	"A self-cleansing and customisable way to overcome the problems related to unhygienic and inappropriate sized apparatus used by healthcare professionals that allow a sterile and efficient method for screening for cervical cancer in middle-aged women "
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Nature of Need criteria synthesized

Table 5-L displays a comparative review of the sample need criteria generated in the two workshops. Experts have acknowledged the slight modification made to the process of need criteria generation by the participants in Workshop 2. The results indicate a categorical breakdown of both clinical and implementation issues, providing equal importance to both clinical and implementation requirements.

Table 5-L: Nature of Need criteria developed in the two Workshops

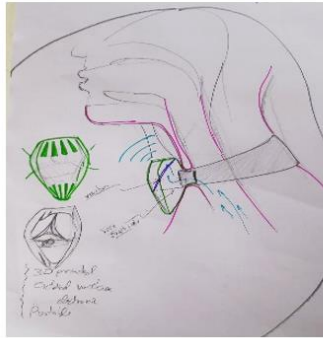
	Sample 'need criteria' (screenshots from team Excel sheets)				Expert comments	
Workshop 1	Must haves		Need Criteria	Nice to have		
	inexpensive <2000 Provide fast results <10 mins portable weight<500g size <20cm3 Skill independent, Accessible easy to use easy Maintenance			Patient Comfort sterilizable Over the counter product Aesthetic,minimal visibility to clinical setup and device functioning Expert consultation Environmentally friendly		
Workshop 2		Must have criteria	Specification/measure		Nice to have criteria	Specification/measure
	Clinical requirements	Faster way of detection of lesions	< 5 minute for detection	Need criterias	Portable	Hand-held device
		High accuracy in the detection of lesions	90 % accuracy		Low waste generation	Consumable to be biodegradable
		Biocompatible	Biocompatible material must be used			
	Implementation requirements	Self -screening	Should have easy and lesser number of steps			
		Trust worthy	Should maintain privacy			
Accessible		Should be made available in local store				

Nature of concepts generation process and outcome

Experts have noted that the concept generation technique utilized in workshop 2 is systematic and guided in comparison to workshop 1, particularly in defining the product's Unique Selling Proposition (USP) and addressing clinical problems. The concepts formulated during workshop 2 effectively address the backend need criteria, as illustrated by the example in Table 5-M.

Table 5-M: Nature of concepts generation process and outcome in the two Workshops

	Sample ideation process and concepts		Expert comments
Workshop 1	Sl no	ideas	"In Workshop 2, the ideation and concept generation technique felt more systematic and guided compared to
	1	3D printed voice box	
	2	External voice box at TEP (electric)	
	3	Text to voice	
	4	Thought to voice system	
	5	External voice box at TEP (non electronic)	
	6	flap to automatically close TEP when speaking	
	7	create bifurcation	
	8	baloon closure	
	9	valve to close TEP	

Sample ideation process and concepts		Expert comments																																				
<p>Embed concept images below</p> <p>Concept1 :</p> 		<p>Workshop 1. It really helped us grasp the underlying need criteria, making the whole process much clearer and effective."</p> <p>"the emphasis on understanding the need criteria helped them develop concepts that were more focused and targeted towards addressing those needs."</p>																																				
<p>Concept description</p> <p>3D printer external voice box. In case of complete destruction of voice box this external voice box helps develop sound which is transferred to mouth cavity which allows for normal speech</p>																																						
Workshop 2	<table border="1"> <thead> <tr> <th></th> <th></th> <th></th> <th>Concept 1</th> </tr> </thead> <tbody> <tr> <td></td> <td>Must have criteria</td> <td>Generate ideas</td> <td>battery operated acetic acid dispenser with automatic solution mixer</td> </tr> <tr> <td rowspan="3">Clinical requirements</td> <td>portable</td> <td>A wet wipe like equipment which is use and throw but compact enough to carry along battery operated acetic acid dispenser with automatic solution mixer</td> <td>an automatic solution dispenser to guide nurses through the process of preparing 5% acetic acid,</td> </tr> <tr> <td rowspan="2">easy to use</td> <td>User-friendly kit that contains pre-measured ingredients and easy-to-follow instructions, which allows nurses to quickly and easily prepare 5% acetic acid</td> <td>a piston pump that automatically sucks in precise amount of acid and water and pumps out on demand</td> </tr> <tr> <td>an automatic solution dispenser to guide nurses through the process of preparing 5% acetic acid, ensuring consistent results</td> <td></td> </tr> <tr> <td>reliable</td> <td>A precise liquid dispenser that automatically prepares and dispenses acetic acid sol a piston pump that automatically sucks in precise amount of acid and water and pumps out on demand</td> <td>syringe type device which will prepare fresh sol. While application</td> </tr> <tr> <td rowspan="4">Implementation requirements</td> <td rowspan="2">low cost</td> <td>A low-cost kit that contains all the necessary ingredients and equipment for preparing 5% acetic acid (like first aid kit)</td> <td>syringe type device which will prepare fresh sol. While application</td> </tr> <tr> <td>syringe type device which will prepare fresh sol. While application</td> <td></td> </tr> <tr> <td rowspan="2">easy to adopt</td> <td>syringe type device which will prepare fresh sol. While application</td> <td>An online ordering system that allows healthcare facilities to easily order and receive the new device or kit for preparing</td> </tr> <tr> <td>A wet wipe like equipment which is use and throw but compact enough to carry along</td> <td></td> </tr> <tr> <td rowspan="2">accessible</td> <td>An online ordering system that allows healthcare facilities to easily order and receive the new device or kit for preparing 5% acetic acid, regardless of their location.</td> <td></td> </tr> <tr> <td>A self examination kit which and be purchased from local pharmacy</td> <td></td> </tr> </tbody> </table>				Concept 1		Must have criteria	Generate ideas	battery operated acetic acid dispenser with automatic solution mixer	Clinical requirements	portable	A wet wipe like equipment which is use and throw but compact enough to carry along battery operated acetic acid dispenser with automatic solution mixer	an automatic solution dispenser to guide nurses through the process of preparing 5% acetic acid,	easy to use	User-friendly kit that contains pre-measured ingredients and easy-to-follow instructions, which allows nurses to quickly and easily prepare 5% acetic acid	a piston pump that automatically sucks in precise amount of acid and water and pumps out on demand	an automatic solution dispenser to guide nurses through the process of preparing 5% acetic acid, ensuring consistent results		reliable	A precise liquid dispenser that automatically prepares and dispenses acetic acid sol a piston pump that automatically sucks in precise amount of acid and water and pumps out on demand	syringe type device which will prepare fresh sol. While application	Implementation requirements	low cost	A low-cost kit that contains all the necessary ingredients and equipment for preparing 5% acetic acid (like first aid kit)	syringe type device which will prepare fresh sol. While application	syringe type device which will prepare fresh sol. While application		easy to adopt	syringe type device which will prepare fresh sol. While application	An online ordering system that allows healthcare facilities to easily order and receive the new device or kit for preparing	A wet wipe like equipment which is use and throw but compact enough to carry along		accessible	An online ordering system that allows healthcare facilities to easily order and receive the new device or kit for preparing 5% acetic acid, regardless of their location.		A self examination kit which and be purchased from local pharmacy		
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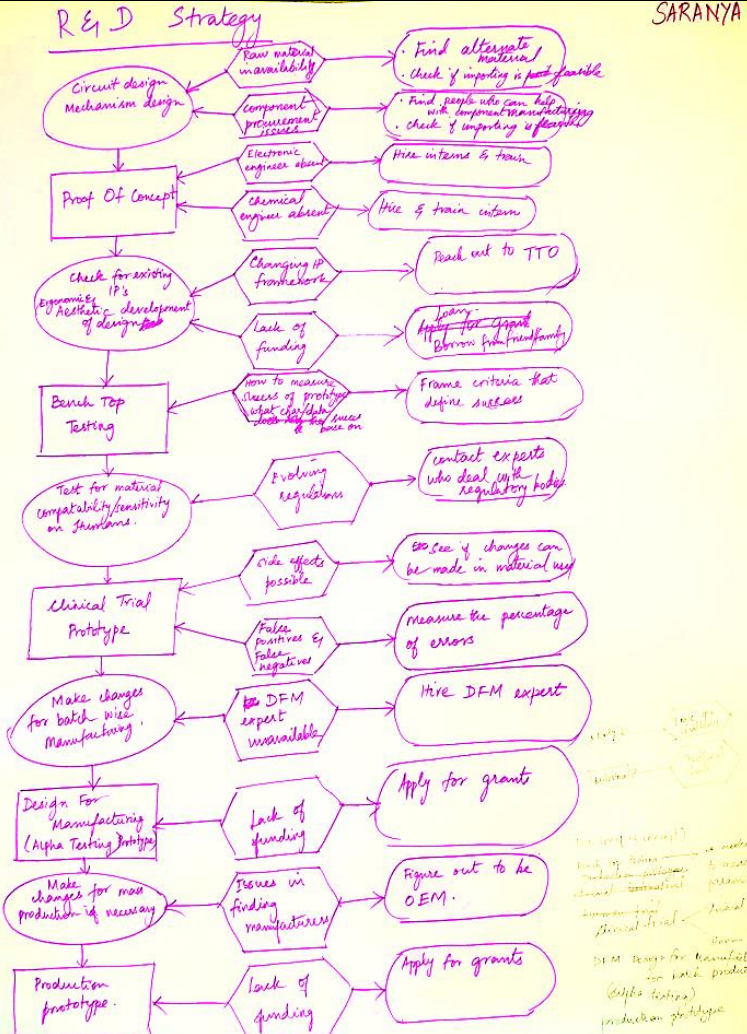
Sample ideation process and concepts		Expert comments
<p>Concept 1 integrates</p> <p>battery operated acetic acid dispenser with automatic solution mixer</p> <p>an automatic solution dispenser to guide nurses through the process of preparing 5% acetic acid, ensuring consistent results</p> <p>a piston pump that automatically sucks in precise amount of acid and water and pumps out on demand</p> <p>syringe type device which will prepare fresh sol. While application</p> <p>syringe type device which will prepare fresh sol. While application</p> <p>An online ordering system that allows healthcare facilities to easily order and receive the new device or kit for preparing 5% acetic acid, regardless of their location.</p>	<p>Upload image</p> <p>Description</p> <p>A gun like equipment which dispense required amount of solution in required concentration that is directly pumped to a cotton ball which is directly applied to cervix. The cotton ball is removable and is replaced for every patient.</p>	

Nature of strategy making approach

The experts found that, in comparison to workshop 1, the strategy-making approach used in workshop 2 is easier, more useful, and unique (see comments in Table 5-N). The unified approach, coupled with the provided examples of external challenges, was realized to be a comprehensive and effective approach for strategizing medical technology design and innovation objectives such as R&D, regulatory compliance, clinical trials, etc.

Table 5-N: Nature of strategy making approach in the two Workshops

Sample R&D strategy development approach					Expert comments
Workshop 1	Sl no	R & D Milestones	Critical Technical Challenges (eg. material science, electrical engineering, product development, manufacturing)	Risk to be retired based on results	<p>“I was thinking about the project planning, and I believe having a common strategy-making method is a good idea.”</p> <p>“you know, I also think it's important to understand the distinction between technical challenges and other external or</p>
	1	Proof of concept	material science and air leakage	Material rupture of Stoma cover	
	2	Human testing prototype	Voice production	Risk of infection, Allergic reaction	
	3	Preproduction demo manufacturing	Size and adhesiveness of Stoma cover		
	4	Production support scalable manufacturing			

	Sample R&D strategy development approach	Expert comments
Workshop 2	<p style="text-align: right;">SARANYA A</p>  <p>The flowchart 'R&D Strategy' outlines the following stages and associated challenges/solutions:</p> <ul style="list-style-type: none"> Design Phase: Circuit design, Mechanism design, and Proof of Concept. Challenges include 'Raw material unavailability' (solution: Find alternate material, check if importing is possible), 'Component procurement issues' (solution: Find people who can help with component manufacturing, check if importing is possible), and 'Electronic engineers absent' (solution: Hire interns & train). Validation Phase: Check for existing IP's, Economics, & Aesthetic development of design. Challenges include 'Chemical engineer absent' (solution: Hire & train intern) and 'Changing IP from network' (solution: Read out to TTO). Testing Phase: Bench Top Testing. Challenges include 'Lack of funding' (solution: Apply for grant, borrow from family) and 'How to measure success of prototype' (solution: Frame criteria that define success). Material & Regulatory Phase: Test for material compatibility/sensitivity on functions. Challenges include 'Evolving regulations' (solution: Contact experts who deal with regulatory bodies) and 'Side effects possible' (solution: See if changes can be made in material use). Prototype & Manufacturing Phase: Clinical Trial Prototype. Challenges include 'False positives & False negatives' (solution: Measure the percentage of errors) and 'DFM expert unavailable' (solution: Hire DFM expert). Final Production Phase: Design for Manufacturing (Alpha Testing Prototype) and Production prototype. Challenges include 'Lack of funding' (solution: Apply for grants) and 'Issues in finding manufacturers' (solution: Figure out to be OEM). 	<p>organizational challenges. Identifying the type of challenge, we're dealing with is crucial because it helps us plan better and allocate roles and solutions accordingly."</p>

Nature of the need selection and concept selection filters

Table 5-O listed the various criteria for need selection and concept selection utilized by the design students in the two workshops. Comments from experts revealed that the conventional Biodesign approach lacked consideration of specific matrices to evaluate need statements and concepts from the perspective of the available healthcare system, societal norms, and the innovation ecosystem. The new toolsets successfully addressed these factors.

Table 5-O: Nature of the need selection and concept selection filters in the two Workshops

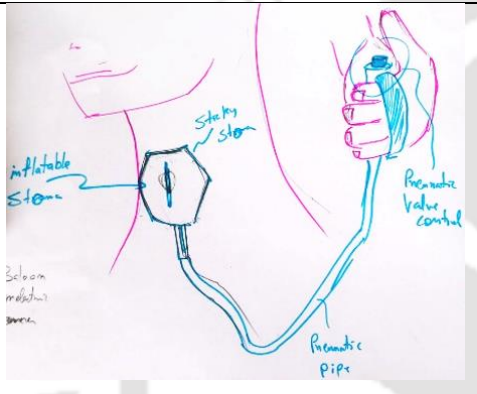
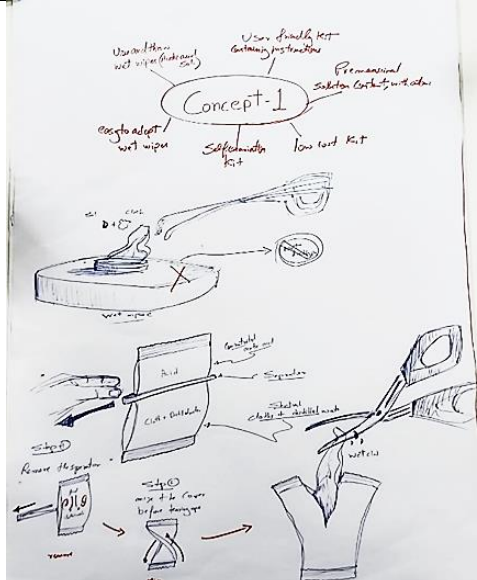
	Need selections filters (screenshots from team Excel sheets)	Expert comments					
Workshop 1	<p>Round 1 screening : Gut check screening</p> <table border="1" data-bbox="359 1848 758 1960"> <tr> <td>Team interest</td> <td>Need type mixed/incremental</td> <td rowspan="2">Final score</td> </tr> <tr> <td>y=1, n=0</td> <td>blue sky=0</td> </tr> </table>	Team interest	Need type mixed/incremental	Final score	y=1, n=0	blue sky=0	<p>“Those additional filters were a game-changer. They</p>
Team interest	Need type mixed/incremental	Final score					
y=1, n=0	blue sky=0						

	Need selections filters (screenshots from team Excel sheets)										Expert comments																									
	<table border="1"> <thead> <tr> <th colspan="7">Round 2 need screening</th> </tr> </thead> <tbody> <tr> <td>Estimated market size L=3, M=2, S=1</td> <td>patient impact L=3, M=2, S=1</td> <td>Number of affected patients L=3, M=2, S=1</td> <td>Understanding of Disease state H=3, M=2, L=0</td> <td>Treatment landscape no soln=3, some=2, crowded=1</td> <td>Provider value (cost, time, skill) 3 changes=3 2 changes=2 1 changes=1</td> <td>Total</td> </tr> </tbody> </table>										Round 2 need screening							Estimated market size L=3, M=2, S=1	patient impact L=3, M=2, S=1	Number of affected patients L=3, M=2, S=1	Understanding of Disease state H=3, M=2, L=0	Treatment landscape no soln=3, some=2, crowded=1	Provider value (cost, time, skill) 3 changes=3 2 changes=2 1 changes=1	Total	<p>provided a practical lens to assess the need statements in terms of how feasible and viable they would be during implementation.”</p>											
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Workshop 1	Patentability y=2, n=1	FTO y=2, n=1	Device class class 3=1 class 1&2=2	Product type disposal=5 Reusable=4 implantable=3 capital equipment=2 service=1	Renewal model Fee per use =2 subscription=1	Availability Over the counter=3 Prescription=2 Physician sell=1	Total				<p>“it’s essential to have that practical viewpoint, especially when we’re trying to translate ideas into real-world solutions. Workshop 2 really honed in on that aspect.”</p>																									
Workshop 2	Patentability Yes=2, No=1	Freedom to operate Yes=2, No=1	Product type disposal=5, Reusable=4, implantable =3, capital equipment=2, service=1	Renewal model Fee per use =2, subscription=1	Availability Over the counter=3, Prescription=2, Physician sell=1	Fitment to non-uniform healthcare system Fit to entire hierarchy = 3, Fit to few = 2, Fit to specific healthcare setting=1	Fitment to resource constraint setting Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1	Fitment to society and culture Socio-cultural values addressed= 2 Socio-cultural values not addressed = 1	Funding and investment availability High = 3, Occasional= 2 Low = 1	Product developmental support Developmental knowledge and strong collaboration exist= 3, Either developmental knowledge or strong collaboration exist= 2, No knowledge and collaboration exist=1		Manufacturing support All manufacturing and parts procurements can be done via vendor within country= 3, Partial dependency on foreign vendor for manufacturing or component procurement= 2, Complete dependency on foreign vendor for manufacturing =1	Regulatory hurdles Class 1 device = 3, Notified device = 3, but FDA 510k = 2, Non-notified device (needs PMA) = 1																							

LMIC-Specific Relevance Scoring for final ‘Need statements’ and ‘Concepts’

Furthermore, the eleven experts provided relevance scoring for the finalized need statements and concepts resulting from the two workshops in the context of LMICs. The eleven Biodesign fellows utilized a scoring scale ranging from 1 to 5, where 5 signified the highest relevance and 1 indicated the lowest relevance, to evaluate the final need statements and concepts. The results indicate that the need statements and concepts from Workshop 2 received higher total scores compared to those from Workshop 1, highlighting their superior relevance in addressing LMIC-specific criteria. Table 5-P reveals average relevance scores for sample final need statements and concepts from the two workshops.

Table 5-P: LMIC-Specific Relevance Scoring for final 'Need statements' and 'Concepts' in the two Workshops

	Sample final 'Need statements'		Criteria 'A'	Criteria 'B'				Total score
W 1	Workshop 1	A way to help people who have undergone Tracheo-esophageal Puncture to speak continuously for longer periods of time	2	3				5 out of 10
W 2	Workshop 2	"A (easier and low cost)way to (prepare 5% acetic acid) by (nurse) that allow (hassle free cervical examination for squamous intraepithelial lesion)"	4	4				8 out of 10
	Corresponding final 'Concepts'		Criteria 'A'	Criteria 'B'	Criteria 'C'	Criteria 'D'	Criteria 'E'	Total score
W 1			2	3	3	3	3	14 out of 25
W 2			4	4	4	4	4	20 out of 25

W1 = Workshop 1, W2 = Workshop 2,

Criteria 'A'=Addressed non-uniform healthcare system and delivery related problems,

Criteria 'B'=Addressed socio-cultural problems and barriers

Criteria 'C'=Considered underdeveloped innovation ecosystem

Criteria 'D'=Considered organizational problems of innovation management

Criteria 'E'=Considered market entry problems

In conclusion, the results demonstrate the greater effectiveness of the proposed new toolsets and processes in meeting LMIC-specific requirements compared to the conventional Biodesign process.

5.4 Discussion and practical implications

The practical implications of the study are profound, offering a modified Biodesign process that addresses the unique challenges faced in Low- and Middle-Income Countries (LMICs) during the development of medical technology. The conventional Biodesign process, while valuable, revealed limitations in its application to LMICs, particularly in the 'Identify,' 'Invent,' and 'Implement' phases. The study's proposed modifications, encompassing three toolsets (Toolset 1, Toolset 2, and Toolset 3) and supporting methodologies, provide a systematic and contextually relevant approach to healthcare innovation in LMICs.

Firstly, the 'Identify' phase is enhanced by introducing tools that go beyond clinical problems, considering local context and implementation challenges. The development of visual templates and methodologies in Toolset 1 ensures a more comprehensive problem definition by identifying healthcare service gaps, clinical issues, and implementation problems. This phase addresses not only the clinical needs but also the broader healthcare challenges, including local socio-cultural barriers. Secondly, the 'Invent' phase benefits from the incorporation of LMIC-aligned filters and matrices in Toolset 2. This ensures that ideation and concept screening processes consider local challenges during solution synthesis, resulting in contextually relevant and effective solutions. The study introduces a co-design approach that facilitates multidisciplinary collaboration, emphasizing the importance of understanding both clinical and implementation requirements for complex healthcare problems. Finally, the 'Implement' phase is strengthened by Toolset 3, which integrates tools and approaches that consider real-world challenges and local context. A standardized strategy development approach addresses not only technical challenges but also underdeveloped design ecosystems, organizational problems in design management, and market entry issues. This holistic strategy development ensures that the implementation strategies are robust and adaptable to the unique healthcare landscape in LMICs.

The evaluation results, comparing the conventional Biodesign process with the

modified toolkit, demonstrate the effectiveness of the proposed modifications. The systematic and categorical approach of the modified toolkit leads to a more diverse range of identified problems, need statements that address a broader spectrum of healthcare challenges, and a more effective concept generation process. The new filters introduced for need and concept selection are considered game-changers, providing a practical lens to assess feasibility and viability during implementation. In practical terms, the study's outcomes have immediate implications for designers, healthcare practitioners, and policymakers involved in medical technology design for LMICs. The modified Biodesign process equips designers with innovative methods and procedures tailored to the complexities of healthcare design in LMICs. The emphasis on a comprehensive understanding of local contexts fosters interdisciplinary collaboration, ultimately contributing to more sustainable and impactful healthcare solutions. Policymakers can leverage these insights to develop strategies that promote innovation ecosystems and overcome barriers to effective implementation of medical technology in LMICs. Overall, the study's practical implications extend to improving the impact of medical technology in LMICs by providing a tailored and effective framework for innovation.

The prescribed modifications to the Biodesign process represent a thoughtful and comprehensive approach to design and innovation in LMICs, where healthcare needs and constraints differ significantly from high-income settings. By adapting and expanding upon the conventional Biodesign framework, these adjustments are intended to facilitate the seamless incorporation of the revised process supports requirements into the existing MedTech innovator community. Templates of the new toolsets and work out details are added in the Appendix A.6 section

5.4.1 Practical limitation

A practical limitation identified in the use of Tool 2B of the modified Biodesign process is the difficulty in securing clinician participation during the Clinical and Technical Solution Synthesis phase. In LMIC settings, clinicians often manage large patient populations with limited resources, leading to hectic schedules that can hinder their availability for collaborative ideation processes. Given these challenges, it is crucial to establish a strong, multidisciplinary team at the start of any medical technology project, as advocated by the Biodesign process. This team should ideally comprise clinicians, designers, and engineers, whose collaborative dynamics are essential for success.

Throughout the project, consider including additional domain experts as the project's

needs evolve. In Biodesign fellowship programs, forming such a team from the outset is common practice. However, individual industrial designers using the Biodesign process should focus on extensive networking and collaboration to further their projects. Engaging clinicians early and scheduling meetings well in advance can mitigate the logistical challenges posed by their busy schedules, facilitating ongoing, effective collaboration.

5.5 Conclusion

In conclusion, this study addresses the critical challenges faced in the development of medical technology within Low- and Middle-Income Countries (LMICs) by proposing and evaluating modifications to the conventional Biodesign process. The research introduces a comprehensive toolkit and methodologies, encompassing three distinct toolsets designed to enhance the 'Identify,' 'Invent,' and 'Implement' phases. Through a systematic evaluation involving workshops with design students and expert analysis, the study demonstrates the effectiveness of the modified Biodesign process in meeting LMIC-specific requirements. The new toolsets, integrated seamlessly into the Biodesign framework, provide a holistic approach to address clinical problems while considering local context, implementation challenges, and socio-cultural barriers. Results from the comparative workshops indicate significant improvements in problem identification, need statement development, criteria synthesis, concept generation, and strategy formulation when employing the modified toolkit.

Chapter 6. Developing Clinical Solutions for the Resource-Constrained Healthcare Context of India: A Case Study on Utilizing the Modified Biodesign Process

Abstract

This research study explores the application of a modified Biodesign process to address healthcare challenges in resource-constrained contexts, specifically focusing on wound management and cervical cancer in India. Employing a new workflow toolkit, the study involved extensive clinical immersions in healthcare settings in Assam, India, identifying healthcare disparities and challenges. The modified Biodesign process, with phases such as Identify, Invent, and Implementation, was applied for data analysis and medical technology design. The study concludes by highlighting the process's effectiveness in addressing healthcare design challenges in low- and middle-income countries.

Furthermore, the study identifies a lack of skilled professionals as a significant implementation gap and proposes an AI-infused solution for semi-autonomous healthcare delivery. The extended research study recognized a research gap in usability heuristics for Conversational User Interfaces (CUIs), developed prototypes, conducted usability testing, and synthesized 16 new heuristics for CUIs in medical device applications. The results highlight 873 usability issues and demonstrate the comprehensive applicability of the new heuristics across various clinical procedures. The study contributes valuable insights and guidelines for designing and evaluating CUIs in healthcare applications, with implications for both Indian and broader clinical settings.

6.1 Brief about the case studies

One of the objectives of the current research was to explore applicability of the modified Biodesign process (see Figure 6.1) in solving real life healthcare problems of resource constraint settings.

Modified Biodesign process with new toolsets

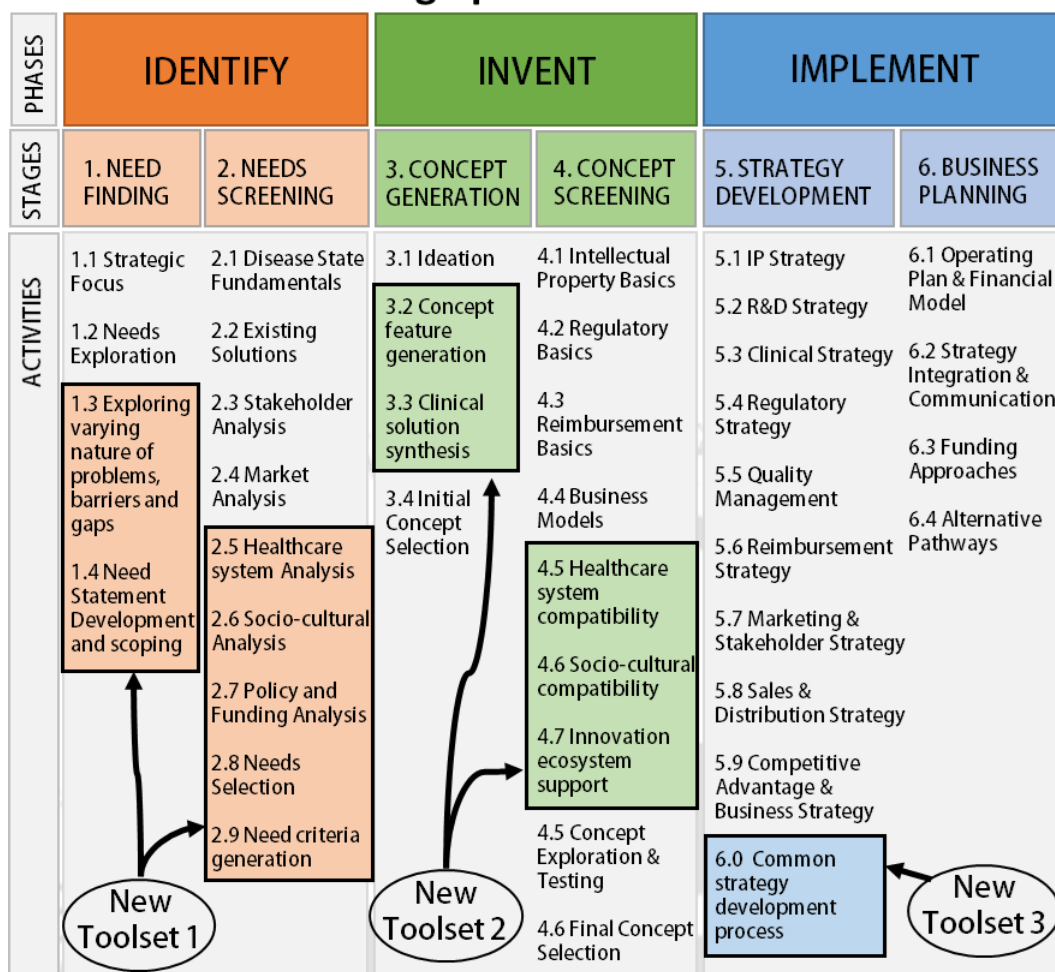


Figure 6-1: Modified Biodesign process (source: author generated)

The goal was to capture healthcare disparities and challenges of LMICs for specific clinical problems and document the use case scenario of the modified Biodesign process in addressing solutions for those. Here are the details as follows.

6.1.1 Clinical immersion and initial background research

Two clinical areas, Gynecology and General medicine, were selected as strategic focus area based on research interest and the recognized healthcare burden associated with the two clinical areas in India. A team of designers and researchers actively participated in the initial contextual inquiry task, under the guidance of healthcare professionals. They engaged in clinical immersions at various levels of the Indian public healthcare system and private hospitals. These included GNRC Medical Hospital in North Guwahati, Assam, India, two district hospitals (Jorhat Medical College and Hospital and Titabor Sub-divisional Civil Hospital) in Jorhat district, Assam, India, one Community Health Center (Mohkhuli Health Center) in Nogaon district, Assam, India, and one Primary Health Center in Kamrup district, Assam, India (North

Guwahati Block PHC)

During the clinical immersion phase, the typical data collection process involved visiting Outpatient Department (OPD) settings at various healthcare centers. This included observing and tracking various disease conditions for which patients visited the OPD settings, gaining insights into clinical conditions, identifying patient pain points, and understanding how healthcare providers managed these conditions. The team of researchers also conducted occasional informal interviews with patients and doctors to gain a better understanding of patient backgrounds, disease history, available treatment options, and healthcare services. Observations were primarily documented as notes, but photography and videography were also conducted with the consent of doctors and patients to capture various clinical and implementation issues related to healthcare delivery.

Following that the modified Biodesign process, which includes the new workflow toolkit, was employed for further data analysis and the design of medical technology. In the subsequent sections, a detailed explanation of how the new workflow toolkit was used is discussed. To demonstrate the tool's usage, we focused on examples from the final clinical problem areas: wound management and Cervical cancer management. The same procedure was followed for all other observed clinical conditions.

6.2 Utilization of the Modified Identify Phase explained

6.2.1 Analysis of data from Clinical immersion and initial background research

Understanding of Indian healthcare system and issues

Field observations conducted at various tiers of the public healthcare system and private hospitals have allowed us to recognize variations within healthcare settings in terms of healthcare services, patient flow, and infrastructure. Figure 6.1 illustrates these findings from our clinical immersion.

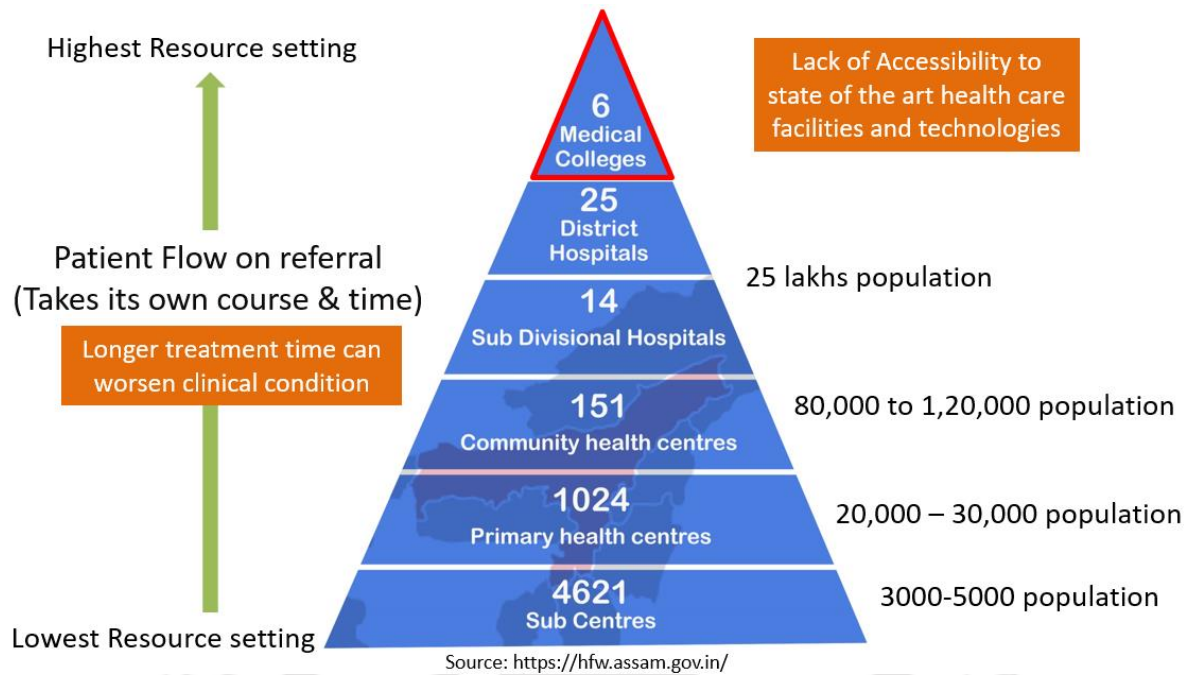


Figure 6-2: Public healthcare system of Assam: demonstrating facilities and population coverage (source: author generated)

As depicted in the illustration, it was found that the public healthcare system in India exhibits a hierarchical structure. There are very few resource-rich healthcare facilities at the top tier, while the majority of the population in India relies on services provided by Community Health Centers (CHCs), Primary Health Centers (PHCs), and Subcenters (SCs) located at lower tiers. Access to state-of-the-art facilities in the public healthcare system is typically through a referral basis. This analysis highlights systemic issues, such as longer treatment times for non-urban populations and lower quality of care at healthcare settings lower in the pyramid due to resource constraints. Furthermore, given the large population of the country, clinical settings often become overcrowded with patients, resulting in longer waiting times, challenges in healthcare service management, and a decrease in the quality of care.

Understanding disease etiology, pathophysiology and pathogenesis

In light of the various clinical scenarios observed and the patient conditions experienced during clinical immersion, the subsequent task involved gaining a comprehensive understanding of the fundamentals of various disease states. We conducted detailed secondary research and in-depth studies on the disease etiologies, underlying biomechanisms, pathological changes, and the overall clinical course and presentation for each observed clinical condition, particularly in the fields of Gynecology and General Medicine.

For instance, Figure 6.3 illustrates the information we collected regarding wound

healing biomechanisms, the factors contributing to delayed healing, and the key events in the human body's inflammatory response when a wound occurs. Reasons identified for delayed wound healing are infection, ischemic conditions, metabolic conditions, immunosuppression, radiation etc.

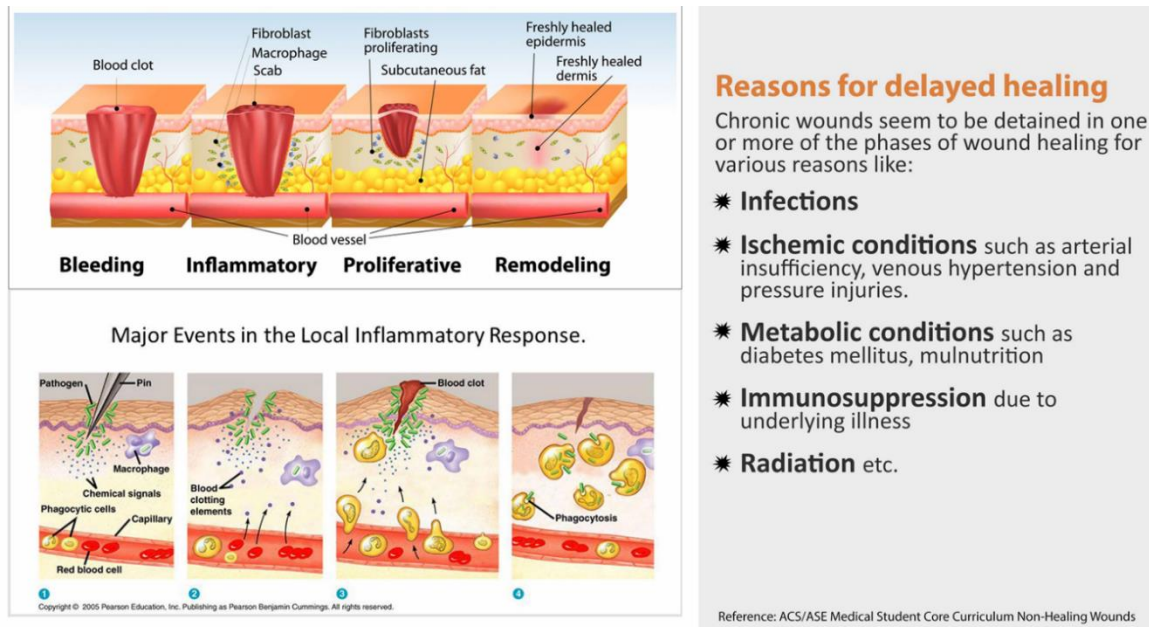


Figure 6-3: An example: understanding wound healing mechanism and reasons for delayed healing (source: author generated)

Understanding disease burdens

Another aspect of the secondary research following clinical immersion was to gather information on the incidence, prevalence, and mortality or morbidity rates for each previously identified clinical condition in India. Detailed data on how these various clinical conditions affect patients and healthcare providers, as well as their impact on the Indian healthcare system, was collected with supporting statistical evidence. For instance, Figure 6.4 provides information related to the burden of chronic wounds on the Indian healthcare system and how it impacts patients' quality of life. It was found that chronic wounds can lead to patient discomfort, pain, impact families financially, may lead to social discrimination and in long run may lead to amputation and disability. Such information is essential for comparing the importance of addressing various clinical conditions during the needs evaluation phase.

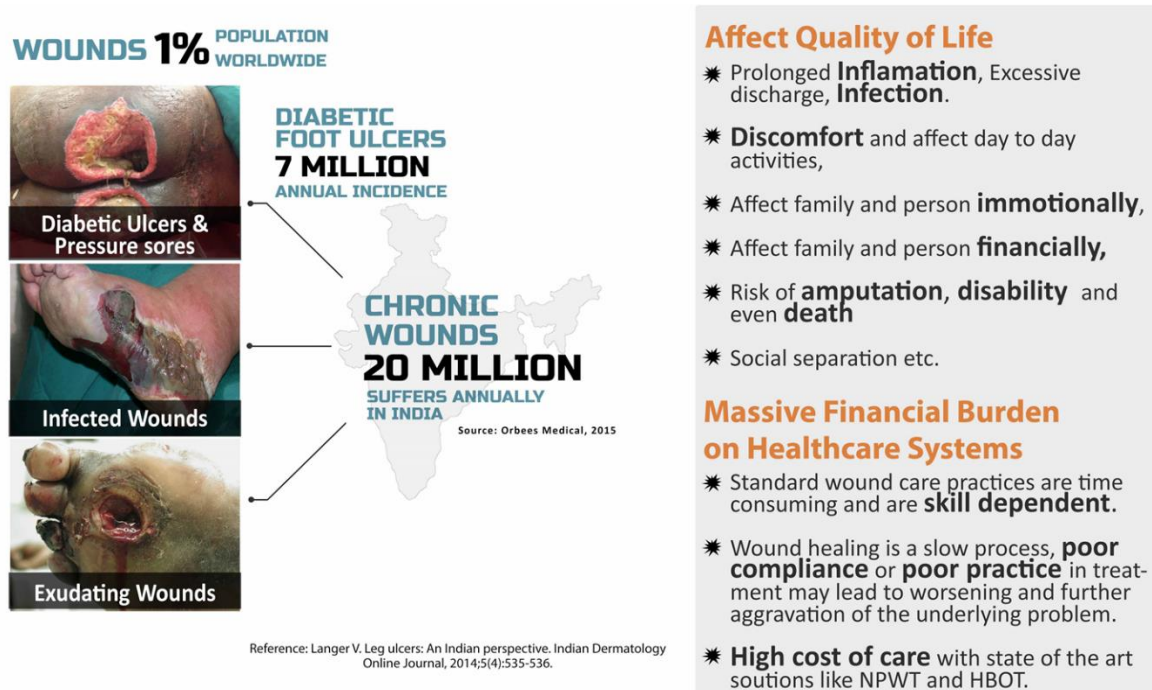


Figure 6-4: An example: Burden of chronic wounds on India (source: author generated)

User study: understanding patient perspectives and persona creation

During the clinical immersion, patients were frequently observed, shadowed, and interviewed to gather detailed information about their disease history, clinical presentation of underlying conditions, patient pain points, treatment regimen, and other demographic information. This enabled us to understand the socio-cultural and economic impacts of the disease and healthcare implementation issues. Additionally, we created personas to represent patients with various clinical conditions. The persona creation process involved aggregating information such as the patient's age, education, income, family details, clinical condition, pain points, socio-economic status, etc., and visually representing this information by providing a character representation or picture of the patient. This was done so that personas could be utilized in the future for decision-making related to need evaluation, concept ideation, and evaluation, among other purposes. For example, Figure 6.5 represents a persona for the clinical condition of an infected chronic wound, while Figure 6.6 represents a persona for a patient with a diabetic foot ulcer.



Figure 6-5: Patient with infected chronic wound (source: author generated)

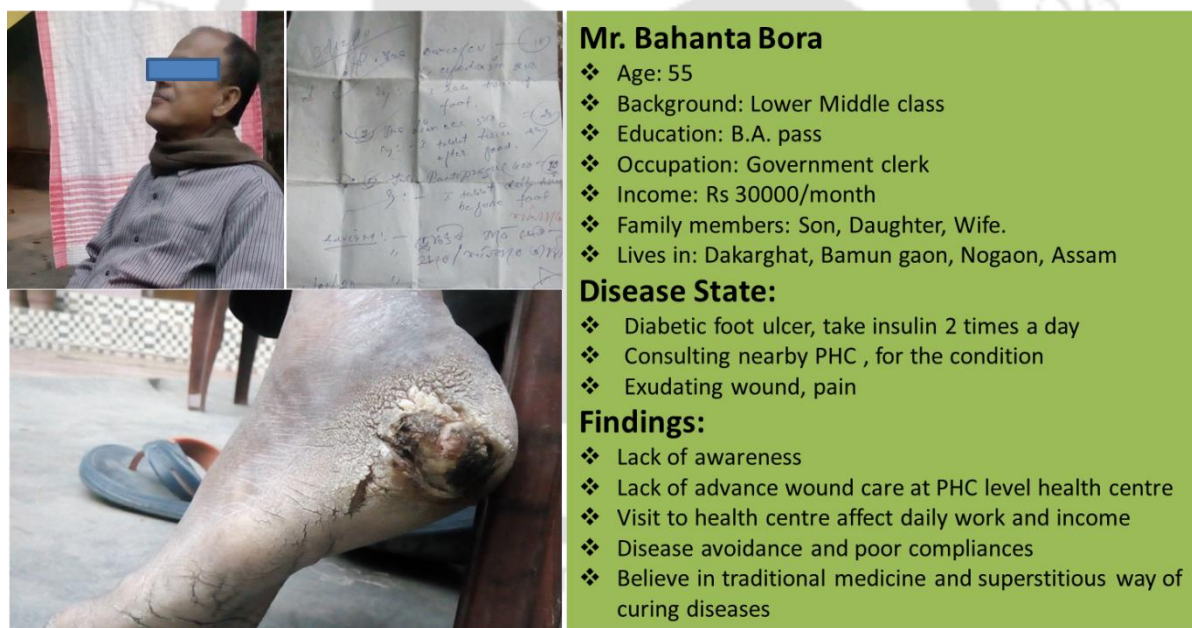


Figure 6-6: Patient with diabetic foot ulcer (source: author generated)

Identifying healthcare service gaps- using Tool 1-A

To identify healthcare service gaps for various clinical conditions within the Indian healthcare system, we utilized Tool 1-A of the modified Biodesign process. Using this tool, we mapped the findings from clinical immersion and secondary research related to disease etiology, pathogenesis, and pathophysiology for various clinical conditions. Additionally, we mapped

our findings regarding available healthcare services and solutions in relation to the clinical course and presentation of each disease. Finally, we assessed the availability of all such healthcare services and solutions across various healthcare facilities to pinpoint service gaps. Figure 6.7 showcases an example of the mapping process for the clinical condition of Cervical cancer. As depicted in Figure 6.7, the detailed clinical course and presentation of Cervical cancer are represented in green (in section 2 of the Figure). In section 3, available solutions for the prevention, diagnosis, and treatment of cervical cancer are mapped. Furthermore, in section 4 of the Figure, after assessing the availability of services within the Indian healthcare system, we identified several service gaps. These gaps include the absence of Cervical cancer preventive vaccination services at District Hospitals and healthcare settings lower in the hierarchy. Similarly, there is no provision for chemotherapy or radiotherapy at these healthcare settings. Community healthcare settings (CHCs) only offer conventional visual inspection techniques and Pap smears for diagnosis, with no treatment options or preventive vaccination services available. Furthermore, healthcare settings below the pyramid, such as Primary Health Centers (PHCs) and Sub-centers, which serve a significant portion of the population, lack any services or facilities related to cervical cancer care.

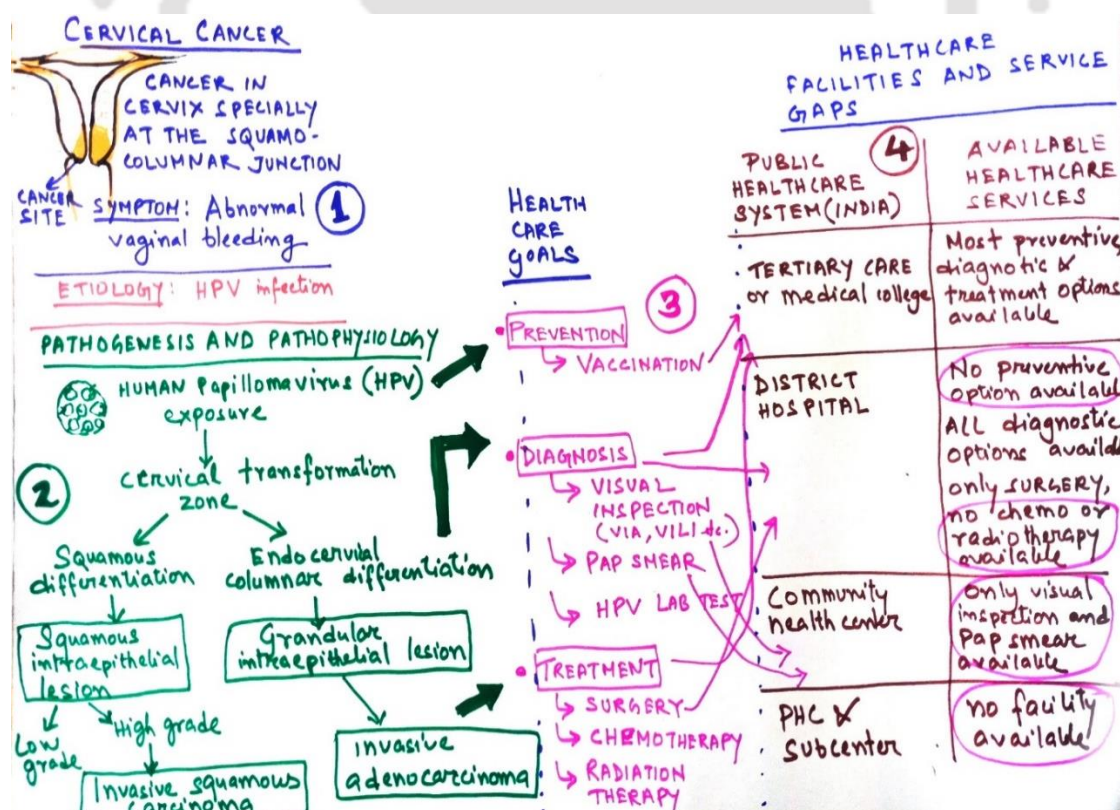


Figure 6-7: Identifying healthcare service gaps related to cervical cancer (source: author generated)

Similarly, Figure 6.8 demonstrates the same mapping process using Tool 1-A for the

clinical condition of Diabetic foot ulcer. The service gaps realized were the absence of treatment options such as Negative pressure wound therapy and Hyperbaric oxygenation at District hospitals and other healthcare centers lower in the hierarchy. Furthermore, CHCs, PHCs, and subcenters do not have any advanced therapeutic and diagnostic facilities except for standard wound dressing.

