Enabling Inclusive Technological Change through Transformative Policies:

Frugal innovations from medical device manufacturing firms in South Africa

Sanghamitra Chakravarty
International Institute of Social Studies
and
Peter Knorringa
International Institute of Social Studies

UJ-TRCTI Working Paper Series
P 2021-07
December 2021

Thematic track: Transformative Innovation in Times of Change: Lessons for Africa from COVID-19

DSI/NRF/Newton Fund Trilateral Chair in Transformative Innovation, the Fourth Industrial Revolution, and Sustainable Development (UJ-TRCTI)

About the DSI/NRF/Newton Fund Trilateral Chair in Transformative Innovation, the 4IR and, Sustainable Development (UJ-TRCTI)

The Trilateral Chair is hosted at the University of Johannesburg (UJ), where it operates as a research centre located in the College of Business and Economics. Funded by the South African National Research Foundation and the British Council, the programme is an international research collaboration between the University of Johannesburg, the African Centre for Technology Studies (ACTS) in Nairobi and the Science Policy Research Unit (SPRU) at the University of Sussex in the UK. The programme builds on the expertise of three partners to strengthen African scholarship for examining transformative innovation and its policy dimensions in the context of the fourth industrial revolution (4IR) and efforts to achieve sustainable development. The Trilateral Chair started operating in July 2019. It is formed by a dynamic team of national and international researchers that engages in cutting-edge research; builds the capacity of younger scholars to help develop the next generation of African thinkers leading transformative change; and engages with policymakers, key stakeholders and research partners, to influence policy change.

Funding acknowledgement

The South African Research Chairs Initiative (SARChI) was established in 2006 by the then Department of Science and Technology (DST), now known as the Department of Science andInnovation (DSI), and the National Research Foundation (NRF). The Chairs are designed to attract and retain excellence in research and innovation at South African public universities. The funding support for the Working Paper Series comes from the DSI and the NRF through Grant Number 118873.

Disclaimer

Working Papers can be downloaded from **UJ-TRCTI** in PDF (Adobe Acrobat) format.

Suggested citation: Chakravarty, S. and Knorringa, P. (2021). *Enabling Inclusive Technological Change through Transformative Policies: Frugal innovations from medical device manufacturing firms in South Africa*. UJ-TRCTI Working Paper Series (WP 2021-07). University of Johannesburg: South Africa.

ISBN: 978-1-998972-44-9

Enabling Inclusive Technological Change through Transformative Policies

Frugal innovations from medical device manufacturing firms in South Africa

Sanghamitra Chakravarty* and Peter Knorringa**

Abstract

The lack of appropriate and affordable medical devices to serve the needs of developing countries is a global health concern; a need felt even more acutely during the COVID-19 pandemic. In recent years, the growing medical device manufacturing sector in South Africa has drawn policy attention, with some studies highlighting its significant potential to contribute to South Africa's National Development Plan 2030. The prompt deployment of funding and home-grown technologies by the South African government during the pandemic to address medical device and diagnostics shortage through local manufacturing reaffirms the country's capabilities. This study explores firm-level innovation processes through a fresh lens. It adapts the heuristics of an 'institutional triad' to highlight the institutions, interactions, and tensions between the three stages of innovation – generation, production, and diffusion – which are influenced by different policy domains. Further, it explores the ways in which the harmonisation of policies can enable South Africa's medical device manufacturing sector to reconcile the twin objectives of industrial growth and social development, including lowering its own healthcare cost. Empirical evidence from three case studies demonstrates that, despite facing many constraints and challenges to innovate, some small and medium enterprises (SMEs) engaged in medical device manufacturing in South Africa have high levels of innovation capabilities and have successfully brought various frugal innovations to market. Frugal innovations in this study are fundamentally new products – they are not adaptations or stripped-down versions of products initially developed for Western markets. The evidence suggests varying levels of involvement of the state in the three case studies presented. However, much more proactive support, particularly to innovative SMEs, would be needed to enable more inclusive technological change where both economic and social goals can simultaneously be achieved.

Keywords: frugal innovation, medical devices, South Africa, transformative policies, innovation policies, inclusion, technological change, technological capabilities

Acknowledgement

The findings of this paper are part of a doctoral research project funded by the International Institute of Social Studies, Erasmus University Rotterdam. We are grateful to Prof. Erika Kraemer-Mbula (UJ); and Dr Il-haam Petersen and Dr Glenda Kruss (HSRC) for their support during fieldwork. We thank the interviewees for so generously sharing time and information; the University of Johannesburg for funding support and the editorial team for their critical reading and valuable feedback.

* International Institute of Social Studies, Erasmus University Rotterdam and Centre for Frugal Innovation in Africa; chakravarty@iss.nl

** Private Sector & Development, International Institute of Social Studies, Erasmus University Rotterdam and Centre for Frugal Innovation in Africa; knorringa@iss.nl

1. Introduction

The lack of affordable and appropriate medical devices to serve the needs of developing countries has been a global health concern (WHO, 2010a) long before the pandemic. Most medical devices meant for developing countries are designed by firms in high-income countries who innovate primarily for their home markets (WHO, 2010b). This market gap for frugal medical devices, largely unaddressed by Western multinational firms, offers an opportunity for innovative firms in developing countries. South Africa, with its growing medical device manufacturing sector, well-established science and technology infrastructure, and world-class universities with high-level biomedical research capacity, is well positioned to tap into this market gap. Studies suggest that the sector offers significant potential to contribute to South Africa's National Development Plan (NDP), which aims to eliminate poverty and reduce inequality by 2030 (SAMRC – PATH, 2014). This paper offers complementary micro-level perspectives, making connections with existing macro and sectoral studies; and, in addition, focusing on pathways to accelerate capability accumulation and inclusive technological change.

The pandemic has highlighted three aspects of healthcare delivery in developing countries. First, it put frugal health technologies at the centre stage of the COVID-19 response, particularly in the initial stages of the crisis. Frugal innovation has been conceptualised as good enough, functional, and significantly cheaper products for resource constraint settings (Weyrauch & Herstatt, 2017; Zeschky, et al., 2014), developed in bottom-up processes driven by necessity (Basu, et al., 2013). During COVID-19, frugal approaches around healthcare were observed to exhibit characteristics of repurposing, reusing, and rapid deployment, in addition to affordability (Harris, et al., 2020). Numerous frugal innovations emerged, from low-cost ventilators to temporary hospital facilities with repurposed equipment and infrastructure, giving developing countries with limited resources ways to deal with the crisis. Frugal approaches were rapidly and resourcefully deployed during the pandemic, not only in developing countries but also in the richest[1] (Harris, et al., 2020; Corsini, et. al., 2021). For developing countries on tight budgets, it has reaffirmed the urgent need for frugal health technologies for inclusive healthcare delivery.

Second, geopolitical uncertainties and global trade conflicts have given rise to a call for technology sovereignty (Edler, et al.,2020), bringing to the forefront the need to enhance regional capabilities, self-reliance, and resilience. International policy debates on access to healthcare do not yet focus on building local innovation and manufacturing capabilities in Africa, though there has been a slight shift. For example, access to medicines in Africa is focused around funding procurement of essential medicines from Asian manufacturers (Mackintosh, et al., 2016). Africa's needs for medical devices are mainly met through imports of equipment designed for high-income countries and through international donations, and a disproportionate percentage remains nonfunctional or broken[2] (Howitt, et. al, 2012;

[1] Such as the design of a ventilator made with primarily off-the-shelf components already existing in the NHS supply chain in the UK (Harris, et. al., 2020) and repurposing full-face scuba masks into Continuous Positive Airway Pressure (CPAP) ventilators in Italy (Corsini, et. al., 2021).

[2] https://www.npr.org/sections/goatsandsoda/2016/09/08/492842274/rage-against-the-busted-medical-machines?t=1621597274176

Marks et. al., 2019; Perry & Malkin, 2011; WHO, 2010a). The World Health Organization observes that addressing disparities in access is a complex challenge dependent on a variety of factors[3] and not singularly related to local production (WHO, 2012). Rooted in a historical political economy approach and offering a different perspective, Mackintosh, et al. (2016) argue that to tackle the acute health care needs of Africa, the development of industrial production and related capabilities in pharmaceuticals are necessary elements. The pandemic witnessed an intermittent disruption of most global value supply chains. In South Africa, the supply of reagents that are sourced internationally was disrupted due to a rise in global demand, fluctuation in exchange rates, and restricted transport. The government responded with funding support to strengthen the local manufacture of reagents, diagnostic kits, and ventilators to address shortages, tapping into research capabilities built over decades.

Third, the "shocking imbalance"[4] in the global distribution of vaccines has made evident that the availability of technology does not ensure its equal access; nor does having production capability, as seen in the case of India, ensure its efficient and timely delivery. Inclusive healthcare requires coordinated action across policy domains as well as capabilities.

In the eventual aftermath of the pandemic, this paper focuses on pathways to strengthen existing capabilities in medical device firms in South Africa for both public health security and economic development. One of the fundamental challenges of policymakers in developing countries is aligning inclusive development with technological progress and innovation (Cozzens, 2008; Cozzens & Kaplinsky, 2009; Kaplinsky, 2011; Srinivas, 2012). Technological change is a contextual process (Srinivas & Sutz, 2008), and in specific sectors, it has shown to be the nucleus of economic and social transformation for industrialising countries (Kim, 1997; Srinivas, 2012). Medical devices could be such a high potential sector for South Africa, intersecting industrialisation and improvement of its own healthcare delivery as well as having an impact on global health.

Using three cases of medical device manufacturing firms in South Africa, this paper analyses firm-level innovation capabilities and processes at various stages of innovation generation, production, and diffusion to the market. It is based on primary data collected in phases between July 2018–September 2019, as well as secondary data. Some follow up online interviews to gauge firm resilience in COVID-19 were carried out during the pandemic. Our research follows a nonlinear abductive methodology involving systematic combining of framework, theories, fieldwork, and case analysis (Dubois & Gadde, 2002). Two key sources that have influenced our analysis are Srinivas (2012) and Bell & Figueiredo (2012). First, in our framework, the innovation processes are viewed as a "web of three interlinked relationships" (Srinivas, 2012) involved in the generation, production, and diffusion of innovation, similar to the concept of technology systems determining technological change (Carlsson & Stankiewicz, 1991). Second, the evaluation of innovation capabilities is based on Bell & Figueiredo (2012), who have integrated technological capabilities and organisational

[3] Such as business environment, financing mechanisms, regulations, and policies (WHO, 2012).

[4] https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-9-april-2021

capabilities in their study of capabilities accumulation in innovative firms in developing countries. Bell & Figueiredo propose a "revealed capability" approach where the innovation activity, understood in terms of increasing novelty and significance (from basic, intermediate, advanced to world-leading or innovation frontier)[5]; and the associated elements of capabilities (knowledge base, production, and organisational) are matched (see Fig. 1 and Fig. 4 below).

Anchored in these theoretical groundings, our paper makes several contributions. First, the empirical evidence suggests that the firms in this study have intermediate to advanced innovation capabilities demonstrated by the development of frugal innovations, which are fundamentally new products suitable not only for the local market but also for export. Despite the complex challenges of a resource constraint environment and an emerging sector, these firms have successfully designed and commercialised product innovations. Second, the high level of innovation activity does not always match the equivalent technological and organisational dimensions as expected from our reference framework (Bell & Figueiredo, 2012). A likely explanation of this could be due to frugal processes and the creative ability of firms in developing countries of "doing more with less" (Radjou, et al., 2012). Further, as frugal products, they point towards a different direction of innovation than global incumbents and new pathways of technological change (Romijn & Caniëls, 2011). Third, the evidence shows that while the firms have been supported by the state in some activities to an extent, they have not been direct recipients of large R&D grants. Fourth, all three firms have contributed to varied levels of inclusive technological change through innovation generation, production, and diffusion processes. Fifth and last, the data suggest that within the context of South Africa, innovation procurement of frugal medical devices not only enables domestic firms but creates access for those solely dependent on public healthcare. In order to accelerate the pace of inclusive technological change, future policies may take into account these findings.

