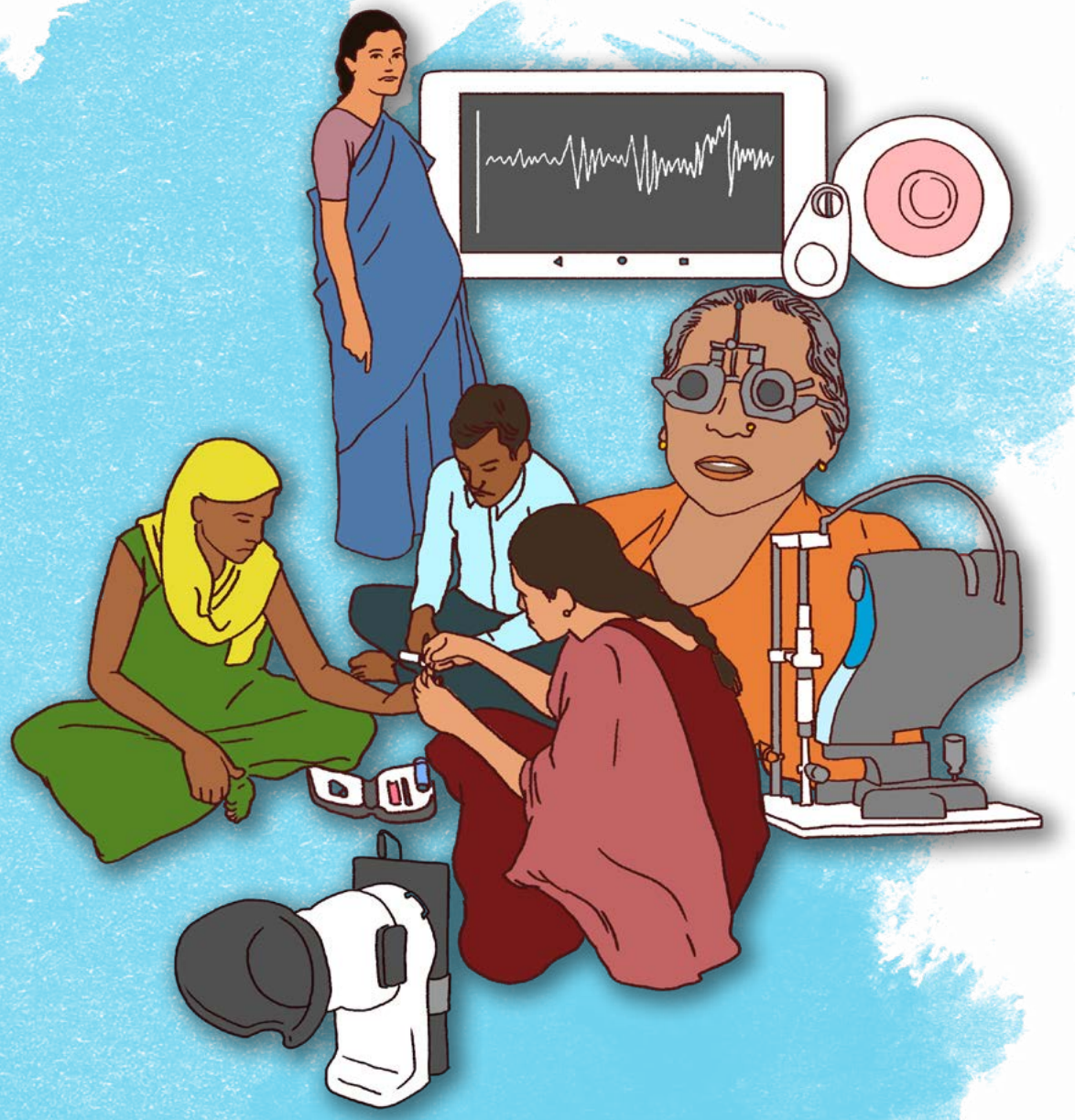
Scaling technology innovations in healthcare

A handbook for social enterprises



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While the authors have tried their best to acknowledge all the valuable resources they have referred, they extend their sincere apologies to any author/ source they have inadvertently missed citing.

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Foreword

The Covid-19 pandemic demonstrated that the Indian healthcare system lacks depth, a thought that has been in the minds of many for a long time. However, given India's size and resource constraints, there are no easy solutions to the challenge of building a system that is robust and responsive.

When we take a step back and try to identify bright spots, several pockets of healthcare excellence stand out. Many of these were created by path-breaking entrepreneurs and innovators who looked for ways of making healthcare accessible and affordable without compromising on quality and standards. I am, of course, thinking of people like Dr Devi Shetty and Dr G. Venkataswamy who pioneered world-famous models of healthcare in the cardiac and ophthalmology domains respectively. Yet, for every such pioneer we have dozens of intrepid healthcare innovators who tried to create alternative models but failed.

In recent years, India has witnessed an explosion of entrepreneurship – both for-profit and driven by social objectives. Government programmes such as BIRAC, run by the Department of Biotechnology (DBT), have done a commendable job in supporting the conversion of ideas into prototypes and proof-of-concept. Yet, several of these ventures have struggled to have an impact on the healthcare challenges faced by India.

A common thread running across these experiences is the challenge in scaling-up.

Scaling technology innovations in healthcare: A handbook for social enterprises by Anil Misquith and Dr Satya Dash is a very timely compilation that helps address the scaling problem. I particularly like the way it combines concepts and frameworks from global literature and best practices with contextual examples and relevant information from the Indian ecosystem. This combination should prove invaluable to healthcare innovators and entrepreneurs in the years ahead.

Hopefully, the picture of Indian healthcare will look very different in a decade from now.

Rishikesha T. Krishnan
Director & Professor of Strategy
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Foreword

The Azim Premji University's Social Enterprise Cell was set up in 2015 as a platform to encourage students who are trying to come up with innovative solutions to complex social problems such as lack of markets for rural producers, water crisis, education for children of migrant workers and dignified livelihoods for people with disabilities. The cell enables students to share, debate and discuss their ideas and network with individuals, incubators and like-minded groups towards creating their own social ventures.

One key objective of the cell is to act as a resource center for the social enterprise ecosystem in India through various events, programmes and publications. In that context, we are pleased that Anil Misquith, a student of our MA Development programme has authored the report. In fact, the genesis of this book was in the various public health domain electives offered within the course. Anil and contributing author Dr Satya Prakash Dash have conducted extensive field visits, interactions with healthcare workers, founders of organisations and domain experts for the book.

This publication is meant to guide individuals interested in creating technology-based social enterprises in healthcare. It is our sincere hope that such social ventures will help deliver quality health services to the most marginalised groups of people, not just in India but also in remote corners of the world. Such transformation can only be brought about by innovative ideas from individuals who have passion and dedication.

Thank you

Social Enterprise Cell

Azim Premji University

Contents

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Success is achieved twice.
Once in the mind and the
second time in the real world

- Azim H Premji

Source: https://yourstory.com/2020/03/inspiring-quotes-wipro-chairman-azim-premji-leadership

Preface

Public health, technology innovations and social enterprises, and what the combination of these could mean for healthcare in a country like India was something that sparked curiosity in me. In my corporate avatar at Intel, my team focused on enabling software solutions on the latest platforms that Intel designed. When I transitioned to the social sector, it gave me a completely new perspective and triggered my interest to explore this combination of technology and healthcare from a different lens.

Is public healthcare in India a space where technology innovations can make a difference? What are the impediments in adopting such solutions? Can social enterprises meet the need of providing equity and access? Several conversations around these questions with Dr Arun Venkatesan, then CTO of Villgro (now co-founder and CEO of Villgro USA), one of India's pioneering incubators of social enterprises, led to interesting discussions with founders of healthcare social enterprises. A common challenge that emerged was the difficulty in scaling technology innovations, given the complex nature of the public health system in India.

While social enterprises do provide important solutions, we do not know much about why some are adopted by the government for large-scale implementation and others fail to cross the pilot stage. What are the key considerations to keep in mind while conceiving, designing, piloting and scaling such enterprises? Is there an enabling ecosystem for the social enterprise that can help it succeed?

I had the opportunity to pursue these questions during my M.A. at the Azim Premji University (2017-19). I embarked on a study that mapped the journey of social enterprises, specifically working with maternal and child health in the first phase. Insights from this phase led to the second phase of the study that focused on understanding the enabling ecosystem, the question of scaling up and circumstances for the government to adopt these solutions. This study then paved the way for an industry-academia collaboration that culminated in this handbook.

The study was based on 65 interviews and interactions with incubators, philanthropic organisations, social enterprise founders, members of their organisations, academicians, employees of district hospitals, and the primary health centers (PHC) and community health centres (CHC) where innovations were implemented. The field visits, interactions and the findings were followed by discussions with industry experts and the team at the University.

The idea of this handbook emerged from this journey, in response to a need expressed by many social enterprise founders and others associated with healthcare innovations. This handbook draws upon the findings of the expansive study including field visits and interviews, as well as follow-up interactions with incubators, social enterprise founders and academia in outlining the role of social enterprises in healthcare innovations. In addition to field visits and interviews, this handbook has been compiled by referring to many valuable resources.

I am extremely grateful to Dr Venkatesan of Villgro, Dr Satya Prakash Dash of BIRAC & Venture Center, Prof Arima Mishra, Prof Annapurna Neti and Nazrul Haque of Azim Premji University who have been a part of the journey. Their multidisciplinary expertise in public health, ethics, social enterprise, medtech and healthcare shaped the direction of this book. The team, though based across continents and time zones, deliberated over the findings and the best ways to present the content. I sincerely appreciate the time they devoted, their constant encouragement, discussions and reviews.

A special thanks to Dr Dash, who not only brought his expertise to the book but also his immense passion for start-ups. He has co-authored 'Chapter 2: Innovation and the product life-cycle' and 'Chapter 3: The enabling ecosystem'.

- Anil Misquith

About the handbook

This handbook is meant as a guide, to provide visibility into the entire process of creating technology-based social enterprises, from ideation to conceptualisation and scaling. It captures details of the enabling ecosystem, well-known frameworks and other resources. A dedicated chapter on scaling features a wide cross section of case studies across social enterprises — for profit and not-for-profit — that have found their own paths to scale. The case studies that are covered are across products, services and diagnostics in preventive and curative care.

A special section covers interviews with domain experts in this ecosystem. These interviews provide deep insights into trends in innovation, the enabling ecosystem, the pitfalls that a social enterprise team could encounter and suggestions for social enterprises. While the emphasis is on healthcare innovations, the approach and learnings are also relevant to innovators from other industry domains.

The following readers will find this handbook useful:

1. Founders of start-ups
2. Incubators and accelerators
3. Impact investors and philanthropists
4. Students of public health, development, business, engineering and medical sciences
5. Managers of entrepreneurship programmes
6. Public health practitioners
7. Policymakers

This handbook progresses through the following sections:

- **Introduction**: This chapter introduces healthcare challenges in India and some of the key providers addressing healthcare needs, including social enterprises.
- **Innovation and product development cycle:** This chapter covers design thinking principles and refers to two frameworks – 'A Conceptual framework for Innovation in Healthcare' from Omachonu and Einspruch (2010), and 'A framework to scale up technological innovations' from Herzlinger (2016), outlining stages of the product development cycle and factors to be considered while developing a new product.
- **The enabling ecosystem:** This chapter covers the ecosystem that is currently available to assist social enterprises at various stages of the product life cycle. The ecosystem is mapped across two dimensions: government and non-government.
- **Scaling up: Navigating through the ecosystem:** This chapter covers three frameworks for scaling – 'Six Factor Analysis' from Diffusion of Global Innovations in Healthcare (2017), 'From

Blueprint to Scale' from Monitor Research (2012) and 'Scaling barriers' from Monitor Deloitte analysis (2014). This chapter then follows through with the decision-making process in the government system at the national and state levels, budget heads for innovation, critical timelines, conditions for adoption and insights from interactions with health departments.

- **Lessons learnt from organisations that have scaled up:** This chapter covers the 'Diffusion of Innovation theory' from Everett Rogers (1961). It includes case studies of five social enterprises across India that have crossed multiple valleys of death to scale up. The case studies cover a wide spectrum of services, from products to digital platforms, to help an innovator across portfolios.
- **Recommendations:** A section for all stakeholders – founders of social enterprises, enabling ecosystem and decision-makers of the public health system. This chapters reflects on questions posed at the beginning and responds to critical questions the study pursued; it also covers suggestions for stakeholders across the product life cycle: From inception to deployment.
- **Voices of experts**: This chapter captures the detailed interactions with domain experts. These interviews are truly insightful and bring out the depth of the experience they have gained over the years.

Never invest in an idea you can't illustrate with a crayon

– Peter Lynch, American businessman

Source: Metcalf, Fred (2014). *The Biteback Dictionary of Humorous Business Quotations*, Biteback Publishing, London

Chapter 1: Introduction

The need for innovations and new business models in healthcare

Over the last few decades, the world has achieved several public health milestones, such as eradication of certain diseases, increase in life expectancy and the decline in infant mortality. According to Lancet (2016) however, India still accounts for 16 percent of maternal deaths and 27 percent of new-born deaths globally. With a 22 percent shortage of primary health centres (PHCs) and 32 percent shortage of community health centres (CHCs), it is estimated that more than 50 percent of beneficiaries travel more than 100 km to access quality healthcare (Lancet, 2016).

Access to quality and affordable healthcare for everyone, and the double burden of diseases, continue to remain a challenge. Almost 100 million people are pushed into extreme poverty each year because of high out-of-pocket health expenses.[1]

India's out-of-pocket expenditure (62.4 percent) as percentage of healthcare expenditure is almost twice that of China (32 percent) and more than thrice that of the world average (18.2 percent).[2] With the government's allocation to healthcare being 1.2 percent of GDP, it is not surprising that the World Health Organization (WHO) ranks India's healthcare system at 112 out of 190 countries.[3]

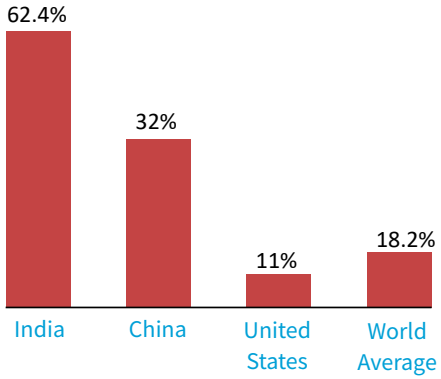

Figure 1.1: OOPE as a percentage of health expenditure (2014)
Source: NATHEALTH, PWC 2017

1 Taking Universal Health coverage : 2017 Global Monitoring report

2 Funding Indian Healthcare – Catalysing the next wave of growth (NATHEALTH & PwC)

3 http://healthcare-in-india.net/healthcare-delivery/indias-healthcare-system-ranks-112th-in-the-world/

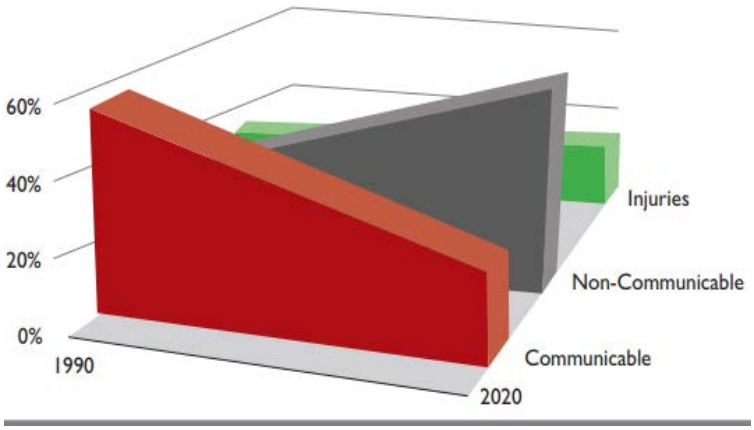

Figure 1.2: Changing disease burden
Source: (Nutrition Transition in India, 1947-2007, Ministry of Women and Child Development as cited in PAHAL Healthcare Innovations report)

Furthermore, over the last three decades, there is a perceptible change in both the types of diseases and their prevalence in rural areas. While communicable diseases are on the rise, rural India accounts for 50 -70 percent of non-communicable diseases (NCD). Another point of concern is that leading NCDs such as cardiovascular and respiratory diseases and diabetes occur at a much earlier age (<45) versus the global average (>55), with many of them going undiagnosed due to lack of access or awareness.[4]

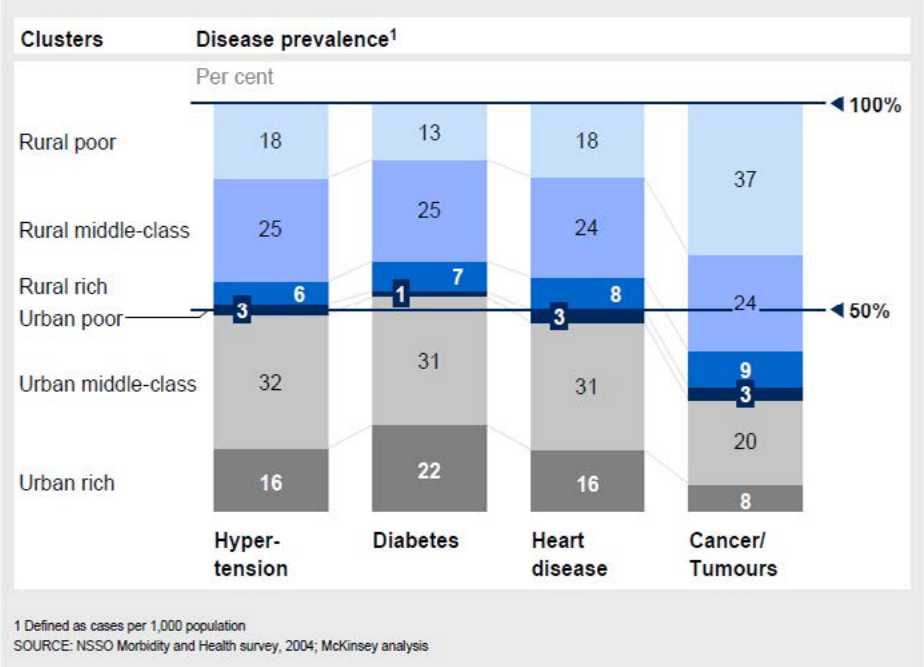

Figure 1.3: Rural India accounts for 50-70% of non-communicable diseases
Source*: India Healthcare : Inspiring possibilities, challenging journey, McKinsey & Co (2012)*

4 India's escalating burden of non-communicable diseases

The changing disease patterns coupled with lack of awareness and access have an adverse and severe impact on household finances.

A report on Indian household finance[5] shows that medical emergencies featured as the second biggest risk for households, and this aligns with the high out of pocket expenses incurred by families in India.

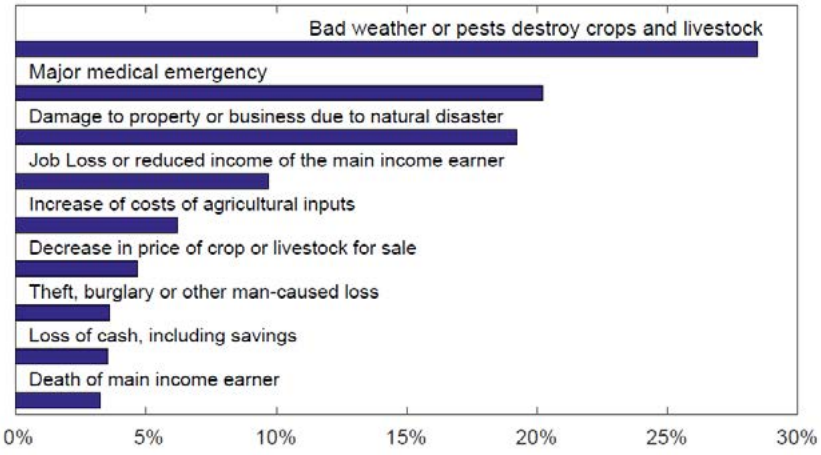

Figure 1.4: Events with major financial impact on household finances
Source: *India Household Finance 2017*

While government and civil society efforts work in tandem and strive towards ensuring effective, quality healthcare, one new area that is emerging is tech innovations in healthcare led by social enterprises

To address the challenge of access and affordability of healthcare, as well as public awareness, the Government of India has launched several initiatives such as the National Health Protection Scheme,
National Health Mission and Public-Private Partnership model for healthcare. More recently, the National Health Policy 2017 has recognised the importance of Sustainable Development Goals (SDGs) has called out specific areas that need focus intending to achieve 'health for all'. Some of the objectives of the policy are to expand preventive, curative, palliative and rehabilitative services provided through the public health sector with a focus on the quality of healthcare.

Several civil society organisations[6] (CSOs) and social enterprises (hereafter referred to as SEs) are increasingly playing a role in healthcare across the country and complement government efforts by developing models such as community healthcare programmes, community hospitals and so on.

5 India Household Finance 2017

6 Association for Health welfare in the Nilgiris (ASHWINI), Society for Action, Education, Research in Community Health (SEARCH) in Gadchiroli, Tribal Health Initiative (TBI) in Sittilingi, Karuna Trust in B.R.Hills, Ekjut in Madhya Pradesh, West Bengal Voluntary Health Association (WBVHA) and Eleutheros Christian Society (ECS) in Nagaland. http://ecstuensang.org/ http://ashwini.org/, http://searchforhealth.ngo/, http://www.tribalhealth.org/, https://www.karunatrust.org/, http://www.ekjutindia.org/, http://www.wbvha.co.in/, http://ecstuensang.org/

There are multiple definitions for social enterprises, but in general it is a term used to differentiate socially motivated enterprises from those motivated only by profit. Social enterprises can be 'for profit' or 'not for profit'. 'For profit' SEs are set up to address societal needs, while also ensuring that they are economically viable and a large part of the returns are reinvested in driving social good, while providing nominal return to the investors. 'Not for profit' SEs are also set up to address societal issues but are not profit-oriented and are primarily supported by grants. SEs are present across sectors ranging from healthcare and energy, to education and livelihoods.

Social enterprises in healthcare

In the last two decades, India has seen a diverse range of technology innovations in healthcare led by SEs, from Aravind Eye Care System conducting cataract surgeries in an assembly line model to Yostra Lab's KADAM, a therapeutic device to reduce healing time of chronic wounds. The entry of impact investors and philanthropists has broadened this emerging ecosystem and enabled the development of innovative solutions to key challenges in healthcare. While many of these solutions are being piloted and deployed across the country, some of them are commercially ready and getting into 'scale' mode.

While the SE landscape is extensive, we have attempted to represent a macro view of the categories.

Point-of-care diagnostics	Medical devices	Digital health/ICT platform	Services
BEMPU	NAYAM INNOVATIONS	FORUS CARE	ARAVIND EYE CARE
CARENx	YOSTRA LABS	HEALTHPLIX	DOCSAPP
FORUS	ONEBREATH	PIRAMAL SWASTHYA	GLOCAL
JANITRI		MY UPCHAR	NEUROSYNAPTICS
NIRAMAI			

Figure 1.5 Four categories that social enterprises in healthcare are broadly classified under
Source: https://inc42.com

A brief description and examples of the categories are provided below:

a. Point-of-care diagnostics:

Solutions used to diagnose a range of health conditions from anaemia and retinopathy to breast cancer. These are mostly non-invasive and preventive.

1. Bempu (https://www.bempu.com/): Innovative life-saving products for children — such as Bempu Tempwatch, KangaSling and ApneBoot — in low-resource settings
2. CareNX (https://caremother.in/): Products for pregnancy care at home and in hospitals

3. Janitri (https://janitri.in/): Solutions for maternal and child care, such as a labour monitoring tool and a foetal heart rate and contraction monitoring device
4. Niramai (https://www.niramai.com/): A novel breast cancer screening solution

b. Medical devices:

These are solutions used to treat a particular health problem and are mostly curative.

1. Nayam Innovations (http://www.nayaminnovations.com/): Solutions such as intraocular lenses to eliminate needless blindness
2. Yostra Labs (www.yostra.com): A therapeutic device to reduce the healing time of chronic wounds
3. OneBreath (http://www.onebreathventilators.com/): Ventilators to provide continuous respiratory support

c. Digital health/ ICT platforms:

Used to store medical records, upload images of diagnostic tests and so on.

1. Forus Care (https://www.forushealth.com/platform.html): Connects multiple stakeholders in the eye-care ecosystem, data generated by their system can be reviewed by specialists
2. Healthplix (https://healthplix.com/): Electronic medical records for patients, clinics, pharmacies and others
3. Piramal Swasthya (https://www.piramalswasthya.org/): Accessible Medical Records via Integrated Technologies (A.M.R.I.T), a platform to store electronic health records for public primary healthcare
4. myUpchar (https://www.myupchar.com/en): A platform to consult doctors, book lab tests and so on

d. Services:

Solutions used to provide curative care

1. Aravind Eye (https://aravind.org/): Aravind is engaged in patient care, research and manufacturing
2. DocsApp (https://www.docsapp.in/): Consult doctors online
3. Glocal (https://ghspl.com/): Healthcare to the rural population through an integrated model of block-level comprehensive primary and secondary care hospitals
4. Neurosynaptics (https://neurosynaptic.com/): Facilitates remote diagnosis of the patient by capturing various basic physiological parameters, providing an extremely affordable method for remote healthcare delivery

The trend in rapid innovations in healthcare does, however, raise a few key questions:

- Can social enterprises solve some of the major problems like equitable access to quality healthcare?
- Which models adopted by SEs are 'beginning to scale up'?
- What are the key factors that would drive public health systems to adopt innovative solutions?
- What key factors should SEs bear in mind while designing healthcare solutions?
- Does the current ecosystem provide end-to-end support (from risk capital and product design to product trials) for healthcare innovations from SEs?

The following chapters of this handbook will explore these questions.

Nothing is more dangerous than an idea, when you have only one idea

– Emile August Chartier, French philosopher

Source: Metcalf, Fred (2014). *The Biteback Dictionary of Humorous Business Quotations*, Biteback Publishing, London

Chapter 2: Innovation and the product life cycle

While there are different categories of innovations, we will focus on technology-led products and process innovations in healthcare.

