HOW HAS DEVOLUTION AFFECTED THE IMMUNISATION PROGAMME IN KENYA? AN ETHNOGRAPHIC EXPLORATION OF HEALTH SYSTEMS

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Candidates' declaration

I, Saumu Chisinde Lwembe, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Disclaimer: The views expressed in this article are those of the author and not necessarily those of the sponsors.

Dedication:

To my mother, Fatuma Mwamtsuma Rodgers Lwembe, in fulfilment of the promise I made to you.

“PRODUCED BY FAITH”

Abstract

Background

Decentralisation of health systems has been commonplace in many Low- and Middle-Income Countries (LMIC) in the last three decades. Despite several normative and theoretical arguments for decentralisation, little is known about the impact of health system reforms on vaccine systems. The contribution of vaccine systems to the reduction in childhood morbidity and mortality from vaccine-preventable diseases is significant; therefore exploring the effects of decentralisation on the vaccine systems is critical. In the 2013 policy changes in Kenya, responsibilities for vaccine systems were reconfigured. This Study explores the extent to which the quality of the vaccine systems was affected in the reconfiguration.

Methods

An ethnographic approach was adopted in this qualitative Study. The researcher was partially immersed in Kilifi, Kenya, for a six-month period, obtaining an in-depth understanding of the participants' perceptions and experiences of devolution. Thirty-eight face-to-face interviews, twenty policy-related observation events, three peer-debriefing sessions, research diaries and document reviews were used to collect and triangulate data from multiple sources. Data were exported into NVivo 12 software, coded thematically then analysed using Donabedian and Maxwell's quality frameworks.

Results

The Immunisation Programme was operationalised in a challenging context. Policy changes in the health sector were effected at lightning speed, congruent with political expectations, but in an apparent disregard of technical recommendations. The accountability mechanisms for immunisation service delivery changed from linear to a mix of linear and lateral relationships. The quality of end-to-end programmatic processes were significantly compromised, characterised by parallel procurement systems, demotivated workforce, delays in monetary outflow from Treasury to Sub-Counties. There was demonstrable commitment and heroism in the way actors absorbed the devolution shock thereby preventing the system from grinding to a halt.

Conclusion

At its early stages, decentralisation had a negative impact on the quality of vaccine systems in Kenya. Executing health system decentralisation as part of a wider politically driven structural reforms can be problematic for policy planning and implementation.

Contents

Abbreviations

AEFI: Adverse Effects Following Immunisation

AIE: Authority to Incur Expenses

AO: Accounting Officer

BCG: Bacille Calmette-Guerin

CA: County Assembly

CCH: County Coordinators of Health

CDH: County Department of Health

CDOH: County Director for Health

CECM: County Executive Committee Member

CG: County Government

CGA: County Government Act

CHAI: Clinton Health Access Initiative.

CHC: Community Health Committee.

CHEW: Community Health Extension Workers

CHMT: County Health Management Team

CHU: Community Health Units

CHV: Community Health Volunteers

CIMO: Context, Intervention, Mechanism, Outcome

CMYP: Comprehensive Multi-Year Plans

COG: Council of Governors

COH: Chief Officer for Health

CPSB: County Public Service Board

CRA: Commission for Revenue Allocation

CS: Cabinet Secretary

DANIDA: Danish International Development Agency

DHIS: District Health Information System

DHMB: District Health Management Boards

DHMT: District Health Management Teams

DPHK: Development Partners in Health Kenya

DSS: Demographic Surveillance System

DTP: Diphtheria, Tetanus, Pertussis

EHIS: Electronic Health Information System

EPI: Expanded Programme on Immunisation

FIC: Facility-In-Charges

FIF: Facilities Improvement Fund

Gavi, the Vaccine Alliance; formally known as Global Alliance for Vaccine and Immunisation (GAVI)

GOK: Government of Kenya

HFMC: Health Facility Management Committees

Hib: *Haemophilus influenzae* type b

HR: Human Resources

HRM: Human Resources Management

HSFATPP: Health Sector Function Assignment and Transfer Policy Paper

HSSF: Health Sector Service Fund

IGRF: Inter-Governmental Relations Forum

JP: Jubilee Party

KCDH: Kilifi County Department of Health

KEMRI-WTRP: Kenya Medical Research Institute-Wellcome Trust Research Programme

KEMSA: Kenya Medical Supplies Agency

KEPI: Kenya Expanded Programme on Immunisation

KNBS: Kenya National Bureau of Statistics

LMIC: Low- and Middle-Income Countries

LSHTM: London School of Hygiene and Tropical Medicine

MCA: Members of County Assembly

MCH: Maternal Child Health

MCHIP: Maternal Child Health Integrated Programme

MOH: Ministry of Health

MOMS: Ministry of Medical Services

MOPHS: Ministry of Public Health and Sanitation

NGO: Non-Governmental Organisation

NHS: National Health Service

NHSSP: National Health Sector Strategic Plan

NIHR: National Institute for Health Research

NPHL: National Public Health Laboratories

NUV: New and under-Utilised Vaccines

NVIP: National Vaccine and Immunisation Programme

ODM: Orange Democratic movement

OPA: Organisational Policy Analysis

OPV: Oral Polio Vaccine,

PCV: Pneumococcal Conjugate Vaccine 10

PFMA: Public Finance Management Act

PHCF: Primary Health Care Facilities

PS: Permanent Secretary

PSCA: Public Service Commission Act

SCHMT: Sub-County Health Management Teams

SIA: Supplementary Immunisation Activities

TUPE: Transfer of Undertakings and Protection of Employment.

UK: United Kingdom

UNICEF: United Nations International Children's Emergency Fund

US: United States

USAID: United States Agency for International Development

UVIS: Unit of Vaccines and Immunisation Services

VIIA: Vaccine Independent Initiative Agreement

VMS: Vaccine Monitoring System

WHO: World Health Organization

DrPH Integrating Statement

"If anyone can do this, it is you", said a voice that was soon to become instrumental in my explorative journey to a familiar but yet foreign territory.

"Kenya has recently undergone devolution, and the health system is as much affected as the UK was when the responsibility for Public Health was shifted from the National Health Service (NHS) to local government. I know your original intent was to pursue a research thesis on mental health service delivery in the UK. But it might be worth exploring how the Kenyan health system changes have impacted their Immunisation Programme, something that sounds to me like a natural progression from the Organisational Policy Analysis (OPA) project you have just completed". How could I resist that prospect…a perfect opportunity for an ambitious comparison on how health system changes affect Immunisation Programmes in both developed and developing country contexts?

As soon as the dust of excitement settled, the reality of transposing myself to Kenya's health system became very daunting. How do I immerse myself in a country I have been out of for twenty years? Here I was, a native yet a foreigner. So much must have changed in the twenty years. How will be I received by the host institution: as a foreign student, or a local? How will my research be interpreted: a native seeking to find solutions, or an 'exploitative' foreigner out to reinforce the 'nothing good comes from Africa' narrative? What lens do I use, or will be realistically using in approaching this research: as a westerner or an African, or both? If both, how do I adjust the lens to achieve a clear objective focus? What epistemological position can I realistically adopt to make sense of the realities and findings from the research?

Little did I realise I had just embarked on a journey of reflexivity and sense-making that was to last through my research project. I would soon find myself questioning every question, doubting every doubt, interrogating every intellectual position I would seem to take. I would always try to reflect if my personal bias, my western training and professional exposure, or if my Kenyan upbringing and foundational training were in any way skewing my interpretation of reality on the ground. My constant question

would be, what am I benchmarking the health system changes against? Who defines what good looks like? On what platform should I base my intellectual judgements?

Then came the contribution question. I had seen my professional journey, graduating from an interest in health care, health service provision (or the lack of it) [1], and its 'appropriateness' for its customers [2,3] to a strong interest in health system policies [4]. It dawned on me that my doctorate, through the OPA and research thesis, would in some way make attempts to unlock some of the most elusive health system rhetoric. It would contribute to some of the global intellectual debates on the impact of structural changes on health service planning and delivery. This felt like a worthwhile undertaking, and with that, the flight tickets to Kenya were booked.

It took me a good four weeks to find my feet in Kilifi, Kenya, where I was hosted for six months. I felt so lost! People could not understand how I could appear to not know so much, even the basics, or the people, given that I was born in the County. How could I explain myself without appearing insincere or pathetic? I soon gave up trying to explain myself or trying to be understood. I came to terms with my rather 'strange undefinable' status which received mixed reactions. I then immersed myself in what had brought me there in the first place. For a moment, it felt like I was dealing with the complex mesh Andrew Lansley had set up in the English National Health Service. There were all these entities I had to contend with: National and County governments, Members of County Assemblies, Members of Parliament, Senators, Women Representatives, County Governors, County Departments of Health, national Ministry of Health and the immunisation department, health stakeholders, Community Health Units...it felt like never-ending pieces of a puzzle! It took me a while to figure out what part they played, if any, in the Immunisation Programme arrangements. That helped clarify and finalise my study participants list and identify key policy activities to observe. And so, the data collection started. I was amazed at how people were willing to talk, especially when you switched off the audio recording device, when they have gained your trust in upholding confidentiality and anonymity! Six months felt like six days. It was soon over; and I returned to my confidante: my study desk at London School of Hygiene and Tropical Medicine (LSHTM); a confidante I am glad is not able to tell the immeasurable joys, tears, laughter, frustration and relief that the analysis and writing took me through.

It then dawned on me that as a matter of fact, the notion of reflexivity and sense making was actually not borne out of, or unique to, the research thesis journey. It is something that I learnt a long time ago and somewhat perfected in my OPA. It is in fact the cornerstone for policy analysis, in understanding what policy issues need to be addressed, why them, how you get them prioritised, how you influence policy decisions. These are some of the issues I picked up in my OPA undertaking. I came in to the DrPH at a time when the 2010 health system changes had just been effected. Our Public Health department had been uprooted from the defunct Primary Care Trusts to the Local Government. How was Public Health to pan out from a technical to political leadership? How could the department position itself to influence a policy shift from health leadership to health scrutiny and influence? My DrPH inception then seemed timely. In the first three months of the study, I undertook taught modules, which were invaluable in setting both the theoretical and personal reflexivity foundations. Through the Evidence Based Public Health and Policy module, I got to understand the role of sound evidence in influencing policy, and indeed the policy analysis framework [5,6]. I will never forget the formative assignment under the Understanding Leadership and Management in Organisations module that got us to think of who we are as a leader. Because really, out there in the policy world, issues don't get up on the policy ladder just because evidence says so, otherwise some politicians would never win elections. Rather, it is about who you are and how you position yourself and the evidence that will gain relevance.

After this training, I felt ready to test out my skills by undertaking a health systems and policy research project that would contribute to setting a public health policy agenda or influencing changes to existing policy. I picked the Immunisation Programme in the three Inner North West London Boroughs of Hammersmith and Fulham, Kensington and Chelsea and Westminster. Of all public health functions, the Immunisation Programme had been highly fragmented by this policy shift, thereby lending itself as a mirror to the complex changes that had been instituted in the English NHS. The NHS had been broken up, so to speak, new organisations formed, and others abolished. Health functions spread out across the new and different organisations. Immunisation programme functions followed a similar pattern: commissioning by NHS England, training by Health Education England, provision by NHS trusts and

General Practice, scrutiny by local governments and Health and Wellbeing Boards, local oversight by Clinical Commissioning Groups, surveillance and data analysis by Public Health England. This arrangement looked too neat and assumed an efficient coordinating mechanism, but in a context where the organisations were either newly established or taking up its new responsibilities, how realistic was the expected seamlessness of this arrangement? How were the immunisation programmatic arrangements affected? This then became the research topic for my OPA, whose findings are reflected on chapter nine of this thesis. As soon as I completed my data collection, I was invited to take part in a similar piece of work, but this time looking at how the Immunisation Programme was adapting to the organisational changes across England. This was part of an NIHR funded Health Protection Research Unit study. My OPA findings would soon offer a perfect case study. The findings [4] were published here. Around the same time, I was also involved in an evaluation of a 'Celebrate and Protect' programme, developed to improve the uptake of childhood vaccination across several boroughs within London. The study illuminated two key issues: (i) novel approaches to engage with parents and carers of vaccine eligible children may make vaccines acceptable and (ii) working with industry can be beneficial if applied within the right governance and regulatory frameworks [3].

It is my hope that this thesis will demonstrate my conceptual understanding of health systems and policy research and contribute to the global debate on health systems and policy reforms.

Acknowledgements: It Takes a Village to Raise a Child

"It takes a village to raise a child" is an ancient African proverbial wisdom that dictates a "community of interest", defined by parameters like geographical, linguistic, ethnic, and in this case, academic boundaries pool their material and psycho-social resources to fend for a given child within that community. The contribution is not defined, measured, or prescribed; it is somewhat voluntary, expected and accepted by virtue of belonging to the given community. This concept couldn't be truer than in this instance. The production of this thesis, and indeed the whole DrPH journey is a product of concerted efforts of many people who offered their material, spiritual, social, academic and psychological resources that contributed to my successful completion.

First and foremost, my primary supervisor, Prof. Nicki Thorogood, who believed in the material within my original expression of interest, and against all procedural dictates, chose to chance on me. Her faith in the substance within me did not waver throughout the six-year journey...now that's a commitment, a trait too unique to find in the prevailing highly capitalistic individualised world we live in. I am blessed to have been found a worthy beneficiary of this unique trait.

My associate supervisors: Prof. Sandra Mounier-Jack and Prof. Anthony Scott, who stumbled upon me at the beginning of research study 1. They both saw the potential scholarly contribution of my work, and not only invited me to join their wider NIHR Health Protection Research Unit study, but more so, provided intellectual and material guidance in my research study 2 undertakings. Through them both, my entry into health systems and policy research discourse has been both exciting and enlightening.

My research host, gatekeeper and local mentor, Dr. Benjamin Tsofa, who through his guidance and support, doors were opened to me in Kenya, which enabled my immersion in Kilifi County. Through this process, I was welcome as a 'foreign-insider' and accessed organisational nuances and individual thought processes that enriched the data collected in the field. Through Dr. Tsofa, I extend my gratitude to (i) Dr. Ifedayo Adetifa, (ii) the members of the Health Systems Research and Pneumococcal Conjugate Vaccine Study groups at Kenya Medical Research Institute-Wellcome Trust Research Programme – Kilifi, (iii) the Kilifi County Department of

Health (especially Matron Christine Mataza and Dr. Bilal Mazoya) and (iv) Dr. Collins Tabu from the Unit for Vaccines and Immunisation Services at the Ministry of Health for collaborating and supporting the research.

The immeasurable value of peer support is widely recognised. A study on Social Return on Investment in Hampshire showed that every pound spent on peer support yields £4.94 [7]. If I could quantify the emotional, psychological, intellectual and social support I received from my peer, Stuart Green, we could probably have enough to sponsor a fulltime doctorate study. Through the support you extended me Stu, you helped keep me sane in a world where one can easily feel so lost. Thank you.

Speaking of money, I am very grateful to the Public Health department of the defunct Inner North West London Primary Care Trusts and the Tri-borough Public Health Service in Inner North West London Boroughs of Hammersmith and Fulham, Kensington and Chelsea and Westminster for sponsoring Research Study 1. Thanks to the Kenya Medical Research Institute-Wellcome Trust Research Programme–Kilifi, for facilitating data collection in Kenya for Research Study 2. Last but not least, I extend my gratitude to the London School of Hygiene and Tropical Medicine for their generous contribution towards living costs.

In my social circles, I keep hearing ‘behind every great man is a great woman’, a slogan commonly associated with Elinor Roosevelt for her initiatives in support of her husband’s (Franklin Roosevelt) presidency. But then I also hear that **‘**behind every successful woman is a tribe of women who has her back’... That may be true, but how about the unsung heroes: the husbands, the brothers, the children…? I honour and am greatly indebted to the selfless sacrifice of my husband, Kakou Jean Kodjo, who was denied of my physical presence literally a month after our marriage, when I embarked on the DrPH journey. One year into it, our son, Daniel Devine Kakou entered the scene. Daniel journeyed with me through the fieldwork escapades and going back home to him gave my research efforts such a great meaning. One year into data analysis, David Delight Kakou also came forth…together, the trio bonded, giving me protected time to write the thesis, and made mementos that gave me purpose and energy to keep going even at the most challenging moments. *Merci beacoup*.

And above all, all my gratitude and honour I dedicate to my Heavenly Father, to whom I am most privileged and honoured to belong. All this would be vanity without Him.

PART ONE: BACKGROUND

This section consists of four chapters (1-4) which provide background to and rationale for the Study. It also presents the conceptual framework and methodological considerations underpinning the research.

Chapter 1: Introduction

1.1 Background

The decentralisation of health systems has been commonplace in many Low and Middle-Income Countries (LMIC) in the last three decades [8]. Despite the numerous normative and theoretical arguments in favour of decentralisation [9], little is known about the impact of this type of health system reform on vaccine systems. Studies of the impact of decentralisation on Immunisation Programmes are limited, and very little has been written that illuminates the complexities in health system changes and how they affect vaccine systems. Yet the effectiveness of vaccine systems in the reduction of childhood morbidity and mortality from vaccine-preventable diseases worldwide is widely reported [10,11]. Studies indicate that vaccination comes second to clean water in the reduction of the infectious disease burden worldwide [12]. In several regions of the world Immunisation Programmes have contributed to the eradication of small pox and are close to eliminating poliomyelitis and measles. According to the World Health Organization (WHO), vaccinations prevented over 2 million childhood deaths in 2013 [13]. A study by Cowgill *et al.* (2006) reported that through vaccination, the incidence of invasive *Haemophilus influenzae* type b *(*Hib) disease in Kenya was reduced by 88% within three years of conjugate vaccine introduction [14].

Many countries across the world have reformed their health sectors in ways which have impacted on how immunisation services are planned, coordinated and delivered. In 2013, structural changes in the United Kingdom (UK) saw responsibilities for different components of England's vaccine systems fragmented across different organisations [4]. Likewise, in 2013, Kenya underwent a major structural shift in governance, one which the World Bank described as the most ambitious policy implemented worldwide [15]. The changes were characterised by devolution of power, authority and resources from central government to newly formed County Governments, triggered by the promulgation of a new constitution in 2010 [16]. These reforms brought significant upheavals in the Ministry of Health (MOH) due to the rapid and radical restructuring of the national and regional administration levels in the MOH.

In the new disposition, the governance of immunisation service delivery was shifted from one single coordination unit at the MOH to 47 new County Governments through their County Departments of Health (CDH). All immunisation services in the country's immunising health facilities previously supported by the MOH's Unit of Vaccines and Immunisation Services (UVIS) became the responsibility of the CDH. The MOH retained responsibility for policy, procurement of routine vaccines, donor coordination, regulation, standards and quality. The CDH on the other hand became responsible for overseeing vaccine systems across the Counties, including coordinating service delivery and procurement of vaccine consumables and non-routine vaccines. The National and County levels are jointly responsible for supply and cold chain logistics, Immunisation Programme training, surveillance, forecasting and implementation of supplementary immunisation activities. The complexities of this significant shift need to be investigated and the changes in roles and responsibilities well managed as otherwise the Immunisation Programme runs the risk of losing the significant gains achieved so far. The following section explores further some of the potential areas of risk to the Immunisation Programme under the current devolution arrangements.

1.1.1 Vaccine system components at risk

1.1.1.1 Immunisation Programme funding

Sustaining and improving on the current immunisation gains is, to a large extent, dependent on the availability of adequate and timely funding for all programmatic activities. Currently, the Expanded Programme on Immunisation (EPI) receives technical and financial support from various organisations (Appendix H) including the WHO, Clinton Health Access Initiative (CHAI), United Nations Children's Fund (UNICEF) and Gavi, the Vaccine Alliance. The Kenyan government provides the bulk of funding for traditional vaccinations [17], and receives subsidy from Gavi for new and under-utilised vaccines. The MOH financial allocation for KEPI activities was ring-fenced, and through a system of regular audit and related monetary controls, it was guaranteed that this money was almost always spent solely on the national Immunisation Programme.

In the new health system landscape, the funding for EPI is not ring-fenced. The national Treasury makes bulk payments for health care delivery (including

immunisation) directly to the County Governments as one resource envelope. These funds include those that were previously earmarked for procuring traditional vaccines, as well as the government's contribution to the Gavi co-financing agreement. The funds received by the Counties are not specifically earmarked for immunisation purposes. What this means therefore is that it is up to the Counties to decide how much of the treasury allocation they will allocate to the EPI. This means that the effective implementation of the national immunisation policy in Kenya is wholly dependent on individual County budget decisions regarding the percentage of revenue allocated towards the EPI. There have also been reports that the payments to the Counties are often delayed [18]. When faced with difficult budget allocation decisions regarding the scarce and sometimes delayed resources, there is a potential risk that Immunisation Programme will not be accorded the priority they deserve.

1.1.1.2 Procurement roles

The current health statute giving guidance on vaccine procurement is quite muddled. The Health Bills 2012 [19] and 2015 [20] give the Kenyan national government the function to enact regulations on the procurement of drugs (including vaccines). Part 10 Section (57), (1) of the 2012 Health Bill states that the procurement for the public health services of medicines, vaccines and other medical goods shall be undertaken primarily by the Kenya Medical Supplies Agency (KEMSA) [20,21]. Although procurement of routine vaccines is undertaken by UVIS through UNICEF, this role is not well articulated in the Health Bill. According to subsection (3) of the Health Bill, decision making about vaccine procurement has been devolved to the County Governments: Counties reserve the right to independently procure their own vaccines and vaccination supplies from other sources where KEMSA is unable to supply them in good time or at a competitive price [18]. This may be interpreted to mean that UVIS is not expected to play an active role in procurement, and Counties may ignore KEMSA if they can find credible alternatives. Although devolving decision making is welcome in fostering the independence of Counties to exercise their rights in reducing bureaucracy in procurements, this concept introduces discrepancies and non-uniformity in the way Counties reach their decisions on resourcing and supply chain management. There is also a potential loss of the economies of scale accrued through bulk purchasing and the risk of vaccine price manipulation.

1.1.1.3 Supply and Cold Chain Management

Devolution also affects cold chain management. Pre-devolution, vaccine procurement and supply from manufacturer to immunising facilities was managed by UVIS who engage suppliers (such as UNICEF) with well-regulated stock control systems. Under the new constitution, the Counties are able to choose from other suppliers that import and distribute vaccines in Kenya; in this case responsibilities for regulatory arrangements and assuring the quality of the suppliers' stock control system will be entirely up to the Counties. This requires that the Counties have good quality regulatory mechanisms to mitigate against risk of receiving vaccines with compromised quality, potency and efficacy.

1.1.1.4 Health Workforce caught at cross roads

The job security of the health workforce involved in the management and coordination of the vaccine systems in Kenya has been under threat since 2008. In 2008, following the formation of a grand coalition government, the MOH was split into two: Ministry of Medical Services (MOMS) and Ministry of Public Health and Sanitation (MOPHS) [22]. The MOMS was responsible for medical services generally and administered secondary and tertiary hospitals (level 4-6), while the MOPHS was responsible for primary care via levels 1-3 of the health system. Together, the two ministries provided leadership for the entire process of health policy development and monitoring implementation [23]. The split of the MOH brought new challenges around employment securities, harmonization and coordination of programs, and planning processes [22], reflected by the multiplication of technical departments, the proliferation and fragmentation of support service departments, and a lack of clarity in roles and responsibilities [23].

Following the formation of a new government in 2013, and in an apparent tacit acknowledgement that the ministerial split was unsustainable, the health sector was reformed yet again. In early 2013, the two ministries were merged into one [21], a situation which led to scramble for job security and resultant job losses in affected departments. Shortly afterwards, the health functions, including employment of health workers, were devolved to County Governments. An emerging concern in the devolution arrangements is that when devolution policy was effected, health care workers were not entitled to an automatic transfer to Counties of their choice, instead,

they were required to resign from their substantive positions, then apply to the prospective County. The Counties reserved the right to reject the application. Reports indicated that some of the Counties offered fewer salary perks and worse employment conditions, which resulted in mass resignations of health professionals who subsequently opted for private sector employment [24,25]. By extension, this may mean that some Counties may have a reduced and possibly demotivated health workforce, resulting into a potential inability to effectively deliver on its health mandate.

1.1.2 Summary

With the foregoing, it is emerging that different components of the vaccine systems in Kenya have been affected by the health sector reforms. The implications of these changes need to be understood against the backdrop of the immunisation gains previously recorded. Kenya has made significant strides in improving vaccine coverage since the establishment of the Kenya Expanded Programme for Immunization (KEPI) in 1980. KEPI has improved, expanded and intensified immunisation services across the country. The inception of KEPI was followed by a range of initiatives, including obtaining donor funding commitments, introduction of new vaccines, and training of healthcare workers on EPI management, development of immunisation policy guidelines, equipping health facilities with cold chain equipment. On average, the coverage for all childhood vaccinations has been rising. For example, according to the 2013-2017 comprehensive multi-year plan that was published just before devolution of health services, the percentage of fully immunised children increased to 82 in 2011 from 64 in 2005/06 [17]. Likewise, the country has recorded significant disease control gains characterised by a reduction in the incidence and prevalence of vaccine preventable mortalities and morbidities. Under 5 mortality is reported to have reduced by almost 50% from 93.2 per 1,000 live births in 1993 to 51.3 per 1,000 live births in 2014[26]. The sustainability of these gains has been under continuous threat posed by the continual reforms to the health sector and other wider contextual factors. This brings home the importance of making sure that the immunisation platform remains stable in the event of a health system transition in order that these benefits can be sustained and enhanced.

As most health systems studies show, it is quite difficult to attribute specific changes to prevailing reforms, given the interplay of other contextual factors. The health sector

reforms in Kenya are set against a backdrop of complex and challenging structural, epidemiological, economic and political factors [27], therefore, it is difficult to attribute changes in EPI performance solely to devolution. As a way forward, Fielden and Neilsen [28] suggest that close monitoring of the intermediate inputs that produce outcomes and eventually impact is valuable for immunisation studies. This Study leans towards this approach and may even be the first of its kind to explore the impact of devolution on the end-to-end processes of vaccine systems. This Study attempts to contribute to the scholarly discourse on the impact of health system reforms by offering insights on how the immunisation arrangements are playing out at both the macro (National), meso (County) and micro (Sub-County and Health Facility) level. Moreover, many developing countries have either recently undergone or are undergoing structural reforms in their health sector, and the implication of these for Immunisation Programmes is bound to be significant. Therefore, it is hoped that the findings from this study will be able to provide lessons that are applicable more broadly than to just Kenya.

1.2 Scope

The Study is not about the health system reforms implemented since independence and prior to devolution in 2010. It is certainly not a debate about whether devolution, per se, is good for immunisation (although it provides insight and opinion for a potential debate).

This Study is looking at the vaccine systems in Kenya; at how the planning and delivery of Kenya's EPI is carried out under the current devolved health system. It looks at how the different components of the vaccine systems are carried out and explores the roles and perceptions of key stakeholders in the process. It assesses the effect of health system changes on the quality of this important public health programme. It centres on the example of Kilifi County to allow further insights into the complexities of managing vaccine systems at a County level. It focuses exclusively on the supply side, consolidating views from National and County health managers and stakeholders. Views from the demand side (general community, and consumers of the Immunisation Programme - children, guardians/parents) are not included.

1.3 Description of Key Terms

1.3.1 Decentralisation

Decentralisation in the health sector is a structural change to the health system characterised by the transfer of decision-making authority or power, resources and functions from central authorities or national governments to peripheral or subnational government entities, in this case; the County governments. Decentralisation can be enacted in varying degrees, one of which is commonly known as devolution. In this Study, the term decentralisation is adopted as the main entry point to the concept of devolution; the discussion on the issues related to devolution are situated in the wider literature on decentralisation.

1.3.2 Vaccine systems:

Vaccine systems broadly refers to a set of immunisation components working inter-connectedly to an agreed standard. These include the end-to-end processes that govern and coordinate the movement of vaccines from manufacturer to eligible genetic host; the supply chain and quality control, logistic cold chain and vaccine delivery/safety systems operating under conducive structural arrangements.

1.3.4 Centre, Periphery

In the decentralisation literature, the term ‘centre’ is popularly used to refer to the Central authority or national government. It is usually viewed as the source from which power, authority, functions or resources are shifted to lower levels of government. In this thesis, the word ‘centre’ is used universally to represent agencies with a national function: National Government, Ministry of Health (MOH) or UVIS.

The word ‘periphery’ in the decentralisation literature is commonly used to refer to the structures receiving the decentralised power, resources or functions from the centre; which are ordinarily smaller jurisdictions than the centre. In different health systems literature, the terms sub-national, regional or local government units or authorities are used instead of periphery. In this thesis, periphery is used as an overarching term encompassing the County Government (CG), County Department of Health (CDH), and County Health Management Team (CHMT), Sub-County Health Management Team (SCHMT) or Facilities-in-Charges (FIC). For the purpose of clarity, this thesis further sub-divides periphery into two: ‘inner and outer periphery’. Inner periphery refers to County structures with a County-wide mandate. These include County Government administration (Governor, County Treasury, County Executive Member for Health (CECM) and Members of County Assembly (MCA) and CHMT). Structures within the outer periphery include: SCHMT, Hospital Management Boards, Health Facility Management Committees (HFMC) and Community Health Units (CHU).

1.3.5 Health System Reforms

Refers to the changes to the configuration of organisations, people and resources to deliver services in a manner that is intended to meet the needs of the people targeted.

1.4 Organisation of thesis

This thesis is organised into three main parts:

- Part one covers introductory chapters 1-4. Chapter 1 gives the background to and rationale for the Study. Chapter 2 provides an overview of the schools of thought underpinning this Study. Chapter 3 attempts to give a detailed description of the Study setting. Chapter 4 explores the aims and questions that

the Study hoped to answer and outlines how the data collection and analysis was approached.

- Part 2 presents key result areas across three Chapters, 5-7, highlighting findings from the field. Chapter 5 looks at the context within which the EPI is planned, coordinated and delivered. Chapter 6 reflects on the processes that underpin the organisation, management and delivery of the EPI. Chapter 7 reflects on the outcomes; the immediate effects of the changes on EPI structure and delivery.
- Part three consists of two chapters 8 and 9. Chapter 8 offers a detailed interpretation of the Study findings based on the theoretical underpinnings presented in chapters 2 and 4. It then explores insights from a similar study conducted in a High-Income Country (HIC) as part of my OPA, which offers lessons for consideration by health system and policy researchers from a global health perspective. Chapter 9 presents methodological considerations of the Study, considers the unique contribution to knowledge the Study makes and then concludes by identifying some systemic leverage points that can be optimised.

Chapter 2: Literature review

This chapter presents the theoretical framework within which the Study is situated. It starts by presenting the way the review was approached, then moves on to look at the thematic areas which serve as a theoretical frame upon which the Study is based. It highlights some of the scholarly dilemmas that the theories do not fully address, and ones which the Study attempts to answer in subsequent chapters.

2.1 Approach to the literature review

A secondary data search was undertaken at the beginning of the Study and continued iteratively throughout the Study. The literature review was conducted to map available literature on structural health sector reforms, to appraise it in relation to relevant themes, and to identify areas for further research. Since devolution is generally understood to be one of the categories of decentralisation, the literature review adopted decentralisation as the main entry point to the concept of devolution and situated the discussion on the issues related to devolution in the wider literature about decentralisation. My interest was in understanding the theoretical and conceptual debates on devolution and/or decentralisation. Primarily, the review gave more weight to empirical studies relevant to health care systems. Although historical underpinnings were considered, the Study focussed on more recent and current policy contexts of developing countries. In particular, the review focused on literature that contributed to the understanding of the policy context of developing countries (and Kenya in particular) providing insight into how this has impacted on health service performance in devolved structures. The search strategy was developed using the Context, Intervention, Mechanism, Outcome (CIMO) framework (Table 2) and applied the parameters listed in Table 1 below:

Table 1: Search Strategy

Parameter	Description
Key words (synonyms, alternative spellings and/or regional variations - for example, decentralisation (UK) vs decentralization (US) - were considered,	Devolution, decentralisation, decentralization, Impact, experience outcome of decentralisation or devolution Developing countries, low and middle-income countries Health system, health sector, health reforms, structural changes
Language	English language only
Time-frame	Literature published since 1963 to 2018. 1963 being the year that Kenya gained independence: it was assumed that evidence obtained may have applicability to post-independence Kenya.
Data sources	An electronic database search was undertaken in AfricaPortal, Global Health, Health Systems Evidence, Google scholar, Google, Open Grey, Social Policy and Practice, Web of Science, among others. A manual and electronic search of reference lists and grey literature (mainly policy reports and statements) was conducted. Relevant grey literature was obtained from key contacts at the MOH (Kenya), KEMRI and Kilifi County.
Inclusion (geographical scope)	Only studies deemed relevant to developing country contexts and appropriate in terms of quality of evidence were included

Table 2: CIMO framework [29]

Domain	Inclusion/search terms
Context	developing country
Intervention	Decentralisation, devolution
Mechanism	Political
Outcome	experiences of decentralisation, positive or negative impact of decentralisation changes health sector performance changes in health outcomes

References were extracted and imported into Mendeley Desktop then de-duplicated, assessed for eligibility and reviewed. References found relevant to developing country contexts and appropriate in terms of quality of the evidence were included. The process is summarised below.

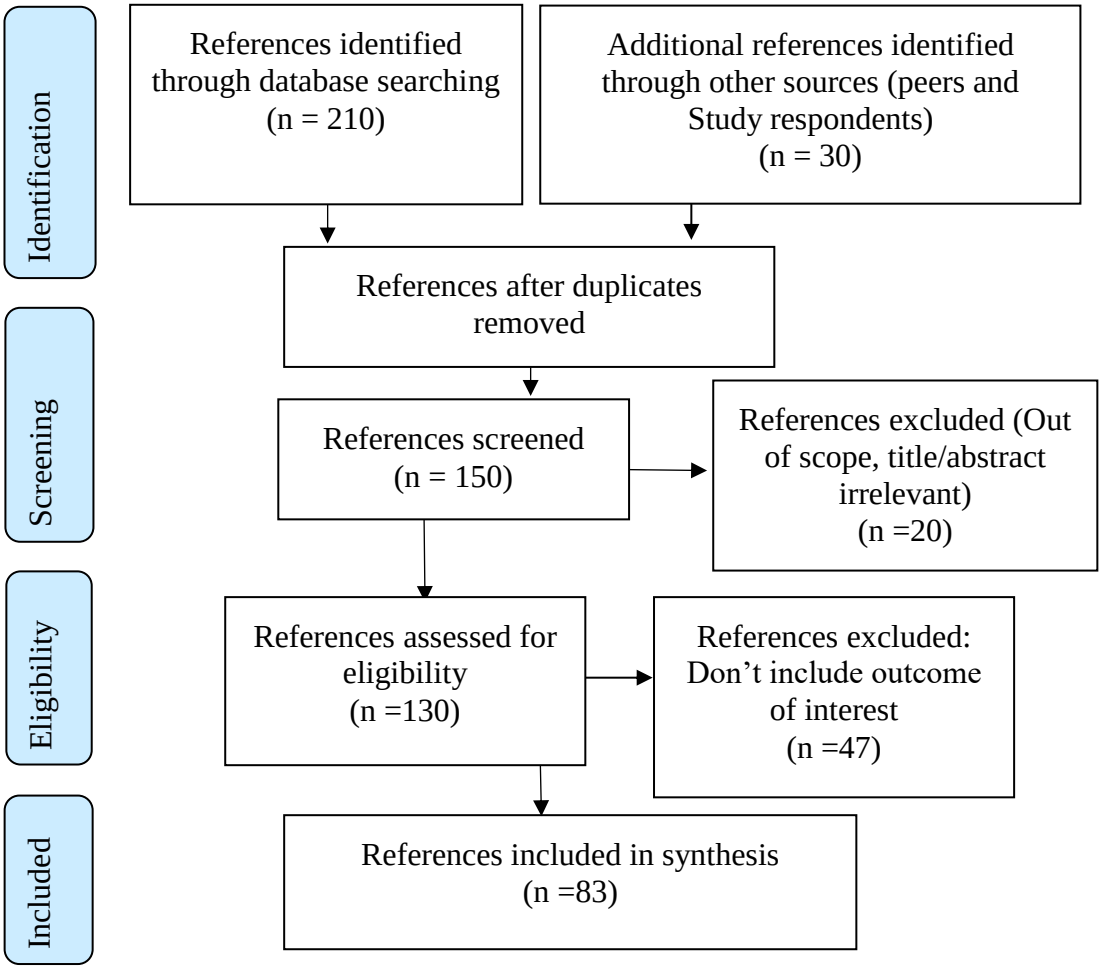


Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow chart describing systematic search strategy results (adapted from Moher D, et al 2009)

Overall 210 references were obtained in the initial electronic search while another 30 were retrieved by hand-search (which included records from peers and Study respondents). After screening on title, abstract and full text 83 references were included in the final analysis as presented in Figure 1 above.

2.2 Health Sector Reforms

The WHO views health sector reform as 'a sustained process of fundamental change in policy and institutional arrangements guided by the government, designed to improve the functioning and performance of the health sector and ultimately the health status of the population' [27, p115.] Health sector reforms have been seen both as a means and a solution to resolving systemic problems that affect population health outcomes [30,31]. Historically, health systems in many LMIC were reported to suffer from 'grossly inefficient and inequitable resource allocation, declining quality and demoralised workforces' [27, p1], inequity in service provision, poor governance and massing powers at the centre [32]. In these settings, the health systems, which were also centralised, were seen to have several disadvantages, including, but not limited to, poor efficiency, slow innovation and lack of responsiveness to patients' preferences [33]. Although minimal reforms had been introduced to improve population health in these settings, systemic problems persisted which made it difficult to support or sustain any changes [34].

