Making essential medicines accessible

Policy analysis of the revision and implementation of the national essential medicines list in Kenya

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Declaration by candidate

I have read and understood the LSHTM definition of plagiarism in the 2020-2021 Research Degrees Handbook. I have acknowledged all results and references from published or unpublished work of others.

This thesis presents original and independent work of the author.

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Abstract

BACKGROUND. Many countries, including Kenya, face challenges in ensuring equitable access to essential medicines. National essential medicines lists (EMLs) are policies to select priority medicines for which access should be ensured. The literature on the influences shaping EML formulation and implementation is scarce. This thesis aims to understand the factors that influence the policy processes of EML selection and implementation in Kenya to identify strategies to improve access to essential medicines.

METHODS. Through a case study, I explored Kenya EML (KEML) policy formulation (revision) at national level and implementation at national (macro), subnational (meso) and health facility (micro) levels. I used a qualitative health policy analysis approach, guided by a conceptual framework adapting the policy triangle and multiple governance frameworks. 41 semi-structured purposively selected interviews with key stakeholders were conducted and data were gathered through documents and non-participant observations. Deductive and inductive thematic analysis was applied.

RESULTS. Findings on the KEML revision highlighted that the medicine selection process was affected by resource constraints, evidence use limitations, insufficient stakeholder engagement, inadequate institutionalisation of the National Medicines and Therapeutics Committee, and the political context of universal health coverage. Macro- and meso-level factors influencing implementation included inadequate KEML dissemination and communication, insufficient medicines financing, and procurement restrictions. Support and accountability by sub-county health managers for health facility procurement and supply management facilitated implementation. At the micro-level, KEML uptake was constrained as it was perceived primarily as a procurement tool by healthcare workers, reflecting limited KEML awareness and knowledge. Local discretion in selecting KEML medicines was exercised based on perceived KEML content limitations, prescriber preferences, and through hospital medicines and therapeutics committees. Implementers were also often not provided the human or infrastructure resources to meet KEML goals.

CONCLUSION. The KEML revision process could particularly benefit from more representative stakeholder engagement and context-relevant evidence to guide decisions. Other strategies include institutionalised medicines and therapeutics committees at national and local levels, functional information channels between national and local levels, and alignment of the KEML with clinical guidelines and health financing policies. This study illustrates medicine selection as a multi-level process shaped by macro-, meso- and micro-level actors and contexts.

Acknowledgements

A tree has roots in the soil yet reaches to the sky. It tells us that in order to aspire we need to be grounded and that no matter how high we go it is from our roots that we draw sustenance. It is a reminder to all of us who have had success that we cannot forget where we came from. […] our power and strength and our ability to reach our goals depend on the people, those whose work remain unseen, who are the soil out of which we grow, the shoulders on which we stand.
— Wangari Maathai[1]

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[1] From "Unbowed: A Memoir"

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Asanteni sana.

DrPH Integrating Statement

After working in the field of public health policy in diverse roles for several years, the dual focus of LSHTM's DrPH programme in providing doctoral-level research training in pursuit of health improvement, as well as practical skills to manage and lead in public health drew me in. Pursuing this DrPH has been both a profound privilege and a challenge, particularly during the global pandemic. In this integrating statement I highlight my learnings throughout this degree and its three components: the taught courses, the Organisational and Policy Analysis (OPA), and the research thesis. In particular, I reflect on the links between my OPA and thesis, which allowed me to explore health policy research questions in two diverse countries, Canada and Kenya, that have both shaped who I am today in different ways.

The first four months of the DrPH involved two full-time taught modules in London. These were: 'Evidence Based Public Health Policy (EBPHP)' and 'Understanding Leadership, Management and Organisations (ULMO)'. EBPHP equipped me with skills to better evaluate scientific evidence, synthesize research and conduct systematic reviews, cultivate a theoretical and empirical understanding of public policy, and effectively communicate research findings to policymakers and the public. Through ULMO I learned about management frameworks and theories, particularly related to the public sector and non-governmental organisations; my own leadership style and how to strengthen these skills; and conceptual knowledge on governance that I've been able to apply as a board member for non-profit organisations. The most enriching aspect of the taught component was the opportunity to learn from and share experiences with my DrPH cohort. We came together from diverse countries, cultures, and professional backgrounds and bonded through our shared aspiration to improve health. I also took the MSc module on 'Economic Analysis for Health Policy' and audited distance learning modules on qualitative and social research methods.

I commenced this DrPH seeking to gain and contribute practical knowledge on policy as a structural driver of health and health inequities. Having completed my undergraduate and master's level education in biological sciences—deeply rooted in a positivist research paradigm—I was initially drawn to studying medicines as technical solutions to improve health. Throughout the DrPH, however, I engaged more deeply with the social determinants of essential medicines access, which Greene posits "is to engage with the project of understanding health disparities and the challenges of strengthening health systems at the most detailed level." [2] As a recovering positivist, this social research journey taught me how to analyse complex topics and to avoid reducing them to simplified versions of reality, as removing their complexity removes them from reality.

For the OPA, I undertook a project that would help me deepen my understanding of health inequities and health policy in Canada. I completed my OPA with a research team at St. Michael's Hospital (SMH), MAP-Centre for Urban Health Solutions in Toronto. The team, led by Nav Persaud, was working to develop evidence to guide the prospective development of an essential medicines list for Canada to support national pharmacare policy. With increasing public and political attention to pharmacare (prescription medication coverage) due to the inequities in access across the country, I conducted a qualitative study investigating the acceptability and feasibility of a national essential medicines list (EML) in Canada. In my previous advocacy work I considered EMLs as a policy tool to improve equitable medicines access based on the best available evidence, yet their application in high-income countries has been more limited. I sought to understand the opportunities and challenges in introducing such a list in Canada. The OPA findings were published in the Canadian Medical Association Journal in October 2019.[2] They were also shared with the Government's Federal Advisory Council on the Implementation of National Pharmacare through a 2018 consultation process. In 2019 the Advisory Council recommended the development of a national formulary, starting with a list of essential medicines.[3] I presented the OPA work at both the North American Primary Care Group Conference and at a SMH Global Essential Medicines Meeting in 2019.

In contrast to Canada, the national EML is a health policy fixture in Kenya, despite more recent efforts to achieve UHC. In the OPA I approached policy analysis for a national EML prospectively, whereas the thesis research took a retrospective approach. In both cases, I sought to analyse EMLs as tools to advance UHC and health equity. This thesis research was conceived out of my previous advocacy work on essential medicines and conversations with colleagues in Kenya and at the WHO on practical policy needs, and further developed through exploration of the literature. Through the application of similar qualitative methods in the OPA and thesis, I focused on deepening my qualitative research skills and knowledge through this DrPH. Examining EMLs and questions about their ties to and utility to advance UHC in the diverse contexts of Canada and Kenya provided empirical insight on the complex social dimensions of context and actors to determine policy adoption (in Canada) and implementation (in Kenya).

[2] Jarvis JD, Murphy A, Perel P, Persaud N. Acceptability and feasibility of a national essential medicines list in Canada: a qualitative study of perceptions of decision-makers and policy stakeholders. Canadian Medical Association Journal. 2019;191(40):E1093. https://www.cmaj.ca/content/191/40/E1093.abstract

[3] https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

Finally, I was able to complement my DrPH with additional work, master's level teaching, and extracurricular experiences that allowed me to further apply new knowledge and skills acquired through the DrPH. This included teaching on the distance learning MSc in Global Health Policy, consulting for the WHO's Essential Medicines & Health Products Department, serving on the Medicines Patent Pool Expert Advisory Group, and working part-time for the Global Alliance for Chronic Diseases.

Abbreviations

CDOH	County Department of Health
CEC	County Executive Committee
CHMT	County Health Management Team
COVID-19	Coronavirus disease 2019
DANIDA	Danish International Development Agency
DHPT	Division for Health Products and Medical Technologies
DrPH	Doctor of Public Health
EML	Essential medicines list
GDP	Gross Domestic Product
GOK	Government of Kenya
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
KEML	Kenya Essential Medicines List
KEMSA	Kenya Medical Supplies Authority
KEMSL	Kenya Essential Medical Supplies List
LMICs	Low- and Middle-Income Countries
LSHTM	London School of Hygiene and Tropical Medicine
M&E	Monitoring & Evaluation
MEDS	Mission for Essential Drugs and Supplies
MOH	Ministry of Health
MSH	Management Sciences for Health
MTC	Medicines and Therapeutics Committee
NACOSTI	National Commission for Science, Technology and Innovation
NCDs	Non-communicable diseases
NGO	Non-governmental Organisation
NMTC	National Medicines and Therapeutics Committee
NSA	Non-state actor
OPA	Organisational and Policy Analysis
SCHMT	Sub-County Health Management Team
SDGs	Sustainable Development Goals
SOPs	Standard Operating Procedures
STG	Standard Treatment Guideline
TWG	Technical Working Group
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organisation

1 Introduction and background

1.1 Introduction

Essential medicines can save lives, reduce suffering and improve health. Nonetheless, many countries, including Kenya, still face challenges in ensuring that such medicines are available, affordable, of good quality, and used appropriately by all people who need them [3]. Research on national essential medicines lists (EMLs), policies that delineate priority medicines for the country, could help shed light on ways to overcome these challenges. This DrPH thesis focuses on how the national EML in Kenya is implemented across national, subnational and health facility levels. Specifically, this work describes and critically analyses the policy processes for the Kenya Essential Medicines List (KEML), both national decision-making and implementation, and key influences on these processes. By providing an understanding of these processes, this research furthermore aims to inform policy and practice in a way that improves equitable access to essential medicines and achieves public health gains in line with the goals of the DrPH programme.

In this introductory chapter, I begin by describing the background and rationale for this study, followed by the thesis aims and objectives. Thereafter, I provide additional background to the study of access to medicines and describe the context for the Kenya case study. I conclude this chapter with an overview of the remainder of the thesis.

1.2 Study rationale

Significant health improvements have been achieved through the provision of essential medicines over the past century. Nevertheless, the benefits are unequally distributed: an estimated 2 billion people, primarily in low- and middle-income countries (LMICs), still lack access [4]. Essential medicines are those that "fulfill the priority healthcare needs of the population" and are "intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford" [3]. Through the Sustainable Development Goals (SDGs), governments have committed to the attainment of Universal Health Coverage (UHC) to ensure that all people receive necessary health services without suffering financial hardship. In order to achieve UHC, significant progress in ensuring "access to safe, effective, quality and affordable essential medicines and vaccines for all" must be realised, as described in SDG 3.8 [5].

Availability of essential medicines in sub-Saharan African countries has long been inadequate to meet health needs in all sectors at about 40% in the public sector and 60% in the private sector

[6]. While comprehensive data on medicine prices across the continent are limited, a lack of affordable medicines can leave households impoverished [7-9]. With expected epidemiological and demographic transitions in the region, in which the burden of communicable diseases persists alongside a rise in non-communicable diseases (NCDs) and populations are growing, the need for affordable and quality essential medicines is likely to rise further [10].

Essential medicines policies have enabled expanded access to effective medicines that are appropriate to health needs, of assured quality and affordable to individuals and health systems [11]. Their importance has been reaffirmed in global efforts to realise UHC. EMLs are considered fundamental policy tools to promote access. The central idea behind EMLs is that selecting a limited number of medicines, vaccines and health products based on national health needs can improve access to the most effective and quality-assured medicines and result in maximum public health impact through efficient procurement and supply, reduced costs to health systems and patients, and by supporting appropriate prescribing and use [12]. The WHO Model List of Essential Medicines (WHO EML) guides country-level development of national EMLs and is updated by an independent technical expert committee through an evidence-based process on a bi-annual basis. The WHO EML has been lauded a milestone in the history of public health and the promotion of health equity [13, 14]. Governments and regional authorities worldwide have adopted EMLs. National EMLs are intended to be used by government bodies and institutions (e.g. health facilities) as a basis for financing, procurement, and appropriate or rational use, which includes diagnosis, prescribing, dispensing and patient consumption.

When it comes to the essential medicines literature, Bigdeli et al. (2018) note the importance of and relative paucity of research looking beyond the narrow pharmaceutical sector, across all levels of the health system, to understand the underlying causes of insufficient and inequitable access to medicines. These underlying systemic causes remain insufficiently studied despite decades of work focused on defining, measuring and improving access [15].

Despite the enormous consequences that public policy can have on health, a review of the wider health policy and systems research literature identified the need for more research *on* policy, policy processes and their implementation, particularly in LMIC contexts [16]. Research is often technocratic and directed *at* policy, including in the access to medicines domain; relatively fewer studies have been published *on* policy to offer an understanding of the forces that shape health policy and its implementation in practice [16-18]. Importantly, both policy processes and the task of ensuring access to medicines require a constant balancing and negotiation between a range of actors with diverse values, needs and interests in a complex health system, making them

inherently political subjects [19].

A review of policy implementation research in LMICs illustrates that a range diverse factors associated with both the "hardware" and "software" of health systems shape policy implementation [17]. The former includes financing, infrastructure, human resources and organisational structures, whereas the latter includes understandings and meaning given to policies, communication and information, relations between actors involved in implementation, and consultation with implementers during policymaking. In the African context, the literature on policy implementation has been deemed relatively sparse. Health policy researchers have suggested that to help advance the field, future research could contribute to building the collective understanding of how the multi-level nature of governance influences implementation [20].

Recent studies have underscored the need to understand how the KEML is implemented [21, 22]. Kenya has had a national EML since 1981, with the most recent edition revised in 2019 [23]. Nonetheless, ensuring access to essential medicines has been a persistent challenge in Kenya [24, 25]. Reports suggest that the KEML is "underused", although the reasons and possible implications for this are unclear [26]. With recent updates of the KEML in both 2016 and 2019, an opportunity arose to study both its revision and implementation. The ongoing UHC reforms in the country also make it an interesting case to study the relevance of the national EML in the UHC era and how the EML can play a role in advancing UHC and health for all in Kenya.

1.3 Thesis aim and objectives

The aim of this thesis is to understand the factors that influence the policy processes of KEML revision (medicine selection) and implementation in Kenya to identify strategies to improve access to essential medicines. The three objectives of this research are:

1. To describe the national KEML revision process and analyse how actors and context influence the process
2. To investigate key factors influencing KEML policy implementation at national and county levels
3. To examine key factors influencing KEML policy implementation at the health facility level

1.4 Background

1.4.1 Access to essential medicines

Access to essential medicines is recognized as a basic human right alongside food, clean water and housing. To attain the right to health as per the International Covenant on Economic, Social and Cultural Rights, governments must progressively realise access to health services including essential medicines through "deliberate, concrete and targeted steps" backed by the maximum available resources [27]. Five health systems dimensions are commonly used to define access to medicines: availability, affordability, accessibility, acceptability and quality (of medicines, vaccines and health technologies) [28]. Availability is the relationship between the supply of the type and quantity of medicine received and the demand of medicine type and quantity needed. Affordability is the relationship between the price of a medicine and the user's ability to pay. Accessibility refers to the ability of the user to obtain medicines from the supply location when they are needed, which can be influenced by factors such as geographical distance to a pharmacy. Acceptability or adoption relates to the features of a product and how the user, which can be the individual, prescriber or others in the health system, perceives and uses it in practice. Quality conveys the defined and approved use and specifications of medicines, as per the regulatory environment and standards [28].

Common patterns have been documented related to essential medicines access across LMICs. Availability of essential medicines is often lower in the public sector compared to the private sector and in rural compared to urban settings [6]. With challenges faced in accessing medicines in the public sector, patients often default to the private sector, where prices are often higher and quality may be less assured [15]. Access patterns have also reflected health priorities to date: with medicine availability for NCDs on average 40% lower than those for acute conditions [29]. Aside from the immediate health impacts, low and unreliable medicines availability also has broader impacts on the health system, as it can determine utilisation and access to overall health services and shape patient perceptions of (low) quality care [30, 31].

Essential medicines policies and their management are often described through four key components of the pharmaceutical management system: (1) selection of essential medicines based on priority health needs; (2) procurement, including quantifying medicine needs, managing contracts and ensuring quality of products; (3) distribution, including stock control and appropriate delivery to facilities; and (4) appropriate (or rational) use, which includes diagnosis, prescribing, dispensing and patient consumption [32].

1.4.2 Kenya

1.4.2.1 *Country characteristics*

Kenya is a lower middle-income country in East Africa with a population of 50 million, about 70% of whom reside in rural areas [33]. Roughly 75% of the population have received some formal education, whereby 52% have received primary education and 23% secondary education or above. The gross domestic product (GDP) per capita has risen in the past decade, reported at US$1816 in 2019. Nonetheless, approximately 45% of the population live in poverty. Income inequality in Kenya is comparable to that of many other countries, wherein in 2015 the bottom 40% received only 9% of national income whereas the top 10% received 48% [34].

Life expectancy at birth in 2018 was 66.3 years. There are significant variations in life expectancy and the causes of ill health across different subnational regions. Top causes of mortality include HIV/AIDS (accounting for 17.4% of deaths), lower respiratory infections (7.3%), diarrheal diseases (6.3%), neonatal disorders (6.2%), and stroke (6.1%). Communicable, maternal, neonatal and nutritional diseases represent 54.1% and NCDs represent 38.97% of total deaths, with a rise in those affected by NCDs since 1990 [35, 36]. High regional inequalities in access to healthcare exist, with areas with poor road infrastructure, poverty and lower levels of education associated with poorer health service access [37].

1.4.2.2 *Governance and devolution in Kenya*

Kenya declared independence from British colonial rule in 1963, after which a federal system of government was adopted [38]. In 1965, powers were concentrated through a unitary government system, administratively organised into eight provinces comprised of various districts. After several decades of mixed results in democratic and public participation attributed to political patronage and ethnic factions, the 2010 Constitution of Kenya promised a participatory devolved system of government. With the new Constitution, devolution meant the transfer of political power and resources from central government to democratically elected semi-autonomous subnational units known as counties. This system of governance intended to give the people power to participate in decision-making at all levels of government, strengthen accountability, reduce regional development and resource disparities, and enable equitable and efficient access to basic services [39].

In 2013, the devolved system with two main administrative levels of national and county governments was established, with progressive decentralisation of government functions and resources transferred to the 47 counties over three years thereafter. Under devolution the national government formulates national health policies and oversees national health referral

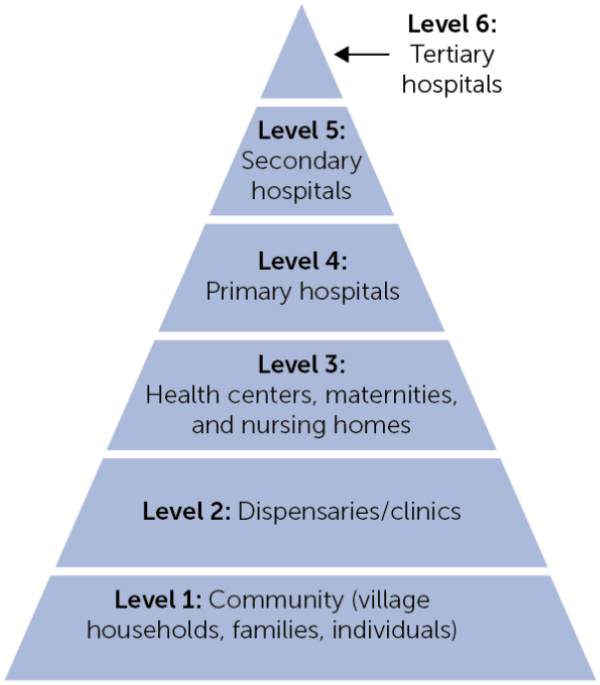
services and the 47 county governments hold most of the political, fiscal and administrative responsibility for service delivery [40]. County governments have two main arms: the County Executive, led by an elected Governor and Deputy Governor and committee members appointed to lead various departments such as health, treasury, agriculture etc.; and the legislative arm known as the County Assembly, made up of Members of County Assembly elected to represent electoral wards [41].

Several studies report challenges in county level health sector planning and budgeting due to the rapid transition of governing functions from national to county level without ensuring sufficient clarity of roles and capacity to fulfill necessary functions during the early years of devolution [42, 43]. Limitations in community and stakeholder participation in county government decision-making processes also persisted throughout and after devolution reforms [44, 45]. Nonetheless, in various counties devolution has reportedly improved administration and service delivery [44], development infrastructure including health facilities [39], local resources and availability of services, and health equity in counties previously neglected by the national government [45].

1.4.2.3 *Health system and pharmaceutical governance*

The healthcare system incorporates both public and private service delivery, which are approximately equally represented. An additional 11% of health facilities are owned by faith-based organisations [46]. Kenya's health system is comprised of six delivery levels, organised to promote upward referral from community through primary care to hospital levels (Fig. 1-1). Community and preventive health services are provided at community health units (level 1); primary healthcare is offered at dispensaries (level 2) and health centers (level 3); comprehensive inpatient services are provided at sub-county and county referral hospitals (level 4), medium-sized private hospitals, and regional referral and large private hospitals (level 5); and specialized care is the remit of national referral and large private teaching hospitals (level 6) [47, 48].

County governments hold jurisdiction over service delivery at levels 1-5 and national government is responsible for level 6 referral hospitals. Private clinics and pharmacies/drug shops deliver about 23% of all outpatient care [49]. Over 2000 registered retail pharmacies and approximately three times as many unregistered pharmacies and drug shops also play an important role in delivering access to medicines [26, 50]. The national Ministry of Health formulates policies, guidelines and standards, and enforces regulation, while County governments set budgets and are responsible for some purchasing functions [41, 45]. Within counties, County Departments of Health (CDOH) are responsible for health sector planning and implementation activities [47].



Source: [26]

Figure 1-1. Structure of Kenya's Healthcare System

Multiple actors are responsible for diverse roles in pharmaceutical policy, regulation and supply management. The national drug regulatory authority, the Pharmaceutical and Poisons Board, authorizes registered products and oversees pharmacies in Kenya. Medicines and medical supplies for the public sector are primarily procured (via tenders and price negotiation), stored and distributed through the Kenya Medical Supplies Authority (KEMSA), a state corporation under the Ministry of Health. The Mission for Essential Drugs and Supplies (MEDS) handles medicine procurement for faith-based organisations, mission hospitals, non-governmental organisations (NGOs), some donors, private hospitals and government facilities [26].

The public procurement system via KEMSA changed with devolution from a "push" to a "pull" model, whereby responsibility for quantification, financing and procurement of health commodities was shifted from the national MOH toward counties and health facilities. However, for priority programmes, like HIV or malaria, responsibility remains with the national MOH. Thus, counties and facilities procure essential medicines based on their needs [26]. KEMSA is responsible for centralised bulk procurement of essential medicines and their distribution to health facilities. Following devolution, counties and public facilities were able to procure from sources other than KEMSA; MEDS saw increased orders from public facilities. Substantial segmentation of supply chains between public, faith-based/non-profit, and private sectors have

been documented [51]. The public sector relies primarily, yet not exclusively, on KEMSA; faith-based facilities procure from a mix of MEDS, KEMSA and the private market; and private health facilities rely almost exclusively on private suppliers [46].

1.4.2.4 *Health financing*

About 10% of GDP is spent on health, which falls short of the 15% pledged by African Union governments to improve health in the Abuja Declaration [33]. The major health financing sources in the country are national and county governments (40% of expenditure), households (31%), and donors (29%) [33, 52]. Thus, the healthcare system relies heavily on donor funding and out-of-pocket expenditure, with chronic underfunding from Kenyan government sources and regressive healthcare contributions (i.e. the poorest pay a larger proportion of their income than richer people) [52, 53]. Donor contributions and donor dependency between 2002 to 2016 have been substantial, albeit declining, with most of those funds allocated to HIV/AIDS, reproductive health, immunization or health systems strengthening [54].

County governments, in addition to their role in healthcare delivery, also control a greater proportion of healthcare resources than the national government and have been responsible for an expansion of total government budget allocation to health. Budget allocation to curative services has been expanding and represents the highest proportion of the Ministry of Health 2018-2019 health budget at 45%, whereas the budget for prevention and promotion has been stagnant at 11% over three years [54].

1.4.2.5 *Access to medicines in Kenya*

Inadequate and inequitable availability of essential medicines due to frequent stock-outs and shortages have often been reported as a challenge across the country, although there are limitations in the availability and reliability of data to assess the extent to which essential medicines and non-essential medicines are accessible to the population due to a lack of systematic routine data collection [55]. The most recent government service availability and readiness assessment in 2014 assessed the capacity of health services to provide necessary services, whereby availability of essential medicines is considered a key element [24]. The assessment shows variation across facility levels and disease types. For example, availability across most therapeutic groups tended to be higher in hospitals than in primary care facilities [24, 55]. At primary care medicines for general services (e.g. anti-infectives, anesthetics) and vaccines were most available (85%), whereas in hospital vaccines (80%), antimalarials (65%), and "life saving commodities" (e.g. oxytocin, antibiotics) were most available. Both at primary care and hospital levels, the percent availability was lowest for medicines intended for NCDs (25%) and maternal health (24%). While studies on availability, generally cross-sectional surveys

indicating same-day availability, have been highly variable, they paint an overall picture that availability of most essential medicines is often well below the WHO target of 80% availability in both public and private sector facilities [21, 56]. Counties and regions with higher poverty levels are associated with lower availability of medicines. Access is also poorer in rural compared to urban settings and in public compared to private sector [24, 57, 58].

Affordability is often a barrier to access. Annually over 450,000 Kenyans are pushed into poverty due to direct healthcare payments—out of these, medicines represent the highest proportion (45%) of out-of-pocket payments [8]. Some medicines, such as those for children under five, maternity and family planning commodities, and medicines for tuberculosis and HIV, are provided for free in the public sector, but this is not the case for NCD medicines [59]. A lack of timely pharmaceutical pricing and expenditure data from public and private sectors disaggregated by type of medicine obscures a thorough understanding of ongoing affordability and access problems.

As is the case in many countries, fragmented data due to a lack of routine data make it difficult to understand changes in access over time and to assess KEML implementation based on meaningful quantitative measures of access and equity.

1.4.2.6 *KEML and policy context*

The Kenya EML (KEML) is described as “a priority-setting tool for [UHC]” and “guide for the investment of healthcare funds in financing the most appropriate medicines to achieve therapeutic aims in response to prioritised public health need” (Box 1-1) [1]. The intended benefits and uses of the KEML are:

i. *The medicines supply system:*
   For improved procurement, storage, distribution, stock management, and local production.

ii. *Cost control:*
   To lower treatment costs (through selection of the most cost-effective items), greater purchasing power (selection of products for national investment to generate a larger market for potential suppliers) and lower supply management costs due to fewer products.

Box 1-1. The Kenya Essential Medicines List

The KEML is a cornerstone of the national healthcare system, and a key component of both the national health and national pharmaceutical policies. It is a vitally important tool and reference for managing common health conditions in the country, as well as managing and utilising medicines at national, county, and institutional (health facility) levels. The KEML aims to support the smooth functioning of the healthcare system and radically improve the availability and appropriate use of medicines, for improved health status of the population. [1]

iii. *Prescribing:*
   To focus medicines information on selected products for prescribers and prescriber training (more experience to be gained with fewer medicines), and to improve appropriate prescribing and recognition of adverse drug reactions.

iv. *Patient use*:
   To focus education efforts on fewer, well-known medicines, improved patient knowledge on medicines use, increased treatment adherence and improved medicines availability.

The KEML was first published in Kenya in 1981 and has been revised five times—in 1993, 2003, 2010, 2016 and 2019 (Table 1). The KEML exists within and has been influenced by a framework of different policies within and outside of the health sector over time. Notably, the overarching National Pharmaceutical Policy (2008) and its predecessor, the Kenya National Drug Policy, have been linked to the KEML. The most recent version of the National Pharmaceutical Policy, Sessional Paper No. 4 of 2012, aims to improve the performance of the pharmaceutical sector and governance of medicines and health products across sectors [60].

The Kenya Essential Medical Supplies List (KEMSL) was published alongside the KEML for the first time in 2016 and delineates “the most appropriate medical supplies to achieve therapeutic aims in response to prioritised public health need” in the country [61]. The Kenya National Clinical Management and Referral Guidelines were last published in 2009 [62].

Table 1-1. Timeline of policy events relating to the Kenya Essential Medicines List

Year	Event/Policy launch
1977	First WHO Model List of Essential Medicines
1981	**First edition of the KEML (1981)**
1993	**Second edition of the KEML (1993)**
1994	Kenya National Drug Policy
	First National Medicines and Therapeutics Committee
2003	**Third edition of the KEML (2003)**
2008	Kenya Pharmaceutical Policy
2009	National Clinical Management and Referral Guidelines
2010	Constitution of Kenya
	Fourth edition of the KEML (2010)
2013	Devolution in Kenya
2014	Kenya Health Policy 2014- 2030
2016	**Fifth edition of the KEML (2016)**
	Kenya Essential Medical Supplies List
2017	The Health Act 2017
2019	The Health Laws (Amendment) Act, 2019
	Sixth edition of the KEML (2019)
2020	Planned UHC launch

Political commitments to achieving UHC by 2022 were made as part of President Jomo Kenyatta's "Big Four Agenda" for economic and social development [63, 64]. The National Hospital Insurance Fund (NHIF) is the country's public social insurer and financing structure for UHC [63]. Although gaps persist, the country has experienced some progress toward attaining UHC since 2003 [63]. Policy reforms have taken place aimed at realising UHC; notably, inclusion of UHC as one of the "Big Four" development priorities [64] and in the national health policy and Health Bill [47, 65]; reforms to the NHIF to serve as health insurer [63]; removal of user fees for primary healthcare and maternal health services [66]; health financing reforms [67, 68]; and legal changes in 2019 to restrict health commodity procurement to KEMSA [69]. These reforms, driven from the highest political levels, are ongoing and likely to have considerable impacts on the demand and supply of essential medicines.

Beyond the health sector, the manufacture and sale of health products implicate diverse trade and economic actors. Kenya is an economic and pharmaceutical hub in the East African region, with interests to boost the competitiveness of its domestic pharmaceutical manufacturing

industry at home and abroad [70]. A 2018 survey indicated that 55% of essential medicines found across health facilities in public, private and faith-based sectors were made in Kenya, and the majority of imported products came from India [59]. Political prioritisation of trade over health has indeed hindered essential medicines policy implementation in the past [71]. The above-mentioned national governance context and broader political climate may therefore also shape the KEML and its implementation.

1.5 Organisation of this thesis

In this chapter, I described the rationale for this study and relevant background information to set the scene for this thesis. I also summarised the study aim and objectives and what I set out to achieve in this study. The remainder of the thesis moves figuratively from the national to the local level and conceptually from policy formulation to implementation.

Subsequent chapters are organised as follows:

- Chapter 2 examines the literature on essential medicines lists relevant to this research and provides further rationale and contextualisation for this study.
- Chapter 3 goes on to map out the conceptual framework that guides this work and the literature underpinning it.
- In Chapter 4 the methods are described.
- Chapter 5 is the first results chapter and focuses on the national policy process to select priority medicines for the KEML, or the KEML revision process, and how actors and context influence the process, as per study objective 1.
- Chapter 6 is the second results chapter, which focuses on macro- and meso-level factors that influence KEML policy implementation as per study objective 2.
- Chapter 7 is the third results chapter, which focuses on micro-level factors that influence KEML policy implementation as per study objective 3.
- Finally, Chapter 8 includes the discussion, conclusions, and considerations for KEML policy and practice.

2 What is known about essential medicines lists? A literature review

> [P]harmaceuticals are complex social objects. Their meanings and uses are continually contested by multiple stakeholders— physicians, policy makers, politicians, pharmaceutical executives, civil society groups, donors, and bilateral and multilateral organizations— no two of which approach pharmaceuticals as an object in exactly the same way. – Jeremy Greene [72]

2.1 Introduction

In this chapter, I review a selection of the academic literature on country level EMLs to examine what is known about EMLs and their policy processes, and some of the factors that may influence these processes, including medicine selection and list implementation as related to my primary research aim. The purpose of this literature review is to provide an interpretive overview of current knowledge on national EMLs and approaches to their study, to advance a theoretical understanding of EML policy processes for this thesis. Moreover, this overview highlights the gaps in the literature that informed this work and to which I aimed to contribute.

An interpretive approach was chosen to facilitate meaningful synthesis and critique of a broad literature that could incorporate diverse disciplinary approaches and ways of knowing [73]. Such an approach was deemed appropriate for this review as I sought broad clarification and insight on the topic of EMLs, rather than to gather data to address a narrow research question that would lend itself to a systematic or scoping review. I was guided by the following questions: [4]

1. What is known from the existing literature about national EMLs and their benefits?
2. How are EMLs developed?
3. What factors influence the implementation of national EMLs?

To set the scene, this chapter begins with a brief history of the essential medicines concept, followed by a summary of what is known about EMLs at country levels. The latter starts off with an overview of the evidence base for EMLs and moves to other key themes of the EML literature: studies on the content of these lists, on the selection/decision-making processes, and lastly, on what is known about EML implementation processes and the factors that may affect implementation. To conclude this chapter, I reflect on this body of research and how I see my

[4] Methods used in the search included (1) a key word search using MEDLINE and Google Scholar using the search term “essential medicine* list*” (and its alternative terms “essential drug* list*”, “essential medicine* policy”, and “essential drug* policy”), (2) snowballing to identify sources from reference lists of the initial papers identified and through the “cited by” function on Google Scholar, (3) hand searches of publications by known researchers working on this topic, and (4) articles shared through an pharmaceutical policy e-mail listserv called e-Drug.

research contributing to the literature.

2.2 Brief history of the essential medicines concept

The “therapeutic revolution” of the twentieth century brought discoveries like antibiotics, corticosteroids to treat inflammatory and chronic diseases, anticoagulants and antidiabetic medicines. Simultaneously, the global pharmaceutical market in the mid-twentieth century became increasingly saturated with “me-too” drugs and expensive products of questionable clinical value, although these were increasingly promoted through pharmaceutical marketing [72]. A recognition of the need to select safe, effective and affordable medicines that would meet national or local priority health needs in an increasingly crowded market began to emerge worldwide. In this context the concept of essential medicines became widely discussed at international fora in the 1970s as a possible solution to global demand and supply challenges [2, 74].

Countries began to adopt national prioritised medicines lists—Cuba in 1963, Tanzania in 1970, and Peru in 1972 [11]. As more countries began to develop national pharmaceutical policies, WHO Member States mandated the organisation to provide normative and technical support on medicine selection and procurement [75]. In 1977 the first WHO EML was published. In its early days, the WHO EML was met with significant opposition by pharmaceutical companies, who did not believe in “inessential” medicines [2, 74, 76]. The WHO EML, contrary to industry interests, only lists medicines by non-proprietary or generic name; no references are made to brands or manufacturers. Industry opposition promoted a framing of the essential medicines concept at the time as only applicable to “developing countries” and to public sector service delivery, not the private sector [74].

The Lancet Commission on Essential Medicines Policies depicted the evolution of essential medicines policies through three political eras: (1) the movement toward primary healthcare for all that ignited in the 1970s, (2) the era of growing vertical global programmes in response to the HIV/AIDS epidemic in the 1990s-2010s, and (3) the current global push toward UHC. Essential medicines policies took root across sub-Saharan Africa and elsewhere in the first era during the rise of the primary healthcare movement [71]. Expanded access to essential medicines was one of eight fundamental elements in the 1978 Alma-Ata declaration, which sought to radically shift the dominant global health focus on siloed disease-control initiatives toward a human rights-based approach to universal access to health services and the social determinants of health [77]. Throughout the first and second era, medicines for the prevention and treatment of communicable diseases, like HIV, malaria and tuberculosis, became prioritised through domestic and donor financing and provision [11]. The WHO EML also became widely used by UN agencies

in response to emergencies, non-governmental organisations, and other stakeholders to prioritise medicine provision [13].

In the second era, the WHO process for selecting essential medicines went through three critical changes. First, influenced by the evidence-based medicine paradigm, the WHO EML process began to emphasise selection based on evidence of efficacy, safety, and comparative cost–effectiveness, with decisions made by a scientifically independent expert committee in 2001 [78]. Second, the process allowed for broader input from stakeholders and instituted transparency, with committee decisions relating to each update, the evidence used in decision-making, and the reasons for decisions made public (which can aid in national selection processes). Third, cost was removed as a selection criterion, which meant that affordability was no longer a prerequisite for listing but that once listed as essential, medicines were expected to be made available [79]. With this change, largely due to pressure based on enormous inequities in access to HIV/AIDS medicines at the time, expensive, patented antiretrovirals were added to the WHO EML for the first time.

In the current era, essential medicines are widely recognised as a key component of UHC and as broadly necessary for sustainable development—entrenched in the UN Political Declaration for UHC and the SDGs [11, 12]. EMLs have been adopted in at least 137 countries and some countries, such as India, also rely on sub-national EMLs, demonstrating the widespread diffusion of this policy worldwide [80].