The next sections of the paper are divided as follows: Section 2 provides a background of the medical device manufacturing and innovation in South Africa, including initiatives in pandemic management. In Section 3, the literature review has four subsections and explores the concepts of and relationships between frugal innovation, inclusion in healthcare, evolving policy perspectives, and innovation capabilities in developing country firms. Sections 4 & 5 introduce the methodological approach and the three case studies. Section 6 discusses the findings with respect to innovation capabilities, inclusive technological change suggesting possible policy directions; and Section 7 offers a conclusion and future research direction.

2. Background: South African medical devices sector – innovation and manufacturing

South Africa has a small but growing medical devices manufacturing sector that has recently received attention from the state. Some industry-level studies have been carried out (DTI-Deloitte, 2014; SAMRC-PATH, 2014). The perception is that South Africa is uniquely placed

[5] In terms of novelty and in similar lines with the Oslo Manual.

to develop its medical device manufacturing and, through it, improve its healthcare as well as bring economic benefits, all contributing towards the National Development Plan 2030 (SAMRC-PATH, 2014). However, success would be dependent on political commitment and aggressive policies, the key recommendations being the strategic alignment of core healthcare device areas and technology focus, establishing and enforcing local standards and a regulatory framework; and developing a transparent public procurement process (ibid). The South African Medical Device Industry Association (SAMED), consisting largely of importing companies, has also funded a similar sectoral study (SAMED-KPMG; 2014). The country has many world-class universities and a legacy of frontier level research on healthcare and biomedical engineering. Many cutting-edge medical device innovations have emerged from universities and public research organisations and are at various levels of development. Some of these can be categorised as frugal. One such example is a cost-effective and non-occlusive solution for rheumatic heart treatment being developed by Strait Access Technologies (SAT), a University of Cape Town (UCT) start-up. Another example is the UmbiFlow – a cheaper alternative to the conventional 2D ultrasound with Doppler mode to track foetus health developed by Council for Scientific and Industrial Research (CSIR) and South African Medical Research Council (SAMRC).

At the onset of the pandemic, as governments across the world tried to urgently build internal capacities for diagnostics test kits and essential equipment like ventilators, many initiatives were undertaken by the South African government. They involved public research organisations and universities as well as the private sector. The Department of Science and Innovation (DSI), South African Medical Research Council (SAMRC), and Technology Innovation Agency (TIA), awarded R18 million (1.2 mil USD) funding to enhance national research and production capabilities of reagents and diagnostic kits (Department of Science & Innovation, 2020). Another important COVID-19 response was the National Ventilator Project – a national effort to design, develop, and manufacture ventilators. This project was initiated by the Department of Trade, Industry and Competition (DTIC) and managed by the South African Radio Astronomy Observatory (SARAO)[6] with technology support from CSIR.[7] One of the products developed under this project is the Continuous Positive Airway Pressure (CPAP-100) device. The fact that it is an affordable device and can be operated by nurses with minimum training suggests that it is a frugal innovation[8]. Part of its production was carried out by the South African Emergency Ventilator Project (SAVE-P) – a local consortium, and purchased via the Solidarity Fund set up by the government. SAVE-P is constituted of a group of manufacturing companies and expert professionals working together to redesign CPAP machines with existing locally available technology. Table 1 is a compilation of some of the initiatives in South Africa to manage the need for diagnostic kits, reagents, and ventilators during the COVID-19 crisis.

[6] https://www.sarao.ac.za/media-releases/sarao-mandated-to-manage-the-production-of-respiratory-ventilators/

[7] https://www.csir.co.za/csir-supports-national-covid-19-response-locally-developed-ventilator

[8] https://www.sarao.ac.za/wp-content/uploads/2020/06/Fact-Sheet-CPAP-ventilator-2.pdf

Table 1: Examples of COVID-19 initiatives to address medical device needs in South Africa.

Project/Area	**Technology/ Manufacturing**	**Key Supporting Agencies**
Diagnostic reagents – Local manufacture of nucleic acid isolation kits for nasal and oropharyngeal swab samples.	Council for Scientific Research (CSIR) that will work closely with several spin-off companies.	Department of Science & Innovation, South African Medical Research Council, and Technology Innovation Agency.
Application-ready RT-PCR reagents – Cost-effective technology for production of Taq DNA polymerase, a key ingredient in RT-PCR reagents previously developed by CSIR.	CSIR and CapeBio Technologies (Pty) Ltd; technology licensing to CapeBio.	
Diagnostic reagents – Develop and produce highly stable synthetic DNA and RNA molecules containing all of the commonly used target sequences used for SARS-CoV-2 nucleic acid detection, as well as internal control sequences to check for the integrity of the nucleic acids.	Biopharming Research Unit (BRU) of the University of Cape Town.	
Antigen-based rapid test for detecting acute cases – Point of care diagnostic designed to directly detect the COVID-19 spike glycoprotein S1 in saliva to determine currently acute infection.	Medical Diagnostech (Pty) Ltd.	
Rapid test kit – Detecting the SARS-CoV-2 viral antigen in PoC or near-patient settings.	Mintek, other South African institutions and biotech companies as partners.	
Aptamer based diagnostic kit – Building on long term HIV research, the project will leverage an in-house developed algorithm to identify several aptamers against any target, viral, or bacterial protein for more sensitive, accurate, and cost-effective way diagnostics.	University of Western Cape, Aminotek & Amasu Technologies, and Medical Diagnostech (Pty) Ltd.	
Design of loop-mediated isothermal amplification (LAMP) rapid diagnostic test to run on both open RT-PCR platforms and closed ParaDNA PoC platform for rapid testing.	Gknowmix (Pty) Ltd., a spin-off from SAMRC, initially supported under Newton Fund (UK) for development of diagnostic testing and screening of breast cancer.	
Setting up of a new manufacturing facility based on recombinant proteins from *Nicotiana benthamiana* for a serology test to detect antibodies in blood at Cape Biologix, Mauritius. Also establishing laboratory and climate-controlled hydroponic grow rooms.	Cape Bio Pharms, a spin-off from Biopharming Research Unit of University of Cape Town.	European Investment Bank, Foundation for Innovative New Diagnostics.

National Ventilator Project where stream 1 addresses the need for non-invasive Continuous Positive Airway Pressure (CPAP) ventilators – a device used for COVID-19 patients in the initial stages of infection suffering from respiratory distress. Stream 2 focuses on ventilator demand for a smaller number of critically ill patients.	CSIR, South African Emergency Ventilator Project (SAVE-P), Siemens, Akacia Medical, and others.	South African Radio Astronomy Observatory (SARAO), Department of Trade, Industry and Competition (DTIC), Solidarity Fund, Siemens.

Source: Authors' own based on: CSIR, 2020; Denel, 2020; Department of Science & Innovation, 2020; SARAO, 2020; Siemens, 2020; University of Cape Town, 2020.

Many medical device innovations have also emerged from private manufacturing firms in the country, which are the focus of this paper and discussed in the case studies below. While South Africa imports medical devices worth USD 670 million annually, local manufacturing comprises mainly IVD (in-vitro diagnostic) products, implants (orthopaedic, cardiac, dental, etc.), and surgical devices, most of which are exported (WHO, 2013; WHO 2016). Its domestic market, as in all emerging countries, is dominated by multinational corporations selling mainly imported products (WHO, 2012). For small firms in the local manufacturing sector, competition from international companies is one of the key deterrents for manufacturing (WHO, 2013; WHO 2016). The innovation system offers challenges of resource constraints and bureaucratic inefficiencies. Many enabling institutions are in the process of restructuring and transition. The South African Health Products Regulatory Authority (SAHPRA), which is the central authority governing the import, purchase, use, etc., of medical devices, was established in 2015, following the passing of the Medicines and Related Substances Amendment Act 14. Previously, the Technology Development Agency (TIA) was also restructured to improve innovation funding. Unlike in countries with a well-developed medical devices sector, there are few ISO 13485 certified contract manufacturers, an essential requirement for the sector.

In recent years, many academic articles have also shone light upon various facets and challenges of the medical devices sector in South Africa. For example, Jager, et al. (2017) characterise domestic collaborations in medical devices using bibliometric analysis. They suggest a need for translational partnerships (i.e. including academia, healthcare, and industry) as pivotal for enabling commercialisation. Investigating technology transfer and absorptive capacities of local manufacturing firms, Ramaoka (2020) observes that from the key channels of external technology sources such as FDI, embodied technology, and joint ventures, partnerships were more exploitative (technology purchasing) rather than explorative or involving knowledge sharing. Saidi & Douglas (2018) note that while the establishment of a comprehensive regulatory framework such as SAPHRA is a milestone development, this transition poses formidable challenges for the industry. In focusing on innovative manufacturing firms and a micro-level qualitative approach, we complement these sectoral studies and this academic literature with a fresh perspective.

3. Literature review

3.1. Frugal innovation and inclusion

Despite its undeniable contributions to development, the impacts of technological change on developing countries have not always been positive. Inequalities in innovation generation and diffusion have led to increased global social justice challenges (Papaioannou, 2011), increasing relative poverty among vulnerable sections of society in the Global South. Development studies scholars have drawn attention to the complex relationship between innovation, technological change, poverty, and inequality, to show how in a highly interconnected and globalised world, technological change has reproduced and magnified, rather than reduced prevailing inequalities (Arecona & Sutz, 2003; Cozzens & Kaplinsky, 2009; Kaplinsky, 2011; Lazonoick & Mazuccato, 2013). Product innovation, particularly in healthcare, is a space where inequality plays out prominently (Cozzens & Kaplinsky, 2009). For example, the 10/90 gap highlights that only 10% of global health research expenditure is devoted to the health needs of developing countries, which accounts for 90% of the global disease burden (Global Forum for Health Research & WHO, 2004). Just as partnerships such as the International AIDS Vaccine Initiative (IAVI) have tried to bring new science and technology closer to the needs of the poor (Chataway & Smith, 2006), the Priority Medical Devices Project was initiated by World Health Organization to address the total lack of affordable context-specific devices for low and middle-income countries (WHO, 2010a).

Frugal innovation has been positioned as being enabling more inclusive development and is popularly understood as "doing more with less and for more people" (Prabhu, 2017; Radjou, et al., 2012). In this paper, we identify frugal innovations in medical devices as products that are significantly cheaper and more appropriate[9] for resource constraint settings. These are driven by underlying frugal processes making significant cost reduction and suitability to context possible.

While a more exhaustive discussion on the various discourses around frugality is beyond the scope of this current paper, the prominent debates that have shaped our methodology and arguments are elucidated here. First, the term "frugal innovation" is not commonly used amongst local firms in South Africa. "Inclusive innovation" is more widely used and relevant given the pervasive inequalities in the society; and implies broadly similar phenomena, notwithstanding differences in philosophical lineages (Onsongo & Knorringa, 2020). Second, the discourse around how frugal innovation relates to inclusive development remains ideologically polarised and lacks detailed empirical evidence (Knorringa, et al., 2016). The initial discourse dominated by business literature, focused on benefits of frugal innovation from a product perspective and the latent purchasing power of the poor (Prahalad, 2006), has drawn sharp criticism from development scholars (Arora & Romijn, 2011; Knorringa, et al., 2016; Meagher, 2017; Papaioannou, 2014). Much of this initial frugal

[9] Referring to features like ruggedness (performance is not easily affected by high temperatures, humidity, etc., requiring less infrastructure to house); operation (simple to operate, not requiring specialised skills which may be scarce); using fewer utilities and consumables; and maintenance (locally serviced, including ease of availability of parts and consumables).

literature ignored local participation and capability building as part of the innovation process and a necessary step in inclusive development. Inclusive innovation, scholars argue, should explicitly conceive development in terms of active inclusion of those who are currently marginalised, satisfying one or more of the following: inclusion in terms of relevance, in terms of development, ease of absorption, and impact on livelihoods (Foster & Heeks, 2013). Inclusion is a multi-dimensional concept, and innovations should meet the principles of global justice of equitable participation, not only in their diffusion but also in the way they are generated (Papaioannou, 2014). Third and last, firm-level capability building and transformation of production processes, which lies at the heart of economic development (Chang & Andreoni, 2021; Chang, 2014), has not been taken into consideration in the frugal innovation discourse. These debates and gaps in literature have informed our analysis of inclusive technological change, as discussed in the methodology section (below).