Defining innovation

Innovation has been the main driver of humanity's progress, especially technological progress. There are several definitions of innovation. In the early 20th century, legendary economists such as Joseph Schumpeter defined innovation as "new combinations of new or existing knowledge, resources, equipment and other factors".[7] The phrase "new combinations" referred to novel solutions and Schumpeter urged a distinction between inventions and innovations through the prism of commercialisation. He also called the social agents of innovation, "entrepreneurs" and he believed that entrepreneurs had to find "new ways" since inertia was always prevalent.

Innovation in healthcare

Innovation in healthcare faces several unique challenges, uncertainties and obstacles. Some of them include long gestation periods of product development, especially in terms of technological feasibility, navigation of regulation and standards for adhering to safety and efficacy of the product, and finally adoption by customers (doctors and patients). Varied business models are adopted, depending on payment models and existing national health systems.[8]

Many other system-level factors also influence a health innovation's path to the market and its commercialisation outcome. Herzlinger (2006) mentions six forces that drive healthcare innovations — industry players, funding, public policy, technology, customers and accountability. Each of these forces is complex and is impinged upon by other undercurrents that influence the success of a healthcare innovation.

Herzlinger also highlighted the different "players" in the health sector — incumbents compete to hold on to their market share, while innovators are focused on dislodging the incumbents. Additionally, there are other players in the market such as the patient advocacy groups that seek to influence policymakers.

7 Fagerberg, Jan. (2009), 'A Guide to Schumpeter. Confluence. Interdisciplinary Communications 2007/2008. 20-22'

8 Herzlinger, R E (2006), 'Why Innovation in Healthcare Is So Hard', Harvard Business Review

Funding is key to productisation of innovation, but because of long gestation periods, it is difficult to attract private investments into healthcare innovation. Herzlinger also points to funding and investor confusion because of complex reimbursement procedures in different healthcare markets.

One of the important factors Herzlinger pointed to is the policy environment around healthcare, be it laws governing hospitals, surgical procedures or import duties on components. In the realm of technology as a part of the six forces, Herzlinger reminds innovators to be aware of evolving technologies that may impact medtech, including vaccines and drugs. For example, the polio vaccine eliminated the need for drugs, devices and associated services needed to treat patients with polio. She said that customers — patients in this context — are transitioning from being a passive party to an active party, and a company that understands this shift in patient behaviour would be better placed to successfully productise health innovation and scale it. Furthermore, empowered consumers and payers are demanding accountability from healthcare innovators and innovators have to take into account the demands of "agents of accountability".

Research in healthcare innovation is not extensive. Omachonu and Einspruch (2010) observed that there is a paucity of research on healthcare innovations. In 'Conceptual Framework for Innovation in Healthcare', the duo defines healthcare innovations "as a new concept, idea, service, process or product aimed at improving treatment, diagnosis, outreach and prevention with the long-term goal of improving quality, safety, outcomes, efficiency and costs".

Omachonu and Einspruch cite that healthcare organisations often develop innovations by relying on new or existing information technology, and successful ones are those that focus on three areas the most:

1. How the patient is seen
2. How the patient is heard
3. How the patient's needs are met

A conceptual framework for innovation in healthcare

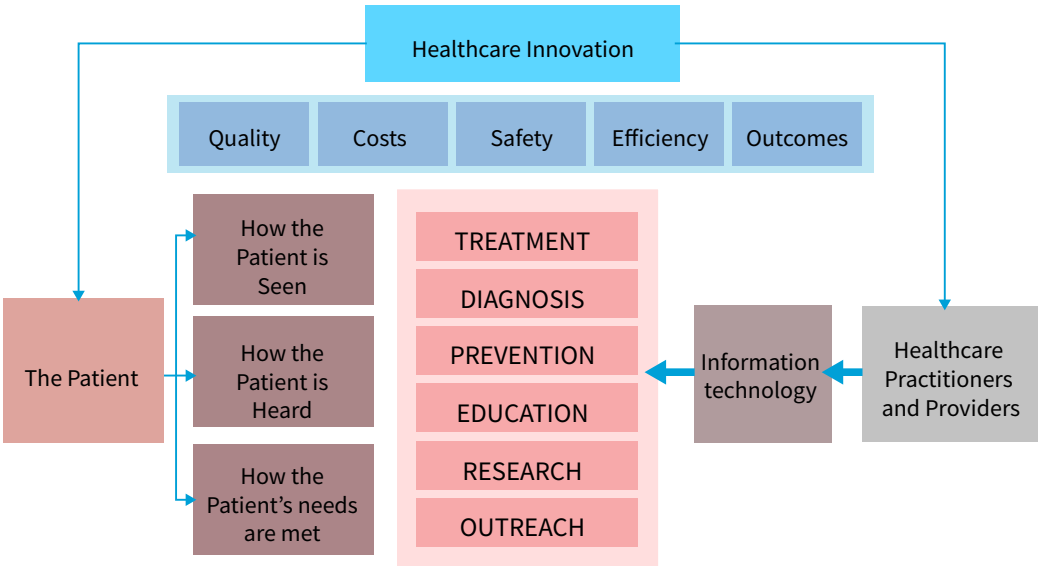

Figure 2.1: A conceptual framework for innovation in healthcare
Source: Omachonu and Einspruch (2010)

The framework recommends that given the complex situations under which healthcare innovations function, it is important to map the key stakeholders and understand their priorities.

Stakeholders	Priorities
Physicians and caregivers	Improved clinical outcomes, diagnosis treatment
Patients	Improved well-being in a shorter time
Organisations	Efficiency, cost reduction, quality and outcomes
Innovators	Solving healthcare challenges and profitability
Regulatory Bodies	Patients safety in cost-effective way

Figure 2.2: Unique priorities of key stakeholders of the healthcare inovation process
Source: Omachonu and Einspruch (2010)

In the framework, Omachonu and Einspruch mention that healthcare organisations typically cater to prevention, diagnosis, treatment, research, education and outreach, in order to deliver quality, safety and efficiency and outcomes.[9]

While questioning the process of innovation, they suggest that an important aspect to discuss is the trigger for the innovation: "Are innovative solutions looking for a problem or does the problem need an innovative solution?"

In Omachonu and Einspruch's framework, Varkey et al (2008) observe that the process of innovation is not linear after the problem is identified; it goes through multiple iterations of idea generation, idea evaluation, development, and proof of concepts, commercialisation, diffusion and more.[9]

A brief introduction to the innovation process through the frameworks below would help one understand the different stages of innovations before scaling.

Design thinking

The journey of an innovation from idea to the market is fraught with several uncertainties including technical feasibility, its appropriateness as a solution, its ability to meet regulatory requirements and, finally, adoption. Additionally, there are externalities that cannot be predicted. For example, bureaucracy, dealing with internal team structures and turbulence such as pandemics that may wipe out demand and bring down consumption. All of these uncertainties could make it difficult for innovation to take root and eventually reach the market.

9 Vincent K. Omachonu and Norman G. Einspruch (2010) 'Innovation in Healthcare Delivery Systems: A Conceptual Framework', The Innovation Journal: The Public Sector Innovation Journal, Volume 15(1), 2010, Article 2

Additionally, solutions for social challenges require a systemic approach that cover a gamut of issues including behaviour patterns of communities. Over the last few decades, a new term called 'design thinking' has emerged in the vocabulary of innovation and problem-solving, led by several experts such as David Kelley at Stanford University and Timothy Brown (founder of Ideo)[10] (Brown and Wyatt, 2010). The usage of the term 'human-centred design' is also interchangeably used with' design thinking'.

Brown and Wyatt say that the traditional problem-solving approaches — involving surveys and focus groups — have their flaws, especially in understanding customers and communities in granular detail. Design thinking attempts to overcome these flaws through a deeply human process of understanding the problem, the people encountering the problem and behaviour of users and communities, before recognising patterns and designing solutions by keeping the users at the center of things.

The design thinking method encompasses overlapping and iterative 'spaces' which are 'inspiration, ideation, and implementation'.

A. Inspiration

The design process starts with what is referred to as an 'inspiration space', which is an area or field where people and innovators are motivated to search for solutions. This phase has several components including a starting point called 'brief', which is a technique that innovators or the project team uses to chart a framework for assessing the problem, defining benchmarks for progress and identifying objectives.

At the heart of design thinking lies empathy and observation, hence design thinkers are generally advised to embed and immerse themselves with communities (through extensive field research, for instance) whose problems they are trying to solve.

One of the reasons for the immersion is to allow innovators to see the problem through the eyes of the communities who have to deal with the problem on a daily basis and not to bring pre-held assumptions on board. They observe granular details of behaviour patterns, the environment where the problem exists, and clues about unmet needs. Through this observation, they identify the pain points as well as the available resources and solutions.

B. Ideation

The second phase of design thinking is called ideation and it generally follows the immersion phase. Innovators gather the insights and observations into one place and then attempt to list all possible ways to find a solution. The focus here is to freely list all possible ideas without bias or practicalities and encourage the immersion participants to be open about any prospective ideas that they may have. It is then followed by a brainstorming process to test different ideas and their appropriateness to provide an optimal solution.

Teams of innovators attempt this through a structured brainstorming process using simple tools such as white boarding, sticky notes, coloured pens and open discussions about different solutions. Experts in design thinking urge innovators to defer judgement about picking solutions but take a much more measured approach in assessing different solutions.

10 Tim Brown & Jocelyn Wyatt (2010), 'Design Thinking for Social Innovation, Stanford Social Innovation Review, 30-35

C. Implementation

The third and final phase of design thinking is implementation, where some of the ideas are taken forward simultaneously to build prototypes. Both alpha and beta prototypes are taken as first steps (and this phase has a "work in progress" kind of approach) towards eventual productisation. This process involves rapid prototyping followed by testing in field conditions.

This is a highly iterative process and involves taking the prototypes (sometimes also referred to as minimal viable products or MVPs) into actual field conditions to test early adoption behaviours, identify flaws in initial design and learn from initial use case scenarios. Design thinking experts recommend building and testing several prototype designs — including meeting technical and regulatory standards — and integrating the feedback into refining the product.[10]

Once prototyping is completed, the design team proceeds to craft a communication strategy. It is important to take into account the cultural and language aspects while designing the same.

Once prototyping is successful with initial testing, the innovation leads to piloting and scale-up strategies. The piloting and scale-up may reveal additional problem areas about the product or the service, hence innovators should keep an open mind and accept and resolve new issues and problems that may emerge.[10]

It must be remembered that these methods are one way to approach designing and building solutions. Innovators can design their own methods to understand the problem areas, identify opportunities and then build product or service solutions.

Scaling has a different order of complexities. The typical design thinking framework does not delve much into the scale-up issues and this remains one of the lacunae in design thinking methods.[10]

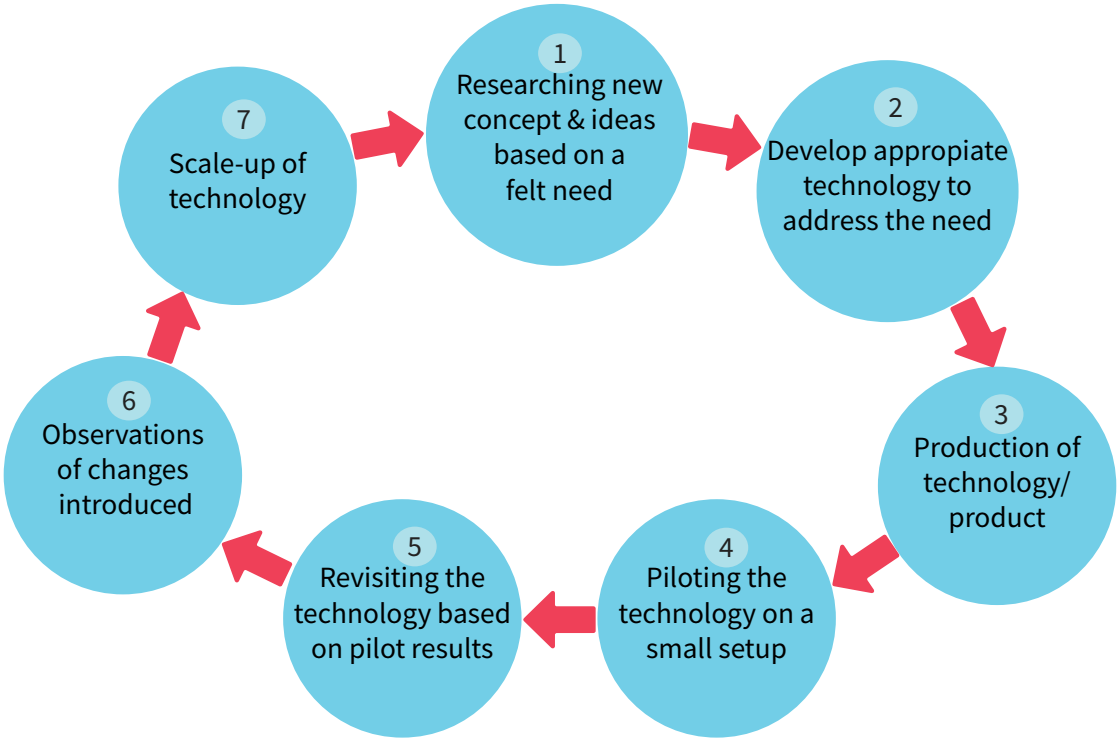

Figure 2.3 A framework to scale up technological innovations
Source: Adapted from Herzlinger (2006)

10 Tim Brown & Jocelyn Wyatt (2010), 'Design Thinking for Social Innovation, Stanford Social Innovation Review, 30-35

As one of the focus areas of this handbook is to look at the challenge of 'scale', this framework to scale up technological innovations can be a useful reference.
We have summarised the framework below.

Concept stage

A phase where a founder or a small team of founders explore a need in a society/community and identify gaps in delivering healthcare to meet that need. The ideas are often triggered by personal experiences, observations of people or a focused effort to understand gaps based on their professional background. The founding team lists out various approaches to solve the problem and narrows down the approaches to two or three ideas that are further developed into a concept.

Choosing technology

Based on the shortlisted ideas, the team identifies various technologies that can be used to address the problem. A conceptual blueprint is subsequently prepared. A bill of materials and approximate costing for various scenarios and quantities are developed. Its efficacy v/s existing solutions and methods or an adjacent method to address similar problems is used as a base for comparison.

Creating a prototype

A blueprint enables the creation of a prototype, which is either a software solution, a hardware product or a combination of both. Costs anticipated in the previous stage are validated during the prototype development phase.

Piloting the prototype

A smaller set-up is chosen to test the features, assumptions are validated, user feedback is gathered and additional features are identified. Costs anticipated in the previous stage are validated and revised.

The first set of deployments

Locations are identified for the first set of deployments. These pilots are generally intended to test the nearly complete product and are either paid pilots or grant-funded pilots.

Business development

Organisations identify their market segments and geographies (public v/s private healthcare or both, state, national or international) to deploy their solutions. SEs then finalise their strategy (either to market directly or to team up with partners).

How could these frameworks help?

The 'Conceptual Framework for Innovation in Healthcare' (Omachonu & Einspruch (2010) is relevant in the very early stages, when an innovator starts ideating. The framework draws the innovator's attention to three key aspects: how the patient is seen, how the patient is heard and how the patients' needs are met.[11]

The design thinking model focuses more on product design, development and implementation.

The Herzlinger framework[12] looks at the product cycle and is very useful to understand each stage of a product development cycle, right up to scaling.

While each framework is different, there is also the need to look at the 'voice of the voiceless' such as children and patients with intellectual disabilities. In many cases, decisions are not in the hands of the patients, but in the hands of the caregiver, a parent, a spouse or children for elderly patients. What modes should innovators adopt to ensure that this voice is not lost? Another area that is not covered is the need to develop evidence to facilitate decision making.

Balasubramanium and Srinivas (2018)[13] write that although there are many advances in technology, solutions should be chosen to ensure they are user-friendly, achieve the desired results and are empowering the communities and health workers without making them dependent on these solutions.

Given the above stages, it is important to understand the role of the ecosystem and the various players at different stages of the product life cycle, including the views of people from the healthcare sector. In the course of this study, we have also sought views from key people across industries. The next chapter presents the landscape of entities across the innovation cycle, featuring both government and non- government entities.

In the next chapter, we look at the enabling ecosystem at different stages of this process. In the subsequent sections, we cover learnings from some SEs that have been through this journey.

11 Omachonu & Einspruch (2010), 'Innovations in Healthcare delivery systems'

12 Herzlinger R., et al. (2017),' Diffusion of Global Innovations In Health care - How to make it happen'

13 Balasubramaniam and Srinivas (2018), 'Towards a healthy India – A call for action'

If at first, the idea is not absurd, then there is no hope for it

– Albert Einstein, German theoretical physicist

Source: Metcalf, Fred (2014). *The Biteback Dictionary of Humorous Business Quotations*, Biteback Publishing, London

Chapter 3: The enabling ecosystem

It takes a village to raise a child
- African proverb

In developing innovative healthcare solutions, the life cycle is different from other areas such as fintech and e-commerce. The gestation cycle across stages in healthcare – from identifying a problem, developing a prototype and testing it to the first set of deployments and scaling – is a long process. Founders of social enterprises in this sector have experienced that it takes anything from seven to 15 years for organisations to reach sustainable levels.

Social enterprises require different enablers at different lifecycle stages. The enabling ecosystem has many entities across government and non-government sectors, some of them are briefly described below.

In the government ecosystem, we have featured the **Biotechnology Industry Research Assistance Council** (BIRAC), which has been at the forefront of enabling healthcare start-ups through several programmes for almost a decade. We have also featured another relatively new entity called **Accelerating Growth of New India's Innovations** (AGNIi), which plays a role in the early stages. As product validations are critical for public health adoption, the role of **National Health Systems Resource Center** (NHSRC) in **Health Technology Assessment** (HTA) is also featured.

In the non-government ecosystem, we have not only featured leading incubators such as Villgro and Social Alpha but also other organisations such as Piramal Swasthya and WISH Foundation that play an important role in providing reach to social enterprises.

Enablers: government

1. Biotechnology Industry Research Assistance Council (BIRAC)

A well-known entity from the Government of India in this space is the **Biotechnology Industry Research Assistance Council (BIRAC)**, which was set up in 2012 by the Department of Biotechnology. BIRAC is the nodal biotech and medtech innovation agency in India. It has made a significant contribution and has supported over 1,000 science and technology (S&T) start-ups with grants in the early stages. BIRAC works with students, entrepreneurs, innovators, start-ups, entrepreneurial faculty and SMEs.

Since its inception, BIRAC has partnered with several national and international organisations and launched more than a dozen programmes such as Biotechnology Ignition Grant (BIG),

BIRAC has done a brilliant job of seeding MedTech, most of innovators have got some kind of help from BIRAC
- Dr Abhishek Sen, Co-founder, Biosense

SPARSH (for social innovations), BioNEST (for incubation), SoCH (for innovations in sustainability), WiNER, SBIRI, BIPP and Product Commercialization Program for creating a clear path for BIRAC-funded projects to be taken to market. These programmes encompass product journeys from ideation, proof of concept (POC), and validation to commercialisation and scale (figure 3.1). BIRAC's funding ranges typically from USD 25,000 to USD 2 million. Most of the funding is a non-dilutive grant; however, BIRAC has also brought some dilutive funding instruments such as BIRAC-SEED, LEAP and BIRAC-AcE that are delivered by partners.

Biotechnology Ignition Grant (BIG) is now India's largest early-stage biotech and medtech innovation programme and has funded more than 500 innovators and start-ups with grants up to USD 70,000. Similarly, SPARSH has created a network of social innovators across India. Both BIG and SPARSH work with partners to deliver their programmes across the country. BIRAC's BioNEST programme has created more than 50 bio-incubators that together house over 600 S&T start-ups which are building products for social innovation, be it healthcare including medtech (devices and diagnostics), vaccines and drugs, environmental sustainability, agriculture or waste management.

BIRAC also has created national and international partnerships including WISH Foundation for providing access to healthcare technologies for clinical testing, Bill & Melinda Gates Foundation for Grand Challenges programme in healthcare, agriculture and nutrition, Nesta's Longitude Prize in solutions for antimicrobial resistance, TEKES Finland and the UK's University of Cambridge for providing start-ups ways to interact with other innovation ecosystems.

Some of BIRAC's programmes are as follows:

SIIP: Social Innovation Immersion Program (18-month fellowship programme with a grant of INR 5 lakh)

BIRAC-SRISTI: Funding programmes for researchers and innovators in academia, INR 15 lakh spread over two years (also known as BIRAC-SRISTI-GYTI awards)

BIG (Biotechnology Ignition Grant): India's flagship biotech and medtech funding programme. Grant funding up to INR 50 lakh for 18 months for taking the idea into proof-of-concept (POC). Implemented by several partners across the country. The BIG call for proposals is twice per calendar year. BIRAC has funded close to 500 projects under this programme.

SPARSH: Social innovation programme in biotechnology modelled for both early-stage POC as well as late-stage products.

CRS (Contract Research Scheme): Aims to fund joint industry-academia project and build partnerships between industry and academia

SBIRI (Small Business Innovation Research Initiative): This is an equal matching contribution grant fund for validation studies of POC projects up to INR 1 crore. It has a smaller component support of INR 25 lakh where the company has to contribute INR 5 lakh and BIRAC contributes the rest.

BIPP (Biotechnology Industry Partnership Program): This is for product development from validation up to scaleup TRL 6-8.[14] This is also an equal matching contribution grant funding programme with no limitations of the project cost. Generally, projects up to INR 10 crore (INR 5 crore from industry and INR 5 crore from BIRAC) are funded.

PDF/PDP: BIRAC has also initiated a product development fund/programme that is targeted at technologies that are either market ready or have taken steps to be in the market.

Equity funding: BIRAC also has equity programmes that are delivered via its partners. SEED and LEAP funds are equity programmes delivered by BIRAC's BioNEST incubators with ticket sizes of INR 25 lakh and INR 1 crore respectively for which the incubators take a share in the equity. BIRAC also has a fund equity program called BIRAC-AcE Fund (not shown in the diagram) that is delivered by SEBI-registered venture funds who then take equity for the investments up to INR 7 crore.

These cumulative interventions from BIRAC have created an entrepreneurial surge across the country.

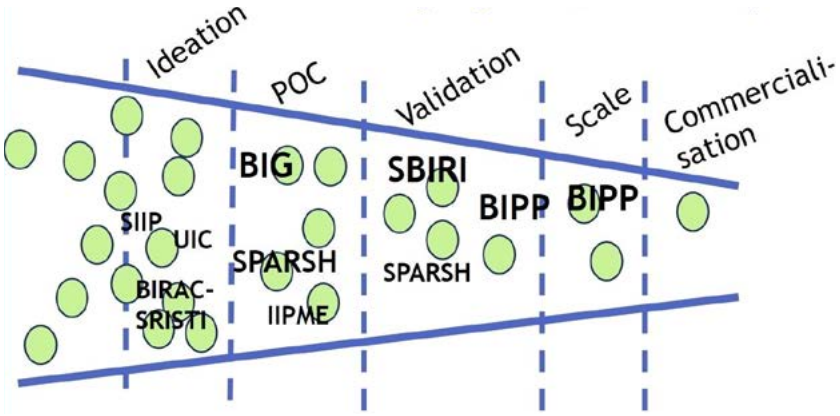

Figure 3.1 BIRAC'S programms across various stages
Source : BIRAC website

BIRAC's funding programmes extend from early ideation stages to late product commercialisation. Individuals are also funded during the early stages; however, registered Indian companies are funded at the later stages.

Increasingly, institutions that encourage innovations both in India as well as globally are incorporating the process of 'immersion' as part of the conceptualisation stage. This has stemmed from the adoption of several design thinking concepts during this nascent stage. In India, the Department of Biotechnology (DBT) partnered with Stanford BioDesign and launched the Stanford India Biodesign. As mentioned earlier, BIRAC also launched a social innovation programme called SPARSH (especially its SIIP fellowships), with several partners simultaneously, that not only incorporated elements of design thinking but also provided early micro-grants to entrepreneurs even during conceptualisation stage.

2. Millennium Alliance http://www.millenniumalliance.in

Millennium Alliance (MA) was set up in 2011 as a multi-stakeholder consortium involving the Department of Science and Technology (DST), Government of India, Federation of Indian

14 https://www.birac.nic.in/webcontent/birac_trl_doc5_medical_devices_and_diagnosis_12_09_2018.pdf

Chambers of Commerce (FICCI), United States Agency for International Development (USAID), the Department for International Development, Government of UK, Marico Innovation Foundation and Facebook.

MA provides grants to start-ups and SMEs at different stages of the innovation journey. The grant stages are categorised as:

- Stage 1 (piloting or testing an innovation)
- Stage 2 (scaling a successfully piloted innovation in India)
- Stage 3 (replicating and scaling in another developing country).

We received a grant from BIRAC. From a Non-Financial standpoint, ICMR has helped us a lot, National Institute of Biologicals has helped us a lot in validation, NHSRC has done Health technology assessment for three of our products - Co-founder Biosense

Depending upon the stage of the product, the funding support extended by MA ranges between INR 25 lakh to INR 2 crore.

Over the last decade, MA has supported 124 social enterprises and has helped scale 22 social enterprises to African countries such as Kenya, Ethiopia, Rwanda, Malawi and Tanzania, and has encouraged the adoption of some solutions in South Asian countries such as Bangladesh and Sri Lanka.

3. Indo-US Science & Technology Forum (IUSSTF) https://www.iusstf.org/

IUSSTF was established as a partnership between the governments of India and the USA in 2000, in order to promote science, technology, engineering and innovation. Within the innovation and entrepreneurship vertical, IUSSTF has three funding programmes:

- Indo-US Technology Endowment Fund (IUSTEF)
- India Innovation Growth Program (IIGP)
- Women Entrepreneurs Quest.

IUSTEF provides grants up to USD 4,00,000 or INR 2.5 crore, while the support from IIGP ranges from INR 10 lakh to INR 25 lakh.

4. Department of Science & Technology's National Science Technology & Entrepreneurship Development Board (NSTEDB) http://www.nstedb.com

The Department of Science & Technology (DST) is a pioneer in innovation, establishing NSTEDB in the early 1980s with the focus of technology entrepreneurship, besides launching partnerships such as Millennium Alliance and IIGP amongst others.

