

Social Technologies for Inclusive Innovation: Investigating development of affordable healthcare technologies for low income populations in developing countries

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Abstract

Healthcare systems all over the world increasingly rely on healthcare technologies for accurate diagnosis and effective cure in the treatment of diseases. In low-income countries, availability of essential medical devices, diagnostic equipment and biological drugs has emerged as a key part of healthcare policy and area of grave concerns for ensuring effective and inclusive healthcare. Yet, majority of developing countries struggle with access to affordable and appropriate healthcare technologies and rely on imports to satisfy local needs. In this context, this research explores the role of social technologies in the development of inclusive innovative health technologies targeted at low-income populations. Using case studies based in India, Kenya and Tanzania, this paper shows that the emerging new institutional arrangements and partnerships linking local needs, local institutions with global resources can pave the way in resolving unequal access to affordable and appropriate healthcare technologies. However, it also reveals that lack of adequate supportive infrastructure, absence of appropriate regulations and missing sustainable collective action may limit the ability of inclusive innovations and social technologies to meet local healthcare needs.

1.0 Introduction

Healthcare systems all over the world rely on drugs, vaccines and medical devices to provide effective and inclusive healthcare (WHO, 2012). However, the development and access to some healthcare technologies such as medical devices and biological drugs for low income populations has remained a neglected area in the studies focused on healthcare challenges in the developing countries. Medical devices include everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors (WHO, 2010). They are critical for diagnosis, effective use of medicines, patient care in operating theatres, at the bedside, and even before a patient is admitted into hospital, or after being discharged. In developing countries majority of research has focused on development and access to pharmaceuticals and vaccines even though medical devices constitute a key component in the health care technologies (Kale, 2011). WHO (2010, 2012) highlights that developing countries depend on the imports from the advanced countries to satisfy their healthcare needs, creating challenges of access to affordable and appropriate medical devices. Cheng (2007) revealing the 'mismatch' between supply and demand shows that in most cases imported medical devices are mostly unsuitable for local conditions and endanger lives of patients, health workers and communities. Referring the situation in Africa as 'medical device graveyards', Miesen (2013) comments,

"The premature and low birth weight babies lie cordoned-off from the rest in a narrow space where 20 incubators are arranged like Tetris pieces; most were donated by NGOs and bilateral agencies like USAID. Many lay open, and the silence is interrupted only by cries of newborns; no sound emanates from the machines. They aren't on. 13 of the 20 incubators are broken. The instructions for one (are) in Dutch. Ugandans typically speak Luganda, Kiswahili and English. Mulago's experience is not unique. Across Sub-Saharan Africa, "medical device graveyards" litter the empty closets and spare corners of hospital"

A World Bank review of the Bank's investment in medical devices from 1997 to 2001 provides clear evidence of this mismatch. The review found cases where, "about 30% of sophisticated equipment remained unused, while those in operation have 25% to 35% equipment downtime because of weak capacity to maintain the equipment" (World Bank, 2003). Similarly, a recent WHO (2010) report shows that more than 50% of devices remain unused in developing countries due to structural and cost factors, indicating further widening of the mismatch. As a result, access to appropriate and affordable medical devices has remained an ongoing challenge for most developing countries.' In similar vein, 'biosimilars' - imitative versions of biologicals – a therapeutic drug category comprising large complex molecules has emerged as key challenge for developing countries. Traditionally biologicals have been developed to address the most challenging Non-Communicable Diseases (NCDs) such as cancer, autoimmune diseases, diabetes, growth hormone deficiency and arthritis. The promise of biosimilars as significant opportunity for reducing healthcare costs and create affordable treatment for non-communicable diseases (NCDs) is being heralded in an era of growing aging populations and increasing healthcare costs. However, for many firms from developing countries the complexity of manufacturing biologicals and lack of financial resources has emerged as entry barriers and created a need for new sets of regulatory frameworks, institutional arrangements and partnerships (Kale and Niosi, 2017).

In the last decade, some research has focused on the issues of diffusion and access of medical devices and biosimilars in developing countries and much has been written about development of local production capabilities in developing countries, import from MNCs and

emerging country firms and role of global institutions (WHO, 2012; Kale, 2011, Nadvi, 1999; Loureiro et al., 2008; Kale and Niosi, 2017). Yet, the healthcare technology needs of low-income populations and inequality of access to imported devices and biological drugs appears largely intractable challenge and needs more attention. This raises the question: How healthcare technology needs of low-income population will be met? Evidence increasingly suggests that innovations based on traditional research and development (R&D) investment and existing institutional arrangements over the years have excluded healthcare needs of low-income populations (Chataway et al., 2014). There is a gap between skills and knowledge required to understand healthcare needs of this excluded populations and the intersection of private and public sector boundaries towards meeting them. This calls for a new framework of engagement and some researchers argues that the emerging ideas and models around inclusive innovations and social technologies incorporates the needs, interests and knowledge of low income populations with resources and capabilities of private sector, thereby providing opportunities to create appropriate solutions for intractable challenges of accessibility, availability, affordability and appropriateness (Kale et al., 2014). While much progress has been made on recognising the new models of innovation and institutional arrangements, discussions failed to provide overall coherent theoretical and policy insights that can aid in resolving healthcare needs of low income populations. This paper bridges this gap by using case studies inclusive innovations and social technologies from India, Kenya and Tanzania. It explores the role of inclusive innovation and social technologies in generating and delivering new 'physical technologies' and innovation processes needed by low-income users. Specifically, this research critically examines the potential for new 'social technologies' (innovative institutional and organisational forms and divisions of labour) and inclusive innovations, to provide a way forward to improve the development and delivery of physical technologies in medical device and biological drug needs.

2.0 Healthcare industries and needs of low-income populations

Healthcare policy researchers argues that “a strong local capability for both technological and social innovation in developing countries represents the only truly sustainable means of improving the effectiveness of health systems” (Gardner et al., 2007). Evidence from pharmaceutical industry suggests that local production potentially offers a cost-effective pathway to improving access to health care (Mackintosh et al., 2016). However, without adequate supportive infrastructure and active government support may lead to high costs of production and limit ability their ability to meet local healthcare needs (WHO, 2012). As such, a wider understanding of factors that influence access to medical devices and biological drugs in developing countries, and a better assessment of barriers that hinders this process, is essential for achieving the objective of inclusive healthcare.

There are two key characteristics of healthcare industries, which have clear implication for development of accessible and affordable healthcare in low-income settings. First key characteristic of healthcare industries relates to role of science and technology in evolution of the industry. In healthcare industries, there is significantly higher spending on R&D than in many other sectors and innovation in healthcare industries are driven by the progression in science and technology (Henderson and Cockburn, 1996). For example, in 1930s synthetic organic chemistry and soil microbiology generated significant opportunities for pharmaceutical innovation while in the 1940s and 1950s, advances in virology provided another set of new opportunities for entrepreneurship, followed shortly by a new wave of breakthroughs in microbial biochemistry and enzymology provided the basis for a new style of targeted pharmaceutical research and development (Galambos and Sturchio, 1998). This supply driven nature of healthcare industries influences technology development and has serious

implications for satisfying needs of healthcare market. As a result, industrial and technology policies adopted by the state have significant impact in shaping development of domestic healthcare industries.

Second key characteristic of the healthcare industries relates to the important role of regulation and Intellectual Property Rights (IPRs) in shaping evolution of industry and markets (Tait et al. 2009). Here regulation is viewed as a process involving the sustained attempt to control, order or influence the behaviour of actors so as to produce identified outcomes (Harmon and Kale, 2015). Regulation and IPRs forms an important third dimension to two pillars (Science & Technology policy and industrial Policy) of healthcare industries (Kale et al., 2012).