In the 1990s there was a renewed enthusiasm for health sector reforms, in line with which the World Bank published a World Development Report in 1993 entitled "investing in health" which called for a substantial rethinking of health sector strategies in LMIC [35]. Further health sector reforms were instigated in these countries, which took many forms including decentralisation, which can be loosely defined as the transfer of power and/or decision-making authority, resources and functions from central or national governments or authorities to subnational or local government entities [36]. In Kenya, decentralisation has been pursued since 1963, when the country gained independence from colonial rule, as presented in section 2.4 below. It remains debatable whether reforming the health systems has translated into solving systemic problems.

2.3 Decentralisation Categories

Decentralisation means different things to different people. Autonomy theorists view decentralisation as the transfer of democratic government authority and power in planning and choice from higher to lower levels of organisational control [379]. They argue that "real decentralisation is marked by the degree of autonomy in organisations – the extent to which organisations have a high degree of authority over particular functions and activities with limited responsibility (or accountability) to others" [9, p33]. To others, decentralisation is about the physical sub-division of a central government territory into smaller political and administrative units [38,39]. Administrative theorists explain decentralisation as the transfer or dispersion of operations and responsibilities of functions to lower levels of administration [40] or distribution of authority from a smaller to larger number of actors [31]. Fiscal theorists view decentralisation through the lens of the degree of autonomy for revenue generation transferred from state actors to the Periphery, while political theorists focus on the separation of powers from the Centre to the Periphery [16].

In their book 'The Politics of Decentralisation', Burns *et al*. (1994) argue that there are two distinct types of decentralisation; one which is centred on the physical spread of operations to local offices and another which relates to delegation or devolution of decision making to lower administrative levels [40]. In synergy with Burns et al (1994), Hambleton *et al*. (1996) proposed a framework relating to organisational change, geography and the shift of power from central to lower administrative units [41]. Reviewing the literature on decentralisation, Peckham *et al.* (2005) argue that a common mistake occurring in the studies of decentralisation is the tendency to view decentralisation solely in terms of organisational or geographical concepts but to completely miss out the individuals: the role of the patients and health care professionals – which are pertinent in health and health care delivery [9]. They suggest that it is important that any framework captures the organisational contexts as well as the place of the individual within the health care system (either as patient, clinician or health care practitioner), the role of central government (either as a funder or regulator or steward) as well as the role of central professional and regulatory bodies [9]. As a solution, they developed an arrows framework which includes the individual at the far end of the decentralisation spectrum and identifies the properties being decentralised[9]. The framework separates inputs, process and outcome as conceptual points. They give

an example that, in the case of fiscal decentralisation, one needs to highlight if resources are being decentralised (input), whether there are guidelines on how the resources should be utilised (process) and how much resource should be spent on what (outcome). They argue that it is important to demonstrate the role of the centre and the relationships between the different levels of the centralisation-decentralisation continuum. In line with this, Bossert argues that it is also worth looking at the decision space – the parameters within which the centre allows the peripheral units in which to operate[42]. Both Peckham's and Bossert's framework are of particular interest to this Study, as they capture the experiences of actors at the Outer Periphery and decision-making allowances accorded to health system actors, respectively.

Focussing on the legal frameworks of decentralised organisations in developing countries, Rondinelli (1981) presents a framework for decentralisation that identifies four distinct categories: de-concentration, delegation, devolution and privatisation [43]. He defines de-concentration as the shift in authority to regional or district offices within the structure of government ministry; delegation as the situation where semi-autonomous agencies are granted new powers. Devolution on the other hand is presented as a shift in authority from the state to provincial or municipal governments, whilst privatisation occurs when the ownership is granted to private entities. This framework has not been without criticism: opponents argue that not all privatisation is decentralisation, and that in fact some privatisation occurs in centralised units and may or may not involve transfer of power or authority [9]. Likewise, it is argued that the separation of authority and power in the framework as the key distinct feature separating delegation from devolution is questionable, and that the transfer of authority as is the case with devolution does involve the assumption that power shifts to the receiving units [9]. A devolved unit will often have the power to make legislation relevant to the area. Some scholars have defined devolution as the transfer of power from central to peripheral units [44]. Nonetheless, Rondinelli's framework is the most widely used as the basis of analysis of decentralisation. Indeed, the structural health system reforms in Kenya seem to map into Rondinelli's categories of decentralisation [43] as shown below.

2.4 Health Sector Reforms in Kenya

Like many other developing countries, the health sector has been reformed several times since 1963 in a deliberate effort to make health services more affordable, accessible and effective. At independence, in 1963, a federal form of government was in operation, one that was organised around eight autonomous regions which later became provinces. At the time, responsibilities for health sector provision were decentralised to Municipal and County councils. Soon after independence, Kenya adopted a *Majimbo* (regional) constitution which provided for ***devolution*** of government to regional assemblies, based on the premise of the need to secure the rights of ethnic minorities. However, in 1964, no substantive devolution of functions or resources had taken place, instead, devolution was deemed unsuccessful and the National government seized all the functions the colonial government had allocated to local authorities [16].

Subsequently, increasing concerns over disparities in several parts of the Country led to health service provision being centralised and in 1970 it became the responsibility of the MOH. In 1977, following the publication of the 1974-1978 Development Plan [27], decentralisation was pursued. This involved establishment of rural health units and decentralisation of procurement of hospital drugs. However, the decentralisation decision was reversed a few years later [45]. Upon the increasing anxieties about an excessively centralised governance, the District Focus for Rural Development Strategy (1983) [46] and the National Guidelines for the Implementation of Health Care in Kenya (1986) [47] were published. These led to a major reorganisation of the health system anchored around decentralisation, inter-sectoral collaboration and community involvement. In 1994, the government published the Kenya Health Policy Framework (KHPF) through which the government reconfirmed its commitment to provide equitable health services to all citizens [48]. A complementary Health Sector Strategic Plan 1999-2004 [49] was also published. At this time, decentralisation was presented as a solution to health sector performance improvement which would ensure equitable and responsive health provision, increased stakeholder collaboration and attract new funding [50]. The decentralisation policy involved the pursuit of ***deconcentration*** in which all health management decisions were made at the district level [51]. This resulted in the creation of District Health Management Teams (DHMT) and District Health Management Boards (DHMB) which took on responsibilities for facility-level

operations within their districts. The DHMTs and DHMBs had increased authority for decision making, resource allocation and management of health care at district and health facility level [27,50].

Following the publication of the KHPF Paper in 1994, ***privatisation*** models were pursued, whereby some curative and palliative services were transferred to private sectors and Non-Governmental Organisation (NGO) health providers [27]. This was a way to free up more government resources allocated to preventive and promotive health services in order to reduce the burden of diseases [52]. The 1999-2004 National Health Sector Strategic Plan (NHSSP)-I proposed to decentralise the licensure and certification process as well as the enforcement of rules and regulations by the provinces [49]. From 2002, it became a requirement for NGO/private providers to obtain registration certificates and licences. The MOH ***delegated*** this function of licencing and certification to the Medical Practitioners and Dentists Board (a partially autonomous agency of the MOH) to regulate the NGO/private providers [51]. As noted in 1.1.1.4 above, following the formation of the grand coalition government, the MOH was split into two in 2008 [22], then merged back into one in 2013 [21]. The merger was precipitated by political events which culminated in a constitutional review process initiated in 2000. This process resulted in the development of a draft constitution with substantive provision for devolution and a marked reduction of presidential and Central government powers. The draft constitution was adopted in a national referendum in 2010 [16]. Soon after, the two MOH merged, and 47 new County Governments were established. In 2013, the responsibilities for financing, coordinating, planning, monitoring and overall health service delivery were devolved to the County Governments in the spirit of ***devolution*** enshrined in the 2010 constitution [53]. The main goal in devolving health service delivery was to realise the constitutional right of every person to the highest attainable standard of health which includes the right to health care services, including reproductive health care as stipulated in Article 43 (1) (a) of the 2010 Constitution of Kenya [53]. These continual reforms in Kenya, like many other developing countries, have had a significant impact on the health system, a concept explored further below.

2.5 Impact of Decentralisation on Health Systems in Developing Country Settings

In attempting to analyse the impact of decentralisation, several possible theoretical frameworks have been proposed [42,54–57]. Agrawal & Ribot (2000) caution that before embarking on assessing the impact of decentralisation, it is important to first discern whether the policy choices implemented do in fact constitute decentralisation [58]. They provide an analytical framework which calls for the investigation of the changes in accountability, nature of powers and actors present in a named reform. They also call for an examination of what is not decentralisation in order to unearth the politics and hidden interests behind decentralisation. Implicitly, if there are no changes in any of these three factors: accountability, actors and powers, it would be foolhardy to consider the reforms as decentralisation.

Thomas Bossert propounded a decision space theory which defines decentralisation in terms of a set of functions and a degree of choice formally transferred to local officials [42]. He argues that for decentralisation to have positive impact, a significant transformation must occur in that appropriate levels of authority, functions and responsibilities must be shifted to the decentralised units. This framework assumes that, for effective implementation of decentralisation, the decentralised units must have the necessary capacity to receive the new powers and authority to take up the new responsibilities and functions. However, in a context where decentralisation decisions are largely politically driven, as was the case in Kenya, to what extent can the decentralised units be ready to receive and effect the new responsibilities?

Together with Beauvais, Bossert further expanded the decision space framework to a Principal-Agent theory [57]. This framework views the central authorities, usually the MOH, as the 'Principal', and the decentralised units as the 'Agents'. The Principal sets the national health policy and then gives the agents resources and authority to implement. The Agent has some decision-space margin to manoeuvre on how to prioritise and deliver on the policies. To mitigate against abuse however the Principal usually institutes concessions, inducements and sanctions to guide the behaviour of agents. These could be in the form of transferring formal authority, performance monitoring, grants and many others. This theory assumes that, for decentralisation to have a positive impact, a good degree of cooperation, coordination and

communication between the Principal and Agent need to exist. I question however, how possible this can be, in a context where implementation decisions are politically driven, effected rapidly and without following due process as was the case in Kenya. To me this remains a subject for further investigation.

Human resource theorists have developed an organisational justice theory which can be useful in assessing the impact of decentralisation on human resources. Organisational justice is essentially a summation of how employees perceive the extent to which they are fairly treated in their work environment [56]. How the employees perceive the impact on 'fairness' that the health reforms have on their terms and conditions of employment will have an impact on job performance, motivation and work-related outcomes. Franco *et.al. (*2002) argue that health sector reforms generally destabilise the work environment by changing health sector arrangements; in that health workers are generally not given satisfactory consideration in the planning and implementing of reforms [59], which contributes to significant demotivation amongst health workers. They do not however, demonstrate how satisfactory consideration can be provided for when major reforms occur in a short space of time as was the case in Kenya's health sector (see 1.1.1.4 above) which experienced two major reforms within one year (2013).

Ascertaining the impact of decentralisation on health systems has been one of the most challenging tasks for health system researchers. Literature examining the relationship between decentralisation and outcomes is patchy [9]; with what little there is tending to be quantitative; examining the relationship between outcomes as the dependent variable and decentralisation as the independent variable with a range of controlled variables [37], the qualitative studies often produce mixed results [9]. Implicitly acknowledging the scholarly limitations, some researchers argue that decentralisation is a complex phenomenon, and the use of quantitative methods with a small number of control variables runs the risk of over-simplification [33]. Nonetheless, some efforts have been made to deduce the outcomes of decentralisation, although some researchers rightly urge caution when considering the element of causation as decentralisation strategies rarely operate in isolation [33].

Professional autonomy and human resource management theorists argue that decentralisation reduces red tape, makes decision-making easier, gives freedom to manage and allows discretion in responding to individual needs hence leading to improved health outcomes and higher staff morale [9]. Boyer, *et al.* (2012) argues that decentralisation is the most realistic method of increasing access to medicines in the developing world [60]. This was demonstrated in Cameroon where decentralisation led to increased medical access characterised by an efficient distribution of anti-retroviral therapy drugs across the country [61]. A study in Colombia established that decentralisation led to increased access to and improved quality of public services [62]. Winchester and King's (2018) study in South Africa shows that under decentralisation, access to healthcare centres improved [63]. Frumence, et al (2013) found that decentralisation in Tanzania led to improved experiences for staff in training, supervision, and donor coordination [64]. The study also noted increased democracy and participation of health care consumers in decision making processes, as well as a reduction in bureaucracy.

Game change theorists suppose that decentralisation allows for better coordination as it enables individuals to adopt a policy of cooperation towards one another, whilst network theorists suggest that decentralisation strategies help in managing complexities due to their ability to nurture the development of emergent means of dealing with difficulties [65]. Democratic theorists argue that decentralisation allows for greater participation and increased visibility of individuals within organisations – which leads to increased accountability [33]. Many scholarly optimists predominantly view decentralisation as a good thing – a cure to the systemic problems within the health sector [30,33]. As Pollitt *et al.,* (1998) put it, decentralisation miraculously solves bureaucratic and political problems [31].

There are some other schools of thought however, that have disputed the 'good nature' of decentralisation, they suggested instead, that decentralisation is not a panacea [66,67]. These schools claim that decentralisation does in fact contribute to increased inequities and inefficiencies [67,68] and that many of the outcomes claimed for decentralisation, such as innovation, can be achieved through centralisation [69]. Some economic theorists have argued that decentralisation can lead to the loss of economies of scale and poor

control of the already scarce financial resources channelled from the central government [37].

Moreover, other studies generally predict a negative impact of decentralisation, especially for services with public good characteristics, like immunisation [33]. In a study to assess the impact of devolution on health services from the user perspective in Pakistan, Ansari *et al.* (2011) [70], established that although people were positive about the concept of devolution, the reforms did not lead to improved experience or use of government health services, instead, medicines in government health facilities were either of poor quality or unavailable. The study notes that devolution was not implemented fully as had been envisioned, and that there was a perception that provincial governments were sabotaging full implementation of devolution manifested in delayed and inadequate funding to the district governments. Similar observations were made in other studies of devolution in Pakistan [71]. Berman and Bossert (2000) report that radical decentralisation was imposed in Senegal's health system without any funding or operational guidance [34]. As a result, the health system broke down, with little or no communication between the central and decentralised units. Grundy *et al.* (2013) report that devolution of health services in the Philippines was followed by a negative experience, shown by underfunding, decline in utility, quality and coverage of health services and poor staff morale [44]. Another study assessing health system performance in Indonesia revealed no change in childhood vaccination coverage and little performance improvement in the health system after devolution [72].

Cheshire (2010) argues that in cases where decentralisation has not had a positive impact, this is not down to decentralisation per se, rather, it is down to limitations by decentralising authorities [60]. In China for example, decentralisation was followed by a decrease in total expenditure in health, with a reduction in funds directed to support health provision in decentralised units. In Pakistan, the implementation process was hampered by insufficient funding to devolved units [44,73]. This may explain why devolution failed to bring the much-needed improvement in health services performance or uptake in these contexts [70,74].

This highlights an important point that, whether or not decentralisation is inherently a positive change, the results of a decentralisation process will depend critically on the

completeness of implementation. Studies indicate that aspects such as phased strategic implementation, adequate resourcing of peripheral administrative units, adequate capacity development of all actors and sustainable infrastructure are necessary if devolution is to work well for health sector performance [33]. In Kenya, a phased implementation of health functions was originally intended. However, in 2013, the president ordered all health functions to be devolved at once. This meant that although a strategic plan for implementation of devolution had been drafted, it could not be followed through. A similar speedy and sweeping implementation in Mali is reported to have undermined the considerable opportunities that could have resulted from devolution of the health sector [75].

2.6 Health System Devolution and Immunisation Performance

In relation to the Immunisation Programme, studies on the effects of devolution reveal mixed results. Some studies indicate an increasing concern about the potential negative effects of devolution on immunisation performance in LMIC [33]. In Papua New Guinea a decrease in uptake of BCG among children under one year was noted post devolution, while in Indonesia, devolution implementation was reported to have resulted in stagnation of immunisation coverage [76]. An evaluation of the impact of devolution on Tanzania's immunisation services reported a decline in the quality of health care services at the peripheral levels, attributed to the reduced supervision of health care workers, cold chain breaches and poor relations between national and devolved [73,77]. In Uganda, vaccine coverage declined sharply due to a reduction in supportive supervision [78]. Indonesia had a significant reduction in the role of the Centre in vaccine programme implementation with subsequent stagnancy of immunisation coverage [76]. Decentralisation in Nepal was reported to be accompanied by substantial staff cuts which resulted to undesirable consequences on the EPI across the country [34]. In Nicaragua, immunisation coverage fell by over 50% in the three years following decentralisation [79].

In other countries, however, devolution has been noted to have positive results: in India implementation of devolution policy resulted in improved access to immunisation services and increased coverage [76], a factor that was attributed to increased accountability in the health care system. The study also found that decentralising fiscal responsibilities led to provision of more health facilities in

Indonesia which in turn led to increase in access to immunisation services [76]. There was a reported increase in immunisation coverage against measles across six developing countries following decentralisation [80].

Khalegian (2004) argues that devolution of health care services works well for immunisation if there is an appropriate and clear separation of roles and responsibilities between the national and peripheral units: that policy making, donor coordination, vaccine procurement and overall monitoring should remain the prerogative of central government while formulation of service delivery strategies and undertaking front-line disease surveillance remain the purview of the local authorities [33]. This appears to be the ambition in Kenya: coordination of (international) partners, monitoring and evaluation, procurement, surveillance and policy development is the prerogative of Central Government. Under the devolved system, although drug (including vaccines) supply is the responsibility of the MOH, procurement can also be carried out at the local County level. This creates both complexities and tensions within the health systems that needs further exploration. This Study will explore this arrangement in detail.

Chapter 3: Study Setting

This chapter provides background information that contextualises the Study. It starts by giving a chronological account of the development of the EPI in Kenya, showing some of the challenges and achievements the programme has recorded over time. The chapter proceeds to describe Kilifi County, one which was selected as an example to illuminate the complexities of the health system changes at a County level.

3.1 Kenya

Kenya is an East African country classified by the World Bank as a lower middle-income country [81]. In 2009 Kenya's population was estimated at 38.6million, including 3million children aged 0-4 years [82]. Administratively, Kenya is divided into forty-seven County Governments. The health system is organised around (i) four levels of health service delivery (community, primary care, County and national), (ii) five intervention health cohorts: pregnancy and the new born (up to 28 days), early childhood (29 days–59 months), late childhood and youth (5– 9 years), adulthood (20–59 years), elderly (60 years plus), and (iii) three types of health services (promotive and preventive, curative and rehabilitative, and planning and governance) [83]. Immunisation services are clustered in the promotive and preventive service category. The health system is financed through taxation, user fees, donor funds and health insurance. The health sector actors in Kenya can be grouped into three main categories: governmental, non-governmental and international partners. The overall health sector leadership, governance and stewardship is shared between the County and National Governments (Appendix A). The health system enjoys strong partnerships characterised by active local, national and international stakeholder involvement.

Kenya recognises immunisation as a high impact public health intervention which has a significant ability to reduce child mortality and morbidity [84]. As such the government has progressively invested in the development of the EPI since independence.

3.1.1. Immunisation Programme in Kenya; a Journey through Time

The first records of epidemics of vaccine preventable diseases and the practice of immunisation in Kenya can be traced to the pre-colonial era with the outbreak of smallpox, which occurred around 1882 and 1898, followed by the Spanish influenza

from 1918-19 [85]. One of the strategies the local people used to contain the disease in the 1882 smallpox outbreak was the practice of inoculating the diseased people [85]. Though contentious, the practice continued well into the colonial period and is credited as one of the reasons the western vaccination system was accepted (as it mirrored the local inoculation practice) [86]. In the colonial period, an improved vaccination system was introduced by the colonial rulers borrowing from experience they had acquired in fighting the disease across Europe. Vaccination against smallpox and other diseases like tuberculosis and polio became mandatory as the goal was elimination or control of the epidemic. By 1946 Kenyans were among the 14million people in Africa who were reported to have been vaccinated [87].

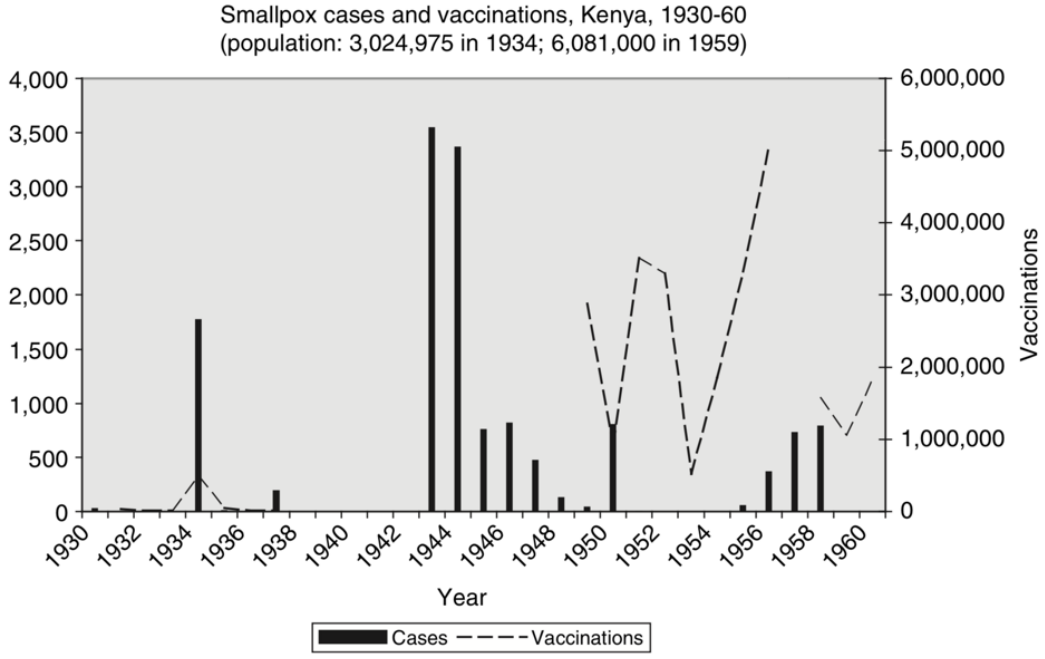


Figure 2: Smallpox Cases and Vaccinations in Kenya (1930-60)[87, p220]

The colonial department of medical services then established comprehensive Immunisation Programmes and coordinated their delivery [86]. Immunisation services were delivered in fixed posts (health facilities or isolation camps designated for diseased people) or through monthly outreach activities, mass campaigns and educational seminars [86]. Pockets of resistance to vaccination were recorded alongside other logistical challenges around cold chain management and adequate staffing levels. However, due to its relative success in disease control, the Immunisation Programme was quite well received. By the 1950s, BCG vaccination was common. Some laboratories in Nairobi started producing vaccines which were later supplied

across Africa. Vaccines were transported in vacuum flasks covered in sawdust, ice and salt in order to maintain the required temperatures to ensure vaccine potency [86].

In the immediate period following independence, (1963-1980), vaccines were offered opportunistically through major health facilities and primary schools targeting school-going children [88]. In the early 1970s, Kenya started offering cholera and yellow fever vaccines through the Nairobi City Council, a role that was later subsumed into the MOH.

In the late 1970s, Kenya's MOH, through its National Public Health Laboratories (NPHL), instituted a surveillance programme that investigated major disease outbreaks and ventured into the manufacturing of cholera and smallpox vaccines to combat outbreaks [88]. NPHL also assumed a national repository and coordination function for Typhoid, Rabies, Hepatitis B vaccines and anti-snake venom. NPHL ended the manufacturing of smallpox vaccine a few years later when the WHO declared that smallpox had been eradicated globally.

In 1974, WHO established the EPI and then required each member state to create and implement policies in accordance to EPI guidelines. In 1980, Kenya established KEPI working towards the overall WHO goal of reduction of childhood morbidity and mortality due to vaccine preventable diseases across the world [89].

KEPI followed the standardised vaccination schedule established by WHO for BCG, DTP, Oral Polio vaccine and Measles vaccine. Over the years, other new vaccines were introduced in line with national priorities. These include Hepatitis B (Hep B), *Haemophilus influenzae* type b (Hib), Pneumococcal Conjugate Vaccine (PCV-10), Rotavirus, Rubella. Other life-saving vaccines introduced but not on the KEPI schedule include anti-snake venom, anti-rabies and anti-typhoid [90]. A child is considered fully immunised if they have received all antigens delivered under the KEPI schedule (Appendix B).

At inception, KEPI focussed on establishing and strengthening vaccine delivery. The programme relied heavily on donor funding, (major funders included Danish International Development Agency (DANIDA) and UNICEF) with the understanding

that Kenya would match-fund. At the onset, the management of KEPI was handled by DANIDA. Plans were set in motion to expand and sustain the programme through capacity building and facility expansion. Vaccine coverage rose to 51% by 1987 [91]. This prompted the programme to shift its focus from establishing and strengthening vaccine delivery to eradication of vaccine preventable diseases. In the early 1990s, Kenya started to renege on its financial commitment to DANIDA, subsequently, DANIDA withdrew its financial and material support in 2000. Unsurprisingly, overall vaccine coverage declined sharply due to lack of vaccine supply. As a contingency, the Treasury injected about Kshs.40million to prevent the programme from collapsing.

In 2000, Kenya developed its first immunisation policy [88]. In 2001, Gavi offered Kenya a three-year grant for vaccines and equipment and supported the introduction of pentavalent vaccine against *Haemophilus influenzae* type b and Hepatitis B. Three years later, Kenya published the first ever budget for KEPI. In 2007, UVIS took over responsibilities for all vaccination services including policy oversight, surveillance, vaccine supply logistics as well as quality assurance systems.

Currently, Kenya and Gavi provide the bulk of EPI funding [92]. Kenya resources all the traditional vaccines and personnel cost. Gavi supports the introduction of new vaccines, injection supplies and health systems strengthening. Many other international agencies (Appendix H) also play a big role, offering programme support in areas like the financing of supplementary immunization activities, vaccine monitoring and logistics, outreach and supportive supervision.

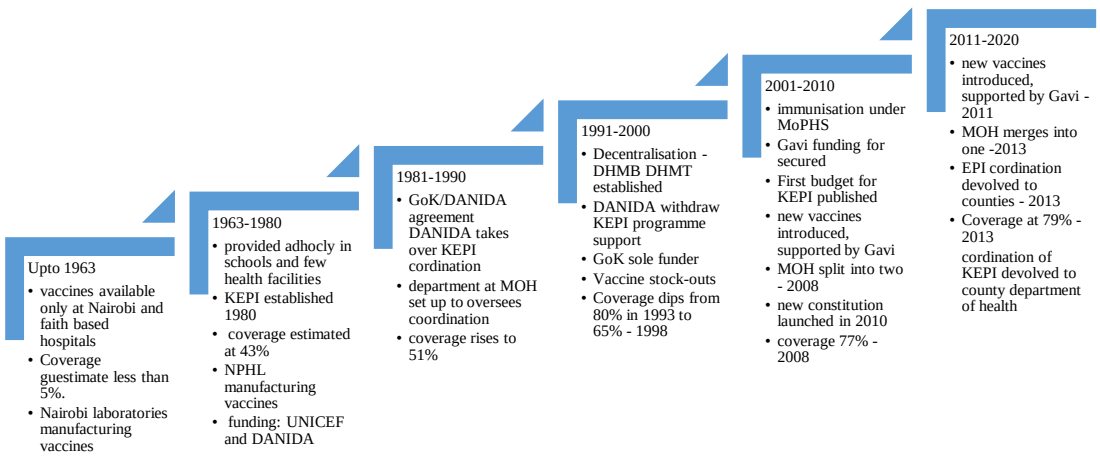


Figure 3: Developments in the Kenyan Immunisation Programme across time

KEPI is currently delivered through three main strategies [17]. The main one is fixed posts, which includes health facilities within the public, private, faith-based and non-governmental sectors. The second, outlined in the Reaching Every District framework, is the outreach programme, targeting people who do not have easy access to a fixed post. The third is the programme of Supplementary Immunisation Activities (SIAs). SIAs are run periodically to augment population immunity.

After devolution in 2013 immunisation funding was redirected to the Counties as part of a wider health budget. This made it difficult for UVIS to meet its procurement obligations to UNICEF. In 2016, a Gavi audit on vaccine procurement processes questioned expenditures which led to Kenya repaying USD 631,943 to Gavi. The cold chain system has also been impacted. Reports indicate that many health facilities have experienced recurrent fridge breakdowns which has affected vaccine potency or overall stocking levels within the facilities [93]. Supply chain is disjointed, with immunising facilities arranging own collection. The introduction of new vaccines has met challenges in some areas where health workers have not been sufficiently trained or upskilled before the new vaccine is introduced [94].

These challenges notwithstanding, the EPI has been relatively successful. Although the country has not been able to meet its ambitious target of reaching at least 90% national vaccination coverage set out in the 2011-2015 Multi-Year Plan [95], at least 82% was achieved as of 2011 [17]. The country is also inching closer to measles elimination [96].

3.2 Kilifi County:

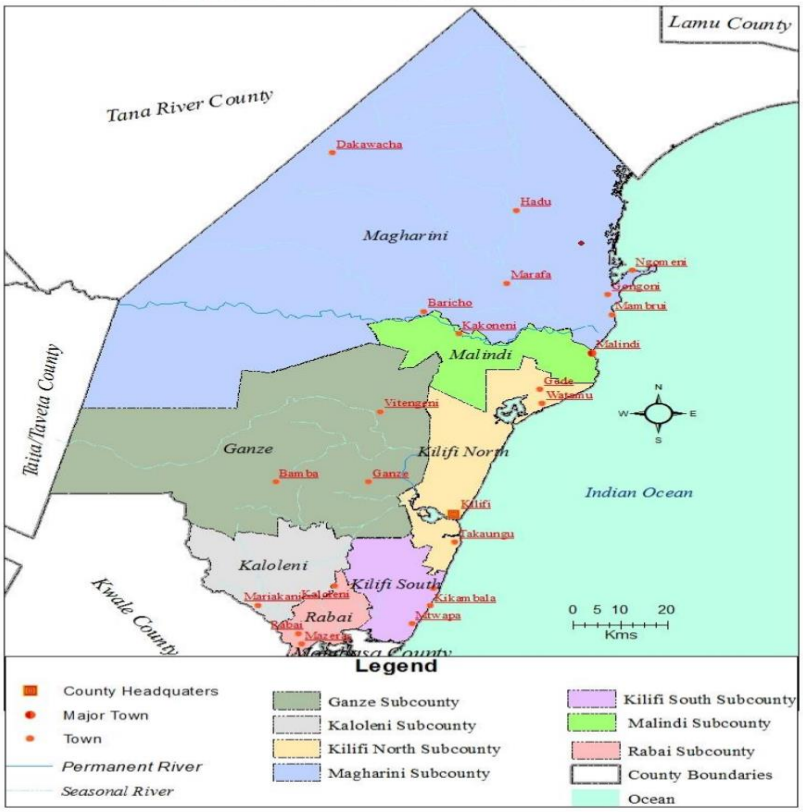
3.2.1 Demographic attributes

Kilifi County is situated at Kenya's Coast region. As of 2013, its population was estimated at 1,246,296 (2.9% of the National population), of which 3.6% constituted children under one year of age [97]. The County has a higher poverty rate than the national average [98], a vulnerability that has led to its inclusion in the WHO Protracted Relief and Recovery Operations programme and the national MOH's supplementary feeding programme that targets 0-5yr children [99]. The deprived child population is

estimated to be at 57.71% [98]. At 71 per 1000 live births, infant mortality ratio is reported to be higher than the national statistics figuring 2 per 1000 live births [100].

Kilifi County encompasses the former Malindi and Kilifi districts and is divided into seven regions (Figure 4 below) referred to either as Sub-Counties. Administratively, the County has 17 divisions, 54 locations and 165 sub-locations.

Figure 4: Kilifi County Map showing the seven Sub-Counties [97]



3.2.2 Health Infrastructure

Health service accessibility across the County is overall rather poor; most health facilities are located close to major roads, but a great majority of the population live far away from these and have to travel over 5kms to the nearest facility [101]. The low density of health facilities in the rural areas leads to distance decay; a phenomenon characterised by significant reduction in health facility access due to long distance traversed. The most popular mode of transport relied on by the Health Department in delivering health services is *boda-boda* (motorcycle) followed by utility vehicles and ambulances [99,102].

Health service delivery (see Figure 4 below) is managed by three Sub-County Health Management Teams (SCHMT) organised along the former District Health Management Teams (DHMT). The SCHMT jurisdictions map onto the former administrative districts of Malindi, Kilifi and Kaloleni. These health management blocks are referred as Sub-Counties, but their boundaries go beyond the seven political Sub-County administrative units within the County. The SCHMT feed upwards to the County Health Management Team (CHMT), Chief Officer of Health (COH), and County Executive Committee Member (CECM) for Health who in turn is accountable to the County Governor. The Governor is the executive head of the County, sitting on a democratically elected position, performing a role akin to the president of a country. The CECM is the County Minister for Health responsible for implementing policy, while the COH is the officer accountable for health services across the County.

Below the SCHMT are Hospital Management Teams, Health Facility Management Teams (HFMT) and Community Health Committees (CHC) that oversee the delivery of health services within the hospitals, primary health care facilities and community, respectively.

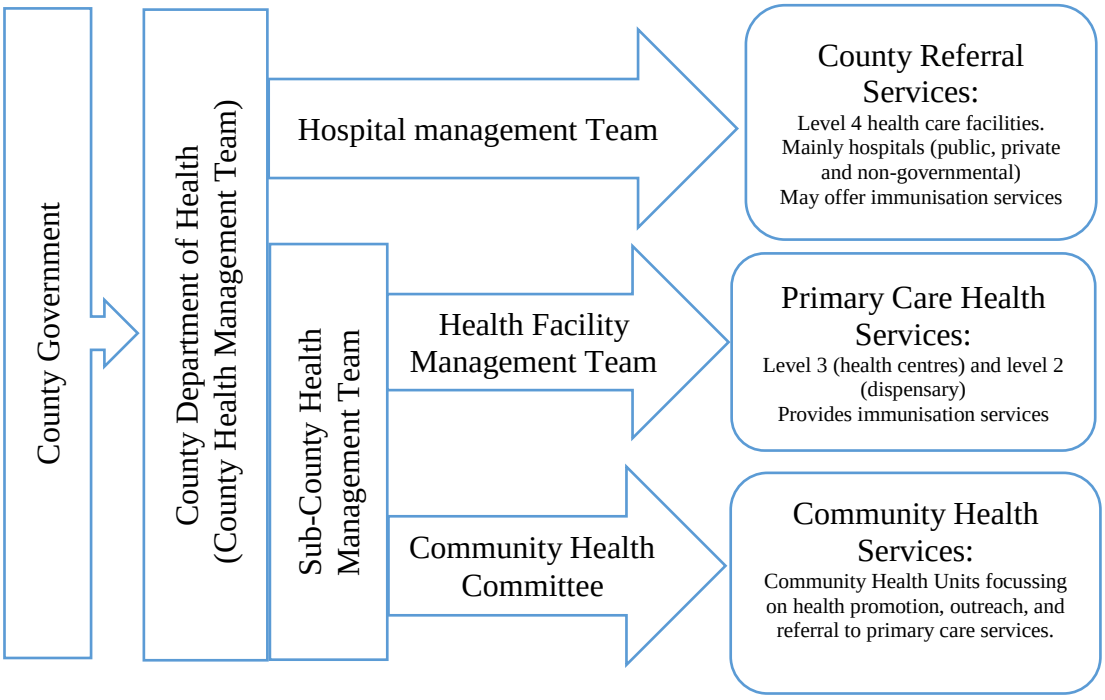


Figure 5: Organisation of health service management in Kilifi County

The organisation of health service delivery in the County is clustered into three tiers: County Hospitals, Primary Health Care Facilities (PHCF) and Community Health Services (CHS) (Figure 5 below). Tier 3 facilities include 3 County, 6 private and 2 mission hospitals. Tier 2 PHCF include health centres, dispensaries and maternity homes. CHS on the other hand are driven by Community Health Volunteers (CHV) recruited to implement a community health strategy to support residents to take charge of their own health. Trained to check health parameters and responsible for 20 houses, the CHV report to Community Health Extension Workers (CHEW), who in turn report to Public Health Officers designated to each Health Facility. Of the 199 Health Facilities in Kilifi, 87 are publicly owned, 23 charitable, 82 private. Of the 188 PHCF and 11 hospitals, 100 (53%) and 9(82%) offer immunisation services [102] whilst 124 (66%) of 188 PHCF and 100% of all 11 hospitals offer health promotion and education messages which include immunisation related messages.