NSTEDB has several institutional mechanisms for supporting innovation such as its National Initiative for Developing and Harnessing Innovations (NIDHI) that includes seed support, acceleration and an entrepreneur in residence programme, i-STED programme, Technology Business Incubators and Science & Technology Parks.

NSTDEB also has been actively promoting entrepreneurship awareness programmes as well as entrepreneurial training among faculty and students across the country.

5. Accelerating Growth of New India's Innovations or AGNIi is a recently launched initiative of the Government of India under the guidance and support of the principal scientific adviser to the government. It aims to boost the innovation ecosystem in the

country by connecting innovators across the industry. Of the 900+ innovations that were evaluated during a three-month interval, roughly 30-40 percent of them were in healthcare developed by research labs and/or start-ups.

As an ecosystem matchmaker, AGNIi has been working closely with partners – CSR arms, philanthropy organisations, impact investors including NBFCs, agencies that can take innovations to Africa and other markets.

Figure 3.2 Amplicube, a portable isothermal device
Source: https://www.agnii.gov.in/innovation/amplicube

AGNIi's mandate is to reduce the valley of death for pilot-scale healthcare innovations that are unable to reach the market"
- Senior Leader, AGNIi

AGNIi also works with other stakeholders – NITI Aayog, industry associations and the Ministry of Health – to create a sandbox for healthcare start-ups to pilot their innovations in a more streamlined manner.

Amplicube from ShanMukha Innovations (portable isothermal PCR device at 1/10th cost of commercial devices). Used for molecular diagnostics for kala-azar, malaria, dengue and other diseases closer to the sample collection location

For more details: https://www.agnii.gov.in/sector/545/healthcare-pharma

6. National Health Systems Resource Centre (NHSRC)

National Health Systems Resource Centre (NHSRC) in Delhi works through the National Innovation Portal, which in turn supports two categories of innovations – product and programme innovation. Health Technology Assessments (HTA) is one of the important functions of NHSRC.

HTA is a process where the following are evaluated:

a. Intervention
b. Clinical impact, cost-effectiveness analysis
c. Strengths, limitations and challenges
d. Regulatory aspects
e. Recommendations

The more evidence you have, the stronger chance, you'll hold.
- NHSRC official

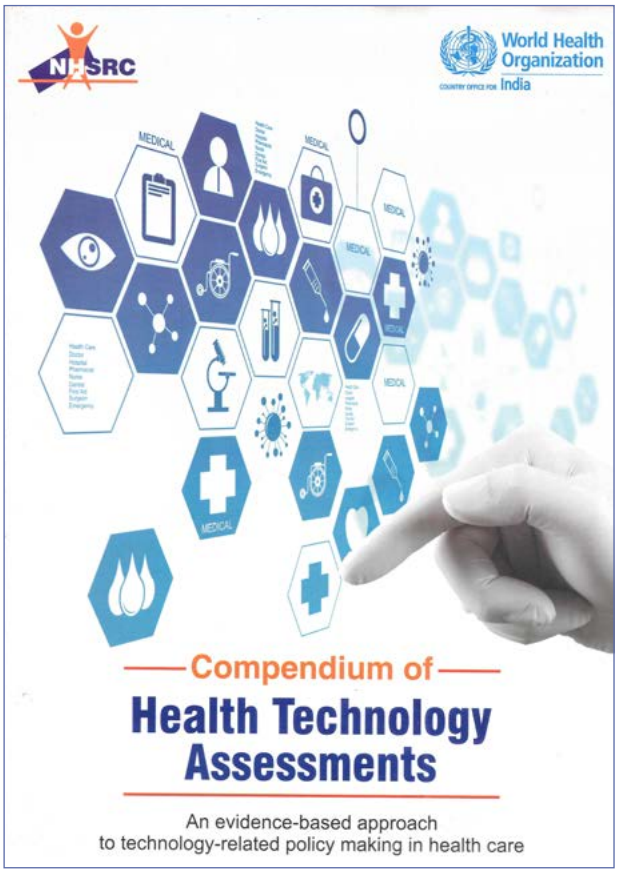

Figure 3.3 Compendium of Health Technology Assessments
Source: NHSRC

The results are published by HTA and shared at a best practices workshop. Also, HTAs are typically done for solutions that align with national priority – which implies that every innovative solution or programme may not make it to the HTA.

The National Best Practices Workshop is an annual national event organised by the Ministry of Health, where programme and product innovations and best practices from the HTAs are shared.

An example of an innovative product showcased at a workshop on best practices is the TrueHb Hemometer from Wrig Nanosystems, which is used for quantitative measurement

of haemoglobin applying the principle of reflectance photometry. Some states such as Uttar Pradesh have adopted it and some of them have included it in their Programme Implementation Plan.

Another recent initiative, 'National Digital Health Blueprint'[15] from the Ministry of Health and Family Welfare seeks to provide a framework to enable interoperability of data, capture data once and use many times and move from silos to systems. The above initiatives show promise; time will tell how they translate into ground realities.

Many experts feel that social enterprises usually look at the government as a funder and that they should perhaps look at the government as an *enabler* for their businesses. We spoke to an expert in the field of evidence to help social enterprises understand more about the HTA and the following:

- The process for assessments
- Criteria for assessments
- Dissemination of learnings to states
- Barriers to adoption

7. Social Stock Exchange

An emerging funding source for social enterprises to watch out for is the proposed Social Stock Exchange, a platform for social enterprises and voluntary organisations to raise capital through different types of funds. As per the report[16] submitted by the technical group set up by the Securities Exchange Board of India (SEBI), both not-for-profit and for-profit social enterprises can access these funds for social welfare work.

Voices of experts

In our interaction with **Denny John**, an evidence specialist, John demystifies HTA and talks about health technology assessment, regulatory and financial components and HTA as a prerequisite before scaling. John discusses market access strategies and regulations for innovative solutions and explains methods of evidence, their effectiveness, comparisons, systematic review, clinical trials, evidence and bias associated with it.

John also explains multi-criteria decision analysis, HTA recommendations, multi-technology assessment, and the cost-effectiveness of interventions. Another important aspect that John covers is the need to hear the voice of the patient; he speaks about different scaling strategies and the challenge of communicating evidence.

*Detailed interview with Denny John is in the Chapter titled '**Voices of experts**'*

15 https://main.mohfw.gov.in/sites/default/files/Final%20NDHB%20report_0.pdf

16 https://www.sebi.gov.in/reports-and-statistics/reports/may-2021/technical-group-report-on-social-stock-exchange_50071.html

Enablers: Non-government

1. Villgro Innovations Foundation

Founded in 2001, one of the first incubator-cum-impact investors in India, Villgro has incubated over 300 businesses across different verticals and has been nurturing several healthcare start-ups. Villgro mentors and funds early-stage start-ups that impact the lives of the poor in India.

Selection process

Villgro seeks to improve health outcomes for India's poor and supports social enterprises that are developing products/services, especially products that are sustainable, affordable and accessible. They look for social enterprises that have early customer traction, have the potential to achieve financial sustainability and have wider geographic acceptance.

Programme details

With a comprehensive programmatic model, Villgro provides support from the Idea stage to the Enterprise stage. During the incubation process, Villgro has a diagnostic panel that helps social enterprises think through both short-term and long-term goals. The technical advisory panel helps in product development and intellectual property strategy. Villgro also has its human resources advisory and financial advisory go-to-market strategy support.

Areas of interest in healthcare

- Maternal and child health
- Non-communicable diseases
- Infectious diseases
- Digital health platform and solutions

Impact on healthcare

Ideas evaluated as of 2020	Start-ups incubated	Start-ups invested in	Successful exits	Capital commited
1200+	17	13	1	INR 4 crore+

For additional details refer https://www.villgro.org/incubation/#incmentoring

Voices of Experts

Dr Arun Venkatesan, CTO of Villgro, shared his views on the ecosystem in India, trends in Investments in healthcare, Villgro's portfolio and notable successes. Venkatesan also spoke about emerging business models such as product as a service and public-private partnerships, and also shared his views on current policies and barriers to government projects. He shares another important aspect that every founder needs to understand – his perspective on risk capital and the impact that investors expect.

Detailed interview with Dr Arun Venkatesan is in the chapter titled '**Voices of experts**'

2. Social Alpha

Social Alpha felt that social enterprises developing healthcare innovations face multiple challenges – product engineering, clinical validation, testbeds, understanding regulatory requirements, business models and market dynamics. Social Alpha, PATH and Tata Trusts joined hands to address this with a programme called Social Alpha Quest for Healthcare. It provides support from product design all the way to clinical trials and grants.

There is a big flaw in the way we handle innovation, in most of these programmes that are supported by government and foundations, the entrepreneur is not at the center .
- Manoj Kumar, co-founder, Social Alpha

The Social Alpha Quest for Healthcare provides mentoring to start-ups in business models, regulations, facility, access to hardware for product engineering, funding support and access to other funders for scaling up. This programme provides access to expertise in the design of clinical studies for validation and access to clinical testing at hospitals and PHCs. Support is also provided for Design for Manufacture and Assembly (DFMA).

The USP of the programme is that it provides end-to-end support through a multitude of means; for example, funding support in the form of a grant for conducting clinical validation studies, intensively focused mentoring to the selected start-ups in product engineering and design, business model validation, regulatory understanding and market dynamics.

Areas of interest in healthcare

- Medical devices and diagnostics
- Affordable and accessible healthcare delivery
- Digital health
- Innovative financing
- Care enablement
- Life sciences and biotech

Impact on healthcare

Ideas evaluated as of 2020	Start-ups incubated	Start-ups invested in	Successful exits	Awards by portfolio companies	Capital commited
>1000	28	20	0	29	INR 18.66 crore

More details of the Social Alpha programme can be found at https://www.socialalpha.org

Voices of experts

Manoj Kumar, co-founder & CEO of Social Alpha, shares his views on the landscape of incubators and impact investors and their own experience at Social Alpha, the gaps in the enabling ecosystem and public health procurement policies. Manoj also talks about the time to market from the prototype phase, the subtle differences between innovators and entrepreneurs and that not all innovators may want to be entrepreneurs. He strongly believes that the entrepreneur is critical to the whole equation.

Detailed interview with Manoj Kumar is in the chapter titled **'Voices of experts'**

3. WISH foundation (Wadhwani Initiative for Sustainable Healthcare)

The WISH foundation aims to transform primary healthcare through innovation. WISH focuses on scaling innovations to enable an equitable and accessible primary healthcare system for underserved populations. They have a model that helps social enterprises scale by facilitating conversations with state governments. WISH has an initiative called 'Scale Program' for states like Rajasthan, Madhya Pradesh and Odisha. This programme is a strategic scale-up mechanism for promising healthcare innovations that impact the access and availability of quality and affordable primary healthcare. The key intent is to build a robust service delivery platform at the last mile.

WISH provides the following support to innovators:

- Funding (grants, debt, equity)
- Management and technical assistance
- Leads to potential funders and donors
- Mentors and advisors
- Shared services platform
- Leads for large-scale government programmes
- Assistance in adapting innovations to the local context

WISH has published a compilation of Inclusive Business Models of Healthcare in India, which can be accessed at https://www.wishfoundationindia.org/node/28

More details about WISH Foundation can be found at https://www.wishfoundationindia.org/

4. Piramal Swasthya

With over a decade in healthcare, Piramal Swasthya has developed a range of programmes.

- One of Piramal Swasthya's transformational programmes is the Aspirational Districts programme developed at the invitation of NITI Aayog. The six areas under this programme are health, nutrition, education, agriculture, financial inclusion and water. Piramal Swasthya has developed 31 indicators for this and has a large field force to support its programmes across 25 districts in seven states.
- Piramal Swasthya also has a Remote Health Advisory and Intervention (RHAI) programme or Health Information Helplines. Available in six states, these helplines provide 24/7 advice to beneficiaries calling a toll-free number

Figure 3.4: A remote health advisory

Source: *Piramal Swasthya, Email communication*

(104). They also run the Mother and Child Tracking Services (MCTS) in the same states. This MCTS helpline does antenatal check and postnatal check calls to pregnant mothers and new mothers.

Figure 3.5: Telemedicine services

Source: *Piramal Swasthya, Email communication*

- Piramal Swasthya also runs telemedicine services across 80 nodes in remote areas of Himachal Pradesh to ensure doctor and specialist availability for beneficiaries.
- Another programme by Piramal Swasthya is the Mobile Medical Units in the state of Assam where NCD care is provided at the community level.
- With the focus on health and wellness center s, Piramal Swasthya is working on enabling the front-line health workers to connect to the public health facilities. By doing so they can establish referral linkages and availability of health information at these facilities to ensure quality delivery of healthcare services.
- All these public health interventions are enabled by AMRIT, the digital platform for health records. The platform is developed as a public good and facilitates the creation and storing of longitudinal health records for primary healthcare. It will also help the government in disease surveillance and evidence-based decision-making. AMRIT is designed to collect, translate, process and communicate information from India's decentralised health system into a unified health database and interface. It is built on secure and scalable open-source technologies, and is compliant with National Digital Health Mission guidelines.
- The Tribal Health programme aimed at addressing preventable deaths started in a tribal belt in Visakhapatnam. Piramal Swasthya is now developing an initiative to build a Tribal Health Platform linking multiple partners.

Figure 3.6 Piramal Swasthya's work

Source: https://www.piramalswasthya.org

Interesting perspectives emerged from the conversation with Devesh Verma, CTO Piramal Swasthya. Verma expressed the need for more social enterprises to be focused on primary healthcare v/s on tertiary healthcare (as is seen currently). Another key suggestion from him is the need to design multi-function devices because the public healthcare system will be challenged to invest in multiple devices. For example, imaging devices – could they be multi-functional instead of single purpose?

More details about Piramal Swasthya can be found at https://www.piramalswasthya.org

5. PAHAL

Partnerships for Affordable Healthcare Access and Longevity is another example of a platform that can help social enterprises innovate for healthcare.[17] PAHAL is a joint initiative of USAID and IPE Global to provide affordable and quality healthcare to the urban poor.

- PAHAL aims to provide catalytic support in the following areas:
- Identifying innovative business models
- Technical assistance
- Market access
- Access to capital

Figure 3.7:PAHAL is a platform that helps social enterprises scale healthcare solutions
Source: https://www.ipeglobal.com/pahal

More details about PAHAL can be found at https://www.ipeglobal.com/pahal

17 PAHAL Healthcare Innovations report (June 2017)

6. Venture Center

Venture Center was established in 2006-07 as a non-profit company, being an initiative of the National Chemical Laboratory (NCL) at Pune under a Council of Scientific and Industrial Research (CSIR) programme titled 'Scheme for setting up incubation centers in CSIR laboratories'. It is a pioneering effort by CSIR and NCL and is one of the earliest technology-focused incubators in India.

Over the last decade, Venture Center has grown to become one of the largest science and technology focused incubators in the country with more than 80 resident start-ups that are building relevant products for society. Venture Center provides access to instrumentation facilities (including a center for biopharma analysis and a medtech prototyping and packaging facility), incubation and mentoring (business and technology) programmes as well as a technology transfer office (TTO). It also extends advisory support, ranging from IP support and guidance on business and market dynamics.

Venture Center has partnered with the National Science and Technology Entrepreneurship Development Board (NSTEDB), DBT-BIRAC and many other national and global agencies. It is a leading partner of NSTEDB's Nidhi PRAYAS, BIRAC's BIG, BioNEST, SPARSH and SIIP fellowship, SEED & LEAP and National Biopharma Mission (NBM).

Figure 3.8: Venture Center, technology business incubator for science and technolgy startups
Source: http://www.venturecenter.co.in

More details of Venture Center's activities can be found at
http://www.venturecenter.co.in/aboutus.php

7. Icarus Nova

Icarus Nova is a strategic design-thinking consultancy specialising in healthcare with more than 25 years' experience and participation in over a hundred cutting-edge innovation projects.

Icarus uses Design Thinking and Design Doing to clarify different stages of innovation and translate a client's vision into holistic, scalable solutions. Icarus has built a wide repertoire of delivery capabilities in-house as well as with ecosystem partners.

Icarus Nova's work in healthcare product and service design has been awarded multiple times by the CII Design Excellence Awards, the de facto national recognition for design excellence. The organisation partners with:

- New businesses and corporate innovation labs to conceptualise and pilot disruptive business models. Clients include Medtronic Labs, TCPL, Fujifilm Healthcare and Embraco.
- Social enterprises and foundations, to apply human-centerd design for social innovation. Clients include Gray Matters Capital.
- Healthcare and medtech organisations to provide industrial and digital design services. Clients include Philips, GE Healthcare, Renalyx, Office of the PSA, NIMHANS and AFMC.

Figure 3.9: Products designed by ICARUS NOVA
Source: ICARUS NOVA, Email communication

More details about Icarus Nova can be found at https://www.icarusnova.com

Other key ecosystem players are the likes of Unitus Ventures, IKP Knowledge Park, Selco Foundation, Access Health International and C-Camp. Besides these, there are other organisations that provide specialised support services through the product life cycle.

Enablers at different stages of the product life cycle

Figure 3.10: Logos of respective companies

Note: Company logos are arranged in an alphabetical order, some of them play a critical role across multiple stages of the product life cycle

Source: Company websites

A common thread among the enablers in the above figure is the deep level of hand holding they provide across the product life cycle. Organisations such as BIRAC, Social Alpha and Villgro have played a significant role in nurturing social enterprises.

While it may seem that there are several organisations helping in the enabling process, a consistent message from some of the founders we interacted was the lack of sufficient capital for the long gestation cycle, aptly called 'Patient risk capital' for the healthcare sector. Could we have more philanthropists step in? What could trigger this move?

As we move from exploring the enabling ecosystem to the deployment section, it is important for us to hear from several founders. One criticism has been the ambiguity and lack of clarity in the decision-making process in public health.

To understand the decision-making process in public health better, we interacted with NHSRC and National Health Mission teams and sought their views. The next section covers some of the learnings from our interactions with the government and social enterprises, and three frameworks to scale.

'Results are achieved only by action, not by riding the chariot of the mind'

-Panchantantra

Source: Proverbs & Quotes for Entrepreneurs, Your Story

Chapter 4: Scaling up: Navigating through the system

Poet Robert Frost wrote "Two roads diverged in a wood, and I—/ I took the one less travelled by, and that has made all the difference." Could this be relevant for social enterprises?

There are many paths to take based on the solutions and the category of users. Each innovative solution has unique nuances and critical aspects that social enterprises must consider as they cross key milestones of their journey. Varkey et al. (2008) aptly write, "While developing innovations are quite challenging, disseminating them are tougher; the best of innovations may not be successful if the market or environment is not ready for adoption."

To help navigate through this crucial phase, we discuss three frameworks that cover the nuances of innovating and scaling. Our intent of choosing these frameworks was driven by the need to ensure that social enterprises look at all aspects in the 'innovate to adopt' process.

Framework 1: Six-factor analysis

In their study titled 'Diffusion of Global Innovations in Healthcare: How to make it happen', Herzlinger and Schulman (2017) arrived at two important conclusions about business model innovations that meet healthcare challenges.

Their first conclusion was that Innovations that are successful focus on only one of the three opportunities: Consumer facing activity, system integration or technical advance.

Their second conclusion talks about six factors which are summarised from several case studies from emerging markets such as India, Brazil and Spain.[18]

Structure: Develop a map of entities and people 'for and against' the proposed solution. Current incumbents can be in the 'against' category, while early adopters would be in the 'for' category.

18 Case studies for each of these sections are available at https://hmpi.org/2016/10/17/diffusion-of-global-innovations-in-health-care-how-to-make-it-happen/?pdf=1

Finance: Understand the current procurement and financing model. For example, self-funded v/s government-funded v/s third party institutions. How would budgets be allocated if the innovation is funded by the government? Would it be classified under a current programme or would it be a new programme that needs to be initiated?

Accountability: State measures of success and the desired impact on stakeholders (people/ organisations) in the value chain. Will the outcomes be cost effective and efficient without adverse impact on the stakeholders?

Consumer: Opinion of the consumers is important; how do they perceive this innovation? Has sufficient consideration been given to the user's needs? Would they adapt to a new intervention easily?

Public policy: Are the current regulatory systems and policies favourable to this innovation or will there be deterrents? Any possible impediments when the new solution is introduced?

Technology: Evaluate the usage of technology within the innovation. Will the chosen technology stand the test of time for the next decade? Would there be backward compatibility issues in integration with existing systems?

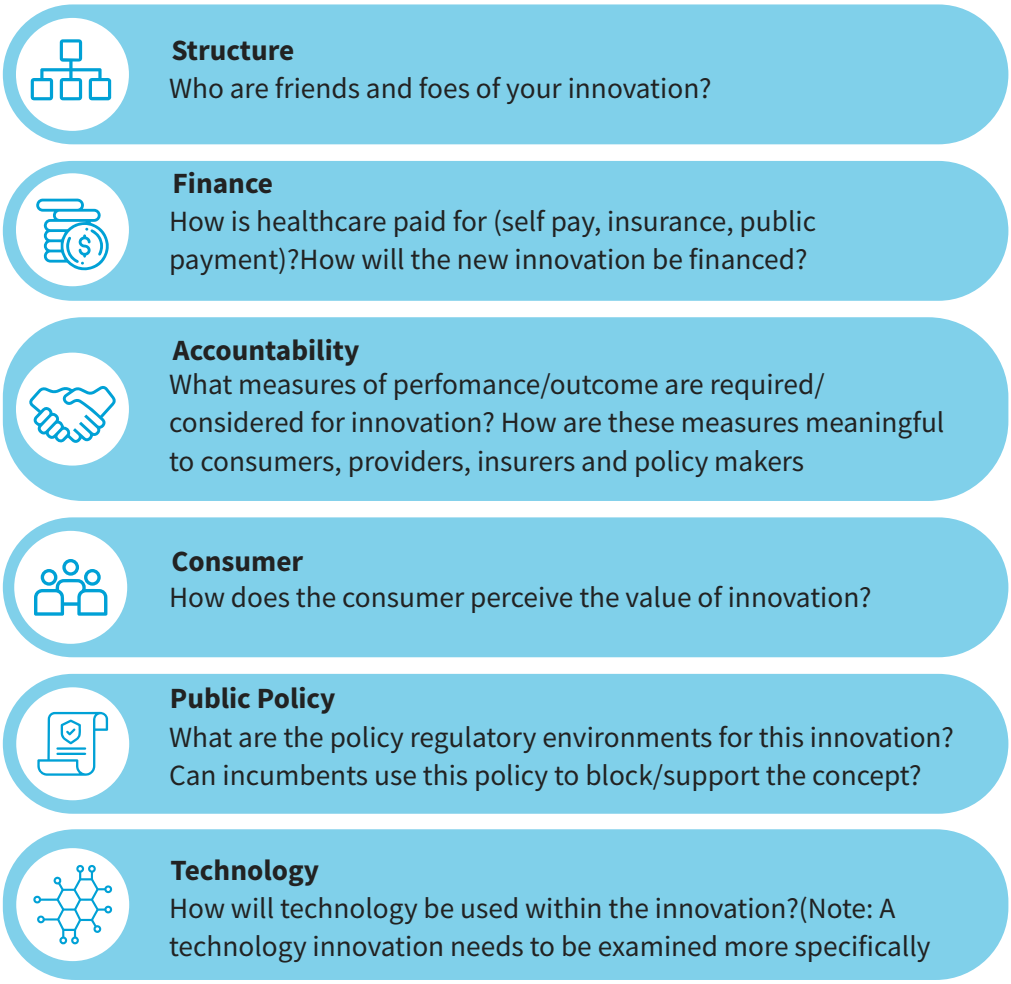

Figure 4.1: Framework 1 - six-factor analysis. Adapted from Herxlinger R, et al(2017)
Source: *https://hmpi.org/2016/10/17/diffusion-of-global-innovations-in-health-care-how-to-make-it-happen/?pdf=1*

Framework 2: From blueprint to scale

Monitor (2012) published a report titled, 'From Blueprint to Scale' based on extensive research of 700 social businesses across Africa and India as well as Acumen Fund's experience as an impact investor, other funders and academics. We believe that the framework published in their report will be a useful reference to social enterprises.

Figure 4.2: Four stages of development for Innovative firms
Source*: Monitor's research in 'From Blueprint to Scale'*

Blueprint
While conceptualising a product for a price sensitive segment, the challenge is to innovate while developing a viable business model for a segment that is not affluent. While developing the blueprint, the social enterprise needs to factor in the on-ground expertise and the associated environment around the proposed solution and ensure that the focus doesn't remain on technology innovation. The blueprint needs to also encompass a business plan that covers what the solution will do and how it will do it. This stage may culminate in identifying technologies and prototypes, also referred to as 'technical proof of concept'.

Validate
Concepts outlined in the blueprint stage need to be validated in the field. The concept needs to be tested for acceptance by various stakeholders, capability to pay for the solution at the price points envisaged, the viability of identified technologies, user interface, form factors and so on are critical at this stage. In most cases, this is an iterative process and the initial concept in the blueprint could get revised based on learnings from the field.

Prepare
Social enterprises need to prepare their organisation as well as their external stakeholders involved in decision-making, deployment and using the innovative solution. This stage encompasses several areas: supply chain management, inventory, post-sales support, breakdown support and software updates, and ensuring there is sufficient awareness of the unique value proposition of the proposed innovative solution. A critical area is the human resource need of the growing social enterprise, this often gets neglected in the pursuit of accessing markets, resulting in unhappy customers and staff.

Scale
As social enterprises pass the first three stages and successfully address some of the challenges along the journey, they need to start considering new geographies and competition, and manage a diverse set of stakeholders from impact investors and decision-makers to regulators.
This could also be a good time to consider developing the roadmap for future versions of the product or identifying products for adjacent markets/needs.[19]

19 Case studies for each of these stages are available in Monitor's research's 'From Blueprint to Scale' and 'Hardware Pioneers'. https://www.fsg.org/publications/blueprint-scale & https://www.fsg.org/publications/hardware-pioneers

Framework 3: Scaling barriers

Koh et al (2014) authored the report 'Beyond the Pioneer' which looked at barries faced by social enterprises in getting to scale. They looked at case studies across continents, over decades and studied enterprises which adopted market-based approaches. We have extracted the model presented in their study as a reference for social enterprises.