A good regulation also ensures availability of safe and effective quality healthcare products at a cost affordable to local population. An appropriate regulation and regulatory infrastructure restricts entry of counterfeit producers, provides clear regulatory guidance for manufactures and supports growth of healthcare market. However, in healthcare technology industries the existing regulatory requirements and resources needed to satisfy them has created an expensive R&D process that led to formation of an industry structure skewed in favour of MNCs with small firms struggling to survive. This costly and risky R&D process is hindering development of technologies required to satisfy needs of low-income populations.

Significance of IPRs in healthcare industries is evident in the emergence of biotechnology industry. The ruling in a landmark case of the 1980s, *Diamond vs Chakarvarty* that allowed patenting of live organisms has been credited with the rise of the biotechnology industry. That case involved a patent claim on a genetically modified, oil eating bacterium. USPTO rejected the claim on the basis subject matter was living organism and ineligible for patent protection and that resulted in patenting only methods of production and not produced 'strains'. But in 1981, the US Supreme Court granted extension of patentability to genetically engineered bacteria, which gave birth to the current biotechnology industry (Eisenberg, 2006). Another example of the way in which IPR have impacted on the evolution of the sector in developing countries is provided by rise of Indian pharmaceutical industry as a main source of cheap generic medicines all over the world. The Indian government intervened through weakening of IPR and created an industry with required credentials to better serve the needs of its people (Chataway et al, 2007). Shifts in policy and investment encouraged the growth of an industry focused on the healthcare needs of poor people with producing medicines at affordable prices being the main concern.

These two characteristics have given rise to the MNC dominated industry structure and key market constraints, that are playing a role in heightening on-going health inequalities and slow progress in developing healthcare products for low-income populations in developing countries.

In response, there has been significant activity in last decade by government in advance countries and philanthropic foundation to create the 'pull' mechanisms in form of providing demand incentives for companies to invest in product for low income users as a complement or an alternative to push initiatives (Chataway et al., 2007). For example, the Gates Foundation launched Advance Market Commitment (AMC) scheme to resolve market failure and push development of pneumococcal vaccine at affordable cost to poor populations in low-income countries. However mixed success of these initiatives suggests that neither demand pull nor supply push will (on their own or in combination) solve the problem of health innovation for low income countries. Kale et al., (2012) suggests that there is a need for new institutional and organisational forms which can address the requirements of low income users as their core concerns and it requires new systems and new interactions built on the back of them. In this context, there has been significant academic research and policy interest in examining the

emerging models of inclusive innovations and institutional arrangements that can incorporate the needs, interests and knowledge of LMIC populations (Kaplinsky, 2013; World Bank, 2013; UNCTAD, 2014). This has lent to urgency to understanding how LMICs populations can effectively participate in and benefit from inclusive innovations and social technologies, and to develop theory, concepts and metrics that can guide policy making and implementation. This research contributes to the emerging social science discourse focused on whether innovation and innovative institutional arrangements can contribute to greater inclusion and sustainable prosperity of low-middle income countries (LMIC) by focusing on the healthcare technology sectors in emerging countries. It focuses on understanding how innovation and social technology can aid in facilitating inclusive healthcare, thereby creating an evidence base that can shape policy to foster affordable and accessible healthcare to LMICs.

3.0 Healthcare technologies in developing countries: Medical devices and biosimilars in developing countries

This section focuses on medical device and biosimilars and discusses key characteristics, industry and market structure and challenges associated with their access in developing countries.

3.1 Medical device industry

Medical devices cover the spectrum from in-vitro diagnostics, medical imaging, single use devices, surgical instruments, assistive devices to all medical equipment, including diagnostic and interventional imaging, laboratory and all electro-medical equipment (WHO, 2012). As a result, medical device industry is characterised by the diversity in medical devices, their applications and underlying knowledge bases that goes into their development. There are over 10000 different types of medical devices ranging in complexity, price and life span from single-use catheters to complex equipment for radiotherapy.

Import driven and handicapped medical device industry in developing countries

The medical device industries based in developing countries are few and focused on the low-tech part of the sector. The diversity and scale of health challenges in developing countries make the role of medical devices even more significant but according to WHO (2012) only 13% of manufacturers are located in developing countries. Many developing countries depend on imports rather local production to satisfy their healthcare needs. For example, table 1 shows that leading developing countries import significant proportion of medical devices from overseas countries and in 2010 they were valued at just over US\$3.2 billion. It showed the rise of 4.9% over 2009 and a CAGR (compound annual growth rate) of 7.5% for the period 2006-10 with Western and Northern Africa showing faster import growth compared to other regions in Africa.

(Table 1 here)

The leading suppliers of medical devices to the African region are: Germany, France, the United States, China, and the United Kingdom. Some emerging countries such as India, China and Brazil are leading exporters of medical devices to other developing countries. But analysis of manufacturing patterns suggests that these countries dominate low-tech segments while advanced countries dominate high-tech segment (WHO, 2010).

- **Mapping of technological capabilities in developing countries**

In this research, the manufacturing capability in the developing countries is mapped by employing a novel - technology intensity and local product capability - matrix using data from WHO reports (2010, 2012). In this matrix, the technological intensity of products is classified

based on risk categorisation used by the MHRA (Medicines and Healthcare Regulatory Agency); devices with low risk are categorised under low technological intensity while devices with medium and high risk are taken under medium and high technological intensity. Local production capability refers to domestic production of medical devices by a country utilising that device to solve a local public health need (WHO, 2012). This domestic production can be either through international or domestic firms, though majority of this ownership should be national.

(Fig 1 here)

This analysis points out that the advanced country firms extensively dominates high risk, high tech segments and for developing countries, this creates a mismatch between the design and cost of devices and the user context. Resource constraints – along with the environmental and operating conditions, including climate, access to water, electrical supplies and transportation conditions – add to the complexity of using these medical devices in developing country contexts. Further in developing countries diversity and scale of diseases makes role of medical devices even more significant.

Thus, prevalent resource constraints, along with the diversity and scale of disease, make the imported devices either unaffordable or inappropriate for local populations. Given the levels of inequality in purchasing power and divisions between public and private healthcare, there is a case for increased research on the access to affordable and appropriate medical devices in developing countries.

3.1.2 Key challenges

Researchers focused on issues of the access and diffusion of medical devices in developing countries points out that purchasing power and the structure of medical payment and reimbursement systems as key determinants (Oh et al., 2005). Analysing issues of access and diffusion of medical devices in Latin America, Loureiro et al., (2008) demonstrates the need of a 'regulatory agency' to develop guidelines for priority setting and allocation of devices to achieve goal of both efficiency and equity. Their explorative study concludes that unequal diffusion of essential medical devices may be the key aspect of healthcare inequality in developing country contexts.

- **Missing government – Industry interactions**

The lack of national industrial policy in majority of sub-Saharan African countries creates a key barrier in development of effective and efficient manufacturing infrastructure and local technological capabilities. This absence of national industrial policy and lack of infrastructure is hindering opportunities for sustainable technology transfer. For example, according to WHO (2013) 54% of lower middle income countries do not have any guidelines for the procurement of medical devices and more than the half of African countries procure devices with no national guidelines. This lack of procurement guidelines gives rise to malpractices and hinders access to appropriate medical technologies. A senior manager with South African Medical Device Association (SAMED) suggests that policy makers struggle to grasp requirements of medical device industry due to diversity of products and different types of knowledge bases:

“I think that we need to create greater awareness of the challenges that our industry faces and educate stakeholders on how our industry is different and it requires different policies, diff procurement practices and different requirements than pharmaceuticals. Our government (South African) has been managing pharmaceuticals for a very long time and they take what they know and try to apply it to medical devices and it doesn't often work”.