3.2. Inclusion in healthcare: the institutional triad

The pandemic has made evident how providing healthcare in a more inclusive and equitable manner is a highly complex issue, particularly for governments in developing countries. High innovation and industrial capability in the health sector is by no means a guarantee for improving health outcomes. Pre-COVID lessons from India and Brazil suggest that inclusion in healthcare is not possible without coordinated policies to ensure access. India, often referred to as the "pharmacy to the world", accomplished an impressive level of innovation and industrial capability. However, despite being a major pharmaceutical exporter, India has not been very successful in meeting its own health needs (Srinivas, 2012; 2016). In contrast, Brazil, since adopting the Unified Health System (Sistema Único de Saúde or SUS) in 1988, progressively brought together industrial development, science technology initiatives, and health care needs of its citizens through a series of policy interventions such as the National Medicine Policy and National Policy of Pharmaceutical Care (Aragão, et al., 2016). In view of these complexities, Srinivas (2012) suggests the health sector be viewed as a "web of three interlinked relationships" consisting of industrial production, the system of delivery, and that of consumption, and makes the following observation:

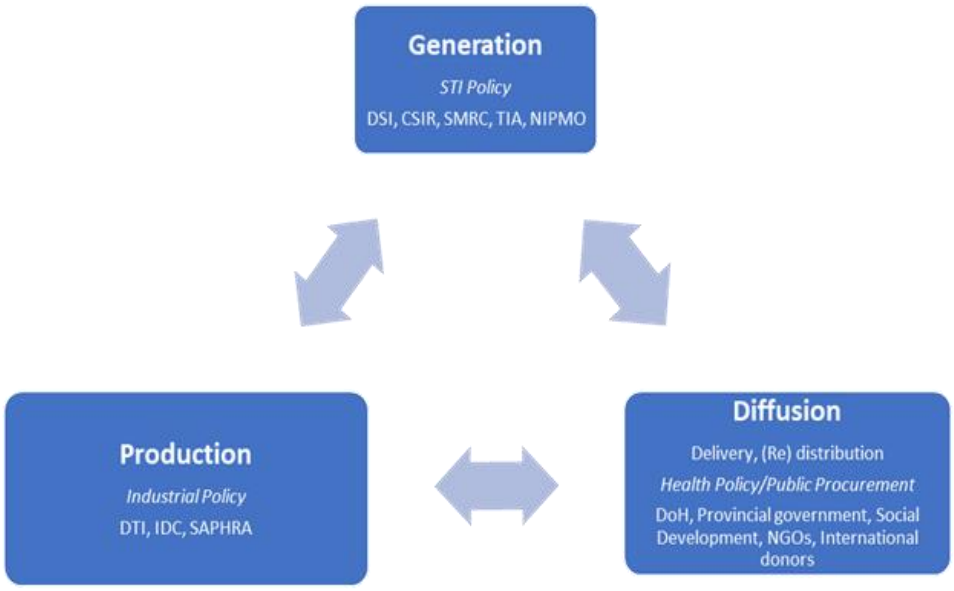
> "*Markets for health technologies have several unique characteristics, such as limited information and autonomous choice, blurred distinctions between producers and users (…), risks of use, and particular cultural traits. (…) neither patients nor health professionals but third-party payers (…) may be the buyers of the end products. (…) This collective aspect of consumption and demand shapes late industrial technological advance and constrains how states can reconcile economic and social goals."* (Srinivas, 2012, pp. 3–4).

Rather than viewing health technologies solely from the innovation perspective/supply-side or from the health policy/demand side, Srinivas suggests that institutions of the triad are in dynamic co-evolution, interacting with each other and requiring the consistent intervention of the state to maintain a "comfortable equilibrium" (Srinivas, 2012, p. 9). This is analogous to the concept of technology systems understood as a network of agents within an institutional infrastructure involved in the generation, diffusion, and utilisation of technology (Carlsson & Stankiewicz, 1991) and determining technological change. This heuristic is adapted to our research context for analysing inclusive technological change. In contrast to the triad as production, delivery, and consumption (which was mainly in view of

pharmaceuticals and especially generics studied by Srinivas), in this paper, we have adapted the three vertices of the triad as innovation generation, production, and diffusion. Further, we are specifically looking at frugal innovations emerging from innovative South African SMEs which are appreciative of resource constraint environments typical in developing countries. We focus on to what extent these firms play a role in innovation generation (design and development of frugal medical devices), and along with their local production and use, catalyse a nucleus of more inclusive technological change.

What is evident from the above discussion is that attaining inclusivity in healthcare requires a coordinated effort across different policy domains. The three vertices of the framework also indicate the three stages of innovation design to delivery, with each stage dominantly influenced by a particular policy domain such as science, technology and innovation policy; industrial policy; and health policy. Figure 1 (below) illustrates the adapted institutional triad and the associated policy domains.

Figure 1: Institutional Triad & interconnected processes influencing inclusive technological change.



Source: Adapted from Srinivas (2012).

3.3. Emerging policy perspectives

Exploring extant literature, we identify three emerging policy trends relevant to our research context. First, industrial policy has resurfaced in mainstream development discourse and with it the importance of building manufacturing capabilities (Andreoni & Chang, 2019; Chang & Andreoni, 2021). Second, over the past few decades, the understanding of how science, technology, and innovation (STI) can be harnessed for economic growth and social benefits has evolved, and so has policy-making. Starting from a narrow R&D focus, recent recommendations for innovation policies have proposed greater

attention to inclusion (Chataway, et al., 2014) and are targeted towards transformative change for addressing social and environmental challenges (Schot & Steinmueller, 2018). Thus, on the one hand, there is an understanding that innovation should drive economic transformation towards desirable social change, while on the other hand, there is the idea that innovation policy should strongly target economic diversification and structural change (Uyarraa, et al., 2020). Third, there is renewed policy interest in the demand side of innovation and public procurement of innovation (PPI) as an integrated component of innovation and industrial policy (Edler & Georghiou, 2007; Edquist & Zabala-Iturriagagoitia, 2012; Uyarra & Flanagan; 2010; Uyarra, et al., 2020). PPI is being viewed as an instrument that can harmonise the competing policy agendas of transformative innovation policy and industrial policy (Uyarra, et al., 2020). However, the primary objective of state procurement is to address human needs or societal problems, and stimulating new product development or diffusion of innovation from procuring organisations are secondary objectives (Edquist & Zabala-Iturriagagoitia, 2012; Uyarra & Flanagan, 2010). Early empirical studies have suggested that long term state procurement is more efficient in stimulating innovation compared to R&D subsidies (Geroski, 1990; Rothwell & Zegveld, 1981), with Aschhoff & Sofka (2009) highlighting the role of universities; Malerba (2007) that of experimental customers; and Uyarra & Flanagan (2010) recommending "innovation friendly" procurement for tackling trade-offs between conflicting policy goals.

Closer to our geographical context, in Sub-Saharan Africa, there has been a renewed interest in science policy and funding in recent years, but with greater recognition that science needs to be aligned with pressing social challenges (Chataway, et al., 2019) and that research excellence should not be limited to publications (Kraemer-Mbula, et al., 2020). The study of the sectoral ecosystem in collaboration with PATH (SAMRC-PATH, 2014) had also observed that despite high research capacity in healthcare and biomedical field, "research is almost exclusively publication driven rather than also focusing on innovation and product R&D" and commercial exploitation of IP remains low (SAMRC-PATH, 2014, p. 7). Neoliberal policies and a free market environment have led to insufficient industrial growth and premature deindustrialisation in many African countries. Kraemer-Mbula & Monaco (2020) argue that industrial policy must follow a bottom-up approach by strengthening innovation capabilities of small-scale firms, including those in the informal sector. One key issue in developing countries, as is in the case of South Africa (Kruss & Lorentzen, 2009; OECD, 2007), is that too much policy attention is concentrated in public research organisations and universities; and dedicated to radical or disruptive innovations (Bell & Figueiredo, 2012). Without adequately supporting the productive base towards incremental or design innovations and accumulation of capabilities, it creates an imbalance of complementarities (Bell & Figueiredo, 2012). Nevertheless, what is evident from the COVID-19 related innovations, is that the research capacity built over decades has made it possible for South Africa to quickly respond to the needs of the pandemic. Recognising the importance of imitative, frugal, and incremental innovation, as well as design and engineering activities, within its developmental context, South Africa's recent White Paper on Science, Technology and Innovation (DST, 2019) has also adopted a broader conceptualisation. The White Paper has also proposed to strengthen the focus on demand-side innovation through co-funding, public procurement and sectoral innovation funds, working in collaboration with other government departments. Public procurement is a highly technical (and political) process

requiring consideration of both immediate costs and of health priorities as part of longer-term development goals and of building innovation capabilities (Chataway et al., 2016). For medical device frugal innovations in cases where no equivalent product exists or procurement was based only on imported standardised products, this can be even more complicated. It may involve adjustment or introduction of standards and regulations, a time consuming and long-drawn process.

3.4. Innovation capabilities in developing country firms

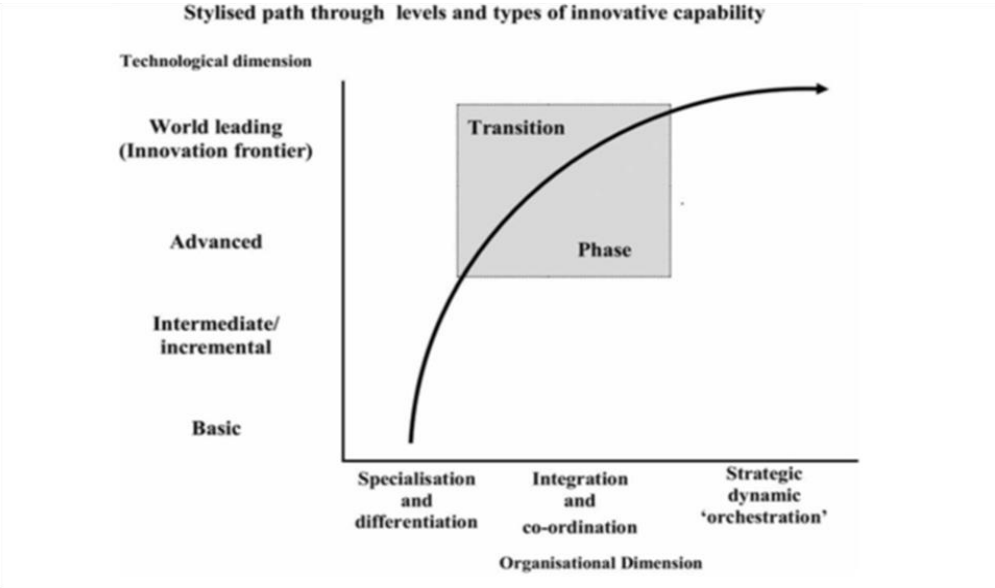
Developing countries are posed with the challenges of industrial transformation in an environment of highly regulated global policies – a context very different from how the now industrialised countries built their technological prowess and wealth (Chang, 2002). Recent studies by The World Bank have also made similar observations, suggesting that innovation in developing countries is several times more challenging as compared to already industrialised (Cirera & Maloney, 2017). Intellectual property regimes rigidly enforced by multilateral agreements like TRIPS[10] has led to "intellectual monopoly capitalism" (Pagano, 2014), benefitting firms from the global North while creating barriers to entry for indigenous firms in industrialising countries. Accumulation of capabilities in firms in developing countries may lead to different types of products, processes, and organisational configurations from that found in developed countries, and new patterns of technological change may emerge (Bell & Figueiredo, 2012; Romijn & Caniëls, 2011).