This model suggests that barriers to scaling can be at four levels:

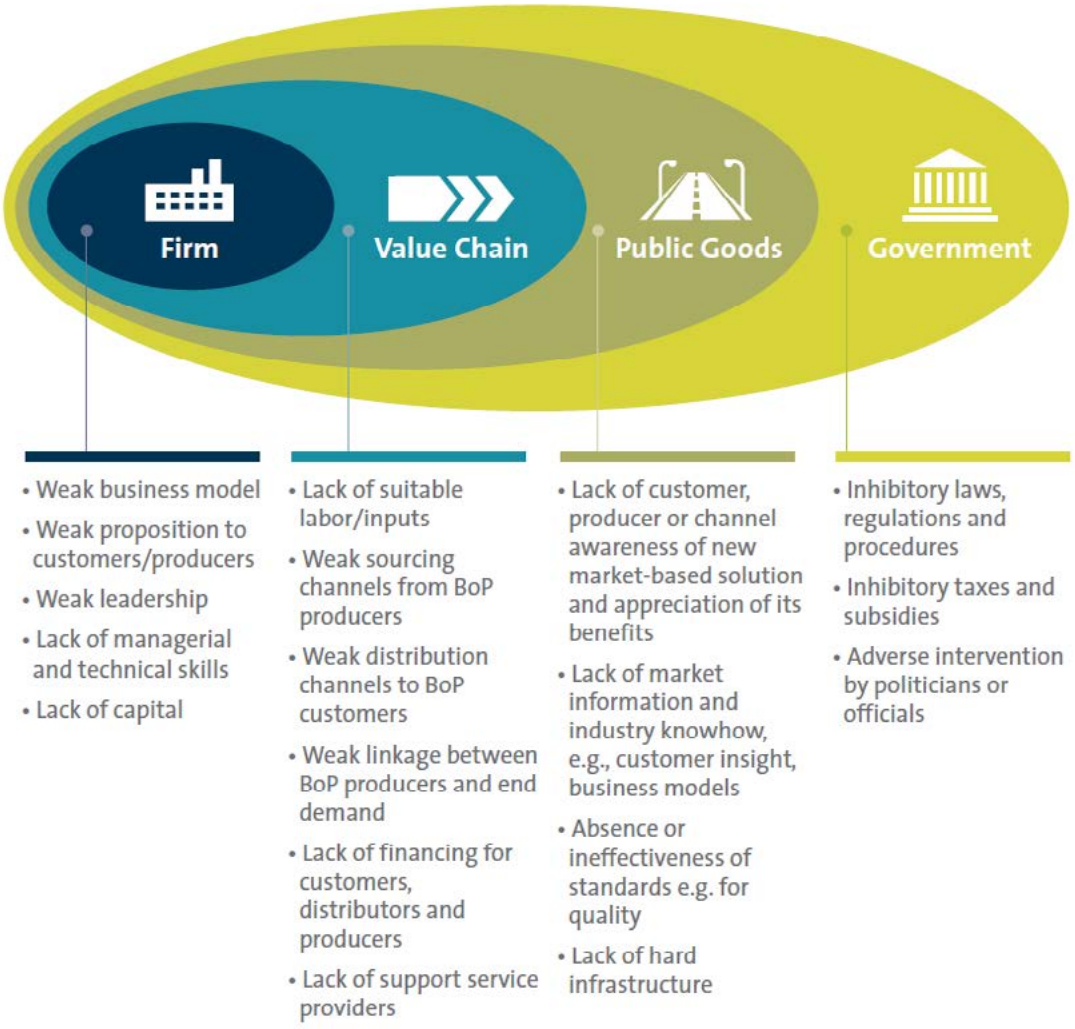

Figure 4.3: Scaling barriers
Source: *Monitor Deloitte analysis(2014), Beyond the Pioneer*

The organisation – The social enterprise may not be adequately set up for growth; it may not have relevant leadership, managerial or technical skill sets to drive growth. It could have a business model suited for a smaller set of people but not for scale, it may not have the financial resources to set it for a path to grow.

The industry value chain – The social enterprise may not have the right or adequate distribution channel developed for the market it intends to pursue. The supply chain system may not be ready to provide specialised technical components, access to finance or credit across the system from customers to suppliers to the social enterprise could be a barrier.

Public goods - While the product or solution may be an innovative one, the customers may not be ready to buy it, the users may not be adequately equipped (trained) to use it or may not be aware of the product (benefits), there could also be situations wherein the supporting infrastructure isn't adequately ready for a new product.

Government – The laws, regulations and procedures could be more tuned for a mainstream product versus innovative products. Taxes and duties could make the products and solutions unattractive to the customers or if they may have to compete against products that have subsidies.

Source: www.BeyondThePioneer.org

How could these frameworks help?

These three frameworks add value by helping social enterprises pose the right questions. A social enterprise could use a combination of these frameworks to pre-empt hitting roadblocks during their journey as each of them presents different angles.

In 'Six factor Analysis', Herzlinger brings out several key points – the need to understand potential supporters for the proposed solution, clarity on who will pay for the solution, are the regulatory systems in favour of such an innovation or a model, and so on. Areas that Herzlinger does not cover are 'a view within the organisation' and business planning.

In 'From Blueprint to Scale,' the emphasis is on planning – from the blueprint or drawing-board stage to validating assumptions made at the blueprint stage, and finally preparing the ground for launching a product. While the natural tendency would be to focus on market growth, social enterprises are cautioned to pay attention to human resource requirements. In the final stage of preparing to scale, crossing the borders would mean understanding regulations, competition, standards, etc. Areas that this framework does not focus on are capital for the start-up, leadership teams, quality standards and political intervention.

In 'Scaling Barriers', the focus is around challenges to scale, some of them within an organisation, in the ecosystem, or at the government-end. A leader who may be a good technologist may not be well versed in marketing aspects, business development, customer relationships or healthcare expertise. The need is to ensure that the founding team complement each other in critical areas. Capital could be a showstopper as an organisation gets ready to transition from the preliminary stages into accessing markets, investing in products, building inventory, developing supply chain and so on. Areas that this framework does not cover are the need for evidence of efficacy and cost-effectiveness, which a social enterprise focused on healthcare also needs to consider.

While a single framework may not cover all the aspects that a start-up needs to consider at an initial stage, it would help to look at two or three frameworks, or at least the 'six-factor analysis' to ensure that a robust plan is in place. In case a social enterprise is in the field trial/product readiness stage, the other two frameworks could provide valuable insights.

A common refrain from some founders was about the lack of transparency in the government decision-making process; they said there were no special provisions for adopting innovations and the decision-making cycle was quite long. Interactions with the Ministry of Health and Family Welfare (MoHFW) and National Health Mission (NHM) at the state level helped get some visibility into the decision-making process. The next section provides insights into the government decision-making process to help social enterprises gear up to address this challenge.

The government decision-making process

Public procurement remains one of the major scaling strategies for social enterprises. Hence, understanding public procurement processes is critical. Two dimensions are important here:

- Understanding the conditions under which governments would adopt innovations
- Timelines for decision-making

The government adoption process starts with the development of Program Implementation Plans (PIPs). This is an important process through which the States/ UTs plan, prioritise and propose strategies and activities to address the challenges in public health. There are about 18 categories listed under the PIP guidance document. Based on the plan and the budget proposed, appraisals and discussions are carried out which culminate in National Program Coordination Committee (NPCC) meeting, approvals are accorded through the Record of Proceedings (ROP).

States/UTs must provide a document that sums up the major problems in health (based on evidence with source/s) after a situation analysis and describe the strategies through which it intends to tackle these problems, along with outputs expected and expected level of achievement in process indicators.[20]

A lot of innovations are taking place. It is essential that the Department of Health Research evaluate them and those that are likely to have maximum impact on the health outcomes, be supported to work on a pilot basis.
An evaluation would also need to evaluate the product in the backdrop of other alternatives existing and do a cost-effective assessment. An idea may be good but if not cost-effective, it can't be taken up
- Sujatha Rao, Former Union Secretary, Ministry of Health and Family Welfare, Government of India

From our interactions with the officials at National Health Mission, the learnings were that Health Technology Assessments (HTAs), not only adds credibility to the solution but also provides a platform to showcase the solution at the annual National Best Practices workshop. This workshop has presentations of innovative programmes and products with participation from ministries at the central level as well as the state level.

From the stages outlined in the planning process figure below, it's critical to note that if a social enterprise wants to have their solution commercially deployed through the government in the upcoming financial year, they need to have sufficient evidence of its success before July of the previous financial year. This effectively means that discussions with government officials should start at least nine months to a year prior, based on the category of the intervention.

State budgets

Budgets for adoption start at the PHC level, followed by district and then the state. Social enterprises could begin small 'funded pilots' at PHC level or at the local municipality level or the district level to develop sufficient evidence of efficacy and cost-effectiveness of their solution.

20 Source – PIP Guidance Note 2018-19

States typically have a 10 percent annual budget that could be used for innovative products or programmes; however, this needs to be factored into the Program Implementation Plans (PIP) proposal and approved through Record of Proceedings (ROP). An alternate approach to develop smaller proof points is to seek support for the pilots from grant-making organisations such as BIRAC, Grand Challenges, philanthropists or impact investors.

Evidence

Most states prefer to have the solution tested in their environment, either at a block level or a district level, because this gives them first-hand knowledge of the solution in local operating conditions. Decisions are easier when social enterprises develop sufficient evidence of the efficacy of their solutions and cost-effectiveness of their solutions. Publishing evidence in peer-reviewed medical journals strengthens their case.

Planning process

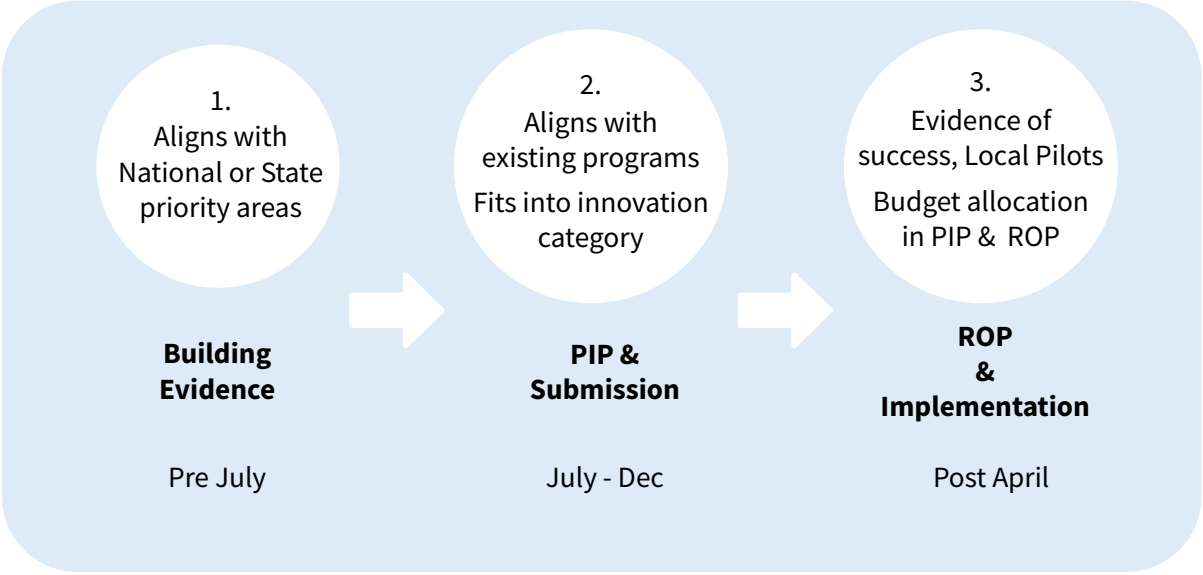

Figure 4.4: Adapted from the Plan - Do - Check - Adjust (PDCA) cycle @ Karnataka
Source: Figure developed by author based on interactions with NHM officials

Conditions for adoption

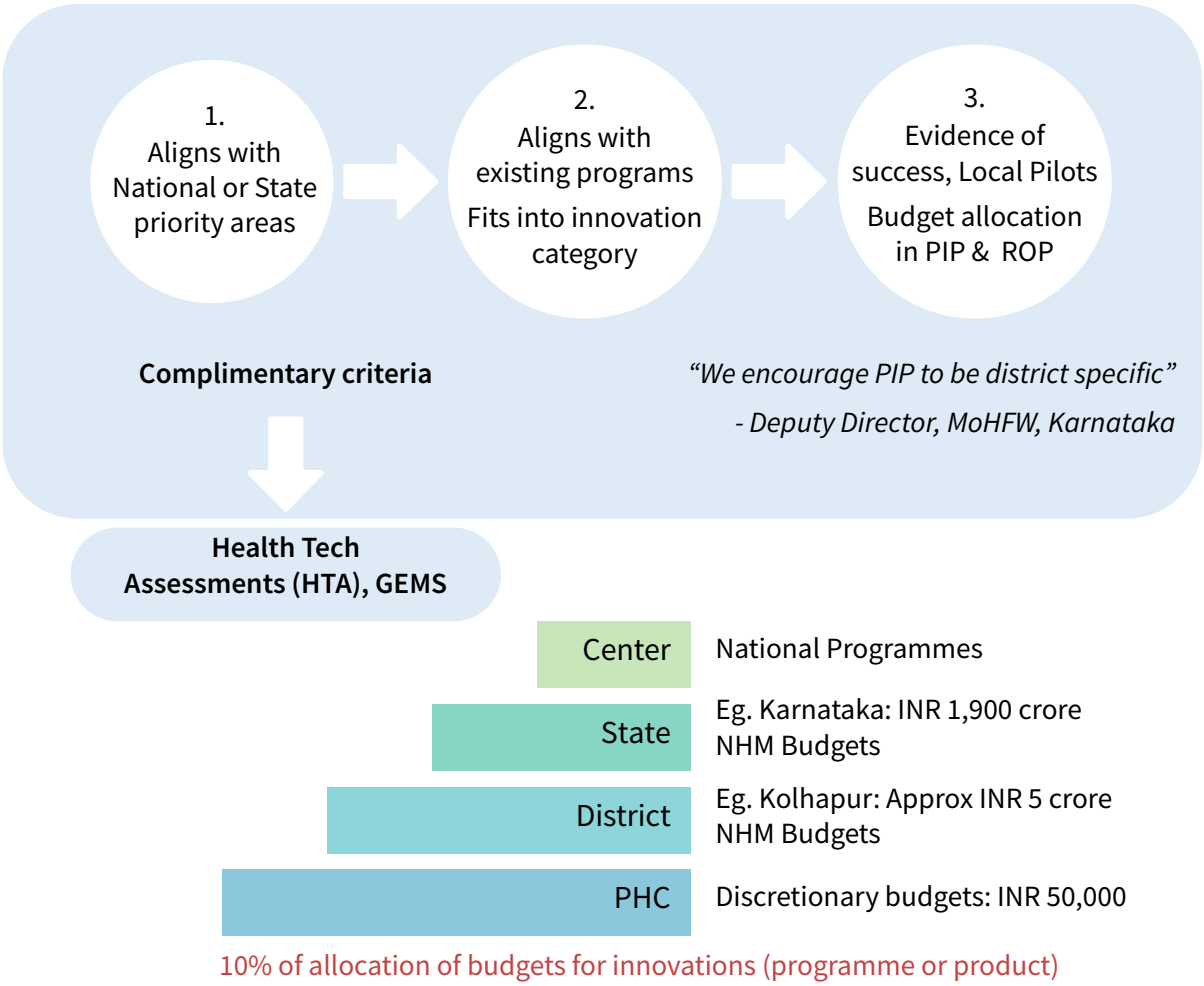

Figure 4.5: Conditions for adoption

Source: *Figure developed by author based on interactions with NHM officials and public documents*

Voices of experts

Dr Anand Bang, shares his views on areas that social enterprises need to focus on to have a larger impact. He talks about approaches and rigour that are needed to have a successful solution. Dr Bang shares his views on the gaps in the ecosystem and talks about possible models that governments could adopt. He also shares his perspectives on policies and approach to addressing healthcare problems in states such as UP, Bihar, Odisha, and the need to engage political leadership. He gives an insight into the mistakes social enterprises make by viewing community healthcare workers as mobilisers and most importantly the need for social enterprises to spend significant time in the field.

Detailed interview with Dr Bang is in the chapter titled **'Voices of Experts'**

The hardest thing to learn in life is which bridge to cross and which to burn

- David L Russell, American educator

Source: Metcalf, Fred (2014). *The Biteback Dictionary of Humorous Business Quotations*, Biteback Publishing, London

Chapter 5: From pilot to scale: Lessons learnt

The trajectory from pilot to scale is unique to each social enterprise. We felt that understanding the model Everett Rogers presented for Diffusion of Innovation in 1961 would be an important consideration as we look at scale. Rogers explains that irrespective of the field (agriculture, education, medical and so on) innovations follow a certain pattern before adoption as outlined:

1. Innovators
2. Early adopters
3. Early majority
4. Late majority
5. Laggards

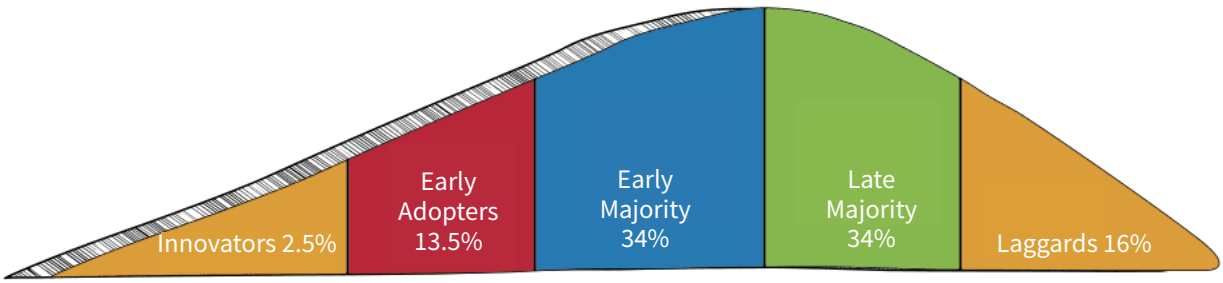

Figure 5.1: Diffusion of Innovation Model
Adapted from: https://www.smartinsights.com

During the study, many questions arose on whether social enterprises were successful in scaling. We thought it was important to address this and bring in their experiences because healthcare social enterprises go through these phases for each of their products or programmes.

We have featured a few social enterprises that have gone through the phases outlined in Roger's theory. It hasn't been an easy journey for them; each one has chosen to address a different need based on their experiences.

Some of the criteria applied to select these organisations were as follows:

1. Role in public health – preventive, curative or diagnostics
2. Solutions implemented in more than three states (with commercial arrangements)
3. 'For Profit' and 'Non-profit' entities
4. Product or service entity
5. Developed partnerships
6. Portfolio of healthcare solutions

Sl. No.	Organisation	Type	Category
1	Aravind Eye Care System	Not-for-profit social enterprise	Curative
2	ARMAAN	Not-for-profit social enterprise	Services
3	Biosense	For-profit social enterprise	Point-of-care diagnostics
4	CareNX	For-profit social enterprise	Point-of-care diagnostics
5	Forus Health	For-profit social enterprise	Point-of-care diagnostics

Interactions with the founders were around:

- Approach around the ideation and concept development
- Engagement with governments
- Challenges in implementation
- Views on current policies and the government decision-making process

While all the case studies are from direct interactions, an exception is the case study on Aravind Eye Care, which is based on secondary research.

Voices of experts

Dr Satya Prakash Dash - with deep experience in developing programmes and working with start-ups - explains that it is indeed a long journey from ideation and proof of concept to scaling up. He questions if all systems are in place for the journey and the need for the ecosystem to help social enterprises.

Dr Dash discusses 'multiple valleys of death' and how a social enterprise can avoid them; he talks about the need to design for different batch sizes, understanding the willingness to pay, and the need to have a go-to-market strategy. Another interesting view that he shares is the definition of 'Scale'; he feels the social enterprise should define it and be accountable for the time frame to achieve it.

*Detailed interview with Dr Satya Prakash Dash is in chapter titled '**Voices of Experts**'*

Case Study #1

Point-of-care diagnostics

Forus Health

https://www.forushealth.com/

Inspired by the work of Aravind Eye Hospital, K Chandrasekar of Forus Health wanted to complement their efforts in eye care with diagnostics, using technology.

The following learnings emerged from the interaction with K Chandrasekar, founder - Forus Health, about its journey:

The need

According to Forus, 12 million people in India are blind, and 80 percent of these cases can be avoided. Among infants particularly, even though the literature mentions that premature babies survive because of improvement in facilities over the years, some of them could be susceptible to retinopathy of prematurity. One estimate puts the number at 17000 blind infants every year in India. The main causes for this are poorly controlled oxygen therapy and uneven care of preterm babies. Another challenge is the shortage of qualified doctors; the ophthalmologists to patient ratio in India is approximately 1:60000

Solution

Forus Health develops medical devices for effective management of visual health (to end preventable blindness). Their product, 3nethra neo is an imaging device that takes pictures of the retina and can be operated by para medical staff or volunteers. This device uses remote diagnostics to detect conditions that surgeons can then attend to with laser therapy. This solution also addresses the challenge of a shortage of qualified doctors in rural settings.

Figure 5.3: 3nethra classic: A digital imaging device that displays, stores, and transmits images of the posterior and anterior surfaces of the human eye
Source: Forus, Email communication

Implementation is the most critical aspect, we have been able to do that. The ground reality is very different from what you really see.

- K Chandrasekar,
Founder- Forus Health

Design

Team Forus designed a solution for the mainstream market and then ensured that the same device worked in rural settings with some tweaks and an appropriate business model. They didn't make a separate product for the public health system.

Ecosystem support (financial and non-financial)

- The Forus team worked with Dr. Anand Vinekar, a globally acclaimed expert in retinopathy of prematurity (ROP) treatment, right from the product idea up to building and validating the product.

Go-to-market (GTM)

- The initial engagements were directly with potential adopters in the private healthcare space. Gradually, they teamed up with reputed hospitals such as Narayana Nethralaya and Public Health Foundation to access the public health segment.
- Government engagements meant either ensuring compliance with tender specifications or engagement with the National Health Mission.

When you go to the market, you are surprised, lot of things what you thought are there or what you have assumed are not correct. So right from the concept stage to first level proto-typing, second level prototyping, I think we should check in two three places on what are the issues

- K Chandrasekar,
Founder- Forus Health

Implementation

- The ground reality was different from what was perceived; the ability to adapt to the challenges of the product or its usability are essential to implementation.
- De-risking the proposed solution, based on the capability of the operator, needs to be factored in.

Figure 5.4*: 3nethra neo: Bringing quality eye care for the new borns*
Source: Forus, Email communication

If you go to the camp and find out that 80 percent of the time there is no power, then the real usability of the product becomes the question.

- K Chandrasekar,
Founder- Forus Health

Suggestions for social enterprises

- For a company to be relevant, a social enterprise cannot stop with one product; they need a portfolio of products. For social enterprises catering to medical devices, it takes 9-10 years to reach a sustainable state.
- Unless social enterprises get funded continuously or have the visibility of government orders, survival is a challenge.

The complete portfolio

In addition to products such as 3nethra classic, 3nethra neo and 3nethra flora, Forus health has also set up a cloud-based digital healthcare platform that connects multiple stakeholders in the eye-care ecosystem, enabling multiple specialists to access and review data generated by web and mobile applications.

Publications

Vinekar, A. 'Screening for ROP', Community eye Journal, Volume 31, Number 101, 2018, South Asia Edition

Vinekar, A et al. 'A Novel, low-cost, wide-field, infant retinal camera, "Neo": Technical and Safety report for the use on Premature Infants, Volume 8, No. 2, Article 2,2019, Translational vision science and Technology

Reach and impact

36 countries, 2,400 installations, 6 million lives touched

Recognitions and awards

NASSCOM®
Emerge 50 Startup Category 2011

CNBC TV18
Young Turks Award 2012

The Tech Museum of Innovation
Tech Global Good Laurette 2017

FROST & SULLIVAN
New Product Innovation Award in Opthalmoscopic Screening Devices 2014

Case Study #2

Services

mMitra by ARMMAN

Advancing reduction in mortality and morbidity of mothers, children and neonates
http://armman.org/

The following learnings emerged from the interaction with the Dr Aparna Hegde, founder of ARMMAN, about their journey:

The need

The trigger for Dr Aparna Hegde, the founder of ARMMAN, a practising urogynaecologist, were her experiences in 1998 with pregnant women in a hospital in Mumbai. One of the key contributors to maternal morbidity and mortality and neonatal mortality was the lack of access to information on preventive care. Dr Hegde felt many high-risk situations could be avoided by educating pregnant women during pregnancy, after delivery and by addressing some systemic issues.

I think the three-delay model really tells you what is wrong, why does a mother or child die. The first delay is lack of access to preventive care information, the second delay is lack of transportation, and the third delay is when they reach the facility and nothing exists there.

- Dr Aparna Hegde, founder, ARMMAN

Solution

ARMMAN developed a programme called mMitra, a free mobile voice call service. Pregnant women enrolled into the programme through health workers posted in government hospitals and through partner NGOs working in slum communities. Subsequently, the women were provided 141 timely messages on pregnancy and infant care at a pre-scheduled time every week in their language. This continued for a year after the birth of the baby. In case they missed a pre-scheduled call, there would be at least three attempts to reach them. The time of the call was decided by the pregnant woman, who also had an option of dialling into a call center or getting a call back from the call center by dialling a number that was a designated 'missed call number'.
The uniqueness of the mMitra was the design and a combination of technology with the human touch. This has helped the mMitra programme successfully scale to nine states.

Impact of mMitra*

- 25 percent increase in the number of pregnant women who took IFA tablets for 90 or more days
- 47.7 percent increase in the proportion of women who knew at least three methods of family planning
- 17.4 percent increase in the proportion of infants who tripled their birth weight at the end of one year
- 26.3 percent increase in the proportion of infants under six months who were exclusively breastfed

*From midline and end-line survey of Randomized Control Trial (RCT)

Tech plus touch model is essential; technology alone cannot work at all, and a touch model is needed too.

