



Open Research Online

Citation

Kale, Dinar; Nabar, Janak; Garda, Laila and Tol, Varsha (2024). Exploring Inclusive MedTech Innovations for Resource-Constrained Healthcare in India. *Innovation and Development*, 14(3) pp. 539–561.

URL

<https://oro.open.ac.uk/89393/>

DOI

<https://doi.org/10.1080/2157930X.2023.2215099>

License

(CC-BY-NC-ND 4.0) Creative Commons: Attribution-Noncommercial-No Derivative Works 4.0

<https://creativecommons.org/licenses/by-nc-nd/4.0/>

Policy

This document has been downloaded from Open Research Online, The Open University's repository of research publications. This version is being made available in accordance with Open Research Online policies available from [Open Research Online \(ORO\) Policies](#)

Versions

If this document is identified as the Author Accepted Manuscript it is the version after peer review but before type setting, copy editing or publisher branding



Exploring inclusive MedTech innovations for resource-constrained healthcare in india

Dinar Kale, Janak Nabar, Laila Garda & Varsha Tol

To cite this article: Dinar Kale, Janak Nabar, Laila Garda & Varsha Tol (2024) Exploring inclusive MedTech innovations for resource-constrained healthcare in india, Innovation and Development, 14:3, 539-561, DOI: [10.1080/2157930X.2023.2215099](https://doi.org/10.1080/2157930X.2023.2215099)

To link to this article: <https://doi.org/10.1080/2157930X.2023.2215099>



© 2023 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group



Published online: 30 May 2023.



Submit your article to this journal [↗](#)



Article views: 906



View related articles [↗](#)




View Crossmark data [↗](#)



Citing articles: 1 View citing articles [↗](#)

Exploring inclusive MedTech innovations for resource-constrained healthcare in India

Dinar Kale ^a, Janak Nabar^b, Laila Garda^c and Varsha Tol^c

^aThe Open University, Walton Hall, Milton Keynes, United Kingdom; ^bCentre for Technology, Innovation and Economic Research, Pune, India; ^cKEM Hospital Research Centre, Pune, India

ABSTRACT

The potential of inclusive medical technological innovations to create access to affordable and appropriate products and services for local healthcare systems in developing countries has emerged as a critical area of academic and policy debates. This research contributes to these debates by studying the key factors, actors and their interactions influencing the development and adoption of three innovative diagnostic devices to resolve the healthcare needs of the local population in the Indian healthcare systems. It highlights the critical role of the state in influencing the development and adoption of inclusive MedTech innovations in resource-constrained settings. It further reveals that the availability of finance facilitated the early-stage development of innovations. At the same time, collaborative arrangements with a diverse set of stakeholders contributed to late-stage development and adoption of innovations in the local healthcare systems. This research also expands on the conceptualization of inclusivity in the MedTech sector by providing a holistic interpretation of affordability as reducing healthcare costs over a longer period through access to early diagnostics rather than the purchase cost of a product. These research findings have significant implications for innovation and healthcare policies that can help to resolve the challenges of accessible healthcare in developing countries.

ARTICLE HISTORY

Received 1 November 2021

Accepted 13 May 2023

KEYWORDS

Inclusive innovations; medical devices and diagnostics; India; innovation policy; healthcare systems; industrial development

1. Introduction

Healthcare systems worldwide increasingly depend on medical devices for accurate diagnosis and treatment of diseases. The global health community has focused on ensuring access to vaccines and medicines, but the area of medical devices and diagnostics has remained neglected in academics and policy debates on universal healthcare (Beruman et al. 2018; Kale and Wield 2019). Medical devices include a range of technologies, from highly sophisticated computerized medical equipment to simple wooden tongue depressors (WHO 2010). They are critical for diagnosis, effective use of medicines, patient care in operating theatres, bedside, and even before a patient is admitted to the

CONTACT Dinar Kale  dinar.kale@open.ac.uk

© 2023 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group
This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License (<http://creativecommons.org/licenses/by-nc-nd/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited, and is not altered, transformed, or built upon in any way. The terms on which this article has been published allow the posting of the Accepted Manuscript in a repository by the author(s) or with their consent.

hospital or home after discharge. Globally, medical devices and diagnostics accounted for 27% of the total value of healthcare technologies traded in 2019 (WTO 2020). Primarily, the leading exporters of medical devices to developing countries are Germany, France, the United States, China, and the United Kingdom supplying more than 85% of imports (Hakobyan and Cherif 2021). The medical device industries based in developing countries are few and primarily focused on the low-tech part of the sector. Most developing countries have struggled with the development of the local medical devices industries and rely on imports from advanced countries to satisfy local healthcare needs, creating challenges in access to affordable and appropriate medical devices (Cheng 2007; Kale and Wield 2019; WHO 2010; WHO 2012). For example, Sub-Saharan Africa is a net importer of medical goods, which accounted for 6.8 per cent of total imports but only 1.1 per cent of exports in 2019 (Hakobyan and Cherif 2021). The evidence in the form of medical device graveyards in developing countries suggests that the global health technology market is inefficient in delivering to the needs of local populations from developing countries. These unmet needs of local healthcare systems in developing countries are seen as a global health concern and an intractable challenge that needs serious attention.

In the last decade, some research has focused on the issues of diffusion and access to medical devices in developing countries, and more has been written about developing local production capabilities in developing countries (WHO 2012; Kale and Wield 2019; Nadvi 1999). The increasing awareness and significance of unmet medical technology needs of the local population in developing countries have led to the emergence of innovative solutions from MNCs and local firms targeted at bridging these access gaps. As a result, the inclusive innovations aimed at resolving these healthcare needs in developing countries have emerged as a critical area of research in Science, Technology and Innovation (STI), business and development studies generating widespread academic and policy interest worldwide (Chakravarty 2022, Agarwal, Brem, and Dwivedi 2019; Winterhalter et al. 2017; Govindarajan and Trimble 2012; Zeschky, Widenmayer, and Gassmann 2011). However, these studies primarily focus on innovative R&D and manufacturing associated with the development of these inclusive innovations while paying limited attention to their adoption in resource constraint health systems of developing countries (Hossain, Simula, and Halme 2016). This focus on positive one-off engineering alternatives leaves a major gap in understanding the institutional and firm-level processes associated with the development and adoption of inclusive innovations in the resource-constrained healthcare systems of developing countries.

This article focuses on this issue: how are MedTech inclusive innovations developed and adopted by local healthcare systems in a resource-constrained setting? Specifically, it explores how key factors, actors, and their interactions influence the development and adoption of inclusive medical technology innovations in resource-constraint healthcare systems of developing countries. This study builds on the work focused on innovation in healthcare technology industries in developing countries (Srinivas 2000; Srinivas and Sutz 2008; Kale and Wield 2019). This paper engages with this research gap by studying the institutional processes associated with the development and adoption of three innovative diagnostic devices in the Indian healthcare system. This study was undertaken as part of a research project exploring ways to foster a supportive ecosystem of healthcare innovation in India. These three devices diagnose ailments such as Diabetes, Anaemia,

Hypertension, and Infections. A criterion for inclusivity was developed by reviewing the inclusive innovation literature to identify the three devices. Their selection was further corroborated by interviews with medical practitioners and press reports about these devices. The primary data was collected by conducting semi-structured interviews with entrepreneurs and manufacturers involved in developing three innovative devices.

This study contributes to the inclusive innovation literature by providing a broader interpretation of affordability as an inclusivity criterion. It redefines affordability as saving the cost of treatment over a longer period by enabling access to early diagnosis rather than reducing the cost of the device at the point of purchase. It further shows the contrasting role of the state and the significant impact of collaborative arrangements from design to delivery of inclusive MedTech innovations in the Indian healthcare systems.