- **Missing regulation**

Medical device regulations are established in over 70 countries in the world. Medical device regulation is vital in not only ensuring safety and efficacy but also access to medical devices. The difficulty in establishing regulatory system is related to financial resources, organisational infrastructure and availability of human resources with specialised scientific and clinical expertise. According to WHO (2013) 53% of low-income countries (18 out of 34 low income economies) and 45% countries in Africa do not have any medical device regulatory authority. Evidence suggests that ignorance of medical device industry along with lack of resources and capability has resulted in absence of regulation in significant number of developing countries. A member of South Africa Medical Device industry association comments,

“Unfortunately, in South Africa, we are primarily unregulated industry, electro-medical equipment is regulated by the Department of Radiation Control, which is sub-department of the National Department of Health and some combination of health devices are regulated by the Medicines Control Council, inappropriately so we believe. In fact, it’s interesting that a lot of the provincial departments of health don’t even realise that we are unregulated”

- **Missing research ecosystem**

The product development in medical device industry requires close collaborative relationships between research hospitals, research institutes and private firms. It needs continuous interactions between clinicians, surgeons and engineers to identify a technological solution of healthcare challenge. The weak public health system in Africa makes it challenge to create a research ecosystem and in the process severely hampering development of local technological capabilities. Further, there is significant lack of quality education for biomedical engineers and effective training programmes for clinicians and other health care professionals. A member of SAMED comments,

“No enough is being done to build capacity, to educate and upskill people in other fields other than pharma. There remain infrastructure issues, IT issues’

Next section focuses on the key characteristics, industry and market structure and challenges associated with development of biosimilars in developing countries.

3.2 Biosimilars: Generic biological drugs

Biosimilars are generic versions of biologics - a therapeutic drug category comprising large complex molecules. Biologicals drugs have emerged as significant therapy in treatment for cancer and autoimmune disease but only 8% of patients are able to access these therapies due to high costs of these drugs (Rao, 2016). In last few years some block-buster biological drugs have gone off-patent creating potential for developing biosimilars and providing scope for affordable therapies. But in developing countries absence of local production capability and dependence of import continues to make it harder to deliver affordable therapies.

Mapping of technological capabilities for biosimilars in developing countries

Switching to biosimilars is not an easy, minimum risk strategy. Biosimilars are too complex to manufacture in the same way as simple small molecule drugs (e.g. aspirin) and require considerable financial and organisational investment in developing regulatory, technical and scientific capabilities. A novel technology-market capability matrix is employed to map technological capabilities of key firms from developing and advanced countries involved in the development of biosimilars. In this matrix, technological capabilities are classified based on diversity of biosimilar product portfolios while market capabilities are classified on the basis of diversity of a firm’s markets. Market capabilities are linked with regulatory and technical capabilities in that advanced country markets have more stringent regulatory requirements

relative to emerging and developing countries. Firms operating in advanced country markets or a significant number of other emerging markets, show superior technological and regulatory capabilities.

(Figure 2 here)

Firms from Germany, Israel and USA dominate biosimilars markets in advanced regions and has contributed to reduction in cost of healthcare in those regions. But these firms don't cater to low-income markets of developing countries. Some firms from emerging countries such as South Korea and India have made transition towards the development of advanced level of biosimilar capabilities. However, firms from these countries are catering to their domestic market and targeting affluent populations in other emerging countries as well as advanced countries (Kale and Huzair, 2017; Hwan, 2017). There is evidence that suggest that firms from China and some Latin American countries such as Argentina and Mexico has made investment in development of biosimilars, yet to make impact on needs of low-income countries (Gutman and Laravello, 2016). In case of China, biosimilars have been on domestic market for 20 years with the launch of first human interferon beta 1b in 1989 and now there are over 200 firms producing over 2000 biosimilars (Gabi, 2010). Unlike other countries there is no specific regulation process for biosimilar in China and that has restricted dominance of Chinese firms to their domestic market.

3.2.1 Key challenges

The challenge of different knowledge base

Accessing small molecule generics markets in advanced countries involved creating non-infringing processes or invalidating an existing patent. The knowledge base for this builds on organic and synthetic chemistry skills (accumulated through reverse engineering). Some firms have used this base to add a patentable innovative element that provides value through leveraging process R&D capabilities. In the case of biosimilars, these firms need expertise to reverse-engineer biologics and develop stable, therapeutically active cell lines. They also need to develop manufacturing processes to meet specifications and to invest in new infrastructures for controlling living cells, purification, and producing biologic products consistently at commercial scale (Lee et al., 2011). The mechanism of action for some novel biologics is yet unclear, particularly with precision medicines. Here, knowledge from structural biology, rational drug design and systems biology becomes more important. The main constraint for developing country firms is the lack of knowledge in particular areas of medicinal chemistry and biology pertinent to biosimilars and expertise with regards to quality, safety and efficacy (Interview, senior scientist, Serum Institute of India, 2014).

The challenge of regulatory requirements

In the case of small molecule generics markets firms have to conduct bioequivalence or bioavailability studies to establish similarity of the therapeutic product and get approval from regulatory authorities to sell in the market. However, in the case of biosimilars, regulatory authorities demand extensive clinical data requiring clinical trials over a longer period. Developing countries are facing severe challenges in understanding the detail in the regulatory requirements for biosimilars, which are not only different from that, which applies to generics and biologicals; creating a generic version of a biologic that is identical to its reference product is close to impossible. Understanding the possibility and consequences of even small variation requires knowledge in new fields of biology. The head of biosimilars at a leading Indian firm illustrates this with the example of immunogenicity. In the case of small molecules, drugs rarely elicit immune responses but large molecules such as biologicals can trigger immune responses

of varying consequences (Interview, 2014). In the case of biosimilar vaccine candidates there must be equivalent immunogenicity compared to a reference biologic. Further, establishing systems for phase 4, post-market adverse event reporting and generation of pharmacovigilance data (which is especially important for vaccines) involves significant financial investment and organisation capability over a longer period. African countries are still struggling to frame appropriate biosimilar legislation although in 2014, regulatory experts and pharmaceutical industry representatives from 11 African countries convened to discuss the implications of biosimilar development and introduction across the region.

Financial and infrastructural resources

The complexity of biological drugs emanates from the elaborate manufacturing and regulatory processes involved in their production. Technical competencies are required for upstream verification of similarity or comparability with an innovator product and downstream pharmacovigilance data generation. As biosimilars can compete not just on price, but with improved formulations and different methods of drug delivery, some innovative capabilities can be advantageously employed for competitive advantage (Barei et al., 2012). Referring to financial challenges, a senior pharmaceutical scientist based at Utrecht University in the Netherlands argues:

“[US and European] markets will be dominated by ‘Big Pharma’. It takes between 50 and 100 million euros to develop a biosimilar that meets the regulations in Europe, the US and Japan.... that’s in addition to post-marketing costs and pharmacovigilance demands. I do not see how a small company, especially from India and China, even if they have the technical skills and money to develop a high quality biosimilar could be able to compete with Teva, Sandoz or Hospira” (Interview, Jayaraman, 2010)

This discussion highlights key challenges for creating access to medical device and biosimilars for low income populations in developing countries. It reveals that Low-middle income countries struggle with technological know-how and financial resources to create innovative products appropriate to local context and that demands a new framework to engage and satisfy healthcare needs of developing countries.