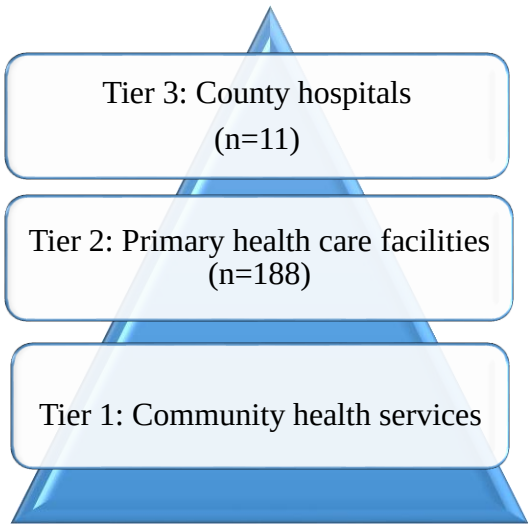


Figure 6: Health Service Delivery Tiers in Kilifi County

Health service provision in Kilifi County is supported by various agencies and the support ranges from organisational development to increasing health service consumption. Among the key agencies supporting health service and system research in Kilifi County is the Kenya Medical Research Institute – Welcome Trust Research Programme (KEMRI-WTRP). Formed in 1989, KEMRI-WTRP has developed a structured programme of engagement and research with the CDH managers to

understand and effectively respond/adjust to health system changes. Additionally, KEMRI-WTRP has extensive research programmes on vaccines ranging from Ebola vaccine trials, pneumococcal conjugate vaccine impact to surveillance. In 2008, KEMRI established a Vaccine Monitoring System (VMS) which provides the CDH with real-time surveillance vaccine data [103]. The VMS is set-up in 26 public and 8 privately owned health facilities.

Vaccine preventable diseases were among the most prevalent in Kilifi County in 2013[99]. Respiratory infections, diarrhoea and pneumonia were among the ten major causes of mortality and morbidity in Kilifi County [97]. In 2015, there were 78 suspected cases of measles in Kilifi, a 16% increase from 2014 [104]. On the other hand, invasive Hib disease has almost eliminated following the introduction of Hib vaccine [105]. Immunisation coverage increased from 50.7% in (2012), to 67% in (2013) [99] to 86% in 2014 and to 85% in 2015 [104]. An exploration of how the health system changes are affecting or impacting the sustenance of these gains is attempted in the subsequent chapters.

Chapter 4: Study Aims and Methodology

This chapter describes the overarching purpose of, and key issues focussed on in the Study. It outlines how the Study was approached, giving a detailed description of the data collection methods employed as well as the epistemological stance adopted.

4.1 Theory of Change for Health System Devolution

Devolution gives greater control to devolved units in the overall health management and delivery processes, which, in theory, contributes to health system performance improvement. In the Kenyan context, devolution has brought human resource departments and the health workforce into closer proximity, increased access to resources and given greater decision-making powers to the County Governments. The expectation is that a devolved health system will improve efficiency of, access to and accountability in service delivery. By giving coordination powers of the EPI to the County Governments, there will be closer monitoring of implementation and quicker troubleshooting, which will lead to better execution and potentially, contribute to the sustainment of the gains realised to date.

4.2 Purpose of the Study

This is an exploratory Study investigating whether the health system changes in Kenya has impacted on the quality of the EPI.

4.3 Aim and Objectives

4.3.1 General aim

To analyse the current arrangements for vaccine systems in Kenya and the implications these have for the quality and sustainability of the programme.

4.3.2 Specific objectives:

Specifically, the Study sought to assess (i) how structural reforms impact on health systems in developing countries, (ii) how EPI is implemented under devolution in Kenya, (iii) how the quality of the Immunisation Programme may have been affected by the health system changes, and (iv) potential implications for policy and practice.

4.4 Research questions

The principal research question for the Study was: has devolution affected the vaccine systems in Kenya? A sub-set of this question includes:

i. How the EPI is currently organised under the devolved health context in Kenya?
ii. How is the EPI being operationalised in Kilifi County?
iii. What are the implications of the current arrangements for the effective implementation and sustainability of the EPI in Kilifi, and in Kenya in general?

4.5 Study Design and Methods

4.5.1 A Quest for Appropriate Epistemological Position and Study Design

The epistemological discourse is largely dominated by two knowledge paradigms: positivism and relativism [106], with others somewhere in between. The positivist worldview suggests that knowledge can be acquired, and absolute truths discerned through observation and measurement using deductive approaches. In the Immunisation Programme for example, knowledge of immunisation performance can be reached through measuring the number of children vaccinated compared to the number of vaccine eligible children in a certain geographical location. The relativist perspective on the other hand is based on the premise that truth is relative, and that subjective human construction of meaning is important [107]. This knowledge paradigm considers issues such as health systems and policies as social constructs that are enacted through people's experiences and beliefs. Central to the relativist inquiry is the appreciation that the participants' perceptions are important and real to them. It becomes important therefore to resist temptations to either justify or discredit the experiences or dispositions but instead respect and acknowledge them as true to the respondents. To synthesise the positivist perspectives which underpin Immunisation Programme performance analysis and the relativist standpoints taken to critically appraise health system and policy issues, I adopted a critical realist paradigm [108]. I felt that critical realism somewhat converges the positivism and relativist paradigm; the observed and the experienced. As Archer, *et al.* (2016) argues, critical realism allows the mapping social realities to be combined with the interpretation of observable phenomena, based on a critical approach to causation and suppositions [109]. In this Study, I interpreted participants' accounts of their experiences, in the context of the complex interaction of multiple factors in the devolved setting, against the predefined knowledge and expectations on Immunisation Programme performance.

Given the embrace of a critical realist paradigm, in view of the complex nature of health systems and health policy reforms, and the contestable nature of attribution of causal mechanisms in health system reforms, an ethnographic approach to data collection was chosen (quantitative approaches were discounted, as that would need a reductionist approach fitting complex contextual into a quantifiable frame). Ethnography allows for the systematic study and interpretation of participants' behaviour in a complex setting [107,110] and is particularly recommended when an in-depth and interpreted understanding of an issue(s) by the research participants is needed [111]. According to Dixon-Woods (2003), "ethnography is especially good at probing into areas where measurement is not easy, where the issues are sensitive and multifaceted, and where it is important to get at the tacit, not the already evident. It can capture the winks, sighs, head shaking, and gossip that may be exceptionally powerful in explaining why mistakes happen, but which more formal methods will miss" [112, p.326-327]. Qualitative approaches enabled me to have an in-depth understanding of the participants' perspectives on health service devolution, which then enabled an assessment of what that means in relation to the quality of the immunisation service delivery.

4.5.2 Selection of Study Site

In order to gain an in-depth understanding of how the devolution policy was unfolding in Kenya's health system, the Study focussed on one county: Kilifi. The selection was pragmatic, informed less by which County would be representative of the country or the 47 counties, but rather more by informed by the anticipated richness and relevance of health system and immunisation related information. This was hoped to enable a deeper insight and understanding of how the complexities of operationalising the devolution policy are impacting on EPI. Some of the factors that led to the selection of Kilifi County were: (a) the County has a long history of innovation and involvement in immunisation and health system research and hosts one of the largest research agencies in Kenya (KEMRI) that undertakes significant health system and immunisation related research activities; (b) the County's Department of Health delivers the immunisation service collaboratively with KEMRI and other partners; (c), my familiarity with the geographical, ethnic and language context of the County; (d) my previous research work in the County as well as knowledge of key contact persons, who had potential in providing special access to essential data and; (e) the limited

resources in time and finance acquired for the fieldwork, which did not permit more than one county to be studied. Moreover, the geographical and demographic nature of the County was one that provided the required diversity in terms of ethnic mix, socio-economic status, literacy levels, and urban/rural neighbourhoods.

4.5.3 Data collection methods

Qualitative methodology allows for the use of flexible methods of data generation that are both sensitive to the context and can be tailored to specific respondents, which then allows one to interrogate any emergent themes [111]. In this Study, multiple ethnographic methods were used to collect data from different stakeholders, the latter which offered collation of multiple perspectives which gave a better understanding of the context and provided complete picture of the phenomenon under investigation. This section describes the methods in more detail.

4.5.3.1 Approaching data collection

In ethnographic studies, it is not uncommon to find that local communities are suspicious about the motives of researchers [113], and feel threatened personally and professionally [114]. At the early phase of fieldwork, feelings of suspicion and personal/professional threats were encountered. My "strange undefinable" insider-outsider status (see Integrating Statement) was met with mixed reactions. On the one hand, some people speculated whether I was out to discredit the County's efforts (since I was domiciled in the West), more on a fault-finding mission feeding on the narrative that Counties (read Africans) cannot manage health affairs on their own, or whether I had genuine interest in understanding the changes in the health system. My western training and professional undertakings in public health were perceived by some as a threat to their professional aptitude. Questions abounded as to whether the research was an inroad to securing employment at the County, and if indeed people should be worried about their jobs. Through continuous engagement and dialogue, these barriers were overcome with time. Spending time forging links with the community of interest as well as offering explanations on the Study benefits created inroads and acceptance of the research.

Primarily, I spent the whole fieldwork duration (six months) at the Study site: Kilifi County, hosted by KEMRI-WTRP. As part of the arrangements with the host

institution, I was partially immersed in the Kilifi County Department of Health (KCDH) and the KEMRI-WTRP's Health System Research group. I was welcome to participate and observe meetings, policy and planning events. I held several meetings with gatekeepers to gain acceptance and access to the research facilities, actors and events. These were coupled with briefing events as well as a promise to present a summary report at the end of the research Study. Inadvertently, a sense of expectation that the research would 'fix' some of the challenges presented by the health system changes was registered among the Study participants. The overall data collection process was undertaken in three key stages as shown in the table below.

Table 3: Data Collection Phases

Stage	Activity	Duration
One: preparation	Stakeholder mapping Collecting background information on each of the stakeholder groups. Setting up a local (Kenya) research advisory committee – not to 'steer' the research, but provide advice and feedback Identifying and contacting potential respondents Setting up interview appointments Peer debriefing with: • Colleagues and peers to discuss methodology • Key actors and potential respondents to raise awareness of research and gain permission and buy-in to the proposed research. Pilot interviews	One month
Two: active data collection	• Ethnographic and face to face interviews • Identification of and attending to shadowing and observation of meetings and immunisation activities. • Collecting documents and archival records. • Interim data analysis	Four months
Three: Study wrap up	Peer debriefing with: • Collaborators and stakeholders to discuss emerging findings. • Study participants to present and validate interim findings Supervisory visit	One month

4. 5.3.2 Interviews

Unstructured and semi-structured interviews were used to capture participants' experiences, views and perceptions of the health system changes [115]. Because they were open-ended, unstructured interviews were useful for collecting contextual information and to allow the expansion of themes emerging from observation. This allowed me to confirm and clarify my understanding of specific issues [111]. I developed standard interview discussion guide (Appendix F), a participant information leaflet and consent forms which were ratified by LSHTM and KEMRI ethical approval processes. I piloted these tools with five different stakeholders. Findings from the pilot interviews were used to refine the discussion guide.

I developed a sampling frame to identify potential respondents (Table 4 below). This entailed five categories clustered into two main segments (National and County) spread across three levels: Macro, Meso and Micro. The National level (Macro) category was further sub-divided into two; informants from the Unit of Vaccines and Immunisation Services (UVIS) informants and stakeholders of the national EPI. The County level sampling frame was sub-clustered into two spheres: Inner Periphery (Meso) comprised of County Department Health Managers and Senior Leadership Team, Kilifi County EPI stakeholders and Outer Periphery (Micro) consisting of SCHMT and facility level informants. Facility level informants included a mix between KEMRI supported Vaccine Monitoring System (VMS) Health Facilities (see 3.1 above) and non-VMS Health Facilities. Participants were purposively selected using the WHO health systems framework that identifies service delivery, health workforce, information, medical products, vaccines and technologies, financing and leadership and governance as health system pillars [116]. Altogether, the diversity of functions of the informants provided a wholistic view of how the EPI is planned, coordinated and delivered across the country.

Recruitment was primarily done via email; although many of the Outer Periphery respondents were recruited by telephone through a SCHMT gatekeeper. The inclusion criteria were 'individuals from the supply side and with some definable involvement in the coordination or implementation of the EPI in Kilifi County'. Individuals from the demand side defined as consumers of the Immunisation Programme (either as patients, carers/guardians, contractors), or people with no involvement in the

coordination or implementation of the EPI were excluded. Respondents were then mapped into the respective categories within the sampling frame. To maintain confidentiality, the respondents were given a serial identifier as per the segments they were clustered into.

A total of thirty-eight key informant interviews were conducted; with UVIS (n=6), national EPI stakeholders (n=5), County Managers and Senior Leadership (n=7), County EPI stakeholders (n=2), SCHMT (n=5), VMS supported Health Facilities (n=5), non-VMS supported Health Facilities (n=8). Thirty-six interviews were conducted face to face, while two were done via internet/telephone protocols. One refusal was recorded at the National level.

Table 4: Study Sample for Key Informant Interviews (n=38) held from May to August 2016

Level	Category		Total
Macro	**National Level**		**11**
		UVIS	6
		national EPI stakeholders	5
Meso	**County Level**		**27**
	Inner Periphery	County Managers and Senior Leadership	7
		County EPI stakeholders	2
Micro	Outer Periphery	Sub County Health Management Team	5
		VMS supported Health facilities	5
		Non-VMS supported Health facilities	8

4. 5.3.3 Observation

Observation is a useful tool for capturing the complexity and richness of events; with the potential to offer a much deeper insight into the meaning attached to experiences and comprehension beyond the standard narrative presented in interviews. This Study observed actual policy operations in various contexts; namely team meetings, health worker training events, policy planning meetings with collaborators and potential funders, meetings with stakeholders at immunising outposts, and policy-related celebratory events at immunising facilities. Participant consent in observational studies can be quite complex [117]; in this Study, consent for observation was obtained from meeting organisers in advance. Additionally, the gatekeepers and the research hosts introduced the researcher in many of the events/activities observed, a mechanism

that was also used to obtain general consent for observation. A total of 20 events were observed, between May and August 2016, summarised in the table below.

Table 5: Observation of policy related events (n=20) from May to August 2016

Event Description	Total Number
County level events (training, meetings)	3
Sub-County Management meetings	8
Supplementary Immunisation Activity planning meetings, training, briefing/debriefing activities	7
New facility operation sessions	2

4. 5.3.4 Peer Debriefing /Feedback Session

The usefulness of peer debriefing has been contested, especially if adopted to tease out affirmations in data credibility with the hope of getting peers to arrive at the same interpretation of data [118]. In this Study, the main purpose of peer debriefing was to verify whether the methods proposed were agreeable, and whether the preliminary results reflected the correct picture of the phenomena under investigation.

A communication strategy was developed to inform peers and key stakeholders about the research and invite feedback to improve on the concept and process. Peer debriefing with colleagues from LSHTM and the Study site was undertaken at three points (i) during protocol development (iii) at the beginning of fieldwork and (iii) towards the end of fieldwork. The first point was done as a process of appraising and consolidating the approach and theoretical postulations proposed in the protocol. The second point was done upon arrival at the fieldwork site, in order to gather preliminary intelligence regarding the field site, potential respondents and proposed approach to data gathering. It was also a useful tool in getting support for the project as well as access to grey literature. In the third point, preliminary findings were presented to peers and Study participants; the briefing acted as a feedback event to confirming/validating the findings, as well as increase understanding of issues identified in the research and teasing out any gaps.

4. 5.3.4 Research Diaries

In this Study, I kept voice and paper diaries throughout the fieldwork period, as Altrichter and Holly (2005) state, "diaries can be particularly useful for making detours, for taking side roads that offer possible insights into phenomena that were not obvious or predictable when the research journey began" [119, p.27]**.** The elements recorded in the diary included

i. Descriptions of observed events: the goal, deliberations and key outcomes of the events observed, the interactions and team dynamics, the setting, hierarchies and roles of actors involved in these events.
ii. Key issues arising from informal conversations relevant to the Study topic, including nuances and subtle conflicts between different actors.
iii. Notes from newspaper commentaries, blogs and opinion pieces from stakeholders opining on the changes within the healthcare sector and the implications to the Immunisation Programme.
iv. Reflections on data collection process and progress, emerging themes and congruence or divergence in preliminary results. Also noted were any discrepancies between what interview respondents believed was happening from what I understood to be happening from my interactions with the decision-makers

Moreover, the diaries were useful in recording specific events in real time that enriched and illuminated underlying issues – some of which had either been implied or unmentioned in interviews. Quite personally, the diaries were a key companion and a critical friend, allowing me to off-load daily experiences in a state of constant reflexivity, consciously acknowledging and questioning the preconceptions held.

4. 5.3.5 Documents

Documents are a useful way of supplementing research data, offering background information that maybe unobtainable during fieldwork. In this Study, many documents were obtained, and although it was not possible to examine all of them in depth, they were helpful in providing contextual background to the health system changes and policy processes in Kenya. The documents were obtained from multiple sources including Study participants, research hosts, stakeholders and the internet. Extra attention was given to information obtained from websites to ensure authenticity and

reliability. To this end, only information from nationally and internationally recognised organisations like WHO or Kenya's MOH were included. Documents that were judged as relevant to the context and subject under Study were reviewed. Document research, like other qualitative data collection methods can be subject to bias, calling for the researcher to maintain a high level of sensitivity and reflexivity in order to achieve credibility and validity [120]. The documents were assessed for quality, authenticity and author intent using a tailored guide (Appendix C). Eligible documents then had their content interrogated to extract relevant information.

4.6 Conceptual Framework

In looking at how devolution impacts the quality of the vaccine system, I focused on how the EPI is structured (including the interplay of the broader contextual and political considerations) and the way the various components are coordinated in order to illuminate the overall performance. I found Donabedian's Structure, Process and Outcome framework [121] useful for identifying the key elements on which to focus. Although originally developed to assess the quality of medical care delivery systems, the framework is appropriate in analysing public health systems [122]. According to Donabedian, the Structural dimension revolves around assessing the setting within which care is delivered and the instruments which support its provision. This may include an assessment of whether facilities and equipment are adequate, health care workers are well qualified and financial arrangements to support the programme are well set. In this Study, the Structure dimension involved the assessment of the context within which the EPI is structured considering the influence of both the macro and micro environment; the wider political drivers for health sector devolution as well as the interplay of local party politics. Specifically, the Study examined the organisational structure and governance of EPI responsibilities, financial systems and health workforce. Donabedian's Process dimension is interested in assessing whether the agreed standards of medical care are being met. One would be concerned with parameters like whether diagnostic and therapeutic processes are justified and appropriate, data collected are complete and appropriate, and whether care is well coordinated and integrated. In this Study, interest was placed on assessing intergovernmental relations and the EPI end-to-end processes that facilitate movement of vaccines from manufacturer to consumer (planning, logistics, data management, supervision, forecasting, procurement and training). Finally, Donabedian's Outcome

dimension helps to assess whether the care or programme delivered is efficient, equitable or effective. In relation to the Immunisation Programme for example, considerations may be given to quantifiable outputs like immunisation performance measured through coverage data, disease eradication or control, number and nature of adverse effects following immunisation. In this Study, an additional outcome of interest from a health systems point of view was in assessing how the health system was adapting to the reforms.

In complement to Donabedian's Structure, Process and Outcome framework in the assessment of quality, Robert Maxwell offers six dimensions of quality; access, efficiency, equity, relevance, acceptability and effectiveness, which are useful in characterising quality in health systems [123,124]. These dimensions are inferred in the Donabedian quality framework used in this Study and will be explored further in Chapter 7. Appendix D outlines the Donabedian model and the way it has been applied to this Study.

4.7 Data Analysis

I conducted interviews in English (one of the official languages spoken by all participants, although participants also used Swahili language in their responses). Recorded data were transcribed verbatim by a transcription company. I then translated the data excerpts featured in Swahili into English. I exported transcribed data, documents and text (from observation, diaries and debriefing/feedback sessions) into NVivo 12 software. I read and re-read the data to identify emerging themes and then coded them thematically [111] while examining association between the outcomes of interest. I presented and analysed the data using the Donabedian and Maxwell's framework (4.4 above). In a quest to understand the dynamics of the intra-County and County-National relations, I used Bossert's decision space and Principal-Agent frameworks [42,57] as well as Baldwin's organisational theory [125,126].

4.8 Data Management and Ethical Considerations

I obtained ethical approval from the LSHTM ethics committee **(**LSHTM Ethics Ref: 10716) and the Kenya Medical Research Institute (KEMRI, SSC No. 3217) the latter which handles research governance on behalf of the Kenya's MOH. All participants had the Study explained to them sufficiently to enable them to give informed consent, as well as be aware of their right to terminate their involvement at any stage. I gave each interview respondent an information sheet with further details on the research and a consent form to sign. With their consent, I took notes anonymously, and, for interview respondents, I undertook additional audio recording. I gave all participants an opportunity to ask questions during and after data collection events.

I anonymised all research data for privacy and confidentiality reasons. I handled all data according to the LSHTM and KEMRIs' Data Protection policies. I securely stored all data collected on a password protected private laptop and a secure database hosted by the LSHTM.

PART TWO: RESULTS

The next three chapters present the findings from the field, centred within the Donabedian conceptual framework (see section 4.4) [122]. It presents data primarily gathered from interviews backed by minimal references to that which was collected from the other sources outlined in 4.3.3 above.

Chapter 5: Key Result area one: Structure (Infrastructural Perspectives)

This chapter will look at the structural context within which the EPI is planned, coordinated and delivered, focussing on three main resource areas: organisational, human and fiscal.

5.1 Organisational Infrastructure

5.1.1 Planning for health system devolution

Arrangements in preparation for health service devolution were guided by the 2010 Constitution which broadly stipulated that service delivery should be a County function and that policy and capacity building be a National government function. In 2010, health services were already decentralised within a provincial administration structure which had the district as the level within which government service delivery was managed and coordinated (see section 2.4 above).

The health system discussions were mainly technical, centring on identifying, assisting and developing capacities in readiness for the formal functional transfer scheduled to begin in 2013. A position paper on the technical understanding of devolution for the health sector [127] was produced, followed by the Health Sector Function Assignment and Transfer Policy Paper (HSFATPP) [128]. The HSFATPP outlined the functions of the County and National level and presented a process for capacity assessment, capacity building and transfer of services.

Early in 2013, just before the general election, the MOH appointed County Coordinators of Health (CCH) to create interim structures at the County level in preparation for the establishment of the CDH. The CCHs changed their title to County Directors of Health (CDOH) and organised the interim structures to conform to the existing DHMT structures, albeit with a broader mandate than the DHMT. These interim structures were created without clarity on terms of reference or guidelines on mandates, configuration or responsibilities[129].

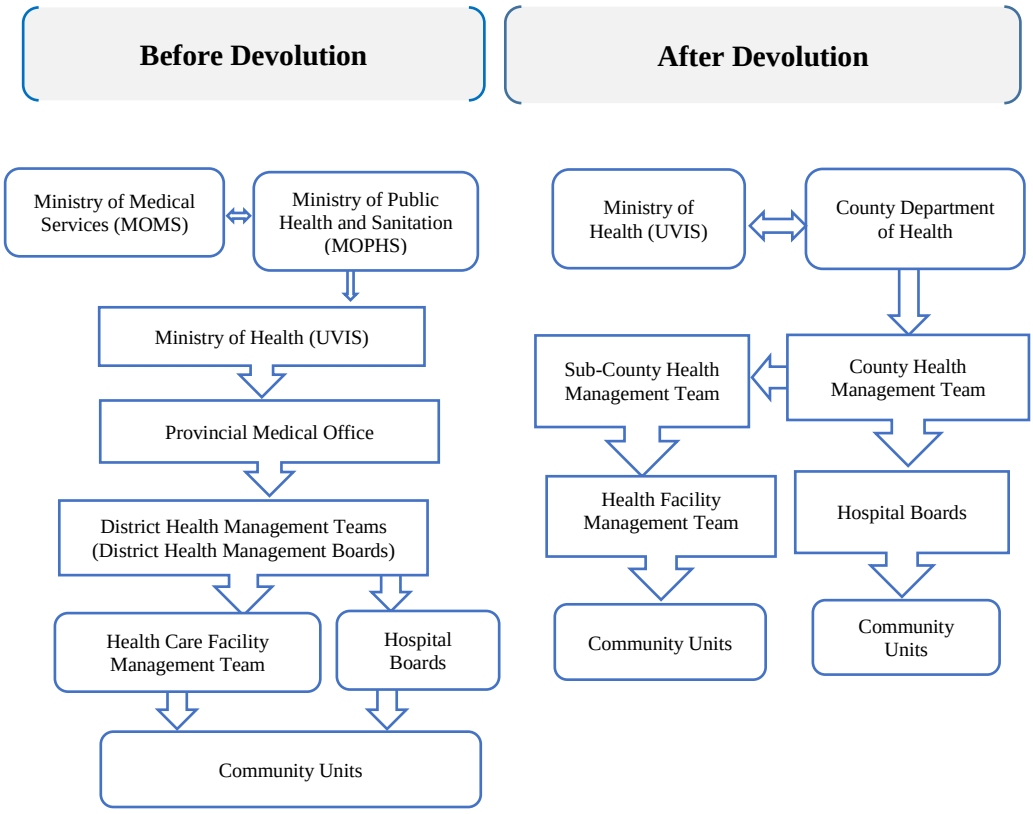


Figure 7: Accountability for health service management pre-and post-devolution

Note to the figure above:
Before devolution, UVIS had vertical relations with the structures below it. This reflected accountability for vaccine delivery. Post devolution, the relationships between UVIS and County Structures are lateral: the CDH are not accountable to UVIS, as Counties are independent governments. The accountability relationship is replaced by mutual consultation and cooperation arrangement founded in the 2010 constitution.

A significant context that the discussions missed was the fact that devolution in Kenya was politically driven, and since the County governments had not been established by then, they and their political leadership were not included in the discussions. The discussions did not anticipate and/or factor in the political interplay this created. When the County governments came into force, they formed a forum bringing together all 47 County governments; an entity referred to as the Council of Governors (CoG). The CoG gives the Governors a collective voice, and this turned out to be an extremely powerful entity in censuring the National government. At their first convention in July 2013, the CoG demanded an immediate transfer of all functions and resources,

contrary to the three-year phased implementation that was originally agreed by the Transition Authority [130]. In response, the President directed the National Ministry of Devolution and the Transition Authority to transfer all the functions to Counties at once. All Ministries which had devolved functions were mandated to transfer those functions immediately. The National Treasury had to realign the budget they had recently published to factor in County functions and respective resource allocation.

This seems to have been the genesis of chaos, especially within the health sector, firstly because, the MOH was going through a structural change, merging two ministries into one; MOPHS and MOMS (see 1.1.1.4 above). Naturally, workers were focussed on succession planning with job security playing an integral role. Secondly, all the planning envisaged by the HSFATPP was voided. The presidential decree was pronounced without consultation with anyone within the health sector and in disregard of the prior discussions held within the sector. It was therefore unclear to everyone concerned how the devolution of health functions would pan out. As one respondent put it:

> "...there was a lot of uncertainty on the part of the health workers at the national MOH on what their role and function would be over time since a lot of their work was managing Provinces and Districts, yet all this was going to the Counties and there was no clear mechanism on how the Counties would report to the MOH. Health workers feared being jobless, idle or powerless [as the power they drew from managing or supervising people at the Districts/Provinces had suddenly been withdrawn]. The immediate response was depicted by lack of keen-ness in letting go of the functions, but the political push was irresistible" NL10.

Functions were nonetheless transferred to the Counties; to a context with few interim structures and a lot of capacity issues, as observed by this interviewee:

> "The way in which health was devolved, there was almost no involvement of the technical offices…the directive was given, basically 'health is a devolved function', so everybody had to conform, national level is supposed to do policy and technical assistance…a function is only carried out at the national level if it is of such magnitude that it cannot be carried out at the County or if there is economies of scale or benefit in it being given by the national government,

which at the time there was nothing like that in immunisation. So, what happened was that immunisation was considered devolved..." NL8

And with the following impact on staffing and structure:

"What happened is now immediately the Ministry is formed, your jostling happens, the government implemented the constitution according to the word without you even having a plan. So, now that was the problem". NL5

The current responsibilities for health functions are shown in Figure 10 below.

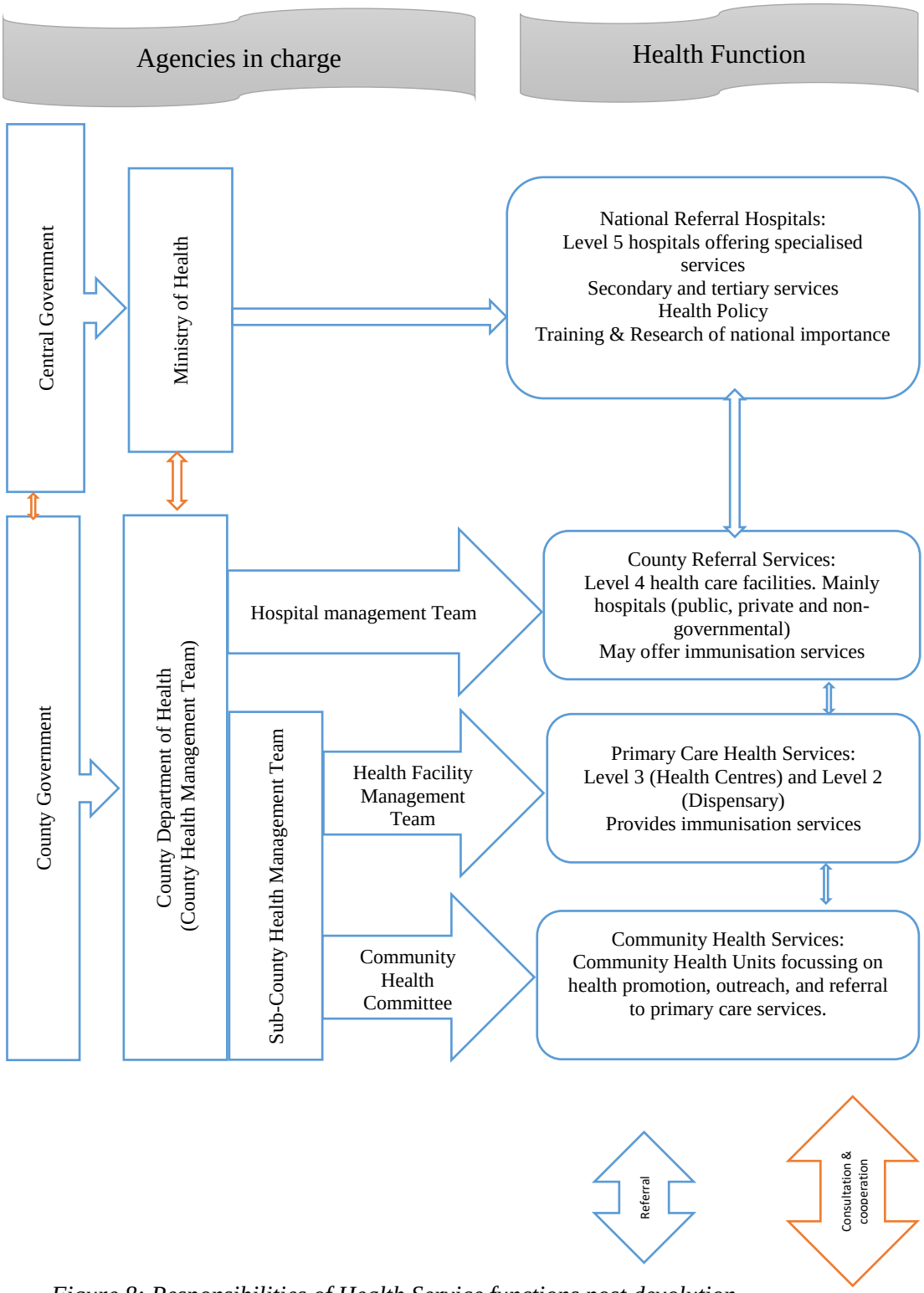


Figure 8: Responsibilities of Health Service functions post devolution

5.1.2 Governance of the transition process

Upon the presidential decree, several forums were enacted to govern the transition process. One of the forums was the Inter-Governmental Relations Forum (IGRF), composed of members of the Central and County governments, and international stakeholders interested in Kenya's health sector, namely Development Partners in Health Kenya (DPHK), WHO, UNICEF, DANIDA, and United States Agency for International Development (USAID). This forum identified two urgent issues that seemed to be causing the health system to come to a grinding halt: first, for several months there had been a country-wide stock-out of all commodities in the health facilities, and second, health workers were not being paid.

The international stakeholders intervened and a mechanism was agreed: DPHK offered to invest their own money to procure a buffer stock for six months for all registered government health facilities across the country during which time IGRF would agree a mechanism on resolving the commodity crisis, and Counties would establish procurement structures and systems. In relation to workers' pay, the IGRF agreed that the MOH would continue to pay salaries for six months since they still had the payroll management system. However, the MOH did not have the money because it had been sent to the Counties. It was agreed therefore that they would invoice the Counties for the six months, with the expectation that the Counties would set up their payroll systems to take over the responsibility after the six months. This assumed that the CDH (mandated to coordinate this function) would be up and running within that time period. This, however, was not the case for many Counties like Kilifi.

In Kilifi County, the establishment of a permanent CDH structure was delayed. An interim structure for the coordination of health services was in existence, established before the 2013 general elections in accordance to the directive from the national MOH highlighted in 5.1.1 above. The interim structure was led by the CDOH supported by CHMT and three SCHMTs. This structure was intended to operate provisionally until such time when the County Governor assumed office in March 2013. With the Governor in place, a permanent CDH would then be established, starting with the appointment of a CECM for Health and a COH. An initial appointment of the COH did not happen until late 2013 [129]. A lot of contestations arose, on the COH's management of stakeholder relations. Eventually, the COH

resigned. A subsequent appointment in 2014 was amicably received by key stakeholders. Under the leadership of the COH, the Kilifi County Department of Health (KCDH) was formally established, and so embarked on completing a five-year strategic and investment plan that had been started in 2013[97].

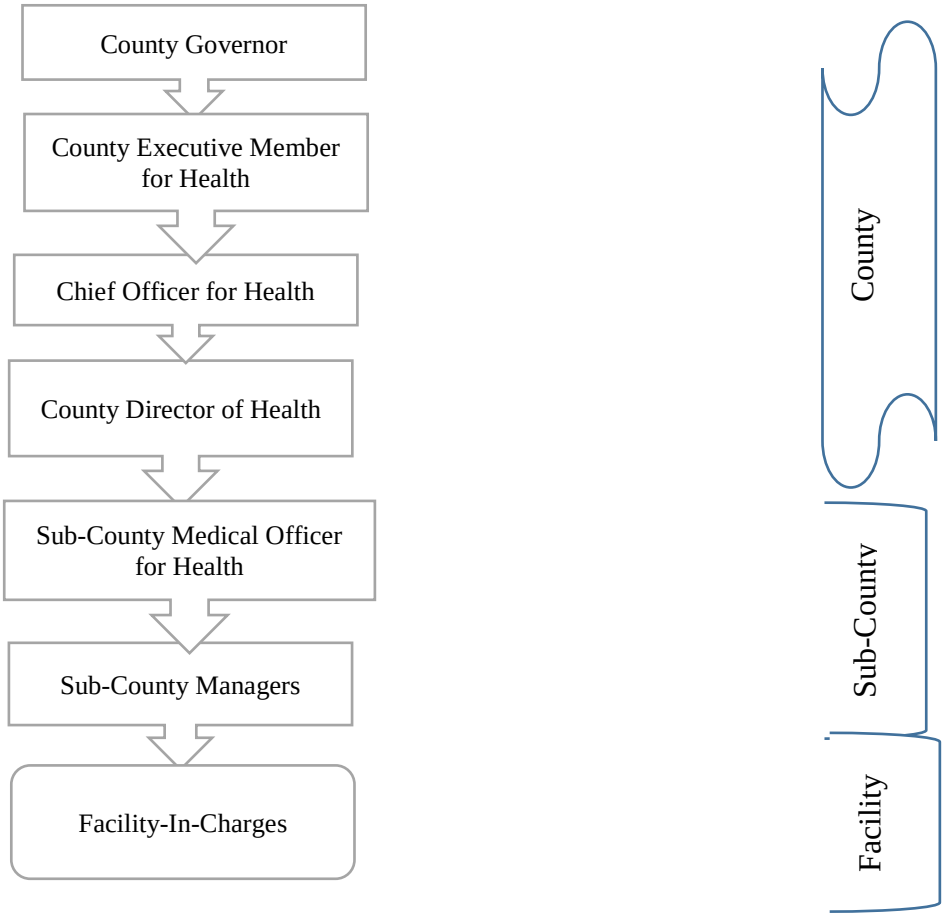


Figure 9: Accountabilities for the management of County health services

The KCDH structured the management of health service delivery around three main levels: County, Sub-County and Health Facility (see Figure 5 above). Within each level, management teams were established to oversee service coordination across the respective jurisdiction. At the County level, the CHMT were established to oversee service coordination across the county. At the Sub-County level, three SCHMTs were established to oversee the three Sub-Counties. At the PHCF level, Hospital Management Teams (HMT) were established to look after hospital affairs while Health Facility Management Committees (HFMC) were established to oversee the PHCF.

Another entity, the Community Health Committees (CHCs), which were established under the Kenya Community Health Strategy (2006), continued after devolution. The CHCs govern the coordination of health affairs at community level delivered under Community Health Units (CHUs). The CHUs deliver health promotion, preventative and basic curative services within the community. Each CHUs is linked to a primary health care facility, and has its services provided by CHEWs and CHVs. These units are responsible for vaccine outreach, defaulter tracing and identification of vaccine eligible children.

The structures discussed above provide the oversight for the implementation of the EPI among other health services. Through the CHUs for example, a well-defined communication system is established, between the health service providers and consumers, as noted in the quote below.

