The COVID-19 Impact Statement.

The research was impacted by the COVID-19 outbreak in data analysis. Some medicine samples of essential medicines had been collected from the Open market at Idumota in Lagos for analysis at the Department of Chemistry in the University of Manchester. However, government lockdowns made it impossible to secure any lab space for an entire year and a half. In order to mitigate this loss of data, the cases were written up using already existing peer-reviewed data in published literature as recent as possible. It would have been useful however to gauge the success of past efforts at reducing the incidence of fake and substandard medicines in Nigeria's open drug markets with current prevalence levels. As such the case on the Open drug market relies on an extensive desk-based fieldwork to fill in the gaps due to the inability to analyze the samples early.

The challenges of working from school hostel accommodation on a small laptop during lockdown also took its toll on the authors eye health. Hardship funds were applied for with the support of the authors supervisors and used to pay for expensive eye tests and new prescription glasses to prevent further eye strain and deteriorating eyesight. The ability to return to work using desktop monitors in the designated PhD office at the Alliance Business School has been a boon to research again.

Blank page

Improving Access to Medicines in Noncore Markets: (Re)Designing Robust Governance in Healthcare Global Value Chains.

A thesis submitted to The University of Manchester for the degree of
Doctor of Philosophy
in the Faculty of Humanities

2022

Arinze Chukwunanu Ekwem

Alliance Manchester Business School

Innovation Management & Policy

Blank page

Table of Contents

List of Maps and Diagrams:

Word Count: 78,632

Abstract:

This PhD addresses the research gap on global value chains in Health. Specifically, it operationalizes the global value chains framework into a Pharmacy to map access to medicines as an outcome of global value chains governance by lead firms and institutional intermediaries.

What it contributes are twofold. First is that it operationalizes global value chains into the world of health using a world-system analysis. Second it identifies the performance dimensions of successful interventions to bridge institutional voids in noncore contexts that truncate access to medicines through value chains. In so doing, there are two theoretical - or more modestly - methodological improvements to theory.

The first is to reposition an expanded global value chains framework in which the eight possible configurations come alive in health as opposed to the five configurations accepted in the literature.

The second is the contribution of an eighth design principle for health communities; common knowledge. This presents an advance on the seven principles of common pool resource governance.

The PhD is a work in theory development that employs the case study method to process trace the performance dimensions of global value chains and collective action in health.

It is hoped that the PhD offers much for practice to those in the field who work to improve access to medicines. Indeed, there is a case on Nigeria's notorious open drug market and how design principles can be applied to govern the value chain for generic medicines where the government is unable to do so and lead firms do not find it economical to lead.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Dedication:

This PhD is dedicated to the members of the Chevening Alumni Association of Nigeria, especially the Chairman of the Channels Television Group, Dr John Momoh who contributed immense personal resources to sponsor my coming to the United Kingdom.

Acknowledgement.

My gratitude is due to both my Supervisors Professor Philippe Laredo and Ms Kate Barker who mentored, supported, and midwifed this PhD with painstaking care over and beyond the call of duty.

Many thanks are due to my wife Dr Adwoa, for her love and support, my brother Chidozie for his insightful advice, and my mother, Lois, for her unceasing encouragement throughout these years. This PhD is for them as much as it is for me.

Dr Ronnie Ramlogan deserves my warmest thank you for employing me as a Teaching Assistant and giving my feet a first rung on the ladder of academia here at Manchester.

The Author:

A Pharmacist with seven years' work experience in the pharmaceutical industry, government hospitals, and NGO in health. The author gained a Masters in Operations, Project and Supply chain Management with Distinction here at the University of Manchester in 2015 as a Chevening Scholar, and this PhD is an extension of a professional and academic inquiry into the lack of access to medicines in noncore economies.

Blank page

Chapter 1: Globalization and Health

Health today is global. That goes without saying, whether in terms of its implications or in terms of capital investments in what is now a trillion-dollar industry. But the idea of 'global' in health up till now has mostly been framed in terms of international risks to health like viral diseases and worldwide collaborations for health investments. Whether that be respiratory viruses becoming a global health problem, or universal healthcare being promoted as a public good to be generalized worldwide are examples of health under globalization.

But few if any have attempted to frame the 'global' in health as a world-system. That is, to apply a structural approach that examines the articulation between the constituent parts of the global health system, and how the dynamics of that articulation structures differently the outcomes of disease, wellbeing, and access to medicines for the people who consume healthcare services.

There is a paradox in global health today that demands interrogation. As much as ninety percent of the medicines required to manage ninety percent of the health problems in the world exist, and they can be made available at low cost. Globalization and its polarization of the world has produced an uneven world of health outcomes with a geopolitical distribution of communicable and noncommunicable disease burdens. With this uneven double burden of disease distribution, there is a market failure for effective medicines in the global health industry, in indication, quality and quantity. That is to say that the medicines are either unavailable, or they are of questionable quality, or simply unaffordable in many parts of the world especially for people in low-income countries.

At the same time there is a shift in drug development platforms from simple fine chemicals for which the absorptive capacity is unevenly distributed and this has important consequences for access to medicines. For example, most biologics being proteinaceous require cold chain storage from factory to bedside that is not widely available in most low-income countries. This technological shift in the pharmaceutical industry therefore comes with the risk of billions of people being left behind with poor access to medicines.

In their article *International Trade and Uneven Development*, Hymer and Resnick (1970) analyze the world economy using structural history, into three phases of mercantilism: precolonial, colonial, and postcolonial periods. The history of global health can also be

traced according to these three epochs to conduct structured analytical research. Geels and Turnheim (2013) here at the University of Manchester use a similar historical approach to process trace the changes in the British energy sector over the last 100 years. They posit that this epistemological style of 'narrative explanation' allows them to capture in longitudinal case studies, "complex interactions between agency and changing contexts, time, even sequences…", while drawing on primary, and secondary sources of information and data. The American Sociologist and father of world-system theory Immanuel Wallerstein would also employ this structural history in developing his unique analysis of capitalism. But it was Fernand Braudel the French historian and pioneer of the Annales School of History who developed this historical method by differentiating idiographic history from cyclical and structural history of systems.

This cyclical and structural historical analysis is relevant to studies that seek to process trace the transitions and destabilizations that have globalized the current orthodoxy of western medicine. The closest application of this structural approach to the analysis of healthcare systems is the seminal work of Robert W. Scott tracing the transformation of the American healthcare system across a fifty-year period from Professional dominance (1945-1965), Federal dominance through Medicare and Medicaid (1966-1982), and to Managerial dominance by Health Management Organizations (1983-2000). This PhD embarks on a more ambitious project to process trace the transitions and transformations in global health throughout the 400-year history of capitalism. The three phases in the Hymerian analysis provide a historical backdrop with which to analyze the impact of globalization in health and what this means for access to medicines as products of international trade.

This chapter serves as an introduction to health through the lenses of international business to focus on medicines as international products and problematize access to medicines as the key factor in healthcare today for consumers of healthcare services. It begins with an introduction of the Hymerian historical model and from it derives three domains of enquiry in global health today that are contemporary, articulated (or systematic), and critical to understanding the uneven access to health and medicines world over. From these three domains respectively, the chapter proposes three issues of globalization that serve as precursors around which the theorization and research strategy of the PhD precipitates. It

ends on a note of theoretical equifinality by realizing the high degree of alignment with the eclectic OLI[1] framework of international business.

1.1 The Hymerian Historical Analysis of Globalization

1.1.1 Mercantilism I: (15th century to 1870)

This phase was marked by the commodities trade between countries based on advances in shipping technology that triggered fighting over the control of shipping routes. Braudel points to this trade across the Mediterranean during the long 16th century as the birth of modern capitalism (Braudel, 1981). A capitalist class of entrepreneurs (and pirates) would arise around this international shipping trade across the seas using monopoly privileges granted by the crowns of Europe for seafaring expeditions to explore access to markets and new resources. These royal charters and privileges would eventually become the patent system that is at the heart of the capitalist world-system. This merchant class would also trigger a host of societal changes that would reverberate throughout science and technology in the period called 'the enlightenment' which saw the replacement of the landed nobility (feudal lords) by new captains of industry and the beginning of the industrial revolution. Capital accumulation shifted from land ownership and appropriation of agricultural surplus from the peasantry to international trade in commodities, their transformation, and speculation. It also marked the replacement of the humoral model of disease with the histopathologic view that made therapy with medicines the mainstay of healthcare. This was the triumph of the scientific method, of *logos* over *mythos* in health. Healthcare under this feudal regime was a largely patronage affair under the imprimatur of the crowns who established workhouses for the sick and indigent organized around the parish.

1.1.2 Mercantilism II: 1870 to World War II

This period ushered in the colonial phase. As the competition over the seas and shipping routes was resolved through international maritime law, the competition shifted to the hinterlands as European empires expanded into the new worlds of the Americas, Africa, Asia, and Latin America. The Berlin Conference of 1884-1885 was largely to resolve the

[1] The Ownership-Location-Internalization framework was developed by the English economist John Dunning to explain the internationalization strategy of the multinationals.

disputes arising from this colonial scramble for imperial expansion. In this phase, the colonial administrations pursued a health policy that was largely curative for attending to the tropical infectious diseases that befell colonial officers. It was cheaper for the colonial government to import quinine for malaria treatment than to invest in sanitation and hygiene of the colony, while reserving government expenditure to expand exports through investments in plantation agriculture and mining. This curative colonial bent for deepening rather than widening access to health has had lasting implications for health systems in postcolonial states. Only the medical missionaries of the Church were an exception in this regard.

Deepening access to health rather than widening access was in keeping with the colonial economic policy capital deepening and not capital widening. As such while wages rose in the centre (cities) for a few administrators, traders, and literati, labour wages stagnated or rose slowly in the periphery (hinterland). Only this local bourgeoisie class could afford capital intensive healthcare in the cities and major towns where wages were high even if employment rates were low.

Hymer points out the immiserizing nature of the colonial government expenditure; cities were the engines for capital accumulation, and as such attracted the larger chunk of government expenditure in health and infrastructure. The hinterland was supplier of unlimited amounts of low wage limited skill labour, and commodities for export, and as such attracted only scant government attention. Even a rise in commodity prices did not result in any improvement in the economic fortunes and health outcomes of the hinterland population, as the government quickly moved to expand production to take advantage of the price increase. The resulting glut from overproduction would quickly restore prices to previous or lower levels. This left the rural population working harder to produce more in order to earn the same as before to meet their obligations to pay colonial taxes. Yet there was no need to expand access to medicines to them, as the virtually unlimited supplies of labour in the hinterland could be continuously exploited without any serious thought about their welfare or replenishment.

It was this neglect of the hinterland that inspired Ernesto “Che” Guevara, an Argentine physician, during his motorbike tour as a medical student of Latin America, to play a prominent role in the Cuban revolution. In fact, he coined the term ‘Revolutionary Medicine’ for his vision to “provide health services for the greatest possible number of

people"(Guevara, 1960). His ideas for widening access to health as a major plank of independence movement marks the Cuban healthcare system of one doctor per neighbourhood block.

This sustained neglect of the hinterland would engender the mass migration of people from the hinterland seeking to escape the exploitative nature of colonial agriculture in search of clerical and manual jobs in the city. This army of low wage and limited skill workers, unable to afford the high rent of the city centre, would aggregate in conurbations of peri urban settlements. These are the shanty towns that have persisted as gigantic slums in postcolonial states till this day. In the metropole, these slums, and the health challenges they created, were the product of rapid urbanization around the docks and new industries. They are described in a passage by the Catholic Cardinal Wiseman thus:

> "Close under the Abbey of Westminster there lie concealed labyrinths of lanes and courts, and alleys and slums, nests of ignorance, vice, depravity, and crime, as well as of squalor, wretchedness, and disease; whose atmosphere is typhus, whose ventilation is cholera; in which swarms of huge and almost countless population, nominally at least, Catholic; haunts of filth, which no sewage committee can reach – dark corners, which no lighting board can brighten."(Ward, 1900)

1.1.3 Mercantilism III: World War II to present.

This phase has largely followed the tracks of Mercantilism II with some changes which included political independence of colonial states and more importantly, the dominance of the multidivisional multinational through the multilateral institutions of the World Bank, International Monetary Fund, and the World Trade Organization. The local elite replaced the foreign colonial officers, but their education, tastes, mannerisms, economic principles remained largely the same. Their national growth strategies and government expenditure still follow the capital deepening colonial strategy of mineral extraction and plantation agriculture.

As such, their infrastructure and health systems are largely, concentrated in the cities, and focused on the control of infectious diseases with a curative focus but paying scant attention to the lifestyle and environmental challenges to health that arise from industrial urbanization. This uneven state of health in the postcolonial context is reproduced by the

unequal exchange with the multinational firm leaving the postcolonial state stuck in the commodities trap but favouring a small local elite.

This third phase of mercantilism is marked by the fierce open competition between former colonies for access to the markets of the metropole, in order to sell mineral and agricultural commodities. Thus, the immiserizing growth of commodity trade has worsened under independence as the postcolonial states no longer enjoy the most favoured nation status of the metropole that guaranteed some level of income. Now coffee farmers in Brazil, Vietnam and Tanzania have to struggle for the patronage of a few multinationals who operate in several countries and control the market. Previously, the farmers in the German colonies had the German market all to themselves, and the farmers in French colonies had the French market all to themselves. Today coffee farmers in French Guyana may as well be outcompeted by coffee farmers in Tanzania (a former German and British colony) for access to French markets. The hyper competition in commodities markets does not leave Tanzanian farmers better off either, as the competition is based on the ability to keep prices lowest, resulting in low profits.

In this condition, post-colonial states have competed away their commodity prices against each other, and at the same time bidden away their ability to tax the multinational all in a bid to attract foreign direct investment. The result has been the dwindling ability of the postcolonial state to guarantee and subsidize the production and distribution of healthcare services. In the face of dwindling revenues and economic collapse, post-colonial states as part of painful neoliberal aid conditionalities to restructure their economies have had to cut back, scale back, and pare back the range, depth, and size of welfare programmes including healthcare. Thus, in most postcolonial states, out-of-pocket spending has become the mainstay of access to medicines for up to 90% of the population as the governments are no longer able to internalize the costs of welfare services.

1.2 Globalization in Health: Patents, Slums and Governance.

What emerges from this hymerian analysis of the uneven access to medicines are three main domains of inquiry. The first domain covers access to medicines under increasingly strong ownership patents. The second domain is concerning how to distribute access to medicines for people located along the rural-urban continuum especially in the half-way houses of slums where the double burden of communicable and noncommunicable diseases are prevalent (and where most people in developing countries live). The third domain focuses attention on the dwindling capacity of governments to internalize the costs of access to medicines in a neoliberal world order where it is increasingly difficult to tax "footloose foreign direct investment" (Yamin and Sinkovics, 2009).

1.2.1 Domain I: The International Patent System

Beginning in the 15th century, royal authorities in Europe granted exclusive rights to private explorers, tradesmen, and manufacturers to exploit opportunities in the form of inventions, trade routes and eventually even entire territories in the new world (Archibugi and Filippetti, 2010). By the end of the 18th century, nearly every European nation was granting monopoly rights backed by the state with varying durations from 10-20 years. An international Convention for the Protection of Industrial Property was created in 1883 to harmonize the recognition of patents in different countries irrespective of the location of first filing. Later on, at the Berne Convention, another body was set up for the Protection of Literary and Artistic Works in 1886, and later merged with the body for the Protection of Industrial Property to form one international bureau for the Protection of Intellectual Property. Their main remit however was overseeing the system of monopoly privileges for industrial property and copyrights for artwork. This combined bureau called IBRID was later folded into a specialized agency of the UN and renamed World Intellectual Property Organization (WIPO) (Bogsch, 1992). it is interesting to note that there were reservations about this move from the industrialized nations who feared that its membership would come to be overwhelmingly dominated by developing countries who argued for weaker property rights protection to favour capital widening. However, the industrialized nations allowed it to go forward as they were keen to have some sort of copyright system in place all over the world than to have nothing internationally agreed upon. Indeed, as of 1970,

only about half of the members of the earlier conventions were developing countries compared to 70% under WIPO. The developing counties had even earlier argued at the Stockholm conference of 1967 for the right to set variable levels of intellectual property protection compared to the developed countries. As such, pro-developing country mechanisms were built into the framework of WIPO to provide support for technology transfer agreements, advice on legislations, capacity building for policy making, and training and research.

Some multinationals in the Pharmaceutical and IT sector felt the need to write stronger intellectual property rights into the international trading system. Unable to push through these changes at WIPO due to the overwhelming pro-developing country arrangements in its membership and stance, the industrialized nations of the quad (USA, Canada, UK/EU, and Japan) embarked on forum shifting to move the agenda for toughening intellectual property rights to a parallel arrangement called the 'trade rounds' (Drahos, 2002, 2007; Sell, 2009). At the Uruguay round (named after the host country for that year), international trade was made contingent on Intellectual property rights and framed their noncompliance as a violent crime through a series of articles in the popular media that linked them with ocean piracy in the public mind. At the Uruguay Round two major changes to the rules of GATT were made. First was to abolish the lack of reciprocity in the agreements, that is hitherto, nations were not penalized if they didn't reciprocate intellectual property legislation. The second was to get rid of decision by consensus making where every member state had to agree for the decisions to be passed. Following these changes to GATT, a mercantilist negotiation trade began (Finger and Nogués, 2001). The offer by the industrialized nations was that they would remove non-tariff barriers to agriculture and allow increased access to their domestic markets to non-industrialized nations. In exchange, the non-industrialized nations would strengthen their intellectual property rights legislation under reciprocity especially within the service sectors. In mercantilist terms this was a win-win according to comparative advantage, but experience has shown that this is actually a serious loss for the non-industrialized nations. An intergovernmental organization was set up called the World Trade Organization to administrate the trade agreements of the Uruguay round in 1994. Countries which refused to join would be left out of the trading system as the quad made their intentions clear to move into the new organization.

Following the outcry against the set of intellectual property rights written into the GATT collectively known as TRIPS (Trade Related Intellectual Property Rights), a clause was inserted known as Article 31 in December 2005 to allow member states to license compulsorily medicines during a health crisis. However, it is interesting to note that even though Article 31 allows developing countries to compulsorily licence patented medicines for production during a health emergency, the trade law prevents them from exporting same to other countries who may be in dire need of these medicines. Other conditions include that there must be adequate remuneration for the rights holder, and efforts should be made to negotiate a reasonable arrangement on commercial terms first.

Many have argued that these allowances for improving access to medicines are purely cosmetic and unworkable especially for countries who do not have the drafting capacity to manoeuvre around the legal aspects of TRIPS (Ur Rehman, 2011; Correa, 2018). Yet the quad nations still argue for even more muscular IPR laws that abolish compulsory licensing, and outlaw early registration of patents close to patent expiration. Whether these patents are fit for purpose is not the focus of this PhD, nor their morality need detain us here. The main takeaway is that ownership of medicines through 20-year patent monopolies introduce a dynamism into the trajectory of medicines: the international product life cycle - comprising a brand and generic phase. The focus is on understanding how these dynamic structures access to medicines on the ground.

TRIPS agreements cover not only production (research and development) but also distribution rights in each and every country. Therefore, parallel importation is largely illegal in most countries of the world. For innovative medicines which cost a premium, without parallel importation, there is a large profit margin between the price of the generic and the price of the branded product which incentivizes the production of fake and substandard copies of the brand product.

Thus, tight, and muscular intellectual property rights have in negative feedback led to the proliferation of a black market for medicines that poses a very serious quality assurance problem especially with the rise of online internet pharmacies and the pressure on consumers to find affordable medicines (Harris, 2004, 2006). The quality assurance dimension for medicines asides represents a very important domain of enquiry on the PhD especially in the parts of the world where the state does not have the capacity guarantee the quality of medicines within the domestic supply chains.

1.2.2 Domain II: Rapid Urbanization and Slumification

Hymers law of uneven development applied within the context of cities and their hinterlands, (reframed as core and periphery in world-system theory) raises the question of location in the distribution of healthcare services and access to medicines in global health. But there is also a local dimension to this core-periphery relationship between cities and hinterlands in the same country worth giving serious consideration. The high rates of capital formation in the cities leads to a widening differential of wages between the rural and urban areas that triggers a massive rural to urban migration. In Lagos, Buenos Aires, and Ho Chi Ming city they come looking for jobs outsourced there by multinationals seeking low labour costs. The greater the wage differential is between the rural areas and the new jobs, the greater the urban drift will be. When this rural to urban drift exceeds the capacity of the city to absorb them, it results in slums. These slums also outstrip the capacity of the municipalities to create social infrastructure; pipe borne water, drains and sewers, electricity, and transportation links, swelled daily by the internal migration from the rural areas to the city of job seekers. This slumification process also describes London's East End, Manchester's Deansgate, and Liverpool's Merseyside over a hundred years ago as people migrated towards the new jobs created at the docks by international trade of mercantilism's second phase. High and sustained rates of economic growth however would provide the resources for slum clearance in the United Kingdom and other metropoles.

But today that growth is in competition with other wage labourers of other countries. The loss of jobs in the manufacturing sector of the USA to cheaper imports from China demonstrates the importance of this analysis. As much as 3.7 million US jobs have been lost to China between 2001 and 2018 (654,100 jobs lost in California; 334,800 jobs lost in Texas; 185,100 jobs lost in New York; 162,400 jobs lost in Illinois; 150,700 jobs lost in Florida) (Scott and Mokhiber, 2020). It also shows the roots of the steady urban drift of millions of young people from the post-industrial suburbs of America into the cities seeking a better life. Unfortunately, capital deepening in the few remaining sectors favours a low employment rate that privileges capital accumulation over job creation (it is now a mark of the American economy to see firms with billions of dollars in market capitalization employing less than 300 employees). Coupled with increasing mobility of international capital and advancements in information technology, there is little to no need for capitalists to retain production and jobs in any one country when they can slice and dice

their value chain and move production to other foreign hinterlands where labour is cheap and infrastructure is good: for now, South-east Asia. The teeming unemployed left behind in great American cities by this exodus of jobs are often re-engaged working zero-hour jobs in the service industries of tourism and entertainment or rely on unemployment benefits[2].

Not earning enough to live in the pricey cities, they agglomerate in and commute daily from urban slums where desperation, drug abuse and criminality are rampant. This is the dilemma of San Francisco one of the richest cities in the world with a personal per capita income over $130,000 and a GDP over $590 billion, but which has the highest rate of homelessness and drug abuse in America. There is a gradual slumification of the city as makeshift tents and shacks grow in open spaces. These slums in the peri-urban areas are a ring of political contestation between a green agenda located in the core which argues in favour of parks and green spaces (slum clearance) and against rent controls versus a brown agenda arguing for construction of low-cost housing with rent controls. Unfortunately, homelessness is often framed as a drug or opiate crises, rather than as a fallout of industrial competition between workers in the manufacturing heartland of America and low wage labour in other parts of the world. Some counties in California report as many as 11 deaths a day from drug overdoses[3] in these slums. These agglomerations present a double burden of disease featuring communicable diseases like Tuberculosis with noncommunicable diseases like Diabetes, originating from poor hygiene and poor nutrition respectively. In these slums, a meta-analysis found a three to five-fold greater occurrence of Tuberculosis than in general population (Noykhovich, Mookherji and Roess, 2019). Others have drawn attention to the fact that slums are increasingly implicated in the outbreak of pandemics (Ross *et al.*, 2021).

In Africa and Asia, these slums are the worst off. In the Philippines, 12 million slum dwellers have no access to pipe borne water (Ross *et al.*, 2021). With the population increasing rapidly in these low-income countries, the rate of slum growth outpaces the capacity of the governments to keep pace with planned urbanization programmes or the

[2] Ha-Joon Chang the South Korean economist makes the important observation that those unemployed by job emigration are likely to remain so, and are unable to transition into high growth sectors in other industries without state support for retraining (You and Chang, 1993; Lin and Chang, 2009).
[3] The drugs provide a palliative to the harsh reality of their broken dreams.

resources to ameliorate the living conditions in them. For example, the Central African Republic has over 90% of its urban population living in slums. Nigeria has just over 50% for the same measure, while Latin America and the Caribbean have 21%. More importantly is that these slums pose an organizational problem for the planning and delivery of healthcare services because they spring up without government support or infrastructure. To compound issues, their informal economy also harbours illicit activities and criminal elements, making them risky for health workers to provide welfare services. In spite of this accessibility problem, over 90 percent of the healthcare needs of the slums can be met with a basic package of care using generic medicines to supply an Essential Medicines List (WHO, 2000). Yet much of government health expenditure is spent on deepening health access in the urban core of cities (where there is effective demand) rather than expanding it (Asenso-Okyere, 1995). For example, new hospitals being built tend to be of the multi-specialist type that are complex and expensive to run, located in the cities and major towns. Manpower training is constantly geared towards the development of high skilled health professionals who would rather be under- and unemployed in the better parts of the city and later emigrate, than to go work in the slums (Dussault and Franceschini, 2006). Scant or misplaced attention is paid to the slum. It is not unrelated to the fact that those employed in the capital-intensive jobs in the cities have more effective demand and can better argue for increased personalization of healthcare services and deepening of access to medicines. Some authors have even suggested that there is no incentive for politicians to upgrade the slums, especially where they are a source of cheap votes during elections that are easily to manipulate by politicians promising jobs (Zhang, 2018; Klopp and Paller, 2019). Slum dwellers themselves misunderstand the fundamental law of uneven development operating locally and internationally in the labour market of the nations in the core and periphery. This competition was hitherto assuaged by tariffs and government subsidies but has been intensified by neoliberalism[4] (Hilson and Potter, 2005) .

1.2.3 Domain III: Governance

This last point brings the third major plank into view; the dwindling ability of governments to intervene meaningfully in market failures for health and social services due to their weakened ability to raise revenue from effectively taxing international trade(Parilla, 2017).

[4] The loss of world status in the fabric industry by Manchester to India marked an industrial decline and slumification of the midlands region.

In 1984, Jane Jacobs the self-taught urban critic had chronicled this global shift where governments world over are hard pressed to offer tax breaks to multinationals to locate some part of their global value chains in their countries, in competition with other cities in the global periphery as behind the death of America's great cities (Jacobs, 1984, 2016). In the neoliberal economic competition between cities for manufacturing jobs, those with a combination of cheap labour and good infrastructure, will win versus those with either a poor infrastructure/cheap labour combination or a good infrastructure/high wage labour mix[5]. This leaves cities with a high wage unemployment poverty such as in San Francisco to struggle with a with a dwindling middle class tax base. The cities like Lagos despite teeming low wage labour lose out due to parlous state of the infrastructure which raises operating costs and erodes profits. San Francisco and New York however can afford to raise taxes on the service sectors left behind to fund its infrastructure and welfare programmes. Lagos on the other hand, lacking the capacity to do so, and a wealthy service sector, resorts to borrowing and foreign aid.

These issues of governance have been made most acute in postcolonial states by the IMF led Structural Adjustment Programme of the 1980's which has led to an increased vulnerability of the economy to FDI flows crowding out local entrepreneurship (Shafaeddin, 2012). The shock therapy of SAP included currency devaluation, privatization of public infrastructure, wage freezes, and reduction in the size of and depth of welfare services. Meredeth Turshen (1999) has traced the health fortunes of pregnant women in rural Africa between the post-colonial period before SAP and after SAP. The results demonstrate that the privatization of healthcare driven by the neoliberal package has worsened the health outcomes of these women especially where the cost of medicines can become a barrier to antenatal services. Without the central purchasing schemes of government welfare programmes, most health institutions in Africa are unable to negotiate better deals for medicines. In fact, Meredith Turshen also traces the situation in Nigeria post-SAP to observe that

> "[SAP] called for a high tax on imported raw materials and the devaluation of the naira; between them these policies wiped out 65% of the local manufacturing

[5] The entire economic policy of the Trump Presidency was to halt this haemorrhaging of jobs from New York to China. The morality or rationality of the economic policy is not the focus here, rather it is to ask, how do governments can continue to fund healthcare as a social good in the face of dwindling revenues from taxation and job losses from international labour competition.

pharmaceuticals. Currently, local drug manufacturing meets only 20% of the nations health needs; 80% of drugs are imported" (Turshen, 2014).

Some authors like Ayinam (1994) have pointed out the spatial dimension of the "growth now, redistribution later" effect of FDI favouring the cash crop export region of southern Ghana over all the other regions of the country which are largely crop production zones.

Mo Yamin and Noemi Sinkovics (2005) have identified that the FDI attracted by the neoliberalism of low-income countries is largely the asset exploiting type, with low value adding activity. As such value-added taxation revenue is low from such activities. Their finding is that the low development potential of most FDI leads to three main propositions.

i. "Attracting FDI diverts resources from public investment in infrastructure and thus constrains basic infrastructure development.
ii. The negative impact of attracting FDI on infrastructure development is greater in rural areas and poorer regions in LDCs more generally.
iii. The negative impact if attracting FDI on infrastructure is greater in countries with low human capital development." (Yamin and Sinkovics, 2009)

The pressure on governments to compete away tax revenues to attract foreign direct investment, and retain jobs introduces a critical governance problem that destroys the capacity of governments to fund social welfare programmes. First is that without the power to govern international trade within its borders, states lose the ability to govern the costs of welfare for their citizens, especially where international trade represents the bulk of revenue. This funding problem forces the government to externalize unto its citizens the cost of these social welfare services through privatization. This privatization is going on even in the high-income countries[6]. In sum, the ability of the government to internalize the costs of welfare programmes is hinged on the capacity of the state to tax. Neoliberalism took away the ability to impose taxes on international trade in the form of tariffs. The loss of this revenue has forced governments which are import dependent to externalize the costs of health services.

[6] In 2017, the NHS in the UK introduced a health surcharge on visa applicants for the first time in over 50 years to raise funding shortfalls as the government which had hitherto internalized all the costs of healthcare service delivery since 1947 is starting to externalize those costs to consumers (first to the foreigner, soon to the citizens).

These three issues of patents, slums, and governance frame the performance dimensions facing the global world-system of health. They are the three key areas or sets of questions for interrogation of global health systems using international business theory. The first area is around ownership of medicines and the whole gamut of intellectual property rights that structure the regimes (branded or generic) under which people may exercise access to medicines. The second area is around the location of healthcare services in the world-system of globalization, between the core cities which demand for increasing health personalization and their peri urban slums whose health challenges call for quickly widening access to basic medical health services through redistributive health programmes. The third is around the issue of health governance, and how much of healthcare costs the state should internalize as government expenditure and how much should be left to the consumers as out of pocket costs. The first consideration of ownership touches on the availability of medicines. The second consideration of location deals with how to distribute health services and where to locate health resources between primary health clinics distributed throughout the slums, or tertiary multispecialty medical complexes located in the heart of town. The third consideration looks at who will pay for health and how much they must pay to have access to medicines, especially where the state has to reconsider and renegotiate the social contract and its promise of universal healthcare as a social good in the face of new realities.

The PhD will therefore consider access to medicines in all three dimensions of ownership, location, and internalization, with emphasis on the new realities of patents, slums, and governance. If these bear any semblance to the OLI framework by John Dunning, that is simply because all truths are parallel. It however lends credence to the fact that the issues identified pitch the PhD academically in international business scholarship.

The PhD is thus organized in the monograph format. What follows is an in-depth literature review of Global Value Chains and the Institutional Voids literature. In chapter 3, World-System Theory is introduced to (re)develop a typological theoretical framework of Global Value Chains. This is done by first developing effective proxies for Gereffi, Humphrey and Sturgeon's 2005 framework, and using them to operationalize Global Value Chains in health. Chapter 4 discusses these methodological and theoretical contributions to Global Value Chains scholarship using the case study method developed by Alexander George and Andrew Bennett in their book *'Case Studies and Theory Development in the Social Sciences'*(George and Bennett, 2005).

Chapter 4 is important because it presents the methods of analytical explanation and process-tracing are used to create the case studies, and how theoretical case selection strategy was designed using Institutional Voids. The next four chapters are four cases of institutional intermediaries working to bridge access to medicines across Institutional Voids in product, labour, and capital markets in health. An introductory lead in case is used to introduce the dynamics of Institutional Voids on Global Value Chains governance by following the failed introduction of an antiasthma product into Nigeria.

In chapter 9, these is an analysis and discussion of these cases as types of value chain configurations in the noncore institutional context of health. What emerges is a typology of value chains and the associated purchasing strategies for access to medicines in noncore contexts in which most of the world live and work. Across Chapter 9 and 10, there is a theme of policy-orientation to guide action in the field of health.

Chapter 10 concludes with the three main contributions of the PhD which are first; an updated and operational framework of value chain governance in health which fulfils a 17-year wait for a fully empirical typology of value chains demanded by Gereffi, Humphrey and Sturgeon in 2005. The second main contribution is the demonstration that the open health market and its value chain for fully commoditized generic medicines is the cornerstone of medicines policy in the noncore context, upon which health communities, health clubs and global partnerships for health can be built. This is an important addition to classical economic theory to show that free markets exist as a concept and a real phenomenon, but only in those noncore parts of the world where the state is unable to internalize the quality guarantee for these markets. The third major contribution is the addition of common knowledge as a performance dimension to common pool resource governance theory by Elinor Ostrom.

Taken together these contributions to theory and practice are a look forward to the trajectories of health in a globalized world increasing marked by polarization and inequality between its core and noncore parts, and what the implications for value chain governance in health will be for today and tomorrow.

Chapter 2: An Introductory Literature Review of Global Value Chains

What follows is an outline mapping the development of the 'chain' metaphor through Global Commodity Chains scholarship, Global Production Network literature and Global Value Chains theory into the dominant framework for the analysis of the world economy.

To theoretically position Global Value Chains within the context of the 'world economy', this chapter adopts the World-System Theory of Immanuel Wallerstein and Fernand Braudel to frame Global Value Chains as operating through a distinctly capitalist world-system with definite features, mechanisms and dynamics that structure the outcomes of Global Value Chains as they touch down in different parts of the world.

The chapter concludes by operationalizing Global Value Chains theory into the world economy in order to frame a research agenda into the 'make or break' question implicit in International Business.

The concept of economic value chains as the unit of analysis in globalization mobilizes the transaction cost economics by Oliver Williamson beyond the boundary of the firm into transboundary spaces and across international borders (Williamson, 1979, 1981, 2000).

Williamson sets out the elements and attributes of transaction costs that enable managerial analysis to decide what parts of the economic value chain are internalized within the firm and which parts are not (Williamson, 2002b). Writ large it can also be used to understand the geographically distributed economic activities which comprise an integrated production system in the world economy, and to ask under what conditions do these chains break down, and how to fix them.

Building on these micro foundations, global value chain theory employs World-System analysis (Wallerstein, 2004) in framing the dynamics between the institutional discontinuities that exist in of the world-system. It provides a framework to understand the various configurations that value may adopt as they move from core to noncore. The argument is that the economic value chains incur transaction costs as they move from core economic zones into noncore zones with different institutional arrangements. The transaction costs may be so high as to reduce the efficiency of the global value chain, thus severely limiting or truncating the value chain.

In health, this has serious implications on access to medicines through economic value chains, especially global value chains which transverse the world-system of global health from core to noncore institutional arrangements.

While the supply chain literature has been content to focus on the mechanics of exchanging commodities between firms, it is of limited value in the analysis of the institutional arrangements that structure the cultural environments in which global value chains touch down (Gereffi, 2001). The global value chain literature has taken a historical sociology approach to study the elements and attributes of this institutional context especially first in the Global Commodity Chain approach to the present theory of Global Value Chains (Gereffi, Humphrey and Sturgeon, 2005).

The Global Commodity Chains literature steeped in world-system theory has its focus on the study of how economic value chains structure development outcomes, with states as lead actors, sometimes enabling and sometimes driving the governance of these chains (Gereffi and Korzeniewicz, 1994; Gereffi, 1996; Raikes, Friis Jensen and Ponte, 2000; Bair, 2005). Global Value Chain literature which is a meso level theorizing focuses on

global firms as the lead conductors in the orchestra of suppliers in the world economy. Indeed, in Gereffi, Humphrey and Sturgeon (2005), the articulation of Global Value Chains theory is between the lead firm and the supplier.

In addition to this, there is a rather overwhelming focus in much of Global Value Chains literature on the upstream activities of design, manufacture, production, while paying lip service to consumption as economic activity. This is understandable, the action and drama of Innovation Management, Research and Development, is often always upstream. But the career of a commodity doesn't begin and end between supplier and producer as it is made out to be in Global Value Chain literature. It is between producer and consumer. And that consumer may well be a single individual admitted in a clinic requiring access to medicines through a global value chain of healthcare.

This study adopts the consumer (end-user) focus on the Global Value Chains for medicines and examines the interaction between these value chains and the different institutional contexts they encounter as they transverse the globe. The focus is on how changes in institutional contexts affect the governance of Global Value Chains for medicines, and how these changes in the governance of global value chains impact on access to medicines for consumers in the noncore economic context where the market for global health is either poorly formed, weak or non-existent (noncore markets).

There is much to be said for the merits of Global Value Chain scholarship in research on access to medicines. Its theoretical framework contains an agenda for research and policy that has also found wide acceptance and application in diverse industries and sectors such as energy (Zhang and Gallagher, 2016; Kaltenegger, Löschel and Pothen, 2017), aquaculture (Jespersen *et al.*, 2014; Bush *et al.*, 2019), coffee (Grabs and Ponte, 2019; Behuria, 2020; Richey and Ponte, 2020), wine (Ponte, 2009; Staricco and Ponte, 2015; Goncharuk, 2017), automobiles (Sturgeon, Van Biesebroeck and Gereffi, 2008; Contreras, Carrillo and Alonso, 2012), fashion (Lan and Zhu, 2014; Perri, 2017), mobile electronics (Dedrick, Kraemer and Linden, 2010; Sun, Chen and Pleggenkuhle-Miles, 2010; Lee, Gereffi and Nathan, 2013, 2013), and even human trafficking (Gilbertson, 2015; Stringer and Michailova, 2018). The Global Value Chains framework provides a tractable middle range theory for industry analysis due to its modular structure.

Therefore, this study employs the Global Value Chains literature and framework to research the chronic lack of access to medicines in developing countries. In order to

contextualize the Global Value Chains in developing countries without resorting to a caricature of the context or an overly descriptive account of the unique situation of these post-colonial countries using the usual adjectives like corruption, poverty and underdevelopment, the study employs World-System Theory and Institutional Voids literature to provide a structured approach to the study of institutional discontinuities that truncate and fragment Global Value Chains for medicines in developing countries. The World-System Theory operationalizes Global Value Chains into the two main analytical spaces (institutional contexts) that characterize the world economy, Core and Noncore.

2.1 Make or Break: A 'brief' History.

Coase's paper in 1937 *The Nature of the Firm* was essentially trying to answer the question of how to organize contracts according to the relative efficiencies of the transactions organized by the entrepreneur within the firm or the price mechanism of the market (Coase, 1937).

> "We may sum up this section of the argument by saying that the operation of a market costs something and by forming an organisation and allowing some authority (an " entrepreneur ") to direct the resources, certain marketing costs are saved"(Coase, 1937).

To establish the raison d'etre for the boundary of the firm, he tried to position the firm as a non-price mechanism for producing things that the market would not deliver efficiently.

> "The point has been made in the previous paragraph that a firm will tend to expand until the costs of organising an extra transaction within the firm become equal to the costs of carrying out the same transaction by means of an exchange on the open market or the costs of organising in another firm"(Coase, 1937).

But the specific elements and attributes of this efficiency calculus was never fully conceptualized. It would remain so until Williamson established in 1973 that the firm and market were both governance structures for controlling transaction costs when faced with risk of opportunism arising from incomplete information, and varying asset specificity depending on the futurity of interactions (Williamson, 1973, 1975; Williamson & Ouchi, 1975).

The important contribution of Williamson (2000) to the make or buy question was to explain the efficiency of transactions in operational terms of Asset Specialization, risk of opportunism from Asymmetry of Knowledge, and the Frequency of transactions over time and their degree of futurity (Williamson, 2000). Long-term transactions with high asset specificity, and imperfect knowledge of every possible contingency, over an extended period of interaction required contractual safeguards (the firm) to govern them. The other short-term transactions with easily specified contingencies and low degrees of asset specialization were so efficient that they could be performed between anonymous economic agents in a Market.

This study demonstrates that the changes in institutional contexts lead to changes in these operational variables of asset specificity, bounded rationality, and frequency that explain the make-or-break decision within value chains. These changes also shift the efficiency curve of the firm to the point that transactions which can be done efficiently in the market of the core context may require to be folded into the firm in a noncore context (Williamson, 1999).

It stands to reason that Williamson's science of contracts (Williamson, 1981) can be, or indeed should be applied to the micro foundations of Gereffi, Humphrey and Sturgeon's Theory of Global Value Chains published in 2005. In it the science of contracts is extended to unpack the operational elements and variables that structure the managerial decision of how lead firms slice and dice the economic value chain and the implications for value chain governance.

The Global Value Chains literature however is the product of a long period of scholarship. The next section traces the evolution of the Global Value Chains framework from the earlier Global Commodity Chains formulation by Gereffi and Korzeniewicz in 1994 and takes a detour through the Global Production Network ideas of the Manchester School (Henderson *et al.*, 2002), before presenting the current positioning of Global Value Chains in Gereffi, Humphrey and Sturgeon (2005).

2.2 Global Commodity Chains.

Wallerstein and Hopkins in 1977 applied the term global commodity chains to describe the international trade links between the core and periphery parts of the global production system. They defined commodity chains as "…a network of labour and production processes whose end result is a finished commodity" (Hopkins and Wallerstein, 1977)

Using a long-range study of the shipbuilding and wheat industry, they present a four-point framework for unpacking the "transnational interdependence of productive activities".

(a) The types of commodity and nature of flows between each node of the production process, whether by market transfer across firms or nonmarket transfers within firms.
(b) The relations of production and labour in terms of wage rates, paid or unpaid labour.
(c) The organization of production by type of technology and the unit of production.
(d) The geographical location and distribution of the production process within a political unit (Gereffi and Korzeniewicz, 1994).

With this they were able to find evidence of a globally integrated system of production around an international social division of labour between core and noncore parts. They went further to demonstrate that both commodity chains for ships and wheat showed the same structural transformations across the expansion and contraction phases of the capitalist world-system. This evidence further strengthened their thesis that the wealth of core contexts resulted from

> "…the transformation of trade surpluses between distant points into a true division of labour with integrated production processes crosscutting political jurisdictions, and that the state-level and local processes ensued therefrom" (Gereffi and Korzeniewicz, 1994).

Gereffi and Korzeniewicz's work in 1994 on Global Commodity Chains (GCC) did two major things. First it identified the role of lead firms and client firms, with the lead firms as coordinators within the global production systems involving two or more autonomous firms (Gereffi and Korzeniewicz, 1994). Secondly in making the distinction between buyer and supplier type of lead firms, they opened the research space for the study of how firms govern the value chain; determining who can participate, where, and how much in the

process of capital creation, accumulation and (re)distribution within a distributed global production system that is both economically and geographically oriented.

They would go on to sharpen the three-point agenda of global commodity chains research into a framework built around (1) and input-output structure (2) territoriality (3) and the governance type.

It is important to note that the use of the term 'Global' in global commodity chains literature is to emphasize the implicit worldview of a global production system functioning as an integrated world economy composed of geographically distributed industrial processes (Dicken, 2015). Thus, relegating the state to an interventionist role. In so doing, the analysis abstracts away the national borders and implies that the economic calculus of the managers within the global system is driven purely by a view of the world as one single market governed by a universal set of rules.

Indeed, this position is supported by the borderlessness of investment capital, international mobility of managerial talent and instant transmissibility of knowledge in todays networked world. Thus, the global production system (Gereffi, 1995; Buckley, 2009) is free to float around the world and touch down virtually anywhere the economic conditions (especially tax incentives) are right. The increasing integration of economic activities across international borders thanks to digitally enabled communication technology have made it easy for firms to carve up their value chains into 'slivers of activity' which they easily ship and shift for economic advantage and market power (Buckley, 2009). This is the global feature within the global commodity chains literature. The question is how do lead firms govern the global value chain without owning most parts of the world economy. It is this question that Gereffi and Korzeniewicz tried to answer in 1994.

Gereffi and Korzeniewicz (1994) identified the two principal kinds of commodity chains in the global economy; Producer Driven Commodity Chains (PDCC's) and Buyer Driven Commodity Chains (BDCC's) (Gereffi and Korzeniewicz, 1994), derived from the two sources of leadership in Global Commodity Chains; control over market access and ownership of technology. In Producer-Driven Commodity Chains, the source of leadership stems from the control of lead firms over strategic factors of production, and in Buyer-Driven Commodity Chains, from strategic control over market access. In the former it was power of large producers built on technological and firm capabilities. In the Buyer-Driven

Commodity Chains it was the power of large buyers to consolidate retail channels and access to markets and consumers (Gereffi and Korzeniewicz, 1994).

This distinction brought into sharp analytical focus the effects of large department stores which had started around the turn of the 19th century, had risen into prominence by the mid-20th century (Sainsbury; 1869, Marks & Spencer; 1884, Sears & Roebuck; 1892, JC Penny; 1902, Carrefour; 1958, and Walmart; 1962) and began to exert a distinctive influence on the global economy by their purchasing choices and supplier management practices while devoid of any manufacturing capability. It also frames the unit of analysis in International Business literature away from state as the unit (or driver) of trade and investment.

In framing the lead firm as the new sheriff of the international economy, it was Gereffi's genius to demonstrate that power had changed hands in the global economy and to characterize the new control points within buyer driven or producer driven chains (Gereffi, 1996). In this way he opened the door for institutional theorists to postulate on the mechanisms used by these lead firms to organize the value chains driving the global economy, and what the elements of this new governance are. Gereffi himself offered some clues in this exegesis with their three-points of reference; input-output process, geography, and governance (Gereffi and Korzeniewicz, 1994).

It is important to note that this three-point framework ignored the fourth item in Hopkins and Wallerstein's paper, that is, the idea of the political unit in which production processes are organized either as national or international (Hopkins and Wallerstein, 1977).

This omission would lead to a well sustained critique by Prof Jennifer Bair, Professor of Sociology in Globalization at the University of Virginia USA, which argued for this dimension of the global to be brought back into the largely firm-centric approach that divorced global commodity chain scholarship from its world-system heritage (Bair, 2005). This PhD takes into consideration this well-reasoned critique and remarries the world-system analysis to create a methodology for operationalizing a research programme on access to medicines.

2.3 Global Production Networks:

The role of geography and institutional context as part of the variables determining the where and when of global commodity chains attracted the interest of economic geographers to study the impact of local conditions on the dynamics of the commodity chains at a regional level (Alford and Phillips, 2018; Barrientos et al., 2012; Coe et al., 2008a, 2008b; Coe and Hess, 2013; Ernst, 2002; Hess, 2004; Yeung and Coe, 2015).

In this approach which later became known as the Manchester School after the University of Manchester where this intellectual tradition flourished, it is the socio-spatial networks of local institutional arrangements which play a leading role in the way and manner in which GCC's arise and were governed within the global economy. This approach has garnered respectable patronage as the Global Production Network body of literature (Dicken *et al.*, 2001; Henderson *et al.*, 2002; Hess and Yeung, 2006; Yeung, 2016).

The Global Production Network literature (re)entangles the economic chain into the social for a largely descriptive explanation of production efficiencies within a commodity chain. But it doesn't come close to mobilizing a science of transaction costs like the Global Value Chain framework.

2.4 Economic Value Chains:

But it wasn't until Tim Sturgeon's work on contract manufacturing in the electronics industry which identified modularity as an explanatory factor in the decision to make or break the value chain that something radically new was contributed to the conversation, using a microeconomics of transaction costs in explaining the governance of value chains (Sturgeon, 2002). The concept of modular manufacturing which enabled outsourcing in large automobile firms offered sufficient explanatory scope to the question of 'how do lead firms organize the global commodity chains they control over a widely distributed geography of production (Ponte and Sturgeon, 2014).

The concept of modularity borrowed from engineering design conceptualizes that systems and relationships can be decomposed into constituent parts that can exist separately as autonomous modules but coordinated centrally. Ronald Coase had earlier mentioned in 1937 that "all changes which improve managerial technique will tend to increase the size of the firm" (Coase, 1937). It remained to be understood how firms increased their

managerial span of control without expanding the boundary of the firm through acquisition (ownership).

Baldwin and Clark (2000) applied the concept of modularity to Organizational Design to show that even property rights can be modularized and exist separately as strategic bottlenecks that constrain access to factors of production (Baldwin and Clark, 2000; Baldwin, 2015). What Sturgeon showed that contributed to the Global Commodity Chains discussion was that value chains were themselves modular (Sturgeon, 2002). Not only were they modular, but also the recombination of these modules gave rise to the different possible types of value chains in an industry or sector. And that firms could manipulate these modules and the linkages (nodes) between them to achieve control without ownership (Sturgeon, 2008). Thus, what had previously been lumped under transaction cost economics as 'efficiency' and 'governance' became 'modularity' and 'configuration'. This provided a way to translate Oliver Williamson's science of transactions into a theory of value chains. It suggested that there was an underlying structure to determining how the governance design would shape up over the economic transaction. Whereas Williamson had modularized the governance of economic transaction into Asset Specialization, Knowledge Asymmetry and Frequency, Sturgeon provided an agenda for a modular study of chain governance (Sturgeon, 2001, 2007; Sturgeon, Van Biesebroeck and Gereffi, 2008).

In a skilful rehearsal of Williamsons rendition of transaction cost economics, Sturgeon went further to demonstrate that the ability of lead firms to modularize the transactions in the production process at specific nodes within the chain is what enables them to fragment, disarticulate - and coupled with borderless financialization - to transplant and rearticulate specific segments of the chain in new locations (Sturgeon, 2002).

For the first time, Sturgeon's work on the US automobile industry points of disarticulation (nodes) in the economic chain provided a reference point for scholars of international business to posit about the transaction costs of certain economic activities. This applied science of transaction costs within the chain provided a structured way of understanding which activities were likely to be modularized and shifted around, and which were likely to be integrated into the firm.

In his 2002 paper, Sturgeon showed that modularization of the value chain was dependent on the degree of codification required to perform a transaction across an organizational

boundary (Sturgeon, 2002). If the information was complex and difficult to codify, then the transaction would require specialized capability. Often this specialized capability required that a firm be set up over the value chain to govern the transaction. On the other hand, if the information required for the transaction is easy to codify, and simple enough to allow hands off coordination of the transaction, for example, through the use of standards, conventions and fully specified 'contracts', then there was no need to fold the exchange under a firm. These easily codifiable transactions would then be outsourced from market transfers. The degree of codifiability of the information required to coordinate the economic activity was according to Sturgeon (2002) the key factor in deciding where modularization would be feasible. Transactions requiring complex information that had low codifiability and high internal capability for governance would end up in an integrated value chain requiring strong ownership and control in the hierarchy of the firm. These complex and difficult to codify transactions having high transaction costs had to be performed in the firm. However, transactions requiring simple information, easy to codify and not requiring any specialized governance capability could easily be modularized and shipped around without requiring ownership to achieve control. These simple and easy to codify transactions having low transaction costs could be performed in the open market.

This theoretical contribution of modularity as a design concept in the governance of economic chains was picked up by Gary Gereffi who teamed up with Sturgeon and Humphrey in 2005 to develop a new theory for global commodity chain scholarship (Gereffi, Humphrey and Sturgeon, 2005). Their latest effort showed that governance of economic value chains was contingent on the complexity of the information required to perform the transaction, its codifiability, and the capability of the firm to operationalize the transaction accordingly (Gereffi, Humphrey and Sturgeon, 2005). They explain the make or break within the global production system of the world economy.

On the other hand, the network approach of the Manchester school of GPN scholarship proposed that the governance of interfirm linkages within the global production system required strong social ties between firms (Hess, 2004). These social ties they propose explains the geographical clusters of regional production networks in the global economy (e.g. Silicon Valley in California) and the governance of the interfirm links in these clusters built on trust developed over repeated exchanges in a geographically rooted spatio-temporal arrangement.

On the contrary, Sturgeon (2002) showed that widely shared and understood industry codes and standards, could and did substitute for trust in chain governance by lead firms. Sturgeon demonstrates that the nature of the input-output process (and the extent of its modularization by codification) was a more robust variable for an explanation of the governance structures in between hierarchy and markets in Williamsons framework (Williamson, 1973), than the strength of embedded social ties in the economic network between firms in the commodity chain(Sturgeon, 2002).

This is again another major reason why the Global Value Chains theory has won acceptance over the Global Production Network School for industrial analysis. It explains this triumph in terms of a parsimonious theoretical elegance versus the more descriptive, pragmatic approach of GPN scholarship which is more in keeping with the French filière tradition for analyzing commodity sectors between the metropole and the colony (Raikes, Friis Jensen and Ponte, 2000).

2.5 A dynamic framework of upgrading in value chain governance.

These theoretical advances would not have been possible without the contribution of Humphrey and Schmitz (2002) who developed a language of upgrading for suppliers in Global Commodity Chains. Gereffi had earlier introduced the idea that firms located in Global Commodity Chains could and should endeavour to 'move up' the chain to higher value activities. In 1999 he identified a gap for a methodology of analysing 'upgrading'(Gereffi, 1999). He wrote that upgrading "involves organizational learning to improve the position of firms or nations in international trade networks" (Gereffi, 1999) and that the research agenda for study of upgrading must specify "not only why industrial upgrading occurs in global commodity chains, but also how it occurs" (Gereffi, 1999).

Schmitz and Humphrey (Humphrey and Schmitz, 2002a) later described the four types of upgrading as product, process, functional and sectoral (or supply chain upgrading) (Humphrey and Schmitz, 2000, 2002b, 2008). The different aspects of these dimensions need not detain us here, but what is important is that they lend a dynamism to economic value chains in demonstrating that firms could change their position within the chain hierarchy with respect to the lead firm. This provided a much less deterministic outcome

than the earlier global commodity chains approach which only classified lead firms by governance types into Buyer and Producer lead firms.

The remaining job of demonstrating how these changes in the leadership of economic value chains could occur was accomplished in the 2005 Gereffi, Humphrey and Sturgeon paper which showed how changes in complexity, codifiability and capability led to changes in the dynamics of Global Value Chain governance between lead firm and suppliers (Gereffi, Humphrey and Sturgeon, 2005).

2.6 Global Value Chains: A translation from transaction cost economics.

These micro-foundations of the new institutional economics approach in Sturgeon's work were strong enough to inspire Gereffi et al to refurbish the GCC framework to develop a more robust explanation for the different types of interfirm dynamics that didn't neatly fit the binary dichotomy of Producer Driven Commodity Chains and Buyer Driven Commodity Chains (Gereffi, 2001).

Gereffi, Humphrey and Sturgeon (2005) adopt the transaction cost approach to their study on Global Value Chains as follows to derive the attributes that structure a value chain. They rely on much the same theorization of Williamson in structuring the attributes of transactions.

2.6.1 Product Complexity and Asset Specialization

In deriving from Williamson, asset specificity becomes translated into complexity because

"Lead firms increase complexity when they place new demands on the value chain, such as when they seek just-in-time supply and when they increase product differentiation" (Gereffi, Humphrey and Sturgeon, 2005).

In this translation, product differentiation is Oliver Williamson's (Williamson, 2000) Asset Specialization as the first element of transactions in Global Value Chains.

2.6.2 Information Codifiability and Bounded Rationality.

When Gereffi, Humphrey and Sturgeon (2005) employ codification as the second variable for a framework of Global Value Chain Governance, they rely heavily on constructs from information sciences (codes) to describe the "adoption of technical standards that codify information and allow clean hand-offs between trading partners" (Gereffi, Humphrey and Sturgeon, 2005). This they suggest is to enable the "…transfer of non-price information flowing across inter-firm boundary" (Gereffi, Humphrey and Sturgeon, 2005) with "especially the conservation of human effort" (Gereffi, Humphrey and Sturgeon, 2005). This "conservation of human effort" in the last line means the conservation of fiduciary functions required to overcome the bounded rationality resulting from an asymmetric distribution of knowledge. This asymmetric distribution of knowledge and the resulting bounded rationality is the second element of Williamson's transaction cost framework stated differently.

2.6.3 Supplier Capability and Frequency (ordering).

Keesing and Lall (1992) construct supplier capability on the requirement for "producers in developing countries to meet requirements that *frequently* do not (yet) apply to their domestic markets." Gereffi, Humphrey and Sturgeon (2005) point out that this creates a capabilities gap that in turn requires frequent monitoring by the lead firm due to being difficult and time consuming. Capable firms would require less monitoring and would be able to enter into these transactions, and that capable firms are those which are able to "take full responsibility for competencies surrounding process technology…and make capital outlays for components and materials…"pg 84. (Gereffi, Humphrey and Sturgeon, 2005).

"Transaction cost economics acknowledges this fact by employing the variable of frequency. If an input, even an important one, is required infrequently, then it will likely be acquired externally" (Gereffi, Humphrey and Sturgeon, 2005). That is, their participation in these transactions will be devoid of transaction specific *capital outlay*.

2.7 The Global Value Chain Matrix: Types of Governance

Using the three elements of value chain transaction costs, Gereffi, Humphrey and Sturgeon (2005) construct a Global Value Chains governance framework, using Complexity

(derived from Asset Specialization), Codifiability (derived from Bounded Rationality) and Capability (derived from Frequency/Futurity). Gereffi, Humphrey and Sturgeon propose that these elements as characteristics of the interfirm exchange relationships can adopt either of two states, 'high' or 'low'. They then proceed to combine the three elements into these two degrees of freedom. Mathematically this yields eight configurations of the value chain relationship between firms as shown in the table below.

	Complexity	Codifiability	Capability	
Market	Low	High	High	
Modular	High	High	High	
Relational	High	Low	High	
Captive	High	High	Low	
Hierarchy	High	Low	Low	
X	Low	Low	High	Unlikely
Y	Low	Low	Low	Unlikely
Z	Low	High	Low	Ungovernable

Fig 2.2 Global Value Chains Framework from Gereffi, Humphrey and Sturgeon (2005)

Gereffi, Humphrey and Sturgeon (2005) argue that low codifiability cannot coexist with low complexity in the two categories 'X' and 'Y', while high codifiability and low capability would make 'Z' ungovernable as the supplier would exit the value chain. They also go on to submit that the ordering of relationships from Market to Hierarchy demonstrates an increasing asymmetry of power between the lead firm and its supplier with the Market category of interfirm relationships showing little or no power on either side to influence the other, Relational relationships showing perfectly symmetrical power on either side to influence the other in a finely balanced marriage of two firms with equal power, and Hierarchy showing complete dominance and integration of the supplier into the Lead firm.

Gereffi, Humphrey and Sturgeon (2005) closed out their seminal article with a call for the further fine-tuning of the operational variables in their framework.