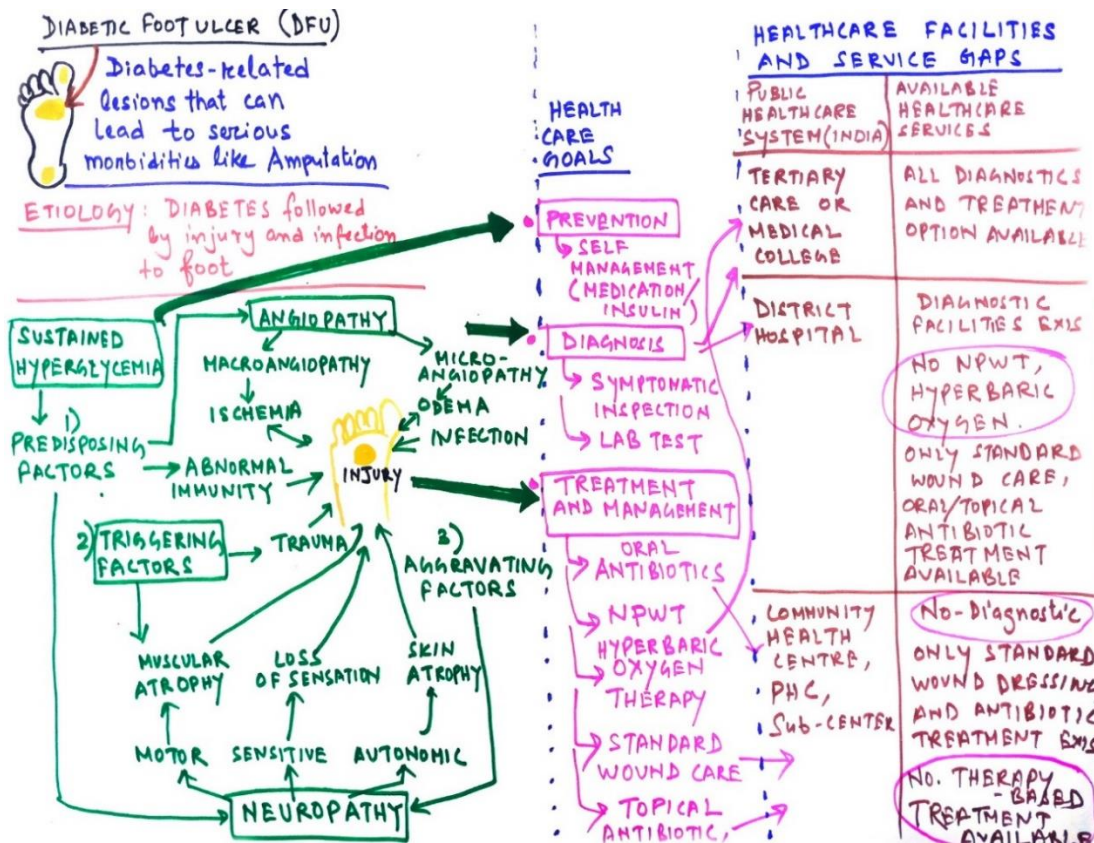


Figure 6-8: Identifying healthcare service gaps related to Diabetic foot ulcer (source: author generated)

Observation and nature of healthcare problems – Based on Tool 1-B

The problem identification process based on field observation data utilized the method proposed in the new Tool 1-B of the modified Biodesign process. We analyzed the observations from the field study using the template provided in Tool 1-B, which allowed us to identify problems from multiple perspectives. For instance, Table 6-A demonstrates how field observations related to Cervical cancer diagnosis were captured in tabular format as notes and analyzed to identify various problem types, their impact on the population/stakeholders, and desired outcomes. Various problem types identified include gaps and issues with current instruments/consumables, patient pain points, procedural issues, environmental issues, sociocultural issues, healthcare facility and management issues, and healthcare service gaps. Specific examples of problems identified include the improper size of the speculum causing

pain in the patient, the lack of proper lighting provision to visualize the cervix area, inefficient procedures, medical waste generation, culturally sensitive procedures, etc.

Table 6-A: Observation from clinical immersion, identified problems, effected population and desired outcomes

Observation	Problem type	Problem	Population	Outcome
An outreach program was able to perform a low-cost cervical cancer diagnosis (using freshly prepared acetic acid) among low income community women who do not have access to doctor for regular check-ups or follow ups. After finding lesions , which can cause cancer in future, they were asked to visit district hospital for cryotherapy. The doctor said that the inspection after applying acetic acid solution needs to be done in good light, while the nurse was seen using a simple torch. The women are hesitant to come up for a check-up due to lack of access to affordable healthcare systems near them the women neglect their own health	<i>Gap and issue with current apparatus, instrument, consumables</i>	Speculum size identification issue	Health care provider	Be able to identify size of vagina
		No proper lighting provision	Health care provider	Be able to visualize the cervix
	<i>Patient pain points</i>	Improper size of speculum causes pain in patient	Women above 30 years of age	Identify correct speculum size
	<i>Procedural issue</i>	Quantity of acetic acid to be mixed can't be guessed and gets wasted since excess needs to be discarded by end of day.	Health care provider	Be able to gauge and control the quantity taken for mixing
	<i>Environmental issue</i>	Medical waste generation	General population	Minimize medical waste generation
	<i>Socio-cultural issue</i>	Getting women to consent is difficult,	Women above 30 years of age	Get consent
		The procedure is culturally sensitive	Women above 30 years of age	Should maintain privacy, dignity
	<i>Healthcare facility and management issues</i>	One person doing all the tasks	Health care provider	Sufficient staffing
		Overcrowd in healthcare centre	Health care provider	Should provide rapid diagnosis
	<i>Healthcare service gap</i>	Lack of Immediate treatment procedure after diagnosis at the facility	Health care provider	Should enable follow up treatment

Identifying healthcare implementation gaps -Using Tool 1-C

The next activity involved the identification of issues within clinical procedures. To achieve this, we employed the mapping technique outlined in Tool 1-C of the modified Biodesign process. This technique allowed us to pinpoint various issues within procedural activities, as well as those arising during the interaction between the patient and the healthcare provider, and any challenges related to specific instruments or consumables. We also examined clinical decision-making processes and the issues associated with them.

In Figure 6.9, we present a process and interaction flow mapping of a procedure known as Visual Inspection with Acetic Acid (VIA test), which is used for early-stage cervical cancer

screening. Utilizing the methodology described in Tool 1-C, we mapped our observations from clinical immersion. This mapping included the registration of patients for the procedure, communication between clinicians and patients to prepare for the procedure, the execution of the procedure itself, the assistance required by clinicians from nurses during the procedure, challenges faced by both patients and clinicians, the duration of wait times and execution times for each activity, the clinical decision-making process, and the prescriptions given to patients, right up to the moment the patient concludes the procedure. All the various problems identified during the procedure were indicated by red arrows, with descriptions provided in red ink. Examples of identified issues include an overcrowded patient registration process, difficulties in obtaining patient consent due to the cultural sensitivity of the procedure, the discomfort associated with speculum insertion, inadequate lighting sources, and the lack of a reliable method for determining the correct ratio of mixing acetic acid and water, among others.

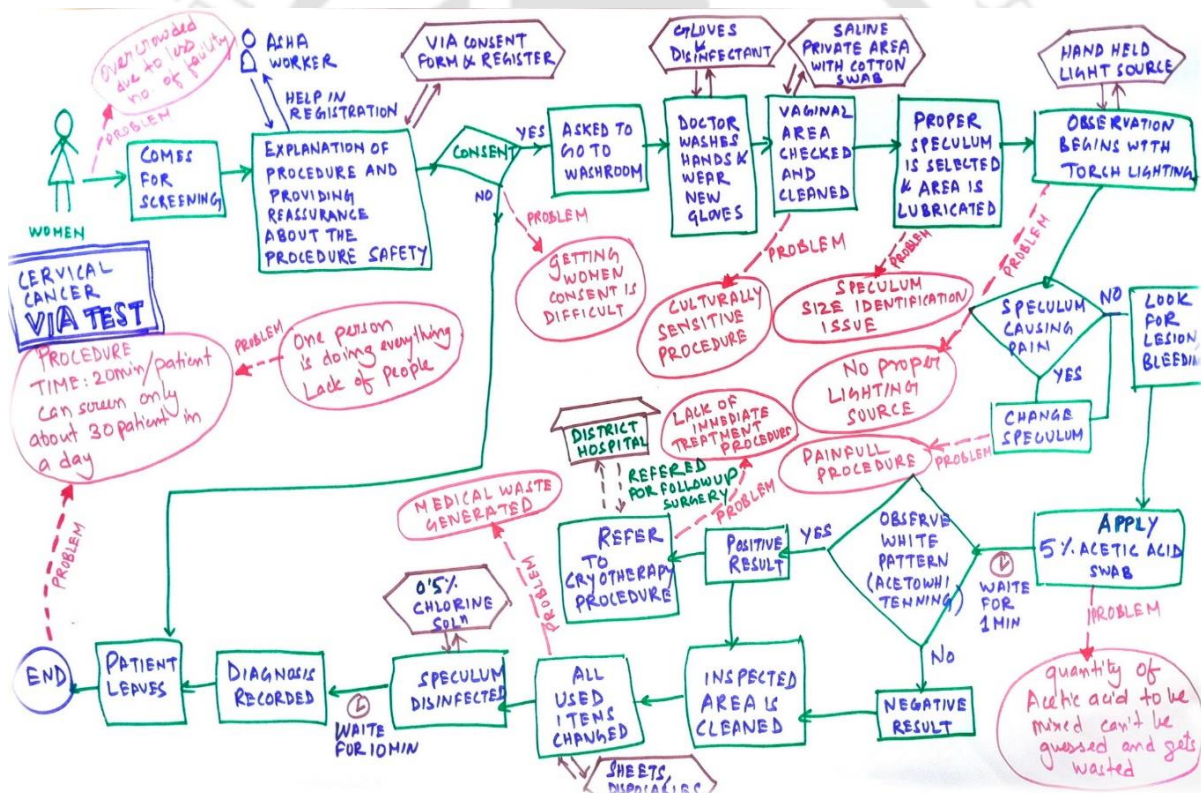


Figure 6-9: Issues mapped within current VIA test for cervical cancer (source: author generated)

6.2.2 Need statement development and need scoping – using Tool 1-D

After identifying various problems and gaps, the next task was to systematically develop need statements. We referred to the template proposed in the new Tool 1-D of the modified Biodesign process, which included both implementation and clinical issues within each need statement. Initially, we formulated a total of 18 need statements. These initial need statements

underwent a further process of need scoping to refine their scope with respect to the clinical course and specific presentation of the disease, as described in Tool 1-D. This process of need scoping allowed further elimination of redundant, overly narrow, and overly broad need statements, resulting in a set of 10 final need statements for further evaluation.

Figure 6.10 demonstrates the need statement development and scoping process for cervical cancer screening. As shown in Figure 6.10, four need statements were initially formulated based on their scope concerning the specific clinical stage of cervical cancer development. Finally, the one with the green-colored box was chosen as the final need statement for cervical cancer screening. The need statement is as follows: "A rapid, cost-effective, skill-independent, effective, and culturally acceptable way to screen cervical epithelial lesions in Indian women that allows for effective public healthcare implementation." As mentioned before, the need statement portrays characteristics of both clinical and implementation requirements, including the clinical need, the population affected, and the broad expected healthcare outcome.

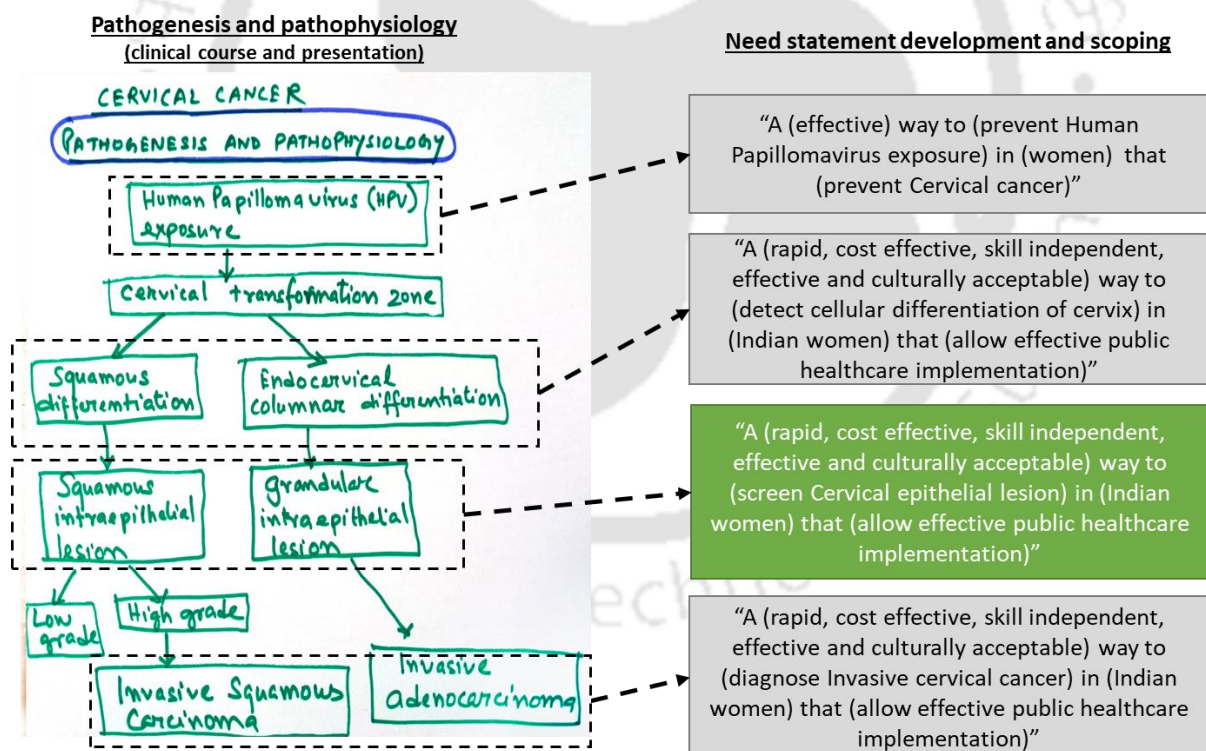


Figure 6-10: Need statement development and need scoping (source: author generated)

6.2.3 Need screening- using Tool 1-E

The follow-up process, which occurred shortly after arriving at the final set of need statements, was the Need Screening Process. This process was conducted in three successive rounds.

Rounds 1 and 2 involved need screening based on filters suggested in the conventional Biodesign process, while Round 3 utilized the newly defined need screening filters defined by Tool 1-E of the modified Biodesign process.

Round 1 Need filtering

In round 1 of the filtering process, the team scored the need statements based on two very basic initial filters: Team interest (yes=1, no=0) and Need type (mixed/incremental=1, blue sky=0). This round of filtering resulted in the elimination of 4 initial need statements and the selection of 6 need statements for further rounds of need screening. Table 6-B demonstrates the Round 1 need screening process.

Table 6-B: Round 1 need filtering process

Need statements	Team interest yes=1, no=0	Need type mixed/ incremental=1 blue sky=0	Total
A 'portable, effective and stealthy' way to 'provide neural monitoring' in 'epileptic patients' that 'allow timely management'.	0	0	0
A 'skill-independent and effective' way to 'self-screen cervical cancer' by 'Indian women' that 'allow culturally appropriate early disease detection'	1	1	2
A 'rapid, effective' way to 'alert and inform person who is nearby to the seizure attack patient', that 'allow timely help to the patient'.	0	1	1
A 'low-cost, frugal and effective' way to 'heal infectious foot ulcers' in 'diabetic patients' that 'allow easy adaptation in resource constraint healthcare settings.	1	1	2
A 'culturally appropriate and pain free' way to 'monitor the progression of labour' in 'pregnant women' that 'improve patient comfort and intrapartum outcome.'	1	1	2
An 'effective and low-cost' way to 'screen squamous cell carcinoma' in 'patient having pharynx or larynx cancer' that 'allow improve diagnostic outcome at resource constrain settings.'	1	1	2
A 'rapid, cost effective, skill independent, effective and culturally acceptable' way to 'screen Cervical epithelial lesion' in 'Indian women' that 'allow effective public healthcare implementation'	1	1	2
A 'non-invasive' way to 'measure intracranial pressure' in 'patients with heal injury' that allow timely management of brain damage'.	0	0	0
A 'effective, comforting' way to 'reduce aspiration' in 'aged patients during ingestion' in order to 'improve the quality of life'	0	0	0
A 'minimally invasive' way to 'treat acute compartment syndrome' in 'patient with leg injury' in order to avoid further complications like tissue necrosis.	1	1	2

Round 2 Need filtering

In Round 2 of the need screening process, the team evaluated the remaining six need statements using a set of six filters, as described in the conventional Biodesign process. The filters were as follows: estimated market size (Large=3, Medium=2, Small=1), patient impact (Large=3, Medium=2, Small=1), number of affected patients (Large=3, Medium=2, Small=1), understanding of disease state (High=3, Medium=2, Low=1), treatment landscape (No solution=3, Some=2, Crowded=1), and provider value (Cost, Time, Skill) (Three changes=3, Two changes=2, One change=1). Table 6-C illustrates the Round 2 need screening process. In this round, three need statements were selected to advance to the final third round of need screening.

Table 6-C: Round 2 Need filtering process

Need statements	Estimated market size <i>Large=3, Medium=2, Small=1</i>	patient impact <i>Large=3, Medium=2, Small=1</i>	Number of affected patients <i>Large=3, Medium=2, Small=1</i>	Understanding of Disease state <i>High =3, Medium=2, Low=1</i>	Treatment landscape <i>no solution=3, some=2, crowded=1</i>	Provider value (cost, time, skill) <i>Three changes=3, Two changes=2, One changes=1</i>	Total
A 'skill-independent and effective' way to 'self-screen cervical cancer' by 'Indian women' that 'allow culturally appropriate early disease detection'	2	3	2	3	2	1	14
A 'low-cost, frugal and effective' way to 'heal infectious foot ulcers' in 'diabetic patients' that 'allow easy adaptation in resource constraint healthcare settings.	3	3	2	3	2	3	16

Need statements	Estimated market size	patient impact	Number of affected patients	Understanding of Disease state	Treatment landscape	Provider value (cost, time, skill)	Total
	<i>Large=3, Medium=2, Small=1</i>	<i>Large=3, Medium=2, Small=1</i>	<i>Large=3, Medium=2, Small=1</i>	<i>High =3, Medium=2, Low=1</i>	<i>no solution=3, some=2, crowded=1</i>	<i>Three changes=3, Two changes=2, One changes=1</i>	
A 'culturally appropriate and pain free' way to 'monitor the progression of labour' in 'pregnant women' that 'improve patient comfort and intrapartum outcome.'	2	1	1	3	3	1	11
An 'effective and low-cost' way to 'screen squamous cell carcinoma' in 'patient having pharynx or larynx cancer' that 'allow improve diagnostic outcome at resource constrain settings.'	1	3	2	3	1	1	11
A 'rapid, cost effective, skill independent, effective and culturally acceptable' way to 'Cervical epithelial lesion' in 'Indian women' that 'allow effective public healthcare implementation'	3	3	2	3	2	3	16
A 'minimally invasive' way to 'treat acute compartment syndrome' in 'patient with leg	1	2	1	3	2	1	10

Need statements	Estimated market size	patient impact	Number of affected patients	Understanding of Disease state	Treatment landscape	Provider value (cost, time, skill)	Total
	Large=3, Medium=2, Small=1	Large=3, Medium=2, Small=1	Large=3, Medium=2, Small=1	High =3, Medium=2, Low=1	no solution=3, some=2, crowded=1	Three changes=3, Two changes=2, One changes=1	
injury' in order to avoid further complications like tissue necrosis.							

Round 3 Need filtering

In Round 3, the final three need statements are evaluated for their relevance in the context of Low and Middle-Income Countries (LMICs) using the suggested filters from the new Tool 1-E in the modified Biodesign process. The filters include: Fitment to the non-uniform healthcare system (Fit to the entire hierarchy = 3, Fit to a few levels = 2, Fit to a specific healthcare setting = 1), fitment to a resource-constrained setting (Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce = 2, No Fit = 1), fitment to society and culture (Socio-cultural values addressed = 2, Socio-cultural values not addressed = 1), and fitment to policies and funding options (Fit to WHO goals or government health planning = 3, Fit to market demand = 2, Fit to stakeholder requirements = 1). Table 6-D illustrates the final Round 3 need screening process. Ultimately, two need statements were selected for further design and development tasks.

Top two scored need statements

- i. A 'low-cost, frugal and effective' way to 'heal infectious foot ulcers' in 'diabetic patients' that 'allow easy adaptation in resource constraint healthcare settings'.
- ii. A 'rapid, cost effective, skill independent, effective and culturally acceptable' way to 'screen Cervical epithelial lesion' in 'Indian women' that 'allow effective public healthcare implementation'.

Table 6-D: Round 3 Need filtering process using LMIC specific filters

Need statements	Fitment to non-uniform healthcare system	Fitment to resource constraint setting	Fit to society and culture	Fit to policies, funding options	Total

	<i>Fit to entire hierarchy =3, Fit to few = 2, Fit to specific healthcare setting=1</i>	<i>Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1</i>	<i>Socio-cultural values addressed= 2, Socio-cultural values not address = 1</i>	<i>Fit to WHO goals or government health planning = 3, Fit to Market demand =2, Fit to stakeholder requirement =1</i>	
A 'skill-independent and effective' way to 'self-screen cervical cancer' by 'Indian women' that 'allow culturally appropriate early disease detection'	2	2	2	2	8
A 'low-cost, frugal and effective' way to 'heal infectious foot ulcers' in 'diabetic patients' that 'allow easy adaptation in resource constraint healthcare settings.	3	3	2	3	11
A 'rapid, cost effective, skill independent, effective and culturally acceptable' way to 'screen Cervical epithelial lesion' in 'Indian women' that 'allow effective public healthcare implementation'	3	3	2	3	11

6.2.4 Need criteria generation- using Tool 1-F

Furthermore, a set of need criteria was formulated for the two need statements based on the systematic approach described by the new Tool 1-F of the modified Biodesign Process. The procedure involves the development of need criteria for both 'must-have' clinical requirements and implementation requirements, as well as for 'nice-to-have' design requirements. Specifications or measures for each need criterion were also established. In Figures 6.11 and 6.12, the systematic need criteria development process is demonstrated for the two final need statements related to the treatment of diabetic foot ulcers and cervical cancer screening, respectively. Each need criterion encompasses the characteristics described in the solutions according to the need statements.

Need criteria generation for diabetic foot ulcer treatment solution:

A 'low-cost, frugal and effective' way to 'heal infectious foot ulcers' in 'diabetic patients' that 'allow easy adaptation in resource constraint healthcare settings

	Must have criteria	Specification/measure		Nice to have criteria	Specification/measure
Clinical requirements	Multitherapeutic	Trigger multiple biomechanism of wound healing	Need criteria	Battery operated	Longer battery based operation
	Portable	Weight < 2Kg		Weather proof	Safe from rain, humidity
	Enable wound diagnosis	Detect types of chronic wound		Provide help and assistance	With voice or visual assistance
	Remote and central monitoring	Data should be available online all time		Easy to carry with patient	Does not effect patient's daily activities
Implementation requirements	Low cost	< Rs 15000			
	Minimum infrastructure requirement	Should fit within existing healthcare facility			
	Easy to use and adopt	Can be used by nurse			

Figure 6-11: Need criteria for diabetic foot ulcer treatment solution (source: author generated)

Need criteria generation for Cervical cancer screening solution:

A 'rapid, cost effective, skill independent, effective and culturally acceptable' way to 'screen Cervical epithelial lesion' in 'Indian women' that 'allow effective public healthcare implementation'.

	Must have criteria	Specification/measure		Nice to have criteria	Specification/measure
Clinical requirements	Rapid screening	Procedure takes < 5 minute	Need criteria	Battery operated	Provide longer battery life
	Effective	Sensitivity, specificity > 80%		Aesthetic looking	Should look safe and elegant
	Minimum number of procedural steps	Maximum two step procedure		Provide automatic assistance	Visual aid or voice aid
	Pain free procedure	Safe and painless		Easy to disinfect	Washable or autoclavable
Implementation requirements	Low cost	< Rs 10000		Environment friendly	Less disposable waste
	Minimum infrastructure requirement	Should fit within existing healthcare facility			
	Easy to use and adopt	Can be used by nurse			
	Culturally appropriate	Enable procedural trust and maintain privacy			

Figure 6-12: Need criteria for Cervical cancer screening solution (source: author generated)

6.3 Utilization of the Modified Invent Phase explained

6.3.1 Concept feature generation tool 2- part A

After establishing the need criteria, the subsequent task involved devising solutions to address these criteria. Our initial step was the generation of concept features based on the procedures

outlined in Tool 2-A of the modified Biodesign process. This entailed generating ideas for each need criterion previously developed for the two clinical problems at hand. We initiated the process with brainstorming, to generate ideas for each need criterion. Subsequently, we consolidated ideas from individual criteria to create a pool of concepts. Figure 6.13 illustrates the development of ideas to address the need criteria for diabetic foot ulcer treatment, which were later integrated to formulate six distinct concepts. These concepts encompass various features aimed at providing solutions to the problem.

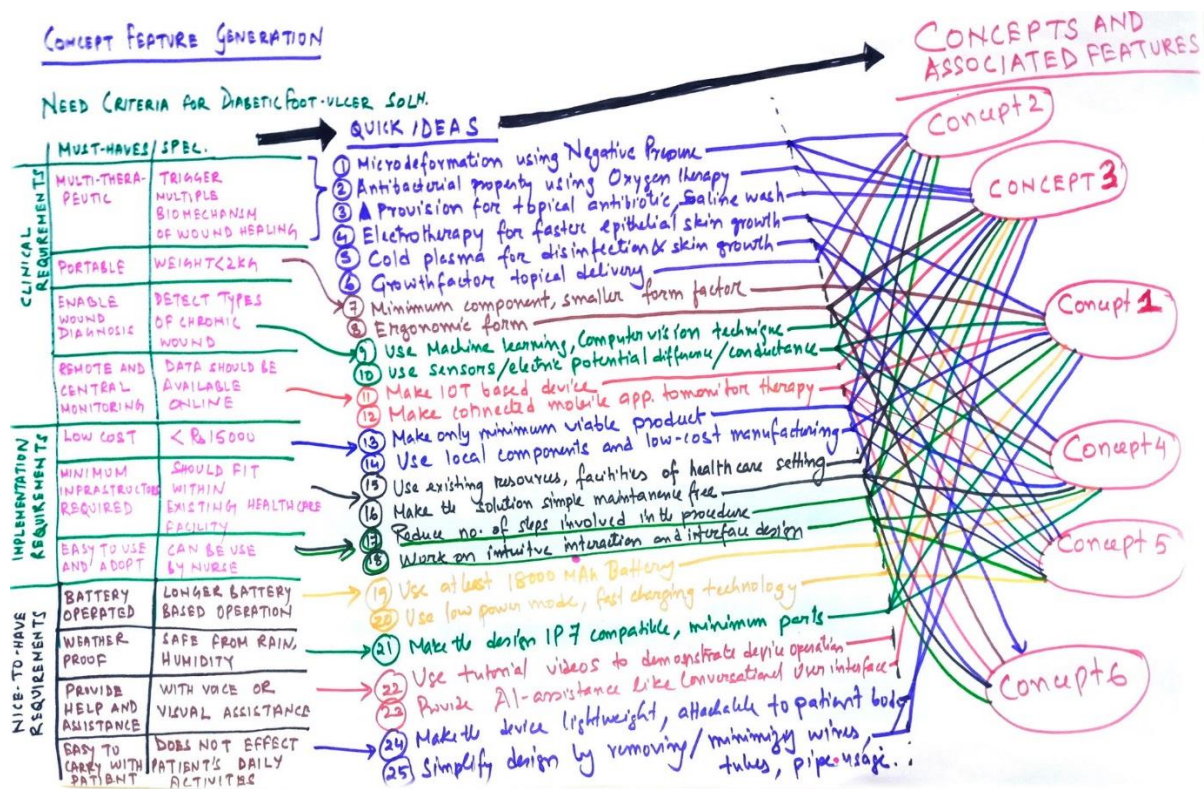


Figure 6-13: Concept feature generation process for the treatment of Diabetic foot ulcer (source: author generated)

6.3.2 Clinical and technical solution synthesis tool 2- part B

The final stage of the concept generation process involved the clinical and technical solution synthesis process, following the methodology discussed in Tool 2-B of the modified Biodesign process. This was a collaborative process in which inputs from clinicians, biotech researchers, engineers, and designers were considered to address core clinical and technical problems. During this process, based on the team's understanding of two disease states and underlying biomechanisms, various initial conceptual solutions in the realms of design, engineering, and technology were developed as potential solutions for further exploration and analysis. The process was iterative, and several alterations and improvements to the concepts were made before generating final concept visualizations and renderings. Figure 6.14 illustrates how

various features envisioned for a previously conceived concept for diabetic foot ulcer treatment underwent detailed analysis to arrive at a more precise clinical and technical concept, as seen in the visualization.

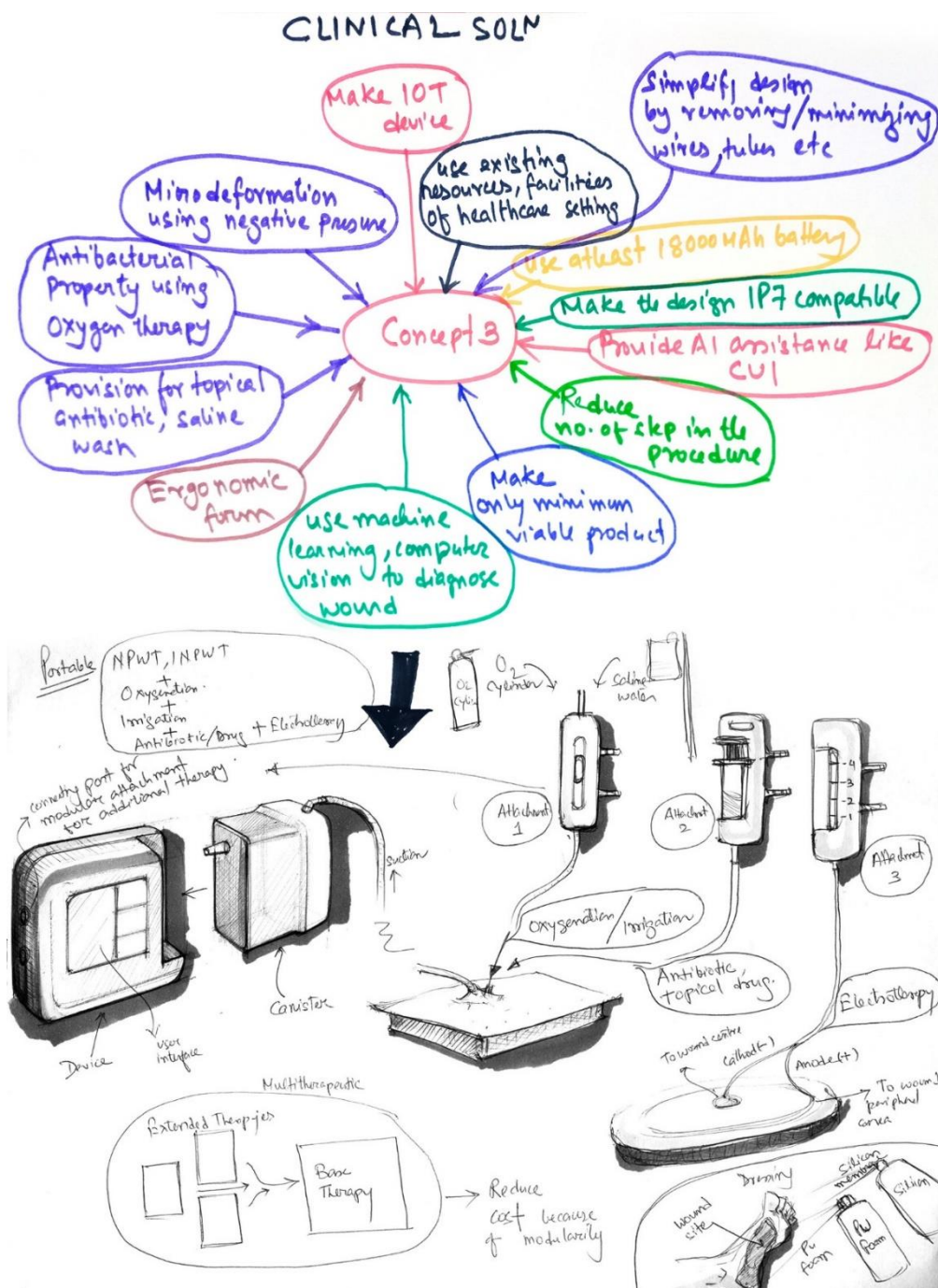


Figure 6-14: Example of clinical solution synthesis process (source: author generated)

Furthermore, Figure 6.15 and 6.16 demonstrate the various concepts generated for the two specific need criteria: cervical cancer screening and diabetes foot ulcer treatment, respectively. Colorful hand visualizations, accompanied by detailed descriptions, were

Figure 6-15: various concepts generated for Cervical cancer screening (source: author generated)

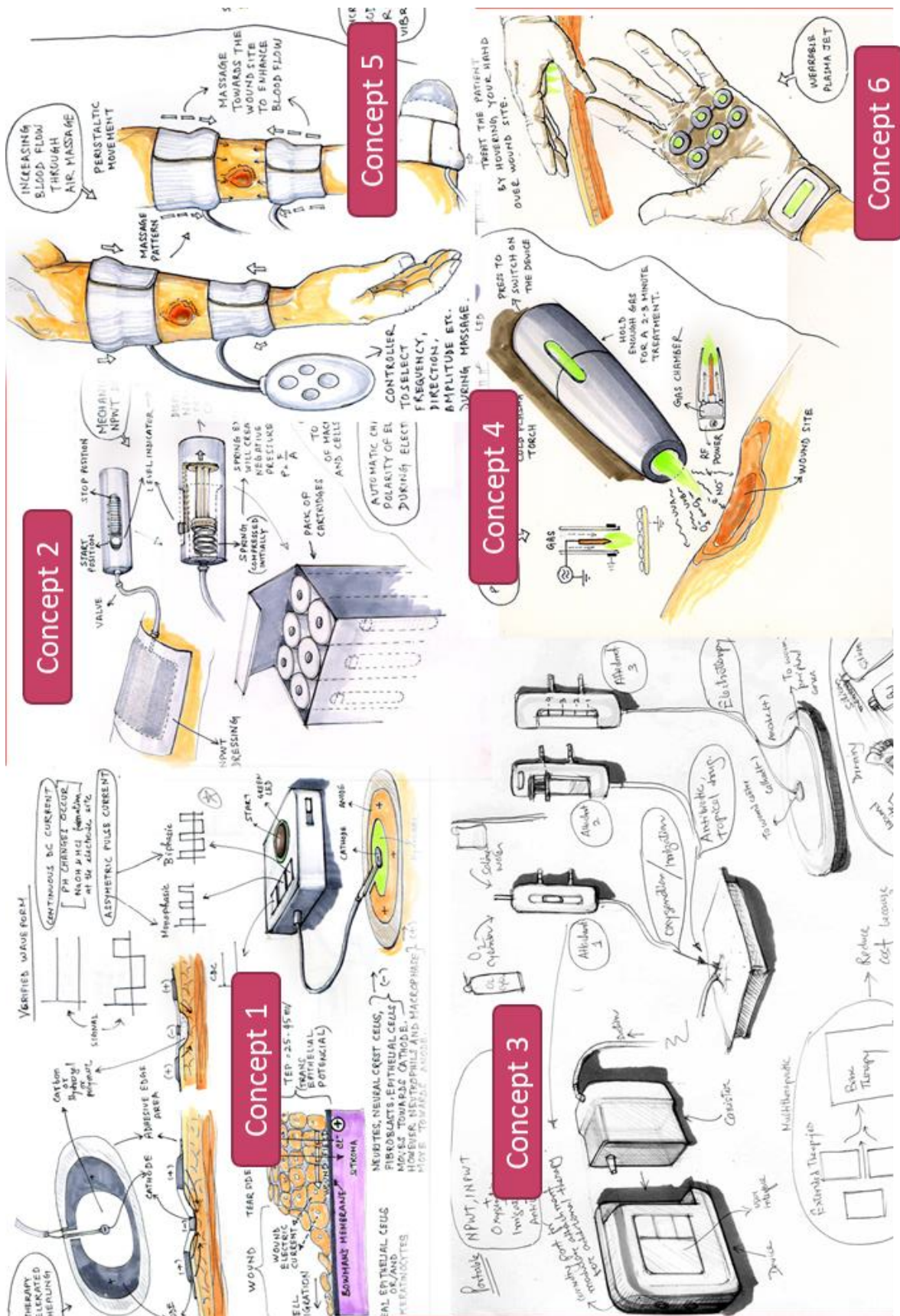


Figure 6-16: Various concepts generated for diabetic foot ulcer healing (source: author generated)

6.3.3 Concept selection using tool 2- part C

Similar to need selection process, the pool of final concepts was also further evaluated against certain matrices or filters, to select one or two concepts for further prototyping and development. The concept selection process was carried out in two rounds: Round 1 and Round 2. Here are details.

Round 1 Concept Screening

In Round 1, a team of experts, comprising researchers, designers, and faculty members having more than 5 years of experience in product design, assessed the final concepts using various filters outlined in the new Tool 2-C of the modified Biodesign process. These filters included fitment to the non-uniform healthcare system (with ratings of 3 for fit to the entire hierarchy, 2 for fit to a few, and 1 for fit to a specific healthcare setting), fitment to resource-constrained settings (with ratings of 3 for fit to existing infrastructure and workforce, 2 for fit to either existing infrastructure or workforce, and 1 for no fit), fitment to society and culture (with a score of 2 for addressing socio-cultural values and 1 for not addressing them), funding and investment availability (rated as 3 for high, 2 for occasional, and 1 for low), product development support (scored 3 when developmental knowledge and strong collaboration existed, 2 when either of them existed, and 1 when no knowledge and collaboration were present), manufacturing support (with ratings of 3 when all manufacturing and parts procurement could be done within the country, 2 for partial dependency on foreign vendors, and 1 for complete dependency on foreign vendors), and regulatory hurdles (rated as 3 for Class 1 devices or Notified devices, 2 for non-notified devices with FDA 510k, and 1 for non-notified devices requiring PMA). The concepts that received similar high aggregate scores proceeded to the second round of filtering.

Round 2 Concept Screening

In Round 2, the previously recruited team of experts conducted a further evaluation of the remaining concepts, applying filters for Efficacy (with ratings of 3 for proven, 2 for somewhat, and 1 for not proven), Patentability (rated as 2 for yes and 1 for no), Freedom to operate (scored as 2 for yes and 1 for no), Product type (with disposal rated as 5, reusable as 4, implantable as 3, capital equipment as 2, and service as 1), Revenue model (with a score of 2 for fee per use and 1 for subscription), and Availability (rated as 3 for over the counter, 2 for prescription, and

1 for physician sell). After aggregating the final scores, the concepts with the highest scores in the two clinical areas were selected for further development and implementation.

Tables 6-E and 6-F below respectively disclose the Round 1 and Round 2 screening processes for concepts related to the treatment of diabetic foot ulcers.

Round 1 Concept filtering (for Diabetic foot ulcer) :

Table 6-E: Round 1 Concept filtering (for Diabetic foot ulcer)- considering LMIC specific requirements

Concepts	Fitment to non-uniform healthcare system	Fitment to resource constraint setting	Fitment to society and culture	Funding and investment availability	Product developmental support	Manufacturing support	Regulatory hurdles	Total
	Fit to entire hierarchy = 3, Fit to few = 2, Fit to specific healthcare setting=1	Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1	Socio-cultural values addressed= 2 Socio-cultural values not addressed = 1	High = 3, Occasional= 2 Low = 1	Developmental knowledge and strong collaboration exist= 3, Either developmental knowledge or strong collaboration exist= 2, No knowledge and collaboration exist=1	All manufacturing and parts procurements can be done via vendor within country= 3, Partial dependency on foreign vendor for manufacturing or component procurement= 2, Complete dependency on foreign vendor for manufacturing =1	Class 1 device or Notified device = 3, Non-notified device (but FDA 510k) = 2, Non-notified device (needs PMA) = 1	
C 1	2	2	2	1	2	1	2	12
C 2	3	2	2	1	2	2	2	14
C 3	3	3	2	2	3	3	2	18
C 4	1	1	1	2	1	1	2	9
C 5	3	2	2	1	2	2	3	15
C 6	1	1	1	2	1	1	2	9

Round 2 Concept filtering (For Diabetic foot ulcer) :

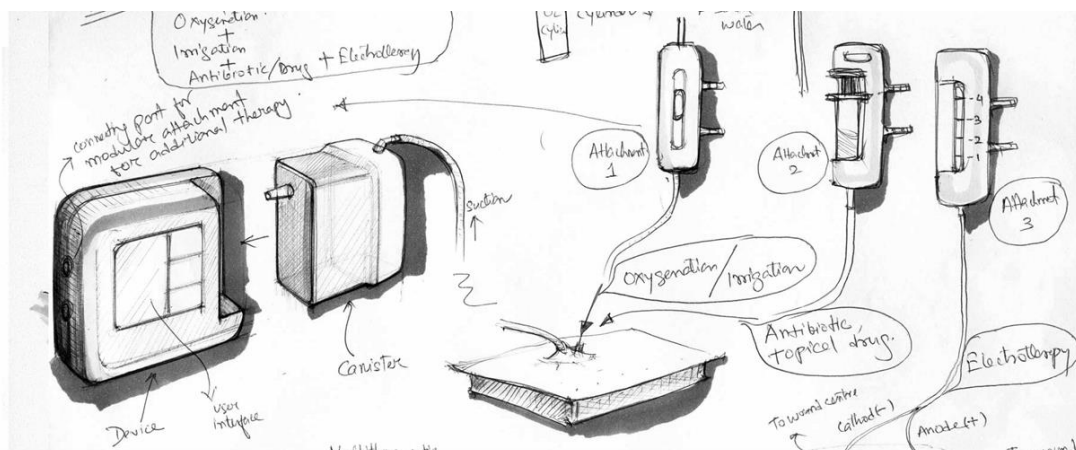
Table 6-F: Round 2 Concept filtering (For Diabetic foot ulcer)

Concepts	Efficacy	Patentability	Freedom to operate	Product type	Revenue model	Availability	Total
	Proven=3 Somewhat=2 Not proven=1	Yes=2, No=1	Yes=2, No=1	disposal=5, Reusable=4, implantable=3, capital equipment=2,	Fee per use =2, subscription=1	Over the counter=3, Prescription=2, Physician sell=1	

				<i>service=1</i>			
C1	2	1	2	5	2	1	13
C2	1	1	2	5	2	2	13
C3	3	2	2	5	2	2	16
C5	1	1	2	4	2	2	12

Final concept for diabetic foot ulcer management - Concept 3:





- **NEGATIVE PRESSURE WOUND THERAPY (NPWT)**
Two modes: Continuous NPWT and Intermediate NPWT to enhance biomechanisms favourable for wound healing.
- **EASY TO USE**
Intuitive user interface and minimal steps procedure for wound site application.
- **IOT BASED REMOTE CONNECTIVITY**
Internet of Things (IOT) based technology enable clinician, hospital to monitor/control the therapy remotely at runtime.
- **PORTABLE**
Portable form factor along with provision to carry the therapy setup without affecting day to day activities.

Cost of System: < Rs 10,000
72hours treatment costs: < Rs 500

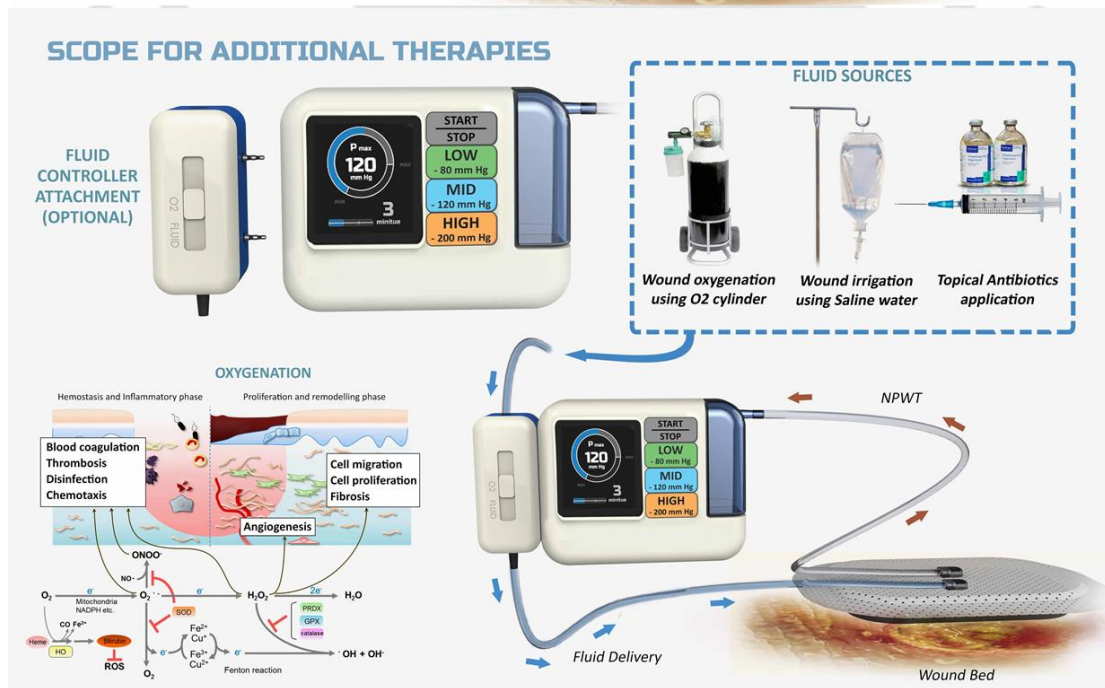


Figure 6-17: Final selected concept for wound therapy (source: author generated)

Tables 6-G and 6-H below respectively disclose the Round 1 and Round 2 screening processes for concepts related to the screening of cervical cancer.

Round 1 Concept filtering (for Cervical Cancer):

Table 6-G: Round 1 Concept filtering (for Cervical Cancer)- considering LMIC specific requirements

Concepts	Fitment to non-uniform healthcare system	Fitment to resource constraint setting	Fitment to society and culture	Funding and investment availability	Product developmental support	Manufacturing support	Regulatory hurdles	Total
	Fit to entire hierarchy = 3, Fit to few = 2, Fit to specific healthcare setting=1	Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce =2, No Fit =1	Socio-cultural values addressed= 2 Socio-cultural values not addressed = 1	High = 3, Occasional= 2 Low = 1	Developmental knowledge and strong collaboration exist= 3, Either developmental knowledge or strong collaboration exist= 2, No knowledge and collaboration exist=1	All manufacturing and parts procurements can be done via vendor within country= 3, Partial dependency on foreign vendor for manufacturing or component procurement= 2, Complete dependency on foreign vendor for manufacturing =1	Class 1 device or Notified device = 3, Non-notified device (but FDA 510k) = 2, Non-notified device (needs PMA) = 1	
C 1	1	2	2	2	1	1	3	12
C 2	2	2	1	1	2	2	2	12
C 3	3	3	2	2	1	2	2	15
C 4	2	1	1	1	2	2	2	11
C 5	3	3	2	3	2	2	2	17
C 6	2	2	1	1	2	2	2	12
C 7	3	3	2	3	1	2	3	17

Round 2 Concept filtering (For Cervical Cancer) :

Table 6-H: Round 2 Concept filtering (For Cervical Cancer)

Concepts	Efficacy	Patentability	Freedom to operate	Product type	Revenue model	Availability	Total
	Proven=3 Somewhat=2 Not proven=1	Yes=2, No=1	Yes=2, No=1	disposal=5, Reusable=4, implantable=3, capital equipment=2, service=1	Fee per use =2, subscription=1	Over the counter=3, Prescription=2, Physician sell=1	
C3	1	1	2	5	2	2	13
C5	3	2	2	5	2	2	16
C7	1	2	2	5	2	3	15

Final concept for cervical cancer screening device-Concept 5 :

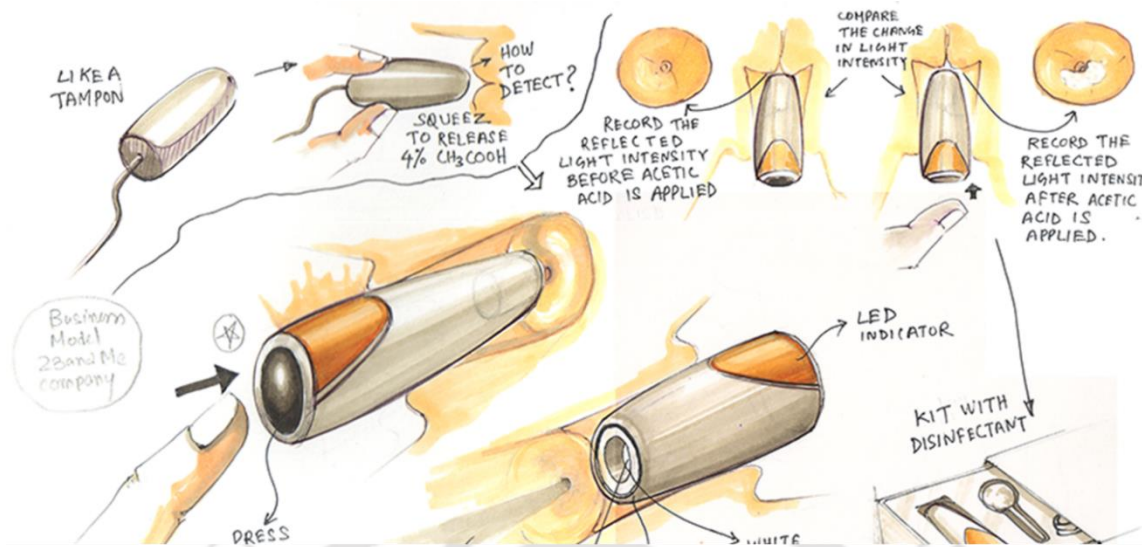


Figure 6-18: Final selected concept for Cervical cancer screening (source: author generated)

6.4 Utilization of the Modified Implementation Phase explained

After finalizing the selection of concepts in two clinical areas, wound healing and cervical cancer screening, the subsequent tasks included the development of strategies to address all major implementation requirements. In this specific case study, we focused on strategy development for concept/technology research and development, intellectual property protection, and clinical validation. We utilized Tool 3 of the modified Biodesign process for these strategy development tasks. Here are the details.

6.4.1 R&D and manufacturing strategy development using new tool 3

Figure 6.19 illustrates an example of the R&D strategy development process for the wound healing concept, utilizing the mapping process outlined in Tool 3.



Figure 6-19: R&D strategy for the final selected wound healing concept (source: author generated)

The mapping process enables the identification of key R&D milestones, as represented in Figure by the blue-colored boxes. These milestones include POC development, bench-top testing, alpha-prototype manufacturing, clinical trial prototyping, initial batch manufacturing, and production-ready manufacturing. Additionally, we analyzed and identified the required

R&D activities that would lead to achieving these milestones, represented in Figure by pink-colored ellipses. Furthermore, we forecasted the various technical and implementation challenges that could potentially act as barriers in the R&D process, as indicated in Figure by red-colored hexagons. As we progressed in the process, we proposed various strategies that could be adopted to overcome these barriers and challenges, which are represented in Figure by green-colored ellipses.

After planning all the various strategies, we executed various design activities related to the first two R&D objectives: POC and functional prototype development for product bench-top testing.

Activities related to POC and Functional prototype development

Here are examples of activities relate to POC and product functional design for the wound healing device.

(a) Interaction and User interface design

For interaction and User interface design the 5 levels of Garrett model was used as template for interaction and graphical user interface design for the final wound healing concept (Garrett, 2010). Figure 6.21, defines the execution of tasks in Garrett model from bottom to top.

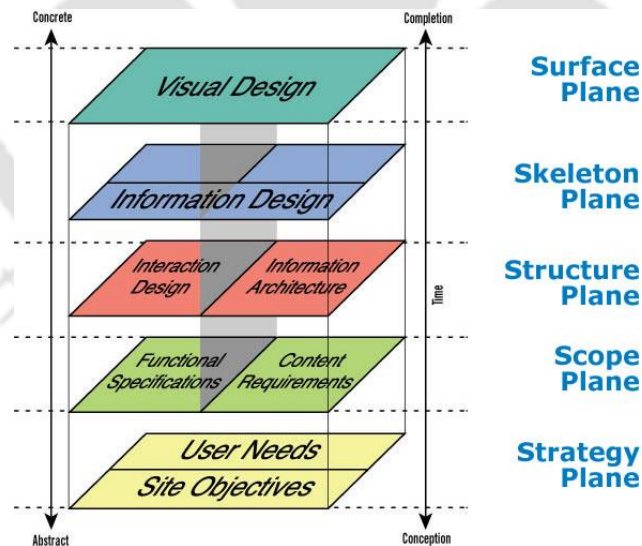


Figure 6-20: Garrett model for UX design (source: <http://exinfm.blogspot.com/2016/06/embracing-ux-design.html>)

Based on our experience with the wound healing procedure, we have identified a set of stakeholder requirements for the final concept chosen for the treatment of diabetic foot ulcers (refer to Figure 6.20).