> "…if there are issues in that village, they [Facility-In-Charge] communicate to that community health assistant [CHEWs] responsible for that village, who communicate with the volunteers [CHVs]. So the community report [back] to the community health volunteers who report to the community health assistant [CHEWs] who will report to the [Facility] In-charge".CL9

The HFMC, which existed pre-devolution, were seen by Facility level respondents to be a positive add-on to the EPI as they brought in community intelligence and promoted two-way communication between the providers and consumers. When referring to the HFMC, one respondent noted:

> "…it [HFMC] is also helping because…views from the community, it's easier for them [HFMC] to bring it here [to the Facility] and any clarification from the facility it goes directly to them [community, through the HFMC]". CL7

5.1.3 Stakeholder Involvement in EPI

The EPI is supported by a variety of stakeholders including academic partners, advocacy groups, and international organisations, the media, individuals, health care system providers and vendors and vaccine investors. In addition to specific management structures presented above, other forums exist which act as a springboard for stakeholder involvement in governance and operational (technical and financial) support for the EPI, at both national and county level. At the national level, the main clusters of EPI stakeholder forums identified in this study include: (i) technical

working groups supporting different programmatic areas, such as training, monitoring and evaluation, logistics and cold chain management, (ii) the Kenya National Immunisation Technical Advisory Group which provide technical and scientific advice to the MOH on immunisation policy and vaccine related issues, (ii) a health non-governmental organisations network, (iv) Inter-Religious Council of Kenya and (v) Inter-Agency Coordinating Committee for vaccination which advocates for efficient systems and process to minimise service disruption.

Responses from National level informants indicated that the support from stakeholders was invaluable. In a crisis characterised by lack of funds to procure vaccines and subsequent vaccine stock-outs for example, one respondent noted how agencies like UNICEF strongly supported UVIS efforts to find solutions;

> "…there is also a peace of mind that UNICEF… has not just been giving us vaccines. It has an interest in getting the child vaccinated. So, they will do everything so, we are always sure. Even when we are in trouble…they have our back…which they have done…quite a lot" NL1.

One notable accomplishment of stakeholder involvement cited by some National level informants was the development of a web-based electronic Stock Management Tool (SMT) led by Clinton Health Access Initiative (CHAI). The tool enables one to see the vaccine quantities available from the national stores to the health facility level and generates warning signals automatically when the vaccine stock level falls below the anticipated demand. According to a national level respondent, the tool was...

> "…something that was just built from ideas that were thrown around [by stakeholders] …it's an online tool that you can just open you'll see (stock levels)" NL9,

This was followed by a correspondent development of a joint action plan at the County level, between CHAI and the KCDH for the implementation of the electronic data capture tool.

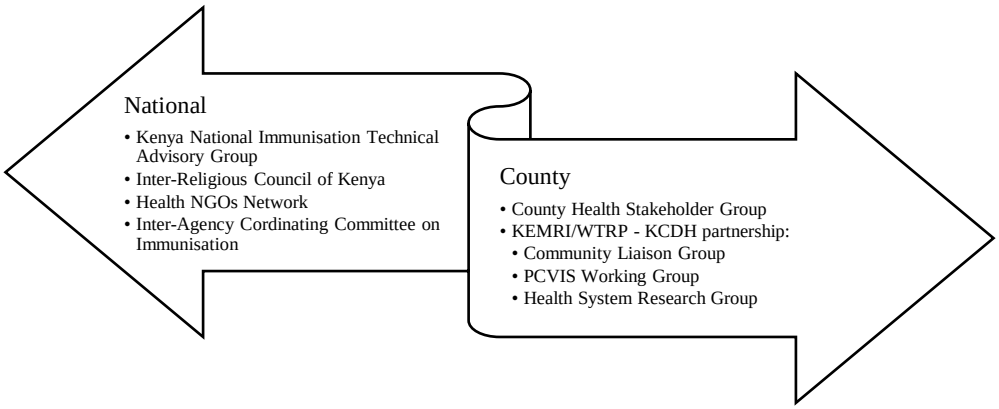


Figure 10: Stakeholder groups at National and County level

At the county level, the study identified a County Health Stakeholder Group attracting non-governmental, private sector and faith organisations interested in supporting the health agenda across the County. Also existent is a partnership between KEMRI and KCDH (see section 3.2 above) encapsulating other forums that feed into the Immunisation Programme, including (i) a Pneumococcal Conjugate Vaccine Impact Study working group committee that meets regularly to discuss issues faced by health workers recording immunisation data from health facilities with a VMS [103], (ii) Community Liaison Group that supports engagement with the communities in immunisation activities, and (iii) Health System Research Group which undertakes research and promotes dialogue on health system policies.

As part of promoting citizen participation and transparency in health service delivery, another key group of stakeholders at the County level, the local elected politicians (Members of County Assembly (MCAs) and Members of Parliament), tend to be actively involved in the governance and operations at the PHCF. From observation and interview notes, this involvement was received with mixed feelings, as noted by this respondent where on the one hand, the MCAs were depicted as advocates;

> "…the MCA I think is one of the most supportive person I have ever seen, he promised to build us a lab and buy us a new tank…In fact there was a period

when there was no one [referring to data clerks] attached to this place he followed it up until there is somebody here. So, he has been positive". CL7

But on the other hand, they were perceived as an unnecessary imposition and interference to service provision:

"…but I know some [MCAs] are interfering because as they are speaking to other people and they feel either they don't have the right capacity, or you know it's like their roles are conflicting, they will come to ask things like performance reports from the in-charges just like that" CL7.

Many other Facility level respondents also felt MCAs made unreasonable demands, a sentiment that was echoed in many observation events in this study. One respondent noted:

"Actually the MCAs are a big threat to us including me because they believe they own the health facility…they want to overrule you…recently they came here and like, they need all the reports we do...we had wrangles…I'm saying 'for me I cannot give you any information, you just go to the MOH'. Then they are saying, 'now you're denying us, it's our people who are treated here, now why are denying, why you are hiding'…we usually have those challenges … they don't follow any protocol. They just come when they want, they speak what they think they can speak".CL15.

This perceived political interference was also noted by respondents from the national level in instances where County Governors used their executive positions as overall in-charge of County health services to stop immunisation services. This was said to happen in instances where Adverse Effects Following Immunisation (AEFI) were recorded. Instead of tapping into the technical advice of their COH to understand the circumstance within which the AEFI occurred and any future mitigating measures, the governors instead moved to stop all immunisation activities within their jurisdiction.

"...when it comes to dealing with the issues like now, Adverse Effects Following Immunisation, are finding now people at the County level making decisions that they should actually not be making…I'll give an example in last year, a child died after immunisations and the governor came and stopped immunisations…when it comes of consultation and cooperation, it's not just in politics, even on a matter like that people need to sit and say we have this issue, how do we handle this one…Now, when they have stopped

immunisations and the National government is busy telling people immunisation is safe, people don't trust the National government".NL3

In such instances, a lot of effort had to be put in having discussions with the community responsible for them to accept further immunisation activities. A conditionality of that was that a report would be produced to explain the reasons for the AEFI that would be shared with the community. To the dismay of the respondent, this had not happened at the time of fieldwork.

> "So, that again is part of what I was telling you management issues that we lack, because for me if you tell me that I will do everything possible and then you don't…You cannot come to me again (to immunise), you lied to me last time. I cannot really say that person was not reasonable". NL3

5.1.3 Organisation of EPI services.

EPI services appear to be well organised both within the County and the National level (Figure 14 below) with a distinct chain of command. The chain of command is implemented vertically within each level of government. The relations pertaining EPI across the two level of governments are implemented within the framework of consultation and cooperation provided for in the 2010 Constitution of Kenya. The responsibility for EPI stops ultimately with the Cabinet Secretary (CS) for Health at the National level and the CECM for Health at the County level. The CS is supported by the Permanent Secretary (PS) who also is the accounting officer at the National level, correspondingly, the CECM is supported by the COH who is also the accounting officer at the County level. The CS and PS are appointed by the President of Kenya, while the CECM and COH are appointees of the County Governor. Below the PS at the National level, is the UVIS team who provide policy leadership and technical support to the CDH.

At the County level, the CDOH sits below the COH and head the CHMT within which managers with a County-wide operational EPI mandate sit. These include a named immunisation focal person who oversees the delivery of EPI services across the County, supported by surveillance, data and public health managers. At the Sub-County level, there are managers (mainly senior nurses) directly in charge of the EPI who supervise, coordinate and consolidate reports from PHCF. The overall in-charge of the EPI at the Sub-County level is the SCMOH who reports to the CDoH. At the

Health Facility level, the Hospital Superintendent (HS) and Facility-In-Charge (FICs) have overall responsibility for EPI in the hospitals and PHCF respectively. The HS report to the County Immunisation Logistician while the FICs report directly to the Sub-County Immunisation Logistician.

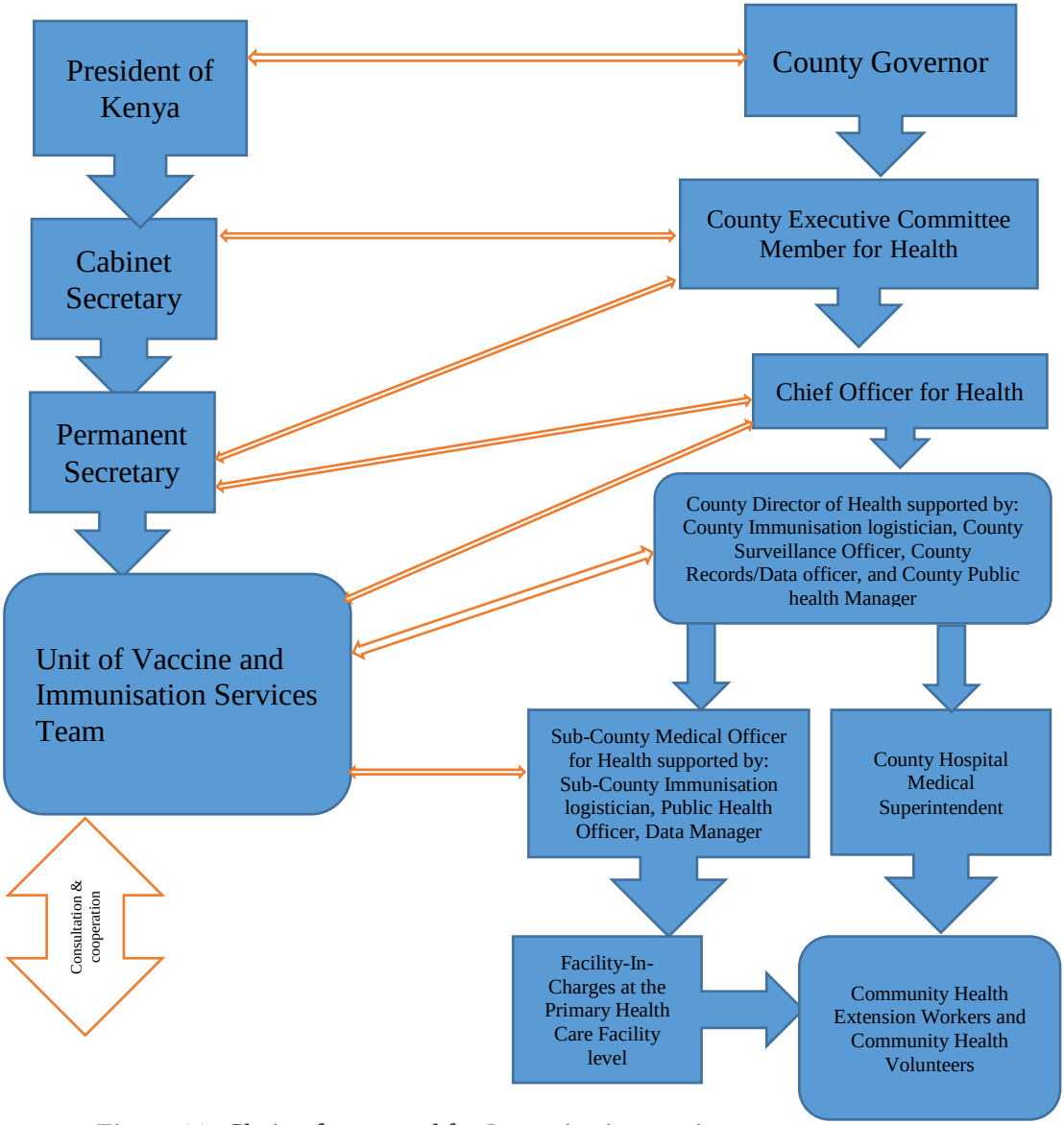


Figure 11: Chain of command for Immunisation services

5.2 Fiscal organisation

"Kilifi County Health Services is a one man show" CL5

5.2.1 Resource Allocation Strategies

The government of Kenya gets its revenue from donors, grants and taxes which it then pools and allocates to Counties through a resource allocation criterion developed by the Commission for Revenue Allocation guided by the 2010 Constitution and the 2012 Public Finance Management Act (PFMA). The constitution stipulates 'ceilings' within which allocation should be made between National and County government while the PFMA outlines how resource allocations and planning budgeting cycles are to be adhered to. The constitution specifies that at least fifteen percent of the total revenue in government should be allocated to Counties as discretional funds, and up to a maximum of five percent as an equitable allocation to Counties that are deemed as marginalised. The central government has additional resources, conditional grants, through which it finances the Counties; this money has to be spent on the specific purposes dictated by the central government. The Counties also have other mechanisms for generating local revenue, mainly through local taxes and user fees.

Within the context of devolution, as dictated by the constitution and the County Government Act (CGA), the PFMA identified two accounting levels: the national government and the County level. At the County level, the County Treasury and the Chief Officers are recognised as Accounting Officers with the sole responsibility for financial resource management. At the KCDH, the Chief Officer for Health (CoH) is the Accounting Officer (AO) for the department. Before any money is spent, the AO needs to draft a budget and request approval to spend on that budget. The approval would be granted as an Authority to Incur Expenses (AIE).

Before devolution, the legal structures below the district level able to receive the AIE included the Hospitals, Health Centres and DHMTs. This meant therefore that although the financial management was centralised at the MOH, it was operationalised with significant decentralisation to the District and Health Facility level. A hospital for instance, had the right to receive funds, but would then have to request AIE from the central government in order to receive them. Post devolution, the PFMA withdrew

all budgeting and spending rights from the structures below the County (the Outer Periphery – see Figure 8 above) and centered them within the County level, effectively reversing the decentralisation that previously existed. The recentralisation was extended to all revenues collected at the Outer Periphery mandating them to be banked in to the County Revenue Account (CRA). This means, therefore that the COH is recognised as the sole AIE holder for the health services within the County by virtue of being the AO for the entire health sector budget. This potentially created a disconnect in service planning and delivery at the lower levels.

> "…you heard yesterday what they were saying, we used to get AIE but nowadays there's nothing like that. So those are some of the challenges that we are having. Initially we could give about Kshs150, 000 to Kshs200, 000, (to the EPI focal person) but nowadays...*haiwezekani* [it is not possible]". CL5

To access the funds from the County, the AO prepares a budget and presents it to the County Assembly (CA) who would then approve the budget by giving spending rights to the AO. So essentially, the power to debate and prioritise on health activities lies within one person; the AO. Article 176 (2) of the Constitution, however, allows the County to devolve its function to lower structures "to the extent that it is efficient and practicable to do so" pg.108 [53]. This, however, has not happened in Kilifi. At the time of fieldwork, accounting responsibilities were still managed centrally. It was reported that despite a lot of detailed discussions, there seems to have been very minimal effort towards further devolution. Instead, a preferred option pursued was the enactment of a local legislation to create a mechanism within which the accounting responsibilities can be devolved further. The local legislation, it is argued, would be able to guard against any misinterpretation of the allowance offered by the Constitution, PFMA and CGA. This option had yet to materialise, three years after devolution. It is within this reality that all County level respondents insinuated that the running of health services across the County is a 'one man show'.

> "…there is a lot of capacity lower down, but someone just refuses to devolve because they want to manage everything. You want to manage every single biro pen to be bought from the County Department of Health, because you want all the expenditure to happen from your office…" CL2.

In trying to address the recentralisation rhetoric, the CA published a Facilities Improvement Fund (FIF) bill which has provided allowance for the hospitals to receive AIEs. This, however, does not cover the PHCF and also comes with its challenges. Before devolution, the hospital bank accounts had as signatories' members of the HFMC and Hospital Boards. Post devolution, it has almost become mandatory for some County Officers to be signatories to the account. This has been reported to cause delays in accessing funds from the account as some of these officers have been unavailable to counter-sign the necessary documents allowing withdrawals due to frequent travel on official duties.

The current system (recentralisation of finances and AIEs) does not seem to be working well for its people. Previously, the structures within the Outer Periphery used to do the planning and budgeting, a role that has now been taken over by the County. Being an AIE holder that was once the privilege of the Health Facilities has now been taken over by the County, so financial autonomy for the Outer Periphery under devolution is almost non-existent. The system allows each actor to collect money but then requires all the money collected put into the CRA. Some health facilities, such as the hospitals, still have their bank accounts and can deposit their revenue in them. However, they may not be able to access the funds when required for reasons explained earlier on. Thus, the hospitals have also lost autonomy as the County always has a say in their financial expenditures.

> "There is a challenge… [before devolution] we used to have challenges but definitely not as of now specifically in relation to financial issues and because by then the story was different. The [Health Facilities Management Committee] HFMC and the facility will have a meeting, come up with priorities. They'll be picked up by the [Facility-In-Charge] FICs, deliberate the same issues at the Health Management Team meeting, propose the same priorities which have got financial implications to the Board of the Hospital or either the HFMC, which after approval, it was basically procuring the items, settling the expenses, paying the expenditures, but as of now, most of the things have been taken at the County level, which they are supposed to do themselves…". CL17

Some County respondents intimated insincerity in the way they were involved in the health sector planning and budgeting. It seemed ironical that they were blinded on the actual amounts the health facilities had since everything was rerouted to the County Revenue Account but were asked to plan and budget for their health facilities.

> "…the County keeps calling us to plan and to budget, you know, how can we plan, how can we budget when we don't know? I mean, you need to know that I have a hundred thousand, so I may budget. So, if you don't have a hundred thousand, then what are you doing? If you don't have resources how do you plan, how do you budget, you know…" CL7

5.2.2 Health facility funding

Hospitals and PHCF in Kilifi County receive funding from three main sources: the County Treasury, user fees and Central Government through its Health Sector Service Fund (HSSF). The HSSF, established in 2009, pools funds from DANIDA, Central Government, World Bank and UNICEF which are then paid on a quarterly basis directly to the bank accounts of the PHCF. The fund is overseen by the HFMC. At the on-set of devolution in 2013 there were tussles between the County and Central government over the management of the HSSF [131]. The Counties demanded an active role in selecting the HFMC and required HSSF channelled through the CRA. The Central government on the other hand were opposed to the redirection of HSSF to the CRA. The County position was supported by DANIDA while the Central Government had the support of the World Bank. This tussle led to significant delays in funding disbursement to the PHCF and subsequently, to DANIDA's refusal to continue its contribution under the finalised terms. At the time of fieldwork respondents reported reduced or delayed HSSF funds reaching their accounts.

> "…those facilities [where] we have HSSF it comes in the facility…for the last one year, we have not received (HSSF), in this financial year, we have not received any cash from the government and what we had is only from DANIDA that came once". CL8

User Fees as a resource revenue for health service delivery were first introduced in the 1980s as a mechanism for consumers to share the costs of health service provision incurred by the Central Government [132]. Its implementation was contentious at best; over time, the policy underwent significant modifications including waiver of charges

for certain population categories and a significant reduction in contributions [133]. Eventually, in 2013, the Central Government abolished user fees in all PHCF as a move towards universal healthcare coverage [134]. However, for several reasons, many PHCF re-introduced the User Fees [129], a fact that was also established in this study; as one participant observed when discussing the financing of their PHCF:

> "[Things have been] up [and] down but we manage. We talked with the committee when these changes came. We don't have any [money]...we find ourselves we're lacking the basic things like we have KEPI gas [but] we don't have electricity. Sometime that KEPI gas is so essential for us and we don't have. So, we had to talk to the committee, and we started charging that 20 [Kenya Shillings]. So that 20[Kenya Shillings] is what keeps us going. Right now, there is a supply [of KEPI gas] but there is a time *ilikuja ikaenda* [it finished] she [Sub-County immunisation focal person] didn't have [financial resources], we had to procure for ourselves. We must get the user fee. Sometimes they don't allow, but sometimes we just must do it". CL8

Access to funds from the County Treasury commences with the budgetary process by the AO described in the section above. Facilities-In-Charges (FICs) then submit financial requests for routine recurrent expenses to the AO. This process has not been seamless. This study established that prior to devolution, PHCF received quarterly financial allocations which they could spend upon receipt of an AIE. With the withdrawal of the AIE in the Outer Periphery structures, FICs are now required to prepare a budget and submit to the AO for approval before receiving funds. The budget preparation only commences upon receiving a directive from the AO.

> "…last week we were told to write budgets. So, we send the budget because the County advises me, they give funds according to the budgets..." CL15

For reasons the study could not establish (as the key informants were not available for follow-up interviews due to other official commitments), this directive was not always given out in a timely manner, and FICs financial requisitions for recurrent expenditure were not always honoured. An incident I observed was one such directive given out to FICs at a FICs meeting. The meeting happened to be on a Thursday, 48hours before the financial year end; FICs received letters from the KCDH directing them to prepare and submit budgets to KCDH by 9. 00a.m the following day. The money budgeted

was required to be spent before the anticipated year book closure: within 24 hours. To put the directive into context, the meeting ended around 4p.m, most of the FICs had to traverse long distances, some journeying over four hours to their respective work stations. Some FICs were away on leave. Here are some of the comments on this directive:

> "I received that letter at eight [Friday morning], and I'm supposed to present it by nine o'clock same day. That's what usually happens yeah. If you don't present it by nine, you don't get the money. Now I don't know because…I'm told it is supposed to be used before the end of this month. I mean the end of tomorrow, the end of the financial year, and the reports delivered".CL15
>
> "I was not able to attend that In-Charges meeting, but I received a feedback from a colleague, from another facility. So, that budget was only for the arrears but not for the coming month. You get the money to pay the debts and then you get into debt again. But that budget cannot cater for the arrears even for the casuals, for the number of months they are owing the facility". CL6
>
> "Usually what happens is with the County Government and the funding is like some emergency. They give this amount; they tell you we must spend this money in two days". CL7.

It is clearly unrealistic to expect the Facility to be able to spend money in twenty-four hours, which raises questions about why this requirement would be made. All Facility level respondents stated that they felt hard-pressed to respond appropriately to the directive, and that they were also aware that failure to do so would result in them receiving punitive measures.

> "So that's another problem, if you delay [submitting budget and spending the money] for the period stated then it's your pay slip that will cater for that. I must make everything within required time [otherwise] then you sort yourself". CL7.

With the County Financial Management Act requiring all finances to go to the County accounts before trickling down to PHCF, the Counties have insisted that HSSF and User Fees be redirected to the CRA. Although the recentralisation of funds to the CRA might have been a good idea for ensuring transparency and equity in resource

distribution, the disbursement process to hospitals and PHCF has been inefficient. Again, many of the County level respondents commented on this:

> "…one of the challenges that we're facing with the devolution, previously we used to receive funds from different sources, especially donors and well-wishers…Unfortunately this money is now channeled to the County Government. So, here we are just left hanging like that. We had to slash some of the activities, like outreaches, till we receive funds…" CL9
>
> "…whatever user charges are collected at the Facility level now must go back to the Counties - the County decides on the major priorities to spend on. This is not done in consultation with the Facilities-In-Charge -They'll do what they think..." CL8
>
> "We just hope funds will come because why the delays? Because the County Government does not have direct fund to us, its donor's money. So, what happens, it is delays in the County. So, the donor tells us that we have given you the money, but the County doesn't disburse them to the Facilities as required". CL15

All Facility level respondents reported delays in receiving funds which caused great liquidity problems which in turn hampered efficient service provision, for example;

> "…see this level of Facilities, the Dispensaries, Health Centres receive funding for the day-to-day running of the activities including paying the support staff but apparently, we have gone for over three months without the funding. So, the support staff have gone for that long time without pay, no outreaches. You can't do anything". CL7

And one respondent speculated that employees would begin to hold the PHCF to ransom:

> "Actually in some Facilities you find that the watchman has not been paid for six months though he is still giving his services but one day now he says that he has picked the microscope…*ni deni yangu, lazima munilipe* (it's what you owe me, you must pay me)…before I can give you". CL12

Some respondents expressed difficulties in getting challenges brought by financial deficits addressed.

> "Is a big problem, you see some of these things we can do ourselves if at all there is money but remember there is no money, they are aware that we don't have money, I called Chief Officer the other day…these guys were pressing on me, they want money, *wanasema niwakopeshe* [they say I lend them] from nowhere. There are some chairs, that were donated [loaned for a specific time] and now they want their furniture back. Where do I get furniture if they are removed and on Friday, they are coming for their furniture? I called the Chief Officer and he said he was going to discuss my issue and since then I have not received any response". CL6

5.2.3 Immunisation Programme funding

Prior to devolution, all the traditional vaccines were fully financed by the Central Government and the New and Under-utilised Vaccines (NUV) funded through a co-financing mechanism between the Central Government and Gavi. The Central Government's allocation for traditional vaccines and contribution to NUV was ring-fenced and the money sent directly from the National Treasury to the MOH earmarked for EPI. The national logistician within UVIS would then requisition MOH accountants to pay the procurement agent to acquire traditional vaccines and send the government contribution to Gavi for the NUV. This arrangement changed significantly under devolution.

The devolution policy affected the EPI funding in two major ways. Firstly, it removed the national level ring-fence, which included the financial contribution to Gavi. Money is sent to the Counties as a consolidated budget. The County then allocates the money across all County departments through a process known as 'vote rights'; whereby each department develops a budget itemising the expenditure needed and then lobbies for the funds from the County Assembly. Depending on the lobbying skills and the strength of the proposal, the immunisation related projects may or may not receive enough votes and therefore, may or may not be funded.

> "[Money] it comes in as a basket, then it is within the County that it allocates the budget along the various departments within the County…So in that respect when you get money, you don't say this is money for immunisation, for example, or this is money for malaria. So, it's within the department to see if we can reserve. So, and again money is spent through what we call vote rights, so

> as much as we initially do what we call programme budgets, where you will say we have an Immunisation Programme what do you require? You require logistics, you require commodities, you require staffing, and things like that but then that is still spread over within the votes. So, vaccines would probably be procured as any other commodity that will procure within either the bracket of pharmaceuticals". CL3
>
> "…the way the allocation is done, we have vote items – we have a vote for non-pharmaceuticals – that's where you buy any syringes in that vote. As departments (we are ten) each comes up with a proposal of the budget on the vote items. So, you say we are going to spend this on emoluments, and this is the budget implications, through the recurrent and development expenditure. So you are allocated based on how well you lobby for those resources within the county..."CL4

Many County level respondents (20/27) reported they had not received funds to support immunisation related activities since 2013. Sub-County and County level managers expressed frustration at the apparent disregard for the effect the lack of funding was having on the quality of the Immunisation Programme delivery. They reported to have approached senior leadership in several occasions, and the response they got was that the County as a new formation was facing teething problems. Some managers were however, either not fully convinced or satisfied by the response. One respondent exasperated:

> "...every time you ask you are told it's because of teething problems. But this child is three years old and still teething? How long should this child teeth before s/he can be fully formed?" CL5

A common view expressed by 7 of 11 participants at the National level and 15 of the 27 participants at the County level was that EPI is very sensitive to funding and that the removal of the funding ring-fence in the devolved fiscal management system puts the sustainability of the programme under threat. This is more so because traditionally the priority for health spending in Kenya has been towards curative health care and tangible infrastructural resources at the expense of public health interventions. It was particularly felt that if such fears became real, and early indications seemed they might

be, then all the efforts UVIS had put into getting buy-in at the national level would have gone to waste.

> "We have tried to fight for a long time in this Country at the national level to get the leaders to appreciate it [the importance of the Immunisation Programme]. If you go to the MOH today, the top leadership; the CS, the PS…they know so much about immunisation, and there's a lot of goodwill. But now, they cannot influence the decision at the local level". NL1.

The second major aspect of funding for the EPI that devolution affected was in the classification of the programme and the implication that this had for the money flow. In the new devolved governance structure 'service delivery' is a County function and the Immunisation Programme was classified as a service delivery function. It then follows that all its monetary allocation was devolved to the Counties. As one National level respondent observed:

> "…the immunisation funds have been devolved so, to some extent... the government [Central Government] contribution to the EPI is devolved to date and that's a major headache...what the Treasury does…they say service delivery function is a County function, give it to the Counties. So, immunisation service delivery, is a County level function, you give the money to the County". NL10

And another explained:

> "It's [EPI] funded directly from the National Treasury but because most aspects of the Programme were considered devolved, so then for the last three years the funds do not come to National level [MOH], to the Programme [UVIS], because look at a function like supervision [for example]. Counties are expected to be independent entities so there is no function called supervision that we [Centre] are supposed to undertake. So, therefore, there is no support for that, funds for training again do not quite come to our [Centre] level so basically there has been very minimal operational support. Most of it go to the Counties directly as part of that bigger package, so what we get is main funding for procurement of vaccines and related logistics…the [Central] Government also puts in a bit of funding for equipment and procurement of spares. So mainly it's heavily procurement of those specialized equipment which is thought that Counties may not be able to procure and a bit of

equipment to support the vaccines. And the operational funding almost a hundred 100 percent goes to the Counties". NL8

The claim that there was procurement of specialized equipment for immunisation by the Central Government on behalf of the Counties could not be corroborated.

A startling omission in the design of the new funding arrangement was the appreciation that the Central Government finances part of the EPI (that is, all the traditional vaccines and part of the NUV) and receives counter-funding from Gavi for vaccine procurement. This co-financing arrangement requires that all parties put their money in one pool before the procurement agent can initiate the buying process. With the money devolved to the Counties, it was then required that the 47 County Governments return their monies (15% of their Health Budget) to the Central Government to enable it to meet its co-financing commitments. This was soon to prove impossible. For one, there is no legal mechanism by which the Counties can return money to the Centre, and two, the Counties are hesitant to bring back what they believe is rightfully theirs. Gavi on the other hand took a stance not to honour their commitment until they had seen the Central Governments' contribution. This standoff (which had not been resolved by the time of fieldwork) contributed to a lot of logistical challenges to EPI, manifested in procurement delays and vaccine stock-outs, as one respondent noted:

"….in 2013 what happened the first time**...** all the money went to, to the Counties, including the money for vaccines. And there was a huge problem, because we could not even afford to do our international obligations. That caused a lot of stock-outs". NL1

Commenting on the tension created by the Counties' reluctance to return any of their funding to the Central government two National level respondents noted that:

"…Gavi would not put in their money until they see the Government contribution but now, we're…talking about 47 Governments. So, the argument was to have Counties pool those resources together then Gavi puts the remaining bit. That has not happened to date [2016] by the way. It's been a tension going on back and forth and it's because, as the Swahili said *kiendacho kwa mganga hakirudi (what goes to the healer does not return"*. NL10

And;

> "…as it is, the Counties are still complaining that they are not getting enough money. So, if we are not getting enough money you want to take more money from us, in an indirect way, no. In fact, if you try to do that, that's the time they'll say let's just go and buy the vaccines directly which was one of the problems we had initially. That they thought they could go to India and buy vaccines, how?"NL5

The appetite by the County Governments to explore vaccine procurement had not been satiated, as will be presented in Chapter 7; the call for tenders for vaccine procurement were in process during the fieldwork (Appendix E).

Another aspect of the EPI that was seriously affected by devolution was the procurement of injection devices. Pre-devolution, antigens and injection devices (syringes, needles and safety boxes) were procured and distributed to the immunising Facilities as a package. Currently, the Centre procures the antigens through the procurement agent and leaves the injection devices to the Counties. None of the respondents knew for sure why the separation occurred. Speculations were that the procurement of injection devices is not viewed as a specialised function and less regularised than the antigens, and therefore one that the Counties could perform with relative ease. The County respondents felt this aspect should be the responsibility the Centre should be undertaking in making sure they provide a complete package that will necessitate vaccine administration. This parallel procurement system puts the Immunisation Programme at risk as instances were cited in which the antigens were available but no injection devices or the injection devises available did not match the number of antigens. In either of these instances, it would not be possible to administer vaccines.

5.3 Human Resources for Health

5.3.1 Staff transfer

The health workforce has been recognised by WHO as one of the essential components in a health system. A strengthened, motivated, dedicated, competent and empowered workforce is a cornerstone for providing quality immunisation services [135]. One of the main risks in organisational changes is high levels of staff turnover mainly due to

uncertainties over job securities. The staff transfer process therefore needs to be well handled to sustain staff retention.

The transfer of health workers into Counties and the overall public service management was envisaged in the 2010 constitution and the complementary 2012 Public Service Commission Act (PSCA) [136]. The PSCA created both the Public Service Commission (PSC) at the national level and mechanisms for the establishment of the County Public Services Boards (CPSB). The CPSB is the default employer of all public servants at County level. The PSC acts as the arbitrator for and overseer of the functioning of the County Public Service. In relation to the worker transfers, it was suggested it become established in law that at devolution any public servant performing functions being devolved will be assumed to be devolved to that County where they are providing those services. The respective employing departments were then expected to work out formal transfer of undertakings and protection of employment (TUPE) mechanisms to the CPSB as new employers.

Having agreed on the transfer of MOH staff into the CPSB, a crisis was soon to develop. For a period of six months, health workers went without pay for two main reasons: (i) the salary budget was too high compared to the actual numbers of workers on the ground and so Counties were hesitant to spend their money on it, and (ii) Counties had not established payroll management systems. The discrepancy between the salary budget and the headcount on the ground could be explained by the staff transfer system that used to happen pre-devolution. Staff were deployed or transferred from one facility, district or province but the national records were not updated to reflect the move. Additionally, the system was paper based and could take two to three years for the staff records to be updated.

> "So, for the next three years I would still be receiving my salary with my pay point as Kilifi Hospital [Kilifi County] and yet I had been moved to Kwale [Kwale County] then Kinango [Kwale County], then Taita Taveta [Taita-Taveta County] and even go back to HQ [Headquarters – Nairobi County]". NL10.

After protracted discussions moderated by the Inter-governmental Relations Forum (IGRF), an arrangement was reached that the MOH and the donors would fund three

months salaries each. The caveat to this arrangement was that the Counties would set up their payroll systems to take over the responsibility after the six months.

The oversight in this new law was the assumption that only one mechanism exists within which public servants are employed, a position contrary for the health sector. This study established that there were at least three mechanisms through which public servants were employed in Kilifi County: (i) directly by the MOH, (ii) USAID-MOH partnership, (iii) KEMRI-MOH agreement. The USAID-MOH partnership was initiated three years prior to devolution through a health system strengthening process. One issue they had identified was the need to strengthen the HR element through increasing number of health workers. USAID reached an agreement with MOH to match the numbers of health workers MOH would employ, and that over a three-year period, MOH would progressively absorb the USAID-employed health workers.

The end of the three-year period coincided with the advent of the County governments. By implication, this meant that the health workers were to be the responsibility of the County governments, because the National government no longer had a mandate over County staff. For many reasons, some Counties refused to absorb all of the health workers. USAID gave these workers three months' notice to terminate their employment, but that time lapsed, and the workers were still in employment. USAID then then gave the workers gratuities as they (USAID) continued negotiating with Counties. After a series of lengthy discussions, Kilifi County agreed to absorb the USAID-MOH agreement staff under its jurisdiction, while some other Counties disagreed.

The KEMRI-MOH agreement on the other hand was initiated around 2007 when KEMRI was approached by Gavi to undertake surveillance for the Immunisation Programme at the District (now County) level. The work was taken up as a collaboration with the MOH, guided by Memorandum of Understanding between KEMRI and the MOH. One of the activities of the surveillance programme was to capture data on vaccinations. Since MOH was already undertaking that activity as part of the routine Immunisation Programme, it was agreed that instead of setting up a parallel system, KEMRI would invest resources to undertake this activity, but in a

more systematic way. After a capacity assessment, the partners agreed to employ data clerks in all the immunising facilities within the DSS as well as to provide computer hardware and power sources for Facilities without electricity to enable digital data capture for vaccinations. The data clerks were employed by MOH on a contractual basis over a period to deliver on the project, with funding from KEMRI.

When Counties took up the health function at devolution the data clerk's employment was not formally transferred from the MOH to the County. At the time of fieldwork, it was reported that KEMRI and MOH were still in protracted negotiations on the same. Meanwhile, the staff remain in limbo; with no clarity on who their rightful employer is. This predicament is aggravated by the conditions they find themselves in.

> "... we do not have pay slips, we can't take time off… we are not pensionable… we're not County employees… we don't know whether we're KEMRI or not…that's how it is…we're struggling…" CL18

5.3.2 Staff shortages

Kenya as a country has been battling a shortage of health workers to a point of inclusion into the 'HR for Health Crisis countries' category developed by the WHO[137]. The health sector HR strategy 2014-18 [138] found low staff levels among the many challenges encountered within the HR for health in Kenya. Similar challenges were reported in this study. At the national level, respondents insinuated to high levels of workload due to staff shortages that had made it virtually impossible for them to take time off work.

> "…you'll find many people especially on national level we hardly go on leave. Just before you go on leave even when your boss is still thinking of releasing you or not, something comes up that you can't… always…*saa hii ofisi si yako* [you do not own this office] whether you are here or not this office will run. But then at a personal level you wonder is that actually possible because you feel like you are the one who is always doing…"NL9

At the County level, in most PHCF visited, respondents named staff shortages as one of the main impediments they faced in providing quality care to patients. Most of them had one nurse who doubled up as the sole service provider for the Maternal Child

Health (MCH) clinics within which immunisation services are offered. They reported high levels of burnout:

> "So, if somebody is overwhelmed during immunisation in that day he postpones... he tells [parents/caregivers] to come another day and you can imagine somebody coming from very far. Then you tell somebody come tomorrow not because you can't give but you're overwhelmed". CL15.