The paper is structured as follows. Section 2 reviews the literature on inclusive innovation, specifically focusing on inclusive innovation in the Medtech sector. Section 3 describes the research methodology adopted for the study. Section 4 provides case studies, including a brief synopsis of innovative characteristics and development processes associated with the development of three diagnostic devices. Section 5 discusses the key findings of the research focusing on key processes involved in the development and adoption of inclusive MedTech innovations in the Indian healthcare systems. It also offers insights into the emerging conceptualization of inclusivity in MedTech sector. Section 6 concludes with a discussion of the policy implications for fostering the growth of inclusive medical technological innovations in India and other developing countries.

2. Inclusive innovations in theory and practice

In the last decade, the limitation of traditional innovation models to incorporate the needs, interests and knowledge of low-income populations has led to increasing interest in alternative models of innovations. These alternative models draw inspiration from architectural innovation (Henderson and Clark 1990), appropriate technology (Schumacher 1973) and 'Bottom of the Pyramid' (BOP) approaches (Prahalad 2005), blending traditional and new technologies (Kaplinsky 2011) to meet the needs of low-income populations. Inclusive innovation has emerged as one prominent model (Radjou, Prabhu, and Ahuja 2012; Khanna and Palepu 2010; London and Hart 2004). Papaioannou (2014) highlights the resolution of the basic needs of the low-income population as a central characteristic of inclusive innovations. There have been multiple definitions of inclusive innovations, and their meaning varies across disciplines (Hoassain 2018), but it is argued that innovation is inclusive if it addresses the excluded group's needs, wants or problems. Inclusive innovation might also be identified by whether it is adopted and used by the excluded group or involved in its development. Some researchers have focused on product aspects of inclusivity (Weyrauch and Herstatt 2017), while few others explored the process or combination of products and process features of inclusive innovations (Basu, Banerjee, and Sweeny 2013). Building on this, Pansera and Owen (2018, 32) suggest a need for research that 'explores the framing construction, dynamics and impacts of inclusive innovation for development in situated practices in the field'. This points towards a need for a broader interpretation of inclusivity to

include access and societal relevance of inclusive innovations in resource-constraint settings.

One alternative framing of inclusive innovation relevant to this research comes from Srinivas and Sutz’s (2008) work on the scarcity-induced innovation (SII) concept. SII focuses on innovation and development drawn from micro-processes of problem-solving embedded in a broader socio-economic context of industrialization. According to this view, the contexts in which developmental processes are embedded in scarcities are not widely present in advanced industrialized societies and lead to different technology incorporation and production. In developing countries, the scarcity conditions include challenges in accessing materials and equipment to measure quality or accuracy, lack of institutional support for building capacities, non-availability of skilled human resources and absence of finances to develop ways to solve problems. These countries suffer from institutional voids, infrastructural problems, and fragmented innovation systems. Taking cognizance of scarcities, Srinivas and Sutz (2008:, 136) provide a taxonomy for SIIs based on the nature of the issues and solutions that exists in developing countries (DC) and advanced industrialized countries (AICs) (Figure 1).

Srinivas and Sutz (2008) suggest that scarcity-induced innovation (SII) emerges because available solutions are non-existent worldwide or existing solutions are inappropriate or unaffordable to be adopted in developing contexts. Thus, SII is developed amongst strong resource constraints through creative management of limited skills, finances, and technological capabilities to provide inexpensive solutions for more people with fewer resources. Based on these insights, inclusive innovations can be conceptualized as an innovation that focuses on resolving the problems of local populations through a creative reconfiguration of existing process and production technologies in a resource constraint environment. Here the goal of inclusivity is not aimed at developing a

| | Problems for which solutions have been found in AICs | Problems for which solutions have not been searched or found in AICs |
|---|---|---|
| Problems for which solutions suitable for DCs conditions exist | The vast majority of solutions acquired through technology transfer (eventually with minor modifications) | Solutions to problems mainly posed in DCs and developed locally |
| Problems for which solutions suitable for DCs conditions do not exist | “Canonical” solutions exist, but for different scarcity reasons they are not suitable for DCs conditions | No solutions (yet) Typically health issues like vaccines against Cholera or AIDS |

Figure 1. Taxonomy of Scarcity-induced innovations (Srinivas and Sutz 2008).

low-cost innovation but an innovation that resolves the problems of local populations holistically in multiple ways.

This review suggests that much progress has been made in recognizing the diverse models of inclusive innovation; discussions failed to provide coherent theoretical and policy insights that can aid the development and adoption of inclusive innovations in existing trajectories (Kale and Srinivas 2022). Pansera and Owen (2018:, 32) argue that much of this extant literature on inclusive innovation remains theoretical and is not informed by reporting practices on the ground. This study offers insights to extend some of these interpretations with empirical evidence.

2.1. Inclusive innovations and healthcare needs in developing countries

The lack of access to appropriate and affordable medical devices to meet the needs of developing countries has emerged as a key global health challenge (Srinivas and Kale 2021; Marks et al. 2019; WHO 2010; 2012, 2016). This gap between needs and supply led to increasing interest from Western firms to develop medical devices that can satisfy needs using innovative solutions. The burgeoning research on innovation in medical technologies aimed at local populations in developing countries has focused on business models, R&D processes, and diverse areas of inclusivity, such as performance, scalability and appropriateness (Chakravarty 2022; Ramdorai and Herstatt 2015; Heeks, Foster, and Nugroho 2014; Govindarajan and Ramamurti 2013; Agarwal, Brem, and Dwivedi 2019; Winterhalter et al. 2017; Govindarajan and Trimble 2012; Zeschky, Widenmayer, and Gassmann 2011; Tiwari, Kalogerakis, and Herstatt 2014). This emerging model of innovation in healthcare technology industries is viewed as a potential disruptor to the status quo by reconfiguring existing systems, institutions, and ways of working to resource constraint environments (Dandonoli 2013). However, some researchers suggest that institutional gaps, such as existing governance frameworks rooted in traditional R&D models and the rent-seeking behaviour of stakeholders, make it challenging to realize the full potential of these innovations (Smith, Fresoli, and Thomas 2013).

Pietrasik's (2009) article on frugal practices and technology adopted by Indian firms in the resource-constrained environment has been credited with igniting the discussion on inclusive innovation in the healthcare sector. Taking it forward, some researchers have explored the development processes and manifestation of inclusivity and its various characteristics across various domains, such as the point of care diagnostics (Miesler et al. 2020; Long et al. 2020); low-cost prosthetics (Arya and Klenerman 2008), affordable cataract surgery (Virmani and Lépineux 2016) and heart surgery (Gupta and Khanna 2019). Chakravarty (2022) highlights the significance of the collaborative bottom-up process in developing frugal MedTech innovations in resource-constraint settings of South Africa. Winterhalter et al. (2017) argue that these innovations do not compete with other low-cost alternatives but with non-consumption or lack of access in resource constraint environments with the choice between a frugal product or no solution. The potential of inclusive MedTech innovations developed for resource constraint settings to become reverse innovations has emerged as an area of interest in business studies (Govindarajan and Trimble 2012). Focusing on the diffusion aspect of inclusive innovations, some researchers have studied the impact of

adopting inclusive innovation on public health spending (Prime et al. 2016). Building on these ideas, Bianchi et al. (2017) suggest that frugal innovations as an adequate approach for organizations operating under severe resource restrictions and universal access to healthcare mandates.

Primarily, these studies have focused on new products as inclusive innovations and highlight their potential role in making healthcare accessible to local populations. Most literature has portrayed inclusivity as a 'one-off' attempt to resolve the issue (Karnani 2007). However, it is important to go beyond one-off well-meaning product ideas with weak institutional links to improve their scalability and likelihood of market acceptance. Only limited studies have focused on the development and diffusion of inclusive innovations in healthcare systems from the resource-constraint environments of developing countries (Hossain, Simula, and Halme 2016).