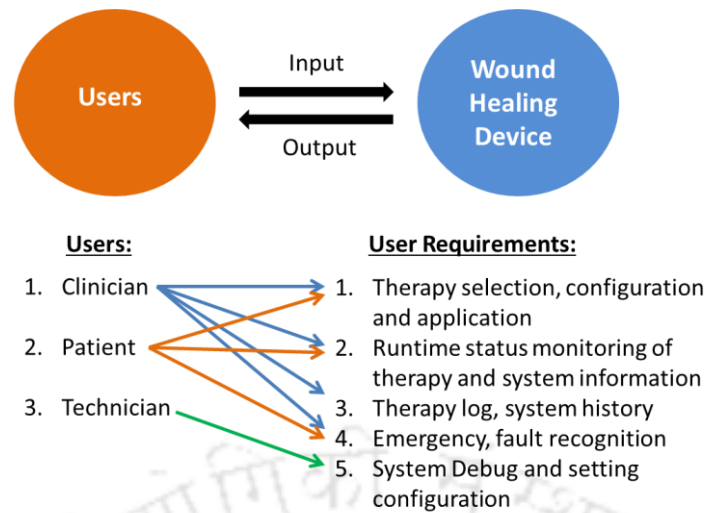


Figure 6-21: Deriving user requirements based on procedural experience gathered from using Tool 1-C (source: author generated)

The usage of Tool 1-C aided in understanding detailed procedural requirements for wound therapy. The stakeholders involved in the process include clinicians, patients, and technicians. We considered the distinct perspectives and requirements of these three stakeholders to create a consolidated list of user requirements. Subsequently, we conducted a systematic analysis to derive various system-level requirements and generated interaction ideas. Table 6-I illustrates the systematic approach used to synthesize system requirements and interaction ideas in a tabular format.

Table 6-I: The process of synthesizing system requirements and interaction ideas for wound healing device

User Requirements →	Requirement analysis →	Interaction ideas
1. Therapy selection, configuration and application	Therapy Mode selection	1 tactile 'Mode' button to switch different therapies
	Selecting and setting parameters which vary for each therapy	4 tactile buttons 'Prev', 'Next', '+', '-' to select and configure parameters
	Starting, pausing and stopping therapy	1 tactile 'Start/Pause/Stop' button for therapy operation.
2. Runtime status monitoring of therapy information	Real Time monitoring of high priority therapy related information	GUI central elements representing therapy related information
	Therapy duration/time to finish indication	GUI elements and counter representing duration/time related

		information
3. Runtime status monitoring of system information	Monitoring of low priority system status such as Battery status, Clock and time, Canister % full status etc.	GUI elements at the periphery of LCD
4. Therapy log, system history	Offline mode system log and therapy history showing patient and therapy information with date and time	GUI log data sheet Use 'Mode' button to enter Log Mode
5. Emergency, fault recognition	Hard real time indication of emergency situations such as leakage, canister full, blood in the canister, therapy error etc.	LCD blinking, High frequency Buzzer sound along with GUI emergency message
6. System Debug and setting configuration	Offline/Online monitoring of sensor, actuator, voltage, current information in Debug mode.	Press &Hold 'Prev' and 'Next' buttons together to enter Debug Mode
	Offline setting of system parameters clock, various mode etc.	Use 'Mode' button to enter System Setting mode
7. IOT operation	Remote therapy monitoring	Configure IOT server setting System Setting mode. Use Web socket, html 5 for online update and visualization.
	Remote therapy configuration	Remote IoT service on any device with a TCP/IP stack
	Remote emergency communication	Secure Remote Connections via SSH tunnel (Secure Shell)

The next task involved the development of wireframes to arrange the elements of system information and interactions. This was followed by the development of graphical user interfaces (GUIs). Separate GUIs were designed for various therapies possible within the wound therapy concept. Figure 6.22 displays the different UI concepts for the various therapies available with the wound therapy solution.

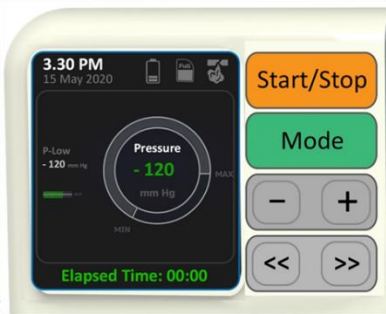
Therapy 1: Continuous Negative Pressure Wound Therapy

Parameters:

1. Negative Pressure

Process:

1. Use 'Mode' button to select CNPWT
2. Use 'Prev' and 'Next' button to select the pressure parameter.
3. Use '+' and '-' button to increment and decrement parameter values
4. Use Start/Pause/Stop button to start therapy



Therapy 2: Intermediate Negative Pressure Wound Therapy

Parameters:

1. Pressure High
2. Time-High
3. Pressure Low
4. Time-Low

Process:

1. Use 'Mode' button to select INPWT
2. Use 'Prev' and 'Next' button to select the four parameters.
3. Use '+' and '-' button to increment and decrement parameter values
4. Use Start/Pause/Stop button to start therapy



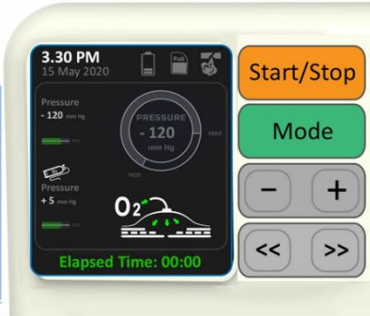
Therapy 3: INPWT + Oxygenation

Parameters:

1. Negative Pressure
2. Time-P
3. Oxygen Pressure
4. Time-O2

Process:

1. Use 'Mode' button to select INPWT
2. Use 'Prev' and 'Next' button to select the four parameters.
3. Use '+' and '-' button to increment and decrement parameter values
4. Use Start/Pause/Stop button to start therapy



Therapy log, system history



Figure 6-22: Various UIs developed for the wound healing concept (source: author generated)

(b) Product Functional Design

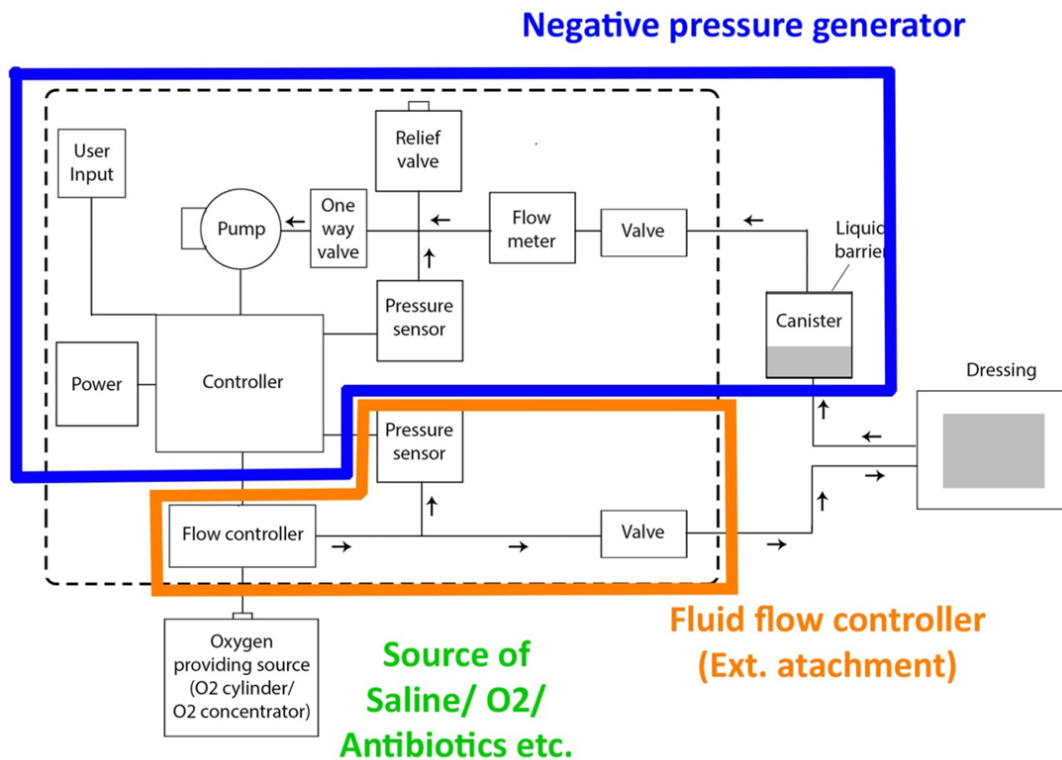


Figure 6-23: High level solution architecture of the wound therapy device (source: author generated)

The detailed functional development of the concept began with the functional decomposition

of various technical requirements and product features in order to arrive at a solution architecture for the final product. Figure 6.23 demonstrates the solution architecture of the wound therapy device. As shown in the figure, the architecture provides a modular arrangement for additional therapies, such as wound irrigation, topical antibiotic delivery, and subdermal oxygenation, in addition to the main therapy, negative pressure wound therapy for wound healing. The various therapies would be delivered to the wound site through fluid lines and a special dressing.

(c) *Electronic Hardware level breakdown*

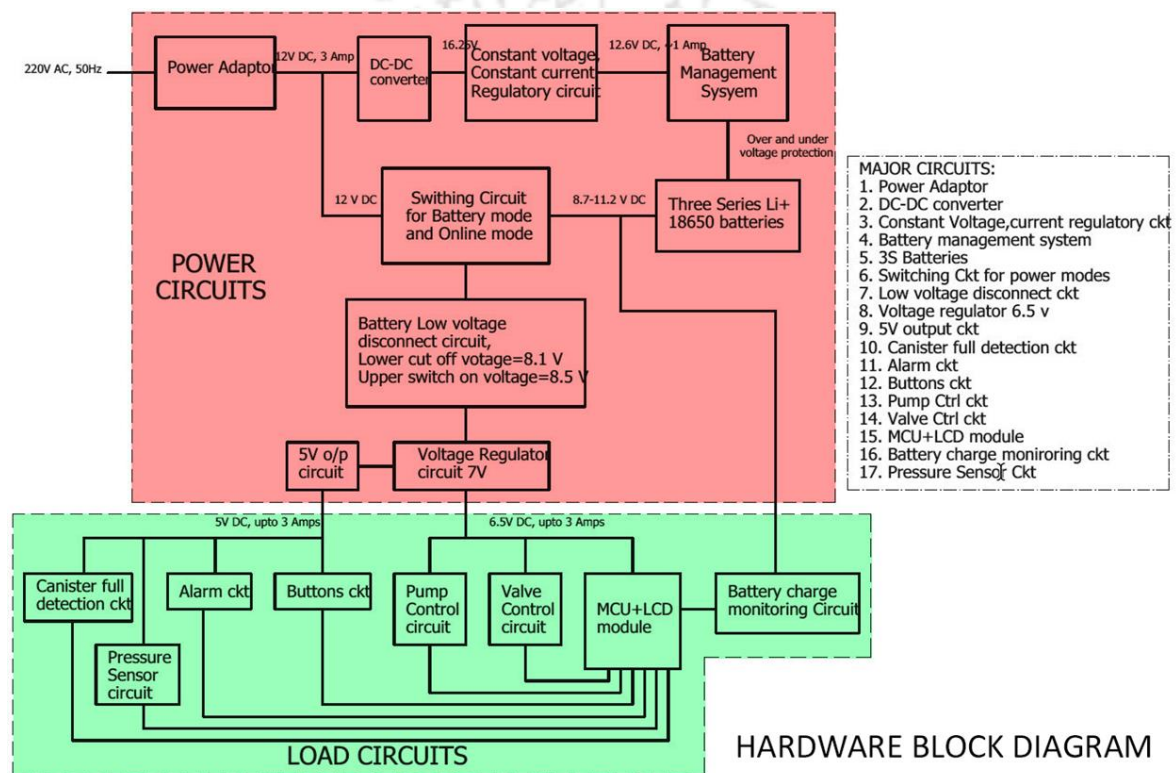


Figure 6-24: Electronic hardware and circuitry design plan (source: author generated)

A second round of functional decomposition was carried out for the planning and development of electronic circuitry and hardware modalities. Figure 6.24 represents the final electronic circuitry and hardware level decomposition of the device. The circuitry represented inside the red rectangle defines the 'power circuits,' which will manage rectification and input power division to different parts of the system as regulated voltage and current. The power circuitry also manages the switching of power supply between the in-line AC source and DC Lithium-ion battery source without affecting the system's operational condition. Again, the circuitry represented inside the green box represents 'Load circuits' which will control various input/output devices and actuators of the system. The load circuitry also includes sensors to

provide a closed-loop feedback.

(d) Physical circuitry prototyping and PCB Design

After planning the electronic circuitry for the system, a series of tests were conducted to evaluate the functioning of individual circuits, actuators, and sensors. This involved prototyping specific modules of the overall circuit, such as voltage regulation, constant current regulation, battery charging circuit, pump drivers, etc., on a breadboard and performing tests to determine the needed values of passive electronic components like resistors, capacitors, inductors, etc. Once these tests were validated, the next task involved detailed PCB design using CAD software. We utilized KiCad, an open-source PCB development tool, to design the resulting PCB based on the specific size estimated for the device. Figure 6.25 depicts the final PCB design for the device.

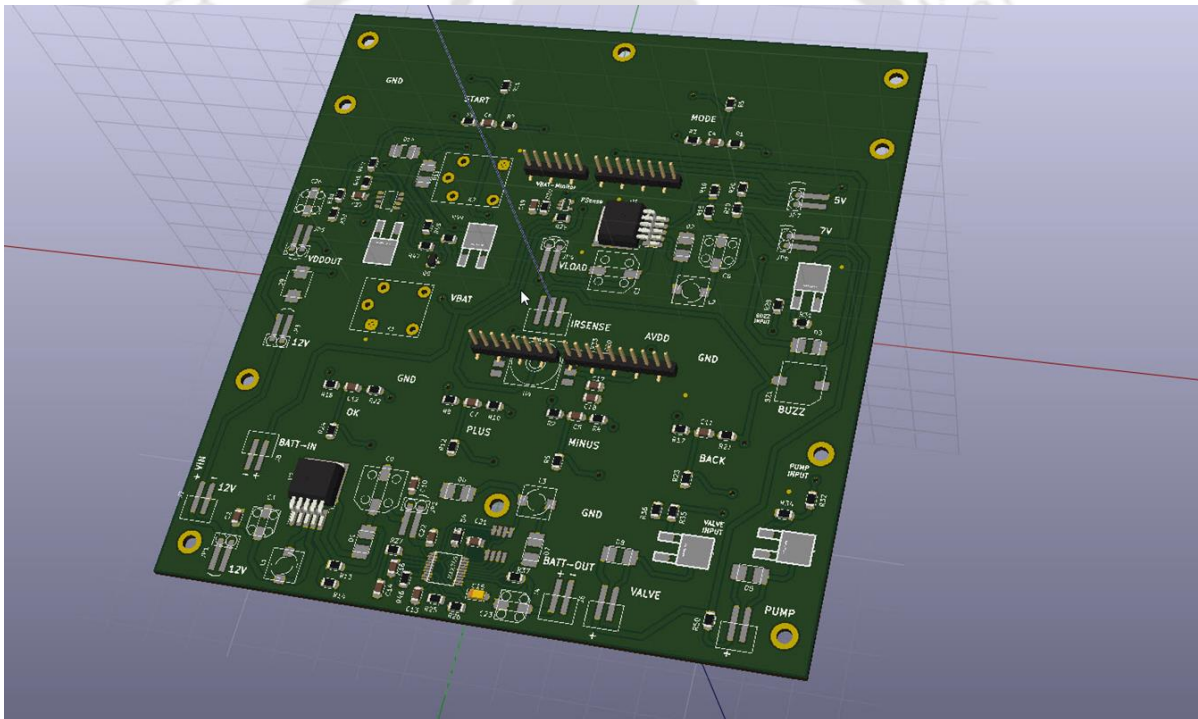


Figure 6-25: Double sided PCB design for the system (source: author generated)

(e) CAD modelling and engineering design

The final R&D task accomplished within this case study was the development of the product enclosure with the goal to use 3D printing as the mode of developing the initial prototype. Open-source 3D CAD software (Iron CAD) was used to create the device enclosure. The design task involved planning for 3D printable parts, product aesthetics, housing for various actuators, components, sensor, and a PCB. A separate modular arrangement for the attachment and

detachment of canisters and other consumables was planned so that these items can be easily removed from the system once used for a wound therapy procedure. Figure 6.26 reveals the final CAD model of the device along with engineering details.

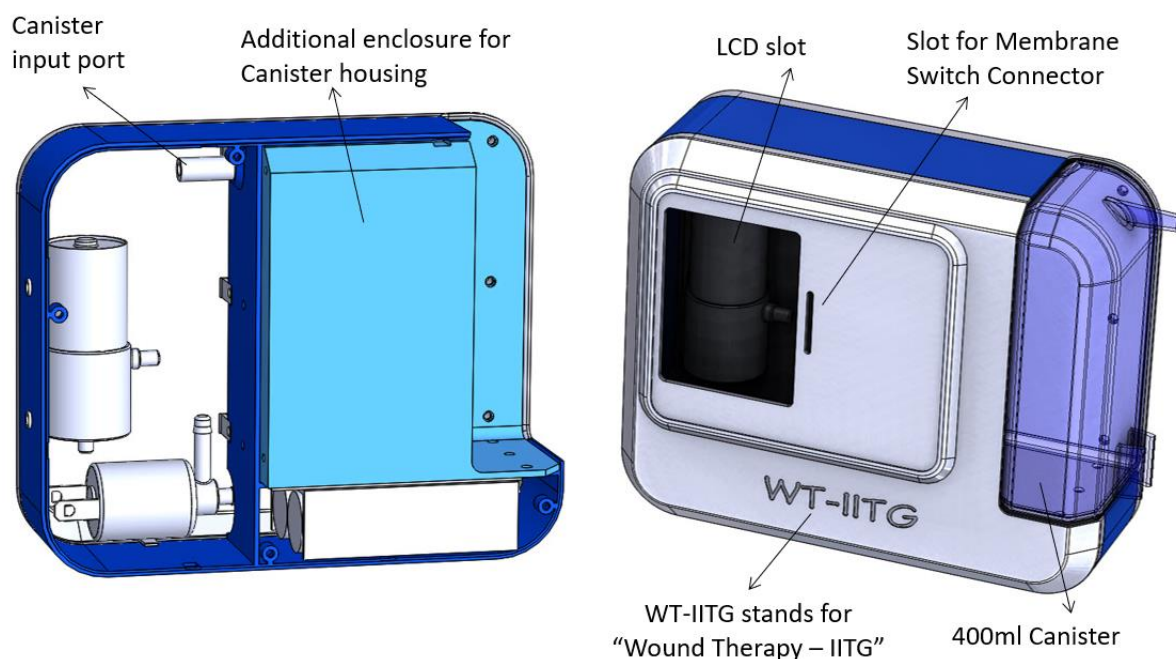


Figure 6-26: CAD model and engineering detailing of final wound healing concept (source: author generated)

6.4.2 IP strategy development using new tool 3

The task of developing a strategy for intellectual property protection began with seeking answers to some initial questions regarding the scope of IP protection for our solutions to two clinical problems. Table 6-J reveals the responses to the various initial IP-related questions.

Table 6-J: Initial IP related questions

IP related Questions	Answers
What all IP we would be protecting?	Patent, trademark, company logo
Which Patent route to follow? PCT or National	National
What are the jurisdictions where we want to sell and protect our invention?	India only
Do you plan for Licensing?	Yes
How will you manage IP expenses?	IITG research Fund
Decide what to protect- component vs process vs product	Product and Process
Are there trade secret involved	No
Who will be inventors?	Neelarnab Dutta, Debayan Dhar
Who will be applicant?	Indian Institute of Technology Guwahati
What is novel in your invention?	The device technology
Is the solution obvious for any skilled person/ expert	No
Are there any ethical issue or negative societal impact	No

The next step involved identifying key milestones, activities, challenges, and barriers

in the process of IP protection and planning the appropriate strategy. This was accomplished using Tool 3 of the modified Biodesign process. Figure 6.27 illustrates the process of developing a strategy for the intellectual property protection of the core technologies for the two solutions addressing clinical areas of wound healing and diabetic foot ulcer treatment.

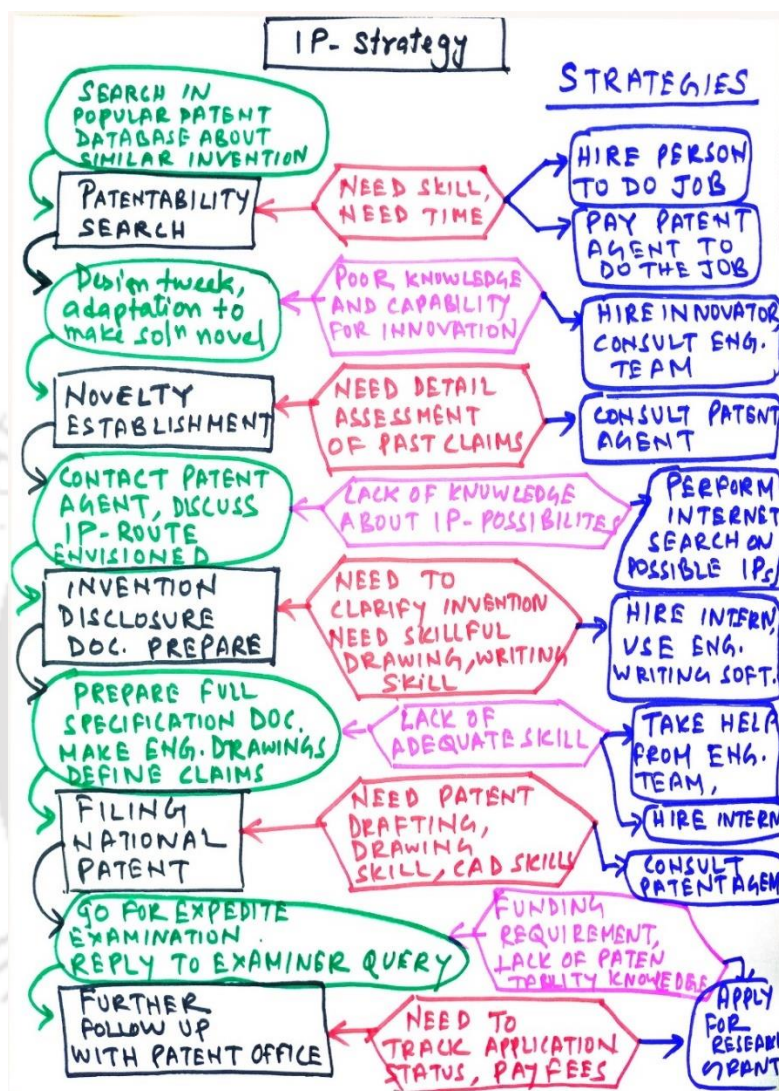


Figure 6-27: Common IP protection strategy for both the final medical technologies (source: author generated)

Subsequently, two Indian patents were filed for each of the two clinical areas. Here are details regarding these two patents.

6.4.3 Clinical validation strategy development using new tool 3

The final task in the strategy development within the case study was the creation of clinical validation strategies. These strategies were developed in accordance with the methodology outlined in Tool 3 of the modified Biodesign process. Figure 6.28 provides specific details regarding the process of developing clinical validation strategies.

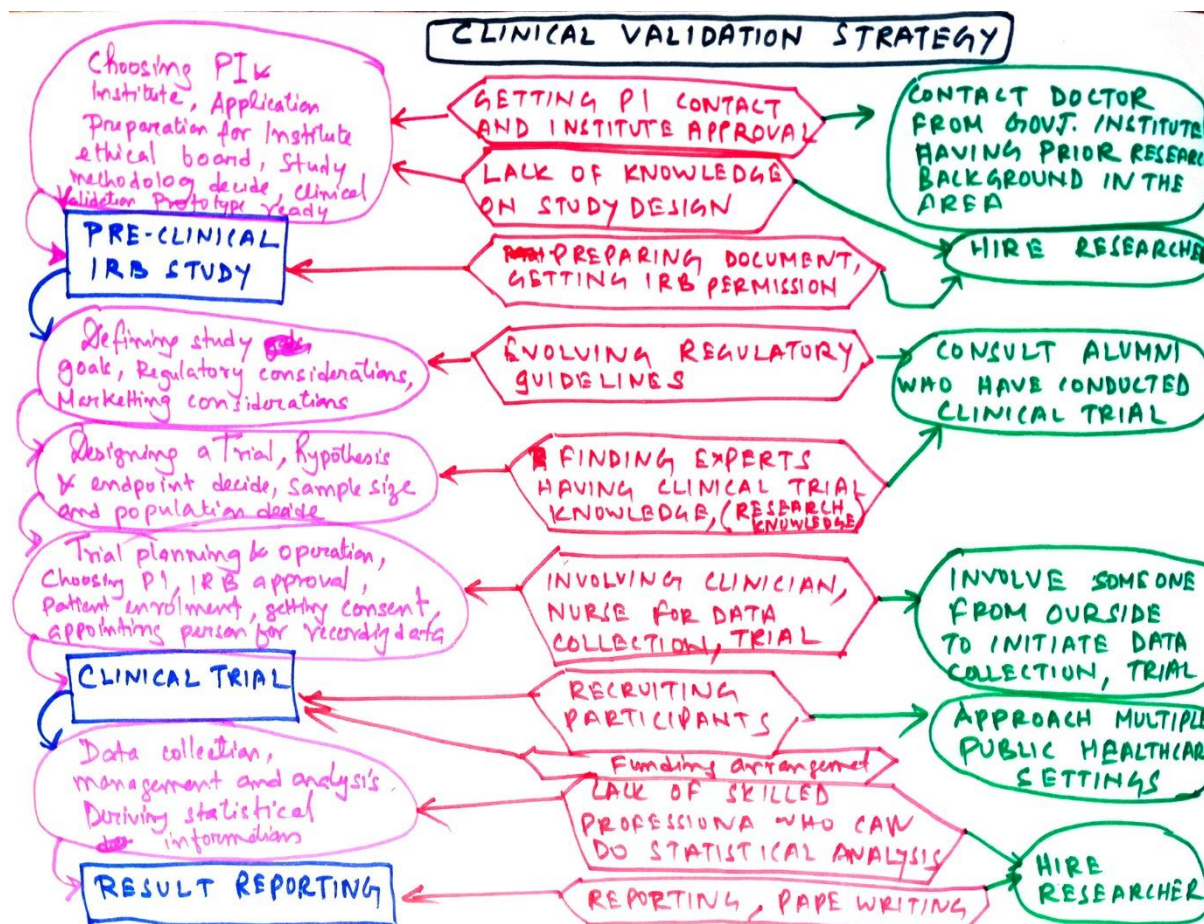


Figure 6-28: Clinical validation strategy (source: author generated)

There were primarily three key milestones identified for the two devices: a pre-clinical small-scale IRB study, a full-fledged clinical trial, and the reporting of the results from the clinical trial. Various underlying activities necessary to achieve these milestones were also realized in the process. For instance, activities that would be conducted before the Pre-Clinical IRB study include selecting the Principal Investigator (PI) and an institute where the initial device testing would be conducted. Subsequent activities involved preparing the application for Institute Ethical Review Board (IRB) clearance, developing the study methodology, and ensuring the clinical validation prototype was ready, among others. Similarly, key activities realized before embarking on a full-fledged clinical trial include executing pre-clinical trials, defining the study goals for the full-fledged clinical trial, incorporating regulatory considerations, designing the trial, determining hypotheses and study endpoints, identifying the required sample size and target population, planning and conducting the trial, selecting the principal investigator, obtaining IRB approval, managing patient enrollment, securing patient consent, and collecting data during the trial.

Next, several technical and implementation challenges and barriers were anticipated in

relation to clinical validation milestones and activities. These challenges included: contacting a Principal Investigator and obtaining Institutional approval, identifying resource persons with expertise in clinical research, understanding the requirements and preparing technical documents for an Institutional Review Board (IRB) application, grasping government regulatory guidelines for our device classes, underlying difficulties in engaging clinicians and nurses for data collection during the clinical trial, recruiting patients for the trial, and finding skilled professionals capable of performing statistical analysis of trial results, among others.

Furthermore, we devised a set of strategic measures to address the diverse challenges and issues on our path to achieving clinical validation objectives. For instance, for the issue of identifying the right Principal Investigator for the clinical investigation, the solution realized was reaching out to doctors from government institutes with prior research experience in the clinical field relevant to our project. Similarly, we identified various strategies to overcome the issues and barriers forecasted in the clinical validation process.

This concludes our exploration of the proposed modified Biodesign process in the development of medical technology for resource-constrained settings like India. The case study demonstrates how the novel Workflow Toolkit developed in this research has facilitated the resolution of various context-specific healthcare design and innovation challenges in low- and middle-income countries (LMICs).

6.4.4 Limitations

Due to the time constraints and the extended development timeline inherent in medical technology research, the implementation scope of Tool 3 from the modified Biodesign process was limited to strategy development in areas of R&D, IP, and clinical strategy. It was not possible to apply it to other activities. Future research could explore how the modified Biodesign process performs in addressing different clinical problems and in developing strategies for regulatory compliance, quality control, product scale-up, and manufacturing, among other areas.

Another limitation identified while applying the modified Biodesign process to real-life clinical problems was that certain issues, such as the shortage of skilled professionals in lower-tier healthcare settings, limit the adoption and implementation of innovations. Such problems are beyond the scope of a design process. Further investigation is needed to determine how these issues can be addressed within the scope of design guidelines and/or through technological interventions.

6.5 Chapter Conclusion

This chapter showcases how the modified Biodesign process was applied to address two clinical issues in India: Diabetic foot ulcers and cervical cancer screening. These problems have a significant socio-economic impact on the Indian healthcare system, going beyond clinical implications. Using a new toolkit revealed substantial service gaps within Indian healthcare, including socio-cultural taboos, procedural issues, and the unsuitability of existing care for Indian patients. The case study explains how these problems were identified and how need criteria were formulated to address clinical and implementation challenges. The case study also illustrates how the new workflow toolkit was used to develop concepts that tackled both clinical and implementation issues effectively. Finally, it outlines the planning of various implementation strategies and follow-up activities.



Chapter 7. Investigating the Constraints of Adapted Biodesign Processes in Mitigating Challenges Arising from the Shortage of Skilled Healthcare Professionals through AI Technology Integration

Abstract

Chapters 2 through 6 of this thesis address most of the research questions and objectives initially outlined in Chapter 1. Throughout the process of factor analysis, tool development, and evaluation, a significant barrier identified specific to LMICs was the lack of healthcare professionals and resources, which hampers the implementation of innovative healthcare solutions in resource-limited settings. A case study discussed in Chapter 6 highlighted that overcoming such challenges extends beyond the scope of design processes and requires technological interventions to implement healthcare solutions effectively. Initial expert brainstorming suggested the use of conversational AI to tackle this issue. However, it became apparent that there was a critical research gap in understanding the interaction requirements and usability guidelines needed to design and evaluate such systems.

This chapter explores follow-up research aimed at investigating the usability and interaction requirements of Conversational User Interfaces (CUIs) within the complex context of real-world interactions, using an experimental study. The study focused on a clinical scenario involving wound therapy, where two AI-driven conversational interfaces, one text-based and the other voice-based, were integrated into a medical device interface. The usability of these interfaces was assessed while performing standard clinical tasks. Usability testing led to the creation of 16 new heuristics, derived from various identified usability issues. These heuristics were then validated in other use case scenarios and proved effective as guidelines for designing and evaluating Conversational User Interfaces.

7.1 Introduction and Background

A major setback realized in the implementation of the final solution across different Indian healthcare settings is the lack of skilled professional and resources. The same has been identified also as challenges and barriers of successful Medical technology adoption within the factor ‘Healthcare context and system’, discussed in Chapter 2 of this thesis. This is an external

factor that the modified Biodesign process considered as implementation problem while using Tool 1-C and developing need criteria for further solution invention. While the proposed solution caters required design characteristics like portability, low-cost, easy to use, to make the final solution adaptable in below pyramid healthcare settings, yet the problem of 'lack of human resources would impact the grass root diffusion of the solution.

Therefore, an additional phase of brainstorming was conducted to make the solution feasible for grassroots implementation. During a team brainstorming session, various solution concepts were generated, drawing inspiration from technology fields such as telemedicine, Internet of Things, and assistive technologies like AI-powered bots. Subsequently, an assessment of these solution concepts was performed, considering the specific infrastructure and resource needs in low- and middle-income countries (LMICs). This comprehensive analysis led to the development of a unique strategy: the use of an offline AI bot for semi-autonomous healthcare delivery, which emerged as a viable approach to effectively address the identified problem.

7.2 Background

7.2.1 Scope overview

The literature research concerning 'assistive technologies in healthcare delivery' has illuminated numerous potential applications of artificial intelligence for addressing the scarcity of skilled personnel in resource-limited healthcare settings. A notion introduced by Sabet Sarvestani and colleagues in 2021, involving the redesign of medical devices to make them skill-independent, was identified as a suitable strategy to tackle resource constraints in the context of healthcare in India (Sabet Sarvestani, Coulentianos, & Sienko, 2021). In line with this concept, a scope realized was to employ Conversational AI agent as assistant technology embedded into current medical devices. Such a integration could facilitate 'task shifting' in healthcare delivery and enhance accessibility in healthcare settings where there is a shortage of highly skilled professionals. With the advancements in machine learning, natural language processing, computer vision, and robotics, there are significant scopes for Conversational AI-based automation in clinical diagnosis, virtual assistantship, communication, patient monitoring, and treatment management without the need for skilled professionals.

Literature findings relate to 'Indian healthcare system' revealed that, medical device positioning in a healthcare system is related to skill dependency. Indian Public healthcare system is hierarchical in nature where at the epic we have tertiary care hospitals with state of

art health technologies, medical devices and healthcare professionals (Selvaraj, Bhan, & Mahal, 2022). However, as we go down the hierarchy towards community healthcare centers, Primary healthcare centers one can find scarcity of resources, infrastructure and moreover skilled professionals. High skill dependency, infrastructure requirements of a medical product does not allow it to be available in low resource settings. So, to make a medical device available at low resource setting a Conversational AI system needs to reduce skill dependency by providing domain and operational knowledge.

7.2.2 What is Conversational AI and Conversational User interface?

Conversational User Interfaces (CUIs) refers to human computer interfaces that allows users to interact with a computer or a system through natural language conversations (Mctear, 2004). This can include text-based interactions (chatbots, messaging apps) as well as voice-based interactions (virtual assistants, voice assistants). Compared to early Voice or Speech based interactions which primarily focused on detecting spoken and linguistic information as user input, current generation CUIs aim to mimic human conversation patterns, making interactions more intuitive and user-friendly (Hwang, et al., 2019). Again, Conversational AI refers to the underlying technology and systems that powers CUIs and use artificial intelligence and machine learning to enable natural language conversations between humans and computers (P. Kulkarni, 2019). Conversational AI often involves advanced NLP, ASR, and text-to-speech (TTS) technologies to understand and generate human-like responses.

CUIs have come a long way in terms of their application scope. Initially, they were limited to simple dialog-based software applications like Google Assistant (Google). However, they have now evolved to support more complex application tasks such as human-robot interfaces for industrial automation and robotic surgery (Berg, 2020; Jacob, 2012; K. Zinchenko, 2017). These advanced applications enable collaborative interactions between humans and computer systems, allowing them to perform physical activities in the real world. The field of human-robot interaction/collaboration plays a crucial role in defining the various ways in which humans and machines can interact. This includes using combinations of conversational interfaces, visual displays, hand and facial gestures, non-verbal audio alerts, and physical interactions (Berg, 2020; Schultz., 2007). The goal is to create a natural and seamless exchange of information and enable humans and machines to work together in the same workspace.

7.2.3 Complex integrated system-physical interactions associated with CUI based healthcare delivery

AI-infused medical systems/devices define an emerging area where collaborative human-machine interaction is needed. Such systems can help healthcare providers with clinical decision support, and context-aware assistance in medical tasks like diagnostics, surgery etc. via use of CUIs (K. Zinchenko, 2017; Sebastian Bodenstedt, 2020).

The proposed scenario of integrating Conversational User Interfaces (CUIs) within medical devices for semi-autonomous treatment delivery in resource-limited settings is safety-critical and complex. This integration involves a synergistic blend of both human-computer interaction and interaction with the physical world. This study introduces the term "integrated system-physical interaction" to describe such complex interactions.

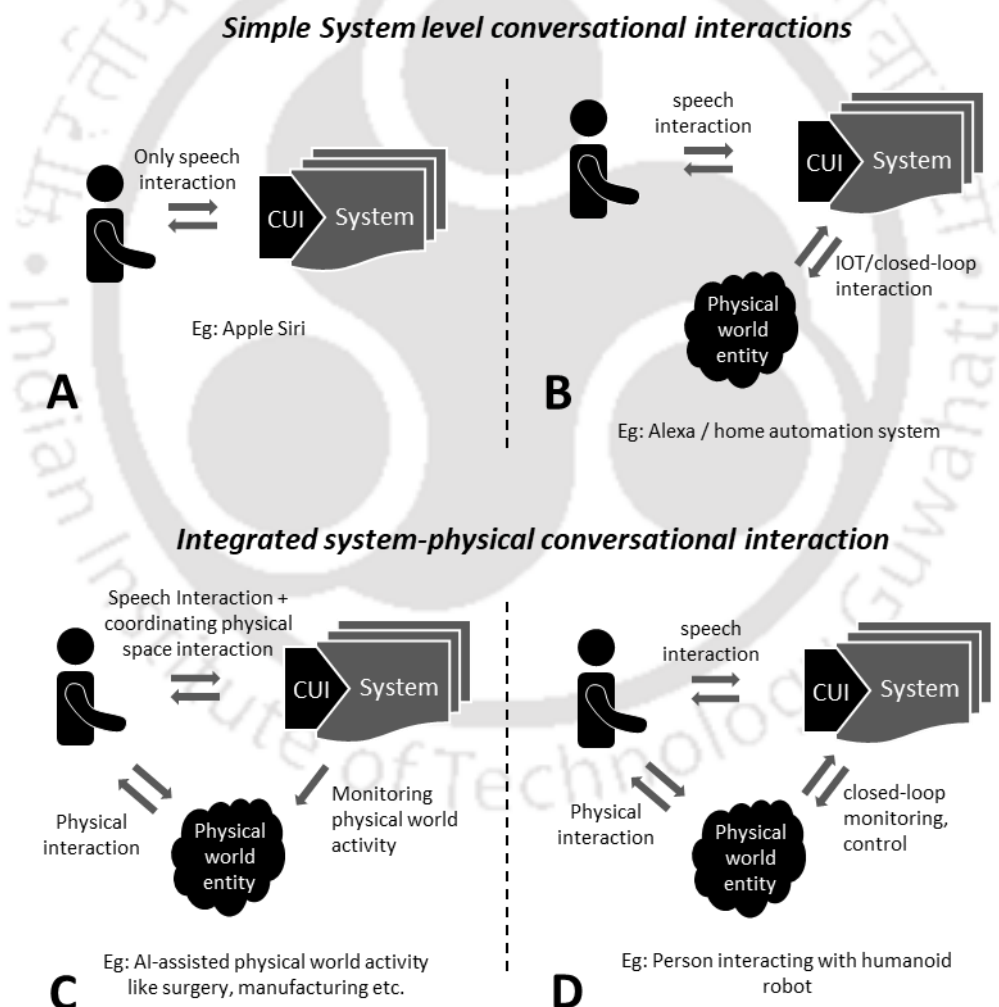


Figure 7-1: Evolving complexity of CUI based systems (source: author generated)

Figure 7.1 depicts two types of CUI-based interactions in relation to possible needs. Illustrations A and B represent simple system-level conversational interactions. As depicted,

illustration A confined to speech-only interactions where the goal is to exchange information at the system or media level. Example: interacting with Apple Siri to know about weather conditions. Illustration B represents interaction with the physical world entity via a mediating CUI-based computer system. This represents the basics of a pervasive or ubiquitous computing environment (Genco, 2010). Examples: Cyber-physical systems, Amazon Alexa providing control of room light via voice command. In both, A and B, a user is only interacting with the system to perform tasks. On the other hand, illustrations C and D represent applications of CUIs requiring integrated system-physical interactions. That are scenarios where a user is interacting with both CUI-based systems and some physical-world activity to achieve specific goals. Illustration C depicts a scenario where an intelligent CUI-based system is interacting and assisting a user in performing physical tasks. The system also poses the context-awareness of the physical space. Examples: AI-assisted robotic surgery, semi-automatic manufacturing and assembly task. Again, Illustration D represents similar interaction but here the physical world entity or process is a closed-loop part of the CUI-based system. Example: Tangible interaction with a humanoid robot along with voice command.

In the past, similar interaction model is defined in literature as H-P-M-E model where H= User, P= Interface, M= Media space and E= environment (Lim, 2000). Here, the media space facilitates the interconnection of various environmental components, allowing for the enhancement and effective support of human activities within the physical space. Additionally, it enables advanced management and manipulation of these environmental elements. They also represent the most basic and effective model to form a physical environment for knowledge-intensive work.

Both interaction scenarios illustrated in C and D signify the complex application demands of CUIs beyond one-to-one user-system interactions. As a result, the process of usability engineering and evaluation for a CUI-based system goes beyond merely focusing on dialog-level interaction. Instead, it involves assessing usability from the standpoint of delivering integrated system-physical interaction.

7.2.4 How to evaluate usability of CUIs for Complex integrated system-physical interactions?

An effective development and integration of CUI as a part of medical device for seamless healthcare delivery in resource constraint setting, demand system usability evaluation for said integrated system-physical interactions. Usability issues of user interfaces are often identified using Heuristic evaluation which is an informal way of identifying and fixing the usability of

user interfaces. This method of evaluation is popular as this consumes less time and requires less domain expertise than formal analysis techniques or empirical testing of user interfaces (Nielsen J. a., 1990).

Past heuristics and guidelines for design and evaluation of CUIs

Early guidelines and heuristics by Molich (1990), Nielsen (1994) and Shneiderman (2010) were felt insufficient to analyse the interaction possibilities that speech user interfaces facilitate (Molich, 1990; Nielsen J. ; Shneiderman, 2010; Rosenfeld, 2001; Wei, 2018). This is because most of the early research considered user interactions primarily with GUIs. Similarly, studies that establish guidelines or heuristics for spoken language dialogue systems, by Rudnicky (1996), Dybkjaer (2001), and Suhm (2003), are ineffective for possible speech interactions with current natural language processing technologies and computation capabilities (Rudnicky, 1996; Dybkjaer, 2001; Suhm, 2003). This is because early speech-based interaction and system designs were rule-based and limited to carrying out simple tasks like telephonic interaction. Recent studies supported the urge for more social, natural and engaging human-like interaction to enhance trust and efficiency in Conversation based interactions (Nass, 2005; Bickmore, 2005; Jain, 2018; Kocielnik, 2019; Thomas, 2020).

Conversation design guidelines by Google (for Google Assistant) and by Amazon (for Amazon Alexa) are specific to their smart devices and are limited to only dialogue or action design (Google; Amazon). In 2018, Wei introduced 17 usability heuristics for Speech User Interfaces (SUIs) and validated them on Google Home, Amazon Echo, and Apple Siri using 8 usability experts (Wei, 2018). However, the validation primarily focused on simple tasks, requiring further exploration for integrated system-physical interaction in AI applications. Murad (2019) expressed concerns about Wei's (2018) novel heuristics for Voice User Interfaces (VUI), which deviated from established GUI heuristics. Murad emphasized the importance of aligning new VUI guidelines with Jacob Nielsen's heuristics to aid adoption in the HCI community. She recommended a unified set of 10 VUI guidelines, with two extensions, derived from GUI heuristics (Murad C. a., 2018; Murad C. a., 2019; Murad, Munteanu, R. Cowan, & Clark, 2021). While these guidelines can address simple VUI-related issues, they might oversimplify complex Conversational interactions. Similarly, Langevin (2021) contributed to the field by proposing two additional heuristics in addition to Nielsen's (1994) nine heuristics for the heuristic evaluation of conversational agents like chatbots and voice bots (Langevin, 2021). However, the validation of these heuristics was limited to simple

conversation-driven software tasks on Amazon Echo and Apple Siri.

Despite the significant contributions of the literature mentioned, there is a lack of studies focusing on the integrated system-physical interaction requirements of CUIs and the associated usability issues that arise when coordinating activities between the physical and software worlds.

7.3 Research gaps, Aims and objectives

While the integration and development of a CUI as a part of medical device for healthcare delivery is the current goal of the study, there is a lack of usability heuristics that can guide the evaluation of such a system. The primary research gap found is the insufficient exploration of CUI heuristics for real-world context requiring a complex blend of system-level and physical-world interaction that demands synergic use and awareness of both physical and software world interactions. Existing CUI heuristics have been hardly explored beyond dialogue-level interactions.

Previously conducted research on heuristics specific to CUIs primarily relied on literature reports or analyses of simple speech-based application tasks to develop and validate these heuristics (refer to (Murad C. a., 2019; Langevin, 2021)). The majority of these applications were designed for mobile devices and interactive systems like Apple Siri and Amazon Echo, utilizing speech engines and algorithms that represented first-generation Conversational AI applications. For example: giving voice command for setting alarm, or switching on lights to Amazon echo system only involve media or system level interaction, without the need for the system to sense the user's bodily movement in physical space. However, the advancement of more sophisticated AI systems has increased the requirements placed on CUIs beyond the capabilities of basic user instruction handling (K. Zinchenko, 2017). The focus now is to establish a more social, multimodal, and engaging conversational experience that resembles human-like interaction, capable of sensing and addressing physical-world activities that previously required human intervention and expertise. This necessitates exploring various usability and interaction requirements for achieving a realistic human-like conversation.

The study aimed to develop an AI-infused medical device for clinical therapy and identify CUI heuristics for integrated system-physical interaction scenarios that demand synergic use and awareness of both physical and software world interactions. The key objectives of the study are:

- i. To develop CUI embedded medical system for clinical therapy
- ii. to investigate usability issues of CUIs in integrated system-physical interaction scenarios and analyze the scope of existing generic and CUI-specific usability heuristics,
- iii. to synthesize CUI heuristics for integrated system-physical interaction scenarios and validate them.

7.4 Methodology

Most past studies considered available systems/ interfaces/ applications to synthesize and validate usability heuristics (like (Langevin, 2021)). Unlike past studies, this study took a ground-up approach to investigate the usability and interaction requirements of CUIs for a complex physical-world interaction context. The authors considered a clinical context of wound therapy, implemented two conversational AI-based interfaces, text-based and voice-based as a part of a medical device interface, and evaluate their usability for executing standard clinical tasks. The use case scenario of the intelligent medical system for assistive healthcare services via CUI incorporation resembles the types of interactions represented in C and D of Figure 7-1. This approach of customized development and usability testing was necessary for the study because the majority of existing CUIs are incapable of directly assessing intricate interactions, as they are primarily designed for basic dialog-level interactions. Additionally, CUI-embedded smart home devices, such as Amazon Echo, are specifically developed for their own closed-loop systems and cannot be tailored to suit our study. Here are further details.

7.4.1 Development of Conversational AI integrated medical device

A Negative Pressure Wound Therapy (NPWT) device and procedure have following clinical characteristics: it has a longer duration compared to other therapies (72 hours in one session), it necessitates some level of technical expertise to operate, it is classified as a non-high-risk medical device, the clinical procedure varies depending on the location of the disease, and it requires a moderate level of physical and mental coordination to operate.

Two prototypes of CUI embedded NPWT devices were developed and considered for the study. One prototype had a text-based Conversational AI interface, while the other had a voice-based Conversational AI interface. The purpose was to examine all potential challenges related to user interaction when providing wound therapy. To comprehend the diverse interaction needs for designing the CUIs, a group of interaction designers collaborated with

clinicians and gathered their feedback to identify intricate user interactions and their characteristics during various stages of the clinical procedure.

We have chosen two hardware base boards namely STM32F407 Discovery board and Jetson Nano board for the purpose. The STM32F407 Discovery board is a 32-bit general-purpose microcontroller board, which was initialized and configured with additional hardware, actuators, sensor to build the NPWT modality. Again, Jetson Nano is a 64-bit Single board computer that hosted the Conversational AI systems and provide required computational power for natural language processing. Rasa: open-source conversational AI framework was used as a base software platform to develop the chat-based CUI. It comprised of Rasa NLU modality for natural language understanding (NLU) and Rasa Core modality for natural language generation (NLG). The conversational AI system needed to understand natural conversations and decode user inputs/requirements into low level system parameters to control the NPWT device functionalities. The electrical communication between the Conversational AI-hosted Jetson Nano board and the STM32-based NPWT modality was established via additional GPIO hardware interfaces. Moreover, custom algorithms were written as a part of the Rasa action framework to make the Conversational AI bot capable of controlling the embedded system task of the NPWT device. Figure 7.2 below represents the hardware integration between the Jetson Nano board and the NPWT system.

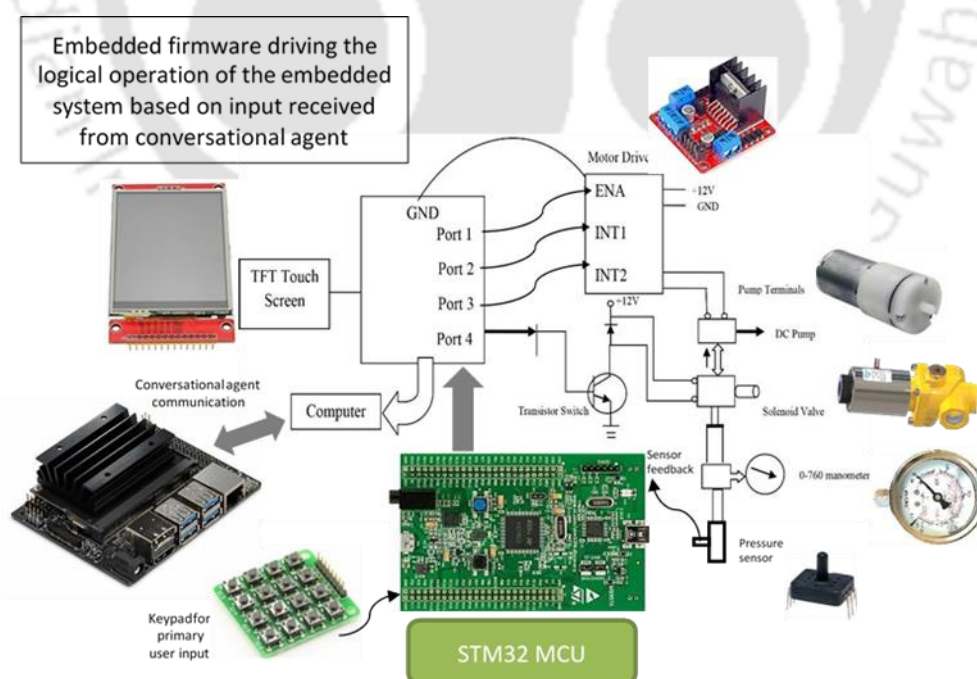


Figure 7-2: Hardware integration of the Conversational AI-based clinical system (source: author generated)

The custom developed NPWT systems were capable of producing suction pressure

ranging from 0 to 220 mmHg, meeting the standard clinical requirements for facilitating the healing of wounds. In our study, we created a test scenario wherein a specific negative pressure had to be applied to a dummy wound site (3d printed foot model) using an airtight dressing. Figure 7.3 illustrates the NPWT hardware modality, which is functionally compatible with the standard clinical device, equipped with an LCD display and a secondary tactile button interface.