2.3 What is known about essential medicines lists at country level?

Across the literature on EMLs at country level, studies most commonly sought to (1) build the evidence base for EMLs, by investigating the impact of the EML on various access indicators like availability, cost or affordability, and/or quality use of medicines; (2) examine the content of these lists to analyse which medicines have been prioritised; and (3) to describe or analyse the medicine selection process for an EML. Few studies have investigated the implementation processes of EMLs explicitly, but what is known is presented below (section 2.3.4). In this section, each of these four areas of the EML literature is discussed.

2.3.1 Benefits of EMLs

The literature on national EMLs in LMICs provides insight into the possible benefits of implementing a national EML, based on findings from diverse settings. These are presented in this section, followed by a discussion of the inherent challenges in assessing and interpreting the impact of the EML due to its role as part of a broader pharmaceutical policy framework in most

countries.

A small set of multi-country studies provide encouraging evidence on the benefits of the EML in improving *availability*, *appropriate or quality use*, and *affordability* of medicines. In terms of *availability*, medicines included on national EMLs were found to be more frequently available than those not on these lists (61.5% vs. 27.3%) via a multi-country analysis of publicly available WHO data, although availability nonetheless fell short of the international 80% availability target [81]. This difference was more pronounced in the public sector than in the private sector, although the median availability of essential medicines was higher in the private sector. Generic medicines made up almost all available medicines in the public sector, whereas in the private sector branded essential and non-essential medicines made up 20% of the medicines available. These findings suggest that EMLs have been implemented to a greater extent in the public sector, which aligns with the historical emphasis as EMLs as applicable primarily in the public sector. Pharmacoepidemiologic studies have further examined essential medicines policies with respect to their *appropriate use* and *acceptability* outcomes, including national EMLs, and found that the implementation of the EML and other policies was associated with improvements in appropriate prescribing and patient use (no over- or under-use) of medicines and antibiotics [82-84].

Greater *affordability* of medicines was furthermore reported in 13 sub-Saharan African countries, where anti-hypertensives listed on national EMLs were priced lower than those not listed, particularly in public pharmacies [85]. Studies in the West Bank, Palestine also found that the EML improved quality use of antibiotics and injectables, reduced over-prescribing and inappropriate medicine utilisation, rational selection based on the EML, and resulted in aggregate cost savings of $5.38 million after it was introduced in 2000 [86].

Although EMLs and a suite of other essential medicines policies have been widely adopted and promoted as important policies to achieve access goals [11], much of the evidence available from national and subnational studies on EMLs tends to be a challenge to interpret. This is because it is difficult to attribute policy outputs and outcomes to an EML formulated, implemented and evaluated in tandem with other essential medicines policies aiming to promote the same access goals. Studies on EMLs in Delhi, India and China illustrate this, while simultaneously indicating the importance of the EML to achieve improved access to medicines.

A study of the Delhi (India) essential medicines policy noted the “inability to isolate a specific policy measure for investigation of specific effects” [87]. The essential medicines policy adopted in 1994 included an EML as well as an accompanying set of activities such as establishment of a

pooled procurement system, prescriber training, quality control measures and the development of standard treatment guidelines (STGs). Policy implementation was associated with greater *availability* of medicines, *appropriate use* in terms of increased prescribing from the EML and improved antibiotic prescribing, and improved knowledge by patients on appropriate use of prescribed medicines, although generic medicine use declined [87, 88]. Nonetheless, inappropriate prescribing practices like prescribing outside the EML, low use of generics, excessive antibiotic use, and incomplete information on prescriptions and guidance to patients, while improved with the policy, where still prevalent [88].

In China, a national essential medicines system reform was adopted in 2009, which emphasised evidence-based medicine selection. The EML was coupled to insurance reimbursement of essential medicines, provincial centralised procurement, pricing reforms, comprehensive financing for primary care facilities, quality improvement through pharmacovigilance measures, and measures to improve appropriate medicines use [89]. Many studies demonstrated significant decreases in medicine prices, costs per prescription, and patient fees in primary care facilities and hospitals across different provinces [90-94]. Benefits also included reduced reliance of prescribers and health facilities on medicine sales for their income and revenue, a widespread problem that the reforms sought to address which fueled inappropriate prescribing and use [91, 94]. Studies on the implications of reforms on the appropriate use of medicines have reported varied results [90, 93], but collectively suggest that the essential medicines system led to improvements in appropriate use, particularly in public facilities [95, 96].

2.3.2 Content of EMLs

Studies investigating the content of EMLs include comprehensive comparisons of all medicines listed across 137 countries [97], comparisons by therapeutic groups [98-101], comparisons in particular contexts or regions [102, 103], and single-country comparisons between different EML editions and the WHO EML [104, 105]. These studies frequently found large variations in medicine listings between countries and that most country lists differed a great deal from the WHO EML [106]. For example, across 137 countries EMLs contained between 44 and 983 medicines and all but one of these lists included one or more products that have been withdrawn by a regulator or lacked market authorisation due to safety issues [97, 107]. The variations found in medicines listings do not appear to be associated with country characteristics like health expenditure, raising questions about the process by which medicines are selected [97]. Collectively, these studies emphasise the need to better understand national EML selection processes, given the possible health and resource implications of listing decisions. Current knowledge pertaining to such processes are discussed in the next section.

2.3.3 EML selection processes

An increasing number of studies from different countries, mostly descriptive in nature, have explicitly focused on the process of selecting medicines and revising EMLs. In this section, I explore this literature by first describing the general features of EML selection processes in different countries. The studies often focused on two general themes: the use of evidence in the selection process and/or the influence of actors involved; each of these are discussed in turn.

Processes examined in the literature to update national EMLs in Brazil, South Africa, Ghana and Tanzania show the adoption of similar approaches to the WHO EML in that selection is (1) led by a multi-disciplinary expert selection committee appointed or approved by authorities in the Ministry of Health and (2) decisions are most often guided by a set of selection criteria on efficacy, safety, quality and affordability or cost, although other criteria like availability, cost-effectiveness and market authorisation, are also considered in some countries [108-111]. Processes to revise national STGs and the EML are coupled in many countries, like South Africa, Ghana, Tanzania and Uganda, as recommended by WHO [22, 109, 110]. Management of conflicts of interest are considered important aspects of the process to build transparency, accountability and trust [12].

2.3.3.1 *Use of evidence*

The role of evidence in the medicine selection process has been documented or analysed to varying extents in different settings, showing variations and challenges in the use of evidence to guide medicine selection decisions. What evidence-based, or sufficiently evidence-based, means in several of the studies is often not detailed to make any meaningful comparisons. Normative assumptions about what "good evidence" and good use of evidence" means, as discussed by Parkhurst [112], are often not made explicit in these studies. In Nepal, for example, the process lacked transparency and was not deemed evidence-based [113]. In South Africa, the process is considered "predominantly" evidence-based and evidence-based medicine tools applied in the process are specified [109]. Nonetheless, quality of evidence available to support decision-making, a lack of in-country health economics expertise and country-specific information, and insufficient monitoring and evaluation of previous EML outcomes and on appropriate medicine use were reported as limitations to evidence use. Similarly, in Mali several factors were identified as influencing evidence use for EML decisions. These included: limited relevant and trustworthy evidence; poor access to research and necessary information—in part due to limitations in the capacity of decision-makers to assess the evidence; lack of policymaker time; "uncritical reliance on specialists" who may be voicing opinion; cultural preference for verbal reports over documentation; and pressure from interest groups [114]. The latter two factors emphasise the importance of actors in influencing medicine selection.

2.3.3.2 *Role of actors*

The influence and roles of actors is highlighted in studies from Ghana, Mexico, and Brazil, which are detailed in this section. In Ghana, the consideration of evidence intersects with the views and interests of actors engaged in the process in the EML and STG selection process [110]. This was illustrated through the use of public arenas theory in the interpretation of findings. The authors describe how the revision process for the STGs and the EML moves from what they call the bureaucratic arena, which are the technical sessions of the national medicines selection committee where evidence and expert opinion shape decisions, to the public arena, where negotiations via a consensus-based process with professional bodies and healthcare managers who scrutinised policy decisions based on their practical application.

Studies from Mexico and Brazil, however, reveal more overtly how politics can shape the EML decision-making. Selection of medicines in Mexico was found to be based primarily on political and economic interests [115]. This process was largely shrouded in secrecy, with a lack of meaningful participation from experts or the public. The study revealed the significant influence of the pharmaceutical industry and other powerful actors in controlling and weakening the selection process itself and thereby the medicine selection decisions made within the process. The result was a lack of "rational" selection of medicines based on the actual health needs of the Mexican population [105, 115].

Brazil's EML guided medicines supply management and use from 1998; an evidence-based process adopting WHO EML selection criteria was applied in 2000. A standardised, transparent, and timely process involving a selection committee was established to comprehensively review the list regularly. Yet, legislation introduced in 2012 effectively replaced the essential medicines concept that included a comprehensive review of the list with a process that selects a financed list of medicines using health-technology assessment. Final decision-making power shifted from a technical committee to administrative and political actors and the WHO EML no longer served as an important guide for selection. These changes were instituted in the context of increased litigation faced by municipal and state governments based on patients' legal access to medicines in the country. Governments were pressured to include novel and often high-priced medicines, often for cancer, on the EML [108]. Consequently, a larger number of medicines were selected for the list and a small subset of specialized anti-neoplastics and immunomodulators accounted for about half of all drug spending, although not aligned with disease prevalence. The addition of high-cost medicines to the EML in 2012 did not appear to result in reduced drug prices [116]. Nonetheless, these studies on the Brazil EML should be interpreted with caution due to

sparse reporting of methods which precluded assessment of their quality.

2.3.4 Studies on the implementation of EMLs

Few studies have explicitly sought to understand the implementation process. Most of the research that uncovers these implementation challenges did not set out to understand implementation, but their findings are discussed here nonetheless. The studies that are available suggest that EMLs are often not implemented as intended based on stated policy goals. This is not surprising, as is often, if not always, found in policy implementation studies [17]. This literature suggests that diverse factors influence the implementation of these lists and while some of these are common across different countries and settings, the set of factors involved are often context specific. The four most common factors in the literature, based on this interpretive review, discussed below are: communication and education, policy incoherence, stakeholder participation in medicine selection, and supply chain systems and financing.

2.3.4.1 *Communication and education*

The importance of communication and education related to EMLs to promote implementation, and in particular the use of EML by prescribers, was identified as important in diverse settings. In South Africa, information dissemination and communication processes from national to subnational institutions and other national departments was seen as a shortcoming in the STG/EML implementation [109].

Undergraduate education on EMLs in countries across Africa and various other different regions were associated with better medicines use than countries without such education [82, 84]. Across six editions of the EML in Brazil, its use by prescribers was more limited than intended and the list did not result in improved prescribing practices [117]. A lack of awareness of and adherence to Brazil's EML was reportedly due in large part to insufficient dissemination and communication of the list at national, regional and local levels—notably by the lack of engagement of local actors, particularly prescribers and professional organisations, in the strategic promotion of the list, poor communication of listing decisions and lack of prescriber awareness of listing changes over time, and the paucity of educational initiatives aligned with the EML aimed at improving physician prescribing culture [116, 117]. Two studies on the EML in Delhi illustrate the importance of training. In an earlier study, prescriber training programmes led to greater prescribing based on the EML, and higher rates of patients receiving the medicines prescribed [87]. In a later study, 82.5% of prescribers were not aware of the essential medicines policy and 64% reported awareness of the essential medicines concept, which was seemingly

linked to insufficient training initiatives in medical education and in-service training to promote the essential medicines concept [88].

2.3.4.2 *Policy incoherence*

Another set of studies indicate that policy incoherence or misalignment influences EML implementation. In China, although the national EML included a comprehensive range of conditions and medicines, it was undermined by irrational selection of medicines on provincial supplementary lists that were not based on evidence [118]. Medicines were selected based on the existing practices of local health institutions and doctors, and large variations existed between subnational lists. Furthermore, the EML was not aligned with medical insurance coverage—essential medicines represented only 1/7th of medicines covered.

A study in Papa New Guinea further builds the evidence on the need to align the EML with other important guidelines and policies. It found that discrepancies between the national EML and STGs resulted in inappropriate prescribing practices and prescriber restrictions for chronic conditions in rural and remote areas [119]. In South Africa, poor alignment between the EML committee and other structures responsible for pharmaceutical management (e.g. procurement, education) were considered a challenge for implementation [109]. Past reports also indicate that national vertical programmes were often not aligned with EML selection, as far more medicines were procured than listed on the EML [13].

2.3.4.3 *Stakeholder participation in medicine selection*

Participation and engagement of stakeholders in the medicine selection process, and particularly those expected to implement the EML, has been emphasised as having an important influence on implementation in some contexts. The lack of involvement of prescribers in the medicine selection process was seen as a barrier to EML implementation in Brazil [117]. Past EMLs in Eritrea suggest that widespread acceptance of an EML was facilitated by the inclusion and involvement of health professionals, professional organizations, and other stakeholders in the EML decision-making process [13].

2.3.4.4 *Financing and supply chain*

Financing and supply chain were influential in EML implementation. In Shaanxi Province, China, 84% of hospital pharmacists viewed supply and distribution systems as a problem in implementing the essential medicines system and 66% perceived that insufficient government financing was a problem [120]. Another study in China reported that the deficiency and inequity

of financial subsidies in rural compared to urban areas impeded implementation of the essential medicines policy in rural settings [91]. In Delhi, the pooled procurement system linked to the EML played an important role in reducing costs and improving availability of essential medicines [87].

2.4 Reflective summary

I approached this literature review to broadly encompass what is known about essential medicines lists. It does not capture the grey literature and the surely rich knowledge that likely exists in practice based on decades of experiences with EMLs. Situating the essential medicines concept within its historical context provides insight into how global health policy and actors, and the prevailing political contexts at a given time, have shaped the norms and rules around its application.

The literature shows a frequent emphasis on the *content*, or the 'what' questions, of national EMLs [121]. Studies often describe policy goals and whether it achieved said goals, or what the most suitable policies are to achieve intended outcomes, such as the EML impacts on availability, appropriate use, and affordability of medicines [81, 82]. Scholars have noted that, broadly, the health policy literature has disproportionately focused on the content of policies while often neglecting the politics of policy-making [121]. Few studies on EMLs have asked the 'who' and 'how' questions, particularly when it comes to implementation.

Studies have illustrated the benefits of EMLs, although these benefits often cannot be attributed to EMLs alone, given their co-existence and co-implementation with other essential medicines policies, like pricing and fiscal policies, treatment guidelines, and training requirements. It is widely recognised that the mere presence or implementation of an EML does not guarantee access to affordable and quality-assured essential medicines or ensure appropriate use. For example, although medicines for asthma and chronic obstructive lung disease were listed on EMLs, they were not available in health facilities [99, 101]. Yet, the challenge in associating outcomes with individual policies due to the complex policy and social milieus they exist in is one that is hardly unique to EMLs [122, 123]. The overall benefits of EMLs are nonetheless rarely contested. Thus, the range of different approaches, policy 'packages', and outcomes of EMLs in different settings bespeaks the importance of understanding the underlying EML implementation processes and the role of context.

Valuable insights are also offered by studies on the national EML policy process to select medicines. These studies collectively emphasise that diverse approaches exist to updating the EML and that while many of them have adopted aspects of the evidence-based approach

recommended by WHO, national EML selection processes are, like any other policy, subject to contextual and political influences associated with time and space. Two broad factors identified from this literature that influence EML selection processes are the *use of evidence* and the *role of actors*. Key factors that influence implementation of EMLs based on the literature are communication and education on EMLs, policy incoherence, stakeholder participation in decision-making, and supply chain and financing systems and policies.

Among the few studies that do offer insight on EML policy processes, most are descriptive. Those discussed above explicitly focused on EML selection processes mainly applied qualitative methods, primarily document reviews and interviews. The application of theory or existing conceptual approaches in these studies was mostly absent, which highlights the need for more theoretically and conceptually grounded approaches to understanding EML selection and implementation processes. The scarce literature suggests that EMLs, while technical policies, are formulated and implemented in political and social realms, constructed by actors and power dynamics. A policy analysis approach has been used to study a wide range of health policies and draws on broader fields of public policy and administration to understand how politics and the actors driving policy processes shape the systems organised to deliver health [20]. Yet, health policy analysis has insufficiently been applied to better understand EMLs. By addressing questions of how EML policies are developed/updated and implemented at different levels of the health system through a health policy analysis approach, this thesis seeks to contribute to a deeper understanding of the social and political influences in the EML and access to medicines literature. The theories and concepts from the health and public policy literatures that informed this thesis and selected conceptual framework are presented in the next chapter.

3 Theoretical and conceptual background and selected conceptual framework

3.1 Introduction

The conceptual framework is an important component of my research design as it provides "system of concepts, assumptions, expectations, beliefs, and theories that supports and informs [my] research" [124]. Given that EMLs have often been studied as technical tools rather than as policies in their sociopolitical context, the rich and established multidisciplinary public and health policy literatures provided a pragmatic basis for this study. While other approaches, such as implementation science and political economy analysis were considered, a health policy analysis approach seemed best suited to address my research question focused on the complex policy process across different levels of government and the health system. An implementation science approach may have facilitated the identification of key factors influencing implementation, but as Nilsen et al. (2013) note, its perhaps more reductionist approach may not have facilitated insight on the inherent interdependency between the various factors and the overall policy context [125]. On the other hand, a political economy approach may have provided deeper insight on the broader economic and political dynamics at play beyond the health sector, but an important first step of this study was also to map out the process within the health system.

My interest in studying the KEML through a health policy lens led me to explore apposite public policy theories and frameworks with an emphasis on policy implementation. While a framework "lists the basic structure and components underlying a system or concept" and how those fit together, theories "may be explanatory or predictive, and underpins hypotheses and assumptions about how implementation activities should occur" [126]. Models of the policy process are also referred to, which help describe and simplify a complex process.

Here, I present an overview of key public policy theories and analytical frameworks to set the scene for the conceptual approach and, where relevant, explain how these guided my analysis and interpretation. Finally, the conceptual framework used for this thesis is described.

3.2 An overview of key public policy theories and concepts

In this section, I define public policy and give an overview of policy analysis approaches relevant to this thesis. I have understood public policy, including health policy, according to Dye's definition: "Whatever governments choose to do or not to do." [127] The policy process has often been described as "messy" due to the large number of diverse actors involved in most

contemporary policy processes [121, 128]. Decision-making responsibility is often shared across different levels of government and with policy actors outside of government.

A classic way of studying public policy has been to break it down into stages. The stages heuristic model and its more dynamic variant, the policy cycle, describe that the policy process moves through the stages of agenda-setting, policy formulation, policy implementation and evaluation [128, 129]. The policy cycle is presented as a continuous process whereby the evaluation stage of the previous policy sets the agenda for the next policy. While this model is widely recognised as an oversimplification of the complex policy process and does not offer explanatory value [128], I found it useful when thinking about EMLs, as they represent a type of policy where these stages appear to be clearly delineated. As EMLs are also intended to be revised at regular intervals, applying this heuristic was presumed to enable an understanding of EMLs as moving through dynamic policy cycles. For the KEML case, the stages of policy formulation (KEML revision), policy implementation, and evaluation were useful phases to consider based on the literature. Although the primary aim of this research is to analyse policy implementation, the literature review underscored how these stages are linked and merit being studied as such.

3.2.1 Policy implementation

Policy implementation research has been concerned with the relationships, and often gaps, between what is promised in policy and the practical outcomes [130]. The focus of Chapters 6 and 7 in this thesis are on policy implementation. For the purposes of this research, I define policy implementation as the processes that occur and series of activities undertaken by governments and other stakeholders *between policy expectations* (goals and objectives articulated in policy) *and the (perceived) policy results* [131, 132]. This definition is commonly used by public policy scholars [130].

Implementation challenges arise from the design of policies via policy-makers, often seen as those “at the top”, but also based on the practices of implementers or those working on the front-line, or “at the bottom”[130]. In this section, I present the dichotomous top-down and bottom-up theories, followed by theories that have integrated the two. Finally, I discuss how these theories have informed my understanding of implementation and study design. I will also refer back to these in the Discussion.

Top-down implementation theories align with rational models of the policy process, which viewed policy-making as a linear process and that while policy formulation was seen as political, the implementation was viewed largely as an apolitical technical and administrative process

[133]. The emphasis in this approach is on central decision-makers setting policies "at the top" (e.g. national government bodies) and understanding how to ensure that implementing agents facilitate the realisation of intended policy goals, and the extent to which these goals are achieved [129, 134]. Pressman and Wildavsky described implementation as action that relies on a vertical chain requiring cooperation between each of the links in the chain. They introduced the notion of "implementation deficit"—that the decisions made at the top may not be what is practiced by those tasked with implementing. The success or failure of policy implementation as defined by top-down theorists has been measured by criteria such as those described in Box 3-1, taking a 'rational model' approach of considering what makes achievement of policy goals difficult [130, 135]. Various policy implementation theories, particularly those with a top-down approach, have described characteristics that policies should have to increase the likelihood of implementation as intended, such as policy design and clarity of communication and lack of interdependence [129].

Box 3-1. Top-down criteria for policy implementation success

1. The policy has clear and consistent objectives, is well communicated and understood.
2. There is adequate causal theory as to how actions will produce intended policy outcomes.
3. The implementation process is structured and resourced to enhance compliance by implementers.
4. Policy is implemented by skillful and compliant officials.
5. Success does not depend on cooperation/dependence between many actors and there are few additional decision-making (or so-called "veto points"), or there is sufficient support from interest groups and policymakers.
6. No changes in demography, socioeconomic conditions or unpredictable events that undermine political support or the causal theory underlying the policy process.

Source: Sabatier & Mazmanian, 1979 [135]

Bottom-up theorists on the other hand view implementation as a "policy/action continuum in which an interactive and negotiative [sic] process is taking place over time, between those seeking to put policy into effect and those upon whom action depends" [136]. This approach emphasizes emergent networks and actors that turn a policy into practice [121]. Implementation success here is not measured by compliance to intended practices and rules, but by the outcomes produced by implementing actors through strategic interaction, relationships, negotiation and compromise [130, 136].

Lipsky's street-level bureaucracy theory is the seminal bottom-up perspective, which explains that the decisions made by front-line workers, like physicians and nurses, will shape policies in ways that may be supportive or unsupportive of intended policy goals set at higher levels [137]. Contrary to top-down perspectives, Lipsky illuminated that street level bureaucrats, the public service workers tasked with implementing policy, have discretionary power which can dictate how policy is experienced by intended beneficiaries. Implementers conduct their work based on many diverse and often unclear directives from the top and due to the difficulty of operationalising them all, they develop routines and rules of thumb to guide their work and often make their own decisions in response challenges and local circumstances. The discretionary actions of street-level bureaucrats are influenced by their sociopolitical context, working environment and resource availability, and their own personal values and beliefs. These actions may include conserving resources, rationing services, and may entirely shape the relationships patients have to the health system [138]. Gilson summarised this discretion as "the space between the legal rules in which actors exercise choice, the sphere of an actor's autonomy for decision-making" [139]. Several studies have drawn on street-level bureaucracy theory to demonstrate the importance of understanding factors that influence street level behaviour and practice, since the values and experiences of local actors can shape implementation in a way that leads to unexpected outcomes and "may widen the gap between policy as written and policy as performed" [137, 138, 140].

Other implementation theories have integrated top-down and bottom-up theories, also described as integrating or 'third generation' implementation theories. These often emphasise a more complex, interconnected and fluid policy process where implementation cannot be easily separated from policy formulation or evaluation [121, 130]. Goggin and others who bridged the top-down versus bottom-up debates explained that each perspective disregarded the implementation reality of the other [141]. In this study, I endeavored to capture implementation realities of those at the top and the bottom. Elmore sought to understand policy design and implementation through forward-mapping that emphasizes the context and perspectives of policymakers, as well as backward mapping that explores the reality of those at the bottom [142]. This approach was applied in this thesis, as further detailed in Chapter 4. With this third generation, there has also been an increasing focus on governance and the fact that multiple actors are involved in implementing policy [122].

In addition to 'implementation', I also refer to the term 'KEML use' throughout this thesis. I define KEML use as the specific activities carried out by actors guided by the KEML that contribute toward the broader implementation process. Thus, I often combine discussion of KEML

implementation and use. The intended uses of the KEML described in section 1.4.2.6 provide a conceptual basis on how the list is meant to be applied in the health system from a top-down perspective. However, these are not included in the study conceptual framework because I did not aim to evaluate the extent to which each of the intended uses were realised in practice. Instead, I sought to explore how KEML implementation was understood in the local context based on an approach that allowed bottom-up perspectives to emerge from the data.

3.2.2 Multi-level governance

The concept of multi-level governance can be defined as the presence of interacting authority and decision-making institutions, spanning the local to global [128, 143]. It is a concept that has been studied mostly in the context of the European Union to understand how the various governing "levels"—supranational, national, subnational governments as well as non-governmental organisations—shape policy [143, 144]. Given the devolved governance structure of Kenya, this appeared to be a useful concept to analytically distinguish the different governing levels and to contextualise analysis to national and subnational levels. It has been applied in the Kenyan public policy context [145]. Multi-level governance has been described as a useful heuristic device to understand policy processes. Where decision-making authority is distributed across levels of government and interest groups, an understanding of the presence and nature of negotiations between the different formal and informal decision-making layers and actors may be more important than formal authority [128]. The involvement of non-governmental and private actors in decision-making processes, in addition to governments, explains the emphasis on *governance* rather than *government*. Cairney denotes two characteristics by which governance can be understood: first is the interdependence and shared power between official decision-makers and the actors that they consult and negotiate to produce policy, and second is that governments rely on other organisations to implement policy [128].

3.2.3 Multiple governance framework

Through their multiple governance framework, Hill and Hupe combined the concepts of multi-level governance, the stages heuristic and policy implementation in an analytical framework that maps both different "loci" in political-societal relations and different levels of action, as presented in Table 1 [130, 146]. The locus of the *system* setting represents national government and "high institutions of state", where there is "legitimate attention to and responsibility for the whole" [130]. The locus of the *organisation* represents the organisation and the vertical and horizontal relations between organisations, where vertical refers to cooperation between higher and lower levels of government (e.g. administrative or technical roles, finances) and horizontal refers to relations between organisations. Finally, the micro-setting entails individuals, including street level bureaucrats as per Lipsky's work described above, doing the work of implementation.

Within each of these loci, the framework presents three levels of action: *constitutive*, *directive* and *operational*. This is adapted from Kiser and Ostrom's 'three worlds of action' [130, 147]. *Constitutive action* involves the *structural choices* and *design of institutions* relevant for policy—the rules about the rules and system as a whole. *Directive action* entails *decisions* about policy content—action shaping the overall policy direction and formulation. Lastly, *operational action* involves *managing policy processes* and the tasks involved in implementing policy. These actions, similar to the political-societal loci, have a nested character whereby *operational* acts of managing implementation proceed from *directive* choices that occur in the context of prior *constitutive* or structuring decisions. Hill and Hupe emphasise that in studying implementation, it is important to recognise the distinct competencies and context (e.g. politics at play) at each 'locus' of the system, organisation or individual. In this framework, one action level (e.g. constitutive action) is not necessarily confined to one administrative level such as the national government. It thus removes normative questions about where actions should take place and whether, for example, one level of government practices 'policy formation' or 'implementation', becomes an empirical question open to interpretation based on actions. Some loci may play a bigger role in determining how policy is formulated and implemented. The framework was adapted in the conceptual framework discussed below and analytically guided an understanding of the types of action that are important for policy formulation (KEML revision) and implementation at particular loci/levels in political-societal relations. The framework facilitates examination of implementation as the policy moves from the "top" to the "bottom".

Table 3-1. Multiple governance framework

	Level of action		
Level in political-societal relations	**Constitutive**	**Directive**	**Operational**
System/macro-level	Systems and institutional design (e.g. intergovernmental relations)	Policy formulation and decisions	Managing policy processes
Organisational/meso-level	Systems maintenance	Planning, budgeting, and organisational/regional decisions	Managing inter-organisational relations
Individual/ micro-level	Developing local institutions (e.g. professional norms)	Situation-bound rule application/ discretion	Managing contacts

Sources: Hill and Hupe (2006, 2014) [130, 146]

3.3 Study conceptual framework

Given the evidence from the EML literature on the diverse "hardware" (e.g. financing and supply chain) and "software" (e.g. communication) factors that affect EML policy processes and the devolved government structure in Kenya, I explored frameworks and theories that were broad enough to help me understand the diverse factors, as well as roles and dynamics between governments and other stakeholders. The conceptual framework that I adopted for this study to guide study design, analysis and interpretation is depicted in Figure 3-1. The framework draws on two widely used frameworks from the health and public policy literatures: the *policy triangle* and the *multiple governance framework*. The *policy triangle* is a flexible and widely used framework to analyse complex health policies in diverse settings [148, 149]. It has four interrelated constructs to help systematically explore how different factors may influence policy:

(1) *content* – the policy objectives and rules;

(2) *process* – the procedure by which the policy is formulated, communicated, implemented and evaluated;

(3) *actors* – the roles of governments, organisations and individuals in the process; and

(4) *context* – overall structural, political, or economic factors influencing the process.

Given the broad constructs of the policy triangle, I drew on other frameworks and the insights from the literature review to further guide the application of the framework and to facilitate analysis and interpretation of the complex decision-making and implementation processes.

The *multiple governance framework*, as detailed above, appeared well-suited for analysis of a national EML, as it is determined at the central government or system level with diverse roles and actions delegated to other organisations and individuals in the health system. This framework was adapted to the policy triangle based on their apparent conceptual and epistemological compatibility. I analysed the *actors* domain through the 'levels of action' lens (constitutive, directive, and operational actions) to understand the types of actors and actions that are influential at different levels [130]. Additionally, the political-societal levels of the framework enabled me to analytically demarcate the system levels of interest within the study objectives. As characterised above and applied to the KEML, the macro-level represents the national government and national bodies; the meso-level refers to the organisational, primarily including the county government and its sub-counties; and the micro-level is defined here according to Hill and Hupe's definition as the level "on which contacts between individuals take place" at the local level [130]. While the "meso" in terms of the organisational level of health facilities and the "micro" (individual level) are often separated, the boundaries between them

were blurred in the data, as has been noted elsewhere [150]. Thus, in this thesis the micro-level encompasses both individuals and the health facility level. This also aligns with the notion of "pragmatic contexts", where social actors and their behaviours are at the center of the implementation context [151]. Based on the objectives of the study, the EML policy process was sub-categorised into the *stages* of policy formulation (EML revision) and implementation to assist in careful analysis, recognising the need to understand how these stages interact and therefore understand the process holistically. EML revision is governed at the macro level, although stakeholders from various levels may be engaged.

To further operationalise the conceptually broad *process* and *content* domains to analyse *EML revision* (Chapter 5), I also used the descriptive framework for priority-setting processes by Barasa and colleagues, an adaptation of the policy triangle based on a review of the empirical literature on priority-setting practices, including medicines selection [152]. It has also been applied to healthcare priority-setting in Kenya, primarily in hospital settings but also at the county level [153]. For this thesis, I specifically applied the key *content* factors (namely, decision-making structures and priority setting rules) and *process* factors (priority-setting/revision process and use of evidence) from Barasa et al., based on their applicability to help describe the priority-setting process, assessed during preliminary data analysis.

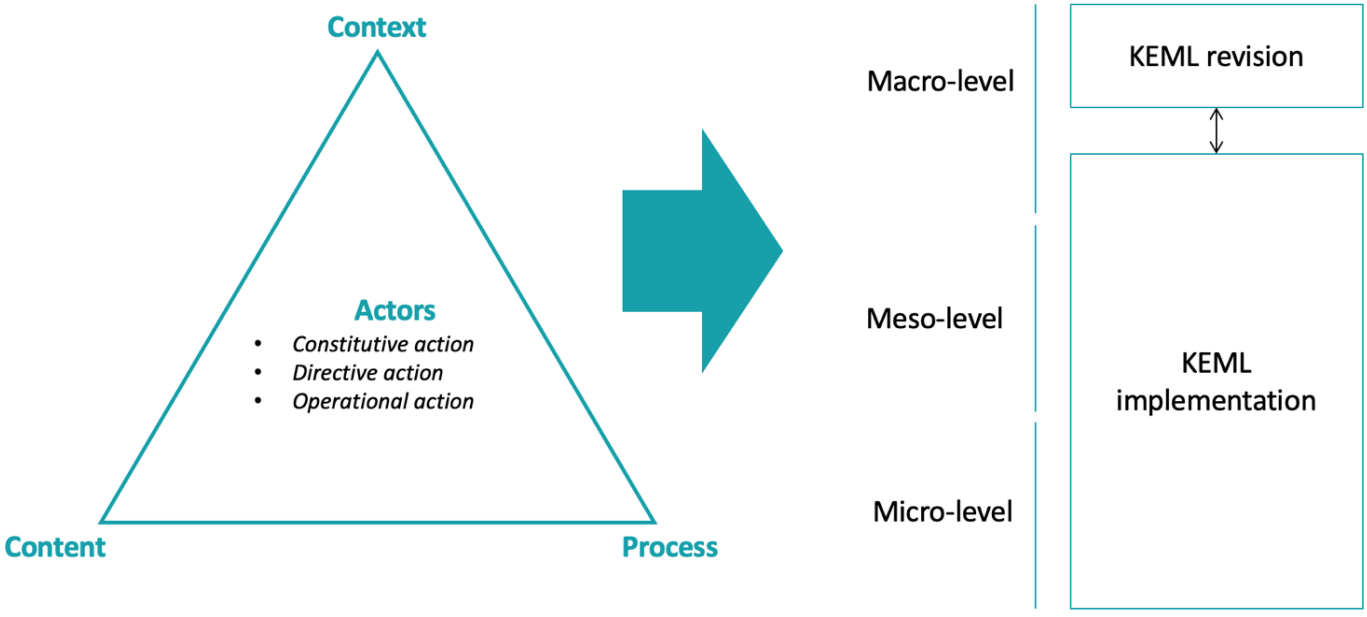


Figure 3-1. Study conceptual framework to analyse the factors affecting essential medicines list revision and implementation

3.4 Chapter Summary

Key theories and frameworks were introduced at the beginning of the chapter to provide important background and set the scene for the description of the conceptual framework applied in this thesis. The conceptual framework (Fig. 3-1) that underpins this thesis is chiefly adapted from the policy triangle and multiple governance frameworks. I approached the study objectives based on this framework, where ***KEML revision*** (addressed in Chapter 5) occurs at national or macro-level; ***KEML policy implementation at macro and meso-levels*** (Chapter 6) involves national actors and focuses on the county government and its organisational relations; and ***KEML policy implementation at the micro-level*** (Chapter 7) involves the individuals and the relations between them within health facilities. In the next chapter I discuss the methods used.

4 Methods

4.1 Study design

This study employs a case study design which allows for in-depth investigation of contemporary social phenomena in real life settings. Case studies are widely used to describe and explain context-dependent policy processes and holistically reveal the political and social processes involved [154, 155]. This approach is also suitable when the boundaries between the phenomenon (EML policy formulation and implementation in this case) and its context are not clear and these contextual conditions are thought to be critical to understanding the phenomenon of interest. To produce rich data that would enable me to explore the "how" and "why" questions underlying the complex policy process of EML formulation and implementation, I adopted the methods of semi-structured interviews, document analysis and non-participant observations. Drawing on these diverse methods of qualitative data collection allowed me to combine information from multiple sources. While the strength of the case study is widely recognised to be its high internal validity, single case studies may also elucidate features or categories relevant to other settings [156].

4.1.1 Case selection

Kenya was selected as the study setting based on its recent EML policy revisions (2016 and 2019) and perceived active use of the policy in country, relative similarity of the KEML content to the WHO EML and to other countries [97]. It was also selected for pragmatic reasons based on my ongoing experience in conducting health policy-oriented research in the country since 2013 and existing relationships with national stakeholders [157, 158]. For the case study context at the subnational level, one county—Kilifi County—was purposively selected for two reasons. First, Kilifi was chosen as a case closely resembling the national average based on diverse characteristics (Table 4-1) such as life expectancy, percentage of the population living in rural settings, percentage of total county budget allocated to health, health service readiness, and, importantly, mean availability of essential medicines [24]. The second reason for selecting Kilifi was pragmatic due to my affiliation with the KEMRI-Wellcome Trust Research Programme in Kilifi through my advisor, Prof. Barasa. The selection of one case study context allowed me to conduct a thorough and deep examination of one EML formulation and implementation context, which would likely offer useful insights on EML revision and implementation in other contexts. Details on the case study setting of Kilifi County are described in the next section.