Within these studies, the Indian healthcare technology industry has emerged as a locus of innovative activity and has dominated the inclusive healthcare innovation literature. The growing economy and per capita income, along with an increasing understanding of the need for innovative solutions to resolve local healthcare challenges, has fuelled the growth of the innovative MedTech start-up boom in India (Kale et al. forthcoming). Most of these have focused on developing innovative solutions to improve access to detection and monitoring services for local populations. However, the emergence of dynamic and lively tech start-ups raises questions about the key actors and policy environment driving the growth of the Indian diagnostics sector. From an inclusive innovation standpoint, some questions about supporting ecosystems for entrepreneurship and the progress of innovations to the market have not been well-researched compared to a mature body of scholarship on innovative products, business models and R&D strategies. This research engages with these issues by focusing on the development and adoption of three inclusive healthcare technological innovations in Indian healthcare systems.

3. Research methodology

India presents an appropriate research setting to investigate how inclusive innovation in healthcare industries is developed and adopted into resource-constrained healthcare systems and institutional contexts in developing countries. There has been a strong movement in Indian healthcare industries towards developing market-based inclusive innovations using technological advances to resolve the needs of local populations. For example, the cumulative number of start-ups focused on developing healthcare technologies in 2021 was estimated at 5365, with about 1128 companies registered in 2021 (Bioeconomy report 2022).

We employed a multi-stage research methodology using diverse sets of data collection instruments and sources. In the first phase, this research conducted healthcare needs assessment survey of 102 doctors across urban and rural facilities in the western part of India to understand key ailments and diagnosis methods employed to treat them. The facilities included public primary health care centres, rural public hospitals, private primary, private secondary, private tertiary, urban primary health centres (UPHCs) and civil hospitals. This survey revealed diabetes, anaemia, hypertension, and acute upper respiratory infections as the most common ailments. It helped focus

Table 1. A brief description of the devices under study.

| | Device Name | Ailments | Company | Function | Tests | Launch year | International standards approval |
|---|---------------|------------------------------------|-----------------------------------|--|--|-------------|-------------------------------------|
| 1 | TouchHB | Anaemia | Biosense | Needle-free and painless anaemia screening | Haemoglobin test | 2013 | ISO13485 ISO14971 CE (Europe) |
| 2 | Lifeplot UNIQ | Hypertension/ Cardiovascular | Sofomo Embedded Solutions Pvt Ltd | Portable and paperless ECG | 12- lead ECG | 2010 | |
| 3 | ENTravier | Acute upper respiratory infections | IcarusNova | Affordable ENT viewing and diagnostic device | Captures, stores and uploads high-resolution images of patient's tympanic membrane | 2015 | CE (Europe) |

the research on case studies of the inclusive MedTech innovations used to diagnose and cure these ailments.

Based on the review of literature focused on inclusive innovations in healthcare sectors, we set up criteria of what constitutes an 'inclusive device' as one that can help create access, is affordable, can be used in an under-resourced setting, is easy to use and maintain. At the same time, the device was meant to be comparable in terms of accuracy to the gold standard equipment. Using these criteria, we identified three devices that significantly resolved local resource constraints and improved the local population's access to diagnosis and treatment (Table 1). We corroborated our assessment of the inclusivity of the three devices using online searches and through discussion with medical practitioners. These inclusive innovations have been adopted in local health systems and are available in the market. They formed the unit of analysis for this research.

Multiple sources of evidence and a triangulated approach through semi-structured interviews, documentary evidence, publications and others were used for data collection to ensure construct validity (Yin 2014).

3.1. Data collection and analysis strategy

The qualitative case study approach used in this research builds on Jaroslowski and Saberwal's (2013) research on medical devices. In total, we conducted in-depth interviews with five innovators involved in the development of these devices. The detailed notes from the interview were shared with the respondent. The respondent were then provided with an opportunity to add or suggest any corrections to the notes to enhance our understanding of their interpretation of inclusivity, motivations, constraints, and key business strategies. The secondary data was accessed through annual reports, firms' websites, business magazines, industry association publications, UNCTAD reports and the WHO website.

We used a semi-structured interview questionnaire and designed it to capture innovators' motivation, understanding of inclusivity and the features that the device

manufacturers had considered to enhance user application and experience. It also explored the opportunities and barriers associated with the Indian healthcare system. The questionnaire focused on the current landscape to capture institutional factors that would have impacted the development and commercialization of the device, whether in terms of financial support or the barriers to market entry. We also interviewed primary health clinicians and medical staff who used these devices. We designed a different semi-structured instrument to capture their motivation to purchase these devices, their experience of using them, and other recommendations they may have had to support inclusive innovation in the MedTech industry.

The primary data was analysed using a pattern-matching strategy (Eisenhardt 1989), focusing on three key themes: an emerging understanding of inclusivity, the main challenges faced by innovators and key strategies associated with the development and adoption of inclusive innovations in the Indian healthcare system. We also created a different theme focusing on key economic and industrial policy constraints affecting their development. In the analysis, first-level coding is used to capture segments of data, while pattern coding is carried out by grouping those codes into a smaller number of overarching themes. This data analysis strategy allowed us to codify and analyse the key concepts, meanings, and relationships.

4. Case studies of inclusive innovations

This section briefly presents the evolution and functions of the three inclusive innovations under study.

4.1. Touch hb

TouchHB is a portable device that helps to diagnose anaemia. It was developed by an Indian startup Biosense and launched in the market in 2009. A group of entrepreneurs started Biosense in 2008 to develop low-cost medical devices that can assist in diagnosing chronic diseases in India. The key motivation for innovators was to find a way to make diagnoses available for curable diseases in under-resourced settings by developing innovative solutions that fit local contexts.

Two founders of Biosense have a medical background. During their internship in the rural part of Western India, they came across the widespread presence of anaemia among children and women and the absence of an effective way to diagnose the ailment in the resource constraint environment (Rajappa 2018). A typical diagnosis involves a blood test to measure estimated haemoglobin levels in the blood. However, the lack of medical doctors, clinical facilities or supply chains to ensure the availability of needles in rural areas makes blood tests a significant challenge. Furthermore, patients suffering from anaemia do not show any acute symptoms, making it harder to diagnose the disease. This situation alerted the Biosense founders of the need for a device to perform the test without a drop of blood and consumables. That realization led to the development of TouchHB; a non-invasive haemoglobin estimation device that gives instant readings. Touch HB does not require needles for testing blood and other consumables. Advani (2013) explains that TouchHb works on the science of photoplethysmography—an optical technique to detect blood volume changes. It involves fitting a probe to the

patient's finger, which displays different types of light on a finger and measures the amount refracted, reflected and transmitted. The sensor inside the probe captures the values and, depending on the differences in signals, shows various substances in the finger. This lack of needles also meant specific compliance requirements for avoiding needle stick injuries became redundant. It is easy to use and can be operated by ASHA (Accredited Social Health Activists) workers and helps take appropriate action on the spot without going through lengthy processes. TouchHB helped increase access to diagnosis for anaemia in rural areas that often went undiagnosed. The device also enables the physician to monitor a patient's progress constantly, as it is possible to keep an electronic record of the test results and ongoing treatment.

Biosense received seed corn funding from CIIE (Centre for Innovation Incubation and Entrepreneurship), set up by IIM (Indian Institute of Management) Ahmedabad, a leading management institute in India. This funding played a significant role in acting as seeding and incubation support to create a prototype of the product. Within a few years, Biosense received further funding from BIRAC (Biotechnology Industry Research Assistance Council) and ICMR (Indian Council of Medical Research) to assist in the development of prototypes into affordable devices. Biosense then started tapping private venture capital to roll out products on a commercial basis (Kopsick 2018). These included international investors such as Insitor Impact fund, Menterra Social Impact Fund, Fireside Ventures, Lesing Artha Limited and domestic funders, including Villagro. These additional investments allowed Biosense to expand the salesforce and gain trust in its products among key organizations and actors in Indian health systems. One of the founders explain the challenges of entering the government procurement system,

'Till you get to a certain size, the government does not buy from you. Public procurement is also a complex and long-dated process'

(author interview, 2018)

Kopsick (2018) notes that Biosense worked with public institutions on prominent pilot programmes, built partnerships with academic innovators, and secured endorsements from leading physicians to achieve the ambition of creating awareness and reaching as many patients as possible. He further suggests that in 2015, these efforts led to Biosense becoming the first pre-approved company with pre-negotiated prices for central and state-level government tenders in pan India, allowing an easier procurement process in all states.