4.0 Social technologies and Inclusive innovation

Innovation can be defined as entrepreneurs search for new goods and services, methods of production, factors of production and new markets and industry, shaped within social context to address public needs (Schumpeter, 1942) or ‘the successful application of new idea to use’ (Kaplinksy and Morris, 2008). Kim and Nelson (2000) argue that in developing country context “most innovations do not involve breakthrough inventions but are deeply rooted in existing ideas” (Kim and Nelson, 2000:5). Elaborating on this further, Malerba and Nelson (2012) point out that “catching up does not mean cloning”. They suggest that the outcome of an imitation effort reflects modifications required to fit practice to local contexts. Due to this, the development process involves innovation in the Schumpeterian sense: ‘as a break from traditional ways of doing things’. However, evidence that increasingly suggests inability of innovations based on traditional research and development (R&D) investment over the last decades to meet needs have excluded a significant portion of the world's population. It is argued that to the larger extent these innovations have focused on meeting needs of higher income consumers in advanced and developing countries (Heeks et al., 2014). The profit seeking nature associated with traditional innovation model, requirements of capital intensive expenditures and inability to understand requirements of low-income needs makes traditional innovation model redundant in meetings needs of poor populations (Kale et al., 2014; Papaioannou, 2014).

This has given rise to concepts such as inclusive innovation and social technologies that focuses on participation and needs of low-income populations. These concepts draw inspiration from the 'Sussex Manifesto' (SM) (Singer et al, 1970), The Appropriate Technology (Schumacher, 1973) and the 'Bottom of the Pyramid' (BOP) approach (Prahalad, 2005) blending traditional and new technologies (Kaplinsky, 2010) to meet the needs of the low-income populations. These emerging models point towards innovation that incorporates the needs, interests and knowledge of low-income populations and has been discussed using a variety of terms including; reverse innovation; Frugal innovation; grassroots innovation; jugaad innovation; below the radar innovation; and of course, inclusive innovation (Govindrajan and Trimble; 2012; Chataway et al., 2014; Smith et al., 2013; Arocena and Sutz; 2012; Srinivas and Sutz; 2008; Prahalad 2005). This form of innovation attempts to make innovation paths, processes and products inclusive and aims to fill the gaps that remains neglected by the traditional R&D models of innovation and/or mainstream model of innovation (Heeks et al., 2014). Here the inclusivity refers to inclusivity of product and diffusion (including by meeting unmet demand or need), of process (including disadvantaged groups in production), of systems of production and delivery (integration of different market and non-market mechanisms to ensure production and delivery to products and services) and inclusion in the innovation system (including marginalized knowledge systems and practices in the innovation process) (Kaplinsky, 2013). Dandonoli (2013) points out that inclusive innovation tends to be highly durable and broad spectrum and has potential to challenge status quo by disrupting existing systems, institutions and ways of working. This discussion does suggest the centrality of social technologies and inclusive innovation in meeting the needs of low income populations (Mukherjee, 2014).

While there has been significant academic research in recognising the need for a new way for thinking about innovations that can incorporate the needs, interests and knowledge of LMIC populations (Kaplinsky, 2013; World Bank, 2013; UNCTAD, 2014), not much has yet resulted in coherent policy insights and failed to provide overall coherent theoretical and empirical picture of this new phenomenon (Papaioannou, 2014). Some researchers have raised questions about performance and ability of these innovations to satisfy needs of low income populations compared to innovations derived from traditional innovation model (Heeks et al., 2015). This has lent urgency to understanding how LMICs populations can effectively participate in and benefit from inclusive innovations and social technologies, and to develop theory, concepts and metrics that can guide policy making and implementation. At present, however, there is not yet a systematic way to measure how well different approaches to inclusive innovation and social technologies succeed in resolving healthcare needs of LMICs. There is a clear need for systematic, integrated and interdisciplinary investigation of the full range of actors, interactions and institutions involved in inclusive innovation activities as well as clarity about their impact on satisfying 'needs' of low income populations.

This research engages with these issues by focusing on the inclusive innovations and their impact on healthcare sectors in developing countries. Evidence suggests that market for global health technology is not efficient to deliver needs of low-income populations from developing countries. MNCs have technological capabilities and financial resources but so far have shown limited understanding of the needs of fragmented low income markets. While local production of technology and technology transfer is one potential way to increase access to medical devices and biosimilars, additional research is needed to understand how to create an adequate environment that will transfer the benefits of innovations and technologies to the most vulnerable and disadvantaged groups. In this context, the partnerships between different

stakeholders to develop a solution to local need has emerged as a possible route for addressing healthcare systems gaps. WHO (2012) report suggests that addressing disparities in access to healthcare technologies is a complex challenge, as it requires enhancing regulatory, technology, management and procurement assessment systems, and developing innovative and appropriate technologies that more effectively address the needs of populations in low-income countries. It aims to explore how innovation and social technology can aid in facilitating inclusive healthcare and create an evidence base that can shape policy to foster affordable and accessible healthcare to LIMCs.

4.1 Inclusive innovations and healthcare sectors in developing countries

The global healthcare technology industries and market structure raises three key issues of affordability, accessibility, and appropriateness in context of low-income countries. As a result, healthcare technology sectors and systems have witnessed significant proliferation of inclusive innovations and social technology solutions (Vadakkepat et al. 2015; Govindrajan and Ramamurthy, 2013). Recent research has focused on inclusive innovation in healthcare technologies (e.g. Ramdorai and Herstatt, 2015) and role of social technologies in healthcare – although these researchers have not explicitly used the terminology of social technologies (e.g. Burns, 2015; Singh and Lillrank, 2015). However, not much research is focused on the intersection between the two through case studies or looked comprehensively at the healthcare technology sectors in low-income settings. This research aims to fill this gap by focusing on four social technologies for inclusive innovations in low-income setting.

In last decade, some developing countries have witness the emergence of new institutional arrangements through collaborations between MNCs, government authorities and local firms or NGOs targeted at resolving local needs. The Global Medical Technology Alliance (GMTA), a medical technology association whose members supply nearly 85% of the medical devices and diagnostics purchased annually around the world, responded to the WHO (2010) report on mismatch of medical devices by arguing for more focus on new institutional arrangements. These new arrangements in medical device sector are relatively recent phenomenon but quite a few such partnerships have been working on issues of global health. Table 2 lists some of the partnerships involving leading MNCs and local institutions focused on medical device sector.

(Table 2 here)

In case of biosimilar efforts to create access to affordable biosimilars in low-income countries is led by private firms from emerging countries. These firms are working with local government and civil society organisations to set up production and distribution networks in low-income countries. For example, in 2016 the WHO launched an initiative with the support of Utrecht University, local manufacturers in low income countries to bring a biological drug to market at the lowest possible price. The drug, called palivizumab, protects against the common virus RSV; the second most common cause of death in children up to one years of age in low income countries. The four companies, mAbXience, Libbs, Medigen and SPIMACO, have signed a contract to produce this drug with Utrecht University and the WHO. The companies in the consortium will share development costs while Utrecht University will be carry out pre-clinical, clinical research and quality control of the locally produced medicines. One more initiative in this direction has been Cipla, an Indian pharmaceutical firm's initiative to set up biological production in Africa. These initiatives provide a good background to study the role of social technologies in the development of inclusive innovative health technologies targeted at low-income populations.

5.0 Research Methodology

This research investigates how well different approaches to inclusive innovation and social technologies succeed in resolving healthcare needs of LMICs. It focuses on understanding how innovation and social technology can aid in facilitating inclusive healthcare, thereby creating an evidence base that can shape policy to foster affordable and accessible healthcare to LIMCs.