"High priority for the future will be the development of methods for measuring the key variables in the model. Effective proxies for transactional complexity, level of codification, and supplier competence must be identified and tested in the field" (Gereffi, Humphrey and Sturgeon, 2005).

Operationalizing these three elements and their two degrees of freedom is a required translation in order to construct a unique framework of Global Value Chains for industry analysis.

2.8 Operationalizing Global Value Chains Theory through World-System Analysis:

Wallerstein proposes that the world is split into two economic zones: core and noncore (Wallerstein, 2004). Core economic zones are characterized by high wage incomes, and monopolization of production processes, innovative products and capital-intensive manufacturing. Noncore or peripheral economic zones are characterized on the other hand by low wage incomes, free or generic production processes, standardized products and labour-intensive manufacturing. Wallerstein (2004) goes further to point out that there is an axial division of labour in the world economy which divides the world into capital-intensive versus labour-intensive modes of production. And that the relationships between economic actors within these two economic zones are different with markedly different outcomes even for the same transaction.

Emmanuel Arghiri (1972) would solidify this point with his theory of unequal exchange to demonstrate empirically that actors in core economic zones sold capital-intensive goods at high prices to noncore consumers who in turn sold labour-intensive goods to core consumers at relatively low prices . This unequal exchange reproduced over a long period of time, he argued, produces the structural and reproducible patterns of the capitalist world economy. Arrighi et al show the permanency of these structural inequalities by demonstrating that even when noncore consumers employ the capital-intensive manufacturing technology of core consumers, they are unable to reproduce the same level of capital formation or capture required to transform themselves into high wage income earners. (Arrighi, Silver and Brewer, 2003)

Applying a much older conceptualization between capital-intensive and labour-intensive makes the distinction between core and noncore clearer. In the labour intensive noncore economic zones, even though there may be a great deal of capital investment in the production process, the value created is not protected by the unique set of social relationships called monopoly rights and is therefore competed away.

This is the situation for middle range countries involved in manufacturing generic products such as India, Brazil and China and Russia and South Africa. it is a situation of

immiserating growth because the production process for a standardized product, no matter how capital-intensive, is not protected by monopoly rights. In this situation of labour-intensive noncore production, the manufacturing fails to attract more capital investments because it is devoid of monopoly protection. This situation fits the description of a subsistence economy in an earlier formulation of capital-intensive versus labour-intensive by Arthur Lewis in his seminal 1954 paper titled *Economic Development with Unlimited Supplies of Labour* (Lewis, 1954). In it he writes that the subsistence sector is "…by difference all that part of the economy which is not using reproducible capital. Output per head is lower in this sector than in the capitalist sector because it is not fructified by capital…". Arrighi et al (2003) show on the other hand that even when fructified by capital, the outcomes of the value chain in core and noncore contexts are markedly different (Arrighi, Silver and Brewer, 2003).

Therefore World-System Theory produces two main categories of economic relationships: core and noncore. The noncore category is devoid of monopoly rights and is often labour intensive and undercapitalized, while the core category is protected by monopoly which supports the ceaseless accumulation and retention of capital.

The central thesis of this study is that as Global Value Chains move from core to noncore contexts, they encounter a range of different social relationships and incur transaction costs. The costs impact the efficiency of economic activity in value chains especially in developing countries were the institutions that support market economies are in short supply or too weak to produce core economic conditions.

Operationalizing global value chains into research requires a focus on the implications of these changes in transaction costs on the efficiency of access to medicines through global value chains. First by demonstrating how these institutional differences between core and noncore impact on global value chain performance, transaction cost economics as a science of transactions allows to unpack the dynamics between the global value chain and its institutional environment.

Whereas Gereffi, Humphrey and Sturgeon (2005) frame the value chain as between lead firm and supplier, here it is framed as an economic linkage between two social actors; producer and consumer who live in core and noncore contexts respectively. This framing repositions Global Value Chains as economic transactions writ large, and therefore needs to encompass the innovation and consumption processes to provide a complete picture.

The first step in this operationalization of Global Value Chains is to develop effective proxies for the two degrees of freedom within which the elements of complexity, codifiability and capability may vary. This operationalization exercise provides an opportunity to respond to Jennifer Bair's (2005) critique and call to bring back the 'global' by re-introducing the world-system approach into Global Value Chains research (Bair, 2005). In her opinion it is the wider institutional context that frames the spaces in which Global Value Chains enter and structure the outcomes at the "global-local nexus". She argues that "…what we need to study more closely are the factors external to chains that shape their geography and configuration" (Bair, 2005). It is these factors she goes on to say that make value chains in general to "reflect core-periphery relations" (Bair, 2005).

2.8.1 Degrees of Freedom in the World-system of Capitalism: A first translation.

The world-system approach provides only two degrees of freedom in the world economy. These are the core and noncore spaces that are characterized by a distinct set of institutional relations between product, labour and capital. Reframing the degrees of freedom in Gereffi, Humphrey and Sturgeon (2005) from 'high and low' into core and noncore respectively is the first step in the operationalization of Global Value Chains into world-system research. It is these core and noncore spaces and their institutional arrangements that structure the trajectory and distribution of Global Value Chains to reflect the waves of expansion and contraction of the world economy. Reflections which are captured in the gestalt of Kondratieff waves (Kondratieff, 1979).

Core being filled with Innovative products held under monopoly and produced by high wage income labour under Capital-intensive manufacturing. Peripheral economic zones being filled with Standardized products, produced by low wage income labour, and under subsistence or labour-intensive manufacturing. These two analytical spaces and the sets of relationships they contain provide the two operational spaces or degrees of freedom in the world economy for Global Value Chains to operate in.

On this PhD, core and noncore imported from world-system analysis serve as analytical spaces[7] within which to process-trace the dynamics of Global Value Chain governance brought about by changes in the wider institutional context.

	Complexity	Codifiability	Capability
Market	Non-core Complexity	Non-core Codifiability	Core Capability
Modular	Core Complexity	Non-core Codifiability	Core Capability
Relational	Core Complexity	Core Codifiability	Core Capability
Captive	Core Complexity	Non-core Codifiability	Non-core Capability
Hierarchy	Core Complexity	Core Codifiability	Non-core Capability
X	Non-core Complexity	Core Codifiability	Core Capability
Y	Non-core Complexity	Core Codifiability	Non-core Capability
Z	Non-core Complexity	Non-core Codifiability	Non-core Capability

Translated from Gereffi, Humphrey and Sturgeon (2005)

2.8.2 Elements and Attributes of Global Value Chains: A second translation.

Following from this first translation, the study derives the elements of Global Value Chains from the attributes of Global Value Chains. Wallerstein's (2004) definition of the market as "…both a concrete local structure in which individuals or firms sell and buy goods, and a virtual institution across space" (Wallerstein, 2004) requires that the Global Value Chains that constitute the market can be conceptualized on two levels: the concrete and the virtual. He provides a list of the concrete elements that constitute markets in saying that

[7] Mair and Maarti (2009) define analytical spaces as "spaces in which elements from a variety of institutional spheres, each built around central systems of meanings and social practices, come together and affect the interpretation, enforcement, embodiment of certain focal institutions…."(Mair and Marti, 2009).

"…there are of course separate virtual markets for all commodities as well as for capital and different kinds of labour" (Wallerstein, 2004) and identifies them as "…the factors of production - of labour, capital and commodities" (Wallerstein, 2004).

The important distinction and linkage made by Wallerstein between the "concrete local structure" and its "virtual institution" provide a handle with which to operationalize the variables in the Global Value Chains framework into World-System Theory. Gereffi, Humphrey and Sturgeon (2005) derived Complexity from the increasing 'product differentiation' imposed by lead firms on their suppliers, and Codifiability from the use of codes to 'conserve human effort', and Capability from the ability of the suppliers to make transaction specific 'capital outlays'. The very seeds of the operational elements are already foreshadowed in their derivation as shown above.

Therefore, it is possible to carry out a second translation of governance attributes and to operationalize Complexity, Codifiability and Capability respectively into the objects of Product, Labour and Capital which embody these variables as the basic elements of a Global Value Chain. Operationalizing the attributes of Global Value Chains (complexity, codifiability, capability) into the respective elements of Global Value Chains (product, labour, capital) represents the second translation of Global Value Chains into the world-system approach. This translation presents complexity as an attribute of product, and codifiability as an attribute of labour, while capability is an attribute of capital investment required to perform the transaction between producer and consumer.
The first translation presents the degrees of freedom 'high' and 'low' as the configuration of the value chain in core and noncore contexts respectively. Combining these two translations to recreate the Global Value Chains presents a new framework based on the elements of the Global Value Chain and their contexts.

	Product	Labour	Capital
Market	Non-core Product	Non-core Labour	Core Capital
Modular	Core Product	Non-core Labour	Core Capital
Relational	Core Product	Core Labour	Core Capital
Captive	Core Product	Non-core Labour	Non-core Capital
Hierarchy	Core Product	Core Labour	Non-core Capital
X	Non-core Product	Core Labour	Core Capital
Y	Non-core Product	Core Labour	Non-core Capital
Z[8]	Non-core Product	Non-core Labour	Non-core Capital

This technique of identifying the elements and attributes of global value chain borrows from Williamson's technique of separating the elements of transaction costs and matching them to their respective attributes (Williamson, 2002b). In his 1979 paper, he identified the elements of a transaction as asset specialization, bounded rationality, and frequency (Williamson, 1979). These he subsequently matched with their attributes of incentive intensity, administrative control, and ordering in a later article. In his proposal (Williamson, 2002b), the degree of asset specialization determined the level of incentive intensity. He argued that highly specialized assets are easy to monopolize and to govern compared to generic and unspecialized assets. Specialized assets under monopoly he went further to say are protected from the intense competition for their incentives in the market by monopoly patents. Unspecialized assets on the hand, faced highly intense competition for their incentives and as such could not be used to accumulate capital. Similarly, he demonstrated (Williamson, 2002b) that where knowledge required to perform the transaction was limited and very asymmetric (e.g., transactions for highly specialized assets), there was a need for intense administrative controls, compared to other transactions with complete and symmetric knowledge between buyer and seller (e.g., transactions for unspecialized assets). Finally, he showed (Williamson, 2002b) that transactions which

[8] From the above we immediately see that what the Gereffi, Humphrey and Sturgeon (2005) framework identifies as 'Market' is not the truest approximation of the free market. It still requires the asymmetrical distribution of capability into a core capability. Instead, the truest approximation to the market is the 'Z' category which is performed by non-core labour using non-core capability to generate non-core products devoid of monopoly or asymmetry in distribution of the variables within the market.

were frequent and unspecialized could be publicly ordered suing the market, while transactions which were infrequent and required specialization would require the private ordering of the firm (Williamson, 2002b) (Williamson, 1999).

In so doing, Williamson lays out a precedence for deriving the elements of transactions governance into their respective attributes, which has been followed to derive the elements of Global Value Chains (product, labour, capital) from the attributes of Global Value Chains (complexity, codifiability, capability). This double translation allows for world-system research to be operationalized into any sector and industry by process tracing the product, labour and capital in a way that allows a framework to predict the dynamic interactions between the Global Value Chain and its institutional context.

Healthcare contexts provide an excellent research site to trace the evolution and globalization of Global Value Chains that deliver western medicine under capitalist arrangements.

In the next chapter, this study will employ the Institutional Voids literature as a tool to operationalize Global Value Chains in healthcare.

Chapter 3: An Introductory Literature Review on Institutional Voids and Intermediaries.

The paradoxical situation in Global Value Chains such that although 90% of the medicines required to treat 90% of the world's diseases are available as generics, they are unavailable, unaffordable or of low quality and do not reach the consumers in low-income parts of the world. Rather the Global Value Chains for health are truncated by institutional voids and are unable to deliver access to medicines. This is the practice gap identified by the author as a pharmacist and health care practitioner with over 10 years' experience working in Africa.

This conundrum poses the need for a translation (or reframing) of Global Value Chains framework into health in a way that demonstrates the causal mechanisms, the impact of local institutional arrangements, and interactions of social actors that impinge on the dynamics of governance in the noncore context.

Khanna and Palepu first coined the term 'institutional voids' in their 1998 study on the challenges of global firms in emerging markets (Palepu and Khanna, 1998). They describe emerging markets as characterized by inefficient market transactions due to inadequately developed exchange mechanisms for products, labour and capital. In their 2011 book, 'winning in emerging markets', they furthered this idea into a diagnostic framework for the absence of specific market institutions that facilitate trade (Khanna and Palepu, 2011). The diagnostic framework was intended as a managers guide for global firms seeking to go into emerging markets.

Their work provides a heuristic for describing the presence or absence of well-developed market institutions. In their view, emerging markets with poorly developed market institutions incurred high transaction costs due to the difficulty of performing transactions. Developed markets of the world with strong market institutions allow both seller and buyer to locate, specify and carry out economic exchange with high efficiency and low cost. It is this fundamental idea of transaction costs and the managerial strategies to mitigate them, that they propose as the key to winning or failing in emerging markets.

Their framework provides two things for this PhD. First, it allows the framing of noncore contexts without using well-worn adjectives like underdeveloped, corrupt, or poor. Instead, their framework provides a structural approach to analyzing the unique institutional features of noncore parts in world-system research. Secondly, their framework provides a

useful heuristic for programming the research on Global Value Chains. Without this, it is difficult to operationalize Global Value Chains into noncore contexts with overly descriptive narration which is eventually difficult to generalize or transfer. It also allows to sift out the common themes in the noncore situation that can occur not only in Africa, but even in the developed parts of the world. As this chapter will demonstrate, the idea of institutional voids does not only frame the emerging markets of Africa, Asia and Latin America, but also the weak and fragile collective action arenas of the slum, the inner city, the favela and the sprawling camps for millions of refugees and internally displaced persons. These are all in themselves noncore contexts and are marked by deep institutional deficits for mechanisms and processes that facilitate efficient economic exchange.

It is the broad generalizability and transferability of the institutional voids framework that recommends it for use on this PhD. The idea of noncore itself as a world-system construct has undergone much refinement. Originally used to describe those parts of the world economy marked by low wage labour engaged in subsistence agriculture in contrast to those parts fructified by capital in Lewis' dual mode economy (Lewis, 1954; Prebisch, 1962), the term has come to represent those processes that are generic and devoid of monopoly (Wallerstein, 2004). These processes are not limited to the third world economies but can be seen even in 'developed countries' with industrialized processes producing generic commodities. They can be found in the hollowed-out automobile towns of North America, or the post-industrial towns of Great Britain, and the sweatshops of southeast Asia.

The next section organizes institutional voids as a meso-level construct, or some sort of middle level theory around weak, fragile, or completely absent institutions of the State.

3.2 Types of Institutional Voids

Khanna and Palepu define emerging markets as "…those where [these] specialized intermediaries are absent or poorly functioning" (Khanna and Palepu, 2011). They argue that the absence of these intermediaries creates institutional voids according to the particular strategic factor or outcome markets in which they are missed. These intermediary functions which government institutions often step in to provide or subsidize are critical for the efficient functioning of economic transactions. Khanna and Palepu

(2011) go on to identify the factor and outcome markets in which the institutional voids occur as product, capital, and labour markets.

3.2.1 Institutional voids for Products:

Khanna and Palepu (2011) argue that the lack of physical infrastructure that support the production or distribution and consumption of 'market' goods are an institutional void of the hard kind. These infrastructures include stable electricity supply, a network of motorable roads, efficient sea- and airports with logistics handing capabilities, and a large well developed industrial base. Without this infrastructure to support the submarket for products, the noncore is unable to play host to the lead firms and its value chains. When Global Value Chains originating from lead firms in core contexts try to touch down in these noncore contexts with institutional voids in product markets, they are truncated and unable to deliver access to the products they carry. Other institutional voids in the product market are manifest as the absence of soft infrastructure such as lack of product information around quality, prices and even stock levels. These can be expressed as inadequate product advertisement and marketing agencies, third party and product comparison sources of information in the product market that make transactions inefficient by introducing a great deal of information asymmetry between buyer and seller.

3.2.2 Institutional voids for Labour:

In emerging markets, the market for skilled labour especially can be hard to find. This may be due to the chronic underinvestment in educational institutions or the lack of skills certification boards and examinations. Again, this produces a lack of supporting infrastructure for value chains to touch down in the noncore context. Often lead firms have to import marketing managers, operations managers, business consultants from the core context to work as expatriates in these noncore markets. Lack of union activities is also a feature of limited skill and noncore labour markets as they often preclude the low wages that make skills acquisition and upgrading difficult for workers.

3.2.3 Institutional voids for Capital:

The presence of a sophisticated financial infrastructure is important for Global Value Chains. Central banking systems and sound economic indices expressed in stable exchange rates and wide interconvertibility go a long way to support the international exchanges in

Global Value Chains. These infrastructures however are the nearly exclusive preserve of the core context. Noncore contexts are marked by the absence of these financial infrastructure, derivative financial instruments that make sourcing for capital difficult for lead firms. Institutional voids in capital markets of noncore contexts are marked by unstable currencies, weak central banks, retail banking insolvency and collapse, and poor risk management.

3.4 Strategies for Coping with Institutional Voids

Lead firms operating in these noncore markets have three options facing them when they encounter institutional voids (Khanna and Palepu, 2011).

3.4.1 Subsidiary:

Lead firms which encounter institutional voids for product, labour and capital in noncore markets can decide to import the missing pieces by using a subsidiary to fil in the voids. This often involves importing finance and expatriates from the core context to fill the voids for labour and capital and then market semi-finished or finished goods from Global Value Chains.

This strategy is mostly employed by lead firms in the pharma industry to market branded medicines in noncore markets.

3.4.2 Intermediary:

Lead firms can also work with local institutional intermediaries that work to bridge the institutional voids in noncore markets. These local actors can mobilize local elements of product, labour, and capital to act as a bridge between producer and consumers. These actors often employ institutional bricolage by riding on already existing institutional arrangements in other sectors to bridge institutional voids. For example, they may raise capital from cooperatives, they may train and substitute limited skill workers to work alongside expatriates and reduce headcount for highly skilled professionals, or they may set up local quality assurance proxies for organizing the market. Less scrupulous institutional intermediaries develop an entrepot system of trade to bypass institutional voids. This has serious implications for access to medicines in noncore environments

where they may knowingly or unknowingly be used to introduce fake and substandard medicines.

3.4.3 Exit:

Lead firms may also decide that the cost of working with local institutional intermediaries to bridge the institutional voids are too great and leave the market entirely. Exits are also common for products which have been retired and replaced completely by other products. The usual trajectory for lead firms and global products is that branded products are introduced through a subsidiary, and after a successful run of several years, the subsidiary and the global product is sold especially on patent expiry to a local intermediary who will oversee the production and marketing under license from the lead firm. When the product finally retires due to dwindling demand or substitution, the lead firm withdraws its license completely and retires the product. On the other hand, a lead firm can sometimes opt not to introduce a certain product into a market either to protect its technology, or to avoid sharing governance of the Global Value Chains with a local subsidiary. lead firms take an intermediary strategy in response to nationalist policies that require local content in manufacturing. But what has deep implications for health in noncore contexts is the complete exit of the lead firm and retrieving its products from producers and distributors. If the retirement is accompanied by changes that introduce new substitutes that replace the old product from medical and treatment guidelines, then access to medicines is truncated. This is fairly common for medicines used to treat what were formerly global diseases but are now neglected diseases afflicting the noncore consumer. The old product simply disappears into the institutional voids for its production, distribution and consumption in product, labour and capital markets respectively.

In some instances, there is still willingness to pay for the product among the neglected consumers, but the capital investments required for its manufacture has emigrated into the core innovative processes that manufacture the newer protein-based medicines through patented technologies. For some, the knowledge base simply withers away as practitioners skilled in the use of the old product shift their prescribing patterns to the new products and with them the teaching and practice of medicine moves into the core. In some more severe types of migration, the physicians or practitioners migrate physically into the core context leaving knowledge gaps in the labour markets. In other instances, the product void left

behind by product retirement may be filled with fake and substandard medicines from suppliers trying to fill the supply gap. In markets without strong quality assurance systems, this can lead to serious problems.

3.5 A Conceptual framework for Global Value Chains Research in Health.

The modularity of institutional voids suggests that they can be researched exclusively using in-depth case studies to trace the dynamics between institutional voids in specific markets and their impact on Global Value Chains. This is also supported theoretically by the fact that there is a high degree of theoretical equifinality between the micro-foundations of Global Value Chains theory and institutional voids.

Product voids are equifinal with the variable of complexity and asset specialization in Global Value Chain theory, while the codifiability of transactions and conservation of human effort using codes has much to relate with the labour voids left by emigration in health systems where skilled physicians are unavailable to interpret the medical codes for complex treatment. Deep institutional voids in capital markets also scuttle the ability of suppliers to maintain the availability of old generics, and the absence of health insurance systems in this market has serious impact on access to medicines for consumers in noncore markets engaged in the informal sector.

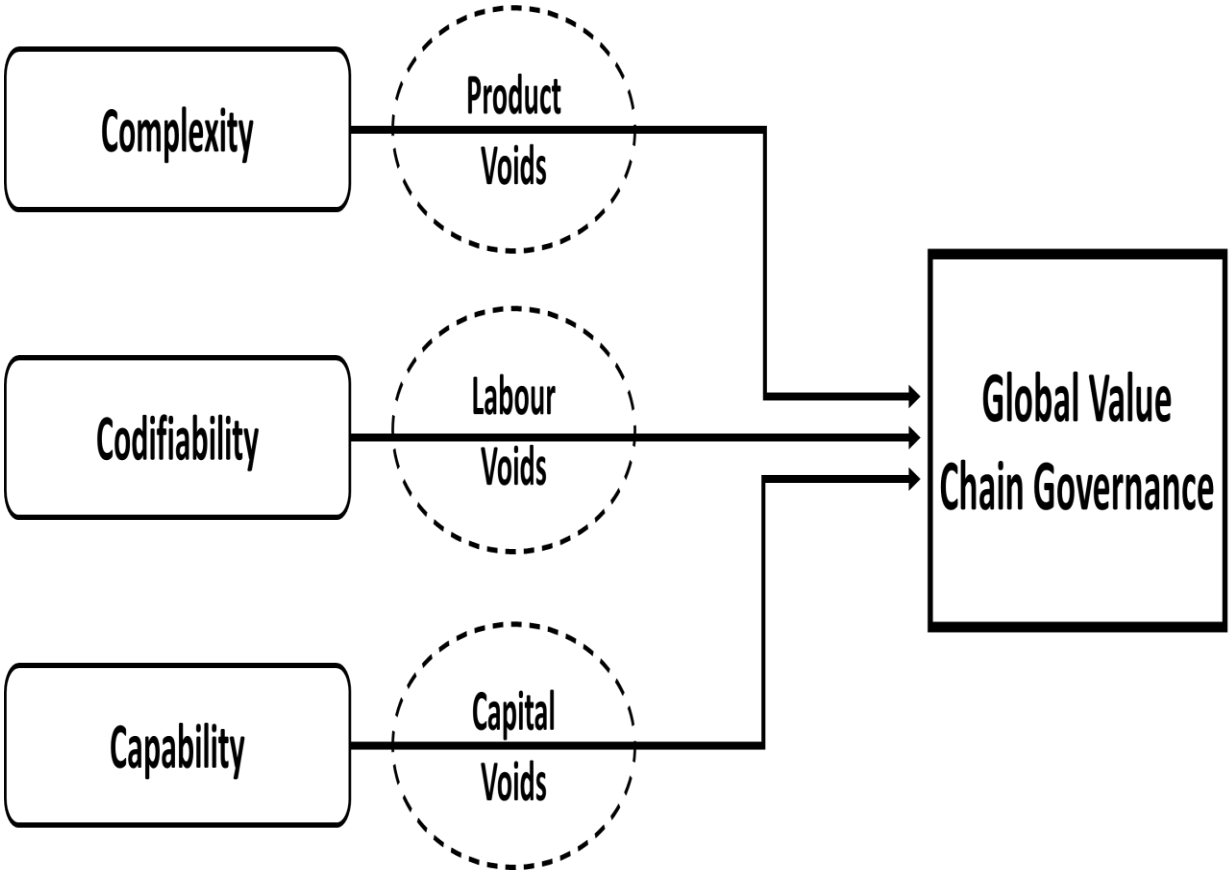
So that while this study employs the Global Value Chains framework for mapping the bilateral exchange relationships and its variables, the Institutional Voids framework provides a ‘method’ for structured focused comparison of the institutional context and problematizing the interaction between the Global Value Chains and the local institutional arrangements. In this conceptualization, the variables of complexity, codifiability and capability in the Global Value Chains framework are the independent variables that structure changes in the governance of Global Value Chains as the dependent variable. Institutional voids bring in the conditions under which various types of governance are predicted to be successful or unsuccessful. This institutional dimension is completely absent in Gereffi, Humphrey and Sturgeon (2005). This weakens the predictive power of the Global Value Chains framework as a middle range theory for decision making by policymakers.

This integration of Global Value Chains in Institutional Voids is a theory driven research agenda for investigating access to medicines with the goal to demonstrate how changes in

the institutional context affect the dynamics of Global Value Chain governance and configuration. It also allows the research agenda to process trace the actions of institutional intermediaries to bridge the gaps within each institutional void.

This enables us to empirically separate the organizational fields which intermediaries operate in and to understand the impact of these institutional intermediaries on the efficient functioning of product, labour, and capital markets.

Conceptual framework of Global Value Chains under institutional voids:



This matching of voids against institutional elements of the global value chain framework allows us to theoretically analyse the evolution of GVC relationships and trace their evolution in emerging markets where institutional voids truncate them. This exogenous variable is absent in Gereffi, Humphrey and Sturgeon (2005). There is an implicit assumption that Global Value Chains will everywhere find or be able to create the local institutional arrangements that support their transactions. Khanna and Palepu argue through their work on institutional voids that this not so.

There are implicit assumptions in the overlapping of these two infra-theories. First is that they are equifinal. The second implication is that this allows a structured focused comparison of each independent variable (complexity, codifiability, and capability) and its exogenous variable.

Nobel Laureate Elinor Ostrom originally created the "action arena" metaphor to characterize social dilemmas of high rivalry with low excludability (Ostrom, 1990). In her words, "The term action arena refers to the social space where individuals interact, exchange goods and services, solve problems, dominate one another, or fight (among the many things that individuals do in action arenas)" (Ostrom, 1990).

But it is her insight that "…the variables that are treated as exogenous when examining an action arena (but may themselves be an outcome of another action arena) …(Ostrom, 1990)" is what makes her institutional analysis and development framework a useful device for characterizing and studying Global Value Chains as theatres of collective action.

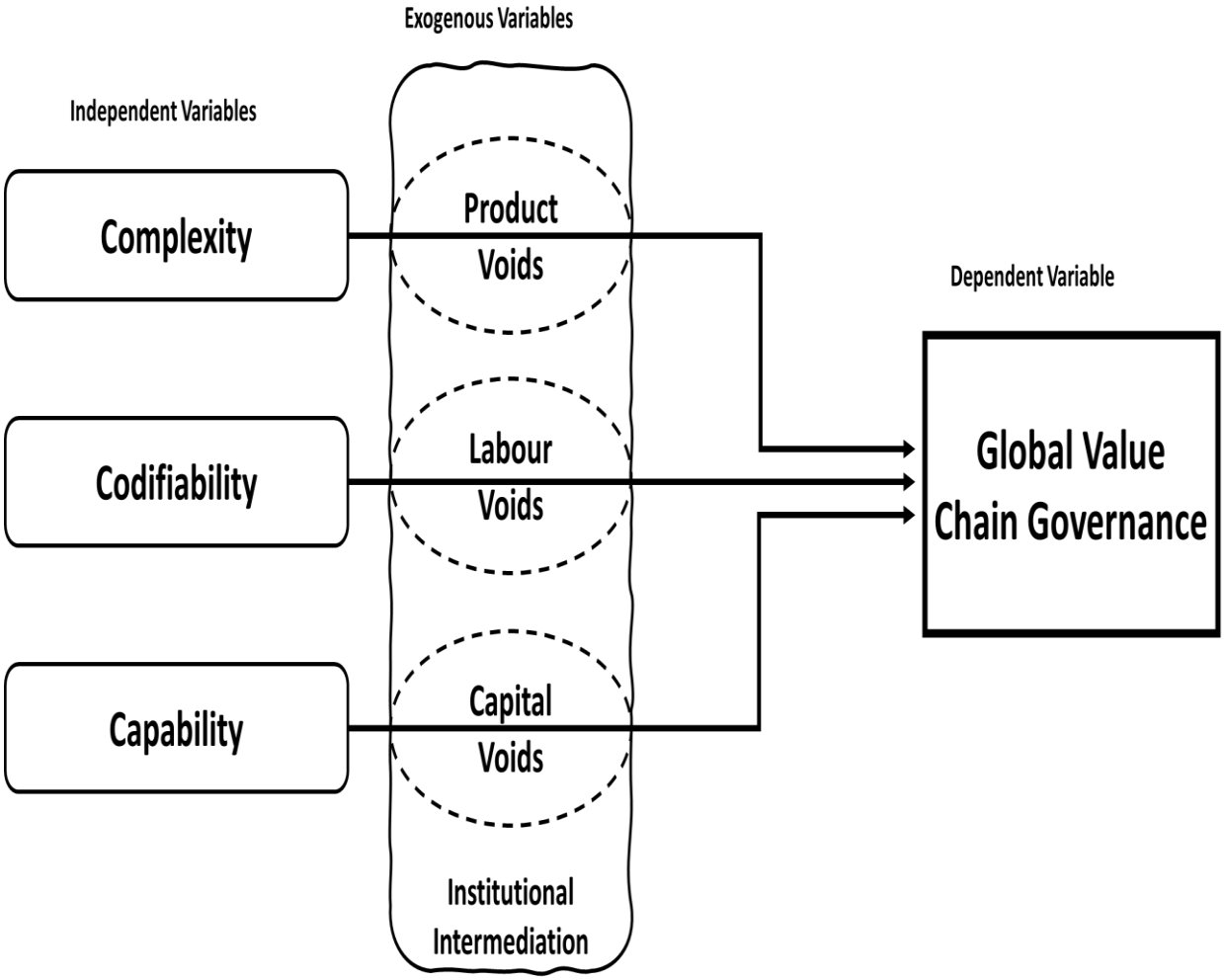
In aligning these institutional elements of the GVC framework with the corresponding institutional voids that impinge on them directly, we can then devise empirical field observations that capture the roles of institutional intermediaries within these specific voids and analyze the resultant dynamics of governance as a dependent variable. There is a rich strand of literature in the Academy of Management Journals on institutional intermediaries.

McDermott et al (2009) conceptualize Government-sponsored Support Institutions as institutional intermediaries brokering the collection, systematization, and dissemination of new knowledge among local groups of producers in the Argentinian wine industry, promoting product upgrading from cheap wines of low quality to upmarket brands of international repute (Mcdermott, Corredoira and Kruse, 2009).

Mair, Marti and Ventresca (2012) in their study of the Bangladeshi NGO BRAC present a picture of intermediation within voids of products and financial resources which exclude women and deprive them of market access. Their study brings into view an important role of not for profit and non-state actors as institutional intermediaries in emerging markets which create market infrastructure and legitimate new customers (in this case women in rural Bangladesh) (Mair, Martí and Ventresca, 2012).

Dutt et al (2016) further stretch this conceptualization of institutional intermediation by distinguishing the market infrastructure development and business capability development functions of open system intermediaries such as governments and NGO's who work with an inclusive mandate in emerging markets to expand market access to resources versus closed system intermediaries which seek to limit the benefits of their market infrastructure and business capability development functions to members of a managed group of value chain actors (Dutt *et al.*, 2016).

Armanios et al (2017) conceptualize science parks in China as institutional intermediaries and economic nodes between foreign entrepreneurs seeking local certification (or context relevance) in emerging markets, and local businesses looking to gain knowledge and resources for business capability (or skill adequacy) (Armanios *et al.*, 2017).



3.6 Designing robust governance for Healthcare Global Value Chains in Africa.

The PhD is thus built on a research agenda that seeks to investigate the role of institutional intermediaries working to bridge institutional voids in product, capital, and labour markets. The selection of these three research objectives is theory driven according to an institutional voids research programme to trace the efforts of institutional intermediaries in Global Value Chains for medicines. As such they allow the phd to process trace the dynamics of exogenous institutional voids on the elements of Global Value Chains in health, and to develop effective proxies for operationalizing these independent variables.

What follows is then a deep dive into the dynamics of Global Value Chains governance under institutional fragility/voids. Using a qualitative approach, the cases reconstruct retrospectively, ongoing cases of institutional intermediation in two African countries located in the East and West of the continent.

The first case is located among coffee farmers in Tanzania, who employ collective action with an international NGO and actuarial service provider to create a micro health insurance system to bridge the gap for access to capital finance in the health market and improve access to medicines.

The second case follows the intervention by an NGO to distribute self-injectable long-acting contraceptives among women living in the largest slum in west Africa marked by an institutional void for high-skilled health professionals. The case traces the performance dimensions that explain the initial success and eventual collapse of the shared governance arrangement using collective action theory.

The third case presents the intervention by a private firm to provide a quality guarantee in the global value chain for generic medicines in Africa's largest open drug market. They employ a fully digital supply chain that enables end to end tracking of generic medicines from port to patient. This simple innovation provides an externally guaranteed quality guarantee for products in a market notorious for fake and substandard medicines.

These three cases are introduced by a capstone fourth case that traces the introduction of a branded inhaled corticosteroid in nebules for aerosolization as an asthma controller by a lead pharma multinational in Nigeria. The case serves to illustrate the global strategy of a lead firm in a noncore context which ignores the institutional voids of the noncore that eventually truncate access to medicines in these parts of the world. The fourth case as lead

in case shows the three institutional voids for a product designed to be administered using costly nebulizers (product voids), at doses calculated by specialist paediatricians (labour voids) and sold as an out-of-pocket expenditure not covered by health insurance (capital voids).

Taken together these cases demonstrate that social actors working as institutional intermediaries can bridge institutional voids by mobilizing institutional resources within the noncore context to improve access to medicines through Global Value Chains. The cases also show that these efforts at institutional intermediation have design principles that are common to them, and where these principles are lost in translation, Global Value Chain governance breaks down in noncore contexts. It is these design principles and the performance dimensions that they enable institutional intermediaries to fulfil which form the bulk of the discussion chapter that follows the four case studies.

But before these cases are developed, the next chapter operationalizes Global Value Chains and the institutional voids that impact on their governance into Pharmacy. The result is an updated Global Value Chains framework for healthcare which maps the eight possible configurations that are possible only in the noncore context. This updated framework shows that the three configurations which were discounted in Gereffi, Humphrey and Sturgeon (2005) actually exist and have the greatest implications for access to medicines in global health.

Chapter 4: Methodology and Theory-driven Case Study Selection

Alexander George and Andrew Bennett in their book; *Case Studies and Theory Development in the Social Sciences* propose case studies as a way of doing complex research on small 'n' problems with complex causal mechanisms which require process-tracing. Their proposal is built on three seminal contributions: Alexander George's 'structured focused comparison', Robert K Merton's idea of 'middle-range theory' and Paul Lazarsfeld's notion of 'property space' (Lazarsfeld, 1966; Merton, 1968; George, 2019).

These three methodological foundations provide in their opinion a way for researchers to develop typological theories by studying aspects of 'historical instances'. They develop an analytical explanation as an inductive tool for theory building (and testing) in what they call analytic induction approach to case study research. The result is a disciplined configurative study (Eckstein, 2000).

George and Bennett (2005) define the case study approach as "the detailed examination of an aspect of a historical episode to develop or test historical explanations that may be generalizable to other events". Their positioning of case study research as the source of middle range typological theories in political science is in between the large 'N' statistical methods for modelling and the formal deductive models of grand theory.

The strength of the case study approach is its ability to allow the exploration of causal mechanisms. It weaknesses however are the selection biases it allows and therefore a lack of representative sampling. These can be mitigated through theory driven case selection.

George and Bennett (2005) developed their unique approach to case study research within the political science literature, especially studying the democratic peace programme. This research agenda focused on the 'inter-democratic peace' which tried to answer why democracies were less prone to go to war against other democracies. They find that case studies can identify new variables, process trace causal mechanisms, and produce typological theories. These typological theories they define as "theories on how different combinations of independent variables interact to produce different types of dependent variables" (George and Bennett, 2005).

The Global Value Chain framework in Gereffi, Humphrey and Sturgeon (2005) is a typological theory derived from a set of five case studies. Thus, this PhD in keeping with Global Value Chain tradition retains this methodology for developing the theory further, in health, and in noncore spaces. George and Bennett (2005) set out to "identify conditions under which specified types of democracies behave in various contexts to produce specific types of conflict behaviour". In similar fashion, the PhD seeks to understand how different institutional conditions under which specific configurations of Global Value Chain elements combine to produce specific types of governance. In so doing, bringing back institutional context into Global Value Chain scholarship and research. In George and Bennett (2005), they produce 'differentiating configurations of independent and dependent variables into qualitatively different "types" such as types of war or types of democracy'. In similar fashion, this PhD is a qualitative study of types of Global Value Chains under various institutional contexts.

Although the case study method sustains a critique of bias in its selection, that is mitigated by the theory driven case selection using institutional voids framework translated into health. There is a clear departure from the deductive nomological approach in Yin and other case study specialists in grounded theory followed in the management literature. The main reason is in keeping with the original methodology of typological theorizing employed by Gereffi, Humphrey and Sturgeon (2005). The case study approach of George and Bennett (2005) is more in keeping with this methodology and deployment of case studies.

4.1 The Role of Globalization in Creating and Sustaining Institutional Voids in Health.

The history of western healthcare took a capitalist turn in the early 1800's with the takeover through regulation of the practice of medicine by central government in order to 'standardize' the field and remove quackery. Following on the heels of the French Revolution, confiscated monasteries were turned into wards where patients and cadavers were subjected to close observation by physicians and their students, giving rise to bedside teaching in medicine. Under this mode of instruction, Xavier Bichat's anatomical medical view of disease at the tissue level, took root and branched out into specialisms organized under the central Paris Hospital and Health Council (*The Project Gutenberg eBook of*

General Anatomy, Applied to Physiology and Medicine. Volume I, by Xavier Bichat., no date). Elsewhere, as Weiner and Sauter note, the medical world was fragmented into pockets of research, especially in England where it was organized around a few chief medical men at Guys', Queen Mary and Brigham in London.

This centralization through the state is important to note in the genesis of Global Value Chains in Healthcare especially that peculiar form of clinical medicine centred around the government funded and controlled city hospitals that took shape in France shortly after the Revolution.

The absence or failure of the State Institutions to play this guarantor role for the economic bracket is what is referred to as institutional voids in this study. These Institutional Voids may be primarily as a result of in vivo conditions of weak states which are historically intrinsic to their formation. They may also be secondary to transformations in the global context, that truncate the ability of the state to perform the economic bracketing (marketization) required for product, labour and capital markets to operate, by self-interested agents.

Institutional Voids in healthcare arise due to the inability of governments to provide the level bracket and boundary objects required to perform markets for healthcare. This can be seen in post-colonial states in Africa which are unable to effectively produce the products (medicines), labour (healthcare professionals) and capital (health finance) required to organize public health. On the other hand, strong and powerful states in Europe are able to coerce through taxation the resources to organize and centralize healthcare as public health services, through universities, research institutes, central banks, and economic policy.

Global Value Chains require this unique socioeconomic and socio-political frame to operate efficiently. Without the presence of strong and effective states organizing public health as a centralized and universal service, lead firms are unable to find the boundary objects of product, labour and capital they require to perform healthcare transactions and govern the value chain.

4.1.1 Institutional Voids for Labour in Heath

Zander (2000) demonstrates that as more people engage in the culture of 'modernity' through globalization in the 21st century, they are faced with three choices: loyalty, voice and exit. They will either stay and remain loyal to their local cultures, or they will attempt to exercise their social voice to bring about westernization in the local environment. Unable to westernize, they can also exercise the exit option to leave and join like-minded people in core countries (cathedrals of modernity). This leaves behind only those who are loyal to the peripheral or noncore culture, or who are too weak to leave. When they do leave, they leave behind institutional voids in the noncore environment for people with the institutional skills for performing western culture (Zander, 2000).

Dussault and Franceshini (2006) point out the geographical dimensions of this polarization of markets in the World-System Theory of health. They argue that "A well-balanced distribution of infrastructures needs to go hand-in-hand with a well-balanced distribution of health personnel to be worth the investment…" (Dussault and Franceschini, 2006). Their paper points out that "in Nicaragua, around 50% of the health personnel are concentrated in the capital city of Managua which holds only 15% of the country's population. In Bangladesh the metropolitan areas contain around 15% of the country's population but 35% of doctors and 30% of nurses, in government positions" (Dussault and Franceschini, 2006).

In Africa they note that the imbalance in places like Côte d'Ivoire, where some "doctors remain unemployed in Abidjan, the principal city" (Dussault and Franceschini, 2006)

The demonstrate how that this "…overstaffing in urban areas can lead to underuse of skilled personnel while increasing the total cost of health care system [and that] Paradoxically, instead of encouraging movement of staff towards rural areas, excess numbers of health professionals in urban areas often promote external "brain drain", as professionals start leaving for employment opportunities abroad."(Dussault and Franceschini, 2006)

The under- and unemployed health professionals who leave for "abroad" often go to fill up the rural posts in core countries, but at the same time are able to earn sufficiently to create a western (core country) lifestyle for themselves and their loved ones. Veblen's theory of tastes is useful in understanding that remuneration is only important factor insofar as it is unable to allow the high skilled health professional to recreate the western standards of

living that they feel entitled to, and through western education, that they have come to expect.

4.1.2 institutional Voids for Capital in Health

The liberalization and structural adjustment programme of the IMF in the eighties essentially deprived developing countries of their ability to raise capital through tariffs on imported goods and services (Yamin and Sinkovics, 2009). In exchange for access to much needed capital and financial integration into the global money supply. Nearly forty years after, and the reality for developing countries has been dwindling revenues and Capital flight from noncore and subsistence markets through the multinationals and international financial banks who insist on tax exemption in exchange for Foreign Direct Investment in peripheral countries (Konadu-Agyemang, 2000). Core countries are less pliable and are able to extract their operating costs for hosting the multinationals. This has effectively created an Institutional Void for capital in developing countries who squander away their ability to tax foreign investment in a competitive scramble with other noncore and subsistence countries to attract foreign direct investment. In recent times, these institutional voids for capital have also shown up in core countries where municipalities struggle with each other in competing away their tax revenues to hold on to a few manufacturing jobs threatened by cheaper imports from Asian manufacturers. These post-industrial towns have become the new noncore economies within developed countries with serious implications for social cohesion and political sustainability. In short, the capital formed in noncore and subsistence economies does not display loyalty or voice, but mostly exit.

4.1.3 Institutional Voids for Products in Health

In the global economy, the product needs and priorities of core economies command most of the investment in research and development. Although the population of core economies number far less than those in noncore economies, their high wage incomes ensure that firms will shape innovation management strategies to prioritize the health needs of core markets. This is seen especially in the marketing priorities of the Pharma multinational in peripheral countries, where they prefer to invest in the commercialization of treatment for noncommunicable diseases which afflict a small percentage of the population, rather than the infectious diseases that exact a heavy toll on people. Even when the treatments are free

and easy to produce, the large numbers of people with unmet needs for infectious disease treatments for diseases like malaria, tuberculosis and diarrhoea remain underserved. Rather the emphasis for the global firm is global products for global diseases like hypertension, diabetes and other noncommunicable disease.

The author remembers pointing out this polarization to his managers at a strategy meeting, saying that the sales targets could be met selling commoditized treatments for infectious diseases rather than the lifestyle treatments. His points were waved away as not in line with the company strategy from London.

4.2 Designing Case Studies of Global Value Chains in Health under Institutional Voids

The method of structured focused comparison of cases to build typological theories requires that the same set of questions be asked in each case. It is focused on specific aspects of the history in each case. In essence this study, is a historical based analysis of governance by lead firms and the role of social actors in trying to bridge gaps due to institutional voids.

This requires that the researcher should identify theoretically the full universe, the set of instances possible. The Global Value Chains framework by Gereffi, Humphrey and Sturgeon (2005) specified eight cases as the full universe, with five predicted cases and three deviant cases. The focus here is on those three deviant cases in Gereffi, Humphrey and Sturgeon (2005), to operationalize them and extend the framework in health.

4.2.1 Identifying the Problem and Research Objective:

There is as already mentioned a practice gap within Global Value Chains for health, which leads to poor access to medicines especially for those in the noncore parts of the world. This practice gap is such that although the majority of medicines required to alleviate the majority of human health problems exists as generics, they remain unaffordable, unavailable, inaccessible or of poor quality in general. This is especially true of those noncore parts of the world where the state is fragile or absent, and thus unable to organize

and guarantee access to medicines. This is the practice gap that shapes the research agenda. But there is also a knowledge gap. And that is the need for effective proxies to operationalize the Global Value Chains framework in the field of health. This methodology chapter therefore does two things. It first develops effective proxies for the Global Value Chains framework derived from world-system theory and proceeds to operationalize them in health.

4.3 Access to Medicines as Proxy for Global Value Chains in Health.

The field of Pharmacy provides a language for operationalizing Global Value Chains in healthcare. Medicines are framed as capital-intensive innovative manufacturing processes and therefore can be held under patent, or they are generic copies produced with standardized manufacturing processes free of monopoly. These two categories of medicines overlap with the two analytical spaces of the capitalist world-system: core and noncore.

Practically they can represent on the field, the two categories of healthcare: public and community health. Public health representing core healthcare exemplified by medicines held under monopoly, which requires high wage income populations and centralized procurement for access. Community Health on the other hand represents the free noncore health system that is markedly generic and free of monopoly, produced using freely available resources, whose knowledge is contained in folklore for easy assimilation, and operated by the individual out-of-pocket, using freely available resources and widely held information, that is reproducible at little or no cost to the individual and the community.

Operationalizing Global Value Chains into health using access to medicines requires a translation of the elements into pharmaceutical variables that can be measured in the field and analysed. The following section translates the three World-System derived elements of product, labour and capital derived from the three attributes of Global Value Chains: complexity, codifiability and capability respectively, into access to medicines. Using two degrees of freedom, the Global Value Chain governance framework is recreated to yield 8 types of access to medicines through Global Value Chains in healthcare.

The research objective here is to develop a disciplined configurative set of case studies – using Global Value Chains theory and institutional voids to analytically explain the cases.

4.3.1 Product

Medicines produced are described as either Original Brand Medicines of innovative type held under patent monopoly, while those in noncore economies are Original Equipment Medicines of standardized type which are generic and freely available. The represent core and noncore medicine products respectively.

Thus, the two analytical spaces of the World-System yield two kinds of Medicines as boundary products of the healthcare system between producer and consumers: Original Brand Medicines (Core) and Original Equipment Medicines (Noncore).

Analytical Space	Product	Abbreviation
Core Economy	Original Brand Medicine	OBM
Noncore Economy	Original Equipment Medicine	OEM

4.3.2 Labour

Since the 12th century when the art of the apothecary began to be recognized as a business in Persia, the knowledge of medicines' use and administration has been often the preserve of a few who employed secrecy and strict rules of access to regulate the transmission of the craft. Government regulation all but destroyed the monopoly of the guilds and craft societies, the licence granting powers for the administration, sale and distribution of medicines in core countries has been the reserve of the state.

Alongside this monopoly, the governments of core countries set up agencies to oversee standards of medicine use which determine the accessibility of medicines by prescription of a government qualified health care practitioner. These are classified as Prescription Only Medicines.

Prescription Only medicines are often complex, difficult to administer and require long years of training in the scientific principles to be able to apply them correctly and prevent abuse. Western medicine as a practice is heavily dependent on the presence of a large number of people who have undergone this process of training, often in Colleges of

Medicine and Schools of Pharmacy subsidized largely by public funds raised through taxation. The Boards of Physicians and Pharmacists which grant these institutions degree granting powers are de facto regulators of the labour supply on which accessibility of medicines depends.

Following the globalization of western medicine as the orthodox system of healthcare, countries have implicitly taken upon themselves the functions of state required to generate these health care professionals in sufficient quantity to meet the healthcare needs of the population. Often, with markedly different results.

Core countries are able to produce sufficient numbers of these highly skilled health care professionals to cover their populations. Noncore countries are unable to produce sufficient numbers of these health professionals or to convince them to stay, losing them to core countries with higher wages.

Prescription Only Medicines are available through high wage income health professionals Over the Counter Medicines through low wage income health workers of limited skill such as the 'chemist' on a street corner with basic education who can dispense simple remedies for simple ailments.

As much as 70% of the population in subsistence countries have no access to medicines through healthcare professionals (Dussault and Franceschini, 2006; Adeloye *et al.*, 2017). The absence of high skilled health professionals in the labour markets of noncore economies creates gaps in the value chain for healthcare services. These gaps are the Institutional Voids in the labour market that truncate access to medicines through Global Value Chains in noncore economic zones.

Analytical Space	Labour Market	Abbreviation
Core Economy	Prescriber Only Medicines	POM
Noncore Economy	Over the Counter Medicines	OTC

4.3.3 Capital

The view of capital taken here is that as a measure of purchasing power, risk pooling mechanisms such as health insurance represent a greater consumer capability for gaining access to medicines compared to the out-of-pocket consumer. A community of insured members can access healthcare global value chains without resorting to catastrophic

spending. Therefore, out-of-pocket expenditure represents low capability and health insurance especially of the universal kind represents high capability to consume within the community.

Western healthcare is expensive to operate. And gaps form easily in the capital market for western healthcare due to its centralized and bureaucratic nature. For this reason, most governments and firms core countries act as intermediaries and have resorted to actuarial science of health insurance to raise levies for filling these gaps in the capital market for health care services.

Core countries are able to raise sufficient levies. Therefore, the capital market for healthcare is formed through a public health approach through universal health insurance systems.

People living and working in noncore economies face a double jeopardy where the state is weak and too small to raise the capital required, and the wage incomes are too low to sustain Out-of-Pocket health expenditure, with resulting undercapitalization of the capital market for health.

The universal health insurance scheme represents a monopolization of accessibility using a single point of payment (Health Management Organization), and is therefore characteristic of core technologies and process, while out-of-pocket expenditure is free of monopoly and characteristic of noncore technology and processes.

Taken together, these are the two types of Capital markets in the World-System of healthcare: Universal Health Insurance where consumer capability required is high, and Out of Pocket Expenditure where the consumer capability required is low.

Analytical Space	Labour Market	Abbreviation
Core Economy	Universal Health Insurance	UHI
Noncore Economy	Out-of-Pocket Expenditure	OOP

4.4 Operationalizing Global Value Chains into Pharmacy Practice.

Substituting the operational variables of derived from Pharmacy, generates the following table.

	Global Value Chain Elements			
Analytical Spaces (Degrees of Freedom)		Product	Labour	Capital
	Core	Original Brand Medicines (OBM)	Prescription Only Medicines (POM)	Universal Health Insurance (UHI)
	Noncore	Original Equipment Medicines (OEM)	Over the Counter Medicines (OTC)	Out of Pocket Expenditure (OOP)

From this table it is demonstrated that the elements of product, labour, and capital each have two degrees of freedom in the World-System Theory of Healthcare. Corresponds to the two degrees of freedom in Gereffi, Humphrey and Sturgeon (2005). These two degrees of freedom when translated using World-System Theory generate core and noncore as operational variables.

As Global Value Chains move from one analytical space to another it is expected that to the extent that Global Value Chains can find elements of product, labour and capital, it will function easily (Core). However, when it encounters institutional voids for any of its constituent elements (Noncore), there will be gaps that truncate access to medicines.

It may be more accurate however to simply say that as Global Value Chains move across these analytical spaces, they adopt one out of eight possible configurations to fit the institutional context. Each configuration can be represented using the extended Gereffi, Humphrey and Sturgeon (2005) framework.

	Product	Labour	Capital
Market	Non-core Commodity	Non-core Labour	Core Capital
Modular	Core Commodity	Non-core Labour	Core Capital
Relational	Core Commodity	Core Labour	Core Capital
Captive	Core Commodity	Non-core Labour	Non-core Capital
Hierarchy	Core Commodity	Core Labour	Non-core Capital
X	Non-core Commodity	Core Labour	Core Capital
Y	Non-core Commodity	Core Labour	Non-core Capital
Z	Non-core Commodity	Non-core Labour	Non-core Capital

In this translation, Core Commodity is represented by Original Brand Medicine (OBM), Noncore Commodity by Original Equipment Medicine (OEM), Core Labour by Prescription Only Medicines (POM), and Noncore Labour by Over-the-Counter Medicines (OTC), while Core Capital is represented by Universal Health Insurance (UHI), and Noncore Capital by Out-of-Pocket Expenditure (OOP).

These operational variables oof Global Value Chains translated into access to medicines allow the researcher to study the dynamics of Global Value Chain as they enter noncore healthcare markets with Institutional Voids for Product, Labour and Capital. Therefore, this study will employ a research agenda designed around case studies of interventions by institutional intermediaries in each of these three types of institutional voids to bridge these gaps and improve access to medicines on the field. This fulfils the call by Gereffi, Humphrey and Sturgeon in their 2005 paper.

“A high priority for the future will be the development of methods for measuring the key variables in the model. Effective proxies for transactional complexity, level of codification, and supplier competence must be identified and tested in the field.”

These table below represents these proxies of Original Brand Medicine (OBM), Original Equipment Manufacturer (OEM), Prescription Only Medicine (POM), Over the Counter Medicine (OTC), Universal Health Insurance (UHI), and Out of Pocket Expenditure (OOP).

	Complexity	Codifiability	Capability
Market	Generic (OEM)	Over the Counter (OTC)	Medical Health Insurance (MHI)
Modular	Brand (OBM)	Over the Counter (OTC)	Medical Health Insurance (MHI)
Relational	Brand (OBM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)
Captive	Brand (OBM)	Over the Counter (OTC)	Out-of-Pocket (OOP)
Hierarchy	Brand (OBM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)
Fragmented	Generic (OEM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)
Distributed	Generic (OEM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)
Open	Generic (OEM)	Over the Counter (OTC)	Out-of-Pocket (OOP)

Fig 4.1 Updated Global Value Chains Framework

4.5 Specifying the Universal set of Global Value Chains in Health.

The Role of the Researcher:

The researcher on this project is a subject matter expert in healthcare. The operationalization of the global value chain framework into access to medicines rests on his professional training and work experience as a pharmacist, having worked in Government, Private and NGO sectors of the Pharmaceutical and Healthcare industry. The Gereffi, Humphrey and Sturgeon (2005) framework was operationalized using cases from respectively, the bicycle manufacturers, vegetable suppliers, apparel, and electronics industries. This (re)operationalization exercise in health has been done to show that all eight types of configurations are possible in healthcare global value chains that provide access to medicines. Over the last ten years, the author has worked in noncore countries in several capacities as a Clinical Pharmacist, A Drug Representative for a Pharma multinational and Project Officer for an international NGO working to improve access to

contraceptives for women in underserved communities. Therefore, first-hand experience of working under institutional voids in healthcare have been brought to bear on this project. As a postgraduate researcher, the author has also worked from time to time as a health worker despite having adequate qualifications, but unable to meet the financial obligations for registering as a full health professional. This has presented an opportunity to draw insights in core countries' system of health of health and understanding the axial divide between high skilled and limited skill work and workers in the world-system of health.

In selecting the cases for investigating institutional voids in healthcare that truncate access to medicines through Global Value Chains, the author has drawn upon professional contacts developed during his working career for access to organizations as research sites for gathering data.

There is much to be said about the role of the researcher as the central agent in the research process. The historical sociology school of thought within the humanities has employed this research programme as the mainstream technique. The world-system theory which this research draws heavily upon is a brilliant example of such a research programme into the origins and dynamics of capitalism.

In order to avoid the danger of researcher bias presented as fact, the cases have proceeded first with theory and then used established theoretical frameworks to drive both investigation (desk-research and fieldwork), analysis and discussion writing.

It is hoped that this approach will at one and the same time draw the seasoned theoretician into the nuts and bolts of healthcare, and still appeal to the veteran practitioner to put on the lenses of theory to cross examine practice in the field.

Global Value Chains in healthcare:

The author will apply these types of Global Value Chains theoretically generated into real life examples – vignettes – that illustrate how Global Value Chains mediate access to medicines in all eight possible configurations.

4.5.1 Market Global Value Chains in Healthcare: Medical Devices

Generic (OEM)	Over the Counter (OTC)	Medical Health Insurance (MHI)

These Global Value Chains configuration carries generic medicines, that do not require the services of a skilled prescriber to administer, but are costly to access, thus requiring group insurance to raise the capital required for access. Poor economies of scale lead to high cost of access. Medical devices also come under this category. They may be easy to use such as wheelchairs and mobility scooters, and manufactured free of patent, but their acquisition may require pooled risk schemes for guaranteed access.

4.5.2 Modular Global Value Chains in Healthcare: Vaccines

Brand (OBM)	Over the Counter (OTC)	Medical Health Insurance (MHI)

These Global Value Chain configurations carry medicines that are under patent monopolies, however whose therapeutic windows are wide enough, and methods of administration are simple enough to allow for over-the-counter sale. However, their high cost indicates a need for group purchasing schemes to pool risk and raise capital for access to medicines. An example of these medicines are vaccines. Although their administration is very easy for example, the oral polio vaccine, only a few drug makers have the patent right and abilities for which consumers pay a premium for. This requires that their access is mediated through group purchasing schemes.

4.5.3 Relational Global Value Chains in Healthcare: Recombinant Anticancer Drugs

Brand (OBM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)

These Global Value Chains carry medicines whose entire life cycle from production to consumption is completely under monopoly. These medicines have their administration under monopoly of skilled medical professionals and come at a cost to the community that requires group purchasing to guarantee access to the Global Value Chain. Anticancer drugs of the newer kind which are proteinaceous in nature are under this kind of situation. Cancer therapy is highly individualized and requires the skilled oncologist to titrate the dose to the

stage of disease. While the simple chemicals used in treating cancers in the early 1900's are now generic, the newer drugs produced by recombinant DNA engineering are still under patent monopolies and are priced at a premium.

4.5.4 Captive Global Value Chains in Healthcare: Galenical (Herbal) Drugs.

Brand (OBM)	Over the Counter (OTC)	Out-of-Pocket (OOP)

Galenical preparations of the herbal kind come under this Global Value Chain configuration. Because they are proprietary mixtures of herbal ingredients in formulas and quantities that are not disclosed, they remain under a monopoly of secrecy. Because they are simple herbal preparations, they can be easily administered with a basic knowledge of dispensing and are easily affordable out-of-pocket. Medicinal teas and bitters for malaria, stomach trouble, insomnia are examples of such products.