In some instances, staff cited long queues of mothers awaiting immunisation for their children and reported unfortunate instances where they had to send people home as they could not attend to them due to exhaustion.

> "…*si umeona msitari wote huo* [you've seen the queue]…*mtu unachoka* [one gets tired]. *Sasa wewe* [you] imagine, *ni mimi tu hapa mmoja* [I am the only one here]…*ni chanje* [I vaccinate], *nipeane dawa* [I dispense medicine], *nifanye* [I do] assessment, *niangalie mambo yote hapa* [I look after all affairs here]. *Jioni inakufikia na bado watu wasubiri* [it gets to evening and people are still waiting]. *Siwezi saidia kila mmoja* [I can't help everyone]" CL6

This poses the risk of an increasing rate of incomplete vaccinations, and the attendant health risks, as in the instances cited, mothers had to travel long distances to access the clinic, which reduces the chances of them returning later to access the vaccines.

The staffing problem at the PHCF manifested in trying to balance out staff absences. In some Facilities there were appropriate staffing levels, but numbers were insufficient on the day of the immunization clinic. There were various explanations given for this, including time off for training, annual leave requirements or sickness absences. The remaining workers were then spread thinly, having to address multiple demands:

> "…currently we have six nurses actually, but you can see [we] have only one on duty. One is night off, the other one is on duty. Just one is on duty. The others (4) have gone for training. You can imagine...she is having deliveries, giving immunisations and other things". CL15

As part of their innovative arrangements, some participants reported situations where support staff were brought in to help with the EPI delivery; including sometimes for sensitive tasks or vaccine administration. They justified this undertaking by stating

that they personally train the support staff prior to engagement. The engagement of support staff in EPI delivery potentially opens the door for errors and avoidable AEFI incidents as health workers at the Facility levels are not certified trainers and there is no system to validate or assess the quality of the training.

This study did however record positive steps by the County to address the health worker deficit, manifested through regular recruitment and deployment drives to balance health worker ratios across Health Facilities:

> "…there has been an increase in workers that offer services since devolution, the County has employed about 110-150 nurses over a period of three years".CL4
>
> And,
>
> "…understaffing has been a problem ever since [devolution] but at least no, there is some improvement. I used to be alone when I came here, but I'm glad at least this year February I got a colleague…still understaffed but is not as bad as before".CL7

5.3.3 HR Dilemmas

The Human Resources (HR) directorate at the MOH is responsible for the development of HR policies and providing capacity building to the Counties. They have developed a guideline for the Counties which calls for each County to establish an HR unit within the CDH. At the time of fieldwork, KCDH had not implemented it. HR, especially at the extreme end of the immunisation chain, is an important contextual issue because ultimately, they are the ones administering the vaccines. The terms of employment, their motivation and continuity are an essential component within EPI. The need for there to be a suitably qualified health worker available for administering the vaccines is just as important as the vaccine itself.

This study identified several HR dilemmas that were yet to be addressed. First, the employees that were transferred to the County governments had not received official letters confirming their employment status. The transfer did not include the benefits (like pension entitlements) staff had accrued. The Counties on the other hand did not receive financial allocation to cater for that need. To date, it is not clear who pays for

benefits accrued before devolution. A situation now exists where people are retiring without retirement benefits.

Secondly, responsibilities for workers' in-service training are yet to be clarified. It was not clear who would pay the salary bill for workers undertaking in-service training as the staff would be working in County Health Facilities whilst on a National level training. Similarly, when health workers go for specialised training, they are supposed to be on study leave, employed by the County Government but seconded to training entities belonging to the National Government. Debate on who is to be the rightful employer is still ongoing.

An area of concern raised by all respondents was salary increment and promotions. Since 2013, salary increments were frozen without discussion or communication with the employees involved. There was no clear cutoff point of when and how staff should be promoted within the County employment arrangements, something that was not the case under the National employment structures.

Finally, the workers employed by the County since 2013 and those absorbed through the USAID-MOH agreement were still on probationary terms with no immediate signs of it coming to an end. This is despite the workers' continued reminders, requests and or demands for their probationary contract to be reviewed. Due to the probationary status, workers claimed not to receive employment related benefits like training. As these quotes illustrate, there was a sense of exasperation and despair among the people affected

> "… like me am still there (on probation) I was supposed to be confirmed but I have not been confirmed…it's like you have to be going every time. You must follow up…there is no concrete reason…so it's a bit hectic".CL16.
>
> "…you know there are some benefits you miss out and you are due for and there is no explanation, like basic training, so it's a lot of things… it's a bit demotivating…what they say is that the process is a bit slow and tiresome, so we don't know what to do next". CL8.
>
> "…the issue of promotion, I've stagnated, been job group H for 7 years …it demoralise ... cannot access a loan if you're on probation and the [National Hospital Insurance Fund] NHIF [provides health insurance for people aged 18

years and above] is also another issue because you're not fully covered…the NHIF says, you're not eligible for the insurance because you're on probation… We don't recognize you…You are not an employee of the Government, I don't know what that means…we're not [on pension] …" CL7

Respondents narrated several efforts they had made in seeking redress, but even in this, they were yet to see any meaningful resolution. It was not clear to health workers on how their HR grievances could be resolved.

"We tried to follow up…they know everything that is going around they send letters. They say you forward your names; we have forwarded our names severally. So many issues, you know, we followed up, we followed up and we are yet to see anything". CL8

From observation and conversations with respondents and senior managers at the County Department of Health, there does not appear to be a remedial process in place that is clear to everyone affected.

"…you go to the Sub-County you are referred to County, you go to the County you are referred to the Sub-County... So, I don't know what's happening …we've had a very cold shoulder as far as the Human Resource is concerned. We don't get direct answers". CL9

Some respondents indicated that they were able to raise their concerns with the Sub-County Managers. From some of the meetings observed, the Managers on the other hand reported a state of helplessness and powerlessness to address the concerns. Other respondents noted that it was only the Workers Union left to address their issues from a general perspective.

"…we have raised the issues in the meetings, they're written down but there is no feedback…sometimes we even go (to their offices) and tell them (health managers) they are even confused who is to help you, now everybody is wondering, if them they're like that, what will we do?"CL15.

My discussions with key respondents and observations indicated that the County did not have a named HR person that health workers could approach to raise individual employment related issues. According to the key respondents, there was a lot of

duplication and confusion about who does what. The KCDH manages the HR function for its workforce. However, it is all seems that the KCDH is not very clear on what its role and mandate is as far as HR management is concerned. Within the County, there is a separate entity, a County Department of Public Service which is meant to have a role in managing the health workforce as part of the general County Public Service. The jurisdiction of this Department in relation to its responsibilities for HR management for all cadres of the health workforce is not immediately clear especially to the health workers themselves.

An additional complication is the existence of the County Public Services Board which is meant to handle HR issues for the County. The lack of clarity of the roles, responsibilities and mandate around HR management has led to a significant degree of confusion and frustration. There were reports of instances where some senior health workers were transferred to outside the KCDH jurisdiction or fired without consulting or informing the Department of Health. Such incidents illustrate the tension, confusion and lack of clarity regarding who does what. They also reveal the lack of clear communication systems across the SCHMTs, CHMT and the CPSB.

5.4 Summary

This chapter has shown the challenging context within which the EPI was operationalised. Firstly, the process governing the transition to devolved governments was affected by politics. County Governors were not included in the technical discussions on the transfer processes because they were not in office at the time the discussions were held. Upon assumption of office, the governors put a lot of pressure to the president which resulted in a presidential directive for an immediate transfer of all health functions. The directive was implemented with complete disregard for all the technical recommendations outlined in the Health Sector Function Assignment and Transfer Policy Paper. Secondly, most of the Counties in receipt of the new health functions did not have the Department of Health structures established at the time the functions were transferred. The interim structures existed without clear terms of reference or roles and responsibilities. In Kilifi County, appointments of senior leaders were delayed, leading to further delays in establishing the CDH. Thirdly, EPI was considered a service delivery function; a County function. All monies previously earmarked for vaccine procurement were sent to the Counties, as a consolidated

budget. With this process, the immunisation ring-fence was removed, nothing was left at the national level to fulfil vaccine procurement obligations. At the County level, all funds were recentralised to the County Revenue Fund, AIE rights were withdrawn from all structures below the County level. Processes to access money from the County Revenue Fund to the health facilities were not always efficient or straightforward. Core functions like vaccine procurement, training and supervision were adversely affected by the financial realignments. Finally, there were significant challenges in the management of transfer of the human resource function (also presented in section 7.6 below). All of these, inevitably, will affect programme performance negatively.

This chapter has also shown that devolution reconfigured the accountability mechanisms for EPI delivery. Whereas before devolution, accountabilities were a linear process, from the UVIS at the National MOH to the Community Units. Devolution disrupted the vertical nature of the programme, replacing with lateral and vertical accountability processes. The linear vertical accountabilities now only exist from the community to the County level and are replaced by lateral processes between the County and National level (see also Figure 9 and 11 above). The lateral relationship between the National and County level means that an efficient Immunisation Programme depend on a solid relationship between the two levels of government that cuts across political and jurisdictional divide. Reflections on the extent to which this relationship is sound or dependable will be featured in the following chapter.

Chapter 6: Key Result Area Two: Process

This chapter presents findings reflecting on the processes that underpin the organisation, management and delivery of the Immunisation Programme. The first two sections, 6.1 and 6.2, look at the interrelationship between the two levels of government: the National and County government. This provides necessary background information showing the complexity within which the EPI specific end-to-end processes (section 7.3) are operationalised.

6.1. Intergovernmental dependencies

The notion of governmental interdependencies is underpinned by the constitutional requirements for consultation and cooperation between the two levels of governments. These requirements are also guided by an act of parliament [139] which created structures to necessitate dialogue between the two at both technical and political levels. The main structure is the National and County Government Co-ordinating Summit, a supreme agency for intergovernmental relations bringing together the (National) President and the Council of Governors (CoG) chaired by the President and deputised by the chairman of the CoG. The CoG is a forum that brings together the 47 elected County Governors. At sectoral level, there are forums that bring together the technocrats and political leaders within the MOH. One of these is the Inter-Governmental Relations Forum (IGRF) which acts as the implementing entity for the health agenda for the Country. Study informants reported that the initial meetings of the IGRF forums were extremely tense because the National MOH staff were perceived as having a patronising attitude towards the Counties which was visibly resisted by the Counties. Interesting to note is that this inferred perception existed even though several of the County managers were the same people who had previously worked for the MOH.

The concept of consultation and co-operation between the centre and the periphery is of importance in the EPI programme. Ideally, it can create a seamless relationship between the policy makers and implementing agents, a factor that is necessary for achieving good health outcomes. It has the potential to contribute to ensuring the necessary structures are in place to support delivery, promote trust, enable efficient resolution of systemic impediments and act as an enabler to effective programme planning and delivery.

This research established that the pace and way the health functions were devolved did not create a conducive baseline for sincere consultation and cooperation. Firstly, the technocrats were not consulted on how the health functions should be rolled out, and since the County structures were not yet fully in place to effectively take up their new mandate in coordinating EPI delivery, one would argue that cooperation was not feasible. What followed immediately after the formation of the interim County structures was a stormy phase characterised by conflicts arising from perceived encroachment, suspicion, competition and distrust of either level of government.

> "…most of the time there has been a lot of antagonism for unnecessary reasons…if you give me a responsibility for making a policy for the whole country, I got to tell you what the policy says, and I have got to ask you to follow the policy. I'm not dictating anything. I'm just doing my job. But when you do that it is said you are not respecting the structures". NL1.

This was exacerbated by the fact that the structures governing the consultation and cooperation were not in place and the 'how' had not been ironed out.

> "…the political systems haven't fully embraced the idea...we're still in a tense phase…the governors were not very happy with the way they were being treated by the National government and they wanted to show that they are also powerful. So, they wouldn't want to discuss anything about decentralising power or resources to technical [people]..." NL10

However, in a manner seeming to map into Tuckman's stages of group development[140], early indications were that some form of normalcy on a technical level was happening at the time of fieldwork, albeit forced by circumstances:

> "…we've already gone through the major chaotic phase of talking at each other. There is a bit of more and more talking with each other now…colleagues can call their counterparts at the County level or the County directors and talk to them or talk with them and they would understand that we need to sustain the Immunisation Programme". NL10

An example was cited where a County had BCG vaccines but had not budgeted for syringes, so was forced to consult the Centre to find resolutions without which vaccination would not have happened, for example, as this participant notes:

> "So what is happening now, there is a lot more collaboration brought about by circumstances, because each [Centre and County] is realising now, they can't work without the other. So, that is happening much more forced by circumstances rather than by a real true intention of making laws that will make that possible…the breakdown in systems, the challenges, the gaps that have come up, have made it such that you must talk to each other…to make things work... ..Three years ago, there was all this scramble for resources, power, space… but over a time things fall into place and people realize, you know, look I took this on but it's impossible…can we get the next best person who is able to work on it. Things have got a lot a more cordial". NL8

6.2 Role and interaction between the Centre and Periphery

Organisational changes can potentially generate or intensify tensions within an organisation, fueled by uncertainties related to control, job security and power relations in the new disposition[141]. This study established that there were significant tensions across the health system that worsened with the speedy transfer of functions and health budget (including Immunisation Programme funding) to the County governments following the presidential directive (see 5.1 above). The tensions were manifested in accusations levelled against individuals, departments or the two levels of governments. The Centre was frequently accused of hiding behind allegations of incompetence at the County level in order to cling on to the power and resources they should have directed to the Counties (see section also 5.2/6.3.7 below).

A counter argument observed from some of the National level respondents was that the Counties are inexperienced, with little or no capacity to effectively deliver a successful Immunisation Programme.

> "…the thing is this, you cannot devolve everything because some of these responsibilities need highly trained and competent people each County cannot afford, and it is a waste of time". NL1

But the County respondents observed;

> "…you could see…elements of insecurity, lots of frustration that these County people don't know anything about these things, yet, the very people presently at the County came down from the Ministry. The very people. But the ones that are left claim they (County people) have no capacity. But which capacity

are we talking about? So, we were looked at as people who have come to work differently". CL3

Counties were in addition accused of being proud, insincere or blinded to their skills and knowledge gaps which contributed to their resistance to any input from the national level at the outset.

> "In the initial stage when County governments came on board, they were very straight and vicious to say no; we do not want any interference, we will manage our affairs; health is a devolved function. If you have anything, give us the money we'll do the part". NL7.

6.2.1. Role of the Centre in Special Immunisation Activities

Two areas presented as evidence of the Centre's clinging to power was the lead role, they played in the implementation of the Supplementary Immunisation Activities (SIAs) and managing disease outbreaks. By taking a lead role in coordinating the implementation of the SIAs and disease outbreak response at the County level, the Centre (UVIS) was seen to be going against the very notion of recognising the Counties' mandate as service delivery coordinators. By holding on to some of the functions they used to carry out pre-devolution, the Centre stood accused or guilty of muddling up the role of the County and Centre around the SIAs. The contestation of the Centre's lead role was also shared by some National Level respondents. One of them stated,

> "…I don't understand the national level will be trying to implement campaigns and go to the Counties and pretend that they are the ones who will train, who will give information…It doesn't make sense…we did almost 13 campaigns last year (2015) for Polio and most of the time it is national level guys who go there. Last month the Measles, Rubella and Tetanus. Even in the cases of disease outbreak, you find that it's the national level people who went there to evaluate what is happening or pretend that they would come up with an implementation plan". NL2.

According to some of the respondents both at the County and National Level disputing the Centre's lead role, the correct way would have been for the Centre to ask the

Counties to share their SIA plans for approval and funding. With regards to disease outbreak, the Centre should let the Counties assess and make recommendations, and then collaborate in implementation. As the National Level respondent quoted above continued,

> "…people are holding to power and money because if they were to give the money to implement it means the money would go to the County which the National level doesn't want to…they are still sticking to their old ways. They will even take people from the National to go and supervise areas they don't know" NL2.

The view in the quote above was commonplace in the discussions I had with County Level stakeholders whilst observing the Measles, Rubella and Tetanus SIAs during the fieldwork.

6.2.2 Clarity in Roles and Responsibilities

As with any complex reorganisation, the initial implementation phase is usually marred with lack of sufficient clarity of roles and responsibilities [4]. Clarity in obligations, roles and responsibilities is essential in conflict reduction and implementing quality Immunisation Programme. Clarity enables stakeholders to effectively input and manage the end-to-end process in the EPI chain. In this study, both National and County level respondents decried the lack of adequate clarity in individual and organisational mandates and roles within EPI:

> "…when you look at the bottom line for the challenges that is faced with the devolution, it's related to the different mandates and supervision of the different mandate, and the money".NL3
>
> "…we still have one of the biggest challenge is about clarity on roles and responsibilities between the County Government and National Government. There are still many elements of the programme that need to be clarified…the County still expects the National level to play a major role in some of these things [like printing of Mother and Child Health Booklet, Immunisation register]. Well, as the National level may not be doing that [printing]. Those are still concerns that will arise and they will continue to be a challenge".NL7

It was clear from some of the responses that individuals were conflicted about their previous role and how much of that should be undertaken within the devolved set-up.

The response below suggests that the national MOH has the ultimate responsibility to solve problems at facility level even though, post devolution that is a role that falls squarely on the County as health service delivery overseer:

> "…if for instance right now, there only about 60 percent of the total number of facilities across the county offering immunization. Of course, the ideal will be, every facility you walk in should be offering immunization. I mean maybe a facility has the right workforce but then maybe the reason why they are not immunizing is because they don't have the cold chain equipment then it's, it's upon us to ensure that it is, it is provided. Though right now, the procurement of equipment is a County function". NL9.

The EPI related mandates of the Centre and County were not immediately clear to many respondents. It was hoped that, given that the 2013 devolution of health functions had been anticipated since the adoption of the 2010 Constitution, key policy documents like the Health Bill 2014-2015 and the 2013 guidelines on immunisation would give a steer. This, however, has not been the case. The 2013 guidelines on immunisation clearly outline the role of UVIS in EPI, but it makes no mention of the Counties. A draft 2015-19 multiyear plan exists, touching on the role of the County and the Centre but mainly centres this on the challenges posed by devolution. The 2012 and 2015 health bills [19,20] are not very helpful in clarifying roles of the Centre and Periphery. If anything, the 2012 Bill seems to add to the confusion by stating that all procurement should be done through KEMSA with County governments reserving the right to do their own procurement, should KEMSA delay or not have the medicines/supplies the County needs. The Bill does not specify that vaccine procurement is in fact undertaken by UVIS through UNICEF, and that KEMSA only procures non-EPI vaccines or injectable devices (see 6.3.3 below for further discussion on this).

The fuzzy boundaries in EPI functions were depicted in the perception of responsibilities in the implementation of SIAs (see also 7.1 above) by the respondent below.

> "…most of the time we have had SIAs and even national campaigns. We had the polio campaigns, we've had the [Measles Rubella] MR introduction and MR campaign as well. So those ones have been managed from the national

level, because there was funding targeted for that activity. So that one has been easier because the money was available to be able to do that…So in activities where the money is available you find that you have better outcome, so for like the campaign we have had good outcomes, but in terms of routine activities we've had some challenges". NL3.

The quote above makes the argument that the SIAs have had good outcome because the national level has been custodian of the funds and oversees the implementation of these activities. An observation from the County was that the National level was overstepping its mandate by holding onto the SIAs funds and performing the County duties, an overlap which causes confusion in the overall scheme of things. This also makes using SIAs to strengthen routine EPI very challenging. The County respondents could not understand why, if their mandate was to coordinate service delivery, the SIAs were treated differently. One respondent quipped

"…are they not part of the overall KEPI goals?" CL3.

At the time of fieldwork, three years post devolution, tensions were still prevalent, albeit subtle. One of the strategies engaged to address the conflicts was an ongoing dialogue and continuous stakeholder engagement to bring everyone to the same level of understanding and expectations of the health service devolution. There was a sense of optimism that relations would improve soon, as one respondent put it,

"…in series of meetings we have been able to tell each other. Look yes, I don't know but tell me, I am willing to learn, but also don't be too rigid to continue saying I don't know, yet you are not telling me what I am supposed to do. So, I think it's getting better…it was quite an experience. So, I think even the next five years, things will be much better". CL3

Achieving clarity in roles, responsibilities and mandates is a basis to achieving a seamless end-to-end EPI process.

6.3 EPI end-to-end Processes

This section reflects on views on how the EPI end-to-end processes are panning out under devolution.

6.3.1 Planning for immunisation

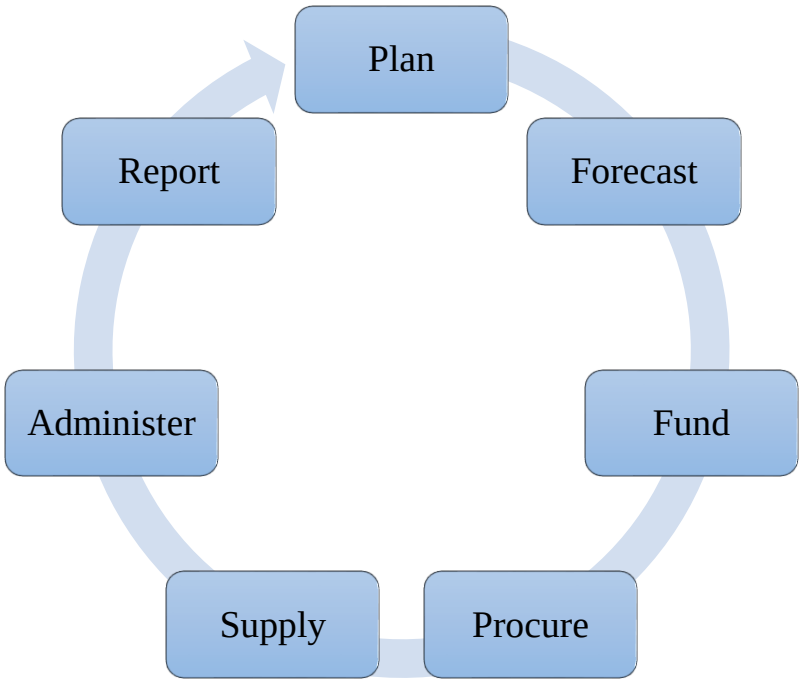


Figure 12: EPI Planning Cycle

As the adage goes, if you fail to plan you plan to fail. Planning is a cornerstone for an efficient and sustainable Immunisation Programme [142]. It helps to assess current needs, anticipate possible challenges and identify strategies to address needs and mitigate disruptions. As a standard practice, Kenya develops comprehensive Multi-Year Plans (cMYP) for immunisation based on WHO/UNICEF guidelines. The plans are sensitive to local priorities and international obligations. The implementation to the cMYPs is supported by annual micro-planning activities. Each health facility develops an EPI micro-plan which feeds into the Sub-County and County micro-planning activities.

In the devolved health sector arrangements, planning for and the provision of quality guidelines for EPI is a function of the Centre while planning for service delivery is a County function. Effective involvement of the two levels of government in the planning processes is fundamental to ensure that plans appropriately feed into each other. This study established that there had been little or no involvement of the County level in the development of the cMYP. The transformation of mind-set that would allow inclusion of Counties as key stakeholders in policy planning had not happened yet. Respondents felt they were being used to validate what had already been decided at the Centre without the Counties' input.

> "…especially EPI, you probably will be involved at the last minute, they would say come and validate this policy. Or we have new guidelines. Just the other day introducing IPV, we came in the last bit as in to say, yes you will call people for the micro-planning and all that, but this is a programme that is already given. Come to this micro-planning workshop". CL3

The lack of adequate involvement of the Counties was explained by the fact that the policies and guidelines in existence were formulated before devolution, and since these had a national outlook, there was no justification for involving Counties. Although seemingly justified, it is questionable whether the 'no need to consult, inform or involve Counties' position is sustainable in the wake of the new governments. Views from County level respondents expressed the desire for active involvement as this was perceived critical to their role as implementers:

> "That forecast and knowing the future is very critical for us…it's about funding…it's about the framework of collaboration. So, it's important for us because of the budget cycles, so that we are not caught mid-stream. We will be able to convince our executive into how we can plan because I couldn't imagine a situation where we stopped vaccinating because we don't have supplies. So that kind of knowledge, that kind of framework to know this is what we are doing because sometimes it's mid-stream then you are told 'oh we don't have funds' or 'oh these funds have come'".CL3

A significant development which affected future planning for immunisation was the announcement by Gavi that as Kenya is predicted to enter into a 'transition' threshold in 2021/22 (Appendix I) Kenya will need to increase their contributions for the New and Under-utilised Vaccines (NUV) over the next five years after which they would take 100% funding responsibility. This prediction was precipitated by the 2015 World Bank's reclassification of Kenya's economic status to a lower-middle income country due to its increased Gross National Income per capita. Discussion of the announcement was met by two, almost opposing views. On the one hand, some respondents believed Kenya would have enough money to take up the additional contributions and did not foresee any problems with continuing to support new vaccines. Other respondents felt that the forthcoming commitment would be huge and that the country may not be able to afford it. A point of convergence between the two school of thoughts is that there is

little or no planning for the transition from Gavi support, and that a lot of political lobbying is needed to secure and sustain the government's commitment.

Despite being major stakeholders in health service provision, at the time of fieldwork the County governments had not been involved in the discussions on Gavi's prediction. Respondents from the Centre felt this was a situation between Gavi and the MOH, the Counties had nothing to do with it, and therefore had no plans to contact the Counties to inform or discuss this issue.

> "What discussion? Counties were not to be told anything about graduation. It's not their problem. It's not is not the Counties' problem. What do Counties know about Gavi...?" NL5.
>
> "We've not had that discussion with County governments…the reason has been that they are not the ones paying for those vaccines". NL7

Some National level respondents feared the adverse effects Gavi pulling out would have on the Immunisation Programme. They noted that the situation pointed at a much larger problem: poor planning within the health system. These national level respondents stated that people should have been aware that Gavi support would not be perpetual and therefore some management planning for weaning off the support should have happened long before the announcement. But this doesn't seem to be the case, as this respondent noted:

> "We have a precedence. [In] 2002 there was a vaccine [Pentavalent]…funded by Gavi…free…we were not paying anything for five years. In 2007 Gavi said okay, it is time for you to pay. A big discussion ensued until the MOH said 'now we can't afford these things let's go back to our old DTP'. It was that bad but fortunately Gavi changed their policy [asked Kenya to co-pay], now we can, you can start paying a very small percentage. 20 cents of a dollar, then move slowly until you pay the price of about five dollars now, that's a huge cost". NL1

6.3.2 Vaccine forecasting

Vaccine forecasting is an essential tool in ensuring vaccine security. Accuracy in forecasting is essential in securing adequate funding and appropriate quantity of the vaccines. Under devolution, vaccine forecasting for all traditional and NUV antigens

for the country is the responsibility of UVIS but done in consultation with the Counties. The MOH works out the population projection then consults the Counties to check against their population figures and the desired coverage for the following year. Wastage rates are worked out on based on the data from the District Health Information System (DHIS), using WHO acceptable wastages based on the vaccine characteristics. The Centre then calculates and applies wastage rates, considers current vaccine stock levels, then settles on the final estimate figure to use for procurement.

The forecasting is done once a year based on projected target populations from the last population census, most recent being 2009. The Counties are also encouraged or supported by UVIS to do similar forecasting processes. However, as the following quote illustrates, the reliance on population projections in vaccine forecasting is not without challenges:

> "...we have taken them through the forecasting processes…realistically what do you think your coverage will be. They apply that. Then we, we also try to work out the wastages as they are within their Counties so that they can apply a wastage factor that is closer to what is the truth…we take what they give us, we compare to what we have projected as a National forecast. If there is a very small difference, then we stick with what we have…that becomes the forecast for the entire year". NL9

In fact, this research observed how the lack of consensus on figures during the MR SIAs impacted on the amount of vaccines allocated. In this case, the vaccines were allocated by UVIS based on the projections they had made on the population of a certain catchment area. The actual numbers on the ground, however, were much more than the projections. When the County requested more vaccines as per the 'real' numbers before them, the Centre refused to supply these as they were adamant the accurate population figures were as they had projected. Likewise, some projections for other catchment areas were much higher than the actual population, so these ended up having more vaccines allocated to them than were needed. Fortunately, this Sub-County had a good management system where they redistributed vaccines from over-stocked to under-stocked areas. Unfortunately, reports from other areas indicated that such re-distribution practice either did not happen or were logistically impossible to

implement, meaning that it is likely that some children missed out on the vaccinations.

6.3.3 Vaccine Procurement

Roles and responsibilities in vaccine procurement

The process of acquiring vaccines is a highly specialised function that needs a good understanding of procurement structures and processes, market dynamics including pricing, among other factors. As mentioned above, there are three main clusters of vaccines procured in Kenya: traditional, NUV, and non-EPI vaccines (those that are outside the routine immunisation schedule, such as anti-snake venom, typhoid, anti-snake and yellow fever). The overall responsibility for vaccine procurement lies with UVIS, who procure all the three clusters of vaccines. The Counties on the other hand procure the non-EPI vaccines. There are two main avenues through which vaccine procurement occurs: (i) traditional (Measles, BCG, Tetanus Toxoid and Polio) and the NUV (PCV, Rotavirus vaccines, Rubella, Pentavalent and Yellow Fever) through UNICEF, and (ii) non-EPI vaccines (Hepatitis B, Typhoid vaccine) including biological sera (anti-snake venom and anti-rabies antibodies) through KEMSA. The UNICEF procurement pathway is governed by a Vaccine Independent Initiative Agreement (VIIA) between the Government of Kenya (GoK) and UNICEF, whilst the KEMSA procurement is dictated by public procurement systems. The Counties, however, may choose to procure the non-EPI vaccines through avenues other than KEMSA.

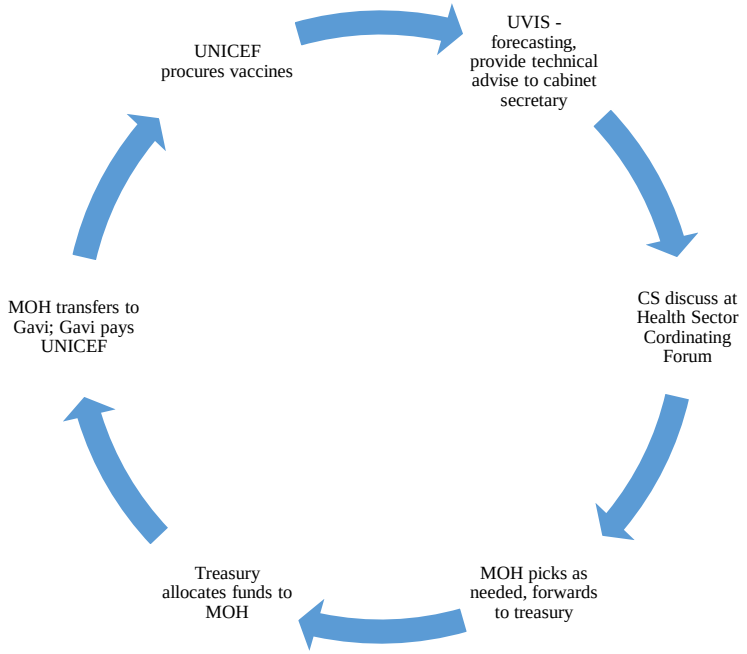


Figure 13: Financial agreement process

Although the Counties are of the understanding that they are not able to procure traditional vaccines as they are not party to the VIIA, the study established that the Counties were exploring other avenues of procurement for these traditional vaccines (see Appendix E). The move was viewed by some County level respondents as a test for independence from the National government, and justified by the provision in the 2012 health Bill [19].

> "We are planning to buy our own vaccines. And that plan is there…I even got the quotes for the vaccines".CL5
>
> "…Kilifi is also a government…so we are in preparation for the long term, preparing to import vaccines. Though it is the long-term strategy. The tender currently…out is competitive…this is more of a pilot for independence". CL12.

Some County respondents felt the move by Counties to procure their own vaccines was quite premature, since the Counties do not have the relevant procurement systems for quality assurance. They were however open to the prospect of joint procurement with other Counties. As one respondent expressed;

> "…it is managing the bulk supply within the chain and being able to have the quality, so that you don't have variations. I mean strictly if you have variations, especially in the antigens, we are likely to witness a lot of problems. So, unless it's a modality of Counties coming together, still, maybe identifying an agreed chain of how we are going to do the ordering. It's still okay, if it is managed centrally, so that we get the value and for economies of scale..." CL3.

Some national level respondents felt this move was risky, as they felt the Counties did not have the necessary infrastructure to undertake end-to-end quality assurance of the antigens, and that the move would also expose them to price manipulation;

> "…one of the problems we had initially, they (Counties) thought they could go to India and buy vaccines. How? If they are going to procure BCG, they will not get it because here is the problem, the manufacturer of the vaccine does not, as in the only reason that Kenya is a big enough deal for them to even consider, is because we are buying in millions of doses. If you're going to buy 10,000 doses, they will stop paying attention to you. In fact, they will even triple the money". NL5

One of the national level respondents was not dismissive of the move by the County government to explore procurement but suggested instead that part of the National Government capacity-building mandate should be about relinquishing responsibilities, including procurement.

> "So, that is a good arrangement…opening up that space". NL1

The respondent was, however, quick to warn that issues around quality of the antigens and price manipulations due to limited bargaining power need to be put into consideration before any procurement move was actioned.

From the interviews, it was apparent that the Counties' desire to explore its role in vaccine procurement was actually not new. As one respondent put it,

> "At the time of devolution all Counties were required to do procurement…they initially started making plans to do that. So of course, the things like documentation tools, the injection equipment, the consent equipment, the Counties are supposed to procure but then they got to a hitch they couldn't

> procure the vaccines. Because the vaccines are procured through national agreements with the vaccine's independence initiative agreements with UNICEF or procured through agreements with the Gavi, for Gavi supported vaccines". NL8

The Counties did not have agreements with Gavi or UNICEF, and the view from discussions with respondents at both National and County level was that Gavi and UNICEF would not be willing to sign agreements with 47 Counties. Further correspondences with Gavi respondents supported this viewpoint stating that it would be unprecedented for Gavi to consider formal arrangements with sub-national governments.

Changes and challenges to the current procurement arrangements

One of the changes that has come in with the devolved arrangements is the establishment of parallel procurement systems for the traditional vaccines. Before devolution the antigens and accompanying injectable devices (syringes, needles and safety boxes) were procured as a package by UNICEF to UVIS. Under devolution, the antigens are procured by UNICEF through UVIS and to the Counties, meanwhile the injection devices are procured by the Counties through KEMSA. This arrangement poses a risk to the Immunisation Programme as expressed by the respondent below.

> "Pre-devolution all those things were coming together as a package. The risk with the current parallel system is that you'll have vaccines, you don't have injection devices, or you have injection devices which are not matching the amount of vaccines". NL7

The changes to immunisation funding also affected the procurement systems. In early 2014 there was confusion about who would procure vaccines since all health funding had been fully devolved and nobody was able to agree on whose responsibility it was to pay for those vaccines. The situation was exacerbated by the parallel procurement process which created conflicts in perceptions of budgeting and responsibilities for vaccine related commodities, with resultant delays in procurements.

> "…procurement for injection devices: syringes, safety boxes, etc. is creating a problem…because now people know that vaccines are bought by the national

> level, the County think that injection devise procurement is to be done by the national level yet they have the money for it. So, what we are experiencing now is a lot of shortage, stock-out for these commodities. We have had stock-out for vaccines."NL1

At the time of fieldwork however, discussions with key informants indicated that Counties are increasingly becoming aware that it is their responsibility to make provision for the procurement of the injection devices.

6.3.4 Supply Chain and Logistics management

A seamless end-to-end logistics management system is essential to ensure a high-quality EPI. This includes efficient cold-chain management in the storage, handling and transportation of vaccines from supplier to immunising facilities. The responsibility for maintaining the logistical chain for EPI is currently shared between UVIS and the CDH. UVIS receives scheduled shipments of vaccines and stores them in the KEPI national vaccine stores in Nairobi which are housed by KEMSA. UVIS then allocate and distribute the vaccines to regional KEPI depots through a local delivery agent. It is the responsibility of CDH to manage the movement of vaccines from the regional depots to the immunising facilities. From the regional depots, vaccines are transported and stored in Sub-County KEPI stores. From here, the Facility-In-Charge (FICs) requisitions the Sub-County focal person and then either gets vaccines delivered to their facilities, or they are asked to make their own arrangements to collect the vaccines.

The study established significant challenges in the logistics management which puts the quality of vaccines and the EPI at risk. The standard vaccine collection policy is that Sub-Counties should collect vaccines from regional depots every three months, with the expectation that their Sub-County store is able to hold three months' supply. A few participants reported that the supply chain regulations are not always adhered to, and that some Sub-County health managers chose instead to visit the regional depots at their convenience. This was said to violate supply chain rules around maximum stock levels in Sub-County stores and frequency of vaccine restocking, which ultimately affect planning:

> "…there is the one that will come every month because they don't have the storage capacity. But we have our own weaknesses in the system, you'll find that someone has just come to town and just decided to visit the KEPI store to collect vaccines…".NL9.