Two phase data collection was carried out. The first phase involved conducting a preliminary research to identify inclusive innovations and social technologies developed to resolve medical device and biosimilar needs of low-income populations (Table 3).

(Table 3 here)

Based on preliminary research four case studies were chosen based on the nature of stakeholders involved, short and long term needs of low income population and potential impact on affordable and accessible healthcare. Each case study involved a different lead player that differed in nature and purpose of engagement with low-income populations. This provides good scope for comparative analysis between roles and contribution between stakeholders. Following preliminary research, semi-structured interviews were conducted with stakeholders associated with inclusive innovations and social technologies. Participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities. In total 15 interviews were conducted. Semi structured questions focused on the technical, organisational aspect of inclusive innovation, impact of inclusive innovations on affordability and accessibility of healthcare for low income populations and their performance compared to products from traditional R&D model. Interviews also elicited information about key barriers and issues associated with development of inclusive innovations in healthcare industries in low-income countries.

5.1 Case studies of healthcare technology inclusive innovations

This section discusses four case studies of social technologies for inclusive innovations in healthcare sectors of developing countries.

5.1 Sree Chitra Heart valve

The rheumatic heart disease is a leading cause for damage to mitral heart valve in developing countries. In 2008, the number of children suffering from rheumatoid heart diseases and needing a heart valve replacement surgery were highest in Africa (1008207) followed by Latin America (136971), Asia (101822) compared to 33,330 in advanced countries (WHO, 2012). In case of India, Satsangi (2011) points out that even though there are over 200 centres performing around 50,000 heart surgeries per year, the total number of cases (3.5 millions) of rheumatic heart disease requiring treatment remains colossal. One of the common treatments to address this disease was the replacement of damaged heart with either an artificial mechanical heart valve or a biological valve of animal origin. Like other high-tech devices the heart valve market in India was largely met by expensive imports that were unaffordable to the low-income population. Leading supplier of heart valve includes three MNCs such as St. Jude, Medtronic and Edward life sciences (Table 4).

(Table 4 here)

The growing need for affordable heart valves led to the initiation of Sree Chitra's mitral heart valve project. In 1973, Prof. Valiathan started Sree Chitra Institute with help of the Royal Family

of Travancore and in 1976 initiated a project to develop indigenous mitral heart valve in India. In 1980, the institute was taken over by the central Indian government and Department of Science and Technology (DST) started providing funds for heart valve project. India's biomedical engineering industry was quite nascent in 1978. Scientists working on the projects reveal that product development was constrained by unique cultural factors such as religious beliefs (which ruled out porcine and bovine transplants), market perceptions, and logistics. As a result, scientists decided that the indigenous valve would be a mechanical device, not one that used human or animal tissue. However, development of heart valve proved a very challenging process.

The artificial valve must withstand the stress of opening and closing some 40 million times a year while the materials used for the valve should be compatible with blood and human tissues (Gopalraj, 2009). Within few years, the project developed a prototype but it suffered a major setback when a model failed to work in sheep due to faulty material and the search for new material had to start anew. Over 12 years, Sree Chitra evaluated four models that incorporated different materials. The result was a mechanical heart valve with a tilting occluder made of tough and wear-resistant plastic, a metallic cage, and a sewing ring of knitted polyester fabric. The device was made entirely of mechanical components, was simple in design, easy to transport, and was manufactured locally. Above all, it was roughly one-third the price of comparable imports. Finally, in December 1990, after clearance was obtained from the Institute's ethics committee, the first Chitra valve was implanted in a patient. Prof. Valiathan explains the process as a 10-year struggle,

“Chitra Valve development happened in the late 70s. In a small institute in Trivandrum with limited resources, we could demonstrate that it could be done. By resources, I don't mean just money but technology resources, like different types of materials, textiles, fine fabrication techniques; all these were available in India. Only thing is you had to shop around, and find them, integrate them and then only you could make a device. We showed that this was feasible”

(Nagrajan, 2013)

Raghu (2007) points out that the Chitra-TTK mechanical valves are sold at about a quarter cheaper than similar imported valves. But leading surgeons demanded that the products meet international quality and safety standards, while local populations felt that products “made in India” were inferior to imports. The absence of specific regulation for the industry created significant obstacles. Dr. Valiathan explains,

“At the time, Sri Chitra was on the cusp of developing a range of local alternatives to imported devices, but we had no clue whose approval to take to launch product. Until there's a law all decisions become ad-hock”

(Kamath, 2007)

Scientists working on heart valve project decided to get the product tested with international regulatory authorities further delaying the project and increasing cost of product development. The product met standards of relevant international protocols for laboratory tests and animal trials and cleared ethics committee review. It debuted in 1990. One year later, TTK Healthcare in-licensed the technology for the manufacture of the valve.

To date, the device is the only locally manufactured heart valve that was made in India and is used in around 275 centres in India. Approximately 55 000 valves have been implanted since

1990. It steadily supplies a sizable portion of domestic demand for heart valves which is roughly 30 000 per year and is being exported to other countries such as Kenya, Myanmar, South Africa, Sri Lanka and Thailand.

5.2 Rehabilitating diagnostic services: ORET and Philips healthcare

A key challenge of providing effective and affordable healthcare in Sub-Saharan Africa is availability of appropriate diagnostic services, trained clinicians and engineers. With this objective “Rehabilitating Diagnostic Services” program was launched in 1998 by Philips Medical Systems BV (PMS) with financial support coming from ORET initiative by the Dutch Ministry of Foreign Affairs and Tanzanian Ministry of Health and Social Welfare (MoHSW). The project aimed at improving the quality of health care services by halting the deterioration of diagnostic services in the country. The transaction amount was € 26,774,848 and the definitive ORET grant was determined at € 16,694,909 (60% of the total transaction costs). This project involved supplying diagnostic equipment to 98 regional and district hospitals in Tanzania and providing training on its use and maintenance. It was based on a comprehensive approach and the long-term cooperation between the PMS and the Tanzanian Ministry of Health and Social Welfare (MoHSW). The Tanzanian project furnished 98 hospitals with diagnostic equipment, such as X-ray, ultrasound scanners and laboratory photometers, and equipment for surgical and dental treatment. Buildings were rehabilitated, water treatment units and power generators were installed to ensure availability of clean water and electricity. Training was provided for hospital staff and service engineers.

There were financial challenges in the Tanzanian project. Halfway through 2000 the Tanzanian government faced difficulties into meeting its financial obligations and that caused delayed in transferring funding to supplier. This led Philips halting supplies and because of which the project was delayed by at least one year. By 2006, all hospitals in Tanzania were supplied with X-ray and ultrasound equipment and with equipment that was more basic, less expensive, and delivered only to selected hospitals. Parallel to installing the equipment, training of professionals – mainly radiographers and technicians (the latter in four zonal workshops) – took place. It was claimed that in the total 434 staff members of 98 hospitals were trained but a review of the project found that the short training (two weeks) considered too short and by 2015, these workshops have been closed. Eight technicians were successfully trained and employed by MoHSW to work in the four zonal maintenance centres. This review points out that the project did improve the diagnostic services at district, regional and tertiary (referral and specialised) hospitals through provision of medical equipment and infrastructure, preventive and corrective maintenance, training and technical assistance. But it reveals that there are severe issues with sustainability of equipment and trained technician and clinicians. For example, review found out most ultrasound devices worked for seven to eight years but after 14 years this equipment has stopped functioning. It further shows that only 60% of the X-ray machines (excluding the dental X-rays) are still functional, and remaining 40% are partly functional. Most manual darkroom equipment is still functional (16 out of 19) but is outdated and/or of poor quality. This situation is further compounded by absence of maintenance after completion of initial implementation stage. The contract between the Government of Tanzania and Philips for maintenance did not guarantee regular maintenance, since MoHSW did not pay for the services provided. Hence, PMS and its local representative (Mokasi) have now stopped services and this has led to technical problems at several locations. Review report also found that none of the eight technicians trained to be employed in the four zonal workshops is currently working for MoHSW. They have retired or changed jobs. The workshops are no longer operational, making MoHSW fully dependent on commercial suppliers such as Mokasi. This report concludes by highlighting uncertainty in the continuation of diagnostic services in

Tanzania due to lack of financial arrangements or any proposed projects to ensure sustainability.