Table 4-1. **Kilifi County and Kenya national characteristics**

	Kilifi	*Kenya*
Population[1]	1,453,787.00	47,564,296.00
Life expectancy (years)[2]	67.6	66.8
Poverty level	58.4%	45.2%
Percent of population urban[2]	26	29.9
Health facility density per 10,000 people [2]	1.9	2.04
Mean availability of essential medicines[2]	40%	41%
General service readiness index (capacity of health facilities to provide general health services) [2]	58%	57%
Percentage of total county budget allocated to health[3]	27.5%	27.2% (average % across 47 counties)

Sources:

[1]Kenya National Bureau of Statistics, 2019 Kenya Population and Housing Census (https://kenya.opendataforafrica.org/msdpnbc/2019-kenya-population-and-housing-census-population-by-county-and-sub-county?county=1000150-kilifi)

[2] Kenya Service Availability and Readiness Assessment Mapping Report, 2013 [24]

[3]National and County Health Budget Analysis FY 2018/19 [54]

4.1.1.1 *Kilifi County*

Kilifi County lies on the coastal region of Kenya (Fig. 4-1). With a population of 1.45 million people, it is the seventh most populous county in Kenya [159]. Kilifi has seven sub-counties: Kilifi North, Kilifi South, Kaloleni, Rabai, Ganze, Malindi and Magarini. The capital is Kilifi town and the largest urban centre is Malindi [160].

Kilifi County allocates about 25% of its total budget to health, which is comparable to the national average [54]. The poverty level is above the national average and a high percentage of the population live in rural areas, which are both factors associated with poor access to medicines [24, 57, 58]. Availability of general essential medicines, based on snapshot availability data from 2013, is around the national average, although this data may not fully represent the current situation in the county for the full range of essential medicines [24]. Characteristics of Kilifi County compared to Kenya national measures are described in Table 4-1. Kilifi is a unique county in Kenya to conduct health research due to a longstanding presence of a major health research centre—the KEMRI-Wellcome Trust Research Programme—embedded within Kilifi County Hospital with strong ties to the County Department of Health and health system. Thus, research

is perhaps more strongly integrated within the local health system than is the case throughout most of the country.

Source: [161]

Figure 4-1. Map of Kenya and its counties

4.1.2 Interviews and topic guide development

I conducted in-depth semi-structured interviews to gather detailed and contextualised information on the experiences and perspectives of policymakers and implementers of the KEML, aligned with my research objectives. Guided by the conceptual framework, participants were selected based on their roles related to KEML policy formulation or implementation (detailed further in section 4.2.1). Given that my research question covers a broad thematic interest in the

factors that influence policy implementation, semi-structured interviews were chosen to generate data that was most relevant from the respective participants. The format of a loose structure with open-ended questions allowed me to extract detailed accounts on the issues of interest, like the processes for KEML revision and public procurement, which would have been difficult using methods that collect mostly fixed choice options (e.g. surveys or structured interviews); while also generating data across the diverse thematic areas of the thesis conceptual framework.

I developed the draft topic guides, one for national decision-makers (macro-level) and one for county (meso) and health facility (micro-level) implementer interviews, based on the thesis conceptual framework, insights gained from the literature review, an initial document review, and drawing on questions used in past policy implementation studies described in the literature review and conceptual overview (Appendices A, B). While the overall approach and structure of the topic guide is the same for both the macro-level and meso/micro-level interviews, some questions were tailored to stakeholders based on whether they had a policy formulation (macro) and/or implementation (macro/meso/micro) role. I gathered feedback from Prof. Barasa and other experts working within the Kenyan health system on the topic guides and piloted the respective tools with an initial macro-level respondent and a meso/micro-level respondent. Thereafter, I made changes to improve the flow and clarity of the topic guides. The topic guides (Appendices A, B) outline sets of questions to explore perceptions on content of the KEML; the processes of KEML formulation and/or implementation; the roles, relations and power of actors involved; contextual features of the broader policy and sociopolitical environment and of local organisations in which participants work; and characteristics of the issue of cardiovascular disease medicines access (based on the initial research focus[5]).

4.2 Data collection

In this section, I detail the three methods I used to collect data: document reviews, semi-structured interviews, and non-participant observations. I aimed to gain a comprehensive

5 **Note on the change to my research focus:** I initially attempted to understand the KEML implementation process as it relates to cardiovascular medicines, but over time it became clear that participants spoke about KEML implementation in broad terms and explained concrete examples from other disease areas. I therefore shifted my analysis to take a health system-wide perspective, as a narrow focus on one class of medicines would have concealed important aspects of the broader KEML implementation experience. Nonetheless, focused questions on cardiovascular medicines in the topic guide and the interviews with participants based in facilities with NCD clinics allowed me to uncover codes and subthemes that facilitated an understanding of how medicine class/disease area plays a role in KEML implementation.

understanding of the phenomenon under study by triangulating these diverse sources and methods of data collection [162].

4.2.1 Participants and sampling

I purposively sampled participants based on their macro or meso/micro roles in the KEML policy process who could "provide rich, relevant and diverse data" [163]. Participants in the macro-level category were eligible if they had direct experience in, or detailed knowledge of, KEML policy formulation at the national level, such as government decision-makers, donors, or stakeholders from professional organisations, civil society, or from faith-based or private sector health service providers. The meso/micro category was comprised of implementers expected to use the KEML at the county government and street-levels, such as health facility and procurement managers, prescribers, pharmacists, and other cadres of healthcare workers [20]. I conducted an initial stakeholder mapping where I identified participants through a document review (section 4.2.3), my own experiential knowledge from conducting essential medicines policy research and advocacy in Kenya, and based on guidance from my study advisor (Edwine Barasa). I further identified participants through snowball sampling, where key informants and participants interviewed suggested others that may fit the study inclusion criteria.

For pragmatic reasons, I chose three of the seven sub-county regions in Kilifi using maximum variation purposive sampling, a method to capture diverse characteristics and conditions (e.g. based on population size, urban or rural) [164]. I also chose these sub-counties due to the presence of NCD clinics, given my initial focus on cardiovascular medicines (footnote p. 48). I selected two representatives from each Sub-County Health Management Team (SCHMT). Within each sub-county, I aimed to select participants from diverse types of facilities, including health centres (primary care, level 3) and hospitals (level 4 or 5), with either public or private financing sources. Within each facility, I sought to interview a diverse range of implementers, such as facility management, procurement staff, pharmacy staff, prescribers, and varied cadres of healthcare workers.

I determined the final sample size using the principle of thematic saturation. This means that I stopped recruiting additional participants within each of the three groups (national level, county level and street-level) at the point at which I judged, with agreement from my research associate (described below), that preliminary themes identified within interview data were repeating themselves and that additional interviews would not provide data on new themes relevant to the research question [165].

The total number of participants interviewed was 41. This included 12 national level stakeholders, 13 county level stakeholders (including SCHMT members), and 16 'street level' stakeholders including frontline healthcare workers and health facility management. A total of 7 health facilities were represented—3 public hospitals, 3 health centres, and 1 private health centre. An overview of all participants interviewed is provided in Table 4-2.

Table 4-2. Number and categories of participants interviewed

Governance level	Stakeholder representation	# of participants
National (macro)	National Ministry of Health	7
	Non-state actors: faith-based organization, professional association, donor	5
	Total national participants	***12***
County (meso)	County Executive Committee	1
	County Health Management Team (CHMT)	5
	County Treasury	1
	Sub-County Health Management Teams (SCHMTs; 3 sub-counties)	6
	Total county participants	***13***
'Street level' (micro)–Healthcare workers & health facility management	**Public hospitals and health centers (Levels 3 and 4):** Hospital and Health Center Management Teams (Medical Superintendent, Facility In-Charge, Pharmacist In-Charge, Stock managers); Healthcare workers (pharmacists/pharmacy technicians, physicians, medical officers, clinical officers, nurses)	14
	Private health center (Level 3): Clinical officer and pharmacy staff	2
	Total street level participants	***16***
TOTAL		**41**

4.2.2 Conducting the in-depth interviews

I first contacted selected participants to introduce the study either by email, phone or an introduction was made in person by participants already recruited. I approached a total of 49 potential participants, but 8 (representing a national MOH programmatic division, donor, NGO 2 pharmaceutical companies, a CHMT member, a member of county assembly, and a private hospital manager, respectively) did not respond to my interview request. After providing the participant information sheet and consent form (Appendix C), I collected written informed

consent from participants. I conducted interviews between January - March 2020 in person where possible and by phone, based on participant preference. A research associate, Evelyn Waweru, who was a PhD student living in Kilifi with expertise in qualitative research and fluent in Kiswahili, supported interview data collection for 26 of the 29 interviews in Kilifi County. The purpose of bringing Evelyn to support interview and observational data collection was to assist in translation and in mediating cultural positions where necessary, taking detailed written responses and field notes, and the presence of a second researcher allowed for discussions on interpretations of data and preliminary findings (see section 4.5). All interviews were conducted in English, although during 2 of the interviews Evelyn helped with brief clarifications on a few questions and responses in Kiswahili. These few Kiswahili responses during the 2 interviews were translated to English by Evelyn during the interview such that the participant could hear the translation. For all 12 national level interviews and 3 interviews in Kilifi County I was the sole interviewer (i.e. Evelyn was not present). Of the 41 interviews, 1 was conducted by Evelyn (in English) in my absence (reason described in section 4.8). Interviews generally lasted approximately one hour but ranged from thirty-two minutes to two hours. The topic guides (section 4.1.2) were used during all interviews. After a few initial interviews in the implementer category, I realised that awareness of the KEML was perhaps less pervasive than I had assumed. My approach to subsequent interviews changed from assuming some participant knowledge to assuming no KEML knowledge (see topic guides in Appendix B). It is unlikely that this affected the data generated, because initial interviewees clearly had KEML knowledge and in the first interview where it became apparent that the participant lacked knowledge, the approach was shifted to ask if they had heard about the KEML.

I audio-recorded interviews using a digital recording device if informed participant consent was given; all but three participants consented to audio-recording. I also wrote field notes during and after the interviews to document verbal responses and detail relevant contextual information (e.g. one participant's boss entered the room during the interview a few times) and non-verbal cues [166], and supplemented these with interview and observational notes taken by Evelyn. I sought to hold in-person interviews in a private space (office or meeting room) and to ensure participants felt comfortable speaking with me. However, in several instances participants couldn't leave their workplace or asked to hold the interview in a shared workspace with other colleagues present, who could conceivably overhear the conversation. Phone interviews were conducted such that external parties could not overhear the conversation.

4.2.3 Document reviews

I reviewed documents for several study purposes, as per Bowen (2009) [167]: (1) to inform data collection through the semi-structured interview topic guide (development of questions that had

relevance to specific actors) and observations based on events or objects that may offer important insights; (2) as a source of primary or secondary data, including contextual and KEML process data; and (3) to verify findings derived from interview or observational data.

I reviewed documents deemed relevant to the KEML and its use during the time of the study (2020). The final list of documents reviewed and included in the study, as well as their type and number are shown in Table 4-3. I included policy or legal documents published by the national or county governments—including KEMLs; reports from the KEML review workshop at national level and from health commodity quantification exercises conducted at county level; Ministry of Health presentation slides describing the KEML 2019; hospital medicines and therapeutics committee meeting minutes and terms of reference; and annual consumption reports for hospital commodities. Reports by development partners found with reference to the KEML were also included. I included documents that interview participants regarded as important in facilitating or understanding KEML implementation. Documents were also included based on whether they provided information relevant to the study aim by assessing whether and how the KEML and its role is described (or not). Although KEMLs were published prior to 2010, I selected the last three KEML editions for the study as they are the ones relevant to the policy context since devolution and would enable some analysis of changes to the KEML over time. Official policy documents were available online. I obtained documents that were not publicly available from official sources in government or hospital leadership.

I conducted a content analysis of the documents to identify pertinent information and organise information into categories based on the conceptual framework. In this process, I extracted data systematically across context of document production (author, intended audience and purpose) and authorial position [168]. I assessed document authenticity, credibility, accuracy and the representativeness of selected documents. I considered the authenticity, credibility and evidentiary value of sources by asking the following four questions proposed by George and Bennett: who is speaking, who are they speaking to, for what purpose are they speaking, and under what circumstances [169]? I also assessed accuracy and representativeness by comparing the information across documents and in relation to the rest of the data set. If data were absent or sparse, I considered the lack of data as possibly offering insight into what was not happening or actors that may not be represented in the policy process.

Table 4-3. Types and number of documents reviewed

Document type	Documents	# of documents
Government of Kenya – official policy and legal documents	Kenya Essential Medicines Lists 2010- 2019	3
	Health Act of 2017	1
	Health Laws Amendment Act 2019	1
	Kenya Health Policy 2012-2030	1
	Kenya Health Sector Strategic Plan 2018-2023	1
	Kenya Essential Medical Supplies List 2016	1
	Sessional Paper No 4 of 2012 on National Pharmaceutical Policy	1
Government of Kenya- other documents	KEML review workshop report (2019)	1
	KEMSA procurement list (dated 02/10/2019)	1
	Presentation slides for KEML launch (2020)	1
	Press release of pharmaceutical reforms (2018)	
Kilifi County Government documents	County Health Commodity Quantification Reports (Fiscal Years 2017- 2018, 2019-2020)	2
Health facility documents	Terms of Reference for Hospital Medicines and Therapeutics Committee	1
	Meeting Minutes of Hospital Medicines and Therapeutics Committee (dated 2020)	1
	Hospital commodities annual consumption reports (2018, 2019)	2
Development partner/donor reports	Kenya Health System Assessment (Health Policy Plus, USAID, PEPFAR)	1
Total		19

4.2.4 Non-participant observations

Stakeholder observation was used in Kilifi County to better understand implementation processes as they occur in the everyday lived context in which people make sense of their lives, and to reveal the actions and relations between diverse stakeholders [166]. The observations were intended to enable data collection regarding how the KEML is used in practical settings and to triangulate the interview and documentary data. Over the course of one month, I conducted

non-participant observations in a sub-county health commodity management training workshop that brought together diverse cadres of healthcare workers; during a supportive supervision visit at a health centre by a Sub-County Health Management Team; and in six health facilities where I observed pharmacy settings, including pharmacists, pharmacy staff and in one facility a prescriber. In these settings, I introduced myself and the purpose and methods of the study, but otherwise sought to make my presence as unobtrusive as possible. Evelyn, who has experience in observational methods, conducted some of the observations with me as described in the interview section.

To guide my observations, I used an existing provisional checklist that defined categories for observation, which I adapted based on preliminary analysis of documents and interviews [170] (Appendix D). The checklist was used flexibly; I added categories deemed relevant during each observation. I took field notes to document what I was observing and to reflect on my interpretation of these observations. I took a reflexive approach throughout all observations, where I thought carefully and wrote reflexivity memos on the role that I played as a visible foreigner, my engagement with others, and how my presence might have been perceived by and shaped the behavior of those I observed [170]. Evelyn also took notes in the observations when present and we discussed our observations and reflections on them following each event.

During my fieldwork between January to March 2020, I also engaged in informal conversations with healthcare workers about their knowledge and perceptions of the KEML. I recorded my personal accounts of these conversations, contextual information, my interpretation of the interaction and information gained in my field notes.

4.3 Data management

Audio-recorded interviews were transcribed into Microsoft Word. All digital audio and text files were stored on my personal password protected laptop and backed up on an encrypted external hard drive kept in a secure location, along with any hand-written notes and my journal. I crosschecked the accuracy of each transcript against the audio-recordings and notes. I typed up my field notes and memos into Microsoft Word and imported interview transcripts, field notes and memos, and documents collected into NVivo 12. Data were stored on an encrypted and password-protected file, only accessible only to the researchers involved with this study who agreed to maintain participant confidentiality.

4.4 Data analysis

My analytic strategy, detailed throughout this section, combined both deductive and inductive thematic analysis [171]. I used the thesis conceptual framework deductively, while allowing for the inductive identification of more specific themes within the broader framework constructs. The steps I took during analysis involved: memo writing, familiarization, coding, developing a thematic framework, a describe-compare-relate approach, and case description.

Memo writing: As is standard in qualitative research, I began my data analysis during the data collection phase by writing memos [172]. After interviews and observations, I either compared notes, discussed insights, developed additional questions, and identified early interpretations with Evelyn, or discussed insights and possible preliminary themes with supervisors or advisors. I documented my insights and summaries of my discussions in my field journal, and this memo writing helped further stimulate my analytical thinking about the data [162]. During this time, I also created diagrams capturing processes or actor relationships and hierarchies described in interviews, observations and documents in my journal to clarify my thinking.

Familiarisation: I immersed myself in the data through interview transcription, revisiting the audio files, and reviewing the transcripts and memos. During this process, I noted possible quotes of interest (or what Saldana describes as pre-coding), preliminary ideas and possible patterns, and reflected on the meaning I interpreted from the data [173]. Revisiting these notes assisted in my subsequent analysis.

Coding: I approached my coding in two stages. To begin, I conducted manual line-by-line coding of all interview transcripts in NVivo 12 by applying both open codes, where I developed inductive codes based on ideas, categories and terms (my own and those described within the data), as well as *a priori* codes derived from the conceptual framework and based on key themes or ideas based on the literature review (chapter 2; e.g. use of evidence, stakeholder participation) [172]. These codes were attribute codes (e.g. private sector), descriptive codes (summarizing the main topic of the excerpt), subcodes (e.g. policy content- legal aspects), process codes (e.g. KEML revision process), versus codes (suggesting conflicts or competing goals between participants/actors), evaluation codes (judgements made about activities or policies), causation codes (attributions or causal beliefs expressed in the data), magnitude codes (indicating intensity or frequency), and structural/organizational codes (representing a topic of inquiry to categorise a data set) [173]. Each type of code was applied with a focus to explore broader processes, participant actions and perceptions within the data, and allowed me to approach the data from different lenses. I approached this first round of coding by simultaneously "lumping" and "splitting", approaching the data both holistically to look for overarching themes or categories to

revisit and in a more granular way to look for specific themes or concepts [172].

During the second coding stage I refined and further interpreted codes from the first stage. I developed pattern codes (which may be explanatory or confer meaning, e.g. KEML as a procurement tool) and focused codes ("the most frequent or significant" codes, e.g. dissemination and communication) that brought together related ideas and concepts [173]. These constituted a set of *a priori* and emergent themes, where themes were understood as the "outcome of coding, categorization, and analytic reflection" [173]. Using multiple overlapping codes allowed me to begin to explore the relationships between codes.

Developing a thematic framework: I developed a thematic framework through an iterative process that began with my coding framework (based on the conceptual framework). I displayed the coding framework in a chart to sort relevant data from diverse participants, documents, and observational notes to their relevant themes, which also allowed me to better detect patterns for further analysis and interpretation (e.g. associated with categories of respondents).

Describe- Compare- Relate: I applied Bazeley's "Describe- Compare- Relate" approach as I wrote my findings, in which I first described the characteristics and boundaries of a theme or category, then compared the differences in the characteristics and boundaries of that theme or category across different actor groups or contexts, and then sought to relate this theme or category to others identified [172]. Writing using this approach was an important part of the analytical process.

I found it useful to structure the results in each of the chapters using the conceptual framework; however, determining the "fit" of underlying themes across the broad categories of the framework was a long and iterative process. Given the frequent overlaps of themes that could be held within the framework constructs, I trialed presenting themes through different lenses as I was writing to determine how to best present the data to avoid concealing important details and give sufficient weight to the most important findings. For example, actors are necessarily part of the policy process, so trial and error was involved in ensuring that the roles of actors were not lost in the process description, while avoiding repetition across the two constructs. Thus, although I highlighted findings within certain framework constructs, they often intersect with other constructs. Notably, throughout the results chapters, the influence of actors permeates all themes, although analysed more closely within the actors and institutions domain. The analytical writing process also involved further examining the similarities and differences between the

three data sources, reflecting on whether the data supported or challenged the emergent interpretations across the full data set.

I sought further explanations and ideas to strengthen or complement my analysis across a range of theoretical and empirical literature in health policy, governance, and public administration. Overall, my approach to developing my findings was done through a cyclical and iterative process. Throughout analysis I constantly aimed to seek out divergent views to challenge generalisations or interim conclusions [172].

Case description: Given that the KEML policy process has not been described in detail in the literature, I sought to develop a comprehensive descriptive-explanatory narrative of the KEML revision and implementation processes [154]. I charted codes and themes developed associated with the KEML revision process to find patterns and construct a chronological sequence of events and activities that constitute the processes of interest. I incorporated primarily qualitative, but also some quantitative data (with basic descriptive analyses, such as number of stakeholders who participated) derived from documents, to provide information on particular events, actions or features of the process.

4.5 Positionality

Walt et al. describe the importance of health policy researchers engaging in an analysis of "their own institutional power, resources and positions (in much the same way they would analyse actors in the policy process) and their role in defining research agendas and generating knowledge (rather than assuming they are 'objective' and 'independent')" [174]. I took a reflective empirical research approach in which I considered, as much as I was able, how my own values, perceptions based on the dominant societal structures I was raised and educated in (e.g. Canada as a capitalist, settler colonial society; the colonial legacy of LSHTM and the United Kingdom), the assumptions I hold based on my educational background and work experiences in global health, cognitive abilities, and linguistic and cultural background may have shaped my interpretations during this research, rather than assume that I was handling objective "empirical material" [175]. I also noted how my own interpretations were shaped by the interactions with participants and how their interpretations, based on what I knew of their contextual realities, may have shaped the information conveyed to me. I kept a research journal with reflexivity memos, where I documented my reflections on these factors, any personal reactions I had to social interactions, the choices I made in the analysis and interpretation and the reasons for these.

I acknowledged that my research, in seeking to affect resource distribution in the form of essential medicines, is inherently political. I frequently found myself interrogating the values and assumptions I hold based on my positivist education in the biomedical sciences and the associated propensity to make sense of complex social phenomena in a de-contextualised or "technical" way. I also reflected on how my current disciplinary background (the interdisciplinary nature of health policy and systems research) and my experience and self-perception as an activist working globally and in Kenya on access to medicines issues may have affected data collection and analysis, documenting how my ideological positioning could influence the findings [174].

My knowledge of existing literature and conversations I have had with colleagues on the topic of national EMLs may have shaped my study design, the questions I asked and how I interpreted findings. I held an existing belief, and perhaps bias, that EMLs can be useful tools to promote access to medicines. I made efforts to approach my fieldwork and the analytical process by repeatedly questioning this belief and actively seeking out evidence to refute my bias.

The field of policy implementation research has often been dubbed "misery research", due to an often cynical orientation in studies to assume the inevitability of an "implementation deficit" [130]. I reflected on whether I emphasised this orientation in my research and sought to correct for it by presenting aspects of "implementation success" based on my interpretation of the data.

During data collection and interpretation, I also reflected on my position as an "outsider" to the policy process and the Kenyan health system and how participants' viewing me as such may have shaped their responses or behaviour. There were possible benefits as well as limitations to conducting this research as an outsider. Possessing a "foreign gaze" means that I was less likely to carry engrained personal biases associated with the study context and could approach inquiry through a curiosity with the "unfamiliar" [176, 177]. I could easily ask participants "naïve" questions and could perhaps in some cases elicit more candid responses based on perceptions that I was outside of "the system" and therefore not a direct threat. Conversely, my role as an outsider means that I held a limited understanding of specific power dynamics and nuances around politics, social or professional hierarchies, ethnicity, class, and historical legacies, which could have impeded a deeper understanding of the phenomenon under study. For example, as someone who is not a healthcare worker or patient within the healthcare system in Kenya, I may have lacked understanding of some practical health service delivery realities. Many interviewees generally did not seem to hold an assumption that I would understand their role or position, which could have limited the detail or candor in their responses. I attempted to correct for the shortcomings of being an outsider by involving "insiders" at all stages of this study, from study

conception and design to the presentation of findings. I was introduced to several of the participants through my advisor or colleagues who are policy or health system "insiders", which often appeared to facilitate a level of trust. As a policy "insider", my study advisor was able to sense-check the findings. I engaged in "verbal collective reflexivity" with Evelyn and some of the research participants, to openly explore and discuss positionalities that could affect the research. I likely benefited to some degree from previously having lived and worked in Nairobi, which means I held some insight into the health system, social and cultural realities, such that I may classify as an "informed outsider" [176].

Finally, given the persistent colonial practices in global health research, I considered how the audience I was writing for may have shaped the analysis and writing [177]. As a foreign researcher my natural inclination may be to write for a global health audience, but in my analysis and writing I made concerted efforts to focus on these key audiences: Kenyan experts, policymakers and practitioners; those examining this DrPH thesis; and academic audiences to whom Kenya may be foreign.

4.6 Quality and rigour in qualitative analysis

To enhance the quality of this study, I adopted a number of different approaches regarded as standard in improving qualitative case study validity and reliability [154]. The concepts of validity and reliability in qualitative and interpretive research should be understood in their own terms. Validity as applied here is not necessarily the "truth", according to positivist ideas but about credibility and legitimacy of research [166]. Reliability is similarly about whether the interpretation offered is credible, recognising that it is rooted in my positionality.

The interviews allowed me to collect "*rich data"* that provided a significant amount of detail and context to ground and test conclusions drawn in this study, which Maxwell describes as a strategy to test validity and give qualitative work a level of transferability, or theoretical generalisation [162]. While I did not conduct long-term participant observations that would provide an additional validity check for the study due to the time limitations associated with the DrPH thesis and the onset of the COVID-19 pandemic, I recorded detailed, descriptive notes of the observations I was able to undertake.

Triangulation was used to assess reliability of findings during data collection and analyses. My study was guided by theory, or theoretical triangulation, through the application of the thesis conceptual framework and theories detailed in Chapter 3 to the study design, data collection and analysis.

I also drew on diverse data sources—interviews, documents and observations—that allowed me to compare and complement findings between these different sources. This was particularly useful to gain a more comprehensive understanding of the policy process and the relationships between actors. I was able to select a wide variety of participants to gather data representing a range of diverse experiences and perspectives, for example from national policymakers, county health managers with diverse roles and responsibilities, healthcare workers both with and without a professional training background, and supply chain actors at national and local levels. By using different analytical methods (section 4.4), I was also able to approach the inquiry from different angles, for example, case description allowed me to gain a different perspective on the data compared to the thematic analysis approach. Finally, I involved a team of researchers (a research associate, supervisors and advisors) who participated in data analysis and assessing the consistency of the findings. Specifically, where possible, for interviews and observations undertaken in Kilifi County, I discussed each of the interview experiences, early interpretations and observations with Evelyn after they occurred, recorded summaries of these in my journal, and later we cross-checked our notes and discussed and interrogated some of the findings based on our diverse backgrounds. A subset of my thematic coding was reviewed by a supervisor, which allowed us to discuss alternate ways of coding and interpreting the data and to arrive at some mutual agreement on their interpretation. Importantly, the use of triangulation allowed me to gather divergent perspectives to form a more multifaceted understanding of the case study [178].

During my analysis I also searched for *discrepant evidence* to test the validity of my claims. For conclusions I drew, I endeavoured to approach both supporting and discrepant data with the same rigour.

I also shared and presented preliminary findings with my four supervisors and advisors, as well as other research colleagues at the KEMRI-Wellcome Trust through a research seminar (January 2021) and at LSHTM (Research Degree student work in progress presentation in September 2020, Kritikos qualitative research group presentation in June 2021) at different stages of the analytical process to benefit from feedback, to identify possible biases or assumptions I may have missed, and further interrogate the interpretation of findings and test my conclusions.

Reflexivity represented another important practice throughout this study. I constantly reflected on my personal reflexivity and epistemological position might influence data collection, analysis and interpretation (see section 4.5).

Comparison was another strategy applied, as I was able to compare the macro-level interview responses with the meso/micro-level responses, document data and some interview data allowed me to compare the same policy (the KEML) at different times (2016 and 2019 editions), and during the interpretation I also compared by findings to previous studies that reveal policy process associated with national EMLs [162].

4.7 Ethical considerations

The Amref Health Africa Ethics & Scientific Review Committee (ESRC) granted ethical approval for this study in Kenya (ref. number: P713-2019; Appendix E), as did the London School of Hygiene & Tropical Medicine (LSHTM Ethics Reference number: 17773; Appendix F). I obtained a research permit from the Kenya National Commission for Science, Technology and Innovation (NACOSTI, Ref: NACOSTI/P/20/3495; Appendix G). Additionally, I received a letter of authorization to conduct the study in Kilifi from the Kilifi County Department of Health Services, County Government of Kilifi (Appendix H).

4.7.1 Informed Consent

I spoke with all participants about the study purpose, details, and methods to gather data, and shared a participant information sheet (Appendix C) prior to conducting interviews or observations and accessing documents that were not publicly available. Participants had the opportunity to ask questions and I obtained written informed consent from participants before conducting any interviews or observations [166]. The consent form included the option to consent or decline digital audio-recording of interviews. I notified participants that they were not required to answer any questions they did not wish to and that they were free to withdraw their participation at any time without any negative consequence.

For data collection at health facility levels I contacted hospital medical superintendents and health centre in-charges to provide detail about the study purpose, what it would involve, allowed time for them to read the participant information and consent forms, and obtained their verbal consent to undertake study activities in their facilities. I also sought permission to conduct observations from relevant leadership involved (e.g. meeting hosts), who helped disseminate information to participants involved about my identity as a researcher, as well as the study purpose and procedure. While it was difficult in some contexts, such as for a large meeting, to obtain informed consent from all members present, I made efforts to ensure that participants present during such observations were made aware that any of their interactions in my presence could constitute some form of data gathering. I endeavored to communicate that if they did not wish to take part in the study, they were free to request that no observational data be gathered

that included them.

4.7.2 Confidentiality

I sought to ensure confidentiality of the participants by removing all identifiers or any information that can trace back to the participants from the interview data during the transcription stage. Codes noting the type of respondent (e.g. national MOH) were used in place of names. Similarly, I ensured that field notes, observation notes and reflexivity memos did not contain participant identifiers. Findings were presented in aggregate and data were anonymised as much as possible. Any quotes reported were not attributed to named individuals and I made all efforts to exclude information that may reveal the participant's identity.

I explained to participants that this study was not an audit and that I was not there to monitor their adherence to the KEML or report to others on their work. Nonetheless, some participants appeared to answer questions based on what they thought I wanted to hear or perhaps felt that their knowledge or skills were being assessed. I made efforts to assure them that they were not expected to have specific knowledge or practices associated with the KEML, but I did document where these types of responses may have arisen, how I interpreted this response and how it might affect the findings. I did not intend to collect sensitive information about participants and explained to them that I simply sought to understand their views and experiences on the KEML and its implementation. Nevertheless, some of the information disclosed to me could have possible negative consequences for participants and therefore I erred on the side of caution to protect their anonymity.

4.8 Impact of COVID-19 pandemic

I left Kenya unexpectedly before the planned conclusion of data collection due to COVID-19 restrictions, which meant that I was unable to conduct some of the planned observations. The associated limitations associated are discussed in chapter 8. As noted earlier, my research associate conducted one interview in my absence that had been scheduled prior to my revised plans to depart due to COVID-19. While the interview could have been done remotely, the participant preferred to conduct the interview in person prior to the first lockdown in Kenya. While my fieldwork and immersion in the research context for this study was relatively short (2 months) due to pandemic limitations, I attempted to seek remote immersion as possible through regular exposure to Kenyan media and through regular discussions with the research associate, friends and colleagues working within the health system.

4.9 Chapter summary

In summary, I designed a case study to explore both KEML formulation and policy implementation at macro-, meso- and micro-levels of the health system. The processes of collecting data through in-depth interviews, documents, and non-participant observations were detailed in this chapter. I also described my analytic strategy using thematic analysis and case description, the role of positionality in this research, and reflections on study validity and reliability and ethical considerations. Further considerations on the limitations of the methods and generalisability are discussed in chapter 8. Over the next three chapters I discuss the study findings.

5 Selecting essential medicines for Kenya: description and analysis of the Kenya Essential Medicines List revision

5.1 Introduction

Understanding how priority medicines are selected for the KEML and the factors that influence medicine selection can help inform strategies to improve the process and ensure that it is responsive to health and social needs in the country. Additionally, based on the literature review (Chapter 2), the decision-making process for EMLs can influence their implementation. In this chapter, I describe the KEML review and revision process (hereafter referred to as *KEML revision*) and analyse key factors that influence medicine selection at the national level, as well as key implications for KEML implementation.

I present a case study of the national KEML revision as it occurred for the latest two editions of the list, in 2016 and 2019[6], comparing differences where applicable. These two editions were chosen because the 2016 edition was the most recent to be implemented and the 2019 edition is the most recent for which the selection process was completed. The findings in this chapter are based primarily on analysis of documents and interviews with national level participants (n=12), but also draw on the views of implementers (county and street-level) about the KEML revision process (n=29) (see Chapter 4). The findings are presented based on the conceptual framework and summarised in Figure 5-1. To begin, I present descriptive findings on how the revision process occurred, setting the scene for the remainder of the chapter. Thereafter, I present analytical findings on the strengths and limitations of the KEML revision *process* and the influence that political *context* and key *actors and institutions* had on this process. Based on my literature review (Chapter 2), no previous studies have been conducted that focus on describing the national KEML revision process and analyse how actors and context influence the process.
An important contribution of this chapter lies in the 'thick description' of the medicine selection process and the key factors shaping that process, which further illuminate opportunities to strengthen the process in the future.

[6] Links to full KEML documents (accessed September 2021):
https://www.health.go.ke/wp-content/uploads/2016/07/KEML-2016Final.pdf
https://www.health.go.ke/wp-content/uploads/2020/03/Kenya-Essential-Medicines-List-2019.pdf

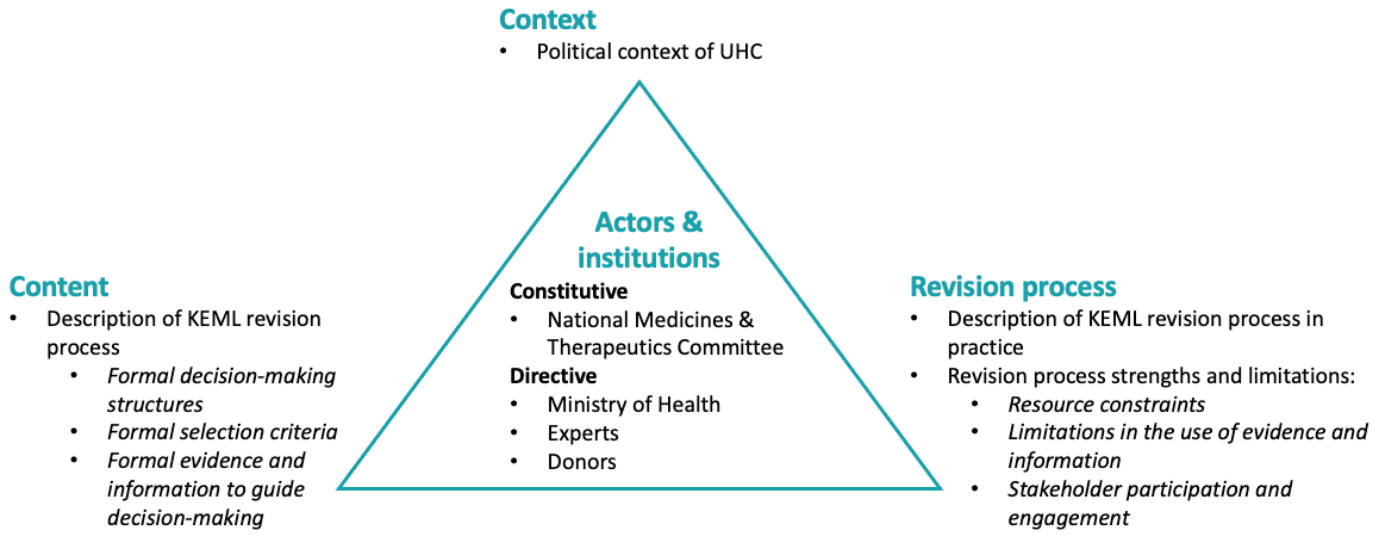


Figure 5-1. Overview of descriptive findings of the KEML revision process and the key process, actor and contextual factors influencing KEML revision

5.2 Description of KEML revision

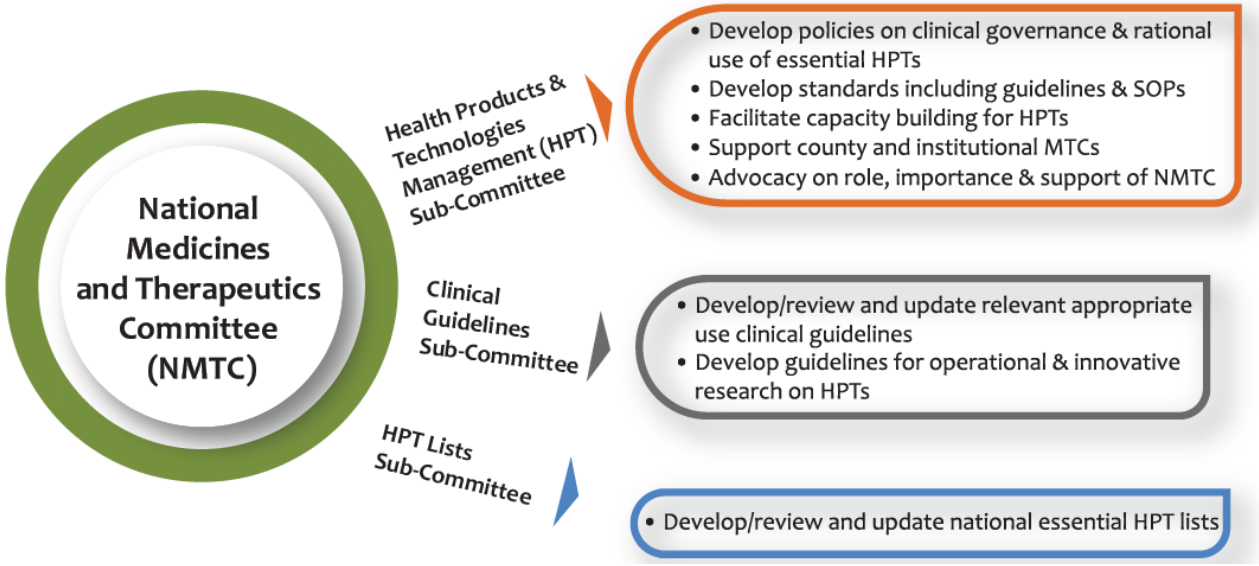
In this section, I begin by describing formal rules and features of the KEML revision process on paper: the decision-making structures, medicine selection criteria and the type of evidence intended to guide decision-making. Subsequently, the overall KEML revision *process* as it has occurred in practice over the past two revisions is described.