4.5.5 Hierarchy Global Value Chains in Healthcare: Multidrug (re)formulation.

Brand (OBM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)

Prescription medicines which go off-patent can be brought back under patent monopoly by evergreening strategies. One of which includes the use of multidrug formulations. For example, some drug makers citing need for convenience have resorted o formulating antihypertensive drugs with anti-cholesterol medicines and even some with a diuretic to improve adherence by reducing pill burden. The patient swallows one pill or two a day as against three to six tablets. Some drug makers rely on pharmaceutics techniques to change the delivery profile of a drug from instant release to slow/sustained release tablets and therefore reduce the doe of the medication from three to four times a day to once a day. These reformulated generics can be repackaged and marketed as new medicines under brand new patent monopolies. But because their active pharmaceutical ingredients are freely available as generics, they are still affordable out of pocket due to price competition also from the older formulations.

4.5.6 Fragmented Global Value Chains: Antiretroviral drugs

Generic (OEM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)

These Global Value Chains carry generic prescription medicines that still require a prescription and afflict low numbers of people or costly to produce and require group purchasing to guarantee access to medicines through the value chain. Anti-retroviral drugs are in this category. Although generic, they still require careful dose and drug selection by a trained infectious diseases specialist. Access to these medicines requires pooled risk schemes, because the disease affects either too few people in core countries to be affordable out-of-pocket or the majority of those it affects in noncore countries, they are too poor to pay on their own.

4.5.7 Distributed Global Value Chains: Hormonal Contraceptives

Generic (OEM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)

These Global Value Chains carry a group of medicines whose production is free of patent monopoly and can be produced cheaply enough to not require risk pooling for centralized purchasing, but whose administration requires a skilled intervention of the healthcare professional. An example is the range of hormonal contraceptives that require deep intramuscular injection. Although fully generic and affordable out of pocket, they require that consumers find a skilled clinician for their administration to avoid the risk of serious complications arising from a punctured nerve. Other injectables like saline infusions for use in hypovolaemic patients needing electrolyte replacements are in this category also. Whereas normal saline is readily available, its titration requires deep clinical skills to be done properly.

4.5.8 Open Value Chains: Non-steroidal anti-inflammatory drugs

Generic (OEM)	Over the Counter (OTC)	Out-of-Pocket (OOP)

Most nonsteroidal anti-inflammatory drugs are delivered by these Global Value Chains. Paracetamol, Ibuprofen, to mention a few are examples of medicines which are produced devoid of patent monopoly, whose administration is simple to codify to be used over the counter and come at a cost that can be afforded by out-of-pocket expenditure.

This eighth category of Global Value Chains labelled 'Open' is different from what Gereffi, Humphrey and Sturgeon (2005) call 'Market'. In their formulation the 'Market' still retains core capability requirements for suppliers. In this formulation consumers only require noncore out-of-pocket health expenditure to enter the Global Value Chain. A market where consumers require monopoly of access through centralized purchasing is an antimarket, and not a market.

	Complexity	Codifiability	Capability	Archetype
Market	Generic (OEM)	Over the Counter (OTC)	Medical Health Insurance (MHI)	Medical Devices
Modular	Brand (OBM)	Over the Counter (OTC)	Medical Health Insurance (MHI)	Vaccines
Relational	Brand (OBM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)	Recombinant Anticancer Drugs
Captive	Brand (OBM)	Over the Counter (OTC)	Out-of-Pocket (OOP)	Galenical (Herbal Medicines)
Hierarchy	Brand (OBM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)	Multidrug (re)formulation
Fragmented	Generic (OEM)	Prescription Only Medicine (POM)	Medical Health Insurance (MHI)	Anti-Retroviral (HIV)
Distributed	Generic (OEM)	Prescription Only Medicine (POM)	Out-of-Pocket (OOP)	Hormonal Contraceptives
Open[9]	Generic (OEM)	Over the Counter (OTC)	Out-of-Pocket (OOP)	Paracetamol (NSAIDS)

Fig 4.2 Updated Global Value Chains Framework with Vignettes

[9] Proposed names for the extended categories are
'X'; Fragmented
'Y' Distributed
'Z'; Open

These vignettes of global value chains in healthcare demonstrate that the eight types of value chains theoretically generated by Gereffi, Humphrey and Sturgeon (2005) actually exist but only when the focus is extended over the entire value chain from producer to consumer, and not just from supplier to lead firm. Each of these eight configurations can be thought of as individual cases i.e., these cases exemplify Global Value Chain theory or specific instances of Global Value Chain theory. This extended Global Value Chain framework serves as a development or extension of the original Gereffi, Humphrey and Sturgeon (2005) framework, bringing to life those neglected configurations (deviant cases) discounted as unfeasible.

Each of these three deviant cases presents a veritable research site to explain the observed variation in the outcome of governance in the noncore situation. The independent variables being patents, prescriptions and financing in Global Value Chains for health. The dependent variable being governance.

4.6 Developing a research strategy

The vignettes demonstrate that the independent variables in Global Value Chains of health are the patents, prescribers, and the health financing. These independent variables structure the dependent variable of Global Value Chain governance in health. Deciding which variables will be held constant relative to the other is predicated on the presence or absence of institutional voids in the product, labour, and capital markets. Where there are product voids in the market, brand medicines are likely to be fakes or substandard, leaving the generics as the only viable alternative for consumers. Where there are institutional voids in the labour markets for high skill health professionals, then prescription medicines are inaccessible, leaving only over-the-counter medicines at the street corner shop as the only recourse to health. In similar fashion, where there are institutional voids in the capital market for health financing through insurance, then consumers have no option that to pay out-of-pocket for the medicines they need. These institutional voids in health are characteristic of the noncore context. Therefore, it is possible to alternate the independent variables to predict access to medicines in practice under institutional voids.

4.6.1 Case selection: relevance to the research objective

The research design allows to do a structured focused comparison between any of the five types of value chains in Gereffi, Humphrey and Sturgeon (2005) and the three deviant cases which have been translated and operationalized in health. Again, this fulfils two research objectives. The first is to fill the practice gap around the trajectory of generic medicines in the noncore parts of the world where most of the world's population live and work. The second is to fill up the theoretical spaces left behind as deviant cases by Gereffi, Humphrey and Sturgeon (2005). The selection of these three deviant cases in health is important on a policy level for thinking and decision making around the complex issue of how to improve access to generic medicines for people in noncore zones marked by institutional voids. What is really of interest is a structured focused comparison method that will be employing process tracing to identify the causative mechanisms which institutional intermediaries employ as they bridge gaps in institutional voids. As such the cases will be selected for not only being archetypes or exemplars of the deviant cases, but for also being examples of successful institutional intermediation in noncore parts of the world to improve access to medicines through Global Value Chain governance. This selection is therefore theory driven to look for exemplars of the three deviant cases of

Open, Fragmented, and Distributed value chains which have successfully bridged institutional voids through institutional intermediation in the noncore context. For this, the author relies on deep working knowledge of the institutional voids literature and extensive contacts in the healthcare industry within noncore parts of the world. The knowledge of institutional voids literature was first gained as a Masters' student at the Manchester Business School and honed under the project supervision of Professor Nuno Giles who leads taught courses on the management of mega-projects which are prone to institutional voids leading to cost overruns and time delays. As a pharmacist with over 10 years work experience in the healthcare industry posted to the largest noncore markets of Africa, the author has also developed contacts within the multinational private sector, government public sector and the international NGO's during his work experience in each of these sectors. This extensive network of contacts came in useful for knowing about and identifying successful examples of institutional intermediation in health, under guidance of the supervisors Professor Philippe Laredo and Ms Kate Barker. The key to case design was to find adjacent types with differing outcomes of governance, i.e., successful improvements in access to medicines. And for one year and a half, theory went in search of cases in a two-stage fieldwork.

4.6.2 Case Development: Desk-Based Fieldwork.

The first stage of fieldwork was a desk-based theorization to identify the variance in variables. That is, to first translate the independent variables of complexity, codifiability and capability from Global Value Chain theory into world-system theory and develop effective proxies for them in health. Although there is criticism that institutional voids theory is a largely western insult to the noncore parts of the world and should be discouraged, this PhD stoops to conquer by sustaining the 'insult' and subjugating it as a theoretical device for structured focused comparison within and across the case types. This allows the author to identify the deviant cases in the field by mapping which independent variables are held in core or noncore conditions respectively and how this affects governance.

Having identified the deviant cases in the field, data requirements were formulated for building ahistorical account of access to medicines through these value chains. Five major questions were used to build each of the cases.

i. How does the social actor frame the need for access to medicines?
ii. How does the social actor enter the field?
iii. How does the social actor mobilize institutional resources?
iv. How does the social actor bridge institutional voids?
v. What are the performance dimensions of successful institutional intermediation?

These questions were used to deep dive into the literature in building a chronology of successful institutional intermediation in improving access to medicines in noncore contexts. Three exemplars were identified: one for each type of deviant case. Only after these were identified and built up as case studies from purely desk-based research was actual physical travel into the field contemplated in order to plug gaps in the history of these cases through the eyewitness accounts of those who were either involved and/or impacted directly. Because there were gaps in the history of these cases, field travel permission from the school was sought for, approved, and embarked upon for ten weeks between the middle of October until the end of November 2019. Armed with a set of questions the researcher travelled to two countries in Africa where the cases were located: Tanzania and Nigeria.

The travel field work was also important to eliminate competing analytical explanations of the cases in the already written histories of the interventions. Due to the small 'n' problem of case study research, it is not feasible to resort to large 'N' type statistical analysis for this elimination of spurious explanations. Theory building in case studies follows this rather inductive approach to theory building from observation to theory, however in this PhD, using the typological theories already developed in the first stage of fieldwork allows to construct a deductive typological case(s). This is done by first spelling out the full universe of Global Value Chains based on a theory-based map of the property space (core and noncore). This typological theory is defined as;

"…a theory that specifies the independent variables, delineates them into the categories for which the researcher will measure the cases and their outcomes, and provides not only hypothesis of how these variables operate individually but also contingent generalizations on how and under what conditions they behave in specified conjunctions or configurations to produce effects on specified dependent variables …called types" (George and Bennett, 2005).

The advantages of typological theories are that they allow creation of ideal types that are very useful for policy makers. They enable to classify without oversimplifying and provide a complete inventory of ideal types. They may also identify impossible types that cannot or have not yet occurred. These are the "empty cells" in Gereffi, Humphrey and Sturgeon (2005). Most importantly is that they make obvious the similarities and differences among cases to facilitate a structured focused comparison (George, 2019). When structured focused comparison is integrated into typological theories, there can be an iterative loop between the case and the theory. Also there can be cross case and within case analysis to reduce inferential errors (George and Bennett, 2005).

A well-defined 'type' answers the questions "What is this a Case of?" (Becker and Ragin, 2009). Using the design principle of adjacent types with differing outcomes, process tracing is used to establish the variation in the outcomes of Global Value Chains governance is due to change in a single independent variable. As such each of the three cases identified are cases of institutional voids in capital, labour, and product markets respectively. This iteration between theory and case data, both within case analysis and cross-case, gives a greater structural focus that mere comparative studies. Process tracing is thus a check on spurious explanations and identifies variables previously overlooked in older studies and can identify the interaction between independent variables (such as capital) and dependent variables (in this case governance) in specified value chain types and the causal mechanisms.

4.6.3 Case Development: Interrogating the Field

The first case demonstrates the formation of a fragmented value chain for medicines to supply private hospitals serving a farmer's cooperative in Tanzania. The creation of a micro health insurance scheme through the coffee cooperative is what is of major interest on this PhD as an exercise in collective action for Global Value Chains governance.

KNCU Health-Plan Case Interviews				
	interviewee	Duration	Meetings	Total duration
1.	Country Manager	1:25:38; 46:56; 38:07; 13:24	4	03:04:05
2.	Country Director	1:11:08; 25:17	2	01:36:25
3.	Field Manager	1:21:30; 23:52; 08:48; 06:31	4	02:41:00

4.	Government Medical Officer 1	39:02	1	39:02
5.	Government Medical Officer 2	1:11:27	1	01:11:27
6.	Government Medical Officer 3	1:12:04; 15:43	2	01:27:47
7.	Government Medical Officer 4	37:16	1	37:16
8.	Government Medical Officer 5	44:10	1	44:10
9.	Government Medical Officer 6	38:18	1	38:18
10.	Government Medical Officer 7 (Regional Administrator)	02:32:34	1	02:32:34
11.	NHIF Manager 1	01:16:46	1	01:16:46
12.	NHIF Manager 2	01:17:43	1	01:17:43
13.	SafeCare Manager PharmAccess	01:05:52	1	01:05:52
14.	Manager Private Hospital	01:20:37	1	01:20:37
15.	Manager Mission Hospital	39:18	1	39:18
16.	Medical Officer PharmAccess	22:19	1	22:19
17.	Medical Officer Mission Hospital	19:13	1	19:13
18.	Project Officer PharmAccess	38:56	1	38:56
19.	Medical Officer Mission Hospital	50:00	1	50:00
20.	Medical Officer Private Hospital 1	51:33	1	51:33
21.	Medical Officer Private Hospital 2	20:32	1	20:32
22.	Chief Pharmacist Private Community Pharmacy	01:22:52	1	01:22:52
23.	KNCU Vice-Chairman	53:10	1	53:10
24.	KNCU Enrolment Officer 1	26:09	1	29:09
25.	KNCU Enrolment Officer 2	20:55	1	20:55
26.	KNCU Manager Primary Society	39:03	1	39:03
	Total		34	28:00:02

The second case demonstrates the creation of a distributed value chain for hormonal contraceptives by an NGO in Nigeria working in the slums where there are no doctors to perform the fiduciary role for long-acting injectable hormonal contraceptives that are available out of pocket and as generics. The democratization of the knowledge dimension using community health workers to teach young women how to safely self-administer injectable hormonal contraceptives is what if of interest here as an exercise in bridging institutional voids for high skilled labour in global health.

DKT Nigeria Interviews				
	Interviewee	Duration	Meetings	Total duration
1.	Programme Manager DKT	47:14	1	47:14
2.	Head Nurse DKT Bees Programme	37:55	1	37:55
3.	Programme Officer DKT	01:01:59	1	01:01:59
4.	Nurse Slum Community Health Centre	23:56	1	23:56
5.	DKT Bee Community Health Extension Worker	49:17; 18:19	2	01:07:36
	Total		6	03:58:40

The third case presents a classical open market with a serious quality assurance problem where the generic medicine has no way of demonstrating its quality guarantee without a brand name of a lead firm. In this case, the use of digital technology presents an innovative approach to solve the knowledge asymmetry that unscrupulous suppliers exploit with fake and substandard medicines in Africa's largest unregulated drug market. As part of fieldwork on this particular case, medicine samples were collected from the Open Drug Market and from the quality guaranteed supply chain to compare the incidence of fake and substandard medicines between the two sources. Medicines were also polled from street corner chemist shops in the city and rural areas for cross comparison in two thirds of Nigeria's 36 states. However, the arrival of these medicines at the University of Manchester coincided with the lockdown of the laboratories as part of draconian health controls against the Coronavirus scare of 2019. This product analysis was abandoned. A

fourth covering case was then drawn up using semi-structured interview with the Product Manager for Pulmicort in Nigeria.

Drug Stoc Interview				
	Interviewee	Duration	Meeting	Total duration
1.	Co-Founder and CEO	53:43; 12:54	2	01:06:37

These cases are introduced by the covering case of a lead firm introducing an inhalational asthma controller into a noncore market. The need and absence of nebulizers for administration, and highly skilled health professionals for dosing, eventually truncate the value chain for this medicine in Nigeria despite heavy budgets for marketing and promotional activities including free physician samples.
The Hierarchy Value Chain however represents the de facto strategy of a pharmaceutical lead firm whose medicines are unable to justify health insurance cost in the face of generics, but which can be introduced not the market through lobbying for prescriptions. This value chain is included in the PhD as a covering case to introduce the global strategy of lead firms in the noncore context.

AstraZeneca Interview				
	Interviewee	Duration	Meeting	Total duration
1.	Product Manager (later East and Central Africa Regional Manager)	47:00	1	47:00

These interviews were proposed and planned with one main consideration in mind; to interview as many people as required to fill in the gaps in the historical account left over from the desk-based fieldwork. In the AstraZeneca case for instance, the author could have recreated the case from memory having led the launch of Pulmicort as a Medical Representative in Nigeria. But there was a need for a senior management perspective to clear up the competing explanations of why the lead firm chose to bring in an ill-suited

formulation of an antiasthma medicine despite the presence within the firm of a more suitable dry-powder formulation which could have been a greater marketing success. Secondly the thinking was to interview those with a bird's-eye view of the situation as at the time. This meant that the people with the highest responsibility for the intervention were approached for interviews and once the gaps were filled in the historical account and other competing explanations had been ruled out, interviews were ceased. The interviews were recorded on an encrypted voice recorder bought specifically for that purpose in line with the GDPR requirements for safe handling of interview data. These interviews were confidentially transcribed and anonymized by the author without recourse to any third-party often at night when the author had retired to the hotel. This necessitated that sometimes, the author had to go back to clarify points made previously by interviewees. This explains why there are in some instances as much as two, three or even four meetings especially with interviewees who offered much insight at key points in the historical account of each case. These insights served to sharpen and shorten the subsequent interviews with others. Prior to the interviews, before travel, agreement was sought with interviewees by sending out Letters of Intent and confidentiality agreements signed by the author. Signed returned copies were returned to the author as proof of consent to be interviewed. Interviewees were informed that they could withdraw at any point from the process and have their data withdrawn. Up till the writing up of this PhD, there has been no request for withdrawal. Only two interviewees were unavailable for comment; these were senior members of the KNCU who were in detention over allegations of financial misconduct.

4.6.4 Case Analysis: Process Tracing, Structured Focused Comparison and Analytical Explanation.

Each of the three deviant cases are written up as retrospective case studies that begin by tracing the history of the indigenous health systems before globalization and afterwards. This history is divided into three phases: precolonial or Mercantilism I, Colonial or Mercantilism II, and Post-Colonial or Mercantilism III. Oliver Williamson identifies changes in the institutional environment as occurring within the time span of 10-100 years. Considering that the PhD is focused on the role of institutional intermediaries in health

systems, the timeline selected is appropriate. George and Bennett (2005) define process tracing as a method to "…identify the intervening causal process – the causal chain and causal mechanism – between an independent variable (or variables) and the outcome of the dependent variable". They go on to argue that process tracing can be particularly "…useful for obtaining an explanation for deviant cases" and in so doing "offers an opportunity to differentiate and enrich the general theory".

Each case follows the same timeline to process trace the transitions and changes in the institutional environment that institutional intermediaries initiate. Geels and Turnheim (2013) follow the same process tracing approach in their tracing of the British coal and energy industry transitions over a nearly two-hundred-year period.

Each case builds around one institutional void and the institutional intermediary which bridges the gap. The aim is to process trace the causal mechanisms for the institutional voids in the first place and the attempt to bridge them. George and Bennett (2005) define causal mechanisms as "…processes through which agents with causal capacities operate, but only in specific contexts or conditions, to transfer energy, information, or matter to other entities." The challenge here is to identify the conditions and contexts under which these agents act. In this PhD, the condition is either of the institutional voids for product, labour, and capital that truncate Global Value Chains for medicines in noncore parts of the world.

Direct quotations are lifted from the interviews to illuminate these causal mechanisms in the case. Because the cases are structured theoretically, what unfolds becomes an analytical explanation of institutional intermediation within Global Value Chains or what George and Bennett (2005) refer to as "an analytical causal explanation couched in theoretical forms".

Each case is compared against the other two cases in a structured focused comparison to yield a discussion chapter which identifies the performance dimensions that make for successful institutional intermediation and how these performance dimensions can be reproduced in translation.

4.6.5 Limitations

There is a tendency to overgeneralize with typological theories. This is managed by sticking the conclusions to only what the findings allow the researcher to say. On this PhD, the findings, whatever they may be, can only be carried so far in the field of health. This parsimonious explanatory power is a strength that provides better guidance for policy as

middle range theories compared with general (grand) theories with a much lower batting average. It is better to know why democracies do not go to war against each other than to aim for a general theory of wars. The former is more useful, and the latter is likely to be spurious.

There is also a risk of leaving out some ‘types’ from the typology as Gereffi, Humphrey and Sturgeon (2005) did. This problem is more difficult to repair as is demonstrated by the tedious two step translation, first into world-system theory and then into health that this chapter has undertaken in order to bring back to life the deviant cases set aside by the Gereffi, Humphrey and Sturgeon (2005) framework. But it is this iteration between theory and data, between theory and casework both within and across cases that is the best hope of the researcher. For older ideas and frameworks must give way to newer and more accurate rites.

.

Chapter 5: The AstraZeneca Case

The following case traces the history of a subsidiary for a British Pharmaceutical multinational in Nigeria marketing a new product for asthma management. The case traces how the multinational defines its target market and seeks to fulfil the unmet need for asthma controller inhalers using global strategies. Using a deep narrative account from a product manager responsible for the implementation of the marketing plan in Nigeria, the case is constructed retrospectively, analyzed historically using Vernon's product life cycle theory to demonstrate the failure of the global firm in a local noncore market. The analytical explanation also demonstrates the triumph of a pre-existing commoditized asthma management approach based on a street-corner medicine stores distributing generic medicines using limited skill labour.

5.1 Bridging Institutional Voids in Product Markets for Healthcare.

Pharma marketing fills the product void for medicines in developing markets. Peter Drucker argued that the first principle of any business is to create a customer (Drucker, 2012). Through subsidiaries, global firms create customers for their products in international markets. in those markets where market infrastructure and business capabilities are not fully marketized, the firm must invest in either creating these infrastructure/capabilities or import them into the local market through a subsidiary altogether.

The research based pharmaceutical firms when faced with institutional voids in noncore markets opt for the strategy of market entry by subsidiaries. In core markets, pharmaceutical firms may employ a mix of both, either entering joint licensing arrangements for production and distribution, or choosing to go it all alone using subsidiaries. The difference is that while the subsidiary of pharmaceutical firms in core markets are actively knowledge seeking with innovation functions, the subsidiaries in noncore markets are essentially marketing outfits.

As a result, the subsidiary in noncore markets is tightly controlled by headquarters, with little or no headroom for flexibility in marketing strategy. Often the revenue from noncore markets pale in comparison to that from the core market subsidiaries which are often innovative and located at the upstream segment of the Global Value Chains that the multinational controls. It is this location at the upstream segment that involves the core subsidiaries in innovative activities such as clinical trial development, laboratory analysis, joint ventures, and market shaping activities.

The noncore subsidiary of the multinational firm plays a more marketing and distribution role focused on managing supply chain relationships and brokering in country product licensing, reporting adverse events and market surveillance.

5.2 The Multinational: AstraZeneca in Nigeria

The Firm entered Nigeria in 2009 and registered a range of premium products across all seven divisions of internal medicine; Cardiovascular products for hypertension and heart failure, antiacid medicines for peptic ulcer disease and reflux, general anaesthetics for surgery, antimalarials for prophylaxis, and oncological products for cancer treatment. Hypoglycaemics for diabetes, antibiotics for severe infections and inhaler for pulmonary diseases would come later.

These products were initially registered through a Nigerian distributor. But ten years later, the lack of managerial knowhow in marketing science based premium brands in Nigeria's chaotic medicines market led to a dissolution of that arrangement. In the words of a former senior exec from London who was parachuted to wrest control of the products from the local partner; "those guys just didn't know what they were doing".

The Firm established its Nigerian subsidiary with a full fleet of cars for at least one rep to cover each of the 6 geopolitical zones in the country. It must be pointed out that one of these zones is sometimes the size of Belgium or Liberia.

Confronted with the sheer size of the country and its 170 million people, the Firm added reps and managers, until the Firm boasted about 40 reps and a manager to rep ratio of 2 reps to a manager. The managers were split evenly between operational managers in charge of regional teams, whose remit was to extract performance for the sales reps, and

product managers in charge of implementing global marketing strategy in-country. The entire management team reported to a National Sales Manager who in turn reported to the Country Manager. Direct Reports to the Country Manager included Finance Manager, and Human Resource Manager, and later Supply Chain Manager.

It was on the back of this structure that the firm would launch an inhaled corticosteroid for the control of asthma targetted especially at children below the age of 6. As such the product formulation chosen was the liquid nebules for use in a Nebulizer.

See below.

Fig 5.1 Nebulizer

Compared with handheld pressurized metered doses, nebulizers have the advantage of being able to administer the medicine through passive inhalation. This is especially important in little children who have difficulty coordinating the breath holding technique required for effective use of a pressurized asthma inhaler.

This strategy was confirmed in the interview by the product manager:

> "So I think in this case, of AstraZeneca is something that looking at that age advantage that Pulmicort had and that's the right delivery device for that age group, they'll rather want to satisfy that age group, even though unfortunately in few countries which Nigeria happens to be a part of, there is access issue."

The cost of nebulizers in Nigeria is about 30,000 naira per unit. The cheapest power generating set would cost at least 50,000 naira. The minimum wage in Nigeria is 18,000 naira a month.

The product:

Pulmicort is a licensed asthma medicine containing the inhaled corticosteroid budesonide. Its patent license was applied for by clinical use by AstraZeneca in the USA on the 22nd of October, 2002. The abstract of its patent reads as such:

> "The invention provides finely divided, substantially crystalline particles of budesonide characterized in that they are substantially smooth and having a BET value of from 1 to 4.5 m2/g, a process for their preparation, a pharmaceutical composition comprising said particles, the use of said particles in the treatment of and in the manufacture of a medicament for use in the treatment of respiratory disorder, and a method of treatment of respiratory disorders by administration of said particles to a host in need of such treatment."

When formulated as a liquid suspension, the delivery device of choice is a nebulizer. However, when formulated as a dry powder, the delivery device is a either a dry powder inhaler or a pressurized metered dose inhaler. The pressurized metered dose inhaler is ideal for use in adults who can coordinate the breath holding technique. The dry powder inhaler is a more modular design that allows strips of blisters containing the drug to be loaded into a delivery device as required.

Fig 5.2 Metered Dose Inhaler

5.3 The medication: Budesonide Nebules for Asthma

The budesonide molecule, which is the active pharmaceutical ingredient, possesses a unique property among inhaled corticosteroid that recommends its use as first line drug in the prevention of bronchial asthma. Asthma being a chronic inflammatory condition of the airways is amenable to steroid therapy. Corticosteroids are able to exercise an inhibitory action on the cells of the lungs expressing inflammatory metabolites. A reduction in the production of these inflammatory cell products leads to improvements in lung function. People living with asthma, the response of inflammatory cells to allergens is exaggerated compared to most people and can result in life threatening airway constriction which must be relieved within minutes using a bronchodilator. Bronchodilator medicines like salbutamol are useful when airway constriction has set in, to give immediate relief from an asthma attack. But it is long term use of a corticosteroid administered orally, intravenously or by inhalation that gives long term reduction in the sensitivity of the airways to triggers like pollen, dust, and strong odours. Therefore, the Global Initiative for Asthma Management, a self-appointed body of researchers advocates that long term corticosteroid therapy be employed alongside bronchodilators which only relieve the airway restriction as a way to reduce the incidence and severity of asthma attacks in people with asthma.

5.4 The marketing gap: Nebulizers, Paediatricians and Health Insurance.

Corticosteroids were first invented in the 1940's, and by 1950's were available for oral use. Now generically available, oral corticosteroids can be easily gotten cheaply over the counter in most chemist shops and pharmacies.

However long-term use of corticosteroids is marked by serious side effects like growth retardation, metabolic disturbances, hormonal imbalance, skin thinning, and even diabetes. Also, sudden cessation of corticosteroid therapy can be fatal due to suppression of the body's natural cortisol production which is essential to life. These side effects are especially pronounced with oral and intravenous use of corticosteroids. Inhaled corticosteroids due to localized administration require much lower doses and therefore have less and fewer side effects. Therefore, the GINA guidelines stipulate the use of

inhalers as delivery devices, reserving injections, oral tablets and syrups, for supervised use in a hospital under the expert care.

For most people in core countries, these delivery devices that allow for corticosteroid use outside the hospital are widely available under health insurance. But in noncore countries like Nigeria, few people can afford them, given that mist of healthcare is out of pocket. In order to manage their asthma attacks, most people in noncore countries still rely on the cheap and widely available tablets and syrup formulations of oral corticosteroids and bronchodilators (reliever), for asthma control and relief respectively. They pay in cheap local currencies and in side effects as well.

Pulmicort was introduced as a nebule containing 0.25mg or 0.5mg of Budesonide per ml in 2ml nebules distributed in packs of 20 nebules each. The product was launched in Nigeria in 2012, ten years after it was patented in the USA. With nebulizers out of reach for most people in Nigeria, the product was largely confined to use in children's clinics and wards in hospitals.

The promotion of Pulmicort in Nigeria was targetted at children who were too young to use inhalers that required coordinated breathing techniques for use. In this age group, often under 6 years, the standard therapy was the use of pleasantly flavoured syrups, especially for management outside the emergency room. But the notorious growth inhibitory effect of oral corticosteroids in children with asthma was a perennial source of concern and worry for clinicians and parents.

With the introduction of Pulmicort, it was hoped that the inhalational route of administration through passive breathing could be extended to children as young as four years through a nebulizer.

Ideally, the use of inhalation corticosteroids is a long-term treatment strategy based outside the hospitals. The success of this outpatient strategy for Pulmicort however rested on how many parents could afford to buy a personal nebulizer for home use as an out of pocket expense. With epileptic power supply in the country, buying the nebulizer was not the only critical success factor, getting a generating set to continue a 30-minute nebulization at home when the public power supply went down was also a contingency to contend with and an added expense.

It was not surprising therefore to see many parents opt to continue with the syrups and tablets in spite of the superior technology available.

Oral corticosteroids for a month's treatment can be bought for as little as 500 naira. This is about £1. On the other hand, Pulmicort sold for up to 6,000 naira for twenty nebules (about £10). Even at one nebule a day, this would not be sufficient quantity for a month's therapy. Once opened, a pack of Pulmicort had to be consumed within two weeks. Corticosteroid tablets had a shelf life of up two years in contrast.

Pulmicort also required some experience in how to operate a nebulizer, so most patients who could afford them came with their children to the clinic to be trained on how to use them. Oral corticosteroids tablets on the other hand are fairly standardized. They always come in 5mg tablets. Most people know the standard adult dose of two tablets three times daily and one tablet three times daily for children. Although widely inaccurate, this standard dose was guaranteed to have a very wide margin of safety and acceptable efficacy. The new nebulizer therapy however required the intervention of a skilled paediatrician to set the doses before they could be used successfully as few people in the community had any experience with nebulizers.

During the numerous doctor visits in the field, the author who worked as a sales rep marketing Pulmicort in Nigeria encountered a paediatrician specialized in childhood asthma. The physician challenged the author as to why the Firm did not introduce a pressurized metered dose inhaler to substitute for the nebulizers. He demonstrated that with the use of a spacer device[10], the pressurized metered dose could be used in children who were younger than six. This would have ben an easier solution to the needs of children than the nebulizer-based strategy, as the spacers do not need electricity, and the pressurized metered dose inhalers are easier to dose by many people in the community. This mismatch in marketing strategy bothered the author as that conversation is the inspiration for this case. The firm actually had in its global portfolio a pressurized metered dose inhaler called Flexihaler which contained exactly the same active pharmaceutical ingredient budesonide. In theory, and as the physician pointed out, this formulation could be used in adults as well (albeit without the need for a spacer device), and so presented a far greater marketing opportunity in a market with poor nebulizer penetration and few paediatricians.

[10] The spacer device is a holding chamber that can be attached to an inhaler and allows the recipient to breathe easily and passively what the inhaler discharges into the chamber

Fig 5.3 Pulmicort pack and nebules.

Fig 5.4 Pressurized metered dose inhaler and spacer device attached (blue).

5.5 The interview.

During interviews with the product manager, this was raised, and this is what he had to say;

> "And even the players [other Big Pharma competitors] had age issues too because a lot of them had age of use starting from six years, while we have our own age starting from four years. So its more of a gap that the thing could easily …its like a low hanging fruit. Its not so competitive but the need is there. So you spend less on marketing, and all the other things if you're able to focus on that segment."

Essentially the use of a nebulizer strategy was perceived as a quicker win than competing with GSKs Seretide in the adult segment with the Flexihaler.

When pressed further that the Flexihaler could also deliver this low hanging fruit in conjunction with a spacer device, he said this;

> A: Yes. In the Nigerian context, you're very right. But remember multinationals are global, they think global. So in the Nigerian context yes, it was let me say, would I say, a loophole? or an unmet need in the Nigerian market because people don't have nebulizers in their homes. And like you said asthma is an emergency situation and people need to administer something immediately, in order to save life so unlike inhalers that are portable and can be carried around and can be easily administered. [If] people don't have nebulizers, they will not be able to do the same. So yes, I agree with you, totally when it comes to the Nigerian context, but AZ is a global company and Nigeria was not even as at that time contributing significantly to the African market, and Africa usually does not contribute significantly to the global market, when you compare to countries, places of similar size. So yes, global access to medicines is part of the objective that health companies have to be considered by global companies, all life matters like they say, but then the truth is that for [developing countries] if government is not making effort, multinational companies will not do it for them. So, it's a local problem that people don't have access to nebulizers.

> "A: Normally leaders get pressure from global, he is a leader in Africa, so global will tell him look, 'do this, do that', his own boss will be on his neck, as well as somebody is on his Boss' neck. The pressure is usually passed down, but then the thing is that if you make it clear, and you have clear understanding of your market, they will do a trade-off with you; 'so you're not selling Pulmicort, what will you sell?' because the first thing will be that they need to deliver numbers, numbers is very important. Then secondly there are now priority products that need to be promoted. But for priority products, depending on your market reality, you can always trade-off.

However, in order to test this trade-off at managerial level as an explanatory variable for wrong strategy, the author related to him a situation where a quick win opportunity was identified for a generic antihypertensive medication in Nigeria at a management meeting. The idea was shutdown by my line manager at the time citing the fact that that particular product was not up for consideration as it was not part of the strategic focus for the company going forward. This is despite the fact that the opportunity would present a huge windfall for the Firm in the local market. The product manager responded in a long exchange which formed the concluding part of the interview:

> "A: yes, I understand. There are two things in what you just said now. Because I know then I was quite...I still remember Plendil even though I never went into the cardiovascular products, but I remember the Zestril and Plendil. The thing is that there are products that have reached maturity, that are not of promotional priority and in every company, you have them.
>
> So, for those ones [mature products] there's no way you are going to tell people at the global level that your reps are detailing them as first line or second line. They'll tell you that if you have excess reps, then you lay them off, rather than putting them to detail a matured product. So, its commercial strategies that you put.
>
> Q: but Pfizer is still detailing Norvasc as first line in Nigeria.
>
> A: yes, so if Norvasc is still a growth product – I know its an old product – but some old products are still growth products, so if its still a growth product…
>
> Q: so, the thinking is that we could make plendil a growth product again in Nigeria.
>
> A: yea, it has to be global [growth product], not local [growth product].
>
> Companies have…okay take for example, when I was in Pfizer, we had…because that was where I started my detailing career. So we had emm …Neo Medrol. Neomedrol was selling so badly [very well], as in, that we were just, in fact, for most of us [reps], we even thought it was something that we can expand the sales, take it to even non pharmacies and see how it will grow and all that. So, you make all those things…and then they [senior management] tell you that they just put it in

your portfolio to make the numbers. If you like, sell one million Neomedrol, it's not going to affect your performance and your incentive, and anything. But yet if you look at the contribution to our portfolio, it's the product that is bringing in the big chunk of the money. But yet you can't even mention it that you want to promote it. Rather they just deploy commercial strategy on it.

Q: Globally? A: yes, Globally.

A: So, but I understand that because products come late to this part of the world, we tend to still see these products as growth products even when they are matured in other parts of the world.

And most times, these countries that the products go to very late which are countries that cannot afford the product when they are still under patent, those countries unfortunately don't contribute much to the global budget. So, when the decision is made to make those products not of promotional priority any longer, the budget to put behind them and make them a continuous brand is no longer there.

So, it's a global picture that impacts on the local. So, its one of those things. So, in local companies, they make those decisions based on what they can see immediately [in the environment], and all that and they make their money by the day and its based on the consideration of one country. But for global companies, its complex and the company has a lot of decisions to make. And the easiest most times is to look at what is the global profitability, what is the global impact, rather than a country that contributes 0.0001% to that product, then you are making decisions based on that country. Do you understand?

Q: I understand."

5.6 Analytical Explanation: The African Product Life Cycle in the International Context.

What the author had come to understand is that the global firm was never going to bend its corporate strategy to fit the local realities, and that the product life cycle of the product in core markets being ahead of its life cycle in noncore markets was the chief factor responsible for truncating access to medicines in noncore countries.

The diagram below illustrates:

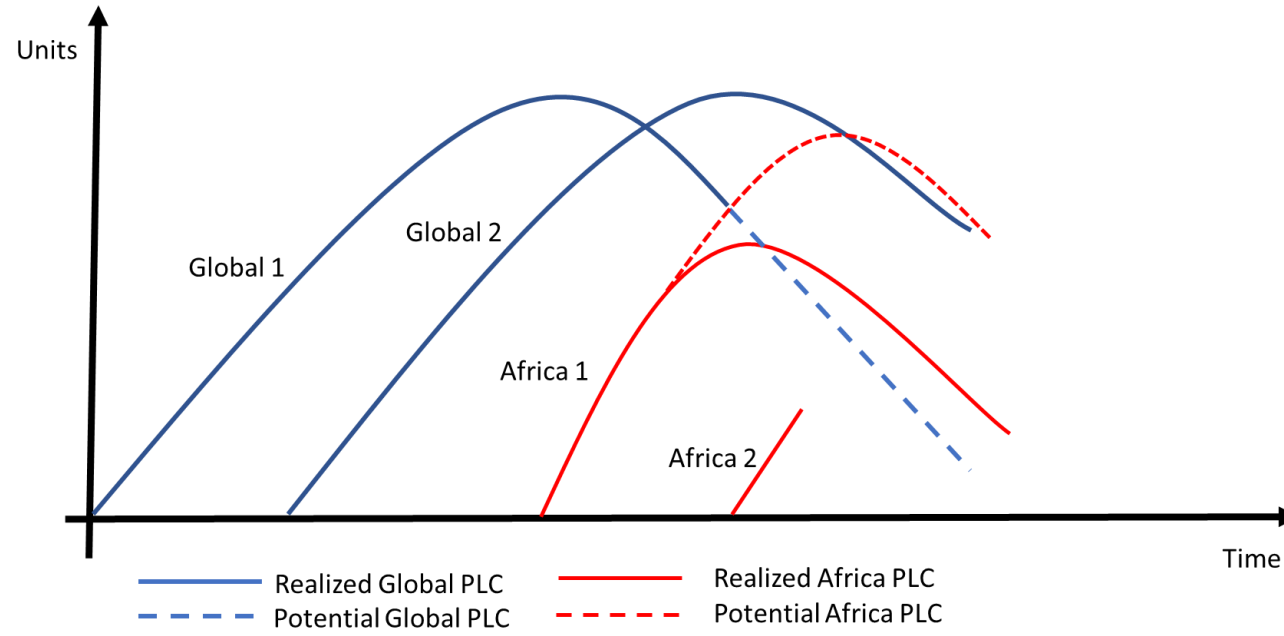


Fig 5.5 Kondratieff waves in Core and Noncore Contexts

The product life cycle (PLC) of the local product in Africa is truncated by the rise of a new priority Global product (Global 2). At its introduction, Global 2 takes up the marketing budget for Global 1 and therefore the Africa 1 product loses priority status at a time when it is just entering growth phase locally in a noncore market. The time lag between when Global 1 product was launched and Africa 1 represents the difference in time for the product trajectory to move from core to noncore. Managers who are not aware of the time required for institutional voids to fill up in noncore countries will introduce products prematurely even after framing the need correctly. Upon entry, these managers are stuck with a global strategy that demands results no matter what the local realities are. And this

has been the bane of many a country manager relived of their position, not to mention the reps who are far more expendable.

5.6.1 Gaps in the Product Market.

From the authors experience the portfolio of multinational subsidiaries in noncore markets is littered with high growth potential products that introduced prematurely when the institutional environment cannot support their marketization. It is this situation that Pulmicort fell victim to, in not being able to recognize the gaps in the market for the infrastructure of nebulizers, paediatricians and health insurance required for it to win in the Nigerian market, thus leaving an unmet need for asthma therapy among 13 million people living with asthma in Nigeria. Fully commoditized products such as salbutamol tablets, corticosteroid injections and syrups, fill the need for asthma therapy for most people in noncore markets like Nigeria, albeit with often disastrous side long term side effects like growth Cushing's syndrome.

The unrealized potential in the noncore market due to a global strategy which ignores local institutional realities leads to product failures when global firms introduce innovation developed to function in core markets with a particular type of institutional arrangements between product, prescriber and consumer.

From a product perspective, the lack of nebulizers represents a gap in the physical infrastructure of healthcare required to support the use of Pulmicort nebules. The author remembers that in the whole of Enugu state with a population of over 3 million people, there were only a handful of nebulizers available from few shops located in the state capital. The cheapest one cost $40 ad the handheld one cost $150. In a country where nearly 50% of the population live in abject poverty, these technologies are out of reach for the majority. This is also besides the fact that Nigeria has a power supply deficit. The Country produces and distributes less than 5000 MW of electricity. Power outages of 18 hours a day are usual in most parts. This requires a further investment in petrol or diesel power generating sets to power the nebulizers at home when the public power supply is off. This adds another gap in the product infrastructure required for Pulmicort in Nigeria.

The alternative is that older products be made the mainstay of treatments. Products for which the institutional infrastructure already exists. However, these products are often inferior to the innovative product. They are also starved of marketing funds in order to prioritize the new. These products are therefore left out of promotional activities left to the

fully commoditized supply chain of street shop keepers in noncore countries. In this supply chain medicines abuse is common.

5.6.2 Gaps in the Labour Market.

With Pulmicort and similar innovative global products, the physical infrastructure required is not the only institutional limitation that truncates access to medicines.

Often the knowledge and skills required are not available or in short supply. For Pulmicort, the lack of trained paediatricians to administer the nebules in the right doses posed a knowledge gap in the market.

For example, in the interview above the Product Manager alludes to the fact that at its introduction, there were only 5 pulmonologists in the country. The introduction of innovative global products into noncore markets by global firms in the absence of high skilled professionals in the noncore market is a disastrous mistake by lead firms. Pulmicort in this case fell prey to this mistake. Unable to find a large group of high skilled professionals in paediatrics, it could not be widely adopted due to lack of prescriptions. The author remembers that the uses of poor substitutes with easier accessibility from street corner shops remained the mainstay of therapy despite the better side effect and efficacy profile of Pulmicort. These much older and fully commoditized products whose rough dosages have been diffused over time into the community and had a wide margin of safety were now available as over the counter medicines.

In the absence of high skilled professionals in the healthcare market, access to medicines becomes contingent on limited skill health workers providing commoditized medicines with wide safety margins whose doses are easy to calculate. The dosage of Pulmicort nebules required a sophisticated calculation of lung function against which to calculate the does of the does in milligram per kilogram body weight. This is beyond the educational capability of the street corner shop in any country.

5.6.3 Gaps in the Capital Market:

The need for nebulizers to support the use and administration of Pulmicort exposed the lack of healthcare financing in the Nigerian market. Especially the absence of group purchasing and risk pooling schemes such as health insurance.

In Nigeria, less than 15% of the population have any form of health insurance cover. For the few who do, Pulmicort was not covered especially by the National Health Insurance

Scheme. More importantly, the nebulizers required for administration were not available under insurance cover either. In this case, the high cost of the nebulizers and the medication conspired to create a gap for access to Pulmicort in a country where as much as 50% of people live in abject poverty. The finances required to buy power generating sets for use at home also strain even further the out-of-pocket expenditure required to access Pulmicort nebules in Nigeria.

The upfront cost of investing at least $40 aside the cost of hospital visits, and the cost of the Pulmicort nebules themselves proved too much for most patients who rely on out-of-pocket expenditure in a noncore environment.

Taken together these gaps in Product, Labour and Capital in the Nigerian market truncated access to a novel asthma controller with much improved side effect profile. These gaps are the institutional voids that hinder the development of a consumer market for Pulmicort in Nigeria.

5.7 Institutional Voids and the Role of Institutional Intermediaries in Access to Medicines.

The Global Value Chain for Pulmicort in Nigeria was configured as a Relational Global Value Chain. That is, a value chain carrying an Original Brand Medicine under patent monopoly, which required a trained Prescriber to administer and also needed risk pooling mechanism of Health Insurance to be accessed by the consumers.

Brand (OBM)	Prescription Only Medicare (POM)	Medical Health Insurance (MHI)

Khanna and Palepu in 2000 coined the term institutional voids to describe missing elements in emerging market that prevent markets from functioning efficiently.

They argue that in emerging markets, there are structural deficits in the markets for product, labour and capital that create inefficiencies. They develop a theoretical framework to guide multinationals going into emerging markets to scan the environment for these gaps in the local institutional environment. According to their model, gaps in product markets they describe as the absence of critical physical infrastructure that mediate handling such as ports, roads, storage facilities, that impede the effective introduction of

new products. Gaps in the local labour markets they describe as a dearth of trained workers and managers due to the absence of schools, and training facilities. Finally, they identify gaps in the capital market as the lack of a robust financial architecture to structure complex financial deals and instruments for trading internationally, these include banking institutions and financial regulation.

In their book titled "Winning in Emerging Markets", they advise three strategi options for multinationals in these spaces. First, filling the void by importing all the missing institutional elements of product, labour and finance using a subsidiary. Second employ the services of an institutional intermediary to leverage local institutions to bridge these institutional voids. Third, exit the market entirely until these voids are filled by the state government.

The AstraZeneca case above shows what happens when the global firm enters the emerging market through a subsidiary and tries to build the required institutions. Indeed, AstraZeneca gave some units of Nebulizers to the Cardiothoracic society of Nigeria to alleviate the lack of nebulizers in the country. But those efforts were to few and too far in between for a country of 200 million people. Even if AstraZeneca were to import these nebulizers by the millions to fill the gap, there remains the tendentious issue of not enough Paediatricians to teach the patients how to use them at the appropriate doses. Training an army of at least 50,000 paediatricians would come at a cost that few organizations can afford in terms of the universities and medical schools, and teaching hospitals. There is also the lack risk pooling mechanisms to overcome these financial barriers to access the medicines.

It is within these institutional voids that most global firms fall into and decide to abandon their subsidiaries when the market eventually fails to form. This was the picture in Nigeria during the 2015 recession in Nigeria when AstraZeneca finally handed over its products to an institutional intermediary to distribute on its behalf and liquidated its field force. It was not alone in this, at least four multinationals left in the same period when the small group of individuals who could afford their products out-of-pocket dwindled sharply.

Mair, Marti and Ventresca (2012) have identified these institutional vids as analytical spaces within which local entrepreneurs thrive as institutional intermediaries.

> "We treat voids as analytical spaces at the interface of several institutional spheres, each with its own animating logic of meanings and social practices…. By

> accentuating the situated and intermediate nature of institutional voids, we develop a view of voids that originates in the presence of plural, often contending, institutional, rather than continuing the view of "empty" institutional space." (Mair, Marti and Ventresca, 2012).

This study also departs from the western idea of institutional voids as empty spaces. As Mo Yamin would argue, an Englishman does not go to Japan to declare that there is an institutional void for languages (Yamin, 2018). But this requires that Khanna and Palepu's work be reimagined as a heuristic device for identifying not empty spaces but analytical spaces of institutional discontinuity between the global and the local that impede the efficiency of local markets and truncate global value chains in healthcare.

Thus, methodologically speaking, inasmuch as their framework helps to focus the attention of global firms to the structural discontinuities in these analytical spaces, they can for this study, lend themselves as diagnostic tools for theoretical sampling of research cases on the field. This analytic induction method works to direct scholarship into those parts of emerging markets that impact directly on the dynamics of Global Value Chain governance when they touch down in emerging markets (noncore economies).

Mair, Marti and Ventresca (2012) agree on this use of institutional voids theory as a diagnostic tool for analytical induction in research.

> "In sum, we propose that apparent institutional voids can be seen as useful problem-sensing tools. They can help to diagnose conditions that need to be addressed for inclusive market initiatives to develop"(Mair, Marti and Ventresca, 2012).

> "We applied theoretical sampling, a recommended approach for analytical induction, to identify these programmes" (Mair, Marti and Ventresca, 2012).

Going further they point out the ways in which this research programme built around institutional voids can be used to study the impact of institutional intermediaries that try to bridge these gaps in the institutional environment through bricolage.

> "They are analytical spaces in which elements from a variety of institutional spheres, each built around central systems of meanings and social practices come

> together and affect the interpretation, enforcement, or embodiment of certain focal institutions—such as, in our case, property rights and autonomy" (Mair, Marti and Ventresca, 2012)

In this PhD, the cases selected using institutional voids theory are built not around property rights and autonomy, but around the three elements of Global Value Chains (product, labour, and capital). Therefore, three cases are built around the three categories of institutional voids identified from the AstraZeneca case.

Institutional voids in Capital Markets and the KNCU Health-Plan.

The first case is the role of an international NGO acting as neutral broker to support a local institutional intermediary; the Kilimanjaro Native Coffee Union to employ collective action principles to develop a Health plan or coffee farmers in Tanzania that uses micro health insurance to raise capital finance for improvements in health services delivery under a structured programme of leadership and improvement in the quality o healthcare facilities in the private sector called SafeCare.

Institutional voids in Labour Markets and DKT.

The second case examines the role of a local NGO acting as a institutional intermediary in partnership with a global firm to develop a long acting hormonal contraceptive that obviates the need for highly skilled health professionals, in order to meet the needs of women in underserved slums of Lagos in Nigeria.

Institutional voids in Product Markets and Drugstoc.

The third case looks at the efforts of a local firm acting as a supply chain guarantor of quality assurance for generic and medicines produced by firms abroad in an open drug market notorious for fake and substandard imitation products.

Taken together, these cases examine successful interventions to bridge institutional voids in capital, labour and product markets respectively that impede access to safe and effective medicines.

The cases however go a step further, they also trace the expansion of these interventions through extension and meta-organization versus replication. The varied results f these attempts to scale these interventions make for unexpected insights into how to work successfully in emerging markets as against simply winning.

Chapter 6: The Family Planning Case

This case sets out the product trajectory of a global contraceptive from core to noncore and the changes in its governance as it moves from branded to generic and then to branded medicine again. This biography provides a unique opportunity to analyze the outcome of access to medicines under different contexts. The main actor in this case is an international NGO working as a distributor of the contraceptives first as a distributor and then later as a lead firm. Its use of community health workers to fill the gap left by emigrating doctors in the slums of Lagos is what is of interest here. The case traces the success and eventual collapse of a shared governance structure due to mismatch between the institutional context and Global Value Chain governance strategy.

6.1 International Investment and International Trade in The Product Cycle by Raymond Vernon

The most counterintuitive aspect of Vernon's product hypothesis sketched out in 1966 is that "It puts less emphasis upon comparative cost doctrine and more upon the timing of innovation, the effects of scale economies, and the roles of ignorance and uncertainty in influencing trade patterns" (Vernon, 1966). These factors of time, scale economies and uncertainty play a major and underrated role in the dynamics of Global Value Chains especially for people in noncore markets.

Vernon (1966) makes three key assumptions on lead firms, that he goes on to demonstrate in the international economy: unlimited capital, boundaryless knowledge and institutional convergence. He demonstrates that it is the threat of competition from an overseas supplier which prompts a lead firm to venture out of the home market and set up a subsidiary in the foreign market. Knowing full well that with unlimited capital, boundaryless knowledge and institutional convergence, it is a race of 'first with the most' that will win against a rival lead firm in the global market.

Vernon begins with the assumption that these are lead firms, indeed global firms operating in the world economy, for whom scarcity of capital is not an issue, being able to mobilize vast networks in the international operations to raise capital at short notice through the international stock exchanges.

> "Moreover, the assumption that finance capital is scarce and that interest rates are high in a less-developed country may prove inapplicable to the class of investors who concern us here" (Vernon, 1966).

Importantly too he makes the point that for these lead firms, knowledge is boundaryless but not costless.

> "It is a mistake to assume, however, that equal access to scientific principles in all the advanced countries means equal probability of the application of these principles in the generation of new products" (Vernon, 1966)

But he identifies the difference and lag between knowledge and new product development as follows:

> "There is ordinarily a large gap between the knowledge of a scientific principle and the embodiment of the principle in a marketable product. An entrepreneur usually

> has to intervene to accept the risks involved in testing whether the gap can be bridged" (Vernon, 1966).

Importantly he highlights the oligopolistic nature of foreign direct investment by multinationals engaged in international trade.

> "We begin with the assumption that the enterprises in any one of the advanced countries of the world are not distinguishably different from those in any other advanced country…" (Vernon, 1966).

From this analysis, it is not the comparative cost of manufacturing that drives international trade abroad. The following sections outline the changing rationale for a product to go abroad as it moves from innovative product to standardized product.

6.1.1 Innovative Product:

In the first instance, the lead firm creates market access for its products in the host market to suit its demographic population. Traditionally the innovation that takes place in core markets are those that save labour. Core markets like the US, EU and Japan have evolved into labour-scarce markets where the innovative product has to be made bespoke for a few high-income individuals who are able to pay for the cost of the expensive iterations required to cover the error prone research process to create the most efficient version. The lead firm therefore begins innovation in markets with the highest proportion of these high-income individuals; the triad of NAFTA, EU, and ASEAN.

The high level of institutional isomorphism among these markets makes them the first destination for an innovative firm trying to go abroad as these markets share the demographics of the host nation of the lead firm.

The consideration of cost of production only comes in much later when a mature product has achieved a high degree of standardization in its core specifications. Only when the product has reached a high degree of standardization will the lead firm face competition on the basis of cost from a rival manufacturer seeking to capitalize on the product in locations with a comparative cost advantage in a labour-rich market with a different demographic makeup.

The first decision to move into institutionally similar core markets by the lead firm is to rapidly gain market leadership abroad and the resulting economies of scale. The second decision to move from core to noncore market for production and marketing is indicated

when product differentiation around the mature product can no longer yield sufficient return on investment to warrant its production and marketing in the core market due to scarce labour and high incomes.

6.1.2 Mature Product:

The presence of the lead firm and its innovative product in the home market of the competitor forces the competitor to make a choice between doing product research to create an entirely innovative product or product development to simply create an extension along the specifications of the lead product (thereby making it a mature product) and save itself the risk of a radically new innovation; a bird in hand being worth two in the bush.

The competitor abroad is constrained to act as a generic competitor and not as an innovative competitor in the face of uncertainty and similar market demographics at home and abroad with respect to the innovative lead firm.

This type of competition further drives the mature product into a standard product with minor variation between competing versions, and further drives the institutional isomorphism between core markets in different countries.

Stephen Hymer emphasized this fact in his 1970 paper titled 'the efficiency contradictions of the multinational' where he writes that

> "We certainly cannot assume that market forces compel firms to choose the optimum path...Oligopolists tend to copy each other, and their predictions as to what the consumer wants are often self-fulfilling, since in fact this is all that the consumer is offered" (Hymer, 1970)

This oligopolistic market shaping identified by Hymer in product characteristics Vernon identifies as a feature of developed (core) markets in the world economy; NAFTA led by USA, ASEAN led by Japan and the European Union.

Alan Rugman (2001) frames the institutional isomorphism between the triad of regional markets led by the USA, EU and Japan in his 'The Myth of Global Strategy' as

> "…where integration across national borders yields the potential for firm level economies of scale and/or global brand name products. Contingent upon this definition of pure economic globalization is the need for products to be uniform across markets" (Rugman, 2001).

6.1.3 Standardized Product:

According to Vernon (1966), the production of capital intensive (or core products) only shifts to a comparative cost calculus when the product has lost steam. A product that has lost its patent rights rapidly faces tight cost competition from every part of the world. The lead firm responds by shifting the production out of the core markets to save costs on labour. But this is only one half of the story. The standardized product as well as being fully commoditized, is also fully codified. This latter change in the knowledge dimension of the product means that its production and use will conserve human effort.

It is however paradoxical that the standardized product is then spun-off or outsourced into a noncore context where labour is 'abundant'. Apparently, what is abundant in the noncore context is low and limited skill labour. Therefore the standardized product which does not require the intervention of high skilled labour is suited to this limited skill labour context.

Gereffi, Humphrey and Sturgeon's (2005) assertion that products of low codifiability require more human intermediation supports the fact that innovative products require the most human intermediation, while the standardized product allows the conservation of high-skilled labour.

"When standards for the hand-off of codified specifications are widely known, the value chain gains many of the advantages that have been identified in the realm of modular product design, especially *the conservation of human effort*…" (Gereffi, Humphrey and Sturgeon (2005) emphasis mine).

The standardized product being highly codified, conserves human effort especially of the specialized kind, and can ride on the unspecialized or limited skill labour in the noncore context.

> "…value chain modularity is enabled by the codification of complex information (for example, through computerized product design and automated process technologies) because codification simplifies the hand-off at the inter-firm link" (Gereffi, Humphrey and Sturgeon, 2005)

Computerization and automation have the potential to serve as codification strategies to allow the Global Value Chains to penetrate the noncore context. In health, this has significant implications for improving access to medical treatment that would otherwise

require the “hands-on” intervention of skilled health professionals who are simply not available.