- Dr Aparna Hegde, founder, ARMMAN

Design

- User-friendly. This was reflected in the language options available and the follow-up calls if the pregnant woman didn't answer
- Simple yet effective technology, a technology that was easily available and scalable
- Everything was based on a pregnant woman's unique needs, her language, her dialect and her level of understanding
- Choice of a time slot, so she could ensure that the phone was with her. Additionally, there's a missed call system and a call center staffed by 30 people
- Sustainability; a solution that can expand to cover many more new messages and not necessarily for only one kind of a disease or a problem
- From its inception, mMitra was designed for scale; whether it was one woman or a million women, each one has a similar experience
- Systems change was through non-linear programme design by understanding systemic gaps, community needs assessment and backed by evidence

Ecosystem support

- The first five years were in-house efforts supported by crowd-funding and Inscripts, a technology service provider
- Subsequently, organisations such as Tata Trusts, Glenmark, Johnson & Johnson and DFID supported ARMMAN

Implementation

- ARMMAN partnered with community health NGOs (Committed Community Development Trust [CCDT] and Apnalaya), where members of the staff were incentivised to visit homes and enrol women
- They also partnered with hospitals, where pregnant women came for check-ups
- 'Technology alone cannot work; a touch model is needed too', was their mantra

Partnering with government (Ministry of Health and Family Welfare)

- Organisations need to convince the government on the efficacy of their solution, scalability, along with cost-effectiveness.

- ARMMAN's success with mMitra made them a preferred choice to manage government-initiated programmes such as Kilkari and Mobile Academy - the largest mhealth-based maternal and child health programmes in the world

The complete portfolio

ARMMAN addresses maternal morbidity, mortality and neonatal mortality by following a 360-degree approach. A complementary set of solutions for the health worker, the mother and the child provide a truly comprehensive approach in addressing systemic issues. Solutions for health workers ensured the identification of high-risk cases very early in the cycle.

Some of the solutions from ARMMAN are:

- mMitra
- Kilkari
- Mobile Academy
- Arogya Sakhi
- Moderately Underweight Children
- Mother and Child Tracking System (mKhushali) leading to the creation of protocols for end-to-end management of high-risk pregnancies with demarcated sections for ANMs, MOs and specialists, in conjunction with the Ministry of Health and Family Welfare (MoHFW)

For details refer https://armman.org/programmes/

Reach and impact (across the portfolio of solutions)

18,863,673 beneficiaries across 16 states of India, through a partner network of 43 NGOs and over 100 hospitals

Publications

- Impact of Mobile-based Intervention of Health Literacy among Pregnant women[21]
- Randomized Cluster Trial: mMitra and Arogya Sakhi[22]

Recognitions and awards

Maternal & Child Health Team of the year

Dr Aparna Hegde is a TED Fellow 2020

Save the Children

Healthcare Innovation award

21 https://armman.org/wp-content/uploads/2019/09/Sion-Study-Abstract.pdf

22 https://armman.org/wp-content/uploads/2019/09/Impact_Study_ARMMAN.pdf

Case Study #3

Point-of-care diagnostics

BIOSENSE

https://biosense.in/

The following learnings emerged from the interaction with Dr Abhishek Sen, co-founder of Biosense, about its journey:

The need

'Seventy percent of anaemic cases were no longer a statistic' - this observation from a visit to Melghat in Maharashtra was the trigger for Dr Sen and his team. Further research led them to the fact that most women in India have a haemoglobin count of less than 6g /dl, and 35 percent of the world's undernourished children are from India, of which 50 percent are under three years.[23] Additionally, they observed that there is an epidemiological shift from communicable to non-communicable diseases and that some of these healthcare needs go undetected because of the lack of access to diagnostics.

Selling to the Government requires certain scale, both in terms of Operations and Finance.'

- Dr Abhishek Sen, Co-founder Biosense

Solution

The Biosense team designed and developed a range of diagnostic devices that enable 'point-of-care' testing. Their focus areas are diabetes, anaemia and malnutrition. Solutions are designed both for personal use and for healthcare providers – private and public.

All devices are connected to a secure cloud platform that enables demographic surveillance and data collection.

Figure 5.5 ToucHB, non-invasive Hb testing

Source: Biosense, email communication

23 https://www.biosense.in/our-focus-area.php

Ecosystem support

Biosense got financial support from the Center of Innovation and Entrepreneurship, Department of Science and technology and BIRAC. Additionally, Biosense utilised the credit guarantee scheme of the Department of MSME.

ICMR and the National Institute of Biologicals helped in validation, while NHSRC did a health technology assessment for three of their products.

Figure 5.6: Sync glucometer

Source: Biosense, email communication

Go-to-market (GTM)

Biosense has a combination of strategies for their go-to-market approach. They have distributors, services providers and a direct approach, too.

They believe that social enterprises wanting to pursue government opportunities should start at the entry-level by initially developing proof points at smaller levels and then engage at larger levels; for example - PHC, district level and state. They could look at scaling within a state or across states after establishing the solution successfully and by building sufficient evidence.

From their experience, typically district level engagements would take around three to six months, while state level engagements could take anything between one to three years.

An important view was that it is best for social enterprises to provide their solutions or products to larger service providers as well as government contracts to avoid a financial crunch and operational challenges.

Implementation

A challenge they experienced was the multiple roles a health worker had to perform from vaccination to community mobilisation, which made it difficult to devote time towards training.

You need a partner who has the balance sheet to essentially do it. Government orders don't mature before five-six months and as a start-up you have very limited resources.

State level conversations can take anywhere from one to three years.

- Dr Abhishek Sen, Co-founder Biosense

Figure 5.7: Remote diagnostics kit

Source: Biosense, email communication

Reach and impact

More than 1 crore tests across 5,000 clinics are performed annually using Biosense devices

Publications

Assessment and authentication of Diagnostic accuracy of HBCHEK – Innovative Indigenous Hemoglobinometer [24]

The complete portfolio

- Diabetes
- Anaemia
- Malnutrition
- Haemoglobin

When we go to a new state, we don't start directly at the state level, we start working in key districts. We do a small pilot in the district and show the effectiveness of the solution.

- Dr Abhishek Sen, Co-founder Biosense

Recognitions and awards

Biosense was acquired by Tulip Diagnostics, a Perkin Elmer company, in November 2019. The acquisition provided a profitable exit to private equity investors in Biosense such as Insitor, Menterra, and other angel and venture capital investors in the company and is one of the first acquisitions in the MedTech start-up space in India.

24 https://wjpr.net/download/article/1581491545.pdf

Case Study #4

Cure

Aravind Eye Care System

https://aravind.org/

This case study is developed through secondary research from existing case studies and published material

The need

India was the first country to launch a national programme to control blindness in 1976. One of the objectives was to reduce prevalence to 0.3% by 2020. However, the estimated prevalence of blindness stands at 1.99 percent.[25] In India, cataract accounts for 50-80 percent of bilaterally blind.[26] Though there is a decrease in the prevalence of blindness in the country, the increase in the population of people above 60 years of age means that the risks have increased significantly. One of the biggest barriers to accessing cataract surgery is the cost factor. The other factors are inadequate infrastructure, low per capita income, diseases in epidemic proportions and illiteracy.

Trigger and approach

With the mission to 'eradicate needless blindness', Dr G Venkataswamy, a retired ophthalmologist, started Aravind Eye Hospital in Madurai in 1976. From just 11 beds, the hospital has grown to accommodate 330 paying patients and 920 free patients. They are now present both nationally and in a few international locations and is one of the largest eye care systems in the world.[27]

Figure 5.8: Aravind Eye Hospital
Source: www.aravind.org

25 https://www.downtoearth.org.in/news/health/cataract-top-cause-of-blindness-in-india-finds-survey-67187 Indian

26 Murthy G, Gupta SK, John N, Vashist P. Current status of cataract blindness and Vision 2020: the right to sight initiative in India. Indian J Ophthalmol. 2008 Nov-Dec; 56(6):489-94. doi: 10.4103/0301-4738.42774. PMID: 18974520; PMCID: PMC2612994.

27 Rangan, K and Thulasiraj R.D.(2007),'Making sight affordable', Innovations: Technology, Governance, Globalization (2007) 2 (4): 35–49 Volume (2), Issue 4 Fall 2007

Accessing patients

Aravind Eye Care has a multi-pronged approach to reach patients, via hospitals and outreach efforts such as screening camps, vision centres, community eye clinics and city centres.

Implementation

The magic of the Aravind system is that a doctor performs approximately 2,000 cataract surgeries a year (v/s 400 by an average ophthalmologist in India) and a model where the treatment for the poor is subsidised by the rest of the patients. Their success is largely attributed to a few key strategies:

1. Management systems that helped build a scale model
2. A core leadership team responsible for the growth
3. Learn by doing
4. Choice of strategies

Additionally, some of the factors responsible for Aravind Eye Care's success are:

a. Focus on cataract treatment – There are many ways to address a problem (blindness) but they chose to address cataract.

Figure 5.9: Assembly line
Source: www.aravind.org

b. Client segmentation and quality assurance – A hybrid business model of fee-paying customers (40 percent) and non-fee-paying customers (60 percent) addressed the problem of scale. Given that paying patients had high expectations of quality, the same benchmark was maintained for non-paying patients also.

c. Operational efficiency and cost control – The dearth of ophthalmologists was addressed by an innovative assembly line system for surgeries and outpatient examinations.

d. Vertical integration – People and components were identified as critical factors for success. As the efficiency of a surgeon also depends on the supporting team, Aravind created its supply by developing a 2-year training programme for nurses. To address the challenge of expensive intraocular lens, they innovated by developing these lenses through Aurolab,[28] an internal manufacturing unit.

e. Spirit of service – They set up outreach

28 Mahad Ibrahim, Aman Bhandari, Jaspal S. Sandhu, and P. Balakrishnan, "Making Sight Affordable (Part I): Aurolab Pioneers Production of Low-Cost Technology for Cataract Surgery,"Innovations 1:3 (Summer, 2006), pp. 25-41.

screening camps to improve access, the same team of doctors conduct the surgeries for both categories of patients, but the fee-paying customers have differentiated service options. Understanding and addressing the barriers that rural patients had – transport, food and lodging. Doctors from leading institutes are motivated to collaborate; the staff are encouraged to do research.

Figure 5.10: Screening camps
Source: www.aravind.org

Reach and impact

Aravind is a classic example of how social enterprises can create an impact on public health delivery. Present in over 100 locations, the financial year 2019-20 had close to 46 lakh outpatient visits and 5,20,000 surgeries, continuing a pattern of a steady year-on-year growth.

Publications

Aravind Eye Care does not need any endorsement for the quality of their work. The list of case studies published is a clear indication of why Aravind is a poster child social enterprise for all academic institutes. More here: https://aravind.org/case-studies/

There are around 100 research papers published at https://aravind.org/2020/08/?post_type=aravindnews

The complete portfolio

Aravind is engaged in patient care, education, IT services, capacity building of other eye hospitals, research and manufacturing of intra-ocular lens.

Figure 5.11: Screening of an infant
Source: *www.aravind.org*

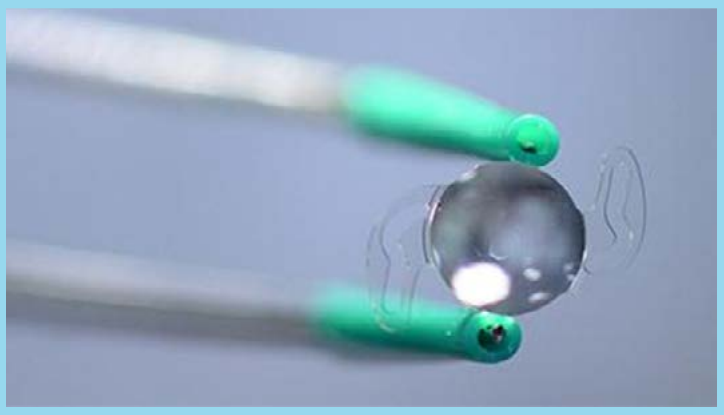

Figure 5.12: Intra-ocular lens
Source: *www.aravind.org*

Figure 5.13: Intra-ocular lens manufacturing
Source: www.aravind.org

Case Study #5

Point-of-care diagnostics

CareNx

https://www.caremother.in

The following learnings emerged from the interaction with Shantanu Pathak, co-founder of CareNx, about its journey:

The need

Every 10 minutes, a pregnant woman dies in India due to excessive bleeding, prenatal conditions, hypertensive disorders and other related complications. According to the WHO, 60 percent of these deaths could be prevented with timely access to quality care. Unfortunately, 66 percent of the 30 million pregnant women in India live in remote areas with poor access to healthcare.

"We should focus on health workers and for us to really be a health outcome oriented organisation and not just a data collection organisation, we should work on high risk management.

- Aditya Kulkarni, Co-founder, CareNx

The trigger and approach: concept of 'Care mother'

The two founders of CareNx, Shantanu Pathak and Aditya Kulkarni, decided to facilitate affordable access to maternal care.

While different possibilities to intervene in maternal health existed, CareNX wanted to build a solution to enhance facilities at healthcare centres, to empower health workers, and that could be directly used by pregnant women. They focused on the following objectives to develop an idea that:

a. Enables doorstep diagnostics in an affordable manner

b. Enables early identification of high-risk pregnancy

c. Empowers the community health workers

The larger goal was to:

a. Increase the weight of pregnant women

b. Reduction in the incidence of low birth weight and preterm babies

c. Reduction of neonatal mortality

Figure 5.14: Screenshots of CareMother app
Source: CareNx email communication

Solution

They developed a prototype app and tested it in both urban and rural settings, and sought feedback from doctors, nurses, health workers and NGO partners.

CareMother is a mobile pregnancy care platform that enables health workers to identify high-risk mothers early. The solution consists of software installed on a smartphone and antenatal diagnostic test devices in a portable kit.

The journey from understanding the problem to developing a concept, validating it through proof of concepts to having a solution that was ready to be deployed took approximately 18 months.

Challenges

Some of the challenges they faced during the proof-of-concept stage were:

1. Operational: Ensuring health workers would reach out to the community
2. Technical: Follow up and action based on the identification of high-risk pregnant women
3. Social: Resistance from pregnant women

Based on the early learnings, the CareNx team decided to provide a diagnostic kit to the health workers to ensure doorstep diagnostics were provided to pregnant women. This helped address the 'awareness' and 'access' challenges outlined by Thaddeus & Maine (1994) in the 'Three delay model'.

Figure 5.15: CareMother kit
Source: https://caremother.in

Partnerships

CareNx has adopted a dual approach to address the needs of pregnant women. In some of the states, CareNx deploys their solution directly, while in others, they partner with local NGOs.

Another interesting partnership they developed was community-led support groups. These consist of 10 elderly women for every 100 households, who provide local support and continuity to the pregnant women and health workers

Reach

Through 10 NGO partners and three government partners, CareNx has:

- Made about 1,00,000+ visits
- Reached 35,000+ mothers
- In 500 villages across 11 states[29]

We counsel them on nutrition and talk to them about iron supplement', even after that if the Hb levels haven't improved, we try to find out why and take them to health posts.

– A health worker

Publications

Mahmoud M, Petkoski D. Ideas for Action: Financing and Implementing Sustainable Development. Chapter-1. International Development in Focus (2019). World Bank

Kulkarni A, Bondre A, Donakonda A, Joshi A, Dehukar P, Pathak S.(2019) Personalized maternal care intervention in a tribal community in India. Maternal Health Task Force. Harvard Chan School Center of Excellence in Maternal and Child Health.

Pathak S, Donakonda A. (2018) Bringing affordable and accessible maternal healthcare to the poorest districts of India. Case Studies on Leaving No One Behind. OECD iLibrary.

29 Source - https://www.caremother.in

Road ahead

This initial journey with their first solution CareMother has given CareNx the foundation to move to the next phase.

CareNx has now developed a new product called Fetosense, a smartphone-based fetal heart rate monitor. Fetosense is a cloud-based heart monitoring solution for healthcare facilities. This was showcased at Lactacon 2018.

Figure 5.16: Fetosense
Source*: https://caremother.in*

Recognitions and awards

Source: CareMother website

A true diagnosis is three-fourths the remedy

– Mahatma Gandhi

Source: Proverbs & Quotes for Entrepreneurs, Your Story

Chapter 6: Recommendations

The journey to understand social enterprises in the maternal and child health space culminated with the quest for 'what it would take to scale technology innovations in healthcare'. The insights gained from extensive interactions, field visits, and the experiences shared by social enterprises will help budding entrepreneurs learn from their peers who have walked a similar path earlier. Additionally, it is important that social enterprises and other relevant stakeholders reflect on the questions outlined below to create a conducive environment for healthcare innovations and adoption:

A. Can social enterprises address major problems like equitable access, quality, etc.?

Innovations are the need of the hour for a country like India, where communities live in remote areas, access is a challenge, and out of pocket expenses push millions of families every year into poverty. Social enterprises have the potential to play an important role in providing equitable access and quality healthcare to the neediest people in the country. For example, we've covered some of these in the handbook:

- Forus Health - 3netra, a portable solution that can detect retinopathy of prematurity in infants, help mitigate the challenge of shortage of ophthalmologists in remote locations and hence address preventable blindness by early detection
- mMitra from ARMMAN that provides information on pregnancy and neonatal care
- Aravind Eye Care addressing preventable blindness caused by cataract

All these provide capabilities in the remote parts of the country and detect risks early, thereby having a potential to address the above question, provided they meet key criteria such as safety, effectiveness and evidence of the cost-effectiveness of their solution.

B. What models have been adopted by social enterprises that are beginning to scale?

Social enterprises have adopted different paths to scale. Those like Forus Health established early proof points by creating a solution for the mainstream market that was later adapted for a public health system. Others like Biosense engaged at a sub-district level with the government system to create early proof points and subsequently partnered with other service providers to scale up. ARMMAN established proof points in multiple states and then teamed up with the government, while Aravind Eye Care adopted a cross-subsidisation model of fee-paying patients and non-fee-paying patients.

Some of the innovative solutions have not just stopped at a single product but developed a range of products and services in adjacent segments. All the five social enterprises featured in this handbook have a portfolio of products and services. Forus Health has a product plus services model, where a cloud-based digital healthcare solution offers the capability of multiple specialists reviewing the data generated from the field. CareNx has teamed up with service providers such as ECS of Nagaland to provide comprehensive diagnostics services. Aravind Eye Care also developed a vertical integration model by not only training healthcare staff but also designing and manufacturing intraocular lenses. Besides developing extensive partnerships, social enterprises have moved into hybrid models of products and services.

C. What key factors would drive the public health system to adopt innovative solutions?

There are three dimensions to this — the government, the social enterprise and the enabling ecosystem.

C1. For the government, some of the important factors are:

- Developing policies based on evidence and a transparent decision-making process for adoption would enable the social enterprises to be adequately prepared to address needs.
- Ensuring that terms and conditions of Tenders encourage social enterprises to respond to Request for Proposals (RFPs)
- Easing payment terms to mitigate cash flow challenges for social enterprises.
- Creating synergy where social enterprises can provide patient diagnostic information to government systems for follow-through may help deliver a quicker response to the patient, reduce duplication and information asymmetry.

C2. For social enterprises, some of the important factors are:

- The need to significantly enhance the understanding of the community needs, the users of proposed systems, the priorities of the National Health Mission and state-level priorities and a deeper understanding of the health technology assessments or HTA.
- Understanding the Program Implementation Plan (PIP) and Record of Proceeding (ROP) process, identifying early adopters in health departments and implementing pilots with local conditions in states where the social enterprise wishes to create impact.
- The need for evidence on safety, effectiveness and cost-effectiveness, which we covered in the section on the government decision-making process in Chapter 5: From pilot to scale and elaborately explained by our domain experts in the HTA section are critical.

C3. From an enabling ecosystem standpoint, some of the important factors are:

- Bringing in complementary solutions, providing access to relationships with hospitals and state governments.
- Plugging the gaps in the healthcare continuum and building the entire portfolio of services for a set of needs as an example in the case of maternal and child health for the entire phase from antenatal care, maternity ward, neonatal care to infants.
- Playing the aggregator role at state governments as an example of a philanthropic

organisation, such as the WISH foundation, which has a scale-up programme in Rajasthan, Madhya Pradesh and Odisha.

D. What key factors should social enterprises keep in mind while designing healthcare innovations?

Given the long gestation cycles of developing innovation in healthcare, the path to scale for social enterprises is laden with many challenges, making it all the more necessary for innovators to focus on developing evidence for safety, the efficacy of the interventions and cost-effectiveness. We believe that partnering early with key stakeholders and the enabling ecosystem could make a difference.

Ideally, most healthcare social enterprises may partner with the government and secure adoption from the government. However, they feel the lack of avenues to partner with the government, and that the process is slow and complicated. While the government needs to do more on this front, social enterprises can also acquaint themselves with the processes better. An additional view shared was that social enterprises can have a bigger impact by focusing on health challenges that have a larger footprint; for example, maternal morbidity.

Based on our findings, here are some recommendations that can help bridge the gap between social enterprise innovations and the public healthcare system:

D1. The relevance of a solution – align with national and state priorities early

While the proposed design of a solution may seem innovative, a social enterprise that wants to address the public healthcare delivery system needs to ensure their idea is relevant to the national and /or state priorities at the ideation and concept stage. For instance, India's maternal mortality ratio[30] (MMR) is at 130 v/s the SDG target of 70, while MMR in the Empowered Action Group (EAG) states[31] such as Assam is at 188.[32] India accounts for 20 percent of global deaths due to preventable causes.[33] An organisation like ARMMAN that focused on addressing the challenges of maternal mortality in the antenatal phase felt that almost 90 percent of maternal deaths in India were avoidable. They designed a programme that provided timely and regular assistance to pregnant women over a standard mobile phone.

Another organisation Janitri focused on helping staff nurses detect high-risk cases and preparing digital partographs in the labour room. This aligned with National Health Mission's 'Labour Room Quality Improvement initiative' (LAQSHYA) and WHO's guidance to plot partographs in the labour room. Aravind Eye Care's intervention focused on cataract surgeries to address preventable blindness is another example of aligning with national priorities.

30 Per 100000 live births
31 The eight socio economically backward states of Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttaranchal and Uttar Pradesh, referred to as the Empowered Action Group (EAG) states
32 https://niti.gov.in/content/maternal-mortality-ratio-mmr-100000-live-births
33 https://www.orfonline.org/expert-speak/an-analysis-of-maternal-health-condition-across-parliamentary-constituencies-in-india50535/

Public healthcare priorities[34]

In its report on 'Opportunities, Ecosystem & Roadmap to Innovations in the Health Sector', the Sector Innovation Council for Health,[35] has identified four 'innovation clusters' for innovation in medical devices and diagnostics:

1. Redesign of the sub-center health kit (not limiting to ANM kit)
2. Improved quality of care in hospitals (in low-resource settings)
3. Improved emergency care in transit
4. In-vitro, point-of-care diagnostics

Another notable reference from the MoHFW is 'Unlocking new Ideas: Good Replicable and Innovative Practices'.[36] It covers a range of case studies across India that can be valuable for understanding programme and process implementations that have worked in low-resource settings.

D2. Innovate using technology but from a public health lens

To solve a public health problem, social enterprises often turn to technology. A technology-driven approach might not be the most optimal approach from a public health perspective, especially if conditions such as low-resource settings and other social issues are not factored. Applying design-thinking principles at an early stage and embedding insights into product features and the business model at the design stage is critical.

For instance, if doorstep diagnostics to identify high-risk cases are provided to pregnant women, there could be unseen challenges in this intervention that addresses the access issues in a rural setting. CareNx felt that the need to understand the social setting is also important. While designing the intervention, they also factored in how to win the trust of the family, space for examination of a pregnant woman and health workers' comfort in using technology.

Another situation is the existing capacity at the implementing location. The public health system doesn't have resources for a technology needs assessment that are required to develop innovative solutions or for carrying out trials of new solutions. Social entrepreneurs may need to consider this in their roadmap and include other partners from the enabling ecosystem.

In Janitri's example, they considered the on-ground situation of maternity centres. A solution designed to identify high-risk cases in the labour room also needed to factor the workload of staff nurses in low-resource settings, especially during an overlap phase where both manual and digital records are maintained. For emergencies where the staff nurse was constrained to key in all details of the pregnant woman, Janitri developed an enhancement that let the staff nurse avoid extensive data entry and to create a new record with minimum data inputs.

When quantitative research methods may miss capturing these insights, ethnography is another useful approach where researchers immerse in the deployment setting and adopt qualitative methods. This enables a researcher to look at different research questions when the problem is complex and embedded in multiple systems.[37]

34 Sector Innovation council for Health 2013, National Health Systems Research Center , MOHFW, Government of India
35 http://nhsrcindia.org/resource-detail/sector-innovation-council/NDcz
36 https://nhm.gov.in/images/pdf/in-focus/MP/Day-1/Coffeetable_Book.pdf

D3. Build evidence in favour of a product, the ethical way (with clinical investigation studies and HTA)

The value of a product for the public health sector needs to be evaluated from various aspects: Necessity, efficacy, efficiency and cost-effectiveness. It also needs to be evaluated against the side-effects or harm it potentially causes, and whether it can be replicated in different environments, such as private hospitals, primary health center s, urban and rural settings and so on.

Decision-makers such as doctors and people in the public health system gain confidence in adopting an innovative solution if its safety, efficacy and cost-effectiveness are tested against those of alternative approaches including:

- Approaches taken by other social enterprises in solving the same problem
- Approaches that the social enterprise considered at the design stage before finalising a particular solution
- An older, more established approach

However, it is not enough to simply conduct this analysis and document it, but to publish it in peer-reviewed journals. Doctors do not get excited about innovations just because it is technology-based. They are keen to know if it is sufficiently tested and what their peers have to say about it. If a social enterprise should collaborate with a reputed health institute or research center at an early stage, published evidence will work in their favour when it is time to scale. Organisations such as ARMMAN published a report on the impact of mobile-based interventions of health literacy among pregnant women while Aravind Eye Care has numerous publications on the impact of their work.

When innovations are implemented in rural locations, the user of the solution could be from the health department or a patient who may not be equipped to resist or question a new solution. It is therefore critical to ensure that 'do no harm' principles and ethics in trials are followed. Getting clearances from the ethics board is imperative.