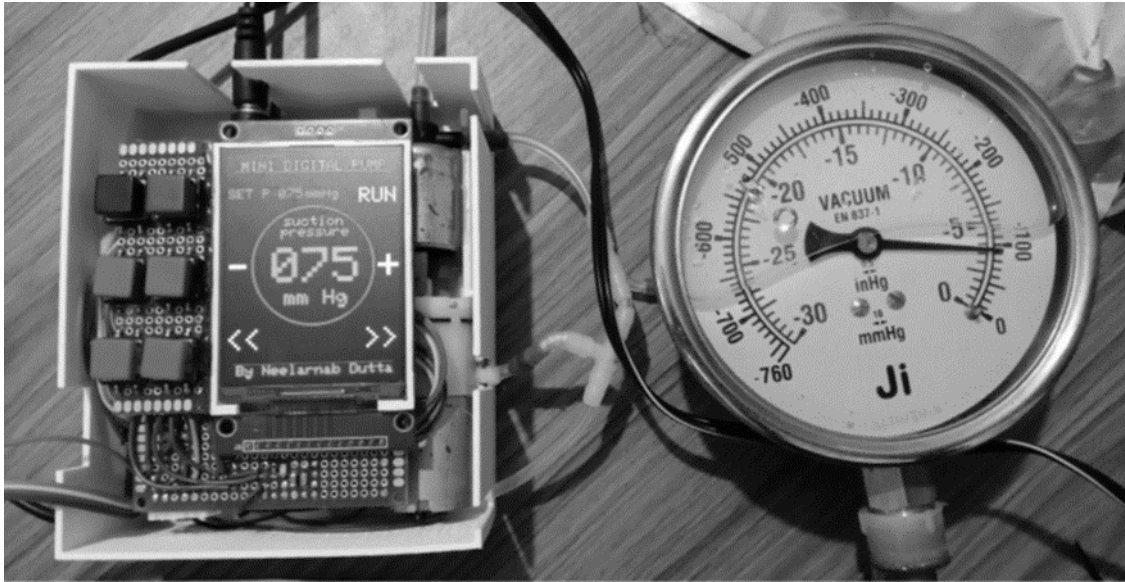


Figure 7-3: The negative pressure wound therapy (NPWT) clinical modality (source: author generated)

Several design modifications related to product enclosure design were carried out for housing the electronics and wound healing therapeutic modalities. For the usability testing of the CUIs, it was realized to have a portable form factor which is easy to carry and operate. The device form factors were kept simple for low cost 3D printing and assembly. Figure 7.4 shows the final CAD model and 3D printed enclosure of the device.



Figure 7-4: CAD model and 3D printed device enclosure (source: author generated)

The CUI architecture includes, Natural language understanding (NLU) pipeline, Speech recognition classifiers, Natural language generation (NLG) modalities, Dialog management NLP policies to enable conversational interactions which are more human-like in an intelligent and natural way. More details about the CUI architecture, NLU pipeline and its integration with the NPWT device modality is presented in Appendix A.1 section. Next, after we set the NLU pipeline the AI model had to be trained for user intents, entities and conversational stories specific to the context of wound therapy, to make the Conversational AI capable of handling clinical interactions of NPWT. More details about training components and datasets are presented in Appendix A.2 section. Figure 7.5 shows an example of a complex user instruction delivery, where the AI system can identify user input and detect required actions and parameters.

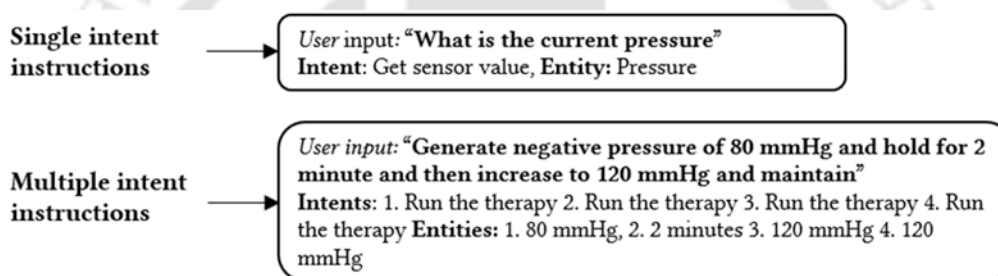


Figure 7-5: A example of Conversational AI based CUI detecting intents and entities from user inputs (source: author generated)

Conversation and interaction planning based on Nielson's 10 usability heuristics

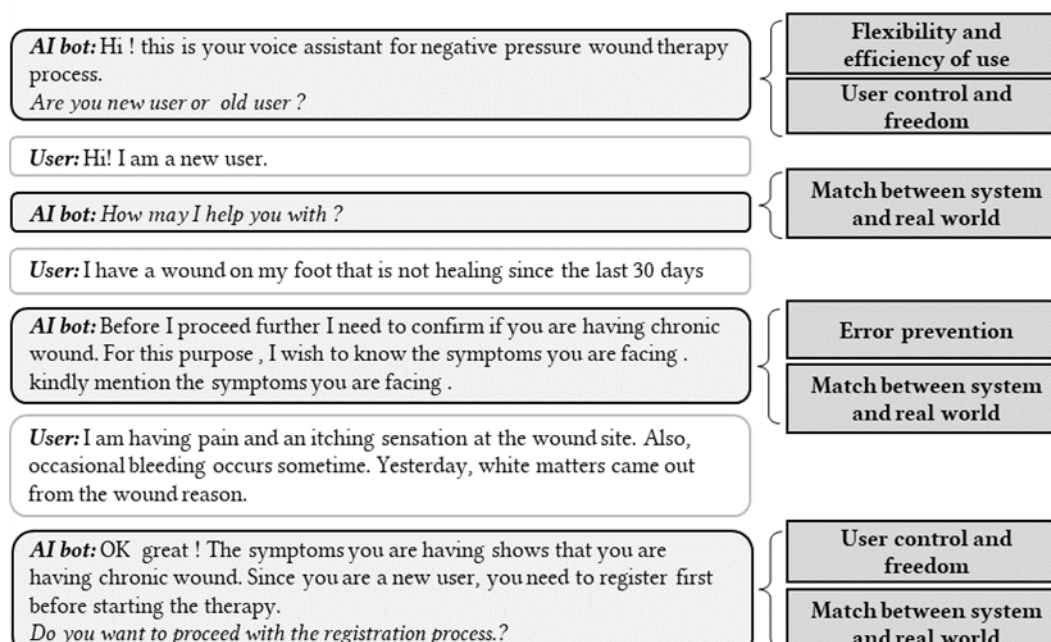


Figure 7-6: Implementation of Nielsen's heuristics in conversational design (source: author generated)

Nielson's ten heuristic principles were implemented as initial heuristics to define the usability requirements and define conversations within the happy paths as shown in Figure 7.6. The devices showcased primarily three categories of conversational interaction: 1) Engaging in casual conversation to respond to user inquiries and provide clinical information, 2) Providing instructions and guidance to users for completing clinical tasks, and 3) Accepting specific user commands and managing the operations of the underlying system.

The NLU modality of the Conversational AI system undergo training using an extensive collection of user intent and entity data, alongside mechanisms for retrieving user responses, such as Slots and Forms. Similarly, in the case of training the NLG modality, a diverse range of potential conversational paths, bot responses, and actions was created. The dataset used for training in this study consisted of linguistically validated text data, which was curated over a span of 6 months. After initial training, the Conversational AI bot undergone interactive training with volunteers to generate and fetch with additional training data. More than 20 such interactive training sessions were conducted. For more details on training data refer to Appendix A.2. Figure 7.7 depicts the manner in which conversations and diverse interactions occurred at the system level, following the intended happy conversation path.

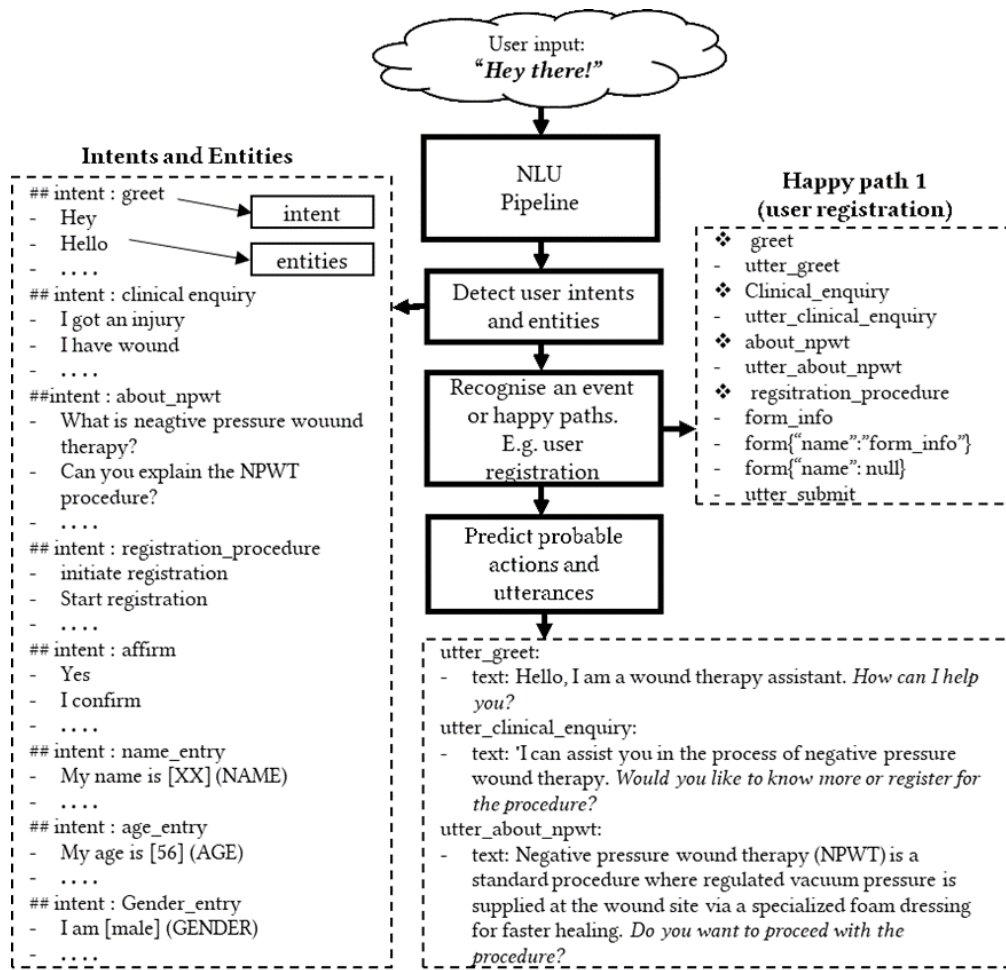


Figure 7-7: A representation of how the Conversational AI based CUI carries out clinical conversations (source: author generated)

The resultant NLU training accuracy achieved was 98.46%. The system demonstrates an "intent prediction confidence distribution" ranging from 0.90 to 1.0, and an "entity prediction confidence distribution" ranging from 0.91 to 1.0 for the final test data. The baseline behaviour of the NLG modality in responding to user intents was found consistent and as expected. Other application-specific assessments like the success rate in initiating custom action algorithms responsible for controlling the operation of the NPWT device, achieved a perfect 100% rate. For more details on system performance and standalone-evaluation refer to Appendix A.3. Figure 7.8 below shows the working of the two AI systems from a benchtop testing session.

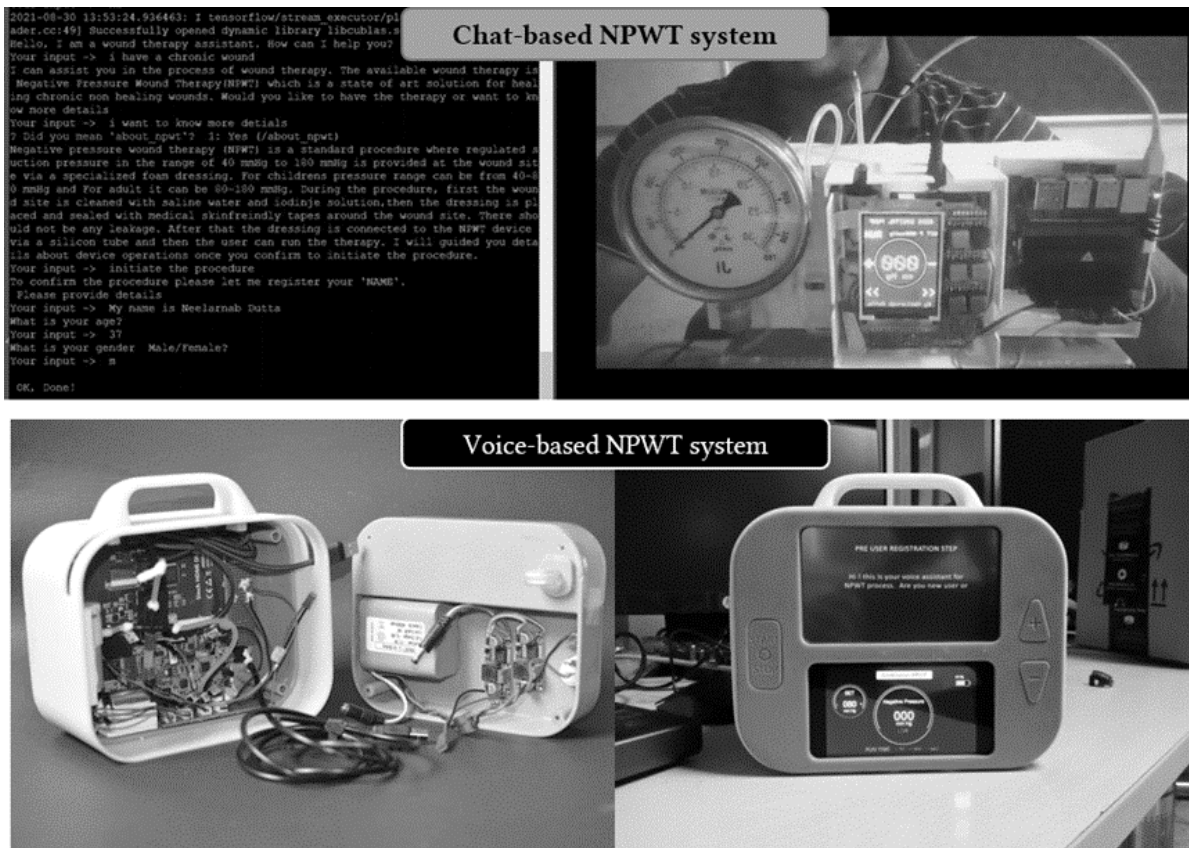


Figure 7-8: The two CUIs with the NPWT modalities (source: author generated)

7.4.2 Usability testing of the CUIs for integrated system-physical interaction scenarios

The purpose of conducting end-user testing was to take a user-centered approach by involving real stakeholders associated with wound management and collect data regarding the usability problems encountered when performing clinical procedures using the interfaces of the two NPWT devices.

Ethical considerations

Shown in Figure 6.38 is a representation of the user testing setup. The user-testing part of the study was confined to benchtop experimental testing of the Conversational user interfaces (CUIs). All tests were conducted while operating the CUI embedded devices on a dummy wound model made from 3D printed parts. It's important to note that, for the study objectives, end-user testing did not require an ethically approved clinical study involving human or animal subjects to operate upon.

Recruitment and Sample selection

End-user testing of the CUIs were conducted in an Institutional laboratory facility in India, between January to May 2023. The user population identified were healthcare staff and

research scholars involved with wound healing therapy. The first few participants were recruited via convenient sampling i.e. based on authors personal and professional contact. Further, snowball sampling recruitment technique was used in identifying potential participants that have prior exposure to wound management related clinical processes. This was done via approaching individual participants and debriefing the project objectives in the form of presentation and providing handouts. All participations were completely voluntary. The participants took part in the study by making physical presence in the laboratory facility. User testing for the two CUIs (text-based and voice -based) was planned to conduct separately, with two user groups. As an inclusion criterion, for both study groups, we chose adults over the age of 18 with basic proficiency in reading, writing and speaking the English language. The two user tests corresponding to the two CUIs were conducted temporally apart with a gap of 2 weeks. A total of 26 participants were recruited for the chat-based device between Jan-March 2023, while 14 participants were recruited for the voice-based device between April-May 2023. Written participatory consent was taken before each user test. The participants were first briefed about chronic wounds, the Negative Pressure Wound Therapy (NPWT) process and the devices' interfaces. A short video demo was shown to participants to help them understand the mode of interaction.

Test setup and protocol

As a part of test activity, users of the two groups were asked to interact with the interactive CUIs to perform the NPWT procedure on a dummy wound site (see Figure 7.10). To address ethical and safety concerns, the user testing of the devices and their interfaces was carried out on a benchtop rig instead of using real patients. The test rig comprised of a 3d printed foot having a marked wound site. During the user testing procedures, users were given seven consumables to utilise from the physical world while interacting with the device. The seven necessary consumables for the study were: 1. Black foam; 2. Iodine solution (dummy); 3. Saline water (dummy); 4. A medical bandage; 5. Scissor; 6. Wound dressing; and 7. Adhesive tapes for the clinical procedure. The participants were asked to interact with the system by initiating with the word 'hi'. During the test procedures, the CUIs allowed two-way conversational interactions with the devices for NPWT therapy, along with physical interaction with the consumables. A sample conversation flow from the user testing session is shown in Figure 7.9.

```

Your input -> initiate the procedure
To confirm the procedure please let me register your 'NAME'.
Please provide details
Your input -> My name is [REDACTED]
What is your age?
Your input -> 37
What is your gender Male/Female?
Your input -> m

OK, Done!

? I am registering you for the NPWT therapy with the following info:
name: [REDACTED]
age:37,
gender:Male.
Do you confirm? 1: Yes (/affirm)
Your confirmation is noted
? I am going to guide you stepwise procedure. You can do it easily at your end:
1: Proceed NPWT (/proceed_npwt)
?
1. Take saline water and iodine solution and clean the wound site thoroughl using cotton dressing soaked with the two solutions one by one. If you are done with step1 then proceed to next step 1: Next step 2 (/next_step2)

```

Figure 7-9: A sample conversational interaction with the interactive AI system (source: author generated)

During ongoing tests, the first author addressed user doubts and questions wherever necessary. The participants were asked to speak their queries and doubts aloud during interactions. User queries, doubts, navigation issues, etc., were documented for analysis. Throughout the testing process, all interactions with the system were carefully documented in the form of log data, conversation transcripts, and video and image data, with explicit consent from the users.

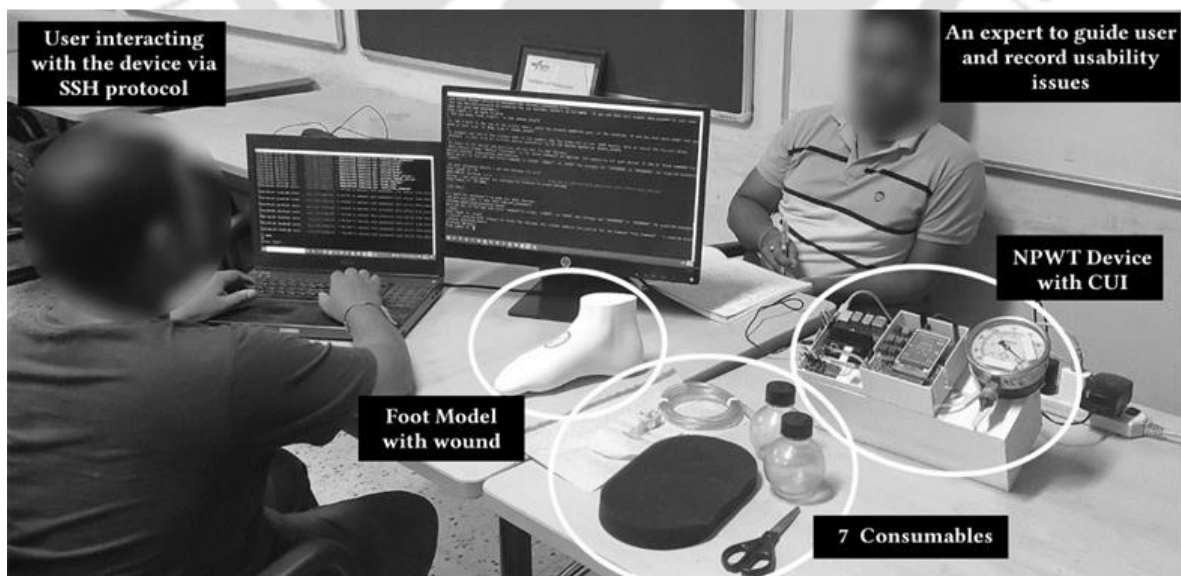


Figure 7-10: A snapshot from user testing session (source: author generated)

7.4.3 Analyzing the scope of existing usability heuristics for CUIs for integrated system-physical interaction

Expert selection

Following the completion of user testing, an in-depth examination of the user testing records was conducted to identify and analyze usability issues present in the two Conversational AI based CUIs. For this purpose, seven usability experts were enlisted, including one professor, four researchers, and two designers who possessed prior experience in designing and developing Conversational AI bots and conducting heuristic evaluations. All the expert participants had an average of over five years of experience with heuristic evaluation. Additionally, the analysis process benefitted from the expertise of a wound care specialist who had more than six years of experience in NPWT procedures. The specialist provided valuable clinical insights regarding standard NPWT procedures, necessary accuracy, and the significance of specific clinical activities.

Analysis of user testing records

To facilitate the review and analysis, the team of experts was provided with videos, system log data, and conversation transcripts from the interactions with the two devices. The experts were instructed to recognize usability issues by considering the 'barriers in' or 'need for' completing clinical tasks and meeting user interaction requirements. Additionally, they were asked to analyze those instances of usability issues using Neilson's (Nielsen J.) and established heuristics for Conversational AI usability (Langevin, 2021). The process involved identifying specific heuristic violations against the usability issues. To facilitate further analysis, the expert evaluators were asked to annotate usability issues that do not fall under the scope of existing usability heuristics and provide appropriate rationales for their judgments.

7.4.4 Identifying Requirements and synthesis of new heuristics

In Phase 2, the seven usability experts, previously recruited, further analyzed the usability issues which they failed to map against existing heuristics. A second cross-verification round was conducted to check if there were errors in identifying usability issues from the user testing records. This was followed by the synthesis of new heuristics to address those usability issues. This choice of engaging usability experts for heuristic development instead of users was made because design heuristics serve as instruments for user experience designers. And gaining insight into such design needs and the process of synthesizing those requirements requires a

combination of system design knowledge and usability engineering expertise, which might not be present in regular users.

Heuristic coding

The study was aligned with the works of Murad (2019) and Langevin (2021), aiming to expand upon Jacob Nielsen's widely recognized heuristics to make them more accessible to existing Human-Computer Interaction (HCI) designers (Murad C. a., 2019; Langevin, 2021). A thematic coding approach was chosen, for the development of new heuristics addressing usability issues that were not covered by the existing heuristics (Gibbs, 2012). The team of usability experts, who were recruited during Phase 1, engaged in group discussions and constructive debates to synthesize these new heuristics through thematic coding. The thematic coding process consisted of three stages: an open coding stage, an axial coding stage and a selective coding stage. In the open coding process, the coders tried to identify the implicit issues from the previously identified usability or interaction issues and formulate specific requirements or recommendations as primary open codes. During axial coding, the codes have undergone further analysis, and categorization to arrive at a set of usability heuristics as axial codes. The axial coding stage involved several iterations of refinement, regrouping, and scoping. Finally, in the selective coding stage, axial codes of similar concepts got further merged to establish a conclusive set of usability heuristics specifically tailored to the CUIs' design and evaluation. Figure 7.11 shows an example of the thematic coding process.

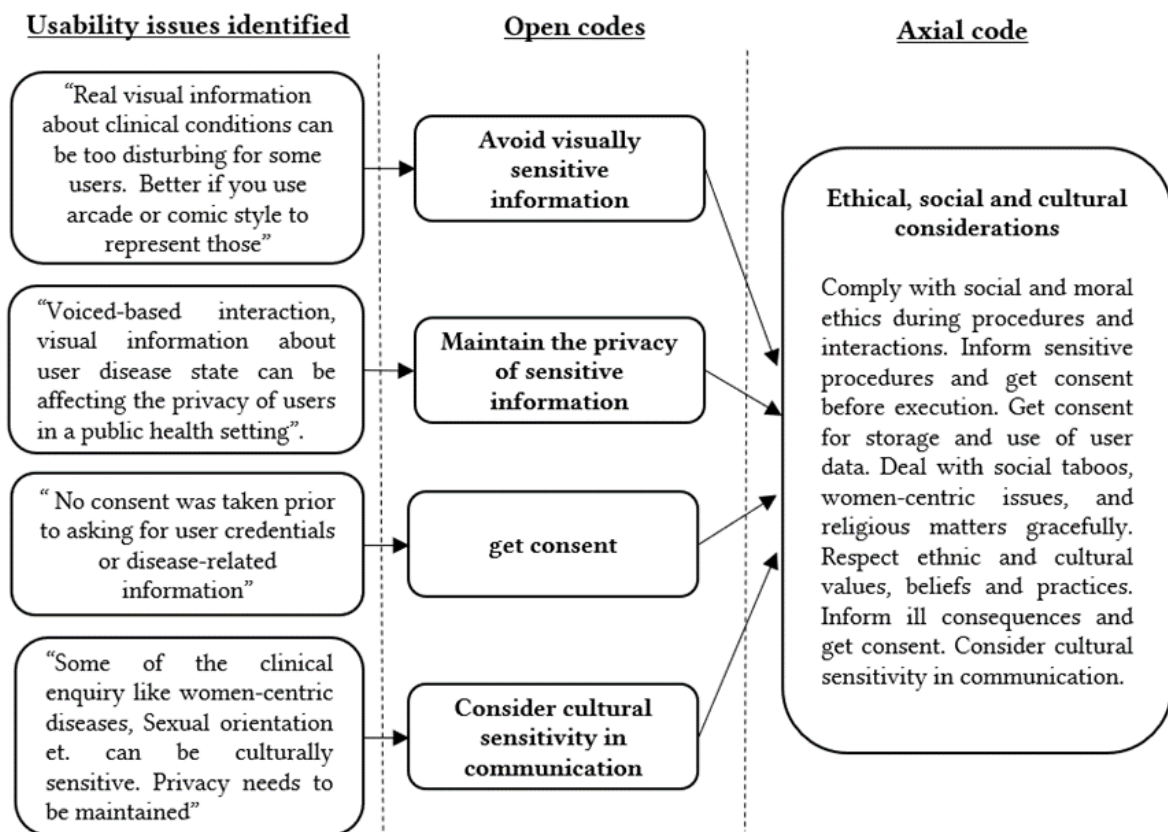


Figure 7-11: an example of the thematic coding process (source: author generated)

7.4.5 Comparative analysis of new heuristics with past heuristics and guidelines

During Phase 3 of the study, a comparative analysis was conducted to assess the novelty and alignment of the new heuristics in relation to existing state-of-the-art generic and CUI-specific heuristics and guidelines. The following resources were selected for comparison: Jacob Nielsen's 10 heuristics for user interfaces, Langevin et al.'s 11 heuristics for conversational agents (2021), Shneiderman's 8 Golden Rules of Interface Design, Wei & Landay's 17 heuristics for speech user interfaces (2018), Murad et al.'s 10 design guidelines for voice user interfaces (2019) and Suhm's 10 guidelines for telephone spoken dialog design (2003). To facilitate the comparative analysis, the usability experts conducted concept mapping of the new heuristics and the past heuristics and guidelines, aiming to identify the alignment and deviations in terms of underlying usability issues and recommendations. Tables were used to map and document the comparative analysis process.

7.4.6 Evaluating the scope of the new heuristics for other use cases

The final sub-objective of the study was to validate the new heuristics for other application tasks. In contrast to previous studies, which followed a process of initially formulating heuristics and subsequently validating them in various application contexts, like (Langevin,

2021), the present study adopted a data-driven approach for identifying the heuristics. As a result, the heuristic validation approach focused on evaluating the suitability of the new heuristics for different clinical contexts and device utilities.

Choosing different clinical contexts and Interaction and process analysis

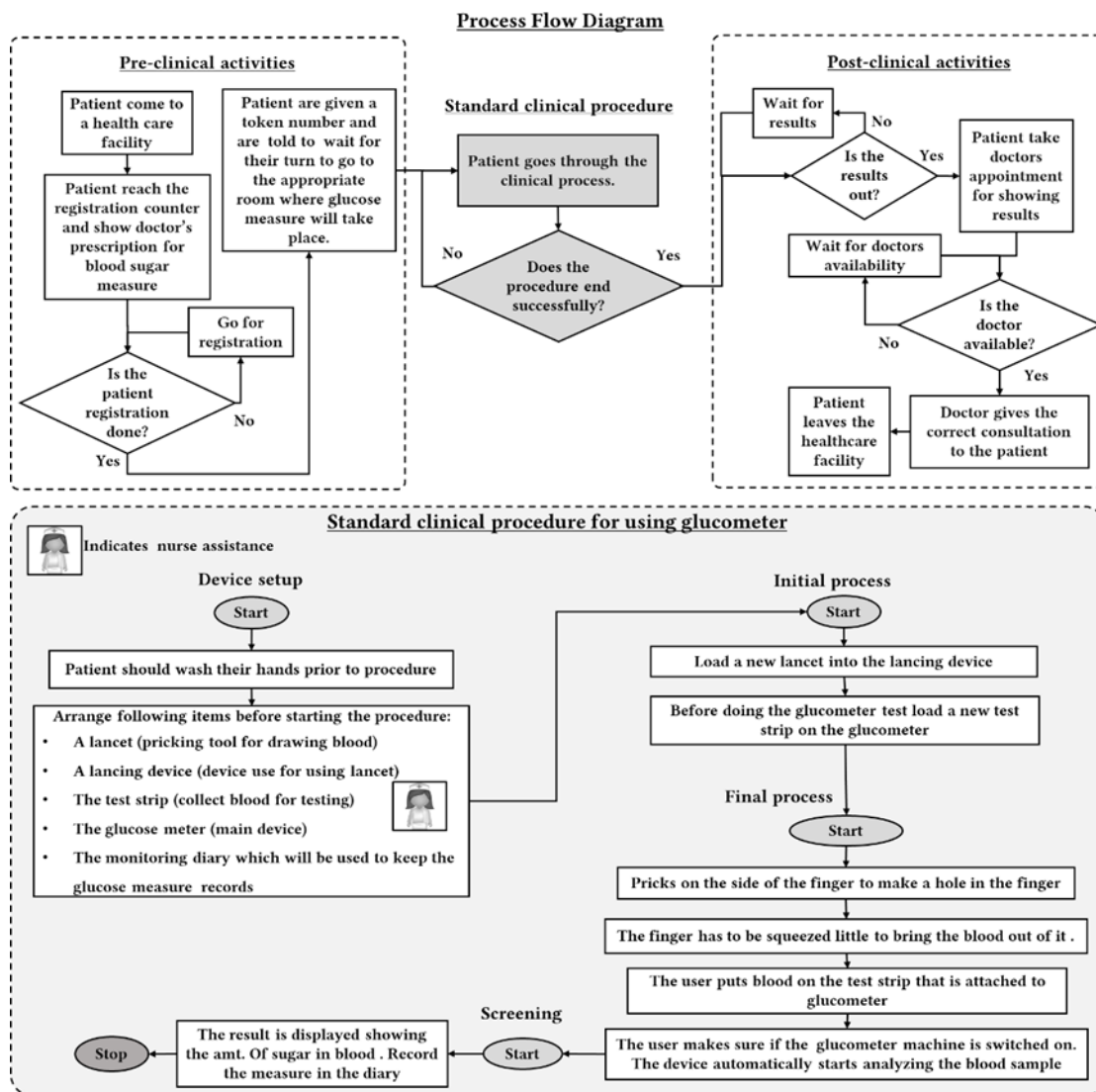


Figure 7-12: An example of a process flow diagram (for blood sugar measurement) (source: author generated)

To assess the appropriateness and usefulness of the new heuristics, nine electromechanical medical devices with different levels of risk were selected. These devices included a blood pressure monitor, glucometer, digital thermometer, electrocardiogram (ECG) device, computerized tomography scanning (CT-scan) device, ultrasound device, magnetic resonance imaging (MRI) device, defibrillator device, and x-ray machine. These devices were found suitable for AI infusion with intelligent Conversational interfaces after conducting an initial feasibility evaluation with a team of designers, engineers, and clinicians. As part of the

preliminary research, clinical immersion and field visits were carried out in healthcare facilities and hospitals of various hierarchies. The purpose was to observe and gain an understanding of the use case scenarios for these devices.

Additionally, process flow diagrams were created to enhance comprehension of the clinical processes. These diagrams visually depicted the sequence of pre-clinical tasks, standard clinical procedures, and post-clinical tasks. Figure 7.12 provides an example of a process flow diagram illustrating various activities involved in the measurement of blood sugar. All the process flow diagrams were re-verified by clinicians to confirm their alignment with actual practices. The process flow diagrams revealed the involvement of various stakeholders and identified the consumable requirements during clinical procedures.

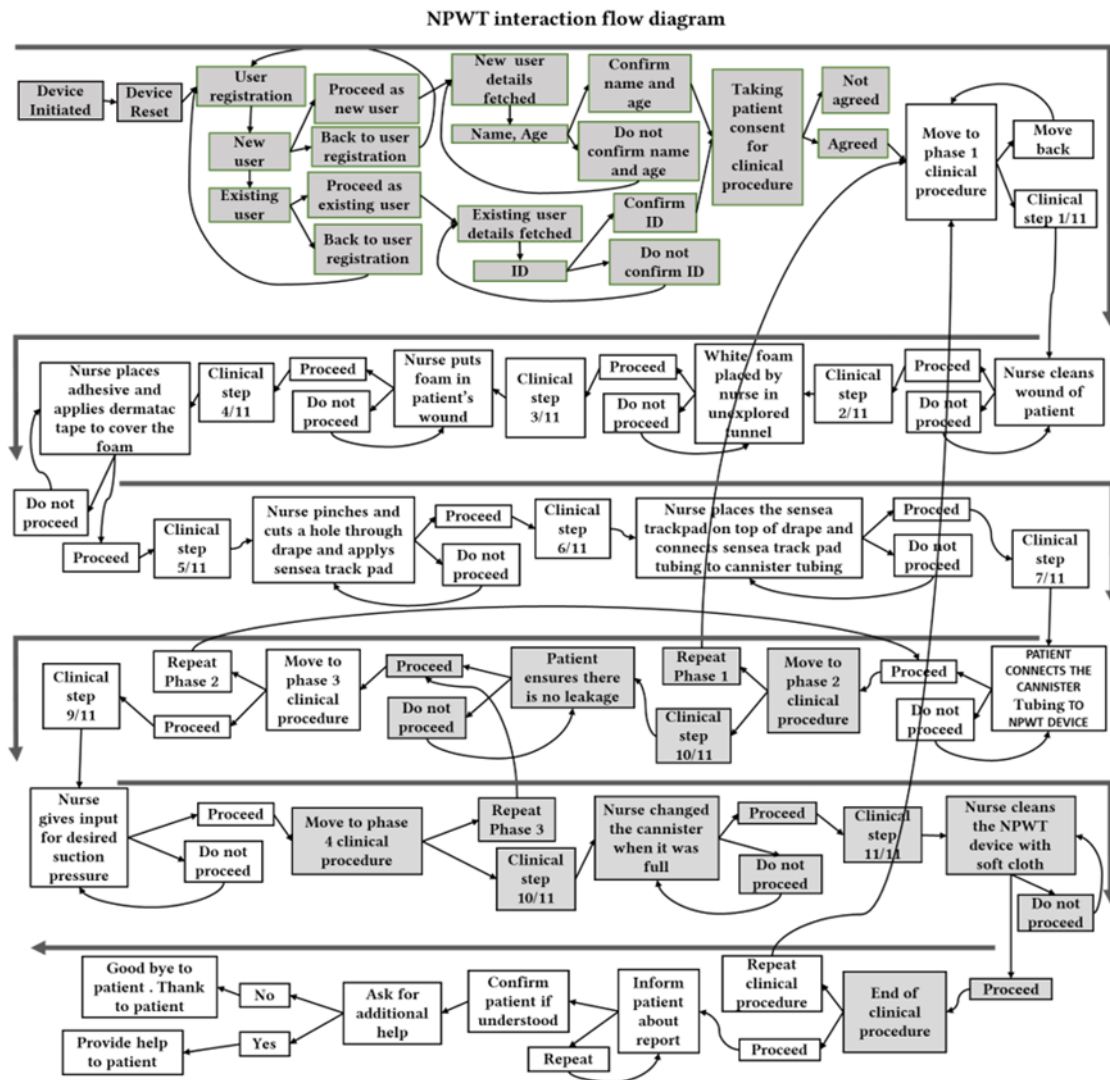


Figure 7-13: Interaction flow diagram for NPWT clinical procedure (source: author generated)

Further, to gain a better understanding of the interaction requirements for designing

CUIs, an interaction design team collaborated with clinicians and used their feedback to identify detailed user interactions and their characteristics at different phases of the clinical procedures. These interactions were then depicted in the form of interaction flow diagrams for each clinical procedure. Figure 7.13 illustrates the interaction flow diagram specifically for the Negative Process Wound Therapy (NPWT) procedure, which served as a basis for defining the user testing scenario and various interaction activities. Similarly, interaction flow diagrams were developed for all nine clinical contexts to enable further analysis and comparison with the NPWT procedure.

Evaluating the scope of new heuristics for different clinical applications

To conduct the critical analyses, a team of twelve usability experts was assembled, all of whom had an average experience of five years or more in usability engineering and heuristic evaluation. The team of twelve newly recruited usability experts was given access to previously developed interaction flow diagrams and clinical process flow diagrams. Their primary task was to perform a comprehensive analysis to identify similarities between the nine clinical procedures and the NPWT procedure, specifically regarding the usability issues, design and interaction requirements for CUI design. The experts were provided with previously identified usability issues and were asked to determine their relevance to the nine new clinical contexts. This was necessary because the newly formulated heuristics were created as recommendations to address these usability issues. And having relevance of the usability issues with the clinical procedures mean the appropriateness of the newly synthesized heuristics. Additionally, the experts were asked to assign a score on a scale of 1 to 5, with 5 representing the highest level of relevance. Initially, the twelve researchers individually performed the critical analysis and relevance scoring for all nine clinical scenarios. Subsequently, the individual scorecards from the twelve researchers were combined to establish average relevance scores for all the heuristics. Throughout the process, the experts were prompted to identify similar activities or interactions that could lead to comparable usability issues. All the findings and observations were carefully documented using tables.

7.5 Results and discussion

7.5.1 Usability issues of CUIs in integrated system-physical interaction scenario

After thoroughly examining the user testing records, a total of 873 issues related to interactions, flaws in conversation, and violations of usability were discovered. These issues were identified across 40 user testing records, which consisted of 26 text-based tests and 14 voice-based tests.

To illustrate this, Table 7-A displays a sample conversation record from the user testing sessions, highlighting the user's interaction with the conversational user interface (CUI) and the usability violations reported by the experts.

Table 7-A: Sample user testing record with expert reviews

Conversations/interactions from user testing	Expert identified interaction / usability issues
Your input -> hi	<ul style="list-style-type: none"> It is awkward to start a voice-based conversation with a bot in the first place. When the patient first processes the device they are not aware if it is turned on or off; saying "Hi" may not always provide an immediate response. The conversation is started by the user, who might not have any idea about what they need to do
<p>Hello, I am a wound therapy assistant. How can I help you?</p> <p>Your input -> I have a chronic wound at my foot</p>	<ul style="list-style-type: none"> The user has to inform the device about the type of wound from memory. The patient would be confused about how precise he has to be with explaining his wound. In the previous line, after the bot says "how can I help you?", and advanced user should be allowed to say "I want NPWT therapy", and directly go to next action.
<p>I can assist you in the process of wound therapy. The available wound therapy is Negative Pressure Wound Therapy(NPWT) which is a state of art solution for healing chronic non healing wounds. Would you like to have the therapy or want to know more details</p> <p>Your input -> I want to know more details</p>	<ul style="list-style-type: none"> no onboarding, the process starts without giving user any tutorial as to how to operate it. In physical processes, the doctors or examiners usually ask some basic questions before providing a treatment.
<p>Negative pressure wound therapy (NPWT) is a standard procedure where regulated suction pressure in the range of 40 mmHg to 180 mmHg is provided at the wound site via a specialized foam dressing. For childrens pressure range can be from 40-80 mmHg and For adult it can be 80-180 mmHg. During the procedure, first the wound site is cleaned with saline water and iodine solution, then the dressing is placed and sealed with medical skinfriendly tapes around the wound site. There should not be any leakage. After that the dressing is connected to the NPWT device via a silicon tube and then the user can run the therapy. I will guided you details about device operations once you confirm to initiate the procedure.</p> <p>Your input -> Please initiate the procedure</p>	<ul style="list-style-type: none"> The design is not minimalistic as they are bombarding the user with too much unnecessary information not everyone is familiar to English hence there will be need of language preference so that it can be accepted by majority of people
<p>To confirm the procedure please let me register your 'NAME'.</p> <p>Please provide details</p> <p>Your input -> My name is Jetty</p>	<ul style="list-style-type: none"> Since this is a voice based interaction there is no way to know whether the bot heard the info for right or wrong
<p>What is your age?</p> <p>Your input -> 37 years</p>	
<p>What is your gender Male/Female?</p> <p>Your input -> m</p>	
<p>OK, Done!</p> <p>I am registering you for the NPWT therapy with the following info: name: Jet tea,</p>	<ul style="list-style-type: none"> When the user gave their name for registration e.g. "Jetty" it did not recognise the name correctly. It detected it as "jet tea" as it is running in dictionary mode.

Conversations/interactions from user testing	Expert identified interaction / usability issues
<p>age:37, gender:Male. Do you confirm? (Use arrow keys) » 1: Yes (/affirm) 2: No (/initiate_procedure) Type out your own message... Your input -> 1: Yes (/affirm)</p>	<ul style="list-style-type: none"> • Since it is an audio conversation, the bot should ask the user to confirm the spelling of their name, and correct if required. If it is difficult to recognize voice input name, age, gender, data should be taken in the form of text typed • Even if short descriptions are provided besides the options, they are confusing. On saying no, it is not clear why the description says initiate procedure. This will lead to errors.
<p>Your confirmation is noted I am going to guide you stepwise procedure. You can do it easily at your end: (Use arrow keys) » 1: Proceed NPWT (/proceed_npwt) 2: Decline NPWT (/decline_npwt) Type out your own message... Your input -> 1: Proceed NPWT (/proceed_npwt)</p>	<ul style="list-style-type: none"> • The ability to type out the answer adds confusion to a simple yes or no question. If that flow is accidentally used, the user might be clueless. Typing out the message might cause further confusion and people typing in random commands that don't work. • Experienced user can skip preliminary steps
<p>Step1. Take saline water and iodine solution and clean the wound site thoroughl using cotton dressing soaked with the two solutions one by one. If you are done with step1 then proceed to next step (Use arrow keys) » 1: Next step 2 (/next_step2) 2: Repeat previous step (/repeat_action) 3: Abort procedure (/decline_npwt) Type out your own message... Your input -> Next step 2 (/next_step2)</p>	<ul style="list-style-type: none"> • A newer user may have considerably less experience in using the medical equipment required for the procedure. In such a case, assistance/intervention from a trained person could become necessary (what if the wound is on the user's dominant hand?). • Does the patient know what saline water is? Is it clearly mentioned on the bottle? If yes can an illiterate patient identify them? How the system can help with identification if the health care worker is not around? • No indication on the take amount of iodine solution. It does not mention proper data when to repeat the process but provides option to go forward, backward or abort.
<p>Step2. Debride the wound site if required to remove infecting portion with the same soaked dressing. If you are done with step2 then proceed to next step (Use arrow keys) » 1: Next step 3 (/next_step3) 2: Repeat previous step (/repeat_action) 3: Abort procedure (/decline_npwt) Type out your own message... Your input -> Next step 3 (/next_step3)</p>	<ul style="list-style-type: none"> • Difficult terms. Difficult and less known terms should not be used in the beginning of the conversation. The idea should be conveyed in a known and familiar processes. • During the steps there is a high chance that patient will fail to complete these steps accurately, as it requires precision and is a painful process. The patient may not be able to reach some of the parts for debriding.
<p>Step3. Clean and dry the outer surrounding area of woundsite. It should be free from moisture and oil. If you are done with step3 then proceed to next step (Use arrow keys) » 1: Next step 4 (/next_step4) 2: Repeat previous step (/repeat_action) 3: Abort procedure (/decline_npwt) Type out your own message... Your input -> Next step 4 (/next_step4)</p>	<ul style="list-style-type: none"> • If communication breaks occur, the system should remember the last context to continue further. Here, it seems like the system is doing conversation without recording or considering past user inputs. • In few steps there maybe sanitation issue as he will be touching different items and can contaminate the site which can hamper the results the system has to notify the user to clean their hands before performing the steps
<p>Step4. Trim the foam part of the dressing to match the shape of the wound roughly. place it on the wound bed. If you are done with step4 then proceed to next step (Use arrow keys) » 1: Next step 5 (/next_step5) 2: Repeat previous step (/repeat_action) 3: Abort procedure (/decline_npwt)</p>	<ul style="list-style-type: none"> • The patient is unaware about the time the process would take and the number of steps he has to follow • System should have soon tell where the required items are kept, if it's user first time experience it would lead to confusion

Conversations/interactions from user testing	Expert identified interaction / usability issues
<p>Type out your own message...</p> <p>Your input -> Next step 5 (/next_step5)</p> <p>Step5. Cut the Plastic sheet of the dressing around 1 inch bigger than the wound bed to be placed on the outer skin area.If you are done with step5 then proceed to next step (Use arrow keys)</p> <p>» 1: Next step 6 (/next_step6)</p> <p>2: Repeat previous step (/repeat_action)</p> <p>3: Abort procedure (/decline_npwt)</p> <p>Type out your own message...</p> <p>Your input -> Next step 6 (/next_step6)</p>	<ul style="list-style-type: none"> The system does not mention the total number of steps that are to be performed by the patient. The system also fails to indicate the step number on which the patient is
<p>Step6. Tape and seal the foam with the plastic sheet against the skin. Use skin freidly adhesive tape. If you are done with step6 then proceed to next step (Use arrow keys)</p> <p>» 1: Next step 7 (/next_step7)</p> <p>2: Repeat previous step (/repeat_action)</p> <p>3: Abort procedure (/decline_npwt)</p> <p>Type out your own message...</p> <p>Your input -> Next step 7 (/next_step7)</p>	<ul style="list-style-type: none"> Errors can occur during the procedure and hence options have been provided to abort, but the options remain limited. There is no option for seeking immediate help from a nearby attendant in the case of an emergency. Emergencies would not be only device based, but complications that can occur while doing the procedure with medical equipment on their own by the user. Voice commands with keywords like “HELP”, “STOP”, “ABORT” should be implemented that also seek attention of the nearby attendant.
<p>Step7. Cut a hole on the top of the plstic sheet. affix the conduit membrane part of the dressing. If you are done with step7 then proceed to next step (Use arrow keys)</p> <p>» 1: Next step 8 (/next_step8)</p> <p>2: Repeat previous step (/repeat_action)</p> <p>3: Abort procedure (/decline_npwt)</p> <p>Type out your own message...</p> <p>Your input -> Next step 8 (/next_step8)</p>	<ul style="list-style-type: none"> A user may feel anxious all the time during the clinical procedure
<p>Step8. Connect one end of the silicon tube to the conduit and the other end to the NPWT device. Proceed to next step to initiate device operation (Use arrow keys)</p> <p>» 1: Go for device operation (/next_step9)</p> <p>2: Repeat previous step (/repeat_action)</p> <p>3: Abort procedure (/decline_npwt)</p> <p>Type out your own message...</p> <p>Your input -> Go for device operation (/next_step8)</p>	<ul style="list-style-type: none"> Too much to coordinate during clinical steps, it involves voice communication, and hand-eye coordination during the process of wound cleaning. Can a normal user do that? The use of advanced terms like 'conduit membrane part might' not be understood by patient
<p>Step9. Power on the device and position the patient for the therapy. Next choose either 'Device interface' or 'AI Voice command' as options for operating the npwt device (Use arrow keys)</p> <p>» 1: Use Device interface for device control (/next_step10)</p> <p>2: Use AI Voice command for device control (/operation_instruction)</p> <p>3: Repeat npwt procedure - initial setup (/proceed_npwt)</p> <p>4: Abort procedure (/decline_npwt)</p> <p>Type out your own message...</p> <p>Your input -> 2: Use AI Voice command for device control (/operation_instruction)</p>	<ul style="list-style-type: none"> Accidents can happen even without the user doing anything wrong. Or a system designed to prevent errors. How the system responds in case of an accident?
<p>Here we go! /n You can use voice command to either 'START' or 'STOP' the therapy and 'INCREASE' or</p>	<ul style="list-style-type: none"> The patient himself would not know what clinical inputs to provide. The system should

Conversations/interactions from user testing	Expert identified interaction / usability issues
<p>'DECREASE' the negative pressure level. At what pressure should I set the therapy for you? Your input -> 55 mmHg</p>	<p>dig out user information based on user responses.</p> <ul style="list-style-type: none"> Usually a user won't know what pressure is right for the therapy, even if the user has read the details in the introduction section, remembering the pressure range is not possible. The patients state of mind also counts, he/she won't be at ease with the pain of the wound so leaving important decisions that affect the therapy shouldn't be left to the patient in such cases.
<p>Got that! I have set pressure = 55 mmHg for your therapy. Do you confirm? (Use arrow keys) » 1: Yes (/affirm_set_pressure) 2: No (/operation_instruction) Type out your own message... Your input -> 1: Yes (/affirm_set_pressure)</p>	
<p>setting specified pressure value Here we go! /n You can use voice command to either 'START' or 'STOP' the therapy and 'INCREASE' or 'DECREASE' the negative pressure level. Your input -> start</p>	
<p>Please confirm your request to start the therapy. For giving complex instruction use the command 'Take Command' (Use arrow keys) » 1: confirm start action (/affirm_start) 2: initiate therapy (/initiate_procedure) 3: Rephrase input (/thankyou) Type out your own message... Your input -> 1: confirm start action (/affirm_start)</p>	<ul style="list-style-type: none"> It would be better if the system can frame sentences differently every time. If the user does not understand a particular way of instruction, he will not get clarified with the same instruction. A bot should simply inform if the user asked him to repeat There does not seem to be a possibility of reversal or going back to previous stage
<p>Starting device.. Your input -> set pressure of 100 mmHg</p>	<ul style="list-style-type: none"> A common patient who has been handed over to the machine might not understand what exactly 55mmHg or 100mmHg means here and how much pressure level they are supposed to go with.
<p>I have set pressure = 100 mmHg for your therapy. Do you confirm? (Use arrow keys) » 1: Yes (/affirm_set_pressure) 2: No (/operation_instruction) Type out your own message... Your input -> 1: Yes (/affirm_set_pressure)</p>	
<p>setting specified pressure value Here we go! /n You can use voice command to either 'START' or 'STOP' the therapy and 'INCREASE' or 'DECREASE' the negative pressure level. Your input -> stop the therapy</p>	
<p>Please confirm your request to stop the therapy. For giving complex instruction use the command 'Take Command' (Use arrow keys) » 1: confirm stop action (/affirm_stop) 2: initiate therapy (/initiate_procedure) 3: Rephrase input (/thankyou) Type out your own message... Your input -> 1: confirm stop action (/affirm_stop)</p>	
<p>Stopping device.. Your input -> take complex command</p>	<ul style="list-style-type: none"> "Complex instruction" is not clearly defined even if it is to help the user.