5.2.1 Formal decision-making structures

The Ministry of Health (MOH) Division for Health Products and Medical Technologies (DHPT) has the mandate to revise the list and initiate the revision process, serving as the KEML secretariat. The MOH developed Standard Operating Procedures (SOPs) as process guidance for the revision process of the KEML and the Kenya Essential Medical Supplies List in preparation for the 2016 KEML (KEML 2016). The KEML should be revised every 2 years through an evidence-based and consultative process [1, 23].

The National Medicines and Therapeutics Committee (NMTC) is the body responsible for selecting priority medicines and health products for the country and overseeing their optimal use within the health system. This includes coordinating the development and review of policies and guidelines, such as the KEML, the National Clinical Management and Referral Guidelines (hereafter referred to as standard treatment guidelines, or STGs) [179], and the Kenya Essential Medical Supplies List. The NMTC membership is specified in its publicly available terms of reference and is to be comprised of 13 MOH officers from across various departments and

divisions (e.g. nursing services, medical laboratory services, strategic national health programs), as well as representatives from the *Pharmacy and Poisons Board (PPB;* regulatory authority) and *Kenya Medical Supplies Authority (KEMSA;* procurement agency*)*. The NMTC is accountable to the MOH. It operates through sub-committees tasked with different roles, such as updating clinical guidelines and the essential health products and technologies lists [23]. The structure and overall roles of the NMTC and their sub-committees in relation to clinical governance are depicted in Figure 5-2.



(Source: KEML 2019)

Figure 5-2. Structure and roles of the National Medicines and Therapeutics Committee

The KEML Technical Working Group (TWG), formed through the NMTC, undertakes the technical task of reviewing medicines and the decision-making task of selecting medicines for the revised KEML (the TWG is represented as one of the health products and technologies (HPT) lists sub-committees in Figure 5-2). The role of the TWG is to apply the essential medicines concept and principles as defined by WHO, review existing government policies and relevant international guidelines, and to consult and engage with "all the relevant experts and stakeholders", according to its terms of reference [1, 23].

5.2.2 Formal medicine selection criteria

According to KEML documents, a set of 9-10 selection criteria have been used in the KEML revision process to guide decision-making on medicine listings. These criteria are adapted from WHO EML criteria and include health needs of the population, safety, comparative efficacy, quality, evidence of medicine performance, comparative cost-effectiveness, suitability for local

use, pharmacokinetic profile and local manufacturing capacity. The criteria are fully listed in Table 5-1. No clear guidelines were found on how the criteria were operationalised in the decision-making process, such as how efficacy, safety, quality, and comparative cost-effectiveness are assessed and established. Nor did there appear to be guidelines on which of the criteria to prioritise in decision-making. Proposed sources of evidence are described in the next section.

Table 5-1. Criteria for selecting medicines to be listed on the Kenya Essential Medicines List

Edition	Selection Criteria
KEML 2016	1. Relevance/Need: Public health relevance and contributes towards meeting the priority health care needs of the population 2. Safety: Scientifically proven and acceptable safety (side-effects & toxicity) in its expected way of use 3. Comparative efficacy: Proven and reliable efficacy compared with available alternatives (based on adequate and scientifically sound data from clinical studies) 4. Quality: Compliance with internationally acceptable quality standards, as recognized by the national medicines regulatory authority (the Pharmacy and Poisons Board), including stability under expected conditions of storage & use 5. Performance: Sufficient evidence of acceptable performance in a variety of settings (e.g. levels of health care) 6. Comparative cost-benefit: a favourable cost-benefit ratio (in terms of total treatment costs) compared with alternatives 7. Single ingredient: Unless there is no suitable alternative available, a medicine should have only a single active ingredient 8. Local suitability/appropriateness: Preference should be given to a medicine which is well known to health professionals, suitable for local use (e.g. dose-form, staff training, support facilities) and socio-culturally appropriate (e.g. method of use/administration) 9. Pharmacokinetic profile: Favourable pharmacokinetic properties (absorption, distribution, metabolism, and excretion; drug interactions) 10. Local production: Possibility of being manufactured locally (for improved availability, reduced procurement costs)
KEML 2019	Same as above except one change: Removal of criterion 7 (single ingredient)

Source: KEMLs 2016, 2019

5.2.3 Formal evidence and information to guide decision-making

The selection criteria outlined in Table 5-1 broadly suggest the types of evidence, such as on efficacy and safety, intended for review in the selection process. The particular types of evidence that should guide decision-making on the selection criteria are, however, not clearly specified

publicly and the evidence and information described in the KEML leave some room for interpretation. These sources of evidence and information intended to guide the NMTC and the TWG in the review process, according to KEML documents, are summarised in Table 5-2. Sources include existing MOH clinical guidelines and protocols, the WHO EML, evidence from operational research or other studies on essential medicines, quality assurance information, and information from manufacturers of products listed or under consideration. Feedback or reports from users in county government, procurement and service delivery roles are also intended for consideration during the review to ensure that the KEML meets local concerns and needs. Lastly, an amendment submission mechanism should inform decision-making.

Table 5-2. Evidence and information sources and types intended for consideration in the KEML revision

Source or type of evidence of information	Examples
Ministry of Health disease management protocols and clinical guidelines	National Clinical Management and Referral Guidelines, which guide management of conditions at all levels of the healthcare system-community level to hospital level. Treatment guidelines for specific therapeutic areas
WHO Model Lists of Essential Medicines (adults & children)	International standards/recommendations for medicines prioritization
Operational research on KEML use by NMTC or MOH	Research on KEML use in medicines financing, health insurance, supply chain, donations, medicines regulation and monitoring/quality assurance, health workforce development, appropriate use, and local manufacturing
User reports and feedback	Feedback from received directly from county governments, healthcare workers, supply chain managers and other users, or through health facility supportive supervisions conducted by sub-county governments on medicine safety, efficacy, etc. (selection criteria)
KEML amendment submissions	Written amendment proposals supported by scientific evidence submitted by users/stakeholders via a form supplied in the appendix of recent KEMLs, wherein stakeholders can propose changes to the KEML in the form of additions, deletions, and changes to dosage form. The form asks for submission of arguments, evidence, and relevant references and documentation for any proposed amendments.
Studies on disease management and medicines utilization	Any studies supplying evidence on selection criteria relevant to medicines/therapies under consideration
Quality assurance systems	New information on pharmacovigilance, post-market surveillance
Product manufacturers	New product information

Adapted from KEML 2016, 2019

5.2.4 Description of KEML revision process in practice

The KEML revision followed largely consistent processes for the 2016 and 2019 editions; this consistency was seen as a strength of KEML revision by several policymakers and appeared to be an improvement from the previous editions (2010 and earlier). The major steps of the revision process and associated decision-making bodies, based on documents and interviews, are illustrated in Figure 5-3. MOH officials appoint both the NMTC to oversee the KEML process and the TWG responsible for medicine selection. The MOH DHPT prepares for the review process through preliminary review of the latest edition of the WHO EML, clinical guidelines and other information (a list of references is appended to each KEML) and creates a KEML review tool that is used during decision-making. The KEML review tools used for the 2016 and 2019 lists were spreadsheets to compare commodities listed in the previous KEML with those in the most recent WHO EML and other sources.

The KEML TWG and NMTC convened two 2–3-day workshops for each edition to review medicines by therapeutic category within the KEML review tool and engage in a consensus-based decision-making process guided by available evidence and information. The tool listed therapeutic category, international non-proprietary name, dose-form (e.g. injection, tablet), strength/ size, level of use in the health system (e.g. levels 1-6), whether it was listed in relevant national or international guidelines (e.g. antimicrobial resistance guidelines), the decision of the TWG, and any comments or justifications for the product. Decisions included whether to retain or delete for medicines listed previously, or to add or ignore medicines that were not on the previous KEML. Changes could also be made to the level of use, dose-form or strength/size of medicines.

During both revision processes, the TWG and NMTC signed forms declaring conflicts of interest. No conflicts were declared for the 2019 workshops; no information was found for 2016. The forms were drawn from 2010 WHO guidance and thus any conflicts of interest appeared to be defined according to this guidance [180]. It is unclear whether all experts consulted in the process, outside of the NMTC and TWG, were required to declare conflicts of interest. I was unable to ascertain whether any explicit criteria were used to determine when a competing interest constituted a conflict of interest, although such criteria can help facilitate decisions [181]. After the workshops, a series of meetings were held to consult specialist experts on particular therapeutic categories. The draft KEML was validated internally through the TWG and externally through stakeholder engagement meetings. The new edition of the KEML was then finalized and endorsed by MOH officials.

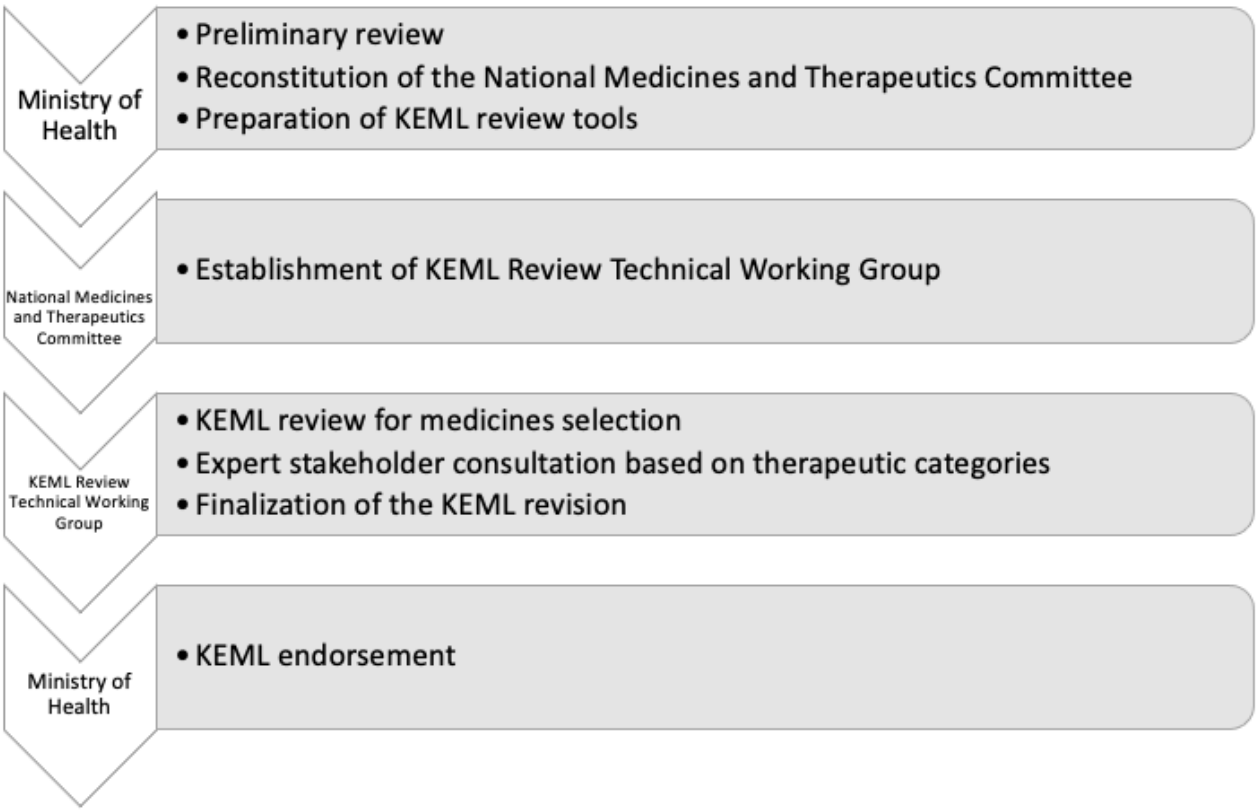


Figure 5-3. Overall process of the KEML review and revision

5.3 Revision process strengths and limitations

Three key revision process factors were deemed as particularly important in shaping medicine selection decisions: resource constraints, the use of evidence and information, and stakeholder participation and engagement. While resource constraints and the use of evidence and information were seen primarily as process limitations, stakeholder participation and engagement were seen as a strength by some participants and as a limitation by others, as further explained below. Stakeholder participation and engagement also had a key influence on KEML implementation.

5.3.1 Resource constraints

Resources, in terms of financial and time constraints, posed limitations in the KEML revision process, which both appeared to be the result of high-level political priorities. Time constraints to complete KEML revisions were seen as a major limiting factor that precipitated "*compromises*" [23, 182] in the use of evidence and stakeholder engagement in the process. For the 2016 edition, after a period of delay in revising the *"obsolete"* KEML 2010 [1], the review was conducted at a time where there was:

> urgency to produce an updated list as soon as possible… to guide medicines procurement decisions and improve current medicines utilisation practices. –KEML 2016

This urgency to complete the review was described as a justification to skip over full adherence to the SOPs developed for the revision process, including that:

> it was not possible to insist on full written justifications to be submitted in support of list amendment proposals. – KEML 2016

Similar time constraints were expressed for the 2019 process by policymakers and in the KEML document, but urgency was imposed from the political level [23]. Several decision-makers described a rushed process and pressure from senior MOH level to finalise the list due to its utility in guiding the UHC benefit package. A NMTC member noted, for example, that:

> …the other thing that didn't work very well I think was time, time conscious; so there was a lot of push and hurries in this document...- National MOH 7

As in 2016, the 2019 KEML notes that time limitations resulted in limitations to the use of evidence:

> it was not possible to fully implement use of the best scientific (evidence-based) practice this time around – KEML 2019

Nonetheless, one policymaker described the short timeline for 2019 as a positive development from previous years, reflecting a well-managed process and improved MOH capacity.

Financial constraints due to limited government funds for the KEML were also expressed. Policy activities related to the KEML over the recent editions have relied heavily on donor funding. There have not been consistent or reliable MOH financial resources dedicated to revising and implementing the KEML. The NMTC also had limited funds to support its broader activities, as described by one member:

> Because when I go back to my comment that we were supported by a donor, then it tells you there are no resources, they are not enough to support the activities of the National Medicine and Therapeutics Committee. […] So if it gets the approval from Treasury then we get the money. But currently, no, we are still hoping for donors to support us. – National MOH 7

The MOH provided partial funding for the 2019 edition. The lack of or limited government funding for the KEML was also contextualised by several participants within a broader landscape of

underfunding health, and that resources are deployed to problems on a reactionary basis rather than through sustainable health systems planning, as noted by one policymaker:

> …generally speaking healthcare in Kenya has been chronically underfunded […] That means the resources that were going to be available, not just for essential medicine list […] when you're underfunded you tend to only work on emergencies, firefighting. Yeah, you don't do governance tools, or you know, health system kind of things. – National MOH 4

5.3.2 Limitations in the use of evidence and information

While there is intent to base KEML listing decisions on the best possible evidence and information available, several policymakers expressed that decisions were often based on expert experience and opinion instead of evidence. Decision-makers emphasised the revision as a consensus-based process between experts.

> …one of the challenges in the review of the EML is where people have no documented evidence of what they say about either it's the efficacy or the safety of the product. […] you may find there is some information which they'll want to be taken authoritatively, but when you ask for the evidence for the documentation of that information, we simply cannot get it. […] in that type of situation you have to reach some consensus. – National MOH 1

Limited *availability* of evidence and information was most frequently described as a challenge impeding evidence-informed decision-making. Several types of evidence and information intended and needed to guide medicine selection, as described in section 5.2.3, were either lacking or sparse. While the need for better integration of information available for decision-making was widely noted among participants and in documents, there was some variation in the types of information that decision-makers deemed missing.

First, a lack of available context-relevant national and clinical evidence for reviewers to judge selection criteria (e.g. cost, number of patients expected to benefit) were cited as a challenge within KEML 2016 and 2019 editions. For example:

> For certain proposed items information was missing or incomplete in terms of such aspects as: (relative) cost, availability, cost-effectiveness, numbers of patients expected to require/benefit from the item (to assist in making a judgement on public health priority), limited published scientific information on an item and its use, and lack of written submissions for proposed list amendments. – KEML 2016

Second, some issues were raised about the appropriateness of evidence used in the selection process. Notably, while the MOH STGs [179] are meant to inform KEML decisions, they were last

published in 2009 and widely deemed outdated and inadequate to guide clinical practice or KEML listing decisions in 2016 and 2019. A national decision-maker noted this:

> What really didn't work very well was […] I am trying to look at the treatment guidelines and the protocols and then you find they are actually very old, they are not even updated so you cannot really work with the treatment guidelines... – National MOH 7

Policymakers noted that they planned to revise the STGs after the KEML 2019 and that the KEML was prioritised primarily due to time constraints. This approach was generally deemed suboptimal, as one MOH participant describes:

> I was actually arguing that we actually need to do the evidence based standard treatment protocols before then we can really revise the EML. But then due to the urgency of the matter, given that now we are rolling out UHC and […] revision of the guideline is something that takes quite a while. And so we put the cart before the horse. - National MOH 3

Third, the amendment proposal mechanism to receive user-submitted evidence or information to guide medicine changes has not been functional, as discussed further in the next section. As is the case with the WHO EML process, amendment proposals supported by scientific justification are meant to guide the decision-making process.

Finally, while not raised in interviews as a concern, the lack of explicit guidance within documents on how selection criteria should be defined and operationalised may have posed a barrier to evidence use. Without these clear definitions and operationalisation rules, such as on quality (e.g. what standards are used to judge quality?) and cost-effectiveness (e.g. if measured based on incremental cost-effectiveness ratio threshold, at which threshold value is a medicine deemed cost-effective?), it is difficult to use evidence to guide decisions [183].

5.3.3 Stakeholder participation and engagement

Participation and engagement limitations were widely expressed—particularly by implementers—in terms of both (1) *types of stakeholders*, which were county representatives and healthcare workers and (2) *inadequate mechanisms* for meaningful engagement, which are discussed in sequence. The *types of stakeholders* that implementers in Kilifi and at the national level felt were insufficiently engaged in the KEML review process were healthcare workers and county representatives—the "people on the ground" (Sub-County Health Manager 2). There was consensus on the importance of engagement of a wide range of health workers active in service

delivery who understand current practice realities, needs and challenges at different levels of care, as expressed by one hospital clinician:

> …you might have people advising you on what's evidence based or what's updated out there, but you need somebody on the ground to know is this accessible, can my patients actually buy them, what sort of programs are there to avail it to the patients. So it helps getting people […] who are actually in touch with grassroots level. - Hospital physician 1

Participation appeared to be valued as a key aspect of the revision process at all levels. Yet, perspectives on the sufficiency of stakeholder engagement and participation differed between those at national policy levels (i.e. those with a decision-making role in the KEML revision) and those at county and health facility levels (i.e. those with implementing roles). This difference in views on what normatively constituted "sufficient" engagement may explain the engagement limitations. Policymakers saw the wide consultation of diverse selected technical experts as the main strength of the revision process, while implementers expressed the need for a more representative and open participatory approach. National policymakers described that consultations were held with diverse stakeholders from county governments, public and private sector facilities, different levels of care, and with varied cadres of healthcare workers and types of experts. Insurers were the only stakeholder that several policymakers noted should be more engaged in future revisions, based on their lack of engagement in the process to date. The importance of engaging county stakeholders in revision decisions was emphasised by several policymakers. For example:

> … the process is structured in a way that they [counties] can participate, they do participate and they do voice their issues. Yeah, so I do think they have some significant influence from a delivery point of view. - National MOH 4

Nonetheless, Kilifi County stakeholders interviewed did not participate in any way and perceived there was inadequate representation and involvement in recent revision processes. They expressed that they lacked ownership of the KEML as a result. Even if not all counties could be represented, participants expressed that it was important to solicit adequate representation and engagement to build county ownership, such as by region (coastal region for Kilifi):

> Not somebody just sitting in Nairobi … deciding this is good for us. - County health official 5

> …I don't know whether there is representation [from Kilifi]. […] even if you picked one person, this person does not represent all of us, so maybe there should be a level where this person engages the counties to get input from the

> counties before they represent us in that larger forum. […] Right now there is no ownership; we just feel like it was imposed, national level developed a policy and they are trying to make us implement it. […] One county pharmacist […] was in that committee but […] they never sought input from the counties. So we had reservations about many things, but at that point in time we could not change. So we thought that during the [next] review they would do it better but it wasn't done. - County health official 2

Stakeholders who participated in the revision process are listed in the KEML documents; the overall number and range of total contributors/participants in the process was 71 for the 2016 edition and 137 during the 2019 edition. Most participants involved (including members of the NMTC and TWG) were from the national MOH or experts, many of whom were specialist physicians or pharmacists, primarily affiliated with public or private hospitals (level 4-6). Engagement of representatives from primary healthcare facilities appeared to be absent (2016) or low (2019) [1, 23].

Additionally, effective *engagement mechanisms are insufficient*. This was described in terms of: (1) insufficient and genuine opportunities for public input during revision, (2) lack of engagement through the KEML amendment proposals, and (3) unclear mechanisms for ongoing feedback and user engagement outside of the revision process. First, both external stakeholders engaged in the review process and those who were not expressed the need for wider and more meaningful stakeholder participation. According to the KEML documents, time constraints as noted above restricted public engagement and input on draft copies of the KEML 2016 and 2019.

> … to enable the rapid completion of the review process […] it was not possible to […] place proposals in the public domain for review and comment. – KEML 2019

Participants in implementing roles often expressed the need for more meaningful representative engagement in the revision process, whereby stakeholders involved in the KEML consultation would also be able to gather broader input from the group/region they represent. For example, experts representing professional associations who participated in the KEML 2019 stated that they could have provided more meaningful contributions had there been more opportunity for consultation with their members or constituents.

> The process of revising that EML list I think could have been more inclusive, maybe have it more accessible to anyone who'd be interested. […] even for this last one [revision]. […] we came in at the last minute, because they needed to get some input from the [specialist group], but that was even at the tail end. […] there should have been more role for a consultation, especially with our

> members […] I think probably feedback they would have given more than what we did sitting here [in a Nairobi office]. – Professional association, National NSA 1

Secondly, the KEML amendment proposal process, as an important mechanism to receive information from diverse stakeholders, has not been functional. In theory anyone can submit a proposal to add, delete or change medicine specifications. Yet, according to the MOH, no amendment proposals were submitted. Their lack of functionality was attributed by MOH officials to a few linked challenges: a lack of public awareness about the mechanism and the KEML more generally and to a lack of consistently operational NMTC to promote and manage the mechanism (detailed in section 5.5.1). The following quotations illustrate these amendment proposal limitations:

> …usually as one of the annexes we put in a form for clinicians and other healthcare workers to share with us their experience […] so that's one of the guides that should assist us as we review […] that's one deficiency I felt we didn't we didn't utilize – National MOH 2

> …anyone with reasonable justification and evidence can actually request or petition the […] National Medicines and Therapeutics Committee […] to actually review adding a particular item to the list or removing a particular item from the list. […] But is it something that's widely sensitized to all stakeholders so that they widely participate?… No, I would actually say no. […] I think the on and off existence of the NMTC has also been […] a challenge to people exercising that, because where do you send your petition to? – National MOH 4

Third and relatedly, there does not appear to be an effective feedback mechanism or clear feedback channels that allow users to engage with KEML decision-makers between KEML editions (and whether it should differ from the amendment form submission channel discussed above), such as if they are facing challenges in using the list. The KEML documents indicate that a "*lack of active solicitation of feedback from users*" were a challenge to the perceived relevance of previous editions (2010 and 2016), suggesting that the government did not communicate sufficiently or that implementers may not have known that they could provide feedback. However, the limitation did not seem to be due only to a lack of active feedback solicitation, based on the account of a hospital pharmacist who contacted the national MOH to request guidance and voice concerns about the use of KEML medicines (via an email address given in the KEML 2016) but did not receive a reply.

> … we've been sending feedback since the [2016] list came out and up to now […] there is no, you know, guideline on what we should do. […] we would benefit

> more if they responded much faster to our concerns. - Hospital pharmacist in-charge 2

The need to develop an effective feedback mechanism to communicate on any essential medicines issues was emphasised by several participants across all levels, such as by a professional association representative:

> Is there a feedback mechanism to inform somebody that […] we feel that this needs to be done differently. So I think that department should work closely with the county level to have that open dialogue about the EML, if there are any challenges they have […] that link to communicate. – Professional association, National NSA 1

5.4 Political context of UHC

The political context of UHC was the key contextual factor identified, seen through differences between the KEML 2016 and 2019 revisions. The UHC political agenda appeared to generate priority for the KEML in 2019 in comparison to earlier editions. High-level political interests to advance UHC were reflected in political pressure to revise and update the KEML in 2019 ahead of the national rollout of UHC, planned for early 2020 at the time. The KEML was requested from the Cabinet level as a tool to select medicines included in the UHC benefit package and guide associated procurement and distribution. KEML decision-makers perceived that the UHC agenda created high-level interest in the list and seemingly fostered enhanced understanding of the importance of the essential medicines concept within the health system. Decision-makers described that MOH funds for the KEML 2019 were provided "as a result of UHC" (National GOK 1) —a new and welcome development compared to previous editions.

> I actually think that there has been a serious lack of understanding of absolute importance of this list and other governance tools in the health system by the leadership at MOH and at county level. […] But now UHC seems to finally be getting through, right? I think this is the first time for example I'm seeing the Minister or the Cabinet Secretary for health actively following where is the revised list, when is it being launched. […] Because when decision-makers don't understand, so why do you need to sit and make a list? They won't make resources available for that purpose. – National MOH 4

The UHC agenda also appeared to influence KEML content in two ways. First, as the UHC agenda emphasises strengthening primary healthcare, the 2019 revision also involved consideration of medicines previously only recommended for hospital use for listing at primary care level, to facilitate greater access while considering their appropriate use. An MOH participant describes this:

> … we were cognizant of the fact that one of the focus of the universal health coverage is to try and focus more on primary healthcare, meaning some of the medications that ordinarily […] would only be found at higher level facilities then […] we might want them to be also available in slightly lower level facilities... –National MOH 3

Second, approaches of the TWG to assessing medicine cost appeared to vary between the two recent KEML editions. In 2016, affordable cost was reported as a precondition for KEML listing, whereas in 2019 the TWG appeared to change its stance to view cost as a dimension that could be managed after listing. Notably, national policymakers described an ongoing and accompanying effort to regulate or control prices of essential medicines to ensure that any medicines listed would be made affordable. Several policymakers described this as an opportunity to promote accessibility and affordability in the context of UHC; for example:

> …there are drugs that have not been on the list before. And when we were listing them, because cost is one of the criteria to list an essential medicine, we hope that even as we list then they have initiatives the government and the ministry have engaged in to reduce cost of medicines with the plan to increase access. Because […] even for patients with insurance it can run out. – National MOH 2

5.5 Key actors and institutions

This section explores specific ways in which key actors influence KEML revision through constitutive and directive action. The key actors and institutions discussed across the two levels of action are the NMTC, Ministry of Health, donors, and experts. A descriptive overview of key actors and institutions and their roles and responsibilities in the KEML revision process, in both direct and indirect, is offered in Table 5-3.

5.5.1 Constitutive action

National Medicines and Therapeutics Committee. The NMTC has strong influence over the KEML revision process. The NMTC has been the MOH technical institution responsible for clinical and pharmaceutical governance, notably the KEML and standard treatment guidelines, since its inception in 1994, following the development of the first National Drug Policy. Since the initial establishment of the NMTC, it has often not been operational for several years at a time and its functioning has been described as “erratic and ineffective”, which was attributed in part due to a lack of NMTC legal status as an institutionalised statutory entity [1, 23]. The inconsistent presence and leadership of the NMTC had significant implications on the timeliness of the KEML and its responsiveness to health needs, as well as the revision of national standard treatment and referral guidelines, and their implementation and use. When the NMTC is not operational,

the KEML is not revised. The lack of NMTC between the 2016 and 2019 lists meant that the list was not reviewed after two years as intended and that it could not be flexible to necessary revisions in between major KEML reviews, such as in a public health emergency:

> …this country has operated without a National Medicines and Therapeutics Committee for several years. […] When the committee responsible is on and off then that creates a problem because you're not adjusting the list to respond to those needs. – National MOH 4

The NMTC and the KEML therefore appear to be insufficiently institutionalised, contributing to inconsistencies in the NMTC and in the KEML revision timeline. For example, the KEML documents state the

> …lack of legal status of the KEML (and the associated clinical guidelines) has […] contributed to a failure to establish sustainable structures and processes within the health system, for the necessary periodic, regular and timely update.
> – KEML 2016, 2019

KEML documents recommend that the NMTC should be a legal entity in the future, particularly as the NMTC contributes to medicine financing decisions in the context of UHC. At the same time, the periods of non-existence or inactivity of the NMTC were also attributed to significant MOH restructuring and health system governance changes following devolution. For example, four different Cabinet Secretaries led the MOH between 2015-2020 and large sections of the MOH were restructured in 2019.

In the absence of an institutionalised NMTC (and KEML) and associated resources for the revision, the revision of the KEML appeared to be strongly shaped by the context of favourable political conditions and the availability of funds through donors and the MOH. For the 2019 edition, this was driven by the political agenda for UHC. Further evidence that the KEML process is not shielded from the broader political context was also seen with the 2016 edition, with delays due to devolution.

> …the NMTC became dormant and suffered from uncertainties, disruption and un-coordination during a period of enormous changes and restructuring within the health sector. These changes included the promulgation of the Constitution 2010, various reorganizations of the Ministry of Health, and the onset of devolution. As a result, the intended 2-yearly review did not take place. – KEML 2016

5.5.2 Directive action

Decisions on KEML content were made at the national government level by the NMTC and the MOH, influenced by experts and donors. No concerns were raised about conflicts of interest by those involved in decision-making; they were generally perceived as neutral and impartial professionals whose primary interests were aligned with health improvement objectives.

> …of course if you have conflict of interest, then ideally you should step out of the process. […] we expect professionalism, and ethics in terms of handling for each request. Because everyone feels the issue is important. – National MOH 2

Decision-makers stressed the need to safeguard KEML decisions from pharmaceutical industry influence. Several MOH participants expressed that the openness of the decision-making process and opportunity given for scrutiny by the NMTC and others served as additional measures to prevent conflicts of interests.

> [The NMTC and TWG] were able to make a deliberation in a very open sense. And we were also at the same time gave them declaration of interest forms which they signed and from there then the medicines and therapeutics committee was able to make some judgements on – once they've seen that somebody is actually very much conflicted when it came to discussion of an issue that is touching on that then he is able to excuse themselves. - National MOH 3

Ministry of Health. The MOH DHPT holds power due to their structural position and technical expertise on health products and technologies meant they shape how medicines are selected. For example, they developed the SOPs for the revision process (KEML 2016). The *MOH DHPT* also initiates and manages the revision process, which includes convening the KEML review workshop with the TWG and NMTC and facilitating expert consultations.

> …the Ministry is the lead in the process – KEMSA, National GOK 5

Key influence appeared to be exerted through the MOH's power to select experts involved in the revision. For example, KEML documents describe that TWGs are appointed by senior MOH officials (e.g. by Director of Medical Services in 2016). However, there did not appear to be a transparent process or criteria to select expert contributors who could heavily influence decision-making. MOH officials described that categories of stakeholders and therapeutic areas were mapped out and that experts were selected based on recommendations by the MOH Secretariat, TWG and NMTC.

> So I can say the TWG of the KEML, which again I said has representation from National, County, public, private, faith-based. And anyone they feel that you can consult, then we consulted for each of the sections. – National MOH 2

Several implementers at the county level commented on the lack of transparency in selecting contributors.

> I don't know how they select who is in that team... – County health official 2

Furthermore, although the overall KEML revision process and its limitations are publicly described in the KEML documents, along with brief descriptors such as "not used/required" or alternative indications, the reasons for decisions on medicines selection were not clearly communicated. This element of transparency was therefore missing for stakeholders to understand medicine selection decisions.

Experts. Based on their recognised expertise in managing certain conditions, the views of experts like specialist physicians, pharmacists and representatives of professional bodies invited to advise on medicine selection decisions in particular therapeutic areas appeared to be influential in shaping medicine selection decisions. Decision-makers emphasised the revision as a consensus-based process that relied on the expertise and guidance of specialists, who could advise on current practice and any "latest useful" (National MOH 3) developments in a therapeutic area. Experts were often linked to professional associations, which also publish or endorse national treatment guidelines for certain therapeutic areas, such as antibiotics, oncology or cardiology. For the KEML 2019, such treatment guidelines published from 2016 onward were used as sources of information or guides in the review process. However, in some instances, medicine selection for the KEML was not aligned with recommendations in recent national treatment guidelines if the decisions were deemed unsuitable for the realities of the Kenyan health system based on the *expertise* of specialists consulted. For example, a policymaker noted that the decision to provide different recommendations in the KEML than those given in the 2018 cardiovascular management guidelines was based on concerns by specialists that medicines may be misused at primary care levels:

> … we were making reference to the current treatment guidelines for different disease areas, but for some of those areas we felt the guideline was more academic than practical. So we didn't we didn't adopt everything the guidelines had said for the list, yeah. Cause even in the process of our engaging like with cardiologists, some were saying that there are drugs that are misused so they don't want them at lower levels. – National MOH 2

Finally, the KEML documents state that some experts lacked understanding of the rationale and purpose of the KEML and the application of the essential medicines concept. Most of the specialists engaged in the KEML process did not receive detailed training on these concepts, which led to the receipt of proposals that

> although mostly representing good clinical practice, did not fit the criteria for listing as an essential medicine on the KEML. - KEML 2016, 2019

This raises questions about the extent to which medicines selected did in fact meet the selection criteria or how judgements were made.

Donors. Donors played direct roles influencing KEML revision and KEML content, based on their funding of the revision process and their technical support in decision-making. The 2016 KEML revision relied solely on support from USAID and DANIDA. The 2019 edition was supported mainly through USAID funding (via Management Sciences for Health, or MSH). Given the resource limitations described above, donors appear to hold significant power over the KEML due to their financial contributions.

> The 2016 edition the review process was only donor supported. That time we were supported by USAID and DANIDA – National MOH 1

> ….they [donors] really helped us throughout the process trying to get us venues for those workshops and facilitating the financial implication of the workshops then also going round to collect information. […] in as much as it's a Ministry of Health-led program […] our development partners also played a huge role in terms of trying to develop this document. – National MOH 3

Donors also appear to influence the technical medicine selection decisions based on the technical expertise they provide. For example for the 2019 KEML, a USAID/MSH program consultant served as the "KEML Overall Process Technical Lead" and sat on the TWG and several other reviewers were from the USAID program [23]. The power donors had in determining KEML content therefore was therefore derived both through their financial means and technical expertise.