While testing a product, or in the 'proof of concept' stage, the design and development team needs to be closely involved so that they get first-hand information about the user-experience. These tests should be conducted in areas that can be easily accessed by the design and development team. This will allow them to observe and address complications in using the product or include specific instructions for users when the product is scaled to areas not easily accessible. Spending a disproportionate time on refining a product during the pilot will ensure a smooth process during scale.

The public health team of a social enterprise should be involved, both to define ethical ways of testing and factor in social aspects while testing.

D4. Engage the government early on (regulations and adoption process)

Understanding the regulatory environment and adhering to the regulatory and ethical protocol is critical for social enterprises.

- **Apply and work within the government processes for test**

  In the early stages, when social enterprises are developing prototypes and seeking user feedback, they think of it as 'feature testing' rather than a formal field trial. And so,

37 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3100516/

many of them skip mandatory government processes such as getting approvals from local ethics committees and registering with the Clinical Trials Registry of India (CTRI). There is also a perception that these approvals are only meant for new drugs or invasive medical devices.

The CTRI requires all trials to be registered before the first participant is enrolled. Their guidelines state that 'any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies is expected to register the trial in the CTRI before enrolment of the first participant'. Many social enterprises are unaware of this, which could be a challenge when it is time to scale. An example of CTRI report is available in the Annexure.

Organisations such as BIRAC, Millennium Alliance, Villgro and Social Alpha provide support to social enterprises during the clinical trial phase. However, their assistance is limited to organisations that are a part of their cohort.

- **Access to health information network and data sharing**

  As innovators develop newer solutions to address public health issues, it is critical to ensure a seamless movement of data from one system to another to improve efficiencies of healthcare delivery. In our case studies we noticed that the valuable data being generated by social enterprises is not being integrated with the public health system.

  For example, social enterprises such as CareNx are tracking high-risk pregnancies. If this data has a provision to update the public health system seamlessly- it can result in appropriate next-level follow ups. This in turn would mean a positive outcome for a pregnant woman in a low-resource setting even if she or the caregiver do not communicate the conditions to the doctor during an ANC check-up.

  Another important issue is transfer of healthcare records between different geographical regions. For example, if the pregnant woman moves to her parental place from her work area which may be in another district or state, ensuring that her healthcare records are available to the doctor in the new location could ensure a seamless transition for continuing and providing better care. Perhaps the concept of 'Anywhere Branch Banking' from the Indian banking system could be adopted in the healthcare delivery system.

- **Engage with the public health experts and officials early in the adoption process**

  At times, social enterprises approach government officials during the later stages, such as the pilot stage or when they seek government procurement. They should engage with the government much earlier, ideally during the design process. There could be similar solutions already available in another part of the country and social enterprises might not know about them.

  A public health official will have greater visibility and exposure to such products and conferring with them at an early stage could potentially avoid duplication of work and provide insights on the product and demand for it, from the government's perspective.

  As far as procurement is concerned, state governments prepare a PIP that lists down

all the health initiatives they plan to undertake in the coming year, and the budgets allocated for them. For a programme that will get implemented in April, the process starts in August of the previous year, which means social enterprises who want to be a part of the list should conduct pilots well in advance of that. Many organisations are unaware of this, which is why they miss out on the opportunity.

- **Avail of opportunities through the National Health Innovations Portal**

  Another opportunity for adoption is through the National Health Innovations Portal, where innovative health solutions can be submitted. Solutions are typically selected based on the government's priorities. Selected solutions then go through rigorous assessments and are compared with other solutions in terms of efficacy, cost-effectiveness and so on. The shortlisted ones are invited to participate in a national workshop where they can showcase their product to health departments of all states. This helps open doors for them to expand to multiple states.

  An example of an innovative product that was showcased at the best practices workshop was TrueHb Hemometer from Wrig Nanosystems. Some states have adopted it and some of them have included it in their PIP.

- **Try a bottom-up approach**

  Many primary health centres have small discretionary budgets for procurements. Social enterprises can tap into that and circumvent the PIP process. Getting a buy-in from grassroots government agencies aids one's chances of partnership at the state or central level. It provides valuable evidence of the efficacy of the product and helps the social enterprise adapt the product to the needs of the state.

D5. Partner with other organisations in the enabling ecosystem to scale

Apart from the government, there are organisations like WISH Foundation, Piramal Swasthya or programmes such as PAHAL (USAID & IPE Global) that have partnered with state governments, presenting opportunities for social enterprises to deploy solutions in public healthcare settings.

A social enterprise based out of Bengaluru, with a small team of about 10 people, might not have the resources to go to the Northeast and launch the product there. But if it can partner with hospitals and other organisations which already have a footprint there, they can leverage their partner's reach to scale operations.

Our study shows that appropriate partnerships with organisations that can help deploy products during testing and adoption, is critical for healthcare social enterprises. The partnerships that CareNx has with Eleutheros Christian Society and the Government of Nagaland, ARMMAN with Apnalaya, Forus Health with Narayana Nethralaya and Apollo Hospitals were important for deployment and scale.

An approach that many social enterprises have successfully tried is to partner with private hospitals with streamlined decision-making processes, making turnaround time for decisions faster. Another approach is to partner with a chain of hospitals that not only provide additional reach but would also provide desired recognition and acceptance of the solution that is very critical at the initial stages, especially when cash flow and capital can be a serious challenge.

D6. Continuum of solutions – (products or services or a combination)

Many social enterprises started with addressing a particular need but gradually realised that they would have to go beyond just a single solution in order to make a dent. In certain cases, they had to also adopt a model where they combined their product with a service to ensure easier adoption.

Social enterprises such as Biosense, Bempu, CareNx, Forus Health and Janitri are examples that began with a single product and then gradually expanded their product portfolio over some time. Organisations like ARMAAN offer a range of services, while Forus Healthcare has an option of the product with a cloud-based service model. Aravind Eye Care is an example of addressing the needs with a 360° approach – from holding community camps, training healthcare staff to ensure surgeons time is efficiently used, to designing and manufacturing intraocular lenses.

E. Does the current ecosystem provide end-to-end support (from risk capital to product design, product trials and so on) for healthcare innovations from social enterprises?

While progress has been made over the last few decades, there is further potential for the government and non-government ecosystems to function in tandem.

Government

While an increase in spending on health as a percentage of GDP will make a difference to our healthcare system in general, providing a conducive environment with special provisions for adoption of innovations will help social enterprises. Provisions could range from encouraging district level pilots with government funds, enhancing allocation for innovations category in the annual budgets, ensuring timely payments, etc. Enhancing the capacities of NHSRC-HTAs will provide additional capacity for them to evaluate innovative solutions. Creating a transparent process will remove the perceived veil of secrecy and ambiguity in adopting innovative solutions. Another possible area is for the government to provide a linkage between the innovation arm (DST/BIRAC) and the delivery arm of the government (MoHFW) to facilitate public-private partnerships with appropriate technology.

Non-government

- **More incubators** - While several incubators have been funded by BIRAC and others such as Social Alpha and Villgro exist that provide deep hand holding, we need many more incubators to assist social enterprises across the product life cycle, from the concept stage, up to scaling deployments. Some of these are specialised requirements, especially product design, field trials and publishing evidence and so on, where we have limited expertise.
- **Access to capital** - Given the long gestation cycles of healthcare innovations, the need for a quantum increase in 'patient capital'[38] is a must. Other sources of impact funds need to be made available to social enterprises so that they service large orders and avoid the pain of running into cash flow constraints.
- **Academic collaboration** - Periodic evaluation and enhancement of courses on innovation and entrepreneurship at the university-level will bring in a level of

readiness amongst our budding innovators. Increasing internship opportunities at start-ups at various stages of the innovation journey will enhance the quality and quantity of innovators, in addition to igniting minds to delve into entrepreneurship. Encouraging collaborations between engineering and medical schools will foster early complementary partnerships that are critical for innovators (who usually come from an engineering background).

- **Evidence specialists** - Another aspect that is critical across government and non-government systems is the need to ramp up capabilities to test healthcare innovation and to develop technical experts who are not only practitioners but also researchers who can enable publishing of evidence for technology solutions in healthcare, leading to more solutions.

While some of the systems in the government and non-government are now in place, we now need these to function in tandem.

38 Capital in the form of equity or debt where the investor is willing to receive returns in the long term and not in the immediate horizon

Ups and downs in life are very important to keep us going because a straight line even in an ECG means we are not alive

- Ratan Tata, former chairman, Tata Sons

Source: https://www.timesnownews.com/business-economy/companies/article/7-ratan-tata-quotes-that-will-inspire-you-to-become-successful/460310

Chapter 7: Voices of domain experts

The discussions with Dr Anand Bang of SEARCH, Dr Arun Venkatesan of Villgro, Denny John of Campbell and Cochrane, Manoj Kumar of Social Alpha and Dr Satya Prakash Dash, formerly with BIRAC & PATH and currently Venture Center, have been extremely intuitive. Here are their valuable insights.

1. Interview with Dr Anand Bang

Innovators should not only be innovator, but an innovator and doer; the greatest people in the world have been both

Anand Bang is a medical doctor and public health practitioner. He works with Society for Education, Action & Research in Community Health (SEARCH), a non-profit in the Gadchiroli district of Maharashtra, and with the Tata Trusts as advisor, health. He was also the health advisor to the Chief Minister of Maharashtra.

Choosing areas for innovations in public health:

In the theme of Reproductive, Maternal, Newborn Child plus Adolescent Health (RMNCHA), I would specifically suggest two areas for innovation: First, neonatal health, specifically focusing on preterm birth, reducing low birth weight and early diagnosis and treatment of neonatal sepsis. It must be emphasised that there are excellent and evidence-based approaches to provide neonatal care in the community. Such an approach is not only cost-effective but also ensures community empowerment.

The challenge in effectively implementing a community-based programme is sometimes operational, hence there is a significant role for technology to play. A great example of this is the ImTeCHO tool (innovative mobile phone technology for community health operations) developed by Seva Rural that helps Accredited Social

The challenge in effective implementing a community-based programme is sometimes operational

Health Activists (ASHA's) and PHC staff deliver maternal and child health services to rural tribes in Gujarat. This simple technology was developed from scratch and refined through multiple user trials — including large field trials — that led to its adoption by the state for implementation across Gujarat.

In the case of maternal health, as maternal mortality has been reduced quite remarkably, I would suggest focusing on maternal morbidities, which, in absolute terms, affects significantly more mothers. This underlines the basic fact that to have a bigger impact, social enterprises should focus on the healthcare challenges that have a bigger footprint.

Views on some of the innovations in the market and the ecosystem

To be honest, I'm not greatly enamoured of several of the innovations promoted. My assessment of most of the social enterprises in India is that there are product innovations, but these have not followed the full scientific process (as ImTeCho for that matter), including conducting rigorous field trials and demonstrating specific impact.

The challenge with innovators in India and probably globally is that the innovator starts with the key and then tries to identify the lock

I consider three challenges in healthcare innovations. The first is that in India, and probably globally, the innovator starts with the key and then tries to identify the lock. The process has to be reversed. The other two challenges are bleeding heart decision making and lack of full academic research rigour essential to take an innovation to the final stages.

There also is a systemic lag in the ecosystem that is the reason for three challenges; some of them could be genuine problems. We need to develop a Bay area-like ecosystem, where all these things are provided. Some of the social enterprises haven't found partners who will work with them and design field trials, randomised trials etc. The other two, bleeding heart decision making and lack of full academic research rigour, are essentially mind-set problems. I don't know a single design that has gone nationally and is really making a path-breaking change. And then there's a buzz of AI and block chain and smartphone fascination.

Views on government

The government should provide the resources, and not necessarily run the programme. It doesn't mean that the government abdicates its responsibility of ensuring the provision of free or subsidised care to all the needy. But engage partners, a good example of which is the work of Karuna Trust or running of the mobile medical units in Maharashtra. A suggestion is that a partnership must involve public, private (or not-for-profit), the people (local community) and appropriate technology.

We must develop a solid evidence base in India. Conduct surveys, trials and be open about our successes and failures

Systemic changes and policies

We have a myth in India that we have great policies, only poor execution. In reality, a large number of our policies are not based on evidence, but on opinion. This is a big bane, and we must develop a solid evidence base in India. We need to conduct surveys, trials and be open about our successes

and failures. There must also be a mechanism to control the undue influence of partners, even if well-meaning, on policy formulation.

Healthcare in states such UP, Bihar, Jharkhand and Odisha

I would suggest three actions. First, to tap the larger number of civil society organisations working in these states and strengthen them through philanthropic funding.
Second, and this is important, strengthen not only in terms of service delivery but also in knowledge generation capabilities. The 'research' abilities promoted through this support can be in better service delivery, innovative design, creating new models, meticulously documenting the experiences as well as establishing results and monitoring framework. Knowledge generation requires financial investment, not necessarily the multi-million dollar projects in the West, but still unquestionably to a certain extent. The significant by-product of such an investment is also better-quality service delivery.

Engage with political leadership – both civil society and philanthropists should engage with decision-makers

Third, creating a powerful discourse that engages civil society and/or the private sector for delivery by developing models which are win-win. Probably such models are missing in adequate numbers, either in reality or at least in perception.

Fourth, engaging more with the political leadership. Both the philanthropic leadership and civil society must engage more with bureaucrats, while the political leadership, which is in some ways directly accountable to the people, are not adequately conversed with.

Government and social enterprises

Innovators working only with and through the government for scale-up is putting all eggs in one basket. Two alternate approaches can be explored. One is to work through civil society, larger philanthropic organisations and the market forces. Another is to work with the government through other large philanthropic organisations, a good example of which is how SEARCH worked in Jharkhand, through the Tata Steel Rural Development Society. This partly equalises the otherwise asymmetrical power equation between the government and other partners or innovators.

Suggestions for social enterprises in public health

Public health innovators ought to live for sufficient time with the community they are looking to serve. Unfortunately, a lot of innovators spend disproportionate time in tech cities or academic institutions, whereas I will be delighted if an innovator is willing to live for three years in Gadchiroli. Probably, there is a myth that innovations only happen in high-tech laboratories. There are several process innovations which take place where the operations are, and which the innovators would completely miss.

Additionally, the innovators should not only be product innovators or process innovators, but also partly the chief architect of the execution. That is also essential for the effective feedback loop. If one notes, several of the greats have been both – Edison, Gates, Gandhi. Probably there is a perceived artificial barrier between innovator and the doer.
Many social enterprises look at public health programmes and community health workers only as a mobiliser or educator, not as an interventionist, which is the biggest mistake. If you want to have a good programme, you cannot have only a salesperson. Nobody wants to delegate to a community health worker. Having too many doctors or nurses is not a feasible option, it's an antithesis of what

public health means by ‘people’s health in people’s hand’. Most social enterprises expect people to come to them, care must be provided where people are.

2. Health technology assessments (HTA)

We insist on methods of evidence, if the methods are less robust or less scientific, we could end up with different results about clinical effectiveness and cost effectiveness

In our interaction with Denny John, we were able to understand the philosophy behind HTA and the process not just in India but across the globe.

Interview with Denny John (www.dennyjohn.in)

Market access and evidence

Market access strategies require that you have to have regulation and evidence that a particular intervention is effective and cost-effective in the context in which it has been applied. There has to be a market access component for innovative solutions, while today market access strategies are done for drugs extensively. For example, a drug company cannot take a study done in the UK if it wants to enter India; they need to do a trial here and test it and only then will market access be granted. There is both a regulatory component and a financial component. The regulatory component ensures that it aligns with the laws of the land and the financial part is to ensure that it is priced suitably. The methodology for generating the entire area of evidence for justifying that the market should be opened up for a particular solution is termed as Health Technology Assessment (HTA). That is one of the prerequisites before scaling. We insist on methods of evidence, if the methods are less robust or less scientific, we could end up with different results about clinical effectiveness and cost-effectiveness.

About HTA

Studying the effectiveness of a solution or intervention is important. For example, for a solution A, which is following a particular approach, the first question would be ‘is there evidence that such methods are effective?’, we cannot do a primary study around it. We have to understand from published literature, identify what interventions are available among which this could be another intervention. There could be another set of interventions, too, for the same objective.

The method that we suggest is termed systematic review, where you build evidence from published studies. They have certain advantages over literature review, like it follows a certain method. This entire process should be free of its own bias also, e.g., are we searching a few studies? Have we included all interventions? Have we identified all-important outcomes? Have we identified study

designs that are not clinically possible? For example, randomised control trials may be more feasible in a lab setting, but in a real-world, case-control may be more appropriate. These are things that are done as part of a systematic review. We also try to see if it is cost-effective against the same method.

We insist on methods of evidence, if the methods are less robust or less scientific, we could end up with different results about clinical effectiveness and cost effectiveness

The second part is whether it is clinically effective and cost-effective. We can either do a clinical trial or develop an economic model by just taking parameters from published studies. Bringing the cost and predicting what will be the cost of introducing it, then extrapolate it to find the impact of introducing the solution in India. This can be modelled to make assumptions such as depending on the coverage and costs etc. the cases can be reduced in the next 10 -15 years. This is the goal of Health Technology Assessments (HTA).

Without this, scaling of health interventions is morally illegal or morally wrong especially in countries like the UK. The UK has the National Institute of Health Research (NIHR) health innovation observatory (the ICMR equivalent for the UK). If they are approached with an intervention, they will do an independent scan and see if there are interventions which are available to manage the same problem – to achieve the same outcome for the same population. From the horizon scan, they would do the above process; you cannot leave it to the manufacturer to do it as it would be a bias or conflict of interest. We don't have that kind of an independent body yet. There is a small initiative under DHR, initially, it was called Medical Technology Assessment Board and now it's renamed as Health Technology Assessment India (HTAIn).

Can HTA define long-term needs?

That's what we need to achieve eventually; right now, we are not at this stage, and we are more reactive. For example, in the UK, there's a similar agency called NICE (National Institute of Clinical and Healthcare Excellence), in Germany there's an organisation called IQWIG, in Sweden, there's an organisation called SBU, in Norway, there's Norwegian Institute of Public Health, New Zealand FARMAC, in Canada it's called CADTH. These are formal agencies where these assessments are conducted before introductions of any new device, drug and vaccine or for that matter a programme. Even if we have to do mammography for breast cancer screening, they will do an independent assessment of the intervention, identify the effectiveness – clinical, cost-effectiveness, budget impact; based on their recommendation, the health system will reimburse if it is a positive recommendation. If there is a negative recommendation, the NHS cannot take the intervention, and it's one of the criteria, not the only criteria. Now there are formal methods called multi-criteria decision analysis (MCDA) where they decide on weightage that has to be given to aspects such as severity and burden of disease, clinical effectiveness, cost-effectiveness etc. before making a final decision.

Multi criteria decision analysis which is basically a method where they decide on weightage that has to be given to clinical effectiveness, cost-effectiveness and make a final decision

Do we have weightage assigned to aspects such as clinical effectivness, cost-effectiveness in India?

No, right now we don't have weightage assigned. I believe that without that foundation, deciding on the scaling of intervention is not right. How do you know that there's evidence of effectiveness or cost-effectiveness compared to current interventions?

In India there's a small movement around it, even if HTA makes a recommendation, the government doesn't need to accept it. In Thailand, there is a voluntary acceptance. We also have voluntary acceptance in India. If HTA makes a positive recommendation, the Ministry of Health can take it or leave it.

Requirements for HTA

For an HTA, you need multiple sets of people: an epidemiologist, a statistician, a person who understands research designs and a health economist. You also need an HTA representative who can understand the feasibility, also because it might not be feasible to do a randomised controlled trial each time. So how do you design the next step? How do you build those cost components within that and measure all that? So there's a whole value that HTA brings in what we look at.

The dearth of HTA researchers

The problem is because we don't have HTA as a training capacity in the country. Not a single institute in the country is teaching HTA as part of any formal course. There's also no formal course on evidence in India, and it's all in the workshop-based approach. In some states, the government has endorsed such HTA bodies; for example, in Andhra Pradesh and Kerala.

It's also a supply issue. So, we are also looking at avenues where we can build this, but it's not a problem with India alone. This is not a very simple discipline because you need multiple skills plus the whole understanding, so it is not an easy skill to have and to generate that kind, the country will have to invest, certain people will have to be moved around in that direction. And that is the problem; the domain is a little too specialised in that way.

Evidence has to be based on internal design factors and we have to design it on our own, you can't expect a regulatory agency to focus on that. In the UK, there is a single technology appraisal (STA), which is HTA done primarily by the drug or device companies directly and then reviewed by NICE. The other is called multiple technology assessment (MTA). Here you will not compare any other device addressing the same problem; you will compare all other interventions that solve the same problem. This is done via commissioned research through NICE. In the US, this is called comparative effectiveness research, because I'm not comparing one intervention versus others, but across all possible interventions possible that can manage the disease. For example, for dengue, the dengue vaccine will be compared against the effectiveness and cost-effectiveness of WASH interventions

It's more cost effective to ensure compliance than screening an additional woman. There's no point in screening additional women if she doesn't complete the entire continuum of care

Patient consideration for HTA

If an intervention has to be integrated into a health system, there are additional things to be considered, also termed as additional considerations for cost-effectiveness. It's one thing to be cost-effective, it's another thing to have a cost-effective implementation, and these are two different things. You need to understand how the health system currently functions. For example, it is more cost-effective to ensure post-screening compliance than screening an additional woman in a

cervical cancer screening programme. There's no point in screening additional women if she doesn't complete the entire continuum of care.

The problem with most entrepreneurs is the lack of understanding and attention to implementation design. They have to talk to implementation scientists to understand and that's again a problem as there aren't too many of them. We need to understand the barriers of why screening doesn't happen. So, we are now talking about patient engagement in HTA.

If you're putting everything from a provider perspective, that's another problem with HTA. We are now emphasising that they design a methodology to integrate patient or stakeholder engagement in HTA. It's important to engage the client or patient in the design phase, if this is not done in the trial phase or the evidence phase, we cannot say we are trying to improve lives. You cannot decide for someone without trying to understand their perspective. I think evidence has to be based on science, at the same time, all stakeholders should be equally engaged in the process; you cannot leave out the beneficiary, as recipients, they should be having a say.

Need for differentiated scaling strategies

In India, till you reach a million, you haven't scaled. It's something like the parking principle – for every 50 cars you plan in a certain way, but when the 51st car comes you need to plan it differently. This is how you plan infrastructure; this is what we were taught in hospital planning. That means when you are reaching 1,00,000, you need a certain strategy, but the moment you are going beyond 1,00,000, you need a different strategy. Typically, the development sector doesn't teach us that. Without evidence there is no point in going ahead. There are specific methods by which you estimate the evidence, which includes both the effectiveness of the programme, the intervention and the cost-effectiveness and also the budget impact of the new intervention compared to the older intervention. Without these, you won't be set to scale up.

Communicating evidence

In India till you reach a million, you haven't scaled. That means when you are reaching 1,00,000 you need a certain strategy, but the moment you are going beyond 1,00,000 then you need a different strategy

It is one thing to generate evidence, the other is how do you communicate evidence, how do you do it for the purpose you want to achieve, whether it is policy or user awareness. Evidence communication is very important. The way you communicate evidence to a lay reader is different from how you communicate the same to a bureaucrat or a policy person. The second important thing is equity consideration in HTA. In some cases, we know that it will be effective to people who are closer to the facility; for people who are further away, it will be less effective, and the reverse is also there. It will be more costly for them to access care when far away. So, in the entire value of HTA, we have to see whether cost-effectiveness is equitable, also termed as equity considerations in health technology assessment.

There are methods to identify it, which have a different drawback on the entire evidence. You can't use cost-effectiveness methods in all scenarios.

3. Excerpts from the interview with Dr Arun Venkatesan, CTO, Villgro

The Indian ecosystem is evolving to be on a par with what the global ecosystem provides, but it is still very fragmented… The jigsaw puzzle is starting to come together

In interactions with Dr Arun of Villgro, He shares his views around the state of ecosystem investments, returns and barriers to scale.

What kind of investments have happened in the health space?

We are seeing investments in maternal and child health, infectious diseases and a lot in non-communicable diseases, especially in cancer and diabetes. Villgro's sector themes are also similar for grants and investments. We have invested largely in diagnostics as compared to devices, and we have not done too much in digital health and apps. Our devices are becoming PRAS (product as service deployments).

In maternal and child health, we have supported labour monitoring through Janitri and some neonatal or foetal monitoring. We have done two neonatal hyperthermia preventions and related neonatal interventions through BEMPU. With Spot, we are doing neonatal sepsis intervention, which follows an investment pattern.

If you paint the picture going forward, what trends would we see in the health space?

There is going to be some excitement around artificial intelligence, digital health and block chain that may last a couple of years, but health services areas will have a lot of investment. People will get excited about new diagnostics with better health outcomes and faster outcomes possible. From an intervention point of view, there may still be imported solutions. There may be some new molecule and drug-based investments.

Villgro's investments are now to plug the gaps, where things are not happening. For example, in cardiovascular diseases, we have invested in solutions for diabetes such as Biosense, Yostra and Adiuvo. We see that for infectious diseases, 'point of care' screening is more important to get better healthcare outcomes for the base of the pyramid (BOP) and that's where our focus lies. We are not quite there, but we would like to provide better and faster reliable opportunities.

If you take the last five years quite several investments have been made by Impact investors, what would you rate as reasonably successful investments?

I would say things to watch for, rather than successful from our portfolio there are three: 5C Network - Teleradiology solution, Adiuvo and OmiX. The other two sensational ones in the digital health space are Niramai and Sigtuple.

What are your thoughts on the Indian healthcare ecosystem? How does it compare with the global ecosystem?

I think the Indian healthcare ecosystem is evolving to be on a par with what the global ecosystem provides, but it is still very fragmented, as the market is not as mature or as organised as the Western market.

Incubators are highly relevant because they integrate and bring the pieces of the puzzle together. The jigsaw puzzle is starting to come together. That is the integration phenomenon; the next is the progression phenomenon. BIRAC is now starting towards that. They have seeded about 1,00,000 innovations and are realising that the next is to move them from project to pilot stage. So now they are helping people with product development and focusing their effort there.

Indian customers are very savvy, but also very price-conscious. The payment is not as structured as the insurance structure in the West. Here you have to convince each segment of the customer with a value proposition that is appealing to them for every product, which is the tiring part of the entrepreneurial journey in India. There are a few things that we are trying like aggregation and so on, but it's tough for one company to do that.