4.2. Lifeplot UNIQ

Lifeplot UNIQ is a mobile diagnostic cardiac care device able to acquire and transmit 12-lead ECGs (Electro Cardiograms) using wireless technology directly to the doctor's mobile phone. This was developed by Sofomo Embedded Solutions, a MedTech start-up based in western India. It was set up by an entrepreneur with expertise in embedded technology and medical instrumentation.

The main motivation was to improve the diagnosis of Cardiovascular diseases (CVDs) in rural areas by creating a device that removes the distance between doctor and patient. Small clinics in rural and urban areas increasingly rely on ECGs to diagnose CVDs which need a monitor and a thermal printer. It was observed that thermal printers are prone to

breaking down in extreme heat conditions, making it difficult to maintain them affordably. These maintenance issues were creating challenges in diagnosing CVDs in a timely manner. Lifeplot Unique incorporates a smartphone that helps overcome the need for a monitor and a thermal printer. By eliminating the need for thermal printers, Lifeplot was able to ensure the suitability of the ECG machine for use in an under-resourced setting and reduced the overall cost of operating the machine by eliminating any associated maintenance costs, including any expenditure for better-quality thermal paper. Further, this device can be operated on a rechargeable battery and removes the need for a skilled operator, as a low-skilled person could operate it with minimal training.

Sofomo received seed funding from the Ministry of Micro, Small and Medium enterprises in 2009, which helped to develop initial ideas into a prototype. The company started working with CSIR scientists, and these collaborations further received grants from overseas funders. However, it was challenging to get market acceptance and enter government procurement systems. The founder of the company elaborates on the challenges,

The government has put a rule of 30% indigenous device procurement in municipal hospitals. However, most indigenous devices are locally assembled parts rather than genuine manufacturing in India. The tender is also often drafted by a medical device dealer who lists product part specifications instead of functions, effectively excluding innovative devices such as Lifeplot.

(author interview, 2018)

The breakthrough for the company came in 2013 with the launch of Aarogya Sakhi programme in partnership with a local NGO, Swayam Shikshan Prayog (SSP). This programme involved training women who are landless but have basic education, an interest in healthcare and community service and an entrepreneurial mindset. These women, called Arogya Sakhis, then go house to house in villages to conduct basic health tests on girls and women at an affordable price. The test data is uploaded to the cloud server and accessed by a doctor who prescribes treatment over the cloud after analysing the test results. The Arogya Sakhi programme received local and international awards in 2014 and 2015 for its social impact, and that created widespread recognition and awareness about the company. Lifeplot UNIQ was launched in 2010, and by 2020, it was used in over 100 medical institutions recording ECGs of over 10,000 patients.

4.3. ENTraview

ENTraview is a portable device that allows routine examination of ear, nose and throat (ENT) ailments, specifically middle-ear infections. It was designed by IcarusNova but manufactured and launched in India by Medtronic in 2015. Medtronic is one of the largest medical device manufacturers in the world.

The motivation was to speed up the diagnosis of ENT infections in rural areas and reduce the patient's discomfort. More than 60 million people suffer from hearing loss in India, and a fundamental cause of hearing impairment is a middle ear infection. These infections remain undetected in rural and remote areas due to the lack of equipment and the absence of ENT specialists. A doctor needs to conduct an endoscopic examination to detect the infection, which prolongs the entire process and increases discomfort for the patient. There were severe concerns about the difficulty and delay

in testing ENT infections in remote areas. Patients are first subjected to an essential ENT examination, and in serious conditions, it is followed by an in-depth endoscopic examination. In rural areas, the lack of endoscopic examinations causes delays and severe patient discomfort. This issue of delays and discomfort led to the development of ENTReview, allowing in-depth investigation during the patient's doctor visit. ENTReview is an easy-to-use handheld device that helps overcome the need for an endoscopic examination by making it possible to inspect the patient's ear and take photos. It is also integrated with a mobile device that allows the upload to a central server so that a surgeon can access the data from anywhere (Joshi Ruth, 2018). These innovative features of ENTReview have helped increase access to diagnosis for ear-related problems that previously went undiagnosed in rural and remote areas.

ENTReview idea and prototype was developed by Indian startup design firm IcarusNova in collaboration with an ENT surgeon from St John's Hospital IcarusNova started with self-funding but then received government funding to take forward some of their ideas. One of the founders highlights the significance of government funds for early-stage development,

In our case, when we said that we have a couple of ideas and we want to take that forward, and we didn't have money to do that. At that point, government funds that were available gave us a huge starting point in terms of being able to take those baby steps from basic concepts to real investments, which require considerable resources

(ICCA India Podcast 2019)

The prototype and patent for ENTReview was then acquired and distributed by a leading MNC, Medtronic, under its public engagement programme, Shruti. Medtronic launched Shruti in 2013 to create a self-sustaining programme of awareness, diagnosis, treatment and rehabilitation of the under-served patients susceptible to chronic ear diseases and preventable hearing loss in developing countries by leveraging technology and inclusive innovation (Medtronic 2020). This programme involved health workers conducting tests using company devices in different locations. Medtronic initiated a partnership between Shroff eye hospital in Delhi, IcarusNova and ClickMedix, a mobile health social enterprise, to build a diagnostic device.

IcarusNova developed more than 40 prototypes and tested them in partnership with Shroff Hospital. Several healthcare workers visited rural and remote areas to collect data and images, which were then uploaded to the central servers. The company researchers worked closely with health workers. They were involved in observing usage and developing solutions for issues on the ground – adding features and testing future functionality that would add to the device's viability. Using these prototypes in real-life conditions for over a year helped prove the device and run the programme. After completing a preliminary assessment, Medtronic approached the company and, in 2014, acquired the intellectual property rights of the product. The data and information acquired during these visits helped validate the device, and Medtronic began manufacturing devices on a larger scale. This collaborative arrangement helped bring together screening, telemedicine, consultation by specialists and feedback to patients in remote and rural areas.

Within three years of the launch, the programme has screened more than 2,70,000 people (Medtronic 2020). It found that over 25% of the screened population needs

some form of ear care, about 8% of the population needs a combination of medical and surgical intervention, and 3–5% need hearing aids.

5. Analysis and discussion: reconceptualisation of inclusivity and role of key actors and interactions for the development and adoption of inclusive innovations

This section presents an analysis of data focusing on key actors and processes involved in the development and adoption of inclusive innovations in resource constraint settings of Indian healthcare systems.

5.1. Reconceptualisation of inclusivity

This section focuses on the reconceptualisation of inclusivity in the MedTech sector based on innovators' interpretation of affordability. Table 2 presents the classification of devices based on the key characteristics of 'inclusive innovation' identified in the literature. It shows that none of the inclusive innovations has prices lower than comparable products available in the market but provides additional benefits absent in the comparable products.

Further probing of the cost issue points towards the emergence of two interpretations of affordability in the case of inclusive innovations under study; the first interpretation involves the long-term saving of cost by effectively monitoring health using inclusive innovations (Figure 2). The second interpretation focuses on saving the cost by reducing the need for maintenance, training and other associated equipment or reagents. It marks a departure from how inclusive innovations in resource-constraint settings are traditionally associated with narrow interpretation of affordability.