A major challenge that was reported by many County level respondents was the inappropriate, or lack of, means to deliver the vaccines to the immunising facilities. Respondents were of the view that before the devolution resources were readily available; a specific vehicle was earmarked for the distribution assignment. Post devolution, health workers must innovate. This ranged from relying on public transport, requesting vehicles from partners (particularly KEMRI) or using motorbikes to get vaccines, issues that are likely to lead to geographical inequities:

> "…there was a vehicle which used to go around, distributing the vaccines, but as it is now, the County is still complaining they lack transport, inadequate fuel… So, most of the time when we are running short of the antigens then we must go…we must send a casual, who will go by public means to go and collect the vaccines…alternative is that, we have an ambulance here. Once it's transporting the drugs from our facility to the County Hospital we use that opportunity to go and lobby for these vaccines…or…we have the staff [from the County headquarters] who come to the facility every Monday or Tuesday, so, sometimes we call them to carry the vaccines for us". CL9

In as much as the health workers are forced to use public transport to bring in vaccines to their facilities, they are very aware of the risks this has on vaccine potency:

> "Also, according to the KEPI regulations, you are not supposed to carry vaccines in a public transport. You can imagine with changes of weather... So, if we can carry the vaccines from the County offices, to here, then it means you may in way expose these vaccines to extreme temperatures…" CL9.

Allied to the supply challenges were the stock outs reported at immunising facilities. In as much as vaccines were available at the Sub-County stores, some health facilities reported stock outs at facility level as neither they nor the County level managers could get vaccines delivered on time:

> "…currently at our facility its nil…they tell us they don't have transport, so we wait…" CL7

A necessary ingredient in ensuring uninterrupted and quality end-to-end supply chain is the maintenance of a functional vaccine information system that makes data visible from the facility to the national KEPI stores. Currently, once the vaccines are dispatched to the Sub-Counties, there seems not to be a centralised system where people can input quantity of vaccines received or utilised at Sub-County level. The challenge around the lack of up-to-date vaccine stock levels from the Counties may mean that the national level is not aware of the amount of the individual vaccine available in the depots at any one point in time, and so fail to anticipate how much time will lapse before stocking out. According to the respondents, stock visibility was also an issue pre-devolution, but one was able to move stock around fairly easily as everything was organised by the Centre, and it was therefore easy for them to pull stock and equipment and move it around. There are efforts being put in place to automate the stock ledgers at the Sub-County KEPI stores into electronic systems. Hopefully, when completed, stock levels in each KEPI store will be visible to the immunisation coordinators at the Sub-County level and the national logistician at UVIS.

Cold chain

The efficacy and potency of a vaccine depends on compliance with the manufacturers' recommended temperature requirements from storage through transportation to the point of administration. Several threats to cold chain compliance at the County level were observed in this Study, many of which were reported to have been exacerbated by challenges brought by devolution. According to one national level respondent:

> "…the funding for cold chain is hit and miss…cold chain logistics has been affected a lot, the amount of money available even for repairs, maintenance, isn't there because it disappeared and the national doesn't have it". NL5

The Study established that provision of electricity at most immunising facilities is intermittent, characterized by frequent power outages. In the event of electricity outage, the facilities use either gas burners or generators connected to vaccine refrigerators to maintain required temperatures. There were reports of frequent fridge

breakdowns and a rather untimely and laborious repair process. The process begins with reporting the issue to the Sub-County focal person and the County maintenance department. The maintenance department would visit the facility to verify the fault then arrange for repair or replacement. The time from reporting to repair or replacement was reported to last for months at times, without the attainment of the desired outcome. There were instances cited where workers had to continue using faulty fridges, especially where the repairs or replacements were taking longer than anticipated:

> "...we've had a challenge with the KEPI fridge. It has not been in order (broken down) …maintenance month after month, month after month…we ferry them to another facility then we pick them in the morning ".CL15.
>
> and,
>
> "…basically, the fridge … it's a bit faulty…we are using the gas together with electricity…there is a lot of blackout in this area, so when the electricity is gone and it's only the gas the temperature tends to misbehave. So you have to be very keen with the temperature so that if it's not in the normal positive two to positive eight, you have to put them in the vaccine carriers then when the electricity is back... so it's a bit cumbersome because the fridge is faulty". CL16

The transfer of vaccines into and out of the portable vaccine carriers was seen to be cumbersome especially in facilities that had only one person responsible both for the immunisation and delivery of other services within the facility. It was also reported that the at times the vaccine carriers were not enough to stock all routine antigens. This runs the risk of vaccine wastages and stock outs due to lack of storage:

> "…another challenge is the stock outs because a child might need some vaccination which is supposed to be due…but the refrigeration when it's faulty, I can't [don't have the required vaccine so can't administer to the child]". CL16

To facilitate an efficient cold chain management system, UVIS has developed standard operating procedures to guide health workers at the immunising facilities on what steps to take to ensure vaccine potency as well as get the faulty equipment fixed or replaced. Efforts have also been initiated by the Centre to develop and implement a

‘replacement, expansion and maintenance plan’ that would guide the CDH in their cold chain procurement processes. The ambition is that the CDH can use the plan to advocate for funding from the County leadership. Within the plan would be details of how to forecast the amount of equipment to be replaced, maintenance measures for equipment longevity, spare parts needed for repairs, as well as the operational processes to ensure correct temperature monitoring. These comprehensive plans will be tailored to the Counties’ requirements. It is informed by an exercise that was conducted assessing the number of fridges available nationally, including their functionality and age. Auxiliary to these plans are the efforts by UVIS to implement a real-time cold-chain monitoring system:

> “Basically, if an equipment breaks down, then they (Counties) should be able to update it in a system that at National level we should see this equipment was not working for this number of days, it was repaired and it started working, you know…we want to gauge the downtime of equipment…”NL9.

This would then enable UVIS to interrogate whether the facility was administering vaccines during the ‘down-time’ as well as understand what measures were put in place to ensure the safety of the vaccines at that time. Although a noble undertaking, the plans do not appear as being developed jointly with the Counties and so run the risk of being interpreted as an imposition and their adoption at the Counties may be resisted, as depicted in the following quote:

> “Now, this [plan] is what we’ll give them and then if there are going to be any tools related to it, then we, we will have to sensitize them on those…we continuously come up with ways to improve the system”. NL9

The potency of vaccines at the point of use is critical, and yet the challenging environment within which vaccines are transported and administered at the County level poses significant risks to vaccine effectiveness. I had the privilege to observe a SIA during fieldwork. I was invited to planning and training events as well as site visits to immunisation centres, which were either at primary health care facilities or outposts, mainly primary school buildings. I accompanied health workers (from County level, National level and EPI stakeholders) undertaking supervision visits. I saw vaccines loaded into storage boxes (cold chain) and ferried by motorbikes (bodaboda) or KEMRI-acquired vehicles. There were reports of incidents where the

storage boxes opened in transit for a number of reasons. In some of the immunising centres, we found some boxes that had been left half-open for long periods as immunising staff were busy vaccinating children in long queues. Some antigens had been mixed with diluents beforehand, but the actual administration took longer than the duration prescribed. The supervision managers remedied the situation by declaring wastage on antigens whose potency was potentially compromised and re-briefed the administrators on the importance of ensuring maintenance of the correct temperatures. I then raised this issue with the immunisation coordinators at the planning, briefing and de-briefing meetings held daily, which they committed to solve accordingly. All in all, the take home message for me was that significant cold-chain breaches were apparent, health workers were operating under difficult environments that made continuous and high degree of cold-chain maintenance an arduous task. These challenges to cold-chain management existed pre-devolution but are exacerbated under devolution.

6.3.5. Data management processes

Accurate, timely and complete records of immunisation data at the point of delivery are an essential planning and monitoring tool. They help attain complete vaccination in children and indicate the necessity of timely action for targeted campaigns, disease surveillance and monitoring adverse effects following immunisation. Coverage data also help in monitoring immunisation efficiency and effectiveness over time. Documenting vaccination data is a County function as it takes place at the point of care, typically at the health facilities. The data from the immunising facilities are collected and integrated into a single source and reported upwards (immunising facility-Sub-County-County- to National level). Their interrogation and utilisation shift upwards or downwards dependent on the need. At the National level, data are used for forecasting and quantification while at the County level, the data are mainly used for monitoring performance.

Electronic health information systems (EHIS) that incorporate immunisation elements exist in Kenya, but with significant limitations and variations in their use [143]. Currently, data capture in Kenya is primarily done manually using a Standardized Paper-Based System (SPBS) and the EHIS is limited in the sense that it does not have

all the data components which exist within the SPBS. The quote below outlines the data capture process (SPBS tools are italicised):

> "The clients come to the facility, they pass through the weighing bay, where the child's weight is taken, *plotted in graph* and the [Ante-Natal Child] *ANC booklet*. After that, the child is screened for eligible immunizations is sent to the CWC room where immunisation is given…after that, they are documented in the *permanent immunisation register* which basically records all the immunisation given to the child and the date. Then, they are also tallied in the *daily immunisation and vitamin A tally sheet* and also they are *documented in the ANC booklet* so that then if the child comes in another visit, somebody will be able to know, during the last visit he got this and this, today is due for this. So, and again now, they do that on daily basis…at the end of the month we do a cumulative, of all the immunisation which were provided in that specific month before we submit the report to the Sub-County level. So, another copy remains at the facility for filling, so that then it can be used for future reference and analysis and decision making and even planning". CL17

However, even the SPBS has the potential for recording potentially inaccurate data. One practice observed during this study that has the potential of affecting data quality was the reliance on parents' ability to recall previous vaccinations which were then used to update the booklet accordingly. This observation was made at one of the immunising facilities whilst awaiting to undertake an interview, where a parent was interrogated to confirm if, and when their child had received vaccinations. This practice was noted in interviews with other respondents as reflected by one respondent in the quote below.

> "So, when they come to access the services, sometimes we go back to the booklet and fill the gaps…if the booklet is still with the mother you sign (confirming receipt of vaccinations based on mothers' recollection". CL18.

A variation to the SPBS is within the KEMRI supported vaccine clinics (see section 3. above) that have data clerks equipped with laptop computers to enter immunisation data into the Vaccine Monitoring System (VMS). This, however, is done as complementary to the SPBS. KEMRI supported facilities reported a lot of efficiency in the data recording, particularly in the reduction of paperwork, however, the repeated

and frequent power outages were reported to cause a lot of inconveniences for using the VMS, in that:

"…sometimes must sit, wait for electricity". CL15.

But, in these moments, it was reported that people reverted to using the SPBS which they later transfer to the computers once power was restored.

Monthly data from the Facility are entered by staff and the PHCF into the District Health Information System (DHIS), an electronic data warehouse used for all health programmes in Kenya. Once in the DHIS, data are visible and accessible to KCDH and the UVIS. Data entry is done by the immunising staff but there were instances where support staff were called in to help. A major challenge reported in the data recording system was the frequency of missing records in the permanent registers and the ANC booklets:

"…missing the information of some children that's the major thing". CL18.

In order to identify and remedy any data quality issues, data quality audits are supposed to be undertaken as a standard practice. Discussions with key informants suggested that, at the time of the fieldwork, data quality audit had not been undertaken for over two years. In addition to the missing data and recall bias reported above, these discussions revealed other problems that affected data quality. Poor coordination between the person administering the vaccine and the recording officer, daily aggregate of tallies by staff who are otherwise tired, double counts or no records for vaccines administered, caregivers presenting without cards or booklets, low numbers on staff who have to multi-task in the Mother-Child-Health clinic were among the problems raised.

County level participants reported significant underutilization of data. This may signify a skills or capacity gap. Once in the DHIS, it is upon the FICs to actively engage the data managers to interrogate and utilise the data to assess progress and improve on their performance. This however, failed to happen as a common practice. It was implied that the health managers at the KCDH did not fully recognise the need for this undertaking:

"…my observation is that we generate a lot of data, very good data. But then after we send it to the data manager we have finished our duty…after we have

done all that, we have compiled, we have gone there, we have received all this data we compile it on monthly basis, so I am finished, I am waiting for another month to compile. So that one has been there of which is not right because we must generate data and then we go through it, utilize it so that it can inform us of the other actions". CL13.

6.3.6 Performance Management

This study established that a comprehensive performance management system was existent at the County level with targets set at each level from the County, Sub-County to the immunising Facility level. Each immunising facility has monthly immunisation targets set by the Sub-County health managers based on the population estimates within the catchment area. The targets are monitored through the records in the immunisation registers and mother/child immunisation booklets. Mechanisms to increase uptake and reduce defaulters are in place, which include regular briefings/health education sessions for the mothers/guardians at the MCH clinic. Immunising staff and data clerks help identify defaulters. The CHVs and CHEWs are then engaged in 'defaulter tracing' which includes visiting the child at the last known address. When a specific need is identified, the health facilities organise outreach events to take immunisations closer to the people.

Each PHCF has a performance appraisal form with the two indicators that they record their performance against: number of fully immunised children and number of children vaccinated against individual antigen. The review of performance recorded on these appraisal forms is done on a quarterly basis. The individual health workers also have quarterly individual appraisals which include discussions on immunisation performance. Some health facilities also hold monthly meetings with their staff to review performance. They also set their own targets on top of what they receive from the County.

> "We have targets we have set. But there are those we are given from the County at the beginning, depending with the catchment population. But sometimes we find the catchment population it's kind of higher and sometimes it does not go with the line with what they are conducting. So, sometimes we set our targets though we still use their targets". CL8

Performance targets are also assessed and reviewed either individually through support visits to the facilities, or collectively in monthly managers' and FICs meetings. In the FICs meetings, the immunisation focal person gives an overview on progress of each facility. Discussions centre on number of children fully immunised, as well as the total number of children across the different antigens. The meeting acts as a forum to share the performance related challenges across all the facilities as well as discuss the way forward.

Among the strategies to improve performance is opportunistic approaches in identifying and immunising a child that missed out on vaccines. When a vaccine eligible child presents for health services, the health workers examine the mother/child booklet to see if immunisation is up to date. If any is missing, the child is referred to the immunising staff who administers vaccines on consent before the child leaves the facility. Other innovations noted in the study were instances where health workers would piggy-back on other programmes to offer immunisation services or offer incentives to parents ensure their children that are fully immunised.

Strategies to overcome vaccine hesitancy were also prevalent. From observation, it was apparent that some feared vaccinations due to perceived AEFI or potential side effects of the vaccines. Rumours were rampant about the AEFI some of which resulted in untimely deaths. Use of multiple media platforms and stakeholder meetings were some of the mitigative measures employed. I observed an incident in Kilifi County where a priest at a Catholic-sponsored school refused to have the establishment as an immunisation outpost nor get any of the children vaccinated in the Measles-Rubella-Tetanus (MRT) SIA. In a period preceding the MRT SIA, the Catholic Church in Kenya contested a maternal tetanus vaccine after a laboratory test (the Church had commissioned) suggested the vaccine induced antibodies in women that could lead to infertility. In response, UVIS developed a national strategic vaccine advisory council, including faith leaders, in future vaccine decision-making. National level informants indicated that the Church did not send its representatives in planning for the national MRT SIA. During the MRT SIA implementation, the Church issued a directive to its Church-sponsored schools to boycott. In compliance to the directive, the priest at the school was perceived as being difficult. The situation was quite tense; the stand-off could potentially influence other establishments to withdraw their consent. Through

conscientious and astute leadership of the then SCMOH health, a meeting was held with the priest. An agreement was reached whereby an immunisation outpost was set up outside the school premises, and children were vaccinated on their way home.

6.3.7 Supportive supervision

Supportive supervision is a popular performance improvement tool within the health sector founded on the principles of mentorship, two-way communication and inclusive problem-solving approaches [144,145]. It promotes supportive guidance and regular contact between health workers and their managers. It stimulates a conducive environment for the development of professional competences and ultimately, effective service delivery.

Supportive supervision within EPI is classified as an operational function, hence, a County mandate and therefore not resourced at the National level. Interviews with a few National level respondents indicated that the function was so crucial and that UVIS was finding a way to provide the service somewhat, mainly through integrating it into other programme elements:

> "There is gap in supervision because it's not supported. So, [UVIS] utilise opportunities for training, for vaccine introduction and many others to carry out supervision. Most Counties don't plan for or budget for supervision. So, you really are forced to, to either an integrated supervision, in the few places when it exists or let it just die its own death because then you'll not be able to do a standalone kind of thing". NL8

and,

> "…cannot remember the last time supervision was done as in supervision dedicated without riding on other exercise…it's been a while mostly because of funding but it does not stop the National level from playing its role of the technical support which includes supervision". NL9

Views from these National level interviews suggested that if UVIS failed to take active supervisory roles, activities like immunisation campaigns would not be delivered well and so they were justified in making this intervention. The fear of things going wrong was used as a justification by the Centre to exert control over the SIAs.

> "You have a strategy that you must implement, you're told, you shouldn't supervise because they are supposed to be an independent entity but we're introducing a new vaccine. So, if the national people don't come and join your team and come up with a strategy that works and, and work plan and everything, teach people, you miss out on that. So, if you are to follow strictly the law, the national policy... the County level person is not going to be supervised by an independent entity but if they do not go, then the vaccine administration and everything goes haywire. So, then you're forced into a situation that you know, despite what the law says, you must make this work".NL8.

In as much as there may be good case for UVIS's involvement in supportive supervision by virtue of their role in providing technical support, the approach would be better if it encompassed sustainability aspects in its design. This could be in working closely with the CDH in sensitizing and building their capacity to undertake the role.

Interviews with County level respondents, especially at the Outer Periphery, indicated that the supportive supervision mandate at the County level was not being appropriately executed. Most of the interviews and discussions in meetings I attended indicated that the function, like many other operational aspects of the programme, had not been funded since devolution. There were no financial resources to support the supervision visits. According to one respondent,

> "…people would vaccinate nobody would even come and see whether they are doing the right thing or not because of lack of funding for operations". CL4

According to many respondents, supervision was left for health managers adept at muddling through to find ways to carry out the function. The frequency of supervision visits to PHCF were said to be erratic and those that happened were dependent on other health programmes, as reported below:

> "…of late have been complaining of transport. So, most of the time you just see a supervisor just comes just because they have been sponsored by another organization to carry out a survey…" CL9

> "…they come but it's a bit reduced and sometimes they tell you there is no vehicle to come, not like before when this was frequent…. sometimes you even stay for two months three months you don't see anyone...". CL16

Another key issue affecting the appropriate implementation of the supportive supervision is the technical knowhow of the supervisor on the issue in question. Responses from some County level participants indicated that some of the managers undertaking the role could in themselves benefit either from training or support. These managers were not trained or lacked in-depth knowledge of the technicalities of managing the EPI. Their visits were therefore reported to be less-helpful as shown in the quote below.

> "…it's not helpful because…in some cases, they come, they find that some louvers are falling off, they tell you repair these louvers. They see my chair hanging causing me backaches, I'm almost falling off, I'm here 24/7, but they say buy this chair, how do I purchase the chair? Using my own cash or from where? They see I'm having this problem at least they can source for help especially for repairs, instead they order do this, do this" …we need to be supervised and to be helped. Not to tell me do A, B, C, D and you very well know I cannot do it …" CL6

Views from some National level respondents indicated that inadequate skills, competing priorities and demotivation were among issues that could explain less productive visits.

> "…you may find the primary objective of that supervisor being there may be totally different, the SS issue is raised as an aside. So, this person doesn't have a lot of time to really fight for that aspect of the programme. There is also demotivation of health workers…let's say we have a fridge that is broken down, you need spares to get it fixed… you have written to the supervisor, the supervisor on his own would advise on the maintenance but cannot implement. He must reach somebody else at the higher level...if he is not getting the necessary support, then everybody down the chain feels very frustrated". NL8

6.3.8 Training

Appropriately skilled and qualified staff are a key determinant for an effective immunisation service as it ensures safe administration of vaccines and reduction of wastage. Moreover, in a population prone to vaccine hesitancy or indecision, a knowledgeable professional is better equipped to re-assure people on vaccine safety thereby increasing uptake. In the context of a health system change, training becomes even more paramount to ensure people entrusted with new EPI responsibilities are well equipped to deliver on their roles.

Training mandates

It is particularly unclear where responsibility for training in EPI lies. Within the end-to-end EPI process, it is not clear where the County function stops or where the National role sets in. In the wider scheme of things, training is seen as an operational function, and therefore a County mandate. But the MOH feel they also have a role especially when introducing new vaccines, rolling out SIAs, or presenting changes to EPI:

> "…say you're introducing a new vaccine; you're just not going to get a drug out there and give people to start injecting. You have to develop a training package, you have to develop a training plan right from National level because not everybody at National level knows, and so then you have to get trainers in the Counties, bring them up here to Nairobi and get them to have the capacity. Then these [County] trainers, they cascade the training to the low level [Counties, Sub-Counties and PHCF] …".NL8

Some of the national level respondents saw their role as that of capacity-building and providing technical training to the County managers. They cited activities initiated by UVIS, namely joint forecasting and planning initiatives or stakeholder advocacy meetings as evidence of where and when they should be implementing their training mandate. The stakeholder advocacy meetings were held with CECM, COH and other senior leadership and were aimed at sensitization to the programme needs in order to achieve successful implementation. According to one National level respondent these training activities have been successful in enhancing capacities, facilitating better communication and significantly reducing the level of confusion about the system changes.

"…when we realised this is how it's going to be, we said let's do joint forecasting so that we can teach these guys how to plan…plan together so that, we can of course, have our bit which we are going to send to UNICEF but they can also have theirs that they can table to their superior".NL9

and

"…and this has worked because initially you would find Counties buying domestic fridges saying a fridge is a fridge after all. But then through those advocacy meetings, things seem to have changed. There's one County that bought 100 cold chain equipment for the facilities that didn't have and it's because someone was able to say there is these facilities in this catchment with this target, if we don't [provide] equipment then these children will go without vaccination".NL9

Training need

This study established that County managers given EPI responsibilities were not sufficiently trained for their new roles. One of the EPI planning events I attended at the County level identified a few training gaps. Only three people across the County had received EPI middle-level management training provided before devolution. EPI specific skills around forecasting, budgeting, data interrogation or influencing were reportedly lacking among managers at the County level. Allegedly, the new nursing curriculum implemented at the technical colleges was outdated. Newly qualified health workers were thereby deployed to health facilities without EPI technical know-how. Poor attitudes of the trainees were reported to hinder effectiveness of job-placement training provided. Other training needs identified were in HR functions; managers not trained in HR were currently undertaking HR functions. The 'health systems managers as business leaders' was identified as critical training need in the devolved setting.

The EPI training need for Counties was also identified by some National level respondents:

"[With devolution came] …change of guard…health workers were moved around…the right technical skills were moved. Meaning you get new people, either the management level or at the health facility level and some of those particular persons were new…they were not trained on the same and they do

not have the depth of knowledge required to run the Immunisation Programme". NL7

"…we have people but we don't have the enough competency…the ability and attitude of the people…when you run a programme like this, you are basically a decision maker, you are a manager…a leader in many things… to make everybody think the same…the soft skill not the hard science that skills is what lacks …". NL1

"At the national level we don't care if Kilifi Sub-County hospital has immunised 20, we just want to know how many did Kilifi immunise and what is their target…if you're seated at the County you can actually tell which facilities are not bringing in your numbers and can even narrow down and say if it's these facilities I can follow up with them, but that level of analysis is not there anymore, it's not…they don't have that skill to be able to do that…and that's actually the sad thing, the data is all there". NL5

and

"…there should be skills within the County to be able to advocate and make investment for their Counties. A good example, if you just give the MCAs [Member of County Assembly] the report of your performance of your wards…this ward is doing poorly because of the following things. It is easy for them to say, what is the problem, they want outreach, give them money for outreach…at that level they can fix it. But the problem is, how to the make MCAs know and understand the importance of immunisation…" NL5

In this Study it was found that the EPI specific training offered at the County level is either in-house or procured through independent training agencies. The in-house training is mainly in the form of periodic updates offered on the job, centred on programmatic aspects like vaccine forecast and ordering and cold-chain management. The in-house training is not done by qualified trainers but by senior managers at the County level and cascaded downwards across the different cadres. What I observed during fieldwork was that the only EPI training the health workers received was at the briefings delivered during the SIAs or FICs meetings which do not go beyond knowing the vaccine, its cold-chain requirements and how to administer it. Challenges were cited in cases where staff in need of additional technical training, like computer skills, were either not approved to attend external training or asked to self-fund.

> "…dedicated funding to train them doesn't exist… who is going to do the training I don't know because it won't be us. We are not implementers, we can identify the problem, and we can show you this is how to do it…" NL5.

Wider discussions with key gatekeepers in post-interviews sessions revealed that EPI specific training was not prioritised by the County leadership and not funded at the national level. It appears to be no thinking around building the capacity of the existent staff beyond the standard technical training undertaken through formal educational channels. In as much as staff were picking up new information from the monthly FICs meetings and briefing events, there is need to have a specific EPI training.

6.4 Summary

This section has reflected on the end-to-end EPI processes and has identified several areas that could potentially affect the quality of the EPI delivery. Firstly, obscurity and overlap in the County and National mandates is contributing to tensions in the relationships between the two levels of governments. The lack of involvement of Counties in planning is unfortunate: a key benefit of decentralisation is in the Counties' ability to identify under-immunised populations, non-involvement disadvantages EPI.

The parallel system of procuring vaccines and injection devices currently practiced under devolution puts the EPI at risk. The system is heavily dependent on the timely procurement and delivery of the vaccines and respective injection devices. Any delays in the logistics, or procurement of inaccurate injection devices runs the risk of having vaccines but no injection devices or having injection devices un-matching the amount of vaccines. This would interrupt vaccine administration. The Counties' desire to explore procurement of traditional vaccines needs to be followed-up with honest discussions on the risks and opportunities. Another option to be included in the discussions is the feasibility of forming regional County blocks to manage procurement.

The cold chain management challenges reported in this study are not uncommon in LMIC [146], and cannot be exclusively attributed to devolution. Nonetheless, the potency and effectiveness of vaccines depends on cold-chain management; attention is

therefore needed to minimise disruptions. Like cold-chain issues, data reliability and missing records reported above existed pre-devolution; and is not unique to Kilifi County [147–149].

The section on supportive supervision shows that although the role has been assigned to the Counties, the Centre still undertakes this function through other avenues like training, SIAs or vaccine introduction campaigns. They base this argument on the fact that the County is not financing the function, and vaccine delivery would go astray if they did not get involved. That may be the case, but the approach might be better if it encompassed sustainability aspects in its design. This could be in working closely with the County to build their capacity in Supportive Supervision. Considering the tendency of the immunising facility staff to employ alternatives like using support staff to record data, or help in other vaccination activities, it makes it even more paramount that supervision should be undertaken to address any potential quality issues. The lack of supervision would leave room for less than desirable practices to continue unchecked at the health facility level.

Now more than ever, training is an essential function needed to help managers/workers adjust to their new responsibilities. Understanding of the political landscape or of how to work with politicians is key. Whilst workers may know the technical aspects of the programme reasonably well, knowing how to effectively position themselves with senior and political leadership to get EPI prioritised is essential.

Chapter 7: Key Result Area Three: Outcome

This chapter presents findings that reflect what is happening as a result of the changes in the health system. It looks at the effect of devolution on the structure and function of the EPI, its implications on resource prioritisation, as well as the effect the changes are having on the health workforce that deliver the service. The findings also reflect on certain aspects that contribute to the overall notion of health system resilience.

7.1 Changes to the structure of the EPI

The overall perception from the interviews and observation activities was that very little has changed in the functional structure of the EPI. The end-to-end processes from planning, procurement, supply chain logistics and vaccine delivery within an MCH context remain the same. The programme is still managed by the same people (at the National level), under the same policy guidelines and processes. What has visibly changed is the command structure: the functions of who decides and who provides the overall coordination for EPI. Previously, EPI was close to a vertical programme with a command structure flowing from the UVIS at the National level, through the Provincial region, the District, and to the Health Facility. That command structure is somewhat lost in many aspects of the programme. A situation now exists whereby UVIS gives the strategic direction, and the Counties decide if, when and how they will implement. However, by virtue of retaining and controlling some functions like vaccine procurement, UVIS has retained some negotiating power to ensure that EPI processes and activities are correctly carried out.

The power dynamics around human resource management have shifted under devolution. This study established that Counties now have more power and control over staff recruitment and deployment (see section 5.3 above) than they did pre-devolution. This control over deployment, however, was received with mixed feelings; on one hand, many respondents from the Inner Periphery (County level service managers and senior leadership) celebrated their autonomy over employment and deployment. On the other hand, some respondents from the Outer Periphery (SCHMTs and Health Facility, see 5.3 above) felt disappointed at the manner in which deployment was done: without consultation with or the involvement of managers directly affected by the staffing change. Accordingly, they felt disempowered; having lost the control and influence they had pre-devolution.

7.2 Opportunities Created by Devolution

All study respondents from both the County and National level expressed the view that devolution was good for the country and for the health sector, a feeling that was noted in the policy events observed. It was felt that many opportunities had come forth with devolution, such as increased platforms to influence immunisation policy, increased number of health facilities and or infrastructure for vaccine delivery, and freedom to deliver tailored services. As one respondent put it,

> "…before I had to convince the National government which was very difficult but now, I have 47 opportunities and if one will work then it becomes an example, a model of good practice…competition between Counties is also healthy…building of new facilities that's a plus. I don't think that devolution in short is a bad thing". NL1

Under devolution, advocacy for immunisation has benefited from the role of the then 'first ladies' at both Country and County level in health promotion. The first lady of the National Government has been on record as leading a Beyond Zero Campaign aimed at improving maternal-child health outcomes. In synchronicity, the then first ladies of the 47 County Governments were reported to lead on EPI campaign activities, thereby increasing visibility and mobilising resources for EPI.

7.3 EPI Performance

Immunisation coverage is widely recognised as a key performance indicator for the immunisation system performance [150] and a signal on the level of protection against vaccine preventable diseases within a community at any given time. The WHO recommends vaccine coverage rates of at least 95% to reduce the incidence of vaccine-preventable diseases [151]. According to some Study respondents, immunisation coverage rates at both National and County level reduced after devolution, as the quotes below indicate:

> "…coverage has been hit we are in the 70's now as opposed to the 80's [pre-devolution] …" NL5
>
> "...here it took a dive, if you look at the County it was 85% then 70 something percent... it took a dive everywhere…2013, 2014 we had a problem with

vaccines because of that shock I'm telling you about, *zinaisha* [stock-outs]…"CL5

"…in the context of devolution, I cannot say our coverages are as good as they were. I can't speak for data because the quality issues there maybe completeness issues. But there are times when coverage for BCG was always known as to be as high as 99%, from 90% above 95% for sure. But I don't think that is the case right now".NL9

The comments above, quoted from key workers, suggest that health workers feel devolution has had a direct negative impact on coverage. However, a study by Ifedayo *et al.* (2018) shows that the coverage in children aged 12-23 months in Kilifi County steadily increased from 71.5% (2010-2011) to 84.0% (2013-14), but declined in 2014-15 (82.8%) and 2015-16 to 76.8% [152], this latter coincides with the data collection phase for this Study. It is not clear therefore if it is devolution per se that negatively affected vaccine coverage.

The misalignment of funding requested versus funding received, vaccine stock outs, low or non-existent targeted supportive supervision, and intermittent outreach activities were cited as some of the reasons contributing to the low coverages reported. As one respondent cited;

"the programme has been hurt…with devolution the vaccine was not readily available because it's not funded…someone somewhere decided at national level we do not need any allocation for operational costs...we do not get money even to service the vaccine store, we don't have any money for training or for the generators…there are certain things that have become orphans…. [If] the County will not buy the syringe then that child will not at any time be vaccinated...".NL9

Another factor cited by national level respondents as potentially affecting coverage figures was uncertainty in discerning the correct number of eligible children (denominator) in a given catchment area, to use in calculating immunisation coverage rates. The population denominator would influence the allocation decisions on vaccine quantities and costing on some immunisation activities like outreaches; the higher the denominator, the higher the allocation value. Traditionally, the Kenya National Bureau of Statistics (KNBS) would provide denominators of the catchment areas

based on the most recent national census figures. Upon onset of devolution, however, some Counties accused KNBS of deflating the figures and thereby instituted court action against them (KNBS). In response, KNBS reportedly took a stance in refusing to provide official data to Counties for immunisation purposes. This situation is presented in the following quote:

> **"**…our denominator is difficult, we don't know…KNBS…they've been taken to court saying that these guys [KNBS] deflated their numbers… now when you ask them [KNBS] give us what the population is, they'll say there is a court order, until the court order is done we are not giving you any number, if you want the number go look at the numbers in the census and extrapolate…when you ask the Counties, they will give you one number depending on what they think they are going to benefit. So, this influx; yes, services were hindered but also the denominators also hindering our coverage".NL5

The ascertainment of the accurate coverage data for Kilifi County was something that I found difficult in this study. Coverage figures seen from three different sources (UVIS, KCDH and KEMRI) on the same jurisdiction were conflicting. Ifedayo *et al.*'s 2018 study also reported on this variation [152]. The limitations to data reporting due to inaccurate population estimates have been reported elsewhere [3].

7.4 Prioritisation of resources

The whole immunisation system depends on the allocation of sufficient financial resources. In the context of limited financial resources and other interests that EPI must compete against, a careful balancing act in allocation prioritisation is needed to ensure effective utilisation of limited resources. The way the County allocated resources was received with mixed reactions by both National and County level respondents. Some County level respondents from the Outer Periphery accused the County of prioritising visible infrastructure projects that would win votes at the next electioneering period, at the expense of essential EPI items like gloves, immunisation record books and skills training, outreaches and supportive supervision. Other respondents from the National and County level (Inner Periphery) were quite welcoming of the prioritisation of infrastructural hardware amenities like warehouses, health centres and cold chain equipment, which they believed has widened access to immunisation services.

> "…infrastructure wise, creating new infrastructure for this [EPI] service delivery. We opened over 10 facilities currently and they are offering these [EPI] services, like the County warehouse [intended to store vaccines]". CL4

The National level respondents supportive of infrastructural investment presented it as an answered prayer as it was an area of need the national level had been unable to fulfil pre-devolution.

> "One of the good things we know that where the technical managers are very good, and the people who are controlling funds are reasonable, Counties now are putting more funds in buying equipment, fridges that the national government was not able to do before NL1.

The examples quoted above indicate that devolution is contributing positively in addressing the cold chain and logistics challenges that existed pre-devolution.

7.5 Proximity to Leadership

Many County level respondents reported that devolution had increased their proximity to senior leadership. This proximity was said to have been instrumental in improving job satisfaction and diffused strike action in 2014 at a time when nurses strike actions were recorded country-wide. Some of the senior leaders reported they had an open-door policy which enables dialogue, a fact reported by the respondent below;

> "They have issues, they will walk into the office and table the issues and address them…here the promotions are being addressed…If it's a promotion why not give it out. If someone is due for promotion, why hold it?" CL2.

The view held by senior leaders that some employment issues like pay and promotions were being satisfactorily addressed was contrary to that of other respondents, especially those at health facility levels who reported problems with promotions, pay and employment terms (see section 6.3 above). From the Health Facility level respondents, better access to relevant authorities or people deemed responsible to address workforce issues did not always translate to a satisfactory resolution of the issues/concerns raised.

7.6 Workforce motivation

Health worker satisfaction, motivation and qualification are essential ingredients in delivering health services [153]. Following on from the discussions presented in section 6.3 above, most County respondents expressed a sense of demotivation and apparent disappointment with their employment terms and status. Those transferred from MOH had employee benefits and employment confirmation letters still outstanding. Those from USAID-County agreement and direct County employees were still under probationary terms, which restricted their entitlement to employee benefits. Those employed under the KEMRI-MOH partnership were in indeterminate state. As a result, it was reported that some respondents had resorted to seeking employment abroad.

The County's recruitment drive was also met with scepticism which impacted on workforce motivation. There were reports of people employed, promoted and deployed based on relationships they had with recruiting and senior managers and not on merit. As one respondent stated:

> "…we are seeing that in the employment it's not the qualified because…automatically they will favour their own. So people go there do the interviews then those qualified, they won't get, they will pick their people…so that one has really affected the services because you will see people who are not qualified but they have been employed because maybe somebody somewhere is a relative…nepotism is really high in the county".CL13

7.7 Health System Adaptation

Despite the many challenges presented, somehow, the Immunisation Programme and the health system still carries on. This study established some innovative and heroic acts that contribute to this resilience. As one respondent put it,

> "…it's been management through 'innovativeness', and 'luck' sometimes and 'crisis' to get the Immunisation Programme running…" NL10

The 'luck' aspect was defined at the national level in terms of stocking of traditional vaccines and Gavi's goodwill. As presented in chapter 6, all monies, including the allocation for procuring traditional vaccines and part-funding to new and under-utilised vaccines, was sent to the Counties. By sheer luck, UVIS had over-stocked

traditional vaccines in a previous procurement cycle, and so had just about enough stock to keep the country afloat in the time immediately after devolution (2013-14). This over-stocking was supported by a financing agreement the national MOH had with Gavi, where Gavi would fund the procurement of all the New and Under-utilised vaccines and then receive the match-funding from Kenya Government. This arrangement was seen as a 'programme saviour' as quoted below:

> "…the other thing that has saved us, is the [over-stocking made possible by] Gavi pre-financing plan…it helped us in a way to manage, to survive through these crisis". NL10

However, this perceived 'programmatic salvation' was short lived. Since all the monies had been sent to the Counties, the National government was not able to honour its commitment to the financing agreement with Gavi. This occurrence was repeated in the following year (2014-2015), because, yet again all the monies were sent to the Counties. There is no legal mechanism of clawing money back from the Counties, keeping the money at the national level or getting treasury to send money to UVIS as was the case in the past, leaving everything to chance as quoted below.