Conversations/interactions from user testing	Expert identified interaction / usability issues
	<ul style="list-style-type: none"> Saying for giving complex instruction use the command take command, user is not comfortable with these terminologies
<i>Ready for command execution</i> Your input -> start generating suction pressure of 45 mmHg first, hold for 2 minutes and then change to 60 mmHg	
<i>starting therapy....</i> <i>initial pressure desired=45 mmHg</i> <i>user defined delay set</i> <i>second pressure desired=60 mmHg</i> Your input -> What are safety related precautions?	<ul style="list-style-type: none"> Conversation lacks in providing a way for the user to clear any doubts he may have by now like for how long he needs to apply this pressure and continue with the therapy? This can cause confusion in the user's mind and make him uneasy, which in turn can lead to the failure of the therapy.
<i>Ensure that there is no leakage at the dressing site. Keep the fluid line free from self tangling. Place the device and power cord in such a position so that they dis not get pulled accidentally.</i> Your input -> ok great let me carry on the therapy	<ul style="list-style-type: none"> This information should be by default provided to users beforehand. Users need not ask for this separately Mentioning of the precaution is too late.the information for the precaution should be provided in terms of warning while performing the procedure
<i>ok great, I hope you understood the procedure. Is there anything else you want me to do.</i> Your input -> no thank you	
<i>Thank you. I hope this interaction session is useful for you</i> Your input -> yeah sure	<ul style="list-style-type: none"> Abrupt ending. No information given about how to or who to contact in case of complications.
<i>great!!</i>	<ul style="list-style-type: none"> Use of the word 'great' a great number of times. This makes the AI feel less human like

Despite achieving high training accuracy during the development stage, the implementation of AI-infused conversational user interfaces (CUIs) for NPWT procedures in user testing sessions uncovered numerous issues related to usability and interaction, as shown in Table 7-A. Many of these issues arose due to the challenges of automating real-world clinical procedures through a conversational AI interface, which otherwise required a combination of system-level interaction and physical world interaction with human intervention. For example, an issue highlighted by an expert in Table 7-A stated:

“Too much to coordinate during clinical steps, it involves voice communication, and hand-eye coordination during the process of wound cleaning. Can a normal user do that?”

This highlights the fact that the developed conversational AI interfaces lacked the ability to manage physical-world procedures and coordinate users in executing various tasks. It became evident that unlike humans, who can handle real-world situations with greater awareness, AI-infused CUIs are currently confined to the boundaries of their architecture, training data, and computational capabilities. However, the results of user testing provided valuable insights into a wide range of complexities associated with CUI implementations,

which had not been explored in previous studies. Based on the expert review of the initial set of 873 usability issues, subsequent grouping, and analysis revealed 116 distinct usability issues that necessitated the development of a fresh set of heuristics for evaluating usability.

7.5.2 Scope of existing usability heuristics for integrated system-physical interaction

It was observed that in many instances' usability issues arose from overlooking certain clinical use case scenario, where failure to incorporate specific Nielson's heuristics in the training data resulted in particular interaction flaws. However, experts reported several unique usability issues and interaction requirements that existing CUI-specific heuristic principles and Nielson's heuristics could not address. Table 7-B showcases examples of usability violations which shows the limitations of Nielson's generic heuristics and Langevin's Conversational AI heuristics in addressing these issues.

Table 7-B: Example of scoping of existing generic and CUI heuristics for expert identified usability problems

Some example quotes of usability issues reported by experts	Applicable Nielson's heuristics	Applicable Langevin (2021)'s CUI heuristics
<ul style="list-style-type: none"> “Since this is a voice-based interaction there is no way to know whether the bot heard the info for right or wrong.” 	Visibility of system status	Visibility of system status
<ul style="list-style-type: none"> “The paragraph looks like something directly extracted from a webpage rather than something that a doctor would explain.” 	Match between system and the real world	Match between system and the real world
<ul style="list-style-type: none"> The bot gives only one option here, which is to confirm and initiate the procedure. What if the user does not want to go ahead with the process? 	User control and freedom	User control and freedom
<ul style="list-style-type: none"> “In some places, the bot address in second person like you need to.’ and in other places the bot use ‘the user can provide.’. Consistency needs to be made” 	Consistency and standards	Consistency and standards
<ul style="list-style-type: none"> “Make Correct Diagnostics before treatment” 	Error prevention	Error prevention
<ul style="list-style-type: none"> “User might not always know what pressure would be appropriate for him. A common patient might not understand what exactly 55mmHg or 100mmHg means here.” 	Recognition rather than recall	Can't be defined by existing Conversational AI heuristics
<ul style="list-style-type: none"> “Is this device for a normal patient or a nurse or a doctor? Because they all have different skillsets. For a doctor lot of information is not necessary however for a patient it is quite a difficult job” 	Flexibility, and efficiency of use	Flexibility, and efficiency of use
<ul style="list-style-type: none"> “Too much information can be overwhelming for the users in one go.” 	Aesthetic and minimal design	Aesthetic, minimalist and engaging design
<ul style="list-style-type: none"> “Since users do not have medical knowledge, users may not recover from errors without assistance. How can an AI system support these issues?” 	Help users recognize, diagnose and recover from errors	Help users recognize, diagnose and recover from errors

Some example quotes of usability issues reported by experts	Applicable Nielson's heuristics	Applicable Langevin (2021)'s CUI heuristics
<ul style="list-style-type: none"> • “What if the user does not understand the clinical steps correctly? There should be an option for additional help against each step.” 	Help and documentation	Help and guidance
<ul style="list-style-type: none"> • “If communication breaks occur, the system should remember the last context to continue further. Here, it seems like the system is doing conversation without recording or considering past user inputs. 		Context preservation
<ul style="list-style-type: none"> • “A user may feel anxious all the time during the clinical procedure” 		Trustworthiness
<ul style="list-style-type: none"> • “It would be better if the system can frame sentences differently every time. If the user does not understand a particular way of instruction, he will not get clarified with the same instruction. A bot should simply information if the user asked him to repeat” 	Can't be defined by Nielson's heuristics	Can't be defined by existing Conversational AI heuristics
<ul style="list-style-type: none"> • “There could be a better layout for the overall conversation. The current conversation-based interaction looks sequential, and lacks user freedom.” 		
<ul style="list-style-type: none"> • “When the user gave their name for registration e.g. “Jetty” it did not recognise the name correctly. It detected it as “jet tea” as it is running in dictionary mode.” 		
<ul style="list-style-type: none"> • “A user may have additional doubts that the system may not have thought about” 		
<ul style="list-style-type: none"> • “It is awkward to start a voice-based conversation with a bot in the first place.” 		
<ul style="list-style-type: none"> • “Some of the clinical enquiry like women-centric diseases, Sexual orientation et. can be culturally sensitive. Privacy needs to be maintained” 	Can't be defined by Nielson's heuristics	Can't be defined by existing Conversational AI heuristics
<ul style="list-style-type: none"> • “It is not very clear as to what happens once the user chooses the option 'no” 		
<ul style="list-style-type: none"> • “The patient himself would not know what clinical inputs to provide. The system should dig out user information based on user responses.” 		
<ul style="list-style-type: none"> • “Too much to coordinate during clinical steps, it involves voice communication, and hand-eye coordination during the process of wound cleaning. Can a normal user do that?” 		
<ul style="list-style-type: none"> • “Accidents can happen even without the user doing anything wrong. Or a system designed to prevent errors. How the system responds in case of an accident?” 		

The heuristic scoping process was carried out with precision. The experts were specifically instructed not to forcefully align usability problems with existing heuristics by losing their unique significance. They were also advised against stretching the consequences of usability problems in order to fit them into existing heuristics. For instance, in Table 7-B, an expert identified a usability problem:

"Users may not always be aware of the appropriate pressure for their needs. The average patient may not comprehend the specific meaning of values like 55mmHg or 100mmHg in this context."

This issue aligns with Nielson's heuristics under the principle of "Recognition rather than recall". However, Langevin (2021)'s Conversational AI heuristics do not address this particular concern. On the other hand, experts also reported usability problems, such as:

"Some of the clinical enquiry like women-centric diseases, Sexual orientation et. can be culturally sensitive. Privacy needs to be maintained",

Neither Nielson's heuristics nor Langevin (2021)'s heuristics address these particular concerns. The experts identified 116 usability issues of this nature that necessitate the development of new usability heuristics through a fresh synthesis process.

7.5.3 New heuristics for design and evaluation of CUIs

During the initial stage of open coding, 116 heuristics were created to address 116 distinct usability issues. In the axial coding stage, experts categorized the 116 heuristics into 23 broad groups and synthesized 23 new heuristics. Subsequent selective coding stage reduced the heuristics to 16. During the stage of selective coding, the team made conscious efforts to merge particular heuristics from the axial coding stage while preserving their contextual relevance to address specific usability and interaction considerations. Table 7-C, summarizes the heuristics development process by revealing 16 heuristics (selective codes), underlying axial and open codes and related usability issues.

Table 7-C: Heuristics coding process

SI no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
1	Visibility of system status	Visibility of system status	<ul style="list-style-type: none"> • Visibility of system status • Give feedback • Inform procedure status • Reveal user made choices 	<ul style="list-style-type: none"> • "Since this is a voice-based interaction there is no way to know whether the bot heard the info for right or wrong." • "User is not given any status info on where they stand in the registration process." • "When the user first processes the device, they are not aware if it is turned on or off; saying "Hi" may not always provide an immediate response." • "Before running the therapy procedure, the system should show log data of user's decisions, provide feedback and correction

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
				option if user make any mistake, or system face any issue.”
2	Match between system and the real world	Match between system and the real world	<ul style="list-style-type: none"> • Match between system and real world • Follow standard real-world procedure • Possess the required domain knowledge • User registration before the procedure • System should dig out the user information 	<ul style="list-style-type: none"> • “Words phrases and concepts used here may not be familiar to the user. too technical” • “Usually when we ask for details, the order of sentences is different than this. First, we ask for permission to take details and then ask the name.” • “The bot should ask the stage/severity of the wound. It should also ask if the user has undergone any treatment before or has taken any measures himself. If the user doesn’t mention the site of the wound, the bot should ask that as well.”
		Effective and engaging conversation	<ul style="list-style-type: none"> • Engaging communication • Use language familiar to user • Avoid jargons or uncommon words, phrases • Context-appropriate expressive communication (emoji, voice expression) • User sober language • Context-appropriate effective communication • user engagement and attention holding 	<ul style="list-style-type: none"> • “It would be better if the system can frame sentences differently every time, a user wants to repeat a step. Otherwise, it is no natural and if user did not understand particular way of instruction, he will not get clarified with same instruction. A bot should simply information if user asked him to repeat” • “Repeated steps might get frustrate the user and written everything this down each time” • “Language used isn’t very easy to understand if you have low literacy (even otherwise).” • “The instructions given by the bot looks like a text book instruction, very mechanical. It is hard to follow, not engaging and lacks expression. Unnatural sounding. User will not be willing to interact like this.”
		Good interaction initialisation and closure	<ul style="list-style-type: none"> • Good initialization and closure • Easy start • familiarity with initiation • good initialization • good closure 	<ul style="list-style-type: none"> • “no onboarding: the process starts with giving the user a tutorial as to how to operate it. The system is aimed to be used by patients themselves but this could lead to patients calling for help instead which beats its original intention.” • “The chatbot could boot it up asking out the user’s issue rather than being ideal for the user to respond first.” • “When the patient first processes the device they are not aware if it is

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
				<p>turned on or off; saying “Hi” may not always provide an immediate response. Providing a power button to initially turn on the device; letting the device speak the first words instead of the patient.”</p> <ul style="list-style-type: none"> • “It is awkward to start a voice-based conversation with a bot in the first place.” • “Abrupt end to bot’s chat. It was supposed to be the completion of the procedure. And AI should give the feedback about how it went if Device is capable to give some kind of the complete output”
3	User control and freedom	User control and freedom	<ul style="list-style-type: none"> • User control and freedom • Provide redo, undo • Give user choices, options • Allow user input modification 	<ul style="list-style-type: none"> • After briefing the user about available services, the bot restricts the user from other options such as going back or contacting an expert. • If there is any mistake in registering the data taken and the user wants to make some modifications to it. the system should give the user the choice to make the changes required apart from starting from the initial stage.
4	Consistency and standards	Consistency and standards	<ul style="list-style-type: none"> • Consistency and standards • Follow platform conventions • Show consistency in interaction style 	<ul style="list-style-type: none"> • “Chatbot followed a very formal tone until this point, after that it looks like the bot is commanding the user” • “The system displays the information processed through voice command and gives the user the option to proceed and go back along with ‘Type out your own message’. There should be consistency.”
5	Error prevention and user safety	Error prevention	<ul style="list-style-type: none"> • Error prevention • Prevent error-prone condition • Avoid confusing choices • Provide error messages and recovery options • Verify user input to prevent errors • Avoid confusing conversation 	<ul style="list-style-type: none"> • “The user should be provided with clear “call to actions” instead of user commands which can vary, which may cause errors” • “Ambiguity in ratio and amount of water and Iodine might lead to confusion and errors” • “Repetitive procedure and confirmation might also cause errors through assumptions and lack of oversight.” • “Error message could come, to inform the user about possible consequences when the machine does not recognise user input or action”

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
		User safety	<ul style="list-style-type: none"> consider user safety all the time provide an abort option give a choice for external assistance recognize and consider the consequences of every action and communication 	<ul style="list-style-type: none"> “Another Step can be added after this step where the device performs a test section to check for air leaks in the dressing.” “Not every user has same biological conditions at the time of the wound therapy. What if the suction pressure is too much for someone and internal blood vessel ruptures? However, for others that pressure work perfectly” “Accidents can happen even without user did anything wrong. Or system designed to prevent errors. How the system responds in case of accident?” “For an inexperienced person this step can be confusing. Since such step being made under the supervision of an expert it can be dangerous.” “Rather than asking, system should give a warning to patients about possible high pressure” “No information given about how to or who to contact in case of complications.”
6	Recognition rather than recall	Recognition rather than recall	<ul style="list-style-type: none"> Recognition rather than recall Avoid user need for memorizing information Consider non-obviousness of information Provide easy to recognise information Avoid cognitive loading of information 	<ul style="list-style-type: none"> “Too much information to recall without visual guidance” “for the voice-based engagement, there is far too much information to process.” “User might not always know what pressure would be appropriate for him. A common patient might not understand what exactly 55mmHg or 100mmHg means here and how much pressure level they are supposed to go with.” “The user would have to remember these commands. it would be preferable if these were always available in a little appendix”
7	Flexible, efficient, and user-friendly multimodal interaction	Flexibility, efficiency and ease of use	<ul style="list-style-type: none"> Flexibility and efficiency of use Intuitive interaction Consider different user profile in conversation and information Consider experienced 	<ul style="list-style-type: none"> “In the previous line, after the bot says "how can I help you?", and advanced user should be allowed to say "I want NPWT therapy", and directly go to next action.” “Experienced user can skip initial steps. There could be more efficient way to conduct the entire procedure. For example user could select one of the profile options at the initial phase and then follow a

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
			user requirements <ul style="list-style-type: none"> Recognise or save previous user profile Flexibility of skipping the process Consider procedural efficiency ease of use 	more tailored process as an expert user.” <ul style="list-style-type: none"> “Some of the steps in clinical tasks can be complex to perform by the user without having prior skills.” “Is this device for a normal patient or a nurse or a doctor? Because they all have different skillsets. For a doctor lot of information is not necessary however for a patient it is quite a difficult job”
		Seamless multimodal interaction	<ul style="list-style-type: none"> choice of effective input choice of User language multimodal input provision provide effective input method choice 	<ul style="list-style-type: none"> “The options should be able to select by using a simple call to action command instead of having keyboard input. A voice-based interaction is better in this case than keyboard entry.” “The best possible user input method should be allowed to reduce interaction complexities”
8	Aesthetic, minimalist and legible design	Aesthetic, minimalist and legible design	<ul style="list-style-type: none"> simplified information design Aesthetic and minimalist design legibility of information (size of text, LCD), Use of correct signage (subjective) Simplified information communication clarity in communication 	<ul style="list-style-type: none"> “Too much of information can be overwhelming for the users in a one go.” “This text is unnecessarily too long and user might skip it, this may result in missing of important information related to the treatment.” “Get to the purpose rather than overwhelming user with so many information” “Texts in the chat window are too small, hard to read and comprehend.” “Once the chat window get filled with conversations, it is difficult to refer to last few conversations” “Better style could be adopted to provide users options or input field. Could be more visually appealing and easily recognizable”
9	Help users recognize, diagnose and recover from errors	Help users recognize, diagnose and recover from errors	<ul style="list-style-type: none"> help users recognise, diagnose and recover from errors Guide user to recover from accidents Suggest solutions Enable diagnosis 	<ul style="list-style-type: none"> “User will not know if they have performed the real-world activities correctly.” “Since user do not have medical knowledge, user may not recover from errors without assistant. How can an AI system support these issues?” Assist users in recognizing diagnosing and correcting errors. There is currently no provision provided that would make the user be able to fully comprehend the

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
				command and execute it without errors?
10	Help and guidance	Help and guidance	<ul style="list-style-type: none"> • Help and guidance • Provide tutorial • Visual guidance • Human like guidance and assistance • Choice of external Assistance 	<ul style="list-style-type: none"> • “There is no visual support here, yet would the user be able to understand the instruction completely and perform it without errors?” • “This message is unclear as to what the user can type. There should be some option for help providing detailed information.” • “What if the user does not understand the clinical steps correctly? There should be an option for additional help against each step.” • “Too much to coordinate during clinical steps, it involves voice communication, and hand-eye coordination during the process of wound cleaning and debridement and simultaneously responding to the bot. Can a normal user do that?”
11	Context preservation	Context preservation	<ul style="list-style-type: none"> • Context preservation • Preserve context within the conversation • Preserve inter-session context or user information • Context appropriate user input understanding • Keep user history • Connect informations logically • Hold overall conversational understanding • Recover from communication loss 	<ul style="list-style-type: none"> • “When a user say “Please initiate the procedure” can have three meaning. One is to initiate the clinical steps from the beginning or just repeat the current step or it can be start everything from the very beginning of the machine start. This can leads to error.” • “ Bot should remember that user already finished step 2 i.e. wound cleaning and debridement. After that there is no logic asking if user want to initialise the clinical procedure. Similarly During the therapy running state the device should not allow the user to go to initial clinical steps. Without that how the system allow the user to start the therapy. System should remember past user activities, because these are real-world physical activities not software tasks. So if executed ones the reality cannot be changed” • “ If communication breaks occur, the system should remember last context to continue further. Here, it seems like system is doing conversation without recording or considering past user inputs.

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
12	Provide trust, comfort and evident intelligence	Provide trust and comfort	<ul style="list-style-type: none"> • Provide comfort • Provide trust • Evident domain knowledge • Demonstrate empathy • Calm down anxious situation 	<ul style="list-style-type: none"> • “The bot should demonstrate domain knowledge and assurance to user that they are in right hand” • “Why someone will undergo such a risky therapy in an automatic mode under an AI-based device.” • “A user may feel anxious all the time during the clinical procedure” • “The system should comfort users about the safety of various processes.”
		Evident intelligence	<ul style="list-style-type: none"> • evident intelligence in communication • consider self-learning AI • Thinking rationally • Acting rationally • Show bot personality 	<ul style="list-style-type: none"> • “The patient himself would not know what clinical inputs to provide. The system should dig out user information based on user responses.” • “The AI bot should have the adequate domain knowledge to answer user queries” • “The AI bot should learn from past user mistakes to warn users for probable errors or accident” • “The AI bot should make the right decision on every situation where there are too many possibilities”
13	Optimized conversation flow and dynamic conversation management	Effective conversation layout planning	<ul style="list-style-type: none"> • effective conversation layout planning • effective means to take user input • avoid dead ends during procedure • change conversational schema if required. • Plan order and timing for taking user input 	<ul style="list-style-type: none"> • “The way the options are provided to users can be further simplified to make them easy to understand by the user. Instead of asking options within the conversation like “Do you want to proceed further?”. It could be a delayed message, of shorter length like call to action options.” • “There could be a better layout for the overall conversation. The current conversation-based interaction looks sequential, and lacks user freedom.”. • “The bot initially asked for ‘NAME’ and then asked for details which include name, age and gender. A user may start saying their name in the first time when the bot asked the user ‘NAME’. However, a second-time inclusion of ‘name’ confuses the user as to what details has to give as he might think the bot missed registering his name. The bot may also get confused due to the untimely input of the name by the user.” • “User does not know which step the system will revert back to if he decided to decline. Will, it lands on

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
		Address conversation deviation and user request	<ul style="list-style-type: none"> • Incorporate possible communication deviation • Give user window for clarifying doubts • give provisions for optional request • give user freedom for enquiry • fail conversation gracefully 	<p>the same selection field or will it reset the whole process?"</p> <ul style="list-style-type: none"> • "The bot gives only one option here, that is to confirm and initiate the procedure. What if the user does not want to go ahead with the process? He may ask about something else like "Can you show me last user procedure, to have a better understanding". Can the bot address such queries?" • "It looks like user decisions and options to proceed further are prefixed which is not natural. A user may have additional doubts that the system may not have thought about" • "Too much information at one go. Users should be able to interrupt and ask the bot to go slowly or explain things in a better way"
14	Accurate input, intent and task perception	Recognize user intent and inputs	<ul style="list-style-type: none"> • Recognize user intent • Correctly recognise user input • consider variation and format of user input • consider user language, dialect variation • context recognition 	<ul style="list-style-type: none"> • "It seems the system did not recognize the user input "Can you elaborate more?". A real human would understand that and reply accordingly." • "The bot did not detect the user input "Forty mm Hg" as "40 mmHg". Since it is a voice bot, sometimes the bot can hear the user wrong due problem with mic, external noise or problem with user pronunciation." • "When the user gave their name for registration eg "Jetty" it did not recognise the name correctly. It detected it as "jet tea" as it is running in dictionary mode. The system should detect user names, can't rely on the user to pronounce his name perfectly." • "When the user asked the bot "Please help me in this" The bot simply gave a random message "I can help you with wound healing". It is irritating and looks like talking to a stupid person."
		Sensory-Driven Interaction and Task Perception	<ul style="list-style-type: none"> • sense the physical world events • sense user gestures, actions, expressions, and emotions. 	<ul style="list-style-type: none"> • "The user constantly is jumbling between voice commands, screen buttons, and medical equipment while doing the procedure. This might cause multiple issues including that of sanitisation, liquid going over the machine, and confusion among the user."

Sl no	Final CUI Heuristics (Selective codes)	Axial codes	Open codes	Example usability issues
			<ul style="list-style-type: none"> Sense the complexity of tasks 	<ul style="list-style-type: none"> “The system should be able to see what users are actually doing in real world. Because users may not actually perform the tasks correctly and system will never know that just buy voice-based interaction.” The bot should start the conversation by sensing human presence, or the screen can display a text message saying "Welcome to Apollo, say "Hi" to begin a conversation".
15	Ethical, social and cultural considerations	Ethical, social and cultural considerations	<ul style="list-style-type: none"> Consider ethics compliance with social ethics inform and get consent get consent for data recording, storage, usage inform status Consider cultural sensitivity in communication Inform user about safety issues, pain points. 	<ul style="list-style-type: none"> “Usually when we ask for details, the order of sentences is different than this. First, we ask for permission to take details and then ask the name.” “ Some of the clinical conditions can be culturally sensitive to be handled by a AI bot in a OPD environment. For example: diagnostic or treatment of Women centric diseases, Sexual diseases can be embarrassing if the bot provide certain visual guidance related to that in an OPD environment. Privacy needs to be maintained” “Voiced based interaction, visual informations about user disease state can be effecting privacy of users”. “Real visual information about clinical condition can be too disturbing for some users. Better if you use arcade or comic style to represent those”
16	Clarity of outcome and system capability	Clarity of outcome and system capability	<ul style="list-style-type: none"> make clear what the system can do inform the interaction outcome inform procedural outcome 	<ul style="list-style-type: none"> “It is not very clear as to what happens once the user chooses the option 'no'” “At the very beginning user have no Idea what service the system provides. Everything is so linear, that after some time only the user knows details about the procedure. User could choose not to go through all these if informed initially.” “If the bot helps with only one type of treatment, the patient would not need to explain their wound.”

The collection of 16 heuristics comprises 10 from Jacob Nielsen (with modifications), 2 from Langevin et al., 2021 (with modifications), and 4 newly discovered heuristics from this study. During the coding process, expert input resulted in several changes. For instance,

Nielsen's concept of "Aesthetic and minimalist design" was adjusted to "Aesthetic, minimalist, and legible design" to specifically address the issue of legibility in conversational content. The modification of "Error prevention" to "Error prevention and user safety" aimed to incorporate considerations for user safety in real-world tasks. The merging of "Flexibility and efficiency of use" with "Ease of use" and "user choice of input method" resulted in the definition and expansion of the concept as "Flexible, efficient, and user-friendly multimodal interaction." Lastly, Langevin et al.'s concept of "Trustworthiness" was rephrased as "Provide trust, comfort, and evident intelligence" to ensure a more empathetic and meaningful experience during interactions.

Additionally, Table 7-C presents details of the newly introduced heuristics, which include "Optimized conversation flow and dynamic conversation management", "Accurate input, intent and task perception", "Ethical, social and cultural considerations," "Clarity of outcome and system capability". Furthermore, the scope and definitions of these new heuristics have been expanded beyond the existing heuristics proposed by Nielsen and Langevin et al. This expansion was necessary to address the newly identified usability and interaction requirements for complex interactions reported in this study. For more elaborate information, please refer to Table 7-D

7.5.4 Results of Comparative analysis of new heuristics with past heuristics and guidelines

Detailed information regarding the comparative analysis process with past heuristics and design guidelines can be found in Tables 7-D and 7-E, respectively. The process of comparative analysis showed that the newly established 16 heuristics encompassed all the previous heuristics and guidelines. Within these new heuristics, there were instances where certain ideas overlapped or ran parallel to those found in previous contributions. For instance, when comparing the newly formulated heuristics to Wei & Landay's 17 heuristics for Speech user interface, it was discovered that Wei & Landay proposed specific heuristics such as "Make conversation a back-and-forth exchange," and "Use speech-recognition system confidence to drive feedback style". These heuristics embody the same concept as the newly synthesized heuristics called "Optimized conversation flow and dynamic conversation management" and "Accurate input, intent and task perception", respectively. Likewise, all 17 heuristics by Wei & Landay are included within the proposed set of 16 new heuristics. These overlaps and parallels demonstrated that the newly synthesized heuristics adequately addressed the important considerations that past researchers had identified for CUIs.

Tables 7-D and 7-E, further highlight that a significant number of heuristics identified in this study were unique and serve as a substantial addition to the existing collection of CUI heuristics. For instance, the newly introduced set of heuristics expands upon the usability requirements of Conversational AI interfaces and extends the existing heuristics proposed by Langevin et al., 2021. It includes an additional 5 heuristics that are synthesized for the purpose of evaluating integrated system-physical interaction scenario of CUIs.

Overall, the comparative analysis validates our results as a comprehensive set of heuristics for CUIs, surpassing the contributions of past research.

Table 7-D: Comparative analysis of new 16 heuristics with past related heuristics

New 16 heuristics for conversational user interfaces	10 heuristics for user interfaces by Jacob Nielsen	11 heuristics for conversational agents by Langevin et al., 2021	17 heuristics for Speech user interfaces by Wei & Landay, 2018
<i>Visibility of system status</i>	Visibility of system status	Visibility of system status	Make the system status clear
<i>Match between system and the real world</i>	Match between system and the real world	Match between system and the real world	Use spoken language characteristics.
			Speak the user's language.
			Start and stop conversations.
<i>User control and freedom</i>	User control and freedom	User control and freedom	
<i>Consistency and standards</i>	Consistency and standards	Consistency and standards	
<i>Error prevention and user safety</i>	Error prevention	Error prevention	
<i>Recognition rather than recall</i>	Recognition rather than recall		
<i>Flexible, efficient, and user-friendly multimodal interaction</i>	Flexibility and efficiency of use	Flexibility and efficiency of use	
<i>Aesthetic, minimalist and legible design</i>	Aesthetic and minimalist design	Aesthetic, minimalist and engaging design	Keep feedback and prompts short
			Give the agent a persona through language, sounds, and other styles
<i>Help users recognize, diagnose and recover from errors</i>	Help users recognize, diagnose and recover from errors	Help users recognize, diagnose and recover from errors	Avoid cascading correction errors.
			Use normal language in communicating errors.
			Allow users to exit from errors or a mistaken conversation.
			Use multimodal feedback when available.
<i>Help and guidance</i>	Help and documentation	Help and guidance	Guide users through a conversation so they are not easily lost.

New 16 heuristics for conversational user interfaces	10 heuristics for user interfaces by Jacob Nielson	11 heuristics for conversational agents by Langevin et al., 2021	17 heuristics for Speech user interfaces by Wei & Landay, 2018
<i>Context preservation</i>		Context preservation	Pay attention to what the user said and respect the user's context.
<i>Provide trust, comfort and evident intelligence</i>		Trustworthiness	Adapt agent style to who users are, how they speak, and how they are feeling. Confirm input intelligently.
<i>Optimized conversation flow and dynamic conversation management</i>			Make conversation a back-and-forth exchange.
<i>Accurate input, intent and task perception</i>			Use speech-recognition system confidence to drive feedback style.
<i>Ethical, social and cultural considerations</i>			
<i>Clarity of outcome and system capability</i>			Use responses to help users discover what is possible.

Table 7-E: Comparative analysis of new 16 heuristics with past related interface or interaction design guidelines

New 16 heuristics for conversational user interfaces	8 Golden Rules of Interface Design by Shneiderman	10 design guidelines for Voice user interface by Murad et al., 2019	10 guidelines of Telephone Spoken Dialog Design by Suhm, 2003
<i>Visibility of system status</i>	Offer informative feedback	Visibility/ feedback of system status	Provide carefully designed feedback
<i>Match between system and the real world</i>		Mapping between system and real world	Carefully select the appropriate persona Abide by natural turn-taking protocol
<i>User control and freedom</i>	Permit easy reversal of actions Support internal locus of control	User control and freedom	
<i>Consistency and standards</i>	Strive for consistency	Consistency throughout the Interface	
<i>Error prevention and user safety</i>		Helping to prevent user errors	
<i>Recognition rather than recall</i>	Reduce short-term memory load	Recognition rather than recall	Coach a little at a time
<i>Flexible, efficient, and user-friendly multimodal interaction</i>	Enable frequent users to use shortcuts	Flexibility and efficiency	Offer alternative input modalities
<i>Aesthetic, minimalist and legible design</i>		Minimalism in design and dialogue	Keep it simple Minimize acoustic confusability of vocabulary

New 16 heuristics for conversational user interfaces	8 Golden Rules of Interface Design by Shneiderman	10 design guidelines for Voice user interface by Murad et al., 2019	10 guidelines of Telephone Spoken Dialog Design by Suhm, 2003
			Carefully control the amount of spoken output
<i>Help users recognize, diagnose and recover from errors</i>	Offer simple error handling	Allowing users to recognize and recover from errors	
<i>Help and guidance</i>		Providing help and documentation	
<i>Context preservation</i>			
<i>Provide trust, comfort and evident intelligence</i>			
<i>Optimized conversation flow and dynamic conversation management</i>	Design dialogue to yield closure		Word options the way users think Yes/no queries can be very robust
<i>Accurate input, intent and task perception</i>			
<i>Ethical, social and cultural considerations</i>			
<i>Clarity of outcome and system capability</i>			

7.5.5 Scope of the new heuristics for other use cases

Table 7-F depicted the similarity analysis of different usability issues and interaction needs across the nine different clinical procedures. The experts, as observed in the figure, opted to examine the axial codes (rather than the final 16 heuristics) and the associated usability issues. This approach allowed for a more detailed evaluation of similarities at a granular level. For example, the experts examined specific usability concerns related to axial codes "Match between system and the real world," "Effective and engaging conversation," and "Good interaction initialization and closure" in order to analyse similarities across clinical procedures, instead of using the combined selective code "Match between system and the real world." This approach facilitated a thorough analysis and evaluation of usability and interaction requirements, enabling a detailed assessment of similarities. Table 7-F additionally presents the average relevance score corresponding to various usability issues across all clinical cases. For instance, as depicted in the table, the usability issue "Since this is a voice-based interaction, there is no way to know whether the bot heard the information correctly or incorrectly" corresponds to the heuristic "Visibility of system status". Experts assigned a lowest average relevance score of 3.92 to the Digital thermometer and a highest average relevance score of

4.75 to the CT scan device. This indicates that experts consider the specific usability issue to be of greater concern for the CT scan device compared to the Digital thermometer, which is a simpler device.

Likewise, similarity analysis and relevance scoring were performed for all the heuristics and underlying usability issues. The outcomes validated the applicability and relevance of the 16 heuristics across all nine clinical procedures. The final relevance scores in Table 7-F (right-most column) signify the comprehensive extent of the new heuristics for other clinical cases.

Table 7-F: Sample evaluation sheet to analyze scope of the 16 heuristics for different clinical procedures

23 axial codes from Table 3	Sample usability issues	Average Relevance scores by 12 research scholars									Final Relevance score
		BP monitor	Glucometer	MRI device	X-Ray device	ECG device	Digital thermometer	Defibrillator device	CT scan device	Ultrasound device	
Visibility of system status	“Since this is a voice-based interaction there is no way to know whether the bot heard the info for right or wrong.”	4.33	4.25	4.58	4.17	4.33	3.92	4.25	4.75	4.67	4.36
Match between system and the real world	“Words phrases and concepts used here may not be familiar to the user. too technical”	4.5	4.67	4.75	4.33	4.75	4.58	4.5	4.67	4.75	4.61
User control and freedom	“If there is any mistake in registering the data taken and the user wants to make some modifications to it. the system should give the user the choice to make the changes required apart from starting from the initial stage.”	4.33	4.58	4.67	4.58	4.67	3.92	4.75	4.5	4.33	4.48
Consistency and standards	“Chatbot followed a very formal tone until this point, after that it looks like the bot is commanding the user”	4.5	4.58	4.58	4.75	4.75	4.67	4.75	4.67	4.5	4.64
Error prevention	“Error message could come, to inform the user	4.83	4.83	4.91	4.75	5	4.25	5	4.83	4.91	4.81

23 axial codes from Table 3	Sample usability issues	Average Relevance scores by 12 research scholars									Final Relevance score
		BP monitor	Glucometer	MRI device	X-Ray device	ECG device	Digital thermometer	Defibrillator device	CT scan device	Ultrasound device	
	about possible consequences when the machine does not recognize user input or action”										
Recognition rather than recall	“The user would have to remember these commands. it would be preferable if these were always available in a little appendix”	4.17	4.33	4.67	4.33	4.75	4.17	4.91	4.75	4.67	4.53
Flexibility, efficiency and ease of use	“Is this device for a normal patient or a nurse or a doctor? Because they all have different skillsets. For a doctor lot of information is not necessary however for a patient it is quite a difficult job”	4.5	4.91	5	4.91	5	4.25	5	5	5	4.84
Aesthetic, minimalist and legible design	“Get to the purpose rather than overwhelming user with so many information”	4.58	4.67	4.5	4.25	4.67	4.33	4.17	4.75	4.58	4.50
Help users recognize, diagnose and recover from errors	“User will not know if they have performed the real-world activities correctly.”	4.67	4.83	5	5	4.67	4.58	5	5	4.91	4.85
Help and guidance	“What if the user does not understand the clinical steps correctly? There should be an option for additional help against each step.”	4.58	5	5	5	5	4.17	5	5	5	4.86
Context preservation	“If communication breaks occur, the system should remember last context to continue further. Here, it seems like system is doing conversation without recording or considering past user inputs”	4.75	4.83	3.75	3.92	4.17	4.67	3.5	4.17	4.33	4.23

23 axial codes from Table 3	Sample usability issues	Average Relevance scores by 12 research scholars									Final Relevance score
		BP monitor	Glucometer	MRI device	X-Ray device	ECG device	Digital thermometer	Defibrillator device	CT scan device	Ultrasound device	
Provide trust and comfort	“A user may feel anxious all the time during the clinical procedure. The system should comfort users about the safety of various processes.”	3.92	4.17	5	4.67	4.91	3.75	5	5	5	4.60
Effective and engaging conversation	“The instructions given by the bot looks like a text book instruction, very mechanical. It is hard to follow, not engaging and lacks expression. Unnatural sounding. User will not be willing to interact like this.”	4.75	4.58	4.5	4.67	4.83	4.75	4.91	4.67	4.58	4.69
Effective conversation layout planning	“There could be a better layout for the overall conversation. The current conversation-based interaction looks sequential, and lacks user freedom.”.	4.25	4.75	4.67	4.33	4.67	3.92	4.33	4.75	4.83	4.50
Recognize user intent and inputs	“When the user gave their name for registration eg “Jetty” it did not recognise the name correctly. It detected it as “jet tea” as it is running in dictionary mode. The system should detect user names, can’t rely on the user to pronounce his name perfectly.”	3.75	4.25	4.58	4.5	4.75	3.75	4.25	4.67	4.75	4.36
Address conversation deviation and user requests	“The bot gives only one option here, that is to confirm and initiate the procedure. What if the user does not want to go ahead	4.17	4.33	4.83	4.58	4.25	4.25	4.17	4.75	4.58	4.43

23 axial codes from Table 3	Sample usability issues	Average Relevance scores by 12 research scholars									Final Relevance score
		BP monitor	Glucometer	MRI device	X-Ray device	ECG device	Digital thermometer	Defibrillator device	CT scan device	Ultrasound device	
	with the process? He may ask about something else like “Can you show me last user procedure, to have a better understanding”. Can the bot address such queries?”										
Good interaction initialization and closure	“It is awkward to start a voice-based conversation with a bot in the first place. Similarly, abrupt end to bot’s chat. It was supposed to be the completion of the procedure. And CUI should give feedback about how it went if the device is capable to give some kind of completion output”	4.83	4.75	4.91	4.83	4.83	4.91	4.91	4.83	4.91	4.86
Ethical, social and cultural considerations	“Real visual information about clinical condition can be too disturbing for some users. Some of the clinical conditions can be culturally sensitive to be handled by a AI bot in a OPD environment”	3.75	3.92	4.75	4.75	4.83	3.5	4.67	4.75	4.91	4.43
Clarity of outcome and system capability	“At the very beginning user have no Idea what service the system provides. Everything is so linear, that after some time only the user knows details about the procedure. User could choose not to go through all these	4.17	4.5	4.91	4.58	4.83	4.17	5	4.91	4.83	4.66

23 axial codes from Table 3	Sample usability issues	Average Relevance scores by 12 research scholars									
		BP monitor	Glucometer	MRI device	X-Ray device	ECG device	Digital thermometer	Defibrillator device	CT scan device	Ultrasound device	Final Relevance score
	if informed initially.”										
Seamless multimodal interaction	“The system should be able to see what users are actually doing in real world. Because users may not actually perform the tasks correctly and system will never know that just buy voice-based interaction.”	4.17	4.25	4.58	4.67	4.33	4.25	4.5	4.17	4.25	4.35
Evident intelligence	“The AI bot should make the right decision on every situation where there are too many possibilities”	4.67	4.75	4.58	4.5	4.67	4.17	4.91	4.58	4.67	4.61
Sensory-Driven Interaction and Task Perception	“The user constantly is jumbling between voice commands, screen buttons, and medical equipment while doing the procedure. This might cause multiple issues including that of sanitisation, liquid going over the machine, and confusion among the user.”	3.08	3.92	4.17	4.25	4.5	2.33	4.67	4.17	4.58	3.96
User safety	“Accidents can happen even without user did anything wrong. Or system designed to prevent errors. How the system responds in case of accident?”	2.33	2.75	4.5	4.33	3.92	2.17	4.75	4.58	4.33	3.74

7.5.6 How the new CUI heuristics can be useful in the design and evaluation of CUIs?

CUIs are emerging human-machine interfaces for new-generation computing systems including emerging expert and autonomous AI systems. The potential variety of interactions

using CUIs depends upon use case scenarios and is also growing towards more human-like interaction with the advancement of technologies. Thus, appropriate capturing of context, usability issues in defining heuristics and validation of CUIs against the real-life context of use is vital for establishing a more useful and comprehensive set of heuristics. The past research works lacked consideration of such real-world use case scenarios that needs conversational interaction and coordination for both system-level and physical-world activities. Our research methodology allowed a better understanding of usability requirements for CUIs as the interactions were not limited to only system-level tasks but rather considered more cohesive and connected interactions and usability issues of varying degrees of importance. Based on the comparative analysis, we established the 16 heuristics as the most comprehensive set covering a wide range of usability requirements for CUIs.

Table 7-G presents a comprehensive outline of the 16 final heuristics, accompanied by relevant explanations and design and evaluation guidelines for CUIs. The heuristics are deliberately defined to maintain their exclusivity and effectively address individual usability issues, avoiding any merging. Moreover, the 16 heuristics are purposefully aligned to Nielsen's heuristics, to make them easy to grasp for designers who are used to Nielsen's heuristics for GUI design. The results of the present study support all the requirements of past heuristics and guidelines for CUIs and also expanded CUIs design and evaluation scope with additional heuristics. For instance, the table defines how the scope of Nielsen's and Langevin et. al. (2021)'s heuristic "Flexibility and efficiency of use" is expanded to include ease of use and provision for multimodal interaction to better serve complex system-physical interaction context. Table 7-G presents how the 16 new heuristics address CUIs' usability requirement in comparison to Nielsen's and Langevin et. al. (2021)'s.

Table 7-G: Heuristics for design and evaluation of CUIs

SI no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
1	Visibility of system status The system should always keep users informed about what is going on, through appropriate feedback within reason-able time.	Visibility of system status The system should always keep users informed about what is going on, through appropriate feedback within reason-able time, without overwhelming the user.	Visibility of system status The system should always keep users informed about what is going on, through appropriate feedback within a reasonable time, without overwhelming the user. <i>Examples of system status:</i> Specific user input, System response, Sensor data, Time required or left in any procedure, number of steps required or left in any procedure, Alarm, the status of any important event etc.

Sl no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
2	<p>Match between system and the real world</p> <p>The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real world conventions, making information appear in a natural and logical order.</p>	<p>Match between system and the real world</p> <p>The system should understand and speak the users' language—with words, phrases and concepts familiar to the user and an appropriate voice—rather than system-oriented terms or confusing terminology. Make information appear in a natural and logical order. Include dialogue elements that create a smooth conversation through openings, mid-conversation guidance, and graceful exits.</p>	<p>Match between system and the real world</p> <p>Make conversations, and interactions analogical to the real world. The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information, appear in a natural and logical order. Address users gracefully to make conversations more engaging and attention-holding. simplify information and bring clarity. Make information appear in a natural and logical order to users. Support social, emotional human-like conversational characteristics. Use 'interjections' and informal sounds (eg. oops, hmm) to reveal human-like reactions or emotions. Support user language characteristics in communication. Allow change in tone and expression as per conversational context. Include dialogue elements that create a smooth initiation and graceful exits. Plan good initialization and interaction modes. Users should not feel awkward initiating a conversation with a system or bot. Decide whether the user or the conversational interface will initiate the conversation.</p>
3	<p>User control and freedom</p> <p>Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.</p>	<p>User control and freedom</p> <p>Users often choose system functions by mistake and will need an option to effortlessly leave the unwanted state without having to go through an extended dialogue. Support undo and redo.</p>	<p>User control and freedom</p> <p>Give users clear options and control to choose from various system functionalities, actions and decision points. Users may choose certain system functions by mistake and will need an option to effortlessly leave the unwanted state without having to go through an extended dialogue. Support undo and redo.</p>
4	<p>Consistency and standards</p> <p>Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.</p>	<p>Consistency and standards</p> <p>Users should not have to wonder whether different words, options, or actions mean the same thing. Follow platform conventions for the design of visual and interaction elements. Users should also be able to receive consistent responses even if they communicate the same function in</p>	<p>Consistency and standards</p> <p>Follow standard procedures, protocol and guidelines. Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions for the design of visual and interactive elements. Users should also be able to receive consistent responses even if they communicate the same function in multiple ways (and modalities). Within the interaction, the system should have a consistent voice, style of language, and personality.</p>

Sl no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
		multiple ways (and modalities). Within the interaction, the system should have a consistent voice, style of language, and personality.	
5	<p>Error prevention Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.</p>	<p>Error prevention Even better than good error messages is a careful design of the conversation and interface to reduce the likelihood of a problem from occurring in the first place. Be prepared for pauses, conversation fillers, and interruptions, as well as dialogue failures, dead ends or side-tracks. Proactively prevent or eliminate potential error-prone conditions, and check and confirm with users before they commit an action.</p>	<p>Error prevention and user safety Even better than good error messages are a careful design of a system, interface, conversation and interactions to reduce the likelihood of a problem or error-prone condition occurring in the first place. Be prepared for pauses, conversation fillers, and interruptions, as well as dialogue failures, dead ends or side-tracks. Classify and rank errors to opt for the suitable countermeasure. Proactively prevent or eliminate potential error-prone conditions, and check and confirm with users before they commit an action. Verify user input and intent with appropriate feedback. Take adequate measures for accidents and emergency situations, which may occur even without the user doing anything wrong, or the system was designed to prevent errors. Consider user safety as a top priority. Recognize and consider the consequences of every communication, procedure, interaction and action. Provide abort option or provision for external help in case of emergency.</p>
6	<p>Recognition rather than recall Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.</p>		<p>Recognition rather than recall Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Specific instructions, guidance, predefined user commands and format of user input should be recognizable or easily retrievable whenever required.</p>
7	<p>Flexibility and efficiency of use Accelerators – unseen by the novice user – may often speed up the</p>	<p>Flexibility and efficiency of use Support flexible interactions depending on the use context by providing</p>	<p>Flexible, efficient, and user-friendly multimodal interaction Accelerators – unseen by the novice user – may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users</p>

Sl no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
	interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.	users with the appropriate (or preferred) input and output modality and hardware. Additionally, provide accelerators, such as command abbreviations, that are unseen by novices but speed up the interactions for experts, to ensure that the system is efficient.	to tailor frequent actions. Allow different user profiles and allow variation in user input and interaction. Give the user choice of language, medium of input and way of interaction. Analyse interaction differences between novice and expert users. Allow interactions for low skill dependency, domain knowledge and ease of use. Frame user-centred interaction. Emphasise seamless and effortless interaction in carrying out tasks and procedures. Support multiple user interactions. Support different modes of system interaction to meet desired outcomes. Support incorporation of other types of user interfaces if Conversation based interfaces fall short in providing effective interaction. Plan appropriately for cohesive and connected interactions. Consider all real-world entities (e.g. people, objects) that need to be part of an interaction or communication to plan seamless interaction and execute tasks effectively. Enable effective integration of user interfaces and systems to achieve the contextual requirement.
8	Aesthetic and minimalist design Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.	Aesthetic, minimalist and engaging design Dialogues should not contain information which is irrelevant or rarely needed. Provide interactional elements that are necessary to engage the user and fit within the goal of the system. Interfaces should support short interactions and expand on the conversation if the user chooses.	Aesthetic, minimalist and legible design Dialogues should not contain information which is irrelevant or rarely needed. Avoid too much information at a time. Similarly, visual content should be aesthetic, effective and less noisy. Use simplified and legible information. Consider hierarchy and significance of information on delivery. Consider the use of appropriate vocal tone, volume, sound, and Persona in conversations. Use effective communication to bring clarity to information. Get to the purpose or functionality quickly. Use visual (emoji) and voice expressions to make conversations, and interactions more engaging. Give users sufficient time for information processing. Avoid jargon and simplify confusing terminology.
9	Help users recognize, diagnose and recover from errors Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.	Help users recognize, diagnose and recover from errors Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.	Help users recognize, diagnose and recover from errors Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution. Provide specific alarm or warning feature to make users recognize kind of error. Take appropriate measures to help users diagnose or recover from errors. Allow external human intervention if necessary.
10	Help and documentation Even though it is better if the	Help and guidance The system should guide the user throughout the	Help and guidance The system should guide the user throughout the interactions by clarifying system capabilities, procedural steps and requirements. Analyse

Sl no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
	system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.	dialogue by clarifying system capabilities. Help features should be easy to retrieve and search, focused on the user's task, list concrete steps to be carried out, and not be too large. Make actions and options visible when appropriate.	interactions and scenarios where the user may face difficulty in understanding and execution and provide necessary help and guidance. Provide human-like guidance and help to solve any issue users face. Give user choice of external Assistance/help in case system help and guidance fail. Help features should be easy to retrieve and search. Provide visual guidance with pictures, animation, video etc., if found more effective.
11		Context preservation Maintain context preservation regarding the conversation topic intra-session, and if possible inter-session. Allow the user to reference past messages for further interactions to support implicit user expectations of conversations.	Context preservation Maintain context preservation regarding the conversation topic intra-session, and if possible inter-session. Allow users to refer to past messages for further interactions to support implicit user expectations of conversations. Allow resume of conversations and interactions in case of power failure.
12		Trustworthiness The system should convey trustworthiness by ensuring privacy of user data, and by being transparent and truthful with the user. The system should not falsely claim to be human.	Provide trust, comfort and evident intelligence The system should convey trustworthiness by ensuring the privacy of user data, showcasing domain knowledge and by being transparent and truthful with the user. Also, the system should comfort users in case of panic or doubt. The system should convey the safety of procedures, and interactions to users, if necessary. The system should not falsely claim to be human. Allow learning for future improvement. A design should evidence intelligence by demonstrating rational thoughts, logic and actions. Evident required domain knowledge in conversations. An intelligent system should dig out user information as required for a specific purpose. Detect context during interaction and execute effectively. Support user recognition. Optimise conversation considering varying levels of user intelligence.
13			Optimized conversation flow and dynamic conversation management Conversational layouts, and format needs to be planned for effective execution of tasks, and presentation of various information and content. Plan procedural stages and checkpoints with appropriate conversation layout. Facilitate effective input field (blank space) and selectors (like check box, drop-down menu, checklist, radio buttons) to capture user input. Provide options

Sl no	Nielsen's Heuristics	Langevin et. al. (2021)'s heuristics	New 16 heuristics for Conversational User interfaces (CUIs) and expanded scopes
			<p>having appropriate and distinct choices. Plan for various branching and loops in communication. Avoid dead ends during conversation or interactions.</p> <p>Make the design able to handle surprises or new instances of communication gracefully. Correctly handle user queries with appropriate utterances and actions. Allow communication deviation by giving user provisions for optional requests. Inform user about system capability and limitations in case specific conversational deviation like user's query can't be addressed. Return to the desired conversational or interaction path though there occurs conversational or interaction deviation.</p>
14			<p>Accurate input, intent and task perception Correctly recognise user input. Consider the signal-to-noise ratio in input recognition. Correctly identify user intention (or intent) in conversation. Consider variation in user pronunciation, tone, volume, dialect and format of user input. Recognize context and scenario during conversation and interaction. Sense real-world entities, activities and events. Monitor real-world tasks and interactions. It is better to minimize multitasking with physical and mental activities. Minimize sensory and motor function overload. Simplify real-world activities and tasks. Manage the coordination of real-world activities with effective conversation.</p>
15			<p>Ethical, social and cultural considerations Comply with social and moral ethics during procedures and interactions. Inform vulnerable procedures, and ill consequences and get consent before execution. Get consent for storage and use of user data. Ensure privacy of user data. Deal with social taboos, women-centric issues, and religious matters gracefully. Respect ethnic and cultural values, beliefs and practices. Avoid visually sensitive or disturbing information. Consider cultural sensitivity in communication.</p>
16			<p>Clarity of outcome and system capability Allow users to understand the system's capability and the service it provides. Declare the purpose and outcome of the events, procedures and user actions. Show the effect or consequence of a user's choice. Declare system limitation, if required.</p>

7.5.7 Implication for research and design

The study revealed that the design and evaluation of CUIs needs multiple aspects considerations like the type of CUI, types of conversational interaction, real-world physical interaction requirements, analysis of contextual requirements and variability. For example: 'Speech only' interfaces (with AI or rule-based) have issues like lack of visibility of system

capability and system status and misalignment between user perception of speech interaction ability and user inputs. Similarly, in our study, participants for user testing of CUIs showed a lot of variation in conversational styles, and expectations from the conversational interactions which is hard to analyze as common ground. By considering a real-world scenario of using CUIs, we realized that sometimes an integrated approach of utilizing different interaction and input modalities like a combination of voice-based, and text-based interaction might better address a contextual requirement, thereby eliminating individual interface limitations.