One of the most widely adopted classifications of technological capabilities was developed by Lall (1992) based on functions (investment, production, linkages) and their degree of complexity (routine, adaptive, replicative, innovative/risky), reflecting the deepening of knowledge over time. While the use of the term technological capabilities implies both production and innovation capabilities and the ability to organise these activities, some authors like Bell & Pavitt (1993) distinguish between production capabilities (improving productivity) and innovation capabilities (new products, processes closer to frontier level). Subsequently, Dutrénit (2000; 2004), in her study of a Mexican firm, emphasised the importance of organisational capabilities, which until then were studied in firms in developed countries. The concept of organisational capabilities is primarily explained by the resource-based view of the firm highlighting distinctive competences that cannot be easily transferred or imitated (Nelson & Winter, 1982; Penrose 1959). Defined using various other terms such as core competences (Prahlad & Hamel, 1990) or dynamic capabilities (Teece & Pisano, 1994), organisational capabilities are understood as the firm's ability to integrate, build, and reconfigure internal and external resources. Bell & Figueiredo (2012) draw from the technological capabilities literature (from the works of Katz, Lall, Hobday, Figueiredo, and others) but also integrate it with literature on organisational capabilities (Dutrénit), which was earlier more prevalent in the study of firms in developed economies (Teece, Pisano, and others). They propose the analysis of innovation capability accumulation through a "revealed capability" approach, understood in terms of increasing novelty and significance of innovation activity; and matching the associated elements of capabilities. Fig. 2 (below) represents the path of innovation capability building (Bell & Figueiredo, 2012),

[10] The TRIPS Agreement – Trade-Related Aspects of Intellectual Property Rights, World Trade Organization.

suggesting that with increasing levels of innovation activity represented by the technological dimension, firms also build organisational capabilities (Dutrénit, 2000). As discussed in Section 4, this understanding has been used as a broad reference in the analysis of individual dimensions of innovation capabilities.

Figure 2: Innovation capability accumulation: changing emphasis on 'technological' and 'organisational' dimensions.

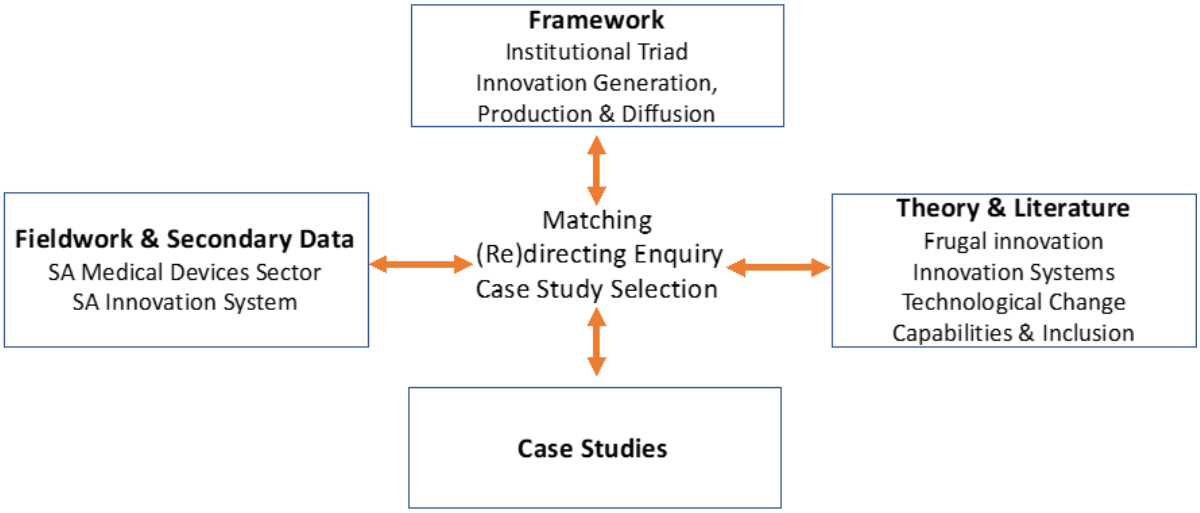


Source: Bell & Figueiredo (2012); adapted from Dutrénit (2000).

4. Methodology and framework

The purpose of this working paper is to understand the innovation profiles of small and medium medical device manufacturing firms in South Africa and in what way these firms can be better supported to enable inclusive technological change. The research methodology follows a nonlinear abductive process involving systematic combining, where the analytical framework, theories, fieldwork, and case analysis are considered to be intertwined (Dubois & Gadde, 2002), as illustrated below in Fig 3. The foundation of this methodology is the constant revisiting of the various types of interrelated research activities or 'matching'. The search for theories and emerging publications was continued in parallel to data collection. Data were analysed throughout the process of redirecting the research enquiry. The initial analytical framework, which was largely based on the notion of solely technology capabilities and sectoral innovation systems, was refined based on new literature. The two most relevant pieces of literature found during this process were the works of Srinivas (2012), which offered an analytical framework for viewing the interconnectedness of the innovation processes influencing inclusive technological change; and Bell & Figueiredo (2012) for analysing innovation capabilities. We applied a case study analysis in a qualitative and explorative manner, which is best suited for a complex and understudied phenomenon that cannot be easily explained by a single established theoretical lens (Yin, 2014).

Figure 3: Methodological approach of systematic combining.



Source: Adapted from Dubois & Gadde, 2002.

In order to analyse in what way the activities of the firm are driving inclusive technological change, we adapt the concept of an institutional triad (Srinivas, 2012), illustrated in Fig. 1 (above). For innovation capability, we follow the "revealed capability" approach (Bell & Figueiredo, 2012) to match the novelty and significance of innovation activity with the associated elements of technological and organisational capabilities. Fig. 2 (above) and Table 4 (below) provide a broad reference to interpret innovation capability, integrating the technological dimension having two components (knowledge base and production capabilities) and organisational capabilities.

4.1. Case study selection

Local medical device firms were identified from desk research, with industry association websites being the key information sources. From about twenty firms initially selected, fifteen were interviewed. The final selection of the three case studies guided by their theoretical relevance (Glaser & Strauss, 1967) was based on the following criteria: Firms (i) must have clinically tested products in the domestic market, indicating that these products could be preferred over competing products due to their 'frugal' characteristics; (ii) must have product innovations developed with sufficient internal effort as indicated by R&D investments, technical personnel, etc.; (iii) must have local production set up; (iv) should be in mature/growth stage, indicating they are sustainable economic entities with cash flow; and lastly (v) should be available and willing to share information and be part of the study. These selection criteria were developed by matching the cases with the analytical framework, and the case studies were 'found' during the course of the research (Ragin & Becker, 1992) through this process. The application of these criteria resulted in the selection of the three cases shown in Table 2 (below). The purpose of selecting multiple case studies was not simply to overcome any weakness of specificity or to enhance validity (Eisenhardt, 1989; Yin, 2014) but to analyse the variations and common thread among them as they are influenced by similar national policies and thus not entirely independent.

Table 2: Characteristics of Case Study firms.

Firm	Product Profile	Maturity	Size	Market
Shonaquip	Several design & Engineering based products	Mature	Large	Primarily domestic. Growing export
Sinapi Biomedical	Five – six design & Engineering based products	Mature	Large	Domestic with substantial export
eMoyo Technology	Two new technology & software-based products	Growth	Medium	Primarily Export
Size (Full-time employees): 1-30 – Small; 31-60 – Medium; Over 61 – Large. Maturity: Early Stage: No product in market; Growth Stage: Few Products in market, more in pipeline; Mature Stage: Products in market, few in pipeline.				

Source: Authors' own.

4.2. Data collection and sources

At the outset, extensive desk research was carried out to understand the sector and the systemic challenges and opportunities of the innovation system in general. Primary data were collected in three phases over several months of fieldwork between July 2018-September 2019. Informed consent was obtained from the firms to use the data for academic and policy purposes. Additional online interviews were carried out in November 2020 to get insight into how the firms were doing during COVID-19, as well as to clarify and reconfirm information. Each case study consisted of two or more semi-structured interviews supported by an innovation survey, both built along similar lines. The survey was drawn up by adapting the Community Innovation Survey (CIS) and following guidelines of the OECD Oslo Manual (OECD, 2018). The broad line of enquiry for interviews was spread out into four quadrants: background/evolution, product innovation, process/operations, and experience and challenges. All interviews were audio-recorded for transcription. The duration of a single interview was approximately an hour forming the key data source to capture the stories and underlying layers of complexity not achievable in a survey. Also, it was anticipated that these were small teams headed by the owner/entrepreneur who may not have the time to complete surveys or may assign the task to someone not fully knowledgeable. With this understanding, the most important source was the interviews. Table 3 (below) shows the data sources for each of the case studies. It is relevant to mention that the broader study involved about forty interviews with firms, academics, and government officials. Those that are not directly related to the three selected case studies have enhanced overall understanding and influenced the data analysis by revealing information and experiences which would not have emerged from these three cases alone.

Table 3: Overview of primary and other data sources for case studies.

Firm	Interviewee	Collection	Duration	Other key data sources
Shonaquip	Founder	Sept. 2019 Dec. 2020 (online) Oct. 2019	160 min Full day interaction at ISS, The Hague	• https://shonaquip.co.za/ • Innovation Survey • Driver-Jowitt, (2017) • Publications and impact reports shared by Shonaquip • Scheffler (2009) • WHO (2006) • Accelovate Design Challenge: Innovative Postural Support Solutions for Wheelchair Users in Low-Resource Settings https://reprolineplus.org/system/files/resources/wheelchair-design-report-2015.pdf
Sinapi Biomedical	Founder & MD International Sales Manager Professor, Obstetrics & Gynaecology, Stellenbosch University	Feb. 2019 Aug.2020 (online) Nov. 2020 (online) Sept. 2019	240 min	• https://sinapibiomedical.com/ • https://www.globalhealth.northwestern.edu/about/improving-sample-collection-for-accurate-tb-diagnosis-a-qa-with-sinapi-biomedical.html • Technical documents shared after interview
eMoyo Technologies	Founder	March 2019 Sept. 2019 Nov. 2020 (online)	210 min	• https://emoyo.net/ • Innovation Survey • Company documents • Swanepoel, et al. (2013) • Visagie, et al. (2015)

Source: Authors' own.

4.3. Analysis of data

The core objective was to analyse the process of technological change from a firm-level perspective; in what ways these processes were already inclusive; and how they could be further enabled through policies for transformative change. To do so, we have analysed (a) innovation capabilities of the firms and (b) inclusion at each stage of the innovation process. The analysis of innovation capability was conducted in two steps: First, understanding the product portfolio and secondly, the illustrative elements of capabilities. The first was used to understand the level of innovation activity as well as the orientation of the firms, which was useful in understanding in what ways they were inclusive at the level of generation of innovations. We examined the product portfolio: What kind of products were the firms innovating? Could one or more of these products find application in the domestic market, or was it solely innovating for Western markets? Did it have any product that specifically catered to domestic health challenges? How were these developed? Who were the firms collaborating with?