If you look at Villgro's portfolio, we have done product development initiatives, now we have moved to provide 'go to market' help. We are going to experiment with some approaches, to move some companies closer towards adoption.

From the government procurement, there's a lot of effort to get solutions into the funnel, but if you look at getting solutions out of the funnel into the market, that part hasn't evolved. Any thoughts? How do we get social enterprises to prepare to handle these government projects?

If you see in the government procurement area, some progress has happened from standard assessment to GEM procurement. Still, start-ups will not benefit from it, because the tendering process continues. Awareness is going up, start-ups are the way to go and import substitution is important. The progressions are happening. We have done some mapping of this; the National Health Mission (NHM) procurement is by far the cleanest and the most transparent structured process but the best that can come out of this is an approval that an intervention can be adopted. Converting that approval to procurement is again the same game of talking to different departments, get three tenders. There isn't a change in philosophy or attitude where a procurement official is entitled to do a proprietary article certificate. Theoretically it exists; practically nobody wants to stick their neck out and say 'this is a great invention, I want to procure it; it is new and there are no comparables'. That is the stumbling block right now. Pilots can run and some NHM money will flow, but pilots will say this product is approved for procurement at best and a start-up might do a large pilot and sell 100 units and claim it's selling, but it's not commercialisation.

We need a little more structured inputs from entrepreneurs incorporated into HTA Innovation will not have an easy comparison, hence the model of tender with minimum three bids in inherently flawed

A possible approach is a public-private-partnership (PPP) model – WISH and similar organisations may be able to figure these out. Two things need to happen. First is that it has to be government money to scale. Each state has a different flavour; they may agree to the approval of another

state or they may say we need another pilot, which is wasteful and tiring for start-ups. Even then the procurement process is not transparent or structured. Even at the national committee for decisions, we don't know how decisions are made or not made. We know the process, but then the transparency of the final decision is not there. The conversion from approval to procurement is still a lottery and it may vary from state to state.

The conversion from approval to procurement is still a lottery and it may vary from state to state

The second thing is **the barrier is reduced in some of the proactive states when you shift to product as a service model.** If you offer a service, for example, 1,00,000 screenings and you may be able to convince the state, but that means the start-up has to put up the capital required to deploy so many devices and wait for the pay-out, All the economics have to be worked upon.

Does this become like a BOOT (build own operate transfer) model, which is very capital intensive?

Yes, the government doesn't want to take a risk by procuring openly. Even if they do, they want to operate at a services model. The classical example is Forus's implementation in Andhra. The back-end system that they developed as software, that service sold.

Are there one or two policy changes that need a change? What would you recommend?

HTA is a good thing. It's a customised process because each technology is different. In some cases, incorrect references are used to validate technology, so entrepreneur's inputs have to be incorporated into it because it is innovation. It's very good and I like it, and we need more structured inputs from entrepreneurs incorporated.

Secondly, the procurement process for start-ups needs to be clarified. Inherently, innovation will not have an easy comparison, hence the model of tender with a minimum of three bids is inherently flawed. Another way of ascertaining that this is a clear process to procure from start-ups, which is robust, needs to be established.

GEM is again not for innovative products; it works for things like for furniture or CT scan machines that are comparable. In healthcare, it is not like that. For example, Yostra's diabetic neuropathy machine has no comparable machine. They have combined four different techniques into one machine, so if you combine those four and get a bid, this will be at one-third the cost and that is a value proposition, but that doesn't fit the L1 rules.

While policy intervention in making procurement of start-ups is easy and registrations of start-ups is already there, procurement has to change because that's the only way money will flow into start-ups and they can work.

Else there would be an unethical practice of selling through a distributor to get the order by creating multiple bids. These are some of the issues.

The real scale in social enterprises is going to happen when you go to the public health market; there procurement is not very transparent and not very organised

The other question is about the risk or patient capital for the healthcare space. Has it changed over the last few years? Are you seeing more impact investors or angel investors willing to invest capital in this space?

There certainly is more activity and interest, but has it really resulted in more impact investors investing in this space – a guarded yes. Exciting investments have been made in the digital health space; philosophically, many of the impact investors are regular mainstream investors with regular mainstream investment thesis… They have added an impact adjective because they are looking for impactful applications, but they have not understood the need for more patience, higher amounts of risk capital, long-run gestation period. I don't think that has happened.

At a high level, what kind of returns do they expect from an industry standpoint?

Impact investors are still functioning as mainstream investors with impact as an afterthought

It's mixed, it all comes to the fund life, and everything is dictated by the fund life restriction. So the activity is always towards more mature investments, unless there is an impact investment fund like Menterra, who takes on the risk, gets involved in the company and matures the company faster. If that involvement and engagement are not there, people are restricted by the fund life model. Impact investors are still functioning as mainstream investors with impact as an afterthought. They don't start with impact and go on to sustainability. It again trickles down from the 10-year cycle (like the pharma model).

What are your thoughts on the business model of social enterprises? As an impact investor, do you evaluate their business model? At what stage should social enterprises validate their business model? Any thoughts?

Yes, we are not just an impact investor; Villgro is an incubator. We get involved in the business models, the earlier the better. Where most of the social innovations fail is where the product-market fit doesn't work out. They think they've understood, but when it comes to which customer in the cycle is really going to pay for you and how much, they fail miserably.

For a social enterprise at an early stage, we at least try to get 80 percent of the way there. We are not exactly there yet. There are questions like 'will your customers be willing to pay x amount for y product or z service?' But there has to be a refinement that needs to happen, to keep the regulatory aspects in mind in the preproduction stage, when you are ready to do a market pilot. That is a stage when you define a minimum viable product (MVP) and do a market pilot so their business models get refined. So, unfortunately, this has to happen pre-revenue and that requires some funding.

What are some of the barriers to scaling?

The private health market is highly segmented, there are multiple regions and multiple segment behaviour patterns which are tough for the social enterprise to establish scale. In a purely digital solution, it gets mitigated because the cost of distribution and customer acquisition is less. But if it is a device— for example, diagnostics — where it has to get to the practitioner either B2B or B2C, then there is a segmentation amongst practitioners. A physician or hospital is not one class; the fragmentation in the markets is one big barrier to scale in the private health market. Some patterns are emerging in terms of diagnostics chains or hospital chains.

The real scale in social enterprises is going to happen when you go to the public health market.

Here the challenge is that their procurement is not very transparent and not very organised. The government is a huge provider of health; however, its procurement is not organised, not transparent and it's not start-up friendly.

4. Interview with Manoj Kumar, CEO, Social Alpha

Strengthening the public health system is something I would like to pursue and Social Alpha would like to incubate any new ideas that would eventually tend to help the public healthcare system

In our interactions with Manoj of Social Alpha, Manoj shares his views around product development life cycle, state of our ecosystem and public health procurement system.

The social enterprise landscapes

When you look at innovation in healthcare – especially, in devices or treatment– you will see few successful start-ups, primarily for three reasons:

1. The product development life cycle is long, unlike building digital platforms or e-commerce or software apps. In this space, you need to spend a lot of time translating lab research into solutions. So even if you have translated science into a working prototype in the lab, the time-to-market of that prototype remains stubbornly long, with the average adoption of innovation into a clinical workflow being five to 10 years.
2. We have 200-plus incubators in the country, but very few offer services beyond real-estate. Translational research requires significant infrastructure and enablement systems, which makes access to world-class labs and mentors essential for innovation. Good technological innovation requires a combination of lab infrastructure, business management, mentoring and investment; unfortunately, it is all at a very nascent stage. C-CAMP(Center for Cellular and Molecular Platforms) in Bengaluru, for example, is one of the finest in the country as it has been able to leverage the ecosystem well.
3. There is a limited number of grant opportunities (apart from BIRAC) and the size of these grants is very small, ranging from INR 2-10 lakh. An innovator is able to raise a significant grant amount only at a very advanced stage of product development.

When we built Social Alpha, we found a clear gap in the ecosystem, impact investors with a long-term view along with a high business risk appetite that suits long product development cycles weren't there. Access to patient and empathetic capital is a necessary condition for nurturing deep-tech innovations, which are trying to address challenges of affordability, accessibility and quality of life.

I think another issue is the misalignment of incentives between innovators and entrepreneurs. **A lot of innovators don't want to be entrepreneurs because their eventual goal may not be to scale the solution beyond their laboratory** So, until and unless you have that common meeting ground where innovators and entrepreneurs can create co-founding firms, you can't start an entrepreneurial activity.

A macro view of the gaps

I think social entrepreneurs need three primary things:

1. A good pipeline of innovators and entrepreneurs who want to take entrepreneurial risks and solve these problems.
2. An enabling ecosystem and infrastructure that provides these entrepreneurs and innovators the opportunity to create, test and validate solutions, combined with customised mentoring for refining the business model, navigating the regulatory landscape and understanding national and global market dynamics.
3. Pool of long-term patient-risk capital that allows you to access everything that you need in order to build successfully. These three things are absolutely important and as and when we fill these gaps, you would get into that direction.

The Need:
1. A good pipeline of innovators
2. An enabling ecosystem
3. Risk capital

Experience of Social Alpha

We just completed three years, and in this time, we have evaluated thousands of start-ups, conducted diligence on about 400, selected 50 for incubation and have invested in 30 out of 50. We have had a mixed track record, and our 'Entrepreneur in Residence' programme has been very successful.

One of our portfolio companies has built the world's first liquid-helium-free MRI machine that runs on a 1.5-tesla magnet and is currently going through clinical trials and validation. Right now, our prototype is ready and is giving excellent results and the radiologists are highly impressed with the output. This is one example where we incubated on our balance sheet through our programme called 'Entrepreneur in Residence' and then hived it off as a separate company. But it's the innovator's entrepreneurial risk-taking and resilience that drives the success.

Then we have some interesting companies in medical robotics, companies in tooling and biomedical engineering. It's too early to talk about success but I think we are on track. The jury is still out but at least the model seems to work.

Strengthening the public health system

Strengthening the public health system via the adoption of innovations into clinical workflow is an essential need that we are trying to address in Social Alpha and would like to incubate ideas that would eventually help the public healthcare system and improve affordability and access or quality of life. From our point of view, we can incubate such companies and create a better supply of innovations to the market.

Crossing the chasm: From fostering start-ups to adoption

A big flaw in innovation management is our neglect of the most important stakeholder, that is the entrepreneur. We have to make public procurement entrepreneur-friendly, as the current systems have been designed to support large-scale firms, as the typical conditions in an RFP are 'x' years' experience, existing installations and so on, which tilts the system towards the incumbent.

The whole tender system is designed to support the incumbent and not the challenger; that has to change

We convinced one state government to give procurement orders instead of prize money to winners of a start-up challenge. They liked the idea. **All national-level events and awards should lead to work orders and not awards.** All cash awards should be replaced by work orders because entrepreneurs are looking at market access

Suggestions for social enterprises

I don't think a social enterprise is different from a conventional enterprise, because an entrepreneur is an entrepreneur. The most important thing to understand is the problem being solved and if the founders have skin in the game. Other than entrepreneurs, everyone else is on the payroll. They are the most important part of this whole equation and if we support them, they will make a large-scale impact. The entire ecosystem has only an enabling role to play, while only the entrepreneur can make that equation zero or infinity.

All national-level events and awards should lead to work orders and not awards. All cash awards should be replaced by work orders because entrepreneurs are looking at market access

5. Interview with Dr Satya Prakash Dash,

founding and former head of strategy, Partnerships and Entrepreneurship Development BIRAC & currently Member Board of Directors, Venture Center

There are multiple valleys of death which start-ups encounter while building a product

In our interactions with Dr Satya Prakash Dash, we cover a range of topics from the increasing efforts towards new product creation, preparing for various stages of new product creation to avoiding the valleys of death, the ecosystem and scaling.

Healthcare innovation in India

India has seen a tremendous seeding and growth in biotech and MedTech start-ups in the last decade because of a variety of vectors, such as BIRAC, and other agencies —DST (especially NIDHI-Prayas), Gates Foundation, Villgro, IUSSTF and Millennium Alliance. While these start-ups are focused on providing solutions aligned with social good, many of them would also be profit-making and that's fine as long as there is a social good in their focus.

There are now close to 2,000 start-ups and innovators in the healthcare space funded by BIRAC. Many of them are building products for the healthcare space; most of them are doing great in terms of ideation to proof of concept. While there is a hurdle that needs to be crossed from ideation to proof of concept (POC), the hurdles from POC to validation and then from validation to manufacturing at scale and adoption at scale are much bigger. This is what I collectively refer to as 'multiple valleys of death'. The complexities at each of these hurdles are huge and this makes the product journey very uncertain.

The drivers

I think several things are happening:

1. There's a lot more collaboration between scientists, social scientists, engineers and clinicians than it was 10 years ago, now, clinicians are also interested to work with engineers
2. Academic research is also looking to start to engage in terms of taking their research to the marketplace. We now have successful examples of such academic-led entrepreneurship in the health sector.
3. Both the Center and state governments are open to giving support to healthcare start-ups
4. Importantly, now there is appropriate funding at the early to mid-stage of a product development cycle. This was the idea when we were setting up several funding programmes in BIRAC such as BIG, SPARSH, SoCH, SEED and AcE Fund.

But we have to see if the systems are in place for that journey from the lab to the market. Each of

the aforementioned hurdles has some common elements; however, each of those hurdles require altogether different kinds of elements to come together.

I think, for this journey, we need bridges, such as technology transfer offices (TTOs). Essentially, for a successful TTO, one needs leadership that is open to orchestrate, engage and catalyse new partnerships. The human resources within these TTOs need to be nimble connectors who are deeply interested in the research taking place at academic institutions, have the DNA to be deeply interested and inclined to understand it, maintain a high degree of professionalism and connect with industry partners to explore possible licensing deals to occur.

It takes a whole village to grow a child'. All of these social enterprises will need the whole community support to support them

Is there enough porosity in the academic systems in terms of these things being seeded and taken forward? This is a million-dollar question. I think some academic institutions will be nimbler than others. BIRAC has taken initial steps in setting up TTOs recently, but we need to give some gestation period to these TTOs. It is also important to mention the role that the Principal Scientific Adviser's (PSA) office is playing in corralling many of these efforts, especially lending its support to Invest India's programmes such as AgNIi.

Preparing for different stages – from ideas to a product

I think this is really where the ecosystem has to help them. I completely believe the old African saying: It takes a whole village to grow a child. All these social enterprises will need the whole community to support them. During the pathway or the runway for a social enterprise to commercialise their healthcare products, they need to navigate several challenges, be it regulatory, dealing with vendors and other partners needed for successful commercialisation. The social enterprises should start early on these issues and these issues should be integrated right at early seeding stages and not after POC. It is very important to create this understanding and awareness amongst healthcare social enterprises.

For example, do they understand the kind of materials needed to build their product, is the material going to be obsolete in the next four years? Should they be thinking about this only after POC; the answer is no. While they are passionate about building a product, their passion has to be harnessed in thinking across different domains – a 360-degree approach. Their understanding of clinical trials, how to take ethical approval, getting in touch with physicians, vendors, contract manufacturers, contract for clinical validation… all that needs to be started early on and I think as an ecosystem, we should be helping them. This is exactly why we started the Impact Lab at Path and we helped design the Quest for Healthcare programme of Social Alpha.

Planning and avoiding the valleys of death

The post proof of concept, early validation and all the way to adoption that is very critical

As I mentioned earlier, it's not a single valley of death, but multiple valleys of death along the way. From ideation to POC is one valley of death, which has possibly now been bridged by funding and networking platforms for knowledge exchange. But there are multiple valleys of death while building a product.

You can identify the challenges at each of these valleys by looking at them granularly. Many of the challenges at these

valleys, a combination of engineering and technical aspects, validating the product in the field (for MedTech clinical validation) and aspects about business models, market access and go-to-market strategies. Marshalling resources including setting up an optimal team for each of these stages is important for product development,commercialisation and scale.

The journey of MedTech product start-ups is gated and there are checkpoints. It is essential to take inputs from all stakeholders (industrial designers, end-users, clinicians, supply chain persons, social scientists) while making the minimal viable product. It is also essential to quickly test it out in real-world settings and learn from any component that causes product failure. One has to also see the workflow issues and the ease of use of the product. The customer (end-users) forms a relationship with the product, and it is critical to see where the chinks in the product strategy are and that may not allow it to be adopted.

It is essential to take these inputs early on so that one could quickly go to the drawing board and modify the product. The cost of modification at the early stages is less. The cost of modification past the lock-in phase becomes higher and another cascade impact may occur.

The gaps I see are in terms of 'manufacturing at scale' to the minutest details during product design, development and rollout. Many MedTech start-ups make the mistake of thinking that the product works when only one or two products are manufactured. The issues about manufacturing at scale and potential risks are not thought through with a looking glass lens. Start-ups do not think about manufacturing at scale. How do you design for that? Where are the networks of vendors that you want to engage with? Secondly, how do you do a sale? And how do you provide services? All these elements are not thought through.

For example, if social enterprises focus only on government procurement, it means it will be a long time before the sale because the procurement policies may not be clear. So the go-to-market strategy other than public procurement is very critical. Pricing becomes important, and it becomes critical that start-ups understand the willingness to pay by different customer segments for the product.

Ecosystem and policy, access to government health systems

This is a classic case of policy silos. I feel that the different arms of the government have to talk to each other. The funding agencies have to talk to the implementation agencies. If the funder of the innovation is not talking to the implementation arm of innovation, then the journey of the MedTech product, especially those that are important for public health, becomes circuitous. In the Indian context, the innovation arm chiefly is DBT-BIRAC and Millennium Alliance while the implementation arm at the center is the ministry of health (ICMR, NHSRC) and various state health departments. They should talk to each other, provide clear guidelines of the requirements of products in public health systems, including the target product profiles (TPP) of the products and a route to conduct HTAs, and finally a connect to the regulatory agencies.

I guess the social enterprise also needs to look at all aspects. The naivety has to be reduced and real conditions that have to be dealt with need to be conveyed, especially their clarity on requirements of public health. This is starting to happen; indeed, the entrepreneurs must jump into the world of entrepreneurship without any blinkers and should know about the ecosystem as much as possible. Have a clinician, an industrial designer and a salesperson in your core team. Learn about government systems and learn about their constraints. Such a holistic view is missing.

Should market-based solutions scale or should they be more for-point requirements?

The scale question to me is the question that makes us are hit our heads against the walls. Scale can mean different things to different people. A social enterprise that is only in Karnataka and serves two million households — has it scaled or do you say that it hasn't scaled because it hasn't gone beyond Karnataka's boundaries? Each of our states is like a European country.

I think the scale question is very relevant but it's very contextual. Let the shareholder of the company decide how they define scale, what frameworks they use to define that scale. Social enterprise by definition is led by people who want to bring that change at the doorsteps of a community.

Let's empower our entrepreneurs to define what they want to scale.

Scaling too fast or without a plan may induce mission drift and have other effects that were not visualised and or were missed. There was a time where microfinance wasn't too big and then microfinance evolved into a phase when microfinance companies started being listed in the stock market, of course, it scaled but did it lose its focus? Indeed, it did. So, I'm a little hesitant to paint a social entrepreneur being successful only because they have scaled. Replication of social enterprise models through partnership and understanding cultural nuances and impacting lives through compassionate interventions are key to social enterprises.

Social enterprise, by definition, should be led by the passion of the entrepreneur and let them define what is a scale and because after the definition if they can raise money (from public and private funders) for that definition that is fine. If they're not able to raise money then the enterprise will fade away. That's also fine; there will be some element of Darwinian forces at play, dependent on their definition of scale and the network they function within.

To put this simply, let the social enterprise define and optimise their definition of scale and once that definition is reached, it is their prerogative to start convincing investors and getting funding for it.

Now obviously if they get it right and if the ecosystem has funding agencies that align with their thinking of scale, they would be able to raise funding. Else, either their definition is wrong or the ecosystem doesn't have funding agencies that align with their thinking.

Time frame to check strategy to scale

I have pondered on scale with time. Social enterprises that are product start-ups and especially those that are highly regulated will have to deal with the gestation period until they can introduce their product.

So, if one hypothetically thinks that the product can reach the market by year four from the start of a product idea, then one should give two-three years for scale to happen. Post product launch, one can start getting a sense about the traction of the product with users within 18-24 months. So, in total, perhaps five-seven years since the product idea is developed. What is crucial is that social entrepreneurs receive support in sales and marketing. I have seen those entrepreneurs who roll up their sleeves and do the initial sales themselves, learn about the nuances of the market and then they hire a professional salesperson.

Government procurement as part of the business model

Coming to your question about government role and as part of the business model — I mean for many decades globally as well, government plays a critical role, sometimes being the first customer and here there has to be a policy relook. I feel few are building innovation, let me clarify these innovations are not jugaad, which is a short-term solution. Public procurement is a huge push for

There is an effervescence of entrepreneurship

scale. I think the Government of India is streamlining the process of listing and procuring healthcare products. In another two years or so, there will be a lot of clarity. The role of regulatory clarity is also important and the government is streamlining regulation too. The MedTech product regulation is evolving, and digital healthcare is now a reality. Therefore, additional issues of data, its ownership and privacy of data will be crucial. This is an evolving space.

The opportunities for innovations in healthcare

There are plenty of opportunities in India… I think we have evolved in the last decade, a lot of the credit goes to agencies such as DBT-BIRAC, DST, Millennium Alliance, incubators such as Venture Center, IKP Knowledge Park, C-CAMP and others, non-profits and foundations such as the Gates Foundation, Wellcome Trust, PATH, Villgro, WISH Foundation, Social Alpha and several others. How do we harness this entrepreneurial energy? This is again something that we ought to address at a policy level. How do we build cutting-edge, high-quality but affordable products that are excellent and meet global standards? A lot of pain for the entrepreneurs can be eased by simply reducing issues of access to information – market information, social and cultural information, regulatory and technological information amongst others, and this lack of information can hurt any start-up. Another area that needs more focus is the help our social entrepreneurs need in connecting with other countries. People who are trying to jump into an entrepreneurial journey are taking a risk and how do we collectively de-risk their efforts to jump into the world of the unknown? This is the key, and this needs coordination, which is starting to happen.

If everything seems to be coming your way, you're probably in the wrong lane

– Anon

"Dream is not that which you see while sleeping, it is something that does not let you sleep"

- A.P.J.Abdul Kalam

Source: https://economictimes.indiatimes.com/

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A nation should not be judged by how it treats its highest citizen, but its lowest ones

-Nelson Mandela from his autobiography – Long Walk to Freedom (1995)[38]

38 *https://www.businessinsider.in/slideshows/miscellaneous/slidelist/65040920.cms#slideid=65040926?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst*

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Figure 5.1	Diffusion of Innovation model	https://www.smartinsights.com, Last accessed 26th June 2022
Figure 5.2	Case studies	Compiled by author
Figure 5.3	3nethra classic	Forus
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Figure 5.8	Aravind eye hospital	www.aravind.org, Last accessed 26th June 2022
Figure 5.9	Aravind eye hospital Assembly line	www.aravind.org, Last accessed 26th June 2022
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Figure 5.14	Screen shots of CareMother app	CareNx
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Figure 5.16	Fetosense	https://caremother.in/, Last accessed 26th June 2022

Success is a science, if you have the conditions, you get the result

– Oscar Wilde, Irish playwright

Annexure – Sample from clinical trials registry

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Sun, 19 Apr 2020 11:08:33 GMT)

CTRI Number	CTRI/2009/091/000577 [Registered on: 17/08/2009] -
Last Modified On	
Post Graduate Thesis	
Type of Trial	
Type of Study	
Study Design	Single Arm Trial
Public Title of Study	A clinical trial to evaluate the immediate safety and efficacy of BACE Device in the treatment of functional mitral valve regurgitation.
Scientific Title of Study	Evaluation of acute safety and efficacy of the BACE [Basal Annuloplasty of the Cardia Externally] device in the treatment of Functional Mitral valve Regurgitation [FMR].

Secondary IDs if Any

Secondary ID	Identifier
Study Number: BACE CT001, ; MA-CT-08-004	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

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Source of Monetary or Material Support

Source of Monetary or Material Support
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Primary Sponsor

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Name	Mardil Medical Medical Devices Pvt Ltd. 20B, ASCI College Park, Road #3, Banjara Hills, Hyderabad 500034, India
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Type of Sponsor	

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List of Countries
India

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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
CARE Foundation Institutional Ethical Committee	Approved	No Date Specified	Not Available
Clinicom	Approved	No Date Specified	Not Available
GKNM Hospital Institutional Ethics committee	Approved	No Date Specified	Not Available
I.E.C Consultants	Approved	No Date Specified	Not Available

Sri Jayadeva Institute Ethics Committee	Approved	No Date Specified	Not Available
The Independent Ethics Committee	Approved	No Date Specified	Not Available

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
	Functional Mitral Regurgitation

Intervention / Comparator Agent

Type	Name	Details
Intervention	BACE Device	Implantation
Comparator Agent	Nil	Nil

Inclusion Criteria

Inclusion Criteria	
Age From	
Age To	
Gender	
Details	- Adults from 18 to 80 years of age, inclusive; either gender - MR of grades 2 and above [Grade 2 or more functional mitral valve regurgitation per 2D or 3D transthoracic echocardiography, must be symptomatic which is defined as NYHA Class ≥ II or heart failure subject with MR - Functional MR with coronary artery disease or aortic valve disease - Subject undergoing concomitant coronary artery bypass graft or aortic valve surgery - Appropriate valve anatomy [normal mitral valve leaflets] - Subject is willing and available to return for study follow up - Ability of the subject or legal representative to understand and provide signed consent for participating in the study

Exclusion Criteria

Exclusion Criteria	
Details	- Known hypersensitivity or allergy to the device materials - Known hypersensitivity or allergy to the device materials - NYHA Class IV after optimal medical therapy - Structural abnormality of the mitral valve - High pulmonary arterial pressure - Severe diastolic dysfunction of left ventricle on ECHO - Transmural myocardial infarction [MI] with in 30 days of enrollment in the study; non ST segment elevation MI within 7days of enrollment in the study - Currently enrolled in another investigational drug or device protocol that would interfere with this study - Subjects with heart size outside of offered BACE device size ranges [25 to 41 cm; correlate to pre-op measurement end diastolic dimension] - Previous mitral valve surgery or other previous cardiac surgery that would preclude proper placement of the BACE - Abnormal coronary or cardiac anatomy such that the device could not be placed without interfering with those anatomical structures - Abnormalities in the mitral valve leaflets that would necessitate mitral valve reconstruction or replacement - Prior Coronary Artery Bypass Graft (CABG) surgery - Acute active infection - Active peptic ulcer - History of IV drug abuse - Chronic renal failure requiring dialysis - Ejection fraction < 25% - Creatinine > 3.0 mg/dl - Open chest surgery contraindication [e.g., acute respiratory distress, endocarditis, myocarditis, pericarditis] - Immune suppression therapy - Subjects with chronic connective tissue disease - Investigator judgment that body habitus or sternal anatomy precludes pericardial access - Females who are pregnant or lactating - Life expectancy of less than 12 months due to conditions other than cardiac status

Method of Generating Random Sequence

Not Applicable

Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
All device and surgery-related averse events and other adverse events over the course of the study	At baseline, post implantaion, at hospital discharge,1, 3, 6, and 12 month post implantaion

Secondary Outcome

Outcome	Timepoints
Durability of or improvement in MR grade over the 12-month follow-up period as measured by echocardiography Improvement in cardiac functionality [as assessed by the NYHA functional class, and Minnesota Living with Heart Failure questionnaire (MLHFQ) over the 12-month follow-up periods. NYHA status, and MLHFQ evaluations at baseline, discharge from hospital,1, 3, 6, and 12 months post BACE Device implantation.	NYHA status, and MLHFQ evaluations at baseline, hospital discharge, 1, 3, 6, and 12 months post BACE Device implantation.