- **Affordability as long-term saving of cost**

Our analysis suggests that innovators are primarily concerned with creating access to diagnosis and treatment for the local population in resource constraint environments. Most innovators did not associate affordability with a direct reduction in the cost at the point of purchase of the device for patients but instead through an indirect saving of the costs through early detection of ailments that can help avoid hospitalization and treatment costs. A device manufacturer comments,

Table 2. Key characteristics of 'inclusive' innovation. Source: CTIER, various company websites.

| Device Name | Undiagnosed need or new to the market | A lower price than comparable products | Use in the under-resourced setting | Easy to use | Maintenance and repair | International quality |
|----------------|---------------------------------------|--|------------------------------------|-------------|------------------------|-----------------------|
| Touch HB | Present | Absent | Strongly present | Present | Absent | Present |
| Lifepilot UNIQ | Absent | Absent | Strongly present | Present | present | present |
| ENTravier | Present | Absent | Strongly present | Present | present | present |

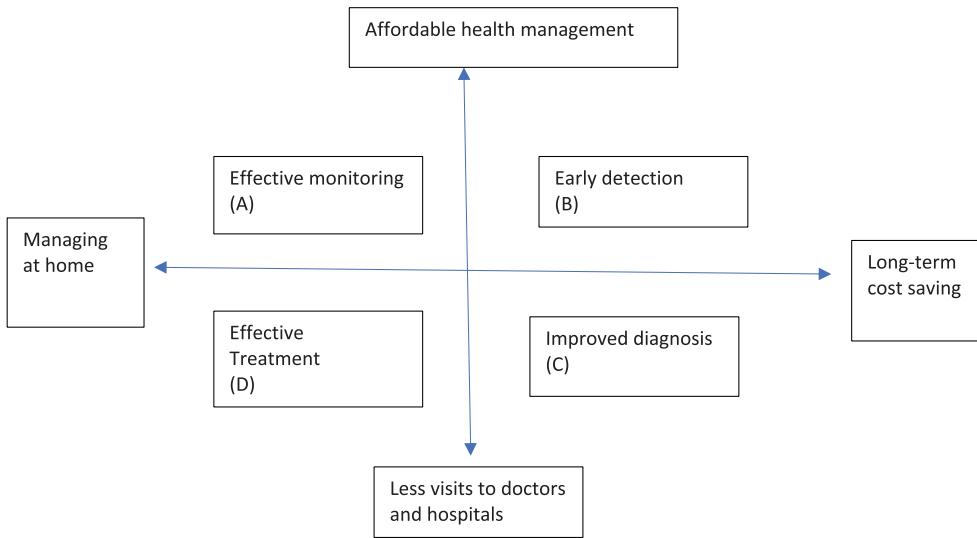


Figure 2. Reconceptualising inclusivity in MedTech innovations (author modifications of Morey 2021).

Inclusivity is about accessibility and availability of the device, not its cost. Inclusivity is generally seen at the product level. Hard to be frugal with respect to engineering because the base upon which engineering is done has already been established for the last 100 years.

(author interview, 2018)

Figure 2 depicts this interpretation of inclusivity. The four quadrants (A, B, C and D) point towards areas impacted through inclusive MedTech innovations that result in cost savings over a longer period and affordable health management. For example, these innovations offer opportunities for early detection, remote diagnosis and effective treatment that can reduce the need for hospital stays and costly consultations. This discussion suggests that a broader reconceptualisation of inclusivity is needed when discussing inclusive MedTech innovations by taking a holistic and long-term interpretation of affordability instead of looking at the point of purchase cost.

- **Affordability as a reduction in associated costs**

The second interpretation of affordability relates to the reduction of cost due to redundancies in need for maintenance, skills and equipment associated with their use. In each inclusive innovation under the study, an innovator has reconfigured the existing components and equipment to reduce cost, facilitate adoption, and improve ease of use without compromising the quality. The innovators purposefully focused on designing devices that reduce the possibility of devices laying waste due to a lack of skills to use, maintain and repair. The device manufacturers were keen on ensuring patients or a lower-skilled person could handle the device. In some cases, this helped eliminate the need for a medical professional or a technician. For example, the innovator involved in the development of Lifeplot Unique ensured that a skilled technician was not needed to put on the leads. This device also removed the need for a monitor and thermal printer. The innovator of Lifeplot comments,

No need to apply electrodes. In hospital ECGs, the device needs a technician to put on the leads, but this device eliminates the need for a skilled technician.

(author interview, 2018)

Similarly, in the case of ENTraview, a health worker needs one week of training on safety, hygiene, cleaning wax from the ear, correctly inserting the device into the ear and the angle at which the device could take good quality pictures.

5.2. Development of inclusive innovations: significant role of the state as enabler and inhibitor

Our analysis highlights that the state has played a contradictory role in the development of inclusive MedTech innovations. The state has emerged as an enabler due to its successful implementation of various financial grants for innovators, while the state is turned out to be an inhibitor due to its mismanagement of linkages between industrial, health and regulatory policies. This section discusses both roles.

• State as an enabler: Easy access to finance

In resource constraint environments, limited financial resources are the foremost challenge for the growth of start-up sectors. Our analysis highlights that the Indian government launched financial schemes over the last decade to support local innovators, specifically financing early-stage development of inclusive MedTech innovations that have emerged as major game changers (Table 3). One of the founders of IcarusNova highlights the significance of state funding for early-stage funding as an enabler of inclusive innovations,

the government's money that comes with not many strings attached as opposed to private equity is a huge encouragement for the first step of innovation, which really is to answer the question: is this just a good idea or is this have a gap and where is that gap. To answer that gap, what may be the shape and form that this answer or this innovation could take? So early-stage funding that nobody wants to fund that.

(ICCA India Podcast 2022)

The Indian central and state (regional) governments have filled the void created by the absence of vibrant private investors by launching financial support schemes to support entrepreneurs in developing their ideas, from basic concepts to prototypes. For example, BIRAC (Biotechnology Industry Research Assistance Council), operating under the Department of Biotechnology since 2012, has been at the forefront of providing initial funding to several start-ups in the MedTech sector. It has established 72 incubation centres all over India and has invested more than Rs 4000 crore

Table 3. State funding for early-stage development of inclusive innovations

| No | Device name | Early-stage funder |
|----|----------------|--|
| 1 | Touch HB | IIM (Indian Institute of Management) incubation fund BIRAC ICMR (Indian Council of Medical Research) |
| 2 | Lifepilot UNIQ | Funds from the Ministry of Micro, Small and Medium Enterprises (MSME) |
| 3 | ENTraview | BIRAC and other government funding schemes |

to support more than 3500 entrepreneurs until 2022 (Indian Bioeconomy report 2022).

The significance of state funding lies in its ability to be no strings or few strings attached compared to private investments, which gives critical freedom to innovators to work on their ideas without the pressure of immediate returns. Further, some innovators point out that private investors struggled to grasp that each stage in the innovation cycle requires a different mindset, assessment criteria and growth strategy. Private investors tend to apply the mindset and criteria of mature products at the early stages creating significant obstacles and a lack of space needed for appropriate development. One of the founders of IcarusNova explains the significance of no-strings or few-strings-attached funding from the state,

The irreducible minimum is that they have an idea. That's taken care off. At that point, some go for self-funding, and we did that, but at the next level, it goes outside most people's ability to be able to put money into their ideas, and at that level, definitely, it helps to have a certain amount of money which is really without any strings attached because it's too early to do anything with the thought. I think no or few strings attached is a very important attribute at that stage.

(ICCA India Podcast 2022)

This discussion highlights that the Indian government has emerged as a significant factor in enabling the growth of innovations by providing no strings attached funds for their early-stage development of development.

- **State as an inhibitor: Institutional voids and infrastructural challenges**

Our analysis of the data point toward two types of institutional gaps hampering the development and adoption of inclusive innovation in the local healthcare systems.

First, the lack of linkages between health and industrial policy has resulted in the lack of appropriate industrial, health and regulatory policies. The missing linkages among these policies emerged as one of the critical institutional gaps that constrain the development of inclusive medical technological innovations (Table 4). Second, market-related factors such as distributor-hospital nexus and dysfunctional procurement policies also emerged as key constraints for broader acceptance of inclusive innovations in the local healthcare systems.