The understanding of innovation comes from the Oslo Manual (2005)[11] and the extensive discussions in the works of Bell & Figueiredo (2012). The typologies of innovation level used in this analysis are summarised in Table. 4 along with the corresponding organisational dimension. We have also given some indication of the quantity of human capital as we feel it is an important element of the firms' economic impact and of technological change. Lastly, in our analysis, we take a cross-sectional view of the innovation capabilities and not accumulation over time. Also, the firms in our study have not emerged as having simple production capabilities having primary manufacturing capabilities.

Table 4: Classification of innovation activity.

Innovation Level	**Technological Dimension**	**Organisational Dimension**
World Leading (Innovation frontier)	Overtaking incumbent innovators at the international frontier by cutting edge innovation in products, production and organisational processes and systems.	Strategic dynamic orchestration
Advanced	Catching up with the international technological frontier and closing in on leading global incumbents, with differing directions of innovation.	Advanced integration and coordination
Intermediate/Incremental	Relatively complex improvements and modifications to products, process organisation and systems.	Integration and coordination
Basic	Minor adaptations and improvements, close to imitation adoptions.	Specialisation and differentiation

Source: Adopted from Bell & Figueiredo (2012).

Both in the interview and survey, special attention was paid to capturing the behaviour/orientation of the firm in the context of frugal innovation. Firms were questioned about product characteristics (affordability, appropriateness), main markets, customers, etc., to identify if any of their key products could be categorised as frugal innovation. Firms were assumed to offer frugal innovations if one or more of their products met all of the following criteria: (a) significantly cheaper than available options, (b) more appropriate for the local context in terms of features and (c) were used or have been used in the domestic market as evidence of being the preferred option. Table 5 (below) draws out the parameters used in the analysis of inclusive technological change.

[11] In levels of novelty such as innovation being "new to the firm", "new to the market", "new to the world".

Table 5: Inclusion at each stage of innovation process/Micro level technological change.

Stage	**Criteria**
Generation	Product portfolio relevant for the domestic market Collaborative development of products with local stakeholders
Production	Local production and manufacturing (as opposed to simple assembly) Local procurement of some materials, supplies & machinery
Diffusion	Use in the domestic market to replace imported products Use in government healthcare delivery and services

Source: Authors' own.

As with data collection, the analysis of data was carried out over time, beginning soon after the completion of the first stage of fieldwork. For each firm, after transcription of the first interview, an initial description was drafted into the lines of enquiry or pillars mentioned earlier. With each additional interview, these pillars were strengthened with more information. Going back to the firms multiple times helped to gauge the consistency of information as well as wean out important issues which were repeated in more than one interview, based on which the data was reinterpreted and the description refined. Several descriptions of the cases have been written depending on research sub-questions, with the narrative in this current paper written to fit our analytical framework. A substantial part of technical information was extracted from secondary sources such as company websites, social media pages, newspaper articles, press releases, YouTube videos and websites of partnering organisations. These also helped to corroborate statements made by the firms about their products and collaborations in order to double-check findings from the interviews (Miles & Huberman, 1994).

5. Case studies

This section introduces the three case studies of local firms in South Africa that have successfully designed and brought frugal innovations to the market. The case studies highlight firm-level innovation capabilities and patterns of technological change. The narrative is structured to the extent possible along the lines of our analytical approach of the three stages of the innovation process; generation, production, and diffusion, which we use as a proxy for micro-level technological change. For detailed frugality analysis of innovations from these firms refer Chakravarty (2021).

5.1. Case I: Shonaquip: Assistive mobility devices, hybrid model, addresses national social objectives

Shonaquip (Pty) Ltd, based in Western Cape, designs and manufactures paediatric wheelchairs for children who need more postural support than a traditional wheelchair. While the company was formally registered in 1992, its inception was years earlier, borne out of Shona McDonald's personal need in trying to find a solution for her daughter born with cerebral palsy. Imported adult wheelchairs were not only expensive and inappropriate

for use in unforgiving terrains, but they are also unfit to provide postural support to children, with their use leading to secondary disabilities, sometimes more complex than the primary. Shonaquip's product portfolio has a range of positioning and mobility devices as well as wheelchair cushions and therapy equipment. In addition to being more appropriate for African settings, a standard Shonaquip device costs less than one-third of imported devices and can be repaired and maintained locally.

The first wheelchairs were developed in collaboration with the Biomedical Engineering Department at University of Cape Town. Subsequently, in 1996 with a grant from Nelson Mandela Children's Fund, the Madiba Buggy (named after Mandela), the first standardised pediatric wheelchair with postural support and adjustable modular seating that could be used on uneven terrain, was designed. The company follows a highly collaborative and bottom-up innovation process, where its design team works together with a gamut of other stakeholders, including users, therapists, and caregivers. There are domestic and international collaborations for learning and development. Some international partnerships include the Stanford Design for Extreme Affordability or Accelovate, a global health programme funded by USAID.

Shonaquip has a full production unit with seventy-five employees, 30% of whom have a form of disability but work fully integrated into an inclusive environment. Shonaquip has ISO 9001 certification and is setting up a testing laboratory ISO 17025 with an ISO 7176-8 certified testbed modified for testing wheelchairs for low resource settings that have longer wheelbases than regular devices, as such a facility does not exist in Africa and testing overseas is prohibitive.

Shonaquip operates as a hybrid social enterprise with other entities to broadly create a more inclusive ecosystem for children with disabilities. These other entities include the Uhambo Foundation, Champions of Change Trust for lobbying and awareness, and a TVET college.

Shonaquip's primary client is the South African government, Departments of Health, Education & Social Development. As it is rooted as a social enterprise, the company sets its profit margins as low as possible so that public budgets have optimum reach. In addition to the domestic market, the company also exports to other developing countries, including within Africa. While the company has received some grants from the Small Business Enterprise Development Agency (SEDA) and Technology Innovation Agency (TIA) and several awards, both nationally and internationally, the key to its sustainability is a hybrid business model where prices can be cross-subsidised as well as being part of the public procurement. McDonald has been part of an international committee of WHO for developing guidelines for manual wheelchairs in low-resource settings. The initiation into the tender system stemmed from McDonald's relationship with champions within the provincial Western Cape government having a shared vision. Prior to the mid-nineties, there was no dedicated government funding for assistive devices and the science behind seating was little understood. Over the years, and not without the relentless lobbying of many, South Africa has passed several regulations such as the Integrated National Disability Strategy White Paper, 1997; National Rehabilitation Policy, 2000; and Standardisation of

Provision of Mobility Assistive Devices in South Africa, 2003. These policy changes have provided a conducive environment for Shonaquip to grow and its devices to reach children who need them most.

5.2. Case II: Sinapi Biomedical: Affordable, high-quality devices for domestic market and export, many addressing national healthcare challenges

Sinapi Biomedical is a Stellenbosch based medical device manufacturing company managed by founder Chris de Villiers, who has an engineering background and diverse industrial experience. While it was started some years earlier, Sinapi has been fully operational since 2006. It has designed and successfully commercialised several products such as a chest drainage, urinary drainage, feeding cup, uterine balloon tamponade and a TB sputum container. One of Sinapi's most innovative and successful products, which has contributed to the growth of the company, is the chest drainage. The product has found commercial success not only in South Africa, which has a high incidence of patients with gunshot wounds, but is also used in Europe. One of its recent innovations costing a fraction of imported alternatives is The Ellavi, a uterine balloon tamponade device for treating postpartum haemorrhage (PPH), a common cause of death after childbirth across Africa.

Sinapi has a strong research, design, and engineering team that works collaboratively with government bodies, academics, surgeons, and healthcare workers. Each product is matured and perfected through numerous iterations throughout the design, development, and trial process with inputs from various stakeholders. For some products, Sinapi has been funded by the South African Medical Research Council (SAMRC) for clinical trials that were carried out by Stellenbosch University in both Western and Eastern Cape hospitals. Important international partnerships include those with PATH (an international global health non-profit that played a pivotal role in the design and commercialisation of the Ellavi) and Center for Innovation in Point-of-Care Technologies for HIV/AIDS (C-THAN) in Northwestern University, USA. Sinapi has complex manufacturing capabilities conforming to FDA's GMP standards and ISO 13485 & ISO 11135 accredited facilities. It also offers contract manufacturing services. The company employs over 150 people, including many technical personnel.

Sinapi has a domestic market selling directly to hospitals in South Africa and through distributors as well as a large international market. For public health, due to the high volumes of sales, it plans to offer the Ellavi at a subsidised cost. Sinapi is a mainstream company but invested in developing affordable products to make healthcare accessible and has partnerships with non-profit organisations. While the company has received some grants from international donors, the Technology Innovation Agency (TIA) and Department of Trade, Industry & Competition (DTIC), its main source of funds, are commercial banks. Sinapi has also received recognition in Grand Challenge Canada for its work.

5.3. Case III: eMoyo Technologies – new technology products, demonstrated in national health programme, export-based

eMoyo is a new technology-based manufacturing company founded by Dr Dirk Koekemoer. The company based in the Gauteng province was formally registered in 2013 but has existed as other entities for several years before. Koekemoer is a medical doctor with a strong belief in telemedicine for efficient healthcare delivery, and this is reflected in eMoyo's product line. The company has two key products, with the initial development and launch of some of the products happening before eMoyo was formally registered. One of the company's products is a portable lung function testing machine (ORCAwave Spirometer) for use in occupational health respiratory testing of people exposed to irritants affecting pulmonary function. The other is a portable audiometer called the KUDUwave that offers an alternative to traditional audiology. KUDUwave comes in the form of headphones by enabling fully booth-free operation for screening and diagnosis of hearing loss. Using proprietary software and cloud-enabled features, it can connect patients in remote locations and find applications in telemedicine.

eMoyo employs about thirty-four people, of which almost one-third work in design and development. To meet the necessary skill set, the company recruits people from South Africa and other countries in Africa. R&D efforts are continuously resulting in improvements in product features, software, calibration, etc. The company has recently developed a slightly differentiated version of the KUDUwave to be sold at a slightly lower cost for the local market. Most R&D is internal to the firm, and no domestic research collaborations currently exist. However, there have been partnerships for clinical trials such as with the University of Pretoria, University of Cape Town, etc. eMoyo has ISO 13485 certified production facilities and some high-value manufacturing, including an in-house 3D printing facility. A large part of eMoyo's components and supplies is based on imports, either due to unavailability or unreliability of local procurement. However, some critical technology services such as high precision milling and extrusion are obtained locally.

Currently, for the South African market, eMoyo conducts screening programmes in schools in partnership with NGOs, but otherwise, there are few sales. Due to limited uptake in the domestic market, eMoyo is primarily export-based. The products find a ready market in Europe and particularly in the US, where eMoyo has set up a branch. However, its products are highly relevant to the local context, and for KUDUwave, its application has been demonstrated. Between 2015 and 2016, the KUDUwave was used in the government's multi drug-resistant-TB programme to track ototoxicity or hearing loss, which is a side effect of TB drugs. eMoyo has been set up largely from personal funding sources. The Technology Innovation Agency (TIA) and Department of Trade, Industry and Competition (earlier DTI) have funded the application of provisional patents and for obtaining CE Mark.