In this study we adopted a ground up approach of developing CUIs, investigating usability issues, synthesizing and validating heuristics due to the fact that we felt limitation of existing systems like Alexa, Siri in representing the context we tried to define. In contrast, our study methodology established that 1) consideration of a physical-world application and need gives researchers/interaction designers the freedom to analyze and formulate interaction ideas logically and naturally, thus allowing an unhindered way of analyzing usability issues which is justifiable, whereas a technology-driven approach (if we considered an existing system like Alexa) limits interactions and usability analysis to the available system, algorithmic capabilities. It also helps in realizing various input modalities required for the Conversations-based interactions; 2) context-driven procedural requirements combine, connect and correlate individual technologies and application tasks more seamlessly. This will result in identifying broader usability issues and realizing additional technological scopes to address the overall contextual requirements; 3) consideration of a real-world situation helps in analyzing conversational requirements, and human-like attributes in dialogue management, like identifying required types and characteristics of conversation while informing, guiding and instructing users.

7.5.8 Limitations of the Study

The study was limited only to medical devices and clinical procedures in analyzing and synthesizing heuristics requirements for CUIs due to the authors' prior expertise and exposure to Clinical pathophysiology, Biomedical design and technologies. Other application areas of CUIs like robotics, space technology, Industrial manufacturing etc. could have been included in the study with the necessary domain expertise. While only two types of CUIs: chat-based and voice-based were developed and selected for study, there could be other types of CUIs or multimodal interfaces that might demonstrate a stronger significance of the results. It is recommended for future studies to evaluate how the new heuristics and guidelines can be applied to different domain areas and contexts of use.

7.6 Conclusion

This chapter discusses research efforts to address the shortage of skilled professionals in lower-tier healthcare settings like Community Health Centers (CHCs), Primary Health Centers (PHCs), and Sub-Centers (SCs), a major challenge in Low- and Middle-Income Countries (LMICs). This extended research focuses on AI-assisted CUI (Conversational User Interface) design to address the medical technology implementation barrier 'lack of skilled professionals in resource-constrained healthcare settings.' The initial objective was to explore the potential of AI-infused CUIs in assisting clinical therapy without the need for skilled professionals. During the exploration of this context, a design research gap became evident, which was the absence of necessary guidelines for designing and evaluating a conversational user interface responsible for managing complex scenarios involving both physical and media interactions. Such a complex system-physical interaction requires the seamless synchronization and management of both physical and virtual world activities. Consequently, the study further developed two types of CUIs: voice-based and text-based. Usability testing was conducted for specific clinical tasks, and a set of 16 heuristics was synthesized based on the various usability issues that were identified. These new 16 heuristics were subsequently validated for other use case scenarios and found to be suitable as guidelines for the design and evaluation of Conversational User Interfaces.

Chapter 8. Thesis Contributions and Conclusion

Abstract

This thesis investigates medical technology innovation in low- and middle-income countries (LMICs), focusing on the design and innovation processes. It presents contributions in design epistemology and praxeology. From a design epistemology perspective, it offers a nuanced understanding of design processes, highlights LMIC-specific innovation characteristics, and identifies gaps in the Stanford Biodesign process. In terms of design praxeology, it proposes a Healthcare Centered Design (HCD) framework, a redefined conceptual model for innovation management, and a modified Biodesign process with new toolsets tailored for LMICs. The research also details practical implications, identifying key challenges and providing strategic tools and frameworks to enhance medical technology innovation in resource-constrained settings. Additionally, the study has led to patent filings and device developments, emphasizing its practical impact.

8.1 Key Research Findings

The key research findings of the thesis study are as follows.

- i. **Characteristics and constraints of medical technology innovation (In Chapter 2, aligning with Objective 1):** Thematic coding of case studies of medical technology innovation reveals four key attributes shaping the medical technology innovation process. These include the *multifactorial nature of healthcare problems, the complex nature of disease states and bio-mechanisms, the critical nature of clinical intervention in terms of biocompatibility and patient interaction, and challenges related to entry barriers and localization for market entry.*
- ii. **Process supports requirements of medical technology innovation process (In Chapter 2, aligning with Objective 1):** The research addresses a significant gap in the understanding of process supports requirements specific to medical technology innovation. Despite the widespread acceptance of design and innovation processes like User-Centered Design (UCD), Human-Centered Design (HCD), Design Thinking, and the Stanford Biodesign process in healthcare, the study identifies a critical need for a nuanced understanding of the process aspects crucial for successful outcomes in medical technology innovation. The study identified a set of detailed process supports necessary for successful medical technology innovation based on critical analyses of

various design and innovation activities from past case studies.

- iii. **Factors influencing medical technology innovation in LMICs (In Chapter 3, aligning with Objective 2):** The study identifies 23 key challenges and barriers in LMICs, categorized into six factors: *Healthcare context and system, Organizational capabilities, Innovation ecosystem, Demographic burdens and characteristics, Market Forces, and the Nature of medical science and technology*. The proposed ‘conceptual model of Medical technology innovation management’ integrates these factors and provides a roadmap for managing medical technology innovation in LMICs.
- iv. **Influence of identified factors on medical technology innovation activities (In Chapter 3, aligning with Objective 2):** The research explores firm-level activities related to medical technology innovation management. Two main categories emerge: *R&D/project management and business management activities*. The study maps interdependencies among these organizational activities, emphasizing their order and relationships in innovation management. The study analyzes how the identified challenges impact various stages of medical technology innovation. It maps the relationship between challenges and biotech firm-level activities, highlighting the influence on stages such as initial research, technology development, intellectual property management, clinical validation, regulatory certifications, product scale-up, and product sales and revenue generation.
- v. **LMIC-specific process characteristics for successful medical technology innovation (In Chapter 4, aligning with Objective 3):** The study categorizes LMIC-specific challenges into issues that are not addressable, partially addressable, and completely addressable within a design and innovation process. It identifies six essential LMIC-specific design and innovation process characteristics, emphasizing the need to address *clinical problems, disparities in healthcare systems, socio-cultural barriers, underdeveloped innovation ecosystems, organizational innovation challenges, and market entry challenges*.
- vi. **Limitations of the Stanford Biodesign process in LMIC context (In Chapter 4, aligning with Objective 3):** The Stanford Biodesign process, while effective in addressing medical technology challenges, exhibits limitations when applied in Low- and Middle-Income Countries (LMICs). Unique LMIC factors, such as healthcare disparities and resource constraints, are inadequately considered. The study identifies

specific shortcomings in the Biodesign process, including its clinical focus, neglect of systemic issues, absence of a market-driven approach, generic idea generation, insufficient concept screening, lack of systematic tools for strategy development, and inadequate consideration of LMIC-specific implementation barriers and real-world challenges. These limitations hinder the process's adaptability to diverse healthcare landscapes, necessitating comprehensive modifications for effective medical technology design and innovation in LMIC contexts.

- vii. **Scope of conversational user interface in resource constraint settings (extended objective):** The study identified a realized unmet implementation gap in the adoption of healthcare solutions in Indian settings. This gap was attributed to a shortage of skilled professionals and resources, despite efforts to design a portable and cost-effective solution. To address the shortage of human resources, the study proposed the integration of an offline AI bot for semi-autonomous healthcare delivery. This solution was specifically tailored for resource-limited settings, aiming to enhance the accessibility and efficiency of healthcare services. This extended study focuses on usability issues in Conversational User Interfaces (CUIs) for healthcare applications in resource-constrained settings. It identifies 873 usability issues and proposes 16 new heuristics to address challenges in coordinating text communication and physical tasks during clinical procedures.

8.2 Thesis Contributions

The overall research aims to address significant research gaps in medical technology innovation, particularly in low- and middle-income countries (LMICs), with a focus on design and innovation processes. The key contributions from the perspective of 'design epistemology' and 'design praxeology' can be summarized as follows:

8.2.1 Contributions from the perspective of 'Design epistemology':

- i. **Insights into design and innovation Processes:** The evaluation of design and innovation processes provides a nuanced understanding of the process supports required for successful medical technology design and innovation projects, addressing the characteristics and constraints of medical technology innovation.
- ii. **LMIC-specific design and innovation process characteristics:** The study contributes by outlining six essential characteristics of a design and innovation process tailored for LMIC contexts. These characteristics include *addressing clinical problems*,

overcoming socio-cultural barriers, navigating underdeveloped innovation ecosystems, managing organizational innovation challenges, addressing disparities in healthcare systems, and tackling market entry challenges

- iii. **Identification of shortfalls in the Biodesign process:** The study systematically identifies shortfalls in the conventional Stanford Biodesign process from both process supports requirements perspectives and LMIC-specific characteristics. This critical analysis contributes to design epistemology and lays the foundation for more effective medical technology design and innovation in LMIC settings

8.2.2 Contributions from the perspective of 'Design praxeology':

- i. **Healthcare centered design (HCD) process:** A modified framework, denoted as "Healthcare Centered Design (HCD)," was proposed with the aim of augmenting UCD specifically for healthcare projects. The proposed framework is designed to address the unique challenges and intricacies inherent in medical technology innovation, thereby offering a tailored and refined approach to design and innovation within this specialized domain
- ii. **Redefined conceptual model for medical technology innovation management:** The research proposes a more comprehensive conceptual model for managing medical technology innovation. The model integrates seven R&D and project management activities and demonstrates their interconnections and dependencies on six identified factors: *healthcare context, organizational capabilities, innovation ecosystem, demographic burdens, market forces, and science & technology*. This conceptual framework places a heightened emphasis on interconnected factors and organizational activities, underscoring their pivotal roles in shaping and fostering innovation in the realm of medical technology within these resource-constrained settings.
- iii. **LMIC-specific design and innovation process characteristics:** Six essential characteristics of the innovation process specific to low- and middle-income countries (LMICs) were identified through the research. These characteristics, provide a framework for evaluating the efficacy of any design and innovation process in meeting the specific design and innovation requirements unique to LMICs. By incorporating these identified characteristics into the evaluation criteria, the design community can systematically assess and enhance the adaptability and relevance of design and innovation processes to the nuanced challenges presented by LMIC contexts.

- iv. **Modified Biodesign process and new toolsets:** The study proposed a modified Biodesign process with three toolsets (Toolset 1, Toolset 2, and Toolset 3) to address the identified limitations of the conventional Stanford Biodesign process in LMIC context. These tools aim to improve data collection, analysis, ideation, evaluation, and strategy development in the Biodesign process. The proposed modifications present a holistic and meticulous adaptation of the Biodesign process tailored to the unique challenges of medical technology innovation in LMICs. The modified toolkit ensures a comprehensive understanding of local contexts, empowering designers to navigate the intricate landscape of LMICs effectively.
- v. **Usability heuristics for conversational user interfaces (CUIs):** A significant research contribution was the synthesis of 16 new heuristics specifically tailored to address usability issues in CUIs for medical device applications. These heuristics covered aspects such as system visibility, user control, error prevention, multimodal interaction, and ethical considerations, providing a comprehensive framework for design and evaluation. The study demonstrated the applicability of the newly synthesized heuristics across nine different clinical procedures, indicating the broad scope and versatility of the proposed heuristics for various healthcare contexts. The comparative analysis revealed that the newly established heuristics encompassed and surpassed existing contributions, validating them as a comprehensive set for CUI evaluation.

8.2.3 Other contributions

- i. **Patents:** Two Indian patents were filed, one for a multi-therapeutic wound healing and diagnostic device and another for an apparatus and method for screening gynecological conditions.
- ii. **Device development:** The study contributed to the field by successfully developing prototypes of Conversational AI embedded medical devices for NPWT, incorporating both text-based and voice-based interfaces. This marked an innovative approach to address healthcare challenges in resource-limited settings.
- iii. **A card-based workflow toolkit for the modified Biodesign process,** has been developed, constituting a valuable contribution to 'Design Pedagogy.' This toolkit facilitates student learning by providing support in mastering tool usage and understanding the essential concepts underlying Medical Technology Innovation.

- iv. **A card-based toolkit for heuristic evaluation of conversational user interfaces (CUIs)** has been developed for use by system developers and UX designers in designing and evaluating conversation-based interfaces. This tool is versatile, suitable for application in both industry and academia for practical use and educational purposes.

8.3 Implications

8.3.1 Theoretical implications of the study:

The study addresses crucial theoretical gaps in medical technology innovation, focusing on design and innovation processes applicable to LMICs. The first theoretical contribution involves a comprehensive analysis of systematic design and innovation processes, such as the Biodesign Process, User-Centered Design (UCD), and Design Thinking, specifically tailored for medical technology innovation. This analysis provides a nuanced understanding of the differences between medical technology innovation and generic product innovation, paving the way for a refined theoretical framework for medical technology innovation.

The second theoretical contribution revolves around recognizing and exploring the unique challenges faced by medical technology innovation in LMICs. By applying theoretical lenses from Social Innovation Theory, Stakeholder Theory, Resource-Based View, and PESTEL analysis, the study expands the existing conceptual framework for managing medical technology innovation to be more inclusive of LMIC-specific factors. This theoretical expansion contributes to a more comprehensive understanding of innovation management activities in diverse global contexts.

The third theoretical contribution delves into the Stanford Biodesign process and its adaptability in LMICs. By identifying LMIC-specific medical technology design and innovation considerations and proposing process modifications, the study enhances the theoretical foundation for designing and innovating in resource-constrained settings. This contribution lays the groundwork for future research on context-specific design and innovation processes, bridging the gap between global design and innovation frameworks and the unique challenges faced in LMICs.

8.3.2 Practical implications of the study:

From a practical perspective, the study offers actionable insights and tools for enhancing medical technology innovation in LMICs. The first practical implication stems from the proposed Healthcare Centered Design (HCD) framework, derived from the comparative analysis of design and innovation processes. This modified framework provides a structured

approach to address the multifaceted nature of medical technology design and innovation, offering practical guidance for designers working on healthcare projects.

The second practical implication relates to the findings on factors influencing medical technology innovation in LMICs. The identified challenges and barriers provide a roadmap for industry leaders, policymakers, and researchers to develop targeted strategies. The redefined conceptual model for medical technology innovation management serves as a practical guide for navigating the complexities of innovation in LMIC contexts, promoting informed decision-making and strategic planning.

The third practical implication lies in the proposed modifications to the Stanford Biodesign process. The study's identification of LMIC-specific design and innovation process characteristics and the development of a new toolkit offer practical tools for designers and innovators. These tools address the real-world challenges of uneven healthcare coverage, resource limitations, regulatory issues, socio-cultural barriers, and inadequate funding, providing a tangible contribution to the field of medical technology design and innovation.

The fourth practical implication emerges from the evaluation of the modified Biodesign process in the context of India. The newly developed toolkit, seamlessly integrated into the Biodesign process, proves effective in addressing context-specific medical technology design and innovation challenges. This practical validation offers a valuable resource for designers and innovators working in similar resource-constrained settings, showcasing the adaptability and impact of the proposed modifications.

8.4 Limitations and Future Scope

8.4.1 Limitations

While the research study strives to address critical gaps in medical technology innovation in low- and middle-income countries (LMICs), certain limitations need consideration. Firstly, the generalizability of the findings may be constrained by the focus on specific regions, such as India. Healthcare contexts can vary widely across LMICs. Secondly, the research heavily relies on qualitative research processes i.e. analysis of case studies and interviews via thematic coding, introduces subjectivity in data analysis. The study's reliance on interviews with Biodesign fellowship alumni startups in India to identify limitations of the Biodesign process may introduce a regional bias. Additionally, the proposed modifications to the Biodesign process and the new Healthcare Centered Design (HCD) framework are based on expert opinions and empirical studies in specific contexts. Further validation through broader

empirical testing in diverse LMIC settings is essential to ascertain the generalizability and effectiveness of these proposed frameworks.

8.4.2 Future scopes

The research study lays a strong foundation for future exploration and expansion of knowledge in medical technology innovation for LMICs. Firstly, the proposed modifications to the Biodesign process and the introduction of the Healthcare Centered Design (HCD) framework could benefit from iterative testing and refinement. Continuous collaboration with healthcare practitioners, policymakers, and industry leaders in LMICs can contribute to the evolution of these frameworks to better suit the dynamic and context-specific nature of medical technology innovation.

In terms of methodology, incorporating longitudinal studies and real-time monitoring of medical technology innovation projects in LMICs could provide a more nuanced understanding of the long-term impact and sustainability of the proposed processes. This could include tracking the evolution of medical technologies from ideation to implementation and assessing their actual impact on healthcare outcomes.

Additionally, the study opens avenues for exploring the role of digital technologies, artificial intelligence, and telehealth in overcoming healthcare challenges in LMICs. Future research could delve into how these technologies can be integrated into the proposed frameworks to enhance the efficiency and accessibility of medical technology innovation in resource-constrained settings.

In conclusion, while the current study offers valuable insights and practical frameworks for medical technology innovation in LMICs, there exists a rich landscape for further exploration and refinement. Future research endeavors can build upon these foundations to create more robust, adaptable, and globally applicable frameworks for addressing the unique challenges of medical technology innovation in low- and middle-income countries.

8.5 Conclusion

In conclusion, this comprehensive research initiative set out to address critical gaps in the field of medical technology innovation, with a specific focus on LMICs. The study's objectives were multi-faceted, aiming to fill voids in the understanding of design and innovators processes, challenges in LMICs, the applicability of existing processes, and the development of a modified Biodesign process tailored to LMIC contexts. The first objective focused on assessing design

and innovation processes for medical technology innovation challenges, leading to the proposal of a Healthcare Centered Design (HCD) framework tailored to LMICs. The second objective identified 23 challenges influencing medical technology innovation in LMICs, creating a conceptual model for navigating these complexities. The third objective analyzed the adaptability of the Stanford Biodesign process in LMICs, resulting in proposed modifications and guidelines. The fourth objective aimed to enhance the Biodesign process in LMICs through the development of toolsets and a workshop toolkit, demonstrating improvements in problem-solving and strategy-making. The fifth objective applied the modified Biodesign process to a case study in India, addressing healthcare challenges and proposing a solution involving an offline AI bot. The final objective addressed the usability challenges of CUIs through the development of new heuristics. In essence, this multifaceted research endeavor contributes significantly to the fields of medical technology innovation. The proposed frameworks, models, and toolsets offer practical solutions and insights, paving the way for more effective and context-aware medical technology innovations in diverse global settings.



References

- A, K., K, S., B, A., & S., R. (2010). Harmonized Medical Device Regulation: Need, Challenges, and Risks of not Harmonizing the Regulation in Asia. *J Young Pharm., 101*(6). doi:10.4103/0975-1483.62221
- Abbas, J. J., Smiath, B., Poluta, M., & Velazquez-Berumen, A. (2017). Improving health-care delivery in low-resource settings with nanotechnology: Challenges in multiple dimensions. *Nanobiomedicine*.
- Abidin, D. M., Junaedi, D., & Sardi, I. L. (2018). Analysis and Implementation of Goal-Directed Design in Reproductive Health Learning Media for High School Student Case Study: Mitra Citra Remaja (MCR). *MATEC Web of Conferences, AASEC 2018*. EDP Sciences. doi:10.1051/mateconf/201819716007
- Abraham MB, N. J. (2016). Safety and efficacy of the predictive low glucose management system in the prevention of hypoglycaemia: protocol for randomised controlled home trial to evaluate the Suspend before low function. *BMJ Open*.
- Abrol, D., Sundararaman, T., Madhavan, H., & Joseph, K. J. (2016). Building inclusive health innovation systems: lessons from India. *Cad. saúde pública*.
- Adam W. Beck, J. V.-D. (2017). Innovative postmarket device evaluation using a quality registry to monitor thoracic endovascular aortic repair in the treatment of aortic dissection. *Journal of Vascular Surgery*, 1280-1286.
- Agarwal, N., Brem, A., & Grottke, M. (2018). Towards a higher socio-economic impact through shared understanding of product requirements in emerging markets: The case of the Indian healthcare innovations. *Technological Forecasting and Social Change*, 91-98.
- Agarwal, N., Brem, A., & Grottke, M. (2018). Towards a higher socio-economic impact through shared understanding of product requirements in emerging markets: The case of the Indian healthcare innovations. *Technological Forecasting and Social Change, Volume 135*, 91-98. doi:10.1016/j.techfore.2018.05.016.
- Agrawal, P. S., Prabhu, R., & Supe, A. (2020). Challenges of Surgical Innovations in India. *Indian Journal of Surgery*.
- Aitchison, G., Hukins, D., Parry, J., Shepherd, D., & Trotman, S. (2009). A Review of the Design Process for Implantable Orthopedic Medical Devices. *The open Biomedical Engineering Journal*, 3, 21-27. doi:10.2174/1874120700903010021
- Alagumalai, V. K. (2019). Interdisciplinarity in New Product Development in an Indian MedTech Perspective: Gap and the Solution. *Health and Technology*, 817–827.
- Alan G Fraser, R. A. (2020). Implementing the new European Regulations on medical devices—clinical responsibilities for evidence-based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology. *European Heart Journal, Volume 41, Issue 27*, 2589–2596.
- Alegre, J., Chiva, R., & Lapiedra, R. (2009). Measuring innovation in long product development cycle industries: an insight in biotechnology. *Technology Analysis & Strategic Management*, 535-546.
- Alegre, J., Sengupta, K., & Lapiedra, R. (2013). Knowledge management and innovation performance in a high-tech SMEs industry. *International Small Business Journal*, 31(4), 454-470. doi:10.1177/0266242611417472
- Amazon. (n.d.). *designing-for-voice*. Retrieved from Amazon Alexa: <https://developer.amazon.com/fr/designing-for-voice/>
- American Nurses Association. (1986). Cultural diversity in the nursing curriculum: a guide

- for implementation. (. *American Nurses Association Publications*, G(171), 1-11. Retrieved from The Virginia Department of Behavioral Health and Developmental Services:
<https://dbhds.virginia.gov/library/cultural%20and%20linguistic%20competence/clc-relateddefinitions.pdf>
- Antonio Migliore, M. R. (2009). Health Technology Assessment: managing the introduction and use of medical devices in clinical practice in Italy. *Expert Review of Medical Devices*, 251-257.
- Arasaratnam, A., & Humphreys, G. (2013). Emerging economies drive frugal innovation. *Bulletin of the World Health Organization*. doi:10.2471/BLT.13.020113
- Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology: Theory and Practice*, 19-32.
- Arun-Kumar, P., Sridhar, S., Chaturvedi, J., & Deshpande, R. P. (2017). Identification of unmet clinical needs in the field of nephrology – A modified bio-design approach. *Medical Devices and Diagnostic Engineering*, 52-56.
- Asim, Z., & Sorooshian, S. (2019). Exploring the Role of Knowledge, Innovation and Technology Management (KNIT) Capabilities that Influence Research and Development. *Journal of Open Innovation: Technology, Market, and Complexity*, 5(2). doi:10.3390/joitmc5020021.
- Atanu, C., Thim, P., Gopalakrishnan, N., Peter, H., & Vijay, P. (2021). Finding your feet in constrained markets: How bottom of pyramid social enterprises adjust to scale-up-technology-enabled healthcare delivery. *Technological Forecasting and Social Change*, 173. doi:10.1016/j.techfore.2021.121184.
- Ayah R, O. J. (2020). Responding to maternal, neonatal and child health equipment needs in Kenya: a model for an innovation ecosystem leveraging on collaborations and partnerships. *BMJ Innovations* , 85-91.
- Ayete-Nyampong, J., & Udofia, E. A. (2020). Assessment of knowledge and quality of essential newborn care practices in La Dade Kotopon Municipality, Ghana. *PLOS ONE*.
- Azagury, D. (2014). Patient safety and surgical innovation—complementary or mutually exclusive? *Patient Safety in Surgery*, 8(17), 1-3. doi:10.1186/1754-9493-8-17
- Bagchi-Sen, S., Smith, H. L., & Hall, L. (2004). The US Biotechnology Industry: Industry Dynamics and Policy. *Environment and Planning C*, 22(2), 199-216 . doi:10.1068/c0345
- Baker, A. (2003). Opinion piece: Biotechnology's growth—innovation paradox and the new model for success. *Journal of Commercial Biotechnology*, 286-288.
- Bano, R., Gupta, S., & Shekhar, C. (2020). Translational research in biomedical sciences in India: Challenges, observations & national perspectives. *Indian J Med Res*, 335-341. doi:10.4103/ijmr.IJMR_1296_19.
- Bano, R., Gupta, S., & Shekhar, C. (2020). Translational research in biomedical sciences in India: Challenges, observations & national perspectives. *Indian Journal of Medical Research*, 152(4), 335-341. doi:10.4103/ijmr.IJMR_1296_19
- Barh, D., & Azevedo, V. (2017). *Omic Technologies and Bio-Engineering*. Academic Press. doi:10.1016/C2015-0-01634-3
- Barney, J., Wright, M., & Ketchen, D. J. (2001). The resource-based view of the firm: Ten years after 1991. *Journal of Management*, 625-641.
- Basargekar, P., Priyadarshini, S., Seth, S., & Ganjoo, V. (2021). Impact of socio-economic factors in reducing malnutrition among children: A comparative study of India, Bangladesh and Sri Lanka. *Asia Pacific Journal of Health Management*, 1-8.
- Beenkens, F., & Stolk, P. (2010). *Medical devices : Managing the Mismatch Context*

- dependency of medical devices (Background Paper 5). *WHO publications*.
- Benjamin, H., WF, S., K, E., H, D., B, v. G., RT, F., & TJ., C. (2020). Point of Care Diagnostics in Resource-Limited Settings: A Review of the Present and Future of PoC in Its Most Needed Environment. *Biosensors (Basel)*, 10(10). doi:10.3390/bios10100133.
- Berg, J. L. (2020). Review of Interfaces for Industrial Human-Robot Interaction. *Robotics in Manufacturing*, 27-34.
- Bhat, B., & Adhisivam, B. (2022). Therapeutic Hypothermia for Perinatal Asphyxia in Low-Resource Settings. *Indian J Pediatr*, 89, 213–215. doi:10.1007/s12098-021-03931-1
- Bickmore, T. a. (2005). Social dialogue with embodied conversational agents (Chapter 2). In *Advances in natural multimodal dialogue systems* (pp. 23--54). Springer.
- Bonfanti, M. F.-V. (2020). A Combined In Vivo, In Vitro, In Silico Approach for Patient-Specific Haemodynamic Studies of Aortic Dissection. *Biomedical engineering*, 2950–2964.
- Bouchard, M., Kohler, J. C., Orbinski, J., & Howard, A. (2012). Corruption in the health care sector: A barrier to access of orthopaedic care and medical devices in Uganda. *BMC International Health and Human Rights*.
- Braun, A., Mueller, E., Adelhelm, S., & Vladova, G. (2011). Knowledge flow at the fuzzy front-end of inter-firm R&D collaborations – insights into SMEs in the pharmaceutical industry. *International Journal of Entrepreneurship and Innovation Management*, 15, 29-46. doi:10.1504/IJEIM.2012.044075
- C, c.-L., C, R.-G., P, E., I, M., Y, B., JF, L., . . . B, T. (2022). Development of a Connected Sensor System in Colorectal Surgery: User-Centered Design Case Study. *JMIR Human Factors*.
- Carpenet, H., Brischoux, S., & Alain Faure, P. (2011). *Barriers to innovation in the field of medical devices*. World Health Organization Press.
- Chachra, P., Chaturvedi, J., Rodrigues, D., Jangir, R., Sirdesai, R., Tauheed, A. S., . . . Pappu, R. (2018). Identification of Unmet Clinical Needs in the Field of Otorhinolaryngology in India - A Modified Biodesign Approach. *Global journal of Otolaryngology*, 1-5.
- Chambers, A. M. (2013). Evaluating the implementation of health and safety innovations under a regulatory context: A collective case study of Ontario's safer needle regulation. *Implementation Science*.
- Chang, T.-Y. (2006). *The management of innovative projects by university scientists: an exploratory study*. PhD thesis from University of Bath.
- Chatpun, S., Liawrungrueang, W., Prukpattranon, P., & Wongsiri, S. (2022). Innovative solution with applying design thinking process: A case study of wireless endoscope for carpal tunnel release. *BMEiCON 2022 - 14th Biomedical Engineering International Conference*. Institute of Electrical and Electronics Engineers Inc. doi:10.1109/BMEiCON56653.2022.10012116
- Chaturvedi J, L. A. (2015). A structured process for unmet clinical need analysis for medical device innovation in India: early experiences. *BMJ Innovations*, 81-87.
- Chaturvedi, J. (2015). *Inventing Medical Devices: A Perspective from India*. CreateSpace Independent Publishing Platform.
- Chaturvedi, J., & Srinivas, G. (2021). MedTech Innovation using a structured Biodesign process Barriers and Opportunities. *Karnataka Pediatric Journal*, 106-112.
- Chaturvedi, J., Logan, A., Narayan, G., & Kuttappa, S. (2015). A structured process for unmet clinical need analysis for medical device innovation in India: Early experiences. *BMJ Innovations*, 81-87.
- Conrad, L. Y., & Tucker, V. M. (2019). Making it tangible: hybrid card sorting within qualitative interviews. *Making it tangible: hybrid card sorting within qualitative*

- interviews*, 397-416.
- COREA, F. (2015). What Finance Can Learn from Biopharma Industry: A Transfer of Innovation Models. *Expert Journal of Finance*, 3(1), 45-53.
- Coulentianos, M. J., Rodriguez-Calero, I., Daly, S. R., & Sienko, K. H. (2020). Global health front-end medical device design: The use of prototypes to engage stakeholders. *Development Engineering*, 5. doi:10.1016/j.deveng.2020.100055
- Cross, N. (2006). *Designerly Ways of Knowing*. Springer.
- D'Souza, R., Tauheed, A. S., Jangir, R., Chachra, P., RishabhSirdesai, Rodrigues, D., . . . Chaturvedi, J. (2018). A structured process to identify unmet needs for Medical Device Innovation in Obstetrics and Gynaecology. *Journal of Biomedical Research and Practice*, 2(1).
- Daalhuizen, J. (2014). *Method Usage in Design : How methods function as mental tools for designers*. (unpublished doctoral dissertation) TU Delf, Netherland. doi:10.4233/uuid:4ac01165-c6b5-4057-a2fe-3418907f251e
- Daalhuizen, J., & Cash, P. (2021). Method content theory: Towards a new understanding of methods in design. *Design Studies*.
- Daalhuizen, J., Person, O., & Gattol, V. (2014). A personal matter? An investigation of students' design process experiences when using a heuristic or a systematic method. *Design Studies*, 35(2), 133-159. doi:10.1016/j.destud.2013.10.004
- Dam, R. F. (n.d.). *The 5 Stages in the Design Thinking Process*. Retrieved from Interaction Design Foundation: <https://www.interaction-design.org/literature/article/5-stages-in-the-design-thinking-process>
- Das, J., Hammer, J., & Leonard, K. (2008). The Quality of Medical Advice in Low-Income Countries. *Journal of Economic Perspectives*, 93-114.
- Data for India, Lower middle income*. (2021). Retrieved from The World Bank data: <https://data.worldbank.org/?locations=IN-XN>
- de Ana, F. U. (2013). Value Driven Innovation in Medical Device Design: A Process for Balancing Stakeholder Voices. *Annals of Biomedical Engineering*, 1811–1821.
- Dharmawan, R., Ho, H., Ng, H. H., Iyer, N. G., Tan, H. K., & Tan, N. C. (2020). Implementing the Biodesign Process for Medical Device Innovation in Head and Neck Surgery. *Surgical Innovation*, 27(6), 653-658. doi:10.1177/1553350620943796
- Dhawan, A. P., Heetderks, W. J., Pavel, M., Acharya, S., Akay, M., Mairal, A., . . . Bhargava, B. (2015). Current and Future Challenges in Point-of-Care Technologies: A Paradigm-Shift in Affordable Global Healthcare With Personalized and Preventive Medicine. *IEEE Journal of Translational Engineering in Health and Medicine*, 3, 1-10. doi:10.1109/JTEHM.2015.2400919
- Dixit, T., Sahu, S., Srivastava, S., & Selvamurthy, W. (2019). Translational model of healthcare innovations in India. *Asian Biotechnology and Development Review*.
- Dixit, T., Srivastava, S., Sahu, S., & Selvamurthy, W. (2018). Intellectual property evolution and innovation ecosystem as effective tools in strengthening Indian healthcare sector. *Current Science*, 114(8), 1639-1649. doi:10.18520/cs/v114/i08/1639-1649
- Dolores, M., & Tongco, C. (2007). Definition of Purposive Sampling. *A Journal of Plants, People and Applied Research*, 147-158.
- Domapielle, M. D. (2023). Barriers to health care access and utilization among aged indigents under the Livelihood Empowerment Against Poverty Programme (LEAP): The perspective of users and service providers in north-western Ghana. *Primary Health Care Research & Development*, 24, E48.
- Dutta, N., & Dhar, D. (2021). From Industrial Design to Healthcare Innovation—A Comparative Study on the Role of User-Centered Design and Stanford Biodesign Process (Chapter 55). In *Design for Tomorrow—Volume 3* (pp. 665--677). Springer.

- Dybkjaer, L. a. (2001). Usability evaluation in spoken language dialogue systems. *Proceedings of the ACL 2001 Workshop on Evaluation Methodologies for Language and Dialogue Systems*.
- Eggington, R. B. (2019). Intrinsic properties of medical devices: considerations for economic evaluation. *Expert Review of Pharmacoeconomics & Outcomes Research*, 619-626.
- Eisenhardt, K. M. (1989). Building Theories from Case Study Research. *Academy of Management Review*, 532-550.
- F. Nativel, L. D.-P. (2019). Economic challenges of using innovative medical devices in major public health pathologies: Example of acute ischemic stroke management by mechanical thrombectomy. *Revue d'Épidémiologie et de Santé Publique, Volume 67, Issue 6*, 361-368.
- Federici, C. P. (2021). Early health technology assessment using the MAFEIP tool. A case study on a wearable device for fall prediction in elderly patients. *Health and Technology*, 995-1002.
- Formicola, R., Ragni, F., Borboni, A., & Amici, C. (2022). Design Process of Medical Devices for Robotic Rehabilitation: An Open Innovation-Inspired Approach. In M. Shamtsyan, M. Pasetti, & A. Beskopylny, *Robotics, Machinery and Engineering Technology for Precision Agriculture. Smart Innovation, Systems and Technologies, vol 247*. Springer, Singapore.
- Freeman, R. E. (2004). The stakeholder approach revisited. *Social Science Open Access Repository*.
- Garrett, J. J. (2010). *The Elements of User Experience, Second Edition: User-Centered Design for the Web and Beyond*. New Riders. doi:ISBN: 9780321688651
- Genco, A. &. (2010). *Pervasive systems and ubiquitous computing*. Wit Press.
- Gibbs, G. R. (2012). Thematic Coding and Categorizing. In *Analyzing Qualitative Data* (pp. 38-55). SAGE.
- Ginsburg, O., Yip, C. H., Brooks, A., Cabanes, A., Caleffi, M., Dunstan Yataco, J. A., . . . Pace, L. E. (2020). Breast cancer early detection: A phased approach to implementation. *Cancer*, 2379-2393.
- Google. (n.d.). *Conversation design*. Retrieved from Google Assistant: <https://developers.google.com/assistant/df-asdk/design>
- Gray, C. M. (2022). Languaging design methods. *Design Studies*.
- Gupta, B., & Thomke, S. (2018). An exploratory study of product development in emerging economies: Evidence from medical device testing in India. *R and D Management*, 485-501.
- Gupta, S. K. (2015). Medical Device Regulations: A Current Perspective. *Journal of Young Pharmacists*, 8(1), 6-11. doi:10.5530/jyp.2016.1.3
- Harmon, S. H., & Kale, D. (2015). Regulating in developing countries: Multiple roles for medical research and products regulation in Argentina and India. *Technology in Society*, 43, 10-22. doi:10.1016/j.techsoc.2015.07.002
- Harris, S. A. (2006). *Landscape analysis of barriers to developing or adapting technologies for global health purposes*. World Health Organization Press.
- Heidi Krantz, B. S. (2017). Heidi Krantz, Barbara Strain, Jane Torzewski., *Surgery, Volume 162, Issue 3*, 471-476.
- Heinonen, L., & Sandberg, B. (2008). Money for nothing? Risks in biopharmaceutical companies from the perspective of public financiers. *Journal of Commercial Biotechnology*, 14(4). doi:10.5912/jcb253
- Hennegan, J., Shannon, A. K., Rubli, J., Schwab, K. J., & Melendez-Torres, G. J. (2019). Women's and girls' experiences of menstruation in low-and middle-income countries: A systematic review and qualitative metasynthesis. *PLoS Medicine*, 1-40.

- Hidalgo, A., & Albors, J. (2008). Innovation management techniques and tools: A review from theory and practice. *R and D Management*, 113-127.
- Hood, R. L., & Rubinsky, B. (2020). Special Issue: Medical Devices for Economically Disadvantaged People and Populations: Perspective Problems and Prospective Solutions. *Journal of Medical Devices, Transactions of the ASME*.
- Hudson P Silva, A. L. (2011). Health technology diffusion in developing countries: a case study of CT scanners in Brazil,. *Health Policy and Planning, Volume 26, Issue 5*, 385–394.
- Hwang, I., Lee, Y., Yoo, C., Min, C., Yim, D., & Kim, J. (2019). Towards Interpersonal Assistants: Next-Generation Conversational Agents. *IEEE Pervasive Computing*, 21-31.
- Nicholas G. Fischer, A. C. (2022). Tapping basement membrane motifs: Oral junctional epithelium for surface-mediated soft tissue attachment to prevent failure of percutaneous devices. *Acta Biomaterialia, Volume 141*, 70-88.
- Incarone, P. P., Bodini, A. P., Sabina, S. M., Colella, R. P., Tumolo, M. R., Fawdry, M. E., . . . Leo, C. G. (2021). Simulated versus physical bench tests: The economic evaluation of the InSilc platform for designing, developing, and assessing vascular scaffolds. *Medicine*.
- Ireland, D. C., & Hine, D. (2007). Harmonizing science and business agendas for growth in new biotechnology firms: Case comparisons from five countries. *Technovation*, 676-692.
- Jacob, M. L. (2012). Gestonurse: a robotic surgical nurse for handling surgical instruments in the operating room. *Journal of Robotic Surgery*, 53-63.
- Jadhav, S., Chunkhare, M., & Jadhav, J. (2017). Medical Devices Access in Asian Countries: Sustainable Growth Trajectory in India. *Journal of Biomedical Engineering and Medical Devices*, 2(3). doi:10.4172/2475-7586.1000132
- Jain, M. a. (2018). Evaluating and informing the design of chatbots. *Proceedings of the 2018 designing interactive systems conference*, (pp. 895--906).
- Jan B. Pietzsch, M. G. (2013). Medical Device Innovators and the 510(k) Regulatory Pathway: Implications of a Survey-Based Assessment of Industry Experience—Part 2: Medical Device Ecosystem and Policy. *Journal of Medical devices*.
- Jarosławski, S. S. (2013). Case studies of innovative medical device companies from India: barriers and enablers to development. *BMC Health Services Research*.
- Jarosławski, S., & Saberwal, G. (2013). Case studies of innovative medical device companies from India: Barriers and enablers to development. *BMC Health Services Research*.
- Jaroslowski, S., & Saberwal, G. (2014). In eHealth in India today, the nature of work, the challenges and the finances: an interview-based study. *BMC Medical Informatics & Decision Making*.
- Johner, P. D. (2015, December 10). *Agile Software Development for Medical Devices*. Retrieved from Johner-Institute: <https://www.johner-institute.com/articles/software-iec-62304/software-lifecycle/agile-software-development/>
- Joshi, D., Sharma, I., Gupta, S., Singh, T., Dhiman, S., Prashar, A., . . . SK., S. (2021). A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. *Environ Sci Pollut Res Int.*, 28(42), 59608-59629. doi:10.1007/s11356-021-16345-5
- Jurgens, M., Berthon, P., Papania, L., & Shabbir, H. A. (2010). Stakeholder theory and practice in Europe and North America: The key to success lies in a marketing approach. *Industrial Marketing Management*, 769-775.
- K. Zinchenko, C. -Y.-T. (2017). A Study on Speech Recognition Control for a Surgical Robot. *IEEE Transactions on Industrial Informatics*, 607-615.

- Kale, D. (2013). Regulation quagmire, inclusive innovations and arrested development: evidence from the Indian medical device industry. *11th Globelics International Conference*. Ankara, Turkey: Open Research Online. Retrieved from <https://citeseerx.ist.psu.edu/doc/10.1.1.669.7026>
- Kaptelinin, V., Kuutti, K., & Bannon, L. (1995). Activity theory: Basic concepts and applications. *Human-Computer Interaction*. Berlin, Heidelberg: Springer. doi:10.1007/3-540-60614-9_14
- Kaur, R., Kaur, K., & Kaur, R. (2018). Menstrual Hygiene, Management, and Waste Disposal: Practices and Challenges Faced by Girls/Women of Developing Countries. *Journal of Environmental and Public Health*.
- Kenneth, F., Enrico, P., & Eric, C. (2014). Biotechnology Commercialization Strategies: Risk and Return in Interfirm Cooperation. *Journal of Product Innovation Management*, 32(6), 971-996. doi:10.1111/jpim.12218
- Kheir O, S. S. (2021). Efficient Quality Management in MedTech Start-Ups (Based on ISO 13485). *Medical Devices*, 313-319.
- Khilji, S. E., Mroczkowski, T., & Assudani, R. (2012). Balancing growth and innovation in Indian biotech firms. *South Asian Journal of Global Business Research*, 256-275.
- Khilji, S. E., Mroczkowski, T., & Bernstein, B. (2006). From invention to innovation: Toward developing an integrated innovation model for biotech firms. *Journal of Product Innovation Management*, 528-540.
- Kimani, S., Kabiru, C., & Muteshi, J. e. (2020). Exploring barriers to seeking health care among Kenyan Somali women with female genital mutilation: a qualitative study. . *BMC Int Health Hum Rights*, 20(3). doi:10.1186/s12914-020-0222-6
- Kocielnik, R. a. (2019). HarborBot: a chatbot for social needs screening. *AMIA Annual Symposium Proceedings*, 552-561.
- Kvale, S. (1996). *Interviews : An Introduction to Qualitative Research Interviewing*. Thousand Oaks California: Sage Publications.
- Landry, L. (2020, Dec 15). *What Is Human-Centered Design?* Retrieved from Harvard Business School Online: <https://online.hbs.edu/blog/post/what-is-human-centered-design>
- Langevin, R. a. (2021). Heuristic evaluation of conversational agents. *Proceedings of the 2021 CHI Conference on Human Factors in Computing Systems*, (pp. 1--15).
- Leonard, E., de Kock, I., & Bam, W. (2020). Barriers and facilitators to implementing evidence-based health innovations in low- and middle-income countries: A systematic literature review. *Evaluation and Program Planning*.
- Li, M., Wang, Z., & Zhao, X. (2018). The role of indigenous technological capability and interpersonal trust in supply chain learning. *Industrial Management & Data Systems*, 118(5). doi:10.1108/IMDS-08-2017-0350
- Lim, K. S.-K. (2000). Physical interaction and multi-aspect representation for information intensive environments. *Proceedings 9th IEEE International Workshop on Robot and Human Interactive Communication* (pp. 436-443). Osaka, Japan: IEEE.
- Luca, L. M., Verona, G., & Vicari, S. (2010). Market Orientation and R&D Effectiveness in High-Technology Firms: An Empirical Investigation in the Biotechnology Industry. *Journal of Product Innovation Management*, 27(3), 299-320. doi:10.1111/j.1540-5885.2010.00718.x
- Magistretti, S., Dell'Era, C., Verganti, R., & Bianchi, M. (2021). The contribution of Design Thinking to the R of R&D in technological innovation. *R&D management*, 52(1), 108-125. doi:<https://doi.org/10.1111/radm.12478>
- Mahal, A. V. (2006). Diffusion of diagnostic medical devices and policy implications for India. *International Journal of Technology Assessment in Health Care*, 184-190.

- Malkin, R., & Oldenburg Beer, K. v. (2013). Diffusion of novel healthcare technologies to resource poor settings. *Annals of Biomedical Engineering*, 41(9), 1841-1850. doi:10.1007/s10439-013-0750-5
- Marks, I. H., Thomas, H., Bakhet, M., & Fitzgerald, E. (2019). Medical equipment donation in low-resource settings: A review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries. *BMJ Global Health*.
- Matthew Prime, I. A. (2018). From Malawi to Middlesex: the case of the Arbutus Drill Cover System as an example of the cost-saving potential of frugal innovations for the UK NHS. *BMJ Innovations*.
- Matthew S. Waninger, R. G. (2013). Manufacturer evaluations of endograft modifications. *Journal of Vascular Surgery, Volume 57, Issue 3*, 826-828.
- Mayaka, M. A., & Prasad, H. (2012). Tourism in Kenya: An analysis of strategic issues and challenges. *Tourism Management Perspectives*, 48-56.
- Mazumdar-Shaw, K. (2018). Leveraging affordable innovation to tackle India's healthcare challenge. *IIMB Management Review*, 30(1), 37-50. doi:10.1016/j.iimb.2017.11.003
- Mctear, M. (2004). *Spoken dialogue technology - toward the conversational user interface*. Springer.
- Medina, L. A., Kremer, G. E., & Wysk, R. A. (2013). Supporting medical device development: a standard product design process model. *Journal of Engineering Design*, 24(2), 83-119. doi:10.1080/09544828.2012.676635
- Messori A, T. S. (2019). Tenders for the Procurement of Medical Devices: Adapting Cost-Effectiveness Rules to the Requirements of the European Public Procurement Directive. *Therapeutic Innovation & Regulatory Science*.
- Ministry of Health & Family Welfare, G. o. (2017). *MEDICAL DEVICES RULES, 2017*. Retrieved from Central Drugs Standard Control Organization: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf
- Ministry of Health & Family Welfare, G. o. (2019-23). *Medical Device & Diagnostics*. Retrieved from Central Drugs Standard Control Organization: <https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/>
- Molich, R. a. (1990). Improving a human-computer dialogue. *Communications of the ACM*, 338--348.
- Moore Jr, J. E., & Maitland, D. J. (2014). *Biomedical Technology and Devices- 2nd Edition*. CRC Press. doi:ISBN 9780367269005
- Murad, C. a. (2018). Design guidelines for hands-free speech interaction. *Proceedings of the 20th International Conference on Human-Computer Interaction with Mobile Devices and Services Adjunct*, (pp. 269--276).
- Murad, C. a. (2019). Revolution or evolution? Speech interaction and HCI design guidelines. *IEEE Pervasive Computing*, 33--45.
- Murad, C., Munteanu, C., R. Cowan, B., & Clark, L. (2021). Finding a New Voice: Transitioning Designers from GUI to VUI Design. *ACM International Conference Proceeding Series*.
- N.G. Patel, R. N. (2020). The first knee prosthesis to go through beyond compliance: A new standard for the safe introduction of orthopaedic implants. *The Surgeon*, 27-32.
- Nass, C. I. (2005). *Wired for speech: How voice activates and advances the human-computer relationship*. MIT press Cambridge.
- Nielsen, J. a. (1990). Heuristic evaluation of user interfaces. *Proceedings of the SIGCHI conference on Human factors in computing systems*, (pp. 249--256).
- Nielsen, J. (n.d.). *Nielsen Norman Group*. Retrieved from 10 Usability Heuristics for User

- Interface Design: <https://www.nngroup.com/articles/ten-usability-heuristics/>
- Nsiah-Asamoah, C., Doku, D. T., & Agblorti, S. (2020). Mothers' and Grandmothers' misconceptions and socio-cultural factors as barriers to exclusive breastfeeding: A qualitative study involving Health Workers in two rural districts of Ghana. *PLOS ONE*. doi:10.1371/journal.pone.0239278
- O'Cearbhaill, R. M. (2019). Medical device patents—a review of contemporary global trends with an Irish comparison. *Irish Journal of Medical Science*, pages 653–659.
- Oeij, P. R., van der Torre, W., Vaas, F., & Dhondt, S. (2019). Understanding social innovation as an innovation process: Applying the innovation journey model. *Journal of Business Research*, 243-254.
- Office of Minority Health, U. D. (2002). *American Institutes for Research. Teaching cultural competence in health care: A review of current concepts, policies, and practices.* . American Institutes for Research.
- P. Kulkarni, A. M. (2019). Conversational AI: An Overview of Methodologies, Applications & Future Scope. *5th International Conference On Computing, Communication, Control And Automation (ICCUBEA)* (pp. 1-7). IEEE.
- Pascale, C., & Ben-Tzion, K. (n.d.). *Workflow Toolkit and*. Retrieved from Digital Healthcare Research: <https://digital.ahrq.gov/sites/default/files/docs/page/workflow-toolkit-and-lessons-in-user-centered-design.pdf>
- Pati S, S. K. (2019). Care-seeking pathways, care challenges, and coping experiences of rural women living with rheumatoid arthritis in Odisha, India. *Prim Health Care Res Dev.*, 20. doi:10.1017/S146342361900032X.
- Paul E Goss, K. S.-W.-B.-G.-C.-I.-L. (2014). Challenges to effective cancer control in China, India, and Russia. *The Lancet Oncology*, 489-538.
- PE, G., K, S.-W., BL, L.-B., L, F., J, L., Y, C.-G., . . . R, B. (2014). Challenges to effective cancer control in China, India, and Russia. *Lancet Oncology*, 15(5), 489-538. doi:10.1016/S1470-2045(14)70029-4
- Piaggio, D., Castaldo, R., Cinelli, M., Cinelli, S., Maccaro, A., & Pecchia, L. (2021). A framework for designing medical devices resilient to low-resource settings. *Global Health*, 17(64). doi:<https://doi.org/10.1186/s12992-021-00718-z>
- Pisano, G. P. (2006). *Science Business: The Promise, the Reality, and the Future of Biotech*. Harvard Business School Press.
- Polisena J, J. J. (2014). A proposed framework to improve the safety of medical devices in a Canadian hospital context. *Medical Devices: Evidence and Research, Volume 7*, 139-147.
- Portales, L. (2019). *Social Innovation and Social Entrepreneurship: Fundamentals, Concepts, and Tools*. Switzerland : Springer Nature .
- R, A., J, O., EM, M., & al, e. (2020). Responding to maternal, neonatal and child health equipment needs in Kenya: a model for an innovation ecosystem leveraging on collaborations and partnerships. *BMJ Innovations* , 6, 85-91. doi:10.1136/bmjinnov-2019-000391
- Rajesh, B., J, C., I, P., F, Y., & SD., M. (2013). Global comparative healthcare effectiveness research: evaluating sustainable programmes in low & middle resource settings. *Indian J Med Res.*, 137(3), 494-501.
- Ramírez-Rios, L., Camargo-Wilson, C., Olguín-Tiznado, J., López-Barreras, J., Inzunza-González, E., & García-Alcaraz, J. (2021). Design of a Modular Plantar Orthosis System through the Application of TRIZ Methodology Tools. *Applied Sciences*.
- Rane, S. B., & Kirkire, M. S. (2016). Analysis of barriers to medical device development in India: an interpretive structural modelling approach. *International Journal of Systems Assurance Engineering and Management*, 356-369.