Table 5-3. Actors involved in decision-making for the Kenya Essential Medicines List

Actor	Description	Roles and responsibilities in KEML revision
President & High-level Ministry of Health officials	Set policy priorities	- Indirect role in KEML due to political leadership on UHC agenda - MOH officials appoint the NMTC and Technical Working Group for KEML - Budgetary allocation to KEML as part of UHC budget
Ministry of Health – Division of Health Products and Medical Technologies	Technical policy division responsible for health products and medical technologies	- Secretariat for the NMTC and KEML TWG - Decisions on rules for KEML process (e.g. determining selection criteria) - Develops KEML review tool - Convened KEML review workshop with the TWG - Consulted external experts for input - Developed first draft of KEML revision based on TWG (internal) & external consensus - Oversee implementation of the KEML
National Medicines & Therapeutics Committee	Body of appointed MOH officers with expertise in medicine, pharmacy, laboratory, nursing, oral health, M&E, procurement, regulation, and a variety of health domains, mandated to oversee all major "clinical governance", such as the KEML, the National Treatment & Referral Guidelines, the Kenya Essential Medical Supplies List	- Policy development in the evaluation, selection & use of medicines & health products; standards & guidelines development & dissemination - Oversight and coordination of revision process - Engage and consult stakeholders - Advocate on importance of NMTC and for financing and funding for its activities, including the KEML - Operational research/ monitoring and evaluation on the KEML
KEML Technical Working Group	A sub-committee of the NMTC, appointed by the Director General for Health (2019)	- Technical review task - Consult external experts for input on therapeutic categories - Decide on selection of medicines for the KEML based on input from stakeholders and consensus - Final validation and approval

Experts	Individual contributors such as specialist physicians, pharmacists, nutritionists, and representatives of County Government, professional associations, vertical programs, private hospitals, NGOs	- Respond to requests for input on medicine selection
Donors/international organisations	USAID- MSH Medicines, Technologies and Pharmaceutical Services (MTaPS) program (2019 edition); USAID-MSH/Health Commodities and Services Management Programme, DANIDA (2016 edition) World Health Organization	- Donor support for the revision process at national level - Technical support in the revision process, involvement in decision-making - No direct involvement in revision, but indirect role via development the WHO Model List of Essential Medicines drawn upon for the KEML review

5.6 Chapter summary and reflections

This chapter provided a narrative description of the formal rules of the KEML revision process and how the process has unfolded in practice, as well as analytical findings on KEML revision process strengths, limitations and key influences. This description and analysis of the KEML revision are key to (1) understanding how the process unfolds and how influence is exerted and (2) identifying opportunities to improve the process in the future. The KEML is a product of the interactions between the NMTC, the TWG, the MOH and selected experts. A largely consistent consultative process was followed across the 2016 and 2019 editions. Key strengths and limitations of the KEML revision process were often interlinked with the influence of particular actors based on constitutive, directive and operational activities or the political context of UHC. First, stakeholder engagement and participation was perceived as both a strength, due to the wide consultations undertaken with experts, and a limitation, due to inadequate mechanisms for broader stakeholder input. Importantly, meaningful county representation and participation was seen as key for county ownership of the KEML and implementation. The NMTC did not have an institutionalised, consistent presence over time, contributing to irregular KEML revision timelines and an unfit amendment submission process. Second, financial and time constraints and an apparent reliance on donors to revise the list posed challenges. Finally, despite best efforts to facilitate evidence-based medicine selection, further transparency on the evidence and application of criteria used to guide decision-making and improved use of context-relevant and appropriate evidence appears necessary. Experts had significant influence over listing decisions, although these were at times based on their opinions rather than evidence. The context of the UHC agenda appeared to have a strong influence over the process and medicine selection decisions in 2019. As part of the UHC agenda, the KEML policy itself became a greater priority for the national government when recognised as a tool for UHC. In the context of seemingly limited institutional entrenchment of the NMTC, KEML revision as a health policy priority therefore appeared to be subject to influence based on the political priorities of the government in power. In the next chapter the implementation of the KEML will be explored at national and county levels.

6 Macro- and meso-level factors affecting the implementation of the Kenya Essential Medicines List

6.1 Introduction

In this chapter I present findings on KEML implementation at macro (national) and meso (county) levels. Following an initial description of KEML implementation as intended on paper, I analyse how implementation of the KEML 2016 occurred at national and county levels and the factors that influenced the process and outcomes. This chapter and the next focus on the KEML 2016, as the 2019 edition had not been implemented at the time of study. The findings are based on the analysis of interviews with all participants (n=41), documents, and observations. The presentation of the findings is guided by the thesis conceptual framework. The key factors found to affect KEML implementation at macro- and meso-levels are presented in Figure 6-1 and further detailed throughout this chapter. Macro- and meso-levels were brought together in this analysis as the relevant factors identified between the two overlapped and were interdependent due to the importance of the relations and interactions between national and county levels when it comes to implementing the KEML. The chapter concludes with a summary and reflections on the findings.

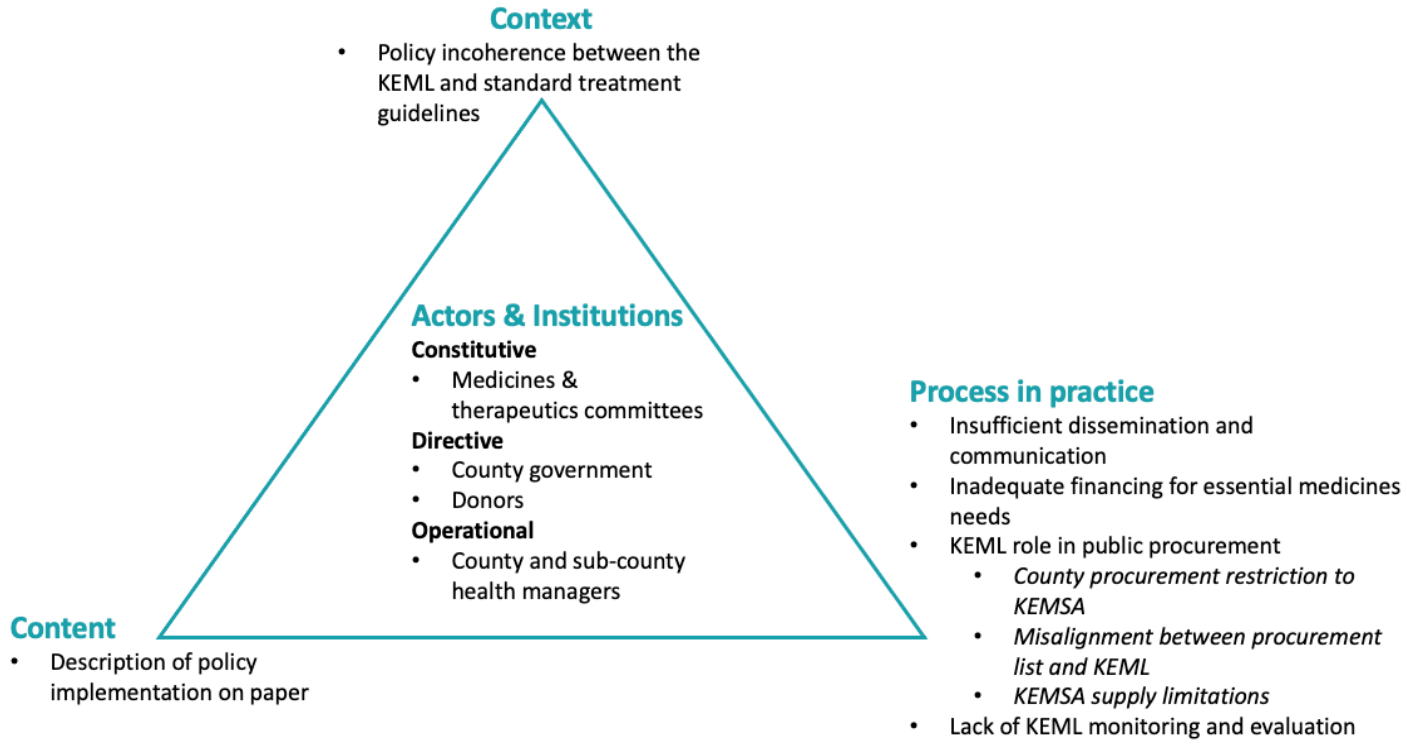


Figure 6-1. Overview of factors affecting KEML implementation at macro- and meso-levels

6.2 Description of KEML implementation and use on paper

The formal relationship between the KEML policy and its implementation is outlined in this section. After revising the KEML, the MOH and the NMTC is responsible for disseminating and communicating the new edition to all relevant stakeholders. The KEML 2016 describes 9 "main uses of the KEML", including: healthcare financing and budgeting; health insurance schemes; procurement, supply and distribution; donations; healthcare workforce development; and appropriate use of medicines (Table 6-1). The list should be used:

> …by policymakers and public sector providers at national and county levels; by private, faith-based, and non-governmental organisation actors, and by development partners" and "by all disciplines of healthcare workers, general practitioners, specialists and healthcare management personnel as well as students and interns – KEML 2016

No specific guidance is given on which stakeholders are targeted for specific KEML uses, although relevant actors are often implied, as shown in Table 6-1 (e.g. procurement managers).

Table 6-1. Intended uses of the Kenya Essential Medicines List

Intended policy use	Description
Health insurance schemes	Basis for selecting medicines for the UHC benefits package for expanded coverage or reimbursement
Financing, budgeting & quantification	As a basis for prioritization of finances, quantification of health product and technology needs, budget estimation at all levels of healthcare system
Procurement and supply chain	Tool to determine procurement requirements and supply of medicines across sectors and levels of care
Management of donations	Donors and recipients to use KEML to meet priority medicine needs
Healthcare workforce development	Clinical guidelines and the KEML to be used to train healthcare workers on prescribing, dispensing and use of medicines, management of conditions (pre-service and in-service training, continuous professional education)
Medicines regulation & monitoring	Basis for quality assurance, regulation activities (registration, import, export, local manufacturing, quality monitoring, pharmacovigilance etc.)
Appropriate use of medicines	As a basis for designing strategies to improve use of medicines, operational research; Antimicrobial resistance prevention
Policy monitoring and operational research	Guide for monitoring & evaluation (M&E) and health research to establish evidence to inform KEML revision and to inform policy strategies
Pharmaceutical manufacturing	To provide guidance on priority products and formulations to inform local manufacturing decisions, guide any incentives for local production

Source: KEML 2016, 2019

6.3 Implementation process

The process of KEML implementation included the following features most widely understood as key factors for implementation success at the system level: dissemination and communication of the list, financing of essential medicines, and public procurement and supply of essential medicines. How each of these elements of the implementation process have occurred in the study setting are discussed below with an emphasis on the roles of and dynamics between key actors.

6.3.1 Insufficient dissemination and communication

Despite being a critical aspect of implementation, dissemination and communication of the KEML 2016 to national, county and local organisations (notably health facilities) after its revision was widely seen as insufficient in Kilifi County and Kenya more broadly. In addition to describing the process of dissemination and communication, this section discusses associated barriers and enablers. Based on the data, dissemination involves the distribution of the KEML and efforts to inform implementers on the availability of the latest edition and communication involves efforts to educate implementers on the purpose and contents of the list. *Dissemination* was often described by interviewees at all levels as occurring "only at national level" (County health official 1).

> …for some reason it [the KEML] just stays at the top - MEDS, National NSA 5

The KEML was primarily disseminated by making it publicly available on the MOH and KEMSA websites and through the sharing of digital copies to facilitate widespread access to the list. Participants in Kilifi at county and health facility levels often described learning about the KEML through their own personal initiative based on their awareness of previous KEMLs or by chance based on a need for such a list, such as in the development of a hospital formulary.

> It [the KEML 2016] wasn't formally disseminated. […] we got the soft copy but you would expect it to be formally disseminated or launched for people to know this exists. […] once they release the list […] I feel like they feel like it's up to us to ensure that we are taught about it – County health official 2

> …we found it online but no one has told us anything about it, we just saw it was published. You get it, you download it, okay so it's the national list, so what? [laughs] …as a pharmacist I would have expect we would have been notified but I just found it by chance. – Hospital pharmacist 4

Few of the participants indicated that they had received a hard copy in the past, although none had an accessible copy of the 2016 KEML when I spoke with them at their place of work. Most implementers never received a copy.

> … they were never distributed – County health official 1

Hard copies were deemed particularly important for rural health facilities, where internet access may be a challenge. Nonetheless, at primary care levels dissemination was described as particularly poor.

> …what we have seen previously is that dissemination just occurs at the specialists' level or at the higher levels of care; that's level six, level five, and level four. The dissemination never gets to level three and so […] how does this knowledge get to the primary healthcare facility? – Faith-based organisation, National NSA 2

There was also a widespread consensus that the KEML, its anticipated benefits, how implementers are expected to use the list, changes to the medicines listed and other content were not *communicated* sufficiently to educate and engage users. Implementers at health facility and sub-county levels often raised the need for periodic continuing medical education focused on the KEML to facilitate its implementation, such as when a new KEML edition is released. Many implementers noted that they had never participated in meetings or talks related to the KEML or the topic of essential medicines, and that there was a "*lack of training to the implementers*" (County health official 1) focused on sharing relevant and up-to-date information and knowledge.

> …we have a problem of it reaching everyone […] So maybe if we strengthen the dissemination and we have […] a launch and it is communicated and also we have CMEs [continuing medical education sessions] on the essential medicine list, I think it will be more successful. […] I never had witnessed anyone provide such CME or maybe a lecture or maybe a presentation on essential medicine list […] as I was here. – Sub-county health manager 6

Two main factors appear to underlie the dissemination and communication limitations: national-county intergovernmental structures and relations and limited resources. First, several national and county respondents and documents indicate that ineffective intergovernmental structures and a broader lack of effective intergovernmental communication between national and county government in the post-devolution context contributed to limiting policy dissemination and communication for the KEML.

> …the weakness there is […] dialogue between the national entity, the Ministry of Health, and the county entities to transfer the meaning of why this was done. […] Because that's where everything now falls apart […] the national government creates policy and the County Government provides healthcare […] But anything needed to bridge those two is […] not clear. It's no man's land. – Professional association, National NSA 4

More broadly, coordination between national and county governments has been limited due to weak health sector coordination bodies, such as the Health Sector Intergovernmental Forum [26]. This challenge did not appear to be unique to the KEML, as several participants noted that for various national health guidelines and policies "getting to the ground […] is the problem" (Sub-County health manager 2).

> ...we need to move with the times as the Ministry of Health. Again, you find we have beautiful documents, but counties don't know they're there. So if you don't go to there then how do they know they're there. – National MOH 2

The second factor that limited information flows from national to county to health facility levels was a scarcity of resources dedicated to KEML implementation. A lack of finances to support implementation for the 2016 KEML hampered national level implementation activities after it was revised, particularly the dissemination and communication, as articulated by a MOH official:

> [After revision] we did not have the resources completely of doing anything around that list […] really lack of budgets to do implementation activities was a big, big challenge for us. - National MOH 1

Despite the limitations in active dissemination and communication from the MOH, the spread of KEML information was enabled to some degree through other sources and informal networks. KEMSA, donors, and other non-state actors also played an important role in facilitating KEML information dissemination through their existing activities and programmes. For example, some dissemination efforts were reportedly conducted by merging with KEMSA activities due to the resource limitations. A participant from a faith-based organisation described how their organisation took initiative on dissemination in the absence of central efforts:

> … they [government] should involve us in disseminating so that whatever we are disseminating on the ground is in line with what the government requires us to do. But because this is not happening, then we take it upon ourselves to do that. – Faith-based organisation, National NSA 2

6.3.2 Inadequate financing for essential medicines needs

The county budgeting process for health and the resulting pharmaceutical budget shape medicine selection and which medicines are made available in the county. The county priority-setting and budgeting processes that dictate financing for health are described in detail elsewhere [153, 184]. The CDOH determines county health commodity needs through a forecasting and quantification exercise that is guided by the KEML, set to occur on an annual basis. This information informs the CDOH annual development plan that further feeds into the county's annual development plan, which consolidates needs across all county government departments (e.g. agriculture etc.). Budgetary decisions are

approved at the political level via the County Assembly and each department, including the CDOH, is given a budget ceiling by the county treasury.

The pharmaceutical budgets were widely described as not meeting the essential medicines needs forecasted by the CDOH. Thus, after the county pharmaceutical budget is allocated, pharmaceutical needs have to be reprioritised by the CDOH based on the lower budget ceiling given. As health facility drawing rights allocated—the financial allocation for each facility—are nested within the allocations determined at the county level, the drawing rights are also lower than the forecasted need. Thus, reprioritisation based on the available budget also occurs at health facility level.

> …the final approved allocation more often than not is not pegged on the [health commodity] quantification that originated from me, it's pegged on the final allocation that is discussed now at the executive level of the treasury determines what to give to health, and then the health department has very many sectors. So at the end of the day […] Unfortunately, we are given a half at best for that. […] it's trimmed down now it goes back to us to now do the prioritization of what to be in order. – Sub-county health manager 5

The county was also often unable to complete regular quarterly procurement orders due to limited funds or issues in the flow of funds from treasury or payment delays to KEMSA, discussed further in section 6.3.3.3.

> …this is supposed to be on a quarterly basis. It's just that sometimes we don't do quarterly. Sometimes it's twice a year, sometimes it's three times. So that depends on the […] availability of funds. […] because the county assembly is the one that approves. We give budget proposals but then based on the money that is available, we may get that or we may get a lower figure. – County health official 2

> I am talking of doing quarterly procurement of drugs. But it never happens that way because […] the excuse that will always be given is that […] we don't have money yet. – Sub-county health manager 3

Financial limitations were generally seen by county officials as a product of the general resource scarcity within which they operate, rather than the result of a lack of prioritisation of health at political levels. Health was considered highly prioritized by several county officials: the health department was reported to have the highest budget of all county departments.

> … any request from the department of health is really considered and may I say even favourably. […] health does not really need to beat the drum hard to get additional

> resources, they only need to have a drum to beat. […] So the health needs in terms of the resources we have... are overwhelming. [...] we just have to work with what we have. – County Treasury 7

> …the budget is never enough. Even though we get the largest portion, but it's never enough. – County health official 4

While this analysis is focused on implementation of the 2016 KEML, it is worth noting that MOH officials described that the KEML 2019 was used to guide the selection of medicines for the UHC benefit package for reimbursement or coverage. Although the UHC benefit package had reportedly not been finalised, several participants expressed that not all KEML medicines would be selected for the benefit package due to "budget reality" (National GOK 4). Policymakers described plans to gradually work toward expanding the list of KEML medicines under the benefit package and to restrict NHIF reimbursement based on the list. For example:

> So the government will strive to mobilize resources towards ensuring that the medicines which are listed on the essential medicines lists are available for service delivery under UHC. That may not be done at a go, but progressively, that will be the target of the government. - National MOH 1

> …we are trying to see how to work with insurance agencies, and mainly the NHIF which is the bulk insurer that you can only then reimburse medicines in the essential medicines list so that we try to have an agreement of what is being prescribed by them. - National MOH 3

6.3.3 KEML role in public procurement

The KEML has had an entrenched and primary role in medicines procurement. Participants, including supply chain actors, perceived that the most frequent use of the KEML has been to guide public procurement, where it offers direction on which medicines can be provided at each level of care. Several people I spoke with thought it was primarily used by procurement agencies, where it was seen as contributing to lower medicine costs by guiding pooled procurement. Participants from the procurement agencies KEMSA and MEDS noted that the KEML guides what products they tender and stock.

> If you come to MEDS, you go to KEMSA, you find they base their procurement and the items on their formulary on the EML. – MEDS, National NSA 5

Through the "pull" system in place since devolution, counties are responsible for procurement and supply chain management. Health facilities determine their health commodity needs. The facility

orders are submitted to and approved by the sub-county and county pharmacists, consolidated by the county, and sent to KEMSA.

Three diverse and interlinked challenges associated with public procurement via KEMSA were, however, identified that shaped and often limited implementation of the KEML. These were (1) county procurement restriction to KEMSA, (2) misalignment between KEMSA's procurement list and the KEML based on content decisions, and (3) KEMSA limitations in supplying essential medicines.

6.3.3.1 *County procurement restriction to KEMSA*

Stakeholders in procurement roles often perceived that KEML implementation was affected by a contentious 2019 procurement law amendment that restricts public procurement to KEMSA [185]. I begin this section by explaining how the amendment has affected enforcement of the KEML and thereafter how procurement actors perceived the change and its impact on their ability to implement the KEML.

Amendments to the KEMSA Act in 2019 mandated national and county public health facilities to obtain health products from KEMSA by law. Consequently, if KEMSA restricts their procurement to the KEML, the law creates a *de facto* enforcement for public procurement based on the KEML.

> …those procurement processes are basically making us follow the medicine list.
> – Sub-county health manager 2

Between 2013 and 2019, after devolution and before the KEMSA Act amendment, counties could procure any medicines approved by the regulatory body in the country and source medicines from public (KEMSA), faith-based (MEDS) or private suppliers. Most of the procurement in Kilifi County was still done through KEMSA prior to the law, according to reports from county officials and documents, although several participants described that they previously ordered medicines from diverse suppliers. Some health facility procurement managers and county officials explained that they were more likely to order off-list from other suppliers before this amendment. The changes in procurement and its influence on KEML "adherence" are illustrated in the following quotation:

> In public facilities and up until we were restricted to KEMSA, we could also access from whichever source as much as its not on the list and you feel like you don't have an alternative you can get it from any other source. […] KEMSA was [then] advised to restrict themselves with that essential drug list. […] so for whatever drugs we buy from KEMSA… the KEMSA order form is already adhering so by default they [health facilities] are already adhering to that. So they cannot order anything outside that order form. - County health official 2

The amendment was described by many participants as a "a double-edged sword" (Sub-county health manager 5)—with positive and negative implications for KEML implementation. It was perceived as positive in terms of its role in reducing irrational prescribing, promoting standardised care, and more control over the quality of products (compared to the private market). Some procurement and facility managers also felt that it provided a system of accountability at different levels of the supply chain, reducing possibilities for corruption. Procurement managers described that it helped them to manage their supply more efficiently, because the county procurement process to order from private suppliers was much more tedious and time-intensive than ordering from KEMSA. Furthermore, prices offered through KEMSA were deemed much more affordable than private suppliers, who were seen as lacking price transparency.

> …there was a lot of politics involved in acquiring medicines out of KEMSA. So I think centralizing it has been a positive thing. – Hospital pharmacist in-charge 1

> … at the level of implementing the essential list and also standardizing treatment, KEMSA act giving KEMSA the sole responsibility of supplying all public facilities would be […] a plus in the sense that KEMSA supplies those things at a very affordable price. […] and they have a very good system of feedback in case we come across poor quality medicines […] also the systems are very clear they don't have any loopholes for kickbacks – Sub-county health manager 5

However, despite these possible benefits to promoting access, the Act was also seen as problematic due to (1) the harsh penalties county procurement stakeholders could be subject to if purchases are made from other sources without permission from KEMSA (significant fines or imprisonment), and (2) its role in undermining the ability of counties and health facilities to take steps toward promoting access considering KEMSA's limitations in ensuring adequate supply as discussed below. The circumstances under which medicines could be procured from other sources were often unclear to facility procurement staff and managers. Some participants articulated that consequently, and due to fears of facing harsh penalties, patients were more often asked to purchase medicines out of pocket. The following quotations exemplify the dilemmas faced in procurement:

> ….the people in charge of procurement, they're so scared of buying from elsewhere because this new law […] it tells you that who makes the purchase will be jailed or you pay big fine for not buying from KEMSA. [...] The lack of clarity of how to go about things you cannot get from the national drug store without getting jailed... [laughs] – Professional association, National NSA 4

> So here you are at the hospital level, you are telling the hospital we have a KEML to guide what you are getting. Then here you are the law tells you, you can only get from KEMSA but KEMSA doesn't have all the drugs in the KEML. So what do you do? […] So it means these patients we are telling them […] they have to find it elsewhere, we can't procure it from anywhere else. - Hospital pharmacist in-charge 1

6.3.3.2 *Misalignment between KEMSA's procurement list and the KEML*

Public procurement of medicines and health technologies via KEMSA therefore, particularly going forward as part of UHC, is meant to be largely restricted to commodities on the KEML and the KEMSL. Policy documents describe that "[c]oherence in the procurement and supply of pharmaceuticals" should involve "adherence to the KEML and KEMSL" [60].

> … ideally they [KEMSA] should not buy anything outside this list unless there's a very good justification. So it helps us in selection of what we need to procure as a country. –National MOH 2

Although KEMSA procurement appears to be largely guided by the KEML, instances of misalignments between the KEML 2016 and KEMSA stock were described by several procurement managers. Misalignments were described as either: (1) KEMSA stocking medicines that were not on the KEML, such as medicines that had already been delisted (i.e. a *content* mismatch between the KEML and KEMSA's procurement list); or (2) that KEMSA did not align their stock with KEML medicines in a timely manner after the list revision in 2016 (i.e. a *process* lag), which affected the ability of health facilities to order essential medicines. For example:

> KEMSA has some medicines that are not in the list and we procure from KEMSA. […] So […] the dispensary may be tempted to place orders even for the drugs that are not on the list but they are on the KEMSA warehouses, right; so this is another challenge […] KEMSA had nifedipine, then the essential medicines list had amlodipine, you see such things. – Sub-county health manager 1

> … we had to engage with KEMSA to ensure that what was introduced in the KEML 2016 […] we had to give that list for KEMSA to start stocking tranexamic acid. […] by 2018 April when we were doing the order, KEMSA did not have any anti-diabetic for elderly patients, yet it was in the KEML 2016. […] So by the time we were doing December 2018 order they now had it and we were able to access. – Sub-county health manager 5

These misalignments appear to be explained by two factors. First, KEMSA's business model is driven by demand from its clients in the post-devolution context, chiefly counties and their health facilities, rather than by directives from national MOH as was the case prior to devolution.

> …we no longer get, you know, instructions from the ministry on "this is what you're going to stock, we are giving you money to procure this and that"… so this will be determined by our customers, who are essentially, you know the counties. And they have their own money now […] So they determine what they need. And as KEMSA, because we are not stocking this for our own consumption but for their consumption, we must align ourselves to their needs. – KEMSA, National GOK 5

Second, a KEMSA official further explained that the KEML has been "just an advisory tool" and "has not been enforced" by national government. However, in the context of the UHC agenda, the MOH has, according to several national participants, placed greater priority on the enforcement of the KEML. As such, the KEMSA participant described that the agency planned to more strictly align its stock to the KEML, that it would no longer be "*a free for all, like it used to be before*" (KEMSA, National GOK 5).

6.3.3.3 *KEMSA supply limitations*

KEMSA is "mandated with guaranteeing the supply of essential medicines and other medical supplies […] to all public health facilities on timely basis" [186]. However, essential medicine shortages, stock-outs, inadequate and unpredictable order fill rates and supply delays through KEMSA were commonly seen as major barriers to implementing the KEML. Stock-outs of several essential medicines at the KEMSA level were described by various participants during the time of my fieldwork. Medicines included paracetamol, neostigmine for the operating room, antipsychotics, and morphine. Order fill rates in Kilifi, or the percentage of the order placed with KEMSA that was subsequently received, were often described as inadequate and unpredictable:

> …there are times when they have stock outs of […] a good deal of the drugs we need. There was a time when our fill rate was about 50%. […] the most recent supplies we got our fill rate was above 80%, which is really good.
> – Hospital pharmacist in-charge 2

The KEMSA supply interruptions and stock outs were attributed to the interlinked problems of (1) counties not paying KEMSA and (2) KEMSA's capacity limitations in meeting country-wide demands for health goods. First, *counties, including Kilifi, frequently delay payment to KEMSA* and accrue debts on their medical and health product orders. These payments matter because KEMSA's current business model relies on funds from county procurement orders to replenish its stocks. The outstanding debt meant that Kilifi County could not place regular quarterly orders in 2019 until KEMSA was paid, as described by a CDOH official:

> …for a whole quarter […] we did not have supplies because we had not ordered.
> – County health official 2

The following quotation illustrates the perceptions of lack of county payments to KEMSA as a major driver of supply chain limitations:

> …if KEMSA were able to get their payment well, they are able to have this essential list work well, yeah. What has been the hindrance I think is about us not able to pay promptly. – County health official 3

County officials described that the payment delays are due to overall resource scarcity, the need to prioritise longer-standing debt over more recent procurement payments, and delays in disbursements from national treasury. Participants stated that counties without or with less debt receive priority service by KEMSA, who was more likely to be stocked out of items ordered for counties later in the queue. This leads to the second reason for KEMSA's supply interruptions and stock-outs: ongoing *limitations in KEMSA's capacity to sufficiently supply* all 47 counties as needed. KEMSA capacity limitations were linked to both the lack of timely payments from counties to in turn ensure KEMSA fill rates meet demand and a lack of "assured market share since devolution" (Professional association, National NSA 4) since counties were free to procure from other sources after devolution and prior to the 2019 amendment. Many participants emphasised that it was very difficult or impossible to implement the KEML if KEMSA is unable to reliably supply essential medicines:

> …something is there in the list as essential but it's not there at the highest source of procurement of the same. So now how do you justify that actually it is essential? – Sub-county health manager 5

6.3.4 Lack of KEML monitoring and evaluation

Monitoring and evaluation (M&E) of the KEML is presented as critical to its continued relevance and to establish evidence for subsequent revisions [1, 23]. However, no monitoring or assessments have been done related to the 2003, 2010 or 2016 KEMLs to understand how it has been received and accepted by those expected to use the list, the patient and health system outcomes related to medicines added, and whether the KEML is meeting its intended policy goals. This is highlighted within the KEML 2019:

> Lack of evidence from implementation moreover limits evidence-based decision-making for subsequent KEML editions – KEML 2019

This creates limitations for accountability in all directions—policymakers cannot hold implementers to account if they do not have implementation information, and the lack of opportunities for feedback and lessons from the ground limit implementer ability to hold policymakers accountable, as noted by a MOH policymaker:

> …there's been challenges in the implementation, enforcement, monitoring and evaluation of this, so it's difficult to hold anyone accountable. - National MOH 4

Thus, any ideas about the success of the KEML to date are *"purely, mainly anecdotal" (National MOH 4)* due to the lack of evaluation. Although each new edition suggests the need for M&E going forward, it has not been realised. A national health official involved in the KEML described that a M&E plan existed but was not implemented due to budget constraints.

> We had it, but we did not implement it. – National MOH 1

Additionally, a policy document notes a lack of "institutionalised structures for monitoring the use" of the KEML and standard treatment guidelines [60]. Those involved in the 2019 KEML revision perceived that this edition would be different and that M&E would be conducted, in part due to commitments from a donor to support KEML implementation and evaluation.

6.4 Context

6.4.1 Policy incoherence between the KEML and standard treatment guidelines

Standard treatment guidelines were most commonly mentioned as a key associated policy that should mirror the priority medicines listed in the KEML, or vice versa, to promote appropriate medicine selection at all levels. The need to align the two is also documented in the national pharmaceutical policy and advised by WHO. However, STGs were last published in 2009 along with the KEML 2010 as noted in Chapter 5. Thus, they've become outdated, but some healthcare workers may still base their medicine selection on the guidelines rather than the KEML. A sub-county health manager describes the challenge of STG-KEML inconsistencies:

> I think the medicines list is, first, it's not in a vacuum; the medicines list always comes with treatment guidelines […] All this […] completes this whole issue of appropriate medicines usage. […] all the documents must be saying the same thing. And how you implement the Kenya essential medicines list is through the treatment guidelines […] you'll have both documents at the point of use [..] Now you don't know, as a practitioner […] the essential medicines list is telling me I shouldn't use aminophylline because there are better drugs, but the treatment guidelines is telling you that you can use. – Sub-county health manager 1

In addition to the STGs, specialized or disease-based treatment guidelines were also referenced and perceived to be more regularly updated and thus more likely to "match" the KEML. These were generally described as aligned, but there were some conditions/medicines where implementers described misaligned medicine recommendations. For example, the medicine recommendations for cardiovascular conditions at primary care level in the KEML are not aligned with those of the National Cardiovascular Management Guidelines, which recommend a range of medicines be made available for either treatment initiation or prescription refills in primary care facilities. The KEML (2016 and 2019)

does not recommend any of the cardiovascular medicines indicated for dispensaries in the guidelines, and recommends a more limited selection for health centres than the guidelines do.

6.5 Actors and institutions

Implementation of the KEML and access to essential medicines is influenced to a considerable degree by national and county government organisations and their inter-organisational relations, as well as donors. Their influence based on their constitutive, directive and operational actions are explored in this section.

6.5.1 Constitutive action

Formal structural design for the governance of health products through *medicines and therapeutics committees (MTCs),* intended to operate at national, county and hospital levels, is set by the MOH. Responsibility for supporting the establishment and operation of county and health facility MTCs rests with the NMTC [1, 23]. MTCs at county and hospital levels were seen as important institutions in promoting the KEML policy goals of ensuring safe, optimal and cost-effective supply and use of essential medicines, which could also facilitate understanding about the purpose and medicine listing decisions of the KEML among healthcare workers and local decision-makers. MTCs were often also seen as potential accountability structures— ways to integrate compliance monitoring and enforcement of the KEML and similar policies from the national to county to hospital MTCs.

> If […] we can have these committees that we are talking about, the MTCs, probably at the county level to be able to go down and ensure that there is the implementation, yeah. And then periodic assessments to assess levels of uptake or implementation. –County health official 1

> There is one […] at the national level, we should be having some at the county level and the other levels all the way to the hospital level. […] if those committees worked then […] it would be a very clear way using and implementing the EML, because these are the committees that actually look at the use of medicines at the various levels. – MEDS, National NSA 5

Nonetheless, control over the county MTC appeared to lie at the county level, as Kilifi did not have a county MTC. County officials however noted that "it's in the pipeline", suggesting an effort to move toward compliance on the national recommendation. The status and operation of hospital MTCs in Kilifi is discussed within the micro-level analysis (Chapter 7). While only circumstantial, the limitations of the NMTC (Chapter 5) including its inconsistent functionality may have had implications for MTC functionality at lower levels.

6.5.2 Directive action

Although content decisions on KEML revision and on associated national policies and guidelines (e.g. STGs) are made at the level of the MOH, key decisions for KEML implementation occur at the county level. Namely, based on its control over resource allocation the *county government* makes explicit and implicit decisions on medicine availability and accessibility. Diverse actors in county government, notably the Treasury, County Assembly, County Executive Committee and the CDOH, hold power to determine resources allocated for health and health commodities. Additionally, the *County Health Management Team* (CHMT) is comprised of the technical decision-makers for health at the county level, which includes the county pharmacist as the primary decision-maker on and coordinator of pharmaceutical services and commodity management. When participants were asked about actors with the greatest influence over KEML implementation, the county pharmacist was frequently described based on their role in procurement decision-making, influence over financial resources and other directive decisions at county level, and was also deemed a key person to disseminate KEML knowledge.

Some national policymakers also suggested that under UHC, the MOH would decide on medicines funded through the benefit package and thus they would regain directive control, similar to the situation prior to devolution. This is because UHC financing for medicines is expected to go directly from the national government to KEMSA, rather than from the county. In this scenario, it is in KEMSA's interest to align its supply with KEML as the basis for medicines covered by UHC. This compares to the current situation where counties hold most of the decision-making power on medicines procurement as payers. A KEMSA participant explained this shift:

> …in those early years pre-devolution […] the ministry had control over what was being stocked at KEMSA, so they used to provide the funds to KEMSA. So KEMSA would procure and would also distribute on behalf of the Ministry of Health. […] what devolution did […] it gave now authority to the counties to determine what they want, not what the ministry, the national level wants them to have. […] with the universal health coverage […] these are funds from the national government. The ministry has already given KEMSA a list of items […] that they will support under the universal health coverage. So, the counties, if they're to benefit from these funds, they will only have to use their funds on the items that are in the UHC list. And … these items are also those ones that are in the KEML. – KEMSA, National GOK 5

However, irrespective of possible recentralisation of some decisions, policymakers expected that the county would still pay for most medicines and thus would continue to hold decision-making power.

Directive decisions made by donors to allocate funds to particular KEML implementation activities have significant influence, both directly in relation to the KEML and indirectly. Dissemination and communication activities on the KEML, at both national and county levels was heavily reliant on donor support. For example, according to the MOH, 1000 hard copies of the KEML 2016 were printed with support from USAID. Reliance on donor support was also felt at the county level throughout diverse supply management activities such as annual forecasting and quantification exercises, commodity management trainings, and supportive/integrated supervisions led by sub-county health managers. Additionally, funding for procurement of essential medicines for priority programmes—notably HIV/AIDS and tuberculosis—is heavily funded by donors.

> …there are specific diseases like HIV for example, malaria, where the medication is heavily funded, so those ones of course influence the access. – Professional association, National NSA 1

Such donor funding affects the prioritisation of particular medicines in supply management and operational governance activities, as well as access to them compared to non-priority programme essential medicines. For example, governing activities around essential medicines supply were described by a county official as having:

> …a bias towards the programme commodities to HIV, TB, malaria – County health official 1

Essential medicines, as a generalised term, were also often spoken about and managed as a separate category from medicines for such priority programmes (also listed on the KEML). This was reflected in fragmented procurement and reporting systems. For example, while procurement orders for essential medicines supplies were placed on a quarterly basis at best from the county level, medicines for priority programme commodities were procured monthly through the national MOH priority programmes.