6. Results and discussion

6.1. Innovation capabilities

All three firms investigated in this paper have one or more products that can be classified as frugal innovations. These are also fundamentally new products against functional or stripped-down versions of existing solutions, indicating that these firms have successfully designed and brought to market new to the world innovations at their respective levels of technological complexity. Table 6 (below) presents the analysis of the innovation capabilities of the three firms. Applying the framework adopted from Bell & Figueiredo (2012) and exploring the illustrative elements of capability shows some deviations and unique patterns. For example, in the case of Shonaquip, the elements of the technological dimension seem closer to an intermediate level – as much of the R&D is highly collaborative, keeping the internal technical team lean. Further, its production base is in the process of ISO 13495 certification. However, the organisational dimension of capability demonstrates many aspects of an advanced level, such as strategic orchestration of not only Shonaquip's own activities but across its many hybrid structures. In the case of Sinapi, its level of innovation activity and the illustrative elements of capability can all be classified as advanced, closely fitting all typologies of the framework. In the case of eMoyo, the level of innovation activity from its product characteristics and R&D spending can be classified as frontier level. However, having been formally established only in 2013, the firm is in the growth stage, still developing its internal structures and organisational capabilities. It may also be relevant to mention here that eMoyo's shows characteristics of a new technology business firm (NTBF) with products that can be classified as disruptive. Therefore, it faces the challenges of being a forerunner in the market. The data suggest that the level of innovation activity, as expressed by the product characteristics and their commercial success, do not always match with the equivalent technological or organisational dimensions with our reference framework of Bell & Figueiredo (2012). One explanation for this could be due to frugal processes and the creative ability of "doing more with less".

Table 6: Analysis of innovation capabilities.

Level of Innovation Activity	**Illustrative Elements of Capability**	
	Technological Dimension	**Organisational Dimension**
Shonaquip		
Intermediate and showing a movement towards an advanced level of innovation. This is because some products have recently received CE certification, and the production base is in the process of ISO 13485 certification. However, products are new, developed in a highly collaborative and bottom-up process and not creative imitations; they are path creating (frugal) products suggesting a new direction of innovation. High levels of organisational capabilities not expected at this level of innovation activity is observed.	*Human capital & Knowledge Base* Seventy-five employees with a lean three-member internal team of industrial designers and engineers. External collaborations in different functional areas such as product development, the introduction of standards, etc., with a multitude of users at the individual level; as well as international and domestic institutional knowledge sharing and generating collaborations. *Production base* ISO 9001 certified manufacturing and in process of securing ISO 13485. Setting up a testing laboratory ISO 17025 with an ISO 7176-8 certified testbed modified to test rural wheelchairs with longer wheelbases.	Strategic dynamic 'orchestration' - Ability to strategically orchesrate activities by sensing and seizing opportunities and threats, reconfiguring assets and organisational structures to innovate profitably. This is more managerial than technical. Demonstrated through periodic organisational changes, hybrid model, many collaborations, policy advocacy, etc., to reach organisational goals.
Sinapi Biomedical		
Advanced. Design, development, and manufacture of complex products with CE certification, which have also been adopted in Western markets. Different (frugal) directions of innovation.	*Human capital & Knowledge Base* Hundred fifty people employed through a highly selective recruitment process showing a preference for people with strong cognitive skills. Within this is a nine-member internal team of various types of design and development engineers as well as many technical persons in the area of quality and supervision. External collaborations in different functional areas such as R&D, clinical trials, etc., with doctors, clinicians, nurses, and health practitioners; as well as international and domestic institutional knowledge sharing and generating collaborations. *Production Base* ISO 13485, ISO 9001 certified, FDA approved GMP manufacturing, ISO 11135 certified sterilisation plant, primary manufacturing facility with injection moulding & extrusion, Class 100 000 cleanroom for assembly.	Advanced integration and coordination demonstrated by domestic and international supplier network, sales & distribution network, product design, development integrating many knowledge sources, periodic organisational changes and restructuring.

eMoyo Technologies		
World-leading/innovation frontier but with some advanced characteristics. Design, development, and manufacture of potentially disruptive innovations which are easily absorbed in US market as reverse innovations, but also have great value as frugal innovations in developing countries. However, the firm is still viewed to be in a 'growth stage' with some characteristics of new technology business firms due to the highly innovative nature of its products.	*Human capital & Knowledge Base* More than one-third of its thirty-four employees work in research, design, and development. Some external collaborations exist in different functional areas, such as clinical trials with domestic research organisations and with foreign universities. *Production Base* ISO13485 certified with a large part of the manufacturing done in-house, including 3D printing of components.	Advanced integration and coordination demonstrated by domestic and international supplier network of speciality components, sales & distribution network including an overseas office.

Source: Authors' own.

6.2. Inclusive technological change

Using our parameters for inclusion at various stages of the innovation process (Table 5, above), we have qualitatively analysed inclusive technological change as a result of the activities of the firms. The innovations developed by these firms are generated and clinically tested in a bottom-up process with the participation of people from the field who were deeply appreciative of ground realities. For firms like Sinapi and Shonaquip, this process is highly inclusive and collaborative. In the case of eMoyo, much of the understanding emerges from the experiences of the founder, who is a medical doctor, and R&D is largely internal to the firm. However, during the early stages of development, as well as for clinical trials, there has been involvement with experts from local universities. Therefore, it is also inclusive in some respects. All three firms have received government support for one or more activities (clinical trials, provisional patent application, certification, etc.). However, this is a small component of their overall product development costs. All three of the firms have well-established manufacturing and production facilities; source materials from domestic and international markets; and together have created over two hundred fifty jobs. Since the medical devices sector is still emerging, there are gaps in necessary technology infrastructure, such as specialised testing facilities. Each firm faces different challenges, which, to some extent, is related to the kind of product they manufacture and their specific infrastructure needs. While Sinapi has a highly sophisticated production base and also a well-established supplier base, eMoyo carries out a high degree of manufacturing in-house due to difficulties in building domestic reliable service providers. To overcome the lack of suitable domestic testing services and prohibitive testing costs overseas, Shonaquip is trying to set up an in-house ISO 17025 with an ISO 7176-8 certified testbed.

One or more products from all three firms have been diffused in the domestic market, assisting more efficient healthcare delivery in South Africa. In the case of Shonaquip, because its products lie in the domain of national initiatives and due to the company's hybrid model, the government is the primary client and has played a critical role in the diffusion process. 70% of Sinapi's products are sold in the domestic market, largely to private hospitals. However, it also participates in government tenders, and some of its products, such as the Ellavi, will be sold to the government at a differential cost due to the large volume of sales expected. In the case of eMoyo, it is primarily export-based due to insufficient local sales. However, one of its products, the KUDUwave, has been successfully used in the Department of Health's decentralised multi-drug resistant TB programme. An overview of the analysis is illustrated in Table 7 (below).

Table 7: Analysis of inclusive technological change at each stage of the innovation process.

Firm/Stage	**Shonaquip**	**Sinapi Biomedical**	**eMoyo Technologies**
Generation	Highly inclusive with all products emerging from specific unmet local needs and developed collaboratively in a bottom-up user-centric process involving a multitude of individuals and organisations, local as well as international.	Highly inclusive with all products addressing important domestic needs as well as having global relevance. The process of product development is collaborative and bottom-up, involving local as well international organisations.	Inclusive in some aspects as both its products are relevant for improving efficiencies in domestic healthcare delivery. However, there are some challenges to their large-scale adoption. Product development has been largely internal to the firm, but there have been domestic collaborations over the years for clinical trials.
Production	Highly inclusive as most procurement is done locally. Work environment is highly inclusive.	Highly inclusive as there is substantial local procurement, network of suppliers, and it provides over 150 employment.	Inclusive in some aspects: Most materials are imported, and production is in-house, but some very critical precision components are sourced locally. Production facility repurposed to manufacture special masks with CE Mark for domestic needs during COVID-19.
Diffusion	Highly inclusive with primarily a domestic market and catering to the government, hybrid model and differential pricing to optimise access to those who need it.	Inclusive with a large domestic market. Sales mainly to private hospitals and to government through tenders. Differential pricing planned for Ellavi to public healthcare due to large volume of sales.	Inclusive in some aspects. Primarily export and some local sales. However, one of its main products has been used in government healthcare programmes and for demonstration by NGOs in schools.

Source: Authors' own.

Typically, medical device frugal innovations would emerge from a point that existing devices may be too expensive or not suitable for conditions found in developing countries (usually both); or a product may simply not exist. Further, since a large percentage of people in these countries are dependent on public healthcare, even if frugal innovations are available but not part of the public healthcare delivery or reimbursed by private insurance, it is unlikely people would be able to afford them, and they would be lost to those who need it most. The empirical evidence, as summarised in Table 5, suggests that the activities of all three firms first have brought about inclusive technological change in different degrees.

It is important to mention here that all three firms were affected during the pandemic or responded to market needs in different ways. Shonaquip developed a Powered Air-Purifying Respirator (PAPR), which offers a flow of pure air for comfortable working, especially for front line healthcare workers. The product has a P3 virus filtration system, a transparent full view visor to enable lip reading and works for eight hours without charging. The cost of making the initial prototypes was crowdfunded through the BackaBuddy Campaign. Shonaquip is in the final stages of certification from the NRCS (National Regulator for Compulsory Specifications) certification. eMoyo, which sources a large part of its supplies internationally, had to stop production intermittently. The firm repurposed its facilities to manufacture high-quality CE certified masks for the domestic market.

6.3. Policy implications

This study offers a fresh perspective for policy actions intersecting medical devices, industrialisation, and inclusion. The medical device sector is a highly sophisticated and regulated industry, requiring accredited specialised testing infrastructure, ISO certification expertise and certified facilities. Multiple actors and institutions shape design, production, and delivery of innovation.

Therefore, the full impact of innovation investments would not be possible without the harmonisation of policies across institutions and actors. While the concept of 'innovation chasm' is very much adopted by South African policymakers in the context of research commercialisation, the production and redistribution of innovation are viewed less within a unified lens. The approach of an "institutional triad" could be a useful heuristic. As the empirical evidence shows, the firms in this study have been supported directly or indirectly by the state to some extent at various stages of the innovation process. However, R&D or innovation grants do not form a substantial component of the funding sources of firms in this study. One reason for this could be because STI funding, as noted in Section 3, is more geared towards state-of-the-art research within public research organisations and universities and less towards the private sector (Kruss & Lorentzen, 2009; OECD, 2007). This is typical in developing countries where public resources are concentrated in building capabilities in centralised organisational structures to create radical technology and less on firms that are dispersed and at the lower end of the innovation spectrum (Bell & Figueiredo, 2012). This structural divide has several implications. First, as pointed out in Section 3, a slower pace of capabilities accumulation at the productive base creates an imbalance of complementarities (Bell & Figueiredo, 2012). For a vibrant industry to emerge with a critical mass of innovations, in addition to high technology, incremental innovation and product

innovations centred around design and engineering with quick time to market is needed. Second, it is important to recognise that while some frugal innovations could be based on new platform technologies and new architectural innovation (Lim & Fujimoto, 2019; Rao, 2013), this is not the norm. Most do not emerge from radical technologies; but from incremental innovations or from product design and engineering. Many innovation studies have demonstrated the economic importance of incremental innovations emerging from the firm's engineering departments building on the existing knowledge base, not reflected in formal R&D budgets (Enos, 1962; Hollander, 1965). Consequently, a "policy mix" (Bell & Figueiredo, 2012) to support incremental or design innovations directly to SMEs, in addition to existing R&D funding initiatives, could boost the sector. It may also be important to recognise that drivers of innovation within academia and for firms are different, with speed and time to market being critical for the economic sustainability of the latter.

Another aspect where policy intervention would be critical relates to improved public health through access to these frugal medical devices and the indirect impact of innovation procurement on small domestic firms. In South Africa, where more than 80% of the population is dependent on the public health system, the primary way to ensure that frugal innovations reach those who need them most is only possible through public procurement. Without a preferential local procurement policy in place, many local companies struggle to compete with cheaper imports. Key components adding to the cost of domestic products where policy can play a critical role include testing infrastructure, accreditation, and registration. One of the key recommendations of the SAMRC – PATH (2014) was also the development of a more transparent public procurement process. As discussed in Section 3.3, public procurement of innovation and innovation-friendly procurement mechanisms proposed as a mechanism of integrating the top-down approach of transformative innovation policies with the narrow focus of innovation policy (Uyarra, et al., 2020; Uyarra & Flanagan, 2010) could be one of the key policy interventions. Some of the mechanisms could be in the form of government becoming the "experimental user" of new technologies and products (Malerba, 2007; Uyarra & Flanagan, 2010;), supporting clinical trials in public hospitals, etc. Table 8 (below) summarises the key discussion points and possible policy directions.