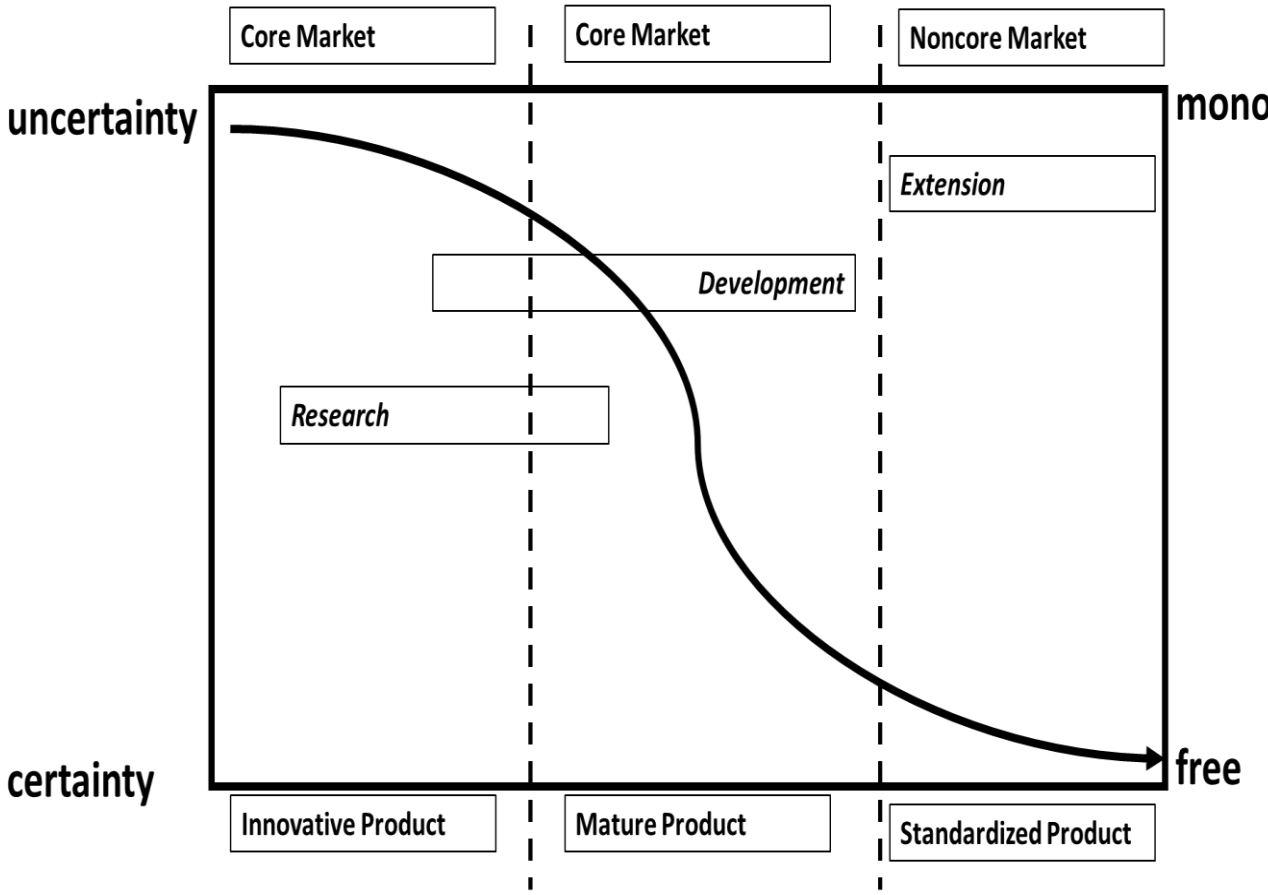


Fig 6.1 The International Product Lifecycle; Adapted from Vernon (1966).

In the diagram above we show the kinds of economic activities that occur at different stages of the product life cycle and the markets under which they are most likely to occur for demographic and income factors explained earlier.

So, what then? Vernon (1966) says that the comparative labour costs for the production of a standardized product are lower in noncore markets, while Gereffi, Humphrey and Sturgeon (2005) say that the standardized product *conserves human effort*. If these statements are true, then it implies that the standardized product merely allows the substitution of high skilled labour with limited skill labour. The “conservation of human effort” which Gereffi, Humphrey and Sturgeon (2005) refer to is then a qualitative conservation and not a quantitative one. This opens up the door for task shifting in Global Value Chains from high skilled workers which are scarce, to limited skill workers which

are abundant. This is only possible through standardization by codification of the global product.

Investing in further standardization through codification may then represent a strategy that lead firms should pursue actively in order to improve access to their products in noncore markets. The challenge however is that the global product exiting the core market as a generic product cannot generate the revenue required to subsidize further investment in its development.

Yet that is what we find on this case. A large International NGO subsidizes the cost of development and marketing on an already standardized product spun off by a Pharma multinational to improve access for women in the slums of Africa's largest urban conurbation. The result is a product standardized further by codification from an injection requiring administration by a trained physician (high skilled labour) to a self-injectable product administered by self or a community health worker (low and limited skill labour).

6.2 The Case.

We present a case of institutional intermediation to further standardize a global product through codification to increase access to contraceptives among women in slums. The study then goes on to demonstrate the coordination failures that occurred in attempts to reproduce the intervention in a nationwide effort.

Our story traces the standardization of a hormonal contraceptive for use in noncore markets by a lead pharma firm in the Global Value Chain. The study goes on to trace the implementation of the automated[11] hormonal contraceptive injection by an NGO and efforts by a consortium of NGOs to expand access to its use among women in the slums.

Injectable medicines especially have lent themselves to early investments for automation. Beginning with the continuous infusion giving set that allowed the physician to set 'a line' for the patient and freed the precious time the physician had on the ward floor in order to save labour. These infusion giving sets still required a careful titration of dosage that required the input of a skilled physician. The risk of adverse events occurring in the event

[11] When we say automated, we mean that the product has been engineered for autonomous use by the consumer without the need for a fiduciary to assist.

of a missed vein or a punctured nerve also meant that for many years the right to set infusions and administer deep intramuscular injections was reserved for the physician with deep knowledge of human anatomy.

However, the need for patients to be able to administer certain kinds of injectable drugs at home in order to free up bed space in the hospital meant that safety and effectiveness had to be automated into the injectable. The result was the design of injection guns with prefilled cartridges to give the medicine as a premeasured shot. These automated injections improved the outcomes of home care especially in diabetic patients requiring regular insulin injections before meals. Today these injection devices have been automated further by digitalization such that the physician miles away can adjust the dose of the infusion according to vital signs delivered by the device to the clinic further saving the cost of hospital visits and the risk of hospital acquired infections.

6.2.1 Automation in Hormonal contraceptives: Depot Medroxy Progesterone Acetate (DMPA).

DMPA became the forerunner of a class of steroidal drugs used to prevent conception in women (contraception). Of these, medroxy progesterone acetate developed by Pfizer was the most effective and safe in class molecule formulation. Originally sold as an intramuscular injection, it has been used in millions of women in over 100 countries.

Being an injection, DMPA requires the services of a healthcare professional to administer. The range of possible contraindications (situations where use is not advised) also warrant clinical services to ensure safe use.

DMPA has been available for over 30 years as an intramuscular injection in the form of a 1ml vial containing 150 mg of the active ingredient. Sometimes DMPA is available pre-packaged in a prefilled glass syringe tipped with a needle of 1 to 1.5 inches length. The length of the needle is standard for injections intended for intramuscular injection. However, in the thirty years since its introduction, there has accumulated a significant amount of knowledge on the dose-effect relationship of the product to understand the incidence of adverse effects, and the minimum effective dosage without side effects. This new knowledge has opened up the possibility of bringing the product closer to the patient in a reformulated dosage that is safe enough for self-administration.

In 2015, following the Family Planning Conference in 2012 hosted by the BMGF, governments took steps to extend the labelling of hormonal contraceptives for self-administration. With this change in legislation, the lead firm entered into a partnership with the BMGF to develop in 2015, a formulation of DMPA for injection under the skin (subcutaneous). To achieve this, the drug dose and its device were redesigned.

Fig 6.2 Sayana Press. Notice the shorter needle of the new design.

Fig 6.3 Depoprovera

The new product version (Sayana Press) was a shorter needle about 3/8 of an inch and a much smaller quantity of the active drug at 104mg in a 0.65ml suspension compared to the older version (Depot Provera) with 150mg in a 1ml solution. Both Sayana Press and Depot Provera are equally effective in preventing conception for 13 weeks (± 1 week), as such would provide full cover for a year with 4 injections.

It is important to point out that subcutaneous injection route is far less risky than the intramuscular route which carries the risk of puncturing a blood vessel or worse, a nerve fibre. It is not uncommon to hear of intramuscular injections into the buttocks that have inadvertently hit the sciatic nerve and led to permanent disability of the leg.

The redesign of Depo Provera into Sayana Press was a knowledge saving device that made it possible to safely self-administer a contraceptive injection for the first time. It is also noteworthy that the extension of labelling by medicine regulators preceded the redesign of the product. Following the partnership of the lead pharma firm and the BMGF to provide Sayana Press at $1 in 69 poorest countries, further changes in legislation within these countries were enacted to expand the cadres of limited skill health workers who could promote the use of Sayana Press within the community.

6.2.2 Task Shifting:

In 2007, the WHO published a policy guideline on task shifting and task sharing for increased access to contraceptives in resource constrained settings where there is a shortage of health professionals. The policy guideline defines task shifting as

> "…a process of delegation or rational distribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications to make more efficient use of the available human resources for health" (WHO, 2007).

First, task sharing implies that the high skilled health professional is available to share tasks, and therefore this occurs in the core environment of the hospital. The main interest in this case is the complete shifting of clinical tasks outside of the hospital and into the community, and not merely sharing them with community health workers[12]. Secondly it would defeat the purpose of task shifting for the professional to continue sharing responsibility for the outcomes of the procedure with the CHEW (Olaniran *et al.*, 2017). We adopt a single term of Task shifting throughout the case as in spirit, "They both reflect the same intention – to include cadres who do not normally have competencies for specific tasks to deliver them and to thereby increase levels of health care access" (Polus *et al.*, 2015).

Task shifting Legislation in Nigeria:

The Federal Ministry of Health in Nigeria in 2014 enacted legislation for task shifting in the delivery of essential healthcare services. The policy stipulated that as part of its goals,

[12] Olaniran et al (2012) define CHEW as "…paraprofessionals or lay individuals with an in-depth understanding of the of the community culture and language, and their primary goal is to provide culturally appropriate health services to the community."

> "…the task shifting policy will promote rational redistribution of tasks among existing health workforce cadres. It will allow moving specific tasks, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available health workers and to improve access to services for the Nigerian people" ("Task-Shifting and Task-Sharing Policy for Essential Health Care Services in Nigeria," FMoH, 2014.).

It is against this backdrop of a knowledge saving device and empowerment of CHEWs for task shifting, that the NGO undertook to employ CHEW's in providing access to contraceptives for underserved women in Nigeria.

6.2.3 DKT International: Innovation Shifting

Deep K. Tyagi International is an NGO which focuses on the provision of subsidized contraceptive technologies in underserved populations especially in Asia and Africa. the NGO traces its origins to a visit by Phil Harvey, an American, who signed up to work for Care International providing food relief to children in poor neighbourhoods. Five years later he teamed up with a British postgraduate student at the University of North Carolina to set up Adam and Eve, a mail-order company selling condoms, sex toys and later pornographic material on American campuses. Success quickly followed, and they decided to use part of the profits to fund birth control programmes in developing countries like India having concluded that population explosion was the cause of their poverty despite foreign aid efforts. Following the death of a key local staff in India (Deep Tyagi), they adopted his name in commemoration (Harvey, 2011).

DKT uses a marketing approach to distribute contraceptives. This model follows from the earlier success with Adam & Eve where Phil Harvey and Tim Black were able to circumvent laws that stipulated those contraceptives couldn't be traded across state lines through non-medical channels. The contraceptives are subsidized through funds from the private organization Adam and Eve (30% of budget) and given to local merchandisers for resale at a small profit. Today, DKT is the world's largest private provider of contraceptives using non-medical channels to push contraceptives in over 60 countries. DKT uses advertising and overt promotional strategies adopted from the private sector to achieve market penetration of contraceptives and sex enhancement products.

6.2.4 DKT Bees: Health Service Delivery Shifting

Having set up shop in Nigeria since 2009, DKT took advantage of the task shifting policy to engage CHEWs as merchandisers of its contraceptives within underserved communities. A colourful campaign tagged honey and banana was launched to raise awareness on the need for birth control and prevention of sexually transmitted diseases with a view to getting people to adopt or switch to its range of products which include flavoured condoms, lubricants, intrauterine devices, hormonal implants, and injections.

The programme deployed CHEW's rebranded as DKT Bees and trained them to "bring family planning services closer to women in their homes, business places, markets and communities". The rebranding and itinerant approach largely to de-medicalize family planning products. Target groups were women living in highly populated slums with "a distinct lack of pharmacies and clinics". The DKT Bees were fitted with a basket of products; male and female condoms, morning-after and daily pills, and Sayana Press injections.

The DKT Bees were recruited according to their locality i.e., they were recruited to work in communities where they lived to leverage on their local knowledge of the area and its people, and ability to communicate effectively, asides having the relevant CHEW certification.

A nurse was appointed as the head of this army of foot soldiers referred to as the Queen Bee. Her role was to supervise the work of the CHEWs in the field and collate reports while serving as a point of first referral for the DKT Bees.

Each DKT Bee made about 50-100 sales of Sayana Press each month. While DKT provided money for their transportation and phone expenses, the Bees were expected to generate their own renumerations via an administrative charge for administering Sayana Press (this was a major problem as we shall highlight in the analysis). In six months, the DKT Bees had reached over 63,000 women with their messaging and administered Sayana Press on over 7,500 women.

"…our target markets are sexually active young people in vulnerable communities and populations" (DKT Bees Programme Manager)

"what informed us taking on that strategy was first of all there was in a contraceptive method just introduced called Sayana Press. Because of the nature of the product and the goal of the funders for the projects to make it very accessible to women and de-medicalize family planning and take it out of the clinics to get into the hands and homes of women". (DKT Bees Programme Manager)

"women in the low-income areas, they don't receive family planning…major reason from the research we did, was misinformation and misconceptions. They tend to tell you…it causes abortion. The purpose of the campaign was to go and debunk all those myths and misconceptions among these low-income earners. The major component was the education part of it". (Programme Officer)

When pressed further about some examples of these misconceptions, the programme officer volunteered three scenarios.

"a popular story…a lady using intrauterine device and delivered a baby holding the copper T in her hand. And that gave the baby an indelible mark or when you put copper T it will remove and go inside your body, or if you want to do family planning, it will mean that you don't want to born again [lifetime sterility]. So most see family planning as making you infertile. So [they say among themselves] have all the children you want because you may not be able to have any children again."

When asked who the prime movers of the intervention were in creating the DKT Bees, the Queen Bee responded by saying that the programme was an afterthought when their attempt at going through the medical channels had not succeeded as hoped.

"… DKT wanted it. They had been using this method of going to the hospitals, taking it to the pharmacies, the results were not absolutely what they wanted, in terms of uptake. When I joined DKT it was something we talked about within DKT and decided to try. Back and forth, it was a team effort".

The programme officer shed some light on reasons for the poor uptake of DKT's products through the public sector and highlighted those operating costs were often shifted to the consumer and became a barrier to access.

"Family planning is free, but most ladies still go to private…we thought we would see more in public…It is free, but the payment you would pay to access the services is even more than in the private. E.g., In public, you have to register, 200-500 naira. You will buy

surgical gloves, Dettol etc, and when you consider these things, you will say let me just go to private."

The use of injectables for contraception was new in these communities and when asked what level of understanding around contraceptive use pre-existed the arrival of DKT Bees, the programme officer recounted some of the experiences he encountered in the field;

"Others knew of pills, postcoital and withdrawal. Rarely did we hear of implants …. Mostly pills and withdrawal".

Although the programme had a wide reach, there were early moves within the organization to stop the programme because it was not profitable enough. The Queen Bee recounted that

"there was a time we stopped the programme, and I had to tell my country director, this is not biscuit and sweets. There has been so much misconception about contraceptives, you have to let them know that it's …you can't see me today and expect me to take the injections today, I have to gain your trust. So, we'll go back there again, especially when you can see a woman needs it. So, I told my boss, you have to give us time."

Even the programme manager admitted that the hope of continuing the DKT Bee programme was hinged on the success of Sayana Press.

"But the challenge, and that was the major thing that taxed that program, was that its performance was based on Sayana Press. Because many of them, because it was in a new product, they didn't push it as much; it was easier to sell the condoms and the pills". (DKT Bees Programme manager)

"this is DKT. If you don't make the sale on your target product, you don't make the [cut]. For altruistic and other impact level things it would have been nice. Some other programme would have said oh this is a success; at least they're selling other products. And for the donor they don't mind. Their own is to preach the principle of informed choice. But for us, the main measure of performance was determined by the number of administrations and repurchases that were made. It (sales) wasn't really coming as much. And they were actually the channel we looked at in delivering the market. We gave them double the targets we gave the reps."

The monitoring and evaluating team hired by the BMGF however scored the programme a success.

"as far as the University of California San Francisco team were concerned, based on their M&E, the DKT Bees channel was a fantastic model because a lot of younger women were more comfortable talking with them, and they had their registers so they could track Sayana Press users, and you notice that more than 30% of the users were younger than 25 and for most of them it weas their first time of using it…from the UCSF analysis the DKT Bees programme was a go. Because a lot of young people were reached. Because they were able to avoid the judgemental bias in the other channels".

It was this success despite the fact that made the BMGF to push for expanding the programme across the entire country despite the fact that senior programme managers weren't satisfied with the numbers (sales) and wanted to kill the project.

6.2.5 Meta-organizing for Access: Organizational Boundary Shifting

Beginning in 2017, the BMGF put together a $9 million grant to facilitate the nationwide rollout of injectable contraceptives using Sayana press as the core product. There were 8 organizations including DKT who came together to build a consortium around the DKT model for access to contraceptives. The leadership of the consortium fell to a large local NGO similar to BRAC (Building Resources Across Communities) an NGO in Bangladesh.

Within a few months however, things began to fall apart and DKT pulled out of the consortium citing organizational differences as the cause.

"First of all, organizational difference is key. The way they operate. The way the decisions are taken here is on the go. You can come in, have a meeting, we take a decision, and we move forward. We cascade it down to sales teams; we move it down to 50,000 outlets. You know it's the speed [at which] DKT operates. Other organizations don't operate it. Things we can do with a phone call, email, and all that, they want to have meetings, fly to Abuja…we are not in Abuja. These are issues that keep coming in, and then when you attend the meetings, its completely different from the way things are done here….in fact that's usually the issue."

"Take for instance, the sapphire project, when we were talking about training, we said 2-4hours [is enough]. We talk about it and we go…my other sister organization said five

days training. What are you going to be doing? …those kinds of things it keeps coming up and that's why it's difficult to align." (DKT Programme manager)

The programme manager of the lead partner in the consortium who refused to go on tape but allowed me take notes had a slightly different understanding of how things unfolded. He listed and explained four reason he felt caused the consortium to break up.

1. Selfishness

The conflict was due to selfish goals and selfish ideas of 'what's in it for me. DKT wanted the salaries of staff seconded to the project to be paid from the consortium money. the donors felt the project could be run without those expenses in sales and distribution, since salaries of the staff were already being paid as it were in member organizations. DKT then felt it not worth their while to remain. He however admitted that every partner had their own interests saying something to the effect that 'you don't form a consortium because you like all the partners, but because being in it has something for you'.

2. Different Organizational Bureaucracies

He identified that as consortium lead, he faced a challenge getting members to cooperate because although as lead you want certain targets to be met, the members don't owe you as much allegiance as they do to their parent organizations. This leads to delays in reporting and conflicting messaging across organizational boundaries, with delays up to a month.

3. Strength of individual organizations

He pointed out that key staff and competencies which were the basis for forming the consortium came back to haunt the consortium in a round-about way because parent organizations were wont to pull out these staff and second them to other projects that may come up during the life of the consortium. This is especially because the consortium benefits from the experience that these staff bring into the consortium from those other projects.

4. Organizational Culture.

The difficulty of building a consistent messaging for the project also stemmed from the cultural differences between member organizations who had their own logo, messaging, materials and language. Policies like per diem (outstation allowances) also caused friction

because different organizations had different allowances and it was difficult getting each partner to agree on a uniform scale when some would feel short-changed.

6.3 Case Analysis.

The four issues highlighted by the manager are much in keeping with the coordination problems identified by Ahrne and Brunsson (2005).

Meta-organizations theory

In their 2005 article, Ahrne and Brunsson (2005) identified the organization of organizations as a fundamentally different epistemological project from that pioneered by March and Simon in 1958. Whereas March and Simon (1958) studied organizations and their constraints as following from the human characteristics of their members, Ahrne and Brunsson (2005) propose that organizations whose members are themselves organizations have a host of differences which lead to radically different organizational outcomes.

They make three assertions; first that meta-organizations differ in three fundamental areas from individual-based organizations (Ahrne and Brunsson, 2005):

1. Constitutional Differences:

Humans by their nature are mortal, finite in mass and have a fairly fixed span of life, while organizations are immortal and infinitely scalable. As a result, administrative control is easier to exercise over human beings than over organizations. Thus, in a meta-organization, the hierarchy tends to be flat, and federating, but in individual-based organizations, the hierarchy is pyramidal and top-down in authority.

2. Functional/Operational Differences:

Most human being function in the same way and respond the same way, sharing the same physiologic and metabolic processes. However, organizations differ radically from NGO to banks. As a result, their operational mechanisms can be so different as to make cooperation impossible. Flowing from this, there is greater differentiation and specialization among organizations, which meta-organizing a veritable way of pooling resources and capabilities quickly and on a vast scale. For this reason, meta-organizations depend on member organizations more than the member organizations depend on the meta-organization.

3. Strategic differences:

Most human beings are after a fixed set of life goals that are fairly generic as seen in Maslow's studies. However, organizations differ fundamentally in what their aims and objectives are as to make them seek radically different outcomes.

Most meta-organizations, Ahrne and Brunsson (2005) note, have a tendency to monopoly. In an attempt to gain efficiency, they exert slow power on the members by asking them to adopt conventions within the group that gradually change the individual organizations to attain uniformity. This uniformity when fully mature calls into question the organizational boundaries later on and results in a totalitarian monopoly which swallows up the members.

Where organizations capture value based on their unique organizational configurations, they may be unwilling to give up their uniqueness and therefore pull out of the consortium entirely.

What we propose is that these constitutional, functional, and strategic differences between DKT and the consortium led to the breakdown of the group. Whereas DKT is a private-sector oriented provider of contraceptives, the seven other members of the consortium were purely public sector oriented in their approach.

> "They take things too too easy. Even me I noticed and stopped going for the meetings. Because when I go there, I become very impatient with some of the things that they do. You know they want to come there pat their backs…"
>
> "We won't give our data to a competitor, you know why? Because when we sell, we know that we need to make some level of profit to cover our operational expenses. But them, they just go and dump, and many of them are already used to collecting free stuff from all these governments, USAID, DFID, JICA they give them all these things and they say it's for public sector, but when you go to your market you see them"
>
> "They gave themselves fat salaries. It looked as if the thing was mainly for per diems and meetings and useless useless things. If you ask me. And they're used to it so. That's the way they run. DKT won't pay you …you'll have to do four jobs before DKT pays you that kind of amount." (DKT Bees Programme Manager)

What the case identifies is that the breakdown arose from these organizational differences. It stands to reason that the first criteria in consortium creation should be uniformity and not organizational specialization per se. Or the administrative centre must be sufficiently weak as to allow for the individualism of each member organization to thrive in a very weak confederacy. This would mean redesigning the overall project and parcelling out individual parts to each member by the grant provider.

Eventually the DKT Bees programme was all but cancelled. As at the time of field work in 2019, only one CHEW remained out of 149. The reason was that for DKT, the sales numbers weren't enough to justify the investment.

> "If counselling was a KPI, I would say it did well. It is reached a lot of people particularly the population that the CD wanted to reach. The University of California San Francisco pointed it out in their report that the programme reached a lot of young people, the counselled a lot of women, but for us [as a marketing organization] sales is key". (DKT Bees Programme Manager)

The author however is convinced that the operating expenses were artificially high. I personally accompanied the last remaining DKT Bee into the field, and what I saw was a gross misunderstanding of what the purpose of the knowledge saving device really is.

Thirty years after its creation, Depo Provera was already a generic medicine available over the counter. This put it within reach of CHEWs already. The task shifting policy also gave legal backing to the CHEW for giving injectable contraceptives. But the extent of automation built into the device placed it even below the need for a CHEW and into the hand of the user. The reduction of the effective dose and replacement of the needle from intramuscular to subcutaneous dimensions meant that it was safe enough for self-administration with less side effects that Depo Provera. It is unusual and superfluous for a CHEW to go about injecting insulin shots as part of improving access to medicines once the physician has set an effective dosage and counselled the patient on how to go about it.

Indeed, the UCSF team had their eyes on the right KPI for a knowledge saving contraceptive designed for self-administration which is, patient counselling. The programme officer also identified correctly the two main issues obstructing access to contraceptives in the community; the deeply held myths against the use of contraceptives

and the biased bureaucracy of the medical channels. The DKT Bees should never have been understood as a contraceptive selling model but as a behavioural change model for debunking the myths of contraceptives in the community. there was absolutely no need for the DKT Bees to have to earn their renumeration by charging the women an administrative fee. If the knowledge saving device had already placed the contraceptive within the reach of self-administration, they why sell to them a service they can render to themselves?

This is an organizational logic that flows from the original operating model of its founders of Adam and Eve, who believed that you could raise the operating expenses for contraceptives in developing countries by selling sex toys and porn in developing markets. what is missing among the managers in Nigeria is the understanding that the focus on selling was largely in America (a core market), and that the knowledge saving device had pulled the rug from under their business model. This is why they were antagonistic to the other NGOs who went and 'dumped' products in the community. Probably the other NGO's knew that this administrative cost was now unnecessary and therefore refused to pay DKT for its foot soldiers to distribute and administer the product since it didn't need anymore skilled worker at the last mile of consumption. Since DKT had sole license from the parent Pharma company to distribute Sayana Press through non-medical channels, they were unwilling to give up their cash cow and decided to walk away.

As at the time of doing these interviews, the lead pharma firm had also withdrawn its license to distribute from DKT through a bitter legal dispute. DKT has gone ahead to develop its own generic version of the same contraceptive, only this time, with an injection needle for intramuscular administration.

A curious case of one step forward, two steps backward.

6.4 Conclusion.

In answering the first question on how to bridge institutional voids in labour markets in noncore countries, we propose that these voids can be bridged by standardization of existing products in a way that obviates the need for high skilled health professionals and puts them within reach of the end user.

The importance of this is twofold. First it brings the healthcare service and its technology within the world of the consumer. If left as mature products that require skilled health professionals, these technology and services are only available by accessing the core medical world of the hospital and clinic where the patient loses the initiative and autonomy to access medicines.

Secondly, bringing the health technology and its service within the reach of the consumer implies a shift from public health to community health. Currently most health interventions in the field are designed by public health practitioners who have first degrees in medical professions. As a result, their interventions often entail the expansion of the pre-existing medical world of clinics and hospitals. With governments in noncore countries unable to subsidize this expansionism, their jobs are often restricted to organizing countless workshops in capital cities about the need for government to invest in healthcare as though governments are suicidal about healthcare. A community health approach however implies that the healthcare intervention must be applied in cooperation with the community, by grounding the intervention within already existing leadership structures such as religious centres, cooperatives, and traditional leaders. A community health approach which led to the establishment of the DKT Bees in the case above was only implemented when the earlier attempt to go through the hospital and clinics (public health approach) had failed.

Therefore, alongside standardization must be institutional alignment with the local realities in a highly polarized world where core and noncore are increasingly dissimilar.

It is worth mentioning that these twin factors of standardization in financial markets and institutional alignment with local realities were fundamental to the successful intervention to create access to micro health insurance among coffee farmers in Tanzania (Maluka *et al.*, 2018; Kapologwe *et al.*, 2020). In this case the standardization of health insurance premiums to suit the willingness to pay of coffee farmers in the Kilimanjaro Native Cooperative Union coupled with a community health approach where coffee union leaders were co-opted to serve as enrollment officers led to over 80% enrollment in the KNCU Health-Plan within two years.

The second question as per the performance dimensions of the institutional intermediaries required for these interventions carries two seeds. The first is the need to separate the distributional intermediary from the knowledge intermediary. The second is to establish

what we should ask of both types of institutional intermediaries in the field, and what we should expect.

The results of the DKT Bees programme shows the answer to the first issue. That 65,000 women reached by a team of not more than 150 members within two years is no mean feat. But more importantly than the numbers is the type of people reached; as noted by the UCSF Monitoring & Evaluation team, these were young single girls between 18-25 who would other wise never have had the knowledge of contraceptives without first getting pregnant and then signing up for antenatal services at the clinic. By this time of course we cannot be sure that the child was planned for. Therefore, we see a superior performance dimension along knowledge intermediation by the DKT Bees compared to a distributional function considering that only 7500 women ever took up contraceptives through this programme. This of course is to the dissatisfaction of the DKT management team who would very much prefer that the numbers were reversed 65,000 units sold for each 7500 women reached!

The case also keeps to the line taken by the UCSF to identify the spread of knowledge among new consumers as the key performance dimension of a knowledge intermediary. The performance dimension of number of units distributed should be applied to a different kind of intermediary.

The above point brings the third question of how to organize these interventions on the field. Following Ahrne and Brunsson (2005) we still keep faith with the meta-organization as an organizational design that can quickly mobilize resources and capabilities into one effort. This is borne out by the fact hat the funds made available for reproduction of the success of the DKT Bees programme ($9 million) by the BMGF would only have been made available to a consortium as opposed to a single NGO.

However, it is hoped that what this case contributes is a better understanding of how to divide the tasks and incentives among consortium members. The failure of the attempt to meta-organize in this case was down to the inability of the consortium manager to get DKT international to either specialize in drug distribution and relinquish the knowledge intermediation role or remain in the knowledge dimension and forego the profit from sales as a driver of governance. Wanting to retain both, coordination failure was inevitable. We could also claim that this case would enable us to demonstrate to the leadership at DKT International that their success in the field was in the knowledge intermediary role.

The author believes that there is some misunderstanding of the organizational design and symbiosis between Adam & Eve in America selling sex toys to high income populations in American and using those proceeds to subsidize community health interventions in noncore parts of the world by DKT international.

Another alternative might be to simply recognize the nature of knowledge as a public good and embed it within the local government. Considering that the DKT Bees were unable to raise sufficient sales to sustain the programme may point to the role of government as knowledge intermediary using tax revenue to run the programme. Considering that these limited skill workers can be trained at a fraction of the cost of high skill health professionals, and these limited skill community health workers are not the sort that core countries look to import with work visas, there is room to expect success. This is not without antecedent either; the transformation of American agriculture with improved farming methods and seeds at the turn of the previous century would not have happened without the farm extension workers who took new knowledge and tools from the land grant universities established for that purpose, to the farmers in the rural areas.

Chapter 7: The Drugstoc Case

A private firm providing a quality guarantee in supply chains for medicines in Africa.

7.1 Bridging the institutional voids for Quality Assurance in Open Product Markets

The case presents a different value chain configuration unique to noncore economic areas. It frames the Open Drug Market in Idumota Lagos as an Open Value Chain, where all the elements of the Global Value Chain are free of monopoly.

The open drug market is predominantly a generic medicines market, for products which have been released from patent monopolies over production, sale and distribution. These open drug markets are the hub of over-the-counter medicines which do not require a skilled health professional to administer.

Due to the loss of patent protection, these generic medicines are faced with a hypercompetitive situation in the Open Drug Market at Idumota in Lagos. The profit margins are very slim, but the volumes are great, thus being able to meet the needs for out-of-pocket expenditure for most people in Lagos with a population of over 20 million. However, the chaotic nature of the Open Drug Market, raises the question of quality assurance in a market which is largely an allcomers affair.

This case has three broad parts, Part A traces the gaps in the Global Value Chain at Idumota Lagos for quality assurance. Part B focuses on the efforts of the institutional intermediary, acting to provide an ISO 90001 accredited supply chain guarantee of quality for generic medicines that would otherwise get lost in the open drug market. Part C analyses the question of what can be done to provide a quality assurance guarantee when brand equity of the Originator Brand is lost at patent expiry and generics are introduced into the market through parallel importation.

This class of medicines are important for noncore countries where 90% of their healthcare needs can be met effectively using generic medicines, but which lack the institutional capacity to effectively regulate Open Global Value Chains.

7.2 Medicines in Healthcare:

Under patent law, medicines today are organized in two groups: branded and generic medicines. The former are medicines held under exclusive patents by the innovator firms, while generic firms are patent free.

Some countries interpret patent rights as solely the right to produce, following a policy of international exhaustion of patents that allows for parallel importation of the same item by different firms sourcing from the same firm but employing different channels (supply chains). In these countries it is not uncommon to see products from the same manufacturer being sold by different logistics providers and wholesalers, even competing with the national subsidiary of the parent firm.

Other countries adopt the national exhaustion of intellectual property rights. This puts the supply chain for medicines into the country firmly in the hands of the patent holder, usually the local subsidiary of the global firm. Under this national exhaustion interpretation, parallel importation of the same medicine by a different supply chain is criminalized. The author remembers a running battle between the local subsidiary of a British firm in Nigeria with parallel imported copies of the same medicines being sold locally through the subsidiary, only that the parallel imported copies sold for at least one quarter the price of the 'original' ones.

The unofficial explanation was that these copies were stolen from other countries and smuggled into Nigeria. In some territories, it was not uncommon to see sales plans go to pieces because for every 10 prescriptions generated by marketing activities, the author remembers that 7 were 'lost', being filled by parallel imported products sold in the open drug market.

In Nigeria, the open drug market is the major source of medicines for most people after they obtain prescriptions from the hospitals and clinics which are always either out of stock or overpriced (Ekeigwe, 2019). The overpricing of medicines in the public hospitals is worth explaining here. Firms supplying government health facilities often mark up with up to 15% of the value of the item. This is to cover the 5% withholding tax charged by the health institutions on behalf of the government, while the other 10% is used to cover the long turnaround time between supplying the product and getting reimbursed. This can often take up to 2 years if the account manager or sales rep does not 'push' the file containing the Purchase Order for payment. This long turnaround time for reimbursement has been the graveyard of many multinationals who for fear of losing out to parallel importers in the open market insist on locating their products on the shelves of government health facilities who serve as script generators. It isn't long before the local subsidiary is being owed millions of naira by different government health facilities. With most of the

funds being tied up in these bad debts, the business case for going into Nigeria quickly evaporates, putting a squeeze on marketing budgets and even operating expenses in an already difficult environment. The author also remembers that most government health facilities operate a drug revolving fund, which the Pharmacy department manages. In order to cover for expirations, losses due to theft, accidents and spoilage, the institutions themselves impose a further mark-up of anywhere between 5-20% on the medicines. Combined with the mark-up from the subsidiary, drugs at the Pharmacy department can easily carry a 50% mark-up just to be on the shelf of a government hospital. On the contrary, the wholesalers in the open market operate a cash and carry model. These businessmen are willing to sell products at 5% mark-up and deliver to any location through a vast network of business relationships with other wholesalers in the country who are willing to accept payment in cash or other products in lieu of cash.

It is therefore not uncommon to see medicines being sold in the open markets of Nigeria to individual customers at 10-50% less than they may cost in the hospitals. These customers are aware that whatever they buy from these shops have no guarantee of quality, but faced with high costs in the government hospitals, they are willing to risk it.

The Open Value Chain is represented by the configuration of generic original equipment medicines, over-the-counter dispensing, and out-of-pocket expenditure.

Generic (OEM)	Over the Counter (OTC)	Out-of-Pocket (OOP)

Due to the open nature of the value chain, it is subject to abuse as there is little or no governance of the value chain. This configuration devoid of monopoly in product, labour and capital approximates closest to the theory of a free market in classical economics. Yet, it is the most understudied configuration of all, even though it fulfils the greatest healthcare need for the most people in the noncore parts of the world where the state is too small/weak to regulate the Global Value Chains for medicines.

This lack of a quality guarantee is not insignificant. At the height of the drug wars against fake drugs in Nigeria championed by Dr Dora Akunyili, then head of NAFDAC, as much as 50-60% of medicines in circulation were either fake or substandard (Ogbonna, Ilika and

Nwabueze, 2015). There is wide variation within the country, with fake and substandard medicine incidences hovering around 10% in some parts (Kaur *et al.*, 2015).

Many interventions have been introduced to curb the incidence of fake medicines within the supply chain. Two bear mention. The first is the text to confirm; a scratch panel containing a number for the customer to send an SMS to and receive a confirmatory message of authenticity about the medicine (Oyetunde and Ilozumba, 2013). The second is the use of handheld mobile drug testing devices that can detect the presence of the active ingredient (Spink, Moyer and Rip, 2016) (Fatoki and Awodele, 2017). The first solution is hampered by the poor quality of the mobile networks in some parts and the lack of penetration of the technology across all brands. Some of the fast-moving generic medicines (in growth phase) for malaria have adopted this already, while others such as slow-moving generics and brand medicines have been slow to adopt them. The reason is simple, the slow-moving generics are produced by firms too small to take on the added cost of the SMS service in a decline phase generic market where margins are slim. Secondly, the local market is too small to warrant global firms to differentiate products intended for Africa with an added layer of protective technology.

The result is that most substandard or fake products have shifted to brand medicine look-alikes (fakes) where volumes are low and margins are high, or substandard generic medicines produced by small manufacturers who cut the percentage content of costly ingredients to stay on top of the price cutting competition for generic medicines in the decline phase. The majority of these fake and substandard medicines originate out of Asian countries and has led to more stringent import conditions like site inspections for imports from these parts of the world. This has added to the cost of licensing generics from Asian countries who supply nearly 70% of the generics imported into Africa. This added cost poses an obstacle to medicines access through increased prices of generics.

7.3 The Generics Promise.

In 1979, the concept of the essential medicines list was born at the Bamako Initiative in Mali (Garner, 1989). Health ministers from sub-Saharan Africa pledged with the WHO and

UNICEF to implement access to essential medicines to be sold at a little above cost. The idea was based on the understanding that 80% of the healthcare needs of a community could be satisfied by a handful of generic medicines. These generic medicines and the essential drug list (EDL) were proposed as the cornerstone of a new community health approach that prioritized a local prioritization of healthcare needs according to prevailing needs of the community. Unfortunately, the EDL has suffered from the market shaping activities of global firms who shift the prescribing patterns of physicians to the new and innovative medicines that consume all of the health spend and deliver only marginal improvements in health outcomes. As a result, the Essential Medicines are often the first to go out of stock once the health budget is overstretched leading to massive impacts on health outcomes for those who cannot afford the innovative medicines.

The inability to fulfil the generic promise in Africa is hinged on the poor purchasing strategy of the buying hospitals and clinics. Their purchasing is fragmented and uncoordinated. However, efforts at centralization have only rendered the supply chain even more vulnerable to capture by the multinationals through changes in treatment guidelines.

But in the open markets, generics can be obtained cheaply and freely at the corner shops albeit without a quality guarantee at the lowest cost to the patient and to the community. This case therefore focuses on how institutional intermediaries can work to restore the quality assurance for generic medicines that are obtained in the street corner shops all around Africa.

The Nigerian market is notorious for Fake and Substandard Medicines (henceforth FSSM) and is home to Africa's largest open drug market (Oyetunde and Ilozumba, 2013). Previous efforts to control and regulate these open drug markets have been met with death threats, assassination attempts, bribes and outright sabotage. As a result, at one point in 2001, a WHO study found half of the medicines in Nigeria were Fake and sub-standard medicines (Kaur *et al.*, 2015). This lack of a quality assurance system in Nigeria's drug market was not always the case. A bit of history may help illuminate this breakdown.

7.4 Quality Assurance Gaps in the Open Value Chain for Medicines.

The Central Medical Store at Yaba in Lagos was established by the colonial administration of Lord Lugard to oversee the distribution of imported medicines throughout the country. Alongside it was established the Yaba School of Pharmaceutical Technology in 1884 to fill the need for staffing the medicines value chain. All that changed one hundred years later with the IMF led Structural Adjustment Program under a package of Neoliberal reforms aimed at cutting government expenditure and freeing the private sector to kickstart the economy from a slump due to the oil price crash of the 70's (Carlson, 1982).

What followed was the reckless award of import licenses for medicines to cronies of the ruling military administration leading to market dysfunction marked by decreasing quality of medicines imported. The collapse in the quality assurance systems for the medicines value chain was due largely to the incapacity of the government to regulate the sector due to nepotism and underinvestment.

Today the pharmacy trade is still heavily fragmented and poorly regulated. Only a few multinationals have established subsidiaries within the country to oversee the distribution of their brand medicines, while others operate from a distance using third party marketing firms to distribute and sell their medicines.

The fragmentation within the distribution channels makes it difficult for all but the largest firms to reap any economies of scale and scope in drug distribution. Thus, the unavailability of essential medicines outside the big cities is a mix of high cost of logistics due to low unit volumes, heavy markups to compensate for operational costs and the failure of trickle-down trade. Therefore, medicines are costliest in the rural areas compared to the urban conurbations of Lagos and Abuja.

Today Drugstoc is attempting to change that, as an intermediary for different firms who would have to either build their own supply chains. In its capacity as a network administrator, Drugstoc relies on a digitally enabled business model that allows registered users to access medicines online in bulk quantities with order tracking through an ISO certified supply chain.

7.5 Drugstoc: A history of the Firm.

DrugStoc was started by two entrepreneurs who were managing a handful of hospitals in the Southwest of Nigeria, and formed a medicine buying group to improve access to quality medicines. That intervention which began on an excel sheet has grown into a sprawling supply chain network managing the drug stock needs for 1500 pharmacies and clinics in Lagos, Nigeria within four years.

> *"We realized that the pharmacies and hospitals had issues with their stock management, portfolio management and things like that. Because they have pressure from health insurance companies, what they're doing is now bottom feeding. They're even going to buy from the open market…for them its price, price, price, very price sensitive market. So, we are creating this avenue for hospitals to affordably access drugs that are not tainted with a counterfeited supply chain…"*

The motivation for setting up Drugstoc came when one of the founders lost his father, a Professor of Surgery at one of Nigeria's most prestigious medical schools in an emergency one night in 2006 because the ambulance had no medicines.

> *"What happened was that because he was a sickle cell patient and he had hypertension, he couldn't take blood thinner, so he was [always] at the risk of throwing a clot. Now this fateful night in 2006, he threw a clot, a pulmonary embolus, a moderate type. And, you know, called the hospital, [they] sent an ambulance, you know and the guy…the important thing is that the ambulance had no medication in it. And what you need in the ambulance is basically very strong pain killers, and you need potent vasodilators that can open the bronchioles so the clot can go down. You'll still have problems, but you'll be able to breathe. So that didn't happen anyway, and I watched him drown in his own secretions."*
>
> *"For me that created existential questions around the fact that you know…what are we doing. How is it that you don't have drugs?"*
>
> *"And I guess I'd say eventually these existential questions led me to say, I want to go do a course in management and finance. So, I went to holland, Maastricht University to do a Masters in Finance, Management and Economics. Because at*

the time I had lots of conversations with people, I found that the conversations around how things got done, in the hospitals were more involving and interesting to me than the practice. Simply that…I still love the [clinical] practice, but the issue for me was more that no matter how skilled, you are as a professional, no matter how many skilled professionals you have, if you don't fix the problem…as a skilled guy you are saving one person at a time, but a system issue is taking hundreds at a time. So that sort of made me move out. So, after I finished, worked for the European Union, the Directorate for Health and Consumers, worked with the World Bank, IFC, all around healthcare financing and supply chain. And then first opportunity I got to move back to Nigeria, I took it. By then I had met my business partner. We met in holland actually. And yea we had discussed all these issues and why we left the healthcare system and what we wanted to go and fix and what we wanted to go and change."

The duo returned to Nigeria and promptly put their plans into motion, which the founder describes over a period of four years.

A: "So we started with an excel sheet and we found out that this makes sense, there value here, the numbers were there, and we now started working on it, built an app, built the web platform, designed something really…id say it was four years ahead of its time. Cos, we launched actually at CcHUB[13] *in 2014, and I remember November of 2014, long before any of these, anybody was thinking this kind of thing. I think the first day we got like 100,000 hits, and our server crashed [laughter], that was just insane.*

Q: but that traction…so soon?

A: yea but it was consumer traction, it wasn't hospital traction.

So we had built the platform in such a way that you could see the drug, but you couldn't access it without registering. To register you had to use a license, so we got a lot of hits from people using the platform and trying to sign up, and this crashed the system. Cos we were thinking like…we weren't thinking that 100,000 people would hit the system. So we didn't really optimize for that flow.

[13] CcHUB is Nigeria's first open living lab and pre-incubation space designed to be a multi-functional, multi-purpose space where work to catalyze creative social tech ventures take place. The HUB is a place for technologists, social entrepreneurs, government, tech companies, impact investors and hackers in and around Lagos to co-create new solutions to the many social problems in Nigeria.

Q: I don't think even Facebook had that much traffic when they started…

A: it was crazy, it was from all over the world. As soon as you put a drug up on a website everybody just goes for it. Don't forget that this was the time of the rx guy [Martin Shkreli] being banned in the US, so people were looking for any and every online source of drugs. So, if we wanted to actually be unscrupulous, we could have just been shipping to the rest of the world and we would have a very good business, and just kept quiet about it. You know, but we decided our primary market was facilities. So emm…we now ran our pilot, we ran back redesigned the system and then ran the pilot. What we realized was that the supply chain was the issue. It wasn't the …access is not just a fancy word to just say go online and …which is what a lot of pharmacies have now. You go online and there's no follow up, there's nothing, because there's no supply chain. There's no back end.

So, we built the backend and internalized after 2015, up till 2016 we were working on the backend. In 2017 we opened our first experience centre where doctors and pharmacists could come. At that time, it's dying down now…but people have a lot of mistrust for online. So, people wanted to come, see, touch and go. That was why we had the experience centre. And it was like a supply route for us, so we got it licensed from PCN, licensed it in 2016, and in 2017 opened our doors for people to come ion. From there we've been growing at 300% since then. So, it's been an interesting ride, lots of chaos, no sleep."

7.6 Institutional intermediation: The Supply Chain Quality Guarantee.

The current testing models for stamping our fake and substandard medicines in Nigeria work through a product guarantee of quality. Where each batch of medicines or lot is sampled, tested, and then certified as meeting requirements.

Drugstoc however has adopted a supply chain guarantee of quality, where the certification is on the supply chain processes used to deliver medicines to hospitals and pharmacies.

"oxytocin is transported in the back of trucks from Onitsha market to places like Adamawa. Hot. They bring it out, drop…I've seen, I took pictures on my phone…they bring out the drug, they drop it outside the pharmacy, the truck, they

go to the motor park, offload, drop it on the floor. Then people come and pick their drugs.

So, you have people complain about postpartum haemorrhage, and you're like???!!...the oxytocin supply chain is messed up. You have only one company Juhel that has a cold truck that drives round the country, to supply [its] drugs. It's completely insane. Cold chain facilities unavailable in Nigeria. The ones that are available, not open to private sector. So, it's just madness. So, this whole supply chain thing is completely crazy. Cold chain for people now in their heads is vaccines.

So, when you come to our warehouse, you'll see that its humidity and temperature controlled. So, we have all the monitors.

A lot of last mile delivery warehouses are not certified. But for us we had to show it, so we got an ISO certification for our processes, because for us we were like, we needed these processes to be legit, to be compliant, so our mantra is quality at all cost. I want to be able to take a drug, and I don't have to think twice about it."

"*What we are doing is increasing the space for professionals to be able to access quality and professionals who are interested in quality.*

Since 2017 one thing I've noticed in the market is there's a shift in the appreciation of quality from professionals. So, we have our core base, that appreciates that quality and keeps coming back for more. So, we've been growing that."

[Q: So this base, is it more private or public?]

A: "It's all private. There are some government agencies. We've dealt with a few but government procurement is an interesting beast. The public sector is also under pressure from two areas. One falling government money. so even if a government is buying 100-million-naira worth of pharmaceuticals, their demand is probably 300 million. So, they never feel like they have enough. And as such they don't see that purchasing power the way you see it as on the other side. Now at the same time they keep driving the price up for generics and compounded on that is now the poor purchasing power of the population and the weird procurement system. So even if you would want this government, ideally as a government you would say something like, if you had…which is what the drug revolving fund is supposed to do…okay I

have…I know I'm going to buy 100 million naira. Why don't I place these orders and get the 100 million in to sell it, drop the price? It doesn't work like that. What you find is that the drugs in the hospitals are much more expensive than the outside, and why? Because if you want to deal with government, your problem is that government doesn't pay, now that means you have to have very deep pockets to manage that. And that means that its either the manufacturer that can deal with them, or a middleman who has layered on so much fat that he can say, even when you [the government hospital] pay once, I can cover my operating cost, and then everything else you pay is profit. These are all supply chain issues which… so for us we look at I like. You know, to get the system working, you might as well focus on the private sector. Private sector supplies, when you look at the health market in Nigeria, over 60% of the people consume care from the private sector. So, for us it's not such a bad idea to start from the private sector and when you get to the point where you have a procurement cycle that can be two years, then you deal with government. Or you do a PPP with the government. But all that needs long discussions and time and things like that.

The hospital administrators they see it as a revenue stream, they're not seeing the consumer dissatisfaction coming from not managing it optimally. They don't see it as a way to retain clients. Because the incentives for government and public sector is different. They don't consider their revenue as I could optimize it, I could get better, it's like I get money from government anyway, so I shouldn't push beyond the envelope because at the end of the month my salary is going to be paid. So that's the public sector".

7.7 Case Analysis.

The interview opens up many aspects of the medicines market in developing countries like Nigeria and how institutional intermediaries work to bridge the gaps in the product market.

In the AstraZeneca case, the critical gaps in infrastructure at the ports are presented as a leading to this case. Drugstoc positions itself from the port to the bedside – the metaphorical last mile. Although it does a great job of providing a digitally enabled supply chain guarantee that is able to track end to end, all its medicines, there still are gaps in the

large majority of the market. As noted, some other product intermediaries have sprung up, but these mostly source from the open market themselves in a bid to undercut Drugstoc. Although Lagos represents a substantial share of the market for medicines in Nigeria with an estimated population of 20 million, there remains the rest of Nigeria with a population of some 180 million to cover.

The borderlessness of the open drug market in Nigeria is compounded by the inability of the hospitals to leverage their demand to ask for quality from the market. This is understandably difficult in a low-income country where pharmacy administrators are always stretching insufficient health budgets. This 'stretching' provides the entry point that allows cheap but substandard medicines to seep into the system. For now, Drugstoc enjoys the patronage of that small base of health facilities who insist on quality assurance. Drugstoc has been on the receiving end of a lot of funds from the BMGF. This may contribute to its ability to make the delivery of medicines free of charge at the moment. Sustaining this model will require substantial investments to expand. At the moment, the patient is not yet provided a full quality guarantee on the medicines they buy as the hospitals and pharmacies still buy from Drugstoc and other sources.

The high cost of quality guarantees using point of sale quality assurance technologies (such as scanners) remains a huge barrier for end users and their points of access. Each medicine scanner (Truscan) costs about 50,000 euros. And can only be used conveniently in one location and per purchase. On the other hand, Drugstoc has invested in cold chain medicine boxes mounted on tricycles and motorbikes that can nip in and out of traffic on the congested roads of Lagos. Each tricycle and its cold chain box costs around $2000 each, while a motorcycle with a cold chain box costs less than a thousand dollars. A 20-ton refrigerated truck comes in at around $30,000. Each of these assets cost less than a single Truscan device. The author personally saw a fleet of these tricycle mounted motorcycles and tricycles as part of the distribution fleet of Drugstoc when he visited their head office in Ikeja Lagos in 2019. The quality guarantee provided by Drugstoc rests on this tightly managed supply chain that can trace each pill to a particular supplier. Therefore, a supply chain guarantee using verified management processes offers a greater promise of fulfilling the promise of a quality guarantee on medicines than a product testing-based quality guarantee. Sadly, it is the more eye-catching product testing device that was received with fanfare by the Nigerian Agency for Food and Drug Administration and Control (NAFDAC) 2010. These devices even featured on a BBC documentary as the new weapon

in the fight against fake drugs in Nigeria. Creating a de jure standardized system for medicines handling may be a cost-effective solution albeit a less glamorous one. That is the easy part. The hard part is how to deal with the downward cheap-medicine-selecting pressure from health management organizations, marketers, buying groups, and cash-strapped government agencies which patronize the open market model of drug distribution. In other words, how to extend the supply chain guarantee over the entire country.

The question is whether an open drug market can become quality guaranteed using management strategies for safe and effective handling of medicines to failproof the supply chain from internally generated fake and substandard medicines that do not work due to poor handling and improper storage. This is unlikely to happen without changes in the purchasing power of patients. Implementing a supply chain guarantee costs money and managerial expertise. The two things noncore countries lack the most. At best there may be a two-tier system of an open drug supply chain for people who are price sensitive to quality and a quality guaranteed supply chain for those who are not price sensitive to quality.

What is important is that under competitive pressures and low incomes, the question of a quality guarantee on generic medicines is best supplied by embedding the quality assurance from the brand to the supply chain itself, for those who can afford quality in generic medicines.

7.8 Discussion.

It is not core versus noncore anymore as such that is the main point of this case. It is distributed global commodity chains. because the global implies a central coordination or centralization of some sort. But distribution speaks to a harmonization and then dispersal, not truncation leading to fragmentation at nodes or axial divisions. Many suppliers, many consumers and an open knowledge platform leads to a distributed Global Value Chains for medicines.

The global firms are trying to re-globalize and centralize this dispersal by dipping into the generics market and it works by providing a quality guarantee in a price insensitive but

quality sensitive market leading to serious implications for market share if not profitability initially.

The logistics providers on the other hand are providing a quality guarantee embedded within the supply chain, by providing test and trace functions for medicines in the open market.

RFID technology is a major advance in the integrity of system-wide quality assurance schemes at very low or better put, marginal costs.

The key issue is that with Global Value Chains and medicines, when patent rights are lost, so also is the quality guarantee of the brand name. efficacy of generics may or may not remain the same, but the equivalency of brand name to quality assurance is no longer equal or interchangeable.

Within the sociology of a brand product, efficacy and quality assurance are collapsed into the brand product. In a generic product, with loss of brand name, the quality guarantee is lost. The question therefore is how to restore quality guarantee without incurring the cost of branding and expensive testing on each and every batch of products; a system guarantees of quality.

The multinational brand ensures its quality through the use of dedicated distribution systems, dedicated sales teams, and distributorship licenses. The multinational establishes local subsidiaries to oversee this quality guarantee system which is strengthened under the national exhaustion principle. This is merely local exhaustion and gives the multinational power over the entire downstream value chain up until the last mile (shelf).

With commodification, this control becomes unsustainable with loss of patent rights opening the door to three successive waves of generic competition. The first wave is the upgrading of API manufacturers into full product packaging. The second is by marketing outfits sublicensing from white goods manufacturers of medicines, and the third is from global buyers reconcentrating control in the hands of a few suppliers.

Commodification is ongoing and is a worldwide phenomenon in core as well as noncore countries. Whereas in noncore countries of Africa, Asia and Latin America, poverty, and low incomes act as pull factors for increasing market share of generics, government policies on purchasing management to drive down healthcare budgets in core countries are the push factor for increased commodification of medicines within the Global Value

Chain. This transformation has important implications for the locus of power within these Global Value Chains. If the upstream concentration of power in the hands of global firms is gone, a leadership vacuum arises for Global Value Chain governance.

Large distributors are rising to fill this void especially in the downstream part of the Global Value Chain. Ideally it would be large buyers in a buying group coming together for a collective purchasing strategy in a decentralized buying group or cooperative. But the competence of the health facility is on health, and most facilities do not apply strategic supply chain management or any purchasing management beyond open tender and bids.

This allows the large distributor of medicines supplying three or more regional health centres to step in and fill the leadership void for Global Value Chain governance in healthcare. The case traces such a firm, providing quality assured supply chain services in Nigeria's open drug market.

In Europe, the rise of internet pharmacies piggybacks on the well-developed postal services. Therefore, logistics providers cannot assume leadership in these markets. However, these is still an unmet need for a quality guarantee that medicines ordered off the internet are not fake or substandard. Website or platform guarantees are not enough as the internet is largely a free market. However, cryptography-based tracking systems may offer a cost-effective solution in these markets.

Drugstoc's success in the real-world open drug markets of Africa may have a lesson or two for the virtual online drug markets of Europe and America which function as free markets for medicines.

Chapter 8: The Kilimanjaro Native Coffee Union (KNCU) Case

An indigenous governance system for medicine supply chains in Africa.

8.1 Bridging Institutional voids for Capital in Health

This case frames the universal health insurance scheme in Tanzania. It traces the near collapse of this scheme due to deep institutional voids for healthcare financing (capital market voids), and efforts by an institutional intermediary to create a fragmented micro health insurance scheme to bridge the gap and improve access to medicines among the coffee farmers in Mount Kilimanjaro's Moshi District of Tanzania.

The case identifies the performance dimensions of a successful micro health insurance scheme, and how these dimensions get lost in translation during an unsuccessful attempt at expanding the micro health insurance scheme into a nationwide universal health insurance programme.

Part A of the case positions the Tanzanian Healthcare system as a Public good using conventional economic theory. This section traces the chronic underfunding for health in Tanzania that leads to poor quality of services and low uptake of health insurance.

Part B is a largely historical account of the attempt by an international NGO to bridge the institutional voids for capital financing in healthcare through a cooperative health insurance plan. This history is reconstructed through interviews with the main actors in the field who set up the KNCU Health Plan and its subsequent extension.

Part C presents the efforts at reproduction to extend the intervention nationwide and uses Ostrom's' theory of collective action to tease out the performance dimensions that are lost in the process.

PART A

8.2 Universal Healthcare as a Public Good.

Garrett Hardin's 1968 article on the tragedy of the commons painted a bleak picture of human rationality when neither the state nor the firm is available as a governance mechanism (Hardin, 1968). A bleak picture of suboptimal human behaviour in

appropriating shared resources, and a seeming inability of actors to break free of the prisoner's dilemma in a zero-sum race to the bottom. His analysis demonstrated that only two alternatives to the tragedy of overuse in common pool resources; the monopoly of the state or the monopoly of the firm. This analysis was re-echoed in Paul Samuelson's essays on Public Expenditure dichotomizing economic goods into private goods and public goods (Samuelson, 1998). That is, that the governance of production systems should be left to the market and where this fails, the government should step in. the following paragraph from Sugden puts it beautifully.

"Most modern economic theory describes a world presided over by a government (not, significantly, by governments), and sees this world through the government's eyes. The government is supposed to have the responsibility, the will and the power to restructure society in whatever way maximizes social welfare; like the US Cavalry in a good Western, the government stands ready to rush to the rescue whenever the market "fails", and the economist's job is to advise it on when and how to do so. Private individuals, in contrast, are credited with little or no ability to solve collective problems among themselves. This makes for a distorted view of some important economic and political issues. "

- (Sugden 1986: 3; emphasis in original)

Buchanan worked out theoretically a third class of goods having properties intermediate between private and public goods (Buchanan, 1965). These he named club goods. He proposed that these goods were excludable, but did not suffer subtractability until the optimum group size was reached, after which point the cost of appropriating the benefits outweigh the benefits of club membership. This he pointed out would happen for resources or services that were fixed in supply.