6.5.3 Operational action

Management of KEML implementation occurs primarily at the county level, with important roles played by the CHMT and sub-county health management teams (SCHMTs). Under devolution, service delivery is not under MOH jurisdiction and any dissemination and communication with health facilities is the responsibility of counties. One MOH official describes the ongoing need to bridge communication between national and county governments in ensuring national policies reach local levels in the devolved context:

> …in the past […] we used to […] give a province maybe 500 copies for them to disseminate downwards. So it was like obvious that guys were supposed to implement. But you find that right now the way it is […] as national government we can't pretend that we're going to service delivery, because that's not our business. So we need to

> engage, consult, if there are things that counties feel we need to guide then we make sure we fill that gap […] - National MOH 2

In addition to the CHMT, the seven sub-counties in Kilifi each have a *SCHMT,* who are mid-level managers that interface between health facilities and the CHMT. Broadly, *sub-county managers* supervise and manage quality healthcare standards and pharmaceutical service provision across the sub-county at health facilities (level 2-4) in public and private sectors. Two important ways in which KEML implementation is managed by the county and in particular sub-county managers is through technical support and accountability in (1) overseeing procurement and (2) conducting health facility supportive supervisions, both examined below.

6.5.3.1 *Procurement oversight*

County health officials described that they largely adhere to the KEML and encourage its use in the county, which appeared to be primarily via the county procurement orders. Sub-county managers stated that they ensured that public health facility orders (level 2-3) placed with KEMSA were in line with the KEML, although there were apparent differences in how these managers approached this oversight in private health facilities. The KEML is generally used as guide in managing procurement and in the review of facility orders by county and sub-county health managers (most notably pharmacists), according to these participants. While any final procurement decisions can be made by county officials, sub-county managers are responsible for detailed review of all facilities in their region. This management of facility procurement orders at the county level was described as a way to manage procurement costs, such as checking on whether a brand or generic was ordered; whether orders comply with appropriate level of use; to add pharmaceutical technical support to facilities that may not have professional pharmaceutical personnel; and to check on any reporting issues.

> …the sub-county is […] closer to the facilities. So they also can really check and quantify what we really need because as much as we make the order, once we forward it to the sub county, the sub county pharmacist also goes through and scrutinizes because we might accidentally make an order for something we actually don't require or maybe make an order for something that we already have good stock.
> – Clinical officer in-charge 1

Nonetheless, the CHMT could exercise discretion on the degree to which procurement adhered to the KEML, especially prior to the KEMSA Act amendment, and the extent to which they encouraged health facilities to stick to the list. An example of discretion exercised at the county level in applying KEML guidance was described based on the need to promote enhanced access to essential NCD medicines at primary care level in Kilifi. NCD clinics have been set up in primary healthcare facilities, where people initiated on treatment in hospital for diabetes or hypertension care, for example, receive follow-up care

on designated NCD clinic days (i.e. not a permanent service). At first, required medicines were not available at the primary healthcare facilities, since the county restricted procurement based on KEML level of care listings, and medicine stocks were sent from the hospital to a primary healthcare facility based on need. Over time, the county permitted facilities that run NCD clinics to order NCD medicines at primary care even though the KEML restricted them to minimum level 4. A county health official explains this:

> … initially the NCD clinics were restricted to those three [hospitals] but then with time we realized that that was not enough. […] So there are selected health facilities that are also offering those services though not on a daily basis but they have clinics. […] initially we used to limit the drugs at a level two order because according to the essential drug list […] so with NCD clinics […] there are those selected facilities that we would allow to order insulin, order amlodipine and you know those drugs that we generally usually restrict. -County health official 2

County and sub-county participants described the tensions faced between promoting availability and access to medicines on the one hand and ensuring appropriate use (especially associated with efficient use or wastage) and effective disease management by qualified personnel on the other.

Views and approaches on supporting compliance with the KEML and oversight of pharmaceutical management in the *private sector* appeared to differ between sub-counties. For example, while one sub-county health manager indicated that high-volume private facilities should comply with the KEML and this was perhaps less important in lower volume facilities, a manager in another sub-county described not intervening in private facility procurement choices:

> I will be expecting in a facility which has a high workload, a private with a high workload, then I will expect to adhere to [the KEML]. But most of these facilities they are smaller. -Sub-county health manager 4

> I also coordinate service delivery in the private sector but I do not interfere of what commodities they stock in their facilities.- Sub-county health manager 6

6.5.3.2 *Supportive supervisions for medicines management*

Sub-county health managers also had apparent discretion when it came to how or to what degree they enforced or ensured that facility essential medicines supply and management were in line with the KEML. Supportive supervisions involve SCHMT visits to primary care facilities to support service delivery based on expected standards and guidelines. Supervisions usually involved checking pharmaceutical stocks and availability, presence and storage of expired or overstocked products, and storage conditions for a subset of medicines, as well as checking monthly reporting for vertical program

commodities and supply management documentation. Facility and procurement managers described the SCHMT support as constructive.

Sub-county pharmacists generally had detailed working knowledge of the list, but supervisions did not involve a detailed medicine-by-medicine inspection of KEML medicines nor did they expect facilities to make all KEML medicines recommended at their level of care available. Rather, several sub-county managers described using a shorter list of medicines to check whether minimum expectations of functional health facilities were met. The shorter list applied appeared to differ across sub-counties, although participants mentioned the desire to develop a common list of basic commodities. Some sub-county health managers expressed that the KEML contains many medicines and that it was not necessarily a useful guide for supervisions, and that they instead consider a more basic list of medicines. For example:

> So for me as a pharmacist, the first thing is to check on those stressor commodities which are basic antibiotics, analgesics […] we were discussing as the pharmacy department it's a very long list. If we go to a level two facility, we don't expect them to have even half of this …we want to customize something to guide us in our supervisions. So that in the very – in a situation where now we are completely stocked out, at least when we have these few basic items available for us to say this health facility is operational. – Sub-county health manager 3

While there is no designation in recent KEMLs for diverse "vital" and "essential" medicines, "vital" medicines were described as being prioritised over essential medicines by some managers. This is a classification that has been used in past KEMLs and is used in other contexts [22], although it is unclear how "vital" medicines are classified in the absence of such KEML classification.

6.6 Chapter summary and reflections

This macro- and meso-level analysis of KEML implementation illustrates the significant influence that the actions and interactions of and between national government, KEMSA, and county government appear to have over KEML implementation. Process factors of dissemination and communication, financing, and procurement were particularly important. Based on the procurement role of the KEML, KEMSA had particular influence over its implementation, at times posing critical limitations. While there was an absence of KEML accountability mechanisms such as M&E from the national government, the restriction of procurement to KEMSA led to a *de facto* top-down enforcement of the KEML. Policy incoherence with STGs, was a key contextual factor that affected KEML clinical integration and apparent use by healthcare workers. At the level of constitutive action, the absence or inconsistency of MTCs at diverse health system levels was seen as an implementation barrier. Where MTCs were functional at

hospital levels they were seen as likely facilitating accountability. Directive budgetary actions at the county level limit availability of and access to essential medicines at health facility level. Donors also had influential directive actions that promoted access to particular donor-prioritised medicines directly, consequently deprioritising others. Operational actions were governed primarily by county and sub-county health managers. The vertical chain of subordination between county—sub-county—health facilities creates accountability for procurement and supply decisions made at facility levels. Overall, although health system decisions on medicine selection are formally determined by the KEML, medicine availability and accessibility in health facilities appeared to be determined to a larger extent by the ability of KEMSA to supply KEML medicines, county resources to purchase medicines, and county management of health commodities. Building on these findings, implementation of the KEML at the micro-level is explored in the next chapter.

7 Micro-level factors affecting the implementation of the Kenya Essential Medicines List

7.1 Introduction

In this chapter I investigate KEML implementation at the micro-level in Kilifi County. I explore how implementation is shaped by the perceptions of and responses to KEML content; the micro-context; the constitutive, directive and operational actions of actors; and the local process features of implementation. Although this chapter emphasises the perspectives and roles of individual implementers and how implementation occurs at health facility levels, the perspectives of county and national respondents are also included to make relevant comparisons between the reality on the ground and policy expectations. The findings are based on the analysis of interviews (n=41), documents and observations (as outlined in Chapter 4), presented using the thesis conceptual framework. An overview of the findings at the micro-level is depicted in Figure 7-1. The chapter concludes with a summary of the findings.

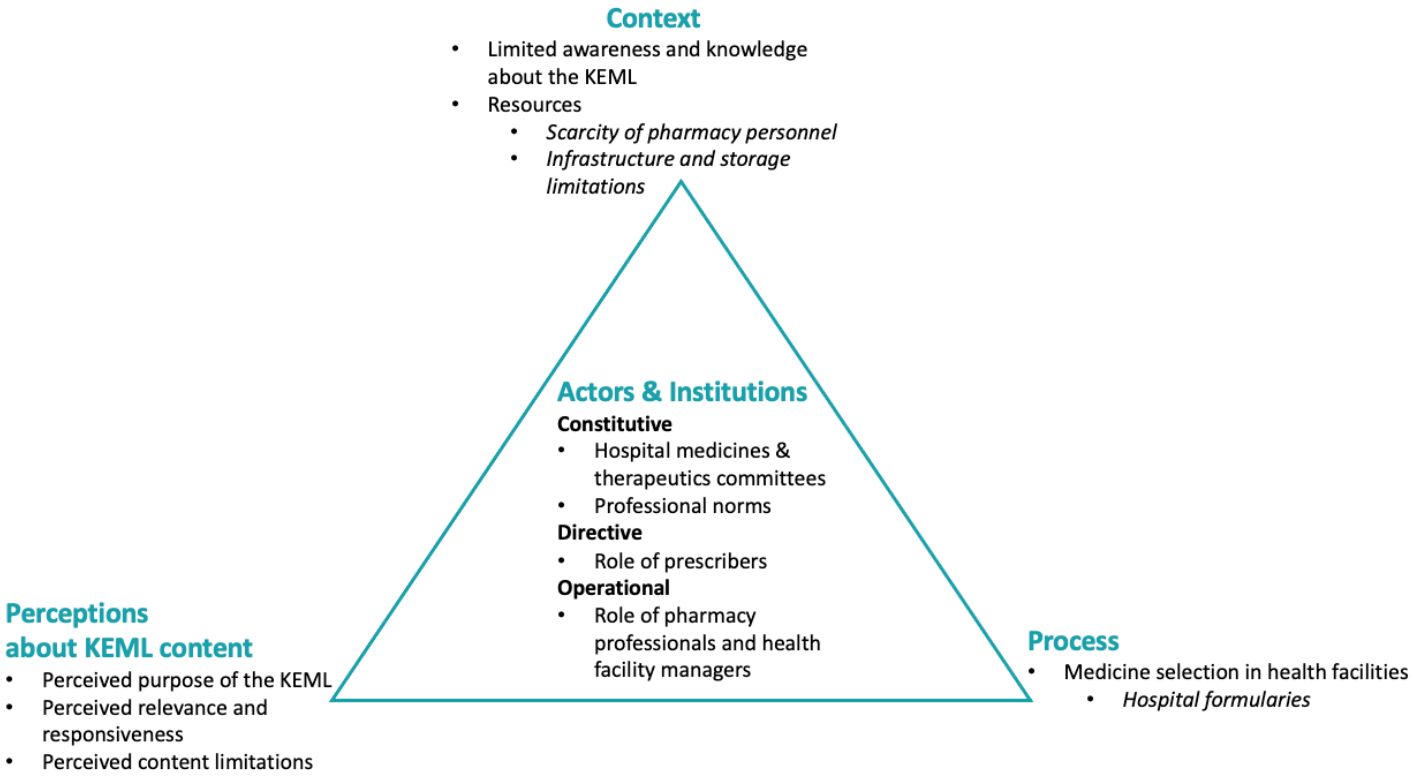


Figure 7-1. Overview of factors affecting KEML implementation at the micro-level

7.2 Perceptions of KEML content

7.2.1 Perceived purpose of the KEML

The perceptions that stakeholders had of the KEML purpose, particularly on how and in which settings it should apply, appeared to affect the list implementation. Although the KEML has diverse intended uses (Table 6-1), it was primarily seen as a procurement and pharmacy tool by participants familiar with the list. When asked what successful implementation of the KEML meant to them, the most common response among implementers was that medicines would be made *available* in the facility or that procurement barriers would be addressed.

> I consider the essential medicines list as – let's say as a guide for the supply chain.
> – Sub-county health manager 1

This perception of the KEML appears to have arisen from practical experience with it to date and past government emphasis, seen in documents reviewed, on its use in public procurement. As found in Chapter 6, in practice, the KEML *is* primarily entrenched as a procurement tool. Similarly, in the past the primary use of the WHO EML has been as a procurement tool [12]. With the more recent global UHC agenda, WHO has further emphasised the role of EMLs as a basis for reimbursement lists in public and private sectors. As one policymaker explains, a wider set of applications for the KEML, particularly in reimbursement have also been emphasised by the Kenyan government through the national UHC agenda:

> So previously it has been mainly on guiding what to stock, guiding what to use in the hospitals for example, guiding what to procure, guiding what to supply, guiding investment. […] but with UHC and particularly with the insurance component, the aspect of guiding what to reimburse as a package, so a child with pneumonia, what will the insurer reimburse for treatment of pneumonia? That I think has not been very apparent before but now is an increasing discussion now with the essential list… – National MOH 4

While much less commonly mentioned, other outputs and outcomes of perceived success in KEML implementation beyond availability included broader goals of ensuring patient access to essential medicines, which included roles for the KEML in ensuring affordability and accessibility in facilities; and emphasis on appropriate use of medicines and ensuring safety and quality in conjunction with assured availability. Another commonly perceived purpose, and importantly benefit, of the KEML was to "standardise" disease management and promote "uniformity" in quality of care across health facilities. This was described as important to ensure that patients seeking care in different geographical regions or facility levels could access the same medicines, whether it be the same person or based on the principle of equal treatment of equal cases.

The KEML was often primarily perceived as a tool for the public sector. Most participants believed the KEML should, however, guide the private sector. A common perspective was that private facilities "are not restricted" to the KEML in the way that public facilities are, as indicated by a sub-county health manager:

> [Private facilities] can have anything else they'll feel they want to for as long as it's within the Kenyan market – Sub-county health manager 3

A sentiment expressed by a smaller number of participants was that private care delivery was not compatible with the essential medicines concept, due to the reliance of private facilities on the sale of services and medicines to generate profit and deliver their services. This perception of the KEML as seemingly irreconcilable with a market-driven model was conveyed by a professional association participant:

> You know the EML is not a treatment guideline. So I wouldn't say it applies to the private sector, because private sector is willing buyer willing seller for whatever commodity it is […] whatever product that is demanded by the market. Yes, so I would, the EML has really no impact on private sector. – Professional association, National NSA 4

7.2.2 Perceived relevance and responsiveness

In this section, the perceived relevance and responsiveness of the KEML to the country's health needs is explored, which was most often described by those familiar with the list in terms of: its trustworthiness as a guide for medicine selection and KEML content limitations.

7.2.2.1 *Trusted guide for medicine selection*

The KEML was viewed by participants across all levels as a trusted and relevant guide for medicine information. Among stakeholders who knew about and used the KEML, the prevailing perception was that "by and large it's a really good guide." (Hospital pharmacist 2). Views of the list as trustworthy and relevant appeared to be related to its perceived status as an evidence-based tool to efficiently guide the selection of cost-effective and quality medicines for procurement tailored to the Kenyan context, its recent updates and the fact that it has "evolved" (County health official 1) to meet most health and health system needs. Several prescribers noted that they could reliably find medicines for most of their patients' needs in the list. Procurement actors and managers at the county, sub-county and health facility levels saw it as a practical guide for evidence-based procurement and pharmaceutical management that offered suitable medicine recommendations for most health conditions.

> …it kind of directs our management and ensures that we are offering quality services within some sort of framework and directed by evidence – County health official 2

> …it's been researched and we've never gone wrong for stocking what it tells us to stock.- Hospital pharmacist in-charge 3

Trust in and relevance of the KEML also hinged on its regular and responsive revision and maintenance as a dynamic list. Although revisions to the KEML are intended to occur every two years to ensure that it is in line with updated evidence and therapies, the revisions have not happened at regular time intervals that stakeholders can expect. This was evident with the KEML 2010, where a lack of revision for 6 years rendered it "obsolete" (KEML 2016) and it was no longer deemed responsive to the needs of healthcare workers or procurement managers. Stakeholders in both policymaking and implementing roles felt that timeliness of revisions has been an issue, although the 2019 list was released in a manner more closely aligned with the intended revision period.

Although implementers were generally satisfied with the list, KEML content limitations were commonly expressed, as detailed in the next section. Some participants estimated that the KEML met 70, 80 or 90 percent of their needs.

> …it probably meets 70% of our needs, but they have room for improvement. – Hospital pharmacist in-charge 2

7.2.3 Perceived content limitations

Two limitations related to KEML content were deemed important by participants and may have influenced their "adherence" to the list. First were concerns about the level of use recommendations for certain medicines and their implications on access to medicines at primary care level. Second were concerns about medicines listed (or not listed). Each of these is discussed in sequence.

First, KEML listings indicate the lowest level of care at which a medicine "is expected to be available for use (i.e. distributed, stored, prescribed and dispensed)." [1] These level of use designations (see Fig. 1-1) align with the Health Act 2017. The designations are based on where medicines "may reasonably be expected to be appropriately used" [1], as assessed in the revision process. The minimum level of use listing was often a concern for chronic NCD medicines. The KEML 2016 listed medicines for hypertension and diabetes at hospital level, which meant that access to these medicines was generally impeded at primary care facilities. Participants described difficulty in gaining access to medicines at primary care that were designated for higher levels of care, particularly for rural patients living with chronic conditions where physical distance to the hospital can create treatment delays.

> …you see like anti-hypertensives, they are to be used by level four and above […] But the dispensary is the first point of contact for any patient before they are referred. So if this patient has let's say maybe high blood pressure today and it's an emergency, the

> dispensary can't do much; they can only refer. […] so in case the drugs are not somewhere along the way, again they have to make the trip to the hospital. – Hospital pharmacist in-charge 1

Particularly in the context of the ostensible UHC priority to strengthen primary healthcare, the level of use restrictions were perceived by some as hindering access to some medicines, like hypertension and diabetes medication. A representative from the faith-based sector at national level described that antihypertensives designated for hospital settings in the KEML were nonetheless made available in their facilities across the country:

> …UHC being geared towards really strengthening primary healthcare facilities […] you would still find there are drugs that are essential but have not been – according to the KEML, you still cannot access them at level two. […] So this really limits access for patients. […] So I was giving an example of nifedipine. It's a very common drug in level three health facilities, but […] it can only be stocked in level four. […] also hydrochlorothiazide […] actually you find it stocked even in level two in dispensaries […] they've only put it in level three. – Faith-based organisation, National NSA 2

The need for some level of discretion, articulated as flexibility, was expressed by some participants. Given the dynamic and complex changes that implementers face in between KEML revision cycles—such as new medicines arriving on the market, availability of new clinical evidence on medicines in use, and health system changes—the updates must reflect current health system realities and enable local decisions to respond to contextual and unforeseen challenges. An example of discretion exercised at county level to overcome the NCD medicine access challenges at primary care level was also provided in Chapter 6. Another example is that some dispensaries conduct deliveries, and so with changing services across the country medicine recommendations must be matched or discretion enabled.

Second, most also had some issue or disagreement with at least one of the medicines listed or removed from the KEML. At times, problems related to medicines recommendations have to be solved in their dynamic local county or health facility settings. A commonly cited issue was the 2016 removal of diclofenac from the KEML, detailed in Box 7-1. Of greatest concern to implementers was the removal of medicines without adequate communication and reasons for delisting. Delistings were often described as "abrupt" and lacking a clear and unified transition from one medicine recommendation to another. A perceived lack of appropriate alternative medicine recommendations were a concern in some cases where a medicine was deleted, as in the diclofenac case (Box 7-1) and for aminophylline for lung conditions (see quotation below). Issues with the dose-forms of some medicines were also mentioned, for example for administration of omeprazole, a gastrointestinal medicine, in neonates:

> … quite a number of commodities were removed from the previous list of 2010, one of them was like ranitidine […] it was used a lot […] it was abruptly removed and replaced with omeprazole IV […] yet […] we don't have a dosage that is formulated […] to fit […] for the neonates […] So that was a very big issue. When aminophylline was removed, it was removed but with no substitute. […] So it was a case of now we have to calm down and bring our heads together and see a way out. - Sub-county health manager 5

Some participants remarked on the need for a greater variety of medicine choices—for clinical reasons as well as to promote better availability of medicines by having more options to draw on, while others believed the list should be more restrictive. Particularly in hospital, participants described certain needs that they had, based mostly on specialised services they offered, were not met by the KEML.

Box 7-1. Case example: Diclofenac use after removal from the KEML 2016

Frequent concerns were raised with the removal of diclofenac, a medicine used to treat pain and inflammatory conditions, in the 2016 edition. The KEML 2016 notes the deletion of diclofenac with the following description: "[n]ot recommended, increased risk of cardiovascular adverse effects (use ibuprofen)." Stakeholders at county and health facility levels reported that this deletion caused issues in several ways. First, due the concern that *"there was no alternative that was offered"* to diclofenac, they were left without recommendations on *"an NSAID that would replace what diclofenac was doing."* (County health official 2) While the KEML 2016 had recommended paracetamol IV injection to manage post-operative pain in hospital, there was no recommendation on how to substitute diclofenac at primary health care facilities.

> … there wasn't a smooth transition, there was no replacement, people were not told don't use this so therefore use this. So that kind of transition becomes difficult especially health centers where you don't have, you know, physician-led teams. - Hospital physician 1

Several healthcare workers and managers felt that this decision left them without suitable options to deliver appropriate care. Some participants explained that they would ask patients to buy diclofenac out of pocket, as they were unable to obtain it through KEMSA and could not purchase it elsewhere due to the KEMSA Act restrictions described in Chapter 6. Thus, costs were incurred by patients that perhaps otherwise would not have been, due to the disconnect between policy recommendations and the needs at the service delivery level.

> … they're recommending we use ibuprofen, which is not available in a parenteral form in the Kenyan market. […] Now, KEMSA does not stock drugs which are not within the Kenya Essential Medicines List […] So now if I want a parenteral anti-inflammatory or analgesic, I cannot get any because if I buy from any other supplier that will constitute an illegality. So now I don't have any option, I have to tell the patient to go buy for themselves. […] so it limits our ability to give the best service we can. – Hospital pharmacist in-charge 2

Secondly, participants noted concerns about the lack of communication on the change. This included (1) communicating the fact that it was deleted at diverse levels of care and (2) the need for information on how service delivery should be adapted at each level, particularly at lower levels lacking healthcare workers with adequate expertise to navigate the change. The removal of diclofenac was often described as a confusing situation that required repeated negotiation between county government and diverse healthcare workers. Due to a lack of adequate communication on the change from both the MOH and KEMSA, facilities would still include it in their KEMSA orders:

> … our people in the dispensaries don't know. So they keep on ordering for diclofenac, when there's something else called tramadol, which they should order, but because they've not been told or sensitized about it […] they keep on ordering diclofenac. - County health official 4

Additionally, due to the limited awareness on the KEML in general, some prescribers did not know where the recommendation was coming from and some perceived that it came from hospital pharmacy departments. Some pharmacists were reportedly viewed as responsible for the change:

> … initially when we stopped ordering diclofenac they [consultants] were like why is there no diclofenac? […] they kept blaming the hospital pharmacist […] because when they learnt that it had been deleted, they thought it was the pharmacy department that deleted. – County health official 2

Based on hospital MTC recommendations or facility procurement decisions, diclofenac was still deemed important by some facilities and in such cases continued to be procured from the private market through health facility budgets (circumventing county procurement). Several participants felt the diclofenac concerns could have been avoided had more healthcare providers or county stakeholders had the opportunity to participate in or provide feedback in the KEML revision.

7.3 Context

7.3.1 Limited awareness and knowledge

Insufficient dissemination and communication of the KEML from national and county levels, as discussed in Chapter 6, was perceived as creating a context of widespread limitations in awareness and knowledge on the KEML at the micro-level. In this case, awareness is understood as participants having a general sense of what the list is, compared to knowledge, which pertains to having more detailed information about the purpose and application of the list. Several of the respondents in roles as that involve prescribing or dispensing of medicines, such as physicians, medical officers, clinical officers, nurses and some pharmacy staff (casual staff, pharmaceutical technicians) reported that they either had a vague *awareness* of the KEML or that they had never heard of the KEML before. Some county officials in managerial (rather than technical) roles also appeared to have low awareness of the KEML, although county and sub-county managers in technical roles generally appeared to have high levels of knowledge about the KEML. This may have been related to the fact that many of these managers had a pharmacy background. The KEML was also often conflated with the KEMSA procurement list or with other MOH policies and guides, such as treatment guidelines or supply chain guidelines. The lack of awareness about the list became evident through both specific accounts, when healthcare workers were asked whether they had heard about the KEML, and through generalised accounts of what participants perceived as typical, as exemplified by quotations from a clinical officer in charge of a health centre and a county official, respectively:

> I: Have you heard of the Kenya essential medicines list?
> R: … Nah? [laughs]
> – Clinical officer in-charge 3

> …if you go to the healthcare workers, most of them do not know the existence of this document. – County health official 1

A widespread lack of operational knowledge on the KEML purpose, the revision process, and on how it is intended to be used by different stakeholders was common among participants who were aware of the list. Pharmacists involved in procurement and supply management often had the most detailed understanding of the applicability of the KEML to their role and to the health system, as well as knowledge of KEML contents due to their expertise in pharmaceuticals and based on the established role of the KEML in procurement. Yet, uncertainty about how they are expected to apply the KEML to their daily work was often voiced, even by those in pharmacy and procurement roles.

> …the implementation of the EML is […] a bit nonexistent because it exists but nobody is following it the letter […] except the pharmacy that knows it exists, nobody else actually knows it exists.
>
> […] I have these five drugs per condition, is it that I am supposed to choose maybe one or should I use all the five available? Just even just a bit of guidance for me on how to implement it. […] it has been this enigma that nobody knows, you know, the EML. I don't even know – would you know who develops the KEML? – Hospital pharmacist in-charge 1

Awareness and knowledge of the KEML was greater at the hospital level than in primary care, which appeared to be related to the presence of professional pharmaceutical staff that were often missing at primary care facilities (detailed in the next section). In private sector health facilities awareness also appeared to be lower than in public facilities, which was seemingly related to the emphasis to date on the KEML as a *public* sector guide. Those involved in the KEML revision at the national policy level also noted that widespread awareness of the list was lacking across the country.

With limited formal dissemination and communication of the KEML from national and county levels (Chapter 6), information and knowledge about the KEML appeared to be more concentrated among stakeholders with direct links to national or county decision-making, as well as professional pharmacy networks – formally through the Pharmaceutical Society of Kenya and informally through pharmacist groups.

> …being in groups of pharmacists, usually we update each other.
> – Hospital pharmacist in-charge 3

> …though our professional associations […] Pharmaceutical Society of Kenya, we usually have these forums for sharing any updates that come regarding policy and practice of the profession. […] there isn't much effort from the county to ensure that […] as health workers or professionals have what we need to guide us through our practice. But professional associations have taken care of that. – Sub-county health manager 3

7.3.2 Resources

7.3.2.1 *Scarcity of professional pharmacy personnel*

The general scarcity of skilled healthcare workers was frequently noted. Insufficient professionally trained pharmaceutical staff was a particular concern in Kilifi. This was seen as a significant barrier to the uptake of the KEML and other pharmaceutical guidelines, especially in primary care and rural facilities. Hospitals would have at least one pharmacist and health centres often had no professional pharmaceutical staff, although they are expected to have a pharmaceutical technologist on staff.

Several participants stated that this health workforce gap had considerable impacts on the quality and appropriateness of care, and that much of the inappropriate medicine use issues, such as dispensing of expired medicines, would originate at the primary care level where pharmaceutical personnel were absent.

> … all the 15 rural health facilities we have, it's only one where we have a pharmaceutical technologist. […] drugs are mishandled down there. The nurses are overwhelmed. All they do is end up training casuals and leaving them at the dispensary level. [...] for me my main concern is […] we have settled on giving pharmaceutical services without getting professional staff there. – Sub-county health manager 3

Some participants also perceived that insufficient pharmaceutical staffing was also associated with poor quantification of medicine needs, lack of quality reporting, and stock management issues. Casual staff, such as receptionists, were often tasked to dispense medicines and would receive some basic orientation or training to enable them to do the work. Some felt that the casual staff were "well equipped" (Clinical officer in-charge 2). Others expressed more concern about the responsibilities given to casual staff, given their limited training or lack of technical expertise. For example, a health facility manager expressed a lack of confidence in the facility's commodity quantification and patient management that relies on casual staff:

> I'd wish probably to have a pharmacist here, because then he would be able to monitor and even if, even if let's say a clinician overlooks something he'd be able to correct that. And when it comes to ordering then he'd be able to know exactly in terms of the quantity and you know, as opposed to a casual running that department. – Clinical officer in-charge 3

7.3.2.2 *Infrastructure and medicines storage limitations*

Infrastructure limitations played a role in influencing pharmaceutical supply management and service delivery, therefore also influencing KEML implementation, according to health facility managers, healthcare workers and county health managers. This was also linked to the broader county health resources limitations. Limitations in the physical infrastructure to store health commodities presented a challenge in most of the health centers and hospitals visited. Storage spaces were often not equipped to maintain the ideal temperature-stable conditions for medicine storage, sometimes due to lack of funds for air conditioners or fans to keep commodities at lower temperatures. A Clinical Officer In-Charge described their concerns about the conditions at which medicines are stored in the health centre:

> …my store doesn't have like an AC, so that becomes a challenge to certain medicines and so we have to leave like that the fans on and the windows open just to try and cool them. – Clinical officer in-charge 3

Several participants involved in supply management noted that the storage limitations had real impacts on how essential medicines supply was planned and managed.

> …mostly when we receive supplies, the store is never enough. And so, even if we had all the money to procure all the drugs we needed, which are also on the list, it would be hard for us to store those drugs in the conditions they're supposed to be in. – Hospital pharmacist in-charge 2

Stock management concerns were expressed, whereby at times it was difficult to complete physical stock counts, for example because "*You can't even enter" (Hospital pharmacist 4)* the storage space. Prescribers also noted the need for the appropriate physical space to manage patients based on their conditions and needs, that lack of space can influence decision-making in prescribing, the need to select medicines based on the existing infrastructural capacities, and that equipment or other supplies that are needed to administer drugs are sometimes missing.

> … if we don't have the essential equipment to offer some services then you can have the drug there but not utilize. So like if we have the solution for nebulization but you don't have the machine, the nebulizer. – Clinical officer in-charge 1

7.4 Actors and institutions

7.4.1 Constitutive action

Structural factors at the *organisational* level of the health facility in the form of committees, and at the *individual* implementer level in terms of professional norms were influential in shaping KEML implementation. At the health facility level, decisions on which medicines to procure and make available are governed by local institutions. In some hospitals formal MTCs mediated decisions, whereas in primary care facilities and hospitals without active MTC, medicine selection decisions were made through the health facility management team or an "informal committee" (County 2). Hospital MTCs were perceived as particularly important.

7.4.1.1 *Hospital medicines and therapeutics committees*

MTCs were viewed as important local institutions to facilitate or otherwise influence the implementation of the KEML in hospital settings. However, these were missing or not very active in some cases, and at times diverged from the KEML in their local medicine recommendations. Hospital MTCs were seen as critical structures to build and maintain "collective responsibility and ownership" (County health official 2) for medicine selection and use across diverse cadres of healthcare workers, serving as institutions to manage accountability related to pharmaceuticals. MTCs have the power to legitimise or permit procurement from sources other than KEMSA or of "non-essentials" by

demonstrating to county decision-makers that medicine needs are justified based on agreement of the committee.

> … we are allowed like to procure non-essentials and especially in hospitals, it is really using the MTC […] So we can also sit as a committee of the hospital and decide we need to procure this outside […] So we review the minutes and then we take it to the county pharmacist and say we've had these deliberations together with physicians and pharmacists, nurses, the whole team and they can allow to. – Sub-county health manager 2

Two of the three hospitals I visited had established an MTC, although it was more active in one of those hospitals. The more active MTC serves as a hospital management advisory body on any medicine-related issues, promotes cost-effectiveness in care, ensures that hospital staff are educated and informed about medicine policies and information, develops the hospital formulary, and leads pharmacovigilance activities (e.g. ensuring reporting of adverse drug reactions). In the hospital that did not have an MTC and the hospital with the less active MTC, participants perceived that their absence or low activity was due to several limiting factors. These included a lack of persistent leadership to steer MTC activities, precipitated by frequent staff turnover as healthcare workers are transferred to other facilities, and relatedly, a lack of priority given to the MTC by the committee members. The latter involved descriptions of members demonstrating little to no interest in the MTC, as well as poor meeting attendance and participation.

> … we haven't had it [MTC] for a very long time. […] There's a bit of lethargy […] I feel when meetings were called the people were not giving it it's importance, you call for meeting only two people show up. Then it just died down, it just died. – Hospital pharmacist 4

Challenges in ensuring the presence and functionality of hospital MTCs were a concern for several national participants, who often referred to MTCs as institutions for accountability and for monitoring medicines issues to inform future KEML editions. Thus, it does not appear to be an issue unique to Kilifi County.

7.4.1.2 *Professional norms*

The norms that guide prescriber and pharmacy professionals, actors with particularly important roles in KEML implementation at the micro-level, were a structural factor influencing KEML implementation at the level of the individual. These professional norms represent the rules and standards and their integration into the local practice of particular professional groups [146]. The KEML did not appear to be as integral to the norms and practices of prescribers and other healthcare workers as for pharmacists.

> …the person who will know about the EML list is probably the pharmacist. But not the other health workers. – Professional association, National NSA 1

The frequent perception of the list as a procurement and pharmacy tool and not as a health systems policy appeared to affect its use and perceived applicability, narrowing the policy intent in practice.

The KEML was part of the pharmacy professional norms, as exemplified by greater knowledge and information sharing of the KEML among professional pharmacy circles. Furthermore, pharmacists often described a sense of responsibility to educate others on the list. When asked why they follow the KEML recommendations, pharmacists often responded because it is a useful procurement guide and that following such policies was *"just professional"* (Hospital pharmacist in-charge 2).

The association of the KEML with pharmacists and procurement, coupled with the limited awareness and knowledge of the list and its purpose, appeared to result in limited ownership and legitimation of the KEML among prescribers. For example, pharmacists noted that prescribers would at times contest KEML medicine selection decisions, assuming decisions were made by pharmacists.

> … sometimes now it brings in some conflicts […] with the clinicians especially because now at that level it is seen as a pharmacy document rather than a health sector document. – Sub-county health manager 5

7.4.2 Directive action: Role of prescribers

Prescribers, in particular medical doctors, make important decisions on medicines in their prescribing practices and appeared to have directive influence over procurement decisions at the health facility level based on their medical expertise. Clinical officers, medical doctors, and other healthcare workers with prescribing responsibilities had expertise which allowed them to exercise some discretion in selecting medicines to help patients manage their conditions. These clinicians described that their *prescribing decisions* were not necessarily based on or limited to the KEML. Non-KEML medicines could be prescribed without facing consequences for not adhering to the KEML. Several prescribers noted that they prescribe based on medicines stocked in the hospital or health centre most of the time. Facility managers and pharmacists also described encouraging clinicians to prescribe from the medicines stocked in the facility. Given the KEML use in procurement, several clinicians therefore believed they were adhering to the KEML:

> The only way to adhere to the EML is to prescribe what we provide at our pharmacy. So sometimes we do have cases, it's there, that let's say for example for a skin condition you need some form of a cream […] that's not in the EML, and it's not within the KEMSA provided drugs. So, one way or the other, it will be prescribed

> outside that list. […] but most of the times we force […] our clinicians to make sure they prescribe from what we have. – Medical Superintendent 2

Decisions on which medicines to prescribe were also often guided by (1) other information sources such as national treatment guidelines, international guidelines (e.g. the British National Formulary), online information; (2) based on prescribing choices promoted in their training and by clinical mentors; (3) pharmaceutical company marketing, particularly in hospital or private sector settings; and (4) based on the recommendation of specialist physicians in hospital.

Several clinicians articulated that they sometimes prescribe medicines not on the KEML based on whether patients can pay for alternative options, which may have equity implications. Some participants believed that access to medicines was more likely to be compromised when clinicians prescribed off-list, because patients are forced to pay higher prices on the private market, especially when the essential medicines are available in the facility. A clinician incentive to prescribe based on the KEML, according to a clinician, was that patients would be more likely to afford and access medicines:

> I'll stick to my list because I know that means my patients will get that drug wherever they go because if I deviate and I write something that is not on the list, I've created some sort of havoc for that patient. – Hospital physician 1

However, in the context of availability concerns, some noted that prescribers could exercise greater discretion in prescribing non-KEML medicines, since patients would have to purchase medicines out-of-pocket regardless. When essential medicines were available in the facility, prescribing off-list meant both that patients pay more and essential medicines were more likely to expire.