Innovators point out that institutional gaps in the form of mismatch in health, industrial and regulatory policies pose a significant barrier to the development and adoption of inclusive innovations in local healthcare systems. For example, the limited availability of dedicated medical device testing facilities, ambiguous regulations and weak monitoring infrastructure hinder the development of inclusive medical technological innovations in India. The wider acceptance of inclusive innovations is related to the credibility of the manufacturers and the quality of the validation studies supporting the device.

Further evidence of the mismatch between industrial and health policies comes from import duty set up by the government on various electronic components. Most innovators argue that manufacturing activity in India is dominated by the assembly of components imported from overseas rather than the components manufacturing. For example, most device manufacturers import electronic components such as

Table 4. Critical sectoral issues in the Indian medical device industry.

| Key challenges | Description |
|--------------------|--|
| Testing facilities | Lack of dedicated medical device compliance testing in government laboratories while few private testing centres remain unaffordable for smaller manufacturers. |
| Regulatory system | Implementation and enforcement of The New Medical Device Rules, 2017 rules remain a concern. |
| Industrial policy | The import duty of components tended to push the device's cost higher. The inverted duty structure that has seen import duty on parts being higher in some cases than a finished good. |
| Procurement rules | Highly stringent, complex and dated procurement rules challenge the acceptance of inclusive innovations. |
| Market acceptance | Dominance of distributor cartels create challenges for market acceptance. |

microcontrollers, semiconductors, LED screens, mobile phones and other parts, while some low-tech parts like plastics are sourced locally. It is observed that the import duty on components is adding a high cost to the development of inclusive innovations. In some cases, the inverted duty structure has resulted in import duty on parts being higher than the final product, as observed in the example of an ECG machine. According to the device manufacturer, the import duty on parts added nearly 40 per cent to the cost of manufacturing the device locally.

Imperfect market access gaps: Issues with procurement rules and distributor cartels

The existing stringent, complex, and dated public procurement rules make it harder for inclusive innovations to be adopted in public healthcare systems. For example, specific rules around the size of a firm before it was eligible to participate in a public procurement exercise emerged as a significant hindrance to the growth of inclusive innovators. Further, according to the device manufacturers, the tender documents were drafted focusing on part specifications and not the device's functionality, which often hurt innovative medical devices that, as part of their innovation, had done away with some components or parts. An excellent example is the ECG machine, where a smartphone replaced the need for a monitor and a thermal printer.

The Indian medical device industry relies significantly on distributors to access the hospitals, government and retail markets. These distributors usually have strong links with the local hospitals and cover complex geographies and remote areas, which MNCs and other manufacturers avoid. More prominent device manufacturers may have the edge over smaller manufacturers in convincing distributors to sell their devices. As a result, MNCs and large manufacturers dominate the distribution set-up as they offer better margins, various products, and marketing support to the distributors. Innovators argue that this distributor-dominated market creates challenging entry barriers. One of the founders of Biosense, comments,

Once we finish designing a product, getting it out successfully is rather difficult, considering the distribution sector for medical consumables is highly fragmented,

(Rajappa 2018)

Most distributors are traders that are primarily concerned about profit margins than having an appreciation or an understanding of innovative devices appropriate to local needs. This attitude of distributors also emerged as a key barrier to market entry.

5.3. Firm strategies for navigating institutional gaps and infrastructural challenges: collaborative arrangements

Our analysis indicates that innovators collaborated with stakeholders to overcome institutional gaps, resource constraints and infrastructural challenges. Two types of collaborations were observed; one collaboration was at the design level, while another collaboration was at the late-stage development and commercialization stage.

- **Collaboration at the design stage and level**

One common theme that binds most innovators is the influence of collaboration with healthcare practitioners and technicians. There were instances of doctors approaching a particular device manufacturer with an idea or even cases where the doctors themselves turned into innovators. In the case of Biosense, two founders are medical doctors and had significant input into the development of Touch HB. Similarly, an ENT surgeon at St John's hospital encouraged and worked with IcarusNova team to build the ENTraview that can help with the in-depth endoscopic examination at the clinical practice. Further, doctors and health care practitioners who use these devices were also involved right from the concept stage and even in improvements of the design of devices. The inputs of these users were vital for adapting devices to local conditions – for example, incorporating regional languages into a device as suggested by a doctor resulted in the device having a wider reach. These contributions from doctors, technicians and health-care professionals were critical to the development and adoption of inclusive innovations.

- **Collaborations at the late-stage development and commercialization: A relay race and not an individual sprint**

This analysis further highlights the relay race nature of late-stage development of inclusive innovations in the MedTech sector and the significance of collaborative arrangements amongst a diverse set of actors, such as startups, MNCs, NGOs, local hospitals and public sector research institutes, in navigating the institutional gaps and infrastructural challenges in the development and adoption of inclusive innovations in the local healthcare systems (Table 5).

Our analysis points out that the inclusive innovation process involving a diverse set of actors through collaborative arrangements helps to bridge knowledge and resource gaps. It aids in gaining social-political legitimacy, overcoming the risk of political capture and limiting rent-seeking behaviour. These arrangements involve a range of unseen activities in the development and delivery of innovation infrastructure with local needs as a central focus. These activities helped innovators to achieve better integration with industrial systems, overcome market barriers and manage regulatory uncertainties. The evidence suggests that this complicated selection environment of inclusive innovation requires a collaborative mix of public, private, MNCs and not-for-profit actors. It shows that within a context of institutional voids, these collaborations and external linkages are even more critical but not always easy to manage. One of the founders of IcarusNova emphasizes the significance of collaborative arrangement by pointing out the relay

Table 5. Collaborative arrangements and inclusive innovations.

| Product | Name of the start-up | Key partnerships | Nature of collaborative arrangement |
|------------------|----------------------|-------------------------------------|--|
| Touch HB | Biosense | Local government and ASHA workers | Funded from private and government grants, Worked with local government and ASHA workers to create access to Touch HB tests |
| LifePlot | Sofomo | Swayam Shikshan Prayog; a local NGO | Forms a partnership with a local NGO to provide testing machines for door-to-door testing in rural areas |
| Unique ENTReview | IcarusNova | Medtronic. Shroff Hospital, | Works with a local hospital to test the prototypes, and then Medtronic acquires the product for manufacturing and distribution under its Shruti programme. |

race nature of the innovation cycle associated with inclusive MedTech innovations in resource constraint environments,

If the innovation proceeds to the next step, then clearly both these actors; that is, the person or group that came up with the innovation and the agency, let's say the government, which invested in encouraging innovation outside the corporate circle. Both of them may not have the expertise to take it to the next step. And there, you would require a completely different set of actors who bring in all kinds of new thoughts; whether it is able to analyse markets, look at markets that may not exist in front of you but somewhere else altogether, background in the MedTech space where they understand the evolution of product itself in order to recognise the opportunities that are emerging at that time and able to vend your way through that. If the innovation cycle is seen by both actors, those who have innovations and those who fund the innovations, as a relay race, than I own this, and I am going to take this to the market, that is a nearly impossible task.

(ICCA India Podcast 2022)

The collaborative arrangements, to some extent, act as innovative institutional and organizational forms and divisions of labour to improve the development and delivery of physical technologies appropriate for local populations. This collaborative approach provides a way for an MNC to access products appropriate to local markets and overcome a lack of local knowledge, while for startup firms, these offer a way to overcome a lack of funds and improve the scalability of innovations. In this context, these collaborative arrangements provide a critical pathway in creating plans for the development, production, distribution, acceptance and use of inclusive innovations, as seen in the cases studied in this research. Without these collaborations, start-ups might remain isolated and struggle to commercialize products successfully despite having a good idea or strong local presence.