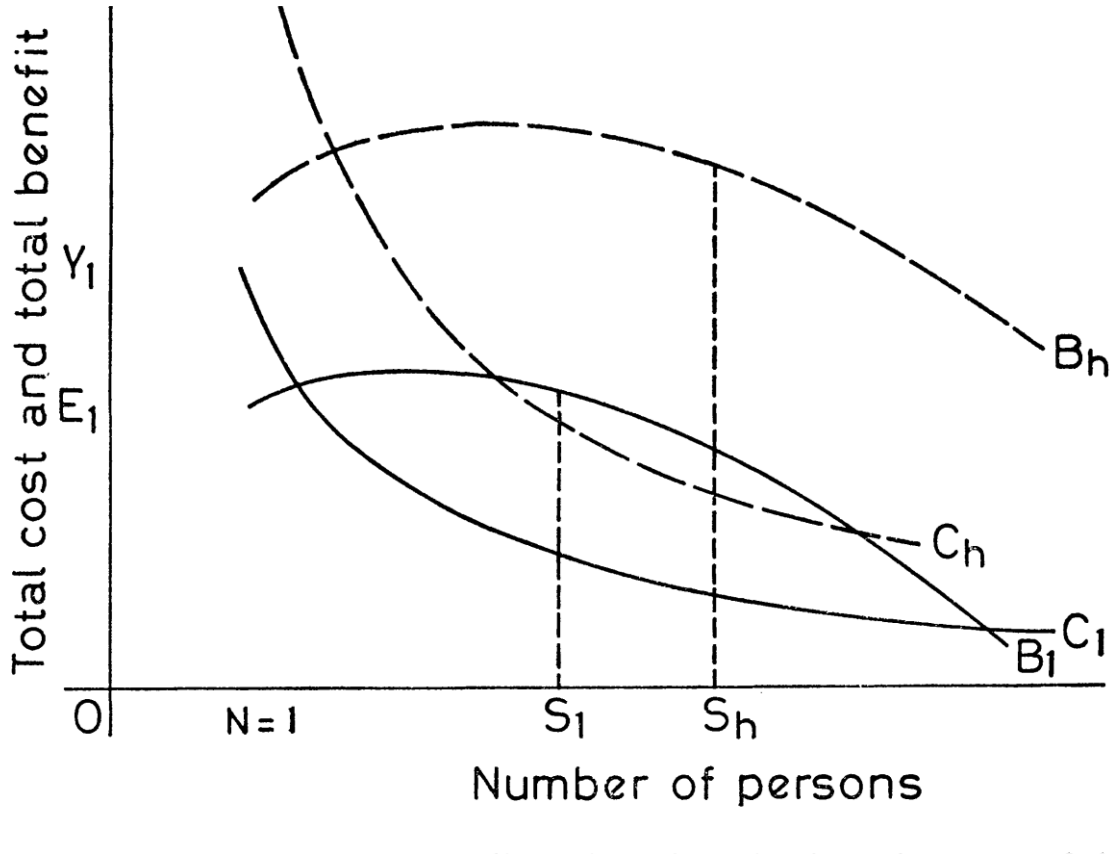


Fig 8.1 Cost-Benefit and Membership curve for Clubs (Buchanan, 1965)

The graph above shows that at the beginning of the club formation with a membership size of 1, the costs are borne by the member and are prohibitively high. Therefore, with increasing membership, the costs are spread and the benefits of club membership begin to rise relative to cost of membership. However, at an optimum group size where N=S1, the benefits derivable from group membership are at a maximum, and the costs are at their relative lowest. Beyond this point the benefits of club membership rise slower than the costs increase, and diminishing returns set in for all members. This can only be offset by expanding the resource base, which creates a shift to the right in the cost and benefit curves from C_1 and B_1 to C_h and B_h. Buchanan points out that for each club good, the optimum membership of the club must be determined and matched with the resource ab initio (Buchanan, 1965).

A cooperative of coffee farmers is a club. The international coffee demand is a fixed resource which the union attempts to appropriate under governance for its members. Therefore, with increasing group size, a point is reached when the coffee produced by union members can no longer be absorbed by the market and international coffee prices begin to drop precipitously. Beyond this point, the benefits for each additional member of

the coffee union for producing an additional unit of coffee becomes smaller. As long as the quantity demanded is inelastic beyond a certain optimum quantity supplied, the coffee union members will have to share a fixed pool among an increasing union membership and suffer the cost of unsold coffee beyond the Q-optimum. Fortunately, coffee unions are excludable and can limit membership if they choose to by raising entry criteria or restricting supply.

Because the group is excludable, it is ideal that the excludability is exercised once this optimum membership is reached.

Health care on the other hand is not easily excludable, at least not ethically, but it suffers from rivalry during use as health services are relatively scarce and expensive. Therefore, health systems face non-excludability of access to medicines, and rivalry of the health services.

Universal health insurance schemes set up by governments are attempts to manage the rivalry by increasing the resource base that provides healthcare services through public finance. In core countries where this has been successfully implemented, healthcare is provided as a public good, through a public health system that is non-excludable and non-rivalrous. This is universal public healthcare as a public good.

In noncore countries where the state is unable to finance this sort of provision, either due to low-income tax base or dwindling revenues from the sale of commodities, the system collapses under rivalry if the users cannot develop local governance systems to manage the value chain, or out of-pocket health expenditure replaces it entirely when private providers use high prices as an entry barrier to manage excludability.

Micro Health insurance systems are a form of group governance by small community of users coming together to contribute and pool risk. Such groups can exclude others, while keeping rivalry among members of the scheme low.

8.3 Institutional Voids in the Capital Market for Healthcare Financing.

Institutional voids for healthcare financing develop in noncore economic areas where the state is unable to subsidize the provision of public health and out-of-pocket expenditure is insufficient to meet the majority of the health needs of the population. Between an incapacity for public health and insufficient private health expenditure, gaps in healthcare financing arise.

These gaps are often set against the background of a developing country heavily dependent on commodity trade. Since the commodities crash of the seventies, Tanzania alongside others in the noncore context has been faced with dwindling revenues resulting in the incapacity to raise sufficient money from agricultural commodities export. The resulting inability to subsidize healthcare systems has brought about poor quality of services in the public health sector which serves 70% of the local population.

The value chain for healthcare in Tanzania relies mostly on generic medicines. And of the $740 million of medicines imported through the private sector, 54% were from India alone, the next biggest source of medicines was Egypt at 12%. Imports from core contexts, sources of branded medicines accounted for less than 20% of trade volume in pharmaceuticals (Ministry of Health, 2000). Medicines in Tanzania are largely dispensed through a network of hospitals, clinics and dispensaries built and subsidized by the government and staffed by healthcare professionals. Access to these medicines has been largely through the government-administered community health fund operated by the local district councils as a decentralized universal health insurance scheme. This combination of generic medicines, prescription dispensing, and universal health insurance gives a value chain with the following configuration:

Fragmented Global Value Chain.

Generic (OEM)	Prescription Only Medicare (POM)	Medical Health Insurance (MHI)

A historical account of the Tanzanian healthcare system and the history of PharmAccess interventions to bridge this gap in the healthcare value chain for finance leading to the establishment of the Kilimanjaro Native Coffee Union (KNCU) Health-Plan and the metamorphosis into a regional and national universal health system follows.

8.4 Tanzania: Country History.

The country of Tanzania is a developing country located in east Africa which plays host to a diversity of peoples and languages. According to the 2019 census, Tanzania has more than 100 ethnic groups and over 20 vigorously spoken languages and over 400 known languages. Formed out of the colonial designs of the German empire, it was originally an area stretching from the southern part of modern-day Kenya and some of the eastern part of Uganda. Following the loss of Germany's status as a world power in World War 1, it was forced to cede control over the region to the British as part of the conditionalities of the Treaty of Versailles.

In 1919, the region came under British colonial administration in its present form until 1961 when it gained independence. Like many African countries, the struggle for independence was borne out of national socialist mobilization against the European colonial rule. A key aspect of the socialist doctrine was the extension of the erstwhile colonial privileges reserved for the white settlers to all indigenous people of Tanzania. It is in this light that the Ujamaa policy of Nyerere, Tanzania's first prime minister was designed to achieve a redistribution of the agricultural sector by collectivising the people into rationalized villages parcelled out under central planning by the national government.

Health for all was also extended under the *Ujamaa* policy with a hospital in each district. Tanzania with 31 regions has 169 districts with an average population of 1.5 million per region.

8.4.1 Tanzania's Demographics (Department of Health Survey, 2016).

Out of a population of 50.1 million people, only half (54%) have access to improved drinking water, while only 24% has access to improved sanitation facilities. As such, maternal mortality, child mortality, HIV/AIDs, pneumonia, and malaria, are major issues that the health system faces, with malaria being the most common infection in children 14%, and occurring more in the rural areas 18% than in the urban areas 3.9%.

Infant mortality rate per 1000	**43**
Under -5 mortality rate per 1000	**67**
Maternal mortality ratio per 100,000	**556**
Total fertility rate	**5.2%**
Modern contraceptive prevalence rate	**32%**
Unmet need for contraceptives	**22%**
Prevalence of HIV in males 15-49	**7.3% (2016)**
Prevalence of HIV in females 15-49	**7.9% (2016)**

Table 8.1 Tanzania Health Demography

Healthcare in Tanzania is organized in a decentralized hierarchy of facilities. With dispensaries and health centres under the control of local governments, and hospitals under the control of regional governments.

Table 8.2 (Below): Distribution of Health Facilities in Tanzania

Region	Population	Dispensary	Health Centres	Clinics	Health Labs	Hospitals	Public	Private
Arusha	1,694,310	305	55	23	63	17	265	305
Dar es salaam	4,364,541	495	63	241	171	53	197	1097
Dodoma	2,083,588	353	41	11	43	13	388	127
Geita	1,739,530	141	26	2	43	8	162	125
Iringa	941,238	235	32	14	13	8	238	115
Kagera	2,458,023	277	36	5	16	17	270	102
Katavi	564,604	78	16	0	9	2	87	31
Kigoma	2,127,930	233	37	2	30	8	244	93
Kilimanjaro	1,640,087	329	50	17	6	20	263	215
Lindi	864,652	227	21	1	7	9	272	33
Manyara	1,425,131	185	28	6	9	10	199	77
Mara	1,743,830	253	46	6	32	14	271	132
Mbeya	2,707,410	294	30	23	18	19	294	161
Morogoro	2,218,492	370	54	13	89	15	359	259
Mtwara	1,270,854	221	29	4	6	7	231	60
Mwanza	2,772,509	312	50	33	110	23	374	282
Njombe	702,097	248	32	3	15	14	260	85
Pwani	1,098,668	316	38	6	48	9	302	156
Rukwa	1,004,539	206	23	1	3	6	216	44
Ruvuma	1,376,891	295	33	8	27	13	301	111
Shinyanga	1,534,808	200	27	11	17	7	206	107
Simiyu	1,584,157	195	18	3	9	7	245	50
Singida	1,370,637	206	22	6	29	11	213	91
Songwe	998,862	184	17	1	2	6	263	45
Tabora	2,291,623	294	26	9	39	13	360	119
Tanga	2,045,205	362	41	21	26	15	381	153
Total	44,624,216	6814	891	470	880	344	6861	4175

In 1999 a voluntary public health insurance scheme was set up empowering local governments to provide cover for the population (community health fund). Presently 25.8% of the population are covered by public health insurance.

Civil servants on the other hand are covered by a National Health Insurance Fund (NHIF). The Community Health Fund (CHF) is viewed as an effective "tool for mobilizing voluntary community involvement and participation in supporting their own health," whereas the National Health Insurance Fund (NHIF) is seen as a "mechanism to ensure medical protection of employees in the formal sector." The Tanzanian healthcare system comprises roughly 10,000 healthcare facilities distributed fairly evenly throughout the country. The wide spread is a heritage of the Ujamaa policy that required at least a dispensary built within each village of at least 5km distance from the next village. "The faith-based sector owns 23.3% of health infrastructure, while the state owns 60%. However, 41.1% of hospitals are owned by FBOs while 40% are owned by the state, making faith-based health facilities the largest providers of hospital services in the country" (Maluka *et al.*, 2018).

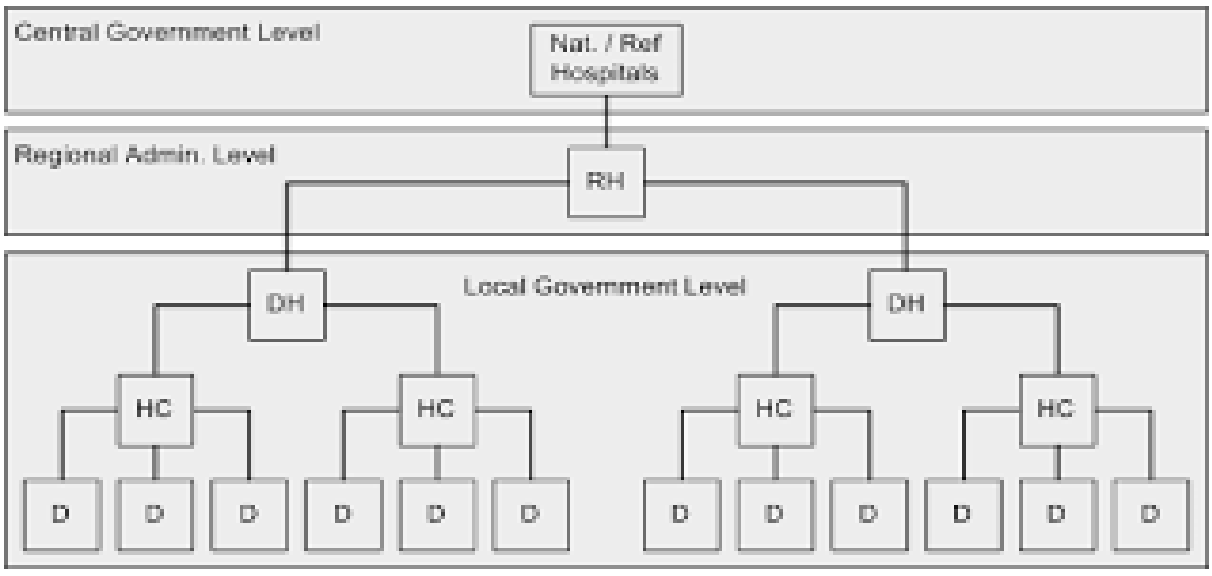


Fig 8.2: Governance of Health Facilities in Tanzania

These local facilities are run by subventions from the federal government and premiums collected by the local government councillors which have oversight of the dispensaries and the health centres. Under the Health Act of 2010, the Councils have the power to administer the facilities under them and to set and collect premiums negotiated with the people for public health insurance. Therefore, it is not uncommon for premiums to vary

from district to district within the same region (between US$ 4.2 and US$ 12.7 per year). However, most of these facilities are not up to standard. According to a study by Kapologwe et al (2020), only about "33% (1673) of all health facilities had piped water and only 5.1% had landline telecommunication system." Further,

> "…of all Health Centers only 115 (22.2%) were offering the Comprehensive Emergence Obstetric Care (CEMONC) services. Of these 115 health facilities, only 20 (17.4%) were offering the CEMONC services with all 9 - signal functions and only 17.4% had facilities that are offering safe blood transfusion services" (Kapologwe *et al.*, 2020)

In 2012, enrollment stood at a low 7.1%. The reasons for the poor uptake are fairly simple, due to a low tax base, the councils and district administrators are unable to generate sufficient premiums to drive the upgrade of these facilities, despite government commitment to match voluntary contributions. Thus, chronic underfinancing impacts the quality of services negatively leading to low enrolment. A vicious cycle of chronic underfunding and poor quality followed by low enrolment.

With a population of 50 million people, about 50% is classed as living in poverty by the World Bank (population living on less than $1.9 a day), with 9.7% in extreme poverty. However, when assessed using $5.5 per day as the cut-off point, the poverty rate is 91.7%. Tanzania has a largely agrarian economy, exporting primary commodities like coffee, tea and spices, the Gross National Income per capita is $1,081. This low-income tax base explains the inability of the local governments to effectively raise premiums for financing the upgrading and delivery of healthcare services through the public health sector.

In this situation, a vicious cycle of poor-quality health facilities unable to raise money for upgrading and offering persistently low-quality health services develops leading to very poor health seeking behaviour among Tanzanians. In this lock-in situation of poor-quality public healthcare services delivery, the private sector presents itself as a the only viable option of breaking the vicious cycle ('Strengthening the Private Health Sector in Africa: The PharmAccess Solution', 2017).

With very low premiums set by the local governments, the majority of private health care facilities in Tanzania do not accept to take on publicly insured patients. Thus, the private health facilities depend on out-of-pocket payments by the few who can afford their services. The private health sector is also constrained by existing laws from setting up and

collecting health insurance schemes in Tanzania. All health insurance schemes must be operated as public health interventions by Act of government.

In order to improve the access to health for vulnerable populations, such as those living with HIV-AIDS, mental illnesses, a system of exemptions is allowed for people to enrol without paying premiums. These exemptions are constantly being expanded to cover pregnant women and children under five, and those with disabilities. These exemptions in a country where the fertility rate is above 5% per woman represent a source of financial burden that strains already limited financial resources for health.

SECTION B

PharmAccess is a Dutch NGO set up to tackle the problem of under capitalization in healthcare and lack of access to medicines through the private sector through quality improvement. Originally set up by a Dutch Physician Joep Lange to improve access to anti-retroviral medicines and care through the private sector partnerships, the fund has expanded to take on general healthcare service improvements in developing countries. Today the NGO goes into developing countries as the implementing partner for a Health Insurance Fund set up by the Dutch Ministry of Foreign Affairs in 2006. As at 2020, the fund had disbursed about 100 million euros through micro credit facilities to health providers and facilities for upgrading.

It is within this situation that PharmAccess created an intervention to provide access to financial resources for health through the private sector in Tanzania. Over a five-year period, a quasi-public health insurance system was piloted with the largest coffee union in Tanzania to generate credit for upgrading private healthcare facilities and the delivery of upgraded health care services.

The following section gives an analytical history of the health intervention by PharmAccess into the Tanzanian Healthcare System. The history is analytical because after each historical dispensation, the key programme dimensions and changes within these dimensions are identified and compared internally within the case.

*8.5.*1 *Joep Lange in Tanzania: 1989-2001*

The history of PharmAccess in Tanzania begins with the pioneering work of the Dutch Physician Joep Lange. “at a time when no one really knew what worked in HIV treatments, Joep was experimenting to find the most effective therapies for HIV-AIDS” (PharmAccess Programme Director).

In 1990, Joep was in charge of a lab in Amsterdam under the University of Amsterdam saddled with the responsibility of finding weak points for chemotherapy against the newly discovered HIV virus.

Much of this work would lay the foundation for the triple cocktail of drugs that became Highly Active Anti-Retroviral Therapy (HAART) guidelines for the management of HIV-AIDS worldwide. Joep would go on to work with the WHO for 3 years between 1992 – 1995. He returned to Amsterdam to take up a professorship and set up a study to find the most effective treatment regimen for the Prevention of Mother to Child Transmission of HIV in pregnant women living with HIV-AIDS. The study started in Tanzania, Uganda and South Africa and lasted for 6-7 years before being published.

Most of these early field trials did much to establish what worked in HIV-AIDS management and what could be deployed cost effectively especially in Africa. But after establishing the therapeutic principles for managing HIV-AIDS, the next obstacle was the unavailability of these therapies in parts of the world where access to medicines was poor.

At the turn of the new millennium, only a handful of companies were invested in manufacturing Anti-Retroviral Treatments for HIV-AIDS. And they were costly to pay for out of pocket. The same director at PharmAccess remarks that

> "when I started going to Tanzania, I did some investigation on what was going on here in the area of AIDS treatment in Tanzania, I found that 6-7 doctors were supplying AIDS treatment, and in a very irregular way…who could afford to pay $2000 per month? Nobody. So people were desperate, they started something, sometimes with three medications, then after a few months it went to two and to one, they sold their house, they took kids from school and then they still died because it was resistant for lack of proper treatment." (Director, PharmAccess)

One of such programmes was with Heineken. The Dutch brewer already had well established brewery operations and state of the art plants in many African countries. They had well organized clinical services on site to treat staff and their families. (The author has personally visited the excellent clinic located at Ama Heineken Brewery in Enugu State, in eastern Nigeria).

Their network of clinics in Africa served as the foundation for the development of clinical services for implementing the HIV-AIDS treatment programmes administered by PharmAccess in African countries with endemic levels of HIV-AIDS.

> "we trained the doctors in these clinics, we made sure their laboratories were in order so that they could provide treatment to their staff."
>
> "we were very much in contact with few pharma companies, and of those, GSK and Roche wanted to start proper treatment programmes in Africa."
>
> "So in 4 countries, they contracted us to offer free treatment to 50 patients…lifelong treatment was guaranteed by these companies. So these were the first activities by PharmAccess." (Director, PharmAccess)

8..5.2 *PharmAccess in Tanzania: 2001-*

After these private sector-oriented interventions with Heineken, PharmAccess looked to replicate these programmes in the public sector.

> "I also looked for other opportunities, I met with the minister of defence for Tanzania who was a medical doctor, and he saw this disaster happening in the army, when we met he asked if we could also do something, for treatment for them in the army. I asked Roche and GSK, I got treatment for 100 patients, to start a treatment programme in the army here." (Director, PharmAccess)

The Clinton Health Access Initiative also undertook to write national plans for health systems in two countries for tackling HIV-AIDS. This was to scale up the successful pilots that PharmAccess had pioneered. These programmes took off in 2003, and the Clinton Health Access Initiative was instrumental in brokering the manufacture of generic anti-retroviral therapies produced in India at $11-13 dollars for a month supply, compared to $2000 dollars with the original Brand manufacturers.

These national programmes received further impetus from the Bush Administration who didn't wait to retire before setting up The Presidents Emergency Plan for AIDS Relief (PEPFAR), to commit 20 billion dollars in funding over five years to scale up these interventions. With generic supplies from India, Technical assistance in National Programme writing from CHAI, and funding from PEPFAR, PharmAccess was able to shift away from HIV-AIDS intervention and look towards improving health financing in general.

From HIV-AIDS to Health System Financing

This shift in programme focus came against the backdrop of PharmAccess' appointment of a new Director/CEO, Onno Schellenkens, an economist by training.

> "That's where the push for health financing came from. Now his idea was health insurance, if you think of how should health be paid in countries like this. In Europe health is paid by, out of tax income, by the governments. But here there's not enough tax income to make money available. So, health insurance, national health insurance plans are sort of an alternative means to make money available for health, that was the thinking behind this." (Director, PharmAccess)

His appointment came on the heels of a 100 million euro grant by the Dutch Government to fund the development of health insurance systems. The first of four countries to benefit from this initiative would be Nigeria. The four countries were selected because they already had large existing PharmAccess Offices carried over from the treatment programmes based in the Heineken Breweries in Nigeria, Tanzania, Kenya and Ghana which was included later on for other reasons. In Nigeria, PharmAccess chose to start in Kwara State,

> "…because, that state has a governor, a religious person, a Muslim person, who was very much in favour of this kind of activity and under his leadership more or less and his promotion." (Director, PharmAccess)

the scheme targeted market women for a number of reasons which seem to mirror the targeting used by the Grameen Bank in Bangladesh for extending microcredit in the rural sector;

> "women very active, they have some income, they know why their health situation is important, they could take care of their kids if they have health insurance, and it was a huge programme, in a rural area in Kwara State." (Director, PharmAccess)

The scheme began with a basic package and was offered to the market women's association in a rural area of Kwara state, in what would prove to be a steep learning curve.

> "we knew it was going to be difficult to get people into health insurance, because, if you have very little money, why would you pay something that you don't know if you're ever going to use it. So we started with highly subsidized schemes, just to

> see how people would appreciate it, and then after some time we thought they were going to be willing to contribute more, so we could reduce the subsidy. That was sort of a naïve thinking." (Director, PharmAccess)

Two years later and the scheme was plagued with high drop-out rates, high attrition rates, and low re-enrolment. In their naïve thinking, the NGO PharmAccess had overestimated the organizational capability of the market association. Whereas the group was effective as a dispute resolution and government lobbying group, it was not effective for much else. These market associations do not have experience in administration as they are based on popularity not on demonstrated ability to organize. In some states, the leader known as 'iyaloja' is even an appointee of the state government and therefore does not have legitimacy in the eyes of the members.

This naïve thinking and the resulting complications would serve as lessons to shape the creation of the KNCU Health Plan in Tanzania.

8.5.3 PharmAccess in Kilimanjaro: The KNCU Health-Plan.

The PharmAccess intervention in Tanzania began with an agricultural partnership in the Kilimanjaro region to bring healthcare services to the coffee farmers in the Moshi region. An eco-conservation NGO Envirocare had earlier pioneered a preventive healthcare approach in the coffee region of Moshi to teach the farmers safe use of pesticides and fertilizers which had been implicated in the incidence of cancers and lung related ailments.

It is within this context that PharmAccess introduced their intervention to improve the quality of healthcare facilities in the Moshi region by triaging farmers with hospitals who had elected to join the SafeCare programme for improving the operational efficiency of existing healthcare facilities.

The intervention had two constraints. One *a priori* limitation was the laws on running health insurance which limited them to public institutions within Tanzania, and another

was *ex post* which was the inability of the PharmAccess to fund the intervention ad infinitum.

The next section begins an analytical explanation of the institutional void for capital in Tanzania's healthcare system to provide background for the interventions into health financing introduced by PharmAccess.

8.5.4 *Old Community Health Fund (Health Insurance or something like it): 2000 – 2011*

Under the strain of rising health costs, in the face of dwindling revenue from coffee beans in the international commodity markets, the federal government of Tanzania passed health legislation, in 2000 mandating the councils to provide health insurance schemes for the poor who have no taxable revenue and are unable to afford out of pocket health care expenditure. Under a decentralized system of healthcare, the councils were mandated to set their own premiums, appoint enrollment officers, supervise the enrollment of people into the scheme, collect premiums and reimburse the facilities for services rendered based.

> "The premiums were set by the politicians under the old CHF. There was no premium calculation by actuarial services. Due to no capacity. Premiums were set council by council. Each council set its own premium because it could enact its own byelaws." (Manager, PharmAccess)

Often the setting of these premiums was subject to primarily political considerations than technical ones. The elected officials would set the premiums very low, as to avoid excluding anyone from accessing health care services through the public sector.

> "With low premiums facilities could not afford to purchase medicines, so automatically the services were poor." (Manager, PharmAccess)

Due to this vicious cycle of low premiums, undercapitalization, and then poor quality healthcare services, the result was that fewer and fewer people enrolled in the Old CHF programme, and those who did were those who had no choice; often the very poor and the very ill.

> "Old CHF started in 2001 and by 2015 had only enrolled 4%."(Manager, PharmAccess)

Even when the premiums were collected, these funds suffered scope creep from other activities at the council level.

> "Funds were supposed to be posted to council directors office. Sometimes the council director would use the funds for other activities and the funds were not reimbursed to the facilities timely. And reimbursement was not based on the services rendered. (Manager, PharmAccess)

Systemic abuses were also common. Enrollment was done mainly at the public facilities, and these ended up being the enrolment of very sick people or those too indigent to afford anything else. It was even common to see people pay the premium in instalments or paying the premium well after undergoing an expensive procedure like Caesarean section to avoid paying for the service out of pocket.

Reimbursement of facilities was even more haphazard. When asked the following dialogue ensued to shed light on this with one of the managers at PharmAccess.

> *"So reimbursement was not based on utilization?*
>
> No.
>
> *What was reimbursement based on then*?
>
> On how much was collected"
>
> (exchange with Regional Administrative Health Secretary, Babati)

It wasn't long before the system began to collapse under the weight of the misuse, in an ever-deteriorating spiral of poor quality, low enrollment and underinvestment in healthcare.

> "The facilities decided to chase away the CHF members or to give them inadequate services."

The private health facilities mostly stayed away from the scheme.

*8.*5.5 *The Coffee Cooperative: KNCU Health-Plan 2011 to 2015.*

It was in the low equilibrium condition of poor-quality healthcare services and undercapitalized health insurance scheme in Tanzania that PharmAccess decided to intervene in 2011. Endowed with a 100 million euro grant from the Dutch Government, PharmAccess set to work in identifying a suitable pilot group to bridge the gap in healthcare financing.

> "We gave the government some criteria of the kind of group we wanted to work with; at least 200,000 members." (PharmAccess staff 2, Dar es Salaam).

Two groups were identified in Tanzania that fit the bill. The first was an association of fish-market traders in Dar-es-Salaam and the second was the Kilimanjaro Native Coffee Union (KNCU) in Moshi. Both had a large membership of well-off traders and farmers, and both were sufficiently organized. But importantly, these organizations were registered as public entities under the Cooperative Act in Tanzania since 1985 and therefore were legally able to 'run' a health insurance scheme for their members. This would be necessary to avoid running afoul of the law on health administration in Tanzania around eligibility to calculate and organize the collection of premiums. Private entities are barred from operating health insurance schemes in Tanzania.

> "So these people they were offered, also health insurance packages, in Dar es Salaam it did not take off, because the organization of the fish market in Karyako was not strong enough to guarantee that they could collect the premiums and pay for it. But with KNCU it went quite well". (PharmAccess staff 1, Dar es Salaam).

8.5.6 Envirocare:

The coffee union intervention was built on an already existing community effort to prevent the high incidence of skin and lung cancers among coffee farmers due to unsafe handling of agricultural chemicals. The intervention was designed to introduce environmentally responsible coffee through organic farming tools and techniques in Kilimanjaro.

> "The first time they [NGO] came, the main thing was teaching people how to use pesticides. Which they use for spraying coffee. Before people used to use the concentrated ether and harm themselves. They would get chest problems and also eye problems... They used to get a lot of lung cancer because of these pesticides" (Primary Society 1 Secretary, Kilimanjaro)

> "Coffee out-growers were a good target due to their health issues and job hazards. And made it attractive to them" (PharmAccess staff 1, Dar es Salaam).

Envirocare partnered with PharmAccess to include health insurance awareness among the coffee farmers in Tanzania. PharmAccess then enlisted the services of MicroEnsure, a UK based actuarial services provider to develop a micro health insurance scheme for these farmers to be able to access healthcare from the private sector which had better managed facilities.

> ". And also, they [farmers] got training on how to produce coffee without these pesticides (organic coffee). From this it came that you can prevent but if you get sick, now you can seek health service." (Primary Society Secretary, Kilimanjaro)

A series of discussions were held with the umbrella KNCU body to discuss the possibility of a shared responsibility for a health insurance scheme. The KNCU leadership in turn opened discussions with the primary societies in each district who then voted to adopt the initiative. Alongside this, the primary societies also gave recommendations as to what level of financial commitments they would be willing to make towards the scheme.

> "The power of negotiation comes from the members. They share with the members and then decide. Then the leaders go to represent this position. When the message goes from up down, it is difficult to implement. But when from down up it is easy to implement." (Secretary General of Primary Society, Kilimanjaro).

This willingness-to-pay was built into the calculations made by MicroEnsure to arrive at a premium of 30,000 Tanzanian Shillings per year for each household to a maximum of 4 persons, plus a deduction of 1 Tanzanian Shilling per kilo of coffee sold which was to be collected by the KNCU at the federal level for the administrative costs of running the scheme. PharmAccess pledged to pay a matching fund on the premiums to raise the amounts to 60,000 Tanzanian Shillings per household, per year.

Importantly, the Moshi region on the slopes of the Mount Kilimanjaro where the coffee farmers are settled has a predominance of private healthcare facilities, with a private to public 60:40 split of healthcare facilities. The scheme was designed to be incentivized enough to attract the retainership of the private facilities. Enrollees could choose any facility close to them for accessing primary services and they could also choose a secondary facility for referral services. Within the primary societies, the administrative functions of promoting the scheme and enrollment was done by the primary society leadership, while PharmAccess took charge of administering the finances, reimbursing the facilities and processing the claims from facilities. PharmAccess also undertook a quality

improvement campaign for facilities which had to sign up to before they could provide healthcare services into the KNCU Health Plan and claim reimbursement services under the scheme. This quality improvement programme called SafeCare was based on an internationally verified system of quality assurance in healthcare developed in conjunction with the Council for Health Service Accreditation of Southern Africa (COHSASA) which is the only internationally accredited quality improvement and accreditation body for healthcare facilities in sub-Saharan Africa.

8.5.7 SafeCare

> "When the programme [SafeCare] came, it helped us navigate our way to quality, we are missing it, we are missing it already…" (Hospital Administrator, Level 3 Private Hospital)

At this particular hospital when pressed as to what it cost the facility to implement SafeCare as a quality assurance programme, the interviewee had this to say;

> "It didn't cost us anything. Mostly it was just time and commitment… So we went on with the human resources we had. It costs almost nothing, but we had to pay for paper to write policies, printing."

The interviewee also mentioned that there was a microcredit scheme for facilities to access funds for upgrading infrastructure at favourable conditions brokered by PharmAccess as part of the SafeCare quality improvement programme.

> "Another important thing is networking they were able to provide as contacts with the government agencies and financial institutions and they provided us with x-rays and where paying in instalments."

> "They keep training, they do training, they coach you to achieve the targets. Unlike the BRN, BRN they don't give you quality improvement plan they just provide you with a mark, then they leave. There is no actionable plan afterwards. Another thing to add, I think the attitude of the assessors is also useful. The attitude of the

assessors in safe care is very good." (Hospital Administrator in Charge, Dar es Salaam).

"The good thing with SafeCare is that they start with what you have…. The approach is good. BRN is not good as SafeCare…" (Hospital Administrator, Level 4 hospital, Dar es Salaam)

PharmAccess would go on to broker access to soft loans for facilities who needed credit to upgrade their facilities in order to qualify for membership of the scheme or to improve their rankings in the SafeCare roadmap from 1 (base) to level 5 (word class excellence).

The Primary Society appointed board members with oversight functions over the scheme to work with PharmAccess in making the scheme successful

"The board members were the eyes over the programme. In the villages, they know each other." (Secretary of Primary Society 3, Kilimanjaro)

"Everyone knew that since I gave my money to so and so…whom I trust, I know I'll get my money when I get sick". (PharmAccess staff 2, Dar es Salaam)

It was these board members who doubled as enrollment officers who went house to house promoting the KNCU Health-Plan. After they had been trained by PharmAccess, these board members also served as a complaints hotline for members to call if the services provided at the facilities were below par or especially when they didn't get medicines at the facility.

"With KNCU Health-Plan, they knew it as their product, so if anything went wrong at the facility, the members would go to the board members of the primary society to seek redress." (Vice President at Primary society 2)

PharmAccess maintained a database of enrolees which they used to calculate capitation payments for prompt monthly reimbursements of the facilities based on claim forms sent to the PharmAccess office.

The facilities were reimbursed by capitation rather than by utilization. This meant that hospitals had a fixed income every month per person registered with them. The facilities then had to cater to those who fell ill from this budget. The alternative system of payment by utilization would mean that facilities would be paid per service provided. When the

author asked the Country Manager why capitation was preferred over utilization as mode of payment, he had this to say:

> "Because it's easier administratively... And reduces roaming as people have to stay where their capitation is paid. This reduces another layer of complexity from the scheme. It's (capitation) a very big cost-effective measure. Under fee for service, costs balloon as the providers add anything they like on the claims". (PharmAccess staff 1, Dar Es Salaam)

> "Payment was done by capitation…if you want to pay by utilization, you need at least 4 people to be doing the checking …including all the clerk." (PharmAccess staff 2, Dar es Salaam)

Although the farmers who enrolled had to wait for one whole month before they started to access the services, the month of service lost at the beginning was reimbursed at the end of the contract. Therefore, a contract signed with the farmer in the end of January, would only expire at the end of February, and in three short years, the scheme had percentage participation of over 40% while the Old CHF programme running in parallel only managed to register 4% of the population. The changes were so keenly felt by the farmers that one board member interviewed describes the scheme as "…something sent by God".

> "…they are very grateful, very happy, because many of them they didn't save money, when they sell coffee they just use the money for other things like drinking, so when they got sick, some died…"(Beneficiary of the KNCU Health-Plan and Board Member of Primary Society 2, Kilimanjaro).

Although the scheme was a basic package for primary health services, it allowed those over 60 to go for free health check-ups at their primary facility, and included inpatient stay for pregnant women and up to 1 week after childbirth. The scheme was so successful that it inadvertently drove increased membership into the union as people scrambled to allocate a half plot of land for coffee farming, which was the minimum requirement for joining the KNCU and elicited renewed confidence in the members for the KNCU.

> "The KNCU has a very big history. Some elderly people who are now leaders in this country, they were taken to school by the union in those years, so when we started in 2011, people were like '…now we see union coming back to the roots,

this is how our union was in seventies and eighties', so that trust helped a lot". (PharmAccess staff 2, Dar es Salaam)

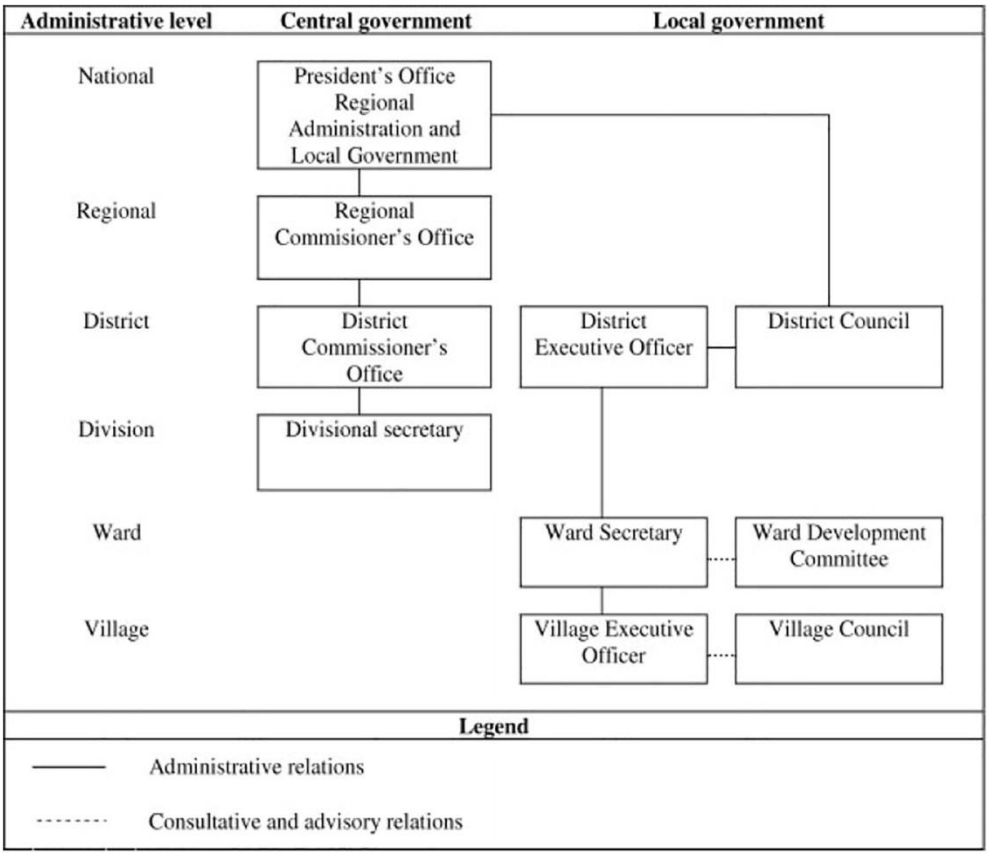
Those outside the KNCU Health-Plan who couldn't join the union were the source of agitation for the scheme to be expanded to cover everyone. These bottom-up pressures would usher in a new chapter in the history of the health insurance scheme as the KNCU Health-Plan was folded into the government administered Old CHF to become the improved CHF (iCHF) in 2015.

*8.*5.8 *The extended KNCU Health-Plan: iCHF scheme 2015-2019.*

The KNCU Health Plan came under political pressure to expand access to others in the community outside the coffee union. However, funding constraints emerged as the Coffee union had failed to set aside adequate funds to ensure the smooth takeover of the administrative costs of running the scheme from PharmAccess. What follows is an account and an explanation of how the intervention was merged with the old CHF, with government taking over the co-payment of matching funds, while the National Health Insurance Fund came in as the new administrators. PharmAccess was relegated to the role of Technical Assistance Partner.

The success of the KNCU Health-Plan created demand from outside the group, especially from those members of the community who were outside the coffee cooperative.

The complaints came to the attention of the local government councillors, who summoned the PharmAccess staff for a meeting (Tanzania is organized into 30 regions comprised of 169 districts(Evans, Holtemeyer and Kosec, 2019)).



At that meeting, the councillors asked that the KNCU Health-Plan be expanded to cover 'everyone' who could afford to pay the premiums irrespective of union membership.

> Then the regional commissioner (same question) said, I think you have to find a way to include other people who are not KNCU members to enrol." (PharmAccess Staff 2, Dar es Salaam)
>
> "The councillors also complained, and then to the regional level. Then the district medical officers were not happy because the KNCU Health-Plan was taking away people from the CHF plan, under which the doctors had their enrollment targets, thus they saw the scheme as a competition… a lot of negative…"

PharmAccess however, were constrained to provide the services to only union members, because a law existed in Tanzania which precluded any entity outside of government from selling health insurance to the public. However, this tended to limit private insurance schemes to those in the formal sector with taxable incomes deductible 'at source'. To get PharmAccess to expand the pool to the entire community would require a fundamental change in the law requiring parliamentary assent at the federal government level.

The programme director at the time went to have a meeting at the Ministry of Health, where he laid out the case for the need to have a change in the status quo. The ministry officials were impressed with what they termed the 'PharmAccess pilot' and made a counter suggestion of their own; rather than change the Health Act to extend the KNCU Health Plan, to have PharmAccess take over the running of the old CHF scheme, since PharmAccess had demonstrated competence in running the KNCU Health-Plan.

> "So he was like okay, but I think, what do you think, I think you have this much experience, of supporting the KNCU scheme and if it is as successful as what you are saying, why don't you just pilot how to improve our CHF which is failing"(PharmAccess staff 2, Dar es Salaam)

For PharmAccess this was an easy way out of the KNCU Health-Plan because despite the success of the scheme, the funds available for the continued co-payment of the matching funds by PharmAccess were running out and the union had been unable to consistently save up money to take over the administrative costs of running the scheme after PharmAccess.

> "We were more interested in working with iCHF for the new scheme "because for us it was a way out." (PharmAccess staff 1, Dar es Salaam)

Although the union had agreed to put the money in escrow deducted from the sale of coffee at the rate of 1 shilling per kilo of coffee, and an account duly created specifically for that purpose, there was no money set aside. Whether the money was allocated and misappropriated or never allocated in the first place is hard to tell. Attempts to interview leaders of the KNCU were unsuccessful as at the time of fieldwork, some union leaders had run afoul of the government and were in detention over allegations of corruption. Under the circumstances it was not prudent to pursue an inquiry in that regard.

> "For us it was a blessing in a disguise. Because we were looking for how to sustain the scheme. And we started to notice that it would be difficult for the union alone to sustain the scheme when PharmAccess goes out. So, we took the challenge as an opportunity." (PharmAccess staff 2, Dar Es Salaam)

The scheme now called iCHF started in Siha where there was a district medical officer (a medical officer with oversight of all the facilities at the district level) favourable to the plan for merging the KNCU Health-Plan and the old CHF into one scheme.

> We expanded to three regions initially because the government asked us to…So we took it to Manyara because there was a feeling that there was more interest on the side of the National Health Insurance Fund and the Regional Medical Officer in Manyara than in Arusha. Sometimes you make these decisions where you think you can be more successful." (PharmAccess Staff 1, Dar es Salaam)
>
> "KNCU was running. When PharmAccess staff 2 came, to introduce it, I listened. I saw the potentials in merging the two plans. There was some element of competition between the two plans, [and] we can't be fighting for the same targets (enrollees)."
>
> (District Medical Officer, Bagamoyo)

Despite of the fact that the iCHF was a government funded programme, it took a lot of lobbying to convince the councillors to give up their power to run the old CHF as contained in the bye laws running councils in Tanzania.

> "At that time CHF were receiving subsidy from the government. We called it improved CHF. We had to lobby because the money which was coming to CHF was owned by the district." (PharmAccess staff 2, Dar es Salaam)

PharmAccess built a lobbying coalition with the regional NHIF office in Manyara and enlisted the support of the District Medical Officers who were favourably disposed to the proposed changes. The reason for the reluctance is simply that the funds collected by the councils were often used to drive other council activities especially administrative and overhead costs.

> So asking them to introduce improved CHF where the money now would be collected from the district but will not go to the district accounts, but to the regional accounts managed by the NHIF. This was a big challenge because it meant less income for the district. But thanks to the NHIF people we were able to convince them to agree to do a pilot for three months. In October to December 2015." (PharmAccess staff 2, Dar es Salaam).

Premiums were collected by the councils or in some cases, the hospitals. Funds collected by the council were reimbursed in the form of medicines and supplies, based on the amount of money collected at the facility or catchment area. The new iCHF proposed to collect the premiums at the household using mobile money transfers to the regional NHIF account.

What started as a 'pilot' eventually lasted for three years and achieved a 24% enrolment before being further absorbed into the state bureaucracy. This time, the winds of change were blowing from the campaign promises of the presidential candidate who had promised universal healthcare in Tanzania during the presidential elections. It is on that wind of change that opens the next chapter in the history of the national iCHF programme.

Exemptions:

The iCHF scheme would inherit all the exemptions that had hobbled the Old CHF scheme without any recalculation of the premium to reflect this change in the user population. Now under the administration of the government through the NHIF, the existing premiums had to be stretched to cover non-paying patients who sometimes constituted over 30% of the patients seen in one day at one facility the author visited who were generous enough to share their data as shown below (about 50 exemptions per day).

Fee status	Number of patients
National Health Insurance Fund (NHIF)	40-50
Improved Community Health Fund (iCHF)	5-15
Fee paying (out of pocket)	~50
Exemptions	~50
Estimated total	150

Table 8.3 Patient Distribution at District Hospital in Tanzania

A breakdown of the exemptions for the month of August 2019 at the same facility was as follows; children under five were 817(male 430, female 387), adults over 60 years were 201 (male 82, female 119), normal deliveries of pregnancy 71, deliveries of pregnancy through caesarean section 11, special programme treatments (tuberculosis, HIV-AIDS) 55, mental health cases 19, and disabled 5. A total of 1179 exemptions out of a total 2, 663 patients seen at the facility in one calendar month.

Category	Clinical group	Number of patients
Children under 5 years	Male	430
	Female	387
Adults over 60 years	Male	82
	Female	119
Delivery of pregnancy	Normal	71
	Caesarean section	11
Special treatment programmes	Tuberculosis, HIV-AIDS	55
Mental health cases		19
Disabilities		5
Total Exempted		1 179
Total patients seen		2 663

"Then five years ago, there was a big activity, 'why are things moving so slow in Africa?' they started a big campaign to copy some Asian countries called big results now…"

"SafeCare was picked up, but according to the world bank, the criteria that SafeCare set were much too high for the biggest partners…so they came up with the star rating under BRN in 2014. What is level 1 in SafeCare became level 5 in BRN. So, they reduced the criteria. 95% of clinics would not even reach level 1 in SafeCare. So SafeCare was a bit out because we were overhauled by this whole thing. "(PharmAccess Staff 1, Dar Es Salaam).

*8.*5.9 *The NiCHF: 2019 and beyond.*

The presidency of John Magufuli was ushered in by the general elections of 2017. During his campaigns, his party had promised to among a host of other things to extend healthcare services to every Tanzanian through a new universal health service scheme.

In the new structure, administration of the scheme would be done by the Regional Administrator's office led by a regional secretary appointed by the President. The NHIF would relinquish its role as administrator and be relegated to providing technical assistance. Quality assurance would be managed by the Ministry of Health through the Quality Improvement Unit, in tandem with the regional and district medical officers. The entire administrative structure would report to the President's Office for Regional and Local Government (PRORALG).

Politicization of health extension:

Th promise of Universal Healthcare has been a key part of the majority ruling party who have held power since independence in 1962. This featured prominently in the campaign of President John Magufuli who campaigned on the platform of the Chama Chama Mapinduzi (CCM) political party. The drive for a universal health insurance system in Tanzania has a strong political influence from the winning campaign which ushered in President John Magufuli. As part of his electoral promises, he promised to deliver health for all in Tanzania.

> The ministry of Health has a unit headed by a director; QA unit. They have the responsibility of assessing and ranking facilities; they also prepare quality improvement plan. The DMO and RMO have the responsibility for executing these plans. The incharge of facility have to set up their quality improvement team. The DMO does a follow-up to ensure the plan is followed. We at Regional level cannot go to see every facility" (Regional Medical Officer, Bagamoyo)

The scheme was largely unclear even to the facilities participating. An enrollment officer in another community had also mentioned this gap in communication around the reimbursements and the negative impact it was having on the quality of service and subsequent enrollments.

> "Three months and no service is being given because there is no contact between FBO and the regional office. These people are now complaining and making it difficult to enrol people going forward in the community." (Community health volunteer, kibosh)

> "But the other people doing pilots said no, capitation has challenges, we should pay on fee per visit, others said no no no, we should pay per fee for service, then at the

end some others came with something else which is say let's use adjusted capitation…"

"But at the end what is used is fee for service, but there is a 10 or 20% which is paid depending on the catchment population…I think 10% or something."

"It has also backfired. Now they are complaining everywhere…about this payment method which they are using."

"Large part of the catchment fee goes to public because when we do the catchment we don't normally include the private, and then all these people will go to get service at private…so it means that the public who didn't provide service will get paid 10% for free and the one providing the big services will get only part of 90%. So due to that not many private facilities are joining the NiCHF."

" One of the big challenges we have is that they took it to the regional commissioner's office, where no one has a background of insurance or health financing or social security, so everyone is like learning something new and then they have to go and train people at the district." (PharmAccess staff 2, Dar Es Salaaam)

PART C

*8.*6 *Analysis.*

The intervention into bridging health financing in Tanzania's healthcare system has undergone four transformations. From a private firm, to a cooperative, to a local government arrangement, to a central government scheme. Over the four phases in our analysis above, the role of organizational architect has changed hands three times. Beginning with the Heineken clinics offering HIV testing and treatment to its employees, the firm takes on the lead firm role of bridging the institutional gap for funding in healthcare in Tanzania. The next phase sees that role taken up by the NGO PharmAccess which was set up to from the quality assurance role played by Dr Joep Lange for AIDS treatment centres supported by Heineken and other multinationals, to bridge the

institutional gap for access to medicines in Africa. In this phase, the KNCU Health Plan is a beautiful pilot project to replicate the quality assurance in the Heineken clinics within the community. Innovatively, the NGO brings in a governance mechanism in between out of pocket and a full-fledged health insurance firm; the cooperative. The KNCU as an organizational device reduces the cost of governing the value chain of access to health and explains why the Health plan became popular very quickly.

Beginning with the KNCU health plan, certain critical dimensions of a successful institutional intermediation for access to medicines begin to be apparent. The discussion uses the same set of operational dimensions across all four transformations for analysis, before translating them into common pool resource governance theory by Elinor Ostrom.

1. Enrollment: the first is the use of coffee board members as reputable members of the KNCU and society, as champions for educating members on the benefits of health insurance and to drive the campaign for enrollment.
2. Quality Assurance: the second is the SafeCare methodology for benchmarking health care services, which when matched with easy access to low interest MicroCredit, made quality control activities a self-reinforcing investment at the facility level.
3. Capitation versus Fee: the use of a capitation model of reimbursements served as a cost control mechanism as facilities were constrained to offer their best service bundle at the lowest price below the cap. A model largely based on fees would have led to spiralling costs.
4. Actuarial Services: the cost control mechanism of capitation could only have worked if the price points set were done by professional actuarial services to determine objectively what it would cost at a given level of resources to provide the bundle of services in the Health Plan.
5. Family enrollment: registering enrollees at the family unit level instead of individually helped to cushion the problem of adverse selection by ensuring that enough healthy members were enrolled per sick person.
6. Waiting period: the one-month waiting period reinforced the scheme from abuse by free-riders who would wait until the last minute to sign up and get expensive referrals on the cheap only to discontinue afterwards.
7. The Cooperative: as a governance mechanism, the cooperative provided an organizational structure that lowered the cost of the implementation. Considering

that the members would sign up en bloc at the primary society level, and their well-developed channels of communication provided a premium group at low cost to the NGO with the resulting economies of scale to the members.

The iCHF stage saw the transfer of this administrative role to the National Health Insurance Fund (NHIF). Here we see the loss of some critical features outlined above. The first is the removal of the KNCU as the owners of the scheme and with that the loss of the organizational subsidy on operating costs like enrollment and marketing the scheme. This necessitated that a new set of enrollment officers be employed, thereby adding to the cost of the scheme via overhead.

Bringing in the government however as the owner of the scheme was a positive change for both PharmAccess and the farmers as the NGO was running out of the funds earmarked from this pilot, and the coffee union had failed to meet up with the obligations, not for the premiums, but for the administrative fees of running the Health Plan.

Another less positive change was the loss of MicroEnsure's Actuarial services. Although the NHIF had competence in actuarial calculation, this was not brough to bear in recalculating the premium for the iCHF when the Old CHF was merged with the KNCU Health Plan. Thus, the KNCU Health plan model and its premiums were adopted into the iCHF alongside the exemptions from the old CHF which were never factored into the discussions at the union level. No exemptions were allowed in the KNCU Health Plan except for free medical check-ups for enrollees above 60 years who still had to register and register as a family member, and a coffee union member. Given the high cost of exemptions brought into the iCHF from the old CHF, it would have been necessary to retain a third-party actuarial services provider like MicroEnsure to provide a new premium and membership targets for running the iCHF.

With the fourth transition into the NiCHF, all the restraints have been taken off. The SafeCare quality improvement methodology and is replaced with the BRN Star Rating system, with no mention of access to Microcredit for investments at the facility level. The NHIF as scheme administrator is replaced by the Regional Administrators Office, which does not have any actuarial services capability. The capitation model is replaced by a largely fee-based model where reimbursements are calculated mostly by utilization rates. And the exemptions continue. The government is no scheme owner, scheme administrator,

and quality assurance provider, just like it was under the old CHF. The results should be the same.

What this case and its analysis demonstrates is the reasons why beautiful pilot projects and interventions fail in developing countries. It is not because the interventions are poorly implemented, rather it is because in the process of spreading the innovation from a pilot to a nationwide system, most of the key dimensions of success at the pilot stage are lost in transit. The objective of this case has been to identify these dimensions in a way that is tractable for policy analysis and to show why interventions to improve access to medicines have varying levels of success from place to place.

There is something to be said that it is not enough to simply import the capacity for each of these dimensions into the government. Rather it is important to see observe that some of these capabilities are better off housed in third parties and free from interference. Without this, it becomes difficult to deliver the market interventions that can improve access to medicines.

The study also points out to which of these competencies the third party should import into the value chain, and which functions should be left to other parties like government. The interdependency of these tasks is also a security from abuse of the system by one or the other partner, for example, actuarial services calculation under MicroEnsure provided the closest measure of the cost of healthcare services under group insurance. Quality Assurance interventions by a third-party NGO produced the most effective improvements in health services delivery compared to first- or second-party guarantees.

It is also important to note that the coordination failures that result when governments try to fold all the competencies required to run utilities and public services under a bureaucracy do not happen because governments are inefficient, they happen because the resulting organizational architecture is inefficient. Therefore, the case is not a vote of confidence on governments or NGO's, but an analysis of how institutional intermediaries can design the most efficient governance systems for access to medicines. We expect that there will not be one particular approach that fits all contexts, rather the most efficient alignment of actors in the value chain will take into cognizance existing resource dependencies among members of the value chain for medicines, and manage the interdependencies of the various tasks required to improve access to medicines in each particular context.

It is this context by context approach that offers the reasonable way forward in planning access strategies to improve access to medicines. We may then question whether the KNCU Health Plan should have been extended all over Tanzania by merging it with the old CHF plan, or whether the KNCU Health Plan should have been replicated with other similar cooperatives in Tanzania in a piecemeal approach.

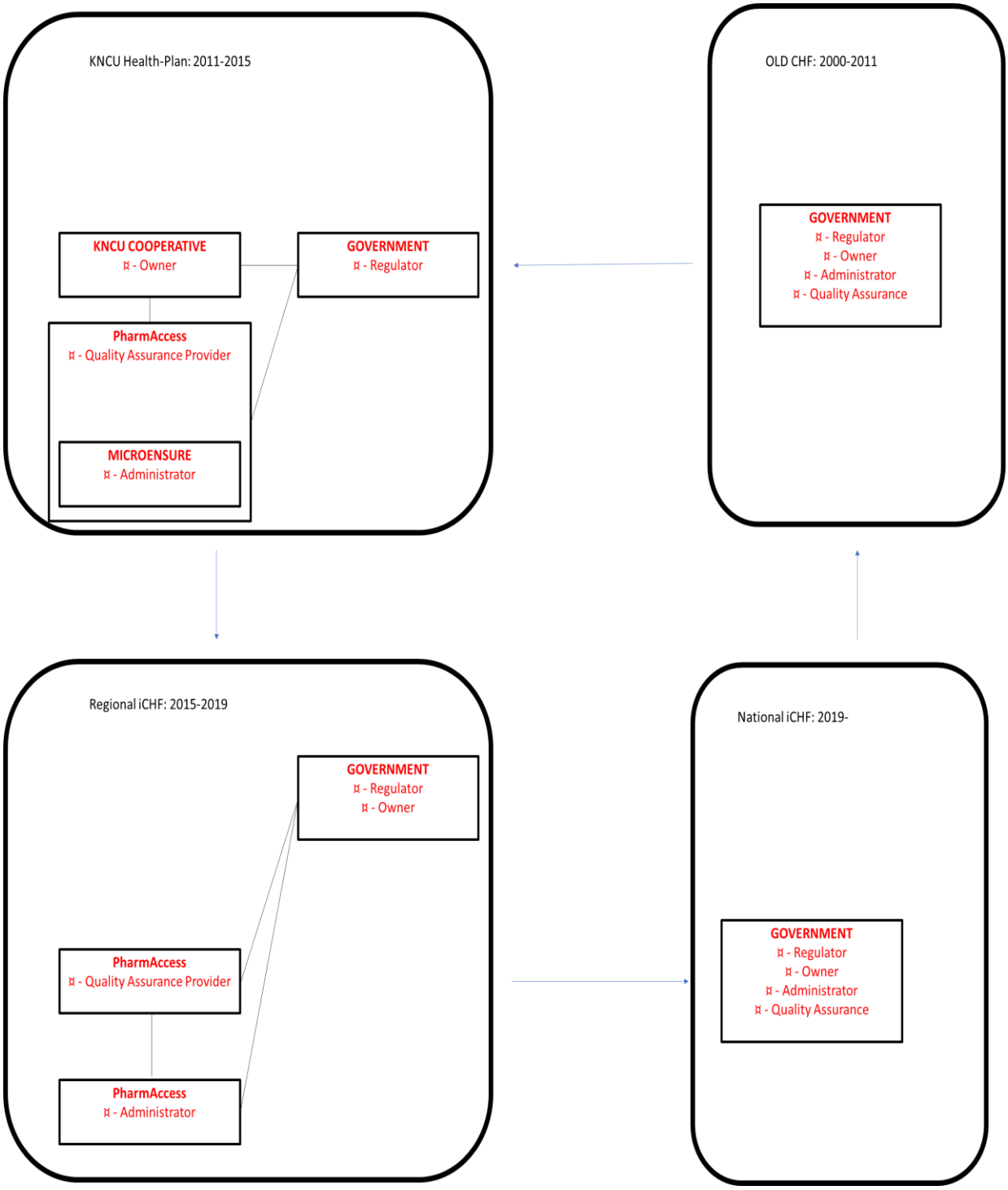


Fig 8.3 Organizational Design Changes in Health Governance: Politicization and Extension.