Building on Tanzanian partnership, in 2001 PMS entered in a seven-year project to modernise the healthcare infrastructure of the Republic of Zambia. This initiative was also part of the Dutch government's ORET international development initiative, with the Dutch and Zambian governments, each contributing 50% of the project's costs. It involved refurbishing and improving 71 hospitals across the country and training over 200 local hospital staff. The €25 million project included the installation and maintenance of diagnostic imaging equipment including mobile X-ray, fluoroscopy, ultrasound scanners, operating theatres and dental treatment systems.

5.3 DREAM (Drug Resource Enhancement against AIDS and Malnutrition)

The DREAM program financed by the Treatment Acceleration Program (TAP) of the World Bank was aimed at providing cost-effective antiretroviral therapy treatment program and ensuring nutritional supplementation and prevention of mother-to-child transmission (PMTCT) of HIV for low income populations in Sub-Saharan Africa. Over a 3-year period, TAP financed three project components: testing approaches for scaling up service delivery for HIV/AIDS care and treatment; strengthening institutional capacity for HIV/AIDS care and treatment; facilitating information sharing among the TAP countries and technical learning at the regional level. Care and treatment components in the TAP project are provided through partnerships between each government and 'Implementing Partners'.

It was launched in 2002 with the Community of Sant'Egidio, an international public association of the Catholic Church, based in Italy as main organisation responsible for implementing the Drug Resource Enhancement against AIDS and Malnutrition Programme (DREAM). Two other organisation join as implementing partners in Mozambique including Health Action International and Pathfinder. In the DREAM project Siemens partnered with a church association (community of Sant'egidio) to reduce cost of laboratory testing of HIV resistance to drug therapies. Siemens also invested 1mn euros to fund this initiative contributing to 35% lowering of testing cost. The DREAM program consisted of 18 laboratories in 10 African countries. According Siemens website so far approx. 48,000 patients have been assisted, approx. 27,500 patients on HAART (Highly Active Antiretroviral Therapy) and over 100,000 viral load tests have been performed.

5.4 Cipla: Manufacturing biosimilar in Africa

The rising number of cases of Non-Communicable Diseases (NCDs) such as cancer and diabetes has brought focus on strategies for dealing with the cost of their treatment. High on the list are biosimilars – imitative versions of biologicals, a therapeutic drug comprising large complex molecules – as in theory generic versions of innovator drugs will deliver the same therapeutic benefit but at significantly lower cost. Frustratingly, however, numerous manufacturing and regulatory challenges are creating serious doubts about their ability to do so. In this context, an Indian company is trying to develop manufacturing facility in Africa to create a local supply of affordable biosimilars to local populations.

Cipla was established in 1935 by Dr A K Hamied with the aim of making India self-sufficient in healthcare needs. Cipla emerged as a technology leader in Indian pharma in the 1970s with its ability to reverse engineer many patented molecules and successfully launch low priced generic versions in the Indian domestic market. Over the last five decades Cipla has developed extensive capabilities in process R&D and emerged as a supplier of cheap generic drugs

around the world. Cipla's international generics strategy received a big boost in 2001 with the launch of antiretroviral drugs (ARVs) in emerging country markets at extremely low prices compared with other products. Cipla led the way in supplying ARVs to some of the world's poorest regions at affordable rates. By 2012 Cipla was credited with transforming the global HIV-AIDS treatment landscape and emerged as one of most successful Indian firms with an average annual growth rate of more than 20%. According to Capron and Mitchell (2012), Cipla's success in international generics markets lies in matching its business model to markets it wants to grow in, building a broad portfolio of products to achieve economies of scale in production and creating a network of alliances and licensing agreements with a wide range of other organisations with complementary skills and resources.

In 2010, Cipla embraced biosimilars with similar approach to their entry into African HIV/AIDs market which is reflected in Hamied's comments to investors,

"We believe this activity (biosimilars) is also humanitarian and like our crusade on the HIV/AIDS front, we will attempt to make a similar contribution in the sophisticated cancer market, reaching one and all cancer patients with valuable drugs at affordable prices,"

(Business Standard, 2010)

But to achieve success in the biosimilar market, Cipla had to overcome major hurdles in the form of R&D and manufacturing capabilities. Cipla had no previous experience of biotech R&D or innovative drug discovery R&D and as a family owned business, Cipla lacked the professional management required to succeed in the emerging biosimilar market. To accelerate biosimilar development in 2004 Cipla in partnership with Avesthagen (an Indian biotech company), created Avesta Biologicals Ltd, a new biotech company. In 2007, Avesta Biological acquired Siegfried Biologicals, a biotech company based in Germany, to access biological R&D expertise. However, this did not lead to the expected progress on biosimilar R&D and in 2009 Cipla decided to dissolve Avesta Biologicals due to lack of progress in the development of biosmilars from Avesthagen.

To overcome this failure in 2010 Cipla acquired a 25% stake in MabPharm, an India based biotech firm and helped it to set up a state of the art biotechnology manufacturing facility in India. In 2014 Cipla gained full ownership of the manufacturing plant by acquiring the remaining 75% share. In parallel to the MabPharm acquisition, Cipla invested \$65 million to acquire a 40% stake in Bio Mabs, a Shanghai based biotech aimed at developing ten monoclonal antibody (mAb) drugs and fusion proteins against rheumatoid arthritis, cancers and asthma for marketing in India and China. To complement these acquisitions, Cipla decided to build a biosimilar product portfolio through in-licencing. In 2013, Cipla launched its first biosimilar product, Etanercept, through in-licensing from China-based Shanghai CP Guojian Pharmaceutical Co, remarkably at a 30% reduced price over competitor brands. In 2014, Cipla in-licensed a second biosimilar, 'Darbepoetin alfa', by entering a co-marketing deal with Hetero Drugs, an Indian biotech company.

Over the years, Cipla has created partnerships in manufacturing, sales and marketing with firms all over the world. In 2012, a new management team initiated a strategy to convert these partnerships into subsidiaries and joint ventures to bolster complimentary capabilities. In 2012, Cipla acquired a distribution partner in South Africa, Medpro, for \$512 million and followed that by increasing its stake in a Uganda-based joint venture, Quality Chemical Industries Ltd (QCIL) from 14.5% to 51.05% for \$15 million. In 2013, Cipla acquired a 100% stake in Celeris, its Croatian distributor, a 51% stake in its UAE distributor and a 60% stake in a pharmaceutical

company based in Sri Lanka for \$14 million. Cipla aims to start selling both biosimilar products in international markets using these newly acquired marketing and distribution entities.

In 2016 Cipla signed a memorandum of agreement for South Africa's first biosimilars manufacturing facility to be set up at a cost of nearly \$91 million. The facility will be South Africa's first biotech manufacturing unit to produce biosimilars. It is set to produce a range of affordable treatments for cancer and other autoimmune diseases for the African and global market.