- Rosenfeld, R. a. (2001). Universal speech interfaces. *interactions*, 34--44.
- Rudnick, A. I. (1996). Speech interface guidelines. *Unpublished manuscript*.
- S, C. R., & D., S. (2012). Tribal recommendations for designing culturally appropriate technology-based sexual health interventions targeting Native youth in the Pacific Northwest. *Am Indian Alsk Native Ment Health Res. , 19(1)*, 76-101. doi:10.5820/aian.1901.2012.76
- S, H., M, D., F, Z., & M., T. (2021). Big data and predictive analytics in healthcare in Bangladesh: regulatory challenges. *Heliyon*, 7(6). doi:10.1016/j.heliyon.2021.e07179
- Sabet Sarvestani, A., Coulestantos, M., & Sienko, K. (2021). Defining and characterizing task-shifting medical devices. *Global Health*, 17(60). doi:10.1186/s12992-021-00684-6
- Sahu, S., & Panja, S. (2017). Current status and challenges of medical device innovations-Indian perspective. *Journal of Intellectual Property Rights*, 329-335.
- Sateesh, J., Guha, K., Dutta, A., Sengupta, P., & Rao, K. S. (2022). Design and Modeling of Bioreactor Utilizing Electrophoresis and Di-Electrophoresis Techniques for Regenerating Reabsorption Function of Human Kidney PCT in Microfluidics Environment. *IEEE Transactions on NanoBioscience*, vol. 21, no. 4, 529-541.
- Schultz., M. A. (2007). Human-robot interaction: a survey. *Foundations and Trends in Human-Computer Interaction*, 203–275.
- Schwartz-Lasfargues, C., Roux-Gendron, C., Edomskis, P., Marque, I., Bayon, Y., Lange, J. F., . . . & Trilling, B. (2022). Development of a Connected Sensor System in Colorectal Surgery: User-Centered Design Case Study. *JMIR Human Factors*, 9(3). doi:10.2196/31529
- Sebastian Bodenstedt, M. W.-S. (2020). Artificial Intelligence-Assisted Surgery: Potential and Challenges. *Visceral Medicine*, 450-455.
- Sehgal, C. (2010). *Medical technology industry in India Riding the growth curve*. Deloitte India.
- Seibert, P. S., Stridh-Igo, P., & Zimmerman, C. G. (2002). A checklist to facilitate cultural awareness and sensitivity. *Journal of Medical Ethics*, 3(28), 143-146. doi:10.1136/jme.28.3.143
- Selvaraj, S., Bhan, N., & Mahal, A. (2022). Indian Health Review 2022. *India Health System Review Health Systems in Transition*.
- Sharma, D., & Chandra, A. (2020). Medical Device Rules - 2017, India: An Insight. *Applied Clinical Research, Clinical Trials and Regulatory Affairs*, 7(2), 126 - 134. doi:10.2174/2666255813666190912114043
- Shneiderman, B. a. (2010). *Designing the user interface: Strategies for effective human-computer interaction*. Pearson Education India.
- Siontorou, C. G., & Batzias, F. A. (2010). Innovation in biotechnology: moving from academic research to product development—the case of biosensors. *Critical Review in Biotechnology*, 79-98. doi:10.3109/07388550903427298
- SK, M., & A., K. (2017). ut-of-pocket expenditure and catastrophic health spending on maternal care in public and private health centres in India: a comparative study of pre and post national health mission period. *Health Econ Rev.*, 7(18). doi:10.1186/s13561-017-0167-1.
- Smith, J. W. (2015). New and emerging technologies for the treatment of inherited retinal diseases: a horizon scanning review. *Eye*, 1131–1140.
- Son, S. C., & Zo, H. (2021). Do R&D resources affect open innovation strategies in SMEs: the mediating effect of R&D openness on the relationship between R&D resources and firm performance in South Korea's innovation clusters. *Technology Analysis & Strategic Management*, 35(11), 1385-1397. doi:10.1080/09537325.2021.2007237

- Song, X., Hu, M., Li, B., Zhang, K., Zhang, X., & Wang, L. (2022). Advancing medical device regulatory reforms for innovation, translation and industry development in China. *Journal of Orthopaedic Translation, Volume 37*, 89-93.
- Stephan Winterhalter, M. B. (2017). Business Models for Frugal Innovation in Emerging Markets: The Case of the Medical Device and Laboratory Equipment Industry. *Technovation*, 3-13.
- Still, B., & Crane, K. (2017). *Fundamentals of User-Centered Design : A Practical Approach* . Taylor and Francis. doi:10.4324/9781315200927
- Stone, V. L. (2012). Modeling technology innovation: How science, engineering, and industry methods can combine to generate beneficial socioeconomic impacts. *Implementation science*, 7(44). doi:10.1186/1748-5908-7-44
- Sudip, B., N, S., & A., S. (2019). Designing culturally acceptable screening for breast cancer through artificial intelligence-two case studies. *Family Med Prim Care*, 8(2), 760-762. doi:10.4103/jfmpc.jfmpc_391_18
- Suhm, B. (2003). Towards best practices for speech user interface design. *Eighth European Conference on Speech Communication and Technology*.
- Suresh, N., & Chandan, S. R. (2021). *India Bioeconomy Report*. "Make in India" cell of Biotechnology Industry Research Assistance Council (BIRAC) by Association of Biotechnology Led Enterprises (ABLE).
- Tarricone, R. &. (2011). Challenges in the clinical and economic evaluation of medical devices: The case of transcatheter aortic valve implantation. *ournal of Medical Marketing*, 221-229.
- Tawate, S., Gupta, R., & Jain, K. (2019). Development of a Technology Commercialization Model for Indian Biotechnology Firms. *IEEE Transactions on Engineering Management*. doi:10.1109/TEM.2019.2939417
- Thaete K, R. K.-R. (2019). User-Informed Medical Device Development: A Case Study for Pediatric Malnutrition Assessment. *Global Pediatric Health*.
- Thomas, P. a. (2020). Expressions of style in information seeking conversation with an agent. *Proceedings of the 43rd International ACM SIGIR Conference on Research and Development in Information Retrieval*, (pp. 1171--1180).
- Tranfield, D., Denyer, D., & Smart, P. (2003). Towards a Methodology for Developing Evidence-Informed Management Knowledge by Means of Systematic Review. *British Journal of Management*, 207-222.
- Tucker, C. M., Marsiske, M., Rice, K. G., Nielson, J. J., & Herman, K. (2011). Patient-centered culturally sensitive health care: model testing and refinement. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association*, 3(30), 342-350. doi:10.1037a0022967.
- Upadhyay, P. (n.d.). *FLOW- Frugal Design Workflow Toolkit*. Retrieved from Pankaj Upadhyay: <https://pankajupadhyaydod.weebly.com/flow---frugal-design-toolkit.html>
- Uppal, A., Chakrabarti, R., Chirmule, N., Rathore, A., & Atouf, F. (2021). Biopharmaceutical Industry Capability Building in India: Report from a Symposium. *Journal of Pharmaceutical Innovation*.
- Verma, G., & Ravichandran, S. (2020). Evolution of Biotechnology as a Million Dollar Market: The Management and Commerce of a Biotech Start-up. In A. Saxena, *Biotechnology Business - Concept to Delivery* (pp. 161-178). Springer.
- Viceconti M, C. C. (2017). In silico assessment of biomedical products: The conundrum of rare but not so rare events in two case studies. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 455-466.
- Wall, J., Hellman, E., Denend, L., Rait, D., Venook, R., Lucian, L., . . . Brinton, T. J. (2017). The Impact of Postgraduate Health Technology Innovation Training: Outcomes of the

- Stanford Biodesign Fellowship. *Annals of Biomedical Engineering*, 1163-1171.
- Walters, A., Thomas, N., Brown, R., & Lewis, A. (2001). Barriers to Effective Product Development Within SMEs In the Medical Manufacturing Sector. *Proc. of the Fourth SMESME International Conference* (p. 113). Aalborg, Denmark: Department of Production, Aalborg University.
- Wei, Z. a. (2018). Evaluating speech-based smart devices using new usability heuristics. *IEEE Pervasive Computing*, 17, 84--96.
- Wenbo Liu, X. S. (2017). Review and approval of medical devices in China: Changes and reform. *Journal of Biomedical Materials Research*.
- WHO. (2010). *Medical Devices : Managing the mismatch, an outcome of the priority medical devices project*. World Health Organization Press.
- Wilfried, Z., & Marcus, W. (2013). The effect of alliances on innovation patterns: an analysis of the biotechnology industry. *Industrial and Corporate Change*, 1497-1524. doi:10.1093/icc/dts042
- Williams, A. (2009). User-centered design, activity-centered design, and goal-directed design: a review of three methods for designing web applications. *SIGDOC '09: Proceedings of the 27th ACM international conference on Design of communication*. ACM Digital Library. doi:10.1145/1621995.1621997
- Women., A. C. (2011). ACOG Committee Opinion No. 493: Cultural sensitivity and awareness in the delivery of health care. *Obstet Gynecol.*, 1258-61. doi:10.1097/AOG.0b013e31821d7db0
- World Health Organization. (2011). *Local Production and Technology Transfer to Increase Access to Medical Devices*. World Health Organization Press.
- Yin, R. K. (2013). Validity and generalization in future case study evaluations. *Evaluation*, 321-332.
- Yock, Zenios, Makower, Brinton, Kumar, Watkins, & Denend. (2010). *Biodesign: The Process of Innovating Medical Technologies*. Cambridge University Press.
- Zaufenberger, L., Stampfer, P., Mader, J. K., Gold, H., & Donsa, K. (2022). Towards the Development of a Medical App for the Detection of Diabetic Foot Syndrome and Pressure Ulcers. *Current Directions in Biomedical Engineering*, 8(2), 293 - 296. doi:10.1515/cdbme-2022-1075
- Zidorn, W., & Wagner, M. (2013). The effect of alliances on innovation patterns: an analysis of the biotechnology industry. *Industrial and Corporate Change*, 22(6), 1497–1524. doi:10.1093/icc/dts042
- Zippel, C. B.-J. (2017). Innovation for Safe and Effective Medical Devices: Contributions From Postmarket Surveillance. *Therapeutic Innovation & Regulatory Science*, 237–245.

Appendix A.1: Conversational AI Natural Language Understanding (NLU) Pipeline

For the natural language understanding (NLU) during conversational interactions following Rasa pipeline comprising algorithms for word tokenization, feature vector creation, and user utterance classification was implemented:

- i. A white space tokenizer algorithm splits an input sentence into a list of individual words or tokens by detecting pauses between the words in a sentence. A representation of the tokenization process is shown in Figure 0.1.

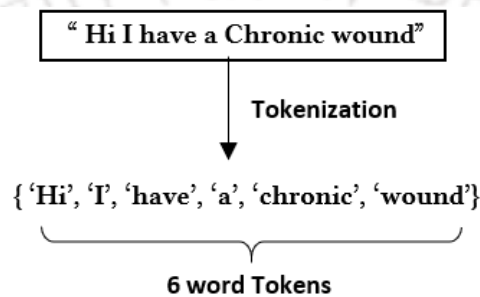


Figure 0-1: User spoken sentence tokenization process

- ii. Then, as shown in Figure 0.2 two featurizer algorithms are implemented: Count Vectorizer and Word embeddings to generate sparse and dense numeric features to make data fetchable to machine learning models as input. Besides features of tokens, we also generate features for the entire sentence that the user utters which is known as CLS (Sentence Classification) token.

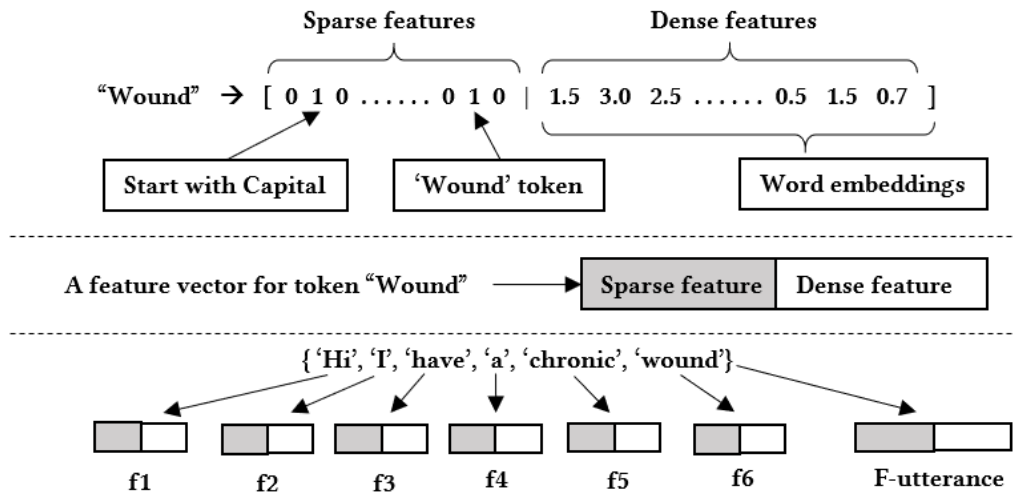


Figure 0-2: Feature vector generation process

- iii. The pipeline uses a Dual Intent and Entity Transformer (DIET) as a classifier to extract user intent and entities from the conversations in a recurrent manner. This enabled the system to detect and recognize user inputs into 'intents' and 'entities'. Intents define 'user intention, purpose', whereas entities define 'specific variables' in a user input sentence. For example, if the user says, "I have a chronic wound", then the system could recognise the intent as 'Clinical enquiry' and 'Wound' as an entity that is a specific 'disease state'. Similarly, if the user says, "My name is X", then the system was capable is recognizing the intent 'Name disclosure' and entity 'user name' is 'X'. A representation of the intent entity extraction process is shown in Figure 0.3.

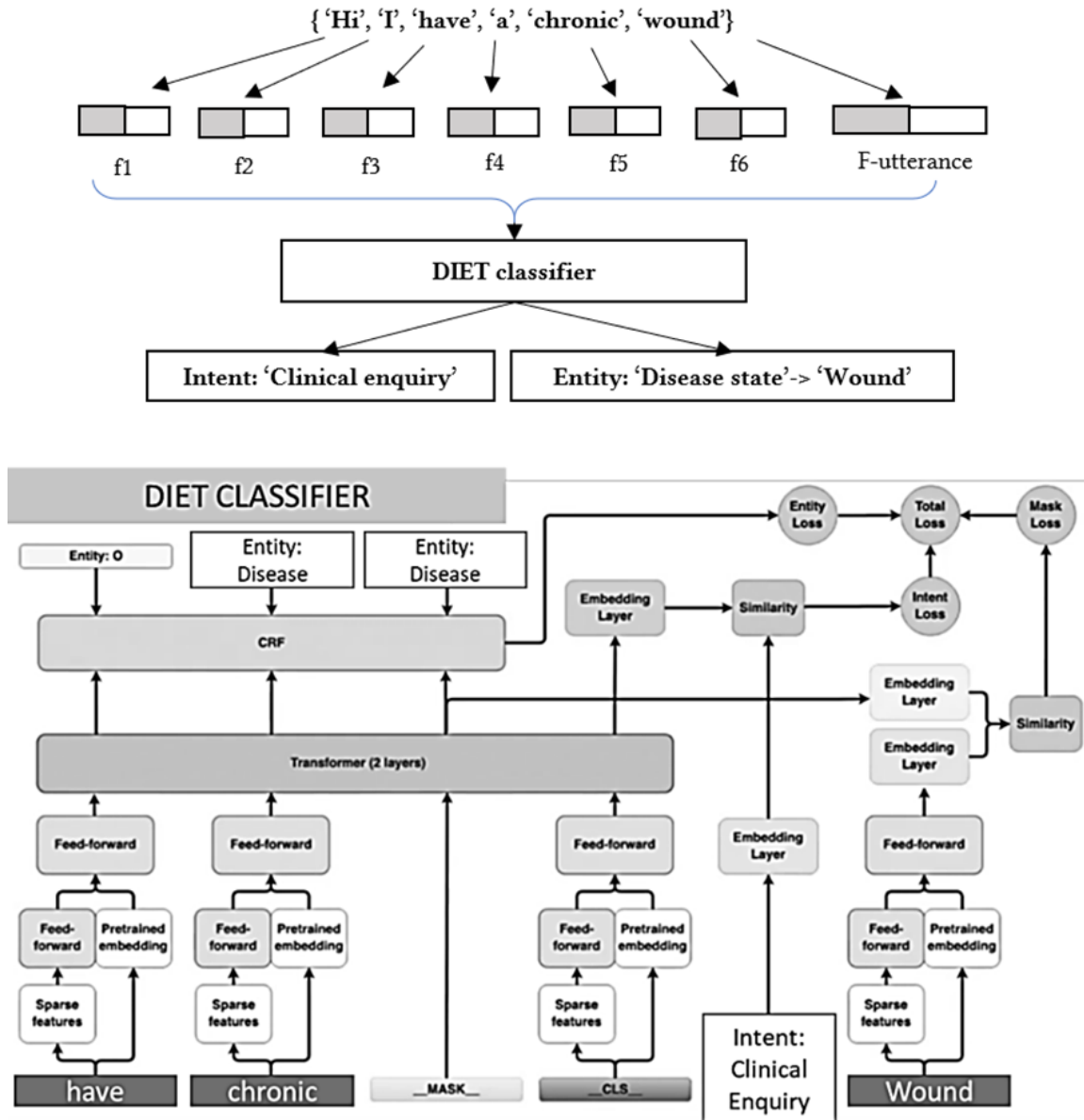


Figure 0-3: Diet classifier and its working process

A representation of the intent-entity extraction process from user utterance is shown in Figure 0.4.

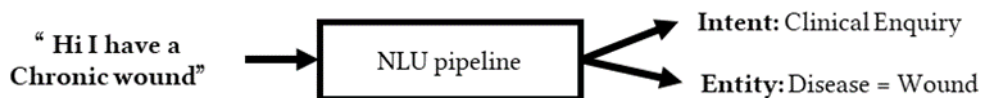


Figure 0-4: A representation of classifying user utterances into intents and entities using DIET classifier

Again, Natural language generation modality (Rasa Core) comprised a probability-based dialogue management model which enable the Conversational AI bot to decide set of actions or utterances based on conversational user input. During development the model was

trained with example conversational flow paths, possible bot utterances and actions. Further, various Rasa policies for conversation management and exception handling were implemented to gracefully hold a natural conversation and handle out-of-context user inputs.



Appendix A.2: Training components and data for the Conversational AI system

Rasa NLU modality handles intent classification, entity extraction, and response retrieval. For that the system needs to be trained with a large set of user intent and entities data, and response retrieval mechanisms (Example: Slots, Forms). Similarly, for the Rasa Core modality training example for various possible conversational paths, bot utterances and actions needed to be generated. The training corpus used in the study comprised of manually validated linguistic text data and was generated over a period of 6 months. Here are details:

- i. Training data for user ‘intents’: Based on real-life conversational data, the NLU model was initially trained with 44 different intents along with example data for each intent type. Examples of such intents are ‘greet’, ‘take command’, ‘affirm therapy’, ‘deny’, ‘affirm set pressure’, ‘out of scope’, ‘clinical enquiry’, ‘about npwt’, ‘safety instruction’, ‘initiate procedure’ etc. Figure 0.5 below shows corresponding training data for intents ‘about npwt’ and ‘initiate procedure’. From such training corpus and data, the Conversational AI bot can detect user intent and perform follow-up utterances or actions, accurately.

```
## intent:about_npwt
- What is npwt?
- What is neagtive pressure wouund therapy?
- Can you explain the NPWT procedure?
- How the npwt procedure will be done?
- What is the procedure for neagtive pressure wound therapy?
- How to perform the npwt procedure?
- What are steps of npwt process?
- I would like to no more details
- Please give me more details about the therapy
- so what is the procedure?
- ok provide me more detail information

## intent:initiate_procedure
- yes please initiate the procedure
- yes initiate the process
- initiate the procedure
- Please initiate the procedure
- Please start the procedure
- Please initiate the therapy
- Can you start the therapy?
- Go ahead with the npwt therapy
- yeah, pls initiate the process
```

Figure 0-5: Examples of ‘intent’ related training data

- ii. Training data for user defined ‘entities’: The NLU model was initially trained with 13 entity types and example text data to make the AI system detect and extract user-defined

input parameters for further use in follow-up bot utterances or actions. Examples of such entities are ‘age’, ‘gender’, ‘name’, ‘pressure’, ‘time’ etc. Figure 0.6 shows example of corresponding training data for entity ‘minus’ and ‘pressure1’. Such training data enabled the bot to recognize user defined pressure value and instruction to decrease it.

```
## intent:minus_intent
- [decrease](minus) pressure
- DECREASE
- [down](minus) pressure
- [reduce](minus) pressure
- [decrease](minus) pressure
- [down](minus) pressure
- [reduce](minus) pressure

## intent:set_pressure
- set pressure of [75 mmHg](pressure1)
- set pressure equal to [65 mmHg](pressure1)
- increase pressure to [55 mmHg](pressure1)
- increase the pressure upto [45 mmHg](pressure1)
- set pressure at [35 mmHg](pressure1)
- set the pressure to [120 mmHg](pressure1)
- decrease pressure to [65 mmHg](pressure1)
- decrease the pressure to [35 mmHg](pressure1)
- reduce pressure to [55 mmHg](pressure1)
- reduce pressure upto [35 mmHg](pressure1)
- [75 mmHg](pressure1)
- [85 mmHg](pressure1)
- [110 mmHg](pressure1)
```

Figure 0-6: Examples of ‘entity’ related training data

- iii. Training data for different conversation flow paths or ‘stories’: The NLG modality (Rasa Core) was initially trained with 40 different happy paths or stories to detect and manage the possible flow of conversations. Such happy paths also train the NLU model to decide recommended utterances or corresponding actions. Figure 0.7 below represents how the Conversational AI bot makes decisions during conversational interaction with the user. Via various stories, we defined how the Conversational AI bot will use Forms, Button feature, Slots, Custom actions and textual Utterances to manage clinical operation of the device. The Form policy allow gather user input in sequential mode. The button feature allow user to make decisions after each instruction to control the conversation flow as per user choice. Similarly, slots are used to store user defined entity values. Figure 0.8 shows example of training data for possible conversation flow paths.

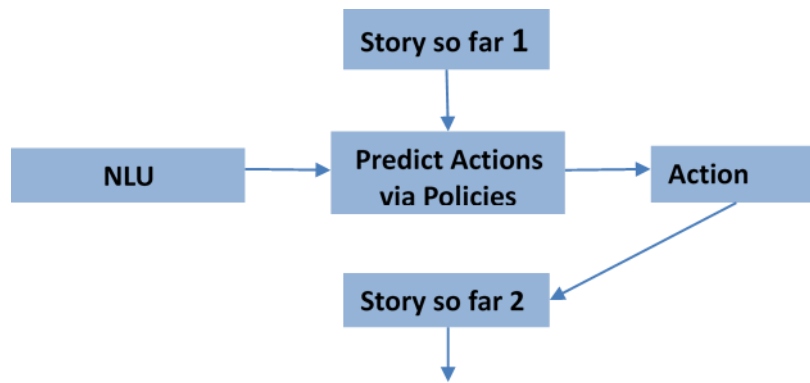


Figure 0-7: A representation of how the bot plan actions/utterances within a story

```

## instruction_1 path
* greet
  - utter_greet
## instruction_2 path
* clinical_enquiry
  - utter_clinical_enquiry
## take_command path
* take_command
  - utter_ask_command
* clinical_tasks
  - form_take_command
  - form{"name":"form_take_command"}
  - form{"name": null}
  - utter_confirm_command

## instruction_3 path
* initiate_procedure
  - action_deactivate_form
  - form_info
  - form{"name":"form_info"}
  - form{"name": null}
  - utter_submit

## instruction_4 path
* operation_instruction
  - utter_operation_instruction
  - form_therapy
  - form{"name":"form_therapy"}
  - form{"name": null}
  - utter_set_pressure
  # - utter_confirm_pressure
## affirm_form_therapy
* affirm_therapy
  - utter_operation_instruction
  # - action_therapy

## set_pressure path
* set_pressure
  - utter_set_pressure
## affirm_set_pressure
* affirm_set_pressure
  - action_set_pressure
  - utter_operation_instruction
  
```

Figure 0-8: Examples of 'story (conversational path)' related training data

- iv. Training data for possible bot 'utterances': The NLG modality (Rasa Core) was trained with a large set of different bot utterances along with example text replies. Examples of such bot utterances are 'utter_affirm', 'utter_ask_AGE', 'utter_ask_GENDER', 'utter_clinical_enquiry' etc. Figure 0.9 shows example training data for some bot utterances.

```

utter_ask_GENDER:
- text: What is your gender Male/Female?
utter_ask_NAME:
- text: "To confirm the procedure please let me register your 'NAME". \
  \ \n Please provide details"
utter_ask_affirmation:
- text: Did you mean?
utter_ask_command:
- text: Ready for command execution
utter_ask_pressure1:
- text: "\n At what pressure should I set the therapy for you?"
utter_ask_rephrase:
- text: Please ask for relevant information
utter_clinical_enquiry:
- text: 'I can assist you in the process of wound therapy. The available wound therapy
  is Negative Pressure Wound Therapy(NPWT) which is a state of art solution for
  healing chronic non healing wounds. Would you like to have the therapy or want
  to know more details '
utter_clinical_tasks:
- text: 'Please provide your inputs Eg: Plus, Minus , Start/Stop'
utter_confirm_command:
- text: "Action1: Initial pressure level={pressure1} \nAction2: time={time} \n\
  Action3: next pressure={pressure2} \n \n Starting the therapy as per command..."
utter_confirm_initiation:
- text: Do you want to initiate the NPWT therapy directly or want to know more about
  it? please confirm.
utter_confirm_pressure:
- buttons:
  - payload: /affirm_therapy
    title: Yes
  - payload: /operation_instruction
    title: No
  text: "I have set pressure = {pressure1} for your therapy.\n Do you confirm?"

utter_set_pressure:
- buttons:
  - payload: /affirm_set_pressure
    title: Yes

```

Figure 0-9: Examples of 'utterances' related training data

- v. Pre-defined 'actions': The Conversational AI system was fetched with specific algorithms as a part of custom actions, which are mostly functions, to sense or control the NPWT hardware modality. Other software level actions were form actions, button actions, etc. Figure below demonstrate example form action for capturing user defined entities 'pressure1', 'time' and 'pressure2'. Also, the Figure 0.10 shows the start/stop action that control the clinical therapy on/off state.

```

class ActionFormTakeCommand(FormAction):
#
    def name(self) -> Text:
        return "form_take_command"
#
    @staticmethod
    def required_slots(tracker:Tracker) -> List[Text]:
        return ["pressure1", "time", "pressure2"]

    def submit(self, dispatcher: CollectingDispatcher,
                tracker: Tracker,
                domain: Dict[Text, Any])-> List[Dict]:
        # utter submit template
        dispatcher.utter_message(text="\n OK, Done! \n")
        return[]

class ActionStartStop(Action):

    def name(self) -> Text:
        return "action_start_stop"

    def run(self, dispatcher: CollectingDispatcher,
            tracker: Tracker,
            domain: Dict[Text, Any]) -> List[Dict[Text, Any]]:
        dispatcher.utter_message(text="Starting device..")

        GPIO.output(7,True)
        time.sleep(3)
        GPIO.output(7,False)
        return []

```

Figure 0-10: Examples of custom actions

- vi. Additional NLU pipeline ‘policies’: A set of additional Rasa policies were chosen and implemented in the NLU, NLG pipeline to manage a graceful natural conversational interaction between the user and the Ai bot. For example, a ‘two-stage fall-back policy’ let the bot handle ‘out of context’ conversations gracefully where the bot does not receive prior training knowledge.

In addition to initial training corpus, the Conversational AI bot was fetched with further training data via Rasa’s interactive learning provision. Around 20 volunteers outside the development team took part in conversational interaction with the Bot for the clinical procedure. This enable further generation of training and testing data in the form of new stories (conversational paths), examples of intents and entities, additional bot utterances, intent labelling and action description. Figure 0.11 below represent the iterative process of interactive bot training

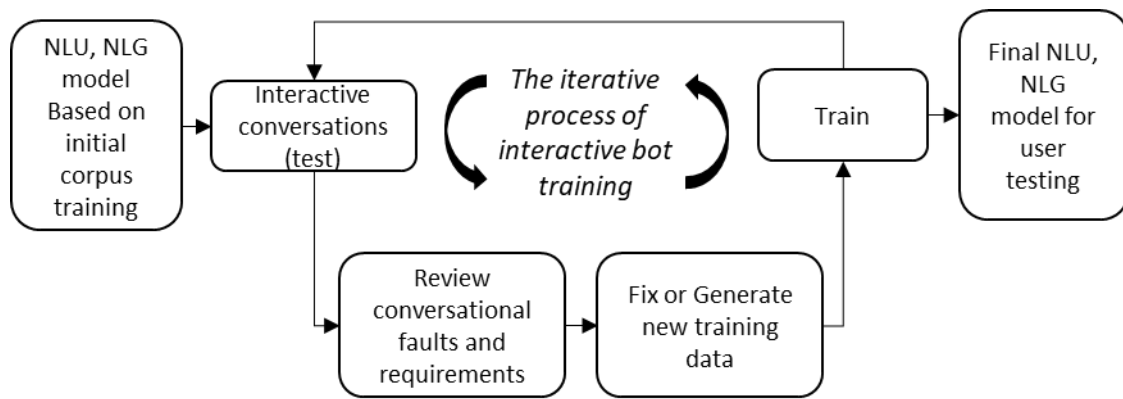


Figure 0-11: The iterative interactive bot training process after initial bot training

The final training data was validated to avoid duplication of similar training data across multiple intents and fix conflicts among the stories (conversational paths).

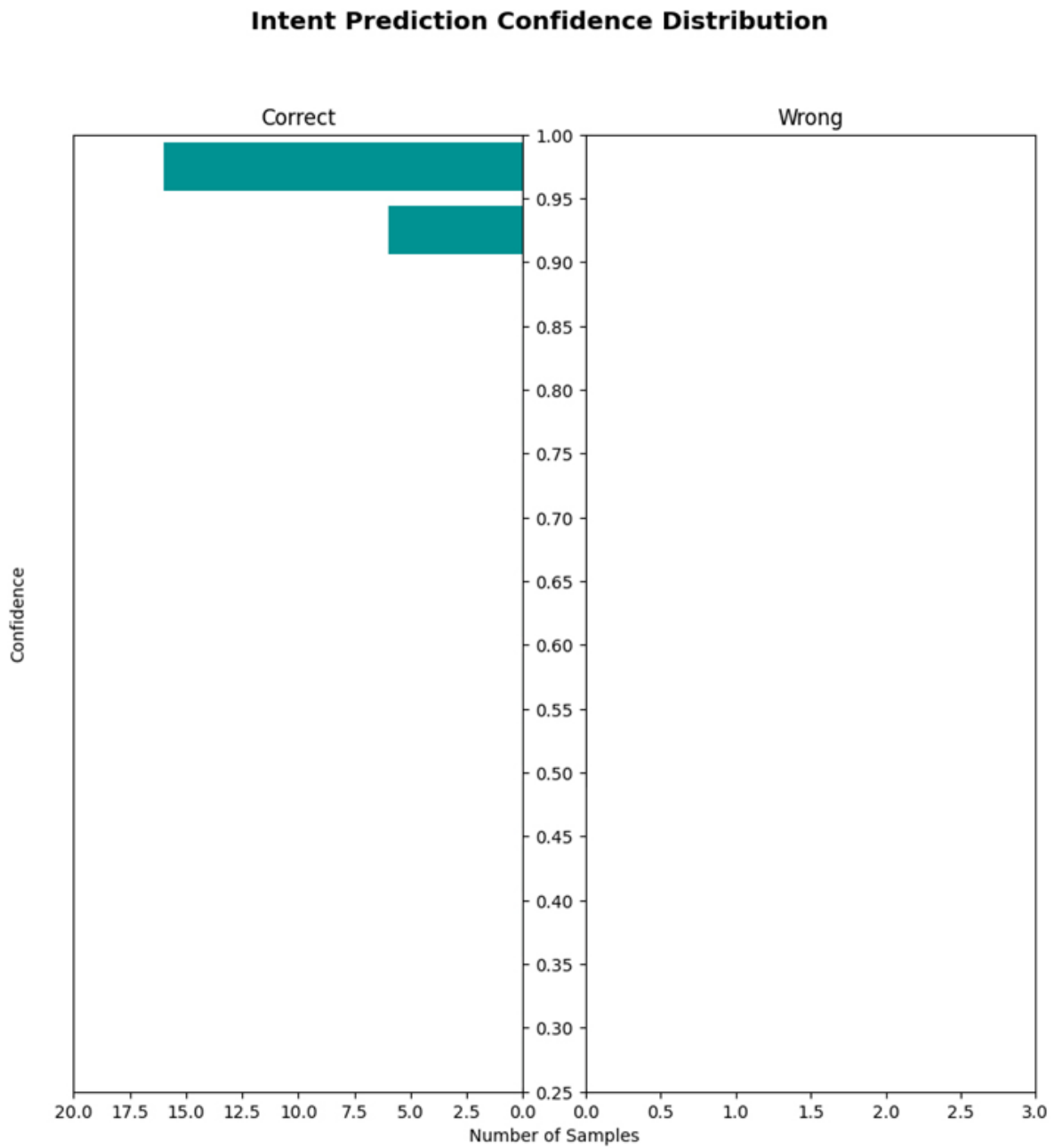


Figure 0-13: Result of Intent prediction confidence of the model on test data

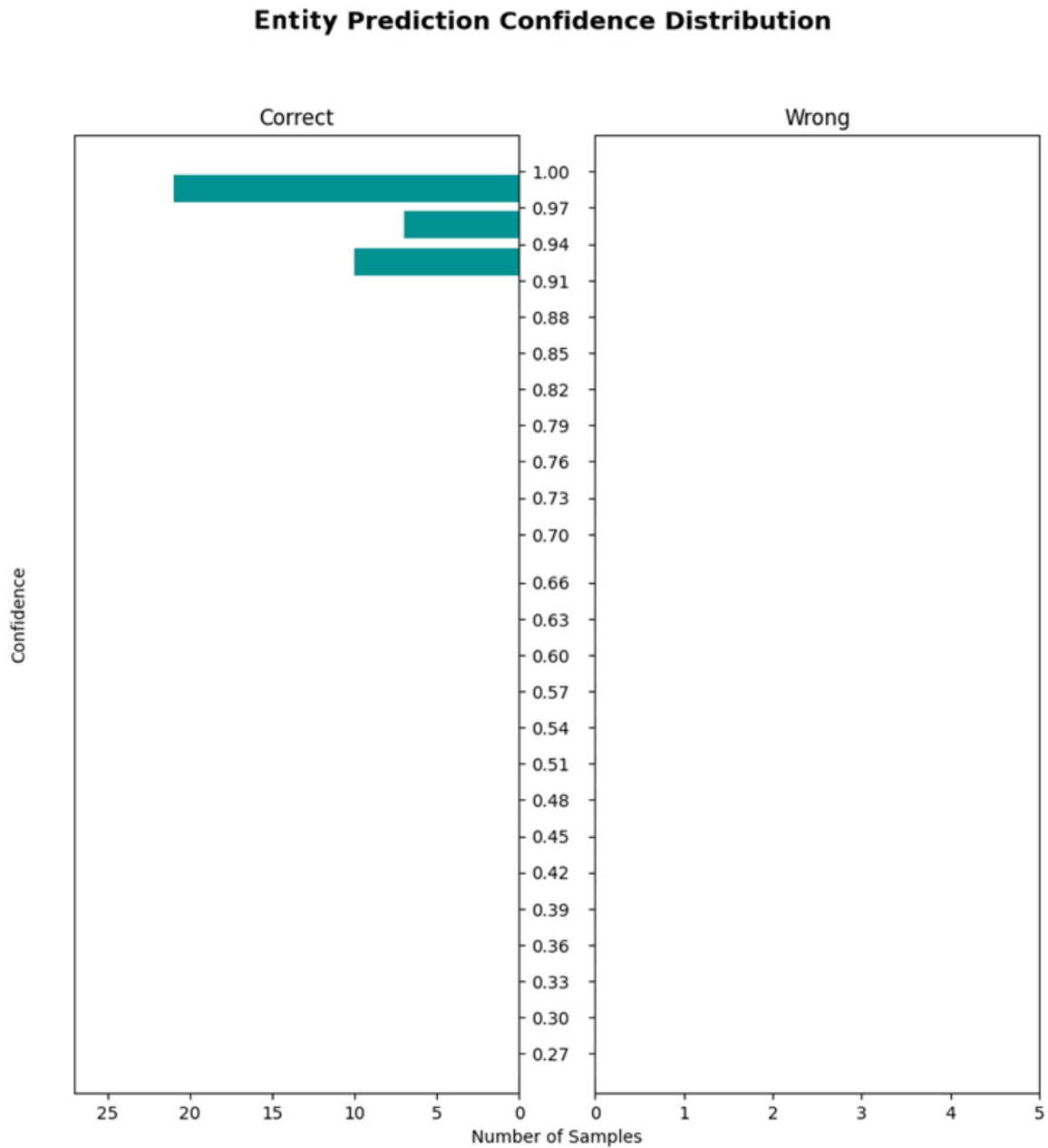


Figure 0-14: Result of Entity prediction confidence of the model on test data

Other Application-specific measures evaluated were success rate in triggering custom actions algorithms that control the NPWT device operation, which was 100%.

Appendix A.4: Open and Axial coding of Literature data to identify LMIC Specific Challenges of Medical Technology Innovation

1) Healthcare context and system

Table 0-A below shows the open and axial codes related to 'Healthcare context and system' along with literature source references.

Table 0-A: Open and axial codes related to 'Healthcare context and system'

Axial codes (challenges and barriers)	Open codes	Literature references
Non-uniform healthcare system and practices	<ul style="list-style-type: none"> Non-uniform healthcare resources and facility Non-uniform healthcare skills and practice 	(Selvaraj et al., 2022; Agarwal et al., 2018; Paul E Goss, 2014)
Inadequate healthcare resources, staff, infrastructure, and services.	<ul style="list-style-type: none"> Limited healthcare workforce poor healthcare and technical expertise lack of necessary laboratory resources, equipment and consumables Poor infrastructure for healthcare, maintenance and repair 	(Abbas et al., 2017; Agrawal et al., 2020; Harris, 2006; Marks et al., 2019; Hood & Rubinsky, 2020; Jarosławski & Saberwal, 2013)
Poor healthcare management of health institutions	<ul style="list-style-type: none"> Poor operational practices of health institutions Reluctance to adopt new technology 	(Ayah R, 2020; Ginsburg et al., 2020; Abrol et al., 2016; Alagumalai, 2019; Jaroslawski & Saberwal, 2014; Leonard et al., 2020; Beenkens & Stolk, 2010)
Inferior healthcare quality and practice	<ul style="list-style-type: none"> Poor healthcare service Poor healthcare coverage 	(Das et al., 2008; Kaur et al., 2018; Dixit et al., 2019; Harris, 2006)
Inefficient procurement and vendor payment processes of health institutions	<ul style="list-style-type: none"> Lack of accountability and inefficient vendor payment system Inefficient operation management activities of health institutions Slow and Complex procurement process and tender bidding system 	(Malkin & Oldenburg Beer, 2013; Beenkens & Stolk, 2010; Carpenet et al., 2011; Gupta & Thomke, 2018)

2) Organizational capabilities

Table 0-B below shows the open and axial codes related to 'Organizational capabilities' along with literature source references.

Table 0-B: Open and axial codes related to 'Organizational capabilities'

Axial codes (challenges and barriers)	Open codes	Literature references
Limited risk capacity and innovation appetite.	<ul style="list-style-type: none"> Unpredictable innovation and commercialization roadblocks Innovation ecosystem sensitive to external shock and crisis situations. Low-risk appetite of innovation firms Tendency for lower-risk class innovation rather than clinical need 	(Agrawal et al., 2020; Dixit et al., 2019; Jarosławski & Saberwal, 2013; D et al., 2021)

Axial codes (challenges and barriers)	Open codes	Literature references
Innovation misfit and misplacement	<ul style="list-style-type: none"> • Poor need and social impact assessment • Diverse contextual requirements beyond just clinical need • Innovation misfit for local conditions and existing healthcare setup • poor consideration of diverse stakeholders' requirements • poor implementation of innovation • innovation misfit to extreme and diverse environmental conditions 	(Couletianos et al., 2020; Bhat & Adhisivam, 2022; Gupta & Thomke, 2018; Marks et al., 2019; Arasaratnam & Humphreys, 2013; Leonard et al., 2020; Rajesh et al., 2013; Carpenet et al., 2011; Hood & Rubinsky, 2020)
Inadequate innovation strategy and execution	<ul style="list-style-type: none"> • Poor technology feasibility analysis • Poor financial management • Poor human resource and organizational capability management • Poor R&D and manufacturing planning • Poor quality management in manufacturing • Poor planning for product marketing, distribution and after-sales service • Poor knowledge and strategy for innovation diffusion • Poor strategy for innovation scaleup • Poor management of resources and funding • Poor initial research for need assessment • Poor design approach • Lack of training and manual for new innovation • Poor cost estimation of innovation • Lack of balancing R&D and business activities of innovation • Miscalculation of execution time and effort • Poor team-building strategy 	(Alagumalai, 2019; Benjamin et al., 2020; Malkin & Oldenburg Beer, 2013; Jadhav et al., 2017; (Harris, 2006; Jaroslowski & Saberwal, 2014; Beenkens & Stolk, 2010; Carpenet et al., 2011; Ginsburg et al., 2020)
Poor stakeholder collaboration and synergy	<ul style="list-style-type: none"> • poor community networking and support • lack of drive and inter- and intra-organizational collaboration • Poor synergy among the team and various stakeholders 	(Harris, 2006; Jadhav et al., 2017; Carpenet et al., 2011; Abrol et al., 2016; Leonard et al., 2020)
Poor Medical innovation knowledge and capability	<ul style="list-style-type: none"> • Lack of knowledge in Biotech innovation management and commercialization • poor understanding of the market and economy of innovation • poor R&D and business development capability 	(Alagumalai, 2019; Gupta & Thomke, 2018; Jadhav et al., 2017; Malkin & Oldenburg Beer, 2013; WHO, 2010)
Lack of innovation culture	<ul style="list-style-type: none"> • poor vision and motivation for innovation impact • Lack of spirit, organizational culture for innovation 	(Agrawal et al., 2020; Carpenet et al., 2011; Leonard et al., 2020; Malkin & Oldenburg Beer, 2013)

3) *Innovation ecosystem*

Table 0-C below shows the open and axial codes related to 'Innovation ecosystem' along with literature source references.

Table 0-C: Open and axial codes related to 'Innovation ecosystem'

Axial codes (challenges and barriers)	Open codes	Literature references
Inadequate government support and policies	<ul style="list-style-type: none"> • inappropriate fund allocation for the health sector • poor attention, priority setting and policy-making of government • Inadequate government initiatives to promote knowledge and information on innovation • Lack of adverse reporting and post-market surveillance to prevent counterfeit and poor technologies • lack of bureaucratic transparency about healthcare reforms • Lack of reimbursement or insurance coverage on device purchase and maintenance • No formalized medical technology assessment • Lack of awareness programs and poor dissemination of innovation 	(Harmon & Kale, 2015; Harris, 2006; D et al., 2021; PE et al., 2014; Jarosławski & Saberwal, 2013; Alagumalai, 2019; Leonard et al., 2020; Malkin & Oldenburg Beer, 2013)
Lack of experts, educational schemes and infrastructure for technology translation.	<ul style="list-style-type: none"> • Lack of medical device innovation talent for organizational hire • Scarcity of professional experience in medical technology innovation • Lack of Experts and experienced professionals in medical technology manufacturing • Inadequate professional education in technology translation • Inadequate institutional ecosystem and infrastructure for technology translation 	(Dixit et al., 2019; Gupta & Thomke, 2018; Jadhav et al., 2017; Dixit et al., 2018; Leonard et al., 2020)
Inadequate and evolving regulatory and IP frameworks	<ul style="list-style-type: none"> • Mismatch between clinical demand and regulations • Inadequate, Evolving, less comprehensive regulatory framework • Poor IP regulations • Inadequate and Evolving national safety and quality standards • regulatory body accustomed to licensing novel, creative solution • Slow regulatory approval and patent grant process • Lack of innovation testing protocols and guidelines • No scope for harmonization with international regulations 	(R et al., 2020; Dixit et al., 2019; Gupta & Thomke, 2018; Harris, 2006; A et al., 2010; Gupta S. K., 2015; Abrol et al., 2016; Leonard et al., 2020)
Inadequate funding and investment support for innovation	<ul style="list-style-type: none"> • Limited monetary resources to support new technology innovation 	(Couletianos et al., 2020; Dixit et al., 2018; Dixit et al., 2019; Benjamin et al., 2020; Jarosławski & Saberwal, 2013; Benjamin et al., 2020; PE et al., 2014)
Lack of local resources, manufacturing and testing provisions	<ul style="list-style-type: none"> • Lack of appropriate local manufacturing and assembly facilities • Lack of high-quality local raw materials, machinery and tools. • Lack of locally available parts and components • Lack of product testing facility 	(Abrol et al., 2016; Abbas et al., 2017; Dixit et al., 2018; Jadhav et al., 2017; Leonard et al., 2020; Malkin & Oldenburg Beer, 2013)

4) Demographic burdens and characteristics

Table 0-D below shows the open and axial codes related to ‘Demographic burdens and characteristics’ along with literature source references.

Table 0-D: Open and axial codes related to ‘Demographic burdens and characteristics’

Axial codes (challenges and barriers)	Open codes	Literature references
Disease diversity, unequal healthcare coverage.	<ul style="list-style-type: none"> Poor healthcare coverage due to large sized population Variation in disease profile and economic burden across geography 	(A et al., 2010; Carpenet et al., 2011; PE et al., 2014; Dixit et al., 2018; Hennegan et al., 2019; Leonard et al., 2020)
Varied socioeconomics and cost sensitivity	<ul style="list-style-type: none"> Low financial strength of small and mid-sized enterprises Cost-sensitive nature of the healthcare system Diverse socio-economic status 	(Rajesh et al., 2013; Jaroslowski & Saberwal, 2014; Jaroslowski & Saberwal, 2013; Hood & Rubinsky, 2020; D et al., 2021)
Socio-Cultural diversity and barriers	<ul style="list-style-type: none"> poor socioeconomic status cultural sensitivity Caste and Gender-related racism Non-scientific healthcare beliefs and practices illiteracy and poor healthcare knowledge and awareness Socio-demographic diversity and linguistic barriers Socio-economic and cultural diversity 	(Sudip et al., 2019; AP et al., 2015; Ginsburg et al., 2020; Hennegan et al., 2019; Kaur et al., 2018; Pati S, 2019; Das et al., 2008; Beenkens & Stolk, 2010; Paul E Goss, 2014; Kaur et al., 2018)
Widespread prevalence of ill practices	<ul style="list-style-type: none"> Multi-layered stakeholder and commission involvement in product sales Risk of fraud in contract manufacturing Existence of Counterfeit products Corruption within the healthcare system Bad politics in innovation adoption Poor product security 	(Bouchard et al., 2012; Abbas et al., 2017; Agarwal et al., 2018; Leonard et al., 2020; Malkin & Oldenburg Beer, 2013)

5)Market Forces

Table 0-E below shows the open and axial codes related to ‘Market forces’ along with literature source references.

Table 0-E: Open and axial codes related to ‘Market forces’

Axial codes (challenges and barriers)	Open codes	Literature references
Competitive and fragmented market	<ul style="list-style-type: none"> Non-uniform market forces High market competition and fragmented smaller market create hurdles for new innovation Brand loyalty and favoritism Large Cap manufacturers dominate market access and technology licensing Poor incentive and profit margins with new innovation 	(Abbas et al., 2017; Jaroslowski & Saberwal, 2013; Malkin & Oldenburg Beer, 2013; Jaroslowski & Saberwal, 2014; Harmon & Kale, 2015; Jadhav et al., 2017; Bano et al., 2020; Harris,

Axial codes (challenges and barriers)	Open codes	Literature references
		2006)
Market entry barriers for new innovation	<ul style="list-style-type: none"> Novel devices bring additional effort to institutional adoption 	(Jaroslowski & Saberwal, 2014; Coulentianos et al., 2020; Benjamin et al., 2020; Leonard et al., 2020; Malkin & Oldenburg Beer, 2013)

6) Science and technology

Table 0-F below shows the open and axial codes related to 'Science and technology' along with literature source references.