8.6.1 Performance Dimensions for Health Insurance Interventions.

This section derives the performance dimensions of the health insurance system as it evolved in Tanzania, and develops seven key areas, which are critical for successful institutional intermediation to bridge access to health financing in noncore markets.

1. Enrollment: this dimension looks at the effectiveness of the enrollment system into the health insurance scheme. In the Heineken clinics, the enrollment was by the staff register. The old CHF enrollment was mostly at the facility, and the KNCU Health-Plan enrollment was done using the coffee board members and local community volunteers drawn from the union. The iCHF replaced the coffee board members with enrollment officers appointed by the local government. This system of government recruited enrollment officers has been extended on the NiCHF. Whereas the KNCU Health Plan relied on the board members' legitimacy and positions of good standing within the community to drive enrollment of their fellow coffee farmers into the scheme, no other enrollment system (old CHF, iCHF, NiCHF) has managed to leverage the local institutional arrangements in Tanzania to drive an effective enrollment campaign into health insurance schemes at the community level through voluntary persuasion and cooperation.
2. Facilities: this dimension examines the level of institutional capacity within the health care facilities to provide and upgrade healthcare services. Under the Heineken access to medicines programme, investments were made under the personal drive and leadership of Joep Lange to improve the quality of Highly Active Antiretroviral Treatment for the staff members and their families living with HIV-AIDS. This investment in quality at the facility level financed by Heineken is largely absent in the old CHF scheme run by the local governments and re-emerges strongly under the KNCU Health-Plan part-funded by PharmAccess. PharmAccess created a veritable channel for health facilities to access microcredit facilities at very low interest rates for investing in facility upgrading. The author visited and saw research labs equipped with machines bought with these funds to improve service delivery at the facilities under the KNCU Health-Plan and the iCHF scheme. However, under the NiCHF plan, there is no clear roadmap as yet to provide this level of access to capital markets for facilities to invest and upgrade the level of their services and attract the level of enrollment into the facilities, without

which they will be unable to sustain provision of these services and become locked into a vicious cycle of underinvestment and poor quality leading to low uptake of health insurance plans.

3. Actuarial services: this dimension examines a critical dimension of performance in health insurance. The professional calculation of health insurance premiums. Under the Heineken plan, there was no actuarial calculations done, as the interventions was done largely under subsidy from the firm as part of its personal commitment to the health of its workers. However, under the old CHF, we observe a politicized actuarial function to set premiums at the lowest possible level. In this regard, premiums were set by the politicians in the local government councils to reflect the lowest purchasing ability in the community. Under the KNCU Health-Plan, efforts were made to set premiums according to economic principles by engaging the services of an actuarial services provider, MicroEnsure, under a negotiated framework with the KNCU as consumers, the facilities as suppliers, and PharmAccess as scheme administrator. This allowed PharmAccess to play the role of neutral broker. Premiums were set according to what level of health services could be provided, given the numerical strength of the KNCU, the cost of service, and the overhead costs of administering the scheme.

   The iCHF scheme saw MicroEnsure relinquish this Actuarial services role to the National Health Insurance Fund (NHIF). It is interesting to note that the NHIF did not make any adjustments to the premium calculated by MicroEnsure with the coffee union in Moshi before going on to extend the scheme to both coffee and non-coffee farmers.

   The NiCHF programme has not yet set any premiums, rather is using a utilization rate system reimbursement, based on expense claims coming from the facilities.

4. Quality Assurance: having established a benchmark for the quality of health services to be delivered by facilities, a critical performance dimension for health insurance schemes is the quality assurance of the health services. Under the Heineken plan, quality assurance was guaranteed by the firm. The old CHF insurance scheme did not have a robust quality assurance system to ensure the quality of health services and protect users from exploitation, and the facilities from freeriding. The high incidence of stockouts of essential medicines, and adverse selection of sick and indigent patients led to the collapse of quality assurance dimension of the system. Under the KNCU Health-Plan, SafeCare was

implemented as a quality assurance methodology to provide a framework for facilities to benchmark the quality of their health care service delivery, and make improvements. This internationally accredited methodology was substituted for a local framework under the NiCHF scheme, despite misgivings from the facilities who preferred the SafeCare approach, citing a lack of programmatic support and the absence of access to microcredit for upgrading the service delivery.

5. Health Outcomes (Preventive vs Curative); The Heineken plan for staff members living with HIV-AIDS, was primarily a 'curative' oriented system based on access to the right medicines at the right does and at the right time. The old CHF plan adopted this curative orientation. Under the weight of large numbers of exemptions, the scheme was always stretched beyond its capacity. Added to this were the lack of limits to adverse selection of enrollees, leading to sick enrollment and heavy losses to the scheme. The KNCU Health-Plan originally took a preventive approach in conjunction with Envirocare to teach farmers how to safely use pesticides and limit their exposure to carcinogenic constituents. This preventive ethos also translated into free health care check-ups for members of the KNCU Health-Plan who were above 60 years of age. However, the iCHF lost the preventive emphasis of the KNCU Health-Plan to focus solely on the curative clinical model of primary healthcare. Following the resetting of the boundaries of the KNCU Health-Plan to include non-coffee farmers in the iCHF plan. In a sense, the KNCU Health-Plan represents the optimum combination of preventive and curative medicine on the production possibility curve of healthcare services. While the iCHF and NiCHF schemes are at the extreme point of the abscissa representing a wholly curative focus and model of healthcare.
6. Organizational Design (centralization vs localization): this performance dimension pays attention to the cost of designing an efficient organizational structure to carry the weight of the entire interventions for bridging access to medicines. The organizational design of the health interventions into the healthcare system has undergone changes oscillating from localized and decentralized network of clinics operated by Heineken in Africa, to a localized but centralized Federal Government insurance scheme (old CHF). The KNCU Health-Plan was a revert to the localized and autonomous health system operated by PharmAccess for the coffee cooperative. That autonomous arrangement has been subsumed under a regional and centralized iCHF programme that has been extended into a centralized national

programme of universal healthcare. These vacillations and transformations have had serious impact on the cost and effectiveness of the system. Whereas the coffee farmers union lends itself as an institutional platform for communication, negotiation and conflict resolution. This organizational device that has reduced the transaction costs between the farmers, and the facilities under the KNCU Health-Plan is sorely lacking in the iCHF and NiCHF schemes subsequently. The organizational legitimacy of the KNCU also provided a major institutional subsidy for the acceptance of the scheme among the famers, without which a huge marketing budget would have been necessary.

7. Reimbursement: a critical supply side performance dimension is the reimbursement of health care facilities for services rendered to members of the health insurance scheme. Not only the equity of the payments are important, but also the timeliness of the payments matter in settings where capital is scarce and health care is delivered on a shoestring budget. Two systems of reimbursement have been tried over the 4 phases of healthcare by insurance in Tanzania. The use of capitation as a system of reimbursement to facilities was developed under the KNCU Health-Plan, whereas payment by services rendered was adopted under the NiCHF scheme (90% utilization and 10% capitation). The use of capitation for reimbursement of facilities under the KNCU Health-Plan helped to control cost inflation and over medicalization at the facility level especially. However, the calculation of the capitation was done in transparent cost calculations with the facilities to set a fair price that would allow the facilities to provide the bulk of primary health services and still turn a healthy profit. This also ensured that facilities were assured of a steady stream of income even if patients were few. However, this meant restricting the choice of primary facility to one for the users so as to reduce roaming and the attendant complexity of splitting capitations between facilities as the system tries to allocate payment for services rendered to an itinerant user. In a resource constrained environment where qualified staff would add to the cost of running the reimbursement by utilization rates, the capitation system of reimbursement demonstrated a better fit with the local realities in Tanzania that reimbursement by utilization.

8.6.2 Fragmented vs Universal Healthcare.

The KNCU Health-Plan however presents a veritable template by PharmAccess for 'bridging' institutional voids that truncate access to medicines. By employing the KNCU as an institutional infrastructure to support the embedding of a local aspect of the Global Value Chain responsible for access to medicines. Whereas the old CHF model of universal healthcare was a Global Value Chain, the KNCU Health-Plan was a circumscribed fragment of this system using elements from the local institutional infrastructure to support elements from the global institutional infrastructure. The KNCU itself is a local institutional infrastructure which subsidized the creation of the Health Plan, while the medicines imported and used under the scheme and the actuarial science used to calculate the premiums represent elements of the global used to perform a localized version of the Global Value Chain for medicines. The resulting system is called a Fragmented Value Chain. The NGO acts as a coordinator of this bricolage between local and global institutional elements. This Fragmented Value Chain was a more successful system than its Globalized predecessor.

We say successful because given it is a scalable model that can be replicated with minimum disruption to the social milieu of Tanzania. Despite the challenges of ensuring steady co-payment from the union (which can be worked around), the legitimacy of Cooperative movement in Tanzania and the strong organization of economic livelihood around these organizations makes them prime for the institutional fit between intervention and context in attempts to bridge access to medicines over institutional voids.

Given that Tanzania has well over 3000 cooperatives like the KNCU (Maghimbi, 2010), with a membership strength of 9,000,000 people, we can project that at a minimum family size of 6 people, this represents a reach of 36,000,000 Tanzanians (total population is about 56 million). Given the enormous institutional capacity within the cooperative for bridging institutional voids, it is hereby suggested that improving access to medicines through health insurance negotiated through the cooperatives is a far more sustainable approach than the present NiCHF plan.

The collective choice arena of the cooperative, provides at low cost, a platform for negotiations between the users and health services providers to negotiate willingness to pay (and willingness to provide) according to local realities. A uniformly imposed government mandate for universal healthcare destroys the polycentricity required for sustainability in a country as complex as Tanzania. In this underlying institutional fragmentation, we question the rational for extending universal healthcare nationwide, instead of replicating successful interventions along the grain of local institutions.

Policy makers may argue that these institutional differences are complex and uneven, and therefore inconvenient. Health professionals would also argue that an eclectic approach (for replicating successful interventions like the KNCU Health-Plan) may leave out large segments of society who are not part of a cooperative. But it may be that a patchwork system of Fragmented Value Chains covering two-thirds of the country will outperform a centralized nationwide system of universal health devoid of localization. This is the lesson which is clear from the old CHF plan but appears to have been forgotten after the success of the KNCU Health-Plan and have been largely under-emphasized in both the iCHF and NiCHF schemes.

A very important aside is necessary here.

During the KNCU Health-Plan, a rival cooperative of coffee farmers with a membership strength of about 300,000 members had expressed interest in joining the KNCU Health-Plan. However, the KNCU refused and effectively shut them out. Eventually the pressure to expand the KNCU Health-Plan to cover other members of society outside the KNCU led to the creation of the iCHF scheme. It is on record that the G42 were among the earliest adopters and also paid the highest subsidies for their members (20,000 Tsh in Year 1 and 15,000 Tsh in year 2) of the 30,000 Tsh for signing up to the scheme. With a membership strength of 42 primary societies with an average membership strength of 800 farmers, a parallel Health Plan for G42 would have a reach of 200,000 enrollees assuming an average family size of 6. This would have been a more sustainable approach and represents the road not taken which would have led to a more effective intervention to improve access to medicines than the iCHF scheme. It would have also allowed the G42 to negotiate a more robust package of health care benefits from the providers to serve as a further incentive for other independent coffee farmers to join them instead of the KNCU. This healthy

competition for enrollment would have checkmated any sloppiness in either cooperative with regards to collecting or saving administrative fees for the continued running of the health plan when the PharmAccess grant would eventually run out.

From the diagram below, most of Tanzania is covered with agricultural producing zones and their primary societies which can serve as a polycentric model for spreading access to health care services by replicating the KNCU Health-Plan through other agricultural cooperatives, rather than by extension.

Another important reason why a polycentric approach to health insurance is required is the realization that health needs and priorities are not the same everywhere. Also, health behaviours, and institutional capabilities vary from core to noncore. That is, institutional voids for health care in the capital city of dar es salaam do not occur to the same extent as they do in the remote tablelands of the Maasai Mara inhabited by the Maasai who still follow their traditional ways of life. Therefore, it would require an unwillingness to recognize and align with local institutional realities, to implement a national health insurance programme by extension of a universal model nationwide, rather than by replication according to local institutional arrangements across core and noncore contexts.

Implicit in this replication approach to the spread of health insurance is a recognition that the economic zones of core and noncore also applies within the nation state and the ‘global’.

8.7 Discussion.

The KNCU Health-Plan was an innovative intervention to bridge access to medicines which was contiguous with the boundaries of the union. When the clamour for inclusion rose in society, the option followed was to extend by integrating the Fragmented Value Chain into the Global Value Chain of the Old Community Health Fund beyond the boundary of the cooperative. Another option would have been to replicate the intervention by reproducing a health plan to match the institutional boundaries of a similar cooperative e.g. the Cotton grower's cooperative. The spread of the intervention by replication would be working within the grain of the existing institutional arrangements to matching resource boundaries (Health Plan) with institutional boundaries (cooperative union membership). Those outside the unions in the employed in salaried occupations can access medicines through the NHIF scheme for the civil service in Tanzania. This would eventually leave only petty traders, and itinerant job-men, the unemployed or unemployable, and those who chose to be anonymous without cover. It is for this group that a government funded scheme can be made 'universal' which is means tested. This approach would in principle reduce the administrative costs of the present NiCHF by at least 70% with less bureaucracy.

The implications of institutional alignment on the success of interventions in Africa are huge. First this case allows us to understand the critical performance dimension of all interventions; the degree of fit between the boundaries of the resource, and the boundaries of the already existing institutional arrangements. It also explains the seemingly intractable failure of development interventions in post-colonial states created by divide and rule, and their hasty integration into Global Value Chains. This failure is seen primarily in the inability of African countries to govern Global Value Chains effectively because the boundaries of the Global are non-aligned with the boundaries of Local institutions.

Applying this understanding of globalization in western medicine from core to noncore economies exposes a need to redesign along the boundaries of indigenous institutions if they are to work within the grain. Otherwise, they will continue to require increasing centralization of power and control in ever larger bureaucracies to destroy and reshape indigenous realities to fit a 'universal healthcare model'. This is unsustainable. Local does not simply mean the old per se, or native for that matter, but a proper institutional grounding in existing institutional arrangements.

The success of the KNCU Health-Plan shows that this it is possible to achieve access to medicines through this localized governance of Fragmented Value Chains, without resorting to expensive global governance in Global Value Chains.

*8.*7.1 *Localization Versus Globalization.*

This dimension arises from the problem of how to integrate interventions for healthcare Global Value Chains. Localizing the intervention requires that lead firms recognize the institutional differences in the environment of noncore economic zones. upon recognition, the scope and integration of the value chain must be aligned with these institutional differences. And the cooperative is arguably an organizational device for governance that fulfils that purpose of localization for the Global Value Chain of health in noncore economic zones.

> "The total number of members of registered primary cooperatives in June 2008 was 1,600,000. Most cooperative members are adult males. The average household size in Tanzania according to the 2002 Population and Housing Census was 4.9 and we can gauge that approximately 7,840,000 people in Tanzania mainland are directly dependent on the cooperative movement." (Maghimbi, 2010).

The above figures demonstrate the opportunity to localize access to medicines through other cooperatives to create their own health plans.

The next by thing by way of conclusion would be to tease out the characteristics with which to identify cooperatives that qualify for use as institutional bridges over the institutional voids that truncate global value chains for healthcare. We had already touched on these during the literature review at the beginning of the case, however it is worth

repeating that the KNCU cooperative for all its wonderful internal democracy is a relatively underdeveloped institution compared to the farmer cooperatives in Europe who have moved beyond the direct democratic model of the village square into the highly sophisticated organizations with a distinct managerial group in charge of administration who are hired and not elected. It is this organizational deficit in managerial capacity that dogged the KNCU Health-Plan in the inability of the Union to retain the coffee tariff exclusively for health care, rather than use if for paying the school fees of indigent members children, an equally noble goal.

It is better to spare developing countries the pain of learning the hard way in their rush to imitate the 'modernism' of core countries by extending healthcare through globalization using the nation-state or region rather than localizing the health intervention among communities.

8.7.2 Centralization Versus Decentralization.

The case also demonstrates the important distinction between centralization and decentralization. More importantly it allows the reader to appreciate what it means to have centralization without globalization, or centralization with localization (Old CHF). Decentralization with globalization is represented by the Heineken clinics. These decentralized clinics designed according to global institutional capabilities imported and subsidized by the multinational represent one way of addressing institutional voids in noncore environments; filling them. The KNCH Health-Plan represents a fully decentralized and localized approach to addressing institutional voids using local institutional capabilities to bridge these voids. The centralized systems of healthcare (Old CHF, iCHF, NiCHF) depend on the apparatus of the state for implementation. In noncore environments where the state institutions are weak, fragile or absent, this presents a crisis of sustainability. Often the scheme depends on heavy state subventions to continue. Inability of the state to raise finances from taxation due to absence of a high wage income population frustrates universal health systems that depend on global models of health insurance that require high wage incomes in the formal economy.

The Old CHF scheme presents a curious mix of centralization and localization. The scheme though nationwide in scope, was localized enough to allow local councils to set

their premiums according to the local socioeconomic and socio-political conditions. The scheme eventually collapsed under the weight of its centralized system.

8.7.3 Replication Versus Extension.

We adopt a theoretical explanation for discussing whether it was an organizationally sound move to extend the KNCU Health-Plan or not, and what the alternative should have been.

> "Why can't a large firm do everything that a collection small supplier can do and more? Were it that large firms could *replicate* 2l collection of small firms in all circumstances where small firms do well, then large firms would never do worse. If, moreover, large firms could always *selectively intervene* by imposing (hierarchical) order on prospective conflict, but only where expected net gains could be projected, then large firms would sometimes do better. Taken together, the combination of replication with selective intervention would permit large firms to grow without limit. Accordingly, the issue of limits to firm size turns to an examination of the mechanisms for implementing replication and selective intervention" (Williamson, 2002 pg 177. Emphasis in the original).

Replication would be a collection of micro-health insurance (MHI) schemes, as a 'collection of small firms', while extension would be to allow the micro health insurance scheme to morph into one gigantic bureaucracy of universal health coverage (UHC). The case answers this question.

The case process-traces the changes in transaction costs for healthcare of transformations from firm hierarchy (universal health insurance) to free market for health care services (out of pocket).

The case demonstrates the inability of centralized systems and why it fails to catch on under institutional voids. The case shows that under replicating autonomous or decentralized health systems is a more cost-effective approach to improving access to medicines in the noncore environment where the state is not robust enough to underwrite the cost of extending the local system into a national system through globalization. The localization of the cooperative allows it to set premiums at a cost close to the willingness and capability of the community. The decentralized nature of the KNCU Health-Plan gives the system sufficient autonomy to self-govern according to robust principles of common

pool resource governance. Globalization destroys the performance dimensions of Common Pool Resource governance. During extension, certain performance dimensions are lost in translation. For example, it is impossible to guarantee that resource appropriators are able to self-monitor each other's actions when the system is beyond the borders of the local community. When the health system is globalized beyond the community, appropriators cannot still maintain knowledge of the resource required to devise local rules for appropriation. Invariably these rules will not be scalable across different communities.

Preventive healthcare requires an inherently local approach. This local approach worked well in the KNCU Health-Plan by catering to the need for health and safety in the use of agricultural chemicals among the coffee farmers in Tanzania and was subsequently lost in translation upon extension nationwide.

Chapter 9: Discussion Chapter.

This chapter brings together the key insights from the four case studies, and the methodology chapter on Global Value Chains. It begins by re-examining the original Global Value Chains framework of Gereffi, Humphrey and Sturgeon (2005) in the light of the new discoveries, with a view to make improvements to the theorization and operationalization of Global Value Chains in health.

In summary what is new is the three new types of value chains that emerge when the PhD takes a consumer-led view of the supply chain for medicines, rather than the producer view in Gereffi, Humphrey and Sturgeon (2005). Secondly the new cases illustrate three new value chains where the lead firm in the value chain arises from within the social world of the consumer; Distributed, Fragmented and Open Value Chains.

These new value chains refocus attention on alternative modes of governance in value chains and responds to the firm centric model of governance developed by Gereffi, Humphrey and Sturgeon (2005). What is especially new is the governance of value chains in health as Common Pool Resources. This governance mode presents through the KNCU case, the most sustainable approach to the governance of value chains in health under institutional voids.

These alternate modes of governance also enable a re-articulation of community health and its tendentious relationship with public health through an analysis of performance dimensions between local and global layers of governance. The discussion also opens up the space to interrogate the processes by which these performance dimensions of governance get lost in translation during reproduction.

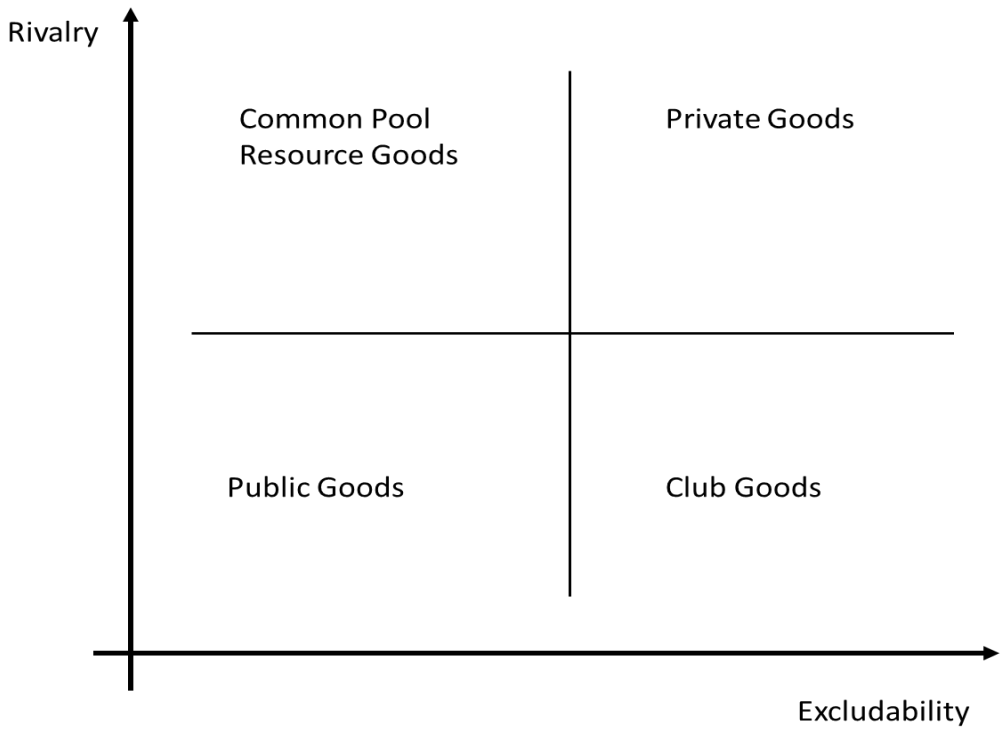
This chapter proposes the first outlines of a policy on how collective action for common pool resource governance can be used by local groups to organize and govern community health systems. The chapter then concludes with a repositioning of the relationship between community health and global health using the idea of polycentricity to show how public health systems can coexist with and support community health systems in the field without getting in each other's way.

Elinor Ostrom, the American Sociologist, and winner of the 2015 Nobel prize for Economics proposed a third approach to governance. She entered along with her husband and colleague Vincent Ostrom into an academic debate with Garret Hardin on the governance of the commons. The seminal article by Hardin in 1968 made the case that the commons could only be sustainably managed either through the market or the state. His paper casted the work of policy makers as a hard choice between two alternatives; the hierarchy of the firm or the bureaucracy of the state. Ostrom disagreed. And over a career spanning more than 50 years Ostrom would go on to demonstrate using case studies of sustainably managed Common Pool Resources which were neither managed by the state nor by the firm. She would in her book Governing the Commons, lay down a set of performance dimensions or principles which made for effective Common Pool Resources governance.

Ostrom's work on Common Pool Resources governance is relevant on Global Value Chains especially for those Global Value Chains that touch down under institutional voids. There is the opportunity for policy makers in health to widen the methodological toolbox for governing Global Value Chains in those parts of the world where neither the state nor the firm is able to do so. In fact, there is evidence from the case studies developed on this PhD to show that the Common Pool Resources governance approach delivers access to medicines better that either the firm or the state, especially for generic medicines and essential health services.

To bring Ostrom into Global Value Chains theory we first construe the Global Value Chain as an action arena. Ostrom originally created the "action arena" metaphor to characterize social dilemmas of high rivalry with low excludability (Ostrom, 1990). In her words, "The term action arena refers to the social space where individuals interact, exchange goods and services, solve problems, dominate one another, or fight (among the many things that individuals do in action arenas)" (Ostrom, 1990). If the Global Value Chain is an action arena where firms interact with suppliers (and consumers), exchange goods and services, solve problems, dominate one another, or fight, (among the many things that firms do in international business), then the Global Value Chain is an action arena. Ostrom also derived that governance must fit the action arena and may itself be the product of another action arena. That is to say, that, the governance rules set up for Common Pool Resources

will differ from those set up to govern the production, distribution, and consumption of Public Goods. So that where the logic of the firm is employed over the Private Goods action arena, the logic of the State drives the action arena of Public Goods. For goods produced under collective action, she identifies two action arenas and two types of governance for Common Pool Resources and Club Goods. She also acknowledges the nested nature of these action arenas, wherein Public Goods created in one action arena can feed into a different action arena or the creation of a different class of goods. In her own words, "…the variables that are treated as exogenous when examining an action arena (but may themselves be an outcome of another action arena) …(Ostrom, 1990)". Using a two-by-two matrix for clarity, Ostrom demonstrates the different goods, before going on to analyze the governance principles that structure the action arena of Common Pool Resources.



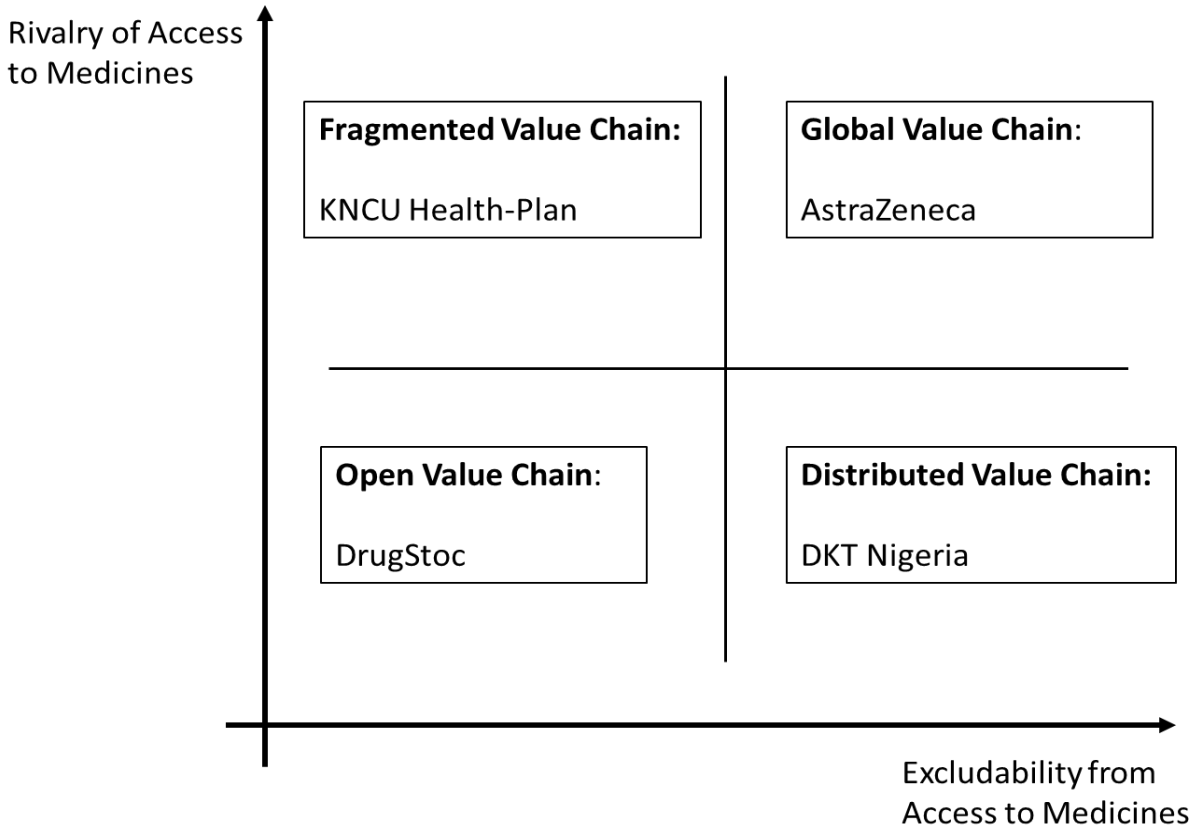
Adapted from Ostrom (1990) Governing the Commons.

9.1 Four Categories of Access to Medicines.

From classical economic theory, there are four types of goods possible. Private Goods, Clubs Goods, Public Goods and Common Pool Resources. These goods are classed according to varying levels of rivalry and excludability. Rivalry refers to the zero-sum game of rivalry for these goods. Goods with high rivalry are subject to diminishing returns with each added user who appropriates from the stock of goods available. As such, there is a high degree of rivalry over these types of goods compared to goods which are not diminished by an added user, or an extra unit appropriated. The ceaseless accumulation of capital suffers from high rivalry and as such lead firms in Global Value Chains employ governance mechanism which collectively titrate a certain level of excludability into the value chain to exclude suppliers (and consumers). Where the lead firm is the state e.g. a public utility providing public goods, the subsidized production of the goods ensures low rivalry or rivalry to match the low excludability of public services. At the polar extreme, Private Goods with high rivalry are matched with tight governance to ensure high excludability. This is the classical Global Value Chain on which the Gereffi, Humphrey and Sturgeon (2005) framework is modelled on. But just as Ostrom found out that there are alternative to the State and the Firm in the production of economic goods, so also the PhD takes a step forward to identify the two other classes of value chains that are not only theoretically possible but have been found to exist in health and have major implications for health policy[14].

The four cases on the PhD map well unto the four classes of economic goods.

[14] In this classification, the state-owned enterprise producing a public good is classed as a 'lead firm' in the public sector; that is the sector with low excludability.



The KNCU Health-Plan being limited in the health resources available to it as negotiated under the capitation payment system of reimbursement suffered from high rivalry in use. However, it also displayed the features of low excludability as anyone who had half a plot could easily plant them with coffee seeds and claim membership of the KNCU and its health plan. Among the Chagga people in Kilimanjaro, land is inherited and kept within the family and as such most of the community has access to the landed requirement for membership (Munger, 1952).

The KNCU Health Plan demonstrates the high rivalry and low excludability of the Common Pool Resource. When it was merged with the old Community Health Fund programme and absorbed the many non-premium paying exemptions including pregnant women, people living with HIV-AIDS, the scheme began to suffer as the hospitals could no longer deliver a quality service due to the dwindling stock of capital available to run the scheme at the same premium that was calculated. Thus, the improved Community Health Fund did not result in any improvement in the delivery of health services, rather it resulted in the deterioration of the services to the point where the coffee farmers wanted no part in the scheme any longer. This combination of high rivalry with low excludability is what defines the Common Pool Resource. The KNCU Health Plan which was developed in line

with the performance dimensions for the successful governance of Common Pool Resources was sustainable and worked very well.

It was not necessarily the increased number of users that destroyed the KNCU Health Plan. Rather it was the decision to preproduce the scheme by extension to other users instead of reproducing a new Health Plan under a new premium renegotiated with the hospitals delivering the health services. This extension without renegotiation violates nearly all of the major principles for successful Common Pool Resource governance which are highlighted below.

9.2 Design Principles for Collective Action in Health.

Ostrom's performance dimensions for common pool resource governance operationalize inductively the attributes for designing effective community health systems using local institutional arrangements especially where the state is fragile or absent entirely.

"By design principles is meant a characteristic that helps to account for success of these institutions in sustaining the physical works and gaining the compliance of generations of users to the rules in use". (Ostrom, 1993).

	Ostrom's Design Principles	Healthcare Performance Dimensions	KNCU Health-Plan Design
1	**Boundary Rules**: Clearly defined boundaries to delimit membership and the resource.	**Resource stock and flow:** Mapping the boundaries of the community to determine those contingent to the resource i.e. user community	KNCU membership criteria made clearly in terms of minimum plot size of coffee farm to determine the size of the health fund and its resources.
2	**Position Rules:** Rules for the provision and appropriation of resources that ensure proportional equivalence between costs and benefits.	**Roles of Provider, Consumer and Broker:** Rules for how facilities provide health services and how users appropriate healthcare services with respect to existing resources and institutional capabilities within the community.	Roles of intermediaries and their technology to fill the institutional voids Actuarial services to define reimbursement and premium levels to achieve fiscal equivalence (Olson,1969).
3	**Collective Choice Rules:** Rules that enshrine participatory decision making allowing users to shape the governance system	**Collective-action arenas:** Platforms of cooperation that democratize access to decision making spaces	The KNCU provided a platform for effective negotiation with a pool of users
4	**Information Rules:** rules for monitoring the conditions of the resource and activities of other users, and making that information accessible to all users.	**Quality Assurance:** mechanisms for monitoring quality of health care services provision and consumption, using a methodology that is actionable by both providers and users	SafeCare quality improvement and assurance methodology; a peer reviewed project management approach with ISO certification.
5	**Scope Rules:** Setting limits to actions and penalties for breaking those limits with a graded system of sanctions	**Health Outcomes Model:** Setting reimbursement models and controls against free riding such as capitation over utilization rate,	One-month waiting period before access to medicines, and family over individual registration.
6	**Conflict Resolution Mechanism:** rules for resolving conflicts between users, between users and providers, and between providers, and between providers and monitoring agents	**Organizational Design for Arbitration:** the organizational choice for an internal governance mechanism separates from the market (individualized, cooperative, or hierarchical)	the KNCU provided a platform for conflict resolution
7	**Minimum Recognition of Right to Self-Organize:** The cardinal rule of autonomy from external interference	**Autonomous and Voluntary:** Independence, Self-reliance and Freedom from interference of Community systems from National or State or Firms.	the KNCU is a chartered organization with a legal right to exist, and to set up a micro health insurance fund for its members. Private health funds are illegal in Tanzania.
8	**Polycentricity:** relationship and legitimacy with other institutions in the environment	**Institutional Alignment:** Health systems nested within a socioeconomic and socio-political system.	the KNCU is part of a larger network of civil society organizations nested within the Agric sector. others exist for similar cash crops.

Table 9.1 Ostrom's Design Principles in Health

9.2.1 Boundary Rules:

The clearly defined boundaries for enrollment by family units, by cooperative membership, and by facility, to specify the resource, and who can have access to it. Without this, the resource suffers abuse, or where the resource is a fugitive one, governance becomes more difficult. It is important to note that boundary rules are effective for local systems, and not

fugitive resources. The role of MicroEnsure, the actuarial services provider is important for specifying the size of the health fund needed to cater for the size of the community at an agreed level of services. Without this, the use of political negotiated settlements invariably leads to undercapitalization, freeriding and overuse. These political premiums are not set according to the boundaries of the community and its demography, but according to electoral priorities of politicians.

The KNCU Health-Plan is a local health community. Local because the health fund required to provide healthcare services was calculated at the level of the prevailing local health conditions and priorities. It is a social arrangement because it is bound up in the way of life of the community; the coffee farming livelihood of the Chagga people who live in the Moshi region. It is a system because it has articulating parts, the facilities as producers, the cooperative as consumers, the NGO as neutral broker and quality assurance provider.

The premium calculated on the KNCU Health-Plan therefore emerged as a best fit between the health needs of the community, their peculiar socioeconomic characteristics, and the appropriate technology (facilities) required to deliver an agreed bundle of health services.

Instead of the universal approach, the KNCU Health-Plan starts with the question. ‘What are the health needs of the community? And what level of health services are the community willing to pay for?

9.2.2 Position Rules:

These rules specify the roles of producer, consumer and neutral broker or arbitrator. Positions within local health systems are important for specifying the type of health facilities as providers. Drucker (2012) writes that the aim of any business is to make a customer. It is important to specify who the customers for a community health system will be, whether they be people living with AIDS, pregnant women, or children.

Position rules also specify who gets what and how much. It is here that design considerations should be put in place to make the rules for appropriation to fit with the local health conditions in the community.

These rules are crucial to balance resource appropriation by users with the stock and flow of the resource. Common pool resources under effective governance like fisheries often set

standards on the type of net sizes to be used and this is contingent on the community having accurate knowledge of the resource conditions and setting boundary rules just below those limits. Community health systems are not able to offer infinite health services, but in cases of health communities such as the KNCU Health-Plan, the bundle of services has to be set at a level which will keep the health facilities in business and at the lowest agreed cost to the coffee farmers.

It is under payoff rules that the strategic outcomes of healthcare systems can be set; whether they will be largely curative or preventive. The payoff for producers who signed up to provide healthcare under the KNCU Health-Plan had to be managed under collective action as a cost-plus fee arrangement between the facilities, MicroEnsure and PharmAccess. The use of capitation model over a reimbursement model based on utilization rates is also a pay-out system that satisfies the need for local health systems to have a steady stream of basic income where numbers are low. In the big city with high utilization rates, and high churn, that may exceed capacity, sustaining the revenue and keeping cost of provision within limits will require reimbursements based on usage and not on membership.

Capitation rules of reimbursement shift the focus of healthcare systems to preventive interventions in order to conserve the use of a limited health budget. A utilization system of reimbursement incentivizes curative interventions that rely on more and more people needing sick care. The longer the days of admission, the better the pay for the facilities. This creates a perverse incentive to overmedicalize the society especially when there are weak institutional controls over the facilities.

9.2.3 Collective-Choice Rules:

Prescribe the set of rule-making rules for governing the common pool resource. These rules determine where and how rules are to be made. They specify how these rules must be ratified. Community health systems are usually folded under collective choice arrangements when they operate autonomously. Decisions are made at local levels often by participative mechanisms involving village leaders. In a primary cooperative such as the KNCU, these rules have been in operation for a hundred years. The one man one vote principle has been used by the KNCU to make rules governing the coffee trade. These rules give the small farmers with a few acres as much say in local matters as the big farmer

with hundreds of acres. This collective action space for rule making provided by the Cooperative is one of the most important performance dimensions for grounding the community health intervention in local priorities and systems.

9.2.4 Information Rules:

These rules specify how information regarding the resource and its condition is shared among the users in the community at a level of knowledge that the community can use to structure their individual strategies. These rules are importantly not only about the resource, but also about the users themselves. The role of PharmAccess in providing a clear ranking system and a transparent quality improvement methodology for health facilities who signed up to the KNCU Health-Plan is an important information function for consumers about facilities and the quality of their services. Users also had access to a complaints hotline through which they could make complaints about poor services in local facilities to PharmAccess the quality guarantor. The KNCU also provided an inexpensive but effective information dissemination platform for the facilities to pass information to the users and set accurate user expectations.

9.2.5 Scope Rules:

These rules set the outer limit of the production possibility curve for resource appropriation by users. These rules set a series of graded sanctions for abuse of the resource. In order to preserve the integrity of the community health system, limits were placed over usage such as a one month waiting period between registration and access to health to prevent adverse selection. These negative rules serve as implicit sanctions borne by the user to discourage freeriding.

9.2.6 Rules for Conflict Resolution:

A key advantage of local systems is that their governance is equally local, or at least it should be. Conflict resolution mechanisms requiring the use of justiciable mechanisms located far away can be a barrier to quick resolution and even access to resource being delayed. Community health system where registration is managed in a national database located hundreds of kilometres away, or where consumers have to seek legal redress

through expensive court processes against violations of service level agreements by health providers and facilities do not bode well for the performance of community health systems.

Williamson (2002) makes an important distinction between public ordering and private ordering of outcomes. Under public ordering, conflict resolution goes to the external 'markets' of public courts for redress. This is when the public law institutions are robust and have integrity. In private ordering however, conflict resolution looks inward within the firm for arbitration. The cooperative filled the function as a platform for conflict resolution between users (coffee farmers) and providers (health facilities) of the KNCU Health Plan.

Thus, access to medicines in the KNCU Health-Plan freerides on the collective action space provided by the coffee cooperative for conflict resolution.

9.2.7 Recognition Rules:

The right of the KNCU to exist as independent entity is enshrined in the cooperative act of 1985 in Tanzania. This right allows the KNCU to exist as a unique organization that is neither public nor private and gave KNCU the right to enter into an arrangement to create a community health system with PharmAccess (private health systems outside of government are not allowed in Tanzania).

The KNCU case demonstrates the unique situation in most low- and middle-income countries where the state is unable to subsidize the production of public goods, yet the product or service retains a nonexcludable character. The institutional voids in the state's capacity introduces rivalry into the action arena as there is simply not enough to go round. Health services and especially medicines in particular describe this situation. In the core zones of the world with high wage income populations, state governments with deep organizational capacity are able to create non-rivalrous access to medicines. Both conditions must pre-exist. There must be a large enough high wage income tax base to fund the creation of a competent bureaucracy to administer access to medicines[15].

In the noncore parts of the world where neither a large pool of high wage income population nor deep organizational capacity within government exists, the KNCU Health-Plan presents a third way to organize healthcare differently without resorting to

[15] The question of which one came first is a matter for the historical institutional economics and sociologists and can well take up another PhD.

privatization which was the ruinous recommendation of the IMF-led Structural Adjustment Programme of the 1980's. In these parts of the world, people can self-organize according to local institutional arrangements such as the parish, the cooperative or the workers associations to negotiate access to medicines through Common Pool Resource governance. The institutional context of the noncore regions of the world is rich with these alternative institutional arrangements which offer a way out for policy makers who struggle between market failure and weak states.

It is important to resist the temptation to extend the arrangements for access to medicines negotiated in these groups over others who do not belong to these groups. Indeed, the very imposition of the merger between the state-led Community Health Fund and the KNCU Health-Plan goes against the grain of Common Pool Resource governance. Rather the reproduction of these health groups such as the KNCU Health-Plan on the same Common Pool Resources governance should be pursued as health strategy. The KNCU Health-Plan introduces two important concepts into health policy: subsidiarity and fiscal responsibility, which make it superior to primary health systems organized under local government.

In her book, Dark Age Ahead, Jane Jacobs writing on the issues of local government states that "subsidiarity is the principle that government works best, most responsibly and responsively when it is closes to the people it serves and the need it addresses" (Jacobs, 2007). She also notes that "fiscal accountability is the principle that institutions collecting and disbursing taxes work most responsibly when they are transparent to those providing the money" (Jacobs, 2007). The KNCU is as close to the members as possible with its one-member one vote policy which does not allow for fiduciary decision making. This subsidiarity is lost through reproduction of its governance by extension. One may argue that the local government is voted into office by the people, but this is not the same as the right and ability to vote on each and every decision made by the government. Reproduction by replication is a sure way to retain the subsidiarity of local institutional arrangements that community health programmes can free ride on. Policy makers must be humble enough to trace the success of community health programmes like the KNCU Health-Plan to their alignment with the local institutional arrangements. Following the KNCU Health-Plan as health policy for improving access to medicines should look to identify local institutional arrangements that can serve as institutional infrastructure for health. The subsidiarity of these indigenous local institutional arrangements trumps conventional local governments as its localization is grounded in indigenous practices that are shared, understood, and

operated by the people it serves. The transparency of the KNCU Health-Plan due to the actuarial science of MicroEnsure was crucial to ensure fiscal accountability in the negotiations between the coffee farmers and the hospitals. Local government agencies are not necessarily transparent. Local governments do not share knowledge of the cost of governance or the cost of the services they provide. The KNCU Health-Plan however was based on the knowledge of coffee farmers about their own health needs and priorities, and the cost of the services they needed to meet their own needs. The neutral broker role of PharmAccess was instrumental in these knowledge sharing processes by providing even a quality framework to ensure that the farmers had full information on the state of the health facilities supplying the scheme. None of this is available under local government run Old Community health Fund and attempts to create an alternative system became shrouded in politics as usual.

9.3 The KNCU Health-Plan as a Fragment of Public (National) health system.

The KNCU health plan and its health community of coffee farmers is a fragment of the national public health system. When reproduced by replication throughout the country, this model presents a number of fragmented health communities coordinated by the central government in terms of premium calculations, co-payment, and reimbursement of facilities. This fragmentation of roles between the local and the national health systems allows both public health and community health to coexist in a symbiotic relationship. Replicating these fragmented health communities is a cost-effective way to reproduce access to medicines in a noncore context. Fortunately for Tanzania, the institutional infrastructure of cooperatives already exists in a very advanced stage that institutional intermediaries can free ride upon to build sustainable health communities. Therefore, the value chains that supply health communities with generic medicines under prescription through micro health insurance systems are hereby referred to as fragmented value chains.

On the other hand, the value chain operated by DKT for the distribution of generic health technologies which can be obtained out of pocket, but which require a knowledge intermediary for the effective uptake are referred to as distributed value chains. These distributed value chains do not need to be centrally coordinated by public health systems but can be replicated to bridge gaps in health knowledge among the community wherever

the need arises. For example, the same community health workers can be deployed to improve knowledge and uptake of multivitamins in school children. The flexibility of these distributed value chains explains their quick deployment by Nigeria to successfully contain the Ebola outbreak in 2015.

While both of these value chains (Fragmented Value Chain of the KNCU and the Distributed Value Chain of DKT) performed the knowledge dimension effectively well, it is important to distinguish that the KNCU Health-Plan rode on a community, while the DKT intervention did not ride on community structures and arrangements[16]. The DKT intervention is a largely producer led intervention spearheaded by the NGO working at the behest of Pfizer to improve uptake of the new contraceptive.

The KNCU Health plan and the DKT intervention both failed at efforts to reproduce them by extension. The term 'extension' in the name community health extension workers may be a misnomer. What these cases elucidate is that 'extending' community health only opens it up to a universalization that destroys community or takes the intervention away from the supporting institutional infrastructure of community groups. Replacing the coffee board members with extension officers recruited from outside the community who depended on the commissions for their livelihood transformed the KNCU Health-Plan into a public bureaucracy which did not work and proved unaffordable for Tanzania in the long run. The national iCHF programme at the time of writing is looking very much like the old CHF scheme complete with its exemptions, lack of quality assurance, and chronic underfunding.

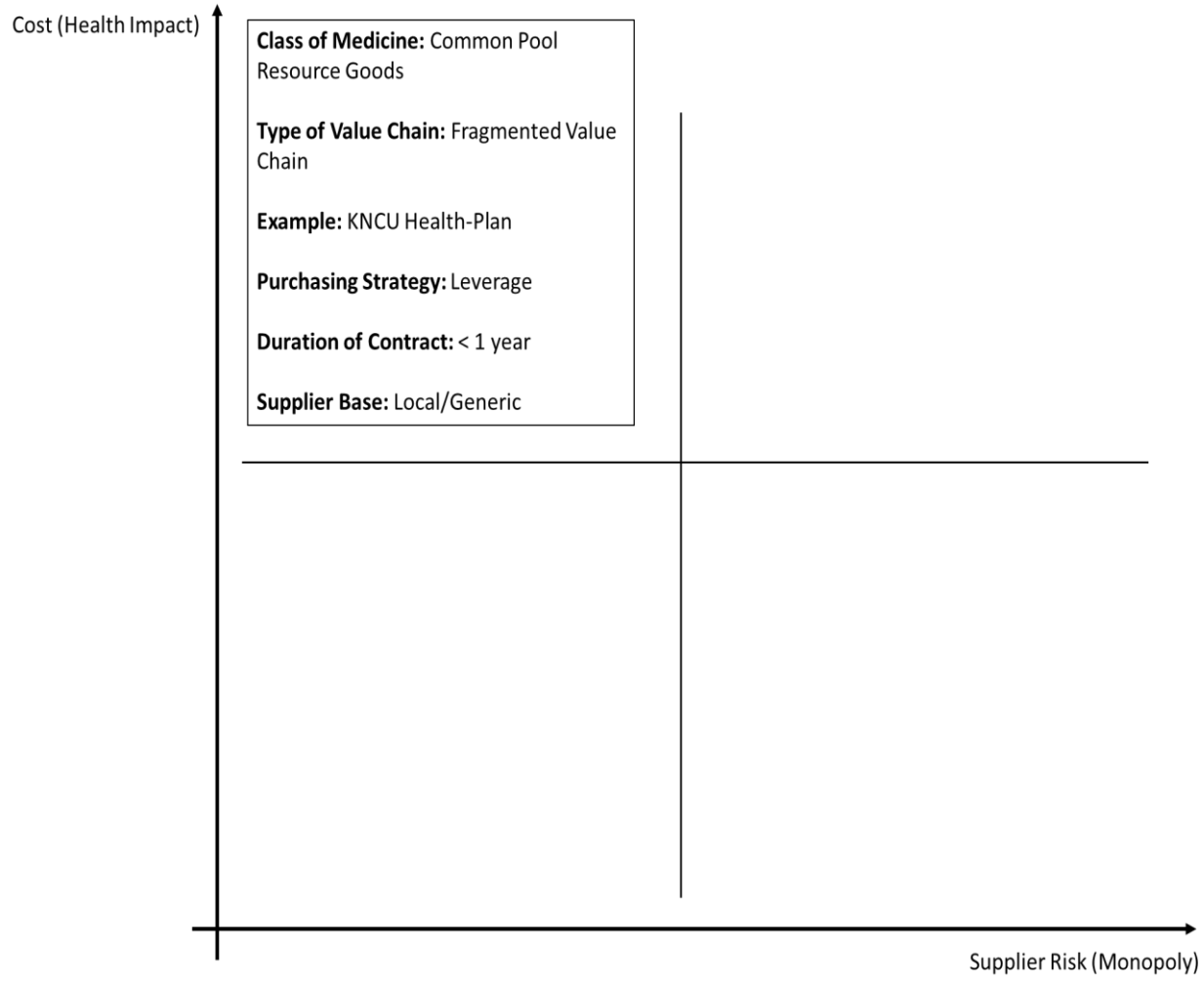
9.4 The KNCU Health-Plan as Purchasing Strategy for Access to Medicines:

The KNCU Health-Plan works well for medicines that are high impact items. These would include medicines for managing chronic diseases like Insulin for Type II Diabetes, Amlodipine for Hypertension and Lipid lowering drugs to reduce the long-term risk of atherosclerosis, heart attacks and strokes. These medicines though generic, and therefore having many suppliers are difficult or expensive to produce and can quickly exceed 30% of income for people in noncore countries if they have to pay out-of-pocket. For these high

[16] Makoko, the slum where the intervention was carried out is a slum society of immigrants both local and foreign who are drawn from all over west Africa. As such it is a fragmented 'community' at best.

impact generic medicines, the KNCU Health-Plan is a veritable strategy for improving access to medicines. Low supply risk (generic), with high impact on the socio-economic welfare of the community both at an individual level and at a group level. It is here that groups of consumers can leverage their buyer power to play off suppliers against each other to secure long term contracts with deep discounts. Better still, these medicine supply contracts can be folded into negotiations for a basic package of care covering the aforementioned diseases which afflict a large proportion of the community. For chronic noncommunicable diseases which can be addressed through generics, the KNCU Health-Plan is the recommended strategy for groups of consumers to drive the value chain to their own advantage. Emphasis should be on sourcing from local suppliers where possible to grow a homebase of manufacturers of high value generics, with the multiplier effect of stimulating local employment and inhibiting capital flight.

Medicines under patent are best avoided, as it is nearly impossible to obtain deep concessions out of these suppliers who have the influence to frustrate the purchasing group through market shaping activities. Instead, costly generics are preferable for leveraged buying where there are many suppliers (where supply risk is low). In these types of value chains, the market for medicines is open (devoid of monopoly), but the cost (health impact) of access to medicines on the individual and the community is great. See below.



9.5 The KNCU Health-Plan as a Community Health System.

The KNCU Health-Plan as a community health plan is an exercise in local governance tailored to fit the institutional arrangements of a community who share the same socioeconomic conditions. Public health interventions on the other hand emerges from attempts to universalize health interventions across heterogenous populations through globalization by the state. Public health as a state-sponsored exercise in reproduction by extension only succeeds where the elements for their reproduction are shared widely across different communities. In polyethnic African states, this is hardly the case. For example, salaried employment which is easy to tax are the backbone of universal health care systems in core economies. In noncore economies where most of the people earn their living from

various kinds of ‘informal’ sectors, it is much harder to promote universal health insurance systems.

Institutional voids in noncore contexts select a community health strategy for improving access to medicines because in these analytical spaces, unique combinations of institutional voids yield a remarkably complex variety of health communities. The success of the KNCU Health-Plan in this institutional void for financing and its failure upon extension into a national universal health insurance scheme provide a clear example and demonstration. Public health appears to work well in contexts where the institutional infrastructure of both the social world of production and consumption are well developed (specialized) and homogenous enough to allow universalization and integration (globalization). Where there are institutional voids, institutional intermediaries will have to work locally within the grain to bridge these gaps for improving access to medicines within each community.

9.6 Key Performance Dimensions for Access to Medicines under Community Pooled Resource governance.

Elinor Ostrom provides eight rules for effective collective action in communities of users to govern common pool resources. These rules when translated into the KNCU case, enable understanding of why the KNCU Health-Plan was successful. The coffee union as an organizational device fulfils and plays most of the performance dimensions for robust governance of collective action for health. A few of the performance dimensions are worth highlighting from the Tanzania case in chapter eight as the key determinants of success in the governance of health communities.

9.6.1 Actuarial Science versus Political Correctness

The shift from the use of opaque political processes in setting health premiums under the old Community Health Fund, to the use of transparent actuarial sciences to determine the premiums according to the size and needs of the community is the first principle. This principle provides a shared knowledge of the costs and benefits of the health plan. Without

it, the KNCU Health-Plan would have collapsed under the weight of chronic underfunding by politically correct premiums set by politicians to gain support during elections. Alternatively, the farmers could be overcharged and exploited by health facilities, without the shared knowledge of the true cost and benefits of the KNCU Health-Plan.

9.6.2 Capitation versus Utilization

Following on from the decision to employ actuarial science to determine the premiums, was the decision to use a capitation-based model of payment where the health facilities were assured of a steady stream of income regardless of utilization. This placed an incentive on preventive healthcare services over curative, as the facilities were better served by preventing disease in the community rather than incentivizing curative health interventions under a utilization-based method of re-imbursement.

9.6.3 Facilities and Services Upgrading

This assured cash flow for the facilities also incentivized facilities to upgrade their facilities. The larger facilities could also leverage the income to access capital at low cost from commercial banks to invest in diagnostic technologies. PharmAccess was instrumental in designing a structured methodology to guide health facilities to use operations management principles to improve the quality-of-service delivery as a precondition for accessing these loans.

9.6.4 Enrolment, Monitoring and Justiciation.

The KNCU as an organizational device provided a platform for collective action in monitoring infractions and conflict resolution between the farmer and the health facilities. This justiciation role was provided free of charge by coffee union board members who also doubled as enrolment officers for the uptake of the scheme among coffee union members. These enrolment officers became very difficult and costly to replace when the scheme was taken over by the government and extended into a universal healthcare system.

These four design principles are the key performance dimensions for the governance of community health systems and their value chains and provide a template for social actors working to improve access to medicines in the field.

9.7 Reproduction vs Extension of Community Health Systems.

The KNCU Health-Plan demonstrates what can go wrong when the community health system is extended through globalization rather than replicated by another community. Many performance dimensions that were crucial to the success of the KNCU Health-Plan were lost in translation during its extension into a regional and then a national public health programme.

Tanzania is composed of various communities whose shared socioeconomic platforms revolve around various types of activities that can serve as a base for health communities. For example, the Chagga tribe who make up the bulk of coffee farmers on the Kilimanjaro comprise a unique community with shared socioeconomic realities. These realities and their implications necessitated the forming of the KNCU over a 100 years ago to intermediate on behalf of the coffee farmers in the value chain for coffee. There are other socioeconomic groupings which offer a fertile ground for collective action in community health.

Extending the collective action agreements developed in one socioeconomic group over another does not bode well for sustainable health communities. The opportunity is therefore greater if replication of these health communities is pursued as health policy strategy. Tanzania has over 3000 cooperatives with an estimated membership strength of about 9 million people. If each of these people represent a family of four, then access to medicines through micro health insurance can reach a potential of nearly 40 million people. This would cover nearly 70% of Tanzania's population. Then the National Health Insurance Fund for government employees and those in the formal sector can combine with the old Community Health Fund to take care of the remaining 10-15 million people who may be left out.

The road less travelled is replication and localization of the KNCU Health-Plan in another community of similar institutional arrangements. For example, the cotton cooperatives in the south of the country who represent 300,000 farmers and their households represents a good candidate for reproduction through the mechanisms of replication and localization.

This would entail that a similar discussion be held between the cooperative and PharmAccess to determine the health needs and priorities of the community, and the use of

actuarial services by MicroEnsure to determine the size of the health fund and contributions to the stock and flow of healthcare services by healthcare facilities given their level of resources.

However, as the KNCU case shows, the cooperatives require institutional support to help ensure that administrative funds can be collected effectively or provided by the government. This latter point provides a handle for the polycentricity of community health systems and public health. Public health systems can be limited to an administrative function and as co-payment partner with consumers. In addition to this, public health services can be used to domicile the knowledge for effective running of cooperatives. Knowledge which can be mobilized to render operational support to cooperatives in the field who want to set up community health systems for their members. Such a faculty exists at the Moshi Co-operative university in Dar es Salaam, where the principles for effective cooperative administration are taught in undergraduate and postgraduate degrees.