Table 8: Summary of discussion and possible policy directions.

Generation: STI Funding ● Currently: (a) Resources concentrated in building capabilities at public research organisations and spin-offs in high technology areas; (b) Less attention to building firm-level capabilities in innovative SMEs creates imbalance in complements (Bell & Figueiredo, 2012). ● Recognise: (a) Innovation drivers for academia and firms differ (SAMRC-PATH; 2014); (b) High economic impact is also possible from process, engineering, and incremental innovations (Enos, 1962; Hollander, 1965). ● Future direction: (a) Mixed portfolio including technology transfer, new technologies, incremental innovations, import, etc. (Srinivas, 2008); (b) Specialised funding schemes for innovative SMEs with a focus on design and incremental innovations (DST, 2019).
Manufacturing & Production: Industrial Policy ● Currently: An emerging sector with several enabling agencies and initiatives in formation/transition (Saidi & Douglas, 2018). ● Recognise (a) Medical device in South Africa represents a technology intense sector in resource constraint setting with competition from firms in HIC with efficient innovation systems (b) Innovative SMEs as "nucleus" of inclusive technological change. ● Future direction: (a) Capability building in innovative SMEs as a bottom-up industrialisation process (Kraemer-Mbula & Monaco, 2020) (b) Upgrade/create specialised S&T infrastructure for testing, metrology, certification, etc. (SAMRC-PATH, 2014).
Access and Diffusion: Public Health & Procurement ● Currently: No preferential procurement, higher cost of registration vs imports. ● Recognise: Frugal innovation users depend on public services, and access would not be possible without public procurement. ● Future direction: Enhance demand-side innovation policies (DST, 2019). More innovation-friendly procurement (Uyarra & Flanagan, 2010); government as "experimental user" (Malerba, 2007).

Source: Authors' own.

7. Conclusion

The COVID-19 crisis has reaffirmed the urgent need for affordable and appropriate (frugal) medical devices to meet the healthcare needs of developing countries as well, as the need to enhance regional capabilities for public health security. Our purpose in this paper was to demonstrate through a review of literature and empirical evidence that enabling innovative medical device manufacturing firms in South Africa offers an opportunity for both economic and social development. In contrast to earlier literature, this study has approached the problem from a micro-level perspective to analyse the stages of the innovation process that

are influenced by different policy domains and are not always well coordinated. Firm-level studies of African SMEs are rare, and the ways in which firms innovate remains a 'black box' in the minds of policymakers (Lorentzen, 2009). This paper has carried out a micro-level analysis of three medical device manufacturing firms in South Africa and proposed policy recommendations to accelerate the accumulation of capabilities.

The evidence highlights that in designing and successfully bringing to market frugal medical devices, these firms are not only enabling new pathways of technological change but also ones that are more inclusive. While these suggest more than an intermediate level of innovation activity in these firms, the equivalent complexities in technological or organisational structures do not always match that proposed in extant literature. It is likely that these differences are due to 'frugal processes' and the creative ability of 'doing more with less'. However, these firms operate in a space dominated by international players coming from high-income countries and resource-rich environments. The question that arises in a highly competitive global environment is: Could these frugal processes become a barrier to the firm's growth? And what kind of policies are needed to prevent that from happening? Future research could explore these questions. The prompt deployment of funding and technology support by the South African government during the pandemic to address shortages through local manufacturing was evidence of the country's capabilities as well as political commitment. In the eventual aftermath of the pandemic, this momentum can be carried forward to strengthen existing capabilities for both public health security and economic development.

References

Andreoni, A., & Chang, H. (2019). The political economy of industrial policy: Structural interdependencies, policy alignment and conflict management. *Structural Change and Economic Dynamics*, 48, 136-150. doi:10.1016/j.strueco.2018.10.007

Aragão, E., Guimarães, J. M., & Loureiro, S. (2016). The dissemination of local health innovations: Political economy issues in Brazil. *Making medicines in Africa* (pp. 166-182).

Arocena, R., & Sutz, J. (2003). Inequality and innovation as seen from the South. *Technology in Society*, 25(2), 171-182.

Arora, S., & Romijn, H. (2011). The empty rhetoric of poverty reduction at the base of the pyramid. *Organization* (London, England), 19(4), 481-505.

Aschhoff, B., & Sofka, W. (2009). Innovation on demand – Can public procurement drive market success of innovations? *Research Policy*, 38(8), 1235-1247. doi:10.1016/j.respol.2009.06.011

Basu, R., Banerjee, P., & Sweeny, E. (2013). Frugal innovation: Core competencies to address global sustainability. *Journal of Management for Global Sustainability*, 1(2), 63-82. doi:10.13185/JM2013.01204

Bell, M., & Pavitt, K. (1993). Technological accumulation and industrial growth: Contrasts between developed and developing countries. *Industrial and Corporate Change*, 2(2), 157-210.

Bell, M., & Figueiredo, P. N. (2012). Building innovative capabilities in latecomer emerging market firms: Some key issues. *Innovative Firms in Emerging Market Countries*. 24-109.

Carlsson, B., & Stankiewicz, R. (1991). On the nature, function and composition of technological systems. *Journal of Evolutionary Economics*, 1(2), 93-118. doi:10.1007/BF01224915

Chang, H. (2002). *Kicking away the ladder* (1. publ. ed.). London: Anthem Press.

Chang, H. (2014). Hamlet without the prince of Denmark: How development has disappeared from today's 'development' discourse. In Held, D., Rogers, C. B. & Charles, R. (Eds). *Global Governance at Risk*. Cambridge. Polity Press, 129-148.

Chang, H., & Andreoni, A. (2021). *Bringing production back into development: An introduction*. Retrieved from https://discovery.ucl.ac.uk/id/eprint/10124056. [Accessed May 24, 2021].

Chakravarty, S. (2021). Resource constrained innovation in a technology intensive sector: Frugal medical devices from manufacturing firms in South Africa. *Technovation*. https://doi.org/10.1016/j.technovation.2021.102397

Chataway, J., Banda, G., Cochrane, G., & Manville, C. (2016). Innovative procurement for health and industrial development. In M. Mackintosh, G. Banda, P. Tibandebge & W. Wamae (Eds.), *Making medicines in Africa* (pp. 224-242) Publisher: Palgrave Macmillan UK.

Chataway, J., Dobson, C., Daniels, C., Byrne, R., Hanlin, R., & Tigabu, A. (2019). Science granting councils in sub-saharan Africa: Trends and tensions. *Science & Public Policy*, 46(4), 620-631.

Chataway, J., Hanlin, R., & Kaplinsky, R. (2014). Inclusive innovation: An architecture for policy development. *Innovation and Development, 4*(1), 33-54. doi:10.1080/2157930X.2013.876800

Chataway, J., & Smith, J. (2006). The international AIDS vaccine initiative (IAVI): Is it getting new science and technology to the world's neglected majority? *World Development*, 34(1), 16-30.

Cirera, X, Maloney, W, F. (2017). *The Innovation Paradox: Developing-Country Capabilities and the Unrealized Promise of Technological Catch-Up*. Washington, DC: World Bank. © World Bank. https://openknowledge.worldbank.org/handle/10986/28341

Corsini, L., Dammicco, V., & Moultrie, J. (2021). Frugal innovation in a crisis: The digital fabrication maker response to COVID-19. *R & D Management*, 51(2), 195-210. doi:10.1111/radm.12446

Cozzens, S. E. (2008). Equality as an issue in designing science, technology, and innovation policies and programs. In Østreng, W. (Ed.), *Confluence; Interdisciplinary Communications 2007/2008*, Centre for advanced study at the Norwegian academy of science and letters.

Cozzens, S. E. and Kaplinsky, R. (2009). Innovation, poverty and inequality: Cause, coincidence, or co-evolution? In Lundvall, B., Joseph, K. L., Chaminade, C. & Vang, J. (Eds.), Handbook of innovation systems and developing countries. (57-82). Edward Elgar Publishing.

CSIR. (2020). *CSIR supports national COVID-19 response with locally developed ventilator*. Press Release. https://www.csir.co.za/csir-supports-national-covid-19-response-locally-developed-ventilator

Dahlman, C., & Westphal, L. (1982). *Technological effort in industrial development: An interpretive survey of recent research*. World Bank reprint series, REP263. Washington D.C.: World Bank Group.

Daniel, L. (2020). SA company gets R900 million to develop rapid covid-19 test – using tobacco plants. *Business Insider, S. A*, (December 27, 2020).

Denel. (2020). *Local ventilator projects are reaching critical stages*. Press Release.
Department of Science & Innovation. (2020). *Minister Blade Nzimande on funding awards to South Africa coronavirus COVID-19 testing ability*. Press Release.
https://www.gov.za/speeches/south-africa-covid-19-testing-ability-6-jul-2020-0000#

Driver-Jowitt, S. (2017). *A hybrid revolution enabling a sustainable response to social problems through multiple entities: A case study on Shonaquip*. [Unpublished Thesis, MPA]. Stellenbosch University.

DST. (2019). *The 2019 White Paper on Science, Technology and Innovation*. Government of South Africa.

DTI - Deloitte. (2014). *Research to guide the development of strategy for the medical devices sector of South Africa*. Deloitte for Department of Trade and Industry, Government of South Africa.

Dubois, A., & Gadde, L. (2002). Systematic combining: An abductive approach to case research. *Journal of Business Research*, 55(7), 553-560.

Durand, C., & Milberg, W. (2019). *Intellectual monopoly in global value chains*. Taylor & Francis (Routledge).

Dutrénit, G. (2000). *Learning and knowledge management in the firm*. Cheltenham, UK [u.a.]: Edward Elgar Pub.

Dutrénit, G. (2004). Building technological capabilities in latecomer firms. *Science, Technology and Society*, 9(2), 209-241.

Edler, J., & Georghiou, L. (2007). Public procurement and innovation – Resurrecting the demand side. *Research Policy*, 36(7), 949-963. doi:10.1016/j.respol.2007.03.003

Edler, J., Blind, K., Frietsch, R., Kimpeler, S., Kroll, H., Lerch, C., & Walz, R. (2020). *Technology sovereignty: from demand to concept*. Fraunhofer ISI, Karlsruhe. Retreived from http://publica.fraunhofer.de/documents/N-599757.html (Accessed on May 20, 2021).

Edquist, C., & Zabala-Iturriagagoitia, J. M. (2012). Public procurement for innovation as mission-oriented innovation policy. *Research Policy*, 41(10), 1757-1769. doi:10.1016/j.respol.2012.04.022

Eisenhardt, K. M. (1989). Building theories from case study research. *Academy of Management Review*, 14(4), 532-550.

Enos, J. L. (1962), Invention and Innovation in the Petroleum Refining Industry. In *The Rate and Direction of Inventive Activity: Economic and Social Factors*. National Bureau of Economic Research, Inc, p. 299-322.

Foster, C., & Heeks, R. (2013). Conceptualising inclusive innovation: Modifying systems of innovation frameworks to understand diffusion of new technology to low-income consumers. *European Journal of Development Research*, 25(3), 333-355.

Geroski, P. A. (1990). Innovation, technological opportunity, and market structure. *Oxford Economic Papers*, 42(3), 586-602.