> "…it's really been a bit of trial and error and to date we haven't agreed on a mechanism within which immunization monies, ear marked or, or allocated to Counties will be pooled at National level…" NL10.

Since co-financing agreement was based on the premise that Kenya would honour its financial commitments, Gavi could therefore not proceed in procuring vaccines before receiving the national government's allocation in full. When it became apparent that the programme was going to crash, a decision was made by senior leadership team at the MOH to re-allocate monies earmarked for other national functions to finance the government contribution to Gavi which then made it possible for Gavi to co-finance and the country to receive the much-needed vaccines.

One finding from this study was that an element of 'innovativeness' would emerge in response to otherwise problematic situations. For example, in order to try to mitigate any future funding crises, discussions had been initiated to officially rename UVIS to National Vaccines Immunisation Programme (NVIP) and have it moved from the Division of family health to that of National Strategic Programmes. This way,

> "…it [NVIP] remains more like national strategic programme so that, we start looking at immunization as a national security issue, as a strategic national programme, rather than as one of those government programmes. So, once that is done, it is assured [of funding]". NL8

The level of 'innovation' was widespread at the County Level. The study established instances where health workers would bring items from home or borrow from shops within the vicinity to keep the health services (including EPI) afloat. The following quotes shows the different innovative actions emphasized in bold.

> "…you see that soap, **it is for my house**, because it is a shame, how can I work handling all the patients with wounds, with whatever, without hand washing yeah? That's how I've been surviving". CL5
>
> "…. under hard conditions. At times you end up **borrowing from suppliers** and they are waiting in event that the money is coming, they'll be able to be paid but there will come a time the suppliers are saying enough is enough until I'm paid, then I will not be able to offer the said services". CL17.
>
> "…like here it is zero. We don't collect anything. No user fees. So, you can just imagine running this facility without funds. We... it's like we've been dealing well with these people and sometimes if you need like a pen, I go to a shop, **I just take**, they know if I get funds, I refund. So, we live with debts. We incur a lot of debts and we have debts from the support staffs and the shopkeepers around here, we just **learn how to survive** with them". CL15

A common thread through the County level respondents was that EPI was a beneficiary of 'goodwill' reaped from several heroic acts within the system. Section 6.3.6 above showed how charismatic leadership prevented a halt to an immunisation campaign. Respondents of different cadres expressed a sense of duty or commitment to ensure vaccination takes place. They expressed an appreciation that immunisation is a cornerstone of good health. The level of commitment was manifest in many ways, one of which was the readiness for immunising staff to use their own financial resources and mode of transport to collect vaccines from the Sub-County KEPI stores. In the same vein, some Sub-County managers would not hesitate to put in extra hours over the weekend to collect vaccines from the regional KEPI stores to prevent vaccine stock-outs. The quote below shows how one facility muddles through.

> "…we have been going for vaccines from the Sub-County ourselves…**from our pockets** because we have to give the vaccines *huwezi mwambia mama kuwa sai hospitali haina pesa kwa hivyo hatuwezi* (you can't tell the mother that right now the hospital has not money so we cannot vaccinate]... meaning there must be some finance for fare for some people to go and fetch those vaccines". CL5.

The staff involved remain in perpetual hope that one day funds would reach the health facilities and may have their expenses reimbursed, as seen in the quotes below.

> "…we collect ourselves and whoever goes to collect every day vaccines, **commit** to the facility that fare, that if at all the money will come, there is my money which I'm going to get from the facility…"CL4
>
> "…if at all you want to do something which you don't have cash, they say... you commit yourself to the facility, that if at all the money will come, they'll receive their arrears." CL6.

7.8 Summary

This section has shown that health system changes have shifted power dynamics. The Centre has lost some degree of command control on how the Immunisation Programme should be delivered. The Counties have gained autonomy over health service provision and employment/deployment of staff. Conversely however, the managers within the Outer Periphery structures at the County level have lost autonomy on employment/deployment decisions of staff they supervise.

Due to transition and financial prioritisation, some EPI functions are not adequately resourced or supported, thereby negatively impacting on immunisation performance.

The impact on the health workforce appears to have been largely negative. Many health workers are still in limbo over their employment contracts or benefits. This inequity in employment conditions contributed to feelings of demotivation and job dissatisfaction. It runs the risk of leading to an eventual compromise in the quality of services provided.

A lot of adaptation is recorded in this section which has somewhat contributed to health system resilience. Staff have notably relied on out-of-pocket expenses, borrowing from shop outlets and casual staff, and a perpetual hope for a better tomorrow. While welcome, and perhaps functional to some point, these acts are not sustainable in the long-run.

PART THREE: DISCUSSION AND CONCLUSIONS

This section consists of two main chapters. Chapter 8 offers a detailed interpretation of the Study findings based on the theoretical underpinnings presented in chapters 2 and 4. It then explores insights from a similar study conducted in a High-Income Country (HIC) as part of my OPA, which offers lessons for consideration by health system and policy researchers from a global health perspective. Chapter 9 presents methodological considerations of the Study, considers the unique contribution to knowledge the Study makes and then concludes by identifying some systemic leverage points that can be optimised.

Chapter 8: Discussion

The Study set out to assess the implications of Kenya's health care devolution on its vaccine systems, looking at to what extent the minimum expectations of what constitutes a good Immunisation Programme as currently conceived are being met. Key to this is assessing whether the quality of the EPI delivery has been affected in any way. In the 2010 constitution, Kenya adopted a human rights approach to health care, and accessing quality health services is a basic human right in this respect. Before assessing quality however, Donabedian (1988) advises that one needs to decide how quality is to be defined [154]. Therein was the first challenge I encountered in this research journey. For one, the concept of quality is rather elusive; pinning down the right definition of quality is complicated by the fact that its nature is subjective and its characteristics intangible. Defining quality therefore becomes like a Rubik's cube, where at one point in the Study analysis, all the squares line up according to the colour codes and it all makes sense, other times they simply do not. Moreover, health systems are complex and multi-dimensional, and so is quality [155]. Nonetheless, a working definition of quality was adopted: the degree to which the activities or inputs increases the likelihood of producing desired outcomes in EPI consistent with local, national, international standards and minimum expectations (see also 8.1 below). These inputs including comprehensive planning, adequate funding, competent workforce, uninterrupted vaccine supply logistics, cold chain and data management must be systematically coordinated to attain the provision of quality vaccines.

Additionally, with devolution came a fragmentation of the EPI functions between the National and County governments, an arrangement that implies all Counties signing up to consistently and effectively delivering on their mandate. But this has not been the case. Counties are autonomous governments and may choose to customise their responsibilities inconsistent with neighbouring jurisdictions. Fundamentally, this brings in a much wider question that could potentially arbitrate the discussion on the fragmentation of the EPI functions. Who is accountable for health protection against vaccine preventable diseases in Kenya? By focussing on a micro-context, the granularity of the vaccine systems within one County, the Study was not able answer this question. A more strategic inter-County research is needed to interrogate the health protection responsibilities.

Considering the immense challenges experienced after the devolution of health functions (see chapter 5, 6 and 7), one could be tempted to conclude that devolution led to a decline in immunisation coverage in Kenya. As a matter of fact, some key informants made this inference, suggesting that devolution had had a negative impact on immunisation coverage (see 7.3 above). However, a quantitative study by Ifedayo (2018) showed that immunisation coverage for children aged 12-23 months in Kilifi County in fact rose steadily a couple of years before and after devolution from 71.5% (2010-11), 74.2% (2011-12), 78.9% (2012-13) to 84.0% (2013-14). These data do however show coverage decreasing in 2014-15 (82.8%) and 2015-16 (76.8%), the latter which coincides with the time when this Study was undertaken. I argue that the time lag between implementing devolution and conducting this fieldwork is too short a time to authoritatively apportion causal links of any outcome to devolution. The Study findings, however, are significant in providing an insight to complexities of health system change which can also be used as a benchmark for further cross-county and cross-country comparisons.

8.1 Quality of the Immunisation Programme as currently operationalised

As noted above, quality is one of the most important considerations in the planning and implementation of immunisation services that are responsive to the local population needs [156]; services that meet expectations from all stakeholders on both demand and supply side of the health ecosystem. In his health care evaluation framework, Maxwell presents six dimensions of quality; access, efficiency, equity, relevance, acceptability and effectiveness [123], which are useful in characterising quality in health systems [124]. The dimensions also offer useful criteria and standards implicit in the assessment of quality of the subject in question.

The Donabedian quality framework on the other hand provides three categories (Structure, Process and Outcome) from which the inferences about Maxwell's quality dimensions can be drawn [154]. The Structural attributes considered in this Study include the organisation and governance of the health system transition including EPI, and resources aspects, both financial and human. In relation to processes, the Study looked at the end-to-end activities that are undertaken from planning to availing vaccines at

immunising facilities. Finally, Outcome considered the effects of health system devolution on immunisation performance, health worker satisfaction and health system adaptation. Donabedian argues that 'good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome' [154, p1745].

On the access dimension, Maxwell (1992) argues that quality could be defined by determining whether people can receive the service they need on demand [123]. Barriers impeding service access could include interruption of supply, distance travelled or waiting time. In this Study, several factors inhibiting access to EPI were cited. Many cases of vaccine stock-outs at facility levels were reported, which hindered access to vaccination. Due to funding constraints, outreach services which had the added advantage of reducing distance travelled had almost come to a standstill. In some instances, due to staff shortages or exhaustion, clients were forced to remain in long-queues to wait for vaccination. Sometimes, clients were sent home and advised to return another day as either the health workers were too tired or otherwise unable to provide the service. All these factors point to the fact that accessibility to immunisation services was severely hindered.

On the equity dimension, Maxwell (1992) urges the assessment of fair treatment, looking at how an individual or group of people are being treated less or more favourably compared to others [123]. This Study established some failings on the equity dimension, especially around the aspect of health worker engagement. Two groups of health workers, those employed by the County from 2013 and those absorbed by the County through USAID-MOH agreement were still in probation at the time of the fieldwork, long past the contractual probation expiry time-period of six-months. Health workers under probationary contract were not receiving some employment benefits they should have been entitled to, ones in which colleagues in similar job cadres were benefitting from. Data clerks engaged under the KEMRI-MOH agreement have their employment undefined and must interact or work alongside other health workers undertaking similar roles but enjoying employment privileges. Health workers transferred from the MOH to the Counties had their official employment letters pending, and their employment benefits accrued from their contract with the Ministry of Health were not transferred to their County contracts. The outcome then is a staff that are highly disaffected; a situation that makes it difficult to say with any

degree of confidence that the staff are able or willing to deliver EPI to the expected minimum quality standard. The EPI is therefore at the mercy of the goodwill of demotivated and visibly aggravated staff to keep toiling to deliver on the professional oaths they vowed in providing health services.

Kimathi (2017) argues that quality healthcare provision can be realised if adequate and functional health facilities are made available, fully resourced with adequate funds, commodities and qualified and competent staff [25]. From the results in this Study Kilifi County is making progress towards the infrastructure provision by building and opening new health centres. At the time of the fieldwork, at least five new primary health care facilities were inaugurated. Attempts at resourcing the health facilities were also prevalent, evidenced by the employment of new health workers across different cadres. At the time of the fieldwork, at least one hundred and fifty nurses had been employed.

Another key aspect the Study noted that can have a negative impact on the quality of health care is around procurement. Two areas of concerns were noted; firstly, the parallel procurement of antigens and injection devices where UVIS undertakes procurement of the antigens and the Counties are expected to procure injection devices. This calls for the UVIS and County procurements timelines and supply volume to coincide in order to have the right number of antigens and injection devices at the right time. Counties were straining to adapt to the new arrangement and there were fears that incidents had occurred where vaccines could not be administered because of the lack of injection devices. Secondly, Counties were reported to be taking advantage of the 2012 Health Bill provision to procure commodities, including vaccines from sources other than KEMSA. Some of the County respondents welcomed this as a true test of autonomy. However, County procurement systems are new, and are yet to have good regulatory and monitoring systems to safeguard against procurement of poor-quality commodities and to curb corruption or exploitation by dishonest individuals and companies.

In relation to the end-to-end EPI processes in general, this Study established several instances where quality was significantly compromised. In planning processes, there appeared to be little or no involvement of Counties. Vaccine forecasting was hampered

by disagreements on denominator figures. Vaccine procurement affected by devolution of funds and parallel procurement systems. Non-adherence to the supply chain and logistics protocol by Counties was reported. Inappropriate or lack of transport for vaccine delivery affected the quality and availability of vaccines at the immunising facilities. Threats to cold chain compliance were rampant ranging from fridge breakdown and related delays in maintenance or replacement and poor storage facilities. Vaccine delivery inefficiencies were reported in many ways, some of which included using support staff to undertake sensitive tasks like vaccine administration or data entry due to staff shortages. Lack of EPI and health systems training, and supportive supervision was reported. Finally, data quality remains of significant concern as reports of missing or incomplete data were voiced, exacerbated by the absence of quality audits. These will inadvertently affect the quality of the country's overall coverage reports submitted to WHO/UNICEF through UVIS.

Quality in health-service delivery systems is an essential contributor to health outcomes. Under devolution, the quality of EPI is apparently negatively impacted. The implementation of the fragmented EPI responsibilities has not been in sync, largely due to the political tensions and challenges in establishing new structures. Given the complex nature of the health system changes under devolution, a whole systems approach is needed to promote system-wide implementation of quality improvement approaches to revert any potential ramifications in the vaccine systems. A quality-oriented approach to planning and delivering vaccine systems is needed at both the National and County level. This could start with incorporating quality as a performance indicator of the EPI. Health system leaders and Governments (County and National) should be held accountable in driving forward the quality assurance processes.

8.2 Health Systems Competencies and Capacity Needs

Donabedian posits that the qualified health care workers are an essential structural attribute for the provision of quality services [154]. This Study established training needs at both County and National level. The County training need was more visible; with only three out of seven Sub-County EPI managers having received mid-level EPI management training before devolution came into being. In addition to the operational

training, health workers need to be equipped with system thinking skills in their new positions as business and health facility managers, in order to effectively undertake roles such as negotiating and lobbying policy actors on EPI needs. None of the Study respondents identified any training need for National level actors. An appreciation of this shift in responsibilities was lacking in all National level respondents; in its stead, a 'them not us' notion (that is, the County workforce needs training) was prevalent. Since the role of UVIS has shifted significantly, from direct management to policy and technical advisors and/or programme monitors, there is need for systematic retraining and reorientation to these new roles.

One of the main arguments expressed by devolution critiques is that often the capacities and knowledge levels at the subnational units are too weak to allow effective decision-making and implementation [157]. This perception of capacity inadequacies at the subnational level was reported in this Study and was one of the main reasons cited for UVIS's active role in overseeing the implementation of SIAs, including undertaking monitoring and supportive supervision. SIAs were reportedly funded by international agencies and needed a high level of coordination and reporting, a role that could only be well performed by UVIS. This perception is arguable given the reports that most County managers worked for MOH undertaking senior immunisation coordination roles prior to devolution. Ironically, it was infact the intervention and demonstration of astute leadership by one of the SCMOH in Kilifi County that prevented boycott to the MRT SIA I observed during fieldwork. The capacity deficiency argument needs to be interrogated further to unpack specific areas to be attended to by the County or UVIS. Regrettably, some of the personnel sent to the Counties as part of the SIA implementation did not invite or involve the County representatives in their field missions. A few of the National representatives that involved the County in their field missions brought in a lot of paperwork for the County managers to fill out but did not factor in or have any session with the County personnel to explain what they were at the County level to do, or how they could work together with the County managers in the campaign. Some of the health workers and managers at the Sub-County level had to use their resources to mobilise communities and hire *bodabodas* (motorbikes) to carry the vaccines to the immunisation posts as funding to facilitate such functions had not reached the County in time to make formal

arrangements; funding did not arrive until about a day before the scheduled campaign date.

The tendency of the Centre to use accusations of 'capacity deficiency' to shield their hesitance to transfer responsibilities and related privileges to the periphery is not unique to this Study. Studies in Colombia showed that refusal by the centre to decentralise some functions were in fact a smokescreen to hide misalignment between national and local priorities [158]. In this Study, the failure to decentralize SIA responsibilities to Counties is perhaps shielding UVISs readiness to relinquish power and control. The position is incongruent with UVIS's new role under devolution, the role of an enabler, of an agency that need to expedite and regulate an environment in which Counties can operate effectively. In aspects other than SIAs, it is fair to say that UVIS plays the enabling role quite well, as presented in Section 7.3.8. UVIS reportedly initiated joint forecasting and planning activities, stakeholder advocacy meetings attracting senior leadership from the Counties and facilitating communication and feedback loops between the Counties and the MOH. Through their active stakeholder involvement, UVIS developed an electronic web-based tool which the Counties can now use to see levels of vaccine stock in their health facilities and vaccine depots.

From a health systems point of view, the County and National health system actors need to work together to list their competency and capacity needs and invest in addressing them in order to drive improvements in health outcomes and health system performance.

8.3 Politics: Friend or Foe?

Bossert's decision space theory assumes that, for effective implementation of decentralisation, the decentralised units must have the necessary capacity to receive the new powers and authority to take up the new responsibilities and functions [42]. Ensuring that receiving units have the appropriate capacities can be challenging in the context where decentralisation decisions are largely politically driven, marred with mistrusts and therefore rushed. In Kenya, the devolution debate was largely politically driven, and its implementation marred with mistrusts of the intentions of the two levels of government. Two main political parties: the Orange Democratic Movement (ODM)

and the Jubilee Party (JP), led the referendum that resulted into the 2010 constitution within which devolution is enshrined. ODM positioned itself as pro-devolution while JP was against. At the 2013 election results, the JP won the presidential and vice-presidential positions, and therefore became the constitutionally instituted de facto overseer of the devolution implementation. Many of the County Governors instituted to lead the implementation of the devolution policy were however, from the ODM. The proposals for phased implementation of devolution presented by the Transition Authority (mandated to facilitate and coordinate the transition to devolved system of governance) were perceived by ODM as a tactic by JP to delay the policy implementation. In the first meeting of the Council of Governors, the governors used their power to demand for immediate transfer of functions earmarked for devolution (including health) without consideration of whether the county governments had the right infrastructure and capacity to receive the functions. This therefore made the journey to health system devolution commence from a very fragile platform.

At the County level, the political inter-play and desire to appease the masses led to delays in appointing a COH and the CECM for Health, which led to delays in establishing a permanent CDH structure within which EPI was to be coordinated. There were reported delays in developing a sector strategic plan and annual work plan that impeded efficient resource mobilisation for the CDH [129]. The delay contributed to disruption of the planning and delivery of EPI services. Some instances of political interferences were also cited at the health facility level where some MCA were reported to overstep their boundaries by getting involved in facility operations.

A common pitfall of many technocrats identified by Reich (1995) is the tendency to perceive and respond to reforms as a technocratic instead of political processes [159]. Reich argues however that by virtue of altering the recipient and/or custodian of the most cherished goods in society, reforms are in their essence political. Leaving out the political in the technical discussions on health system devolution in Kenya (see 5.1.1. above) missed an influencing tactic, in as much as County Governors although not in post at the time the discussions on transferring health functions were had, the major political parties behind the political push for change were known and could have been engaged in these discussions. The political push for a referendum on constitutional change was common knowledge. Technocrats were aware that politics were driving

the structural changes in the country and that should have been signal enough to warrant initiation of dialogue with main political parties forging the agenda. The hesitancy or lack of intention to consult and/or engage stakeholders widely was noted elsewhere in this Study (see chapter 6); Counties are key stakeholders, yet, planning at the National level did not have appropriate involvement of Counties. It is true that involving all 47 County Governments (or managing the politics that will result in the process) can be challenging. Nonetheless, the benefits of appropriate involvement cannot be underrated. Securing political commitment enabled successful health sector decentralisation in India [160].

8.4 Gains and losses under devolution

According to Bossert [42], implicit in the decentralisation design is the increase of choice or decision space at the peripheral levels. The findings in this Study to some extent concur with this position. The Study shows that under devolution, the vertical redistribution of power and autonomy within the periphery varies greatly, with more power and autonomy concentrated at the Inner Periphery (see Figure 8 above). Actors within the Inner Periphery have increased powers, authority and decision-making capabilities. MCAs now have the power to vet, approve or dismiss health budgets, an arrangement that was non-existent pre-devolution. CHMTS and senior leadership have powers in human resources management: hiring, deployment and termination, a role that was a National government function pre-devolution. Nonetheless, this increased decision space was not without its flaws; there were reports of nepotism and patronage in the employment and budgetary allocation processes.

Under devolution however, some health managers, at the Outer Periphery (see Figure 8) lost a significant amount of power and authority. As presented in chapter 5, SCHMTs were created almost as a replacement for the DHMT, with similar operational mandates, that is, overseeing the responsibilities for facility-level operations within their jurisdictions. Since the DHMTs had increased authority for decision making, resource allocation and management of health care at district and health facility level [27,50] the expectation was that this would be continued and mirrored in the SCHMTs. Under devolution however, with the recentralisation of finances to the County headquarters, the authority over resource allocation followed suit. Whilst pre-devolution the managers had influence over deployment of human resources,

under devolution, SCHMTs, who are made up of same individuals that were previously the DHMTs, have less authority for decision making and resource allocation. Their level of influence is low or non-existent, evidenced by reports of deployment of staff under their line-management without their consent or consultation as presented in 5.3 above. This finding is an addition to the literature decentralisation and decision space. Studies analysing the impact of decentralisation using the decision space framework prescribe that on balance, decentralisation increases the decision space for sub-national units, albeit at varying levels [42,57,161]. This Study shows that, while it may hold true that decentralisation has indeed increased the decision space of politicians and senior leaders at the meso (County) level, it has in fact constricted the decision space of actors at the micro level (SCHMTs and PHCF managers).

8.5 Stakeholder relationships revisited

The principal-agent framework [42] sets the basis for understanding the relationship between central and decentralised units as well as the relationships within the decentralised units. This Study established several layers of the principal-agent relationship, and depending on the context and nature of relationship, the actors shifted position from principal to agent and vice versa as needed. On a macro level, the CDH act as the agents with UVIS, County Executive and MCA acting as principals. On a meso-level, the CDH is the principal while the SCHMTs and Hospital Boards are the agents. On a micro-level, the SCHMTs team are the principals with the FICs at the PHCF and Community Units being Agents. These relationships are characterised by the principal setting out directives that the agent is expected to action, implying a top-down relationship between the principal and the agent. The objectives may therefore be set with little or no involvement of the agent. In the Study context, the principal (UVIS) sets the national immunisation policy without any significant contribution from the agents (Counties) and the agents are given resources and authority to implement it. Implicit in the principal-agent framework is allowance of a degree of decision space margin for the agent to manoeuvre on the agreed objectives to allow adaptability to local realities. It then follows that, theoretically, the agent takes on the role of a problem-solver, empowered to make bespoke policy decisions. In this sense, the margin of influence and control of the principal in the local decentralised setting shrinks, while that of the agent increases.

As aforementioned, according to the principal-agent perspective, decentralisation offers room for divergence from common objectives between the principal and agent by allowing greater choice and flexibility on the part of the agent [162]. In this context, both UVIS, the principal, and the CDH (agent) have a common objective of fully immunising eligible children. However, the CDH have room to manoeuvre in making modest adjustments in the adoption and operationalisation of national immunisation policies in a manner consistent and responsive to local realities. The principal in this case has little or no control over how the agent will adopt and operationalise the policies. In a context of 47 County Governments, UVIS as the national policy coordinator implicitly has the additional burden of reconciling the 47 variations of local policy adaptations to control for excessive divergences.

According to Donabedian [154], the principal-agent relationship is the vehicle by which a quality health care service is implemented and is the relationship on which the desired service outcomes are hinged. The lateral relationship between the National and County level means that an efficient EPI across the two tiers depends on a solid relationship between the two levels of governments that cuts across political and jurisdictional divide. The relationship between the National and County Government is pegged on the constitutional dictates around consultation and cooperation. This research established that the pace and way the health functions were devolved did not create a conducive baseline for sincere consultation and cooperation. For one, the technocrats were not consulted on how the health functions should be rolled out, and since the County structures were not yet fully in place to effectively take up their new mandate in coordinating EPI delivery, one would argue that cooperation was not feasible. The Study established tensions and a high level of scepticism about what consultation and cooperation really meant, with some actors insinuating that the concept was merely political and not translating into much in practice. The paradox of aligning the intended versus the real inter-governmental coordination has been reported as a challenge many governments contend with [163].

The principal–agent theory assumes that, for decentralisation to have a positive impact, a good degree of cooperation, coordination and communication between the

principal and agent need to exist [57]. Clarity in roles, responsibilities and mandates are the backbone to this synergy. This Study established that there was a significant lack of clarity about of the scope of individual and organisational roles, responsibilities and mandates. UVIS for example had not fully relinquished the EPI coordination role to the Counties, as evidenced in the active role it plays in coordinating SIAs. Some MCA were accused of overstepping their mandates and interfering with health facility operations. The 2013 guidelines on immunisation clearly outline the role of UVIS in KEPI, but it makes no mention of the Counties. A draft 2015-19 multiyear plan exists, touching on the role of the County and the Centre but mainly focuses on the challenges posed by devolution. The lack of clear guidance and the knowledge asymmetries contributed to the significant tensions that undermined any conducive relationship to deliver on a quality EPI programme.

8.6 Decentralisation and Human Resource Management Implications

A critique of decentralisation propounded by human resource theorists is that decentralisation strategies often fail to have enough consideration of the faces behind the services. According to Franco *et al,* (2002), health workers are generally not given satisfactory consideration in the planning and implementing reforms [59], irrespective of the fact that reforms generally destabilise the work environment by changing health sector arrangements. Other studies indicate that many of the problems that decentralisation poses for human resource management (HRM) is brought about by lack of consultation and dialogue with the health workforce [164]. In this Study, it was apparent that consultation and dialogue with health workers took place [128] (see section 5.1.1). What was missing however, was the room to incorporate the recommendations of these activities to inform the transition process. There were multiple instances of unsatisfactory consideration of health worker input into planning and implementing reforms. For example, the technical report and policy paper was disregarded in the presidential directive ordering immediate transfer of health functions (see page 67). Decisions on financial management and allocation at the County level were happening without enough considerations of the programmatic needs raised by the EPI managers. Implementation of financial policies were done in such a way that health facility managers were left with no financial resources to effectively deliver on their roles. Moreover, it is arguable whether the consecutive structural reforms experienced by

the MOH in 2013 (see 1.1.14 above) would allow for appropriate consideration of health workers' input.

Whilst my findings support Franco *et al'*s (2002) conjecture that health workers are not given sufficient consideration or allowed to inform changes, I further submit that although good practice suggest this should happen, many reforms are not structurally designed to accommodate it. This is especially so when reforms are driven to address wider political considerations instead of technical challenges and given little time between decision and implementation. I propose that further research is undertaken to explore modalities that would inform the accommodation of significant health worker input in multiple health sector reforms that are implemented rapidly.

According to Kolehmainen-Aitken (2004) decentralisation fails HRM by the tendency to transfer human resource functions to managers in decentralised units who are inexperienced and inadequately skilled in such roles [165]. This was evident in some of the structures at the Outer Periphery (see section 5.3.2). In one of the PHCF visited, there was only one member of staff manning all health services including maternity services and maternal child health clinic, a role that is normally undertaken by six members of staff. The five staff members were either on leave, on training or night duties. The respondent viewed the situation as a low staffing issue needing redress by the County managers but did not perceive it as a planning skills gap on their part. Clear definition and understanding of personnel management processes, at least on the part of respondents at sub-county level were lacking at the time of the fieldwork. Moreover, the way employment related concerns were addressed (see section 6) shows that managers approached on human resource issues were rather inexperienced or ill-equipped to effectively attend to their needs.

Kolehmainen-Aitken (2004) adds that such managers at the decentralised units need to be regularly supervised and have their skills and performance needs appropriately met. This Study established that due to resource restrictions, managers at the County and Sub-County level had not been able to undertake adequate supervision of health workers at the facility level, neither had they been able to ensure that employees have the necessary tools to do their job. Given that where health workers were resorting to

utilising support staff to help in technical roles, the lack of adequate and timely supervision is of great concern.

A demotivated workforce is a key impediment to effective service delivery [164]. This Study observed consensus among health workers that devolution had negatively impacted upon their employment entitlements. The Counties have refused to take on the financial liability for employment benefits accrued by workers whilst under the MOH employment. Many of the Sub-County managers did not have a dedicated desk space or hot-desking facility for them to operate from. Robust systems for HRM were either invisible or lacking, evidenced by the widespread dissatisfaction and concerns across all staff cadres. A national human resource policy guidance for Counties[138] has been developed but is yet to be enacted at the County level.

8.7 Fiscal Decentralisation and the Unfolding Challenges

Kelly (2012) argues that one of the factors determining the strength of fiscal decentralisation is the appropriate allocation of revenue functions across the sub-national levels [166]. A consensus amongst fiscal decentralisation theorists is that resources should match function for decentralisation to work [167]. This Study showed weak financial planning in that resources were not flowing down to the Outer-Periphery structures as expected. This imbalance led to cessation or great reduction of some of the services like outreach and support supervision. Failure to allocate funds for training meant that many managers undertaking EPI functions were not EPI-management trained, and many lacked basic data interrogation skills. Lack of funding for transportation resulted in vaccine stock-outs in some facilities. In a nutshell, inappropriate resource allocation led to significant service disruption that compromised delivery of EPI to minimum expected standards. This Study findings are consistent with findings in Papua New Guinea where financial considerations resulted in cessation of payments for some decentralised functions like nurse training [168].

For the delivery of high quality, efficient and effective services at the decentralised units, studies argue that more financial responsibilities must be assigned to structures at the lower level [33,169,170]. This Study shows that the further devolution of financial responsibilities had not happened in Kilifi, and in-fact the very opposite was panning out. The removal of the AIEs at the Outer Peripheral structures (SCHMTs and PHCF)

at Kilifi County has in effect removed the financial responsibilities of these structures. Unsurprisingly, therefore, the provision of quality service is untenable. What remains is PHCF incurring debts from staff who commit their personal finances to resource functions like transportation of vaccines. Services like outreach have been suspended in some areas due to lack of funds. It is likely that the hesitancy to give more financial responsibilities to the Outer Periphery structures post-devolution may be due to capacity concerns around the extent to which workers will be able to efficiently manage the financial resources in view of the new responsibilities. This, however, may not make much sense given that it is the same individuals currently at the SCHMTs and the PHCF that were entrusted with AIEs pre-devolution. Whatever the prevailing concerns impeding further devolution of fiscal responsibilities to the Outer Periphery, this Study agrees with Cavalieri and Ferrante (2016) that the extent to which decentralisation can improve health outcomes is dependent on the prevailing contextual issues [171]. Challenges to fiscal recentralisation are used by some of the health facilities managers to circumvent the rule around User Fees for example, User Fee charges were abolished by the Central Government in 2013 but some facilities are re-introducing them– see 6.2 above. This adaptive response, although playing a functional role to keep services going under the circumstances, reduces accountability, making the service vulnerable to corruption – something that is widespread in Kenya [172].

The financial challenges in the health system are also present at a macro-level. Kenya, as part of the Abuja declaration, committed to invest 14% of the overall national budget in health. Since 2010 however, Kenya drastically reduced the health budget (7.2% in 2010 to 5.7% in 2014) leading to intermittent drug supplies, frequent health worker strikes due to unpaid salaries, with direct negative impact on the quality of care [173].

In conclusion, this Study has established that fiscal decentralisation has not worked well for the EPI so far. The ring-fence for vaccines that existed at the National level pre-devolution was removed when the Treasury sent the total health budget to the Counties as one resource envelope. Immunisation now must compete against other health priorities. All financial revenue for structures below the County level were recentralised to the County headquarters. All funds reaching health facilities like User

Fees are redirected to the County Revenue Account then redistributed to the health facilities. AIE rights were withdrawn from all structures below the County level. There were reported delays in the outflow of monies from the Treasury to the Counties and from the Counties to the Outer Periphery structures. Consequently, reports of vaccine and/or commodity stock-outs were commonplace, which inadvertently, is likely to have a negative impact on immunisation coverage. This means therefore that the overall goals of fiscal decentralisation around improved efficiency, financial accountability and effectiveness [174] are not being met. Yet, for improved performance of the EPI and the health system in general, appropriate devolution of fiscal functions is required.

8.8 Global Health Systems Perspectives

From the foregoing, the Study shows significant systemic challenges to the EPI under devolution. A fundamental question for health system and policy researchers is: to what extent do health systems in different geographical settings vary in their experiences and response to health system reforms? We know from a complexity theory viewpoint that health systems are complex, and complex systems do operate on the edge of chaos [175] especially at the early stages of reforms implementation. In my journey through the DrPH, I undertook a research study (OPA) in a High-Income Country (HIC), looking at vaccine system arrangements across three Inner North West London boroughs of Hammersmith and Fulham, Kensington and Chelsea and Westminster, in the context of the changes to the English NHS [176]. There were common features in the OPA and this Study in how the reforms unfolded across the two settings. Both studies looked at the supply side of the vaccine systems; the reforms changes were triggered in 2010 (following the publication of a White Paper in England [177], and adoption of a new constitution in Kenya) and effected in 2013. The reforms were characterised by major structural changes such as the abolition of existing organisations (like Primary Care Trusts in England, and Provinces in Kenya), creation of new organisations (like the National Health Service England in the UK, and County Governments in Kenya), and assigning new functions to existing organisations. In both settings, the reforms were majorly politically driven and implemented at a fast pace.

The two studies show immunisation services being planned and delivered in a fragile context negotiating several implementation challenges with a varied degree of emphasis. The HIC study showed significant ambiguities on the roles and responsibilities of different actors, with stakeholder relations being in a state of disarray coupled with a lack of an agreed framework for collaboration. There were cold chain breaches, as well as apparent lack of data system support and training for providers. A reduction in immunisation coverage was observed. There were gaps in commissioning and delivery of school age vaccination programmes, with suspension of vaccinations in some settings. Information flow was quite poor; plans to undertake a root cause analysis to flag up or address any concerns were non-existent. The manner in which the policy changes were imposed were both contentious and challenging: contentious in the sense that massive organisational change were proposed without adequate consultation with people on the ground around how specific programmes like immunisation would be affected, challenging as local actors had to embrace the fragmentation of existing services and adapting to new organisations at the same time, and instead of settling in, the actors on the ground were in constant negotiation of an effective frame for delivery. These findings show that systemic dysfunctions are not unique to Kenya.

A crucial question for health system and policy researchers is whether any lessons can be learnt from the two contexts for overall health system strengthening. As showed in chapter 7, the innovation, commitment and dedication of workers to the call of duty and concern on the ramifications on un-immunised child in LMIC made actors continue providing services in extremely difficult situations. In the HIC study, actors fell into the ‘it's not my responsibility’ trap which led to cessation of some vaccination services. In this scenario, a key lesson for the HIC from LMIC is the need to put patients first whilst navigating systemic challenges emanating from reforms. Secondly, the results chapters in this LMIC Study shows substantial heroic acts of individuals that provide the much-needed bridge between the old and the new health system. A lesson for the HIC is the need for continuation of service delivery coordination especially when formal bridging structures are yet to be established. The LMIC on the other hand can learn significant lesson from the HIC, especially in preparation for changes in advance of formal transfer initiation. In the HIC, enactment of some of the provisions of the 2010 White Paper took place even before the Bill had

been passed into law. In anticipation of the incoming changes, planning for transfer of human resource and public health functions started in 2011, with organisations merging to mirror functions in new organisations. In the LMIC, there seemed to have been little formal planning for human resource changes to devolved governments. Amid concerns from a wide range of stakeholders on proposed changes, the HIC paused the progression of the reforms, as part of a 'listening exercise'. This is an important lesson for the LMIC, as it helps in securing buy-in from dissenting voices.

In conclusion, the two studies show that challenges in health system and policy reforms transcend differences in social, economic and political settings. As the discussion on the implications of health reforms on health systems intensifies, there is need for concomitant consideration for rigorous and bespoke studies to undertake cross-jurisdictional comparisons to identify synergies, barriers and enablers to successful health system change.

Chapter 9: Conclusions

9.1 Methodological considerations

There are three key contextual and/or methodological factors that have had an impact on the process and findings of this Study. First, the Study explored the effects of health system reforms on the vaccine systems in Kenya purely from the supply side of health service provision, and from one perspective; that of a health systems researcher. This is bold; the assessment of the complex multidimensional concepts and processes (decentralisation, health systems and quality) could potentially be enriched by inclusion of perspectives from the demand side of health service provision including politicians. Similarly, the Study focussed on only one of the 47 County Governments. Whilst the foregoing will inevitably affect the generalisability of the findings, this limitation is a strength. By focussing on singular perspectives, the Study was able to obtain a richness and granularity in the data that would not have been obtainable had the Study included all other viewpoints from the demand side and across all 47 Counties at once.

Secondly, the timing and duration of the Study created a very specific context for data collection. The Study was conducted at a time that actors were searching for avenues to raise their frustrations, or get concerns addressed. It may be the case that some responses could have been exaggerated to this effect. However, the issues of the 'truth' of the data are addressed by taking an ethnographic approach to data collection, drawing on a qualitative analysis of a range of data sources such as interviews, observation, field notes and grey literature.