Public health can be located within these systems and institutions to support the reproduction of local health systems that fit the needs and priorities of host communities. The quality assurance however should be located in a neutral broker, preferably an NGO or private firm with deep expertise in project management and business process reengineering within health management. The loss of this quality assurance function caused by the exit of PharmAccess from the active running of the KNCU Health-Plan and the iCHF programme led to serious deficits in quality improvement despite the government's best efforts.

There emerges from the discussion a triple cord for community systems to work effectively in providing access to medicines in noncore parts of the world. The first is the organization consumers into voluntary health communities. The second is the institutional intermediary function of quality assurance by a neutral broker. The third is a co-payment partnership organized through public health using actuarial science to support the health communities to negotiate access to health through private health facilities.

9.8 Distributed Value Chains: The DKT Nigeria Case

The initial success of DKT among women in the slums demonstrates the importance of the knowledge dimension for innovation diffusion. It is this knowledge dimension that is performed by the professionals who codify information within the healthcare value chain as high-skilled healthcare professionals. This is the case with Depo-provera intramuscular injection which requires a health professional with deep and extensive knowledge of human anatomy to administer. Knowledge only gained in long years of university education, at the end of at least 16 years of formal schooling.

Re-engineering Depo-provera from a deep intramuscular injection to a subcutaneous injection reduced the skills required from high skill to limited skill. As a subcutaneous injection requiring only a skin prick to administer, the chances of medical misadventure are reduced. Therefore, the knowledge dimension could be performed by a health worker with only basic education.

More importantly is that these health workers were recruited by DKT to serve the particular communities where they lived. This gave the DKT Bees scheme the needed legitimacy with the women in the community. Ideally the new subcutaneous injection could have been made available through an open market model, as a generic product available out of pocket. DKT's insistence on controlling the distribution and administration led to the breakdown of the effort by BMGF to extend the value chain all over the country.

DKT had expected that the distributorship would generate sufficient sales to be profitable. This did not happen and faced with the prospect of paying the health workers for a largely educational intervention, DKT pulled the plug on the programme. This case demonstrates again the tension between community and public health systems in translation.

The public health systems of the world tend to be heavily slanted towards the production of high skilled human resources for health. The language is always about the dearth of doctors and the doctor patient ratio or the patient bedspace ratio. The language is rarely about the role of limited skill community worker who play major role in health extension especially for preventive health services in the community. This shifts the health system towards a curative approach which noncore countries simply cannot afford.

Yet it is this type of high-skill human resource that noncore countries are unable to keep after training them and still continue training in large numbers every year. Bridging the gap

left by emigration using limited-skill human resources to perform the knowledge dimension among communities is a cost-effective approach to improve access to health. Without the knowledge dimension being performed at the level of the community, people do not know when to seek help early, and may arrive when it is too little too late. The knowledge dimension when performed as common knowledge at the level of the community can lead to autonomous and self-reliant, independent health seeking behaviour and even greater willingness to pay for healthcare.

The recommendation following from this is for a healthcare value chain whose knowledge dimension can be performed by limited-skill health workers employed by the local government. Such a healthcare value chain was responsible for the success of the Ebola Control Programme in Nigeria (Vaz *et al.*, 2016) (Shuaib *et al.*, 2014). Nigeria was able to quickly draft in limited-skill health workers trained for polio immunization in the community into a rapid response mobile unit for disease surveillance and reporting. Other countries in the west African region who did not have this capability were unable to mobilize quickly enough to intervene early[17]. Countries like Sierra Leone and Liberia which lacked this community health capability for disease surveillance and had to wait for imported health workers from abroad fared disastrously (Ross, 2017).

If noncore communities expend meagre resources to train highly skilled human resources for health, they will be unable to retain them as they will be poached by core communities in a free market for healthcare. However, if they invest in limited skill health workers, they can at least retain the ability to perform a knowledge dimension for community health. This can make the difference between a minor disease outbreak and a public health disaster.

This knowledge dimension has great promise for health priorities like malaria, HIV, Tuberculosis, Diarrhoea, and pregnancy that account for over eighty percent of death and disease burden in noncore communities. The knowledge dimension required for the effective management of these health issues is well codified through standardization of treatment procedures to allow for limited skill intervention. Even newer priorities like hypertension and diabetes can at least be detected early with limited-skill testing interventions at the stages when lifestyle changes in diet and exercise can reverse disease. Such preventive interventions in diet and exercise do not need a physician or high skilled

[17] Nigeria happens to be the only country in Africa still reporting cases of polio and therefore still retained this health network of limited skill health workers for disease surveillance.

health professional. Community health workers can support healthy lifestyle choices with a knowledge dimension designed at the level of the community.

In core communities today, there is also a shift to these noncore community health systems for performing the knowledge dimensions required for interventions around smoking cessation, dementia, arthritis, and obesity in what is now known as social prescribing.

The job of organizing the knowledge dimension for community health systems is better located within the local government as the value of these roles are difficult to capitalize by private sector firms. Health being an intermediate resource and because this knowledge dimension is a largely preventive performance. Unlike high skilled health professionals, these community health workers will be unable to support themselves without financial aid from a public health system in a fragmented value chain.

9.8.1 The Knowledge Dimension:

The bias against contraceptive use in Nigeria is strong. The belief is that prolonged use of these medicines leads to infertility later on. These widely held beliefs range from the genuine to the patently absurd. The author heard a story on the field that a woman gave birth to a child holding the IUCD in one hand! Yet these beliefs are widely held. Overcoming these required a knowledge service to present the facts that some methods can and will lead to infertility, weight gain and a greater incidence of some cancers, while others will not, e.g., condoms.

Some women who assessed the risk as worth taking accepted to have the long-acting hormonal contraceptives such as Sayana Press. This is the knowledge dimension required for community health to perform, especially preventive medicine. The curative medicine of public health is the exclusive preserve of the medical professional. This opens up a fundamental difference in the knowledge dimension of both systems. In the community health system, the knowledge dimension is grounded within the community at a level they can perform easily. This knowledge dimension makes the community members into active health seeking consumers who are able to access health in a way that is independent, self-reliant, and free from interference. The knowledge dimension of largely curative health systems does not empower the consumer. It empowers the professional over the consumer. It requires that the consumer places faith in the health professional without having the

required knowledge to take initiative in the health value chain. Rather the consumer enters the healthcare world of the clinician in a position of absolute dependency, reliant on the goodwill of the health professional to their detriment in some cases.

The community health system therefore performs a vital preventive knowledge dimension performed by the consumer and not on behalf of the consumer.

This knowledge required to perform community health is non rivalrous and excludable, is difficult to monopolize and cannot easily be capitalized on as a source of revenue by private firms. This preventive knowledge dimension is a candidate for provision as a public good.

This is where the space opens up for institutional intermediaries working in noncore regions to play a leading role, supported by government funding. The need is for a teaching function to present scientific knowledge that the community can appropriate.

Efforts to extend this teaching function into health systems has been perceived as a threat to the monopoly of the professionals. This perceived threat is unnecessary as over 90% of Africa's health problems listed as preventable does not require high skilled professional intervention when addressed early. It should be common knowledge for health communities.

What is therefore wrongly described as 'task sharing' in policy documents for healthcare in noncore countries should actually be 'knowledge sharing'. A knowledge sharing role between public health and the community that enables community health systems to perform.

In the next section, it is important to devote attention to define the role of these community health worker as knowledge sharer, in order to minimize as much as possible, the perceived threat of the establishment of clinical medicine practice.

9.8.2 The community health worker.

The coffee board members within the KNCU were drafted in to work as enrolment officers throughout the Moshi region in Tanzania. The Moshi region is ethnically homogenous as most coffee farming in this area has been the exclusive preserve of the Chagga people (Munger, 1952). The coffee union board members are men of integrity held in high esteem

by the community and who have been exemplary members of the coffee union over long years. In an industry where the average age of coffee trees are forty years, most coffee board members visited during fieldwork were over 50 years of age and were well established coffee farmers[18].

An important aspect of the temperament of the coffee union board members was a deep sense of ownership over the KNCU Health-Plan. Being prosperous farmers, they had no need for the commissions they would get for registering coffee union members. When asked why he was passionate about the scheme, he iterated that he had seen sickness drive many union members into poverty, and that he saw this KNCU Health-Plan as "a gift from God".

At strategy meetings with the PharmAccess representatives, he was trained on the elemental principles of health insurance. The coffee union board member showed me his notes with great pride kept in pristine condition four years after the scheme had been folded into the iCHF.

Another board member whom the author interviewed at the office pointed out that he had decided to stop acting as an enrolment officer for the iCHF programme. He too had been an enrolment officer for the KNCU Health-Plan. When probed as to what the reason for his refusal to continue enrolling people into the iCHF was, he said that this new scheme was not of the same quality as the former, and that at his age he didn't want anybody to insult him in front of his wife if they go to the clinic and didn't get medicines. It was only later that the author upon visiting a few clinics realized under the new iCHF scheme, the weight of exemptions (non-paying users) had stretched the medicine supply beyond the carrying capacity of the health fund, and that some of the medicines were now in short supply and even out of stock.

An enrolment officer who had continued from the KNCU Health-Plan into the iCHF and then into NiCHF shed some light on the transformations that occurred when the enrolment officers were changed from coffee union board members to random people employed even from outside the community. He pointed out that these new recruits were in it mostly for the money, and when the money from commissions on enrolments was not enough, they

[18] A coffee union board member who hosted the author in his house, a decent bungalow of about five rooms, with an adjacent boys' quarters with a 100-bird capacity poultry at the back of the house.

left the job. For the coffee union members, it was not about the money, it was a way to restore the union back to the glory days when they even sponsored children of deceased or indigent members to school.

The tools of the coffee union board members therefore were personal integrity, high standing in the community, and common health knowledge. This picture recommends the ideal recruitment criteria for the knowledge workers as community health practitioners; sound literacy, economically well-off with time to spare, of good standing and reputation within the community and recommended by the majority of the people, ideally at an age no lower than

In organizing health communities, it is arguable that the knowledge dimension should be performed by a government agency due to its public good or common pool resource nature of health knowledge for disease prevention. But in places where there is no government capacity for training, communities can volunteer health workers to be trained institutional intermediaries to bridge the knowledge gap. The training of these limited skill health workers should be funded by government. The quality assurance of the knowledge dimension should be performed by institutional intermediaries with the functional tools of quality improvement methodologies that are peer reviewed and independent.

In this way the community can pick and choose from experience what health interventions are dear to them. This market test is important to maintain collective action at the community level. This may explain the difference between women reached with contraceptive knowledge and those who took up family planning technology. Following Arthur Lewis (Lewis, 1954), people in noncore communities have an incentive to make up for lack of mechanized power with large family sizes. Thus, there may be low uptake of contraceptives despite best efforts since the intervention was done in a low-income community.

it is therefore understandable the opinion of the researchers at the UCSF monitoring and evaluation team that only 7,500 users out of 120,000 reached with knowledge about contraceptives represents a successful intervention. In an industrial society fructified by capital intensive machines, the need for large families is very low, and in these societies, knowledge of contraceptives is acted upon by nearly every woman in choosing a suitable method of birth control.

The results of the KNCU and DKT interventions point out three major roles in health community systems: the community as co-producer of preventive health services, the institutional intermediary as quality assurance provider, and the National Government as sponsor.

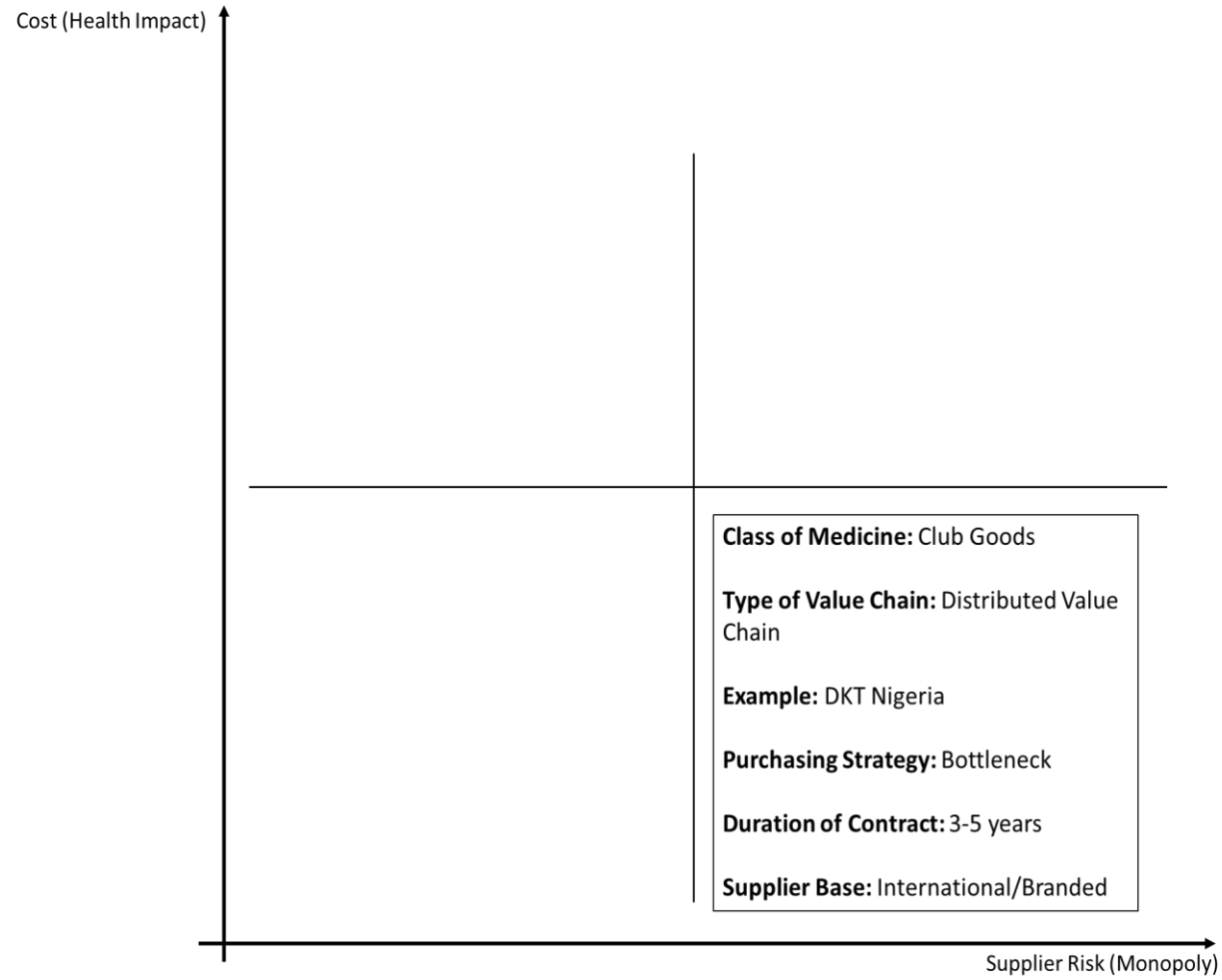
9.9 The DKT Nigeria Case as Purchasing Strategy for Access to Medicines:

The DKT Nigeria case works well for medicines that are constrained in their supply base. That is medicines for which the suppliers are few, but which have a low health impact in terms of cost. For these kinds of medicines, their low cost discourages investments in their supplier base. There is therefore a risk of ineffective demand and as a result these medicines may become extinct.

Neglected drugs for tropical disease fall into this class. Medicines for schistosomiasis, guinea worm, leprosy, trypanosomiasis are few examples of these medicines. In a country where high birth rates are the norm and where contraceptives are distrusted, access to cheap contraceptives may fall through a bottleneck for those who need them. Due to their low cost and little demand, there is no incentive for the manufacturers to produce them, or for the shop keepers to stock them. Ineffective demand may stem from low prevalence of disease, but it may also stem from ignorance, or inability to form community pooled resources for improving access to medicines. In this situation, there is a need for a social actor to perform the knowledge dimension required to make demand effective among those who need them and to subsidize the continued production of these medicines as an incentive for their continued manufacture. Under institutional voids, this is left to the third sector i.e. charity. The first reason is that under institutional voids, the state is either fragile or absent, and the second reason is that where there is no community, such as in urban slums, common pool resource governance is impossible. In those low-income populations of the peri-urban slums too poor for out-of-pocket expenditure, devoid of community, and where the state is fragile or absent, charity can be a strategy. It must be specified that the kind of slums referred to here are the fragmented communities (Crecine and Brunner, 1972) of the inner city where crime, lawlessness and disorder are the rule. In these broken spaces, there is neither community nor government, and only charitable organizations, especially the church can thrive there. The effectiveness of the Church Missions in these

broken spaces supersedes that of the NGO and the Civil Society because it excels at not only improving access to medicines, but also at rebuilding communities around the parish, and centrally coordinating health interventions. This last role of centrally coordinating health interventions across core and noncore areas is difficult for Civil Society Organizations like the KNCU to perform due to their lack of international scope. The DKT although it was international in scope, was willing to improve access to medicines only insomuch as it would satisfy their bottom line, using limited skill health workers drawn from these slums. As such DKT withdrew its services when the revenue could not offset the cost of access to contraceptives. The church has greater staying power, because it is better at cross subsidizing its interventions and is organized around a faith-based ethic. This is hard to recreate by the NGO's such as DKT or the BMGF. The faith-based ethic of the Church Missions also guards against corporate capture of bottle neck situations by patents. This vulnerability was exploited by a notorious US 'investor' Martin Shkreli who obtained the distribution rights to Daraprim in the USA, a drug largely used by people living with HIV/AIDS[19] as adjunct to Anti-retroviral therapy against opportunistic infections, and promptly jacked the price from a few dollars to over $750 overnight!(Pollack, 2015).

[19] About 1.2 million (Bosh *et al.*, 2021).



The purchasing strategy for these types of broken communities or slums should be to view these medicines as critical items requiring a knowledge dimension as explained above and subsidization for these orphaned or neglected diseases. The social actor will have to create a highly excludable club of those affected by the disease and negotiate long term contracts for continued production and access to these medicines through a few brand name suppliers. The US President's Emergency Plan for AIDS Relief (PEPFAR) is an example of creating a club out of people in broken communities for access to medicines that cannot be accessible through Common Pool Resource governance or Public Health by the State. Another important example if the Veterans Affairs Health Programme in the USA which caters exclusively to the American servicemen and women and their families whether serving or retired[20]. In these health clubs, access to medicines is highly excludable and serves to provide a low-cost bundle of health services to low income groups in fragmented communities (Crecine and Brunner, 1972). Ideally generic medicines should be sourced

[20] Originally created to provide occupational therapy and rehabilitation for veterans who due to war injuries were unable to fend for themselves to afford healthcare, and untaxable for moral and economic reasons.

from one or two brand international suppliers to build economies of scale across national borders for medicines that have ineffective demand due to low numbers of those affected or low income. The contracts should be negotiated over several business cycles to guarantee continued investments by the few manufacturers in the supplier base.

9.10 The AstraZeneca Case.

The AstraZeneca value chain represents the value chain for access to medicines as a private good in the healthcare industry. The AstraZeneca value chain is highly excludable through patents over production and distribution and is also highly rivalrous due to their novelty. From a view of the lead firm, this rivalry is constantly under threat from generic manufacturers and parallel importers. However, in the noncore environment, despite the exclusivity of these patents, the AstraZeneca case demonstrates the inability of the lead firm to perform a Global Value Chain for its antiasthma product Pulmicort. The absence of high-skill health professionals (Paediatricians) in the Labour market, inadequate cold chain storage and nebulizers to support the medicine in the Product market, and lack of health insurance cover for the medicine or nebulizers in the Capital market conspired to truncate the Global Value Chain. Lead firms are wont to ignore these institutional voids which truncate the Global Value Chains in the noncore zones of the world.

Where NGO's such as DKT step into to subsidize the provision of public services such as contraceptives for young women in the slums, they provide a service with low rivalry and high excludability. However due to the prevalence of asthma and the high cost of innovative medicines for its management, it is hard to create health clubs for access to these new medicines. In the face of other competing health priorities in the noncore regions, it is difficult to ignore other pressing medicine access needs and budget the kind of money required to perform health clubs for new medicines in asthma care.

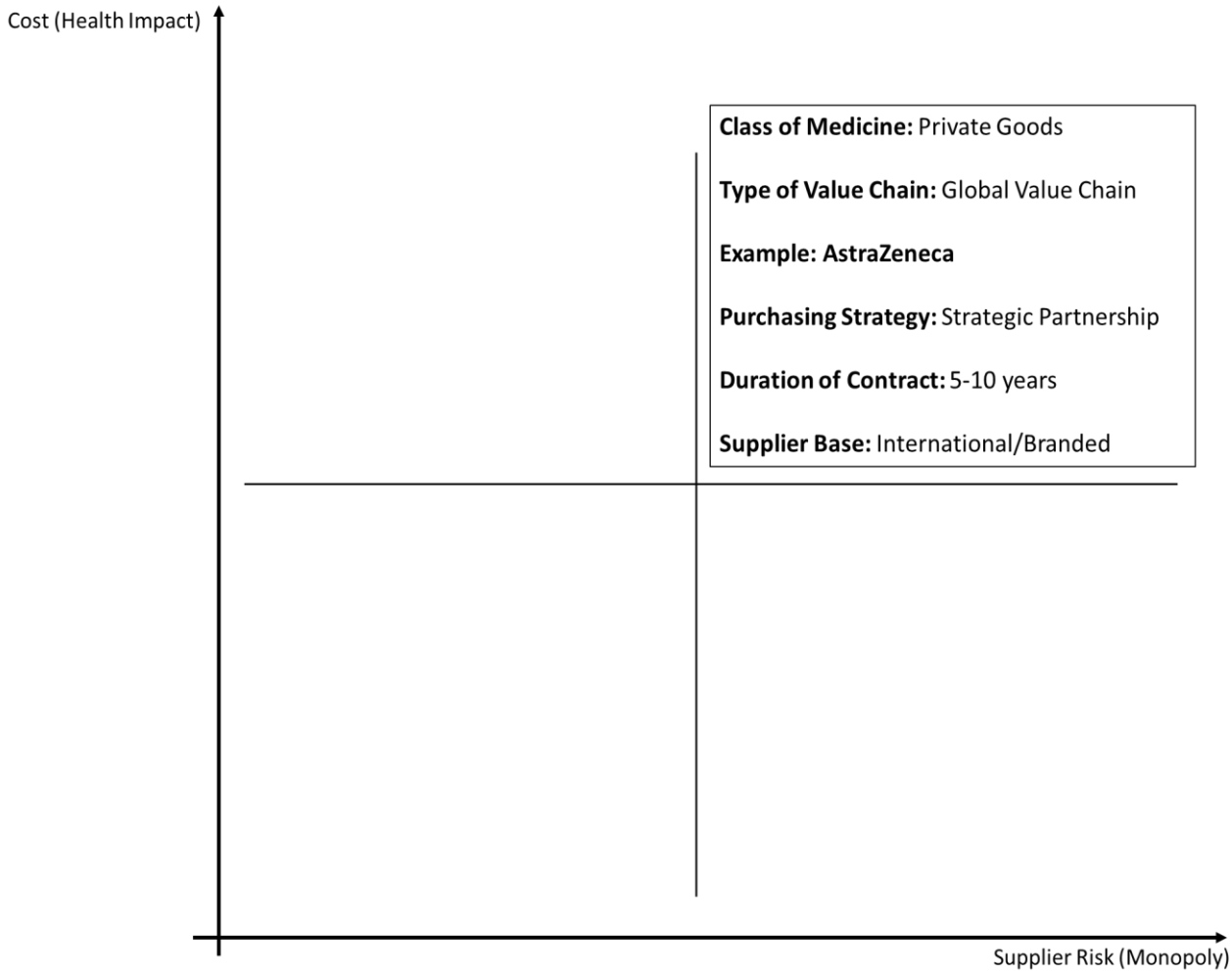
Even where there is community, there is not much scope for access to new medicines through common pool resource governance i.e., health communities. This is due to the fact that new medicines are under patents and as such there is likely to be only one supplier. In this situation health communities in noncore zones with low wage incomes are unable to negotiate effectively for access to new medicines.

In this situation, the nation-state comes into the picture as a way forward.

9.11 The AstraZeneca case as Purchasing Strategy for Access to New Medicines.

Nations and groups of nations can create multilateral partnerships for access to new medicines that they need. Whereas PEPFAR is useful for improving access to old generic medicines for critical bottleneck situations, PEPFAR is unlikely to be useful for brokering access to new medicines due to the conflict of interest between the US government and the pharmaceutical industry. The recommendation is for groups of nations in noncore zones to forge partnerships between academia and industry for research and development into diseases that afflict the people in noncore regions. New medicines, safe and effective vaccines for diseases like malaria are candidates for this purchasing strategy. Under this arrangement, a patent sharing formula can be built in early to the development process to guard against rentierism by the pharmaceutical industry. Patent pools and IP licensing agreements between noncore states can also be developed through these partnerships. In the long term, such arrangements or partnerships can be instrumental to ensure that the next generation of medicines do not fall prey to corporate sharks. Such a purchasing strategy shared by a brad coalition of states can be pushed as an agenda in new Trade Rounds led by noncore states such as Brazil, Russia, India, Turkey, Nigeria, and South Africa to mention a few.

These partnerships should be at least the duration of one drug development process i.e., 5-10 years, and should be multilateral. An example of this would be the Tuberculosis Alliance (a broad coalition of firms, governmental agencies, and NGO's) for developing partnerships around new TB medicines. In February 2019, a new drug called Pretomanid, which is the only new addition to the repertoire of medicines developed specifically for the treatment of Tuberculosis in the last 50 years came from TB Alliance. Unfortunately, PathoGenesis, the firm which developed the drug has been acquired by Novartis. This exposes the need for these partnerships to be multilateral arrangements under the administration of states from noncore economic zones to avoid corporate capture.


Cost (Health Impact)
Class of Medicine: Private Goods
Type of Value Chain: Global Value Chain
Example: AstraZeneca
Purchasing Strategy: Strategic Partnership
Duration of Contract: 5-10 years
Supplier Base: International/Branded
Supplier Risk (Monopoly)

9.12 The Open Market.

DrugStoc presides over a fully commoditized value chain for generic medicines in Lagos State Nigeria. The value chain problematizes the issue of free market versus public health. For fully commoditized medicines with many suppliers, the excludability is low. Coupled with their fully generic nature and ease of manufacture, their rivalry is also low. This class of economic goods approximate the conditions of a free market.

Medicines in this category are not only devoid of patents, but importantly, they are easy and safe enough to administer that they can be sold over the counter without the need for skilled health workers. Due to the open nature of the value chain, under hyper competition, these generics are sold as close as possible to their cost of manufacture. Under institutional voids, where the state is unable to guarantee the quality of medicines within the supply chain, DrugStoc performs an important function by providing end to end traceability of medicines in the open drug market.

This role of the neutral broker means that although DrugStoc governs the value chain, it has no interest in any particular commodity chain within it. Thus, it provides an impartial brokerage of knowledge concerning the quality of the medicines in the supply chain. Importantly, this quality guarantee is provided as a proxy of brand name and covers the entire value chain. As such, all customers have information symmetry shared equally between them and the manufacturer about the authenticity of the medicines. This is predicated on the buying strategy of DrugStoc to only buy medicines directly from the manufacturer and not through third-party importers who cannot be held liable for treatment failure and adverse events. Customers can rest assured that the medicines supplied by DrugStoc can be traced to a verified manufacturer.

In a beautiful essay of nine pages, Clifford Geertz introduces us to the bazaar economy on the street of the Open Market at Marrakech in Morocco (Geertz, 1978). He identifies that this market approximates the classical free market with its intensive bargaining and marginal profits. But he observes a flaw; the issue of clientelization (Geertz, 1978). In the bazaar economy, interactions are sticky over the long term as people develop attachments to particular stalls and merchants after they have settled through intensive haggling.

In the open drug market in Lagos, these bazaar conditions are well reproduced. In a market mostly for generic medicines, there is no other way to recognize quality aside from

clientelization to known brands. But this clientelization opens the door for rentierism by the brand medicine manufacturers, or outright fakes by unscrupulous agents.

Being an unregulated market of generics, it is perpetually open to generics manufacturers who flood the market with medicines of dubious quality as these firms try to undercut one another leading to hypercompetition. The hypercompetition keep prices low and profits marginal, which makes it a big draw for out-of-pocket consumers. The downside however is the obvious lack of quality assurance in the market. These open drug markets in Nigeria serve the needs of up to 70% of the population in a country where nearly 50% of the population is in abject poverty.

The intervention of DrugStoc to introduce a quality assurance dimension into the market at negligible cost to the producers and consumers alike bridges the gap for quality in the Open Drug Market. By making the supply chain open to all generic manufacturers who will allow their products to be traced from port to shelf, DrugStoc creates a classic free market route for access to medicines in a noncore context.

Hitherto, the incumbent generic manufacturer had no way of knowing whether the introduction of a cheaper version of the same medicine by another generic manufacturer was down to more efficient production systems or sharp practices. This leads to an adverse selection where cheap fake and substandard medicines in the absence of quality control drive out the good quality generics from the market.

Using an ISO 9001-2015 certified supply chain, DrugStoc is able to ensure that each medicine can be traced in an open market, to ensure that fake and substandard medicine producers and sellers can be identified and removed. In this way, DrugStoc without controlling the market introduces a quality dimension using a technology that is universally accessible and yet non-rivalrous to guarantee access to medicines at marginal cost. This is a classical free market for medicines supplied by an Open Value Chain for medicines.

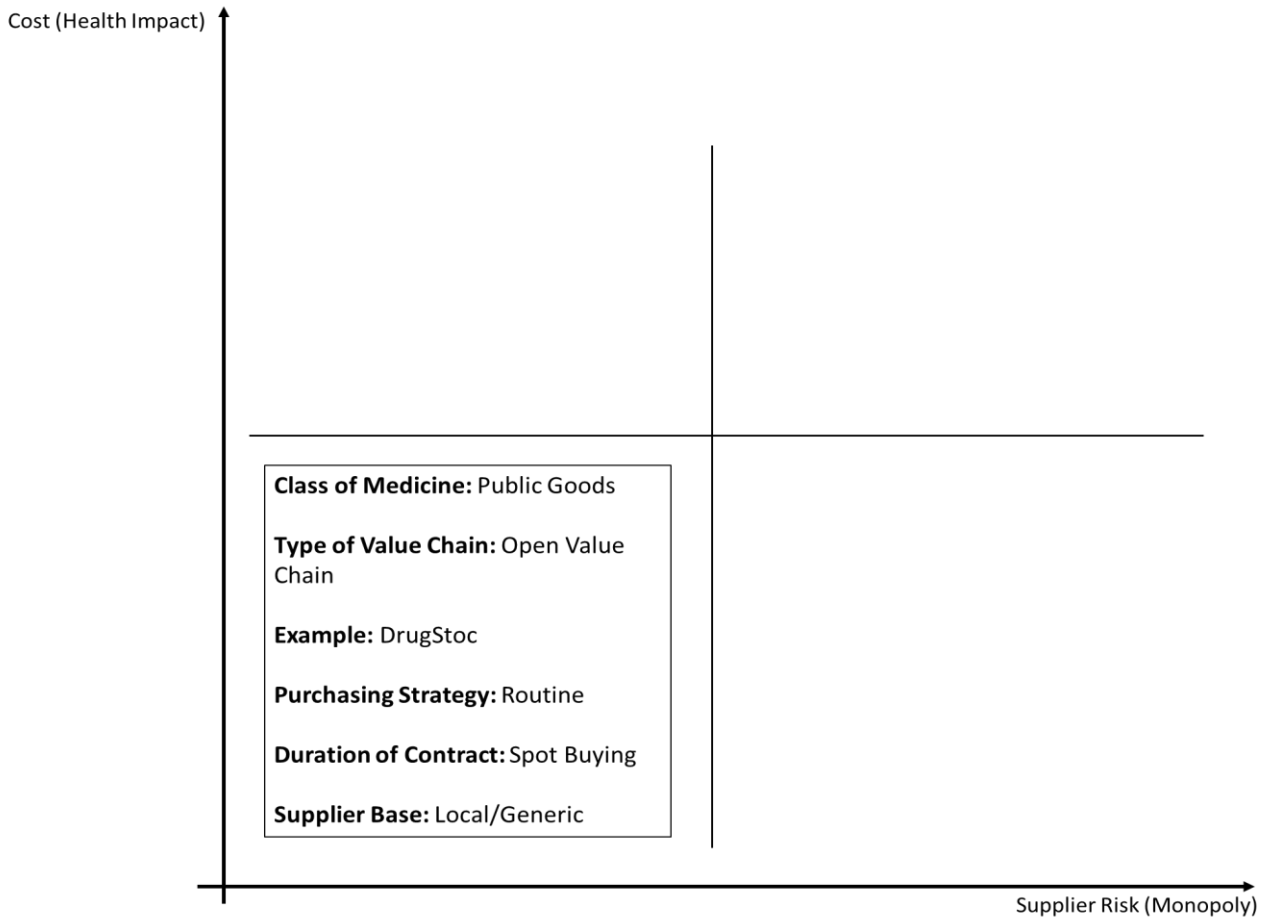
Thus, the ISO certification of good supply chain practice as a ‘code of conduct’ can and will reduce the clientelization that is a major feature of the bazaar economy of the open market and push it further along the path of a true market completely free of asymmetry in its transactions. This spells a major breakaway from the dominance of brand names as a marker of quality medicines which enjoy high patronage through clientelization despite price gouging.

9.13 DrugStoc as a Purchasing Strategy for Access to Medicines:

In the hypercompetition of open value chains between generic commodities, there is no need for a coordinated buying strategy beyond a quality guarantee. The reason is that, using a common pool resource strategy like the KNCU Health-Plan or the bottleneck strategy of DKT will shrink the supply base to one or two suppliers. This will shift the open market into a bottleneck situation. It is not an efficient strategy for all generics to be in bottleneck situations which then require health clubs to improve access to them. As such, fully commoditized generics for which there is healthy demand should be allowed to survive based on the pull of the market. Only when the demand for these medicines falls below the breakeven point for manufacturers should a careful club strategy or common pool resource strategy be contemplated.

It is equally not advisable for the generic medicines to re-enter patency through evergreening, where firms make minor changes to the formulation for the sole purpose of re-registering the drug as a new molecular entity and extending its patent. Neither should these medicines come under public health insurance cover, as the cost of the health management bureaucracy exceeds the cost of accessing them through out-of-pocket expenditure.

The fully commoditized medicines should be left alone in the free market where out-of-pocket expenditure provides the most efficient access at the lowest cost to the individual and the community. Ideally these medicines should be sourced from local manufacturers wherever possible and sourced as routine items.



9.14 Free market versus Public Good:

The Open Value Chain raises the question of what makes a value chain global. This requires a reconnaissance on the idea of 'Global' in Global Value Chain. The 'Global' here being different from International or Multinational. The world-system theory of Immanuel Wallerstein proposes that globalization must integrate core and noncore in the uniquely unequal exchange that marks dependency (Wallerstein, 2004). In this view, a global value

chain is a value chain that sustains, perpetuates, and reproduces itself through exploiting the unequal exchange between core and noncore parts of the world economy. This view is strongly supported by the Manchester School of Geography and Peter Dicken points out that the twin mechanism of globalization are integration and dependence (Dicken, 2015).

Globalization in this light is not inevitable, but it is deterministic. Without unequal exchange, ceaseless capital accumulation is impossible. Without asset specialization and information asymmetry, there cannot be unequal exchange upon which to construct the very foundation of global value chains. At best, what one may have is a free market exchange of generic goods, traded freely and contracted over short-lived instantaneous interactions. This is the open market for generic medicines at Idumota in Lagos state.

There may be many commodity chains in such a free market for fully commoditized medicines, but there can be no brand names, and as such it cannot be theoretically possible to speak of global value chains. This explains why Gereffi, Humphrey and Sturgeon (2005) discounted the three value chains that form under institutional voids.

The global value chain is only route for access to medicines. The global value chain features patent monopolies, asymmetric information, and long-term contracts. The commodity chain on the other hand features generic medicines, common knowledge, and spot transactions done out-of-pocket.

This problematization of the word ‘global’ is important. The earlier global commodity chains framing by Hopkins and Wallerstein was built on exchange of agricultural produce between trading nations. This is mercantilist trade based on Ricardian comparative advantage. In this trade, nations seek to expand their exports at the expense others leading to trade wars fought with subsidies, tariffs and sometimes cannonballs. This mercantilist trade war is now prosecuted globally using patent monopolies written into bilateral and multilateral trade agreements.

Removing their global character precludes their ability to create asymmetries in product markets or knowledge, thus reducing the value chains to international commodity chains or local commodity chains depending on the presence of international borders between producer and consumer. The Open Value Chain of DrugStoc contains many international and local commodity chains devoid of patent monopolies. DrugStoc as lead firm only provides a quality guarantee for the value chain. It does not supply the medicines or

consume them. Therefore, it plays the role of a neutral broker in the open market to eliminate opportunism and the risk of fake and substandard medicines.

The commodity chain(s) in the Open Value Chain of DrugStoc have four main theoretical attributes.

First, they are non-capitalist. That is, they do not allow the ceaseless accumulation of capital. This derives from the absence of monopoly rights in generic medicines manufacture, distribution, and consumption which exposes them to hypercompetition.

Secondly, the transactions within them are best suited to on-the-spot transactions with zero futurity. That is these transactions should have zero ability to structure subsequent transactions. Braudel points out that it was the introduction of long-term bets and hedging into the commodity trade that enabled the ceaseless accumulation of capital in international trade. The out-of-pocket transaction ensures that the exchanges are perfectly elastic in line with economic theory of free markets. Therefore, health insurance systems to govern medicines consumption destroy the 'freedom' of open markets in the same way that patent monopolies over production do.

Third, the free market is not the public health system guaranteed by the government. Following Braudel (1981), the state is also an instrument of capital accumulation and therefore is capitalist in theory. The state has to tax people to accumulate capital, while patents are privileges for private taxation by firms (Drahos, 2007).

Fourth, the free market has only one lead firm; that is the quality guarantee function provided by the neutral broker.

The three types of value chains present in these cases propose three new routes for access to medicines. These three classes of value chains and their three classes of medicines as economic goods select three purchasing strategies as follows in conjunction with the already established Global Value Chains in Gereffi, Humphrey and Sturgeon (2005). In the next concluding chapter, there is a return to the question of how, where and who should organize for access to medicines.

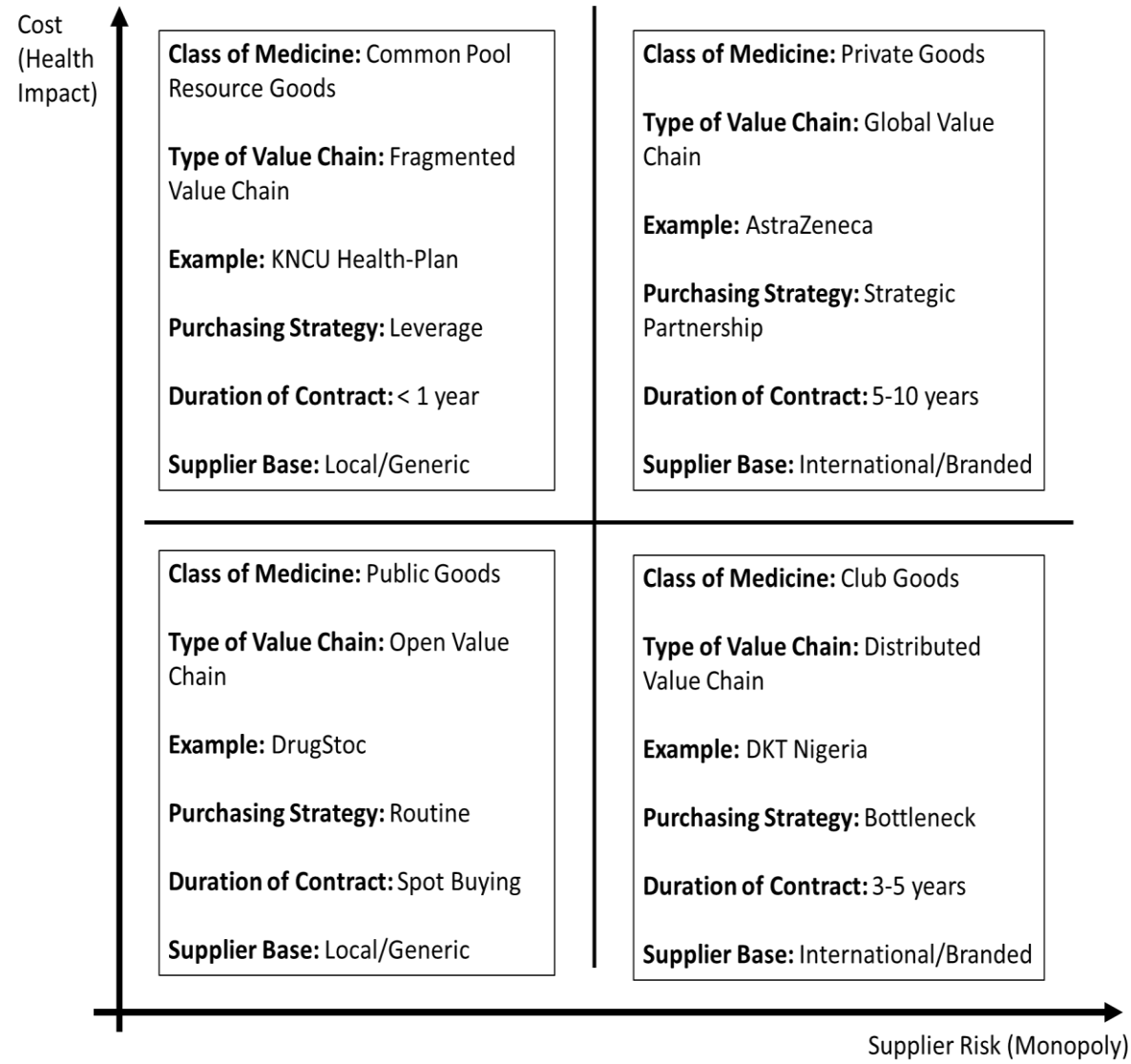
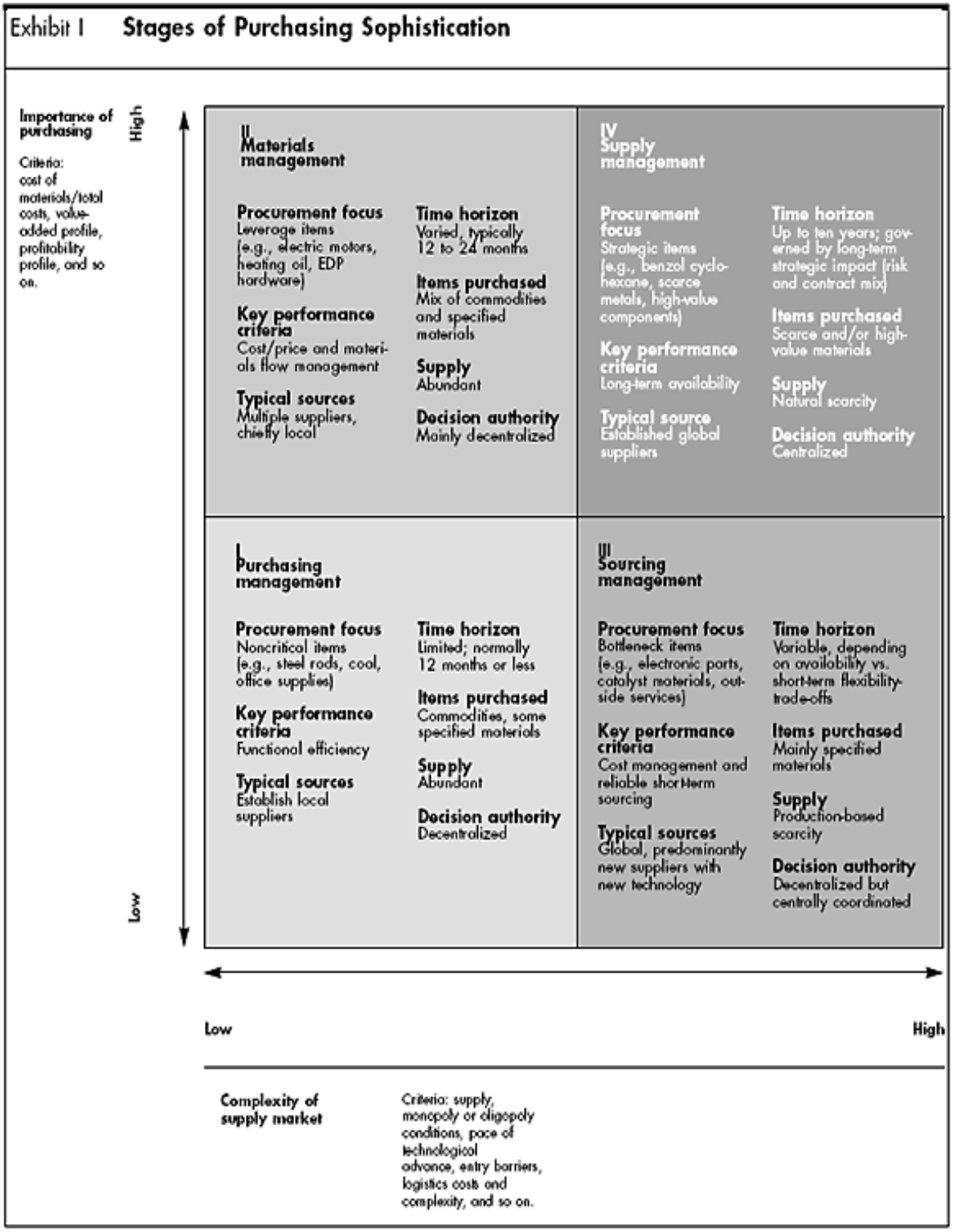

Cost (Health Impact)
Class of Medicine: Common Pool Resource Goods
Type of Value Chain: Fragmented Value Chain
Example: KNCU Health-Plan
Purchasing Strategy: Leverage
Duration of Contract: < 1 year
Supplier Base: Local/Generic
Class of Medicine: Private Goods
Type of Value Chain: Global Value Chain
Example: AstraZeneca
Purchasing Strategy: Strategic Partnership
Duration of Contract: 5-10 years
Supplier Base: International/Branded
Class of Medicine: Public Goods
Type of Value Chain: Open Value Chain
Example: DrugStoc
Purchasing Strategy: Routine
Duration of Contract: Spot Buying
Supplier Base: Local/Generic
Class of Medicine: Club Goods
Type of Value Chain: Distributed Value Chain
Example: DKT Nigeria
Purchasing Strategy: Bottleneck
Duration of Contract: 3-5 years
Supplier Base: International/Branded
Supplier Risk (Monopoly)

Fig 9.

These four classes of medicines, their value chains and purchasing strategies are equifinal with the Kraljic matrix (Kraljic, 1983). In a sense this generalization is a return to supply chain management literature in an attempt to remedy the atheoretical accusation often levelled against it. Whereas Gereffi, Humphrey and Sturgeon (2005) framework is a theoretical explication of the eight possible supply chain configurations that deliver four broad categories of medicines as private, common pool resources, free market, and club goods. These four categories are broad classes and can be fulfilled using one or more supply chain configurations based on the existing institutional arrangements in the local product, labour and capital markets across core and noncore contexts. It is this theoretical underpinning that has never been brought into supply chain literature. Operationalizing access to medicines into Global Value Chains scholarship allows this transferability between supply chain management and international business to occur with important policy implications for those in the field.

Importantly, is that the discussion has arrived at the same point from the consumers view, that Peter Kraljic arrived at through the producer's view of the value chain.



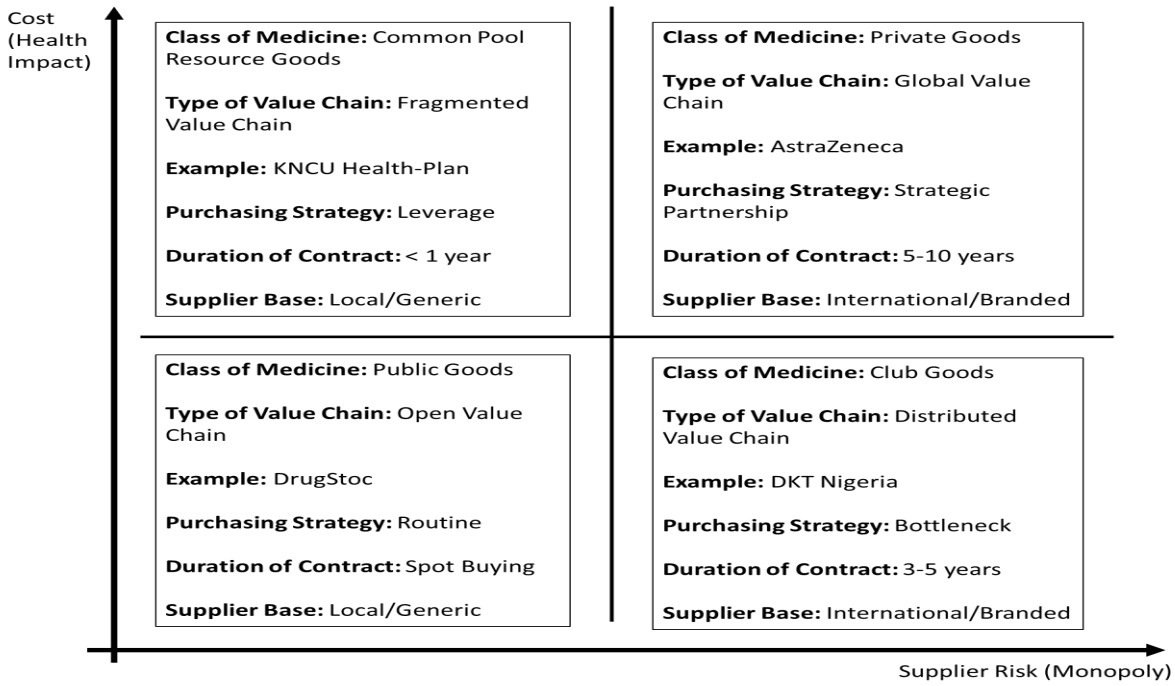
From Peter Kraljic (1984); Purchasing must become Strategic Management

Chapter 10: Conclusion (Four types of Health Systems)

The multinational has ridden roughshod over the 'other' institutional contexts of this world. It has successfully carried out a campaign of delegitimization on these 'other' institutional arrangements through the Institutional Voids literature. This is a harking back to the Thatcherite and Reaganite ideology of TINA – there is no alternative – to the market. Ostrom confronts this ironclad duopoly with common pool resource governance and develops a way for alternative institutional arrangements to regain legitimacy. The PhD has followed Ostrom to re-open the Gereffi, Humphrey and Sturgeon (2005) framework of Global Value Chains. This fruitful research has employed world-system theory to operationalize the Global Value Chains framework into health, specifically into access to medicines to rediscover hitherto discounted Global Value Chain configurations. Configurations which only occur under institutional voids. These are Fragmented Value Chains, Distributed Value Chains and Open Value Chains. Open value chains allow the reconciliation of theoretical free market economics with real world commodity chains in health. These are new realities with important policy implications for those who live in noncore zones of the world.

The PhD opened with an introductory chapter highlighting three major issues facing health today: patents, slums and taxes. The three cases have provided a deep dive into all three issues. The DrugStoc case demonstrates how to organize for health without patents, while the AstraZeneca case shows how not to organize for health using patents. The DKT Nigeria case brings to for the issue of how to locate the distribution of access to medicines in the slums where there is no doctor, while the KNCU Health-Plan provides access to medicines in the face of dwindling government revenue from inability to tax footloose international trade in the noncore context.

The previous chapter also closed with a matrix classifying these cases and their Global Value Chains as purchasing strategies for improving access to medicines.



The matrix also suggests that the three issues in the introduction pose three dimensions for Global Value Chains with two degrees of freedom.

10.1 Open (Non-excludable) and Closed (Excludable) health systems.

Public health systems through the government have had their day beginning with the advent of the welfare state in Europe when Otto von Bismarck made access to medicines an act of parliament. These are closed national health systems subsidized by the state. Special interest welfare programmes for the elderly, the pregnant, children are also closed health systems. It is in these closed health systems that most NGO's operate in. some others specialize according to disease conditions and operate health clubs for improved access to medicines in Tuberculosis management (such as TB Alliance), Leprosy (The Leprosy Mission), River Blindness (Carter Centre, MITOSATH) as closed health systems. Closed national health systems which deliver universal healthcare to all its citizens are only sustainable in core economic zones with strong states who have a deep pool of high-wage income populations to tax. Even in these zones, the cost of subsidizing these public health systems threatens the balance of national budgets, consuming up to twelve percent

of GDP in the UK. Health surcharges for visa applicants to access the NHS of the UK were introduced in 2016 to cushion the costs of public health.

But it is the category of Open Drug Market that merits special mention. Here rivalry is minimized while excludability is virtually zero. The zero excludability of the Open Drug Market while approximating closest to the classical theory of the free market however presents with the problem of quality due to its low barriers to entry. Unscrupulous marketers take advantage of this low excludability to introduce fake and substandard medicines into open drug markets leading to serious problems even in core contexts[21]. The Open Drug Market has no lead firm; therefore, it is a significant contribution to the theory and practice of open markets to find a firm which supplies a quality function in a largely generics market.

Drugstoc's ISO certified supply chain complete with cold storage provides a shared knowledge dimension to both consumers and producers that allows a treatment failure due to a fake or substandard medicine to be traced down to the shop selling the contraband and the particular importer for sanctioning. It is important to note that this marker of supply chain quality is extrinsic to the medicines and as such is not amenable to private monopoly by any one brand manufacturer. This renders the open market for generic medicines symmetrical and complete in quality assurance.

This perfectly symmetrical and complete open drug market guaranteed by Drugstoc is a free market. It represents categorically a Non-excludable Health System that is accessible out-of-pocket, without the need for skilled health professionals to prescribe, and devoid of patents. This is the health system of the patent medicine vendor, the street-corner guy in a shop selling simple remedies for a host of common ailments. This health system is not small. In Nigeria, there are an estimated 200,000 of these street-corner medicine shops registered (Oyeyemi *et al.*, 2020). The Pharmacists Council of Nigeria (PCN), a statutory organ of the Federal Republic of Nigeria under the supervision of the Ministry of Health is saddled with the responsibility of registering them. The entry levels are so low that they require basic education. The PCN website describes a patent and proprietary medicine vendor (PPMV) as a person without formal training in Pharmacy who sells orthodox pharmaceutical products on a retail basis for profit.

[21] The open drug market in core economies manifests itself in the online drug markets where there is no government control. Low excludability and virtually infinite supply of generics combine to present a free market for generic medicines in core economies.

In conjunction with DrugStoc, which provides a quality guarantee over the supply chain delivering medicines to these patent medicine vendors, there is a quality guaranteed free market for medicines which constitutes an effective Open Health System.

The KNCU Health-Plan and its network of hospitals also qualifies as an open health system, thanks to the low entry requirement for joining the scheme. Clinics were free to sign up for the scheme and receive operational support for upgrading their quality standards under the SafeCare quality improvement methodology which was also ISO certified for Hospital Operations Management. Coupled with the fact that the scheme was open to anyone with half a garden plot willing to put it under coffee cultivation, there was also a low entry barrier for farmers. This also, is an Open Health System with its quality guarantee provided by PharmAccess.

On the other hand, the AstraZeneca Global Value Chain for Pulmicort is also a closed health system under private monopoly. A closed health system is not inherently problematic. One may argue that they correct a market failure for old or new innovation as in the DKT and AstraZeneca cases respectively. One may also argue that they help focus attention on the health problems of under-represented groups. The DKT health club was instrumental in correcting a market failure for health knowledge about the correct use of contraceptives among women in the slum and the redesign of an already existing product to make it safe for self-administration. This knowledge distribution proved to be more successful than the actual distribution of contraceptives. It is a useful observation for policy that the two examples of closed health systems i.e., the DKT Health Clubs and the AstraZeneca Global Value Chain, are useful for correcting market failures in the upstream and downstream sector of the medicines supply chain respectively. Whereas excludability in the form of patents upstream may incentivize the research and development of new medicines, excludability downstream is useful for subsidizing the uptake of these medicines through health clubs.

10.2 Local and Global Governance of Health Systems

The problematization of where to locate the governance of Global Value Chains for medicines is central to this PhD. This problematization is against the backdrop of a world-system view of 'globalization' as the functional integration of core and noncore marked by dependency perpetuated through unequal exchange. The AstraZeneca Global Value Chains is the quintessential case of globalization driven by the lead firm from the productionist point of view, which governs through patent monopoly to create access to medicines. The AstraZeneca Global Value Chains displays no regard whatsoever for the local institutional arrangements in the noncore market. If it did, it would never have launched a medicine requiring product, labour and capital market structures that were simply unavailable in the noncore context. This is all the more striking giving that the lead firm had the same medicine in another formulation[22] which was easier to administer as it didn't require nebulizers but chose not to market it in Nigeria. As such cash strapped hospitals depended on donations of nebulizers for them to be able to use the product and teach the few patients who could afford it. The manager interview pointed out rightly, that from the global point of view, the Nigerian market was too small to warrant a change in the 'global strategy' of the lead firm. The global governance is justified on economies of scale by the lead firm. Paradoxically, the population of people with asthma who are 'too small' to justify changes to the global strategy of the lead firm outnumber the number of patients who have access to health insurance, paediatricians, and nebulizers.

On the other extreme of global governance is the free market completely devoid of lead firms and delivering fully commoditized medicines free of patents. This is the Open Value Chain. These Open Value Chains arise where there is no government regulation and where privatization is not possible. Internet Pharmacies in high income countries and the Open Drug Markets in low-income countries are the real-world examples of these free markets. Their nagging problem of quality assurance is the greatest risk to consumers who patronize them. They are local not because they are geographically close to the consumer, but because they do not allow dependency and unequal exchange to develop. The absence of patent monopolies and their spot-buying transactions also do not allow functional integration into universal health insurance systems that may crowd out suppliers and reduce the supplier base. From a world-system backdrop of globalization, the quality

[22] Pulmicort Flexhaler

assured free market is the local market. This is the ‘local’ bazaar (or fruit market) of many sellers and many buyers all jostling for space. The freedom from patents, lead firms, and long-term purchasing contracts is what sets the Open Value Chain apart as a local health system. Considering also that these medicines are sold over the counter and bought out of pocket, the local health system can be performed anywhere and at any time where there is a buyer and seller. The quality guarantee provided by DrugStoc only removed the clientelization which made the transactions sticky as consumers had to stick to known brands or known sellers for a guarantee of quality. Providing quality assurance as a neutral broker over the entire Open Value Chain containing numerous commodity chains which are free to enter and exit at will and at no cost transformed the transactions within the Open Value Chain to non-sticky and perfectly elastic transactions. There is therefore a dimension of local and global along which health governance may be performed ranging from the self-interested lead firm using patent monopoly privileges, to the neutral broker providing a quality guarantee over an open health system. Putting these two dimensions of Open and Closed Health Systems together with Local and Global Health Governance gives the following conceptualization.