Target Sample Size	**Total Sample Size=**20 **Sample Size from India=** **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	No Date Specified
Date of First Enrollment (Global)	04/12/2008
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Open to Recruitment
Recruitment Status of Trial (India)	
Publication Details	
Brief Summary	This is a single arm, multi-centre clinical study in India to evaluate the acute safety and efficacy of the BACE [Basal Annuloplasty of the Cardia Externally] device in the treatment of Functional Mitral valve Regurgitation [FMR]. The study is being conducted at 6 centers in India with 20 patients that have functional mitral valve regurgitation. The total duration of the study is 13 months approximately for each patient. The primary objective of this study is to assess the acute safety and efficacy of the BACE device for the treatment of functional mitral valve regurgitation and the secondary objective are to assess the ease of deployment of the BACE device and the adequacy of the training related to the use of the device. The primary efficacy endpoint: The primary endpoint is the reduction of MR by at least one grade after the implantation of the BACE device as measured by echocardiographic parameters. Durability of or improvement in MR grade over the 12-month follow-up period as measured by echocardiography Improvement in cardiac functionality [as assessed by the NYHA functional class, and Minnesota Living with Heart Failure questionnaire] over the 12-month follow-up period. EC and DCGI approvals have been obtained. Patient recruiitment is started and ongoing.

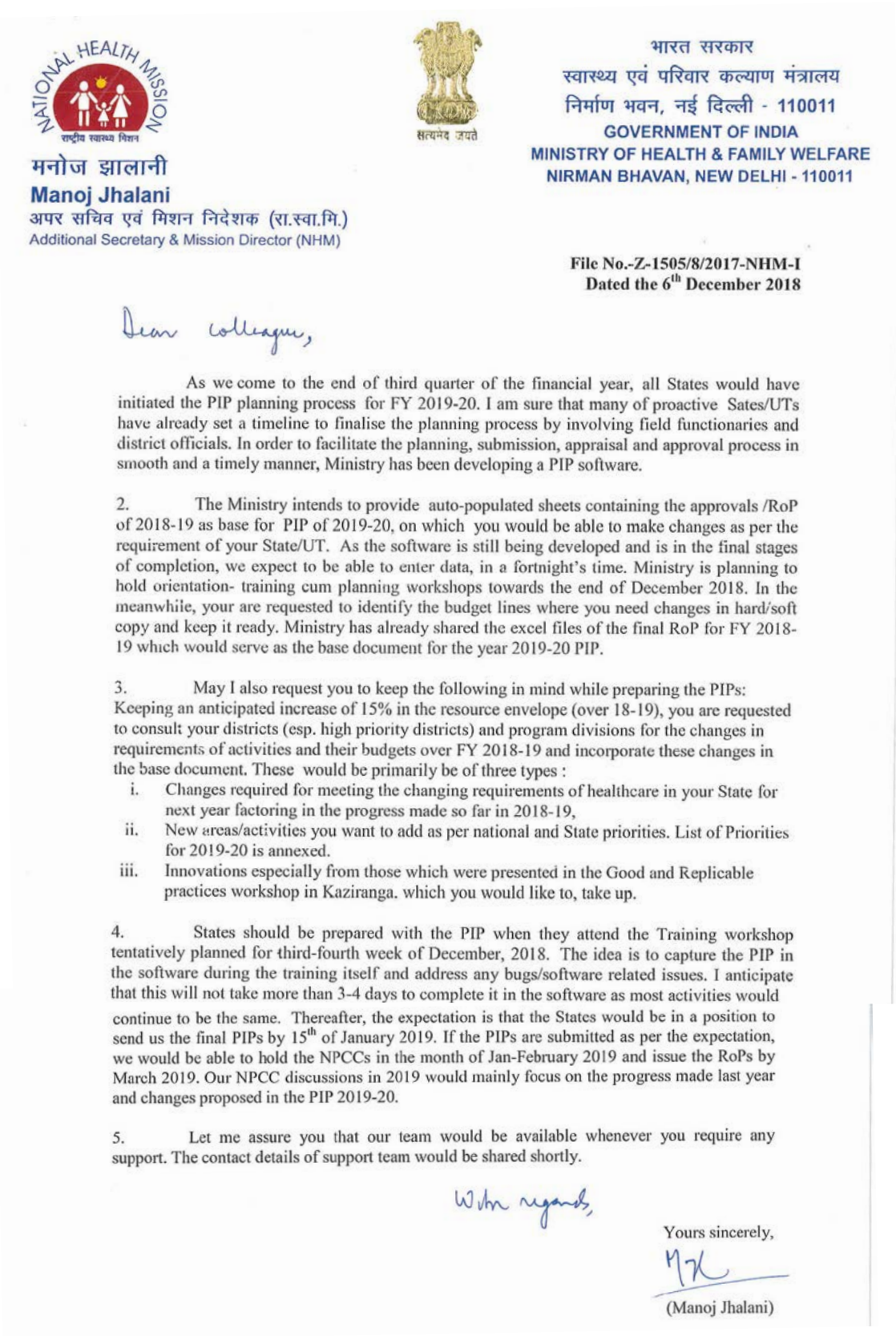
Annexure: Technology readiness levels

5. *Medical Devices and Diagnosis*

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)
Proof of Principle	TRL-2	Market surveillance data and competitor analysis available to support the idea. Basic device design ready and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured. Development of individual components initiated.	Hypothesis formulated and protocols developed. Market surveillance data and competitor analysis available to support idea. Individual core components of kit/reagents(Antibodies/ Antigens/Aptamers/Nano particles) finalized, developed/procured for testing	Market surveillance data and competitor analysis available to support the idea. Basic implant design ready, candidate materials shortlisted and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured
Proof of Concept demonstrated	TRL-3	Individual modules/Components/PCBs/Softwares/Systems developed and tested separately for its functionality on a breadboard/laboratory level. Material safety, electrical safety & biocompatibility of the systems demonstrated	Individual core components optimized at lab scale. Demonstrated the limit of detection/Sensitivity with metabolite serial dilution or ELISA or spiked biological sample studies.	Material research completed and material properties of the finalized material/composites compared against benchmarks. Relevant ASTM standard tests (strength, ductility, corrosion, surface properties, antimicrobial activity, usability, shelf life etc.) on the material performed successfully. Material sterilization method finalized. Biocompatibility (ISO 10993) proven in *in vitro* cytotoxicity assays.
Proof of concept established	TRL-4	Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment or animal model (with Institutional Animal Ethics Committee approvals)	Optimized core components integrated into the kit or platform (Microfluidics/ filter paper/ LFA etc) along with the reagents to come up with a functional prototype of the kit. Integrated system tested in house with metabolite	Material safety and or imaging compatibility proven in *in vivo* small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization and packaging established.

			serial dilution or ELISA or spiked biological sample studies.	
Early stage validation	TRL-5	Relevant IEC & ISO tests (Electromagenetic interference, Electromagnetic compatibility, Electrical safety, Biocompatibility, software test, radiation safety test drop test, packaging test, transportation test, physico –chemical and mechanical testing etc.) of the device performed and safety proven. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	Integrated system tested in-house extensively with clinical samples (Blood, Urine, Sputum etc.) before taking it for clinical validation. Analytical validation of the kit completed. Shelf life, stability data of the kit reagents available. Quality management certification (ISO13485) in place Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	*In vivo* pre-clinical studies performed (with Institutional Animal Ethics Committee approvals) using functional prototype implant device on the relevant small or big animal (disease) models to establish its safety (tissue reactivity/ allergy/degradability, Histopathology) and efficacy (. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO
	TRL-6	Fully functional clinical grade device ready with regulatory dossier for use on human subjects/patients. Quality assurance certification (like CE) applied. Pilot clinical study/trials on limited number of subjects/patients to prove safety and substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval	Clinical study performed on statistically significant number of samples at one or two centres to define the specificity and sensitivity of the Assay/kit. Quality assurance certification for the product applied/obtained	Clinical level implant device fabricated using clinical grade material in GMP facility with safety dossier for use on human subjects/patients. .Quality assurance certification (like CE) applied. Pilot clinical trials performed on statistically significant number of patients against the predicate implant device to prove safety, substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval.
Late stage Validation	TRL-7	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/trials completed and clinical performance data submitted to CDSCO for manufacturing license	Multi-Centric Trials completed at NABL accredited centres and performance evaluation report submitted to CDSCO for Commercial license. Performance evaluation report of notified products (IVD for HIV, HCV, HBV and Blood grouping sera) obtained from NIB, Noida.	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/trials completed and clinical performance data submitted to CDSCO for manufacturing license
Pre-commercialization	TRL-8	Manufacturing license obtained from CDSCO and commercial batch manufacturing initiated	Manufacturing license obtained and commercial scale manufacturing set up/Packing/labelling etc. Commercial batch manufacturing initiated	Manufacturing license obtained from CDSCO and commercial batch manufacturing initiated
Commercialization and post market studies	TRL-9	Commercial launch of the new device, Post marketing studies and surveillance	Commercial launch of in vitro diagnostic kit or reagents and Post marketing studies and surveillance	Commercial launch of the implant, Post marketing studies and surveillance

Annexure – Government planning process



NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

मनोज झालानी
Manoj Jhalani
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Additional Secretary & Mission Director (NHM)

File No.-Z-1505/8/2017-NHM-I
Dated the 6th December 2018

Dear colleague,

As we come to the end of third quarter of the financial year, all States would have initiated the PIP planning process for FY 2019-20. I am sure that many of proactive Sates/UTs have already set a timeline to finalise the planning process by involving field functionaries and district officials. In order to facilitate the planning, submission, appraisal and approval process in smooth and a timely manner, Ministry has been developing a PIP software.

2. The Ministry intends to provide auto-populated sheets containing the approvals /RoP of 2018-19 as base for PIP of 2019-20, on which you would be able to make changes as per the requirement of your State/UT. As the software is still being developed and is in the final stages of completion, we expect to be able to enter data, in a fortnight's time. Ministry is planning to hold orientation- training cum planning workshops towards the end of December 2018. In the meanwhile, your are requested to identify the budget lines where you need changes in hard/soft copy and keep it ready. Ministry has already shared the excel files of the final RoP for FY 2018-19 which would serve as the base document for the year 2019-20 PIP.

3. May I also request you to keep the following in mind while preparing the PIPs: Keeping an anticipated increase of 15% in the resource envelope (over 18-19), you are requested to consult your districts (esp. high priority districts) and program divisions for the changes in requirements of activities and their budgets over FY 2018-19 and incorporate these changes in the base document. These would be primarily be of three types :

i. Changes required for meeting the changing requirements of healthcare in your State for next year factoring in the progress made so far in 2018-19,
ii. New areas/activities you want to add as per national and State priorities. List of Priorities for 2019-20 is annexed.
iii. Innovations especially from those which were presented in the Good and Replicable practices workshop in Kaziranga. which you would like to, take up.

4. States should be prepared with the PIP when they attend the Training workshop tentatively planned for third-fourth week of December, 2018. The idea is to capture the PIP in the software during the training itself and address any bugs/software related issues. I anticipate that this will not take more than 3-4 days to complete it in the software as most activities would continue to be the same. Thereafter, the expectation is that the States would be in a position to send us the final PIPs by 15th of January 2019. If the PIPs are submitted as per the expectation, we would be able to hold the NPCCs in the month of Jan-February 2019 and issue the RoPs by March 2019. Our NPCC discussions in 2019 would mainly focus on the progress made last year and changes proposed in the PIP 2019-20.

5. Let me assure you that our team would be available whenever you require any support. The contact details of support team would be shared shortly.

With regards,

Yours sincerely,

(Manoj Jhalani)

DO Letter to NHM on planning process for the PIP of 2019-20 by AS & MD NHM

Source: https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=1235&lid=659

Preface

Record of Proceedings (RoP) document has the budgetary approvals under NHM for the financial year and serves as a reference document for implementation. The approvals given by NPCC are based on the State PIP and discussions with the State officials. Timely issuance of RoP is expected to fast track the implementation of these decisions and give State and districts ample time to monitor the progress of these activities in detail.

As we all know, the country is going through the epidemiological transition i.e. a shift in burden of diseases. Though RMNCH+A and communicable diseases continue to remain in the prime focus, NCDs are increasingly contributing to higher disease burden. The way to effectively deal with these are life style changes, better prevention, regular screening, timely and continuous compliance to treatment. For effective implementation, it is imperative that these be undertaken as close as possible to the community and hence the concept of Health and Wellness Centre that provide comprehensive primary care including prevention and platform for health promotion. Thus, apart from 12 services, we have to focus on wellness part and incorporate activities such as yoga, eat right campaign, group physical activity, forming laughter clubs etc. This will also help in dramatic reduction of the Out of Pocket Expenses (OOPE) as 72% of the OOPE is on account of outpatient care and our public primary care facilities are currently catering only to 8% of the patients. This year, we have to complete 40,000 of the 1,50,000 HWCs which are to be ready by December, 2022. In order to successfully implement this, we need a transformation in our health system and its capacity to cater comprehensively to health needs of the population. Robust procurement and IT backed logistics system from State down to the facility nearest to the community level i.e. HWCs need to be established. Capacity of the health workforce needs constant mentoring using platforms like ECHO. The provision of Performance Based Incentives (PBI) available under NHM needs to be leveraged not only to push for better performance but also to foster team spirit. We will also need the district health system to work as one unit on IT backbone to provide continuum of care between HWCs and the district hospital (DH) to ensure effective referral and downward follow up.

Dealing with the triple burden of the diseases, is not going to be easy but a strengthened Health System with able leadership at every level can take up this challenge and deliver the results. District and facility level leadership and team formation has so far been a neglected aspect. States should explore the possibility of empanelment of officers with excellent track record and leadership skills to hold key positions of CMHOs, Civil Surgeons and Medical Superintendents.

Motivated and adequate skilled human resources remain as crucial as before. Ensuring high quality recruitment, skill assessment of the clinical HR using OSCE (Objective structured clinical examination) is the first step towards bringing quality HR. We need to have in place a regular specialist cadre to ensure PGMO recruitment at entry level. As a short term measure to overcome the shortage of Gynaecologists and Anaesthetists, EmOC and LSAS training and their proper posting and mentoring is equally important. CPS and DNB courses too will help you overcome the short-supply of specialist and provide additional HR to improve service quality in our DHs..

Karnataka State program implementation plans

Source: https://nhm.gov.in/index4.php?lang=1&level=0&linkid=61&lid=74

The District Hospitals have to be developed as training hubs and specialized training for nurses e.g. neonatal nursing etc. should be started so that we have highly skilled personnel to manage SNCUs.

The provision of essential drugs and diagnostics services free of cost are expected to bring drastic reduction in Out of Pocket Expenses (OOPE). We have examples among State/UTs where the OOPE in public health facilities is almost nil and I am sure that other States can also achieve the same. Putting in place a system with robust procurement system, effective quality monitoring, IT backed supply chain management which has quality monitoring, service guarantee and awareness generation is the need of the hour. While we are providing all these services free of cost we also need to ensure that anyone who doesn't get all or any of these services is able to easily register his grievance and it is promptly redressed.

Among other priorities Eliminating TB and leprosy has to be given prime importance. As a befitting tribute to Mahatma Gandhi on his 150th birth anniversary, we must eliminate Leprosy. Towards this end, LCDC campaigns are to be taken up in the right earnest. In RNTCP we have to focus on early and comprehensive capturing of patient data through TB notification especially private sector notification. Another area that needs urgent attention is identifying and treating drug resistant TB.

We have recently started the National Viral Hepatitis Control Program. We need to understand the huge disease burden of Hepatitis and the associated mortality and morbidity and must ensure at least one model treatment centre in every State and at least one treatment centre in each district.

Ischemic heart disease has emerged as one of the major reasons of premature deaths which can be averted and reduced by operationalizing STEMI so that remote facilities can thrombolize and stabilize the patient before referring them to higher facilities for appropriate treatment.

Similarly accidents and injuries contribute significant DALYs as younger generation are more prone to accidental injuries. Good emergency and trauma care facilities and an integrated approach would therefore help us to reduce the DALYs.

With increasing complexities of modern life and stress, mental Health too has emerged as a big challenge. Mental Health Act provides for assured mental health care services to all who seek such care. States would have to adopt innovative approach to scale up the mental health services not only at district hospital level but also in facilities down below. Short term courses on IT platform should be utilized to quickly scale up the capacities.

While we need to focus of NCD and DCPs, our focus on Mother and Child should not get diluted. LaQshya, availability of basket of contraceptive choice and training and formation of a cadre of midwives for quality delivery services are critical under RMNCH+A. We intend moving the deliveries to higher level facilities having good delivery loads so that we can provide assured round the clock quality services from highly skilled manpower and respectful maternity care. We expect highly skilled midwives to take care of normal deliveries, while the complications would be managed by obstetricians and gynecologists.

We will be failing in our duty towards our future generation if we don't do everything in our capacity to give opportunity to every child to grow to their fullest potential. Early Childhood Development (ECD) is an evidence based step in this direction and

Framework for Implementation of ROP (2019 -20)

1. MOHFW has been moving towards simplification of NHM budget process but given the complexity, the same was decided to be carried out in phases. While it is desirable to have a simplified budget process, for monitoring the outcome/deliverables it should contain some level of requisite details to facilitate implementation and review of the programmes. It is envisaged that over next few years, the planning process will be simplified and yet comprehensive and responsive to individual state's requirements rather than adopting programmatic approach.

2. The process began two years before with integration of IEC, HR, Drugs budget lines. In 2018-19, the process has been forward further. All the existing budget lines have been reclassified into 18 major budget heads required for implementation of any programme. States will be encouraged to adopt decentralised planning based on local requirement using the 18 budget heads which will ultimately lead to reduction of superfluous activities and the corresponding budget lines in the state PIPs.

3. The 18 budget heads have been further categorised into three groups in order to enable states to reallocate fund within approved activities based on requirement.

4. Any reallocation to be conducted by state is to be approved of the Executive Committee and the Governing body of the State Health Society subject to the following conditions:

   4.1. Maximum budget available for states to reallocate fund is 10% of the total approved budget.

   4.2. The maximum amount that can be reallocated/ taken out from any of the budget heads (excluding group B) should not exceed 20% of budget approved under respective budget heads.

   4.3. Upon reallocation of fund to any budget head (excluding Group A), state may increase the quantity of the approved activities; no changes can be made in the unit cost approved by GoI. For instance, if 4 batches of training have been approved @ unit cost of Rs 50000 per batch, states may increase the number of batches to be trained based on requirement. However, the training cost per batch should not exceed Rs 50000.

   4.4. The unit costs/ rates approved for procurement etc. are estimations. The actuals would be as per the 'discovered price' arrived at through a transparent and open bidding process as per relevant and extant purchase rules.

   4.5. States to intimate FMG, MoHFW regarding reallocation of fund on quarterly basis along with the 'Financial Management Reports' in the following format:

Karnataka: NHM Administrative Approval(2019-20)

Framework for Implementation

Source: https://nhm.gov.in/index4.php?lang=1&level=0&linkid=61&lid=74

Summary of Approvals

(Rs in lakh)

FMR	Budget Head	Total Amount proposed for FY 2019-20 (Rs in lakh)	Total amount Approved for approval for FY 2019-20 (Rs in lakh)	Percentage out of total approval (%)	Appendix #
1	Service Delivery - Facility Based	9933.85	8926.84	4.92	I
2	Service Delivery - Community Based	6413.76	5759.49	3.18	II
3	Community Interventions	21607.42	20513.96	11.31	III
4	Untied Fund	10124.15	5147.30	2.83	IV
5	Infrastructure	29636.43	13443.73	7.41	V
6	Procurement	55840.79	38936.40	21.47	VI
7	Referral Transport	4380.66	4359.06	2.40	VII
8	Service Delivery - Human Resource	51486.73	46895.96	25.86	VIII
9	Training & Capacity Building	9463.89	6663.16	3.67	IX
10	Review, Research, Surveillance & Surveys	380.49	283.71	0.16	X
11	IEC/BCC	5774.74	3677.24	2.03	XI
12	Printing	1882.92	1038.88	0.57	XII
13	Quality Assurance	2470.23	2426.00	1.34	XIII
14	Drug Warehousing and Logistics	383.53	383.64	0.21	XIV
15	PPP	6705.34	4415.34	2.43	XV
16	Programme Management	20368.29	16713.76	9.2	XVI
17	IT Initiatives for strengthening Service Delivery	1372.74	1361.49	0.75	XVII
18	Innovations (if any)	523.61	386.95	0.21	XVIII
Grand Total		238749.57	181332.91	100.00%	
Infrastructure Maintenance			35384.0		
Grand total Approved for Approval including IM			231671.47		

 # Though total amount Approvedincludes NUHM approvals as well, However appendix does not include NUHM approvals which have been placed separately.

Budget areas to intercept

Budgetary heads that get approved

Source: https://nhm.gov.in/index4.php?lang=1&level=0&linkid=61&lid=74

Karnataka: NHM Administrative Approval(2019-20)

About the authors

Anil Misquith spent most of his career in the tech sector at Intel before joining the development sector. At Intel, he led efforts to enable the solutions ecosystem on Intel architecture across verticals. He was part of national committees such as rural transformations of post offices and business model and implementation of national optical fibre network.

Anil transitioned from Intel into the development sector in 2014. Joining Samhita Social ventures, he worked with the team to chalk out and implement growth strategies and led key partnerships such as Rockefeller Foundation, International Finance Corporation for projects in clean energy, Gesellschaft für Internationale Zusammenarbeit (GIZ) for enabling the innovations ecosystem through Incubators.

Keen to delve deeper into the development sector, Anil joined the MA programme in Development at the Azim Premji University (2017-2019), with a special interest in Sustainable Livelihoods and Public Health.

Currently, Anil is part of the team at ACCORD that works with the Adivasi community in Gudalur, Nilgiris district, Tamil Nadu to reimagine the Adivasi future in the modern economy. He is part of the founding team that has designed and implemented the Adivasi Innovation Hub, an incubator for micro enterprises run by Adivasi youth.

Dr Satya Prakash Dash is a technology policy, strategy, implementation expert and an innovation ecosystem designer. He was the founding and former Head of Strategy, Partnerships and Entrepreneurship Development of DBT-BIRAC where he designed and implemented 17 national biotech and medtech innovation programmes. A few examples of his work are India's largest early-stage life sciences/biotech/medtech funding programme Biotechnology Ignition Grant (BIG), a social innovation programme called the SPARSH & SIIP, an incubation programme called the BioNEST and equity programmes BIRAC-SEED and AcE fund. He was also the founding coordinator for Make in India at DBT-BIRAC. Cumulatively, more than 3,000 startups have drawn support from the programmes and 400 products have reached the market.

In 2012, at the behest of Department of Biotechnology (DBT), Government of India, he authored the roadmap of the biotech-medtech industry in India that provided policy inputs on achieving a USD$ 100 billion Indian biotech industry by 2025.

Previously, he was the Director of Global Innovations at PATH India, COO at ABLE, Bengaluru, and researcher at the University of Cambridge, UK, and briefly headed the Global AMR R&D Hub, Berlin. He is currently building a bio-cyber physical systems innovation platform across three campuses of BITS Pilani and is a member of the Board of Directors at NCL-Venture Center, Pune, which is one the largest S&T-focused incubator in India with more than 90 resident startups. He is also Board member of Cygenica (an Indo-Irish biotech startup) and has consulted and advised IIM-Bengaluru, Nesta's Longitude Prize, UK, Pandorum India and CARB-X, USA.

Dr Dash holds triple masters from the universities of Cambridge, Leicester (UK) and Sambalpur (Odisha) and a PhD from the University of East Anglia (UK). He is a British Chevening scholar (1998) and was awarded IVLP Award by the Department of State, US Government, in 2022.

"This handbook on technology, innovations and social enterprises is an excellent compilation of what it takes to build great ideas and then to take them to the market. I specifically liked the voices of various experts and the snapshot of key ecosystem players. I am certain that this handbook will be used by budding innovators and entrepreneurs as reference before they venture out in building great companies that can solve India's pressing healthcare challenges."

- Paul Basil (Founder, Villgro Innovations Foundation)

Scaling technology innovations in healthcare – A handbook for social enterprises by Anil Misquith is a great attempt to decipher the complex problem of technology solutions in healthcare, more so if you are working for a social cause and much more so if you are scaling. Pandemics like COVID-19 have proven that healthcare innovations are the need of the hour to solve large scale public health problems. In this context this handbook has greater significance today.

This handbook will be very useful for budding entrepreneurs who want to innovate solutions and products in healthcare. All they have to follow is this framework diligently, fine tune the framework to suit your product/solution.

- K Chandrasekar (Founder, Forus Health)