Glaser, B., & Strauss, A. (1967). The Discovery of Grounded Theory: Strategies for Qualitative Research. Mill Valley, CA: Sociology Press.

Global Forum for Health Research, & World Health Organization. (2004). *The 10/90 (ten ninety) report on health research 2003-2004*. Geneva: Global Forum for Health Research.

Harris, M., Bhatti, Y., Buckley, J., & Sharma, D. (2020). Fast and frugal innovations in response to the COVID-19 pandemic. *Nature Medicine*, 26(6), 814-817.

Hollander, S., (1965), *The Sources of Increased Efficiency: A Study of DuPont Rayon Plants*, vol. 1, 1 ed., The MIT Press.

Howitt, P., Darzi, A., Yang, G., Ashrafian, H., Atun, R., Barlow, J., & Conteh, L. (2012). Technologies for global health. *The Lancet*, 380(9840), 507-535.

de Jager, K., Chimhundu, C., Saidi, T., & Douglas, T. S. (2017). The medical device development landscape in South Africa: Institutions, sectors and collaboration. *South African Journal of Science, 113*(5-6), 1-8.

Kaplinsky, R. (2011). Schumacher meets Schumpeter: Appropriate technology below the radar. *Research Policy*, 40(2), 193-203.

Katz, J. M. (1987). *Technology generation in Latin American manufacturing industries* (1. publ. ed.). Basingstoke, Hampshire u.a: Macmillan.

Kim, L. (1997). *Imitation to Innovation: The dynamics of Korea's technological learning*. Boston: Harvard Business School Press.

Knorringa, P., Peša, I., Leliveld, A., & van Beers, C. (2016). Frugal innovation and development: Aides or adversaries? *European Journal of Development Research*, 28(2), 143-153.

Kraemer-Mbula, E., & Monaco, L (2020). Informality and innovation: an avenue towards bottom-up industrialisation for Africa? In Charmes, J. (Ed.) *Research Handbook on*

Development and the Informal Economy. Edward Elgar Publishing, pp. 363-386. doi:10.4337/9781788972802.00026

Kraemer-Mbula, E., Tijssen, R., Wallace, M. L., & Mclean, R. (2020). *Transforming research excellence: New ideas from the Global South*. African Minds.

Kruss, G., & Lorentzen, J. (2009). The South African innovation policies: Potential and constraint. *BRICS and development alternatives* (pp. 163-190). London: Anthem Press.

Lall, S. (1992). Technological capabilities and industrialization. *World Development*, 20(2), 165-186.

Lazonick, W., & Mazzucato, M. (2013). The risk–reward nexus in the innovation–inequality relationship: Who takes the risks? Who gets the rewards? *Industrial and Corporate Change*, 22(4), 1093-1128.

Lim, C., & Fujimoto, T. (2019). Frugal innovation and design changes expanding the cost-performance frontier: A schumpeterian approach. *Research Policy, 48*(4), 1016-1029. doi:10.1016/j.respol.2018.10.014

Lorentzen, J. (2009). Learning by firms: The black box of South Africa's innovation system. *Science & Public Policy*, 36(1), 33-45.

Mackintosh, M., Banda, G., Tibandebage, P., & Wamae, W. (Eds). (2016). *Making medicines in Africa: The political economy of industrializing for local health*. Palgrave Macmillan.

Malerba, F. (2007). Innovation and the dynamics and evolution of industries: Progress and challenges. *International Journal of Industrial Organization*, 25(4), 675-699.

Marks, I. H., Thomas, H., Bakhet, M., & Fitzgerald, E. (2019). Medical equipment donation in low-resource settings: A review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries. *BMJ Global Health*, 4(5), e001785.

Meagher, K. (2017). Cannibalizing the informal economy: Frugal innovation and economic inclusion in Africa. *European Journal of Development Research*, 30(1), 17-33.

Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook* (2nd ed.). Sage Publications, Inc.

Nelson, R. R., & Winter, S. G. (1982). *An evolutionary theory of economic change*. Cambridge, Mass. [u.a.]: Belknap Press.

OECD. (2007). *OECD reviews of innovation policy. South Africa*. Paris: Organisation for Economic Co-operation and Development.

OECD/Eurostat (2018). *Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation. 4th Edition, The Measurement of Scientific, Technological and Innovation Activities.* OECD Publishing. Available at https://doi.org/10.1787/9789264304604-en.

Onsongo, E. K. & Knorringa, P. (2020). Comparing frugality and inclusion in innovation for development: Logic, process and outcome. *Innovation and Development*, [ahead-of-print].

Pagano, U. (2014). The crisis of intellectual monopoly capitalism. *Cambridge Journal of Economics*, 38(6), 1409-1429.

Papaioannou, T. (2011). Technological innovation, global justice and politics of development. *Progress in Development Studies*, 11(4), 321-338.

Papaioannou, T. (2014). How inclusive can innovation and development be in the twenty-first century? *Innovation and Development*, 4(2), 187-202.

Penrose, E. T. (1959). *The theory of the growth of the firm* (Reprint ed.). Oxford: Blackwell.

Perry, L., & Malkin, R. (2011). Effectiveness of medical equipment donations to improve health systems: How much medical equipment is broken in the developing world? *Medical & Biological Engineering & Computing*, 49(7), 719-722.

Prabhu, J. (2017). Frugal innovation: Doing more with less for more. *Philosophical Transactions of the Royal Society of London. Series A: Mathematical, Physical, and Engineering Sciences, 375*(2095), 1-22. Retrieved from https://www.jstor.org/stable/44678469

Prahalad, C. (2006). *The fortune at the bottom of the pyramid: Eradicating poverty through profits* (1st ed.) Pearson.

Prahlad, C. K., & Hamel, G. (1990). *The core competence of the corporation*. University of Illinois at Urbana-Champaign's Academy for Entrepreneurial Leadership Historical Research Reference in Entrepreneurship.

Radjou, N., Prabhu, J. C., & Ahuja, S. (2012). *Jugaad innovation* (1 ed.). San Francisco.

Ragin, C. C., & Becker, H. S. (1992). *What is a case?* New York: Cambridge University Press.

Ramaoka, S. T. (2020). *Technology transfer and capabilities in the medical device industry of South Africa*. Masters thesis. University of Johannesburg.

Romijn, H. A., & Caniëls, M. C. J. (2011). Pathways of technological change in developing countries. *Development Policy Review*, 29(3), 359-380.

Rothwell, R., & Zegveld, W. (1981). *Industrial innovation and public policy: Preparing for the 1980s and the 1990s* (repr. in 1982 ed.). London: Pinter.

Saidi, T., & Douglas, T. S. (2018). Medical device regulation in South Africa: The medicines and related substances amendment act 14 of 2015. *South African Medical Journal*, 108(3), 168-170.

SAMED – KPMG (2014). *Industry overview and economic impact assessment for the South African medical technology industry*: Prepared for the South African Medical Device Industry Association (SAMED). [Available at file:///C:/Users/63884sch/Downloads/prepared-for-the-south-african-medical-device.pdf. Accessed August 12, 2021]

SAMRC - PATH. (2014). *Developing an ecosystem to support the local medical device & diagnostics industry in South Africa: recommendations from an international perspective*. South African Medical Research Council.

SARAO (2020). *Request for information in support of the national ventilator project*. Press Release. https://www.sarao.ac.za/request-for-information-in-support-of-the-national-ventilator-project/

Scheffler, E. (2009). *What is an appropriate wheelchair?* Western Cape Rehabilitation Centre, Cape Town. Department of Health, South Africa. [Retrieved from https://www.wcrc.co.za/docs/34/What%20is%20an%20appropriate%20wheelchair.pdf Accessed April 30, 2020].

Schot, J., & Steinmueller, W. E. (2018). Three frames for innovation policy: R&D, systems of innovation and transformative change. *Research Policy*, 47(9), 1554-1567.

Siemens. (2020). *Siemens south Africa joins forces with the national ventilator project community in response to the COVID-19 pandemic*. Press Release. https://press.siemens.com/za/en/pressrelease/siemens-south-africa-joins-forces-national-ventilator-project-community-response-covid

Srinivas, S., & Sutz, J. (2008). Developing countries and innovation: Searching for a new analytical approach. *Technology in Society*, 30(2), 129-140.

Srinivas, S. (2012). *Market menagerie: Health and development in late industrial states.* Stanford, Stanford University Press.

Srinivas, S. (2016). Healthy industries and unhealthy populations: Lessons from Indian problem-solving. In Mackintosh, M., Banda, G., Wamae, W., & Tibandebage, P.(Eds.), *Making medicines in Africa*. London: Palgrave Macmillan UK, pp. 183-199.

Swanepoel, D. W., Maclennan-Smith, F. and Hall, J. W. (2013). Diagnostic pure-tone audiometry in schools: Mobile testing without a sound-treated environment. *Journal of the American Academy of Audiology, 24*(10), 992-1000. doi:10.3766/jaaa.24.10.10

Teece, D., & Pisano, G. (1994). The dynamic capabilities of firms: An introduction. *Industrial and Corporate Change*, 3(3), 537-556.

University of Cape Town. (2020). *UCT spin-off receives millions in European funding*. Press Release. https://www.news.uct.ac.za/article/-2020-12-22-uct-spin-off-receives-millions-in-european-funding

Uyarra, E., & Flanagan, K. (2010). Understanding the innovation impacts of public procurement. *European Planning Studies*, 18(1), 123-143.

Uyarra, E., Zabala-Iturriagagoitia, J. M., Flanagan, K., & Magro, E. (2020). Public procurement, innovation and industrial policy: Rationales, roles, capabilities and implementation. *Research Policy*, 49(1), 103844. doi:10.1016/j.respol.2019.103844

Visagie A, Swanepoel de W, & Eikelboom R. H. (2015). Accuracy of Remote Hearing Assessment in a Rural Community. Telemed J E Health. 2015 Nov;21(11):930-7. doi: 10.1089/tmj.2014.0243.

Weyrauch, T., & Herstatt, C. (2017). What is frugal innovation? Three defining criteria. *Journal of Frugal Innovation*, 2(1), 1-17. doi:10.1186/s40669-016-0005-y

WHO (World Health Organization) (2006). *Report of A consensus conference on wheelchairs for developing countries*. Retrieved from https://www.who.int/disabilities/technology/Wheelchair%20Consensus%20Conference%20Report_Jan08.pdf?ua=1 [Accessed on March 30, 2021].

WHO (World Health Organization). (2010a). *Medical devices: Managing the mismatch: An outcome of the priority medical devices project*. Geneva: World Health Organization.

WHO (World Health Organization). (2010b). *Landscape analysis of barriers to developing or adapting technologies for global health purposes*. Geneva: World Health Organization.

WHO (World Health Organization). (2012). *Local production and technology transfer to increase access to medical devices addressing the barriers and challenges in low- and middle-income countries*. Geneva: World Health Organization.

WHO (World Health Organization). (2016). *Towards improving access to medical devices through local production: Phase II: report of a case study in four sub - Saharan countries*. World Health Organization. Retrieved from https://apps.who.int/iris/handle/10665/206545

Yin, R. K. (2014). *Case study research* (5. edition ed.). Los Angeles: SAGE.

Zeschky, M. B., Winterhalter, S., & Gassmann, O. (2014). From cost to frugal and reverse innovation: Mapping the field and implications for global competitiveness. *Research Technology Management*, 57(4), 20-27. doi:10.5437/08956308X5704235

DSI/NRF/Newton Fund Trilateral Chair in
Transformative Innovation, the 4IR and
Sustainable Development (UJ-TRCTI)
JBS Park, 69 Kingsway Ave, Auckland Park
Johannesburg, 2092

General enquiries:
Telephone: 011 559 1792
E-mail: nabilanm@uj.ac.za
Website: www.uj.ac.za