6.0 Analysis and discussion

This section presents analysis of data from the five case studies and it shows that all partnerships had impact in resolving needs of low income populations with some participation of these users in development of inclusive innovations and services (Table 5).

(Table 5 here)

The mixed record of success from these partnerships does raise some questions whether these can provide a more appropriate platform to enable development of healthcare technology appropriate for low-income populations in developing countries. Significantly, analysis reveals three critical implications of this research which are discussed in the following section.

Role of standards and regulations in facilitating inclusive innovation

Case studies discussed in this paper highlights importance of regulations and standards appropriate to local contexts in facilitating inclusive innovations in developing countries. For example, absence of regulations and standards has detrimental impact on development of Sree Chitra Heart valve as research institute had to get approvals from international agencies thereby increasing cost of the project and delaying launch of the product. There is a strong need to set up regulations and standards that matches local context rather than need to match the standards set by the advanced countries. It is imperative that developing countries should avoid recreating the regulatory complexity, accumulation, and fragmentation that characterises regulatory frameworks in advanced countries, and rather focus on how to achieve more 'optimal' regulation. For example, in developing countries some infrastructural challenges and resource constraints create a totally contrasting local context to advanced countries. This makes some surplus regulatory demands unnecessary. This research reinforces argument by Harmon and Kale (2014:25) that "social objectives and performance standards need to be participatively agreed and clearly identified, oversight must be institutionalised, and correctional authority must be enumerated if the regulated fields are to achieve their potential and not contribute to even greater patient risks".

Issues of power, politics and participation

Case studies shows that these arrangements include a strong element of organisational restructuring and power relations. These partnerships originate to resolve a needs of local income users, along with contribution from different organisations and institutions leads to development of inclusive healthcare for local populations. Different institutions have diverse agendas, ability to influence agendas and that shapes incentives and motivations for their engagements. As such there is need for a way of seeing power that is much more dynamic, that focuses on how power relates to change. Such a way of looking at power starts from a concern with the relations between the parties involved in any process of development.

The ideas of 'power struggles' and (shifting) 'balances of power' are important here. To go back to the case of diagnostic services in Tanzania, the ability of seemingly powerless local

hospitals and Tanzania government to influence the agenda depends on their capability to develop effective strategies to engage with Dutch ministry and Phillips. This dynamic notion of power also corresponds with relational sources of power. It implies some negotiation of power in relations between those who wish to act with each other to enable and enact a greater power. It is important to challenge the notion that power can be absolute and durable. Power is not fixed and needs to be cultivated, although some forms of power do undoubtedly appear durable. This dynamic perspective on power points towards the space for contestation and negotiations in societal power relations.

Significance of key stakeholders: state, private sector and civil society

All these case studies point towards significance of shared responsibility among all stakeholders involved in the funding, implementation and sustainability of the project. This suggests that the environment in which decision-making and/or behaviour-shaping authority is exercised is spread amongst actors of very different kinds with varying perspectives, knowledge/power inequalities, some of whom will have very limited remits and diverging agendas. This is strongly evident in the failure of sustainability in Tanzanian Philips project and success of DREAM project in Mozambique. The rehabilitation of diagnostic services project in Tanzania struggled to sustain the working of the equipment and supply of technician due to lack of responsibility from three stakeholders involved in conceiving and implementing project: Tanzanian government, Philips and Dutch government. None of these stakeholders were committed to ensure long term sustainability but more concerned about short-term success in implementation of the project. This was also evident in similar project in Kenya, where Philips delivered equipment five years previously, where no money had been reserved for maintenance and pressure was put on the Dutch government to supply funds to prevent loss of the invested capital. It shows that some of these partnerships are strengthening local capacity in how to use diagnostics developed for advanced markets but are not contributing in building local technical and manufacturing capabilities required to sustain supply of appropriate diagnostics.

7.0 Conclusion

The availability, accessibility and effective use of healthcare technology play an important role in the achievement of inclusive healthcare. Patients rely on safe, high quality, and affordable diagnosis and biological drugs for prevention, diagnosis as well as curative medical care. In developing countries there is a serious concern about unequal access to healthcare hindering the objective of inclusive healthcare and ensuring basic services for healthcare interventions. This research focuses on the new models of innovation and institutional arrangements, that can aid in resolving healthcare needs of low income populations. Using case studies of inclusive innovations and social technologies from India, Kenya and Tanzania, this research explored the role of inclusive innovation and social technologies in generating and delivering new 'physical technologies' and innovation processes needed by low-income users. This research shows that new 'social technologies' (innovative institutional and organisational forms and divisions of labour) and inclusive innovations can significantly contribute the development and delivery of physical technologies in medical device and biological drug needs. However, it also raises some key questions about sustainability of these initiatives and significance of collective action to achieve that.

This paper shows that development of local technological capability in developing countries requires a supportive business environment to produce economically viable devices and biosimilars; financing mechanisms to connect producers, payers and consumers; and regulations and policies to ensure equitable access to quality devices. Due to these barriers, it

remains inconclusive whether local production will help in improving access to essential healthcare technologies in developing countries. Evidence presented in this paper suggests that this vacuum is filled by the emergence of new institutional partnerships that are bridging gaps by matching financial and technological resources of private sector with knowledge about local context of use provided local institutions and government departments. The growing popularity of these arrangements suggests that they provide an effective way to resolve the mismatch between demands and supply. For private sector, it helps to overcome knowledge gaps regarding use of devices in the local context while for local institutions it bridges the financial and technological gaps. These partnerships help match outcomes to:

- Resources: product features and user cues; manufacturing processes
- Processes: user training, monitoring and evaluation
- Priorities: must-have results and acceptable trade-offs

Significantly this research points out three critical policy insights that need attention to facilitate and sustain development of inclusive innovation and social technologies for the benefit of low-income populations. First insight relates to regulation and standards appropriate to local context rather than adopting regulations and standards developed by advanced countries. Second, it shows paying attention importance of power imbalances among different stakeholder to ensure voices of all stakeholders are counted in development of agenda. Finally, this research suggests that shared responsibility among stakeholders is critical to ensure short as well long term success of these partnerships.

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Tables

Table 1 Mismatch between local demand and import in developing countries (WHO 2012)

| Country | Imports (US \$ millions) | Country | Exports (US\$ millions) |
|----------------|---------------------------------|----------------|--------------------------------|
| South Africa | 670.1 | South Africa | 111.5 |
| Egypt | 405.5 | Tunisia | 98.8 |
| Algeria | 307.7 | Egypt | 40.0 |
| Morocco | 171.1 | Morocco | 14.7 |
| Tunisia | 145.4 | Mauritius | 8.1 |
| Libya | 141.1 | Keyna | 4.1 |
| Nigeria | 119.4 | Swaziland | 1.7 |
| Angola | 87.8 | Madagascar | 1.3 |
| Sudan | 56.2 | Sierra Leone | 0.9 |
| Kenya | 50.2 | Libya | 0.9 |