Fig 10.1 Health System Matrix

10.3 Cost of Internalization: Health Impact and Supply Risk Considerations

There is still need for health policy makers to decide on the allocation of resources between health needs and priorities, and which health costs should be internalized in state health budgets, and which should be externalized. There cannot be a one-size-fits all approach to health financing as the epidemiology of noncore zones varies from that of core zones. Core economic zones which have achieved food security, sanitation and environmental control have seen their disease profiles shift from infectious diseases to noncommunicable diseases. Conversely, noncore zones of the world today face a double burden of infectious and noncommunicable diseases. The reasons for this are varied and need not detain us here, but the key issue here is that within the same national boundaries, there are core and noncore areas afflicted with largely noncommunicable and infectious diseases respectively.

In noncore regions with poor infrastructure where sanitation and hygiene predispose people to infectious diseases coexist with core regions where the urban lifestyle predisposes people to sedentary habits and the attendant cardiovascular issues. Malaria, Tuberculosis and HIV are largely health problems with high health impact for noncore regions and zones. Diabetes, Hypertension and Obesity are largely health problems with high impact on the budgets of core contexts. This mixed epidemiology of communicable and noncommunicable requires that health systems should be designed to fit the prevailing health needs. The choice of which health system arrangement to opt for should depend on the health impact and the availability of health service suppliers. This consideration will have to be made on a case-by-case basis for each disease category and in each locality and will also depend on the ability of the people to pay.

For high impact diseases with many health services suppliers, the KNCU Health-Plan shows a way for communities affected to pool risk and negotiate for improved access to medicines using a leveraged purchasing strategy. Originally the need for medical care following the farm accidents provided a high impact health situation around which to build the KNCU Health-Plan. Community health systems allow consumers to self-select their own health priorities and negotiate the cost of access to medicines among many suppliers of health services. This provides medicines at the lowest possible cost to the individual and the community especially when the cost of access to medicines is high and the suppliers are many. Ideally, these community health systems should be open ended to allow the

group to grow and increase in size, and in the effectiveness of its negotiation. However, the notion of community as only those who share a common socioeconomic foundation, such as coffee farming is anachronistic. Digital information technology provides a way for noneconomic communities to form. These are special interest communities which have a shared interest and common knowledge about a common pooled resource. A group of mothers whose children attend different schools within a community can create an online community to negotiate lower fees or better-quality teaching. The point here is that there is room for groups of patients to form online communities of medicine users and effectively negotiate for better access to medicines. They do not need to belong in the same job or industry or district, but with principles of Common Pool Resource governance, they can create virtual, scalable, and effective communities through digital technology.

There are however health conditions with high health impact and for which suppliers of medicines are few and far in between, or for which the current medicines do not provide a definitive cure. Cancer, Hypertension, Type II Diabetes, Backpain, Rheumatoid Arthritis, Asthma are a few examples. These conditions are due for global partnerships between universities, governments, and industry to develop new medicines to cure them. These health conditions require levels of resource, talent, and coordination which may not lie in one firm, country or even industry. Thus, there is a need for global health systems designed to bring these partnerships to bear in solving the global health challenges. The COVID-19 pandemic presented the world with a unique opportunity for such a global coalition, but the results have not yielded equitable access to the technologies developed[23]. It is important that equitable patent sharing agreements are written into these coalitions *apriori* to avoid their corporate and state capture.

For health needs with a low impact on the health budget, access to medicines can be provided efficiently through the Open Health System of the open drug market where the suppliers are plentiful. This open market strategy will provide access to medicines theoretically at the lowest possible cost to the individual and the community. Drugstoc demonstrates that this Open Health System can be quality assured by a neutral broker using digital IT technology to guarantee the supply chain, ideally for a small, fixed fee on out-of-pocket transactions. Trying to fold the open drug market under a government owned

[23] Bill Gates came under fire for refusing to share the patent with Indian generic manufacturers who have capacity to produce and at lower cost (Kilander, 2021).

supply chain as Nigeria has been trying to do proves too costly as the cost of internalization far exceeds the gains from doing so.

Where the health impact of the condition is low and the suppliers ae few, the situation becomes critical for the few people affected by the condition. These people are too few to form community and are often ignored by government health policy. They quickly become those left behind by both community and state. Ideally this is left to health clubs formed for the sole purpose of guaranteeing access to medicines through subsidies. This is where the charities, NGO's and especially the Church medical missions have distinguished themselves, not only in brokering access to medicines but also providing the knowledge dimension to bring these neglected challenges to light.

These four arrangements cover the possible configurations of health systems for working in the noncore regions of the world. It is as much an eclectic strategy for access to medicines as it is an inclusive approach. The state is fragile or non-existent in the noncore zones of the world health system. What this conclusion chapter recommends is that the noncore environment cannot and indeed should not be organized under one universal health system. Rather the more informed and practical approach is to have all four health systems running alongside each other. Open Health Markets, Local Health Communities, Health Clubs, and Global Health Partnerships for new solutions. The fact that the strong states of the core context employ a single system approach to fulfil all four dimensions does not transfer to the noncore situation. Rather health policy makers should endeavour to pay attention to the institutional contexts and provide access to medicines through whichever health system provides medicines at the lowest cost to the individual and to the community. This is the road less travelled.

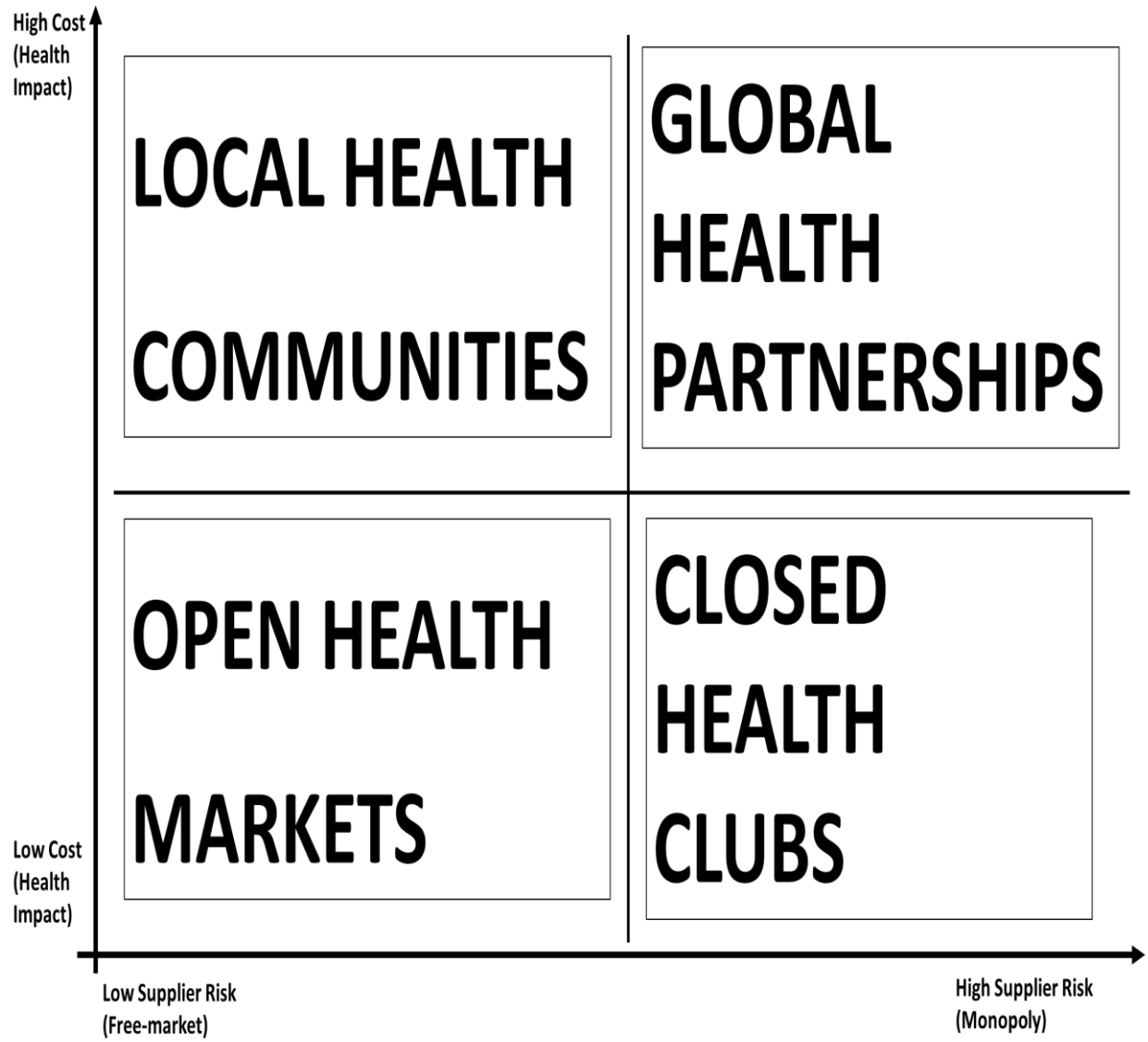


Fig 10.2: Health Group Matrix

10.4 The role of institutional intermediaries.

Institutional intermediaries in Global Value Chains have an important role to play in helping groups of consumers to self-organize towards access to medicines in the noncore context where universal healthcare is unsustainable. Just like PharmAccess they can play a midwifery role to help transform local communities into health communities. The noncore context is awash with these indigenous institutional arrangements such as the cooperative, the market women's group, the trade workers union, and the village age group that can serve as institutional infrastructure for health communities. However, these groups have varying levels of alignment with the eight design principles for Common Pool Resource governance. The market women's association which PharmAccess tried to work with in creating a health plan in Nigeria did not turn out as successfully as the KNCU Health-Plan. There were key dimensions of Common Pool Resource governance that are missing in associations compared to cooperatives. It is in identifying these missing performance dimensions and institutionalizing them into existing groups that institutional intermediaries have their role to play. Institutional intermediaries should also seek to create access to medicines using institutional strategies that align with the purchasing strategy required. Rare disease, orphan drugs and neglected diseases, and fragmented communities require health clubs that can be subsidized either by the state of NGO's. paradoxically, much of the interventions by the WHO in noncore contexts is geared towards 'health system strengthening'. But this strengthening is mostly devoted towards public health systems that promise and fail to deliver universal health coverage. Very few if any health interventions successfully develop health clubs and communities in the field. Even when they do, they are soon hijacked by forces seeking to reproduce them by extension rather than by reproduction. The advice is to hurry slowly. This role of transforming and reproducing health clubs and communities is not only indicated for the noncore contexts of Africa, Asia, and Latin America. Even in the core countries, there are noncore spaces in the inner-city slums that beg for improved access to medicines through institutional intermediation. These spaces include the illegal migrant, the homeless, the unemployed and underemployed, the uninsured and uninsurable. For these groups, is either too expensive to extend existing healthcare systems to them or too difficult to administrate the range of special interest healthcare groups. The problem of drug abuse for instance suggests that decriminalization accompanied by strong health clubs like Alcoholics Anonymous may be

a better strategy than simply decriminalization and free needles programmes. Some organizations are beginning to tap into this strategy of health clubs for solving other social programmes. For example, Kenco the British coffee maker has started a coffee farmers club in Latin America to train young teenagers from the slums to become coffee farmers and avoid a life of crime. The graduates are given interest free loans to start up their businesses after the 11 month training programme (Kenco, 2015). It is important that these institutional intermediaries employ community health workers for reproduction and not for extension. These workers drawn from the communities in which they live bring with them very vital legitimating functions especially when they are people of high repute and moral excellence within the community, as the KNCU Health-Plan demonstrates. It is suggested that they be called community health reproduction workers instead of community health extension workers. In community health reproduction, their job is the reproduction of health communities and clubs through performance of a common knowledge dimension that transforms people from passive consumers of healthcare to active leadership in the governance of value chains in health.

10.5 The role of Government.

Hitherto, the role of governments in health, especially following the core-state model has been as guarantor and provider of healthcare services and systems. That is, governments provide the financial backing for state health insurance schemes, and also undertake to organize the health facilities and workers to provide healthcare services. In noncore parts of the world with institutional voids, this model is simply unworkable. In these parts of the world where the state is fragile or absent, the KNCU Health-Plan proposes an entrepreneurial role for the state rather than the welfare role. The KNCU case demonstrates that the state can take on a role of system architect rather than provider of healthcare services. This implies that the state only acts as co-payment provider and administrator of health insurance schemes. The state can actively encourage consumers to self-organize by providing counterpart funding to health communities to sustain their efforts. The funding should be applied on a capitation model disbursed directly from the state to the health

facilities[24]. This counterpart funding is necessary to cover the administrative costs of the scheme. The KNCU Health-Plan failed to mobilize this administrative fee effectively for reasons unknown. Without it, health communities may collapse due to lack of funding.

This entrepreneurial role depoliticizes the creation and delivery of healthcare services. In this role, the state does not undertake the building of health facilities, nor do they employ the health professionals and health workers to operate them. In the entrepreneurial model, the state does not collect health insurance premiums paid by the consumers in their health communities and health clubs. The premiums and co-payments are managed by a completely autonomous, and neutral broker, acting as an actuarial services provider to these groups of consumers and health facilities. These licensed health management organizations collect the premiums from the consumers and co-payments from the state to pay out reimbursements to the health facilities per capitation. These Health Management Organization can be reviewed by health facilities, consumer groups, and the government for conformance to punctuality in payment and accountability. The health communities and health clubs can in turn vote with their feet according to service level agreements between them and the facilities each year. This feature allows poor service providers to lose business and is an incentive for health facilities to undertake upgrading and improvement.

An important lesson from the KNCU case is the need for soft loans at nearly zero interest rates for health facilities to undertake upgrading and improvement in their service delivery. This is where the Central Bank can set aside health improvement funds which health facilities can apply for. At the moment, the Central Bank of Nigeria has set up a similar funding mechanism at half the commercial interest rates, for farmers to boost food production through agricultural investment. Disbursing these loans under a project management methodology to provide operational support to private health facilities in the country is what marks the purposeful use of capital to generate innovation in healthcare services as entrepreneurial (Drucker, 2002). The disbursement of these soft loans can be made to reflect the policy priorities of the government as fiscal health policy either to emphasize support for primary, secondary, or tertiary health services as the need be. Where these funds are disbursed at federal, regional, and local government levels, they can also be made to fulfil the need for subsidiarity in their allocation.

[24] Funding by utilization rates results in the ballooning of health costs as the KNCU case demonstrated.

In this arrangement, the entrepreneurial state should look upon these health communities and health clubs as start-ups and the health premium co-payment as funding. From the lessons of the KNCU case, these co-payments should include an administrative fee per user to enable the HMO generate income for administrating the scheme. These premiums should be renegotiated annually between the consumers and health facilities to adjust them according to demographic changes in membership and market realities and allow portability after a minimum one-month period to avoid adverse selection problems. The responsibility of regulating Health Management Organizations rests on the Ministry of Health. Antitrust legislation to avoid oligopolies are important and should specify a limit to the number of consumers a Health Management Organization is allowed to serve. Research from the FDA demonstrates that where there are more than ten suppliers of health products in a given market, the prices are competitive with as little as 5% variation. Maintaining a healthy competition between Health Management Organizations is important to avoid powerful organizations which can capture the field and internalize the environment. It is this systems architecture role that the noncore government can effectively perform to ensure free play among suppliers in the provision of health services.

This entrepreneurial role requires that the state in noncore settings completely relinquishes control over health facilities and programmes and leaves this responsibility to the private sector. Thus, limiting the role of government to facilitator and guarantor of health services.

The quality improvement function for upgrading health facilities should also be played by the state through the ministry of health. It should be remembered that the disease surveillance capability developed in Polio programmes which the Nigerian government used to stop the spead of Ebola in 2015 was domiciled at the federal level, while operational capacity came largely from the private sector. Maintaining operational capability at the federal level tasked with helping private health facilities to upgrade using project management methodology to attain international certifications of quality is the third function of the entrepreneurial role of the state in health. There is however a risk that politicians may attempt to politicize the health model by raising the co-payment contribution of the government. Or to create special co-payment rates and even exemptions for indigent groups. The resulting problems from these attempts to extend the KNCU Health-Plan into a regional and national programme of universal healthcare are stark reminder of how good intentions can have perverse outcomes. The indigent patients who *cannot* pay should be catered for through health clubs run by the third sector to avoid

politicization of their plight by politicians in search of cheap popularity. Those who *will not* pay are free to purchase health out-of-pocket through the open market. But in order to do so effectively, there is need for a common knowledge dimension to be performed, which the DKT were unwilling to sustain. This common knowledge dimension of distributing health knowledge throughout the community using community health extension workers can only be effectively sustained by the state. Without it, health communities and clubs may fail to form, and out-of-pocket health expenditure can quickly turn catastrophic.

In conclusion, the state through the Ministry of Health performs three functions: counterpart health insurance funding, a common knowledge dimension, and quality improvement of health services through an internationally accredited project management methodology. These constitute the entrepreneurial role of the state in healthcare service delivery.

10.6 The role of the Private Sector:

The open health market which is the mainstay of the noncore health system is a private health market. The facilities in this market are wholly private sector entities, supplying health services out-of-pocket. However, these is scope for these private providers of healthcare services to at the same time supply services to health communities and health clubs under negotiated health insurance schemes brokered by Health Management Organizations. There is nothing to be gained from forcing these private providers to deliver their services entirely through the health insurance model, and in fact, forcing consumers to take up health insurance should be illegal. Private health facilities should also be precluded from setting up their own Health Management Organization, to avoid possible conflicts of interest in the market. In the same vein, Health Management Organizations should be precluded from setting up or running healthcare facilities and for the same reason. These private health facilities themselves in this noncore model of health can pick and choose which Health Management Organization to work with in providing which service to a particular group of consumers, while retaining their independence to offer out-

of-pocket health services into the open health market. These certifications should be voluntary and independent.

The private health facilities in this noncore model of health carry the capacity for delivering healthcare services as suppliers in the open market, health communities, and health clubs.

10.7 The role of Meta-Organizations:

Large multilateral organizations such as the WHO have a role to play as neutral brokers of global health partnerships for building capability towards health improvement. Beginning in the 1950's, the WHO had championed a largely developmental view of health until the departure of the Soviet Bloc. This allowed the American led coalition to shift the focus from broad comprehensive health programmes to technology driven single focus programmatic interventions. The return of the Soviet Bloc again brought in the 'health as development' view into the WHO. This comprehensive view of health resulted in the Alma Ata declaration which proposed primary health as the foundation for public health.

There is a well sustained criticism of the WHO that today it has relinquished its operational capacity in responding to health challenges. The Ebola crises of 2015 demonstrated this lack of operational capacity in the WHO as it could not mobilize boots on the ground effectively nor coordinate a containment strategy leading to a disastrous outcome. It took the efforts of the British Army in Sierra Leone and MSF to mobilize resources for mitigating the disaster. The Nigerian government however was more successful in mobilizing resources from its National Polio Immunization programme to successfully contain the Ebola outbreak early. It is however important to note that the epidemiological capabilities the Federal Government had been developed at the Ministry of Health in partnership with the WHO. This operational capability in infectious disease surveillance at the federal government level was matched with operational capacity in the private sector to quickly halt the spread of Ebola. Other countries in West Africa which had eradicated Polio and therefore no longer had strong capability in the surveillance and control of infectious disease outbreaks could not mobilize effectively without external aid. The successful match in Nigeria between operations management capability at the Federal level and operational capacity supplied locally by the private sector points exactly where to

locate operations management capability in health. Meta-organizations like the WHO should work with governments to embed these capabilities at the national level in noncore contexts while allowing the private sector to contribute operating capacity.

This role of meta-organizations like the WHO in brokering the knowledge transfer and knowledge sharing at national level is increasingly important for the management of international health problems. Whether it be the creation of new knowledge to guide treatment, or patent pooling for improved access to newer and effective health technologies, meta-organizations should focus on improving operational capability for health within government and leave the operations capacity to the private sector suppliers. Trying to deliver both operational capability and capacity is too expensive, takes too long, and is largely unsustainable. These might be at the root of the criticism that the WHO is increasingly prone to voluntary contributions from external organizations with conflicting interests. A reset of the WHO back to its original role as an intergovernmental agency for brokering cooperation and collaboration in developing new capabilities for solving international health problems is recommended. Not to mention that it can be construed as state capture when meta-organizations take on the responsibility of supplying capacity and capability in national health systems. Rather meta-organizations such as the International Standards Organization can work with national governments to develop accredited quality improvement methodologies for upgrading health facilities in the private sector. This requires deepening the project management capabilities for quality improvement intervention which PharmAccess provided as SafeCare in the KNCU Health-Plan.

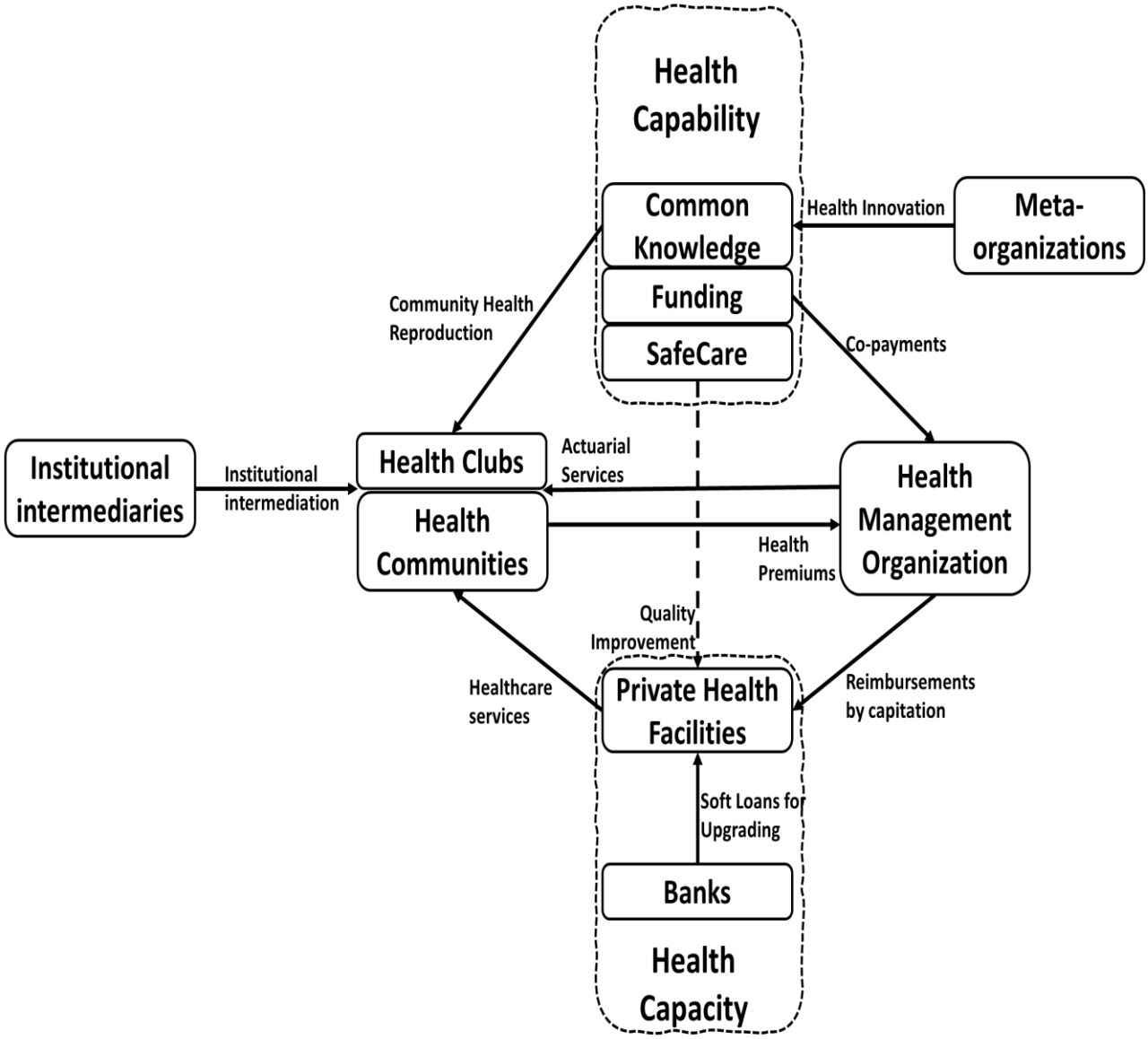


Fig 10.3: A Conceptual Framework for Governance in Noncore Value Chains for Health.

The conceptual framework above summarizes these roles and functions. The major difference is the separation of operational capability from operational capacity in the noncore context where the state is unable to perform both roles. There is also recognition of the institutional intermediaries that play a role in transforming health consumers into health communities and health clubs through the eight design principles for Common Pool Resource governance. This institutional intermediary role is supported by local community health reproduction workers who are domiciled within the community to disseminate common health knowledge within their respective communities supported and funded by the federal government. This knowledge dimension is critical to enable health consumers to take the lead in driving the value chain for health services with a preventive focus.

This model of health offers a new way of organizing and mobilizing for health in the noncore parts of the world where the state is fragile or absent, and where the open market for medicines is the major location of capacity for healthcare services. But it begins with the recognition that the institutional voids are not a curse but simply a different type of institutional arrangement that requires a new kind of value chain governance. As globalization proceeds, the polarization it creates between core and noncore will not go away, rather it will become more acute. Health policy which ignores that the noncore is as much a part of the 'global' as the core, will increasing struggle to be effective across these institutional contexts. What the KNCU Health-Plan, the DKT Bees Programme, and DrugStoc's quality assured supply chain demonstrate is that value chain governance, and health in particular was never global. It is either core or noncore.

References.

Adeloye, D. *et al.* (2017) 'Health workforce and governance: the crisis in Nigeria', *Human Resources for Health*, 15(1), p. 32. Available at: https://doi.org/10.1186/s12960-017-0205-4.

Ahrne, G. and Brunsson, N. (2005) 'Organizations and meta-organizations', *Scandinavian journal of Management*, 21(4), pp. 429–449.

Alford, M. and Phillips, N. (2018) 'The political economy of state governance in global production networks: change, crisis and contestation in the South African fruit sector', *Review of International Political Economy*, 25(1), pp. 98–121.

Archibugi, D. and Filippetti, A. (2010) 'The Globalisation of Intellectual Property Rights: Four Learned Lessons and Four Theses', *Global Policy*, 1(2), pp. 137–149. Available at: https://doi.org/10.1111/j.1758-5899.2010.00019.x.

Armanios, D.E. *et al.* (2017) 'How entrepreneurs leverage institutional intermediaries in emerging economies to acquire public resources', *Strategic Management Journal*, 38(7), pp. 1373–1390. Available at: https://doi.org/10.1002/smj.2575.

Arrighi, G., Silver, B.J. and Brewer, B.D. (2003) 'Industrial convergence, globalization, and the persistence of the North-South divide', *Studies in Comparative International Development*, 38(1), p. 3. Available at: https://doi.org/10.1007/BF02686319.

Asenso-Okyere, W.K. (1995) 'Financing health care in Ghana', in *World health forum 1995; 16 (1): 86-91*.

Bair, J. (2005) 'Global capitalism and commodity chains: looking back, going forward', *Competition & Change*, 9(2), pp. 153–180.

Baldwin, C.Y. (2015) *Bottlenecks, Modules and Dynamic Architectural Capabilities*. SSRN Scholarly Paper ID 2512209. Rochester, NY: Social Science Research Network. Available at: https://papers.ssrn.com/abstract=2512209 (Accessed: 27 May 2019).

Baldwin, C.Y. and Clark, K.B. (2000) *Design rules: The power of modularity*. MIT press.

BARRIENTOS Stephanie, GEREFFI Gary, and ROSSI Arianna (2012) 'Economic and social upgrading in global production networks: A new paradigm for a changing world', *International Labour Review*, 150(3-4), pp. 319–340. Available at: https://doi.org/10.1111/j.1564-913X.2011.00119.x.

Becker, H.S. and Ragin, C.C. (2009) *What is a case?: exploring the foundations of social inquiry*. Cambridge university press.

Behuria, P. (2020) 'The domestic political economy of upgrading in global value chains: How politics shapes pathways for upgrading in Rwanda's coffee sector', *Review of International Political Economy*, 27(2), pp. 348–376.

Bogsch, A. (1992) *Brief History of the First 25 Years of the World Intellectual Property Organization*. Available at: https://www.wipo.int/publications/en/details.jsp?id=3186&plang=EN (Accessed: 2 September 2022).

Bosh, K.A. *et al.* (2021) 'Estimated Annual Number of HIV Infections – United States, 1981–2019', *Morbidity and Mortality Weekly Report*, 70(22), pp. 801–806. Available at: https://doi.org/10.15585/mmwr.mm7022a1.

Braudel, F. (1981) *Civilization and capitalism, 15th-18th century*. London: Collins.

Buchanan, J.M. (1965) 'An Economic Theory of Clubs', *Economica*, 32(125), pp. 1–14. Available at: https://doi.org/10.2307/2552442.

Buckley, P.J. (2009) 'The impact of the global factory on economic development', *Journal of World Business*, 44(2), pp. 131–143. Available at: https://doi.org/10.1016/j.jwb.2008.05.003.

Bush, S.R. *et al.* (2019) 'Emerging trends in aquaculture value chain research', *Aquaculture*, 498, pp. 428–434.

Carlson, D.G. (1982) 'Drug Supply Systems in West Africa: A Historical Overview With Particular Reference to Nigeria', *Pharmacy in History*, 24(2), pp. 73–82.

Coase, R.H. (1937) 'The nature of the firm', *economica*, 4(16), pp. 386–405.

Coe, N.M., Dicken, P. and Hess, M. (2008a) 'Global production networks: realizing the potential', *Journal of Economic Geography*, 8(3), pp. 271–295. Available at: https://doi.org/10.1093/jeg/lbn002.

Coe, N.M., Dicken, P. and Hess, M. (2008b) 'Introduction: global production networks—debates and challenges', *Journal of Economic Geography*, 8(3), pp. 267–269. Available at: https://doi.org/10.1093/jeg/lbn006.

Coe, N.M. and Hess, M. (2013) 'Global production networks, labour and development', *Geoforum*, 44, pp. 4–9. Available at: https://doi.org/10.1016/j.geoforum.2012.08.003.

Contreras, O.F., Carrillo, J. and Alonso, J. (2012) 'Local entrepreneurship within global value chains: a case study in the Mexican automotive industry', *World development*, 40(5), pp. 1013–1023.

Correa, C. (2018) 'Will the amendment to the TRIPS agreement enhance access to medicines?', in *Routledge Handbook on the Politics of Global Health*. Routledge, pp. 321–331.

Crecine, J.P. and Brunner, R.D. (1972) 'Government and politics: A frag-mented society, hard to govern democratically-from another vantage point', in *The Conference Board Information Technology. New York: The Conference Board*.

Dedrick, J., Kraemer, K.L. and Linden, G. (2010) 'Who profits from innovation in global value chains?: a study of the iPod and notebook PCs', *Industrial and corporate change*, 19(1), pp. 81–116.

Dicken, P. *et al.* (2001) 'Chains and networks, territories and scales: towards a relational framework for analysing the global economy', *Global networks*, 1(2), pp. 89–112.

Dicken, P. (2015) *Global shift: mapping the changing contours of the world economy*. Seventh edition. New York, New York: The Guilford Press.

Drahos, P. (2002) 'Developing countries and international intellectual property standard-setting', *J. World Intell. Prop.*, 5, p. 765.

Drahos, P. (2007) 'Four lessons for developing countries from the trade negotiations over access to medicines', *Liverpool law review*, 28(1), pp. 11–39.

Drucker, P. (2012) *Management*. Routledge.

Drucker, P.F. (2002) 'The discipline of innovation', *Harvard business review*, 80(8), pp. 95–102.

Dussault, G. and Franceschini, M.C. (2006) 'Not enough there, too many here: understanding geographical imbalances in the distribution of the health workforce', *Human Resources for Health*, 4(1), p. 12. Available at: https://doi.org/10.1186/1478-4491-4-12.

Dutt, N. *et al.* (2016) 'How Open System Intermediaries Address Institutional Failures: The Case of Business Incubators in Emerging-Market Countries', *Academy of Management Journal*, 59(3), pp. 818–840. Available at: https://doi.org/10.5465/amj.2012.0463.

Eckstein, H. (2000) 'Case study and theory in political science', *Case study method*, pp. 119–164.

Ekeigwe, A.A. (2019) 'Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation', *AAPS Open*, 5(1), p. 3. Available at: https://doi.org/10.1186/s41120-019-0032-x.

Ernst, D. (2002) 'Global production networks and the changing geography of innovation systems. Implications for developing countries', *Economics of Innovation and New Technology*, 11(6), pp. 497–523. Available at: https://doi.org/10.1080/10438590214341.

Evans, D.K., Holtemeyer, B. and Kosec, K. (2019) 'Cash transfers increase trust in local government', *World Development*, 114, pp. 138–155. Available at: https://doi.org/10.1016/j.worlddev.2018.08.020.

Fatoki, S. and Awodele, O. (2017) 'Anticounterfeiting strategies of local drug manufacturers in Lagos, Nigeria: Drug safety and implications for public health', *Journal of Population Therapeutics and Clinical Pharmacology*, 24(3), pp. e99–e120.

Finger, J.M. and Nogués, J.J. (2001) 'The unbalanced Uruguay Round outcome: the new areas in future WTO negotiations'.

Garner, P. (1989) 'The Bamako initiative.', *BMJ: British Medical Journal*, 299(6694), p. 277.

Geertz, C. (1978) 'The Bazaar Economy: Information and Search in Peasant Marketing', *The American economic review*, 68(2), pp. 28–32.

George, A.L. (2019) 'Case studies and theory development: The method of structured, focused comparison', in *Alexander L. George: A pioneer in political and social sciences*. Springer, pp. 191–214.

George, A.L. and Bennett, A. (2005) *Case studies and theory development in the social sciences*. mit Press.

Gereffi, G. (1995) 'Global Production Systems and Third World Development', in, pp. 100–142. Available at: https://doi.org/10.1017/CBO9781139174336.004.

Gereffi, G. (1996) 'Global commodity chains: new forms of coordination and control among nations and firms in international industries', *Competition & Change*, 1(4), pp. 427–439.

Gereffi, G. (1999) 'International trade and industrial upgrading in the apparel commodity chain', *Journal of International Economics*, 48(1), pp. 37–70. Available at: https://doi.org/10.1016/S0022-1996(98)00075-0.

Gereffi, G. (2001) 'Beyond the Producer-driven/Buyer-driven Dichotomy The Evolution of Global Value Chains in the Internet Era', *IDS bulletin*, 32(3), pp. 30–40.

Gereffi, G., Humphrey, J. and Sturgeon, T. (2005) 'The Governance of Global Value Chains', *Review of International Political Economy*, 12(1), pp. 78–104.

Gereffi, G. and Korzeniewicz, M. (1994) *Commodity chains and global capitalism*. Westport, Conn. ; London: Praeger (Contributions in economics and economic history).

Gilbertson, M.R. (2015) 'Globalization and the sex trafficking industry: examination of effects on regional value chain operations'.

Goncharuk, A.G. (2017) 'Wine value chains: Challenges and prospects', *Journal of Applied Management and Investments*, 6(1), pp. 11–27.

Grabs, J. and Ponte, S. (2019) 'The evolution of power in the global coffee value chain and production network', *Journal of Economic Geography*, 19(4), pp. 803–828. Available at: https://doi.org/10.1093/jeg/lbz008.

Guevara, E. (1960) *On Revolutionary Medicine*. Available at: https://www.marxists.org/archive/guevara/1960/08/19.htm (Accessed: 29 August 2022).

Hardin, G. (1968) 'The Tragedy of the Commons', *Science*, 162(3859), pp. 1243–1248. Available at: https://doi.org/10.1126/science.162.3859.1243.

Harris, D.P. (2004) 'TRIPS'rebound: An historical analysis of how the TRIPS Agreement can ricochet back against the United States', *Nw. J. Int'l L. & Bus.*, 25, p. 99.

Harris, D.P. (2006) 'Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion', *U. Pa. J. Int'l Econ. L.*, 27, p. 681.

Harvey, P.D. (2011) *The Government vs. Erotica: The Siege of Adam & Eve*. Prometheus Books.

Henderson, J. *et al.* (2002) 'Global production networks and the analysis of economic development', *Review of International Political Economy*, 9(3), pp. 436–464. Available at: https://doi.org/10.1080/09692290210150842.

Hess, M. (2004) '"Spatial" relationships? Towards a reconceptualization of embedded ness', *Progress in Human Geography*, 28(2), pp. 165–186. Available at: https://doi.org/10.1191/0309132504ph479oa.

Hess, M. and Yeung, H.W.-C. (2006) 'Whither Global Production Networks in Economic Geography? Past, Present, and Future', *Environment and Planning A: Economy and Space*, 38(7), pp. 1193–1204. Available at: https://doi.org/10.1068/a38463.

Hilson, G. and Potter, C. (2005) 'Structural Adjustment and Subsistence Industry: Artisanal Gold Mining in Ghana', *Development and Change*, 36(1), pp. 103–131. Available at: https://doi.org/10.1111/j.0012-155X.2005.00404.x.

Hopkins, T.K. and Wallerstein, I. (1977) 'Patterns of development of the modern world-system', *Review (Fernand Braudel Center)*, pp. 111–145.

Humphrey, J. and Schmitz, H. (2000) 'Governance and upgrading in global value chains', *Governance and Upgrading: Linking Industrial Cluster and Global Value Chain Research. Brighton: University of Sussex* [Preprint].

Humphrey, J. and Schmitz, H. (2002a) 'Developing country firms in the world economy: Governance and upgrading in global value chains'.

Humphrey, J. and Schmitz, H. (2002b) 'How does insertion in global value chains affect upgrading in industrial clusters?', *Regional studies*, 36(9), pp. 1017–1027.

Humphrey, J. and Schmitz, H. (2008) 'Inter-firm relationships in global value chains: trends in chain governance and their policy implications', *International Journal of Technological Learning, Innovation and Development*, 1(3), pp. 258–282.

Hymer, S. (1970) 'The Efficiency (Contradictions) of Multinational Corporations', *The American Economic Review*, 60(2), pp. 441–448.

Jacobs, J. (1984) *Cities and the Wealth of Nations: Principles of Economic Life*. Random House.

Jacobs, J. (2007) *Dark age ahead*. Vintage.

Jacobs, J. (2016) *The death and life of great American cities*. London: Vintage Digital.

Jespersen, K.S. *et al.* (2014) 'What shapes food value chains? Lessons from aquaculture in Asia', *Food Policy*, 49, pp. 228–240. Available at: https://doi.org/10.1016/j.foodpol.2014.08.004.

Kaltenegger, O., Löschel, A. and Pothen, F. (2017) 'The effect of globalisation on energy footprints: disentangling the links of global value chains', *Energy Economics*, 68, pp. 148–168.

Kapologwe, N.A. *et al.* (2020) 'Development and upgrading of public primary healthcare facilities with essential surgical services infrastructure: a strategy towards achieving universal health coverage in Tanzania', *BMC health services research*, 20(1), p. 218. Available at: https://doi.org/10.1186/s12913-020-5057-2.

Kaur, H. *et al.* (2015) 'Quality of Artemisinin-Based Combination Formulations for Malaria Treatment: Prevalence and Risk Factors for Poor Quality Medicines in Public Facilities and Private Sector Drug Outlets in Enugu, Nigeria', *PLOS ONE*, 10(5), p. e0125577. Available at: https://doi.org/10.1371/journal.pone.0125577.

Kenco (2015) *Graduating Coffee vs Gangs: farewell to fear - YouTube*. Available at: https://www.youtube.com/watch?v=DDurjELVAxc (Accessed: 15 September 2022).

Khanna, T. and Palepu, K.G. (2011) 'Winning in emerging markets: Spotting and responding to institutional voids'.

Kilander, G. (2021) *Bill Gates under fire for saying vaccine formulas shouldn't be shared with developing world*, *The Independent*. Available at: https://www.independent.co.uk/news/world/americas/bill-gates-covid-vaccines-countries-b1837884.html (Accessed: 14 September 2022).

Klopp, J.M. and Paller, J.W. (2019) 'Slum politics in Africa', in *Oxford Research Encyclopedia of Politics*.

Konadu-Agyemang, K. (2000) 'The best of times and the worst of times: structural adjustment programs and uneven development in Africa: the case of Ghana', *The Professional Geographer*, 52(3), pp. 469–483.

Kondratieff, N.D. (1979) 'The long waves in economic life', *Review (Fernand Braudel Center)*, pp. 519–562.

Kraljic, P. (1983) 'Purchasing must become supply management', *Harvard business review*, 61(5), pp. 109–117.

Lan, T. and Zhu, S. (2014) 'Chinese apparel value chains in Europe: low-end fast fashion, regionalization, and transnational entrepreneurship in Prato, Italy', *Eurasian Geography and Economics*, 55(2), pp. 156–174.

Lazarsfeld, P.F. (1966) 'Philosophy of science and empirical social research', in *Studies in Logic and the Foundations of Mathematics*. Elsevier, pp. 463–473.

Lee, J., Gereffi, G. and Nathan, D. (2013) 'Mobile Phones: Who benefits in shifting global value chains?', *Capturing the Gains, Revised Summit Briefing* [Preprint], (6.1).

Lewis, W.A. (1954) 'Economic Development with Unlimited Supplies of Labour', *The Manchester School*, 22(2), pp. 139–191. Available at: https://doi.org/10.1111/j.1467-9957.1954.tb00021.x.

Lin, J. and Chang, H.-J. (2009) 'Should Industrial Policy in Developing Countries Conform to Comparative Advantage or Defy it? A Debate Between Justin Lin and Ha-Joon Chang', *Development Policy Review*, 27(5), pp. 483–502. Available at: https://doi.org/10.1111/j.1467-7679.2009.00456.x.

Maghimbi, S. (2010) *Cooperatives in Tanzania mainland: Revival and growth*. ILO.

Mair, J. and Marti, I. (2009) 'Entrepreneurship in and around institutional voids: A case study from Bangladesh', *Journal of business venturing*, 24(5), pp. 419–435.

Mair, J., Martí, I. and Ventresca, M.J. (2012) 'Building inclusive markets in rural Bangladesh: How intermediaries work institutional voids', *Academy of Management Journal*, 55(4), pp. 819–850.

Maluka, S. *et al.* (2018) 'Contracting-out primary health care services in Tanzania towards UHC: how policy processes and context influence policy design and implementation', *International Journal for Equity in Health*, 17(1), p. 118. Available at: https://doi.org/10.1186/s12939-018-0835-8.

Mcdermott, G.A., Corredoira, R.A. and Kruse, G. (2009) 'Public-Private Institutions as Catalysts of Upgrading in Emerging Market Societies', *The Academy of Management Journal*, 52(6), pp. 1270–1296.

Merton, R.K. (1968) *Social theory and social structure*. 1968 enlarged edition. New York: Free Press.

Munger, E.S. (1952) 'African Coffee on Kilimanjaro: A Chagga Kihamba', *Economic Geography*, 28(2), pp. 181–185. Available at: https://doi.org/10.2307/141027.

Noykhovich, E., Mookherji, S. and Roess, A. (2019) 'The Risk of Tuberculosis among Populations Living in Slum Settings: a Systematic Review and Meta-analysis', *Journal of Urban Health*, 96(2), pp. 262–275. Available at: https://doi.org/10.1007/s11524-018-0319-6.

Ogbonna, B.O., Ilika, A.L. and Nwabueze, S.A. (2015) 'National drug policy in Nigeria, 1985-2015', *World Journal of Pharmaceutical Research*, 4(6), pp. 248–264.

Olaniran, A. *et al.* (2017) 'Who is a community health worker?–a systematic review of definitions', *Global health action*, 10(1), p. 1272223.

Organization, W.H. (2007) 'Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines'.

Ostrom, E. (1990) *Governing the commons: the evolution of institutions for collective action*. Cambridge: Cambridge University Press (The political economy of institutions and decisions).

Oyetunde, O. and Ilozumba, P. (2013) 'Mobile Authentication Service: Curbing circulation of fake Medicines and Assessing Consumer's Response', *West African Journal of Pharmacy*, 24(2), pp. 102–108.

Oyeyemi, A.S. *et al.* (2020) 'The potential role of patent and proprietary medicine vendors' associations in improving the quality of services in Nigeria's drug shops', *BMC Health Services Research*, 20(1), p. 567. Available at: https://doi.org/10.1186/s12913-020-05379-z.

Palepu, K.G. and Khanna, T. (1998) 'Institutional Voids and Policy Challenges in Emerging Markets', *The Brown Journal of World Affairs*, 5(1), pp. 71–78.

Parilla, J. (2017) 'America's cities compete for Amazon', *Intereconomics*, 52(6), pp. 379–380.

Perri, A. (2017) *Institutional Brokerage and the Governance of Global Value Chains: The Case of the US Apparel Industry*. PhD Thesis. University of South Carolina.

Pollack, A. (2015) 'Drug Goes From $13.50 a Tablet to $750, Overnight', *The New York Times*, 20 September. Available at: https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html (Accessed: 12 September 2022).

Polus, S. *et al.* (2015) 'Optimizing the delivery of contraceptives in low-and middle-income countries through task shifting: a systematic review of effectiveness and safety', *Reproductive health*, 12(1), pp. 1–13.

Ponte, S. (2009) 'Governing through Quality: Conventions and Supply Relations in the Value Chain for South African Wine', *Sociologia Ruralis*, 49(3), pp. 236–257. Available at: https://doi.org/10.1111/j.1467-9523.2009.00484.x.

Ponte, S. and Sturgeon, T. (2014) 'Explaining governance in global value chains: A modular theory-building effort', *Review of International Political Economy*, 21(1), pp. 195–223. Available at: https://doi.org/10.1080/09692290.2013.809596.

Prebisch, R. (1962) 'The economic development of Latin America and its principal problems', *Economic Bulletin for Latin America* [Preprint].

Raikes, P., Friis Jensen, M. and Ponte, S. (2000) 'Global commodity chain analysis and the French filière approach: comparison and critique', *Economy and society*, 29(3), pp. 390–417.

ur Rehman, H.A. (2011) 'WTO, compulsory export licences and Indian patent law', *Nordic Journal of Commercial Law*, (1), pp. 33–33.

Richey, L.A. and Ponte, S. (2020) 'Brand Aid and coffee value chain development interventions: Is Starbucks working aid out of business?', *World Development*, p. 105193. Available at: https://doi.org/10.1016/j.worlddev.2020.105193.

Ross, A.G. *et al.* (2021) 'Rise of Informal Slums and the Next Global Pandemic', *The Journal of Infectious Diseases*, 224(Supplement_7), pp. S910–S914. Available at: https://doi.org/10.1093/infdis/jiab492.

Ross, E. (2017) 'Command and control of Sierra Leone's Ebola outbreak response: evolution of the response architecture', *Phil. Trans. R. Soc. B*, 372(1721), p. 20160306. Available at: https://doi.org/10.1098/rstb.2016.0306.

Rugman, A.M. (2001) 'The myth of global strategy', *International Marketing Review* [Preprint].

Samuelson, P.A. (1998) *Economics*. 16th ed. Boston ; Irwin/McGraw-Hill (International student edition).

Scott, R. and Mokhiber, Z. (2020) *Growing China trade deficit cost 3.7 million American jobs between 2001 and 2018: Jobs lost in every U.S. state and congressional district*, *Economic Policy Institute*. Available at: https://www.epi.org/publication/growing-china-trade-deficits-costs-us-jobs/ (Accessed: 3 September 2022).

Sell, S.K. (2009) 'Cat and mouse: Forum-shifting in the battle over intellectual property enforcement', in *American Political Science Association Meeting*.

Shafaeddin, M.S. (2012) 'Trade liberalization and economic reform in developing countries: structural change or de-industrialization?', in *The IMF, World Bank and Policy Reform*. Routledge, pp. 155–182.

Shuaib, F. *et al.* (2014) 'Ebola Virus Disease Outbreak — Nigeria, July–September 2014', *MMWR. Morbidity and Mortality Weekly Report*, 63(39), pp. 867–872.

Spink, J., Moyer, D.C. and Rip, M.R. (2016) 'Addressing the risk of product fraud: a case study of the Nigerian combating counterfeiting and sub-standard medicines initiatives', *J Forensic Sci Criminol*, 4(2), p. 201.

Staricco, J.I. and Ponte, S. (2015) 'Quality regimes in agro-food industries: A regulation theory reading of Fair Trade wine in Argentina', *Journal of Rural Studies*, 38, pp. 65–76. Available at: https://doi.org/10.1016/j.jrurstud.2015.02.002.

'Strengthening the Private Health Sector in Africa: The PharmAccess Solution' (2017) *HMPI*, 6 September. Available at: https://hmpi.org/2017/09/06/strengthening-the-private-health-sector-in-africa-the-pharmaccess-solution/ (Accessed: 28 February 2022).

Stringer, C. and Michailova, S. (2018) 'Why modern slavery thrives in multinational corporations' global value chains', *Multinational Business Review* [Preprint].

Sturgeon, T., Van Biesebroeck, J. and Gereffi, G. (2008) 'Value chains, networks and clusters: reframing the global automotive industry', *Journal of Economic Geography*, 8(3), pp. 297–321. Available at: https://doi.org/10.1093/jeg/lbn007.

Sturgeon, T.J. (2001) 'How Do We Define Value Chains and Production Networks?*', *IDS Bulletin*, 32(3), pp. 9–18. Available at: https://doi.org/10.1111/j.1759-5436.2001.mp32003002.x.

Sturgeon, T.J. (2002) 'Modular production networks: a new American model of industrial organization', *Industrial and Corporate Change*, 11(3), pp. 451–496. Available at: https://doi.org/10.1093/icc/11.3.451.

Sturgeon, T.J. (2007) 'From commodity chains to value chains: interdisciplinary theory building in an age of globalization'.

Sturgeon, T.J. (2008) 'Mapping integrative trade: conceptualising and measuring global value chains', *International Journal of Technological Learning, Innovation and Development*, 1(3), pp. 237–257. Available at: https://doi.org/10.1504/IJTLID.2008.019973.

Sun, S.L., Chen, H. and Pleggenkuhle-Miles, E.G. (2010) 'Moving upward in global value chains: The innovations of mobile phone developers in China', *Chinese Management Studies* [Preprint].

'Task-Shifting and Task-Sharing Policy for Essential Health Care Services in Nigeria' (no date), p. 57.

The Project Gutenberg eBook of General Anatomy, Applied to Physiology and Medicine. Volume I, by Xavier Bichat. (no date). Available at: http://www.gutenberg.org/files/56118/56118-h/56118-h.htm#SYSTEMS (Accessed: 29 November 2019).

Turshen, M. (2014) 'A global partnership for development and other unfulfilled promises of the millennium project', *Third World Quarterly*, 35(3), pp. 345–357.

Vaz, R.G. *et al.* (2016) 'The Role of the Polio Program Infrastructure in Response to Ebola Virus Disease Outbreak in Nigeria 2014', *The Journal of Infectious Diseases*, 213(suppl_3), pp. S140–S146. Available at: https://doi.org/10.1093/infdis/jiv581.

Vernon, R. (1966) 'International Investment and International Trade in the Product Cycle', *The Quarterly Journal of Economics*, 80(2), pp. 190–207. Available at: https://doi.org/10.2307/1880689.

Wallerstein, I.M. (2004) *World-systems analysis: an introduction*. Durham: Duke University Press.

Ward, W. (1900) *The life and times of Cardinal Wiseman*. New impression. London: Longmans, Green and Co.

Williamson, O. and Ouchi, W. (1975) 'Markets and hierarchies: origins, implications, perspectives', *Perspectives in organizational design and behavior, New York: Wiley* [Preprint].

Williamson, O.E. (1973) 'Markets and Hierarchies: Some Elementary Considerations', *The American Economic Review*, 63(2), pp. 316–325.

Williamson, O.E. (1975) *Markets and Hierarchies: Analysis and Antitrust Implications: A Study in the Economics of Internal Organization*. SSRN Scholarly Paper ID 1496220. Rochester, NY: Social Science Research Network. Available at: https://papers.ssrn.com/abstract=1496220 (Accessed: 23 October 2018).

Williamson, O.E. (1979) 'Transaction-cost economics: the governance of contractual relations', *Journal of law and economics*, pp. 233–261.

Williamson, O.E. (1981) 'The economics of organization: The transaction cost approach', *American journal of sociology*, pp. 548–577.

Williamson, O.E. (1999) 'Public and Private Bureaucracies: A Transaction Cost Economics Perspective', *Journal of Law, Economics, & Organization*, 15(1), pp. 306–342.

Williamson, O.E. (2000) 'The new institutional economics: taking stock, looking ahead', *Journal of economic literature*, 38(3), pp. 595–613.

Williamson, O.E. (2002a) 'The Lens of Contract: Private Ordering', *American Economic Review*, 92(2), pp. 438–443. Available at: https://doi.org/10.1257/000282802320191769.

Williamson, O.E. (2002b) 'The Theory of the Firm as Governance Structure: From Choice to Contract', *The Journal of Economic Perspectives*, 16(3), pp. 171–195.

Yamin, M. and Sinkovics, R.R. (2009) 'Infrastructure or foreign direct investment?: An examination of the implications of MNE strategy for economic development', *Journal of World Business*, 44(2), pp. 144–157. Available at: https://doi.org/10.1016/j.jwb.2008.05.004.

Yeung, G. (2016) 'The operation of Global Production Networks (GPNs) 2.0 and methodological constraints', *Geoforum*, 75, pp. 265–269. Available at: https://doi.org/10.1016/j.geoforum.2016.07.017.

Yeung, H.W. and Coe, N. (2015) 'Toward a Dynamic Theory of Global Production Networks', *Economic Geography*, 91(1), pp. 29–58. Available at: https://doi.org/10.1111/ecge.12063.

You, J.-I. and Chang, H.-J. (1993) 'The Myth of Free Labour Market in Korea', *Contributions to Political Economy*, 12(1), pp. 29–46. Available at: https://doi.org/10.1093/oxfordjournals.cpe.a035619.

Zander, U. (2000) 'WHEN MUHAMMED GOES TO THE MOUNTAIN: GLOBALIZATION, CATHEDRALS OF MODERNITY, AND A NEW WORLD IN ORDER.', *Academy of Management Proceedings*, 2000(1), pp. G1–G6. Available at: https://doi.org/10.5465/apbpp.2000.5535061.

Zhang, F. and Gallagher, K.S. (2016) 'Innovation and technology transfer through global value chains: Evidence from China's PV industry', *Energy policy*, 94, pp. 191–203.

Zhang, Y. (2018) 'The credibility of slums: Informal housing and urban governance in India', *Land Use Policy*, 79, pp. 876–890. Available at: https://doi.org/10.1016/j.landusepol.2017.05.029.

Appendix.

MANCHESTER 1824
The University of Manchester

Participant Consent Forms

Designing Robust Governance for Pharmaceutical Supply Chains: A Global Value Chains Approach
If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (**Version 1, Dated 08/07/2019**) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3	I agree to the **interviews** being **audio recorded**.	
4	I agree that any data collected may be published in anonymous form in **academic books, reports or journals.**	
5	I understand that data collected during the study may be looked at by individuals from The University of Manchester or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
6	I agree that any **anonymised** data collected may be shared with **researchers/researchers at other institutions**.	
7	I agree that the **researchers** may contact me in future about other research projects.	
8	I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study.	
9	I agree to take part in this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the Privacy Notice for Research Participants.

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of the person taking consent	Signature	Date

[1 copy of this form will be provided for the participant and 1 copy for the research team (original)]

MANCHESTER 1824
The University of Manchester

UoM Research Participant Information Sheets

Designing Robust Governance for Pharmaceutical Supply Chains:
A Global Value Chains Approach

Participant Information Sheet (PIS)

Hello,

You are invited to take part in a research study on improving access to medicines as part of the requirements for the fulfilment of a PhD degree. Before you consider taking part in this research, it is important for you to understand why the research is being conducted and what it will involve. Please take the time you need to read the following information carefully before deciding whether to participate. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you.

If you have any questions, need further clarifications or would like more information, please do not hesitate to contact the primary researcher (details at the end of this document). Thank you for taking the time to read this.

About the Research

The study is on medicines and health services access in African countries. The African context is characterized by the usual suspects; mismanagement, weak systems and institutional fragility.

Currently, only 2% of the medicines consumed in Africa are produced on the continent. Most of it is imported over long distances and a fragmented infrastructure leading to scarcity and high costs. With a population set to add 1.2 billion people by 2050, the need for interventions in Africa to improve access to medicines and healthcare services is critical.

Africa is urbanizing rapidly, giving rise to a complex epidemiological picture of non-infectious (lifestyle) diseases compounded with infectious diseases. Recent and ongoing outbreaks of Ebola Virus Disease have demonstrated that the cost of failure is high not only for Africa, but to the world at large. This study looks at three successful interventions in health to improve access to medicines and health care services.

From: donotreply@infonetica.net
Sent: 19 July 2019 19:41
To: philippe.laredo@manchester.ac.uk; arinze.ekwem@manchester.ac.uk
Subject: Low Risk Ethics Application Received: 2019-7731-11438 (Automatic Email from the UoM Ethical Review Manager (ERM) system)

****Please ensure you read the contents of this message. This email has been sent via the Ethical Review Manager (ERM) system on behalf of the University of Manchester.****

Dear Dr Arinze Ekwem , Prof Philippe Laredo

Thank you for submitting your low risk ethics application for your project entitled: designing robust governance for pharmaceutical supply chains in africa ; Ref: 2019-7731-11438 which has now been approved by your supervisor and logged by the Ethics Administrator.

For those undertaking research requiring a DBS Certificate: As you have now completed your ethical application if required a colleague at the University of Manchester will be in touch for you to undertake a DBS check. Please note that you do not have DBS approval until you have received a DBS Certificate completed by the University of Manchester, or you are an MA Teach First student who holds a DBS certificate for your current teaching role.

If anything untoward happens during your research or any changes take place then please inform your supervisor immediately.

This approval is confirmation only for the low risk Ethical Approval application.

Please let us know if you have any additional queries by emailing:ethics@mbs.ac.uk .

Best wishes,

Mrs Lynne Barlow-Cheetham

Alliance Manchester Business School Panel