Prescribers also strongly influenced decisions on which medicines were *procured*, especially in hospitals. For example, specialist expertise in hospitals was often cited to explain the need for non-KEML medicines in hospital. This influence has been curtailed to some degree with the procurement restriction to KEMSA and KEMSA's alignment of stock with the KEML (Chapter 6). Health facility procurement managers described that they were more likely to order off list based on the demands of prescribers and patients before the amendment:

> … before then [the KEMSA Act changes] […] we use to procure from other suppliers. Some of those drugs were not even in the list […] people wouldn't really care if you told them, this is what the list says, because they knew there was the option of you having to buy for the patient. But now that the option is not there, and they have to stick to what you're providing them. – Hospital pharmacist in-charge 2

Some clinical staff perceived, however, that pharmacy staff often had the most influence over procurement decisions. Pharmacy staff on the other hand often described feeling undervalued in their expertise when it came to making medicine selection decisions because prescriber preferences heavily influenced procurement decisions. A hospital pharmacist explains:

> …the clinical side will tell you, yeah you can tell us the KEML tells you not to procure this but […] at the clinical side we know this is what we want. Then it will have to be a tug of war where the clinical side decides, the lab should provide these services, the pharmacy should provide these services that way. […] this is what you are told as a pharmacy, your point is to provide. So what much can you say there- so you provide… – Hospital pharmacist in-charge 1

7.4.3 Operational action: Role of pharmacy professionals and health facility managers

Pharmacists and pharmacy technicians were often regarded as the most important stakeholders in promoting KEML use and implementation due to their technical knowledge and expertise on pharmaceuticals and common roles in procurement at national, county, sub-county, and health facility levels. Pharmacists were presented as gatekeepers of the KEML—other cadres of healthcare workers often relied on pharmacists for pharmaceutical information and updates. Health facility participants usually directed me to the hospital or sub-county pharmacist when asked if they had a hard copy of the KEML. Prescribers who were familiar with the list often learned about it from pharmacy colleagues.

Health facility managers in hospitals and primary care facilities, based on their position of authority, also had important influence over KEML implementation as they could promote or enforce its use within the facility.

> In as much as the pharmacist is a really critical player, but when it starts from the Med Sup [Medical Superintendent] who is at the top, it's easier for this information to get to the other users, like the clinicians, as opposed to, you know, that coming from us. Because they would you would think of us as being at the same level, at service delivery points, but […] if the Med Sup shares with medical officers, the clinicians, and the pharmacists, I think it would be good to have a better reception. – Hospital pharmacist in-charge 2

7.5 Implementation process

7.5.1 Medicines selection in health facilities

Important medicine selection decisions at health facility level were made through procurement and budgeting decisions, and in some hospitals through formularies. Selection decisions made through procurement and health facility budget allocation were mostly described as occurring through a consultative and consensus-based process between the health facility management team, which often

included a pharmacist/pharmaceutical technologist or procurement manager, clinical staff from different departments, and the facility manager. In some hospitals this involved MTCs, as discussed above. The KEML appeared to be commonly used as basis for procurement at hospital level, but less so at primary care level where facility managers often appeared to have limited awareness about the list. At primary care, some instances were described wherein facilities would stock medicines that were not listed or delisted from the KEML, such as the diclofenac example above, or not recommended for their level of use in the KEML. Nonetheless, not being able to procure all essential medicines needed often appeared to be a larger problem than ordering off-list.

Health facility participants stated that they made procurement decisions based on previous consumption, workload, disease patterns, and current patient needs. Discretion in KEML use for medicine selection in health facilities appeared to be exercised based on the factors described above—awareness and knowledge, perceptions of the KEML purpose, perceived relevance and responsiveness of the list to health needs, and based on the expertise of prescribers or pharmacists, as well as the directives and operational oversight from facility, sub-county and county health managers (see Chapter 6). No clear rules appeared to exist or be well understood by participants on when discretion could be exercised in selecting non-KEML medicines.

> I think one thing as I'm saying is clearly define how this EML is used. Can you change it? Can you go against it? If you can't, what is the process?
> – Professional association, National NSA 1

In addition to the resource allocation decisions that occur at the county level as described in Chapter 6, another level of directive content decisions related to budgetary allocation and financing takes place at hospitals and primary care facilities based on their own health facility funds that they have discretion over from several sources like NHIF, government and DANIDA (separate from the designated county pharmaceutical budget). In all health facilities visited, some portion of the facility budgets was described as used to make supplementary procurement orders and to protect against stock-outs. At the hospital level there appeared to be more flexibility to purchase different medicines that were not necessarily on the KEML and may not be available through KEMSA through the facility budget, as these purchases were often made on the local private market. Nonetheless, purchasing through facility funds usually only catered for a small portion of the facility medicine needs and facility and procurement managers usually described using supplementary orders for emergency medicine needs:

> We have a small kitty within the facility that is generated from Linda Mama, that's NHIF covered, so we try and buy the emergency drugs and a few hypertensive drugs, yeah just so that we can curb the situation prior to referrals. – Clinical officer in-charge 3

> …for other drugs we need which are not on the list they usually do a supplementary order, or if it's a vital drug, let's say dopamine, we had a patient and heart failure which was not supplied or finished, we have to come to the administration office and see whether they can purchase for an individual patient. – Hospital pharmacist 4

7.5.1.1 *Use of hospital formularies*

MTCs developed and used formularies to set medicine priorities for the hospital. In hospitals that had or were developing hospital formularies, these were seen as tools to both integrate KEML use at hospital level and to select additional medicines based on local perceived health needs. The KEML was viewed by hospital pharmacists and managers as a useful tool to guide the development of hospital formularies. By creating hospital formularies that incorporated KEML medicines, they could make the KEML more operational for prescribers and other healthcare workers through further guidance on optimal medicine use:

> You just can't come with a list and say this is what we should be using. You see, now the basis is what you build it up using the formularies so that you encourage the whole team to build on the formulary because at the end of the day you've told let's say the nurse that the drug you should be using here is infusion paracetamol; you know to her, she needs to know how do I infuse? And the medical officer here or the prescribing team will be like, what quantities? – Hospital pharmacist in-charge 3

Formularies were viewed as better customised to the needs of the hospital and the type of conditions that affect their patients. They were often described as tools for the hospital to promote access to medicines that were *not* on the KEML but deemed important based on patient needs or specialised care services provided. The hospital formulary would then be used to procure medicines off-list, usually through local purchases using hospital funds if medicines are not available through KEMSA, as explained by a sub-county health manager:

> So the whole idea is whatever is not in the KEML but we can incorporate in our hospital formulary then it would mean that if we order from KEMSA essential list they will give us, but the money that the hospital uses to do local purchases for drugs now can be directed towards what's not in that KEMSA list but it's in the formulary list as an essential so that we can have all ranges. – Sub-county health manager 5

Thus it appeared that the formulary afforded hospitals more flexibility to procure or prescribe non-KEML medicines. Yet formulary development was also contingent upon hospital resources for such an undertaking and staff capacity and expertise in the hospitals studied, suggesting those with more access to expertise and resources may exert more discretion in KEML use.

7.6 Chapter summary and reflections

KEML decisions were not necessarily fixed; rather, medicine selection was negotiated and discretion was used at health facility or prescriber levels as it was implemented based on a few key factors. The KEML was deemed a trusted guide with an important role in standardising care across the country based on its general responsiveness to health needs; perceptions which apparently served as an enabler to implementation. A key reason for exercising discretion appeared to be due to perceived content limitations in either level of care recommendations or issues faced with medicines recommended, where such discretion allowed implementers to respond to patient and health facility needs not met by the KEML. Discretionary power, or ability to make decisions that did not align with the KEML, was based on implementer expertise, in particular the expert knowledge of prescribers (directive action) and constitutive action (such as hospital MTC decisions to override KEML recommendations based on their health needs). The presence of pharmacy professionals and MTCs were also deemed facilitators of KEML implementation. As a result of the perceptions held about the KEML by those familiar with the list, the KEML policy as experienced and practiced by implementers was narrower—with a focus on public procurement—compared to its intended role. Furthermore, a major limitation to implementing the KEML at the micro-level was the lack of *awareness and knowledge* about the list and its purpose, particularly in primary care and private sector facilities.

The findings this chapter suggest that implementers are often not provided the resources or conditions to meet the goals outlined in the KEML. Although implementers often had limited latitude to make medicines selection decisions due to factors at the macro- or meso-levels (as per Chapter 6), micro-level factors must also be recognised and addressed, as these appeared to influence facility availability and the costs incurred by patients purchasing their medicines outside of public facilities. The findings from the three results chapters are further discussed in the next chapter.

8 Discussion: Medicine selection as a contextualised multi-level process

8.1 Introduction

Although EMLs are considered important policies for UHC and to govern access to essential medicines in many countries, the processes and factors that determine policy implementation have been insufficiently examined. The aim of this thesis was to understand the factors that influence KEML revision (medicine selection) and implementation in Kenya to identify strategies to improve access to essential medicines. The first study objective was to describe the national *KEML revision* process and analyse how actors and context influence the process. In Chapter 5 I address this objective, presenting findings on how the KEML was revised, the process challenges faced such as resource constraints, practices and perspectives on stakeholder participation, and evidence use; as well as the constitutive, directive and operational influences of the NMTC, experts and other actors and the effects the UHC political agenda had on KEML revision. The second objective was to investigate key factors influencing *KEML policy implementation* at the *national and county level*. To address this, I presented findings on the key features and limitations of the KEML implementation process—dissemination and communication, financing, procurement, and M&E, the contextual challenge of policy incoherence between the KEML and the STGs, and the ways in which key actors use constitutive, directive and operational action to affect KEML outcomes (Chapter 6). The third study objective was to examine key factors influencing *KEML policy implementation* at the *health facility level*. These factors include the perceived relevance and responsiveness of the KEML; contextual factors like limited awareness and knowledge about the list and health facility resource limitations; the constitutive, directive and operational actions of key street-level actors such as hospital MTCs, prescribers and pharmacists; and the process of medicine selection in health facilities (e.g. through hospital formularies) (Chapter 7).

Collectively, this thesis provides an empirical case study of how KEML policy outputs and outcomes are ultimately co-produced through a multi-level process, using Kilifi County to understand subnational implementation. It illustrates that although the KEML may appear to be a simple technical list to be adopted in practice, its implementation relies on a complex, interdependent and dynamic set of actors, processes and contexts operating at national, county, and health facility levels. In this final chapter, I discuss the key findings based on the thesis conceptual framework, reflections on the conceptual framework, study strengths and limitations, considerations for policy and practice, future research recommendations, and end with the contributions of this study to the literature and concluding remarks.

8.2 Discussion of key findings

8.2.1 Process

A critical aspect of the study objectives was to understand the KEML revision and implementation processes, and particularly, to understand the key process elements of KEML implementation to facilitate access to medicines. Key findings related to these processes and the ways in which they are interlinked across 'stages' of revision and implementation and political-societal levels are discussed in this section.

8.2.1.1 *KEML Revision*

Discussing the findings on KEML revision in relation to the priority-setting literature helps to situate them in a relevant field of study beyond the narrower EML literature. This literature widely includes key procedural conditions for processes, such as medicine selection via EMLs, to be deemed fair and legitimate. Procedural conditions relevant to the findings are: (1) relevant stakeholders should be effectively engaged and engagement should be done in a way that stakeholders have the power to contribute meaningfully, (2) use of information/evidence, (3) transparency of the process, so that accountability and legitimacy is promoted [187-189].

First, the limitations in meaningful stakeholder engagement mechanisms appeared to have important implications not only in terms of who was involved and heard in the decision-making process, but also diminished Kilifi County ownership of the KEML. Findings from other countries suggest a similar pattern: participation of healthcare workers in the medicine selection process was seen as a facilitator to implementation of EMLs in Eritrea and Sweden [13, 190], and the lack thereof was a barrier to implementation in Brazil [116]. Relatedly, guidelines imposed in Uganda without adequate consultation were less likely to be taken up at the service delivery level [191]. As priority-setting studies have highlighted, engagement mechanisms like the amendment proposals lose their value if they are not functionally utilised [188]. Considerable evidence illustrates the importance of consultation and effective involvement of relevant stakeholders in policy-making processes to promote fairness and legitimacy [128, 188]. Nonetheless, implementer trust of the list did not appear to be negatively affected by those familiar with it, which may be due to the KEML's longstanding presence.

The consultations done with many technical experts were considered by policymakers to be a strength of the process. Perhaps this was due to perceptions of the KEML process as primarily a technical rather than a political one, compared to processes with ostensibly more explicit resource implications like the UHC benefit package where representative participation is deemed critical. However, I would argue that the likely impact of EMLs on many actors in the health system and market-shaping potential makes these processes, like most if not all policy processes, inherently political [192]. The findings highlight

that the EML should be managed with due consideration of power dynamics and political influences, particularly as adequate representation by key stakeholders in decision-making is important to facilitate implementation. Yet this should not preclude processes from being fair and legitimate, with medicine selection based on rigorous evidence [112]. This is where strong process governance of engagement, transparency and evidence use through the NMTC or similar committees is critical.

Secondly, this study found that medicine selection may still be based on expert opinion rather than evidence. Similarly in Mali, expert opinions shaped EML selection in ways that could influence evidence use (to a greater and lesser extent) [114]. Findings from Kenya and Mali demonstrate that to understand evidence use in EML processes, we must closely examine the interconnected influence of actors. However, evidence use limitations in this study were also related to the quality and type of evidence available and the lack of M&E of previous EMLs; these limitations were also described with South Africa's EML/STGs [109].

Thirdly, this links to a discussion of the findings with respect to the transparency condition, which stipulates that the procedures and reasons for decisions made should be accessible and communicated to stakeholders [189]. The WHO EML's transparent process means that the rationales for medicine selection decisions by the expert committee are made publicly available on their website with each edition. Findings throughout this work suggest that the KEML process was insufficiently communicated and the reasons for KEML decisions made were often unclear. Insufficient transparency of EML processes and the need to make the reasons for EML decisions public have also been noted in Nepal and South Africa [104, 113].

8.2.1.2 *Implementation*

Key aspects of the KEML implementation process at national and county levels include dissemination and communication, financing, procurement, and M&E. These form the focus of this section with relevant links to their micro-level implications. Insufficient dissemination of the KEML from the top down—across national, county and health facility levels—was widely noted as a problem and was reflected in the common lack of awareness and knowledge about the KEML at the micro level. These findings are congruent with previous accounts that the KEML has often not been available at health facility levels [52, 193] and that healthcare workers in Kenya have limited awareness about the KEML/the essential medicines concept [22]. Despite the importance of EML dissemination and communication with implementers in diverse roles, similar challenges in information reaching the necessary stakeholders have also been documented in Brazil, South Africa and Delhi [88, 108, 109]. In the health policy implementation literature in LMICs, policy communication, information and understanding issues have frequently been described as important factors influencing implementation

[17]. Zooming out to the broader public policy implementation literature, the need for policies to be well communicated and understood has often been described by top-down theorists as a criterium for successful implementation [129, 132, 135]. Not communicating the KEML updates to the public may also be a political choice, as national governments could be seen as responding to health needs through KEML revisions without provision of resources that enable equitable access to medicines across the population. In third generation implementation studies, Goggin and colleagues also emphasised communication issues, in particular between different layers of government as critical to policy implementation [141]. Nonetheless, while dissemination and communication are operationally steered from the national level, they relied on the directive and operational actions of donors to provide resources and of county government to manage dissemination based on their jurisdiction over health facilities, as well as on the management of dissemination at the individual health worker level to share it with their peers.

Health and pharmaceutical financing decisions have an obvious critical influence and the inadequacy of financial resources stymied KEML implementation. Limited literature appears to exist to understand the extent to which EMLs have practically guided medicine financing decisions at national and subnational levels. This study contributes evidence from Kenya. The KEML informed county-level planning through the forecasting of medicine needs by the CDOH, yet the county budgetary allocation based on the consideration of those plans did not match the projected or actual needs. County budget allocations to medicines and non-pharmaceutical supplies across the country decreased between 2016-17 to 2018-19 [194]. Therefore, county financing for health products appears to be a major limitation to medicines access across Kenya and is thus not unique to Kilifi [26]. The issue of insufficient financing to meet essential medicines needs in LMICs is a longstanding one [10, 11].

The most prominent use of the KEML is in procurement, where it appeared to increasingly influence the supply side and where restriction of public procurement to KEMSA created an indirect enforcement of the list. Yet, the limitations of KEMSA in supplying essential medicines were a major challenge, one that is mirrored within the findings of past studies and reports [40, 193] . As in this study, others have also noted the difficulty of aligning procurement processes with national EMLs, particularly if lists are revised too frequently [13]. Lags in the health system to adapt to a new list are therefore likely to be expected, but this study suggests its uptake should not be assumed but likely requires active management.

The lack of M&E of the KEML's implementation and outcomes to date due to resource and institutional constraints was another important finding. Information from such evaluation to understand the appropriateness and local challenges faced in KEML medicine changes is also critical to improve KEML

revision. In South Africa there was also a lack of continuous or formal monitoring of the EML [104]. Little other evidence appears to be available of evaluations conducted on national or local EML experiences or on how EMLs are evaluated across countries. The policy implementation literature suggests the need to carefully consider the purpose of evaluation, what successful implementation means to a diversity of stakeholders, how to separate the effects of the EML from other policies, and how key evaluation outcomes or benchmarks are defined and who defines them [128, 129]. It is important to recognise, as Greene underscores, that evaluation "is neither scientifically nor politically neutral" [195].

8.2.2 Actors and institutions

8.2.2.1 *Constitutive governance*

A key factor that shaped both KEML revision and implementation was the functionality and consistency of MTCs as structures governing medicines and therapeutics institutions at national, county and facility levels. MTCs have been long encouraged by WHO as structures to promote more appropriate use of medicines and to manage costs, and to address antimicrobial resistance, by bringing together relevant actors in organisational settings to co-produce decisions and problem solve [196]. In hospitals, MTCs are recognised as effective structures for local medicine selection, to facilitate the uptake of new medicines, and to address medicine use problems [196, 197]. Building on this well-established guidance, this study contributes insight on the challenges of establishing functional MTCs and highlights possible opportunities of interconnecting MTCs at multiple governing levels in a system of mutual support and accountability. The findings however describe difficult challenges that must be overcome to realise the functionality of MTCs, as has also been found in other studies. At the national level, Odoch et al. also described that NMTCs in Kenya, as well as Tanzania and Uganda, are frequently established prior to EML revisions and inactive between updates, despite their broader clinical governance roles [22]. As is the case in Kenya, national EML committees or NMTCs in Ghana, South Africa and the Philippines are also set in policy rather than in legislation, creating possible challenges for their institutionalisation [198]. Other reports also denote the need to further establish and strengthen county and hospital MTCs in other regions of Kenya [26, 199]. Similar challenges in ensuring the formation and functionality of hospital MTCs have also been reported in Uganda, Nigeria, and South Africa [200, 201]. While each context has some unique considerations, commonly cited reasons underlying these challenges across Kenya, Uganda and South Africa were insufficient staffing and high clinical workload, a lack of leadership or MTC purpose and goals, poor institutionalisation and support from senior management, and low meeting attendance [199-201]. These mirror the issues described with hospital MTCs in this study with respect to MTC leadership gaps, staffing challenges, and low prioritisation.

8.2.2.2 *Directive governance*

The complexity and multiplicity of actors involved in ensuring access to medicines has been widely noted and is apparent in the KEML revision and implementation processes presented in this work [11, 28]. Top-down policy implementation scholars identified "problems of interdependence" where "veto points", or additional decision-making junctures, exist [129, 202]. Policy formulation and implementation has also long been depicted as continuous decision-making in the public administration field, as the act of 'doing' is often entangled with the act of 'deciding' [122]. From a bottom-up perspective, this case study illustrates how the selection of medicines involves multiple decision levels, with each level a possible site for negotiation, conflict and discretion. The concepts of discretion and adherence related to the KEML, particularly at health facility level, are explored further in this section.

Through seemingly technical views on the EML policy/implementation nexus, as described by Hupe and Hill [122], implementation has often been presupposed, framed in terms of "adherence" to the list by local procurement and clinical decision-makers. In this top-down view, implementers are responsible for any unexpected outcomes and top-down control may be tightened as a means of enforcement. Greater "adherence" by KEMSA to the KEML and central efforts to further limit purchasing and procurement to the KEML may be explained through such a top-down perspective. Past studies and policy documents have raised concerns about "adherence" to the KEML [60]. Yet, there is value in further examining the idea of adherence from a bottom-up perspective and whether adherence necessarily equates to implementation success. As seen in the findings, some degree of local discretion is important because specific medicine recommendations (e.g. diclofenac) and how implementers are expected to use the KEML may not be clear. Challenges may also exist beyond their control that limit their ability to implement or adhere, such as the supply limitations via KEMSA. Diverse contexts in terms of resources, capacities, priority health concerns and health outcomes are found across Kenya's counties and facilities [36]. Decisions at the national level for diverse contextual realities, particularly on decisions related to the level of care recommendation or high-cost medicines, can be a challenge as they require abstracting decisions out of context. Accordingly, implementers must be responsive to problems that arise that may not be centrally predicted, as noted by O'Toole (1986) [203]. Some decision-making is necessarily shifted to the county, health facility or healthcare worker. This notion aligns with practical guidance on national EMLs from MSH, which suggests that lists perceived as too rigid are likely to be undermined, emphasising the need to manage exceptions to the list through controlled administrative or budgetary processes [32]. Street-level bureaucracy further emphasises the limits of central control over street-level behaviour, where the KEML is one of many policies that guide the work of managers and healthcare workers who are professionals in their own right [137]. Work from Hill and Hupe in the United Kingdom suggests that individuals with what may be considered higher levels of specialised professional expertise are given greater space for discretion [146]. In this study, prescribing professionals exerted discretion on medicine selection/prescribing choices in certain

situations and appeared to have important influence over procurement decisions due to their medical expertise. Medical professionals, according to Dalglish et al hold “medical power”, defined as the “authority, influence or leverage derived from recognised membership in general medicine or the specialties” in diverse LMIC health policy settings [204]. While I did not find explicit professional resistance to the list by prescribers, as described elsewhere in the past [205], more limited KEML knowledge and legitimation among prescribers than among pharmacists appeared to impede its clinical use.

By setting medicine priorities in the health system including the priorities of local pharmaceutical manufacturers and by influencing resource allocation KEML decisions have considerable implications for the interests of powerful economic stakeholders. Thus, it was surprising that the findings did not indicate major efforts by such stakeholders, such as pharmaceutical industry, to influence KEML revision. The findings did however show that pharmaceutical industry makes concerted efforts to influence prescribing decisions at the point of service delivery in hospitals. With their apparent exclusion in national KEML decision-making, pharmaceutical companies are thus 'venue-shopping' by seeking influential decision-makers in other venues (i.e. prescribers at service delivery) [128]. This highlights the multi-level process of medicine selection further.

8.2.2.3 *Operational governance*

An important finding of this study is that county and sub-county health managers, through their procurement oversight and supportive supervisions in health facilities, have critical influence over KEML implementation (Chapter 6). Additionally, management approaches to KEML implementation appeared to vary between sub-counties and facilities. According to Hill and Hupe, *implementation* can be seen primarily as operational governance, as the “part of governance that involves activities in relation to public tasks that follow the legitimate, directive decisions on those tasks.” This involves in this case, management of the KEML policy trajectory in the county; the interorganisational relations of the MOH and CDOH with KEMSA, other county government departments like the treasury, across health facility levels and public and private sectors, and relations with development partners/donors (meso-level); and management of street-level implementers in relation to essential medicines [122]. Although this is where the critical work of implementation between organisations and individuals is managed, these actors were disconnected from the KEML revision process with negative implications for policy ownership.

Supportive supervisions are widely deemed important in LMIC primary care settings [206, 207]. Past studies have documented that managerial practices of regular reflection and discussion to engage staff in strengthening policy implementation could enhance personal and organisational commitments to

implementation alongside the generation of practical ideas to improve policy outcomes [140]. Thus, such practices could support more bottom-up engagement in the KEML policy process. Additionally, from a top-down perspective, county and sub-county managers are more closely connected to service delivery. These local relationships, particularly with sub-county managers, can strengthen structures of mutual accountability and promote appropriate procurement and prescribing behaviours [208].

The idea of national ownership over global health policies is often discussed (e.g. Allen et al. 2021 [209]), yet there has been seemingly little attention to subnational ownership of such policies—which is particularly relevant in devolved health systems like Kenya. Furthermore, much of the literature on essential medicines policies is focused on the macro- or micro-level factors affecting access [11, 15, 28, 210]. This work highlights the essential work of sub-county and county health managers in governing access to medicines.

8.2.3 Content

A key finding related to content was the apparent limited use of the KEML in the private sector. Although the KEML is intended to guide the private sector [1, 23], there was a lack of clarity on its application and a seeming inconsistency on how or whether the KEML guided government oversight of private facilities (i.e. should it be actively promoted or enforced in private facilities and to what extent?). As noted in the literature review (Chapter 2), debates about EML applicability in the private sector are not new. The KEML itself emphasizes the list as a tool to guide the public sector and as such, these findings are not necessarily surprising. The issue also raises bigger questions about the authority of government to make decisions on private sector care provision and underscore the challenge of governing a pluralistic health sector. A study in Mali demonstrated the problem of only applying essential medicines policies in the public sector and the interrelations between public and private sectors. Policies based on essential and generic medicines improved the availability and affordability and greater demand for generic products—even in the private sector, but the lack of measures to improve appropriate medicine use in the private sector limited the effects of such measures implemented in the public sector [211]. Given the blurred boundaries between private and public services in Kenya, whereby patients and healthcare workers often move between them, and the prominent gap-filling role of private facilities and retail pharmacies in providing access to medicines [212], the objectives of the KEML and UHC are likely to be undermined if the list is only applied in the public sector. Different standards for the private sector under UHC will continue to create issues related to medicines affordability and quality, but also create equity concerns, given that the rich are more likely to seek care in the private sector. Essential medicines affordability problems cut across sectors; reduction of out-of-pocket costs to patients throughout the health system is paramount [8, 59].

8.2.4 Context

This study emphasises the importance of the context in which implementation takes place, and how multi-level systems mean that multiple interacting contexts shape how an EML is adopted. Furthermore, the investigation of both the macro-meso and micro-levels illustrates how the consequences of action, or indeed inaction, at one level become the context at another level. There is widespread recognition that EMLs should be implemented within a broader policy framework and that they are unlikely to achieve access goals in isolation. Others have credited the ideal of policy coherence in helping to explain whether essential medicines policies are effectively implemented [213]. The constellation of which policies are most effective, however, likely varies with context and the primary policy goals. In a multi-country study, Holloway et al indicate that some of the most important policies to improve quality use of medicines were on financing for provision of free medicines at the point of care, having a government unit responsible for quality use, and undergraduate prescriber training on STGs and the EML [84]. Coherence between the KEML and STGs was important in this study. A lack of updated STGs posed both a challenge to decision-makers in the KEML revision process and to healthcare workers making local medicine selection decisions. Misalignments between the EML and STG were also described in a previous study in Kenya, where 12 additional medicines for NCDs were listed on STGs and disease management guidelines compared to the KEML 2016 [21]. A study in Papa New Guinea similarly described discrepancies between medicines recommended in the national EML and STGs, with many more medicines listed on the EML, as a contributor to inappropriate prescribing [119]. WHO has continuously advised countries on the importance of aligning the methodology and content of EMLs and related guidelines [12, 214]. These content differences frequently appear to be rooted in the separation of EML and STG decision-making processes, as is the case in Kenya. Issues with incoherence do not appear to have been documented in countries that undertake concurrent revisions of their EML and STGs like South Africa, Ghana, Tanzania and Uganda [22, 109, 110].

The influence of the President Kenyatta's UHC political agenda on the KEML revision process is notable and underscores the importance of the preferences of elected governments in shaping access to medicines. These preferences for health improvement necessarily reflect "local historical, cultural and institutional legacies" [215]. It is in the political interest of elected officials in national government to be seen as responding to today's urgent population health needs, such as growing calls to address access to cancer care by pointing to updated policy documents like the KEML as symbols of action. Yet, in Kenya's deeply political devolved governance context, it is clear that many of the tough decisions that most profoundly impact access, such as on resource allocation for and procurement of essential medicines, lie with the county rather than national government.

8.3 Reflections on the conceptual framework and adaptation for future use

The conceptual framework enabled analysis of a national EML in a way that was both holistic, thinking about medicine selection at the top *and* what it means to implement the list throughout the health system, as well as promoting a more granular understanding of the revision and implementation elements in their contextualised settings. The policy triangle and multiple governance frameworks consolidated in the thesis conceptual framework both added unique value. First, the policy triangle as a generalised descriptive framework helped to systematically capture a potentially wide range of possible factors that affect KEML revision and implementation, with attention to the ways in which the context and actors interact with the policy process(es). At the same time, the generalised character of the framework also posed challenges in the analysis, as diverse analytical choices could have potentially been made that could have affected the interpretation of the findings. For example, financing decisions are generally made without direct consideration of the EML and thus could be seen as distinct processes to be analysed as part of the broader context, but the data suggested that financing was a core aspect of implementation and thus I chose to analyse it through the process lens/domain. Odoch et al's study of national EML revision processes in East Africa also applied the policy triangle, further confirming the usefulness of this approach in disentangling the role of actors in the EML process [22]. Nonetheless, other studies have similarly noted the value in applying additional frameworks or theories to the policy triangle to better guide its practical analytical use [148].

Second, the multiple governance framework advanced the analysis in that it emphasised the diverse *actions* that were important in governing essential medicines, to understand how actors at different levels exercise their responsibilities, their space or power to act, and their relations of accountability to each other. The multi-level nature of the framework furthermore rendered it useful to meet the study objectives within a health system with delegated governance and management related to essential medicines. Its use further emphasised that KEML medicine selection is not a one-off event during revision, but part of a wider process of various actions across multiple levels of governance. A possible limitation of using this framework is that its emphasis on constitutive, directive and operational actions may depict a single KEML implementation process based on consecutive actions. In reality, KEML implementation is the sum of disconnected actions and decisions that vary over time across a complex system. Hill and Hupe also recognised this "ambiguous reality" that may manifest "a greater variety of phenomena than captured in these [framework] constructions."[130]

Given that national EMLs are employed in over 137 countries [97], there is a need for a conceptual framework or model to describe and analyse the basic components of such processes and how the components fit together in different contexts. While the above-mentioned frameworks helped to unravel the complexity of the KEML processes, they did not offer conceptual guidance on the basic

components that were important in the *KEML process*. Elements of the EML process that were considered important were empirically identified in this thesis. Based on the *process* findings across this study, the literature review (Chapter 2), and the policy cycle (Chapter 3), I propose a model of a EML policy cycle for future study. The EML policy cycle model (Fig. 8-1) contains six interconnected process factors. It is well documented that through revisions, decision-makers are able to improve the quality of decisions as it provides an opportunity to include emerging issues and to correct errors [128]. Such a model can help guide analysis of EML processes, their improvement across cycles, and to identify possible process limitations. While the model is intended to be a tool to simplify a complex process for study and is depicted as stagist, in reality these factors are dynamically interrelated.

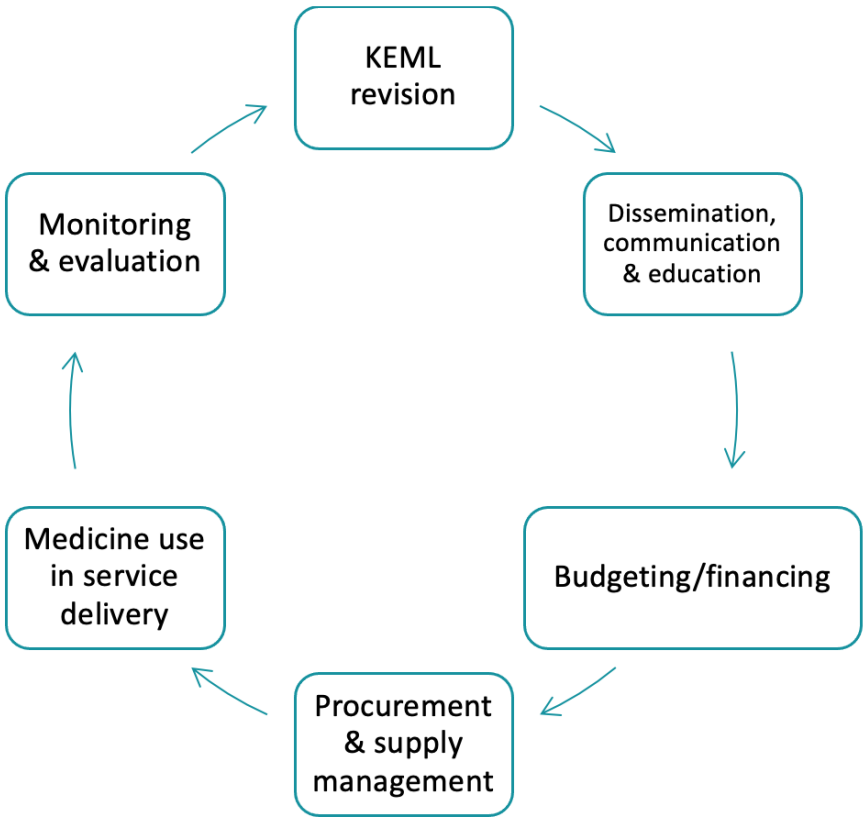


Figure 8-1. Model of a national essential medicines list policy process

8.4 Thesis strengths and limitations

A strength of this study is the in-depth focus on a single case study, which provided detailed and contextualised findings of the policy process that would have been difficult to capture in alternate study designs (e.g. a comparative approach). A limitation is that the contextual differences across settings, both within Kenya and in other countries, do limit the generalisability of the findings. Notably, Kilifi County-specific findings may not necessarily be generalisable across Kenya's 47 counties, although they

can still offer an understanding of the broader factors that could influence implementation in a dynamic health system. The value of this type of case study is not necessarily that it offers generalisability across a population or different countries, but that it provides greater understanding of key processes and principles related to the EML as a particular type of policy. The detailed description of contextualised complexity in this case study of the national EML experience in Kenya and implementation in Kilifi supports informative application to other settings [172]. The understanding gained of the KEML policy processes and the factors that affect these processes could help inform work on this topic in other settings, with appropriate modifications to account for contextual differences.

In addition to providing a deeper understanding about the EML, another strength of this work is its direct relevance for policy and practice at national, county and health facility levels, as well as to inform the financial and technical support provided by donors and international organisations like the WHO. The timing of this study is also a strength, as it was conducted just prior to the launch of the 2019 KEML and at the end of the 2016 edition "cycle", the point at which the implementation of the 2016 KEML was expected to be "complete". I documented the accounts of participants in the KEML revision process within a maximum of 5 months after it was completed, which likely reduced the risk of recall bias [166].

Other strengths of this study include its rooting in the theoretical, conceptual and empirical literature on public policy, health policy and access to medicines. In particular, the study conceptual framework adapts two previously validated and widely adopted frameworks (the policy triangle and multiple governance frameworks), enabling a better understanding of the phenomenon of study anchored within the health policy and policy implementation scholarship. The congruence of some of the study findings with the literature, as discussed above, furthermore strengthen their validity.

Some of the methodological strengths and limitations are discussed in Chapter 4 (sections 4.5, 4.6). A strength of the use of interviews was that it allowed me to gather rich data from a diverse range of actors involved in KEML revision and implementation to study how they made sense of the phenomena I was interested in. Nonetheless, there are a few limitations to the use of interviews. First, the interview data represent participant accounts and interpretations of events and processes in relation to the KEML, which may not represent those of other stakeholders. Furthermore, social desirability bias, where stakeholders sought to present themselves in a favourable light via interviews (e.g. as knowledgeable on the KEML) and documents, or recall bias, where participants were asked to remember details of past events or experiences (e.g. information on the 2016 KEML revision), could have influenced the findings [166]. However, a few strategies were used to attempt to reduce the effects of potential biases. One was to ask additional probing questions during the interview where bias was suspected. For example, some participants responded that they knew about the KEML, but when

probed further, a lack of knowledge was revealed. Secondly, I prioritised viewpoints from data sources external to a particular organisation or group (e.g. pharmacists, prescribers) in the analysis when it came to matters involving them where data was available. Preliminary analyses were checked against possible social desirability and recall bias. To further reduce documentary source biases, I made efforts to use my networks and the interviews as sources to direct me or help me gain access to a range of relevant and detailed documents, and considered their evidentiary value [168].