Table 2 Leading partnerships between MNCs and local governments/firm/NGOs in Africa (GMTA, 2012)

| No | year | Country | MNC | Collaborating institution | Description of engagement |
|----|------|--------------|--------------------------|---|---|
| 1 | 2002 | Somalia | Johnson & Johnson | The Hermann Gmeiner School of Nursing | To train healthcare professionals for local populations |
| 2 | | South Africa | Siemens | Community of Sant' Egidio | To lower costs of laboratory HIV/AIDS testing by 35% to combat HIV resistance to drug therapies |
| 3 | | Uganda | BD | Academic Alliance Foundation, the Infectious Disease Institute, Makerere University | To develop training programs on clinical, public health and laboratory practices for clinicians from Sub-Saharan Africa |
| 4 | 2005 | Zambia | BD | Catholic Medical Mission Board | Building local health capacity in remote areas |
| 5 | 2007 | Ghana | BD | Direct Relief International | Building local health capacity in two health centres |
| 6 | | South Africa | The Medtronic Foundation | University of Cape Town | To improve awareness, diagnosis and public policy in case of Rheumatic Heart Disease |
| 7 | | Ethiopia | BD | Save the Children | Establishments of clinics for HIV positive children |
| 8 | | Tanzania | Abbott | Government of Tanzania | Comprehensive initiatives to strengthen to country's healthcare system |
| 9 | | Uganda | Johnson & Johnson | The African Medical Research foundation, local NGO <i>Sikiliza Leo</i> | To provide testing, counselling, treatment and care in rural Uganda for HIV |
| 10 | | Tanzania | Phillips | The Government of Tanzania | Help in rehabilitating diagnostic services and operating theatres at district and regional hospitals |
| 11 | | South Africa | The Medtronic Foundation | Children HeartLink | To develop a model program that addresses the problem of critical care nurse retention and provides nurse training |
| 12 | | South Africa | The Medtronic Foundation | University of Witswatersand, Johannesburg | To improve local capacity of community based nurses in the primary case clinics to recognise and manage heart diseases |

Table 3 Inclusive innovations under study

| Nature of Inclusive innovation | Funding agency | Lead actor | Key partner | Description of engagement |
|--|--|--------------------------------|----------------------------------|--|
| Heart valve | Department of Science and Technology (DST), India | Sree Chitra Research Institute | TTK Healthcare | To indigenously develop world's cheapest heart valve |
| Biological drugs used in cancer treatments | Cipla | Cipla | Ministry of Health, South Africa | Help in creating production capacity and ensure supply of affordable biosimilars |
| Diagnostic and operating theatres | Development-Related Export Transactions (ORET) program by the Dutch government | Phillips | Tanzanian government | Help in rehabilitating diagnostic services and operating theatres at district and regional hospitals |
| HIV/AIDs treatment and prevention | The World Bank | Community of Sant'Egidio | Siemens and local governments | Prevention of mother-to-child transmission (PMTCT) of HIV |

Table 4 Key players in heart valve market in India

| Company | Headquarter | Product | Key characteristics |
|----------------|--------------------|------------------------------|---|
| Medtronic | USA | Tissue and Mechanical valves | Competitively priced yet unaffordable to low-income populations |
| St Jude | USA | Mechanical valves | Competitively priced yet unaffordable to low-income populations |
| Edwards | USA | Mechanical and Tissue valves | Expensively priced |
| TTK | Indian | Mechanical valves | Prices are lowest in the world and affordable to low-income populations |

Table 5 Performance and impact of social technologies and inclusive innovations

| Nature of Inclusive innovation | Participation of low income populations | Nature of impact | Key barriers | Implications |
|--|--|--------------------------------------|--|--|
| Heart valve | Significant | Significant impact | Lack of medical device regulations in India, absence of local eco-system | Provides an ideal model for development of appropriate innovations |
| Biological drugs used in cancer treatments | Negligible | Potential to have significant impact | Technical know-how and absence of biosimilar regulations | Success could lead other firms starting their operations in Africa |
| Diagnostic and operating theatres | Negligible | Marginal impact | Matching ambition of funders and encouraging local participation | Highlights role of local government and private firm in sustaining capacity building |
| HIV/AIDs treatment and prevention | Significant | Significant | Encouraging local participation | Role of faith based organisations |

Figures

Fig 1 Medical device mismatch in developing countries

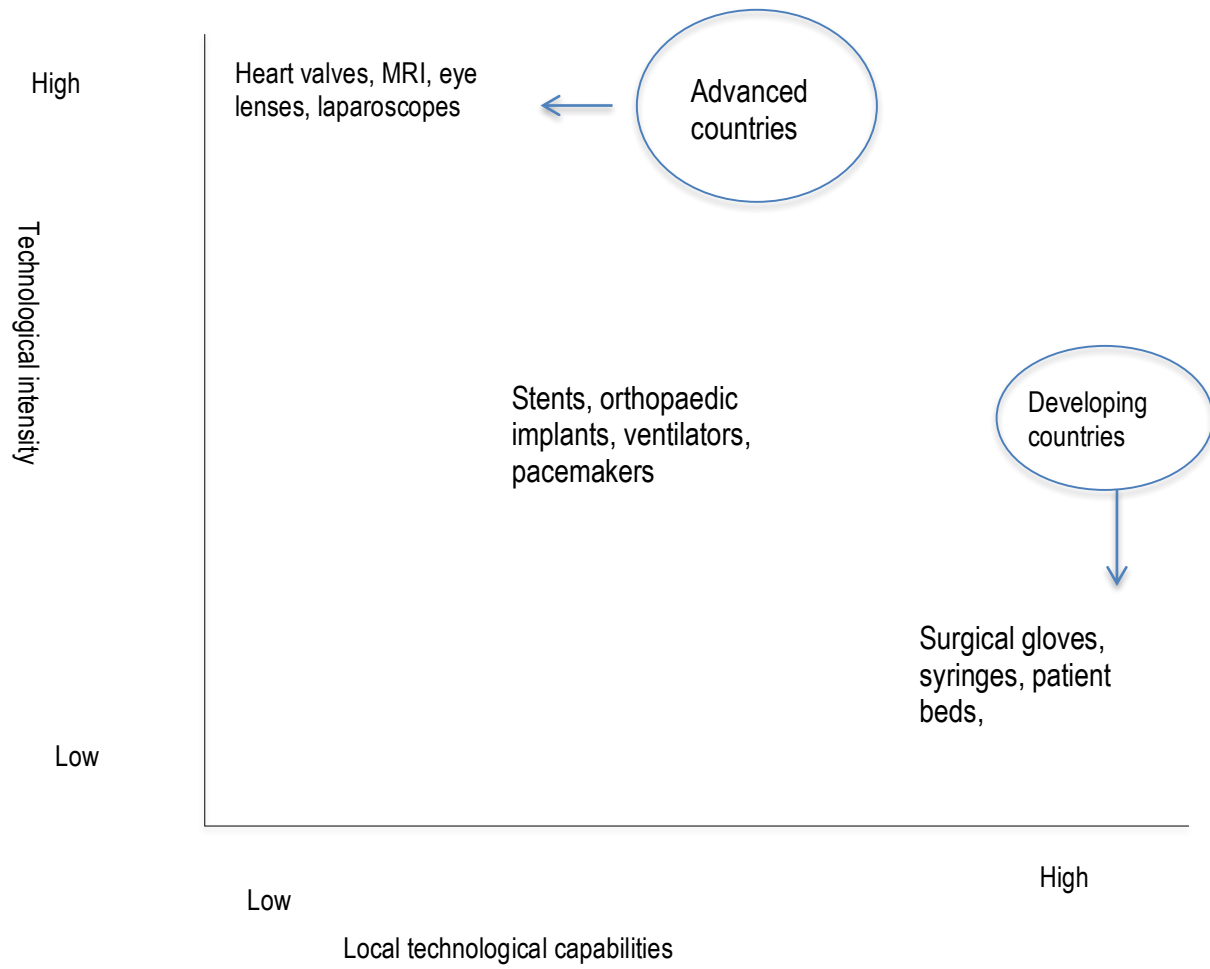


Fig 2 Mapping biosimilar capabilities: Technology capabilities – market matrix