6. Conclusion

Most research on inclusive innovations in MedTech has explored either the process involved in their development or issues associated with their diffusion in the local healthcare systems. But only a few studies have looked at the processes related to the development and adoption of inclusive MedTech innovations in developing countries' resource constraint healthcare systems. This paper fills this gap by focusing on the institutional and firm-level processes associated with the development and adoption of inclusive innovations in developing countries healthcare systems. Specifically, it investigates key factors, actors, opportunities and barriers that influenced the development and diffusion of inclusive MedTech innovations in the Indian healthcare system. With

India investing very little in public health care but the growing start-up activity in the medical technology sector, the growth of the 'inclusive' medical devices industry operating in resource constraint environment provided a good case study for this research.

This paper contributes to the understanding and interpretation of inclusivity in the MedTech sector. The majority of inclusive innovation literature has focused on their scalability, ability to satisfy consumer needs and policy frameworks required to promote the development of these innovations. Less focus has been paid to the conceptualization of 'inclusivity' in the MedTech sector, its implication for resolving local needs and developing appropriate policy frameworks. Traditionally, innovation and development studies have conceptualized inclusive innovations in resource-constraint settings as being low-cost products/services. This paper suggests that innovators' perspective on inclusivity centres more on enabling access and availability to healthcare than on creating cheap devices. It emerged that innovators equate 'inclusivity' with resolving distance issues and overcoming under-resourced settings or adverse weather conditions. Creating access to and early diagnosis of diseases for large segments of the population can also potentially help reduce the life cycle costs of treatment. Therefore, it is necessary to view and understand inclusivity not as a one-off cost-saving initiative or an attempt to resolve a problem but as a long-term philosophy of engaging holistically with all aspects of product development to improve its access and use. This finding provides an alternative perspective from the traditional approach to inclusive innovations in resource-constraint settings in the literature.

This study shows the contrasting but influential role of the state in creating barriers and opportunities for the development and adoption of inclusive MedTech innovations in Indian healthcare systems. The state acted as an enabler by successfully implementing financial schemes that provided capital for early-stage development. In contrast, the state also emerged as an inhibitor responsible for significant institutional gaps that created challenges for scaling up innovations and their market acceptance. This research further emphasizes the role of institutional support as an essential requirement for the development of inclusive innovations in developing countries. It also contributes to a better understanding of the current landscape for innovation in the medical devices industry in India. It provides critical regulatory, industrial and trade policy insights that could help increase innovation in this industry, especially concerning 'inclusive' medical technological innovations.

This paper further points out that most innovators overcame the institutional gaps and infrastructural challenges by engaging in collaborative arrangements with various stakeholders to manage late-stage development and adoptions in the local healthcare systems. The collaborative arrangements facilitated the late-stage development and diffusion of inclusive innovations by bridging resource and knowledge gaps and constraining rent-seeking behaviours. These collaborative arrangements provide a way forward in resolving the critical issue of collective action problem associated with the development and adoption of these innovations in the resource constraint healthcare system. These emerging configurations are likely to generate and deliver appropriate inclusive innovations required by the local healthcare system.

By identifying critical constraints faced by device manufacturers, this paper also lays the ground for further research on how a well-executed innovation policy and a

supportive ecosystem that addresses many of the constraints highlighted in our paper can boost the growth of innovative ‘inclusive’ medical technologies.

Acknowledgement

This paper is part of the research project that received funding from KEM Hospital Research Centre, India and Forbes Marshall, India. The authors would like to thank Mehak Malhotra, Ashwin Shankar and Divya Sebastian for their contributions to the management of the project. We also want to thank two anonymous reviewers for their critical reading and extensive comments, which led to substantial improvement of this paper.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Dinar Kale  <http://orcid.org/0000-0002-2704-0542>

References

- Advani, S. 2013. Biosense Technologies has Developed a Device. <https://www.moneycontrol.com/europe/?url=https://www.moneycontrol.com/news/trends/features/-1684585.html>.
- Agarwal, N., A. Brem, and S. Dwivedi. 2019. “Frugal and Reverse Innovation for Harnessing the Business Potential of Emerging Markets — the Case of a Danish mnc.” *International Journal of Innovation Management*, 2050009. doi:10.1142/s1363919620500097.
- Arya, A. P., and L. Klenerman. 2008. “The Jaipur Foot.” *The Journal of Bone and Joint Surgery. British Volume* 90 (11): 1414–1421. doi:10.1302/0301-620X.90B11.21131
- Basu, R., P. Banerjee, and E. Sweeny. 2013. “Frugal Innovation: Core Competencies to Address Global Sustainability.” *Journal of Management for Global Sustainability* 1 (2): 63–82.
- Beruman, A., S. Garner, S. Hill, and S. Swaminathan. 2018. “Making Diagnostic Tests as Essential as Medicines.” *BMJ Global Health* 3 (4): e001033. doi:10.1136/bmjgh-2018-001033.
- Bianchi, C., M. Bianco, M. Ardanche, and M. Schenck. 2017. “Healthcare Frugal Innovation: A Solving Problem Rationale Under Scarcity Conditions.” *Technology in Society* 51: 74–80. doi:10.1016/j.techsoc.2017.08.001
- BIRAC. 2022. Indian Bio-economy Report, https://www.birac.nic.in/webcontent/1658318307_India_Bioeconomy_Report_2022.pdf.
- Chakravarty, S. 2022. “Resource Constrained Innovation in a Technology Intensive Sector: Frugal Medical Devices from Manufacturing Firms in South Africa.” *Technovation* 112.
- Cheng, M. 2007. An Overview of Medical Device Policy and Regulation, HNP Brief 8, <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief8.pdf>.
- Dandonoli, P. 2013. “Open Innovation as a new Paradigm for Global Collaborations in Health.” *Globalization and Health* 9: 41. doi:10.1186/1744-8603-9-41.
- Eisenhardt, K. M. 1989. “Building Theories from Case Study Research.” *The Academy of Management Review* 14 (4): 532–550. doi:10.2307/258557
- Govindarajan, V., and R. Ramamurti. 2013. “Delivering World Class Health Care, Affordably: Innovative Hospitals in India Pointing the Way.” *Harvard Business Review* 2–7.
- Govindarajan, V., and C. Trimble. 2012. *Reverse Innovation*. Boston, MA: Harvard Business Review Press.