Non-participant observations, while not a major data source primarily due to COVID-19 limitations, may have been affected by the Hawthorne effect, whereby those being observed may alter their behaviour because they know they're being observed [166]. An attempt to reduce this effect was made by attempting to retreat to the background, by sitting outside of the direct field of view of participants, such as at the back of the room during a meeting observation. My observations may have also been limited by a language barrier in one observation that I conducted without Evelyn and in my general fieldwork, where informal comments were made in Kiswahili, which I am not fluent in. Furthermore, the fact that I was unable to directly observe some of the key events and processes analysed here, such as KEML revision meetings or situations where medicines are selected at health facility levels, could mean that important details were missed.

The study findings and conclusions may have been further enriched through the views of patients and community members, insurers, pharmaceutical technologists, retail pharmacy/drug shop staff, and politicians. Limitations to conducting further interviews were imposed by COVID-19 restrictions and subsequent time to conduct interviews in the expected timeline for the DrPH. Nonetheless, thematic saturation was considered met in the three broad categories of interest. Additionally, given the perceived technical nature of the KEML and the limited awareness of the list even among healthcare workers, the views of people without probable knowledge of the KEML (e.g. community members and politicians) would likely not have led to a deeper understanding of the KEML policy process which this study sought to understand and thus were thus excluded from this study. I also excluded level 1 and level 2 facilities, because of my original focus on cardiovascular medicines—which upon initial review of the KEML 2016 were not designated below level 3. This means perspectives from these levels of care are missing in this analysis, although sub-county managers shared experiences based on their insight from working in those settings.

Another limitation is that this study represents a snapshot of a dynamic health system, in which changes will likely occur over time. This is a common challenge in the study of social phenomena like policy and health systems [216]. Yet, this is particularly relevant in the current Kenyan context of ongoing UHC reforms and the ongoing and future impacts of the COVID-19 pandemic. As I conducted my fieldwork,

UHC reforms and related policy changes were underway at national level. Planned changes that could affect KEML implementation at county level, such as the development of a county MTC and a county medicines storage facility, were also described. Thus, some of the study findings may represent a particular time-stamp. However, this does not affect the validity of the findings and the insights gained remain relevant in understanding factors that can impede or facilitate the implementation of future EMLs.

A final and important limitation is my own role conducting this study as a foreign researcher, both representing and funded by western institutions, which may have affected the data collected and their interpretation. The ways in which I attempted to mitigate this bias and enhance validity are described in Chapter 4.

8.5 Considerations for policy and practice

Aligned with the objectives of the DrPH programme and my positionality as a public health practitioner at the intersection of research and policy, the findings contribute knowledge that can help improve policy and practice related to the KEML, and other EMLs in similar settings. I propose four main policy considerations based on the findings that recognise the interconnectedness of EML revision and implementation processes, and the influence of actors and context.

First, key areas for consideration for future EML revision processes are the three conditions of meaningful stakeholder participation, evidence use and transparency. When free from conflicts of interest, bona fide representation and participation can help ensure that the KEML continues to reflect real health needs and promote social accountability of the actions of public and private actors in the health system [217]. Opportunity for public review of national EMLs is also emphasised as important by the WHO [12]. Posting proposed changes to the KEML in the public domain or providing wider opportunity for input from across the country, or what could be seen as governing the KEML revision through a co-production [130], was seen as important to implementers. Notably, ensuring some mechanism of meaningful county representation, with key links to the county pharmacist, appears to be important for gaining county ownership such that county health leaders promote its implementation within health budgeting processes, procurement, and at service delivery levels. A functional amendment proposal mechanism could facilitate both opportunities for engagement and the collection of evidence; however, it appears that clear responsibility and capacity to effectively manage the mechanism and assess proposals need to be established, as well as public communication on the mechanism, and how stakeholders can effectively contribute. Admittedly, there is also an understandable need to balance the ideals of participation and engagement with pragmatism, such that processes remain manageable and the independence of the technical EML committee is not

compromised. Good governance, via *constitutive* structures like the NMTC and TWG and transparent *directive* governance on stakeholder participation and process rules, can facilitate fair and legitimate stakeholder engagement, transparency and evidence use [112]. Importantly, revising and implementing the EML demands both technical expertise and political acuity to develop strategies with sensitivity to both national and subnational political economy contexts to reach EML goals.

Second, sufficiently resourced and institutionalised structures and processes are needed to revise and implement the EML. In the policy implementation literature, scholars have emphasised the importance of "appropriate vertical connections" and coordinating structures from the system level where policy decisions are made to organisational and individual levels where implementation decisions and activities occur [130]. These vertical connections can be viewed from both top-down and bottom-up perspectives. From the top-down, the findings indicate that dissemination and communication activities may be further facilitated to ensure understanding of and encourage compliance to KEML directives. From a bottom-up perspective, decentralised MTCs can serve as street-level spaces for joint deliberation and decision-making on medicines when local issues arise—such as the diclofenac case where local decisions had to be made to facilitate appropriate medicine use and disease management. From a perspective that integrates both views, national and local MTCs could serve as structures for the downward and upward flow of information related to medicines and the KEML, such that local information and evidence could also be supplied to the NMTC and KEML TWG to inform KEML revision decisions. Based on what has been deemed a country-wide situation of "sub-optimally" functioning MTCs across counties and hospitals, a national guideline for the establishment and operationalisation of MTCs was published by the MOH in October 2020 in an effort to rectify the situation [218]. Strengthening of MTCs and related structures at all levels will also likely require the cultivation of sustainable leadership and efforts to ensure sufficient professional pharmacy personnel. M&E could perhaps also be promoted through such a vertical structure to enable decision-making to be continuously improved over time based on contextually relevant information and evidence. The influence of meso- and micro-level actors, and the practice and need for discretionary use of the KEML by street-level bureaucrats, bespeaks the need for M&E or research to understand the list implications across the likely varied Kenyan implementation context. Given that the findings suggest that primary care facilities faced greater barriers to KEML implementation, as well as the known association between poverty and poor medicines access in the country, attention should be given to equity in evaluation [24, 57, 58]. EMLs may not cater to all possible medicine needs within the health system; clear rules on managing EML exceptions and discretion may allow for transparent flexibility in medicine selection while upholding its standardised use.

Third, EML information channels are critical. In the essential medicines policy literature, the availability of hard copies of national EMLs and STGs at health facilities is associated with significant improvements in quality use of medicines [84]. Additionally, the importance of strategic communication targeted at specific stakeholder groups, communication of clear selection criteria that guide medicine selection, and continuous education on the list were underscored as factors facilitating widespread trust and high prescriber adherence to the Sweden's Wise List, a high-income country EML [190, 219]. Therefore, despite the integration of the KEML into public procurement processes, limitations in accessible KEML information and knowledge may have an impact on the appropriate use of medicines. Limited awareness about the essential medicines concept among healthcare workers has also been noted in Malaysia and China [120, 220]. In the latter, knowledge was associated with level of education and the training received, suggesting the value of enhanced training and education on the essential medicines concept and its context-specific application in the country across different groups of health workers. The need for regular training and education was also expressed in the findings. Thus, audience-targeted, regular, and widespread dissemination and communication of the KEML and its benefits should be considered for prioritisation, as well as efforts to ensure integration of essential medicines knowledge/principles across health professional education and through continuing medical education. The findings suggest that such efforts are particularly imperative for prescribers based on the influence they have on medicine selection decisions at diverse levels. From a bottom-up perspective, greater awareness and knowledge could also promote enhanced upward flow of information and context-relevant evidence that decision-makers can draw on during the KEML revision. Furthermore, EML awareness and knowledge among the public are prerequisites for engagement in the revision process and to promote political accountability. EMLs have been used as advocacy tools, whereby citizens can demand that governments take action to ensure equitable access to medicines regarded as essential in the country.

Finally, the EML should be aligned with and integrated into associated medicine budgeting, procurement and decision-making processes at national, county and health facility levels and across public and private sectors. When EMLs are not linked to financial decisions or implications and procurement systems are not equipped to ensure availability of listed medicines, they risk becoming tools for governments to rearticulate their priorities while maintaining business as usual on expanding access. Notably, key macro-level limitations in the supply chain must be addressed for the KEML to be effectively used as intended, outlined in chapter 6. Given the resource limitations to revise the KEML and STGs found in this study, alignment could further avoid the duplication of such resource and time-intensive efforts through transparent committee reports and evidence reviews regarding decisions made. Importantly, the concept of policy coherence between EMLs and UHC policies at large should be emphasised, particularly as it relates to financing. Important steps appear to have been taken with the KEML 2019 to integrate the KEML into financing decisions for UHC at the national level, whereas the

inclusion of essential medicines into insurance schemes such as the NHIF has previously been weak [8]. In an evolving policy context, there is also a need to adapt and change implementation approaches to respond appropriately to the evolving political and structural contexts, such as the devolved health system and UHC. For instance, the National Pharmaceutical Policy [60] that goes hand-in-hand with the KEML has not been updated to reflect the changes of devolution and UHC. Furthermore, the uniformity goals of the KEML, widely deemed by implementers to be a key benefit of the list in this study, and the universality of essential medicines through UHC only appear applicable within the contours of the public sector. Difficult questions abound when promoting universality in a pluralistic health system, such as the degree to which private facilities normatively *should* be guided by the KEML. Policy actions should draw on evidence, such as the experience in Mali [211], rather than be driven by values (e.g. on the role of the state vs. private sector) or the financial interests of private actors. A clear and meaningful minimal requirement for private sector "adherence" to the KEML appears necessary to advance equitable UHC that promotes quality access system-wide, and is likely to also promote more cost-effective care in the private sector. Robust processes for conflicts of interest prevention and management should account for the interests of private sector health delivery organisations engaged in the KEML revision and any decision-making around KEML governance or enforcement. Lastly, further regulatory and legal measures to ensure *affordability* of quality essential medicines should be considered alongside financing to promote efficient spending and universal access. This may be increasingly important as many additional medicines are added to each new KEML edition (e.g. the KEML 2019 saw a net increase of 419 medicines from 2016) [23].

8.6 Future research

Several areas for further study emerged from this thesis. First, given the limitations in evidence use in KEML revision, research that thoroughly examines evidence use in EML processes in Kenya or comparatively across LMIC EMLs would be valuable to inform improved evidence use. One aspect of this could be to compare different country applications of EML selection criteria and the presence or contents of explicit guidance on operationalising these criteria in comparison with the WHO EML process. Through further analysis of the conflicts of interest procedures and political factors shaping EML decisions in future revision processes, ideally through incorporation of observational methods, contextually relevant strategies could be developed to manage underlying power structures to promote a high-quality technical selection process [221]. Second, given the ongoing and forthcoming financing, institutional and policy changes expected with UHC, there is a need to evaluate or assess the impact of these changes like the UHC benefit package and medicine price control efforts on access to medicines measures. Finally, understanding of EML implementation would be strengthened through additional national case studies, which could support further conceptual development and conceivably the development of theoretical claims to the extent that contextual differences may allow. Such studies

could explore implementation variation based on sites where expenditure on non-EML medicines, inappropriate use and/or medicine availability is a major problem compared to "better performers".

8.7 Literature contribution and conclusions

To my knowledge, this is the first in-depth national case study examining the EML revision *and* implementation processes and the factors influencing those processes. The findings on KEML implementation can likely be applied to other counties in Kenya considering the importance of the macro-level factors in shaping implementation locally. Furthermore, given the deeply contextualised nature of the findings and the presence of similar factors that influenced EML revision and implementation processes as discussed in the literature review, the findings can confer insight on important factors to consider as EMLs are revised and implemented in other similar countries. Particularly in countries undergoing UHC reforms the findings can offer some lessons, such as key considerations for medicine selection processes and policy coherence.

Additionally, there is a paucity of policy research on how the recommendations of the WHO EML or similar technical policies/packages are translated not just from the global to national level, but also to subnational/meso- and micro-levels within a health system. This study contributes in this regard to the broader global health literature, illustrating the possible narrowing of the policy at different points along the vertical chain of implementation. Given that EML studies generally take a technical approach disconnected from the health policy and systems research literature, this work contributes an important and heretofore missing conceptual understanding of multi-level governance of an EML. It also fills an important gap in the EML literature on how an EML interacts with the broader social and political context of the health system. Beyond the EML literature, this study adds to a growing body of health policy literature in LMICs that gives attention to diverse administrative layers and the influence of multiple governing levels on policy implementation [222]. Furthermore, from a governance perspective, the KEML findings may provide insight into the challenges and opportunities of a government to steer the actions of public and private actors, such as through the important roles that county and sub-county health managers play.

Through this study, I identified key factors that influence the policy processes of EML revision and implementation in Kenya. By understanding the KEML policy processes at macro-, meso- and micro-levels, it is clear that different yet interconnected sets of factors shape implementation at each level. This thesis offers an understanding of the key points of decision-making, who influences those decisions and the consequences decisions at one level have for others. Macro- and meso-level factors, particularly limitations in the procurement system and financial limitations, created considerable constraints on the ability of micro-level actors to facilitate access to essential medicines. Nonetheless,

the influence of micro-level actors, particularly prescribers, remains important and they require suitable resources to meet KEML goals. In particular, the study highlighted the likely value of governance structures across national, county and health facility levels in medicine selection decisions. Important considerations for policy and practice on how the KEML can better guide improved access to medicines were developed based on the findings.

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Appendices

Appendix A. Topic guide: National decision-makers (macro-level) interviews

Domain	**Questions, sub-questions and probes**
Introductory	1. Can you tell me a bit about yourself and your roles and responsibilities in your roles and responsibilities in your current position? 2. What do you think are the major diseases of concern in Kenya? 3. Do you think addressing cardiovascular conditions like hypertension, stroke and heart attacks is a priority in the country?
Content	4. What is the purpose or role of the EML? 5. What do you see as the primary policy goals of the EML? 6. Do you believe that the EML is a useful policy/tool? - Why/why not? 7. Do you think the EML relevance has changed in the context of reforms toward UHC? - Do you think this is utilized as such in practice? 8. Should the EML apply to both public and private sectors? - Why/why not? 9. How does the EML compare to other policies and guides, like standard treatment guidelines, the UHC benefit package, reimbursement lists or other similar policies? - How are the underlying policy processes connected? 10. How responsive is the EML or the EML process to the country's health needs? - For example, does it include medicines for all or most important health conditions in Kenya? Why/why not?
Process – EML revision	11. What role do you or your organization play in revising and implementing the EML? 12. Can you describe the revision process? 13. What do you think has worked well about the EML revision process? - Why? 14. What do you think could be improved about the revision process? - Why?
Actors – EML revision	15. Who are the key actors involved in making decisions about the EML and EML listing decisions? - Why are they important? 16. In your opinion, who should be involved in revising the EML? - Who should not be involved? Why? 17. What forms of engagement or participation exist for outsiders? 18. What strategies were used to try to promote engagement in the process?
Process – EML Implementation	19. Could you describe the broader process or steps through which the EML is implemented? 20. What would successful implementation look like to you? 21. What do you see as the successes of EML implementation to date?

	22. What are the challenges to implementing the EML? 23. How is the EML communicated to diverse stakeholders? - For example, what supports, such as online resources, IEC/educational materials are available to promote EML implementation? How do you think these do/would affect implementation? 24. How has implementation of the EML changed in the years it has been in place? - Since devolution? - How do you think it will change with the roll out of UHC?
Actors - Implementation	25. What role do you or your organization play in implementing the EML? 26. Can you describe examples of how you interact with other (county and national) government units in order to implement the EML? 27. How much influence do counties have in determining which essential medicines are accessed by the population? 28. Who are the important stakeholders when it comes to successfully implementing the EML? 29. In your opinion, who influences implementation of the EML most? 30. What actors/groups are best equipped to disseminate EML knowledge? 31. Are there relationships with international or national actors that you depend on to implement the EML?
Context	32. What accountability mechanisms exist in relation to the EML? - Are these enforceable? 33. What other policy and regulatory frameworks are important when it comes to implementing the EML? - For example, other pharmaceutical policies or laws. - Do any particular local, county, or national performance measures, policies, regulations, or guidelines influence EML implementation? 34. Do you think that the current political priorities and environment influence how the EML is implemented? - How? 35. What resources were/are available to develop the EML? 36. What resources were/are available to implement the EML? - What other priorities compete for the same resources? 37. What incentives do you or other stakeholders have to implement the EML? - Are there disincentives?

Appendix B. Topic guides: County (meso) and health facility (micro-level) implementer interviews

Domain	**Questions, sub-questions and probes**
Introductory	1. Can you tell me a bit about yourself and your roles and responsibilities in your roles and responsibilities in your current position? 2. What do you think are the major diseases of concern in the county/sub-county/health facility? 3. Do you think addressing cardiovascular conditions like hypertension, stroke and heart attacks is a priority in the county/health facility? - Why/why not? If not, what is a higher health priority? *4.* Have you heard about the Kenya Essential Medicines List? *(Note: If the participant answered no, move to topic guide 2 below. Otherwise, continue if they indicate any level of knowledge about the KEML)* 5. How did you learn about the Essential Medicines List/how has the list been communicated to you?
Content	6. What is the purpose or role of the EML? 7. What do you see as the primary goals of the Kenya Essential Medicines List? 8. Do you use the Essential Medicines List? - How do you apply it in your work/practice? 9. Do you believe that the EML is a useful policy/tool? - Why/why not? 10. How responsive do you think the Essential Medicines List is to the country's health needs? - For example, does it include medicines for all or most important health conditions that you encounter in the county/health facility? - Why/why not? 11. Should the EML apply to both public and private sectors? - Why/why not? 12. How does the EML compare to other policies and guides, like standard treatment guidelines lists or other similar policies?
Process – EML revision	13. What role have you or your organization played in the EML revision process?
Actors – EML revision	14. In your opinion, who should be involved in revising the EML? - Who should not be involved? Why? 15. Do you know about any ways in which you can engage/participate in the EML revision process? - Can you explain these? - How well do these work?

Process – EML Implementation	16. Do you recall learning about the EML in your professional/healthcare training? 17. Do you have a hard copy of the EML? 18. Can you tell me about how the EML is implemented in the county/health facility? 19. What role do you/your organization play in implementing the EML? 20. Do you think it is clear how the EML should be implemented? - Why/why not? 21. What would successful implementation of the EML look like or mean to you? 22. What do you see as the successes of implementing the EML to date? 23. What are the challenges to implementing the EML? - How could these challenges be overcome for the EML to be successfully implemented? 24. What resources were/are available to implement the EML? - What other priorities compete for the same resources? 25. How is the EML communicated to diverse stakeholders, like healthcare workers? - For example, what supports, such as online resources, IEC/educational materials are available to promote EML implementation? 26. How has implementation of the EML changed in the years it has been in place? - Do you think it has changed since devolution? - How do you think it will change with the roll-out of UHC?
Actors - Implementation	27. What role do you or your organization play in implementing the EML? 28. Can you describe examples of how you interact with other (county and national) government units in order to implement the EML? 29. How much influence do counties have in determining which essential medicines are accessed by the population? 30. Who are the important stakeholders when it comes to successfully implementing the EML in the county? - Why are they important? 31. Which persons or groups control financial resources? 32. In your opinion, who influences implementation of the EML most? Why? 33. Which persons or groups are best equipped to disseminate EML knowledge? 34. Who are the main sources of knowledge and how is knowledge on medicines is shared? 35. To what extent do you interact or cooperate with colleagues or people in similar roles to yours in different counties or even countries in relation to ensuring access to essential medicines? 36. What kind of information do you exchange with them?
Context	37. What accountability mechanisms exist in relation to the EML? - Are these enforceable? 38. What other policy and regulatory frameworks are important when it comes to implementing the EML? - For example, other pharmaceutical policies or laws.

	- Do any particular local, county, or national performance measures, policies, regulations, or guidelines influence EML implementation? 39. Do you think that the current political priorities and environment influence how the EML is implemented? - How? 40. What incentives do you or other stakeholders have to implement the EML? - Are there disincentives? 41. How does the infrastructure of your organization (social architecture, size etc) influence implementation? 42. Do you feel that you have the skills and knowledge to fulfill your role in implementing the EML? - If not, what skills, knowledge and support do you require? 43. What kind of supports would help you to fulfill your role in ensuring access to essential medicines?

Topic guide 2: County (meso) and health facility (micro-level) implementer interviews

(No knowledge of KEML)

Domain	**Questions, sub-questions and probes**
Introductory	1. Can you tell me a bit about yourself and your roles and responsibilities in your roles and responsibilities in your current position? 2. What do you think are the major diseases of concern in the county/sub-county/health facility? 3. Do you think addressing cardiovascular conditions like hypertension, stroke and heart attacks is a priority in the county/health facility? - Why/why not? If not, what is a higher health priority? 4. Have you heard about the Kenya Essential Medicines List? (If the participant does not have any knowledge about the KEML,
Content	5. The Kenya EML is described within the document as a tool to ensure "optimum therapeutic interventions", which "should be the basis for selecting the medicines for procurement using public funds" in the country. Do you believe that such a policy tool is useful? - Why/why not?
Actors – EML revision	6. In your opinion, who should be involved in deciding which medicines are prioritised for the country? - Who should not be involved? Why?
Process – EML Implementation	7. Can you tell me about how you manage medicines procurement and supply in the health facility? 8. How do you decide on which medicines to prioritise? 9. Can you describe the process of procuring medicines through KEMSA?

	10. Can you describe the process of procuring medicines through sources other than KEMSA? - How do you decide where to purchase from in these circumstances? 11. Are there challenges that you face in ensuring appropriate medicines supply and access for those who need them? 12. Do you find that medicines that patients need are accessible to them? - Why/why not?
Actors - Implementation	13. Which persons or groups control financial resources related to medicines and the medicines supply? 14. Which persons or groups are best equipped to disseminate essential medicines knowledge? 15. Who are the main sources of knowledge and how is knowledge on medicines is shared? 16. To what extent do you interact or cooperate with colleagues or people in similar roles to yours in different counties or even countries in relation to ensuring access to essential medicines? - What kind of information do you exchange with them?
Context	17. Where do you get your information on medicines? - For example, information on which types of medicines to procure or use to treat particular conditions, or information on medicine dosage. 18. What other policies and regulations are important when it comes to your role in making medicines accessible? - For example, other pharmaceutical policies or laws. 19. Do you think that the current political priorities and the political environment influence how the EML is implemented? - How? 20. Do you feel that you have the skills and knowledge to fulfill your role in ensuring patient access to medicines? - If not, what skills, knowledge and other supports do you require? 21. Do you feel there is accountability throughout the medicine supply chain? 22. What incentives do you or other stakeholders have to implement the EML? - Are there disincentives? 23. Does the infrastructure of the health facility influence how you deliver medicines to your patients?

Appendix C. Participant Information Sheet and Consent Form

Study Title	***Analysis of contextual and health system factors influencing implementation of the Kenya Essential Medicines List to inform improved access to cardiovascular disease medicines in Kilifi County***
Investigator(s)	Principal Investigator: Jordan Jarvis, MSc, jordan.jarvis@lshtm.ac.uk (Local Tel: XXXXXXXXX; WhatsApp: XXXXXXXXXX)
Study Sponsor(s)	London School of Hygiene & Tropical Medicine

Introduction

I am a doctoral student at the London School of Hygiene and Tropical Medicine (LSHTM) conducting research to understand how the Kenya Essential Medicines List is implemented in Kenya, and the factors that influence the implementation of this policy.

I would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve for you. The investigator will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information.

Your participation will involve an interview with a researcher that will last approximately 60 minutes. With your consent, the conversation will be audio-recorded using a digital recorder. If you are not comfortable with being recorded, the interviewer will take notes during the interview instead. Your answers to the various questions, notes taken during the interview and the audio recording will remain confidential and anonymous (see more detail below). You are not required to answer questions that make you feel uncomfortable. You can also ask end the interview at any time.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

The aim of this study is to analyze the contextual and health system factors that enable or constrain implementation of the Kenya Essential Medicines List as it relates to cardiovascular disease medicines in Kenya. By investigating the implementation of the Essential Medicines List, we seek to provide practical evidence on ways to improve equitable access to essential cardiovascular disease medicines, and thus, better and more equitable health outcomes for people living with cardiovascular conditions.

Why have I been asked to take part?
You have been invited because you have been identified as a stakeholder involved in the development or implementation of the Kenya Essential Medicines List.
What will I have to do?
By taking part in an interview lasting approximately 60 minutes, you will be asked a set of questions on your views and role with respect to the implementation of the Kenya Essential Medicines List.

Interviews will be conducted over the phone or in a private location with the participant (yourself), the principal investigator and a research associate present. If you agree, the interviews will be audio recorded. Follow-up interviews may be conducted if further clarification of themes or topics is needed, and if you agree.

What are the possible risks and disadvantages?
We do not foresee any direct risks or disadvantages to you by participating in this study; however, there is some confidentiality risk. The risk of identifiable information being accidentally disclosed are unlikely given the measures we will take to keep your information safe, as outlined further in the 'What will happen to information collected about me?' section below. All possible steps will be taken to maintain confidentiality and anonymity of your responses.

What if I have concerns or change my mind about participating?
You can withdraw from the study at any time. If you withdraw from the study we will destroy your tape recorded interview and any notes taken during the interview, but we will need to use the data collected on you up to your withdrawal.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact info top of document). If you remain unhappy and wish to complain formally, you can do this by contacting one of the following:

Amref Health Africa:
The Research Officer
AMREF Kenya
Wilson Airport, Lang'ata Road, Nairobi, Kenya

LSHTM: Patricia Henley at rgio@lshtm.ac.uk

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

What will happen to information collected about me and will my participation be kept confidential?
The information recorded is confidential, and only myself (Jordan Jarvis) and the research associate, will access the information documented during your interview. Data will be presented in an aggregated form, except quotes, which will not be attributed to named individuals but only to a code identifier. Other members of the research team will only access aggregated and anonymized data (i.e. excerpts from all the interviews summarized in one document with no names provided). While data shared with the research team and in any publications resulting from this study will be confidential and anonymous, given the small number of people involved in certain aspects of the Kenya Essential Medicines List policy process, we cannot guarantee that anonymity will be maintained, as the identities of this small number of people (such as the committee involved in revising the Essential Medicines List) are known. If you have any concerns about your anonymity and prefer not to participate, you are free to make this choice and this will not affect you negatively in any way.

In cases where anonymity would be difficult to maintain (for example, if your role is very unique and responses might identify you), we will ask you whether you are happy to include your professional title (but not your name) to be included in the findings reported for this study. If you agree to participating and that your professional title be associated with any quotes used, you will be provided the opportunity to review and approve any direct quotes before they are used in the report. If you have any concerns about these quotes, no direct quotes will be used at your request.

All audio recordings will be stored in the principal investigator's personal computer and used only for written transcription purposes. The typed transcripts from your interview will not include your name or and all possible efforts will be made to remove any information that may identify you. Any quotations used in the study results will be printed anonymously and I will remove identifying information from quotations as much as possible.

At the end of the project, the study data will be archived at on the researcher's personal password protected encrypted external hard-drive. Seven years after the research has been completed and reported in aggregate, all the transcripts and audio-recordings will be destroyed.

What will happen to the results of this study?
Information gained from interviews will help us improve the understanding of how the national Essential Medicines List in Kenya can best be used to improve access to essential medicines for cardiovascular disease and other conditions. These findings may also be applicable to other countries. The principal investigator will write up the study results in an academic thesis report for the requirements for their Doctor of Public Health (DrPH) degree at the London School of Hygiene &

Tropical Medicine. The final thesis report will be submitted to the London School of Hygiene & Tropical Medicine for marking, copies will be disseminated to study advisors, and the report will be available publicly through the London School of Hygiene & Tropical Medicine library. The study results may also be published in a peer-reviewed research journal so that other policy and public health professionals can learn from them. The findings may also be shared in the form of a policy brief for a wider audience. Your personal information will not be included in the study report and you will not be identifiable in the outputs.

Who is organising and funding this study?

The London School of Hygiene & Tropical Medicine is leading the research and they have full responsibility for the project including the collection, storage and analysis of your data. The project is funded by the investigator's Canadian Institutes of Health Research Doctoral Award and through an LSHTM Doctoral Travelling Scholarship.

Who has checked this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Amref Health Africa Ethics and Scientific Review Committee (ref. number: P713-2019) and The London School of Hygiene and Tropical Medicine Research Ethics Committee (LSHTM Ethics Reference number: 17773).

Further information and contact details

Jordan Jarvis
Jordan.jarvis@lshtm.ac.uk
Tel.: XXXXXXXX

Thank you for taking time to read this information leaflet. If you wish to take part in the study please read and sign the consent form.

Title of Research Project: Analysis of contextual and health system factors influencing implementation of the Kenya Essential Medicines List to inform improved access to cardiovascular disease medicines in Kilifi County

Name of PI/Researcher responsible for project: Jordan JARVIS

Statement	**Please initial**
I confirm that I have read and understood the information sheet dated [DATE] for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without being affected in any way.	
I understand that relevant sections of my/the participant's data collected during the study may be looked at by authorised individuals from the London School of Hygiene and Tropical Medicine and the research team, where it is relevant to my/the participant's taking part in this research. I give permission for these individuals to have access to these data.	
I understand that while data I share with the research team will be treated as confidential and anonymous, due the relatively small number of people involved in the EML process, the research team cannot fully guarantee that anonymity will be maintained, given that some identities of individuals involved in certain roles may be known. I understand that if I have any concerns about my anonymity and prefer not to participate, that I am free to make this choice and this will not affect me negatively in any way.	
INITIAL ONLY IF APPLICABLE: I feel that my anonymity may be difficult to maintain due to the unique role I hold in the context of this study; nevertheless, I consent to participating with the possible use of my professional title associated with any direct quotes. I agree to this based on my understanding that I will be given the opportunity to review and approve any direct quotes before they are used in the report. I understand that if I have any concerns with quotes that I am asked to review, I can decline to the use of such direct quotations in the reporting of this research and this will not affect me negatively in any way.	
I consent to use of audio-taping, with possible use of verbatim quotation.	
I agree to me/the participant taking part in the above named study.	

Printed name of participant/Representative	**Signature of participant/Representative**	**Date**

Printed name of person obtaining consent	Signature of person obtaining consent	Date

Appendix D. Non-participant observation checklist

Observed event:	**General notes:**	**Observer:**
Date:		

Observation category	**Example items**	**Observer notes**
Physical objects related to KEML	• Posters related to pharmaceutical management, medicines • Checklists or clinical guides in use • Drug guides/booklets used in health facility	
Objects not directly related to KEML	• Mission or strategy statements • Medicine stock availability and storage facilities • Pharmacy space characteristics • Donor logos and documents in use	
Meetings	• Who takes part in decision-making? • Who speaks most during meetings, who does not? • What is the relative influence of different actors? • Characteristics of relations between actors (e.g. patterns of tension, cooperation) • Informal comments made about medicines	
The routine organization of daily tasks / the way people go about their	• Routines or rules discussed among those observed (Who directs activity, Information on how routine decisions are made and whether these favour	

Observed event:	General notes:	Observer:
Date:		
Observation category	**Example items**	**Observer notes**
jobs on a day-to-day basis	certain people, any strategies used in relation to medicines supply management)	
Common language and conceptual categories	• Labels that may have consequences for the interactions between actors and medicine selection, use and management	
Encounters between actors	• What is the relative influence of different actors during decision points?	

Adapted from: Centre for Health Policy and Health Economics Unit (2006) as cited in [170]

Appendix E. AMREF ESRC Approval Letter

amref health africa

Amref Health Africa in Kenya

REF: AMREF – ESRC P713/2019 December 13, 2019

Jarvis Jordan
London School of Hygiene and Tropical Medicine
Tel: +47874043167
Email:Jordan.jarvis@lshtm.ac.uk

Dear Jordan Jarvis,

RESEARCH PROTOCOL: ANALYSIS OF CONTEXTUAL AND HEALTH SYSTEM FACTORS INFLUENCING IMPLEMENTATION OF THE KENYA ESSENTIAL MEDICINES LIST TO INFORM IMPROVED ACCESS TO CARDIOVASCULAR DISEASE MEDICINES IN KILIFI COUNTY

Thank you for submitting your protocol to the Amref Ethics and Scientific Review Committee (ESRC).

This is to inform you that the ESRC has reviewed and approved your protocol. Your application approval number is P713/2019. The approval period is from December 13, 2019 to December 12, 2020, and is subject to compliance with the following requirements:

a) Only approved documents (including informed consents, study instruments, advertising materials, material transfer agreements etc.) will be used.
b) All changes including (amendments, deviations, violations etc.) are submitted for review and approval by Amref ESRC before implementation.
c) Death and life-threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the Amref ESRC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to Amref ESRC within 72 hours.
e) Clearance for export of biological specimen must be obtained from the relevant government authorities for each batch of shipment/export.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
g) Submission of an executive summary report within 90 days upon completion of the study to the Amref ESRC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and innovation (NACOSTI) https://oris.nacosti.go.ke/ and obtain other clearances needed.

Please do not hesitate to contact the ESRC Secretariat (esrc.kenya@amref.org) for any clarification or query.

Yours sincerely,

[redacted]

Chair, Amref ESRC

CC: Samuel Muhula, Monitoring & Evaluation and Research Manager, Amref Health Africa in Kenya

Appendix F. LSHTM Ethics Approval Letter

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Ms. Jordan Jarvis
LSHTM

20 August 2019

Dear Jordan ,

Study Title: Understanding the contextual and political factors influencing implementation of the Essential Medicines List in Kenya to inform improved access to cardiovascular disease medicines

LSHTM ethics ref: 17773

Thank you for your application for the above research, which has now been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV Jordan Jarvis_July2019	29/07/2019	1.0
Investigator CV	Pablo Perel (Primary Supervisor) CV	30/07/2019	1.0
Investigator CV	Adrianna Murphy (Supervisor) CV	30/07/2019	1.0
Investigator CV	Edwine Barasa CV (Advisor)	30/07/2019	1.0
Protocol / Proposal	Appendix A. Interview topic guide-Top-down interviews	30/07/2019	1.0
Protocol / Proposal	Appendix B. Interview topic guide- Bottom-up interviews	30/07/2019	1.0
Protocol / Proposal	Appendix C.Observation checklist	30/07/2019	1.0
Protocol / Proposal	Appendix D.Stakeholder analysis tool	30/07/2019	1.0
Advertisements	Interview recruitment email	30/07/2019	1.0
Advertisements	Observation Request Email	31/07/2019	1.0
Information Sheet	Interview Participant Information Sheet	31/07/2019	1.0
Information Sheet	Observations Information Sheet	31/07/2019	1.0
Protocol / Proposal	Appendix J. Data Management Plan	31/07/2019	1.0
Protocol / Proposal	Study Protocol	31/07/2019	1.0
Information Sheet	Informed Consent Form	31/07/2019	1.0

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Appendix G. NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **153878**

Date of Issue: **06/February/2020**

RESEARCH LICENSE

[redacted]

This is to Certify that Ms.. Jordan Jarvis of London School of Hygiene , has been licensed to conduct research in Kilifi, Nairobi on the topic: Analysis of contextual and health system factors influencing implementation of the Kenya Essential Medicines List to inform improved access to cardiovascular disease medicines in Kilifi County for the period ending : 06/February/2021.

License No: **NACOSTI/P/20/3499**

[redacted]

153878

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix H. Kilifi County study authorisation

COUNTY GOVERNMENT OF KILIFI

DEPARTMENT OF HEALTH SERVICES

When Replying quote
Email; chmtkilifi@gmail.com
REF: KLF/DH/DMS/VOL.1/53

P. O. Box 9-80108
Kilifi

Date: 14th February 2020

OFFICE OF THE COUNTY DIRECTOR

Ms. Jordan Jarvis
DrPH Student
Department of Non-Communicable Disease Epidemiology
Faculty of Epidemiology and Population Health
London School of Hygiene and Tropical Medicine.

RE: DEPARTMENTAL AUTHORIZATION TO CARRY OUT RESEARCH IN KILIFI COUNTY

The Kilifi County Department of Health Services is in receipt of your request to conduct a study titled "**Understanding the contextual and political factors influencing implementation of the Essential Medicines List in Kenya to inform improved access to cardiovascular disease medicines,**" and that has received approval from Amref Ethics and Scientific Review Committee Ref: ***AMREF-ESRC P713/2019*** and NACOSTI ***Ref: NACOSTI/P/20/3495.***

The Department is glad to grant you authorization to conduct your study in **Kilifi County public health system** as per the approved study protocol.

Upon completion of the study, you will be required to share your study findings, conclusion and recommendations with the Department of Health Services, Kilifi County.

[redacted]

COUNTY DIRECTOR OF HEALTH
KILIFI COUNTY
14 FEB 2020
P. O. Box 9 - 80108, KILIFI

Dr.Cecilia Wamalwa
Director of Medical Services
KILIFI COUNTY

cc County Executive Committee Member
Chief Officers –Medical Services & Chief Officer Public Health
Directors - Administration & Public Health