Table 0-F: Open and axial codes related to 'Science and technology'

Axial codes (challenges and barriers)	Open codes	Literature references
Complexities inherent to medical technology innovation	<ul style="list-style-type: none"> Longer development and commercialization timeline High cost of Biotech innovation Complex biology and solution space 	(Dutta & Dhar, 2021, Agrawal et al., 2020; Carpenet et al., 2011)

Appendix A.5: Open coding of Interview data to identify issues faced by innovators

Table 0-F below shows the open coding process of interview data

Table 0-G: Open codes generated from interview data

Quotes	Open codes
“Not too many people especially in a country like India seek treatment for those kinds of conditions nor a lot of treatments are provided in such areas”	Poor healthcare services Lack of education, healthcare knowledge and awareness
“The challenge would be access to a clinical environment that’s where most of the innovators really face the real challenge of how to identify a need.”	Poor need assessment Poor alliances and collaboration
“Prototyping short batch manufacturing especially if you doing a class 2 or class 3 device which has to be done in a certain environment, has to be sterilized, and has to be made in a certain kind of material is still a challenge.” “Finding a contract manufacturer in India is still a challenge. Of course, you always, if you have the money and the means you can always go out and work with companies that are in the west or even in south-east Asia.”	Lack of high-quality local raw materials, components, manufacturing and assembly facility
“Sometimes you have to change the product to meet regulatory requirements, let’s say FDA does not or the Indian regulatory agency do not have anything just to take example...US have different regulations for using PVC as a material in your product, India has different regulations and Europe has different regulations, so you may be able to sell your product with PVC tubing and PVC component in your product in India, but you may not be able to change in the US or in Europe. And That’s when you need to make a product change.”	Lack of regulatory harmonization
“I don’t think the road map would be clear to anybody, I mean even today I am developing a new product, I don’t think I will have a clear roadmap.”	Unpredictable innovation and commercialization roadblocks Lack of national innovation database
“if you are not in a clinical setting just getting a clinical trial going is not really straightforward forward and it takes a lot of pain to get clinical trials going on.”	Negligence of healthcare provider Limited skilled healthcare workforce
“It is still not a notified device in India. ..So we took a slightly more proven pathway.. even back then when .. the regulatory framework is not available in India, we still went ahead and got FDA approval first before selling our first product anywhere, whether its US or in India. We got our FDA approval first and we got CE approval also, we were very thorough with our regulatory strategy”	Evolving and less comprehensive regulatory framework Evolving national safety standards
“Yes, you can sell technically because there was no framework available in India, we could have sold but would doctors accept it, is going to be a challenge. That question is going to come whether you have FDA, CE? so thought let’s be on the safe side.”	Harder to get regulatory clearance for new products. Evolving and less comprehensive regulatory framework
“There is not a lot of talents, medical device talents in India. So, we have to hire lot of people fresh from straight out of college and they know nothing about medical devices and we have to train them, because finding trained talent is almost next to impossible.”	Lack of medical device innovation talent
“There is no reimbursement strategy in India.”	Lack of reimbursement or insurance coverage on device purchase and maintenance
“but the fact is repositioning the patient, on a timely basis, for every 2-hour duration, which is recommended, is kind of impossible in a	Low-resource healthcare setting Limited skilled healthcare workforce

Quotes	Open codes
country like country like ours or in a very resource constraint setting.”	
“one challenge would be, like, how would you bring out a solution which can actually solve the problems of different stakeholders? Because once you solve the problem of bit shows, it's not just solving the problem of one stakeholder, there are multiple stakeholders involved.”	Poor need assessment Poor professional, inter-organizational and stakeholder synergy
“A challenge in the design or the implementation part was basically sourcing components because most of the things that we are actually looking at are not readily available in India and we have to figure it out from different countries outside like China and sourcing it from there.”	Lack of high-quality local raw materials, components, manufacturing and assembly facility
“other challenge is the hiring process, which, if I would say or the team building process because you don't have the bandwidth of hiring experienced people in such a grant, funded situation”	Limited innovation funding and investment resources
“so, getting validation requires some sort of a relationship established with the hospitals or the clinics or the user stakeholder groups. So, building that relationship for a validation process is something kind of challenging”.	Poor alliances and collaboration
“the external factor of COVID. that is one thing that really impacted us because we had to stop a complete product development process. there was a delay in the milestones that we could achieve in terms of submitting into the grants”	Innovation ecosystem sensitive to external shock and crisis situations.
“Second thing is we were actually focused more or less on the product development as engineers and we did not give that much time to understand what is the next steps in terms of clinical trials and regulatory.”	Lack of balancing R&D and other commercialization and business activities of innovation
“A thing is, uh, the people in your team have to actually align with your vision, so people come from different backgrounds and they sticking to one culture is kind of difficult. So, I faced those challenges as well. I won't say it's negative. But it's just that it takes time for the team to understand what actually we are working on and what could be the impact and for them to align with the vision of what the company actually wants to build. So that takes a real amount of time.”	Poor professional, inter-organizational and stakeholder synergy
“We were trying to use ultrasound technology, which in itself was a big challenge in terms of procurement from local Indian manufacturers. Uh, we did approach one of the defence labs based out of Delhi, and we got some samples, but the quality was inadequate.”	Lack of high-quality local raw materials, components, manufacturing and assembly facility
“We tried sourcing it from some of the more expensive manufacturers in the USA and then in Norway, where we had some luck. But the cost was just, uh, I would say something like five times the cost of from the Indian vendor.”	High cost of Biotech innovation Cost sensitivity and low affordability Poor financial management
“the biggest challenge for us was when COVID hit Baron for a hardware company to be operating remotely. We had to be on site. We needed access to a lab, and so on and so forth, so we had to halt operations on core electronics as a company.”	Innovation ecosystem sensitive to external shock and crisis situations.
“We spent almost about three years whole and sole just building product, titrating, validating in a clinical setting.”	Longer development and commercialization timeline
“we had issues early on with sensor design; then we fixed that. ... we had challenges in terms of how the displays design, how is it accessed? We had issues with wireless communication.”	Poor human resource and organizational capability management Lack of translational research capability
“While it could be a. You know, still a functional product? Uh, we weren't sold on, you know, the fact that is that what we really wanted to do? And by the time we arrived at a stage where we said, OK, let's	Poor technology feasibility analysis

Quotes	Open codes
try this. I think it is already we were running out of runway. At which point we had to pivot.”	
“So building a product that's just. One aspect to an entrepreneur 's journey. Building a successful company means that one has to decouple himself or herself from. Success is dependent on one product alone. It you know irrespective of that product being successful or not, the company needs to be successful.”	Lack of balancing R&D and other commercialization and business activities of innovation
“I didn't know at the beginning when I started out, and I've almost everyone knows it, for the most part, is unlike most of the products, medical device space is a very. Uh, time-consuming space. It needs an immense amount of. Effort and dedication to stick it out for. At least you know 4 to 6 years to see any outcome in the first place.”	Longer development and commercialization timeline Miscalculation of execution time and effort
“the Indian system we we recently we updated the CDC guidance document in 20172018, so that's fairly new in the grand scheme of things. Before that we didn't really have. That so we I would say we as an industry are just familiarizing ourselves with those standards and with the new configuration, at least from a regulatory standpoint, for medical devices it is all. It is even more important for startups. Simply because there is no established protocol across the industry. Uh, simply because. As a department itself, they they have established protocols for known products, but for new products I would say the department itself is still learning”	Evolving and less comprehensive regulatory framework Harder to get regulatory clearance for new products
“the market forces are very specific to each geography. The players are specific to each geography. Even in India you know the players could be very different from state to state and and it's not always dependent on a set hierarchy defined by the government”	Non-uniform market forces
“More often than not, we we end up being very poor estimators of. Project execution timelines, especially in health care, given that there's so many players that we need to deal with before it even reaches the market, and then some more after it starts selling”	Miscalculation of execution time and effort Complex and competitive market access
“the engineers in my team site every little thing is a problem. But that's how it is like the ground reality is government hospital.”	Poor need assessment
“designers get very carried away, you know. No, no, they get very carried away with their own design. Sort of. You start designing like form factors, ergonomics, all of that stuff. And when some of these processes takes like months”	Lack of balancing R&D and other commercialization and business activities of innovation
“finding good sort of. Talent is, it's it's a. It's a challenge. Uh, 'cause one is, you know the medical device ecosystem. The industry is not as developed, so usually we end up. Uh, finding people from, say, automotive industry or electronics industry or some other industry, and then you know we have to bring them on board and train them for medical devices”	Lack of medical device innovation talent
“we had a road map and everything, but you have to be prepared for sort of. Seeing what the commercial road blocks are going to be and you have to adapt and start solving them, 'cause those will not come in a linear manner to you. There's only sporadic they're going to be very sort of unique to each case that you deal with. So yeah, you you can plan for some of these implementations. But it's not gonna be a straight path for any of these commercial success”	Unpredictable innovation and commercialization roadblocks
“in India because of the way sort of purchasing is structured, reluctance of hospitals to get involved or take on the financial risk early on. You have like multiple layers in between like distributors, sort of purchasing agents, all sorts of things. The the difference is how do you price it and how do you make it attractive for the end user is very different in India versus the global markets”	Lack of reimbursement or insurance coverage on device purchase and maintenance Slow and Complex procurement process and tender bidding system Multi-layered stakeholder and commission involvement in product sales

Quotes	Open codes
“like any entrepreneurship that is in a regulated market like health care. We'll take you anywhere between 7 to 15 years to become successful”	Longer development and commercialization timeline
“These babies are not screened on time just because. There are not particular equipments or suitable equipments which can be used in resource constrained setting.”	Low-resource healthcare setting
“Noise in the environment or like the health care providers are now. Are there? Uhm, many of those things which needs to be solved like they can't be solved with importing equipments”	Non-clinical ancillary requirements
“so the many times what happens is that engineers designers, these people were making the products, but they're not very well aware of market reality.”	Lack of awareness, knowledge and experience in biotech innovation and business management
“Making a device here in India in itself is a is a is a very challenging job like. I don't know how many people would understand that and how many companies are there who are making these devices here in India. You will find many of these vendors who will be making one component or something which like a ball or a syringer a very very basic.”	Lack of translational research capability Lack of high-quality local raw materials, components, manufacturing and assembly facility
“Human resource was a kind of a big struggle. How many times would you really get a good engineer who can?”	Lack of medical device innovation talent
“and even if you get them, you won't be able to provide them the salary that. They would need for a. Uh, matching the corporate world salary, so that's another challenge. So, capital is always a challenge.”	Poor financial management
“physicians obviously would go for something which is like coming from the US or US FDA. Approved or see approved. OK, if you say that I am not notified and I don't require any kind of certification, they might not get convinced. They they might actually say that, uh? They might just say that Oh no, no we want to. We have a preference for. For FDA or RC approved product”	Mismatch between clinical demand and regulations
“our system is not designed for. For medical device innovation. You know who has the patience to really come? Do this for 10 years and then only get the outcome. You're getting my point, right? Like how? How many? How many parents, how many? Uhm, people would agree to you that, OK, I'm going to take the next 15 years or 10 years to really make something and then sell it in the market and then really make it big”	Longer development and commercialization timeline
“in India every step is complex. Like if you go and get the clinical trial done, it is not the clinical. It is not the. Clinical trial, but you have to do lot of relationship building. Uh, before you start the clinical trial, you have to go Ethics Committee. Uh or Ethics Committee approval? You have to. You know, go get. A proper properly like these documentation done and it is much more complex the the clinical trials would take months to collect the data to get the Ethics Committee approval. All those processes are much more. Complex I would say.”	Slow and complex intra-organizational operations Poor alliances and collaboration
“like making silicone parts is not so easy, particularly in India like even getting the raw material is a difficult job. So somehow we got those few samples from the different companies and we try to make a smaller version of the prototype where we tested the cons.”	Lack of high-quality local raw materials, components, manufacturing and assembly facility
“like if you try to hire Master Blaster on day one. So I would say like a very experienced and seasoned marketing player on the day one before even product is ready, that person will get frustrated and that they, the person will leave your company.”	Poor human resource and organizational capability management
“When you are already into the research and development phase and you don't get enough fund to. To give the salary to the people to give the money to or like a payments to your customer like vendors. Then your whole process will be delayed and it will lose the excitement in the team and people will not able to execute in time.”	Poor financial management

Quotes	Open codes
<p>“The reason alignment is very much important. So rather than focusing on just a skill set that you need, you also need to focus on the reason, because chances are very high that like everything will go North and South. And does not follow your plan in such situation. Like short term expectation will not retain the employee or the founder or the co-founder or the team member. But if you have a common vision which is having alignment, it will take you a few extra miles”</p>	<p>Poor professional, inter-organizational and stakeholder synergy</p>
<p>“We have a different kind of the insurance here. which is giving very very low reimbursement to the hospitals and doctors. And another is the private sector where there are two different kind of the insurance when he is the insurance that covers the daycare. Daycare means, like all the OPD, OPD and the single day trip. And and another insurance which is more common in EU India is? For just accidental insurance, which is like any accident or admission which is required, then that insurance will be reimbursed and they have a cap limit starting from 2 Lac rupees to 10 Lac rupees. OK, so they do not cover any kind of prescription, prescriptive devices etc.”</p>	<p>Lack of reimbursement or insurance coverage on device purchase and maintenance</p>
<p>“So in India, even if you make 10 times better product, if you don't compete in terms of the price, chances are. Well, yes, or it's more difficult to establish. In the market. Nobody wants to pay more in India. That is kind of a golden rule”</p>	<p>Cost sensitivity and Low affordability</p>
<p>“when you are designing or developing some innovative product which is having some IPS, you can outsource the maximum process which is non proprietary and you keep the. All the proprietary items in your in-house manufacturing”</p>	<p>Risk of fraud in contract manufacturing</p>
<p>“However, we understood by like second. Half of the year. Or maybe you know the war or something. That we it is technically possible. To make it maybe. It is technically feasible, but the solution will be extremely costly because it will need a very high-quality spectrosopes to make it, and that was very late in the process I would say.”</p>	<p>Poor technology feasibility analysis</p>
<p>“we understood that. This is going. To take us. A much longer than what we expected. To be in. The market and I did not have that kind of resources as a PhD or anything. Go to get it done.”</p>	<p>Poor human resource and organizational capability management</p>
<p>“We tried to collaborate with someone in. Ideally with no names here. Yeah, but it didn't go through as expected. Maybe tried, uh. A lot. To contact some facilities across the country. But I think, uh, more support in that direction would have helped us to collaborate faster and do our experiment first. It's not easy according to be interesting. One, if you keep writing mail, they. Have their own agendas.”</p>	<p>Poor alliances and collaboration Poor professional, inter-organizational and stakeholder synergy</p>
<p>“We had a person who will collect the sample. We had a clinical, you know, data analyst, all those people. And we thought that this will go away in a month, but we have to keep paying their salary with no work for three months, and that also pleaded us like hell. Yeah, so external factor was COVID-19 one of it.”</p>	<p>Miscalculation of execution time and effort</p>
<p>“Difficult to find a collaborator itself in my second project, although. I had a collaborator. Uh, the PhD students that were working on this project had their own timelines. And that that delays the whole prototyping. So if you can find something which is which can be done by you in your lap in your home.”</p>	<p>Poor alliances and collaboration Poor professional, inter-organizational and stakeholder synergy</p>

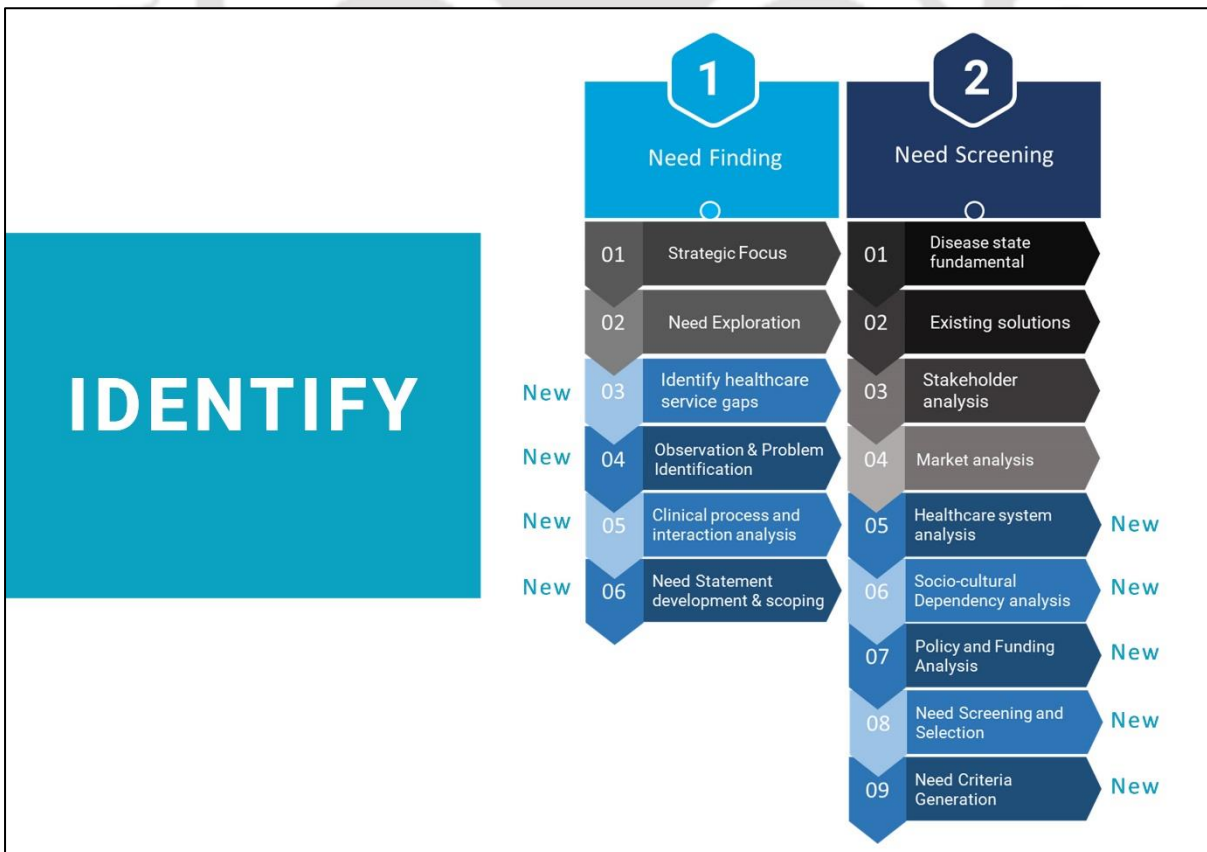
Appendix A.6: Templates of Tools used in Modified Biodesign Process

Workflow toolkit for Medical Technology Design

*in Low-and Middle-Income
Countries (LMICs)*



By
Neelarnab Dutta
Department of Design, Indian Institute of Technology Guwahati,
Assam, India-781039



Identify Healthcare Service Gaps

Starts with defining the Clinical condition. This include from top to bottom :

(a) a short description of clinical presentation of the disease, anatomy, physiological changes, disease histology and clinical impact

(b) a short description of disease etiology that include identification of various causal factors that may encompass biological, chemical, physical and environmental, genetic or psychological factors.

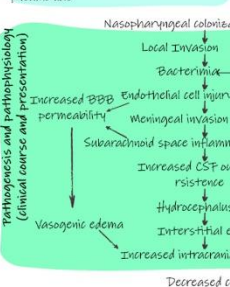
Next step is mapping of pathogenesis and pathophysiology of the disease state i.e. mapping the clinical course of the disease, series of events, pathological changes, risk factors and various clinical presentations.

Bacterial meningitis (Clinical condition)

"An infection of the membranes (meninges) that protect the spinal cord and brain. When the membranes become infected, they swell and press on the spinal cord or brain. This can cause life-threatening problems"

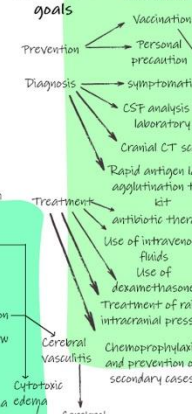
Etiology

3 common meningial pathogens
Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae



The next task is to identify existing healthcare clinical goal of stakeholders (patient, clinician, healthcare facility) in relation to clinical course of the disease and presentation. For example, clinical goals for a disease like cervical cancer can be Prevention, Screening and Diagnosis, Treatment or Management. On a paper, we can map the clinical goals on the right side of the clinical course of a disease state. After that, the follow up task is to understand available solution/options for clinical goals and map them against each clinical goal. For example: For the clinical goal of prevention of cervical cancer available solutions are vaccination and personal hygiene.

Healthcare Solutions



Healthcare facilities and service gaps

Public healthcare system (India)	Available healthcare services
Tertiary care or medical college	Most Preventive, diagnostic and treatment options available No rapid diagnosis option available
District hospital	Vaccination, CSF analysis, Rapid antigen test No CT scan and treatment options available
Community health center	Symptomatic diagnosis only No preventive, advance diagnostic and treatment services available
Primary health center	No service available
Sub center	No service available

The Final task is to identify all Public and private healthcare facilities of the country and map them in hierarchy in tabular format. Tables should include information about type of healthcare facility and available healthcare services in relation to the disease state we are exploring. The final task is to identify healthcare service gaps at various healthcare facilities i.e. identifying the absence of specific healthcare solutions/options. For instance, on performing this procedure for a clinical condition like Bacterial meningitis, we can identify that Cranial CT scan for the diagnosis of the disease is not available in Indian Community Healthcare centers (CHCs)

Identifying problems from observations

This tool defines the approach of taking observations and identifying problems while performing clinical immersion during initial need identification phase.

Before going to field study prepare table templates for formal observation note, on a piece of paper. This table template should have separate vertical columns to capture information about specific observations, type of problem and problem itself, population/stakeholder impacted and desired outcome.

Conversion of field observation into formal observation notes

Observation	Problem	Population	Outcome
1. Narrate down what problem you observed	Define the problem	The person associated with problem	Define the end outcome observed

Build a strong understanding of healthcare related problem types, and examples of desired outcomes before field study. During field study use the paper template prepared in step 1 to capture findings.

a. Note down observations in passive narration defining patient's age, gender related information, clinical presentation of a disease or condition, observed healthcare service, patient - clinician interactions, patient - facility interaction, procedural information, challenges and issues faced.

b. Taking reference from the problem types provided identify and record various problems observed during field study.

c. Identify and record the stakeholder getting effected i.e. problem faced by clinician, patient or other healthcare service guy within thin the cycle of healthcare service.

d. Consult the population affected and identify and record desired outcome and how can measure the improvement

Observation from clinical immersion

A village lady, aged 37, did not visit DOT center regularly for Tuberculosis treatment. She was reported with Drug resistance to TB medication due to treatment lapse. As per her reporting, she stays far away from the DOT center and have 3 kids at home to take care. Her visit to DOT center is time consuming and it effect her work life.

Problems

1. Treatment lapse in TB,
2. Long duration of TB treatment/
3. Poor healthcare accessibility,
4. Effect work life .

Desired Outcomes

1. Timely medication,
2. Effective TB treatment,
3. Improve accessibility,
4. Low opportunity cost

Problems	Example desired outcome	As measured by
Absence of healthcare solution	Non invasive way to diagnose	Sensitivity and specificity
Gap and issue with current apparatus, instrument,	Improved clinical outcome	Treatment success rate
Patient pain points	Improved patient convenience	Frequency and occurrence of required treatment, change in treatment venue
Provider pain points	Improve physician/facility productivity	Time and resource required
Procedural Issue	Less complicated procedures	Ease of use
Complications with outcome	No side effect	Occurrence of clinical complication
Environmental issue	Procedure operable in extreme weather conditions	Operational effectiveness
Socio-cultural issue	Culturally respectful procedure	Degree of privacy maintained
Healthcare facility and management issues	Task shifting of devices due to limited skilled professional	Ease of use, help and guidance
Healthcare service gap	Diagnose cancer in Primary health center	Operational effectiveness

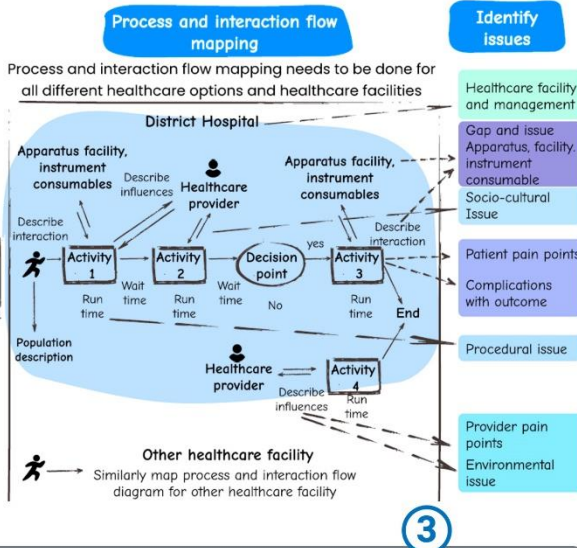
Analysing clinical processes and interactions

The following set of activities aimed to create visual map of clinical procedure and specific interaction of patient, clinician and healthcare facility to identify problems.

It starts with tracking the patients' or clinicians' journey inside a procedure. Both patient and provider perspective are ok to start with. As a mapping task, all various activities performed by patient or clinician needs to be mapped sequentially from start to the end of a procedure. Rectangular shape can be used for defining various activities. While mapping the activities various decision points needs to be identified and represented using Rhombus shape. Different activity paths from the decision points need to be mapped separately till activity endings. Various stakeholder interactions like patient interaction with Clinician or other personal needs to be mapped by defining double sided arrow and the nature of interaction between them. Similarly, stakeholder interactions with specific facilities, devices, infrastructure needs to be mapped using double sided arrow and defining kind of interactions. Once defining structural mapping of activities, decision points, and various interactions the subsequent task is to define Run time and Wait time of each activity and interactions within the procedure. This can be defined using clock symbol and specifying approximate time association

Next, identify or back trace clinical presentation of the disease state, etiology, associated healthcare goal for which we analyzed specific healthcare service or procedure. This step can be seen as a specific instance of data generated for understanding clinical condition. However, during clinical immersion sometimes we may come across procedures without gaining in-depth knowledge about disease state, pathogenesis, etiology etc. So back tracing such details and mapping while analyzing procedure would help in understanding/reasoning the procedural steps better. Back tracing can be done later after taking field observation. For example, for the clinical condition of Bacterial Meningitis, we can observe procedure for reducing intracranial pressure and later connect the information about Procedural goal, and clinical need.

Step 1 and step 2, though are interconnected may happen at different temporal space. This is an iterative process. So, if necessary, add additional information to the process and interaction flow diagram based on back tracing and further realization of procedure and issues.



Need Statements Development and Scoping

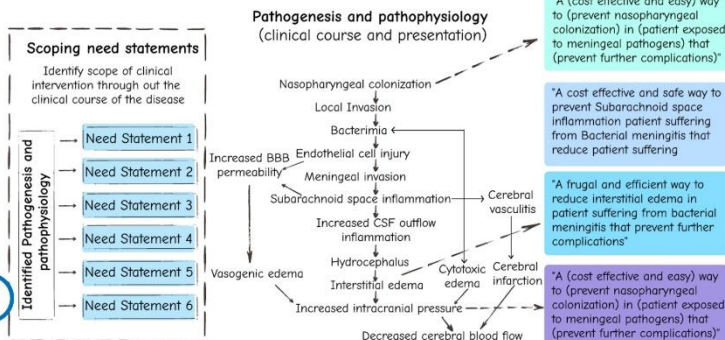
Starts with defining initial need statement. Use previously identified information like healthcare service gaps, healthcare problems, population effected and desired outcome and measure to define need statements. Use the template provided as an example template to bring together all such informations. A typical need statement should include:

- a clinical condition or disease state or healthcare problem
- population affected
- desired healthcare outcome
- desired solution characteristic of healthcare and implementation problem

Refine and scope the need statements based on previously identified disease pathogenesis and pathophysiology. On a piece of paper draw the clinical course of disease progression with the associated information of altered biomechanism, clinical presentation, risk factors. Next, redefine the initial need statements to target specific stage of disease progression or clinical presentation. Make sure the resultant need statements read logically correct and are not too narrow for solution synthesis. Consult clinician if required consultation on the development of final need statements.

Need Statement development

A (desired outcome characteristics of healthcare and implementation problem) way to (address Need Statement development: clinical condition) in (population) that (allow desired healthcare outcome)"



Need Screening and Selection

Use tables/Excel sheets for the need selection process. Within a table, the first (left most) column should define various need statements, the last column (right most) should define Total score against each need statement and in-between columns should capture the evaluated scores against various filters/matrices. The threshold score for selecting a need statement for further round of filtering is subjective i.e. depends on evaluators judgement and comparative analysis. The process involved three round need filtering.

Need filtering process

	Team interest (y=1, n=0)	Need type (m/i=1, bs=0)	Total score
1. Need statement 1	1	0	1
2. Need statement 2	1	1	2

In the second round use filters/ matrices 'Estimated market size (Large=3, Medium=2, Small=1)', 'patient impact (Large=3, Medium=2, Small=1)', 'Number of affected patients (Large=3, Medium=2, Small=1)', 'Understanding of Disease state (High =3, Medium=2, Low=1)', 'Treatment landscape (no solution=3, some=2, crowded=1)', 'Provider values- low cost, less time, low skill requirement (All three improve=3, Two improve=2, One improve=1)

The third and final round of filtering usage the filters/matrices defined in Figure 5.22 to perform a final check on LMIC-specific consideration. Use the Matrices/ filters 'Fitment to non-uniform healthcare system (Fit to entire hierarchy =3, Fit to few = 2, Fit to specific healthcare setting=1)', 'Fitment to resource constraint setting (Fit to existing infrastructure and workforce = 3, Fit to either existing infrastructure or workforce = 2, No Fit =1)', 'Fit to society and culture (Socio-cultural values addressed= 2, Socio-cultural values not address = 1), Fit to policies, funding options (Fit to WHO goals or government health planning = 3, Fit to Market demand =2, Fit to stakeholder requirement = 1)

The first-round usage the filters/matrices 'Team interest (yes=1, no=0)' and 'Need type (mixed/incremental=1, blue sky=0)' to quickly get rid of initial set of non-workable need statements.

1

Round 1 Need filtering

1	Team Interest	Yes = 1	No = 0
2	Need Type	Mixed/ Incremental = 1	blue sky = 0

Round 2 Need filtering

1	Estimated market size	Large = 3	Medium = 2	Small = 1
2	Patient impact	Large = 3	Medium = 2	Small = 1
3	Number of affected patients	Large = 3	Medium = 2	Small = 1
4	Understanding of Disease state	High = 3	Medium = 2	Low = 1
3	Treatment landscape	No solution = 3	Some solutions = 2	Crowded = 1
4	Provider value (cost, time, skill)	All three improves = 3	Any two improves = 2	One improves = 1

Round 3: LMIC specific Need filtering

1	Fitment to non-uniform healthcare system	Fit to entire hierarchy = 3	Fit to few = 2	Fit to specific healthcare setting = 1
2	Fit to resource constraint setting	Fit to existing infrastructure and workforce = 3	Fit to either existing infrastructure or workforce = 2	No Fit = 1
3	Fit to society and culture	Socio cultural values addressed = 2	Socio-cultural values not addresses = 1	
4	Fit to policies, funding options	Fit to WHO goals or government health planning = 3	Fit to Market demand = 2	Fit to stakeholder requirement = 1

2

3

Need criteria generation

Need Criteria generation

Generate a set of well thought of need criteria based on previously identified clinical and implementation problems

1

Starts with the development of Must have need criteria (design requirements) by creating a table as shown in the template. Create a table where the first two columns define the 'must-have' characteristics of the solution and associated 'specifications'. Horizontally, the table should represent these need criteria from two different requirement perspective. One from the perspective of clinical requirements that address core clinical problem, and the other from the perspective of implementation requirements, which capture solution characteristics that can eliminate implementation risks or issues. A well-defined need statement will allow easy understanding of clinical and implementation challenges. Defines the specifications as either values or constraints.

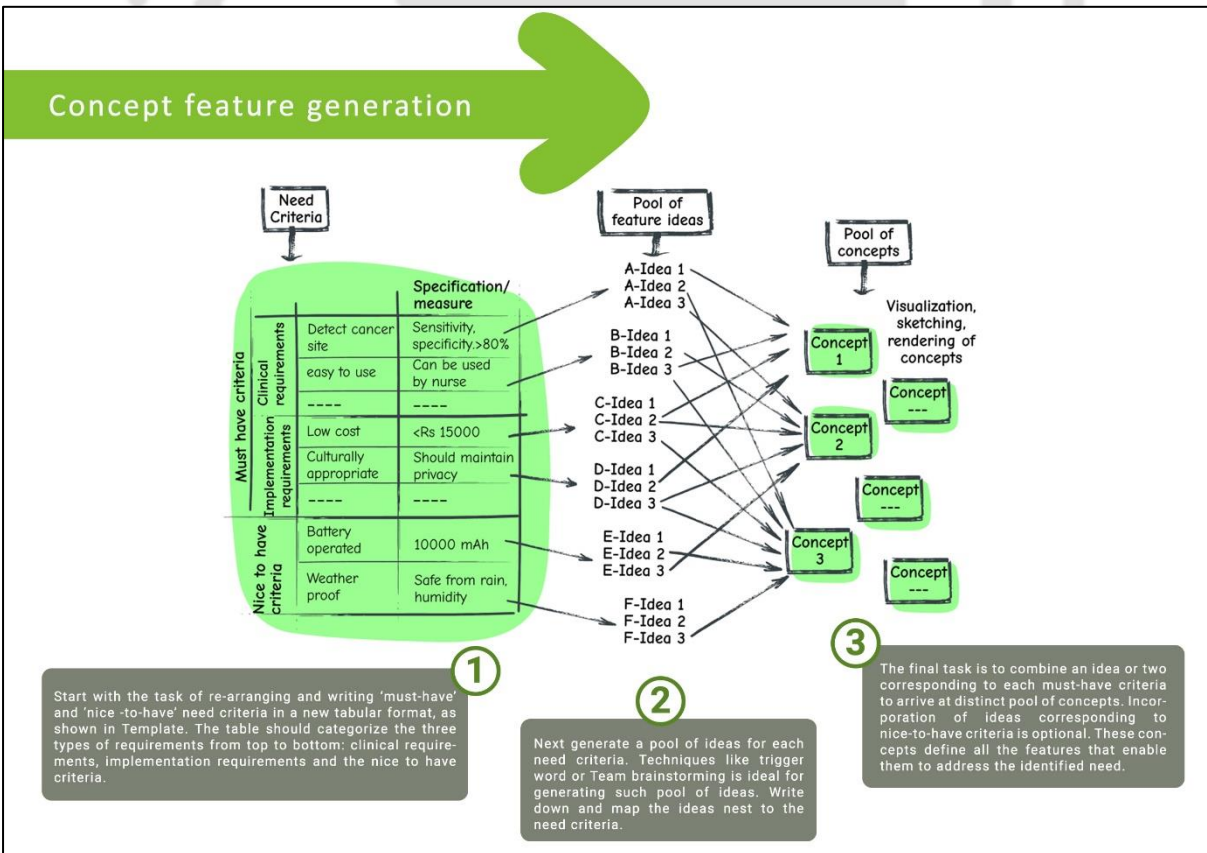
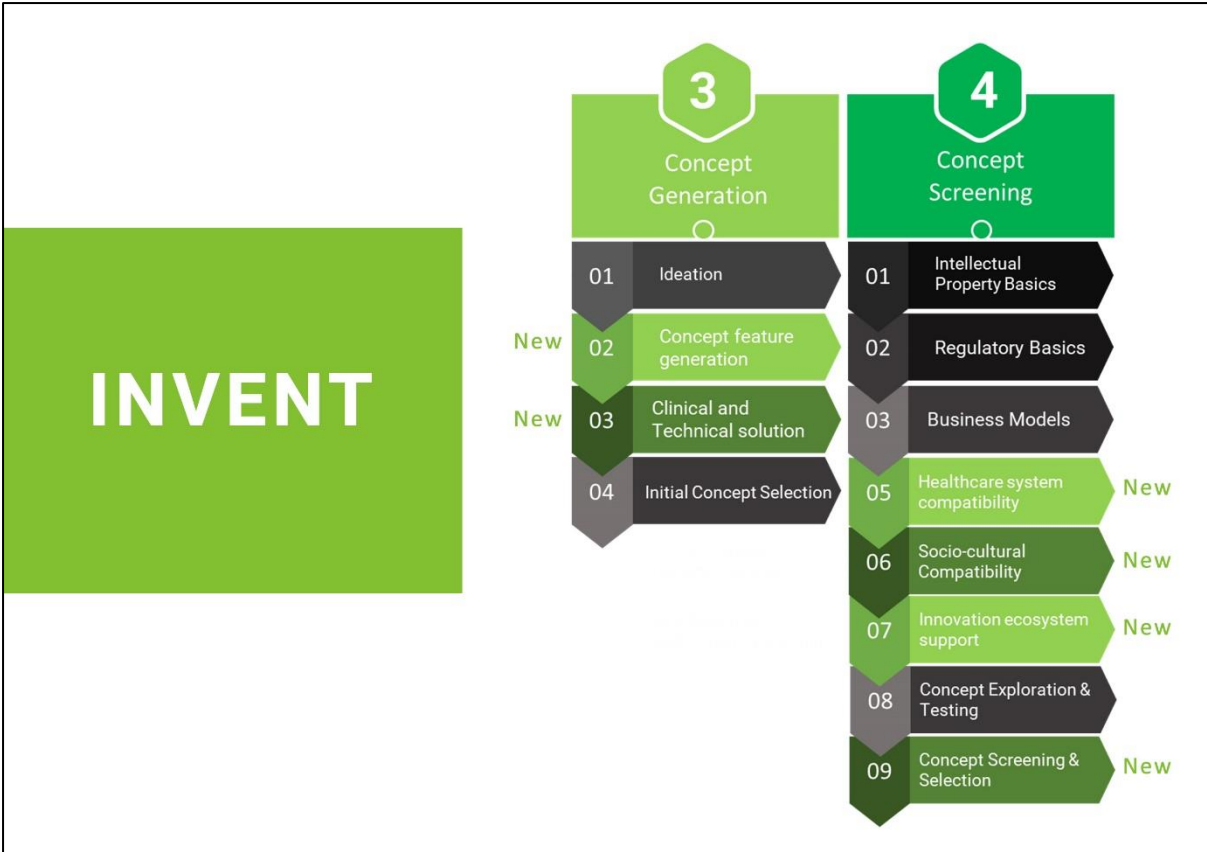
	Must have criteria	Specification/measure
Clinical requirements	Detect cancer site	High sensitivity, specificity
	Portable	Weight <5Kg
	easy to use	Can be used by nurse
	Remote and central monitoring	Data should be available online all time
Implementation requirements	Low cost	<Rs 15000
	Accessible	Should be available at small local healthcare
	Culturally appropriate	Should maintain privacy
	Easy to adopt	Should fit within existing healthcare instrumentations

Need Criteria

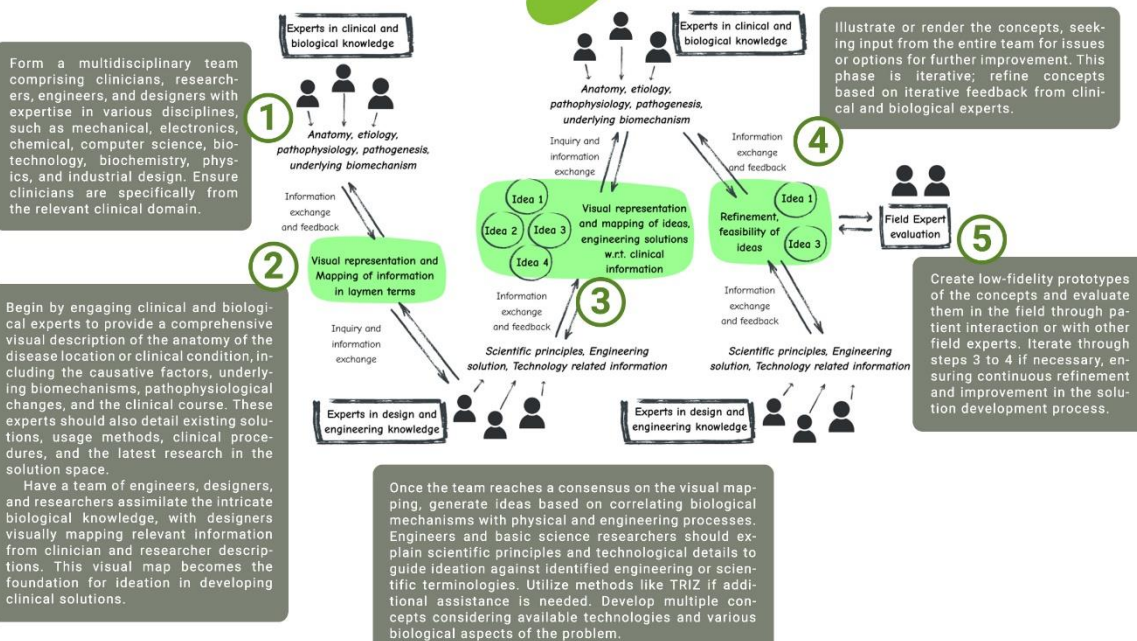
Nice to have criteria	Specification/measure
Battery operated	10000 mAh
Weather proof	Safe from rain, humidity
Provide voice assistance	Female doctor voice in Hindi language

2

The next task is to define the nice to have criteria a similar table as shown in the template. Create a table where first column defines the 'nice-to-have' criteria and the second column defines the corresponding specification. Define nice to have criteria from the perspective of technological usage, additional stakeholder comfort, practical usage requirement etc.



Clinical and technical solution Synthesis



Concept Screening and Selection

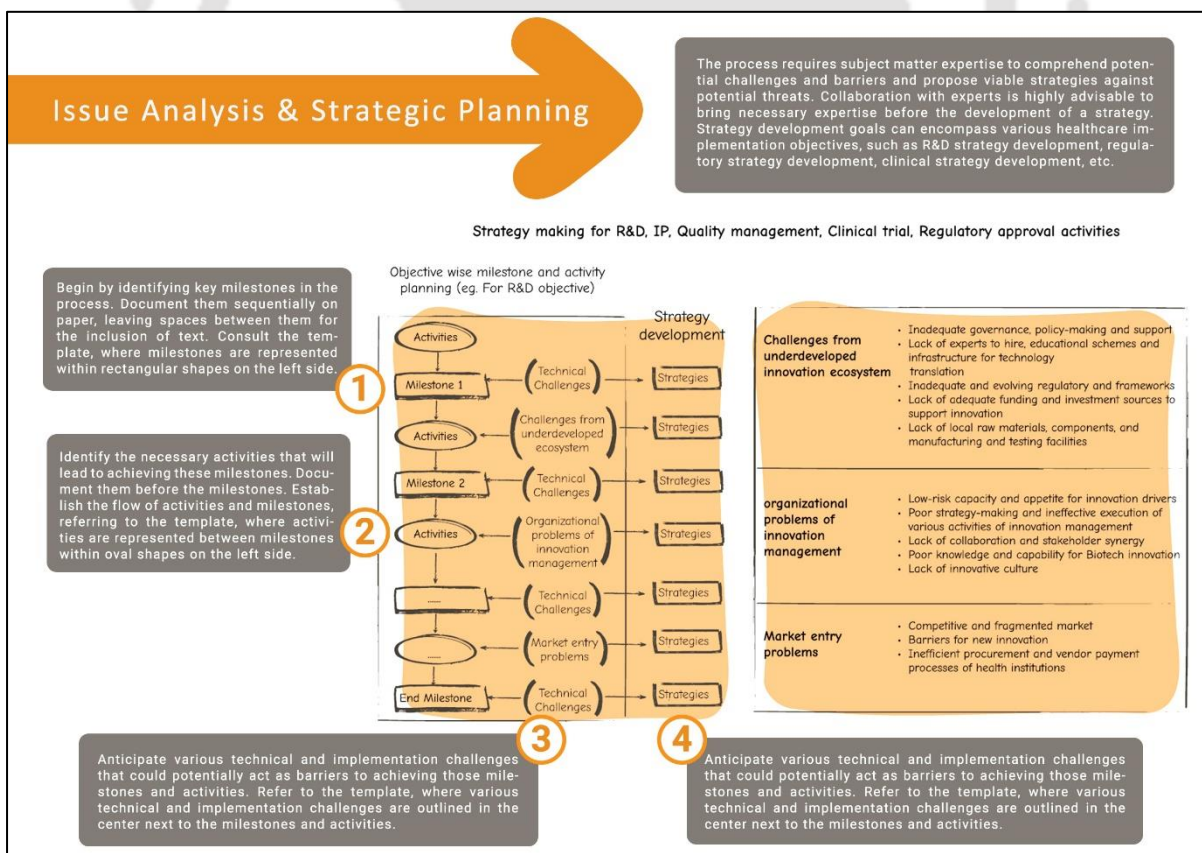
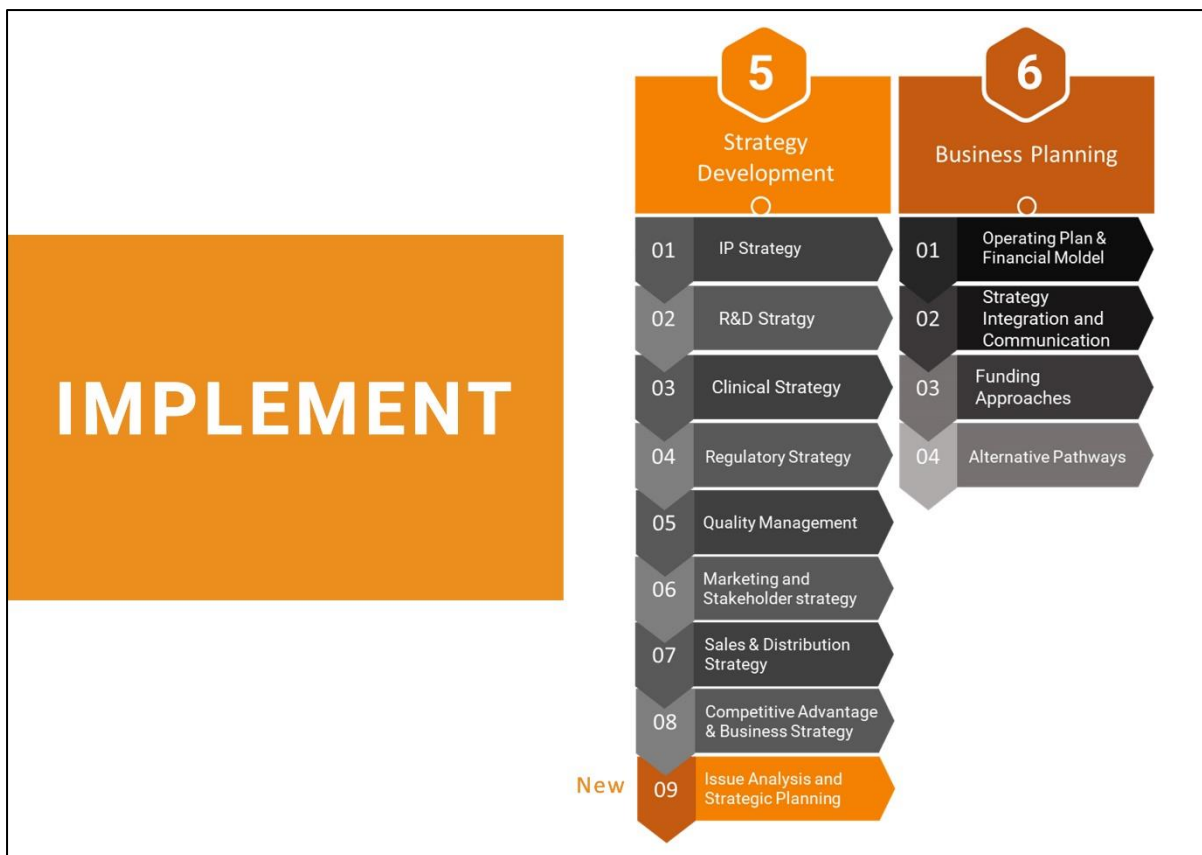
The following process outlines the concept filtering and selection procedure, employing tables or Excel sheets for clarity. In each table, the leftmost column should list the names of the concepts, the rightmost column should indicate the total score against concepts, and columns in between should record the evaluated scores against various filters/matrices. The threshold score for advancing a concept to the next filtering round is subjective, relying on evaluators' judgment and comparative analysis. The process entails two rounds of concept filtering.

1 The first-round usage the filters/matrices: Fitment to the non-uniform healthcare system (fit to the entire hierarchy=3, fit to a few=2, fit to a specific healthcare setting=1), fitment to resource-constrained settings (fit to existing infrastructure and workforce=3, fit to either existing infrastructure or workforce=2, no fit=1), fitment to society and culture (addressing socio-cultural values=2, not addressing them=1), funding and investment availability (high=3, occasional=2, low=1), product development support (developmental knowledge and strong collaboration existed=3, either of them existed=2, no knowledge and collaboration were present=1), manufacturing support (all manufacturing and parts procurement could be done within the country=3, partial dependency on foreign vendors=2, complete dependency on

Round 1: LMIC specific concept filtering			
1. Fitment to non-uniform healthcare system	Fit to entire hierarchy= 3	Fit to few= 2	Fit to specific healthcare setting= 1
2. Fitment to resource constraint setting	Fit to existing infrastructure and workforce= 3	Fit to either existing infrastructure or workforce= 2	No fit= 1
3. Fitment to society and culture	Socio-cultural values addressed= 2	Socio-cultural values not addressed= 1	
4. Funding and investment availability	High= 3	occasional= 2	Low= 1
5. Product development support	Developmental knowledge and strong collaboration exist= 3	Either developmental knowledge or strong collaboration exists= 2	No knowledge and collaboration exist= 1
6. Manufacturing support	All manufacturing and parts procurements can be done via vendor within country= 3	Partial dependency on foreign vendor for manufacturing or component procurements= 2	No knowledge and collaboration exist= 1
7. Regulatory hurdles	Class 1 device or notified device	Non-notified device (but FDA 510K)= 2	Non-notified device (needs PMA)= 1

2 The second round usage filters/matrices: Efficacy (proven=3, somewhat=2, not proven=1), Patentability (yes=2, no=1), Freedom to operate (yes=2, no=1), Product type (disposal=5, reusable=4, implantable=3, capital equipment=2, service=1), Revenue model (fee per use=2, subscription=1), and Availability (over the counter=3, prescription=2, physician sell=1). After aggregating the final scores, 1 or 2 concepts with the highest scores are selected for further development and implementation.

Round 2 Concept Filtering					
1. Efficacy	Proven= 3	Somewhat= 2	Not proven= 1		
2. Patentability	Yes= 2	No= 0			
3. Freedom to operate	Yes= 2	No= 1			
4. Product type	Disposable= 5	Reusable= 4	Implantable= 3	Capital equipment= 2	Service =1
5. Revenue model	Fee per use = 2	Subscription = 1			
6. Availability	Over the counter= 3	Prescription / Occasional home use = 2	Physician sell= 1		



List of Patents and Publications

Patents

- i. **Indian Patent Number - 457400:** *Apparatus and method for screening of gynecological conditions of a subject body.* Date of Patent grant: 09/10/2023,
Inventors: Neelarnab Dutta, Debayan Dhar,
Applicant: Indian Institute of Technology Guwahati
Status: **Granted**
- ii. **Indian patent application – IN 202131004757:** *Multi-therapeutic wound healing and diagnostic device and method thereof.* Date of Publication: 05/08/2022,
Inventors: Neelarnab Dutta, Debayan Dhar,
Applicant: Indian Institute of Technology Guwahati
Status: **Pending patent grant**

Journal papers

- i. **Investigating Usability of Conversational User Interfaces for Interactive Artificial Intelligence System: A Medical Device Perspective**
Authors: Neelarnab Dutta and Debayan Dhar
Journal: International Journal of Human-Computer Interaction, Taylor and Francis (Q1, IF=4.7) DOI:10.1080/10447318.2023.2298534.
Status: **Published**
- ii. **From Industrial Design to Healthcare Innovation—A Comparative Study on the Role of User-Centered Design and Stanford Biodesign Process**
Authors: Neelarnab Dutta and Debayan Dhar
Book: Design for Tomorrow—Volume 3 (pp. 665--677). Springer
DOI: 10.1007/978-981-16-0084-5_55.
Status: **Published**
- iii. **Investigating Medical Technology Innovation in Low- and Middle-Income Countries: Factors, Impact, and Model Proposal**
Authors: Neelarnab Dutta and Debayan Dhar
Journal: She Ji: The Journal of Design, Economics, and Innovation, Elsevier (Q1, IF=2).
Status: **Under Review**

iv. **Designing Medical Technologies for Resource-Limited Settings: A Modified Stanford Biodesign Framework.**

Authors: Neelarnab Dutta, Debayan Dhar

Journal: Design Studies, Elsevier (Q1, IF=3.5).

Status: **Under review**