- Gupta, B., and T. Khanna. 2019. "A Recombination-Based Internationalisation Model: Evidence from Narayana Health's Journey from India to the Cayman Islands." *Organization Science* 30 (2): 405–425. doi:10.1287/orsc.2018.1241
- Hakobyan, S., and R. Cherif. 2021. Trade in Medical Goods: Challenges and a Way Forward for Sub-Saharan Africa, Special series on Covid 19. <https://www.imf.org/en/Publications/SPROLLS/covid19-special-notes>.
- Heeks, R., C. Foster, and Y. Nugroho. 2014. "New Models of Inclusive Innovation for Development." *Innovation and Development* 4 (2): 175–185. doi:10.1080/2157930X.2014.928982
- Henderson, R., and K. Clark. 1990. "Architectural Innovation: The Reconfiguration of Existing Product Technologies and the Failure of Established Firms." *Administrative Science Quarterly* 35 (1): Special Issue: Technology, Organisations, and Innovation, 9–30. doi:10.2307/2393549
- Hossain, M. 2018. "Frugal Innovation: A Review and Research Agenda." *Journal of Cleaner Production* 182: 926–936. doi:10.1016/j.jclepro.2018.02.091.
- Hossain, M., H. Simula, and M. Halme. 2016. "Can Frugal Go Global? Diffusion Patterns of Frugal Innovations." *Technology in Society* 46: 132–139.
- ICCA India Podcast. 2022. Designers Innovating in Healthcare <https://www.youtube.com/watch?v=ycuSiyTQNI8>.
- Jaroslowski, S., and G. Saberwal. 2013. "Case Studies of Innovative Medical Device Companies from India: Barriers and Enablers to Development." *BMC Health Services Research*.
- Joshi–Routh, B. 2018. Health Care Innovations: Designed to Save Lives. <https://www.forbesindia.com/article/innovation-nation/health-care-innovations-designed-to-save-lives/50113/1>.
- Kale and Wield. 2019. "In Search of the Missing Hand of "Collaborative Action": Evidence from the Indian Medical Device Industry." *Innovation and Development* 9 (1): 1–23. doi:10.1080/2157930X.2018.1429807
- Kaplinsky, R. 2011. "Schumacher Meets Schumpeter: Appropriate Technology Below the Radar." *Research Policy* 40 (2): 193–203. doi:10.1016/j.respol.2010.10.003
- Karnani, A. 2007. "The Mirage of Marketing to the Bottom of the Pyramid: How the Private Sector Can Help Alleviate Poverty." *California Management Review* 49 (4): 90–111. doi:10.2307/41166407.
- Khanna, T., and K. G. Palepu. 2010. *Winning in Emerging Markets: A Road map for Strategy and Execution*. Boston: Harvard Business Press.
- Kopsick, B. 2018. Diagnostic Testing for the Poor: The Story of Biosense. <https://socialinnovationsjournal.org/editions/issue-47/75-disruptive-innovations/2823-diagnostic-testing-for-the-poor-the-story-of-biosense>.
- London, T., and S. L. Hart. 2004. "Reinventing Strategies for Emerging Markets: Beyond the Transnational Model." *Journal of International Business Studies* 35 (5): 350–370. doi:10.1057/palgrave.jibs.8400099
- Long, J., H. E. Parker, K. Ehrlich, M. G. Tanner, K. Dhaliwal, and B. Mills. 2020. "Frugal Filtering Optical Lenses for Point-of-Care Diagnostics." *Biomedical Optics Express* 11 (4): 1864–1875. doi:10.1364/BOE.381014.
- Marks, I. H., H. Thomas, M. Bakhet, and E. Fitzgerald. 2019. "Medical Equipment Donation in Low-Resource Settings: A Review of the Literature and Guidelines for Surgery and Anaesthesia in Low-Income and Middle-Income Countries." *BMJ Global Health* 4 (5). Article e00178.
- Medtronic. 2020. Shruti. <https://www.medtronic.com/in-en/about/shruti.html>.
- Miesler, T., C. Wimschneider, A. Brem, and L. Meinel. 2020.   Frugal Innovation for Point-of-Care Diagnostics Controlling Outbreaks and Epidemics." *ACS Biomaterials, Science and Engineering* 6: 2709–2725. doi:10.1021/acsbiomaterials.9b01712
- Morey, G. 2021. Sunday Tech Talks: Journey of a Wearable Innovation in Medical Electronics. <https://www.youtube.com/watch?v=knUJz5z6LnY>.
- Nadvi, K. 1999. "Collective Efficiency and Collective Failure: The Response of the Sialkot Surgical Instrument Cluster to Global Quality Pressures." *World Development* 27 (9): 1605–1626. doi:10.1016/S0305-750X(99)00078-9

- Pansera, M., and R. Owen. 2018. "Framing Inclusive Innovation Within the Discourse of Development: Insights from Case Studies in India." *Research Policy* 47 (1): 23–34. doi:10.1016/j.respol.2017.09.007
- Papaioannou, T. 2014. "How Inclusive Can Innovation and Development be in the Twenty-First Century?" *Innovation and Development* 4 (2): 187–202. doi:10.1080/2157930X.2014.921355
- Pietrasik. 2009. Lessons from a Frugal Innovator: The Rich World's Bloated Health Care System can Learn from India's Entrepreneurs. *The Economist*. Accessed October 2020. <https://www.economist.com/business/2009/04/16/lessons-from-a-frugal-innovator>.
- Prahalad, C. K. 2005. *Fortune at the Bottom of the Pyramid: Eradicating Poverty Through Profits*. Philadelphia: Wharton School Publishing.
- Prime, M., Y. Bhatti, M. Harris, and A. Darzi. 2016. "Frugal Innovations in Healthcare: A Toolkit for Innovators." *Academy of Management Proceedings* 1: 12622. doi:10.5465/ambpp.2016.12622abstract
- Radjou, N., J. C. Prabhu, and S. Ahuja. 2012. *Jugaad Innovation* (1. ed). San Francisco, California: Jossey-Bass.
- Rajappa, A. 2018. This Revolutionary Healthcare Firm Producing Affordable Medical Devices First Started as a College Project. <https://yourstory.com/2018/03/biosense-healthcare-firm-medical-devices/>.
- Ramdorai, A., and C. Herstatt. 2015. *Frugal Innovation in Healthcare: How Targeting Low-Income Markets Leads to Disruptive Innovation*. Heidelberg: Springer.
- Schumacher, E. 1973. *Small is Beautiful: A Study of Economics as if People Mattered*. London: Harper Perennial.
- Smith, A., Mariano Fressoli, and Hernán Thomas. 2013. "Grassroots Innovation Movements: Challenges and Contributions." *Journal of Cleaner Production* 65: 114–124. doi:10.1016/j.jclepro.2012.12.025.
- Srinivas, S. 2000. "Institutional Variety and the Future of Economics." *Review of Evolutionary Political Economy* 1 (1): 13–35.
- Srinivas, S., and D. Kale. 2021. New Approaches to Learning and Regulation in Medical Devices and Diagnostics, IKD working paper series. <https://www.open.ac.uk/ikd/publications/working-papers/90>.
- Srinivas, S., and D. Kale. 2022. "New Approaches to Learning and Regulation in Medical Devices and Diagnostics: Insights from Indian Cancer Care." *Innovation and Development*. doi:10.1080/2157930X.2021.2000145.
- Srinivas, S., and J. Sutz. 2008. "Developing Countries and Innovation: Searching for a new Analytical Approach." *Technology in Society* 30 (2): 129–140. doi:10.1016/j.techsoc.2007.12.003
- Tiwari, R., K. Kalogerakis, and C. Herstatt. 2014. "Frugal Innovation And Analogies: Some Propositions for Product Development in Emerging Economies", in Proceedings of the R&D Management Conference 2014, June 3–6, Stuttgart: Fraunhofer Verlag, pp. 15–23. https://tore.tuhh.de/bitstream/11420/1175/1/Working_Paper_84.pdf.
- Virmani, A., and F. Lépineux. 2016. "Aravind eye Care System as Transformational Entrepreneurship: Spiritual Roots, Multi-Dimensional Impact." *Philosophy of Management* 15 (1): 83–94. doi:10.1007/s40926-016-0032-z
- Weyrauch, T., and C. Herstatt. 2017. "What is Frugal Innovation? Three Defining Criteria." *Journal of Frugal Innovation* 2 (1): 1.
- WHO. 2010. Medical Devices; Managing the Mismatch, An outcome of the Priority Medical devices project, http://www.who.int/medical_devices/en/.
- WHO. 2012. Local Production and Technology Transfer to Increase Access to Medical Devices: Addressing the Barriers and Challenges in Low- and Middle-income Countries. http://www.who.int/medical_devices/1240EHT_final.pdf.
- WHO. 2016. Towards Improving Access to Medical Devices through Local Production: Report of a Case Study in Three Sub-Saharan Countries; Part II. https://apps.who.int/iris/bitstream/handle/10665/206545/9789241510141_eng.pdf?sequence=1&isAllowed=y.

- Winterhalter, S., M. B. Zeschky, L. Neumann, and O. Gassmann. 2017. "Business Models for Frugal Innovation in Emerging Markets: The Case of the Medical Device and Laboratory Equipment Industry." *Technovation* 66–67: 3–13. doi:10.1016/j.technovation.2017.07.002.
- WTO. 2020. Trade in Medical Goods in the Context of Tackling covid-19. https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf.
- Yin, R. K. 2014. *Case Study Research*. 5. edition ed. Los Angeles: SAGE.
- Zeschky, M., B. Widenmayer, and O. Gassmann. 2011. "Frugal Innovation in Emerging Markets." *Research-Technology Management* 54 (4): 38–45. doi:10.5437/08956308X5404007