Third, immunisation coverage data have traditionally been used as an indicator of performance of vaccine systems. The Study design, however, was qualitative and ethnographic and did not consider quantitative coverage data. This meant that no inferences could be drawn from the systemic issues reported in the Study to inform whether devolution per se has led to a change in immunisation coverage. Moreover, the ascertainment of the accurate coverage data for Kilifi County was something that I found difficult in this Study. I was given access to datasets from three different sources (UVIS, KCDH and KEMRI) covering the same time-period (2010-2016) on the same jurisdiction, but the figures showed significant variations. This variation in data on

coverage has also been reported in the study by Ifedayo (2018) [152]. Nonetheless, variation in quality is indicative of good or poor performance; this Study considers quality issues in detail

9.2 What the Study Adds

This Study provides lessons that are applicable more broadly than to Kenya. Potentially, this Study is the first of its kind to investigate the specific impact of devolution on the end-to-end processes of vaccine systems. This provides benchmark data that health system and policy researchers can use further health research in LMIC, or indeed be used for international comparisons.

This Study adds to Donabedian's framework [121] (presented in Chapter 4) by drawing on Maxwell's quality model [123]. This synthesis of the two models enables key elements to be identified and then considered when assessing the impact of decentralisation on the quality of vaccine systems within the context of intra-national politics. This extended framework, derived from data presented in chapter 5-8, has potential for use in other health system studies.

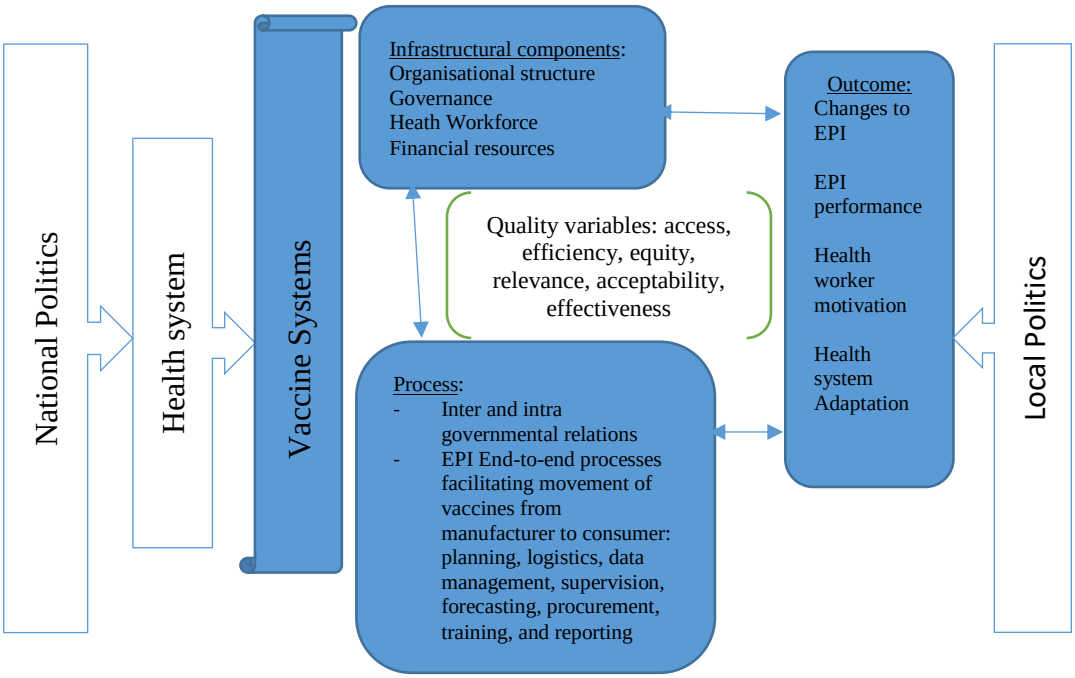


Figure 14: Framework to consider in assessing impact of decentralisation on quality of vaccine systems

According to Donabedian, the Structural pillar encompasses assessing the setting within which care is delivered and the instruments which support its provision (for example relating to facilities, equipment, health workforce, and finances). In the extended model which I propose, this dimension would also include an assessment of the context within which the EPI is structured considering the influence of the wider political drivers for decentralisation. Donabedian's Process pillar is interested in assessing whether the agreed standards of medical care are being met. The extended model replaces these parameters with the inter-governmental relations and the end-to-end processes of the vaccine systems. Finally, while Donabedian's Outcome pillar assesses whether the care or programme delivered is efficient, equitable or effective, this model adds to it by considering quantifiable outputs like coverage data and outcomes like health system adaptation and health workforce experiences. Central to assessing quality in this proposed model however, is the use of the six quality variables by Maxwell to benchmark the extent and the nature in which the three pillars (structure, process and outcome) have been affected.

In 8.2.4, the Study showed that devolution has reduced the decision space of actors at the micro level (SCHMTs and PHCF managers). This is important as most studies analysing the impact of decentralisation tend to stop at the Inner Periphery (County headquarters) as a focus of analysis. This Study has gone further to illuminate the effect of decentralisation on the structures situated at the Outer Periphery (See chapter 5). Moreover, the Study provides inter-continental health system reform comparisons contributing to the global health system and policy research discussions.

The Study has shown that operationalisation of devolution policies on EPI become seamless when all the key actors are fully empowered to perform their duties; and that a mere transfer of coordinating authority to devolved units is not enough for efficient programme implementation. In the sections below (9.2 and 9.3), the Study identifies system leverage points that can be optimised by health system actors in navigating through their implementation efforts, ones they can use to reorient the health system to the intended direction of travel.

The theory of change for devolution is that devolution gives greater control to devolved units in the overall health management and delivery processes which in turn contributes to improvements in health system performance. This, however, can only happen in a context where the transition process to devolution is well managed, the receiving unit well equipped, and the politics prepared to forge compromises for the success of the new health system. For the theoretical promises of decentralisation around improving quality of health outcomes to be realised, there has to be a concomitant appreciation of the complexities of actualising the reforms in the health sector. This Study identified an implementation problem stemming from the way the policy was effected which became problematic for policy planning and implementation. Nonetheless, the way the health system actors absorbed the devolution shock adds evidence to the notion of health system resilience. All EPI actors across the jurisdictional divide went out of their way to prevent the system from collapsing. It goes to show that although challenging, an immediate and unplanned transition of devolution implementation approaches from gradual to big-bang can be managed. The big-bang approach to decentralisation, one in which everything is devolved all at once, reportedly worked well in India [178] and Indonesia[179], and so is safe to say it can work in Kenya. In fact, some argue that the lightning speed in implementing structural changes may be preferable as those standing to lose (power and authority) may form coalitions to stall the process altogether[180].

Although the prospects of devolution are still theoretical, the positive contribution of devolution to health system improvement cannot be ignored. In as much as the Study highlighted areas made visible by the challenges of adopting a big-bang implementation approach to a policy designed and agreed to be effected on a gradual approach, there remains a sense of shared hope, and indeed goodwill that devolution can and should be made to work for the health system in Kenya.

9.3 The calm after the storm

Effective implementation of an ambitious politically driven decentralisation policy like the one Kenya adopted calls for the willingness of stakeholders to forge a meeting of minds. As presented in 7.1 above, there is confidence that the most turbulent period appears to be coming to an end, at least in the short term. Stakeholders seem to be settling into the new reality, that functions have been devolved, that the health system

has been restructured, and that the organisation and management of the EPI is not the same as before. A sense of coming to terms and willingness to make the new arrangements work is dawning. Actors are now speaking with each other in an apparent realisation that bickering is not sustainable, with a concomitant increase in the sense of commitment to explore solutions. At the County level, a realisation that the recentralisation of finances is not sustainable has led to the publication of a health Facility Improvement Fund (FIF) bill [181], to resolve the recentralisation rhetoric. The FIF bill gives hospitals Authority to Incur Expenses, as was the case pre-devolution. Discussions are still underway to extend this function to the primary health care facilities.

9.4 Where to go from here.

Five years on, the devolution dust is now settling. What remains now is the need to pay attention and try to make right some of the imperfections that were prominent during the health system transition. Notable among these are (i) the realignment and rearrangement of political priorities (appeasing masses, solidifying political support, among others) vis-a-vis the programmatic needs (EPI and health facility funding, health worker employment conditions, among others), (ii) unlocking the fiscal recentralisation rhetoric at the County level, which both risks slowing down the devolution momentum by creating anxieties at the demand side and has the potential of raising calls for health system recentralisation, and the (iii) resolution of the employment issues.

Some lessons for leveraging the health system in Kenya can be learned from Thailand who were able to improve health outcomes at low cost [182]. Some factors associated with Thailand's success included service continuity of senior officials, charismatic leadership and continuous dialogue and engagement. EPI was lucky in the sense that the programmatic changes were more bureaucratic with limited or no staff changes at all levels of the programme. This provides for much needed retention of the programmatic memory and continuity of the programme. With devolution a series of charismatic leaders have emerged or have become more visible. This creates an opportunity for EPI managers to forge critical support to set EPI agenda and influence governors and MCAs to endorse and support EPI.

Devolution in Kenya has seen significant shift in accountabilities, responsibilities and powers of the various components of the vaccine systems. This has implications for overall protection against vaccine preventable diseases. Counties are autonomous governments and may have varied EPI delivery systems. Several incidences of disease outbreaks have been reported (Appendix G). It is not yet clear who is liable if the outbreaks spread to adjacent Counties. National policies and strategies are needed to provide direction on the health protection responsibilities. While the Public Health Act (2012) [183] gives the Minister for Health powers to formulate rules in the event of a disease outbreak, the execution of such is at the mercy of the County governments' cooperation. The complexity of the health system arrangements requires that the health system leaders as well as the National and County Governments have discussions to reach a comprehensive agreement on who is constitutionally invested with the responsibility for health protection against vaccine preventable diseases and how the accountabilities for health protection will be carried out.

The health system actors now realise that the CoG is quite a forceful entity, from the manner in which they got the president to pronounce the immediate transfer of all functions earmarked for devolution. The CoG presents a great opportunity for EPI actors to rally support from both the County and National level. The MCA have displayed a great interest in health issues and have been actively involved in health facility affairs. Moreover, they play a vital role in scrutinising and approving health budgets. By virtue of their roles, the MCAs are key policy actors that the County Departments of Health should actively target to influence to get buy-in for EPI. The National level respondents in this Study reported a significant degree of buy-in from the senior leadership; there is a potential here for County Health Managers to learn from the Centre to champion for and sensitise the County leadership on EPI.

Finally, in a post-study development, a political truce between two main political rivals: Raila Odinga and Uhuru Kenyatta, was reached in early 2018 following a hotly contested general election in 2017. The truce was displayed through a symbolic 'handshake'. A key outcome of the 'handshake' is an apparent toning down of political tensions and the creation of an atmosphere where actors are having moderated conversations across the board. The Building Bridges Initiative (BBI) was formed as a result, through which proposals are invited for identifying and addressing reform

challenges. The BBI is a policy window that could be utilised to address some of the health system issues to gain political impetus. The timing of BBI and its optimisation is significant since some of the reform proposals under discussion are around restructuring the country further, which will undoubtedly have implications for the health system.

In conclusion, although the study has shown significant implementation challenges impacting negatively on the quality of the vaccine systems, the situation is not finite. As the health system and health actors settle in the new policy disposition, it is possible that devolution can work for immunisation in the long run.

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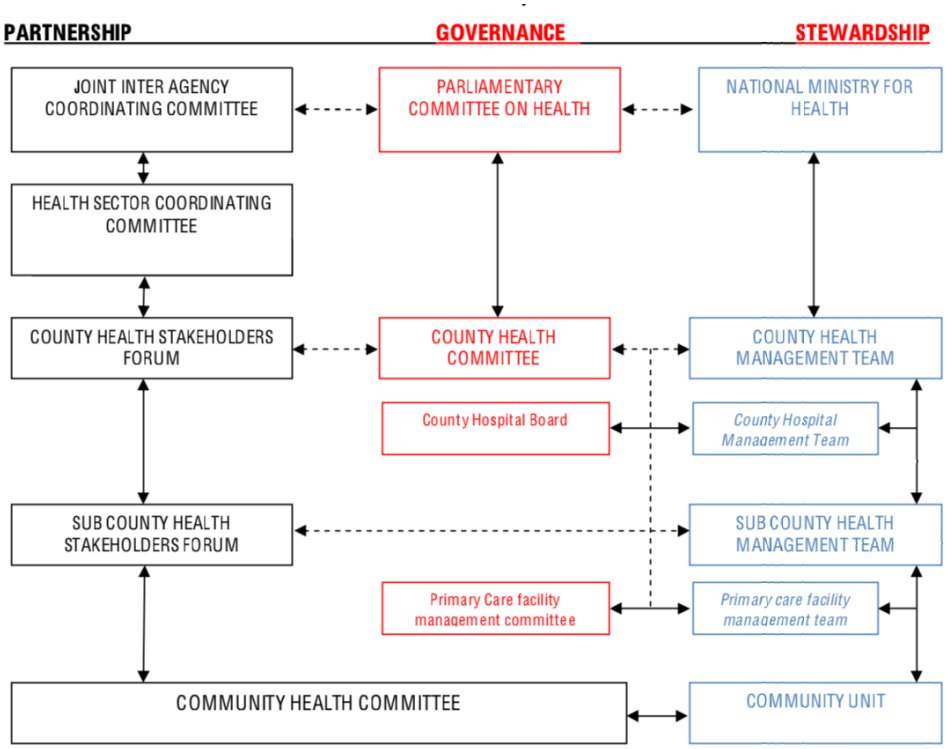
11.0 Appendices

Appendix A : Health Sector Leadership Framework [184]



Appendix B: The National Childhood Immunisation Schedule in Kenya.

Type of vaccines	Age of administration	# of doses	Coverage
BCG	Birth	1	National
bOPV	Birth, 6 weeks, 10 weeks, 14 weeks	4	National
DTP-HepB-Hib**	6 weeks,10 weeks, 14 weeks	3	National
PCV 10**	6 weeks,10 weeks, 14 weeks	3	National
Rota**	6 weeks,10 weeks	2	National
IPV	14 weeks	1	National
Measles	9 months, 18 months	2	National
Yellow Fever**	9 months	1	Baringo, Elgeyo Marakwet, Turkana, West pokot
TT for pregnant women	TT-1 At first contact between (4^{th}-6^{th} months) TT-2 One month after T-1 (latest by 8^{th} month) TT- 3 Third pregnany at first visit (between 4^{th}-8^{th} month)	3	National
HPV**	10 years old girls 2 doses given six months apart	2	National

- ** Co financed between Gavi and Government
- HPV will be introduced in July 2019
- The rest are fully funded by Government
- TT scheduled to change to Td this year
- Other vaccines of strategic importance procured by government include: Hepatitis B for high risk groups, Yellow Fever for travellers, Anti Rabies vaccine, Anti Snake Venom, Typhoid vaccine
- Malaria and Influenza vaccines to be piloted for possible introduction

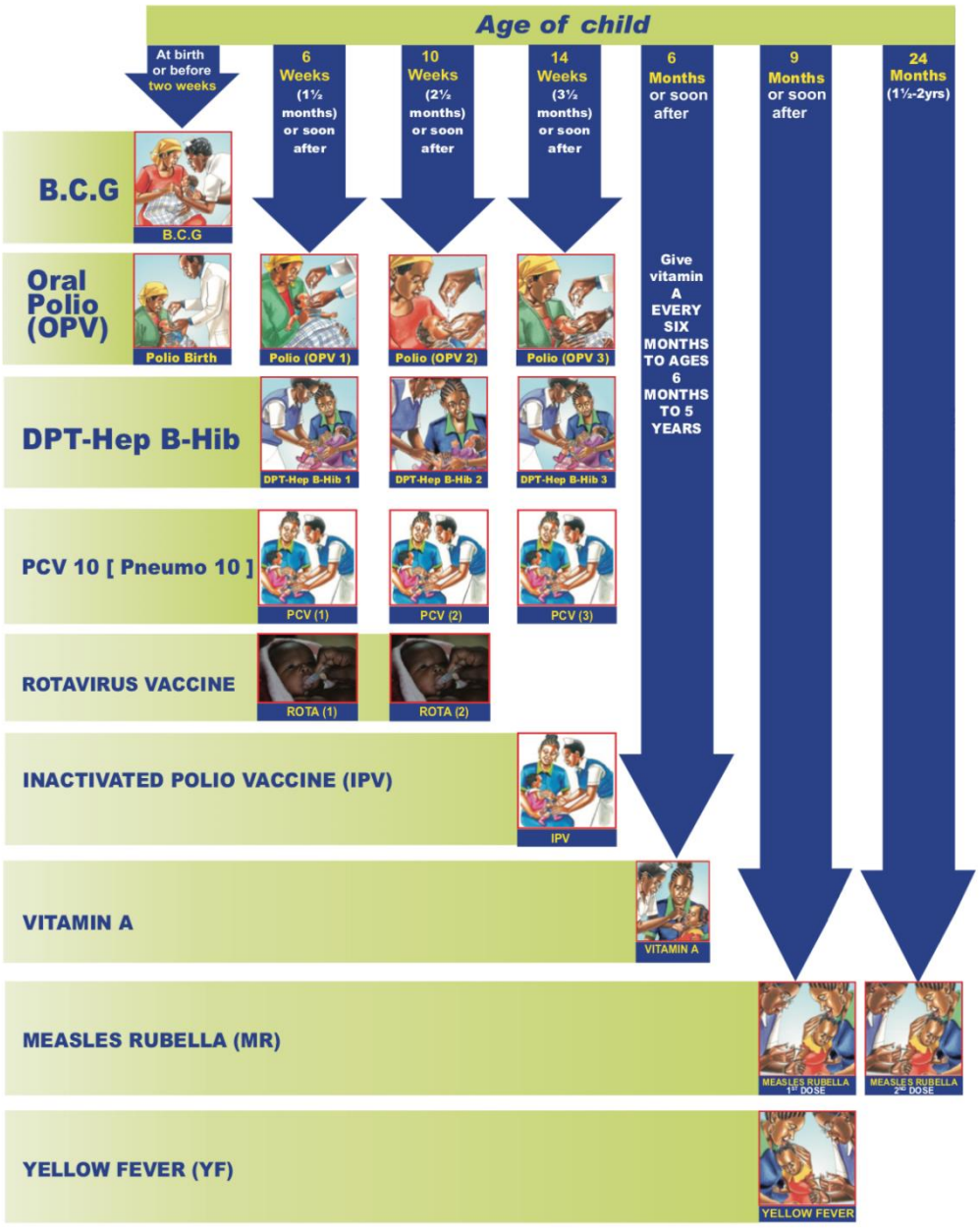
Ministry of Health

NATIONAL VACCINES AND IMMUNIZATION PROGRAMME

ROUTINE IMMUNIZATION SCHEDULE

Ensure your child completes ALL vaccinations as per the SCHEDULE

Revised APRIL 2017



Appendix C: Document Analysis Form

Title of document	
Type of document (government report, journal, newspaper article, etc.)	
Author	
Intended audience	
Main purpose of the document	
Key messages, including perspective represented or projected	
Key sources of information presented in the document	
Significance: What does this document add to the topic in question	

Appendix D: Conceptual Framework Applied to this Study

Concept	Donabedian definition [121]	Application in this Study
Structure	Assessment of the environment within which care delivery occurs. - Health worker qualification. - Organisational structures - Financial organisation.	The context within which the Immunisation Programme is delivered. Includes the macro context (wider political, social and economic phenomena that influence the Immunisation Programme). Parameters include: - Organisational structure & governance - Organisation of fiscal responsibilities. - Health Workforce: current plight and competence.
Process	The transactions effected during health care delivery - Assessment of the suitability, accuracy, relevance and timeliness of information - Specialised abilities in undertaking investigative and treatment measures - Integration and care linkages	Parameters include: - Intergovernmental relations - EPI End-to-end processes facilitating movement of vaccines from manufacturer to consumer: planning, logistics, data management, supervision, forecasting, procurement and training
Outcome	Impact of healthcare on population health. - Loss of life - Re-enablement - Patient attitude, satisfaction, - Physical incapacitation - Recovery	Effectiveness, Equity, Efficiency Changes to EPI EPI performance Health worker motivation Health system Adaptation

Appendix E: KC/07/2016-2017: Tender for Supply and Delivery of Vaccines

REPUBLIC OF KENYA

COUNTY GOVERNMENT OF KILIFI
INVITATION FOR PRE-QUALIFICATION

The County Government of Kilifi invites applications from interested and eligible suppliers, service providers, consultants and contractors for the supply and delivery of goods, works and services to the County Government of Kilifi for the years 2016-2017 in the following categories:

CATEGORY A: GOODS

CATEGORY	ITEM DESCRIPTION	PREFERENCE
KC/01/2016-2017	Supply and delivery of Office Stationery	Reserved Groups
KC/02/2016-2017	Supply and delivery of Tyres, Tubes and Batteries	Citizen Contractors
KC/03/2016-2017	Supply of Fuel, Grease and Oil	Citizen Contractors
KC/04/2016-2017	Supply of and delivery of Building and General Hardware Materials	Reserved Groups
KC/05/2016-2017	Supply and delivery of Staff Uniforms and Promotional Materials and sports kits	Citizen Contractors
KC/06/2016-2017	Supply and delivery of Office Furniture Fittings and Equipment	Citizen Contractors
KC/07/2016-2017	Supply and delivery of Vaccines	Citizen Contractors
KC/08/2016-2017	Supply and delivery of Computers, Laptops and Computer Accessories	Reserve Groups
KC/09/2016-2017	Supply, delivery and maintenance of Communication equipment	Reserved Groups
KC/10/2016-2017	Supply and delivery of Cleaning Materials	Reserved Groups
KC/11/2016-2017	Supply and delivery of Cold chain equipment, spare parts and maintenance	Citizen Contractors
KC/12/2016-2017	Supply and delivery of food stuff (hard cereals, fruits and vegetables) and other special nutrition commodities	Citizen Contractors
KC/13/2016-2017	Supply and delivery of Audio and Videography equipment and other Accessories	Citizen Contractors
KC/14/2016-2017	Supply and delivery of Fire Proof Cabinets and Paper Shredders	Citizen Contractors
KC/15/2016-2017	Supply and delivery of house hold sanitary items (including kitchen appliances)	Reserved Groups
KC/16/2016-2017	Supply and delivery of fire Fighting Equipment	Citizen Contractors
KC/17/2016-2017	Supply and delivery of Tree Seedlings	Reserved Groups
KC/18/2016-2017	Supply and delivery of Scratch and Calling Cards	Reserved Groups
KC/19/2016-2017	Supply, delivery and Installation of Power Generators	Citizen Contractors
KC/20/2016-2017	Supply and Delivery of Medical Plants, Equipment And Accessories	Citizen Contractors
KC/21/2016-2017	Supply and delivery of bedding and Linen	Citizen Contractors
KC/22/2016-2017	Supply and Delivery of Wood Fuel and Cooking Gas	Citizen Contractors
KC/23/2016-2017	Supply and Delivery of Farm Input, Herbicides And Insecticides	Citizen Contractors
KC/24/2016-2017	Supply and delivery of Newspapers and Periodicals	Reserved Groups
KC/25/2016-2017	Supply and delivery of Tonners, Ribbons And Cartridges	Reserved Groups
KC/26/2016-2017	Supply, delivery and maintenance of Air-conditions	Citizen Contractors
KC/27/2016-2017	Supply and delivery of Meat, Chicken, Fish and Fresh Milk	Citizen Contractors
KC/28/2016-2017	Supply and Delivery of Non-Pharmaceuticals and Dressing Materials	Citizen Contractors
KC/29/2016-2017	Supply and Delivery Lab Reagents Plus Glass Wares and Chemicals	Citizen Contractors
KC/30/2016-2017	Supply and Delivery of Laboratory, Dental, X-ray and Medical Related equipment	Citizen Contractors
KC/31/2016-2017	Supply and Delivery of Pharmaceuticals	Citizen Contractors
KC/32/2016-2017	Supply and Delivery of Medical, Chemicals and Industrial Gasses	Citizen Contractors
KC/33/2016-2017	Installation and support for CCTV Security System	Citizen Contractors

CATEGORY B: SERVICES

CATEGORY	ITEM DESCRIPTION	PREFERENCE
KC/34/2016-2017	Provision of Legal Services	Citizen Contractors
KC/35/2016-2017	Provision of Insurance Services	Citizen Contractors
KC/36/2016-2017	Servicing of Motor Vehicles, Motor Cycles And Plants	Citizen Contractors
KC/37/2016-2017	Maintenance of Sewerage and Storm Water system, Emptying and Cleaning of Soak Pits, Septic Tanks and Pit Latrines/ Provision of sludge/ waste oil collection	Reserved Groups
KC/38/2016-2017	Provision of Estate Agency	Citizen Contractors
KC/39/2016-2017	Provision of Various Consultancy Services (indicate area of specialty)	Citizen Contractors
KC/40/2016-2017	Maintenance and Servicing of Computers, Laptops, Photocopiers and Fax Machines	Reserved Groups
KC/41/2016-2017	Provision Of Staff Medical Cover	Underwriters

KC/42/2016-2017	Provision of Publicity, Photography and Video Services	Citizen Contractors
KC/43/2016-2017	Provision of Printing and Publishing Services	Citizen Contractors
KC/44/2016-2017	Provision of car hire and general Transport Services	Citizen Contractors
KC/45/2016-2017	Provision of Air- Ticketing and Air Travel Services	Citizen Contractors
KC/46/2016-2017	Provision of Fumigation and Pest Control	Reserved Groups
KC/47/2016-2017	Provision of Outside Catering and Hotel Accommodation services	Citizen Contractors
KC/48/2016/2017	Provision of ICT Consultancy Services, Software Development and Support Services (Maintenance services for Local Area Network)	Reserved Group
KC/49/2016/2017	Hire of heavy machinery (Graders and wheel loaders)	Citizen Contractors
KC/50/2016/2017	Provision of Garbage Collection Services	Citizen Contractors
KC/51/2016/2017	Provision of Environmental Impact Assessment and Audit Services	Citizen Contractors
KC/52/2016/2017	Provision of Land Surveying and Other Related Services	Citizen Contractors
KC/53/2016/2017	Provision of Office and Compound Cleaning Services	Reserved Groups
KC/54/2016/2017	Provision of Consultancy Services (Financial & Audit services)	Citizen Contractors
KC/55/2016/2017	Provision of security guards	Citizen Contractors
KC/56/2016-2017	Maintenance and repair of Office Furniture	Reserved Group
KC/57/2016-2017	Servicing and Maintenance of Hospital Equipment and Plants	Citizen Contractors
KC/64/2016-2017	Provision of Events Management Services	Reserved Group

CATEGORY C: WORKS

CATEGORY	ITEM DESCRIPTION	PREFERENCE
KC/58/2016-2017	Contractors for Road Works, Bridges and Foot Bridges	Citizen Contractors
KC/59/2016-2017	Contractors for Building Works	Citizen Contractors
KC/60/2016-2017	Contractors for Refurbishment and Repair of Government Houses	Citizen Contractors
KC/61/2016-2017	Contractors for Borehole Drilling	Citizen Contractors
KC/62/2016-2017	Contractors for water works	Citizen Contractors
KC/63/2016-2017	Electrical Installation contractors	Citizen Contractors

Interested candidates may inspect and download the Pre-qualification Documents by visiting the County Government of Kilifi Website www.kilifi.go.ke. Check under tenders. Completed pre-qualification documents in plain sealed envelopes clearly marked with the relevant **category number** and description only should be addressed to:

THE COUNTY SECRETARY
COUNTY GOVERNMENT OF KILIFI
P.O.BOX 519-80108, KILIFI

Completed Tender documents should be deposited in the Tender Box located at the entrance of the County Treasury on or before Monday 30th May, 2016 at 10.30 am. Pre-qualification documents will be opened immediately thereafter in the County Treasury Hall in the presence of the Bidder

Tender Documents may also be obtained **FREE OF CHARGE** from the website link listed above or alternatively from the cashier's office located at the County Treasury ground floor at a non-refundable fee of KSH. 1000 between 9.00am to 5.00pm. A single application is required per category. Those willing to be considered for pre-qualification in more than one category should submit separate applications per category.

NB : SUPPLIERS, CONTRACTORS AND CONSULTANTS WHO WERE PRE-QUALIFIED FOR FINANCIAL YEARS 2015-2017 NEED NOT APPLY.

Head of Supply Chain Management Services
For: County Secretary
KILIFI COUNTY

Appendix F Discussion Guide

Interview Topic Guide: National Level/County level Key Informants
Time: 45-60 minutes

Questions in these interviews will depend on the nature of the key informant and their position and therefore will be developed prior to the interview with the aim of gaining:

1) An in-depth understanding of the roles and responsibilities of senior leaders and their respective organisations with regards to the current Immunisation Programme;

2) A good understanding of how Immunisation Programme functions, is managed and overseen from a policy perspective.

3) A good understanding about how immunisation related policies are developed, authorised and evaluated;

4) Insights into the involvement of key informants and their respective organisations in planning and executing the 2013 changes to the Immunisation Programme; what if any say did the respondent have?

5) An overview of what changed, why and how;

6) Insights into key informants' opinions and experiences of these changes and their views on how they were implemented;

7) Insights into what key informants' opinions and experiences about what worked well, what did not work so well, how this was resolved, and whether any policy adaptations had to be made due to operability problems;

8) Insights into what key informants think about how are the new arrangements are working (are the right structures are in place and working? If not, where are the problems? Are there challenges? Are the challenges (if any) being addressed, in what way? Are there any opportunities that can be optimised? Are they being taken up?)

9) An understanding of how partner organisations collaborate in delivering and managing the Immunisation Programme;

10) Insights into differences in structure and working culture between different partner organisations and how these influence collaborations;

11) An understanding of key informants' responsibilities and views about the performance evaluation of the Immunisation Programme;

12) Insights into other topics which arise in discussion and are considered as important by interviewees.

Possible probes:

- Could you tell us about your current role? What did you do before this, what is your professional training, related to immunisation?
  How is the Immunisation Programme organised: what are the structural arrangements and processes in place?

- What influence do you have when it comes to immunisation policy?
- What is the relationship in practice between policy and implementation? Can you give us an example?
- (What is your relationship to UVIS?)
- Do you have a voice at policy level, can influence policy making, if yes how?
- How were you or your organisation involved in the plans to change the organisation of the Immunisation Programme? What input did you have?
- What actually changed in practice, how and why?
    - Comments on procurement, leadership/governance, training, health workforce recruitment, etc.
- How do you think the Immunisation Programme is working?
    - Comments about procurement, human resources, delivery, training, monitoring, surveillance, introduction of new vaccines, etc.
- What do you think about these changes, what has worked well, what has been difficult?

Interview Topic Guide: sub-county/Immunisation Providers
(Time: 45-60 minutes)

Current practice: What is happening, and how?
About you and your role
Tell me about your role in immunisation at your practice/place of work. What are your main responsibilities, who do you work with and who are you accountable to?

Immunisation service delivery
What vaccination services are offered at your practice/place of work?
How are these services organised and delivered at your practice/place of work?
How do you review and assess the performance of your immunisation services? Do you set immunisation targets (if yes, how and what are these)?
How do you record and store immunisation data, what electronic data systems do you use and who do transfer this data to?
What have been the main successes and the main challenges over the past year?

What has changed?
How have the changes to the organisation of the health service, which came into operation in 2013, affected you and your organisation's role and involvement in the Immunisation Programme?
What has changed for you? In terms of your role.
What has changed for your practice/place of work?

In the way you plan vaccination services (e.g. accessing vaccines, scheduling)

In the way you run vaccination services (e.g. staff involved)

In the terms of the organisations/professionals you work with (e.g. immunisation leads, health visitors)

In the reporting and transfer of immunisation data (e.g. new systems, managing data)

In the way that vaccination service performance is evaluated

In the way that you access training and support

In the way you deal with clinical incidents related to immunisation

In the way you report and are involved in the management of outbreaks

In terms of responding to public concerns of complaints

How was/is change being managed?
How were these changes introduced and managed? What worked well, what was difficult? What could have been done better?
Tell me about your experience of these changes. How have you personally adapted?
How has the practice adapted, and what have the consequences been?
What support was available to manage the process of change?

How are the new arrangements working now? What is working well, what is challenging and how do you try to resolve these challenges?

Reflections on change
Given your experience, what are your views on the changes to the Immunisation Programme that came into effect in 2013?

Any other comments
Do you have any other comments?
Are there any relevant meetings of immunisation related activities I could observe?

Thank you for your time.

Appendix G: Press Release on Disease Outbreak (2018)

MINISTRY OF HEALTH

PRESS RELEASE ON DISEASE OUTBREAK SITUATION IN KENYA AS AT 11th JUNE 2018

Since January this year (2018), several counties have reported suspected and confirmed disease outbreaks. The Ministry of Health in collaboration with the affected counties and other partners has successfully responded to most of the outbreaks leading to timely interruption of transmission. However, outbreaks continue to erupt in new counties as well as recur in previously affected counties due to various reasons including continued existence of risk factors and inadequate resources to facilitate implementation of effective interventions. The following Disease outbreaks have been reported since the beginning of the year:

1. **Cholera outbreak:** A total of **4954** cases of Cholera with **75** deaths have been reported since the beginning of the year. **279** of these cases are laboratory confirmed. Nineteen **(19)** counties have so far been affected namely: Mombasa, Garissa, Siaya, Tharaka- Nithi, Meru, Kirinyaga, Busia, Tana River, Turkana, Murang'a, Trans-Nzoia, West Pokot, Nairobi, Nakuru, Isiolo , Machakos, Elgeyo Marakwet , Kiambu and Kilifi. Nine (9) of these counties have managed to successfully contain the outbreak. Currently ten (10) counties continue to report new cases of cholera. These include: Garissa, Turkana, West Pokot, Isiolo, Kiambu ,Elgeyo Marakwet , Nairobi , Machakos , Tana River and Kilifi,.

In response to this outbreak, The Ministry of Health in collaboration with the affected Counties has taken the following measures:

- Coordinating preparedness and response through a national disease outbreak taskforce
- Conducting risk communication through issuance of alerts, IEC materials and regular press releases

- Enhancing surveillance through active case search in Health facilities and within communities
- Providing technical and logistical support to the affected counties
- Management of suspected and confirmed cases in isolation facilities.
- Provision of laboratory support by distributing testing kits and testing of referred samples at The National Public Health Laboratories(NPHLS), KEMRI and CDC laboratories

2. **Circulating Vaccine Derived Polio Virus type 2 (cVDPV2):** The virus was isolated in a sewage sample collected on 21st March 2018 in one of the environmental surveillance sites in Eastleigh, Kamukunji Sub- County, Nairobi County.It is closely linked to a virus that was isolated from a similar sample in Somalia in October 2017. In response to this isolation, the Ministry has conducted an emergency vaccination campaign in Nairobi County targeting 817, 782 Children under the age of 5 years. Two additional rounds of vaccination campaigns are planned for 30th June to 4th July and 28th July to 1st August 2018 respectively. Each of the additional rounds will target 2.4 million children in 12 high risk counties including Nairobi. The Counties targeted will include: Wajir, Mandera, Garissa, Nairobi, Tana River, Isiolo, Meru, Kitui, Machakos, Lamu, Kiambu and Kajiado.
3. **Measles outbreak:** Measles outbreak was reported in Wajir and Mandera Counties in February 2018 with a total of 39 and 103 cases recorded respectively. This outbreak has since been successfully contained through active case search, case management and enhanced outreach vaccination services
4. **Chikungunya outbreak:** A confirmed Chikungunya outbreak was reported in 3 counties namely; Mombasa (1302 cases, 32 laboratory confirmed), Lamu (199 Cases, 4 laboratory confirmed) and Kilifi (7 cases, 2 laboratory confirmed).The outbreak has since been controlled.
5. **Rift Valley Fever Outbreak:** An outbreak of Rift Valley Fever among humans was laboratory confirmed on 7th June 2018 in Wajir County. Eldas and Wajir Sub-Counties have so far reported cases.A total of 15 cases with 5 deaths have been recorded. The following intervention measures are ongoing;
    - 4 Isolation centers have been set up to facilitate case management in the affected areas
    - Integrated Vector Control measures targeting Mosquitoes are being undertaken in Basir area, Eldas Sub- county

- A ban on slaughtering of uninspected animals has been imposed county wide
- Community sensitization is going on in all sub-Counties
- The butchery business community and opinion leaders are being sensitized on transmission of the disease
- Resource mobilization is on-going
- 60 samples have been collected from animals by the veterinary department and delivered to Kabete laboratories for testing

The Ministry of Health wishes to assure Kenyans that it will continue to monitor and coordinate response efforts in order to contain and control diseases outbreaks in the country. The public is advised to be on high alert, observe personal hygiene/handwash practices and refer any suspected cases of the above disease conditions to the nearest health facility for assessment and management.

[redacted]

Dr. Kioko Jackson K., OGW, MBS
DIRECTOR MEDICAL SERVICES

Appendix H: KEPI Funders

- Government of Kenya
- Gavi, the vaccine alliance
- World Health Organization
- United Nations International Children's Emergency Fund
- Clinton Health Access Initiative.
- United States Agency for International Development
- Japan International Cooperation Agency
- Sabin Vaccine Institute
- Glaxo Smith Kline
- Merck vaccine foundation and micronutrient

OTHER STAKEHOLDERS IN IMMUNISATION SERVICE PROVISION
•• Division of Disease Surveillance and
Response
•• Kenya Medical Research Institute
•• National Public Health Laboratories
•• Private sector players in health
•• Training institutions e.g. Universities, mid-level training institutions
••Pharmacy and Poisons Board
•• National Immunization Technical
Advisory Group
•• Philanthropic individuals and associations
•• Civil society organisations

Appendix I: Gavi announcement on rebase

https://www.nation.co.ke/newsplex/2718262-3182416-9tsebj/index.html